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# GENERAL SURGERY

ЗАГАЛЬНА ХІРУРГІЯ

Cherenko Makar Petrovych  
To the 100th anniversary of his birth

Bipolar vaporization  
of hemorrhoidal nodes in stage III  
chronic hemorrhoids

Clinical case of surgical treatment  
of undifferentiated pleomorphic  
liver sarcoma



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Симптоматичне лікування різних видів болю<sup>1-3</sup>

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## ШВИДКА та ЕФЕКТИВНА знеболювальна дія<sup>1-10</sup>



### Інформація про рецептурні лікарські засоби для медичних і фармацевтичних працівників.

Перед застосуванням, будь ласка, обов'язково уважно ознайомтеся з повним текстом чинної інструкції для медичного застосування.

**Фармакотерапевтична група.** Нестероїдні протизапальні та протиревматичні засоби. Похідні пропіонової кислоти. Код АТХ M01A E17.

### Скорочена інструкція для медичного застосування ДЕКСАЛГІН® (DEXALGIN®)<sup>1</sup>

**Склад:** 1 таблетка, вкрита плівковою оболонкою, містить декскетопрофену 25 мг. **Показання.** Симптоматичне лікування болю від легкого до помірного ступеня, наприклад, м'язово-скелетний біль, болісні менструації (дисменорея), зубний біль. **Противпоказання.** Підвищена чутливість до будь-якого компонента препарату або до іншого НПЗЗ; спричинення подібними речовинами або іншими НПЗЗ нападів бронхіальної астми, бронхоспазму, гострого риніту, розвитку поліпів у носі, кропив'янки або ангіоневротичного набряку; фотоалергічні або фототоксичні реакції на кетопрофен або фібрати; кровотеча або перфорації у травному тракті в анамнезі або в активній фазі, пов'язані із застосуванням НПЗЗ; активна фаза або рецидивуючий перебіг виразкової хвороби; хронічна диспепсія; підвищена кровоточивість; хвороба Крона або неспецифічний виразковий коліт; тяжка серцева недостатність; помірна або тяжка порушення функції нирок; тяжке порушення функції печінки; порушення згортання крові; тяжка дегідратація; III тримістр вагітності та період годування груддю. **Спосіб застосування та дози.** Найменша ефективна доза повинна застосовуватися протягом найменшого часу, необхідного для усунення симптомів. Залежно від виду та інтенсивності болю рекомендована доза становить 12,5 мг кожні 4–6 годин або 25 мг кожні 8 годин. Добова доза – не більше 75 мг. Не передбачений для тривалої терапії; лікування триває, поки є симптоми. Таблетки приймати, жуваючи достатньою кількістю рідини, не менше ніж за 30 хвилин до їди. **Побічні реакції.** Часто: Нудота та/або блювання, біль у животі, діарея, диспепсія. Безпека та ефективність застосування дітям віком до 18 років не встановлені. **Категорія відпуску.** За рецептом.

### Скорочена інструкція для медичного застосування ДЕКСАЛГІН® САШЕ (DEXALGIN® SACHET)<sup>2</sup>

**Склад:** 1 однодозовий пакет містить декскетопрофену 25 мг. **Показання.** Короточасне симптоматичне лікування гострого болю від легкого до середнього ступеня тяжкості, наприклад, м'язово-скелетний біль, дисменорея та зубний біль. **Противпоказання.** Підвищена чутливість до будь-якого компонента препарату або до іншого НПЗЗ; спричинення подібними речовинами або іншими НПЗЗ нападів бронхіальної астми, бронхоспазму, гострого риніту, розвитку поліпів у носі, кропив'янки, ангіоневротичного набряку; фотоалергічні або фототоксичні реакції на кетопрофен або фібрати; кровотеча або перфорації у травному тракті в анамнезі, пов'язані із застосуванням НПЗЗ або виразкової хвороби; хронічна диспепсія; підвищена кровоточивість; хвороба Крона або неспецифічний виразковий коліт; тяжка серцева недостатність; помірна або тяжке порушення функції нирок; тяжке порушення функції печінки; порушення згортання крові; тяжка дегідратація; III тримістр вагітності та період годування груддю. **Спосіб застосування та дози.** Найменша ефективна доза повинна застосовуватися протягом найменшого часу, необхідного для усунення симптомів. Залежно від виду та інтенсивності болю рекомендована доза становить 25 мг кожні 8 годин. Добова доза – не більше 75 мг. Розчинити вміст 1 пакета у склянці води, добре перемішати та приймати відразу. **Побічні реакції.** Часто: Нудота та/або блювання, біль у животі, діарея, диспепсія. Безпека та ефективність застосування дітям віком до 18 років не встановлені. **Категорія відпуску.** За рецептом.

