

# LEKARZ WOJSKOWY

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- Surgical treatment of myasthenia gravis using a robotic system – a literature review and a description of the first surgery in Poland
- Pharmacological treatment of scars after gynaecological and obstetric surgeries
- Intestinal parasitic infections in Polish soldiers deployed to Kosovo
- No improvement of physical capacity during cardiac rehabilitation in a patient with elevated IGF-1 and normal pressure hydrocephalus

**WOJSKOWY  
INSTYTUT MEDYCZNY  
PAŃSTWOWY INSTYTUT BADAWCZY**



## Informacje dla autorów

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„Lekarz Wojskowy” jest czasopismem ukazującym się nieprzerwanie od 1920 r., obecnie jako kwartalnik wydawany przez Wojskowy Instytut Medyczny w Warszawie.

1. „Lekarz Wojskowy” zamieszcza prace oryginalne (doświadczalne i kliniczne), prace poglądowe, doniesienia dotyczące zagadnień wojskowych, opracowania deontologiczne, opracowania klinicznych przypadków klinicznych, artykuły z historii medycyny, aspekty prawa medycznego, opisy wyników racjonalizatorskich, wspomnienia pośmiertne, listy do Redakcji, oceny książek, streszczenia (przeгляdy) artykułów z czasopism zagranicznych dotyczących szczególnie wojskowej służby zdrowia, sprawozdania ze zjazdów i konferencji naukowych, komunikaty o zjazdach.
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■ Letter from the Editor-in-Chief

**Dear Readers,**

We are embarking on the 102nd year of publishing “Military Physician”. We look forward to the upcoming evaluation of our scientific periodical by a panel of experts designated by the Minister of Science and Higher Education. We hope that our medical journal, which has been published continuously for over a century, presenting articles of unquestionable educational value on various aspects of health safety and providing the latest updates on therapies, will be recognised and appreciated by the experts. The Editorial Team spares no effort to ensure that “Military Physician” maintains the highest possible level of academic content and is indexed in international databases.

In the latest issue of the journal, we delve further into the topic of hyperbaric oxygen therapy. In addition, we explore the options for surgical intervention in myasthenia gravis, including a detailed account of the first procedure in Poland conducted using a robotic system. Original papers included in the new issue focus primarily on various aspects of telemedicine. As customary, original studies are accompanied by case reports offering significant educational benefits.

I hope that the latest issue of “Military Physician” will meet your satisfaction. I wish you an engaging read and I look forward to our continued collaboration.

A handwritten signature in blue ink, appearing to read 'B. Kalicki'.

Prof. Bolesław Kalicki, MD, PhD



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## TABLE OF CONTENTS

<b>LETTER FROM THE EDITOR-IN-CHIEF</b> . . . . .	<b>3</b>
Bolesław Kalicki	

### REVIEW ARTICLE

<b>HYPERBARIC OXYGEN THERAPY – PART 2. POSSIBILITIES OF USE IN MEDICINE</b> . . . . .	<b>7</b>
Hiperbaryczna terapia tlenowa – cz. 2. Możliwości wykorzystania w medycynie	
Małgorzata Chochowska, Łukasz Martowski	

<b>SURGICAL TREATMENT OF MYASTHENIA GRAVIS USING A ROBOTIC SYSTEM – A LITERATURE REVIEW AND A DESCRIPTION OF THE FIRST SURGERY IN POLAND</b> . . . . .	<b>12</b>
Surgical treatment of myasthenia gravis using a robotic system – a literature review and a description of the first surgery in Poland	
Michał Wiłkojć, Łukasz Czyżykowski, Aleksandra Kiszka-Wiłkojć, Witold Sońnicki, Jacek Doniec, Marcin Zieliński, Andrzej Kwiatkowski, Maciej Walędziak	

<b>SELECTED PREDICTIVE FACTORS OF NEW-ONSET ATRIAL FIBRILLATION IN PATIENTS WITH HEART FAILURE</b> . . . . .	<b>17</b>
Wybrane czynniki predykcyjne migotania przedsionków u pacjentów z niewydolnością serca	
Martyna Dąbrowska, Beata Uziębło-Życzkowska, Agnieszka Jurek, Małgorzata Maciorowska, Paweł Krzesiński	

<b>PHARMACOLOGICAL TREATMENT OF SCARS AFTER GYNAECOLOGICAL AND OBSTETRIC SURGERIES.</b> . . . . .	<b>22</b>
Farmakologia w terapii blizn po operacjach ginekologicznych i położniczych	
Małgorzata Chochowska, Łukasz Martowski	

<b>THE FULFILMENT OF PATIENTS’ RIGHTS IN THE PROVISION OF TELECONSULTATIONS DURING THE COVID-19 EPIDEMIC STATE FROM THE VIEWPOINT OF ADMINISTRATIVE DECISIONS IN PROCEEDINGS IN CASE OF PRACTICES VIOLATING COLLECTIVE PATIENT’S RIGHTS</b> . . . . .	<b>30</b>
Realizacja praw pacjenta przy udzielaniu teleporad w stanie epidemii COVID-19 z perspektywy decyzji wydanych w postępowaniach w sprawach praktyk naruszających zbiorowe prawa pacjentów	
Katarzyna Maria Zoń	

<b>ORGANIZATIONAL STANDARDS FOR MEDICAL TELECONSULTATIONS AND PERSONAL DATA PROTECTION</b> . . . . .	<b>37</b>
Standardy organizacyjne teleporad medycznych a ochrona danych osobowych	
Łukasz Nosarzewski	

### ORIGINAL ARTICLE

<b>MEDICAL TELECONSULTATIONS – NEW POSSIBILITIES AND LEGAL AND ETHICAL DILEMMAS</b> . . . . .	<b>45</b>
Teleporady medyczne – nowe możliwości i dylematy prawno-etyczne	
Aneta Łazarska, Stanisław Niemczyk	

<b>INTESTINAL PARASITIC INFECTIONS IN POLISH SOLDIERS DEPLOYED TO KOSOVO</b> . . . . .	<b>52</b>
Zarażenia pasożytami jelitowymi u polskich żołnierzy rozmieszczonych w Kosowie	
Krzysztof Korzeniewski, Wanesa Richert	

**A MODEL OF DYNAMIC PLANNING OF MEDICAL SUPPORT FOR COMBAT TROOPS. A NEW LOOK AT THE REQUIREMENTS AND CAPABILITIES OF THE MEDICAL COMPONENT . . . . . 56**

Model dynamicznego planowania zabezpieczenia medycznego wojsk walczących.  
Nowe spojrzenie na wymagania i zdolności komponentu medycznego

Grzegorz Gerard Gielerak, Piotr Murawski

**CASE REPORTS**

**A CASE OF ANASTOMOTIC LEAK DUE TO CANDIDA ALBICANS INFECTION IN A 64-YEAR-OLD FEMALE RENAL TRANSPLANT PATIENT TREATED WITH AN EMERGENCY SUPRAPUBIC ILIOFEMORAL BYPASS GRAFT . . . . . 68**

Przypadek nieszczelności zespolenia wywołanej zakażeniem *Candida albicans* u 64-letniej pacjentki po przeszczepieniu nerki, leczonej w trybie nagłym poprzez wszczepienie pomostu biodrowo-udowego z dostępu nadłonowego

Wojciech Jakub Ciesielski, Alicja Majos, Konrad Kosztowny, Mirosław Stelągowski, Mateusz Tomaszewski, Janusz Strzelczyk, Adam Durczyński, Piotr Hogendorf

**NO IMPROVEMENT OF PHYSICAL CAPACITY DURING CARDIAC REHABILITATION IN A PATIENT WITH ELEVATED IGF-1 AND NORMAL PRESSURE HYDROCEPHALUS . . . . . 73**

Brak poprawy wydolności fizycznej w trakcie rehabilitacji kardiologicznej u pacjenta z podwyższonym IGF-1 i wodogłowiem normotensyjnym

Zuzanna Janicka, Małgorzata Kurpaska, Katarzyna Piotrowicz, Marzena Kubiak, Paweł Krzesiński

**KAPOSI'S SARCOMA IN AN HIV-POSITIVE PATIENT . . . . . 78**

Mięsak Kaposiego u pacjenta zakażonego HIV

Vasiliki Chwiałkowska, Karolina Parciak, Joanna Zalewska, Anna Płatkowska, Elwira Paluchowska, Witold Owczarek



## HYPERBARIC OXYGEN THERAPY – PART 2. POSSIBILITIES OF USE IN MEDICINE

Hiperbaryczna terapia tlenowa – cz. 2.  
Możliwości wykorzystania w medycynie



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### Abstract

The growing interest in the use of hyperbaric oxygen therapy in medicine prompted us to analyse the available research reviews and meta-analyses and to systematize data on hyperbaric oxygen therapy. The second part of the article presents the use of hyperbaric oxygen therapy in the treatment of burns and skin grafts, difficult-to-heal wounds, diabetic foot ulcers, air embolism, decompression sickness, anaemia, genitourinary disorders, carbon monoxide poisoning, chronic osteomyelitis, gas gangrene, radiation necrosis and anal fistulas.

### Streszczenie

Wzrost zainteresowania wykorzystaniem hiperbarycznej terapii tlenowej w medycynie skłonił autorów do przeanalizowania dostępnych przeglądów badań i metaanaliz oraz uszeregowania danych na jej temat. W drugiej części artykułu przedstawiono zastosowanie hiperbarycznej terapii tlenowej w leczeniu oparzeń, przeszczepów skóry i trudno gojących się ran, zespołu stopy cukrzycowej, zatorów gazowych, choroby dekompresyjnej, niedokrwistości, chorób układu moczowo-płciowego, zatruc czadem, przewlekłych zapaleń kości i szpiku, zgorzeli gazowej, martwicy popromiennej oraz przetok odbytu.

**Keywords:** wound healing, hyperbaric oxygen therapy, osteomyelitis, osteoradionecrosis, gas gangrene, radiation necrosis

**Słowa kluczowe:** gojenie ran, tlenowa terapia hiperbaryczna, zapalenie kości i szpiku, martwica popromienna kości, zgorzel gazowa, martwica popromienna

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### Introduction

The first part of the paper was a historical overview of research on hyperbaric oxygen therapy (HBOT), the mechanism of a hyperbaric chamber, as well as indications and contraindications for this form of treatment. Part two discusses the use of HBOT in various medical fields except for the treatment of diving incidents (including decompression sickness and arterial gas embolism) as this is well known.

### HBOT for burn treatment

A burn is an injury to the skin or, depending on the severity, deeper tissues, characterised by the presence of a necrotic zone surrounded by the zones of stasis and hy-

peremia (hypoperfusion) accompanied by oedema [1]. A correlation between increased hypoxia and impaired wound healing has been demonstrated [2]. HBOT is used in the treatment of burns of various aetiologies to reduce oedema, improve blood flow and reduce fluid loss due to vascular damage [3]. In order to achieve an optimal effect, HBOT should be included in surgical and symptomatic treatment as soon as possible, preferably within 24 hours. HBOT is also used for bronchial burns, where, in addition to reducing oedema, preventing anaerobic bacterial growth is an equally important factor [4].

Knefel et al. assessed comprehensive treatment in a group of patients with electrical burns, where 21 out of 61 patients additionally received HBOT, showing that the latter method improved overall treatment efficacy.

There were no cases of mortality in the HBOT group and the rate of late infectious complications was almost twice as low. However, there were some negative effects compared to the control group in terms of a higher number of necessary amputations and longer hospital stays, which were however blamed on the worse baseline clinical condition of these patients [3]. HBOT is also used in the treatment of pain in third-degree burns. A rat study published in 2019 suggested that prolonged use of this method may reduce burn-induced mechanical allodynia [5]. Early HBOT often allows for avoiding intubation in patients with airway burns. Furthermore, it can be used in already intubated patients [6].

However, since not all studies to date have been of good methodological quality and have sometimes yielded contradictory results, research on the efficacy of HBOT in burn care should continue [7].

### HBOT for skin grafts

Although burns are a common indication for skin grafts, the latter represent a separate medical problem. HBOT can be used during allogeneic skin grafting. Misiuga et al. assessed HBOT-assisted burn therapy in terms of the time of graft adherence to the wound bed, length of hospital stay and the number of autologous skin graft procedures in two 20-patient groups. The study showed statistically significant differences in all three areas; HBOT-assisted treatment was associated with faster wound healing, shorter hospital stay and fewer autologous skin graft procedures compared to the standard treatment group [8].

The transplanted tissues vary in size, have an abnormal blood supply and the nutrient supply depends on the recipient's body. HBOT improves fibroblast function and thus increases neovascularisation and oxygenation of blood vessels and tissues [4]. HBOT offers the possibility of salvaging compromised grafts if the degenerated state of the recipient's wound bed was correctly and quickly diagnosed [2]. A study in rats showed that HBOT promoted neovascularisation of transplanted skin flaps, with laser Doppler imaging (LDI) showing an increase in tissue blood flow, consistent with histological findings [9]. The same study pointed to increased SDF-1 and CXCR4 protein expression as the cause of neovascularisation. Further studies on the use of HBOT in skin graft healing have shown a synergistic effect with subcutaneous hirudin [10]. HBOT allows stimulation of leukocyte function, suppression of exotoxin production and a synergistic effect of antibiotic therapy, demonstrating bactericidal activity against anaerobic bacteria. In clinical practice, HBOT has been used during surgical treatment in combination with negative pressure therapy, showing efficacy despite *Pseudomonas aeruginosa* infection [11].

### HBOT for difficult-to-heal wounds

Difficult-to-heal wounds are another challenge of modern medicine. Advanced age, overweight and obesity (poorer blood supply to adipose tissue), chronic comorbidities (e.g. diabetes), poor nutritional and hydration status, smoking and coinfections are factors that correlate with an increased risk of difficult wound healing [12].

Wound oxygenation status is a determinant of healing outcomes, with wound hypoxia correlated with impaired healing. Oxygen supply, on the other hand, accelerates the wound healing process [4]. Furthermore, the use of HBOT in the treatment of difficult-to-heal wounds increases nitric oxide (NO) production, which contributes to the efficiency of the healing process [13]. In their meta-analysis, Longobardi et al. demonstrated the efficacy of HBOT in the treatment of delayed healing ulcers [14]. As pointed out by the authors, the HBOT protocol should be based on the outcomes of standard comprehensive treatment. HBOT should be considered when there is no response to standard therapy after 4–6 weeks [14, 15].

Single clinical case reports confirming the efficacy of HBOT (usually  $\geq 30$  sessions) in the treatment of chronic wounds in children may also be found [16].

### HBOT for diabetic foot ulcers

HBOT is used to improve the healing process of ulcerative wounds and necrotic soft tissue lesions within the foot that develop as vascular complications of diabetes (diabetic foot ulcers, DFUs) [4]. Knefel et al. included 24 patients (11 women and 13 men; mean age 48 years) in their study. DFUs were managed with pharmacotherapy, surgery and HBOT. Local lesions resolved completely and radically in 5 and 8 patients, respectively, while elective amputation was prevented in 5 patients [17]. Kaplan et al. used HBOT as adjunctive treatment in 146 diabetic foot patients. Full recovery and significant improvement were reported in 69.6% and 17.9% of patients, respectively [18].

In their meta-analysis of 20 randomised clinical trials, Zhang et al. showed statistically significant differences in HBOT-assisted therapy for DFUs compared to standard treatment alone. These studies have shown the benefits of HBOT in terms of faster wound healing, a reduced risk of major amputations and pain relief [19].

The use of HBOT as an adjunctive treatment for DFUs appears to be a common and proven standard. However, there are some discrepancies in the literature regarding the improvement of quality of life [20] and reducing the number of total amputations [21].

### HBOT for anaemia

HBOT can be used in anaemic patients with increasing oxygen debt (symptoms such as tachycardia, dyspnoea, fatigue, chest pain, metabolic acidosis and increased cardiac enzymes) who cannot receive packed red blood cells (PRBCs) (due to religious beliefs or massive autoimmune haemolysis [22]), as well as in patients on the waiting list for compatible blood products [23]. Importantly, pulse-flow (intermittent) oxygen supply (normo- or hyperbaric) induces an increase in RBC count in patients with both acute and chronic anaemia [24].

### HBOT for genitourinary disorders

There are also many reports on the use of HBOT in genitourinary disorders, including:

- Fournier's gangrene [25], where HBOT reduces both length of hospital stay and the extent of limb amputation [4];
- cystitis (radiation-induced, interstitial and haemorrhagic [26]), where HBOT limits tissue inflammation, oedema and capillary pressure, as well as promotes activation of fibroblasts and reversal of negative changes associated with abnormal angiogenesis [26];
- pelvic radiation disease following radiation therapy (radiation proctopathy);
- dystrophic calcifications of the prostate.

Further indications include priapism (a case report of an 11-year-old boy with sickle cell anaemia [27]) and erectile dysfunctions (secondary to urethral repair) [26]. HBOT has also been suggested for overactive bladder syndrome and chronic pelvic pain [25].

### HBOT for CO poisoning

HBOT is a well-established treatment for carbon monoxide (CO) poisoning, significantly reducing mortality [4]. Short-term exposure to CO causes influenza-like symptoms, headaches and cognitive impairment, whereas long-term exposure is associated with neuro- and cardiotoxic effects [28]. Unfortunately, up to 30% of recovered patients [28] experience neurocognitive complications (headaches, irritability, personality disorders, confusion, memory loss [29], sleep disorders and impaired concentration, psychotic symptoms and parkinsonism [28]) for up to a year after CO poisoning, which may develop immediately after poisoning or within days to weeks afterwards [28, 29]. The prevention and treatment of these complications is a major area of research on the use of HBOT in this group of patients [29].

### HBOT for osteomyelitis

HBOT is successfully used as an adjunctive treatment (in parallel to antibiotic therapy and surgical wound debridement) in patients with chronic refractory osteomyelitis (which is most commonly caused by *Staphylococcus aureus* [30], but there are also case reports on *Streptococcus pneumoniae* aetiology [31]), as a complication of open bone fractures or intraoperative infection. The use of HBOT was assessed in patients with grade III and IV osteomyelitis (Cierny-Mader classification system) of the femur [32], tibia [33] and ankle [31]. The beneficial effects of HBOT in osteomyelitis are attributed to the activation of neutrophils, inhibition of bacterial pathogens, enhancement of antimicrobial action and healing mechanisms, as well as reduction of inflammation. Adjunctive HBOT inhibited the infection in 60–85% of patients with chronic refractory osteomyelitis [34]. This is important as antimicrobials induce selection pressure among pathogenic microorganisms, resulting in the emergence of resistant strains (which is observed for all classes of antibiotics, regardless of chemical properties or molecular mechanisms [35]). Therefore, the incorporation of HBOT as an effective adjunctive treatment may enable a quantitative and qualitative reduction in the use of antimicrobials, which would certainly be in line with the mission of the National Program to Protect Antibiotics.

### HBOT in necrotizing soft tissue infections (gas gangrene)

HBOT is also used to treat necrotizing soft tissue infections (NSTI) involving the fascia, muscles, tendons, ligaments, etc. [31]. Early diagnosis and treatment are crucial, as shown in a Finnish study, where 12 (22.6%) out of 53 NSTI patients infected with *Clostridium perfringens* [36], responsible for 80% of cases [37, 38] (other culprits included *C. novyi*, *C. septicum*, *C. hemolyticum*, *C. sordelli* [38]), died after surgical debridement of the wound, broad-spectrum antibiotic therapy and HBOT (2.5 atm) [36]. The mortality rate is 100% in untreated patients, 25–30% with properly implemented treatment (a decrease to 20% has been reported in recent years [37]), and up to 5–10% with HBOT [38] (depending on the patient's general health condition, age, immune status and comorbidities [37]). Unfortunately, comprehensive treatment of NSTI with HBOT is usually not possible due to lack of reimbursement from social insurance (the costs of HBO treatment for NSTI patients is approximately 8,000–25,000 euros/patient [39]) and the method is not available in emergency/surgical departments. At the same time, any delay in surgical treatment due to the use of HBOT would be unacceptable [39], especially since, due to the rapid progression of NSTI, wound revision and repeated debridement is usually necessary after 4–6 hours [38].

### HBOT for radiation-induced necrosis of bone or soft tissue

Osteoradionecrosis (ORN) is among the most serious complications of cancer treatment, head and neck tumours in particular [40]. About 9% of patients in this group who received a radiation dose of >60 Gy will develop ORN [41]. Radiation therapy results in vascular endothelial inflammation and obliteration, as well as tissue hypoxia, which leads to fibroblast dysfunction and subperiosteal fibrosis, death of osteoblasts and osteoclasts, and bone marrow atrophy, in line with the "3H rule: hypovascular, hypocellular, hypoxic" [40]. If no spontaneous healing occurs, chronic osteomyelitis develops, which can lead to mandibular fracture and soft tissue necrosis [41]. It should be noted that patients are usually unaware of ORN, with a non-healing wound after tooth extraction being the first sign of the disorder [40]; therefore, it seems important to assess the impact of prophylactic HBOT. Shaw et al. [42] conducted their study in 100 patients following radiotherapy to the head and neck (>50 Gy), who required tooth extraction or implant placement in the mandible and were randomised into two equal groups. All patients received chlorhexidine (mouthwash) and antibiotics. The study group additionally received HBOT (2.4 atm, 80–90 minutes for 30 days). Six months postoperatively, there was a similar number of patients with ORN in the study group (6.4%) vs. control group (5.7%) based on blinded evaluation of clinical and radiographic images, quality of life, acute symptoms and pain intensity. It was found that HBOT could not replace surgery (removal of necrotic tissue [43]) and targeted antibiotic therapy [41, 43] in ORN, and its efficacy was comparable to that of pharmacotherapy (antibiotics and antifibrotics) [43].

**HBOT for anal fistula**

HBOT is also used to treat anal fistulas [44] in the course of Crohn's disease, including those refractory to other forms of therapy. Since about 20–30% of patients in this group develop fistula at least once within 20 years of diagnosis [43, 45], it represents a serious medical and social problem. Although some cases are almost asymptomatic, a fistula can lead to pelvic abscess formation and sepsis [44]. Permanent remission is rarely achieved, with high recurrence rates necessitating re-intervention or stoma formation [45]. Lansdorp et al. [44] described a long-term (12 months) follow-up of 20 patients with at least one active, chronic (average of 4 years) treatment-resistant perianal fistula who received HBOT (2.5 atm, 80 min, 40 treatments over 8 weeks) as an adjunct to biological therapy. At week 16, significant improvement was observed in 13 of the 20 patients, expressed as a reduction in perianal disease activity index (7.5 vs. 4; a score  $\leq 4$  indicates remission), modified van Assche index (9.2 vs. 7.3), fistula drainage, as well as C-reactive protein (4.2 vs. 2.2 mg/mL) and faecal calprotectin (399 vs. 31  $\mu\text{g/g}$ ).

**Conclusions**

The current state of knowledge has prompted many researchers to seek HBOT-assisted treatments for various disorders. Such practice seems reasonable for difficult-to-heal wounds and skin grafts. There is, however, less evidence for the efficacy of HBOT in the treatment of anal fistulas and diabetic foot ulcers (there are discrepancies in the literature regarding improved QoL and number of amputations). It should be noted that although HBOT cannot replace routine treatment (e.g., in the case of ORN surgery), it may be used in parallel with standard of care in many cases. The rapid growth of interest in HBOT, evident in scientific publications in recent years, is a good prognosticator for the development of the method itself. However, although many studies on its utility (e.g., treatment of burns) still need to be continued, the procedure itself, due to its simplicity, versatility and accessibility, is likely to enjoy growing popularity in the coming years.

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# SURGICAL TREATMENT OF MYASTHENIA GRAVIS USING A ROBOTIC SYSTEM – A LITERATURE REVIEW AND A DESCRIPTION OF THE FIRST SURGERY IN POLAND



Chirurgiczne leczenie miastenii – przegląd literatury i opis pierwszego zabiegu z zastosowaniem systemu robotycznego w Polsce

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## Abstract

**Introduction and objective:** Surgical treatment of myasthenia gravis with a use of the robotic system has been applied worldwide over past 20 years. On February 22, 2022, for the first time in Poland, extended thymectomy using robot-assisted thoracoscopic surgery approach was performed at the Military Institute of Medicine – National Research Institute in Warsaw. **Material and methods:** Three port, left-sided approach with CO<sub>2</sub> insufflation was performed. The left phrenic nerve was located and left lower pole of the thymus with fat of the left diaphragmatic angle was dissected. Further dissection of the thymus from the pericardial sac and along the left phrenic nerve with visualisation of the left brachiocephalic vein up to the level of the thyroid lobes was performed. Thymic veins were managed and the upper poles of the thymus were dissected. Right pleural cavity was opened and thymus was removed along right phrenic nerve with right lower pole of the thymus and surrounding fat tissue of right diaphragmatic angle. Specimen was removed and both pleural cavities were drained using single 24 Fr drain. **Results:** The operative time was 162 minutes, postoperative course was uneventful. The total postoperative drainage measured 50 ml and chest tube was removed on the first postoperative day. The amount of pain the patient suffered was moderate. The patient was discharged from the hospital on the second postoperative day. On the pathological study an atrophic thymus with mediastinal lymph nodes and fatty tissue were found. **Conclusions:** Robot-assisted thoracoscopic surgery extended thymectomy allowed for safe and radical resection of the thymus and surrounding fat tissue with a reduction in the time of hospitalization.

## Streszczenie

**Wprowadzenie i cel:** Na świecie leczenie miastenii z użyciem systemów robotycznych jest stosowane w chirurgii klatki piersiowej od 20 lat. W Polsce po raz pierwszy operację torakochirurgiczną z zastosowaniem takiego systemu przeprowadzono 22 lutego 2022 r. w Wojskowym Instytucie Medycznym – Państwowym Instytucie Badawczym w Warszawie. Wykonano wtedy tymektomię rozszerzoną metodą torakoskopii z użyciem systemu robotycznego da Vinci Xi. **Materiał i metody:** Zastosowano dostęp lewostronny z użyciem trzech trokarów roboczych i insuflacją CO<sub>2</sub>. Po uwidocznieniu lewego nerwu przeponowego uwolniono lewy dolny róg grasicy wraz z tłuszczem lewego kąta przeponowo-żebrowego. Następnie odpreparowano grasicę wzdłuż lewego nerwu przeponowego od worka osierdziowego, uwidoczniono lewą żyłę ramiennie-głowową, zaopatrzone gałęzie żyłne do grasicy i wypreparowano rogi górne grasicy do poziomu dolnych biegunów tarczycy. Szeroko otwarto prawą jamę opłucnej i wypreparowano grasicę wzdłuż prawego nerwu przeponowego wraz z otaczającą tkanką tłuszczową oraz tłuszczem prawego kąta przeponowo-żebrowego. Preparat usunięto z pola operacyjnego i do obu jam opłucnej założono pojedynczy dren 24 Fr, wprowadzony przez jeden z portów torakoskopowych. **Wyniki:** Operacja trwała 162 minuty. W okresie pooperacyjnym nie stwierdzono powikłań, drenaż całkowity wyniósł 50 ml, dren usunięto w 1. dobie po zabiegu. Nasilenie bólu pooperacyjnego było na średnim poziomie, co pozwoliło na wypisanie pacjentki w 2. dobie po operacji. W badaniu histopatologicznym preparatu pooperacyjnego wykazano obecność zanikowej grasicy wraz z otaczającym tłuszczem i węzłami chłonny. **Wnioski:** Zastosowanie systemu robotycznego w rozszerzonej resekcji grasicy u pacjentki z miastenią pozwoliło na przeprowadzenie bezpiecznego i radykalnego zabiegu, a przez to zmniejszenie nasilenia bólu pooperacyjnego i skrócenie hospitalizacji.

**Keywords:** thoracic surgery, myasthenia gravis, surgical treatment, RATS, da Vinci robotic system

**Słowa kluczowe:** chirurgia klatki piersiowej, miastenia, leczenie operacyjne, RATS, system robotyczny da Vinci

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## Introduction

Myasthenia gravis (MG) is a rare autoimmune disorder in which autoantibodies directed against acetylcholine receptors (AChRs) cause impaired neuromuscular transmission, which manifests as fatigable muscle weakness [1]. The incidence rate of myasthenia gravis is between 0.25 and 2 cases/100,000 people/year, and the prevalence is between 4.5 and 14.2 cases/100,000 people/year [2, 3].

The diagnosis of MG is based on the characteristic clinical presentation and positivity for anti-AChR antibodies, electrostimulation tests (repetitive nerve stimulation and single fibre electromyography) and a positive Tensilon test [4]. A chest CT or MRI scan should be also performed to exclude a thymic tumour (approximately 10–30% of MG cases are associated with thymomas) [5, 6].

Pharmacological treatment of MG involves the use of pyridostigmine, an acetylcholinesterase inhibitor, as the initial treatment. Some patients additionally receive im-

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munosuppressants and corticosteroids. Intravenous immunoglobulin infusions and plasmapheresis are used in the most severe cases.

## Surgical treatment

Surgical treatment is necessary in cases of thymoma-associated MG (TAMG) and as a therapeutic option to limit or discontinue immunosuppressants in patients who do not improve despite pharmacological treatment or do not tolerate such treatment.

Surgical treatment of MG involves thymectomy, optimally using an extended technique, the goal of which is to remove the entire thymus, including the perithymic fatty tissue that may contain ectopic thymic foci [7, 8]. The extent of adipose tissue resection includes the neck region from the level of the lower thyroid poles, through the adipose tissue around the right and left brachiocephalic veins, the superior vena cava, the brachiocephalic trunk and the aortic arch, to the bilaterally localised fat of the costophrenic angles contained between the right and left diaphragmatic nerve, representing the border of resection (fig. 1).

## Types of access for thymectomy and surgical outcomes

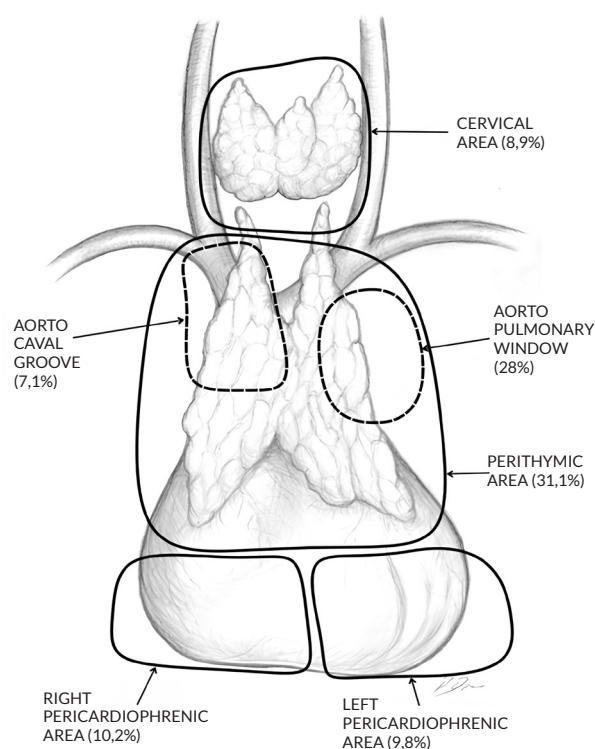
To date, the literature has proposed a number of surgical accesses for thymectomy, which can be somewhat simplified into two main groups:

- open surgery – cervical access, sternotomy and thoracotomy;
- minimally invasive surgery – video-assisted thoracoscopic surgery (VATS) and robot-assisted thoracoscopic surgery (RATS).

The first thymectomy for MG was performed by Ernst Ferdinand Sauerbruch in 1911 in a patient with coexisting hyperthyroidism. It involved partial removal of the thymus gland and partial resection of the thyroid gland from a cervical access and resulted in a reduced severity of MG symptoms [10]. Alfred Blalock was the first surgeon to perform elective surgery for MG and he described a series of thymectomies through median sternotomy in 1939 [11].

In the 1960s, due to the high risk of extensive procedures with sternotomy access, there was a return to the much safer interventions with cervical access. In 1987, Papatestas et al. presented the outcomes of 1,100 subtotal thymectomies from cervical access [12].

A significant number of MG recurrences have been observed in subtotal thymectomies from cervical access, with thymic remnants left in the anterior mediastinum [13, 14].



**Figure 1.** Foci of ectopic thymic tissue in the neck and mediastinal fat in the samples from the Hospital for Lung Diseases in Zakopane [9]

Studies conducted mainly in Japan (Masaoka) and the United States (Jaretzki) found that the increase in full MG remissions is related to the extent of resection not only of the thymus itself, but also of the perithymic fatty tissue containing ectopic thymic foci.

The distant surgical outcomes, as measured by the rates of complete remissions achieved using various extended thymectomy techniques, are up to 47% up to 5 years after resection [15–18].

In 1988, Jaretzki et al. presented the technique and outcomes of a 'maximal' thymectomy performed by sternotomy and cervical incision, allowing for extensive resection of the thymus itself along with the surrounding perithymic adipose tissue located in the neck, large mediastinal vessels and bilaterally in the vicinity of costophrenic angles [19]. In parallel, techniques for extended thymectomy with resection of surrounding adipose tissue from cervical access with sternal elevation, proposed in 1988 by Cooper et al. [20], have evolved. The development of thymic surgery in the form of minimally invasive videothoracoscopic surgery continued in the 1990s. The first report was presented in 1994 by Novellino et al., who combined cervical incision with sternal elevation and bilateral 3-port VATS [21]. Zielinski (2000) and Takeo et al. (2001) described a technique for minimally invasive maximal thymectomy from cervical and subxiphoid access with sternal elevation and bilateral, single-port videothoracoscopy [22, 23].

Minimally invasive surgery has achieved a resection extent comparable to that of sternotomy and, most importantly, equally good clinical outcomes in terms of complete remissions [24].

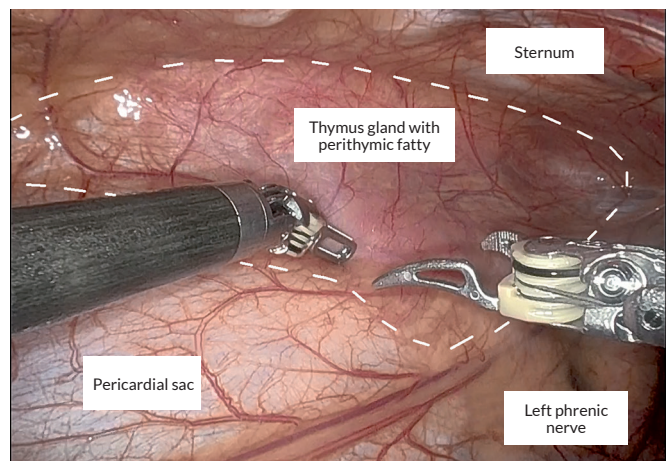
RATS thymectomy for thymoma (Masaoka grade I), performed in 2000 by Yoshino, was the first thoracoscopic thymectomy performed using a robotic system [25]. Ashton et al. performed the first extended RATS thymectomy using the bilateral approach for MG in 2003 [26]. In 2015, Rueckert presented the largest series of 449 RATS thymectomies performed between 2003 and 2014, which included 397 patients with MG, 64 patients with thymoma, 53 patients with TAMG, seven patients with parathyroid adenoma and 29 other patients [27].

The analysis of the largest series of robot-assisted thymectomies demonstrated a high safety profile for RATS procedures and lower complication rates (1.6–7.2%, with lymphadenopathy, bleeding and myasthenic breakthrough being the most common ones), less intraoperative blood loss and shorter hospital stay compared to open surgery. Additionally, RATS and VATS thymectomies are comparable in terms of completeness, number of complications, length of hospital stay and the rates of conversion to sternotomy [28].