### Скорочена інструкція для медичного застосування ДЕКСАЛГІН® ІН'ЄКТ (DEXALGIN® INJECT)<sup>3</sup>

**Склад:** 1 мл розчину для ін'єкцій/інфузій містить декскетопрофену 25 мг. **Показання.** Симптоматичне лікування гострого болю середньої та високої інтенсивності у випадках, коли пероральне застосування препарату недоцільне, наприклад, при післяопераційних болях, ниркових коликах та болю у попереку. **Противпоказання.** Підвищена чутливість до будь-якого компонента препарату або до іншого НПЗЗ; спричинення подібними речовинами або іншими НПЗЗ нападів бронхіальної астми, бронхоспазму, гострого риніту, розвитку поліпів у носі, кропив'янки або ангіоневротичного набряку; фотоалергічні або фототоксичні реакції на кетопрофен або фібрати; шлунково-кишкові кровотечі або перфорації в анамнезі, пов'язані із терапією НПЗЗ; пептична виразка або кровотеча в активній фазі; хронічна диспепсія; хвороба Крона або неспецифічний виразковий коліт; тяжка серцева недостатність; порушення функції нирок середнього або тяжкого ступеня; тяжке порушення функції печінки; порушення згортання крові; виражена дегідратація; III тримістр вагітності та період годування груддю; нейроаксальне (інтратекальне або епідуральне) введення. **Спосіб застосування та дози.** Вміст однієї ампули (2 мл) повільно вводиться глибоко у м'язи. Для внутрішньовенної інфузії вміст ампули 2 мл розвести у 30–100 мл 0,9 % розчину натрію хлориду, глюкози або Рінгера-лактату. Інфузію проводити повільно протягом 10–30 хвилин. При необхідності вміст однієї ампули (2 мл) вводиться внутрішньовенно повільно протягом не менше 15 секунд. **Побічні реакції.** Часто: Нудота, блювання, біль у місці ін'єкції, реакції у місці ін'єкції, у т.ч. запалення, гематома, кровотеча. Безпека та ефективність застосування дітям віком до 18 років не встановлені. **Категорія відпуску.** За рецептом.

<sup>1</sup> Інструкція для медичного застосування лікарського засобу ДЕКСАЛГІН®, РП No UA/9258/01/01, дата останнього перегляду 03.03.2023. <sup>2</sup> Інструкція для медичного застосування лікарського засобу ДЕКСАЛГІН® САШЕ, РП No UA/9258/02/01, дата останнього перегляду 03.03.2023. <sup>3</sup> Інструкція для медичного застосування лікарського засобу ДЕКСАЛГІН® ІН'ЄКТ, РП No UA/3764/01/01, дата останнього перегляду 18.10.2023. <sup>4</sup> Sanchez-Carpena J, et al. Comparison of dexketoprofen trometamol and dipyrone in the treatment of renal colic. Clin Drug Invest 2003; 23:139-152. <sup>5</sup> Bairngar MJ, et al. Clinical pharmacokinetics of dexketoprofen. Clin Pharmacokinet 2001; 40:245-262. <sup>6</sup> Marengo JL, et al. A multicentre, randomised, double-blind study to compare the efficacy and tolerability of dexketoprofen trometamol versus diclofenac in the symptomatic treatment of knee osteoarthritis. Clin Drug Invest 2000; 19:247-256. <sup>7</sup> Metscher B, et al. Dexketoprofen-trometamol and tramadol in acute lumbago. Fortschr Med Orig 2001; 118:147-151. <sup>8</sup> Leman P, et al. Randomised controlled trial of the onset of analgesic efficacy of dexketoprofen and diclofenac in lower limb injury. Emerg Med J 2003; 20:511-513. <sup>9</sup> Ay, MO et al. Comparison of the Analgesic Efficacy of Dexketoprofen Trometamol and Meperidine HCl in the Relief of Renal Colic. American Journal of Therapeutics 2013, May 9, 1-8. <sup>10</sup> Karaman Y, et al. Efficacy of Dexketoprofen trometamol for acute postoperative pain relief after ENT surgery: a comparison with paracetamol and metamizole. Nobel Medicus, 2010, 6(2), 47-52.

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ДО УВАГИ АВТОРІВ

# Cherenko Makar Petrovych

## To the 100th anniversary of his birth

The biographical essay is dedicated to the outstanding Ukrainian surgeon, one of the founders of thyroid surgery in Ukraine, Honored Worker of Science and Technology, laureate of the State Prize of Ukraine in Science and Technology, Professor Makar Petrovych Cherenko – whose life and work became a model of devotion, humanism, and exceptional professional mastery. The essay presents the key milestones of his biography, scientific achievements, pedagogical and public activity, as well as his contribution to the formation of the Ukrainian surgical school.



Professor Makar Cherenko stands out as one of the most versatile and devoted Ukrainian surgeons of the twentieth century. His enduring legacy is defined by masterful surgical expertise, steadfast humanistic principles, and an unwavering sense of responsibility shaped by the hardships of war. The professional path of Makar Cherenko – a graduate of Bogomolets National Medical University – embodies the development of postwar Ukrainian surgery.

Cherenko Makar Petrovych was born on August 26, 1925, into a large family in the picturesque village of Dniprovske, Chernihiv region, situated on the banks of the old Dnipro riverbed. His father, Petro Makarovich, headed the local meteorological service of the village. During the First World War, he was awarded the St. George's Cross – a distinction given «for fearless bravery». His mother, Fedora

Mytrofanivna, was a peasant woman. At the age of 18, Sergeant Cherenko had already served at the front as a commander of a 45 mm artillery crew. He was awarded the Order of Glory for destroying two German Tiger tanks (one by direct fire). In September 1944, during the liberation of Belarus, he was wounded in the leg but soon returned to the front. Later, near Königsberg in East Prussia, he suffered a severe multiple shrapnel chest injury that required several surgeries over a year. The final fragment was removed at a military hospital in Chernihiv. The long treatment and rehabilitation lasted over two years, but he never fully recovered. He continued life as a Group II disabled veteran. He received the Order of Glory (III class), Orders of the Patriotic War (I and II class), and numerous medals for his bravery. The hardships he endured during treatment and his almost miraculous recovery – thanks to the surgeons' skills – determined his future path in life.

In the famine year of 1946, he entered the Kyiv Medical Institute, which was named after academician O.O. Bogomolets that same year. The faculty then included surgical luminaries such as Professors A. P. Krymov, I. N. Ishchenko, M. I. Kolomiichenko, D. M. Horodynskyi, and A. H. Yeletskyi. Soon, M. M. Amosov joined their ranks. After graduating with honors in 1952, his mentor became Professor Oleksandr Kyrylovych Horchakov (1900–1960), a talented endocrine surgeon who perfected the subtotal strumectomy technique and inspired Cherenko's lifelong devotion to endocrine surgery. As a young researcher, Cherenko personally treated patients with thyrotoxicosis using radioactive iodine-131. Underestimating radiation hazards, he handled and dispensed the isotope himself (more than 1,200 patients in five years). Predictably, he developed almost fatal radiation sickness with leukopenia down to 1,200 cells/mL. Yet again, his strong body



prevailed. The results were published as A. K. Horchakov, M. P. Cherenko «Experience in treating patients with hyperthyroid goiter using radioactive iodine isotope», VD, 1955, No8. This work – a rare achievement in Soviet medical science – appeared only nine years after the American pioneers (Hertz & Roberts and Chapman & Evans, JAMA, 1946) but presented ten times as many clinical cases.

Fate granted Makar Petrovych a happy family life: in 1955, he married Lina Serhiivna Roienko, a charming final-year student of the Faculty of Dentistry. Her role in the creative and social life of her war-scarred husband – and of the entire family – defies any measure or description.

Makar Petrovych gained his professional experience going through a multifaceted school of surgery – one that is almost impossible to imagine today. Over the years he performed operations on the heart and great vessels (commissurotomy, suturing of stab and gunshot wounds of the heart), on the lungs and mediastinal organs (lung resections, removal of the thymus and its tumors, intrathoracic goiter), on the brain in cases of head trauma, as well as on the vessels of the limbs and the sympathetic nerve ganglia.

His greatest expertise lay in abdominal surgery. He also never neglected ambulatory and minor surgery, assisting villagers and acquaintances alike – true to the spirit of a real surgeon. His manuals, «Polyclinic Surgeon's Handbook» and «Abdominal Hernias», remain relevant today. His favorite field was endocrine surgery, so he focused mainly on the thyroid gland at that time. His mastery as a thyroid

surgeon was exemplary: zero mortality, minimal bleeding and laryngeal nerve injury, and an almost complete absence of postoperative hypoparathyroidism – achievements that brought him fame throughout Ukraine. He presented his insights in his brilliant monographs «Complications of Thyroid Surgery» and «Diseases and Injuries of the Neck», which trained hundreds of students and followers. In 1968, he defended his doctoral dissertation, «The reactivity of the central nervous system and cardiovascular system in patients with diffuse toxic goiter before and after surgical treatment».

From the pen of a scholar who treated every written line with perfectionist care came not only about 200 scientific articles but also several major monographs: «Diseases of the Thyroid Gland and Their Surgical Treatment» (1989); «Polyclinic Surgeon's Handbook» (1990); «Abdominal Hernias» (1995); and the textbook «General Surgery» (1999) – the first of its kind written in the Ukrainian language. He developed and patented several original surgical techniques for endocrine and purulent diseases.

The fruitful scientific and publishing activity of Professor Cherenko was combined with his tireless work in the clinic. Throughout his professional career, Makar Petrovych performed about 12,000 operations on nearly all organs of the human body. Summarizing many years of his scientific and practical experience in thyroid surgery, as well as his work at several institutions across Ukraine for more than two decades, Makar Petrovych undertook the main responsibility for preparing the materials for nomination for the State Prize of Ukraine in Science and Technology in 1988. Makar Petrovych donated his monetary award to the restoration of the Church of the Assumption of the Blessed Virgin Pyrohoshcha.

At 46 (in 1971), he became a professor of surgery at the Faculty of Dentistry under Professor Vasyl Bratus. Between 1980 and 1993, he headed the Departments of General Surgery, Pediatric Faculty Surgery, and Dental Faculty Surgery. He supervised one doctoral and ten PhD theses, teaching generations of surgeons and endocrinologists. He also founded a family dynasty of physicians that presently includes two professors (Doctors of Science) and two PhDs.

Cherenko was a remarkable teacher, shaping several generations of physicians, an active public figure, a member of the Presidium of the Ukrainian Society of Surgeons, the Kyiv Surgical Society Board, and the chair of the NMU surgical dissertation review council.

Remembering Makar Petrovych, one cannot help but mention his kind and intelligent sense of humor. He could sincerely laugh at good jokes, and it was never burdensome or uncomfortable to be in his presence.

Makar Petrovych could find a common language with anyone, from the uneducated to academicians. His decisions were always guided by an inner moral code that drew its roots from the deep cultural traditions of the Ukrainian people.