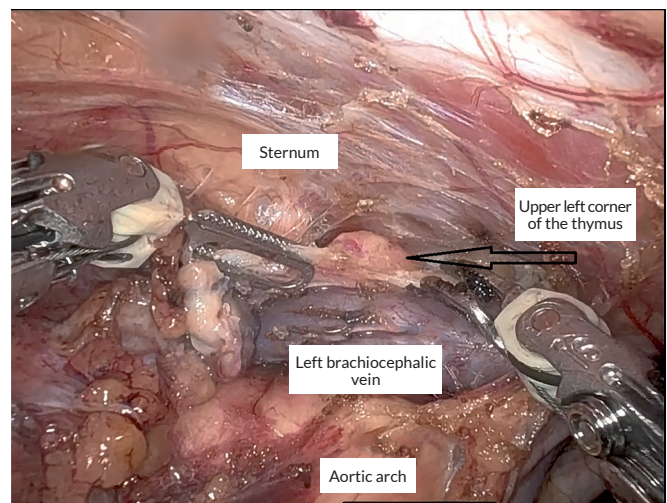
In 2016, Wolfe et al. published their prospective randomised study showing that performing maximal thymectomy using sternotomy access in patients with AChR MG improves treatment outcomes and allows for reduced doses of immunosuppressants compared to patients who did not undergo surgery. This study has delivered the most important evidence supporting the efficacy of thymectomy in non-thymomatous MG (NTMG) [29].

## The first use of a robotic system in surgical treatment of myasthenia gravis in Poland

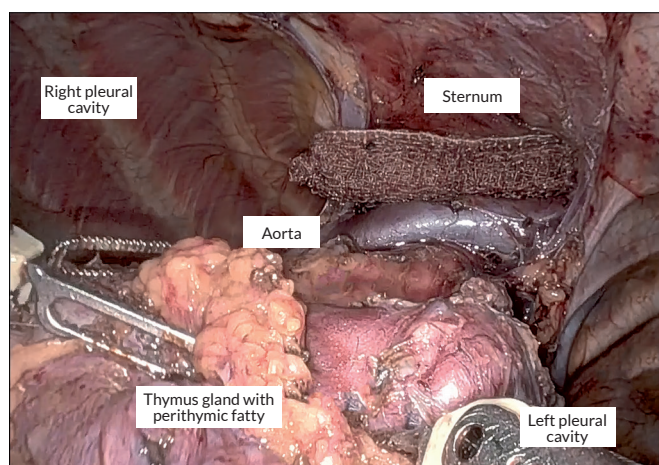
In February 2022, the da Vinci Xi robotic system was used for the first time in Poland for a thoracic surgery at the Military Institute of Medicine – National Research Institute in Warsaw. An extended thymectomy was performed in a 22-year-old female patient with EMG-confirmed AChR MG. Left-sided access was used by sequentially inserting three thoracoscopic ports: two 8 mm working ports (in the 3rd and 7th intercostal spaces) and one 12 mm camera port (in the 5th intercostal space). A CO<sub>2</sub>-induced pneumothorax was created in the left pleural cavity to 7 mm Hg (fig. 2). The left phrenic nerve was located and, along its course, the left diaphragmatic angle fat and the left lower pole of the thymus were dissected. Further dissection of the thymus from the pericardial sac cranially, along the left phrenic nerve with visualisation of the left brachiocephalic vein was performed. In the neck, the upper poles of the thymus were dissected along with the perithymic fat up to the level of the thyroid lobes (fig. 3). The two thymic veins arising from the left brachiocephalic



**Figure 2.** Access through the left pleural cavity – in the marked area, the planned extent of thymectomy including pericardial fat, CO<sub>2</sub> insufflation to 7 mm Hg



**Figure 3.** In the foreground, the dissected aortic arch and left brachiocephalic vein; view during dissection of the left superior thymic horn up to the level of the lower pole of the thyroid gland



**Figure 4.** Wide-open both pleural cavities. The patient was intraoperatively ventilated using a double-lumen endotracheal tube for selective lung ventilation

vein were closed using bipolar coagulation. The right pleural cavity was opened and the thymus along with the surrounding fat was successively dissected from the aortic arch, superior vena cava, pericardial sac and right phrenic nerve, removing the right costophrenic angle fat along with the specimen (fig. 4). At the next stage, lymph nodes were removed from the area of the aortic arch and the left pulmonary artery, as well as the right brachiocephalic vein and the superior vena cava. The specimen was removed in a retrieval bag through a 12 mm camera port and a single 24 Fr drain was inserted through the left pleural cavity, with its end located in the right pleural cavity.

The operative time was 162 minutes and intraoperative blood loss was approximately 20 mL. The postoperative period was uneventful, the drain was removed on day 1 and the total postoperative drainage was 50 mL. The use of the minimally invasive RATS technique allowed for early patient mobilisation and discharge on day 2 postoperatively. The postoperative pain was moderate, requiring paracetamol and metamizol, with no need for morphine. Histopathological examination of the postoperative specimen showed atrophic thymus with surrounding fat and lymph nodes.

At 12 months postoperatively, the dose of the reversible acetylcholinesterase inhibitor was reduced by 67% compared to preoperatively.

### Conclusions

The benefits of using the Vinci Xi robotic system in thoracic surgery include the minimally invasive nature of the surgical access due to the use of 8 and 12 mm thoracoscopic ports. Rapid postoperative patient mobilisation reduces the risk of complications. Magnified three-dimensional visualization of operative field combined with a considerable range of instrument motion allows for precise tissue dissection in small space and makes it possible to achieve the full radicality of the procedure.

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## SELECTED PREDICTIVE FACTORS OF NEW-ONSET ATRIAL FIBRILLATION IN PATIENTS WITH HEART FAILURE

Wybrane czynniki predykcyjne migotania przedsionków u pacjentów z niewydolnością serca



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### Abstract

Atrial fibrillation, which is one of the most commonly diagnosed arrhythmias in adults, is associated with high morbidity and mortality. Atrial fibrillation is also the most common arrhythmia in patients with heart failure, and it has been shown to increase the risk of death, heart failure-related hospitalization, and stroke or transient ischemic attack. Considering these clinical and therapeutic implications, it seems advisable to assess patients for risk factors of atrial fibrillation. The purpose of this study was to present the predictors of new-onset atrial fibrillation particularly in patients with heart failure.

### Streszczenie

Migotanie przedsionków, będące jednym z najczęściej rozpoznawanych zaburzeń rytmu serca u osób dorosłych, wiąże się z wysoką zachorowalnością i śmiertelnością. Stanowi ono również najczęstszą arytmie u chorych z niewydolnością serca i wykazano, że zwiększa ryzyko zgonu, hospitalizacji związanej z niewydolnością serca oraz udaru mózgu i przemijającego ataku niedokrwiennego. Biorąc pod uwagę te implikacje kliniczne i terapeutyczne, wydaje się uzasadnionym, aby oceniać pacjentów pod kątem czynników ryzyka wystąpienia migotania przedsionków. Celem niniejszej pracy było przedstawienie czynników predykcyjnych wystąpienia migotania przedsionków u pacjentów z niewydolnością serca.

**Keywords:** heart failure, atrial fibrillation, new-onset atrial fibrillation

**Słowa kluczowe:** niewydolność serca, migotanie przedsionków, migotanie przedsionków de novo

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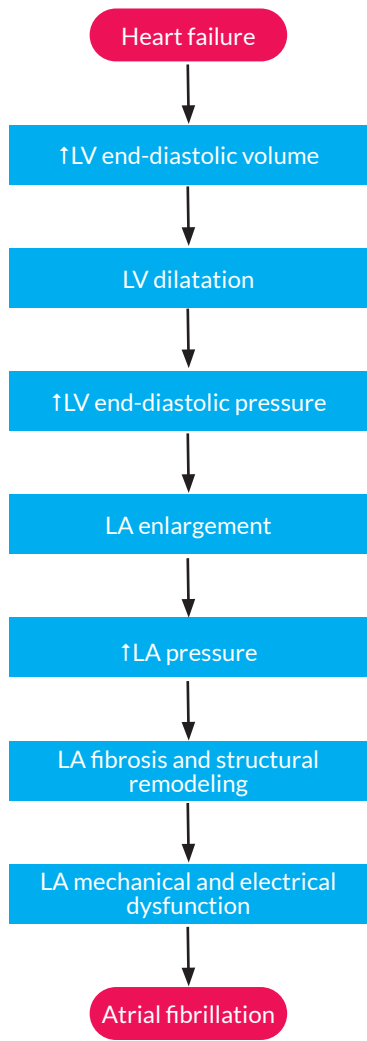
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### Introduction

Atrial fibrillation (AF), which is the most common arrhythmia in adults, is associated with high morbidity and mortality [1]. The prevalence of AF in the general population is 2–4%, with the proportion expected to rise two- to threefold [2]. Due to the close alignment of pathophysiology and risk factors of AF and heart failure (HF), those conditions coexist in a large percentage of patients [3, 4]. Regarding the increasing prevalence of AF and HF, both conditions generate significant costs to healthcare services globally [5, 6]. Moreover, patients presenting with concomitant AF and HF have a significantly worse prognosis [7]. New-onset AF (NOAF) in patients diagnosed with HF considerably affects their prognosis, as it indicates a more advanced condition, with worse cardiac function [8]. There is abundant evidence suggesting that AF increases the risk of death, HF-related hospitalization and stroke or transient ischemic attack [9–12]. These

clinical and therapeutic implications make it advisable to search for novel factors that predispose to AF in patients with HF. The various hemodynamic, neuroendocrine, and inflammatory changes associated with HF result in both structural and functional changes to the left atrium, which contributes to the development of AF. Such changes, known as left atrial (LA) remodeling, alter LA cardiomyocytes and increase noncollagen deposits in the extracellular matrix, which leads to LA dilatation and fibrosis, and subsequent LA dysfunction and electrical conduction delay [13]. These remodeling processes are referred to as atrial cardiomyopathy; with risk factors including old age, obesity, diabetes mellitus, hypertension, and obstructive sleep apnea. Atrial cardiomyopathy not only precedes the development of AF but also, due to blood stasis and endothelial dysfunction, forms a prothrombotic milieu, which may lead to a stroke [14]. Figure shows a diagram illustrating the mechanism of atrial fibrillation development in heart failure.



**Figure.** Diagram showing the mechanism of atrial fibrillation development in heart failure

### Clinical risk factors and biochemical parameters

The main driving force behind the growing incidence of AF is population aging, with such conditions as hypertension, diabetes mellitus, HF, coronary artery disease, chronic kidney disease, obesity, and obstructive sleep apnea, also playing a role. The risk of developing AF is lower among women and non-Caucasians [15, 16]. Considering the aging population, the increasing co-occurrence of AF and HF has been highlighted, as these two conditions have similar underlying pathological mechanisms, which, combined, adversely affect the overall risk of cardiovascular events [17]. Based on a large, multinational, European Society of Cardiology registry of patients with HF, AF has been associated with older age, higher New York Heart Association (NYHA) class, history of HF-related hospitalizations, increased heart rate at rest, and more significant symptoms of congestion [18]. The prevalence of AF in the evaluated population was 27% in patients with HF with reduced ejection fraction (HFrEF), 29% in patients with HF with mildly reduced ejection fraction (HFmrEF), and 39% in patients with HF with preserved ejection fraction (HFpEF). AF rates were associated with age, reaching 50% in over 80-year-olds. Patients with AF were more likely to have non-ischemic HF, history of

stroke, and more advanced mitral regurgitation than individuals with sinus rhythm. Moreover, in comparison with sinus rhythm, AF was associated with higher N-terminal pro-hormone of brain natriuretic peptide (NTproBNP) levels in each HF phenotype subgroup. The mentioned study also showed higher cardiovascular risk and mortality in people with AF irrespective of their left ventricular ejection fraction (LVEF). Pellicori et al. [19] demonstrated that despite having higher LVEF, patients with HF and AF presented with more severe symptoms, higher NTproBNP levels, worse kidney function, and higher rates of loop diuretic treatment than people with sinus rhythm. The study had been conducted in a group of 3,570 patients with HF, 1,164 (33%) of whom had AF at baseline. In this group, HFpEF was more common than HFrEF (40% vs. 26%,  $p < 0.001$ ). Of patients in sinus rhythm, 1,372 had HFrEF and 1,034 had HFpEF. The incidence of AF at one year was similar (3%) for each HF phenotype ( $p = 0.73$ ). Age, male sex, history of paroxysmal AF, and higher NTproBNP levels were found to be independent predictors of incident AF during a median follow-up of 1,574 days.

Coronary artery disease, low systolic and diastolic blood pressure, and increased creatinine and bilirubin levels were other parameters associated with NOAF in the study mentioned above.

A 2018 Chinese study also assessing the association between AF and HF with different categories of ejection fraction showed age, coronary artery disease, heart rate, and both LA and left ventricular end-diastolic diameters to be associated with NOAF independently of LVEF [12]. The 405 patients with HF included in that study were stratified into three subgroups based on their LVEF: HFrEF ( $n = 109$ , 26.9%), HFmrEF ( $n = 94$ , 23.2%), and HFpEF ( $n = 202$ , 49.8%). Patients with HFpEF and HFmrEF were found to have a higher prevalence of AF than those with HFrEF. Moreover, AF was associated with a higher risk of death and HF-related hospitalization.

Electrolyte imbalance is usually linked to an increased risk of NOAF. Hypokalemia and hyponatremia are the most common electrolyte abnormalities encountered in clinical practice, especially in patients with HF. In their studies investigating the relationship between potassium concentration and the risk of atrial arrhythmias, Auer et al. [20] have shown that lower serum potassium concentrations increase the perioperative risk of AF. Krijthe et al. [21] have also reported a link between increased risk of AF and hypokalemia ( $< 3.50$  mmol/l).

A Turkish study demonstrated hyponatremia (apart from other well-known risk factors) to be significantly and independently associated with AF (odds ratio [OR] = 2.457; 95% confidence interval [CI] = 1.586–3.806,  $p < 0.001$ ) [22]. Lu et al. [23] revealed that low sodium and low potassium-induced slowing of sinoatrial node beating rate and increased pulmonary veins burst firing might contribute to the higher occurrence of AF during hyponatremia or hypokalemia.

### Echocardiographic predictors of AF

LA enlargement and dysfunction may be treated as predictors of AF. Furthermore, AF itself additionally contrib-

utes to the worsening of these two parameters. Recent studies have assessed the use of novel echocardiographic techniques, such as speckle-tracking echocardiography, in predicting AF in patients with HF. Park et al. [24] evaluated the prognostic value of reduced peak atrial longitudinal strain (PALS) in patients with HF. The study subjects were stratified by quartiles of PALS, and then further subdivided by LVEF values and history of AF. The primary endpoints were overall mortality and HF-related hospitalization. The incidence of NOAF over a five-year follow-up was shown to be higher in patients with reduced PALS ( $\leq 18\%$ ) (18.2% vs. 12.7%;  $p < 0.001$ ) across all HF phenotypes. Having adjusted for covariates, the authors identified five other predictors of NOAF: age  $> 70$

years, hypertension, LA volume index (LAVI) ( $\geq 40$  mL/m<sup>2</sup>), HFpEF, and no beta-blocker prescription at discharge. Another study on the topic was conducted by Malagoli et al. [25], who assessed the predictive value of PALS in a group of patients with HFrEF, with the study population stratified into HFrEF quartiles. First-quartile patients (with the lowest PALS values) were shown to have the highest risk of NOAF. This subgroup was also characterized by worse renal function, higher NYHA class, higher brain natriuretic peptide levels, greater LA volume, lower LVEF, and worse left ventricular diastolic function than fourth-quartile patients (with the highest PALS values). Additionally, PALS assessment via speckle-tracking echocardiography was shown to be an independent predictor of cardiovas-

**Table.** Proposed predictors of NOAF in patients with heart failure

Publication	Study population	Evaluated clinical parameters	Evaluated biochemical parameters	Evaluated echocardiographic parameters
Xu et al. [12]	HFpEF HFmrEF HFrEF	Age: • 77 $\pm$ 8 in HFpEF • 71 $\pm$ 10 in HFmrEF • 69 $\pm$ 9 in HFrEF Coronary artery disease Heart rate: • 86 in HFpEF; • 98 $\pm$ 25 in HFmrEF • 94 $\pm$ 25 in HFrEF	BNP Cholesterol Triglycerides	LA diameter LVEDd
Zafirir et al. [18]	HFpEF HFmrEF HFrEF	Age: • 74.3 $\pm$ 11.5 in HFpEF • 70.4 $\pm$ 12.2 in HFmrEF • 68.5 $\pm$ 11.2 in HFrEF Resting heart rate: • 89.2 $\pm$ 27.8 in HFpEF • 91.1 $\pm$ 26.9 in HFmrEF • 90.3 $\pm$ 26.6 in HFrEF Male sex NYHA functional class III and IV History of stroke Non-ischemic HF History of HF hospitalization	NTproBNP: • 2,500 pg/mL in HFpEF • 2,615 pg/mL in HFmrEF • 3,320 pg/mL in HFrEF	Moderate-to-severe mitral regurgitation
Pellicori et al. [19]	LVEF $> 45\%$ vs. LVEF $< 45\%$	Age 76 years (70–82) Male sex History of paroxysmal AF Ischemic heart disease	NTproBNP 1,936 (1,057–3,607) ng/L Creatinine 104 (86–130) $\mu$ mol/L; Bilirubin 16 (13–21) $\mu$ mol/L	LA diameter 4.7 cm
Cavusoglu et al. [22]	HFrEF	(-)	Sodium $< 135$ mmol/L	(-)
Park et al. [24]	HFpEF HFmrEF HFrEF	Age $> 70$ years Hypertension	(-)	$\downarrow$ PALS $< 18\%$ $\uparrow$ LAVI $> 40$ mL/m <sup>2</sup>
Malagoli et al. [25]	HFrEF	(-)	(-)	$\uparrow$ PALS LAVI
Choi et al. [26]	Dual-chamber pacemaker or ICD	(-)	(-)	GLAS $< 37.4\%$
Kosmala et al. [27]	Dual-chamber pacemaker	Age Higher SBP	(-)	$\downarrow$ LA strain $\uparrow$ LA volume $\downarrow$ LVEF

Abbreviations: BNP – brain natriuretic peptide; GLAS – global left atrial strain; HF – heart failure; HFmrEF – heart failure with mildly reduced ejection fraction; HFpEF – heart failure with preserved ejection fraction; HFrEF – heart failure with reduced ejection fraction; ICD – implantable cardioverter-defibrillator; LA – left atrial; LAVI – left atrial volume index; LVEDd – left ventricular end-diastolic diameter; LVEF – left ventricular ejection fraction; NTproBNP – N-terminal prohormone of brain natriuretic peptide; NYHA – New York Heart Association; PALS – peak atrial longitudinal strain; SBP – systolic blood pressure

cular events. The lowest PALS values were associated with shorter cardiovascular event-free survival than the highest PALS values. A South Korean study [26] assessed whether global LA strain (GLAS) might be a predictor of AF. The retrospective study included 127 patients with a cardiac implantable electronic device (either a dual-chamber pacemaker or implantable cardioverter-defibrillator). The development of silent AF (SAF) was adopted as the primary endpoint, while death, stroke, and HF-related hospitalization constituted the composite secondary endpoints. The main endpoint was reached in 13.4% of the study population ( $n = 17$ ). Patients with SAF had significantly higher LAVI and lower GLAS values. After adjusting for age, LVEF and LAVI, GLAS values of  $<37.4\%$  were shown to be a single predictor of SAF (HR 7.382; 95% CI 1.64–33.27;  $p = 0.009$ ). GLAS values of  $<37.4\%$  were also independently associated with the composite secondary endpoint after adjustment for the CHA<sub>2</sub>DS<sub>2</sub>-VASc score (HR 5.43; 95% CI 1.14–25.87;  $p = 0.034$ ). A study by Kosmala et al. [27] also demonstrated that, in addition to LA volume and other clinical parameters, speckle-tracking echocardiography might help assess the risk of NOAF. A total of 146 patients with negative AF history who were treated with dual-chamber pacing were included. Over a two-year follow-up, NOAF was observed in 29 patients (20%), two of whom developed permanent AF. NOAF was associated with higher systolic blood pressure ( $p = 0.01$ ), lower LVEF ( $p = 0.03$ ), lower LA strain during atrial contraction ( $p < 0.001$ ), and higher LA volume ( $p < 0.003$ ). A study conducted at a Warsaw center showed that lower LA reservoir strain in patients with AF undergoing radiofrequency catheter ablation was associated with older age, female sex, LA enlargement, and worse left ventricular diastolic function [28]. Moreover, lower LA reservoir strain and lower LA strain during atrial contraction were linked to higher LA pressure values (measured directly), which indicates that these novel echocardiographic parameters may be useful in assessing LA dysfunction.

The proposed selected predictive factors of NOAF in patients with heart failure are summarized in table.

### Carotid artery atherosclerosis

An interesting parameter studied in the context of the risk of developing NOAF, though not assessed directly in heart failure patients, is carotid intima-media thickness (cIMT). Atherosclerosis is an important etiologic factor predisposing to the development of HF, mainly located in the intima of many medium-sized arteries. Non-invasive imaging techniques for assessing anatomic or functional manifestations of atherosclerosis include carotid artery ultrasonography. Carotid intima-media thickness is a less recognized parameter considered to be a predictor of AF (to a similar extent as hypertension and HF). The parameter has been associated with subclinical atherosclerosis, and its increase helps predict the risk of cardiovascular events. Studies have shown increased cIMT to be an independent predictor of AF. Three studies (Rotterdam [29], Bruneck [30], and Malmö [31]) demonstrated that ultrasound-measured cIMT predicted the risk of NOAF. Willeit et al. [30] reported that detectable carotid artery atherosclerosis preceded the development of AF in 8 out of 10 patients, and conversely, atherosclerosis-free individuals were unlikely to develop AF. A recent study on lone AF (i.e., AF in non-elderly patients without un-

derlying heart disease or other risk factors) showed this arrhythmia to be significantly associated with increased cIMT and increased arterial stiffness [32]. The study population comprised euthyroid,  $<60$ -year-olds without diabetes mellitus, hypertension, coronary artery disease, HF, valvular disease, or cardiomyopathy. Increased cIMT and increased arterial stiffness were also associated with sustained (persistent or permanent) AF. The authors proposed that early structural and functional arterial changes might contribute to AF development. A 2015 Italian study showed a strong pathophysiological link between atherosclerosis and the development of AF. The cut-off value for increased cIMT was adopted at 0.9 mm, with values above 1.5 mm defined as atherosclerotic plaque. Out of the 673 patients with AF (paroxysmal [38%], persistent [18%], or permanent [44%]) included in the study, 71% had a cIMT of  $>0.9$  mm. In comparison with individuals with normal cIMT values, patients with increased cIMT were older; had higher rates of previous hypertension, diabetes mellitus, or stroke; presented with persistent or permanent AF; and had CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of  $>2$ . Increased cIMT predicts not only NOAF but also the progression of paroxysmal AF to persistent/permanent AF [33]. The results of the clinical studies mentioned above seem to indicate that carotid artery atherosclerosis and cIMT are closely associated with coronary artery atherosclerosis and microvascular injury, which may lead to impaired LA perfusion and ischemia and, consequently, fibrosis and AF. Moreover, aortic and cardiac remodeling may be a common denominator linking the potentially adverse effects of age, hypertension, and carotid atherosclerosis. Therefore, it seems that cIMT assessment should be considered in predicting AF, irrespective of the established indicators of AF risk.

### Conclusions

In summary, there are many factors that may increase the risk of NOAF in patients with HF, which aggravates the underlying disease in a population whose survival rates are already significantly lower than in the general population. Early intervention and control of modifiable risk factors seem to decrease the incidence of NOAF, thus improving the prognosis in patients with HF. Measurement of the AF predictors discussed in this paper in patients with HF may help identify those at the highest risk of NOAF and improve already known tools for risk assessment. The relative paucity of data on the predictors of NOAF discussed in this paper and the considerable effect of AF on the prognosis in patients with HF warrant a continued search for novel NOAF predictors and validation of the already proposed ones. More accurate prediction of NOAF would most likely help in earlier diagnosis and more effective preventive measures in this population.

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# PHARMACOLOGICAL TREATMENT OF SCARS AFTER GYNAECOLOGICAL AND OBSTETRIC SURGERIES

Farmakologia w terapii blizn po operacjach ginekologicznych i położniczych



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## Abstract

Scarring after gynaecological (e.g., hysterectomy), urogynaecological (e.g., treatment of pelvic organ prolapse and/or incontinence) or obstetric (e.g., caesarean section) procedures is one of the most common reasons for reporting to a urogynaecological physiotherapist. The consequences of surgical treatment may include hypertrophic scarring or keloids; chronic pelvic pain; dyspareunia; infertility; non-specific gastrointestinal, urinary, reproductive complaints; musculoskeletal pain syndromes; abnormal posture and gait patterns. In order to counteract or reduce the consequences of postoperative adhesions, scar treatment should be implemented in a planned manner, using appropriate pharmacological agents as a base. The efficacy of many preparations for this purpose has not been proven or investigated. The article discusses active substances included in preparations for scar treatment, with detailed description of their characteristics, mechanism of action, pharmacological aspects and available scientific studies. We also propose a plan for scar treatment, taking into account the stages of wound healing, and pointing to the methods in which the use of pharmacological agents is justified.

## Streszczenie

Jednym z najczęstszych powodów zgłaszania się pacjentek do fizjoterapeuty uroginekologicznego jest blizna po operacji ginekologicznej (np. usunięcia macicy), uroginekologicznej (np. leczenia zaburzenia statyki narządów miednicy mniejszej lub nietrzymania moczu) lub położniczej (np. cięcia cesarskiego). Konsekwencją przebytej operacji mogą być: blizna przerostowa lub bliznowiec, przewlekły ból miednicy, dyspareunia, niepłodność, nieswoiste dolegliwości układów pokarmowego, moczowego lub rozrodczego, zespoły bólowe narządu ruchu lub zaburzenie wzorca postawy ciała i chodu. Aby przeciwdziałać konsekwencjom wzrostów pooperacyjnych lub je ograniczyć, należy w sposób planowany wdrożyć terapię blizny, najlepiej z wykorzystaniem odpowiednich środków farmakologicznych jako podłoża. W przypadku wielu z przeznaczonych do tego celu preparatów nie udowodniono ich skuteczności lub jej nie badano. W artykule omówiono substancje aktywne wchodzące w skład preparatów do leczenia blizn, wyszczególniając ich charakterystykę, mechanizm działania, aspekty farmakologiczne i dostępne badania naukowe na ich temat. Przedstawiono również autorski plan terapii blizny, uwzględniający etapy gojenia się rany, i wskazano metody, w których zasadne jest zastosowanie środków farmakologicznych.

**Keywords:** physiotherapy, gynaecology, obstetrics, pharmacology, scar treatment

**Słowa kluczowe:** fizjoterapia, ginekologia, położnictwo, farmakologia, terapia blizny

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## Introduction

Scars following gynaecological or obstetric surgery are one of the most common reasons for patients present-

ing to a urogynaecological physiotherapist. Scar therapy can be supported with pharmacological agents used as a base. Unfortunately, many of the preparations intended for this purpose do not have the status of a medicinal

product or even a medical device. Their efficacy has never been proven or even investigated. This interdisciplinary paper will help physiotherapists select a proper preparation and estimate its actual efficacy in scar therapy, which makes the present paper pioneering in this respect.

### Surgical treatment

Since hysterectomy, which is associated with the risk of pelvic organ prolapse (POP), is the most common gynaecological surgery, sparing procedures are recommended whenever possible (i.e. in patients with no risk of cancer) [1].

On the other hand, the goal of surgical treatment of pelvic floor disorders (POP and urinary incontinence, UI), which represent a significant social problem (according to various estimates, urinary incontinence affects 17–46% of women and up to 60% of menopausal women), is to restore normal anatomical relationships and improve the quality of life of patients in all aspects, i.e. eliminate pain, infectious, micturition and anorectal disorders, as well as sexual dysfunctions [2].

Finally, caesarean section (CC) is the most common obstetric surgery. The worldwide caesarean section rates are systematically growing, accounting for more than 80% in the private sector in some countries. The same trend may be seen in Poland, with CCs accounting for 47% of total births in 2022 (>50% in seven voivodeships).

### Sequelae

Poor appearance of both the postoperative scar itself (hypertrophic scar, scarring) and the abdomen is most common complaint reported by patients following urogynaecological, gynaecological (abdominal access) and obstetric surgeries. The postoperative scar, even when properly formed, often adheres to the underlying tissues, which results in an overhang of skin and subcutaneous tissue [3].

However, adhesions, which affect between 46% and up to 100% of CC patients, are a significantly more serious consequence of surgery [4]. Postoperative adhesions may cause chronic pelvic pain (accounting for 10% of the reasons for gynaecologic appointments and affecting 6–50% of women after laparoscopic surgery), dyspareunia, infertility (accounting for infertility in 15–20% of patients), as well as non-specific gastrointestinal, urinary, reproductive and other symptoms [3, 5].

Musculoskeletal pain syndromes can develop as distant (both in terms of time and site) sequelae of postoperative adhesions resulting from restrictions within the healing tissues (i.e. reduced slide between tissue layers). They are caused by abnormal posture and gait patterns, altered tone and resting length of antagonistic muscle groups, and a change in the geometry and reduced elasticity of the fascia, which result from the presence of scarring (i.e. an area of inextensible tissues glued together). This can cause pain syndromes in the head, spine and pelvis [3].

### Work with scars

In order to counteract the consequences of postoperative adhesions in this group of patients, or to reduce

them as much as possible, a well-planned scar therapy should be implemented, preferably using pharmacological agents as a base to promote proper healing of the scar and improve its aesthetics (tab.).

### Pharmacology in scar work

This part of the paper discusses the key active substances included in formulations for scar work, with a detailed description of active substance, its action, pharmacological aspects and available research assessing its efficacy.

#### Allantoin

**Description:** Allantoin belongs to the group of ureides (5-ureidohydantoin). It is a derivative of uric acid, a compound of plant origin, found in raw materials obtained from common comfrey (*Symphytum officinale*), its root in particular [6]. Preparations with medicinal product status are manufactured based on this substance.

**Action:** Allantoin is a commonly applied and widely described pharmacological and cosmetic agent. It is used to improve wound healing, stimulate cell mitosis and provide a keratolytic effect. It also promotes epithelial stimulation, has an anti-irritant and moisturising effect and accelerates granulation [6]. Its efficacy is particularly pronounced when used in combination with onion extracts.

**Pharmacological aspects:** Despite numerous citations, there are very few papers focusing on the actual mechanism of action of allantoin or showing the histological profile of wound healing.

**Research:** Araújo et al. [6] confirmed the efficacy of allantoin in wound healing in 2010. They also showed that the resulting tissue is better organised and has a structure more similar to healthy skin. Importantly, however, the authors pointed out that although 5% allantoin improves wound healing in treated patients compared to controls, the effect is not as strong as reported in the literature. Conti et al. [7] demonstrated that a monthly therapy with patches containing onion extract and allantoin reduced scars, increased their elasticity and improved pigmentation in women after CC. There are studies confirming the interesting properties of allantoin used for skin scaffolds, which have shown that it has antimicrobial and peripheral antinociceptive effects [8]. Allantoin-enriched pectin hydrogels show high potential for efficient use in wound healing [9].

#### Mountain arnica and meadow arnica

**Description:** The flowers of mountain arnica (*Arnica montana*) or meadow arnica (*Arnica chamissonis*), from which liquid water/alcohol extracts and ethanol tinctures are prepared, are used for medical purposes. They are used in a semi-solid form (5–50%), undiluted or diluted with water for compresses. Arnica flowers contain pseudoguaianolide sesquiterpene lactones, primarily represented by helenalin and dihydrohelenalin, as well as their esters, and these are considered the main active substances [10]. This raw material is used as the basis for formulations with medicinal product status.

**Table.** The author's original Scar Therapy Programme for patients after gynaecological and obstetric surgeries – physiotherapeutic methods

Phase	Physiotherapy methods
<b>Inflammation</b> (2–5 days postoperatively)	<ul style="list-style-type: none"> <li>• manual lymphatic drainage (MDL) of the areas adjacent to the postoperative wound (abdomen and limbs)</li> <li>• lymphatic brush drainage of the areas adjacent to the postoperative wound (abdomen and limbs) using the ScarBrushing technique (ScarBru)<sup>a</sup></li> <li>• self-lymph brush drainage of the areas adjacent to the postoperative wound (abdomen and limbs) – ScarBru<sup>a</sup></li> <li>• wound closure strips</li> </ul>
<b>Proliferation and angiogenesis</b> (up to 6–8 weeks postoperatively)	<ul style="list-style-type: none"> <li>• <i>MDL of the areas adjacent to the postoperative wound (abdomen and limbs) and the wound area</i></li> <li>• <i>lymphatic brush drainage of the areas adjacent to the postoperative wound (abdomen and limbs) and the wound area (ScarBru)</i></li> <li>• <i>self-lymph brush drainage of the areas adjacent to the postoperative wound (abdomen and limbs) and the wound area – ScarBru</i></li> <li>• <i>myofascial release of the abdomen and limbs, e.g. by Carole Manheim</i></li> <li>• radiofrequency</li> <li>• low level laser therapy</li> <li>• medical taping / Kinesio taping</li> </ul>
<b>Remodelling</b> (up to 6–24 months postoperatively)	<ul style="list-style-type: none"> <li>• <i>continue the management used in the proliferation and angiogenesis phase (depending on the patient's condition)</i></li> <li>• <i>direct manual scar treatment – gradual introduction of techniques</i></li> <li>• <i>autotherapy – direct manual scar treatment – gradual introduction of techniques</i></li> <li>• <i>gua sha</i></li> <li>• <i>medical (vacuum) cupping</i></li> <li>• <i>pinotherapy/pinopressure</i></li> <li>• <i>instrument assisted soft tissue mobilization (IASTM)</i></li> <li>• <i>iontophoresis</i></li> <li>• <i>high-intensity laser therapy (HILT)</i></li> <li>• <i>dry needling</i></li> <li>• <i>electroneedling</i></li> <li>• <i>neuromodulation</i></li> </ul>
Techniques with recommended use of pharmacological agents as a base for gynaecological and obstetric scar physiotherapy are given in italics. <sup>a</sup> by M. Chochowska.	

**Action:** Helenalin shows selective inhibitory effects against NF- $\kappa$ B factor activation, as well as against RelA binding to DNA, without affecting the activity of  $\kappa$ B inhibitor kinases [10]. A modulatory effect on the NF- $\kappa$ B/I $\kappa$ B complex, preventing the release of I $\kappa$ B, has been postulated. This molecular mechanism of anti-inflammatory action is characteristic of sesquiterpene lactones (SLs) and differs significantly from that of the non-steroidal anti-inflammatory drugs (NSAIDs). NF- $\kappa$ B is a protein responsible for the transcription of genes encoding various inflammatory mediators [11].

**Pharmacological aspects:** SLs contained in mountain arnica flowers are slowly absorbed from the site of external (dermal) application. They penetrate the skin to a small extent and accumulate in the stratum corneum. Distribution and elimination following transdermal absorption is assumed to be analogous to intravenous (i.v.) and intraperitoneal (i.p.) administration. Although there are reports on the toxicity of helenalin, these refer to its oral use (in a mouse study, the LD<sub>50</sub> values of helenalin were 43 mg/kg bw after i.p. administration and 85–150 mg/kg bw after i.v. administration) [12].

**Research:** There are too few studies on the mechanism of action and efficacy of arnica montana-based products. Oliosio et al. [13] have presented new hypotheses from their polymerase chain reaction studies on the effect of

this plant on human macrophages. Importantly, arnica montana ointments have been shown to be effective in the treatment of inflammatory processes and UVB-induced oxidative damage.

### **Allium cepa**

**Description:** Onion bulbs (*Allium cepa*) are used in medicine. Sulfoxides are the main active compounds contained in onion [9]. The enzyme (alliinase) present in the common onion causes the formation of alliin as a product of alliin transformation. Raw material is used for preparations with drug status.

**Action:** Onion extract shows the therapeutic effect on human skin fibroblast cell line. It additionally prevents the formation of keloids and hypertrophic scars. Onion extract is used to improve the cosmetic appearance of postoperative scars, while onion ointments enhance the elasticity of burn scars [14]. Onion extracts have antimicrobial effects, inhibit platelet aggregation and reduce blood pressure [15]. Since studies on the efficacy of these actions are inconclusive (some indicate low efficacy), these extracts are mainly included in combined preparations.