At the same time, despite such a rare combination of qualities, abilities, and professional achievements, Makar Petrovych remained an exceptionally modest man – entirely devoid of arrogance or vanity.

His erudition was also striking – it extended far beyond medicine, grounded in his natural curiosity, constant striving for self-improvement, and remarkable memory.

Makar Petrovych did not live to see our fortunate age of open information exchange – a time when his achievements could be compared with the finest examples in the world. The «Iron Curtain» did not let him travel even to Bulgaria, and his visits to the United States and Canada in the final years of his life only deepened the sorrow of the irretrievably lost opportunities for international exchange of surgical experience.

It is heartening to know that Makar Petrovych's legacy continues – carried forward by his children and grandchildren, by the hundreds of students and disciples who follow in his footsteps.

**L. Y. Markulan**

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## Макар Петрович Черенько

До 100-річчя від дня народження

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Біографічний нарис присвячено видатному українському хірургу, одному з фундаторів хірургії щито-подібної залози в Україні, Заслуженому діячу науки і техніки, лауреату Державної премії України в галузі науки і техніки, професору Макару Петровичу Череньку, чие життя і діяльність стали взірцем самовідданості, гуманізму та високої професійної майстерності. У нарисі подано основні віхи його біографії, наукові досягнення, педагогічну та громадську діяльність, а також внесок у становлення української хірургічної школи.

# Differentiated approach to treatment of severe acute pancreatitis based on organ failure pattern

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Severe acute pancreatitis (SAP) complicated by organ failure (OF) is associated with mortality rates of 15–40%. While the step-up approach has proven superior to primary necrosectomy, its universal application fails to account for the heterogeneity of clinical trajectories. Early stratification of patients based on OF patterns may facilitate the development of personalised treatment protocols.

**OBJECTIVE** – to evaluate the effectiveness of a differentiated treatment approach to severe acute pancreatitis based on organ failure patterns in comparison to standard disease management.

**MATERIALS AND METHODS.** A quasi-experimental study with historical control was conducted in 77 patients with SAP or high risk of its development. The comparison group (n=41, 2014–2019) received standard treatment with retrospectively confirmed OF development. The main group (n=36, 2022–2024) underwent prospective stratification using a prognostic model within 24 hours of admission, identifying three OF patterns: early respiratory-renal, late respiratory, and early multisystem. Pattern-specific protocols were applied: aggressive early drainage for the early respiratory-renal pattern, a maximal conservative approach for the late respiratory pattern, and intensive monitoring with readiness for emergency interventions for the early multisystem pattern. The primary endpoint was hospital length of stay (LOS). Secondary endpoints included OF development, intensive care unit (ICU) utilisation, surgical interventions, and mortality.

**RESULTS.** Median hospital LOS decreased from 35 [23–65] to 27 [15–33.25] days (p=0.015), representing a 22.9% reduction. OF development was prevented in 33.3% of high-risk patients (the number needed to treat is 3). The incidence of persistent OF decreased from 90.2% to 50.0% (odds ratio (OR)=0.11, 95% confidence interval (CI): 0.03–0.37, p<0.0001), and multiorgan failure from 31.7% to 5.6% (p=0.004). The treatment effect was pattern-dependent (interaction p<0.0001): the late respiratory pattern showed a 44.4% LOS reduction (61.1±27.2 to 34.0±23.6 days, p=0.005), the early multisystem pattern demonstrated a 47.2% reduction (50.2±32.8 to 26.5±19.3 days, p=0.042), while the early respiratory-renal pattern showed a non-significant increase (+31.3%, p=0.870). The proportion of staged open operations decreased from 58.5% to 22.2% (p=0.001) without affecting emergency surgery rates. Mortality decreased from 12.2% to 8.3% (p=0.579).

**CONCLUSIONS.** Pattern-oriented treatment of SAP significantly reduces hospitalisation duration and prevents OF development in one-third of high-risk patients. Treatment efficacy is heterogeneous across patterns, with the greatest benefit observed in late respiratory and early multisystem variants. This approach transforms the surgical paradigm from reactive to proactive, optimising intervention timing based on predicted clinical trajectory. Further multicentre validation is warranted to confirm these findings.

## KEYWORDS

pancreatitis, multiple organ failure, acute necrotizing pancreatitis, hospital length of stay, treatment outcome, risk assessment, inflammation.

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Severe acute pancreatitis (SAP) is associated with a mortality rate of 15–30% when organ failure (OF) develops and up to 40% in cases of infected pancreatic necrosis [10, 11, 15]. According to the

Atlanta 2012 classification, the presence and duration of OF represent key prognostic factors [2]. The modern «step-up» approach, validated in the PANTER and POINTER trials, has demonstrated

advantages of delaying invasive interventions up to 4 weeks [4, 8, 21]. However, universal application of this strategy does not account for the heterogeneity of clinical course, potentially leading to suboptimal outcomes in some patients.

Analysis of large patient cohorts demonstrates significant variability in OF development trajectories in SAP. In 20–30% of patients, OF develops within the first 48–72 hours, while in others it occurs in the second or third week of the disease [6, 9]. This heterogeneity suggests the existence of distinct disease phenotypes that potentially require differentiated approaches to timing and the extent of interventions.