**Pharmacological aspects:** The plant extract has effects on connective tissue metabolism, reduces granulation overgrowth, prevents hypertrophic scar formation and

enhances softening and relaxation of scar tissue. Since quercetin contained in an onion bulb shows poor transdermal absorption, this form of administration is not sufficiently effective.

**Research:** Prager and Gauglitz [16] reported that the use of occlusive patches containing onion extract and allantoin overnight effectively reduces acne scars. However, Jackson and Shelton [17] showed no improvement in local pruritus or scar erythema after application of onion extract gel.

### **Dexpanthenol**

**Description:** Dexpanthenol belongs to the vitamin B group and is an analogue of pantothenic acid, a precursor of coenzyme A.

**Action:** Dexpanthenol facilitates wound healing, increases epidermal differentiation, strengthens the skin barrier and has a moisturising and anti-inflammatory effect. It is used for medicinal products and medical devices.

**Pharmacological aspects:** dexpanthenol is well absorbed into the skin, where it undergoes rapid conversion into pantothenic acid, a component of coenzyme A (essential for physiological epithelial function). Data on the expression of genes responsible for wound healing based on 3D skin models indicate that dexpanthenol effectively upregulates these genes (good correlation of *in vivo* model with dexpanthenol compared to 3D skin models) [18].

**Research:** Many studies indicate that dexpanthenol can effectively prevent skin irritation, enhance skin regeneration and stimulate wound healing [19].

### **Hyaluronic acid**

**Description:** Hyaluronic acid (HA) is a polysaccharide with water-holding capacity. It is a component of connective tissue. HA consists of repeating disaccharides (D-glucuronic acid and N-acetylglucosamine). It was first isolated in the 1930s. HA is mainly used in medical devices and very few medicinal products.

**Action:** Hyaluronic acid is used as a dermal filler for correcting acne scars.

**Pharmacological aspects:** HA has the potential to normalise keloid fibroblast characteristic features such as hyperproliferation and growth factor production [20]. This way, fibrosis and keloid manifestation are reduced. High molecular weight hyaluronic acid has an anti-inflammatory effect, while low molecular weight molecules promote inflammation. Hyaluronic acid shows good skin penetration, which further increases when incorporated in formulations using ethosomes (phospholipid nanovesicles). After penetrating the outer layer, HA accumulates in the epidermis, which limits its systemic effects.

**Research:** Experimental studies on tympanic membrane perforations in rats treated with HA have shown that the perforations not only closed faster, but also left behind

significantly less scarring compared to controls [21]. Additionally, the efficacy of combined treatment using 1,540-nm fractional erbium:glass laser and hyaluronic acid injections has been demonstrated [22].

### **Collagen**

**Description:** Collagen is the most abundant protein in animals. It consists of a bundle of three left-handed polypeptide helices. Collagen accounts for one third of total human protein and is the most prevalent component of the extracellular matrix (ECM). It is mainly used in medical devices and dietary supplements.

**Action:** Natural collagen can form into structured, three-dimensional structures that are biocompatible, biodegradable and non-toxic, and is therefore used to support wound healing.

**Pharmacological aspects:** Pilot studies have shown that percutaneous collagen induction (microneedling) at a scar led to a significant increase in collagen content, elastin deposition and thickening of the spinous layer [23]. This mode of administration has the advantage of reaching areas inaccessible to ablative laser therapy. When ingested, collagen is broken down into amino acids, and therefore it is the body that decides on their assimilation and increased collagen production (it is beyond our influence in which tissue this process occurs most effectively). It seems very controversial that collagen, which is a relatively large protein, is able to penetrate intact skin. However, there are studies indicating that such penetration is possible with sufficiently high lipophilicity of fish-scale collagen peptides (FSCPs) (as the dominant factor in overcoming the barrier) [24]. The use of collagen preparations to treat wounds is a separate issue. Collagen gels, membranes, dressings, and injections ensure good collagen accumulation in damaged tissue. However, poor thermal and mechanical properties of collagen mean that it can be used in combination with other substances (e.g. alligans and chitosan) [25].

**Research:** Microneedle patches with collagen seem to be of great interest. A study on type I collagen patches showed that the microneedle system is effective in delivering collagen to the epidermis and dermis in humans [26].

### **Cocoa butter and shea butter**

**Description:** Cocoa butter is a mixture of triglycerides of oleic, palmitic and stearic acids, virtually insoluble in water. This natural fat extracted from the seed kernels of the cocoa tree (*Theobroma cacao*) contains saturated and unsaturated fatty acids. It is also a source of copper, iron and magnesium, as well as polyphenols that neutralise free radicals [27].

Shea butter is an oil extracted from the seeds of the shea tree (*Vitellaria paradoxa*). It contains significant amounts of resins, as well as oleic and stearic acids, which are mainly used for cosmetics.

**Action:** Both substances provide the skin with adequate oiliness, elasticity and firmness, as well as work as an emollient. Cocoa butter additionally contains polyphenols

nols with antioxidant properties [27]. Shea butter also has antioxidant and anti-inflammatory properties and protects against UV radiation [28]. These butters are very popular ingredients of different formulations (mainly cosmetics), combined with other substances, e.g. in the form of creams. Products combining these two butters can also be found.

**Pharmacological aspects:** Studies confirm both the antioxidant and anti-inflammatory effects of shea butter. However, clear data to actually conclude that this substance helps in healing wounds are missing [28]. The same may be said about cocoa butter. Creams based on shea butter show better transdermal absorption compared to lanolin. As a result, higher levels of the active ingredient (if contained in the formulation) reach the site of action. Studies on the moisturising properties of cocoa butter indicate that its combined use with glycerine prolongs the moisturising effect of the composition [29].

**Research:** Moore et al. did not confirm that any topical agent (including cocoa butter and olive oil) could prevent or reduce stretch marks [30].

### Olive oil

**Description:** The composition of olive oil is primarily triacylglycerols, the richest source of monounsaturated oleic acid. Sterols, tocopherols, phenolic compounds, antioxidants, squalene and squalane are also found in olive oil. The raw material is mainly used to produce cosmetics. **Action:** Due to its content of squalane, which prevents transepidermal water loss, olive oil helps reduce moisture loss from the skin. Additionally, the compounds it contains have proven antioxidant and anti-inflammatory effects and promote wound healing [28]. This provides slight lubrication of the outer layers of the epidermis and improved hydration of the deeper parts of the skin.

**Pharmacological aspects:** Polyphenols contained in the oil are mainly responsible for improving wound healing; however, too few studies have been conducted to discuss this issue comprehensively.

**Studies:** Taavoni et al. [31] have not confirmed that any topical agent (including cocoa butter and olive oil) prevents or reduces stretch marks; however, studies in mice have shown that olive oil improves wound healing by reducing inflammation in pressure sores [32].

### Manuka honey

**Description:** Manuka honey is a natural bee product derived from the nectar of the flowers of the manuka shrub (*Leptospermum scoparium*). The plant is native to New Zealand and parts of Australia [33]. Manuka honey is mainly used for medical devices.

**Action:** The health-promoting effects of manuka honey, including its antimicrobial properties, are due to a different mechanism from that of other honeys. This is because manuka honey contains methylglyoxal, formed from the dihydroxyacetone present in the flower nectar. This action has been confirmed against both planktonic bacteria

and biofilm strains of *S. aureus*, *P. aeruginosa*, and partially against *E. coli* and *P. mirabilis* [33].

**Pharmacological aspects:** Methylglyoxal modifies DNA, RNA and cell proteins to produce antimicrobial effects. However, there are no studies on such interaction with human cells. The antimicrobial effects are also due to high osmolarity. The natural high carbohydrate content of manuka honey, which means that diabetic patients should not use it without consulting their doctor (there are no such contraindications with manuka honey dressings), is a significant limitation. The honey has an immunostimulant, anti-inflammatory and antimicrobial effect on the wound, as well as it reduces scar formation [33]. It maintains proper level of moisture, thereby accelerating wound healing, while preventing bacterial growth. Its low pH acidifies the environment and deactivates proteinases that break down proteins responsible for the healing process [33].

**Research:** Seventeen randomised trials (1,965 participants) have reported the benefits of manuka honey used as a wound dressing [34]. Additionally, a study by Malhotra et al. indicated a possible subjective benefit of manuka honey in eyelid wound healing, even in the early post-operative period [35].

### Insulin ointments

**Description:** Insulin is an anabolic peptide hormone secreted by the beta cells of the Islets of Langerhans and has many physiological functions in the human body. Although insulin ointments are a rare prescription drug, they can be encountered in practice. Insulin is mainly used for cosmetics and (prescription) drugs.

**Action:** In the context of wound treatment, insulin induces an early neutrophil response, increases macrophage count and IL-10 levels, facilitates phagocytosis, enhances local keratocyte migration, increases local collagen deposition and maturation, as well as boosts local angiogenesis. It also has antioxidant effects following topical application [36].

**Pharmacological aspects:** Insulin receptors (tyrosine kinase type), which occur in all cell types, are also found in keratocytes and fibroblasts. Topical application of insulin (ointment) on skin wounds enhances keratinocyte migration. Faster wound healing is due to upregulation of integrin  $\alpha3\beta1$  in keratocytes [36]. Systemic administration of insulin is associated with subsequent hypoglycaemia and hypokalaemia, and therefore topical forms are often used. However, due to the need for an additional carrier to stabilise the dose reaching the tissue in a given unit of time (better penetration and relatively constant rate), this form is still imperfect. Consequently, insulin is generally used in the form of ointment and can also be administered on stable carriers, such as hydrogels [36].

**Research:** Lima et al. [37] showed improved wound healing after topical application of insulin creams in their animal and human diabetic studies. Similar findings were reported by Vatankhah et al. [38], with the reservation that further research is needed.

### Jojoba oil

**Description:** Jojoba oil is a type of liquid wax obtained from the seeds of *Simmondsia chinensis* (*jojoba*) plant. Squalene, cetyl palmitate, wax esters, hydrocarbons and phytosterols are the main active ingredients. This raw material is mainly used for cosmetics.

**Action:** Jojoba oil has a wide array of actions to promote wound healing, including anti-inflammatory, antimicrobial, moisturising, antioxidant and regenerative effects on skin tissue [28].

**Pharmacological aspects:** Jojoba oil shows good permeability, including absorption at the wound site. Studies on active substances confirmed better absorption of jojoba oil-based microemulsion of diclofenac compared to classical commercially available preparations [39]. Jojoba oil is included in emollient formulations.

**Research:** Preliminary studies have shown the efficacy of jojoba oil facial mask in improving damaged skin, also in patients with mild acne vulgaris [40].

### Silicones

**Description:** Silicones are siloxane polymers with oxygen-silicon bonds. Organic groups are additionally attached to the silicon atoms. These are anhydrous forms that mix well with ethanol or vegetable oils. These substances are mainly used for medical devices.

**Action:** The mechanism of action of silicone therapy for scars has not yet been clearly explained. However, it is most likely that by occluding the scar site and hydrating the wound bed, these preparations suppress and normalise cell activity within the scar, as well as improve its hydration and elasticity [41].

**Pharmacological aspects:** The use of silicone gels during the initial period of wound healing (1–2 weeks) is not justified as collagen plays a major role at this stage. However, after this period, the new and immature epidermal layer causes abnormal water loss from the site of the developing scar. This activates the keratocyte, cytokine and fibroblast pathways, resulting in excessive collagen synthesis and release. As a result, unsightly, irregular scars may appear. Silicones applied to the scar site promote proper hydration and probably inhibit the fibroblast pathway and collagen formation [41]. Silicones are very well tolerated by the human skin. The occlusive film layer adapts to the shape of the wound.

**Research:** Silicones are mainly available in the form of gels and creams. The former contain significantly higher amounts of silicones and are more widely used. Creams are mainly intended for mild acne scars. Silicone elastomers are increasingly popular means of silicone application. These are used in dressings, often in the form of patches (due to their adhesive properties). The efficacy of silicone dressings in the prevention of hypertrophic scars is approximately 68% [42]. There are studies showing that some silicone products may cause skin irritation in hot climates [43]. Silicone gels show better healing effects when combined with vitamin E than when used alone [44].

### Vitamin E

**Description:** Vitamin E is the collective name of a group of compounds including tocopherols and tocotrienols. It is synthesised by plants and therefore must be supplied with food. Vitamin E is found in large quantities in nuts, spinach and whole grain products. Vitamin E-based preparations usually come in the form of a dietary supplement. For topical use, the vitamin is usually combined with other substances (often with vitamin A), and the preparation can take the form of a cosmetic, medical device or even a medicinal product.

**Action:** Vitamin E has antioxidant effects, prevents lipid peroxidation, nourishes the skin, enhances elasticity and reduces skin inflammation and swelling [45].

**Pharmacological aspects:** Vitamin E can penetrate the epidermis well, improves hydration and, with its additional anti-inflammatory effects, it improves wound healing and reduces scarring. Its potent antioxidant effect is due to its strong anchorage in the skin structures (lipophilic chain). Vitamin E is most often found in preparations in the form of acetate, which is light-resistant and inhibits UVB radiation [45].

**Research:** Despite decades of research, complete evidence to support the efficacy of vitamin E in specific skin diseases is missing. From a pharmaceutical point of view, there are no purely therapeutic applications, but there are many reports on good cosmetic effects, including improved efficacy of silicone gels in combination with vitamin E [44]. Preparations for external use are on the borderline between medicinal products and cosmetics, and are commonly referred to as 'cosmeceuticals' due to their UVB-protective, antioxidant and moisturising effects.

### Conclusions

Physiotherapist is an independent medical profession whose duty is to plan and deliver treatment according to evidence-based medicine. This should also be borne in mind when treating scars with specific pharmacological agents containing different active substances. Knowledge of their mechanism of action, status (medicinal product, medical device or cosmetic) and, finally, their pharmacokinetics and pharmacodynamics cannot be overestimated in terms of the expected outcomes and satisfaction of patients after urogynaecological surgeries.

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# THE FULFILMENT OF PATIENTS' RIGHTS IN THE PROVISION OF TELECONSULTATIONS DURING THE COVID-19 EPIDEMIC STATE FROM THE VIEWPOINT OF ADMINISTRATIVE DECISIONS IN PROCEEDINGS IN CASE OF PRACTICES VIOLATING COLLECTIVE PATIENT'S RIGHTS



Realizacja praw pacjenta przy udzielaniu teleporad w stanie epidemii COVID-19 z perspektywy decyzji wydanych w postępowaniach w sprawach praktyk naruszających zbiorowe prawa pacjentów

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## Abstract

The article analyses the issues of the fulfilment of patients' rights in the provision of teleconsultations in primary healthcare during the COVID-19 epidemic state from the viewpoint of the public law protection instrument being the institution of practices violating collective patients' rights. This study aims to determine the practices of healthcare providers, which were verified by the Patients' Rights Ombudsman in proceedings in case of practices violating collective patient's rights. Moreover, the paper aims to identify particular manifestations of the violation of collective patients' rights. According to the analysis, the aforementioned proceedings focused essentially on two categories of practices of healthcare providers. The first one involves the limitation or deprivation of patients of real possibility to register for an appointment within publicly funded healthcare which are exemplified by such practices as: not answering or rejecting the patients' call and excessive waiting time for someone to answer the phone. The other group of practices constitutes the lack of full information about the conditions of providing teleconsultations in primary healthcare, which was required according to the organisational standard (absence of one, several, or all prescribed elements) on the website and on the premises of the clinic. Taking the above into consideration, it should be pointed out that the competence of the Patients' Rights Ombudsman in conducting proceedings in case of practices violating collective patients' rights has a real impact on the protection of patients' rights in systemic terms.

## Streszczenie

W artykule objęto analizą problematykę realizacji praw pacjenta przy udzielaniu teleporad w podstawowej opiece zdrowotnej w dobie stanu epidemii COVID-19 z perspektywy publicznoprawnego instrumentu ochrony praw pacjentów, jakim jest instytucja praktyk naruszających zbiorowe prawa pacjentów. Celem pracy było wskazanie zachowań podmiotów leczniczych związanych z realizacją tego rodzaju świadczeń zdrowotnych, które Rzecznik Praw Pacjenta weryfikował w postępowaniach w sprawach praktyk naruszających zbiorowe prawa pacjentów. Ponadto prowadzone rozważania zmierzały do zidentyfikowania konkretnych przejawów naruszeń zbiorowych praw pacjentów. Z przeprowadzonej analizy wynika, że przedmiotem tych postępowań były zasadniczo dwie kategorie zachowań podmiotów leczniczych. Pierwszą z nich stanowiło ograniczenie lub niezapewnienie pacjentom faktycznej możliwości rejestracji w celu uzyskania świadczeń opieki zdrowotnej finansowanych ze środków publicznych w podstawowej opiece zdrowotnej. W tym zakresie praktyki te przejawiały się przykładowo w nieodbieraniu czy odrzucaniu połączeń pacjentów oraz w zbyt długim czasie oczekiwania pacjenta na odebranie połączenia. Druga grupa zachowań obejmowała natomiast niedostępność na oficjalnej stronie internetowej czy w siedzibie podmiotu leczniczego pełnej informacji o warunkach realizacji teleporady w podstawowej opiece zdrowotnej zgodnie z treścią standardu organizacyjnego, co wyrażało się między innymi w braku umieszczenia jednego, kilku czy wszystkich wymaganych elementów. Mając to na uwadze, należy podkreślić, że kompetencja Rzecznika Praw Pacjenta w zakresie prowadzenia postępowań w sprawach praktyk naruszających zbiorowe prawa pacjentów realnie wpływa na ochronę praw pacjentów w ujęciu systemowym.

**Keywords:** Patients' Rights Ombudsman, patients' rights, telemedicine, COVID-19

**Słowa kluczowe:** Rzecznik Praw Pacjenta, prawa pacjenta, telemedycyna, COVID-19

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## Introduction

The problems of the fulfilment of patients' rights in the provision of teleconsultations in primary healthcare during the COVID-19 epidemic state may be analysed in multiple aspects. Presenting this issue in the light of the decisions issued by the Patients' Rights Ombudsman (hereinafter: the Ombudsman) in cases concerning practices violating the collective rights of patients during the special epidemic situation<sup>1</sup> is justified by the significant increase of the role of teleconsultations in providing healthcare services for patients during that time<sup>2</sup>. Growth of the number of this type of healthcare services led to a potentially increased risk of violating the patient's rights during their provision, so that it became necessary to develop some fundamental principles for applying such services. The organisational requirements were reflected in the content of the Ordinance of the Minister of Health of August 12 2020 on the organisational standard of teleconsultations in primary healthcare (hereinafter: the Ordinance) [1] that became effective on August 29 2020 and was later amended three times during the period of the state of epidemic. The amendments introduced during the state of epidemic were aimed at solving the most significant problems related to the provision of teleconsultations that emerged as a result of using this manner of providing health services. Another argument that supports the reasonability and validity of the presented analyses is the fact that, although the state of epidemic (and the state of epidemic threa<sup>3</sup>) were revoked, teleconsultations remained an element of the primary healthcare system. Therefore, the Ordinance continued to be important for the assessment of the fulfilment of the organisational requirements by the healthcare provider in providing the analysed form of healthcare services.

The aim of the study was to indicate such behaviour of the healthcare providers related to providing teleconsultations in the special epidemic state that were considered by the Ombudsman to violate the collective rights of patients. In the Introduction, the author explains the nature of proceedings in case of practices violating collective patients' rights. The relevant regulation is provided in Chapter 13 of the Act of 6 November 2008 on Patients' Rights and the Patients' Rights Ombudsman (hereinafter: the Act) [2] and constitutes a fundamental component of the protection of patients' rights under public law.

<sup>1</sup> In Poland, the state of epidemic lasted from 20 March 2020 to 15 May 2022.

<sup>2</sup> Medical consultation in an outpatient setting (including night and holiday care) provided at a distance, i.e. via ICT systems or telecommunication systems, has been a publicly funded service since 5 November 2019.

<sup>3</sup> In Poland, the state of epidemic was revoked on 16 May 2022, and on 1 July 2023 the state of epidemic threat was also cancelled.

In this section of the study, the author uses the formal and dogmatic method that was justified by the need to analyse the existing legal regulations in the scope described above. Then, based on the results of own research<sup>4</sup> and the data from the registers of decisions issued by the Ombudsman in cases of practices violating the collective rights of patients, presented in form of a table containing a list of several decisions [3], the conducts of healthcare providers being the subject of such proceedings were distinguished. The most commonly used practices were categorised and divided into groups.

Based on selected, decisions within the distinguished categories, specific symptoms of the conduct of the healthcare entity were also characterised. Decisions on the refusal to initiate proceedings in case of practices violating collective patients' rights and decisions imposing financial penalties were excluded from the scope of the deliberations.

The analysis of empirical research was conducted mainly with use of the qualitative method, including the quantitative method at the same time. The application of both these approaches allowed for a more comprehensive elaboration of the available data. The Summary contains the main conclusions from the conducted research.

### ***Practices violating collective patients' rights: definition and the outline of the course of the proceedings***

Proceedings in case of practices violating collective patient's rights are an element of the public law protection of the rights of patients treated as a collectivity that includes both current and potential patients. The violation of these rights occurs when the consequences of the actions may threaten or be realised in the sphere of every patient who is in a similar situation [4]. In this context, it is essential to determine that the action of the healthcare provider was addressed to an unspecified set of entities, not to a overdetermined recipient. What is important is not the count, but the nature of confirmed violations and the possibility, also potential, to cause negative effects in a specific group [5]. This results from the fact that collective patients' rights are not a sum of individual rights, but are linked to systemic conditions that enable the fulfilment of individual rights and to the creation of a factual state that characterises the manner of providing healthcare services to everybody who might use them [6].

In reference to the issues related to definitions, pursuant to Art. 59 section 1 of the Act, the term of prac-

<sup>4</sup> The study visit at the office of the Ombudsman for Patients' Rights was one of the elements of the realisation of the scientific activity entitled Implementation of patients' rights in the COVID-19 epidemic era and provision of teleconsultation in primary health care (preliminary research).

tices violating collective patients' rights includes two categories of behaviour that violates the law (unlawful, organised actions or omissions of entities providing healthcare services as well as the organisation a protest action or strike by the organiser, confirmed by a final court decision, contrary to the provision on the resolution of collective disputes, with the additional aimed at depriving or limiting patients of their rights, in particular if such actions are indeed to financial benefits. This means that the entity does not fulfil the patients' rights at all or ensures the fulfilment of these rights only to a certain extent, while acting in the above purpose. In the context of entities that provide healthcare benefits, the legislator emphasises the connection between the violation of patients' rights and the organisational sphere of the entity, pointing out that it refers to such manner of organising its activities that enables the violation of patients' rights or does not prevent it [7]. The application of such practices is prohibited by virtue of law (Art. 59 section 2 of the Act).

As it has been mentioned above, the institution of practices violating collective patients' rights is a component of the protection of patients' rights under public law. The Ombudsman has the necessary competences to make an imperious reaction in the event if such practices are suspected. The aim of the administrative proceedings conducted in this extent is to verify a specific charge concerning the form of conduct attributed to the given entity and to determine whether an administrative offence has been committed, based on the statutory prerequisites specified in Art. 59 section 1 of the Act [6]. The proceedings in case of practices violating collective patients' rights may be initiated both *ex officio* and upon the motion, and it is conducted by the Ombudsman with the support of the Division for Practices that Violate Collective Patients' Rights that operates within the structure of the Legal Department of the Ombudsman's Office [8]. The proceedings are initiated by means of a decision, of which all parties are notified. The parties include every subject that files a motion to issue a decision on a practice violating collective patients' rights or an entity against which the proceedings are initiated (an entity that provides healthcare services or an organiser of a strike). Obligatory grounds for the refusal to start proceedings exist if the conduct obviously does not fulfil the statutory prerequisites to consider a practice as violating collective patients' rights, or if the party who filed the motion for a decision declaring a practice to violate the patients' collective rights has not substantiated the circumstances of the deprivation or limitation of patients' rights. The Ombudsman may refuse to initiate proceedings if he considers it justified. This is made in form of an administrative decision, which may be appealed to the administrative court. On the other hand, the cessation of the given practice does not constitute grounds for the refusal to initiate proceedings. This circumstance is justified by issuing a decision that declares the practice to violate collective patients' rights and determines that the practice has been discontinued (Art. 64 section 4 of the Act). However, in this aspect it should be emphasised that the legislative authorities have foreseen a one-year limitation period of the initiation of the proceedings. The period starts at the end of the year when the given practice was discontinued (Art. 67 of the Act).

The efficient exercise of the statutory competence in terms of conducting proceedings in case of practices violating collective patients' rights would not be possible if the Ombudsman was not granted the right to demand the entities listed in the Act to present documents and information about the circumstances of the application of practices that are reasonably suspected of violating the collective patients' rights. In order to ensure the effective fulfilment of this obligation by the entity to which the demand was addressed, if the entity fails to comply and to submit the documents and information specified in Art. 61. of the Act, the Ombudsman shall impose a decision imposing a financial penalties up to PLN 50 thousand by the way of administrative decision.

The proceedings end with issuing an administrative decision that considers the given practice to be in violation of collective patients' rights, or, if the Ombudsman decides that these practices were not applied, a decision discontinuing the proceedings as unsubstantiated. According to Art. 65 of the Act, in the extent that has not been regulated in the chapter on the proceedings in case of practices violating collective patients' rights, the provisions of the Act – the Code of Administrative Procedure of 14 June 1960 are applied [9]. If the Ombudsman finds that practices violating collective patients' rights were applied, he issues one of the following two forms of substantive decision. The first one is the decision declaring the practice to violate the collective patients' rights and orders the entity to cease to use such practice. In this decision, the Ombudsman may also indicate the actions that are necessary to remedy the effects of violation of collective patients' rights, and provide time limits for taking such actions. If the entity fails to take those actions, the Ombudsman shall impose a fine in the amount up to PLN 500 thousand (Art. 68 of the Act). The second type of decision is the decision that declares the practice to be in violation of collective patients' rights and determines that its application has been discontinued (Art. 64 section 1 of the Act). In literature, it is noted that the decision considering a practice to be in violation of the collective rights of patients, as a form of authoritative reaction by an administrative authority, is intended to lead to the restoration of a state of lawfulness and, moreover, to prevent similar infringements in the future [10].

To illustrate the scale of use of this form of public law protection of patients' rights, it is worth presenting some statistical data. For example, in 2020, the total number of all conducted cases, signals and reports addressed to the Ombudsman was 135 625 [11]. In that period, the Ombudsman initiated 138 proceedings in case of practices violating collective patients' rights, out of which 79 were connected to the COVID-19 epidemic, and issued 136 decisions, in which he assessed the violation of the collective rights of patients (40 connected to the epidemic) [11]. In 2021, the number of signals addressed to the Ombudsman increased to 163 910, and the Ombudsman initiated 181 proceedings in case of practices violating collective patients' rights. A majority of these proceedings concerned access to primary healthcare during the COVID-19 epidemic. In 121 out of 199 issued decisions, the Ombudsman declared the practices to be in violation of collective patients' rights [12].

However, it is worth remembering that the analysed form of protection of collective patients' rights does not exclude the application of other statutory legal measures. This refers, in particular, to the regulations on combating unfair competition and the regulations on competition and consumer protection or on counteracting unfair commercial practice (Art. 59 section 3 of the Act).

### Detailed analysis

Applying the above general considerations to the issues discussed in this paper, it should be pointed out that the matter of the completed proceedings related to the provision of teleconsultations in the primary healthcare during the COVID-19 epidemic state (202 proceedings out of a total of 432 collective proceedings terminated during this period) were exclusively practices violating collective patients' rights in the form of unlawful, organised actions or omissions aimed at depriving or limiting the patients' right to health services under Art. 8 of the Act (Art. 59 section 1 (1) of the Act) [3].

As far as proceedings that are directly related to the provision of teleconsultations are concerned, two main categories of their matters may be distinguished, i.e. behaviour consisting in limiting or failure to provide patients with the real possibility to register to receive healthcare services financed from public funds in primary healthcare, including teleconsultations (105 proceedings altogether) and failure to publish the complete information about the terms and conditions of providing teleconsultations in primary healthcare on the website or on the place of the healthcare provider, according to the Ordinance (10 proceedings) [3]. Some of the conducted proceedings (38) concerned both types of conduct [3]. Apart from that, the Ombudsman also verified the charges of limiting or depriving the patients of access to in-person appointment with a physician in primary healthcare and of providing healthcare services only in form of teleconsultations (49 proceedings), which shows an indirect link to this form of services [3]. For each of the distinguished groups, the specific manifestations were analysed and characterised, based on selected examples of proceedings conducted by the Ombudsman.

#### ***Ensuring a possibility to register to receive healthcare services in primary healthcare***

The first of the distinguished categories of conduct includes the verification by the Ombudsman of the actions of healthcare providers that consist in limiting or depriving the patients of a real possibility to register (on the phone or by electronic means of communication) to receive publicly funded healthcare services in primary healthcare. In this scope, creating barriers or preventing access to healthcare services also applied to providing these services in form of teleconsultations. This form of conduct of healthcare providers manifested in various ways. Sometimes, the patients were deprived of both indicated ways of registering, while in other cases only registration on the phone was limited, without ensuring electronic registration at the same time. This group also includes these actions of healthcare providers that consisted in enabling patients to register for a consultation

only within a specified period of time (e.g. only for the current week).

The analysis of the scale and content of the decisions issued, it should be noted that in general, the Ombudsman considered such practices to be in violation of collective patients' rights. In order to illustrate the above trend, it is worth referring to several proceedings that confirmed the patients' reports about problems with registering for an appointment on the phone. Therefore, the Ombudsman declared the practice used by this entity, consisting in the fact that patients who contact the healthcare provider in order to receive publicly funded healthcare services had limited possibilities to register on the phone, to be violating the collective right of patients to healthcare services that are provided with duty of care (Art. 8 of the Act), and ordered the entity to cease it. In justification it was pointed out that the calls to the registration phone numbers were generally not answered, the line remained busy, and incoming calls were rejected, or the waiting time exceeded 30 minutes. In this case, the Ombudsman decided that the organisational omission of the entity (failure to ensure an actual possibility to contact the clinic) caused a significant limitation of the patients' rights. In a similar factual situation, failure to ensure the possibility to register in all working hours of the clinic was additionally considered as a practice violating collective patients' rights. The Ombudsman pointed out that making only one telephone number available to the patients, which is answered by only one nurse, is insufficient when a large number of patients are trying to contact the service provider. In these circumstances, the entity should have taken adequate actions, i.e. implement the appropriate organisational and technical solutions to improve the efficiency of the registration process.

In another case, the practice that was declared to violate the collective right of patients to receive healthcare services provided with duty of care (Art. 8 of the Act) by the Ombudsman was the way of organising the process of providing healthcare services in which the patient was able to register for a consultation only for the current week. In the execution of this decision, the entity informed that the mode of registration was changed to continuous, which enabled it to fulfil the patients' rights in this respect.

#### ***Providing information about the terms and conditions of teleconsultations in primary healthcare***

In the second identified group of proceedings, the subject was the failure to publish (on the official website or on the place of the healthcare provider) information about the terms and conditions of providing teleconsultations in primary healthcare that would meet the requirements specified in the Ordinance [13]. According to these provisions, the healthcare provider is obliged to inform the patient in scope of the specifically listed elements. The aim of imposing this obligation was to guarantee the patients access to completed detailed, and clear information about the principles of providing teleconsultations in primary healthcare, in a convenient form, taking into consideration the patient's right to express their will to contact the health professionals in person during the consultation.

The irregularities that were identified in the course of the analysed proceedings concerned both the failure to include in the information all the conditions listed in §3 section 1 of the Ordinance and the absence of only of above (for example the specification of services that are provided only in direct contact with the patient) or several components (such as the information about the ways of establishing contact between the primary healthcare service provider and the patient to provide a teleconsultation, the ways of providing teleconsultations, instructions on filing e-prescriptions, e-referrals or e-orders for medical devices, referrals to additional tests and about the possibility to create an Internet Patient Account).

In the light of the analysed group of proceedings, it is important to remember the amendments to the Ordinance that applied to the information which should be provided to the patient. The scope of this information differed in specific periods of the state of epidemic. Therefore, the introduced amendments required healthcare providers to update the provided information, as the Ordinance is a benchmark for the assessment of the correctness and completeness of the fulfilment of their information duties. The analysis of specific proceedings revealed that publishing the content of the Ordinance by the healthcare provider is not sufficient and does not mean that the informational obligation was fulfilled. As the Ombudsman pointed out, this regulation only define the scope of information that should be included in the organisational standards. Therefore, it is essential that the healthcare provider should create a document based on the Ordinance that would contain the information about the conditions of providing teleconsultations for patients at this specific entity.

Example problems that healthcare providers had with the implementation of particular organisational requirements are illustrate by the following cases. The decision that states that the failure to inform patients (at the place of performing services and on the website of the healthcare provider) on the conditions of providing teleconsultations (pursuant to §3 section 1 of the Ordinance) is a practice violating collective patients' rights to receive healthcare services (Art. 8 of the Act) and that ordered the entity to cease the practice, reveals that, apart from the content, the manner of fulfilment of the organisational duty foreseen in the Ordinance is also important. The Ombudsman emphasised that it was not sufficient to provide patients with brief information that does not include all the required elements. In the second of the referenced proceedings, the healthcare provider also failed to provide patients with complete information about the conditions for the provision of teleconsultations. In this case, the missing information concerned services that are provided only in direct contact with the patient (§3 section 1 (a) of the Ordinance) and about the possibility to receive healthcare services in direct contact with the patient if a healthcare service that is necessary due to the patient's condition cannot be provided in form of teleconsultation (§3 section 1 (e) of the Ordinance). In the justification, the Ombudsman pointed out that the internal procedure of the entity concerning the standard of teleconsultations in primary healthcare did not contain correct and complete required information about the conditions for the provision of teleconsultations, as it did

not include all the elements that were provided for in the Ordinance. The decision issued in this case was reversed as a result of indictment of the decision by the healthcare provider and eventually repealed [14]. Currently the case is being considered by the Supreme Administrative Court as a cassation appeal was lodged against the judgement of the Voivodeship Administrative Court in Warsaw.

#### ***Ensuring the possibility to register to receive healthcare services in primary healthcare and publishing information about the conditions for providing teleconsultations in primary healthcare***

Considering the above, it should be noted that the functioning of certain healthcare providers was verified in a single procedure both in terms of providing a possibility to register to receive healthcare services in primary healthcare and providing information about the conditions of teleconsultations.

For example, limiting the possibility to register on the phone and failure to make available the information about the conditions for the provision of teleconsultations in primary healthcare that would meet the requirements specified in §3 section 1 (a–d) and (f) of the Ordinance, at the place of providing healthcare services and on the website of the healthcare provider were considered to violate collective patients' rights. The identified organisational irregularities that consisted in limiting access to registration took the form of not answering calls to the registration telephone numbers, which directly affected the level of the health safety of patients. In the justification for the decision, the Ombudsman stated that the possibility to contact the entity that provides healthcare services must be actual, not only formal.

In the context of the analysed group of conducts, it is worth referencing the case, where the charges of limiting access to phone registration was not confirmed, but the patients did not have the possibility to register by means of electronic communication. Apart from that, the entity did not publish the information about the conditions of providing teleconsultations pursuant to §3 section 1 (a–f) of the Ordinance on its official website. Both these practices were declared to violate the right of the patients to receive healthcare services provided with duty of care (Art. 8 of the Act). The Ombudsman determined that the healthcare provider does not provide electronic registration for healthcare services, because it did not state a dedicated e-mail address, neither on its website, nor in the content of the standard. Additionally, the healthcare provider failed to publish detailed information on the conditions of providing teleconsultations on its generally accessible website. The detected irregularities manifested in the fact that the standard of the entity was only an internal procedure (not an information for patients about the conditions of providing teleconsultations at the clinic), and, apart from that, the document did not include all the required elements (§3 section 1 of the Ordinance).

Providing healthcare services in primary healthcare in form of in-person visits

Finally, it is worth broadening the above considerations by adding the proceedings conducted in cases of prac-

tices that violate the collective rights of patients, whose subject was indirectly linked to the issue of teleconsultations. In this respect, the charges of limiting or depriving the patients of access to in-person visits at the primary healthcare physician was verified, including providing healthcare services only in form of teleconsultations. The issue of refusal to enable consultations in direct contact with the physician was often reported as addressed to patients who had not been vaccinated against COVID-19.