The concept of personalised medicine, successfully implemented in oncology and cardiology, supports patient stratification based on biomarkers and clinical characteristics. In the context of SAP, this approach could optimise treatment tactics according to the predicted disease trajectory. However, there is a lack of validated models for early stratification and corresponding differentiated treatment protocols.

**Hypothesis:** Early identification of the OF pattern, followed by the application of a differentiated treatment protocol for SAP, is expected to improve clinical outcomes compared to the standard unified approach.

**OBJECTIVE** – to evaluate the effectiveness of a differentiated treatment approach to severe acute pancreatitis based on organ failure patterns in comparison to standard disease management.

## Materials and methods

### Study design

A quasi-experimental study with historical control was conducted to evaluate the effectiveness of the pattern-oriented approach to SAP treatment. This design was chosen due to ethical considerations, as randomising patients to a control group would have been unacceptable after the identification of high-risk patterns. The study protocol was approved by the Commission on Ethics and Bioethics of Poltava State Medical University (No. 203, dated March 24, 2022).

### Study population

The study comprised 77 patients with SAP or high risk of its development, divided into two groups from different time periods. The comparison group consisted of 41 patients hospitalised during 2014–2019, in whom OF development was retrospectively confirmed according to modified Marshall criteria. The main group included 36 patients hospitalised during 2022–2024, to whom the improved pattern-oriented treatment algorithm was applied.

## Methodology for the development of a prognostic model

The development of the pattern-oriented approach was implemented through three consecutive stages. In the first stage, agglomerative hierarchical clustering using Ward's method and Euclidean distance was performed to analyse 13 variables characterising OF dynamics in patients from group 1. These variables included time to OF development, episode duration, number of affected systems, and the presence of transient and persistent forms of respiratory, renal, and cardiovascular dysfunction. The optimality of the identified clusters was confirmed by the ratio of within-class (67.02%) variance to between-class (32.98%) variance.

### Characteristics of identified organ failure patterns

Cluster analysis identified three clinically distinct patterns, each exhibiting unique trajectories of disease progression.

The early respiratory-renal pattern encompassed 39.0% of the comparison group patients and was characterised by the earliest development of OF, with a median of 4.5 days from disease onset (interquartile range 2.0–13.5). This pattern was distinguished by a high frequency of early OF within the first 48 hours in 68.8% of cases, a predominance of persistent respiratory dysfunction in 75.0% of patients, and exclusively persistent renal failure in 31.3%. This variant was associated with the shortest hospitalisation duration (median 22.5 days).

The late respiratory pattern was observed in 39.0% of patients and was distinguished by delayed onset, with a median time to OF development of 30.0 days (interquartile range 22.8–49.0). No cases of early OF were identified in this group; instead, in 93.8% of cases, organ dysfunction developed exclusively in the late phase of the disease after day 14. Isolated respiratory system involvement was noted in 87.5% of patients, with minimal involvement of other organs. This pattern was associated with the longest hospitalisation (median 62.0 days).

The early multisystem pattern, representing the least common variant (22.0% of patients), demonstrated intermediate temporal characteristics, with a median OF development of 7.0 days (interquartile range, 6.0–11.0 days). However, this pattern was associated with the most severe clinical course. Multiple episodes of organ dysfunction (four or more) were observed in 77.8% of patients, with a high frequency of both transient cardiovascular and persistent renal failure (77.8% each). Patients with this variant required the longest intensive care unit stay (median 9.0 days).

The identified patterns demonstrated statistically significant differences across all key parameters ( $p < 0.0001$  for time of onset), justifying the need to develop differentiated treatment protocols.

In the second stage, a comprehensive statistical analysis of clinical and laboratory parameters from the first day of hospitalisation was conducted to determine predictors of the identified patterns. For practical clinical application, a simplified algorithm for pattern determination based on key predictors was developed, demonstrating 74.5% accuracy.

The hierarchical decision-making structure was constructed using the CHAID (Chi-squared Automatic Interaction Detector) classification tree method, with a maximum depth of 4 levels and a minimum of 10 observations per node.

### Prognostic model structure

A two-stage prognostic model for risk stratification and OF pattern determination was formed. In the first stage, five high-risk criteria were evaluated during the first six hours from hospitalisation: heart rate  $> 88$  bpm, presence of at least one systemic inflammatory response syndrome (SIRS) criterion, BISAP (Bedside Index for Severity in Acute Pancreatitis) score  $\geq 1$  point, creatinine level  $> 87$   $\mu\text{mol/L}$ , and total protein  $< 64$  g/L. The presence of at least one criterion indicated a high risk of OF development with 94.9% sensitivity and 93.3% specificity.

The second stage, implemented over 6–24 hours, involved determining the specific pattern using a hierarchical algorithm. Patients with a heart rate  $< 85$  bpm combined with a history of arterial hypertension were classified as having an early multisystem pattern. A heart rate  $> 95$  bpm and creatinine level  $> 102$   $\mu\text{mol/L}$  indicated an early respiratory-renal pattern. A combination of tachycardia with SIRS signs indicated a late respiratory pattern. In cases not meeting any of the above combinations, the systemic immune-inflammatory index ( $\text{SII} = \text{platelets} \times \text{neutrophils} / \text{lymphocytes}$ ) was also evaluated for final stratification.