In the example case, where the application of these practices was not confirmed, the Ombudsman determined that patients were taken in regardless of their vaccination status, and that unvaccinated persons were not refused on-site visits. In conclusion, the Ombudsman stated that the healthcare provider did not discriminate patients in terms of providing healthcare services based on the vaccination criterion, and thus it did not use an organised practice that would lead to an authoritative refusal to enable unvaccinated patients to consult physicians in person. In another decision issue in a similar case, it was additionally emphasised that the manner of realisation of the healthcare service was determined only by medical criteria and the condition of the patient, and not by the vaccination status.

As it has been mentioned before, depriving patients who were not vaccinated against COVID-19 from their right to receive healthcare benefits in primary healthcare in form of in-person visit were considered as practices violating collective patients' rights (Art. 8 of the Act) as an exception. A clear example of the use of forbidden practices that meets the prerequisites provided in Art. 59 section 1 of the Act consisted in placing a note on the door of a clinic, stating that patients who were not vaccinated against COVID-19 would only be admitted for teleconsultations. Due to the fact that the entity had removed the note, the Ombudsman issued a decision under Art. 64 section 4 of the Act, declaring the said practice to violate collective patients' rights and that it had been discontinued starting from 16 November 2021.

## Conclusions

Among all the statutory competences of the Ombudsman, the ones that play the main role in ensuring the efficient protection of rights of both current and potential patients are the proceedings in case of practices violating collective patients' rights. The actions taken to this scope are of an imperious nature, and the deciding that are issued in the form of administrative decisions may be appealed to the administrative court. The considerations presented in this study reveal that the healthcare providers complied with the decisions issued in specific cases and, in general, did not file appeals, which confirms that the conducted proceedings had been justified.

The research also demonstrated that, in terms of providing teleconsultations in primary healthcare during the COVID-19 epidemic state, violations of collective patients' rights took the form of unlawful organised actions or omissions of entities providing healthcare services, aimed at limiting the patients' right to receive healthcare services or to deprive them of this right (Art. 8 of the Act). This was the first type of practices specified in Art. 59 section 1 of the Act.

Considering the above discussion, one may distinguish two categories of conduct of healthcare providers that were verified by the Ombudsman in the course of proceedings that referred directly to providing healthcare services in form of teleconsultations. The first category were behaviours that manifested itself in limiting or depriving patients of the actual possibility to register in order to receive publicly funded healthcare services in primary healthcare (including teleconsultations). The decisions of the Ombudsman lead to the conclusion that it is necessary for the healthcare provider to ensure an real possibility to contact it (on the telephone or by electronic means of communication). The healthcare provider is obliged to organise its activities in such a way that will guarantee that the patient will be able to receive access to healthcare services in primary services in this aspect. In particular during an epidemic, this requires taking into account the dynamic nature of the situation and responding quickly to the necessity to meet increased health-related needs reported by the patients of the given clinic. Ensuring the accessibility of healthcare services at the stage of registration has a direct impact on the level of the patients' health security. In this context, it is worth noting that the exceptional epidemic situation only highlighted the difficulties that had already existed before.

On the other hand, the second group of actions verified by the Ombudsman referred to the failure to publish the complete information about the terms and conditions of providing teleconsultations in primary healthcare (to the extent specified in the Ordinance) on the official website or on the place of the healthcare provider. The analysis of the proceedings revealed that the correct fulfilment of the information duty by a healthcare provider requires, first of all, for these conditions to be available for the patients. Apart from that, the provided information has to be complete, detailed, and clear, so that the patient may use it to find out how the given entity carries out this form of healthcare services. Therefore, every healthcare provider should develop a document containing information about the conditions of providing teleconsultations, compliant with the scope provided in the Ordinance. Quoting the content of the regulation does not meet this requirement. Additionally, the amendments to the Ordinance that were introduced during the COVID-19 epidemic state concerned, among others, the catalogue of provided information, so that it became necessary to update the organisational standards developed by the healthcare providers on an ongoing basis.

During the proceedings in case of practices violating collective patients' rights, the Ombudsman also considered the charges of limiting the patients' rights to consult a doctor on site in primary healthcare or depriving them of this right, which, in consequence, meant that healthcare services were provided only or to a dominant extent in form of teleconsultations. The discussed conducts of healthcare providers that were signalled in the context of refusals addressed to patients who had not been vaccinated against COVID-19, were essentially not confirmed during the verification. Therefore, one may assume that, in general, healthcare providers did not discriminate their patients based on their vaccination status, and the form of providing services was determined by medical issues and the patient's condition.

Considering the above, it should be emphasised that conducting proceedings in case of practices violating collective patients' rights is an important aspect of the activities of the Ombudsman. Legal regulations in the scope of the analysed public law instrument has a real influence on the protection of the patients' rights in the systemic approach. This results from the fact that the aim of issuing a administrative decision declaring a practice used by a healthcare provider as violating the collective rights of patients is not only to restitution of the lawful status, but also to prevent similar infringements in the future. The effectiveness of the Ombudsman's actions reflects the fact that proceedings in case of practices violating collective patients' rights were seldom conducted twice against the same healthcare provider.

The analysed data may also lead to a more general conclusion. A large number of the collective proceedings that were initiated during the state of epidemic concerned access to primary healthcare, which is an important element of the healthcare system, whose aim is to ensure comprehensive care of the patient close to their place of residence. Moreover, these healthcare services are used by the largest part of the population. Taking the above into consideration, it should be noted that the availability of services provided in primary healthcare is of key importance from the point of view of the patient's access to healthcare. Due to that, collective proceedings and the decisions are particularly important for overall health security.

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# ORGANIZATIONAL STANDARDS FOR MEDICAL TELECONSULTATIONS AND PERSONAL DATA PROTECTION

Standardy organizacyjne teleporad medycznych a ochrona danych osobowych



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## Abstract

**Introduction and objective:** The article discusses the organizational standards for providing medical teleconsultations, including patient identification, confidentiality rules and the use of technical measures to secure patient data, regulated by the Ordinance of the Minister of Health of 12 August 2020 on the organizational standard for teleconsultations in primary healthcare. The relationship between these standards and the personal data protection regulations established by Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), was discussed. **Material and methods:** The study uses the methods of legal science: the dogmatic and theoretical-legal approach. The analysis included normative acts, recommendations, and guidelines in the field of personal data protection, as well as scientific studies and literature. **Results:** As a result of this analysis, the thesis that the basic organizational requirements for medical teleconsultation are not sufficient to maintain all requirements for the protection of personal data was verified. **Conclusions:** Since the mandatory organizational standard for teleconsultations defined by law is not sufficient for the protection of personal data, teleconsultations should be organized in accordance with the above-standard requirements compared to those provided for by the legislator. It is also worth using codes of conduct approved by the President of the Personal Data Protection Office.

## Streszczenie

**Wprowadzenie i cel:** W artykule omówiono standardy organizacyjne teleporad medycznych, obejmujące identyfikację pacjenta, zachowanie zasad poufności i stosowanie środków technicznych zabezpieczających dane pacjenta, uregulowane w rozporządzeniu Ministra Zdrowia z dnia 12 sierpnia 2020 r. w sprawie standardu organizacyjnego teleporady w ramach podstawowej opieki zdrowotnej. Analizie poddano relacje między tymi standardami a prawem ochrony danych osobowych, uregulowanym w Rozporządzeniu Parlamentu Europejskiego i Rady (UE) 2016/679 z dnia 27 kwietnia 2016 r. w sprawie ochrony osób fizycznych w związku z przetwarzaniem danych osobowych i w sprawie swobodnego przepływu takich danych oraz uchylenia dyrektywy 95/46/WE (ogólne rozporządzenie o ochronie danych, RODO). **Materiał i metody:** Wykorzystano metody z obszaru nauk prawnych – dogmatyczną i teoretycznoprawną. Analizą objęto akty normatywne, zalecenia i wytyczne z obszaru ochrony danych osobowych oraz opracowania naukowe i piśmiennictwo. **Wyniki:** W wyniku analizy zweryfikowano tezę, zgodnie z którą podstawowe wymagania organizacyjne dla teleporady uregulowane w rozporządzeniu Ministra Zdrowia z dnia 12 sierpnia 2020 r. w sprawie standardu organizacyjnego teleporady w ramach podstawowej opieki zdrowotnej nie są wystarczające, aby zachować wszystkie wymogi ochrony danych osobowych. **Wnioski:** Skoro określony rozporządzeniem obligatoryjny standard organizacyjny dla teleporad zbyt nisko ustanowił wymogi minimalne i nie są one wystarczające, aby uczynić zadość wszystkim obowiązkom administratora danych osobowych wynikającym z RODO, to teleporady powinny być organizowane z założeniami wedle wymogów ponadstandardowych względem tych, które przewidział prawodawca. Warto przy tym sięgać do zatwierdzonych przez Prezesa Urzędu Ochrony Danych Osobowych kodeksów postępowania.

**Keywords:** primary healthcare, telemedicine, personal data protection, personal data, medical teleconsultation

**Słowa kluczowe:** podstawowa opieka zdrowotna, telemedycyna, ochrona danych osobowych, dane osobowe, teleporada medyczna

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## Introduction

In legal sciences, a standard may refer to the content of legal norms that describe, in a relatively measurable way, the properties or attributes of the given good or conduct of the given subject of law, in reference to the achievements of specific disciplines of science, with the aim to obtain a relatively accurately defined “product” by indicating those properties or attributes. In law, the notion of standard is used, when the intention is to ensure a uniform, yet in a certain way evolutionary, developing level of the fulfilment of the fundamental goals and tasks of the state. In the doctrine of administrative law, the notion of standard appears in various contexts, and its content remains in various relations with the law. In some cases, the law is either constitutive or declares objectivised properties of the natural law, or transforms them. In others, the law refers to criteria and evaluations that have been developed outside the legal system, however considering them so important for the functioning of the society within certain scopes that it sanctions their realisation in various, direct and indirect ways. At the same time, in its regulations, administrative law ensures the existence of standardisation documents that are developed by authorised entities and ethical committees [1]. Therefore, the notion of standard is not new in the doctrine of law, although it has not been defined in the provisions of medical law. Here, the term “standard” may refer to a certain pattern or model of conduct related to providing healthcare services. Defined standards are norms that define the fundamental requirements that are set in connection with providing healthcare services or organising the process of their provision. However, in legal regulations this term may be expressed with the use of certain synonyms, such as “good practices”, “recommendations” or “procedures”.

In medical law, standards take various forms of legal regulations, and sometimes they do not have normative values. Due to that, they differ in terms of validity, from acts of commonly binding law (e.g. ordinances of the Minister of Health), through acts of internal law (such as by-laws or procedures established by the manager of the healthcare entity) to guidelines or recommendations that support the process of providing healthcare services [2]. An example of a standard in medical law, where the legal regulations directly refer to the notion, is the Ordinance of the Minister of Health of August 12 2020 on the organisational standard of teleconsultations in primary healthcare (Journal of Laws of 2022, item 1194, hereinafter: the “Ordinance”). It was issued based on Art. 22 item 5 of the Act of April 15 2011 on Medical Activity (Journal of Laws of 2022, item 633 incl. further amendments, hereinafter referred to as: the “Act on Medical Activity” or “AMA”), and it is one of the six organisational standards in healthcare that were established by the competent Minister for health.

The requirements contained in the Ordinance are obligatory for entities that conduct medical activity within the scope covered by the standard. Obviously, it is possible to fulfil requirements that are beyond the standard, particularly if it is required by specific circumstances of providing healthcare services. On the other hand, it is unacceptable not to comply with the requirements defined in organisa-

tional standards for healthcare, as they are considered to be minimum requirements. Therefore, the nature of the organisational standard for medical teleconsultations is that of commonly binding law that defines an obligatory model of conduct and contains norms that specify the fundamental, minimum requirements.

## Objective, materials and methods

The article provides an analysis of the relations between the organisational standard for teleconsultations in primary healthcare and the personal data protection law. The author formulates the thesis that such basic organisational requirements for teleconsultations are insufficient to comply with all the regulations on the protection of personal data. The research was conducted with the use of the methods applied in legal sciences, i.e. the dogmatic and theoretical legal methods. The subject of the analysis were normative acts, guidelines and recommendations related to personal data protection, as well as academic studies and subject literature.

Unfortunately, the analysed issue has not been analysed in detail in existing subject literature. The authors of few overview works provided a wider discussion of the legal aspects of telemedicine or teleconsultations, pointed to the need to ensure data security and indicated the related threats. As a result, it is necessary to provide deeper insights in this area. The article presents the legal state as of the 31<sup>st</sup> of May 2023.

## The notion of medical teleconsultation

The term “teleconsultation” was defined in §2 item 3 of the ordinance as a healthcare service that is provided remotely with the use of ICT or communication systems. The person providing a teleconsultation may be a physician, a nurse or a midwife, who provide services at the primary healthcare service provider defined in Art. 9 item 1 of the Act of October 27 2017 on Primary Healthcare (Journal of Laws of 2022, item 2527, hereinafter: the “Act on Primary Healthcare” or the “APH”). Furthermore, pursuant to Art. 2 item 1 (10) and Art. 3 item 1 of the Act on Medical Activity, healthcare services are actions that are aimed at maintaining, saving, restoring, or improving health and other medical actions that result from the treatment process or from separate provisions that regulate the principles of providing them, which may be provided through ICT or communication systems.

Thus, teleconsultation is a traditional consultation provided to a patient who is in a location other than that of the service provider, i.e. a de-localised consultation. The regulations do not specify the location where the person providing the services should provide them. However, they state that, for healthcare services that are provided through ICT or communication systems, the place of providing the services is the location of the person performing a medical occupation who provides these services. Due to that, a teleconsultation provided for a patient who is staying outside the territory of Poland should be governed by the principles of the national legal system and be subject to the same requirements as a teleconsultation provided for a patient who remains in Poland at that time. The regulations do not specify the communication

system, either. Therefore, telephone calls, calls with the use of video communication applications or electronic messaging systems are acceptable [3].

Currently, teleconsultations have become a part of telemedicine [3, 4]. Telemedicine means providing healthcare services with the use of ICT systems in situations when the healthcare employee and the patient (or two healthcare employees) are not in the same location. The services provided in telemedicine involve the transmission of data and medical information (in forms of text, image, sound, or any other forms) that are necessary for preventive actions, diagnosis, treatment, and checking the health of the patient.

Telemedicine includes a wide range of varied services. The ones that are most commonly listed in mutual evaluations are: teleradiology, telepatomorphology, teledermatology, teleconsultations, telemonitoring, telesurgery, and teleophthalmology. Other possible types of telemedicine services are call centres for patient services or online information centres for patients, remote consultations (e-consultations) and videoconferences for healthcare employees [5].

In conclusion, a medical teleconsultation is a healthcare service that is provided remotely by a competent subject, i.e. a physician, nurse or midwife, with the use of ICT or communication systems. The place of providing the teleconsultation is determined by the location of the person who provides the service. However, legal regulations do not provide specific requirements concerning the communication tools used. As teleconsultations are part of telemedicine, the guidelines for providing telemedicine services are applied.

### **Teleconsultations and issues related to the protection of personal data**

For healthcare services that are provided in form of teleconsultations, the principles of providing services and the scope of duties of the physician remain the same. During teleconsultation, one should remember, first of all, about the main duties related to the diagnosis and treatment of illnesses. At the same time, compliance with all legal requirements concerning the security of processing medical data must be maintained.

As legal regulations do not specify the communication tools that may be used for teleconsultations, the service provider may choose them at his/her own discretion, which carries the risk of errors or violations. The requirement to meet the relevant organisational and technical conditions is a priority, in particular from the point of view of the security of personal data of the patients who use such healthcare services [4]. This is also connected to the main risk of teleconsultations, as they involve a threat of the disclosure of information that is subject to medical confidentiality and of sensitive personal data [3]. This opens a wide field for consideration of the scope of responsibility under the provisions of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive

95/46/EC (General Data Protection Regulation) (Official Journal of the EU, L 119 of 4.05.2016, p. 188, hereinafter: GDPR).

The GDPR became effective on May 25 2018. Since that time, the issues related to personal data protection have enjoyed growing interest, which leads to new obligations and an increasing number of the results of inspections of their implementation by the Head of the Personal Data Protection Office (hereinafter: the Head of the PDPO) and administrative courts. The legal instrument that complements the GDPR and regulates the protection of personal data in Poland is the Act of May 10 2018 on Personal Data Protection (Journal of Laws of 2019, item 1781 incl. further amendments).

The protection of personal data of natural persons is one of the fundamental rights. It is guaranteed in Art. 8 item 1 of the European Convention on Human Rights, Art. 8 item 1 of the Charter of Fundamental Rights of the European Union, and in Art. 47 and 51, item 1 of the Constitution of the Republic of Poland, pursuant to which everyone has the right to legal protection of their private life, including the personal data concerning this person. Furthermore, nobody may be obliged to disclose their personal data in a manner other than statutory. The main objective of the GDPR is not only to ensure the right to the protection of personal data of natural persons, but also to ensure the free movement of such data. This dualist approach to the objectives is in line with the concept that the organisation of processing personal data should serve humanity (objective 4 of the GDPR), without obstructing the free movement of such data, which is important for both public and private sectors in terms of conducting business activity and maintaining fair competition.

The notions that are essential for our considerations are those defined in the GDPR, such as the data controller and the processor (i.e. the entity that processes data). The controller means the natural or legal person or entity which, alone or jointly with others, determines the purposes and means of the processing of personal data (Art. 4, point 7 of the GDPR). Joint controllers are two or more controllers who jointly determine the purposes and means of processing (Art. 26 of the GDPR). A natural or legal person or entity which processes personal data on behalf of the controller is referred to as the processor (Art. 4, item 8 of the GDPR). Hence, the personal data controller may be both the healthcare provider that, for example, employs the physician, and the person who provides a teleconsultation and is a sole medical practitioner. In the light of the GDPR, it is the controller who bears the main responsibilities connected to the protection of personal data. Due to that, a healthcare facility should have a binding security policy and the compliance with such policy should be one of the obligations of its employees (e.g. a physician who is employed based on a civil law contract). In such event, the healthcare provider should act in compliance with the security policy and other internal documents that regulate the principles of protecting medical data, including the rules for handling medical documentation [6].

In the context of the adherence to standards, one should remember the principle of accountability provided in

Art. 5 item 2 of the GDPR, which states that every controller shall be responsible for, and be able to demonstrate compliance with the provisions of the GDPR. Due to that, one should take into account the provisions of Art. 24 item 3 of the GDPR, pursuant to which the adherence, among others, to approved codes of conduct as referred to in Article 40 may be used as an element by which to demonstrate compliance with the obligations of the controller. Such code of conduct that has been approved by the Head of the PDPO under the GDPR is the Code of Conduct concerning the protection of personal data that are processed in small healthcare facilities (the so-called Zielona Góra Agreement) of November 9 2022 (hereinafter: the ZGA Code) [7], which contains guidelines concerning teleconsultations. The Code emphasised that in the provision of teleconsultations it is important to ensure the identification of patients who use them, safe conditions of providing teleconsultations, and the adequate means of technical security in their provision (Point 12 of the ZGA Code). Other recommended solutions in this respect are also provided in the Guidelines on exercising the right to information remotely by entitled persons, which were prepared by the Ombudsman for Patients' Rights and the Head of the PDPO [8].

### Organisational standards of teleconsultations in the light of the GDPR

The provisions of the Ordinance regulating the organisational standards for teleconsultations in primary healthcare do not refer directly to the category of personal data protection or to the provisions of the GDPR. At the same time, however, they regulate three important areas that involve the need to ensure the protection of personal data:

- identification of the patient (§3 item 3 of the Ordinance);
- compliance with the principles of confidentiality (§3 item 5 of the Ordinance);
- application of technical means that protect the personal data of the patient (§ 3 item 6 of the Ordinance).

### Standard of patient identification

The first organisational standard for teleconsultations refers to patient identification, i.e. verification of the patient's identity by the person who provides the teleconsultation. This should take place before the telecommunication starts. The identity is confirmed based on the data that are specified in Art. 25 item 1(1) of the Act of November 6 2008 on Patients' Rights and the Ombudsman for Patients' Rights (Journal of Laws of 2022, item 1876 incl. further amendments, hereinafter referred to as: the "Act on Patients' Rights" or the "APROPR") that are provided by the patient via ICT systems or communication systems. This refers to the identification data of the patient, including the surname and first name(s), date of birth, assigned gender, residence address, PESEL number (if it has been assigned, for newborns the PESEL number of the mother, and for persons who have not been assigned a PESEL number – the type and number of the identification document). Additionally, if the patient is a minor, a person who is legally incapacitated or incapable of expressing informed consent, the first name, surname, and residence address of the statutory representative.

Moreover, the identity is to be confirmed based on the data provided in medical documentation or in the declaration of choice specified in Art. 10 of the Act on Primary Healthcare, or by presenting an identification document by the patient during the provision of healthcare services in form of a video consultation, or through the electronic patient's account created by the patient to verify their identity in person, or in the manner specified in Art. 20a item 18 of the Act of February 17 2005 on computerisation of activity of entities implementing public tasks (Journal of Laws of 2023, item 57).

In the light of the GDPR, the notion of personal data applies to all information concerning an identified or identifiable natural person, while the person may be identified by reference to an identifier such as a name, an identification number (PESEL) or to one or more factors specific to the identity of that natural person (Art. 4, item 1 of the GDPR). At the same time, the GDPR provides separate definitions of "genetic data", i.e. personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, and "biometric data", being personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopy data. Moreover, the GDPR regulates the category of "data concerning health", i.e. personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status. These three distinguished data categories constitute, at the same time, so-called sensitive data that require special basis for processing (Art. 9 items 1 and 2 of the GDPR). The European legislator also explained that personal data concerning health include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. These data include:

- information about the natural person collected in the course of the registration for, or the provision of, health care services;
- a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes;
- information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples;
- and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an *in vitro* diagnostic test (Recital 35 of the GDPR).

It should also be noted that the GDPR regulates pseudonymised data, i.e. data processed in such a manner that the personal data can no longer be attributed to a specific

data subject (pseudonyms) without the use of additional information, provided that such additional information is kept and secured separately (Art. 4, item 5 of the GDPR). As opposed to anonymisation, pseudonymisation is a reversible action that is used to protect personal data. On the other hand, anonymisation is a process that transforms personal data into non-personal data. As a result of the process, such data do not refer to an identified or identifiable natural person, so it becomes impossible to identify the data subject. Such anonymised data are not regulated by the GDPR, as they are permanently and irreversibly depersonalised.

During teleconsultation, the identity of the patient is verified by processing his/her personal data. Processing of personal data means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available (Art. 4 item 2 of the GDPR). The filing system is any structured set of personal data which are accessible according to specific criteria, i.e. any structured set of two or more items of personal data (Art. 4 item 6 of the GDPR), for example medical documentation. The content of medical documentation and the rules for maintaining, storage, and disclosure of medical documentation are regulated separately, in Art. 23–30a of the Act on Patients' Rights and the Ombudsman for Patients' Rights).

In this context, the basis for processing so-called sensitive data is important. As a rule, the processing of genetic and biometric data and data concerning health is prohibited, unless the data subject has given explicit consent or the processing is necessary to protect the vital interests of the data subject and the data subject is physically or legally incapable of giving consent (Art. 9 item 2 (a) and (c) of the GDPR).

Other exceptions that enable the processing of sensitive data in the context of providing healthcare services include:

- processing that is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional, provided that in such event the personal data may be processed by or under the responsibility of a professional subject to the obligation of professional secrecy (Art. 9 item 2 (h) and item 3 of the GDPR);
- processing that is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy (Art. 9 item 2 (i) of the GDPR).

The guidelines of the ZGA Code that refer to sources of identity verification and problems with videoconferences may be helpful in identifying the patient. Based on the assumption that the patient is known to the primary healthcare service provider, the source of data for verification of their identity on part of the person providing the teleconsultation may be, depending on the situation, the medical documentation, declaration of choosing the primary healthcare physician, nurse or midwife or the Internet Patient's Account, while on part of the patient such sources are: their identification document presented during the teleconsultation (if it is provided in form of a video call) or the patients themselves, who present their information to the person providing the teleconsultation. It is, however, unacceptable to verify the identity of the patient based on an identity document during a video teleconsultation if the video call is recorded, due to the lack of legal basis for recording and storing the image of such document. If the technical settings allow, recording the video call should be stopped for the moment of showing the identity document (point 12.1.1. of the ZG Code).

In conclusion, the standard of patient identification includes four ways to confirm the identity:

- based on data provided by the patient;
- based on medical documentation or declaration of choice;
- based on the online patient's account;
- for video consultations – based on the presented identification document.

In this context, it should be remembered that the personal data must be accurate in updated if necessary. The healthcare provider that provides the teleconsultation should take every reasonable step to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (Art. 5 item 1 (d) of the GDPR). This is related to the rights of data subjects, i.e. the right to access their personal data (Art. 15 of the GDPR), the right to demand the data controller to rectify or complete the data (Art. 16 of the GDPR), and the right to restrict the processing of personal data, he accuracy of the personal data is contested by the data subject (Art. 18 of the GDPR). The data controller should not refuse to acquire additional information from the data subject in order to facilitate the exercising of their rights (Recital 57 of the GDPR), which may serve as a guideline if patients provide excessive data. One should however bear in mind that in the light of the principle of data minimisation, personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (Art. 5, item 1 (c) of the GDPR).

### Confidentiality standard

The second organisational standard of teleconsultations states that the teleconsultation should be provided in conditions that enable confidentiality, including preventing unauthorised access to information transmitted via ICT systems or communication systems in connection with the teleconsultation. The telemedicine service is a service, whose nature requires providing it in such a way that prevents unauthorised persons to access the transmitted content. The obligations concerning confi-

Confidentiality and security of information are supported by the need to maintain confidential the information related to the patient and obtained in connection with providing healthcare services. The service provider is obliged to ensure that no third parties participate in providing the teleconsultation and that the information provided by the patient cannot be heard outside the room where the service provider is staying. Moreover, the service provider should also implement suitable mechanisms to protect the provided digital data from unauthorised access. Due to the absence of physical contact, it is also reasonable to implement mechanisms that guarantee unambiguous identification. For this purpose, it is recommended to share the data between individual accounts [4]. In this context, the guidelines on the aspects of ensuring the confidentiality of teleconsultations and verifying the patient's identity, provided in the Guidelines of the Supreme Medical Council on providing telemedicine services [6] still remain valid. The guidelines of the ZG Code that recommend that the teleconsultation should take place in such location where it is impossible for unauthorised persons to overhear a telephone or video conversation or to look at the screen, are also consistent. Remote services should be provided in a separate, closed room that cannot be accessed by patients or other unauthorised persons. If the teleconsultation is recorded, the patient must be informed about this before the start of consultation, and information sent by e-mail should be sent from an e-mail account that is inaccessible for unauthorised persons, with means of security that have been previously consulted with an IT technician and data protection inspector (item 12.2 of the ZG Code).

Therefore, the confidentiality standard involves the necessity to prevent unauthorised access to the information transmitted during the teleconsultation, which is consistent with the obligation to maintain confidential all information about the patient that was obtained in connection with performing a medical profession. Only authorised persons should participate in the teleconsultation, i.e. no third parties should be present. The provided information should not be heard by third parties outside the room where the service provider is located. Additionally, suitable mechanisms should be implemented to protect the transmitted content from unauthorised access.

### Standard of safe technical and organisational solutions

The third standard concerns the cases when information about the patient's health status is transmitted, including digital representations of medical documentation, by means of ICT systems. This standard involves the use by the primary healthcare service provider of such technical and organisational solutions that guarantee that electronic documents in graphic and text forms are transmitted in a way that ensures their integrity and protection against unauthorised use, accidental or unlawful destruction, loss, modification, unauthorised disclosure or access. Therefore, the primary healthcare service provider is obliged to protect the patient from the violation of their personal data. Such violations include the security violation that leads to accidental or unlawful destruction, loss, modification, unauthorised disclosure of or access to personal data that are transmitted, stored or processed in any other way (Art. 4, item 12 of the GDPR). However,

in order to comply with this standard, the primary healthcare service provider has to fulfil all its obligations of the data controller that are not mentioned in the Regulation. At the same time, the standard of integrity and confidentiality of personal data results from the GDPR and the principle that personal data must be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

### Other requirements of the GDPR

In analysing the provisions of the Ordinance, it should be noted that they focus mainly on the duties that are performed in direct connection with a specific teleconsultation. It is during such teleconsultation that the service provider is obliged to maintain confidentiality and identify the patient immediately before the start of consultation. Only the issues of technical means of security refer to transmitting information about the patient's health status, which may take place before, during, or after the teleconsultation. Although the Ordinance does not specify the timeframe of the teleconsultation, so it is impossible to determine when it precisely starts and what elements it includes, in the light of personal data protection it should be noted that the organisational standards refer to actions connected with the healthcare service in itself, without focusing on systemic aspects. Meanwhile, jurisprudence demonstrates that in the light of the GDPR the legislation authorities have diverged from the static determination of the technical and organisational measures required from the data controller towards a dynamic assessment of the adopted means of security. This means that both the data controller and processor are obliged to implement adequate security measures. Pursuant to the provisions of Art. 32 item 1 of the GDPR, taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, the controller and the processor shall implement appropriate technical and organisational measures. The assessment of the adequacy of the level of security takes into account, in particular, the risk connected to processing, resulting from accidental or unlawful destruction, loss, modification, unauthorised disclosure of or access to personal data that are transmitted, stored, or processed in any other way.

In consequence, the binding legal regulations do not provide a list of adequate security measures, and it is the data controller who is obliged to make the relevant assessment and to select means of security that are adequate, among others, to the current state of technical knowledge or to the risk of violation of rights (Judgment of the Supreme Administrative Court of February 9 2023, III OSK 3945/21, CBOSA). Pursuant to the GDPR, the primary healthcare service provider as the data controller is obliged to conduct the risk assessment prior to the commencement of processing the data with the use of adequate technical and organisational measures that ensure compliance with the GDPR and the accountability of processing personal data. These measures should take into account the nature, scope, context, and purposes of

processing and the risk of violating the rights and freedoms of natural persons (Recital 74 of the GDPR). However, the Regulation does not provide any specific solutions that ensure adequate protection of personal data. The guidelines of the ZG Code related to the implementation of such measures are also very general. The Code only points out that, in order to ensure that the transmission of information during teleconsultations should take place in a way that will ensure its integrity and protect it from unauthorised access, accidental or unlawful destruction, loss, modification, unauthorised disclosure or access, the service provider should use technical and organisational solutions that have been consulted with an IT technician (in terms of technical security measures) and with the data protection inspector (hereinafter: DPI) in terms of compliance with the requirements of personal data protection and information security (point 12.3 of the ZG Code).

Further obligations to ensure the security of data processing that were not included in the Ordinance are: the necessity to maintain a record of processing activities (Art. 30 items 1 and 4 of the GDPR), to notify personal data breach to the supervisory authority and to document such breaches (Art. 33 items 1, 2, and 5 of the GDPR) and to communicate the personal data breach to the data subject (Art. 34 item 1 of the GDPR). The data controller is also obliged to perform the informational duties (Articles 13 and 14 of the GDPR) and to exercise the rights of data subjects (Art. 15–22 of the GDPR). In order to prepare to perform these duties with respect to providing teleconsultations, the data controller is required to implement a personal data protection system and an adequate organisation of work at the preliminary stage, before providing teleconsultations.

The healthcare provider that performs the activity as the data controller is also obliged to meet the requirements concerning the selection of the appropriate processor (Art. 28 items 1 and 5 and Art. 32 items 1 and 2 of the GDPR). In creating medical documentation, the data controller must follow the principles provided in the GDPR, although in practice, due to the enormous amounts of data, medical documentation is often maintained by specialist companies. However, the Ordinance does not contain the relevant guidelines. Upon entering into an agreement with such a company, the healthcare facility should enter into an agreement on entrusting the processing of personal data that will meet the requirements of Art. 28 of the GDPR. At the same time, the data controller is obliged to use only processors providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements of the GDPR and ensure the protection of the rights of the data subject. Therefore, pursuant to the GDPR, the agreement on entrusting data processing should contain, among others, the subject and duration of processing, the nature and purpose of processing, type of data, categories of data subjects, rights and obligations of the data controller and a clause obliging the persons who are authorised to process personal data to maintain their confidentiality [9]. In some cases, the data controller will be obliged to appoint a Data Protection Inspector. Appointing a DPI is mandatory if the main activity of the data controller consists in large-scale processing of special categories of personal data, includ-

ing data concerning health status. The main duties of the DPI will include notifying the data controller, the processor, and employees who process personal data about their obligations under the GDPR, monitoring compliance with the GDPR and cooperating with the supervision authority. The GDPR formulates the obligations of the Inspector in a general way, without specifying the mode or periods for their fulfilment. The PDI shall perform an advisory and verification function with respect to the activities of the data controller [10], also concerning the provision of telemedicine services.

## Conclusions

It was the intention of the legislator that the organisational standards would define the interrelations and the assignment of duties (rights and responsibilities) related to providing healthcare services. This may refer, in particular, to the qualifications of the healthcare personnel who participate in providing healthcare service, the sequence of performing medical actions in the diagnostic and treatment process and the relations between the competences of the personnel, as well as the scope of the personnel's responsibility [11]. In this light, the organisational standard of teleconsultations, which, as far as personal data protection is concerned, refers only to the identification of the patient and the need to ensure confidentiality and security of the technical and organisational solutions, in fact only reproduces the general requirements for all data controllers, to a limited extent. The standard does not provide any specific practical solutions in these narrowly defined areas, either. One may state that, as far as personal data protection is concerned, the organisational standard for teleconsultations neither takes into consideration nor defines the tasks, obligations, and scope of responsibility of persons who provide teleconsultations and primary healthcare service providers. Moreover, it does not provide them with any specific and practical organisational guidelines. In this respect, the ZG Code or the guidelines of the Supreme Medical Council may be considered more important. As a result, the minimum requirements set by the binding organisational standard for teleconsultations defined in the Ordinance are too low. They are insufficient to fulfil all the obligations of the data controller that result from the GDPR. Due to that, teleconsultations should, in fact, be organised based on higher requirements than those that were foreseen by the legislation authorities. These requirements must take into account the implementation of procedures of conducting the calls and disclosing sensitive data concerning the patient's health remotely, in order to ensure the appropriate level of security and confidentiality. The procedures should include instruction manuals for using IT hardware, technical support, and the principles of conduct in the event of violation of personal data protection, including notifying the Data Protection Inspector. It is necessary to implement procedures in order to meet the individual rights of data subjects, including the rules for informing them about these rights, in particular considering the special basis for processing data for the purposes of providing healthcare services. The adopted procedures should take into consideration emergency circumstances, such as life-threatening situations, when it is necessary to provide aid immediately, or such situations as the lack of cooperation and other improper use of healthcare services.

In every case, the data should be processed to the necessary extent. Due to that, considering the principle of data minimisation, conversations with patients who call should be recorded only in exceptional circumstances, taking into account their purpose and risk analysis.

The healthcare facility should have a security procedure in place, along with mechanisms that ensure compliance. Healthcare providers should introduce the records required under the GDPR, as well as a record of authorisations for persons who act on behalf of the data controller and have access to personal data. At the same time, the provider should ensure that the orders to process data for employees (based on by-law or connected to their scope of duties) are formulated in a transparent way, so as to comply with the requirements of Art. 29 of the GDPR.

In taking actions to protect personal data during teleconsultations it is worth consulting the codes of conduct approved by the Head of the PDPO. Currently, although the GDPR has been in force for over 5 years, only two such national codes have been approved: the ZG Code and the Code of Conduct for the Healthcare Sector, created by the Polish Federation of Hospitals. However, in applying the existing standards, guidelines, and recommendations, one should first of all adopt a systemic point of view, so that the measures applied to protect personal data are adequate to the specific nature of medical teleconsultations and take into account the typical related risks.

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## MEDICAL TELECONSULTATIONS – NEW POSSIBILITIES AND LEGAL AND ETHICAL DILEMMAS

Teleporady medyczne – nowe możliwości i dylematy  
prawno-etyczne



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### Abstract

**Introduction and objective:** Medical teleconsultations, a necessity during the pandemic due to the existing epidemiological conditions, should now be subjected to a thorough, critical analysis and assessment for their compliance with the principles of medical ethics, patient rights and the doctor's obligation to exercise due care. The aim of this paper was to perform a critical assessment of medical teleconsultations, their regulatory frameworks as well as recommendations of medical self-governing bodies. **Materials and methods:** The current regulations of Article 42 (1) of the Act on the Medical Profession have been subjected to critical analysis in relation to the legal framework for providing medical teleconsultations. These include the Regulation of the Minister of Health on the organisational standard of teleconsultation within primary healthcare, as well as the recommendations of the Presidium of the Supreme Medical Council dated July 24, 2020, regarding the adoption of guidelines for providing telemedical services, pointing to a potential conflict with Article 9 of the Code of Medical Ethics. Therefore, this is a study within the field of law and medical ethics. Thus, the appropriate research methodology comprises legal doctrinal, axiological, and sociological methods. **Results:** Despite three years passing since the outbreak of the pandemic, the legislator has still not specified teleconsultation standards by way of an act. Furthermore, in accordance with Article 9 of the Code of Medical Ethics, the regulation does not specify the communication system. Teleconsultations are being overused today and do not guarantee patient safety, because only during teleconsultation can the doctor decide that it is not a sufficient form and the patient's consent will be difficult to consider informed due to the lack of access to the doctor and the restrictions on regular visits. **Conclusions:** The COVID-related regulation makes teleconsultation a principle rather than an exception within primary health care, which could irreversibly alter the nature of medical advice and deteriorate its quality. The commercialisation of medical services cannot be the sole justification for the changes in the model of providing medical advice.

### Streszczenie

**Wprowadzenie i cel:** Teleporady medyczne – konieczność w okresie pandemii z uwagi na istniejące uwarunkowania epidemiologiczne – powinny być po pandemii poddane krytycznej analizie i ocenie z punktu widzenia zgodności z zasadami etyki lekarskiej i prawami pacjenta oraz obowiązkiem lekarza dotyczącym zachowania należytej staranności. Celem artykułu jest ocena teleporad medycznych, ich podstaw normatywnych i zaleceń organów samorządu lekarskiego. **Materiał i metody:** Krytycznej analizie poddano aktualne regulacje, tj. art. 42 ust. 1 ustawy o zawodzie lekarza, w nawiązaniu do ram prawnych udzielania teleporad medycznych, które dookreślają: rozporządzenie Ministra Zdrowia z dnia 12 sierpnia 2020 r. w sprawie standardu organizacyjnego teleporady w ramach podstawowej opieki zdrowotnej, a także rekomendacje Prezydium Naczelnej Rady Lekarskiej z dnia 24 lipca 2020 r. w sprawie przyjęcia wytycznych dla udzielania świadczeń telemedycznych, wskazując na potencjalny konflikt z art. 9 Kodeksu etyki lekarskiej. Jest to więc praca z zakresu prawa nawiązująca do etyki lekarskiej, stąd właściwą metodą badawczą są metody dogmatycznoprawna, aksjologiczna i socjologiczna. **Wyniki:** Ustawodawca mimo upływu 3 lat od wybuchu pandemii wciąż nie dookreślił standardów teleporad w drodze ustawy i zgodnie z art. 9 Kodeksu etyki lekarskiej rozporządzenie nie określa rzeczy fundamentalnej, jaką jest skonkretyzowanie systemu łączności do przeprowadzania porad. Teleporady są dziś nadużywane, a ponadto nie gwarantują bezpieczeństwa pacjenta, gdyż dopiero w trakcie teleporady lekarz może uznać, że nie jest to forma wystarczająca, a zgodę pacjenta trudno będzie uznać za świadomą z uwagi na brak dostępu do lekarza i limitowanie porad zwykłych. **Wnioski:** Rozporządzenie covidowe czyni z teleporady zasadę, a nie wyjątek w ramach podstawowej opieki zdrowotnej, co w istocie rzeczy może w sposób nieodwracalny zmienić charakter porad medycznych i pogorszyć ich jakość. Komerccjalizacja usług medycznych nie może być jedynym uzasadnieniem dla dokonywanych zmian w modelu świadczenia porad medycznych.

**Keywords:** telemedicine, medical ethics, patient's rights, medical teleconsultations, patient's informed consent

**Słowa kluczowe:** telemedycyna, etyka lekarska, prawa pacjenta, teleporady medyczne, świadoma zgoda pacjenta

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## Introduction

Medical teleconsultation (MT) is part of telemedicine, which emerged in the 1970s in the United States following the development of novel technologies. Today, in the 21st century, the times of digital revolution and artificial intelligence (AI), it has become a reality. MT is a form of providing healthcare through teleinformatic or communication systems (i.e., remotely), without direct contact with the patient in a medical office setting. The main aspect here is the physical distance between the patient and the place where the healthcare service is provided [1], which has proven to be a significant ethical and legal challenge from the very beginning.

As set out in the World Health Organization (WHO) guidelines, telemedicine is "the provision of health services by health professionals, where distance is a critical factor, using information and communication technologies to exchange valid information for the purposes of diagnosis, treatment and prevention of disease and injury, research and evaluation, and to facilitate the continuing education of health professionals, with the aim of safeguarding the health of individuals and communities".

Telemedicine was initially used in space medicine to help monitor the health status of astronauts, clearly indicating that the distance of the site responsible for healthcare provision is the main determinant in defining teleconsultations. The United States National Aeronautics and Space Administration (NASA) used the expertise and knowledge of many specialists, whose task was to ensure the health safety of spacecraft crews as it was beyond doubt that addressing health issues remotely, without the possibility of direct contact with the patient, was a necessity [2].

The scope of telemedicine applications was expanded in the years that followed, improving technologies for transmitting histopathological findings and X-ray images. Subsequently, robotics was incorporated and intercontinental surgeries started to be performed. The most advanced diagnostic systems also proved helpful – as pointed out by Susskind and Susskind at the Elizabeth Wende Breast Care in New York, the use of algorithms to scan mammograms was found to reduce breast cancer false-negatives by 39%. The IBM's AI system, known as "Watson," is utilised in cancer diagnosis to recommend treatments. Additionally, half of American physicians use the Epocrates application, which serves as a digital database of medication information and enables screening for drug-drug interactions. Another potential application of novel technologies is exemplified by the Medtronic-CareLink network,

through which cardiac patients can send data from their heart assistive devices to their physicians. Each report is equivalent to a personal medical visit [3].

In turn, the doctrine speaks of the category of e-health, which encompasses not only telemedicine, but also medical informatics, information and communication technology in healthcare or health information management. E-health utilises various types of electronic platforms [4], the use of which undoubtedly offers significant opportunities to monitor patients. The European Union has adopted an appropriate action plan to implement an e-health strategy in all Member States.

In terms of treatment standards, medical consultations in the form of MTs are also part of these new 21st century technologies.

## Aim

Medical teleconsultations, a characteristic sign of the times, were a necessity during the pandemic due to the existing epidemiological situation and life-threatening circumstances. However, in the post-pandemic period, they should undergo critical analysis and thorough evaluation for compliance with the principles of medical ethics, patient rights, and the physician's obligation to maintain due diligence.

The aim of the research was to identify potential risks associated with instrumental and commercial utilisation of MTs, as well as the decline in their quality, especially when conducted via telephone calls or electronic messaging platforms.

## Materials and methods

We assessed the normative framework of medical teleconsultations and confronted it with ethical standards. This evaluation encompassed the provisions of Article 42(1) of the Act on the Medical Profession [5] and the legal framework for providing telemedical consultations, as specified by the Regulation of the Minister of Health of August 12, 2020 on the organisational standard of teleconsultations within primary healthcare [6].

Furthermore, a dogmatic-legal and axiological analysis of the recommendations of the Presidium of the Supreme Medical Council (NRL) dated July 24, 2020, regarding the adoption of guidelines for providing telemedical services [7], in relation to Article 9 of the Code of Medical Ethics (CME), was conducted [8]. In the context of teleconsultations, the position of the Medical Ethics Committee

of the Supreme Medical Council dated February 12, 2023, regarding the commercial online issuing of prescriptions and sick leaves was also discussed [9].

Therefore, this is a study within the field of law and medical ethics, hence the appropriate research methods included dogmatic-legal, axiological, and sociological methods.

## Results

### *The normative framework*

The analysis of the normative foundations of MTs leads to the conclusion that Article 42(1) of the Act on the Medical Profession states that a physician assesses the health status of a specific individual after prior personal examination or examination through teleinformatics or communication systems, as well as after analysing the available medical records. It is generally accepted in the doctrine that the concept of assessing health status should be understood as a substantive evaluation of the patient's health condition, regardless of the form of such assessment. This means that both written health certificates and unwritten decisions regarding the health status of an individual fall into this category [10].

The definition of teleconsultation is found in § 2 point 3 of the Regulation on the Organizational Standard of Teleconsultation within Primary Healthcare, which indicates that teleconsultation is a remote delivery of healthcare services using teleinformatics or communication systems. The definition of healthcare service is provided in Article 2 paragraph 1 point 10 of the Act of 15 April 2011 on Medical Activity [11]. The aforementioned provision defines the essence of healthcare services in general terms, first of all indicating the criterion of purpose, which makes it possible to decide, with regard to a given service, whether it has the nature of a healthcare service. Such a service is defined as an activity aimed at preserving, saving, restoring or improving health and other medical activities resulting from the treatment process [12].

The Act, more specifically the aforementioned Article 42(1) of the Act on the Medical Profession, and the Regulation on the Organisational Standard of Teleconsultation within Primary Healthcare, in fact create a new model of healthcare provision. It offers the possibility of examining a patient through telemedicine systems; however, it does not specify the types of these systems and makes no reference to the quality of consultation.

It is therefore acceptable to use a telephone, video calling applications or even electronic messaging when delivering a medical consultation. According to the guidelines of the Presidium of the Supreme Medical Council dated July 24, 2020, regarding the provision of telemedicine services, regular telephones and phone lines, and online consultations (via video, chat, email), using secure Internet connections within secured telemedical platforms, applications, or communication systems, may be used to provide MTs. However, they must comply with conditions for secure connection, identity verification, etc. in terms of the general standards applicable to telecommunications and teleinformatics systems.

Pursuant to Article 32(1) of the Act on the Medical Profession, a physician may conduct an examination or provide other healthcare services, subject to exceptions provided for in the Act, after obtaining the patient's consent [13]. Therefore, patient's informed consent [14, 15], which should also encompass the method of medical consultation, is a prerequisite for conducting an examination.

According to § 3 of the Regulation on the Organisational Standard of Teleconsultation within Primary Healthcare, the patient largely decides on the most convenient form of contact with the physician, which depends on their preferences rather than the decision of the healthcare provider. On the other hand, Article 4 of the Act on the Medical Profession indicates that it is the physician's obligation to practice the profession in accordance with the up-to-date medical knowledge, using available methods and means for preventing, diagnosing, and treating medical conditions, in line with the principles of professional ethics and with due diligence. According to Article 36(1) of the Act on the Medical Profession, a physician is obliged to respect the privacy and personal dignity of the patient when delivering healthcare services. It is inferred from § 3 of the aforementioned regulation that an organisational standard for teleconsultation provided within primary healthcare has been established, which includes informing by the primary healthcare provider at the place of service provision and on the provider's website, and upon patient's request also by phone, about the conditions of providing MTs, taking into account the patient's right to express the desire for personal contact with the appropriate medical personnel during the teleconsultation. Additionally, it also follows from this provision that situations where the patient or their legal representative has not consented to the provision of the service in the form of MT also fall in the category of services delivered through direct contact with the patient. Thus, the patient may not consent to this form of consultation and in such a case, it is an absolute premise to exclude this form. The regulation also indicates that it is only during an ongoing teleconsultation that the doctor, based on the subjective examination and after assessing the available medical documentation of the patient, including that delivered through the teleinformatics system, provides healthcare services, which encompasses determining whether MT is a sufficient means for a given health problem, or informs the patient of the necessity of providing healthcare services through direct contact if the nature of the health problem prevents the delivery of healthcare services in the form of a teleconsultation (§ 3 point 7 of the Regulation). It follows indirectly from these regulations that no notice of the patient's problem is taken during the registration for an appointment. It is only during teleconsultation that the doctor can assess, after prior examination of the patient through communication systems, that this form of healthcare is not sufficient to resolve the patient's problem, and a regular in-person consultation is needed.

### *Ethical standards of medical teleconsultations*

The solutions adopted within the analysed regulation are new, but not necessarily innovative. Based on 20 years of experience from leading international organisations and professional associations in the USA, it is possible to define a certain ethical standard for telemedicine.

The World Medical Association (WMA) and the American Medical Association (AMA) have emphasised that the patient-physician relationships in telemedicine should resemble those in a direct face-to-face care setting. Maintaining the quality of care, obtaining patient's informed consent, ensuring privacy (confidentiality), and safety are of paramount importance. The patient-physician relationship must be based on mutual trust and respect. Therefore, it is essential that the physician and the patient are able to reliably identify each other when using telemedicine. In case of consultation between two or more professionals within or between different jurisdictions, the primary physician remains responsible for the care and coordination of the patient with the distant medical team. The patient-physician relationship should be based on a personal examination and sufficient knowledge of the patient's medical history. MT should be utilised primarily in situations in which a physician cannot be physically present within a safe and acceptable time period; it could also be used in the management of chronic conditions or follow-up after initial treatment if it has been proven to be safe and effective. Associations warn against potential conflicts of interest that may jeopardize patient care and trust due to commercialisation and cost-cutting measures. Telemedicine should not be viewed as an equivalent of face-to-face healthcare and should not be introduced solely to cut costs or as a perverse incentive to over-service and increase doctors' earnings [16, 17]. Until 2019, AMA significantly incorporated telemedicine into its Code of Ethics, once again emphasising that the ethical duties of doctors do not change during teleconsultations. Appropriate quality of care (including examinations) should be a standard. This relationship may change when care is delivered in a remote, technology-assisted manner. However, mere replacement of traditional face-to-face consultations with telephone conversations is not sufficient to set current teleconsultation standards. Telehealth, as indicated, is a concept, an idea that primarily determines a change in the relationship with a patient. New information technologies contribute to the virtualisation of patients and healthcare, changing the value of touch and physical presence, and focusing on measurements and quantifications, with clinicians likely to be perceived more like machines [18], and certainly requiring a new generation of computer programmes or even artificial intelligence.

Still, the basic principles of providing healthcare remain the same, and according to Article 9 of the Code of Medical Ethics, a physician is obligated to initiate treatment only after prior examination of the patient. Situations where medical advice can only be provided remotely are an exception. This means that, as a rule, the Code of Medical Ethics does not foresee the possibility of examining patients using teleinformatics systems.

The position that there is a conflict between these regulations, specifically Article 9 of the Code of Medical Ethics and Article 42(1) of the Act on the Medical Profession, is indeed accurate. The second sentence of Article 9 of the Code of Medical Ethics states that medical advice can be provided remotely in exceptional cases, but the principle is to personally examine the patient [19]. Therefore, the doctor's obligation to examine the patient is an established principle of the Code of Ethics, with treatment

initiation without prior patient examination considered unacceptable [20].

As pointed out in the doctrine, from a medical standpoint, there is a conflict between the possibilities expressed in the amended provisions of the Act on the Medical Profession and the provisions of the Code of Ethics. This conflict should be resolved as any interpretation of one of these provisions of the Code of Ethics is extremely important for the legal and ethical responsibility of doctors [2]. Furthermore, as indicated by the Medical Ethics Committee in its position on the commercial online issuance of prescriptions and sick leave certificates dated February 12, 2023, the catalogue of duties of a doctor and patient rights remains unchanged regardless of the method of delivering medical advice, with the principles for providing MTs using telemedical technologies and in-person consultations being generally the same [9]. The principles of professional, civil, and criminal liability for telemedical services are also the same as for other services, with patients entitled to all patient rights.

Consideration may be given to whether the doctor's catalogue of duties remains unchanged when holding consultations via communication systems. Given the constraints associated with such forms of patient interaction, it appears that physicians should broaden the scope of their informational duties, in part to mitigate the risk of legal violation. They should dutifully inform patients on the limitations associated with remote healthcare, particularly regarding potential communication challenges and technical deficiencies that may impede the proper delivery of telemedical services. It is essential that both the patient and the physician are aware of the inherent limitations of MTs so that the latter one has a genuine opportunity to choose between in-person and remote consultations. At the same time, physicians should appreciate the expanded scope of responsibilities and risks associated with delivering advice of appropriate quality.

## Discussion

### *Telemedicine as a novel approach to patient care and interaction*

MTs represent a mode of healthcare provision that alters the traditional patient examination process. Physicians need to assess whether the utilisation of novel technologies allows for obtaining a comprehensive clinical picture of the patient. Consequently, there has been a shift in the perception of patients and care – physicians need to take a different approach to assessing the value of touch and physicality and to focus on measurements and quantification [21]. This necessitates a different approach towards the patient, and foremost, an awareness of potential communication errors.

The debate surrounding teleconsultations touches upon an exceptionally important aspect of the patient-doctor relationship. Treatment is a complex process in which the human factor plays a pivotal role. Personal contact and direct examination of the patient by the physician contribute to trust and are imperative conditions for establishing this trust. This implies that the personal examination of the patient is of significantly greater importance

than merely collecting medical history. It helps establish a specific relationship built on trust. Treatment largely takes place on a non-verbal level as well, where appropriate gestures, facial expressions, and eye contact hold significance. As pointed out by Rużyłto, understanding the underlying disease as well as the personality and living conditions of the patient is intended to help better assess the illness and its treatment options, as well as deepen the patient's trust in the physician and foster mutual, personal sensitivity [22]. A question should be therefore asked on how to build this trust in this new, virtual reality and whether we are faced with the risk of dehumanising the patient-physician relationship.

However, considering the professionalism required in providing medical advice and the necessity for the physician to exercise due diligence, in-person consultations should be a standard, with video consultations used only in special cases, and telephone consultations being reserved for exceptional circumstances. The use of video conferencing, while not perfect, allows for collecting medical history and an attempt at physical examination similar to conventional methods (physical appearance, behaviour, dyspnoea, blood pressure, presence of oedema, skin lesions, scars, wounds, ulcers, etc.). Although not identical to conventional examination and assessment methods, it proves to be sufficient in many cases [23].

From a medical standpoint, telephone conversations represent a somewhat superficial method of contact. It is rather a prescription consultation and may unfortunately give rise to many medical and communication errors, which are difficult to avoid if the patient and the doctor do not even see each other. Meanwhile, patients should be aware of the importance of the information they provide. Experience has shown that some patients reported outdated data on their body weight during anaesthesia preoperative history collection. Only face-to-face conversations allow for accurate qualification for procedures under general anaesthesia [2]. This is just one example of potential misunderstandings and difficulties associated with MTs.

In this case, attention must also be drawn to the issue of providing care of appropriate quality and technology tailored to the needs of, e.g., disabled or elderly individuals, such as those with cognitive impairments [24]. At the same time, it is the role of legislators to counteract digital exclusion, particularly for elderly individuals who may lack both appropriate technical equipment and knowledge of how video conferencing systems operate. We can only speculate that the mandatory implementation of video teleconsultations could potentially lead to the exclusion of many individuals, especially considering that primary healthcare facilities may not be adequately equipped to provide patients with the necessary technical support and instructions. Hence, legislators permit the simplest solution in the form of telephone conversations, although it is the least optimal for the diagnostic and therapeutic processes.

The period leading up to the outbreak of the pandemic allowed primary healthcare units to prepare for the professional provision of MTs. Therefore, the position taken by the Supreme Medical Council on July 24, 2020, regard-

ing the adoption of guidelines for providing telemedical services, which allow for MTs using regular telephones and phone lines, seems even more controversial. This approach should now be revised in the post-pandemic period.

### **Teleconsultations – patient safety risks**

MTs may also pose risks to patient safety. The ethical guidelines issued by the UK General Medical Council [25] recommend that healthcare practitioners should prioritise patient safety, protect those particularly vulnerable, ensure that patients understand how remote consultations work, obtain their informed consent, conduct appropriate clinical assessments, provide patients with all available options, and organise care. Physicians should always consider whether remote consultation is appropriate, ensure that patients receive (and understand) all necessary information, and enable them to make decisions [26].

Patients should have access to information about the conditions for providing MTs and the opportunity to express their preference for personal contact, as set out in the Regulation. However, it seems that such information should be provided mandatorily, for example, during telephone registration, rather than only upon the patient's request. However, the question arises as to how effective the patient's objection actually is. If, for pragmatic reasons, limits on in-person consultations are introduced, it is obvious that the patient may be left with no choice. Similarly, if the patient faces difficulties in traveling to the clinic due to distance or place of residence, and, for example, the limit on doctor home visits for a given day has been reached, these circumstances can certainly compromise the patient's freedom of choice and make their decision-making illusive.

Key issues include whether we are truly dealing with patient's informed consent in such a situation, given that the consent itself is questionable, and the fact that patients have little choice in terms of the form of medical advice or acceptance of these terms, especially when it is only during the teleconsultation that the doctor provides information. Therefore, it is not only the issue of freedom of choice that is important but also the stage at which patients are informed about their rights.

The current regulatory framework considers MTs as the primary form of healthcare advice, with few exceptions. While MTs were a necessary solution during the pandemic, it is now worth considering whether they are being over-used and whether they should indeed be the primary form of medical advice since it is only during the teleconsultation that the doctor can determine whether this form is sufficient, and obtaining informed consent from the patient can be challenging due to the lack of access to the doctor and the limitation on regular consultations.

### **Prescription consultation**

The so-called prescription consultation is another issue related to telemedicine. Remote consultations and prescribing medications can potentially pose a threat to patient safety due to issues such as increased attempts

to access medications that may cause serious harm and the necessity of ensuring continuous monitoring of the health of chronically ill individuals [9]. According to Article 42(2) of the Act on the Medical Profession, a physician may issue a prescription necessary for the continuation of treatment and prescribe medical devices as a continuation of their provision if justified by the patient's health condition, as reflected in the medical documentation, without examining the patient. In accordance with Article 15b(2) of the Act on the Professions of Nurse and Midwife [27], a nurse and midwife, as referred to in Article 15a(1), may issue a prescription necessary for the continuation of treatment, as well as prescribe medical devices or issue orders for their provision as a continuation of such provision without examining the patient if justified by the patient's health condition, as reflected in the medical documentation. In both cases, deviation from the requirement of a personal examination of the patient is allowed if justified by the patient's documented health status. It appears that the legislator has placed particular emphasis on the ability to issue prescriptions without the necessity of direct patient contact, solely based on documented health conditions. The Commission of Medical Ethics of the Supreme Medical Council highlights the risks associated with the misuse of MTs for obtaining uncontrolled access to medications [9]. It was emphasised that medical criteria rather than personal preferences or commercial interests are determinants of the feasibility of MTs. Commercial online issuance of sick leave notes and prescriptions upon request is a misinterpretation of the principles of telemedicine. The Commission, in its statement dated February 12, 2023, regarding the commercial online issuance of prescriptions and sick leave certificates, after a detailed analysis of many examples of paid services offered on the Internet for issuing prescriptions and sick leave certificates, critically assessed the access to sick leave notes or prescriptions solely upon completing a short questionnaire that does not meet the criteria of a subjective examination and suggests symptoms to the patient, who receives the document after payment. In such cases, the patient has no contact with the physician, and the offers for issuing prescriptions and sick leave certificates serve solely for their commercial sale. They also show characteristics of advertising and may, for example, offer special discounts for completing a questionnaire. The procedure is very brief (3–5 minutes), suggesting a lack of due diligence, especially when the patient has not been previously examined and treated by the physician issuing the prescription or sick leave certificate upon request. Physicians issuing prescriptions and sick leave certificates in the described manner expose themselves to professional liability due to violations of, among others, Article 8 of the Code of Medical Ethics (regarding the failure to exercise due diligence and dedicate appropriate time to the patient), Article 9 of the Code of Medical Ethics (regarding the exceptions for when consultations can be provided remotely), Article 10 of the Code of Medical Ethics (concerning exceeding professional competencies when issuing certificates outside their medical specialisation), Article 11 of the Code of Medical Ethics (regarding the lack of attention to the appropriate quality of patient care), and Article 40 of the Code of Medical Ethics (regarding issuing certificates without a personal examination or appropriate documentation).

As a result, the legislator introduced changes and restrictions in this area, limited only to prescribing certain categories of medications. The Regulation of the Minister of Health of July 12, 2023, amended the Regulation of the Minister of Health of September 11, 2006, regarding narcotic drugs, psychotropic substances, category 1 precursors, and preparations containing these drugs or substances [28]. According to these changes, a prescription, as mentioned in Article 42(2) of Act on the Medical Profession, for a preparation containing a narcotic drug classified in Group I-N or II-N, a psychotropic substance from Group II-P, III-P, or IV-P, or a Category 1 precursor may be issued if no more than 3 months have elapsed since the patient's last examination [29].

It appears that prescription consultation should not be limited to mere documentation analysis or conducted mechanically, sometimes by unqualified personnel, for commercial reasons or to cut costs. Each decision to continue treatment and implement treatment plan should be consulted with a physician familiar with the patient or a specialist who can assess the situation. Prescription advice provided to chronically ill patients in the absence of periodic medical consultations and direct contact should be considered excessively far-reaching from the perspective of both time and experience, especially in situations where chronically ill individuals, who are on burdensome treatment regimens, have not attended in-person medical appointments for up to 2 years, and their treatment relies solely on pharmacotherapy.

## Conclusions

The regulation establishing the legal framework for medical teleconsultations introduced during the COVID-19 period makes MTs a principle rather than an exception within primary healthcare, which can fundamentally alter the nature of medical advice and carries the risk of irreversible deterioration of its quality. While it may seem that the advancement of telemedicine warrants the application of new technologies in the provision of healthcare services, including medical consultations, it is necessary to introduce legal guarantees for the proper quality of MTs to eliminate conflict between these regulations and Article 9 of the Code of Medical Ethics. The current regulatory solutions allow for a rather provisional formula for MTs, including examinations conducted through electronic communicators or over the phone. However, creating a professional teleconsultation system is still a long way off, primarily due to economic reasons and cost-cutting measures.

MTs provided without ensuring quality standards can compromise the crucial personal relationships in medical care. They can also lead to increased patient isolation, ignoring changes in relationships, and adoption of technology for the sake of cost savings or profit maximisation, rather than health protection [30]. They may even result in medical errors and physician's liability. MTs can be extremely useful in monitoring the condition of already diagnosed patients, implementing established treatment plans, or in preventive care. However, it should be a conscious choice of the patient rather than one forced by limitations. In the case of diagnostic consultations, traditional in-person appointments should be a standard.

Similarly, online consultations should not be reduced to prescription visits aimed at accessing medications. Commercialisation of medical services cannot be the sole justification for introducing changes in the model of providing healthcare consultations.

*De lege ferenda*, it is the legislator who should therefore clearly define, within the framework of the Act on the Medical Profession, the quality standard of teleconsultation, regulating the simplest form, which is a telephone call, as an exception or even limiting it to saving life or health. When defining the quality of MTs, the experience of global medical associations should be utilised at least. These associations emphasise that healthcare professionals must prioritise patient safety, protect particularly vulnerable patients, ensure that patients understand how remote consultations work, obtain their informed consent, conduct an appropriate clinical assessment, and provide them with all available options in order to avoid medical errors. However, despite three years passing since the outbreak of the pandemic, the legislator has not yet specified the quality standards for teleconsultations, formulating only general frameworks for their provision.

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## INTESTINAL PARASITIC INFECTIONS IN POLISH SOLDIERS DEPLOYED TO KOSOVO

Zarażenia pasożytami jelitowymi u polskich żołnierzy rozmieszczonych w Kosowie



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### Abstract

**Introduction and objective:** Soldiers of the Polish Military Contingents currently stationed in foreign countries serve under difficult environmental conditions. Military service abroad is associated with the risk of importing infectious pathogens back to soldiers' home country. The aim of the study was to assess the current prevalence of infections caused by intestinal parasites in soldiers from the Polish Military Contingent Kosovo serving as part of the Kosovo Force operation in the Balkans. **Material and methods:** Parasitological diagnostics was carried out in June 2023 in a group of 221 soldiers from the Polish Military Contingents Kosovo stationed in several military camps across the country. Each participant was asked to provide three stool samples collected at 2–3-day intervals. Faecal examinations were performed using three different light microscopy testing methods (direct smear, decantation, flotation) at the Department of Epidemiology and Tropical Medicine at the Military Institute of Medicine – National Research Institute. **Results:** Intestinal parasites, all of protozoan aetiology, were found in 28 out of 221 Polish soldiers taking part in the Kosovo Force operation in Kosovo included in the study (0.9% participants were infected with *Giardia intestinalis* and 11.7% with potentially pathogenic parasites, *Blastocystis* spp. and *Dientamoeba fragilis*). There were no infections with nematodes, cestodes or trematodes among the study participants. No correlation was found between the detection of a parasitic infection and the presence of diarrhoea or other gastrointestinal symptoms within six months prior to the study. The analysis demonstrated that infections with protozoa were most often found in soldiers aged 35–45 years old. As for the military ranks, the rate of infections in each corps (privates, non-commissioned officers, and officers) was similar. **Conclusions:** Cases of intestinal parasitic infections in soldiers from the Polish Military Contingent Kosovo could be associated with the effects of environmental conditions (poor standards of sanitation in the areas of deployment) and failure to comply with disease prevention principles (food and feed hygiene).

### Streszczenie

**Wprowadzenie i cel:** Żołnierze Polskich Kontyngentów Wojskowych stacjonujący obecnie poza granicami kraju pełnią służbę w trudnych warunkach środowiskowych. Służba wojskowa poza granicami kraju wiąże się z ryzykiem importu zakaźnych patogenów do ojczyzny. Celem badania była ocena aktualnej częstości występowania zakażeń wywołanych przez pasożyty jelitowe u żołnierzy Polskiego Kontyngentu Wojskowego Kosowo pełniących służbę w ramach operacji Kosovo Force na Bałkanach. **Materiał i metody:** Diagnostykę parazytologiczną przeprowadzono w czerwcu 2023 r. w grupie 221 żołnierzy Polskich Kontyngentów Wojskowych Kosowo stacjonujących w kilku obozach wojskowych na terenie całego kraju. Każdy uczestnik badania został poproszony o dostarczenie trzech próbek kału pobranych w odstępach 2–3 dni. Badanie kału wykonano trzema różnymi metodami mikroskopii świetlnej (rozsmar bezpośredni, dekantacja, flotacja) w Zakładzie Epidemiologii i Medycyny Tropikalnej Wojskowego Instytutu Medycznego – Państwowego Instytutu Badawczego. **Wyniki:** Spośród 221 objętych badaniem polskich żołnierzy biorących udział w operacji Kosovo Force w Kosowie infestację pasożytami jelitowymi stwierdzono u 28 osób, we wszystkich przypadkach o etiologii pierwotniakowej (0,9% uczestników było zarażonych *Giardia intestinalis*, a 11,7% potencjalnie patogenymi pasożytami: *Blastocystis* spp. i *Dientamoeba fragilis*). Wśród uczestników badania nie stwierdzono przypadków zakażeń nicieniami, tasiemcami ani przywrami. Nie stwierdzono również korelacji między wykryciem infekcji pasożyticznej a obecnością biegunki lub innych objawów ze strony przewodu pokarmowego w okresie sześciu miesięcy przed badaniem. Z analizy wynika, że zarażenia pierwotniakami występowały najczęściej u żołnierzy w wieku 35–45 lat. W zakresie stopni wojskowych, odsetek zakażeń był podobny w każdym korpusie (szeregowych, podoficerów i oficerów). **Wnioski:** Przypadki zarażeń pasożytami jelitowymi u żołnierzy Polskiego Kontyngentu Wojskowego w Kosowie mogą być związane z wpływem warunków środowiskowych (niskie standardy sanitarne w przydzielonych rejonach) oraz nieprzestrzeganiem zasad profilaktyki chorób (higiena żywności i żywienia).

**Keywords:** Kosovo, Polish Military Contingent, soldiers, intestinal parasites

**Słowa kluczowe:** Kosowo, Polski Kontyngent Wojskowy, żołnierze, pasożyty jelitowe

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**Introduction**

Forces of the Polish Military Contingents (PMCs) currently deployed on foreign operations serve under difficult environmental conditions. Military service abroad is associated with the risk of importing infectious pathogens back to soldiers' home country. This fact was supported by the results of a large study carried out between 2010 and 2014 by researchers from the Military Institute of Medicine in Poland. The study, which involved a total of 24 thousand soldiers, was part of a large project aiming to prevent the transmission of gastrointestinal parasitic diseases among Polish troops deployed on operations overseas. The study findings showed that 5.7% of the participants were infected with intestinal parasites (nematodes, trematodes, cestodes or protozoa) [1]. In order to prevent the spread of parasitic diseases, researchers from the Military Institute of Medicine – National Research Institute have undertaken to continue the epidemiological surveillance of parasitic infections in all areas of deployment of the Polish forces. They are responsible for the parasitological diagnostics and management of cases before the soldiers return to Poland. In 2023, parasitological testing was performed in the contingents relocated to Iraq, Lebanon, and Kosovo [2]. The Polish Military Contingent serving as part of the KFOR (Kosovo Force) operation in the Republic of Kosovo was established by virtue of the Regulation of the President of the Republic of Poland under the act on the forms of engagement or deployment of the Polish Armed Forces outside the country, upon a request from the President of the Council of Ministers. The Polish Military Contingent KFOR in Kosovo is composed of approximately 250 Polish soldiers. They are stationed in several military bases across the country, including the Novo Selo, Film City (KFOR Headquarters in Pristina), Bondsteel, Villaggio Italia, and a camp in Brezovica. Currently, KFOR mainly operates in the northern provinces of Kosovo, i.e., the territories bordering with Serbia. PMC KFOR is carrying out a stabilisation operation. It is part of the Multinational Combat Group – East, whose primary tasks are to fight against organised crime, prevent smuggling and trafficking, and support local authorities and law enforcement agencies in their efforts to ensure law and order in the region [3].

**Environmental situation in Kosovo**

Kosovo is a landlocked country lying in the centre of the Balkan Peninsula, bordering with Serbia (352 km), Macedonia (159 km), Albania (112 km), and Montenegro (79 km). The country's total area is 10,908 km<sup>2</sup>. The territory is dominated by mountainous and high terrain with a mean elevation of 300-600 metres above mean sea level (AMSL), but there are also mountain ranges exceeding 2,000 metres AMSL in Kosovo. The

country has a warm temperate climate, with average temperatures in the capital (Pristina) ranging from 6°C in January to 26°C in July and August. The mean annual rainfall in Kosovo is 1,630 mm, with most rain falling between September and March and in May. The country is rich in surface water. The two major rivers in the country include the Sitnica (which is a tributary to the Ibar river belonging to the Black Sea drainage basin) and the White Drin (which belongs to the Adriatic Sea drainage basin). Around 30% of the land in Kosovo is covered by forests, mostly in the mountainous regions [4].

**Gastrointestinal health risks in Kosovo**

A study by Azemi et al. conducted in a group of 1,050 infants hospitalised at the Kosovar paediatric clinic for acute diarrhoea showed that most infections were of bacterial aetiology (*Salmonella* spp. 38.9%, *Escherichia coli* 21.7%) [5]. In 2017, there was a large outbreak of acute gastroenteritis (manifesting with diarrhoea, abdominal pain, vomiting) among the troops deployed in the region. The outbreak affected not only soldiers from the Polish contingent but also troops of other nationalities. Examinations of cases revealed that most of them were caused by norovirus [6]. Research findings suggest a high prevalence of gastrointestinal parasitic infections in Kosovo. A study by Korzeniewski et al. carried out in Eastern Kosovo (Gnjilane region, Kaçanik municipality) in a group of over 530 children, found infections caused by intestinal parasites in 19.1% of the examined cases, of which 14.9% were caused by *Giardia intestinalis* and 3.8% by nematodes (*Ascaris lumbricoides*, hookworm, *Trichuris trichiura*) [7]. Another study, which involved 773 Polish soldiers serving in Kosovo between 2019 and 2021, showed that 9.6% of the examined cases were caused by infection with *Blastocystis* spp. [8]. Gastrointestinal infections of bacterial and viral aetiology are particularly common in the summer months, whereas parasitic infections (which often take the form of asymptomatic carriage) are reported all year-round.