### Differentiated treatment algorithm

A modified differentiated treatment algorithm was developed based on identified patterns, incorporating the critical timing of complications and the specific features of each pattern's course. The algorithm provided pattern-specific surgical tactics, including the differentiated application of the step-up approach, optimised intervention timing, and individualised intensive care.

The main group comprised 36 patients hospitalised during 2022–2024 who had a high risk of OF development on admission. Unlike the comparison

group, where patterns were determined retrospectively after the onset of complications, the main group underwent prospective stratification using prognostic model criteria for OF pattern determination within the first 24 hours, followed by application of a differentiated treatment protocol.

Inclusion criteria required adult patients aged 18 years or older with acute pancreatitis diagnosed according to the Atlanta 2012 criteria, who were hospitalised within 72 hours from symptom onset. For the comparison group, confirmation of OF during hospitalisation was mandatory, whereas for the main group, the presence of high-risk criteria for OF development was sufficient. Exclusion criteria included chronic pancreatitis, prior pancreatic surgery, or pancreatic malignancies.

### Differentiated treatment protocols

Patients in the comparison group received standard treatment according to 2014–2019 protocols based on a reactive approach to managing complications. In contrast, the main group was treated using a pattern-oriented protocol that applied differentiated tactics depending on the identified variant of progression.

For the early respiratory-renal pattern, the protocol provided aggressive early tactics, including ascites drainage within the first 72 hours when the volume exceeded 500 ml, aimed at reducing intra-abdominal pressure and improving ventilation. Prophylactic respiratory support via continuous positive airway pressure (CPAP) or high-flow oxygenation was provided concurrently with aggressive renoprotection, maintaining diuresis at a rate of at least 0.5 ml/kg/hour. Importantly, necrosectomy was deliberately delayed until the fourth week for necrosis maturation.

For the late respiratory pattern, the most conservative approach was applied, with avoidance of invasive interventions during the first two weeks. Drainage of fluid collections was deferred until at least the third week and was performed only in the presence of infection. From the fourth week onwards, the classical step-up approach was used, gradually increasing the invasiveness of interventions. Respiratory therapy was prescribed preventively for atelectasis prophylaxis.

The early multisystem pattern required the most aggressive management, including immediate admission to the intensive care unit and 24-hour surgical team availability for emergency interventions. Drainage of fluid collections commenced in the second week regardless of infection status, and early initiation of renal replacement therapy was considered in cases of renal failure.

## Study variables

A comprehensive assessment of clinical status and treatment outcomes was conducted by analysing the following groups of parameters:

Demographic and anthropometric data: age, sex, body mass index.

Aetiological factors: biliary, alcoholic, drug-induced, alimentary, and idiopathic aetiology.

Comorbidity: assessed using the Charlson comorbidity index, which includes 19 categories of comorbid conditions with scores from 1 to 6 depending on mortality risk. Arterial hypertension, ischaemic heart disease, diabetes mellitus, chronic respiratory, renal, and hepatic diseases were registered separately.

Severity indicators at admission: BISAP scale from 0 to 5 points, presence of SIRS criteria, the modified CT severity index (mCTSI) from 0 to 10 points for assessing inflammatory changes, and the percentage of pancreatic necrosis.

First-day laboratory parameters: complete blood count with differential white cell count, SII index, biochemical markers (creatinine, urea, total protein, bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), amylase, glucose, fibrinogen), and urine parameters.

Organ failure characteristics: presence and type (transient < 48 hours or persistent  $\geq$  48 hours), affected systems (respiratory, cardiovascular, renal), time of onset (early before day 14 or late after day 14), number of episodes, and the maximum Multiple Organ Dysfunction Score (MODS).

Surgical interventions: total number of operations and procedures, timing of the first intervention, types of operations (elective or emergency for infection/haemorrhage/peritonitis), number of re-operations, performed drainage and necrosectomies.

Local complications: necrotising pancreatitis, infected and sterile pancreatic necrosis, acute peripancreatic fluid collections (APFC), acute necrotic collections (ANC), walled-off necrosis (WON), pleural effusion, and ascites.

## Endpoints and data collection

The primary endpoint was the total length of hospitalisation as an integrative indicator of disease severity and treatment effectiveness. Secondary endpoints included frequency of OF development and its characteristics with differentiation into transient, persistent, and multiorgan forms. Important indicators were ICU length of stay, the total number of surgical interventions divided into staged and emergency procedures, the development of local complications including infected pancreatic necrosis, and hospital mortality.

## Statistical analysis

Statistical analysis was performed using XLSTAT v. 2021.2. Power calculations indicated that a minimum of 35 patients per group was required. This sample size was needed to detect a 25 % difference in hospitalisation duration. The significance level was set at 0.05, and the power at 80 %. Categorical variables are presented as absolute numbers and percentages. Continuous variables are described as either the median with interquartile range or the mean with standard deviation, depending on their distribution. The Shapiro-Wilk test was used to assess the normality of the distributions.

Categorical variables were compared using the chi-square test. For small expected frequencies, Fisher's exact test was used. Continuous variables were compared using the Mann-Whitney U test, as most parameters did not follow a normal distribution. To assess differential treatment effects by pattern, analysis of variance with covariates and an interaction term between group and pattern was applied. Predictors of binary outcomes were determined using logistic regression. The number of interventions was modelled with Poisson regression. Time to surgery was analysed using Cox regression.