**Aim of the study**

The aim of the study was to assess the current prevalence rates of infections caused by intestinal parasites in soldiers from the PMC Kosovo serving as part of the UN-mandated KFOR mission in the Balkans.

**Material and methods**

Parasitological diagnostics was carried out in June 2023 in a group of 221 soldiers from the PMC Kosovo. The soldiers were stationed in five different military bases (Novo Selo, Film City (Pristina), Bondsteel, Villaggio Italia, and

Brezovica). Their tour of duty in Kosovo took six months. Each participant was asked to provide three stool samples collected at 2–3-day intervals. The samples were fixed with SAF fixative (sodium acetate – acetic acid – formalin) and 70% ethanol. Next, they were transported to the Department of Epidemiology and Tropical Medicine at the Military Institute of Medicine – National Research Institute (in accordance with the regulations for transporting biological material) for parasitological examination by light microscopy methods (direct smear in Lugol's solution, decantation in distilled water, Fülleborn's flotation) [9, 10].

### Ethical considerations

Each participant was required to submit informed written consent to participate in the study and be tested for intestinal parasites by researchers from the Department of Epidemiology and Tropical Medicine at Military Institute of Medicine – National Research Institute in Poland. The participants also had to provide their personal details (age, sex). The information clause on personal data processing by the Military Institute of Medicine – National Research Institute was drawn up pursuant to Article 14 (1) and (2) of the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, hereinafter referred to as the GDPR. The legal basis for the processing of personal data is defined in Article 6 (1) (e) of the GDPR, which stipulates that the processing of personal data is necessary to perform tasks carried out in the public interest.

### Results

Intestinal parasites, all of protozoan aetiology, were found in 28 out of 221 Polish soldiers taking part in the KFOR operation in Kosovo (0.9% infected with *Giardia intestinalis* and 11.8% with potentially pathogenic parasites (10.8% *Blastocystis* spp. and 0.9% *Dientamoeba fragilis*). No infec-

tions caused by nematodes, cestodes or trematodes were found in the study participants. No correlation was found between the detection of a parasitic infection and the presence of diarrhoea or other gastrointestinal symptoms within six months prior to the study. The analysis demonstrated that infections caused by protozoa were most often found in soldiers aged 35–45 years old (50%). As for the distribution of infections across the military ranks, the rate of infections in each corps was similar (35.7% among privates, 35.7% among non-commissioned officers, NCOs, and 28.6% among commissioned officers) (tab.).

### Discussion

Infections caused by intestinal parasites are a major health issue in soldiers deployed on operations abroad. Increased prevalence of parasitic infections is caused primarily by two factors: poor standards of sanitation in areas of deployment and failure to adhere to disease prevention principles (personal hygiene, food and feed hygiene) [11]. According to Hotez and Gurwith [12], Kosovo is one of the poorest countries in Europe. A series of conflicts in the Balkans, which have continued since the 1990s, led to the destruction of the healthcare system in the country and promoted the spread of infectious diseases in the local communities. A study by Kondaj [13] conducted in a group of Kosovar refugees seeking shelter in Albania showed 2,179 cases of diarrhoea in a group of over 400,000 officially registered refugees. Quamilè et al. [14], who studied the aetiology of diarrhoea in children admitted to one of the hospitals in Kosovo, reported a high prevalence rate of *Giardia intestinalis* infections in the examined cases. Studies by Korzeniewski conducted in a group of Kosovar children confirmed that *G. intestinalis* was the most common pathogen in the examined cases [7]. The World Health Organization estimates that the prevalence of *G. intestinalis* infections in countries with warm temperate climates (such as Kosovo) might range between 2 and 10% in the general adult population [15]. A study involving

Table. Intestinal parasitic infections in soldiers from the PMC Kosovo (n = 221)

Soldiers from PMC Kosovo			Gastrointestinal symptoms				Sex				Age						Rank					
			Yes		No		Male		Female		<35		35–45		>45		Private		NCO		Officer	
n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
<b>Total</b>	221	100.0	8	3.6	213	96.4	205	92.8	16	7.2	87	39.4	109	49.3	25	11.3	80	36.2	95	43.0	46	20.8
<b>Positive (+)</b>	28	12.6	0	0.0	0	0.0	27	12.2	1	0.45	10	4.5	14	6.3	4	1.8	11	5.0	10	4.5	7	3.2
<b>Negative (-)</b>	193	87.3	8	3.6	213	96.4	178	80.5	15	19.5	77	34.8	105	47.5	21	9.5	69	31.2	85	38.5	39	17.6
<i>Giardia intestinalis</i>	2	0.9	0	0.0	0	0.0	2	0.9	0	0.0	0	0.0	2	0.9	0	0.0	1	0.45	0	0.0	1	0.45
<i>Dientamoeba fragilis</i>	2	0.9	0	0.0	0	0.0	2	0.9	0	0.0	1	0.45	0	0.0	1	0.45	0	0.0	2	0.9	0	0.0
<i>Blastocystis</i> spp.	24	10.8	0	0.0	0	0.0	23	10.4	1	0.45	9	4.1	12	5.4	3	1.3	9	4.1	8	3.6	7	3.2
<b>Nematodes</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Cestodes</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Trematodes</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

NCO – non-commissioned officer; PMC – Polish Military Contingent

a group of Polish soldiers deployed to Kosovo found *G. intestinalis* infections in 0.9% of the study participants. Given the fact that a similar study of German soldiers conducted before they returned home after completing their tour of duty in the Balkans showed no infections with intestinal parasites, and considering that *G. intestinalis* in humans is predominantly transmitted via the faecal-oral route, or in some cases via contaminated water, one may assume that the transmission of parasitic infections in the Polish contingent was linked to poor food and water hygiene [16]. The present study showed infections with potentially pathogenic *Blastocystis* spp. protozoa in 10.8% of the examined cases.

According to Kowalewska et al. [17], *Blastocystis* spp. is the most common parasitic species in Poland and its prevalence is growing each year (in contrast to other parasitic species). A comparison between the findings of the present study and the results of a similar study carried out among members of the PMC Kosovo between 2019 and 2021 (where *Blastocystis* spp. infection rate was found to be 9.6%) reveals an upward trend in the prevalence of infections with this protozoan species [8]. A similar rate of *Blastocystis* spp. infections (13%) was observed in a group of Kosovar children presenting with gastrointestinal disorders [18]. Although there is no consensus among researchers on the pathogenic role of *Blastocystis* spp. in humans, it is crucial that medical services monitor its prevalence in the general population in view of the confirmation of symptomatic cases [19, 20].

## Conclusions

The occurrence of intestinal parasitic infections in soldiers from the PMC Kosovo is associated with two major factors: the effects of environmental conditions (poor standards of sanitation in the areas of deployment), and failure to adhere to disease prevention principles (food and feed hygiene).

## Conflict of interest statement

Authors declare no conflict of interest in relation to this article.

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## A MODEL OF DYNAMIC PLANNING OF MEDICAL SUPPORT FOR COMBAT TROOPS. A NEW PERSPECTIVE ON THE REQUIREMENTS AND CAPABILITIES OF THE MEDICAL COMPONENT

Model dynamicznego planowania zabezpieczenia medycznego wojsk walczących. Nowe spojrzenie na wymagania i zdolności komponentu medycznego



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### Abstract

**Introduction and objective:** The experience of the war in Ukraine has shown that success in the field of medical protection of the population can only be ensured by a complete service, tailored to the nature of operational activities, utilizing solutions that allow the use of the latest organizational and technological achievements in healthcare. The aim of the study was to develop a new method for dynamic planning of medical support for combat troops by modeling battlefield medical care processes to increase the effectiveness and efficiency of health-care system resource management and improve the operational capabilities of combat troops. **Materials and methods:** The modeling of battlefield medical care processes was based on commonly recognized operational factors – force, time, and area, expanding this group with an additional parameter – safety, which is important from the point of view of organizing the work of medical field units. **Results:** A calculation model was developed on the basis of which an analytical tool was compiled that allows for flexible adjustment and combination of the goals and needs of medical care – regulated mainly by the scale and structure of sanitary losses, with progress in the course of the military operation. **Conclusions:** The proposed model for estimating medical needs in the part related to securing military operations is a methodologically advanced and, at the same time, easy-to-use decision-making support tool for planning and organizing medical care. It integrates knowledge on the occurrence and distribution of the key factors determining the conditions and possibilities of providing medical support as well as the needs and expectations resulting from tactical and operational intentions. It optimizes the process of securing battlefield medical resources and reduces the risk of errors in the most sensitive areas that are crucial to the success of a military operation. It also strengthens the healthcare system's resistance to hybrid and military operations by providing key information on the current needs for its organization and functioning in connection with tactical and operational plans and the state's defense strategy. The concentration and coordination of medical resources carried out using the model, both native – assigned to the combat group, and those located in the operational space, creates an environment ensuring high effectiveness and efficiency of the assistance provided.

### Streszczenie

**Wprowadzenie i cel:** Doświadczenia wojny w Ukrainie pokazują, że sukces w dziedzinie zabezpieczenia medycznego ludności może zapewnić jedynie służba kompletna, dopasowana do charakteru działań operacyjnych, korzystająca z rozwiązań pozwalających wykorzystać najnowsze osiągnięcia organizacyjne i technologiczne z obszaru zdrowia oraz opieki. Celem badania było opracowanie nowej metody dynamicznego planowania zabezpieczenia medycznego wojsk walczących poprzez modelowanie procesów opieki medycznej pola walki, służącej zwiększeniu skuteczności i efektywności zarządzania zasobami systemu ochrony zdrowia oraz poprawie zdolności operacyjnych wojsk walczących. **Materiał i metody:** Modelowanie procesów opieki medycznej pola walki oparto na powszechnie uznanych czynnikach operacyjnych – sile, czasie i obszarze, rozszerzając tę grupę o dodatkowy, istotny z punktu widzenia organizacji pracy medycznych jednostek polowych parametr – bezpieczeństwo, przypisując jednocześnie wszystkim zmiennym właściwą, odpowiadającą przedmiotowi zagadnienia charakterystykę i interpretację. **Wyniki:** Opracowano propozycję modelu kalkulacyjnego, na bazie którego skompilowano narzędzie analityczne pozwalające elastycznie dostosowywać oraz łączyć cele i potrzeby opieki medycznej – regulowane skalą i strukturą strat sanitarnych – z postęпами w przebiegu operacji wojskowej w części zależnej od jej dynamiki oraz zdolności do prowadzenia manewru. **Wnioski:** Proponowany model szacowania potrzeb medycznych w części dotyczącej zabezpieczenia operacji wojskowych jest zaawansowanym metodycznie i równocześnie łatwym w użyciu narzędziem wspomagania decyzji w zakresie planowania oraz organizacji opieki. Integruje wiedzę na temat występowania oraz rozpowszechnienia najważniejszych czynników określających warunki i możliwości prowadzenia pomocy medycznej oraz potrzeby i oczekiwania wynikające z zamierzeń taktycznych i operacyjnych. Optymalizuje procesy zabezpieczenia medycznego pola walki. Ogranicza ryzyko błędów w najbardziej wrażliwych, kluczowych dla powodzenia operacji wojskowej obszarach. Wzmacnia odporność systemu ochrony

zdrowia na działania hybrydowe i militarne, dostarczając kluczowych informacji dotyczących bieżących potrzeb w zakresie jego organizacji i funkcjonowania w powiązaniu z planami taktycznymi, operacyjnymi oraz strategią obrony państwa. Prowadzona za jego pomocą koncentracja i koordynacja zasobów medycznych, zarówno natywnych, przypisanych do ugrupowania bojowego, jak i znajdujących się w przestrzeni operacyjnej, tworzy środowisko zapewniające wysoką skuteczność i efektywność udzielanej pomocy.

**Keywords:** operational planning, military health service, armed forces, war in Ukraine

**Słowa kluczowe:** planowanie operacyjne, wojskowa służba zdrowia, siły zbrojne, wojna w Ukrainie

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## Introduction

From the point of view of the tasks related to the need to meet medical needs of armed forces and the obligations to protect and defend population against the consequences of kinetic actions in the course of an armed conflict, the Military Health Service (MHS) enters the stage of implementing an urgent operational need, the most important objective of which is to acquire competence and capacity to provide effective medical care during military actions on home territory.

The implementation of this goal requires a carefully planned and well thought-out consolidation and coordination of the resources generated and accumulated in the MHS system, with additional support derived from the competencies of services and authorities responsible for national security. It also requires the application of solutions that allow the use of the latest organizational and technological achievements in the field of healthcare – their proper selection based on the needs of a modern military operation, concentration and coordination. Finally, it requires novel thinking and acting strategies, with exclusion of elements of the previous strategy of organizing medical delivery for the troops implemented in dispersion, in isolation from the structures that make up the national healthcare system.

The experience of the war in Ukraine has shown that successful securing of medical resources for the population can only be achieved by a complete service, tailored to the nature of operational activities, taking into account the needs and conditions of securing resources arising from the realities imposed by the type, scale and scope of the military operation and, at the same time, rejecting practices based on reproducing the way of thinking about medical needs known from peacetime experience and practice and transferring it directly to the state of war.

### Characteristics of modern armed conflict on the example of the war in Ukraine based on war theory

The course of events accompanying the war in Ukraine has shown that modern technologies, their creative adaptation to the needs of war, can disperse military

power among millions of people, which means that the scope of military action goes far beyond the physical battlefield and allows citizens, civilian companies and institutions to have their contribution in the fight. This also highlights the blurring of boundaries between the civilian and military domains, and the fact that the entire society should participate in the preparation for combat. Victory may be determined by adaptability, as a highly creative response to environmental changes, innovation, but also by public involvement, i.e. combining available civilian and military technologies to reinforce one's own capabilities.

Military force is made up of people and reflects the society's character and values, therefore, as Clausewitz said [1]: "War is a trial of moral and physical forces through the medium of the latter." Although equipment, doctrine, training, and leadership are crucial attributes of any military force, the essence of its combat power stems from what the nation represents, as well as the short- and long-term resilience of the state structures to the effects of military actions [2]. No less important are also the state's resources, especially the part that the state can and is firmly willing to allocate to the army. Inspired by the German experience of the Great War, Ludendorff [3] wrote: "The army is rooted in the homeland. It lives in the country and draws its strength from it. What it needs, it can only receive, not create – and fight only with what the country lends from its spiritual, material, and physical strengths." The reality of military operation, as experienced by Clausewitz – the success of military endeavor in which both state and nation are engaged, requires mature and responsible political leadership – "War is not merely an act of policy but a true political instrument, a continuation of political intercourse carried on with other means" [1].

Military experts largely assumed that "revolution in military affairs" would enable one of the parties to gain such an advantage that the military conflict would practically be reduced to delivering one decisive blow. Such technological asymmetry was expected to result in shorter conflicts, which meant diminishing prospect of an armed confrontation to the point of exhaustion. This was however

questioned by the war in Ukraine, which confirmed a fact that has been known for more than 100 years, that war is essentially a contest of new constantly implemented technologies, especially in terms of firepower. Quantity, when considering both equipment and personnel, begins to matter once again. The potential of states involved in warfare is not solely determined by their gross domestic product, especially if it is primarily derived from services. It rather hinges on their capabilities in the production of ammunition and military equipment, the speed of their mobilization, armament, preparation, and utilization in combat, all while using cutting-edge latest technology tools for reconnaissance, surveillance, intelligence, and communication, i.e. everything that contributes to situational awareness [4].

According to Biddle [5], it is not technology that matters most, but the tactical and operational changes, namely how the combat forces utilize new capabilities. Approaches to target designation, the dispersal of forces, the pace of operations, as well as camouflage and supply systems change in response to new technologies.

Views on how large and armed formations will best work in the realities of the modern battlefield, at what depth operations should be conducted, what capabilities should be utilized and how to coordinate multi-domain activities are evolving. In this sense, modern warfare constitutes a constant arena of innovation and change, as well as adjustment of perspectives and existing approaches. However, it is not, as many incorrigible optimists who believe in the proximity of Hegel's "end of history" would like to see it, merely a straightforward, brutal clash of physical potentials and forces, detached from threats to the fundamental, most valuable resources of the states and societies involved in the conflict. According to Clausewitz, war "belongs not to the Arts and Sciences, but to social life [...] it can better be compared to commerce, which is also a conflict of human interests and activities [...] it has its own grammar, but not its own logic, no way of thinking properly. Accordingly, war can never be separated from political intercourse, and if, in the consideration of the matter, this is done in any way, all the threads of the different relations are, to a certain extent, broken, and we have before us a senseless thing without an object." [1]. Therefore, seeking peace and preparing for war, it is imperative to conduct a mature, forward-looking, and coherent state policy across all domains that could theoretically become areas of kinetic and non-kinetic adversary actions, thereby mitigating their adverse effects on society and the state, its political and economic stability, as well as the ability to defend one's own ambitions, aspirations, and interests.

The great Prussian war theorist also wrote: "...The military genius, that it is not one single quality bearing upon War, as, for instance, courage, while other qualities of mind and soul are wanting or have a direction which is un-serviceable for War" [1]. Instead, "that it is a harmonious association of powers, in which one or other may predominate, but none must be in opposition" [1]. If, therefore, we are not witnessing revolutionary changes in military technologies or a breakthrough in the effectiveness of new technologies in destroying enemy's potential, then

traditional, incremental updates of ideas and equipment are insufficient, and a more radical solution is needed. It is therefore evident that victory is rarely determined by weaponry (unless there is an extreme asymmetry in this regard), but rather by how it is utilized and how quickly we can adapt to new challenges.

If both conflicting sides adapt to rapidly changing realities, the advantage lies with the side that adapts more quickly. Therefore, the primary focus should be on new modes of warfare, novel operational concepts, including new medical supply doctrine. German experiences from the 1930s related to the organization of armored forces confirm that the manner in which combat effectors are employed (integration of different types of weapons, communication, as well as the speed and efficiency of command) is a decisive factor in military success [6]. Such innovative approaches, changes stemming from the ability to learn, and the fullest possible utilization of possessed capabilities, possibilities, and competencies, including their inherent benefits derived from the synergy effect, are the true source of victory. This equally applies to the tactics of deploying elements of medical support system during war [7].

### **Considerations on ways and methods for securing medical resources in the battlefield**

Successful 21st century warfare tactics are based on the pursuit of multiplying operational capability of a soldier on the battlefield. Saturation of the battlefield with weapons, missiles, and bombs is no longer a prerequisite for gaining an advantage or victory. Instead, the key to success lies in precision, range, and speed – indicators and measures that are directly linked to access to modern technologies, as well as the skills of soldiers utilizing these technologies in contemporary battlefield – specialists with competence to operate complex weaponry, available in fewer numbers than before.

Therefore, the changes in methods of warfare that we are witnessing today necessitate the development and implementation of novel approaches for providing combat troops with medical support. The power, precision, and range of weapons on one hand, and modern protection systems (survival on the battlefield and maintaining maximum availability) minimizing the attrition of high-quality soldiers on the other, radically change the perspective on the organization of medical support. The priority is no longer given to the forms of military healthcare that have been in place for the past 200 years, whose main goal was to provide mass access to medical service at the expense of its scope and complexity. New means of transportation, evacuation and, to an even greater extent, the progress made in the field of medical knowledge and technology, unleash previously unknown capabilities for delivering highly specialized medical care in a timeframe that guarantees not only survival, but also minimization of the immediate and distant consequences of injuries suffered [8].

Under these circumstances, the task of the military medical component is to create conditions that allow for the organization and maintenance of medical support as close to the front lines as possible, during both defensive

and offensive operations. Hence, the MHS, given today's needs of armed forces, should be set on the foundation of procedural and product innovations that break through the previously established organizational standards, solutions that correspond to modern methods of warfare, which consider modern possibilities arising from advances in knowledge and technology in practical use. A secure and efficient logistic network of drones, based on modern unmanned platforms delivering medications and medical supplies to the frontline and resistance nests; autonomous casualty evacuation platforms ensuring quick access of the injured to medical units capable of providing first aid; modular, mobile dressing stations distinguished by their ability to easily expand the scope of medical assistance provided to a degree corresponding to the type and scale of sanitary losses, interconnected via medical evacuation vehicles with level III and IV hospitals are a few examples of implementations that could significantly change the way military medical services are organized and operate. Illustrating the capabilities and methods of their practical application to establish new solutions for the provision of medical assistance for the military.

The profile of the units that make up the national network of hospitals of the state security system should include entities that are ready to provide comprehensive multispecialty medical care, with particular emphasis on the management of battlefield injuries. The knowledge and experience of medical personnel and the available material resources will constitute a distinguishing factor for the aforementioned entities in the healthcare market. The list of facilities should be opened by military hospitals, to which civilian entities such as multi-specialty hospitals and trauma centers will be added based on locally defined needs. These units, with minimal effort and resources, will be able to meet the personnel, material, and organizational requirements in the field of medical support for armed conflict.

Implementation of a new approach to aspects related to tactics, command and training of medical personnel is another issue. These should be seen not as an imposed, dogmatic norm, but rather as knowledge grounded in experience, and a detailed and thorough analysis of issues related to battlefield medical support. A provisional solution, necessitating continuous learning, including understanding the enemy's behaviors, improving treatment methods, as well as resource organization and management, subordinating them to the principle of integration of available forces and resources, and adapting the scale and scope of activities to evolving conditions. Finally, the ability to provide medical assistance in the face of dynamically remodeled battlefield needs.

### The war in the East. Lessons from past experience

The conflict in Ukraine is a unique opportunity to update issues related to tactics, training, but also the strategy of organizing healthcare systems in conditions of conflict with near-peer opponents – adversarial nations with equivalent military force. The well-known peculiarity of this type of conflict is the use of weapons with greater force of destruction and range, which directly translates into an increased scale of injuries and fatalities. As a re-

sult, the management of the injured becomes a significantly greater challenge for medical services than previously estimated, with changes in the organization of battlefield medical support involving such key issues as the location of levels (stages) of care.

The types of weaponry utilized, as well as its velocity and precision, account for changes in the severity and nature of injuries that have not been seen before in armed conflicts. Polarization in the area of sanitary loss registry adopting a simplified structure – mild, severe, and very severe injuries – means in the medical service practice that there is a need for advanced methods for stabilizing the condition of the wounded already at the early stage of treatment.

It is estimated that 5–10% of Ukrainian soldiers deployed to the theater of operations were either wounded or killed in action. Multiple cases of casualties with symptoms of hemorrhagic shock or burns, penetrating or multi-organ injuries and barotrauma, which are mainly the result of artillery or missile fire, constitute a new, unprecedented characteristic of sanitary losses, which require medical (often specialized) care provided in close proximity to the enemy.

Given the goal of ensuring the effective implementation of the healthcare system's tasks, efficient, targeted medical evacuation, ensuring conditions for prolonged care in the field, including an expanded volume of medications and medical supplies, and the ability to perform extensive surgeries to limit the consequences of sustained injuries are essential [9]. It is estimated that the capabilities of "leader" surgical teams should be measured, among other things, by their readiness to perform at least 10 rescue procedures, including laparo- and thoracotomies, with simultaneous intensive care for 15 patients for at least 48 hours, without the need to replenish supplies. Expanding the medical competence of these teams, resulting from the need to save the health and life of those wounded, limits their mobility, which is responsible for creating an organizational disharmony between the need for greater medical capabilities and the capacity for rapid relocation, which is difficult to reconcile with the principles of military maneuvers. This implies that raising the level of medical support may have a negative impact on one of the operational indicators (mobility), hence the decision should be considered each time during the planning and implementation of medical support for military operations, being the resultant of expected tactical and operational goals pursued under constraints imposed by the magnitude and structure of sanitary losses, which delineate the competency framework of medical care, setting the limit on achievable military objectives at a given stage.

In addition to the level of medical support, medical evacuation is another factor requiring special attention in terms of maintaining the proper operational efficiency of home troops, especially when it comes to the transportation of those wounded. Conclusions from analyses of armed conflicts occurring in the past decade clearly indicate that securing evacuation routes by operational forces, for instance, through achieving air dominance (medical evacuation, MEDEVAC), should always be re-

garded as a factor enhancing operational capabilities and mitigating the impact of constraints associated with the level of medical support.

The communications system, both its technological and organizational layers, is also an integral, high-priority utility element of medical support according to the new design. In addition to coordinating interaction at the level of autonomous medical structures, as well as between these structures and operational units, the key task of the communication network is to coordinate the flow of the stream of wounded – to optimize the management of the resources at hand, to adapt care processes to the current needs defined by the scale and structure of sanitary losses. The experience from the ongoing military conflict behind our eastern border shows that success in battlefield logistics and medical care can only be ensured by a service that is strictly oriented to securing specific medical needs of the army, as well as the operational objectives that the organizational units of the armed forces are required to implement.

According to the Ukrainian Crisis Media Center, more than 1,300 health care facilities, including 200 hospitals, have been completely destroyed due to Russian military actions. Therefore, temporary medical facilities, such as field hospitals, may need to be placed underground. This may mean that significant investment is needed in high-speed tunnelling and earthmoving equipment, which currently cannot be placed on the battlefield. Despite the current practice of surrounding structures with concrete walls and barriers, these facilities are still exposed to vertical attacks. Hence, point defense elements similar to those used in Israel's Iron Dome should be an essential element in protecting critical military medical infrastructure, guaranteeing the safety of both those wounded and medical personnel.

All this should be kept in line with the previously mentioned principles of civil-military cooperation (colocation), a variant of public-private partnership, and aided by the ability to create an open network for collecting and processing information on medical needs related to the effects of military kinetic actions based on detailed data on the size and type of sanitary losses, with the widest possible use of novel technologies to support decision-making processes at subsequent stages of care. This approach contributes to improved situational awareness and allows for more rapid responses tailored to current needs. The organizational and functional integration of the military and civilian segments of the state healthcare system in the context of the needs emerging during the conflict in Ukraine is currently the best possible approach to issues related to medical support in times of crisis such as war. This solution guarantees measures against the effects of using means of warfare against soldiers and civilians that are coherent in terms of place and time, and involve the entire potential of the state. It is also a method that increases the effectiveness and efficiency of the actions carried out in two dimensions: short-term – the professional capacity and availability of medical assistance, and the long-term – the resilience of society and the state to the exhaustion of capabilities and resources in the course of a prolonged conflict.

### **A proposal for a universal formal principle codifying a new method for organizing medical support for a military operation**

Planning the medical supply system for armed forces and the state requires acceptance and recognition of the importance as well as tactical, operational and strategic significance of the events that have taken place and continue to take place during the armed conflict in Ukraine, a war that has no equivalent in European history since the hecatomb, i.e. World War II, given the scale, extent, dynamics, spectrum of weapons and technology used.

The clash of states of equivalent military force, based on political and economic polarization, accompanied by extreme cultural and ethical differences regarding the rules and principles of armed conflict, imposes an obligation to have a critical infrastructure that provides the highest level of security in the area of civil protection. This means that the schemes for organizing medical supply developed for the previous war are not and will not be useful or effective in countering the effects of future conflicts. Likewise, the specifics of current military operations, which are most strongly influenced by the already mentioned velocity, range and precision, make it possible to consider it necessary to depart from the previous practice of countering the effects of military operations based mainly on a universal (generic), and thus not taking into account the distinctiveness of needs, model of organizational solutions for military health protection. The starting point for thinking and acting in this regard should be the well-established truth, known for over three centuries, that if armed forces are expected to deal with any challenge and any conflict, such an army will not be able to cope with any of them.

The scale and structure of sanitary losses recorded during the war in Ukraine have shown that a modern full-scale military operation has its own specific needs and conditions in terms of medical supply, and that they cannot be met in any other way than by combining all existing resources, capabilities, as well as organizational and technical solutions, including novel technologies present on the health market to support diagnostic and therapeutic as well as decision-making processes that are related, for example, to improving evacuation of the wounded.

Both today and in the foreseeable future, the framework for the composition of such action should be guided by a new model for the organization and planning of the medical support system. This model should prioritize the definition of services that meet the current requirements and needs of the military and the state. The vector of the proposed action should be directed first and foremost to services that guarantee the connection between the current, and this should be emphasized, dynamically changing wartime objectives, and the best possible utilization of available competencies and resources.

### **The role and importance of operational factors in the planning and organization of medical support for a modern military operation**

The dynamics and maneuverability of a military operation, as well as the different ways and conditions of warfare

require new capabilities and skills for the flexible management of healthcare system resources. The starting point for their development is situational awareness based on knowledge of the type and purpose of the military operation, the planned use of combat assets and the associated scale and type of expected sanitary losses. Equally important is the advanced ability to rapidly estimate medical needs and replenish them to a degree and extent appropriate to the current tactical and operational situation, supported by a number of interrelated innovative technological solutions – decision support algorithms.

The implementation of the aforementioned intentions necessitates a change from the current organization of medical support based on norms and completing requirements, endowing it a new dynamism and flexibility, drawing on full subordination, and thereby, effective use of the available resources. It also necessitates closely linking the medical system, appropriate for a given level of support, with the operational activities performed by the combat troops, which in practice means a full departure from the commonly used formal principle, due to which medical system units that are part of the operational troops are inadequate in terms of the specificity and nature, as well as the conditions, mode and dynamics of the troops receiving medical support.

Reference to the specificity of operational units is justified if it stems, for example, from the conviction supported by experiences from the war in Ukraine, which relatively precisely delineate the norms and rules defining the needs regarding the level of medical support for combat troops. There is no doubt that the forecasted scale and structure of sanitary losses is the main variable determining the capabilities of the medical component designated to support a unit or tactical formation. However, considering the scale and the dynamics of events that make up the picture of modern battlefield, the approach presented seems highly insufficient and operationally imperfect. Indeed, the expectations placed on competent, expert medical capabilities required in combat by mobile forces (high maneuverability shifts the level of medical care as close to the line of contact with the enemy as possible) are different from those required by the subunits of light infantry engaged in position defense on their own territory, supported by the national healthcare system. Examples of treating the medical support needs of the battlefield within the polarized framework illustrate the extent to which the current practice of organizing healthcare (universalization of military healthcare) remains imperfect, having been applied in its unchanged form for several decades. It deviates significantly from the actual needs of operational forces, which are normalized by new combat systems and their methods of use.

Just as guns and airplanes of different types are constructed depending on their combat tasks, medical support, whose role is to ensure the full protection of the health and lives of soldiers, maintain combat spirit, and moral strength necessary to overcome one's own instinct for self-preservation, should be tailored to the common goal, which is victory. This implies an urgent need for changes in planning and organizing military medical support, with a recommendation to employ the method of overlaying operational plans of combat and medical forces. Additionally, there is a need to de-

velop new decision-supporting tools utilizing tangential vectors and data resources, would, to the widest possible extent, take into account both common areas and differences – a key characteristic for operational planning of the simultaneous use of types of troops subordinated to a common goal.

### **Assessing the feasibility of using operational factors in planning battlefield medical support**

The proposal of a new organizational model for MHS operational actions as a prelude to the concept of dynamic planning for the medical support of combat forces requires meticulous preparation of a cognitive map to ensure conceptual clarity of the proposed assumptions. For the purposes of the present study, this task was based on transcribing source terms describing operational factors to a conceptual level corresponding to organizational issues within the healthcare system, as well as on linking new organizational and functional proposals with the practice of tactical and operational military operations.

The premise of this reasoning was the assumption that conclusions derived from the analysis of operational factors serve as the basis for thinking and planning. They make it possible to assess the conditions for achieving the intended goal, and their interrelations support, with an appropriate degree of freedom of action, decisions on the choice of the appropriate mode of action, remaining in close correlation with the operational situation of the home troops. They serve as utilitarian and simultaneously pragmatic methodologies in terms of managing the battlefield, expanding and complementing the previously presented aspects of warfare theory.

Conducting war is a reality, not a theory; therefore, the fundamental objective of developing and effectively implementing a new method of dynamic planning of medical support for combat troops through modeling battlefield medical care processes is to pursue rationalization and automation of the actions taken as:

- Support of planning decisions on the preparation and implementation of tasks related to the organization of medical support for military operations. Effective utilization of allocated resources – type, quantity, as well as the time and place of their utilization.
- Optimization of integration processes in the field of available forces and resources and adaptation of the scale and scope of activity of the universal healthcare system, including the possibility of providing medical support in the realities of the dynamically changing needs of the battlefield.
- Determining the role and importance of operational factors as determinants of the validity of actions taken in planning and organizing medical support for military operations.
- Improvements in both planning and organizing battlefield medical support, including integration with the goals of operational troops, while maintaining their dynamics and maneuverability to effectively and quickly achieve the pre-set goals.

### **Methods**

Military medical modeling is based on widely recognized operational factors, i.e. force, time, and area, with this

group expanded to include an additional parameter – safety, which is important from the perspective of the organization of medical work of field units. Simultaneously, all variables are assigned appropriate characteristics and interpretation corresponding to the subject matter [10].

### **A mathematical model for planning battlefield medical support**

#### **Dependent variable:**

- **Force (expected capabilities)** – properly organized and equipped medical units that should be at the disposal of the component commander as part of the preset tasks

#### **Independent variables:**

- **Medical needs** – the scale and extent of sanitary losses forecasted in the area covered by the medical support unit in connection with the implementation of the assigned operational task.
- **Time (dynamics)** – the time required for the preparation of the operation, estimated in terms of forming the necessary forces, their transfer to the area of operation and integration within the other structures, while ensuring the level of maneuvering activities appropriate to the operational situation.
- **Area (space)** – the characteristics of the place where the operation will be conducted, mainly in the context of forces and resources involved, as well as the state of the healthcare infrastructure available for use within the military-civilian colocation system.
- **Safety (protection)** – the level of achievable protection of medical support sites in the area of operation.

The meaning and etymology of the terms used indicate that, in the practice of battlefield, the method of planning medical support for military operations will seek to overlap the intentions of the operational troops and the medical component envisaged for implementation in place and time, which states that the structure – the strength and vector of the impact of each of the above-mentioned operational factors – will draw from both domains to the extent appropriate to the realities of the tactical and operational environment.

### **Structure, complexity, resources, definitions**

#### **Operational structure (O):**

O – combat grouping: brigade, division, corps, army, front, etc.

$d_s$  – the dynamics of activities corresponding to the proportional structure of O mobility, with frontline assigned a value of 1

$p_s$  – number of troops

$l_s$  – number of doctors in the structure completion

$spm_s$  – number of medium-sized medical personnel in complete structure

$lo_s$  – number of medical beds in complete structure.

#### ■ **Medical structure (Sm):**

$n_i$  – number of units for the level (i), i – I, II, III, IV – according to the level of medical support

$d_m$  – the dynamics of medical structure activities proportional to the structure's personnel mobility, with a value of 5 for level IV and a value of 100 for level I

$l_m$  – number of doctors in complete medical structure

$spm_m$  – number of medium medical personnel in complete medical structure

$lo_m$  – number of medical beds in complete medical structure

$b_m$  – safety indicator that defines the minimum requirements for the protection of medical structures involved in countering the effects of military action.

- **Medical structure in the theater of operations ( $Sm_t$ )** – medical structure located in the area of operations as a resource that can be used as a whole or in part during the implementation of medical support tasks.

#### ■ **Medical support resources (Z):**

$zm_z$  – medical resource: doctors, mid-level health providers, hospital beds

$wz_z$  – rate of utilization of the resource in relation to sanitary losses

$wr_z$  – rate of concurrent losses requiring medical attention.

According to the preset operation, the parameters for its implementation have been defined:

$d_o$  – dynamics of operations defining the expected minimum rate of movement of the medical structure during the provision of medical support for combat group

$b_o$  – safety factor for an operation implemented by a combat group, equivalent to the impact of the conditions of the operation on sanitary losses

$ss_o$  – the coefficient of estimated sanitary losses following the operation, with an assumed safety factor ( $b_o$ ).

Under the predefined conditions, the decisions of the medical commander will involve quantitative and generic selection of medical structures (Sm) as resources, so as to be able to maintain the ability to conduct operational activities despite the sanitary losses incurred. A direct consequence of this situation is, among other things, the need for allocating appropriate number of medical resources for the size of losses (tab.).

Accordingly, the following has been estimated:

**Table.** Characteristics of the structure and dynamics of the levels of medical support in the medical security system.

Medical structure	Dynamics	Physicians (n)	Nursing and emergency personnel (n)	Beds (n)
Level 1	100	0	12	10
Level 2	85	8	25	20
Level 3	35	50	200	300
Level 4	5	700	1200	600

*n* - number

- The magnitude of sanitary losses as a derivative of the loss rate ( $ss_o$ ), the number of personnel ( $p_s$ ),  $b_o$ , assuming that the lower the  $b_o$ , the greater the sanitary losses.

$$wss = \sum_{i=1}^{n_i} 1 + (1 - b_{o_i}) \times ss_{o_i} \times p_{s_i}$$

- The potential of home combat group (O) as the size of the medical resource available within the O, without involving the resources of the medical component.
- Potential of  $Sm_t$  as the size of a medical resource with a number (t), providing support in the area of the operation being carried out.

$$p_{sm_t}(zm_z, wz_z, wr_z) = \sum_{i=1}^t (zm_{z_i}, wz_{z_i}, wr_{z_i})$$

- The size of the medical support resource (Z) resulting from the adopted values -  $wr_z, zm_z$ , size of sanitary losses.
- The magnitude of medical structure deficit as the difference between available and necessary resources.

$$D_{zm_z} = (p_o + p_{sm_t} + p_{sm}) - p_{pss}$$

where:

$p_o$  - native medical potential of the combat grouping

$p_{sm_t}$  - medical potential of the medical resource providing support in the area of the operation

$p_{sm}$  - potential of the medical structure in the theater of operations

$p_{wss}$  - necessary potential, resulting from estimated sanitary losses.

Knowing the magnitude of limitations in terms of the available medical resources and the number and type of medical structures ( $Sm$ ) at the disposal of the medical commander, the decision on the organization of medical support for operational activities will be based on such a constellation of forces and resources that will reduce the level of the perceived deficit to the greatest extent possible.

$$D_{zm_{z_i, opt}} = D_{zm_{z_i}}, i = 1$$

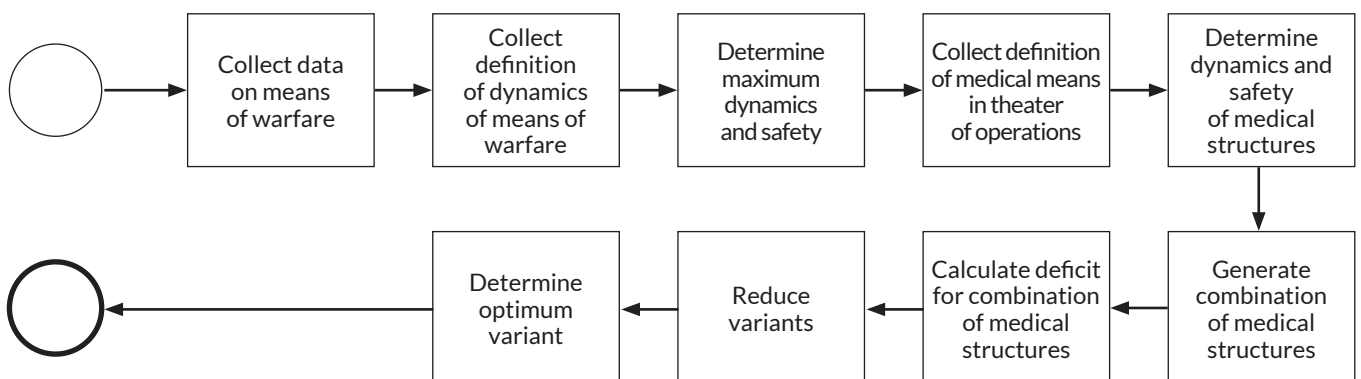
such that

$$D_{zm_{z_i}} > 0 \text{ i } D_{zm_z} = \min(D_{zm_{z_i}}) \text{ i } = 1 \dots N$$

At the same time, it should be kept in mind that any task of this type will be neither simple nor easy. For only one level IV unit, five level III units, 15 level II units and 100 level I units, the number of possible combinations to be evaluated is 7,500 and it grows according to the following relation:

$$N = \prod_{i=1}^{IV} n_i$$

Considering the above, a calculation model was developed according to the algorithm (fig. 1).



**Figure 1.** Algorithm for calculating medical supply variant

By setting the model parameters as follows:

- combat grouping: brigade
- dynamics: 5
- estimated losses: 30%
- operational safety: 60%
- spare medical resources in the theater of operations (operational space): none

the estimated deficit in medical resources will be:

- physicians: 173 persons
- mid-level medical personnel: 347 persons
- number of beds: 158.

By setting the decision space at the level of reduced combinations, assuming minimum medical safety appropriate to the level of security determined by the results of the situational analysis, the medical commander will in fact have a narrowed field of choice resulting from the differences between the dynamics of operational activities and the priorities of care processes implemented by medical structures. Additionally, constraints on key command decisions may be faced due to the frequent cognitive dissonance between the need to maintain the conditions for purposeful medical care that meets the current needs and providing support for the implementation of operational tasks, following the principles of tactical operations (fig. 2).

It should be noted that the dynamics of medical troops in terms with the mode of operation according to the pat-

tern: reaching the target – infrastructure deployment – action – infrastructure redeployment, including unevacuable patients, will always limit the mobility of operational activities. Therefore, it is crucial to possess capabilities enabling flexible adjustment through operational planning tools, to integrate the goals and needs of medical care (modulated mainly by the scale and structure of sanitary losses) with advancements in the course of military operations, dependent upon their dynamics and maneuvering capabilities, and to precisely determine and adjust the planning for the utilization of the designated medical component’s capabilities in terms of both location and timing to support military operations.

The model also shows that the ability to utilize properly arranged and organized medical structures located in the theater of operations (operational space) clearly reduces the requirements associated with the need to engage reserves located in the retreat (fig. 3 and 4). This outcome is a result of the engagement of medical resources situated either at the location or along the direction of operational military activities. While mobile medical structures can follow the army, level III and higher level hospitals may be considered mobile from an operational perspective only in terms of personnel, not infrastructure. This implies that with a defined level of medical security, the medical commander can effectively fulfill tasks using a large number of lower-level medical structures, with the potential for their support through military-civilian collocation with

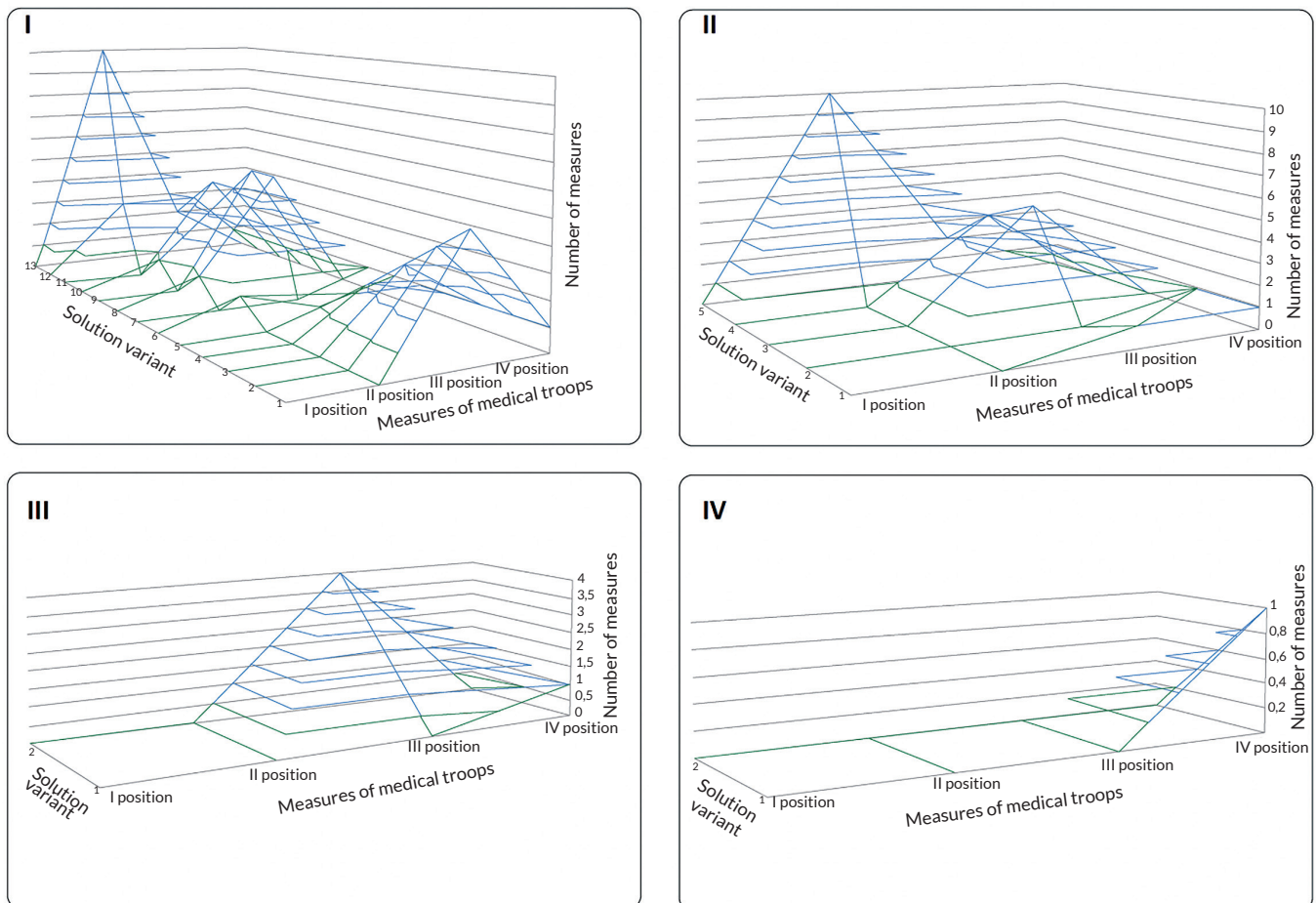
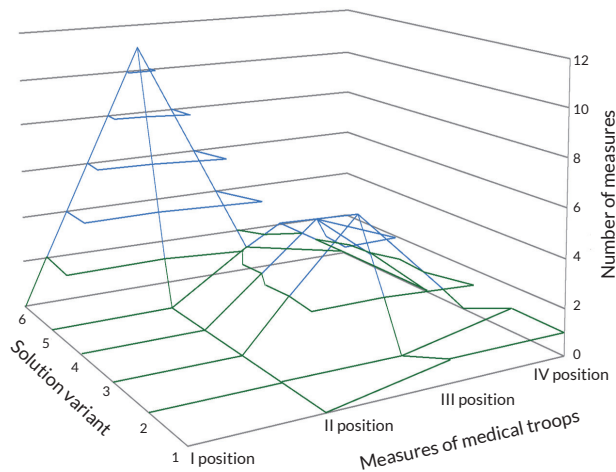


Figure 2. Decision space under conditions of maintaining minimum security at successive (I-IV) levels of medical support



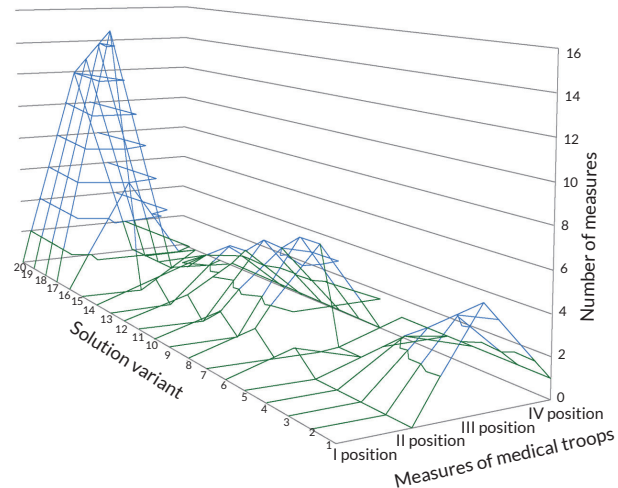
**Figure 3.** Decision space of the medical commander in the context of medical structures in the theater of operations using a single level-III unit

medical teams deployed in the theater of operations, possessing advanced care capabilities, thereby minimizing limitations on the mobility of these units.

### Discussion

From the point of view of tasks related to the protection and defense of the population against the effects of crisis events, the Polish health care system is currently at the stage of transformation, the most important goal of which is to acquire the ability to deliver effective medical care during an armed conflict taking place on its own territory. This necessitates a thoroughly planned, well-thought-out consolidation and utilization of the resources gathered within the system, reinforced by the competencies of services and authorities responsible for state security.

The current threats to Poland's security clearly show that selected operational competencies, which until now have been the almost exclusive domain of the military, should also become part of the "civilian" segments of socio-economic life. Maintaining the conditions for the nation's health security is equally the responsibility of the civilian and military segments of the healthcare market, participating in the development of a crisis-proof health system. Hence, it is so important to organizationally and functionally link the two components of the system, determine the scope of needs and conditions of cooperation, in which having a planning tool that integrates data on the system resources and the current needs for their use provides invaluable support as it sets the framework for a new option, a standard for greater effectiveness and efficiency of the management of civil protection operations, giving priority to the principle according to which basing activities on a primary common operational plan ensures better, more coherent, comprehensive preparation in the field of medical support, optimizes integration processes in the field of available forces and resources, and adaptation of the scale and scope of the activity of the national health protection system, including the



**Figure 4.** Decision space of the medical commander in the context of medical structures in the theater of operations using two level-III units

possibility of providing medical assistance in the realities of the dynamically changing needs in the battlefield.

Both the concept of development and the confirmed results of the assessment of the proposed analytical method are rooted in the viewpoint formulated by von Bülow [11] over 200 years ago, according to which employing mathematics facilitates the planning and execution of all operations with geometric precision. An opposite view was presented by Clausewitz [1], who saw war precisely as an art rather than science based on geometric diagrams. However, the conclusions resulting from the use of the new planning tool show that, contrary to the first impression, the two views cited, although categorical, are neither contradictory nor mutually exclusive. This is because the more strongly military operations are linked to the need for advanced planning (simultaneous management of multiple situations and resources) the more they correspond to the tactical and operational objectives of the battle, the more room they have for mathematical calculations, shaping the space for developed and oriented decision support related to task implementation. On the contrary, the more they are part of politics and the achievement of its goals through military means, the more they correspond to the rules of art expressed through strategy.

Conclusions from the practical use of the presented proposal for a model of dynamic planning of medical support for military operations further indicate that the effective utilization of such tools is possible when ensuring the organization of the medical component of the structure corresponding to the type of troops. If programming of medical support on the battlefield is expected to guarantee the possibility of using the potential of planning military operations taking into account operational factors, then it must ensure rapid and full access to the resources at its disposal and grant formal and legal conditions, and thereby the possibility of flexible management. A military medical component is responsible for preparing conditions that will allow for

organizing and maintaining medical support as close to the battlefield as possible – both during defensive and offensive operations. The actions undertaken should also take into account operational priorities, including those relating to the dynamics and maneuverability of own forces. The application of the new planning model eliminates previous limitations caused by the subjectivity of assessments and the decisions formulated based on them, improving the pace and efficiency of achieving key goals and objectives.

At the same time, conducting a military operation on one's own territory requires the definition of norms and principles for managing the processes of co-location of civilian and military health market resources. Given the estimated needs, it is most expedient to create a network of hospitals on the home territory, the distribution, number and competence and capabilities of which will correspond to the projected size of sanitary losses associated with a potential conflict [12]. Accurate knowledge of the number and type (strength and complexity) of medical support units required for use during a military operation is the basis for conducting effective calculations during the planning process and, subsequently, for the effective use of the resources at hand.

The application of the developed planning tool also clarifies the view on the role and importance of level III hospitals. Under the conditions of a defense operation conducted in an area with a developed network of highly specialized inpatient treatment units, the main task of the above-mentioned units will be to provide support to local medical entities, as well as to serve as a mobile backup of lower-level military hospitals. Hence the conclusion that the potential of level III hospitals can be fully utilized mainly during hostilities conducted in an area devoid of medical infrastructure or operations outside the country, which together should contribute to the knowledge of the operational planning area on the real material and equipment needs in terms of the number and type of field hospitals needed to provide support for military groupings involved in combat.

This also underscores the importance of decisions on the location of medical structures, especially in the field of highly specialized (hospital) treatment, given the anticipated directions of hostilities, as well as initiatives such as military-civilian co-location – arranging for the cooperation of civilian resources intended to support medical care during an armed conflict. The scale of predicted medical needs in this regard, applying the classification included in the system of basic hospital provision of healthcare services, allows us to assume that level I–III facilities, which are multispecialty hospitals (level VI), responsible for ensuring the availability of selected, highly specialized procedures resulting from the needs of the battlefield, will play the key role in meeting these needs.

A state that is strong in the face of threats, safe from the perspective of the needs of society, requires directional, variant plans of action that will allow to reproduce in some areas, or to build from scratch in others the capabilities and competencies necessary for an effective response – neutralizing the effects of all

threats related to the occurrence of a crisis situation, including those having the nature of an armed conflict. Therefore, the widespread awareness and resulting responsibility, an unyielding determination and an understanding, supported by empirical evidence, that departure from the postulated changes that complement and strengthen the existing capabilities of the state security system, including the armed forces, will mean accepting the risk of losing the national fabric should be the measure of Poland's and Poles' commitment to build a safe future for the state and the nation. Given the experience of the war in Ukraine, the scale of the aforementioned phenomenon will be incomparably greater than the tragic demographic consequences caused by the pandemic crisis, which are considered tragic today.

## Conclusions

The proposed model for estimating medical needs concerning the support of military operations is methodologically advanced and simultaneously user-friendly as a decision support tool for planning and organizing healthcare. It mitigates associated dilemmas and uncertainties, integrating knowledge about the occurrence and prevalence of key factors determining the conditions and possibilities for providing medical assistance, as well as the needs and expectations arising from tactical and operational intentions. It optimizes battlefield medical support processes, reduces the risk of errors in the most sensitive areas crucial to the success of a military operation – both on the side of method and conditions of using the resources, and the adequacy of where and when they are used. It reinforces the health system's resilience to hybrid and military operations, providing key data on the current needs for its organization and operation in conjunction with tactical and operational plans and the national defense strategy. Concentration and coordination of medical resources, both native, assigned to a combat grouping, and those located in the operational space, i.e. available within the framework of military-civilian co-location, implemented by this system, creates an environment that ensures high efficiency and effectiveness of the assistance provided.

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## A CASE OF ANASTOMOTIC LEAK DUE TO *CANDIDA ALBICANS* INFECTION IN A 64-YEAR-OLD FEMALE RENAL TRANSPLANT PATIENT TREATED WITH AN EMERGENCY SUPRAPUBIC ILIOFEMORAL BYPASS GRAFT



Przypadek nieszczelności zespolenia wywołanej zakażeniem *Candida albicans* u 64-letniej pacjentki po przeszczepieniu nerki, leczonej w trybie nagłym poprzez wszczepienie pomostu biodrowo-udowego z dostępu nadłonowego

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### Abstract

**Introduction:** Vascular complications are a rare but important risk factor for failure and loss of kidney graft, increasing the mortality of renal graft recipients. **Case report:** We present the case of massive haemorrhage due to the rupture of the arterial anastomosis caused by *Candida albicans* infection in a 64-year old female kidney graft recipient managed with suprapubic iliofemoral bypass during emergency life-saving graft nephrectomy performed in our unit. The postoperative period was complicated by femoral vein thrombosis and intraabdominal fluid collection. After 33 days, with a well-functioning iliofemoral bypass, the patient was discharged to the nephrology unit. At the 12-month follow-up, the patient is functioning well, receiving nephrological care and haemodialysis treatment. **Conclusions:** Routine fungal cultures of graft preservation fluid and radiological follow-up in high-risk patients after transplantation may be helpful in the prevention of fatal complications in the high-risk patient group – especially if digestive tract injury occurred during organ harvesting. Nevertheless, histological examination remains the gold standard for the detection of fungal arteritis. Negative culture samples from the preservation fluid, blood and urine before the transplantation do not exclude the risk of fungal infection. Urgent allograft nephrectomy with resection and reconstruction of changed vessels seems to be the safest approach in ruptured anastomotic pseudoaneurysm, as shown in our case.

### Streszczenie

**Wstęp:** Powikłania naczyniowe są rzadkim, ale istotnym czynnikiem ryzyka niepowodzenia i utraty przeszczepu nerki, zwiększającym śmiertelność u biorców tego narządu. **Opis przypadku:** Przedstawiamy przypadek 64-letniej biorczynie przeszczepu nerki, u której doszło do masywnego krwawienia w następstwie pęknięcia zespolenia tętniczego wywołanego zakażeniem grzybem *Candida albicans*. Podczas ratującego życie zabiegu nefrektomii przeszczepionej nerki, wykonanego w trybie nagłym na naszym oddziale, pacjentce wszczepiono pomost biodrowo-udowy z dostępu nadłonowego. Przebieg pooperacyjny był powikłany zakrzepicą żyły udowej i gromadzeniem się płynu w jamie brzusznej. Po 33 dniach pacjentkę z prawidłowo funkcjonującym pomostem przeniesiono na oddział nefrologiczny. Po 12-miesięcznej obserwacji stan pacjentki jest dobry. Chora pozostaje pod opieką nefrologiczną, jest leczona hemodializami. **Wnioski:** Rutynowe badania posiewowe płynu do przechowywania narządów przeznaczonych do transplantacji w kierunku zakażenia grzybiczego oraz radiologiczne badania kontrolne po zabiegu transplantacyjnym u chorych wysokiego ryzyka mogą być przydatne w zapobieganiu śmiertelnym powikłaniom w grupie wysokiego ryzyka – zwłaszcza jeśli podczas pobierania narządu doszło do uszkodzenia przewodu pokarmowego. Niemniej jednak badanie histologiczne nadal pozostaje złotym standardem w diagnostyce zapalenia tętnic wywołanego zakażeniem grzybiczym. Ujemny wynik posiewu płynu do przechowywania narządów oraz krwi i moczu przed wykonaniem przeszczepu nie eliminuje ryzyka zakażenia grzybiczego. Przedstawiony w pracy przypadek wskazuje, że pilna nefrektomia przeszczepionego narządu wraz z resekcją i rekonstrukcją zmienionych naczyń stanowi najbezpieczniejszą metodę postępowania u chorych, u których doszło do pęknięcia tętniaka rzekomego w obrębie zespolenia.

**Keywords:** pseudoaneurysm, kidney transplantation, fungal arteritis, renal artery rupture

**Słowa kluczowe:** tętniak rzekomy, przeszczep nerki, zapalenie tętnic wywołane zakażeniem grzybiczym, pęknięcie tętnicy nerkowej

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## Introduction

Kidney transplantation (KTx) increases the survival rate and quality of life in patients with end-stage renal disease (ESRD). Vascular complications are a rare but important risk factor for failure and loss of kidney graft, increasing the mortality of renal graft recipients [1–3]. We present the case of massive haemorrhage due to the rupture of the arterial anastomosis caused by *Candida albicans* infection in a 64-year old female kidney graft recipient managed with suprapubic iliofemoral bypass during emergency life-saving graft nephrectomy performed in our unit.

## Case report

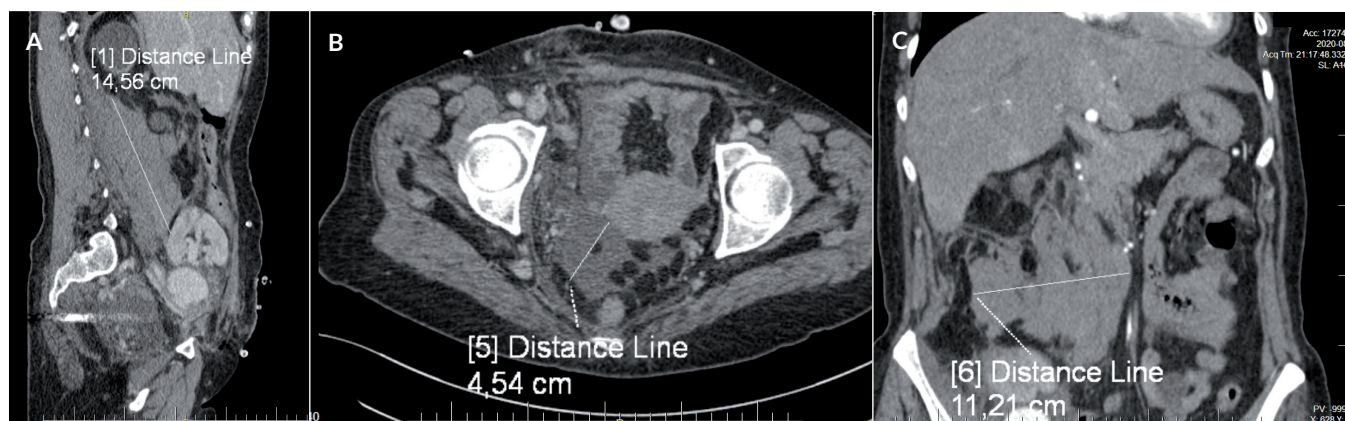
A 64-year-old female patient with ESRD secondary to polycystic kidney disease, after three months of peritoneal dialysis, was first admitted to an external institution in Poznan city for her primary deceased donor KTx; the hospitalisation lasted 11 days and proceeded without complications, with the serum creatinine level of 1.2 mg/dL on the day of discharge. The immunosuppressive regimen included tacrolimus, mycophenolate mofetil, and prednisone. Additionally, the patient was under the care of specialists on account of hypertension (treated pharmacologically with bisoprolol, doxazosin, clonidine) and papillary thyroid cancer (after surgical and iodine-131 treatment in 2001; on the substitution therapy with levothyroxine). Moreover, she was taking the following medications: acetylsalicylic acid, aciclovir, sulfamethoxazole, trimethoprim,

allopurinol, omeprazole, alfalcidol, calcium carbonate. There were no available data on donor status prior to organ harvest, and no microbiological assays of the preservation fluid the graft was stored in.

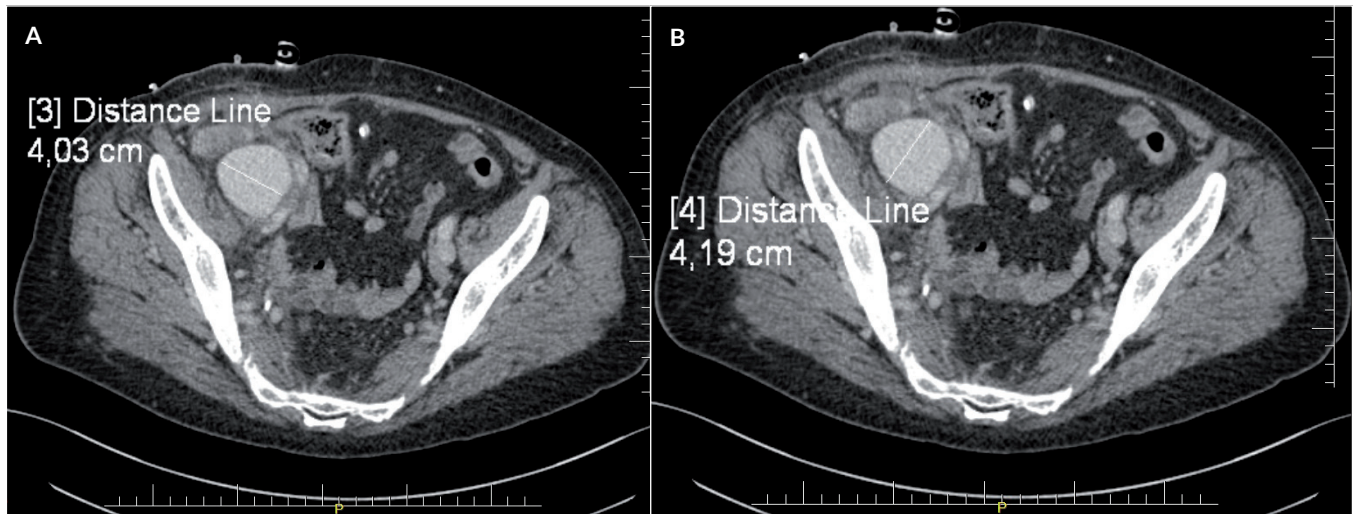
Thirty days after discharge, the patient presented to the emergency room with symptoms of hypovolaemic shock. On admission, she was in a serious condition – conscious, on the verge of circulatory and respiratory efficiency, pale, and drenched in cold sweat.

Computed tomography (CT) of the abdomen performed on admission showed a 145 × 112 × 45 mm haematoma along the right iliolumbar muscle (fig. 1), ischaemia of the kidney graft, and a 40 × 41 × 49 mm pseudoaneurysm/arteriovenous fistula between the right external iliac artery and vein (fig. 2). Laboratory tests revealed leukocytosis (11.6 G/L) with neutrophilia (10.1G/L), lymphopaenia (0.3G/L), and eosinopaenia (0 G/L); and elevated levels of inflammatory markers – C-reactive protein (104.7 mg/L) and procalcitonin (2.38 ng/mL), serum urea (79 mg/dL), and serum creatinine (1.83 mg/dL). The patient was referred for urgent surgery by transplant surgeons assisted by vascular surgeon.

An incision through the KTx scar in the right iliac fossa was performed to reach the graft site. Shortly after the procedure began, the patient suddenly collapsed, which led to cardiac arrest. An effective cardiopulmonary resuscitation was carried out, making the continuation of the surgery possible. A huge haematoma was evacuated from the retroperitoneum and graft site,



**Figure 1.** CT scan of the abdomen performed before admission, showing 145 × 112 × 45 mm hematoma along the right iliolumbar muscle and ischemia of the kidney graft. **A.** Sagittal section **B.** Horizontal section **C.** Frontal section



**Figure 2.** CT scan of 40 × 41 × 49 mm pseudoaneurysm of the arterial anastomosis between the external iliac artery and kidney graft artery. **A.** Transverse dimension in horizontal section **B.** Longitudinal dimension in horizontal section

and the place of active bleeding from the external iliac artery was found in the area of arterial anastomosis. The graft was pale, and the vessels, including the fragile disintegrating external iliac artery and the external iliac vein, were infiltrated by a massive inflammation. However, the blood flow in the iliac vein was normal, with no signs of leakage.

The graft vessels were ligated and cut, and then the graft was removed, denuding a perigraft abscess, which was evacuated after sampling the swab for microbiological testing. To achieve control of the haemorrhage, the surgeons opened the peritoneal cavity through a midline incision to clamp the aorta, which made the identification and dissection of the right common iliac artery possible. The right common iliac artery was clamped above the inflammation, and the aortic clamp was removed. The incision was extended towards the right groin. The right inguinal ligament was cut to expose and clamp the right femoral artery. The stump of the right external iliac artery was ligated, and the pathologically changed part of the artery was removed for histopathological and microbiological examinations. In the meantime, the Tenckhoff catheter was removed.

In order to ensure proper blood supply to the right lower limb, a suprapubic iliofemoral bypass was performed by a vascular surgeon. Impra Carboflo STRAIGHT CARBON-LINED stent was successfully implanted end-to-side with the left external iliac artery and end-to-end with the right femoral artery. Both anastomoses were sealed using a fibrin sealant patch. The blood flow to the right femoral artery was achieved with well-palpable pulse. Drainage was applied at the site of the removed graft. During the surgery, four units of red blood cell concentrate and two units of fresh frozen plasma were transfused. Empirical broad-spectrum antibiotic and voriconazole therapy was administered. After the surgery, the patient was admitted to the intensive care unit, where she spent three days.

The early postoperative period was complicated, with fluid collection at the site of the removed graft and near

the stent. Doppler ultrasound (Doppler USG) imaging four days after the surgery showed good blood flow in the unobstructed suprapubic stent, with two irregular fluid reservoirs near the anastomosis (63 × 25 mm on the right side and 14 × 46 mm in the left side). On day 11 after surgery, a computed tomography angiogram (angio-CT) showed compounding of the fluid reservoirs. Due to ineffectiveness of drainage of the removed graft area, ultrasound-guided percutaneous drainage was performed, evacuating 110 mL of cloudy, blood-tinted fluid.

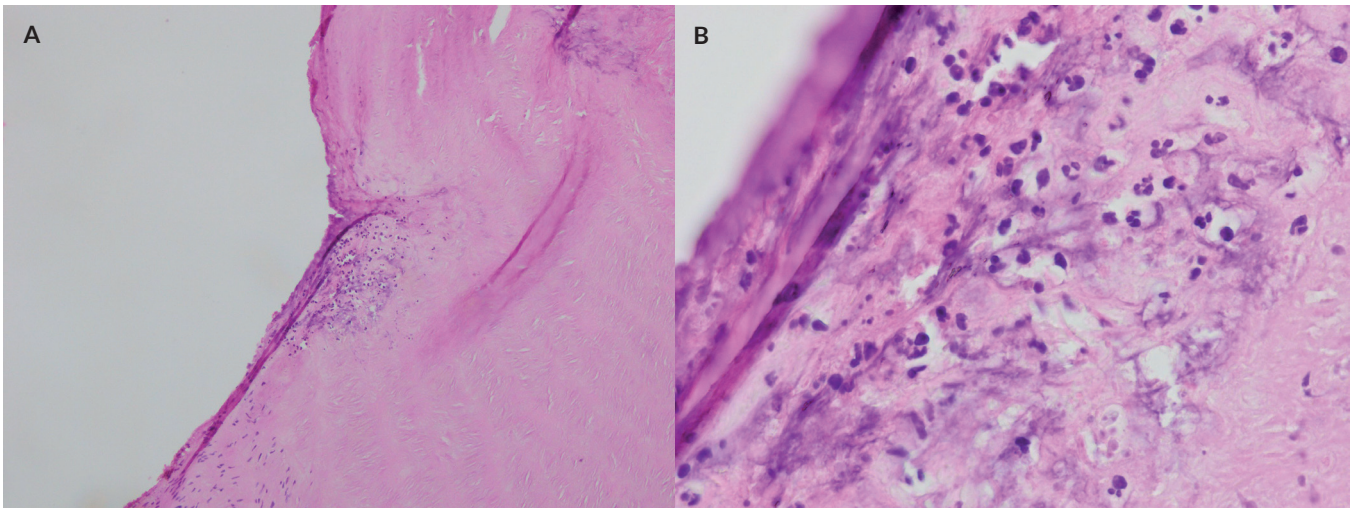
On day 16 after surgery, the patient reported pain and swelling of the right lower limb. Doppler USG showed a 10 mm wide clot extending about 6 cm below the inguinal ligament, closing the right common femoral vein. Fortunately, thrombosis resolved after conservative treatment, and after 33 days spent in our department the patient was discharged to the nephrology unit.

Histopathological examination of removed tissues confirmed fungal invasion and inflammation of the iliac, renal, and femoral arteries (fig. 3, 4). Microbiological evaluation of the swab collected from the perigraft site revealed *Candida albicans* and methicillin-resistant *Staphylococcus epidermidis* (MRSE).