An extended sensitivity analysis was conducted. This involved excluding deaths, including only patients with confirmed OF, and removing outliers that exceeded three standard deviations above the mean. Statistical significance was set at  $p < 0.05$ . The Tukey correction was applied for multiple comparisons.

## Study limitations

The quasi-experimental design does not completely exclude confounders, particularly the general improvement in medical care observed between the study periods. Differences in inclusion criteria, with the retrospective cohort comprising only patients with confirmed OF and the prospective cohort including high-risk patients, introduce methodological heterogeneity. The single-centre setting further limits the generalisability of findings to other populations and healthcare systems. To mitigate these limitations, an extended statistical analysis was conducted using multiple methods to evaluate intervention effects.

## Results

### Study population characteristics

A total of 77 patients with SAP were divided into a comparison group (group 1,  $n = 41$ , period 2014–2019) and a main group (group 2,  $n = 36$ , period 2022–2024). In the comparison group, all

patients developed confirmed OF during acute pancreatitis, whereas the main group included high-risk patients. In group 2, the implementation of differentiated pattern-oriented surgical tactics resulted in OF development in only 24 patients (66.7%).

The groups' demographic and clinical characteristics were comparable (Table 1).

The median age was 43.0 [34.0–56.0] years in the comparison group and 46.5 [40.0–55.0] years in the main group ( $p = 0.272$ ). Males predominated (68.3% vs. 63.9%,  $p = 0.683$ ) with median body mass index (BMI) 26.3 and 25.5 kg/m<sup>2</sup>, respectively ( $p = 0.955$ ). Biliary aetiology dominated in both groups (61.0% vs. 66.7%,  $p = 0.604$ ), while alcoholic aetiology accounted for approximately one quarter of cases (29.3% vs. 25.0%,  $p = 0.675$ ).

The comorbidity profile was characterised by a high prevalence of cardiovascular pathology

without intergroup differences: arterial hypertension was diagnosed in 58.5% and 55.6% ( $p = 0.792$ ), and ischaemic heart disease in 56.1% and 41.7% of patients, respectively ( $p = 0.206$ ). The median Charlson Comorbidity Index was 5.0 [4.0–6.0] in the comparison group and 4.0 [3.0–5.0] in the main group ( $p = 0.106$ ).

Disease severity at admission was comparable: SIRS frequency was 36.6% vs. 30.6% ( $p = 0.577$ ), and BISAP  $\geq 2$  was observed in 19.5% vs. 13.9% ( $p = 0.331$ ). The only statistically significant difference was found for mCTSI distribution ( $p = 0.020$ ), which may reflect the evolution of diagnostic capabilities at our hospital over time.

First-day laboratory parameters showed statistically significant differences between the groups, including higher total protein levels ( $68.3 \pm 8.6$  vs.  $61.3 \pm 8.6$  g/L,  $p = 0.002$ ), which may suggest

Table 1. **Baseline characteristics of study groups**

Parameter	Group 1 (n = 41)	Group 2 (n = 36)	p
<b>Demographics</b>			
Age, years	43.0 [34.0–56.0]	46.5 [40.0–55.0]	0.272
Male sex	28 (68.3%)	23 (63.9%)	0.683
BMI, kg/m <sup>2</sup>	26.3 [24.2–30.2]	25.5 [24.2–31.6]	0.955
<b>Aetiology</b>			
Biliary	25 (61.0%)	24 (66.7%)	0.604
Alcoholic	12 (29.3%)	9 (25.0%)	0.675
Idiopathic	4 (9.8%)	3 (8.3%)	0.828
<b>Comorbidity</b>			
Charlson Index	5.0 [4.0–6.0]	4.0 [3.0–5.0]	0.106
Arterial hypertension	24 (58.5%)	20 (55.6%)	0.792
IHD	23 (56.1%)	15 (41.7%)	0.206
Diabetes mellitus	4 (9.8%)	5 (13.9%)	0.573
<b>Severity at admission</b>			
SIRS positive	15 (36.6%)	11 (30.6%)	0.577
BISAP $\geq 2$	8 (19.5%)	5 (13.9%)	0.331
mCTSI $\geq 6$	21 (51.2%)	15 (41.7%)	0.035
<b>Key laboratory parameters, Day 1</b>			
Lymphocytes, $\times 10^9/L$	$1.84 \pm 0.48$	$1.63 \pm 0.47$	0.012
Total protein, g/L	$61.3 \pm 8.6$	$68.3 \pm 8.6$	0.002
Creatinine, $\mu\text{mol/L}$	$107.1 \pm 46.0$	$107.9 \pm 81.3$	0.450

Note. Categorical variables are presented as the number of cases and percentage, while quantitative indicators are presented as Median [Q1–Q3] or Mean  $\pm$  SD. BMI – body mass index; IHD – ischemic heart disease.

better prior hydration, and lower lymphocyte counts ( $(1.63 \pm 0.47)$  vs.  $(1.84 \pm 0.48) \times 10^9/L$ ,  $p = 0.012$ ) in the main group. The systemic immune-inflammatory index tended to be higher in the main group ( $2297.2 \pm 1424.3$  vs.  $1839.6 \pm 630.6$ ;  $p = 0.089$ ), but this difference was not statistically significant. Other admission parameters were comparable between the groups.

### Distribution by organ failure patterns

Patient stratification by patterns revealed clinically important differences between the groups (Table 2).