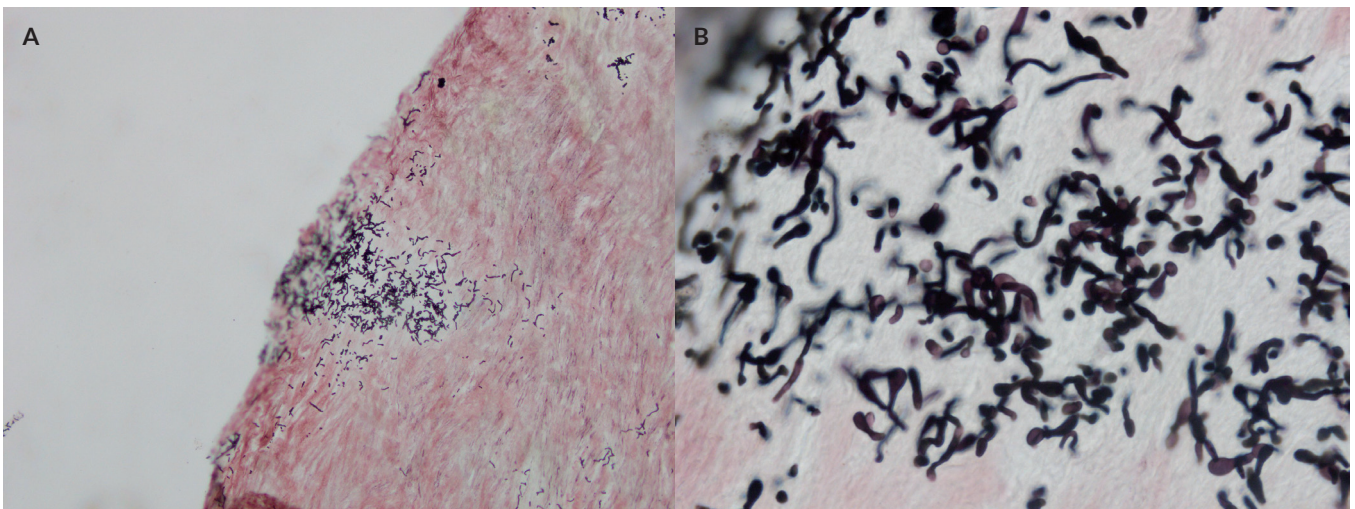
After six months, in January 2021, the patency of the aorta, both common iliac arteries, the graft, and both femoral arteries was confirmed by Doppler USG examination; after one year, the patient is functioning well, receiving nephrological care and haemodialysis treatment.

## Discussion

A broad array of organisms may be transmitted with the living cells of transplanted organs. In order to lower the risk of donor-derived infectious diseases, microbiological assays should be performed prior to transplantation. Procurement organisations recommend screening organ donors for CMV, EBV, HIV, HBV, HCV, syphilis, and toxoplasmosis. Blood and urine cultures should be obtained. Additional tests may be advised based on local epidemiology (i.e. serological test for *Histoplasma* and *Coccidioidi-*



**Figure 3.** Microscopic images of the kidney graft artery aneurysm caused by fungal infection – Haematoxylin and eosin staining. A. Wide view B. Detailed view



**Figure 4.** Microscopic images of the kidney graft artery aneurysm caused by fungal infection – Grocott staining. A. Wide view B. Detailed view

*des* spp.). Thanks to ongoing improvement of microbiological assays, the incidence of donor-derived infectious diseases is low [1, 2]

Nevertheless, contamination during graft procurement should always be taken under consideration, as it might cause life-threatening complications. Metaanalysis performed by Oriol et al. shows that the overall incidence of preservation fluid-related infections is 4% [3]. In nearly 80% of cases, mycotic arteritis in kidney graft recipients is caused by contamination with *Candida* and *Aspergillus* species during donation, storage or handling of the graft [4–7]. Preservation fluid cultures were found to be positive for *Candida* spp. in 8.6% samples. Of those, one-third of patients developed fungal arteritis and needed a transplantectomy [8]. Although fungal infection of the arterial anastomosis in kidney graft recipients is an extremely rare complication [4, 5], it might result in chronic rejection in 60% of cases [4].

Multi-organ donation, death related to multi-organ trauma, broad-spectrum antibiotic therapy, and long stay in the intensive care unit are among the donor's risk factors

for fungal infection of the graft site [5]. Kidney graft recipient's risk factors for fungal infection include immunosuppressive therapy, treatment with broad-spectrum antibiotics, diabetes mellitus, multi-organ transplantation, permanent catheters, malnutrition, and repeated kidney transplantation [4, 5].

Pseudoaneurysm of the graft artery caused by fungal infection in this group of patients usually occurs at a median of 36.2 days after transplantation (range: 1–150 days) [5]. Early presence of this complication is connected with higher mortality. Maozhi Tang et al. reported that in 10 patients who died the median was 9.5 days (range: 4–18 days), and in 40 survivors the median was 43.5 days (range: 1–150 days) [5]. It may be asymptomatic, and cause renal dysfunction or hypertension due to compression of graft vessels [5, 9]. It may also manifest as abdominal pain with a well-palpable pulsating mass in the graft site and haemorrhagic shock [5, 9]. While small, non-infectious and asymptomatic pseudoaneurysms, commonly diagnosed incidentally, do not require urgent invasive treatment, symptomatic, rapidly progressing or ruptured ones require immediate surgical management [10].

The treatment of choice should include invasive procedures and antifungal therapy [4].

Aneurysms with a narrow neck, and those in extraanastomotic locations may be eligible for stenting or embolisation. Reports of graft-preserving operations, including excision of mycotic aneurysm (MA) and vascular reconstruction, have also been published. It seems that in selected patients such management should be taken under consideration by transplantologists [6].

Graftectomy seems to be the safest option for MA in cases where the aforementioned therapeutic strategies cannot be employed. Especially in emergency life-threatening situations, as shown in this case, when dealing with haemorrhagic shock, cardiac arrest, destruction of both allograft artery and the patient's iliac arteries, preservation of the transplanted kidney may not be feasible.

### Conclusions

Fungal arteritis in kidney graft recipients is a very rare but life-threatening complication which in many cases leads to emergency life-saving graft nephrectomy. Its early detection still remains a challenge due to a long asymptomatic course [4]. Routine fungal cultures of the graft preservation fluid and radiological follow-up in the high-risk group of patients after transplantation may be helpful in the prevention of fatal complications among high-risk patients especially if digestive tract injury occurred during organ harvesting [7], but still the gold standard for the detection of fungal arteritis is histological examination [5]. Negative culture samples from the preservation fluid, and blood and urine before the transplantation do not exclude the risk of fungal infection [5].

Urgent surgical treatment, including allograft nephrectomy with resection and reconstruction of changed vessels, seems to be a life-saving procedure in patients with a ruptured pseudoaneurysm of the arterial anastomosis, as in our case [4, 10, 11].

This is a rare case of iliofemoral bypass performed for fungal arteritis in a renal transplant patient.

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## NO IMPROVEMENT OF PHYSICAL CAPACITY DURING CARDIAC REHABILITATION IN A PATIENT WITH ELEVATED IGF-1 AND NORMAL PRESSURE HYDROCEPHALUS

Brak poprawy wydolności fizycznej w trakcie rehabilitacji kardiologicznej u pacjenta z podwyższonym IGF-1 i wodogłowiem normotensyjnym



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### Abstract

**Introduction and objectives:** Multimorbidity (type 2 diabetes, hyperlipidaemia, arterial hypertension, obesity, limited exercise tolerance) is a common challenge during cardiac rehabilitation in patients with chronic coronary syndrome. **Materials and methods:** A 54-year-old man after percutaneous coronary angioplasty followed a cardiac rehabilitation programme. He presented with generalised muscle weakness, phenotypic signs of acromegaly, as well as elevated serum creatine kinase and insulin-like growth factor 1. The qualification for rehabilitation was based on multiparametric assessment of physical exercise using ergospirometry combined with comprehensive physiotherapy examination. Kinesitherapy programme was developed on the basis of heart rate at the anaerobic threshold and then divided into 24 sessions of telemonitoring-guided cycle ergometer interval-training, which was continued for 5 weeks. **Results:** Worsening of muscle strength was observed after the second stage of cardiac rehabilitation, which led to extension of diagnosis. Acromegaly was excluded due to inhibition of growth hormone secretion in oral glucose tolerance test. Normal pressure hydrocephalus was detected on head magnetic resonance imaging. The patient was eventually diagnosed with Hakim syndrome. **Conclusions:** Patients with chronic coronary syndrome require implementation of cardiac rehabilitation as soon as possible after coronary intervention. Attention needs to be paid to every alarming abnormality during examination, therapeutic failures in particular. This allows for quick interventions, further diagnosis or treatment. Physiotherapy examination along with exercise tests is an indispensable element of planning kinesitherapy as part of cardiac rehabilitation and can contribute to individualisation of therapeutic approach.

### Streszczenie

**Wprowadzenie i cele:** Wielochorobowość (cukrzyca typu 2, hiperlipidemia, nadciśnienie tętnicze, otyłość, ograniczenie tolerancji wysiłku) stanowią powszechne wyzwanie podczas rehabilitacji kardiologicznej pacjentów z przewlekłym zespołem wieńcowym. **Materiały i metody:** U 54-letniego mężczyzny po angioplastyce wieńcowej wdrożono program rehabilitacji kardiologicznej. Pacjent prezentował uogólnione osłabienie siły mięśniowej i cechy fenotypowe akromegalii oraz podwyższone stężenie kinazy kreatynowej i insulinopodobnego czynnika wzrostu 1. W kwalifikacji do rehabilitacji wykorzystano wieloparametryczną ocenę wysiłku podczas ergospirometrii w połączeniu z całościowym badaniem fizjoterapeutycznym. Program kinezyterapii opracowano na podstawie tętna osiąganego na progu beztlenowym i podzielono go na 24 sesje treningu interwałowego na cykloergometrze z telemonitoringiem w ciągu 5 tygodni. **Wyniki:** Po drugim etapie rehabilitacji kardiologicznej obserwowano pogorszenie siły mięśniowej, w związku z czym zdecydowano o poszerzeniu diagnostyki. Na podstawie hamowania wydzielania hormonu wzrostu w teście doustnego obciążenia glukozą wykluczono akromegalię. W badaniu rezonansu magnetycznego głowy uwidoczniono wodogłowie normotensyjne, w związku z czym rozpoznano zespół Hakima. **Wnioski:** Pacjenci z przewlekłym zespołem wieńcowym wymagają wdrożenia rehabilitacji kardiologicznej możliwie jak najszybciej po interwencji. W trakcie postępowania należy zwracać uwagę na wszelkie niepokojące nieprawidłowości, a zwłaszcza niepowodzenie stosowanych procedur, aby możliwie szybko i właściwie skierować pacjenta na dalszą diagnostykę i leczenie. Badanie fizjoterapeutyczne wraz z testami wysiłkowymi jest nieodzownym elementem planowania i prowadzenia kinezyterapii w ramach rehabilitacji kardiologicznej, aby zindywidualizować podejście terapeutyczne.

**Keywords:** exercise test, muscle strength, insulin-like growth factor 1, acromegaly, normal pressure hydrocephalus

**Słowa kluczowe:** test wysiłkowy, siła mięśniowa, insulinopodobny czynnik wzrostu 1, akromegalia, wodogłowie normotensyjne

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## Case report

A 54-year-old male patient with chronic coronary syndrome (CCS) was admitted to the Department of Cardiology and Internal Diseases for the second stage of cardiac rehabilitation two weeks after percutaneous coronary intervention (PCI) of the anterior descending artery (ADA) with drug-eluting stent implantation. The patient was also diagnosed with type 2 diabetes mellitus (DM2), hyperlipidaemia, arterial hypertension, abdominal obesity and single ventricular arrhythmia. After PCI, the patient was qualified for conservative treatment of coronary artery disease (CAD). Despite reporting reduced exercise tolerance and more rapid fatigue, he jogged recreationally. Home measurements showed normal blood pressure control. Echocardiography indicated normal myocardial contractility, a left ventricular ejection fraction of 65%, low mitral and tricuspid regurgitation and signs of impaired left ventricular muscle relaxation. Physical examination revealed obesity (BMI: 32 kg/m<sup>2</sup>), limited lumbar spine mobility, bilateral flat feet, valgus knees and generalised muscle weakness (Lovett score of 4.5). No focal nervous system damage or other neurological symptoms (e.g. urinary incontinence, myoclonus) were found. Additionally, phenotypic features of acromegaly, such as frontal bossing, large auricles, large tongue, widened interdental spaces, prominent mandible, low voice and hoarseness, were notable. Laboratory investigations showed increased creatine kinase (CK) activity (325 U/L, with reference values up to 171 U/L) and elevated insulin-like growth factor-1 (IGF-1) (227.5 ng/mL, with reference values up to 196 ng/mL). Also, a tendency towards nocturnal hypertension was noted during 24-hour monitoring. Typical treatment of CAD with statin, hypotensive therapy and oral hypoglycaemics were administered.

A 6-Minute Walk Test (6MWT) and cardiopulmonary exercise test (CPET) were performed in order to plan an individual rehabilitation programme. These tests showed significantly reduced physical capacity, impaired muscle strength and normal chronotropic and tension response (tab.). Furthermore, an abnormal haemodynamic profile in the form of reduced stroke volume (SV) after reaching the anaerobic threshold (AT), with no ECG ischemic changes in ST segment or T-wave, or chest pain, assessed by impedance cardiography, was noteworthy.

As part of rehabilitation, respiratory gymnastics, upper and lower limb active exercises and interval cycle ergometer training with telemonitoring in a progressive

scheme were implemented. The patient received education on the principles of physical activity undertaken, and a training heart rate at AT  $\pm$  5% ( $93 \pm 4$ /min) was recommended. The patient performed 5 cycle ergometer training sessions during hospital stay. Then, due to his low risk of exercise-induced cardiovascular events (CVEs), he was qualified for home telerehabilitation. Over the course of the next 5 weeks, he completed 24 stationary bike training sessions (3 sets of 5–8 minutes each), including 9 at the training HR, rated at 3/10 on the Borg scale (83% of workouts). During home training sessions, the patient reported improved exercise tolerance, denied angina symptoms, and had normal blood pressure control.

During the telerehabilitation follow-up visit, a decrease in physical capacity and increasing muscle weakness were recorded. Follow-up laboratory workup showed low-density lipoprotein (LDL) at 43 mg/dL, with CK levels below twice the upper limit of normal, prompting a reduction in the statin dose. Considering CPET results, the recommended training HR was reduced to 85 bpm. Due to the observed muscle weakness on physical examination, typical features of endocrinopathy along with elevated CK and IGF-1 levels, the patient was referred to the Department of Endocrinology. Biochemical/hormonal tests were run two months after telerehabilitation, confirming elevated IGF-1 levels (215.7 ng/mL, with reference values up to 204 ng/mL) and showing growth hormone (GH) suppression by oral glucose, thus excluding acromegaly. Head MRI revealed four-ventricular hydrocephalus.

Due to the presence of the Hakim–Adams triad (disorders of gait, dementia and urinary incontinence), the patient underwent endoscopic third ventriculostomy (ETV) five months after completing telerehabilitation, resulting in improvement in gait, concentration, and vision. Normal pressure hydrocephalus was diagnosed.

## Discussion

As set out in the guidelines for patients with CAD after PCI [1], regular moderate physical activity is recommended, with an emphasis on aerobic endurance exercises, as well as resistance exercises within the range of 30–50% of maximum muscle strength, repeated 2–3 times per week. An individual training programme was developed for our patient based on the anaerobic threshold HR obtained from CPET [2, 3]. Performing CPET as part of the qualification for cardiac rehabilitation not only allows for the precise determination of training HR in a safe, aero-

**Table.** CPET findings at baseline vs. follow-up

Parameter	Baseline	Follow-up	Difference
6MWT [m]; [% pred.]	556; 83%	584; 86%	+28; +3%
Borg's score	6/10	7/10	+1
Load [W]	155	128	-27
Load [% pred.]	57	48	-9
RER	1,09	1,00	-0,09
VO <sub>2</sub> [mL/min/kg]	16	15	-1
VO <sub>2</sub> [% pred.]	65	58	-7
HR max [min <sup>-1</sup> ]	117	106	-11
% max HR limit	80	73	-7
HR in AT [min <sup>-1</sup> ]	93	85	-8
O <sub>2</sub> Pulse [mL/beat]	17	16	-1
O <sub>2</sub> Pulse [% pred.]	81	80	-1
VE [L/min]	72,8	64,1	-8,7
BR [%]	89	75	-14
BF [min <sup>-1</sup> ]	29	29	0
VE/VCO <sub>2</sub> slope	31,6	34,8	+3,2
OUES	2,3	1,8	-0,5

% pred. – percent of predicted value; 6MWT – 6-minute walk test; AT – anaerobic threshold; BF – breathing frequency; BR – breathing reserve; HR – heart rate; OUES – oxygen uptake efficiency slope; O<sub>2</sub> Pulse – oxygen pulse; RER – respiratory exchange ratio; VE – minute ventilation; VO<sub>2</sub> – oxygen uptake at peak exercise; VE/VCO<sub>2</sub> slope – ventilation efficiency

bic range [3], but also provides a reliable assessment of physical capacity, as well as chronotropic and tension responses, an analysis of potential myocardial ischemia in ECG, risk stratification, and diagnosis of non-cardiac causes of reduced exercise tolerance [4, 5].

The patient exhibited a significant decrease in physical fitness [5] (peak oxygen uptake, VO<sub>2peak</sub> 16 mL/min/kg, 65% of predicted value) of multifactorial aetiology. The CPET result did not indicate any specific cause of dyspnoea. The involvement of CAD, microvascular disease in particular, was considered. It is worth emphasising that the patient had fully patent coronary arteries, was qualified for conservative treatment, reported no angina symptoms, and presented with no ECG ST-segment changes or T-wave abnormalities typical of ischemia. However, the sensitivity and specificity of exercise ECG in diagnosing CAD are estimated at 68% and 77%, respectively [6].

Borderline low absolute values of O<sub>2</sub> Pulse and a reduction in SV values during exercise after reaching the AT supported the diagnosis of ischemic heart disease [4, 7–9]. The inability to maintain an appropriate SV during exercise after reaching AT, along with an abnormal systemic vascular resistance index (SVRI) response, indicates significant vascular stiffness [2], resulting in impaired tissue extraction of oxygen. Additionally, slightly elevated values of ventilation efficiency (VE/VCO<sub>2</sub> slope) were noted, directing the diagnosis towards heart failure. No abnormalities were found in ventilation or gas exchange. During the qualification for cardiac rehabilitation, muscle weakness was pronounced, as indicated by consistently low workload at peak exercise (57% predicted) and oxygen uptake efficiency slope (OUES) reduced to 2.3 (normal 3.06) [10]. Lower OUES values are associated with reduced muscle mass, disturbances in intramuscular blood flow, impaired oxygen extraction and utilisation by muscles, and rapid development of lactic acidosis [11].

The OUES index can be applied during submaximal efforts [3, 12], which is significant in the case of muscle weakness.

Changes in myocardial function and structure (left ventricular diastolic dysfunction, arterial hypertension, vascular stiffness, and progression of atherosclerosis) [13], respiratory system disorders, impaired respiratory muscle function in particular [14, 15], as well as myopathy [16], manifesting as muscle and joint pain [17], and overall fatigue [2, 16, 18] were considered due to elevated IGF-1 levels and clinical suspicion of acromegaly as the cause of low tolerance of physical exercise. Myopathy may result from the direct impact of excess IGF-1 on muscles and from the involvement of accompanying metabolic disorders (e.g. diabetes) [16, 19, 20]. Hypertrophy of type 1 fibres, atrophy of type 2A fibres [16, 21] and increased intramuscular fat content [22] play an important role in its etiopathogenesis. Hypertrophic peripheral skeletal muscles are functionally weaker both in terms of strength and endurance [19, 20, 23, 24]. Sarcopenia may manifest with elevated CK levels [16, 25], as observed in the presented patient. It is worth noting that the patient was treated with rosuvastatin, whose spectrum of adverse effects includes myopathy. However, the downward trend in CK levels (325 U/L followed by 218 U/L within a few days), despite no modification of pharmacotherapy, rather excludes the involvement of this factor.

The patient's muscle weakness was also attributed to chronic normotensive hydrocephalus and the associated damage to the pyramidal system (the corticospinal tract in particular) [26], which, among other things, regulates muscle tone. During cardiac rehabilitation, no classical Hakim-Adams triad of clinical findings (urinary incontinence and cognitive deficits) were seen, and no evident signs of dyskinesia, athetosis, tremors, or myoclonus were found. It was expected that at least reduced muscle

function would be maintained at a similar level following the rehabilitation cycle, rather than the progression of myopathy over a short 6-week period. Increasing, typically hypokinetic gait disturbances, characterised by a slow wide-based gait, drew attention and prompted further diagnostic evaluation [27].

The presented case suggests considering an individual approach to cardiac rehabilitation for patients with generalised muscle weakness. On one hand, chronic elevation of IGF-1 levels significantly increases CV risk, leading to a predicted average reduction in life expectancy of 10 years [14]. On the other hand, progressive musculoskeletal dysfunction results in reduced functionality and activity, necessitating individually tailored kinesiotherapy programmes [19]. Furthermore, hydrocephalus-induced damage to the pyramidal system results in generalised muscle weakness requiring neurosurgical intervention.

Based on the conducted diagnostic workup, the risk of exercise-induced CV events was assessed as low, and the patient was classified for hybrid telerehabilitation. Unfortunately, despite the individually tailored aerobic training cycle, a decrease in physical performance and increasing muscle weakness were observed, along with lowering peak  $\text{VO}_2$ , workload, and OUES. CAD progression was not suspected due to the absence of ECG changes or angina, and improvement in hemodynamic profile, expressed by reduced SVRI. However, workload lower by 27 W and a decrease in OUES value by 0.5 indicate progressive myopathy. It is noteworthy that the patient showed less engagement in the follow-up exercise test, as he did not reach the target respiratory exchange ratio (RER) at peak exertion, which is  $\geq 1.05$ .

Limitation of resistance exercises, which are believed to play the main role in preventing sarcopenia, seems to be the reason for the failure of therapy in the presented patient, who was unable to perform high-intensity resistance training (6 times a week for 40–60 minutes), recommended for older individuals to reverse frailty syndrome [14]. This does not imply, however, that this level of exertion is not recommended for such patients. Previous studies have shown that strength and endurance training should be implemented in patients with elevated IGF-1 levels as early as possible [28] due to the increasing reduction in muscle mass and increasing proximal muscle weakness [19, 24]. Various exercise programmes have been utilised in such patients, encompassing warm-up, endurance, resistance, balance, and stretching exercises, performed three times a week for 60–75 minutes [19, 28, 29]. A reduction in overall fatigue level and improvement in physical endurance, quadriceps muscle strength, and balance were observed following these programmes. On the other hand, the cause of muscle weakness in the presented case was not solely due to elevated IGF-1 levels, but also due to progressive central and peripheral neuropathy. Furthermore, the observed change in IGF-1 levels could have been secondary to hydrocephalus [30]. Neurosurgical intervention involving the creation of an alternative route for cerebrospinal fluid circulation through ventriculocisternostomy, leading to the resolution of clinical symptoms, is the treatment of choice for normotensive hydrocephalus [31]. Therefore, the use of kinesiotherapy did not yield the expected clinical effects.

## Conclusions

We presented a case of a patient undergoing cardiac rehabilitation due to one of the most common indications. The initial clinical presentation did not distinguish the patient from other patients with a similar multimorbidity profile. The follow-up of the rehabilitation process and its limited therapeutic efficacy prompted us to expand the diagnostic process to identify non-cardiological causes of reported exercise intolerance and weakness. Non-standard additional tests and individualised therapeutic approaches may be needed in some patients qualified for cardiac rehabilitation.

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## KAPOSI'S SARCOMA IN AN HIV-POSITIVE PATIENT

Mięsak Kaposiego u pacjenta zakażonego HIV



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### Abstract

Kaposi's sarcoma is a malignancy arising from vascular endothelial cells, associated with infection with the human herpes virus-8 (HHV-8). It has four clinical forms: classic, endemic, epidemic (associated with HIV/AIDS) and iatrogenic. We present a case of a 38-year-old male patient who was admitted to the Dermatology Clinic due to numerous, scattered blue-violet macules, plaques, and nodules. HIV infection was revealed during the diagnostic process. Kaposi's sarcoma was diagnosed based on the clinical picture and histopathological findings. The patient was referred to the Department of Infectious Diseases for antiretroviral treatment and to the Department of Oncology, where he received treatment with paclitaxel with remission of the lesions. The clinical picture of Kaposi's sarcoma, which includes macules, plaques, and nodules, is not sufficient to make the diagnosis. A biopsy followed by a histopathological examination should be performed. Current guidelines do not recommend serological testing to detect antibodies or the HHV-8 genome. Topical or systemic treatment can be used for Kaposi's sarcoma, depending on the extent of skin lesions, accompanying systemic symptoms and involvement of other organs.

### Streszczenie

Mięsak Kaposiego jest nowotworem wywodzącym się z komórek śródbłonna naczyń, związanym z infekcją ludzkim wirusem opryszczki HHV-8. Wyróżnia się cztery postaci kliniczne choroby: klasyczną, endemiczną, epidemiczną związaną z HIV/AIDS i jatrogenną. W artykule przedstawiono historię 38-letniego pacjenta, który został przyjęty do Kliniki Dermatologii z powodu licznych, rozsianych sino-fioletowych plam, blaszek, guzków oraz guzów. W trakcie diagnostyki ujawniono zakażenie HIV, a następnie na podstawie obrazu klinicznego i wyniku biopsji rozpoznano mięsaka Kaposiego. Pacjenta skierowano na oddział chorób zakaźnych w celu rozpoczęcia leczenia przeciwretrowirusowego i na oddział onkologii, gdzie otrzymał leczenie paklitakselem, po którym uzyskano remisję zmian. W obrazie klinicznym mięsaka Kaposiego we wszystkich odmianach występują plamy, blaszki oraz guzki, jednak sam obraz kliniczny nie jest wystarczający do ustalenia rozpoznania. W tym celu należy wykonać biopsję, a następnie badanie histopatologiczne. Aktualne wytyczne nie zalecają stosowania diagnostyki serologicznej w celu wykrywania przeciwciał lub genomu HHV-8. Leczenie mięsaka Kaposiego może być miejscowe lub ogólnoustrojowe, o czym decyduje rozległość zmian skórnych, towarzyszące objawy ogólne i zajęcie innych narządów.

**Keywords:** Kaposi's sarcoma, immunodeficiency, human herpes virus-8 (HHV-8), human immunodeficiency virus (HIV)

**Słowa kluczowe:** mięsak Kaposiego, niedobór odporności, ludzki wirus opryszczki typu 8 (HHV-8), ludzki wirus niedoboru odporności (HIV)

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### Introduction

Kaposi's sarcoma (KS), first described in 1872 by Moritz Kaposi [1], is a malignancy arising from the endothelial cells. There has been no consensus on the origin of the

endothelial cells so far. Neoplastic proliferation of lymphatic as well as blood vessel cells is postulated. Endothelial cells undergo neoplastic transformation as a result of infection with the oncogenic human herpesvirus-8 (HHV-8).

There are four forms of Kaposi's sarcoma:

- classic – usually affecting men aged over 50 years, from the Mediterranean and Eastern European countries;
- endemic (African) – affecting HIV-negative children and young adults in Africa;
- iatrogenic – associated with the use of immunosuppressive therapy in organ transplant recipients;
- epidemic (AIDS-related KS) – an indicator disease mostly affecting men who have sex with men (MSM) [2].

All KS variants share a similar clinical and histological picture of skin lesions [3]. HHV-8 infection is another common feature [4]. HHV-8 is spread horizontally, most often through saliva, less commonly through sperm or blood [5]. KS is a rare malignancy, as evidenced by the fact that only 26 KS cases were recorded among men and 14 among women in Poland in 2020, as confirmed by the Statistics of the National Cancer Registry [6].

### A case report

A 38-year-old male patient was admitted to the Department of Dermatology due to multiple, scattered blue-violet spots, plaques, and nodules (fig.). The first skin lesion had appeared three months prior to admission and was located on the fourth toe of the left foot. Subsequent, ascending lesions involved the lower limbs, trunk, and face.

The patient reported no history of chronic diseases, but he had sexual contacts with other men (he belonged to the MSM group). As part of outpatient diagnosis, he had undergone two biopsies before admission to the Department. The first histopathological result suggested drug-induced lesions. The results obtained one month later indicated that the image could correspond with dermatofibrosarcoma protuberans, but it should be differen-

tiated from other sarcomas of vascular origin. During hospitalization, serological diagnosis of HIV infection was performed - both screening and confirmation tests turned out to be positive. EBV, CMV, hepatitis B and C infections were excluded. Abdominal ultrasound revealed three vascular hepatic lesions up to 11 mm in size. Furthermore, ultrasound of the peripheral lymph nodes revealed multiple enlarged cervical, supraclavicular, axillary and inguinal lymph nodes with blurred echostructure and increased blood flow.

The clinical picture and histopathological findings led to the diagnosis of Kaposi's sarcoma. The patient was referred to the Department of Infectious Diseases for antiretroviral treatment, as well as to the Department of Oncology, where it was decided to initiate chemotherapy (paclitaxel). Remission was achieved and no new skin lesions appeared.

### Discussion

The early clinical picture of all KS variants encompasses patches, identifiable only by changes in skin colour, which may pose a major diagnostic challenge [7]. Lesions involve both skin and mucous membranes, and subsequently evolve into plaques and nodules. The latter ones may ulcerate, form exophytic lesions, cause significant lymphedema and infiltrate adjacent tissues, such as bones. The clinical picture may include coexisting skin lesions at various stages of advancement [8]. The lesions usually develop on the lower limbs, with the first manifestation on the foot in the vast majority of cases [9]. Common extracutaneous locations of KS include lymph nodes, abdominal organs, and airways [2]. Rare cases of the disease occurring in the musculoskeletal system, central and peripheral nervous system, larynx, eyeball, salivary glands, heart, thoracic duct, urinary system, and breasts are also described in the literature [10].



**Figure.** A. Blue-violet nodules on the right arm and patches around the sternum and right arm. B. Blue-violet patches on the face. C. A blue-violet nodule on the right shoulder. D. Blue-violet nodules on the lower limbs

The differential diagnosis of KS includes vascular pathologies with a similar clinical picture, i.e. angiosarcomas, vascular granulomas, haemangiomas and IgA vasculitis [2].

However, the clinical picture is not sufficient to diagnose KS. For this purpose, a biopsy followed by histopathological examination, and optionally immunostaining should be performed. The histopathological picture of KS depends on the stage of the disease. In the patch stage, superficial proliferation of small, dilated vessels lined by endothelial cells may be observed. These vessels tend to separate the collagen bundles. They are accompanied by an infiltrate consisting of lymphocytes and plasma cells. When the patches become more advanced, vascular lesions can invade the deeper layers of the skin and subcutaneous tissue. In the nodular phase, spindle cells are separated by characteristic slit-like spaces containing erythrocytes. This image forms a cribriform pattern typical of sarcoma. The nodules are often surrounded by hemosiderin deposits, lymphocytes and plasma cells [11]. Furthermore, the identification of HHV-8 in the affected cells using a monoclonal antibody against HHV-8 is the most diagnostically useful immunostaining technique [12]. Current guidelines do not recommend serological diagnostics to detect antibodies or the HHV-8 genome in screening, diagnosis or monitoring of any KS variant [13].

Local or systemic treatment can be used for KS. The most optimal therapeutic outcomes are achieved in the classic form of KS, which requires only local treatment [3]. The choice of therapy is determined by the extent of skin lesions, the accompanying systemic symptoms, and the involvement of other organs. Local treatment is recommended for single, small lesions and includes surgical excision, radiotherapy, and cryotherapy [14]. Local treatment using alitretinoin, imiquimod and timolol has also been described in the literature. All three demonstrate significant clinical efficacy with minimal adverse effects [15]. Systemic treatment is recommended for disseminated and symptomatic forms of KS. It includes chemotherapy with doxorubicin, which is effective in patients with classic KS [16], and paclitaxel, which is used in patients with both classic and AIDS-related KS [17], as in described case. Furthermore, the literature also describes therapy with vinblastine [18], etoposide [19] and gemcitabine [20]. All are effective for classic and AIDS-related KS. Other therapeutic options include immunotherapy (pembrolizumab [21] and nivolumab in combination with ipilimumab [22]), biological therapy (a.o. recombinant interferon alpha due to its immunomodulatory and antiangiogenic properties [23]) and antiretroviral therapy (HAART), which allows to achieve remission in many HIV-positive patients [24].

## Conclusions

Kaposi's sarcoma is a rare tumour that poses significant diagnostic difficulties. The clinical picture may include a variety of skin lesions, such as patches, plaques, and nodules. Several biopsies performed in different pathology centres are sometimes needed to establish the diagnosis.

*The patient's consent for the publication of photographs was obtained.*

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## Laureates of the Animus Fortis 2023 Award

For a rescue worker for individual bravery and for an institution representative for making a significant contribution to positive changes that help save human lives more effectively.

During the 7th edition of the Animus Fortis (Brave Spirit) Award, on the 10th of April 2024, the Director of the Military Institute of Medicine – State Research Institute (WIM-PIB), Lieutenant General, Professor Grzegorz Gielera, PhD., Doctor of Medical Sciences, presented the laureates with statuettes and diplomas of honour. The award is graded in two categories: individual and institutional, for rescue actions, achievements and accomplishments in the year 2023. The main prize is a statuette – a miniature of the draft “Monument of the Rescue Worker” that refers to the best traditions of medical services.

In the individual category (Brave Spirit), the winner was a professional soldier who serves at the 16th Sapper Regiment in Orzysz as a driver and paramedic of the Medical Security Team, private Michał Tomczak, who risked his own life to help people who were trapped in the attic of a burning house, without any means of protection, before the fire brigades arrived, and saved an unconscious person.

In the institutional category (Brave Spirit), the prize was awarded to the 2nd Military Field Hospital in Wrocław for support in international medical and humanitarian aid after a series of earthquakes in Turkey, in February 2023.

The members of the awards committee also granted two distinctions of honour:

- in the individual category: to Junior Warrant Officer of the State Protection Service, Piotr Osiński, who, while on holidays in Turkey, saved a 4-year-old girl from drowning in a swimming pool;
- in the institutional category, to the reconstruction and replantation surgery team of the Clinic of Trauma Surgery and Orthopaedics of the 5th Military Multispecialty Clinical Hospital in Krakow, which, in 2023, performed 26 replantation and revascularisation surgeries outside its specified duty days, when there were no other hospitals in the country that would be ready to perform urgent surgeries.

More information available at: <https://wim.mil.pl/2024/04/10/laureaci-nagrody-animus-fortis-mezny-duch-2023/>

# 6th Scientific Congress of the Polish Society of Medical Biology

*The 6th Scientific Congress of the Polish Society of Medical Biology will be held on September 19–21, 2024 at the Airport Hotel Okęcie, 24 Komitet Obrony Robotników St. in Warsaw.*

*It will be a regular meeting of scientists and clinicians engaged in the general problems of Medical Biology. The participants will have the opportunity to listen to lectures by prominent representatives of this scientific discipline and exchange views with them. It will also be an opportunity to present the work and establish new professional and social contracts.*

*The Board of the Polish Society of Medical Biology has entrusted the organization of the Congress to the Military Institute of Medicine – National Research Institute and the University of Warsaw. As always, you are welcome to participate in the congress.*

*Kindest regards,  
Chairman of the Scientific Committee of the Conference  
Prof. Ewa Bulska and Prof. Bolesław Kalicki*

The conference agenda includes:

- The keynote lecture of the 6th Congress of the Polish Society of Medical Biology will be delivered by Prof. Ian E. Alexander (BMedSci, MBBS, PhD), Professor of Paediatrics and Molecular Medicine and Director of Laboratory Research and Senior Scientist at Children's Hospital at Westmead (Sydney, AU). He is also Head of the Gene Therapy Research Facility, a joint initiative of the Children's Medical Research Institute (CMRI) and The Sydney Children's Hospitals Network (SCHN), Professor of Paediatrics and Molecular Medicine at the University of Sydney, and Honorary Consultant in Clinical Genetics at Westmead Hospital.
- Plenary lectures by invited guests (30 min).
- Oral reports (10 min).
- Poster sessions (poster size 70–100 cm). Poster sessions will be held throughout the day; VARIA poster session: Thursday, Young Scientist poster session: Friday.
- Sessions of Young Scientists (academicians under 35 years of age): oral reports (10 min) or a poster.



**Congress organizers:**  
Polish Society of Medical Biology,  
Military Institute of Medicine – National Research Institute, University of Warsaw  
All details are available on the congress website:  
<https://wimcon.wim.mil.pl/VI-Zjazd-Naukowy-PTBM/>