The comparison group exhibited an equal distribution between early respiratory-renal and late respiratory patterns (39.0% each), with a smaller proportion of early multisystem (22.0%). In the main group, the distribution shifted towards a multisystem pattern (41.7%), with a reduction in early respiratory-renal cases to 22.2%. However, these differences did not reach statistical significance ( $\chi^2 = 4.07$ ;  $p = 0.124$ ).

### Primary endpoint: length of hospitalisation

The total length of hospitalisation, chosen as an integrative indicator of treatment effectiveness, demonstrated a statistically and clinically significant reduction. The median decreased from 35 [23–65] days in the comparison group to 27 [15–33.25] days in the main group ( $U = 977.5$ ,  $z = 2.43$ ;  $p = 0.015$ ), reflecting a reduction in patient hospital stay by 8 days (22.9%). The mean duration decreased from  $44.1 \pm 28.5$  to  $30.2 \pm 21.2$  days.

### Differential effect by patterns: interaction analysis

Analysis of variance with covariates revealed a highly significant interaction between the treatment group and the corresponding OF pattern ( $F = 6.179$ ;  $p < 0.0001$ ), explaining 30.3% of the total hospitalisation variability ( $R^2 = 0.303$ , adjusted  $R^2 = 0.254$ ). Importantly, age and BMI did not enter the final model through stepwise selection ( $p > 0.05$ ), confirming that their effects are independent of these potential confounders (Table 3).

Table 2. Patient distribution by organ failure patterns

Pattern	Group 1 (n = 41)	Group 2 (n = 36)
Early respiratory-renal	16 (39.0%)	8 (22.2%)
Late respiratory	16 (39.0%)	13 (36.1%)
Early multisystem	9 (22.0%)	15 (41.7%)

The most pronounced therapeutic effect was observed in patients with the late respiratory OF pattern. In this group, mean hospitalisation duration decreased from  $61.1 \pm 27.2$  days in the comparison group to  $34.0 \pm 23.6$  days in the main group, corresponding to an absolute reduction of 27.1 days or 44.4% ( $p = 0.005$  by Mann-Whitney for subgroup analysis). Post-hoc Tukey analysis further confirmed that the late respiratory pattern in group 1 was associated with the longest hospitalisation among all six subgroups (patterns of groups 1 and 2), with statistically significant differences compared to all other combinations ( $p < 0.05$ ).

Patients with the early multisystem pattern also demonstrated an excellent response to differentiated treatment, as hospital stay was reduced from  $50.2 \pm 32.8$  to  $26.5 \pm 19.3$  days, representing a 47.2% improvement ( $p = 0.042$ ). Notably, this pattern was the only one to demonstrate a statistically significant reduction in ICU stay, decreasing from  $8.2 \pm 5.0$  to  $4.5 \pm 7.8$  days ( $p = 0.036$ ).

Paradoxically, the early respiratory-renal pattern was associated with less favourable outcomes. Hospitalisation duration increased from  $23.6 \pm 8.6$  days to  $31.0 \pm 21.9$  days (+31.3%). However, this difference was not statistically significant ( $p = 0.870$ ) and was accompanied by greater variability. This pattern had the shortest natural treatment duration in the retrospective cohort, which may suggest that excessive interventions were administered in the prospective group.

Table 3. Pattern-specific treatment effects on hospitalisation duration (M ± SD)

Pattern	Group 1 (n = 41)	Group 2 (n = 36)	Difference		p*
			Days	%	
Early respiratory-renal	23.6 ± 8.6	31.0 ± 21.9	+7.4	+31.3	0.870
Late respiratory	61.1 ± 27.2	34.0 ± 23.6	-27.1	-44.4	0.005
Early multisystem	50.2 ± 32.8	26.5 ± 19.3	-23.7	-47.2	0.042

Note. \*Mann-Whitney test for each pattern separately; ANCOVA (Analysis of Covariance) for overall model:  $F = 6.179$ ;  $p < 0.0001$ ,  $R^2 = 0.303$ .

### Organ failure modification

The application of the pattern-oriented approach resulted in enhanced OF parameters (Table 4).

The frequency of any OF development decreased from 100 % in comparison group 1 to 66.7 % in main group 2 ( $p < 0.0001$ ), indicating prevention in 12 of 36 high-risk patients. The number needed to treat (NNT) to prevent one case of OF was 3.

Among the 24 patients in the main group who developed OF, a significant change in the nature of OF was observed. The frequency of persistent OF, which defines a severe course according to Atlanta 2012 criteria, decreased from 90.2 % (37/41) to 50.0 % (18/36), with an odds ratio (OR) of 0.11 (95 % confidence interval (CI): 0.03–0.37;  $p < 0.0001$ ). The incidence of multiorgan failure declined from 31.7 % to 5.6 %, OR = 0.13 (95 % CI: 0.03–0.60;  $p = 0.004$ ).

Analysis of the number of OF episodes demonstrated a shift toward milder forms. The median number of episodes decreased from 2 [1–3] to 1 [1–2]. Notably, no patients in the main group experienced  $\geq 4$  OF episodes during the AP course, compared to 24.4 % (10/41) in the comparison group ( $p = 0.002$ , Fisher's exact test).

### Surgical paradigm transformation

Surgical activity structure demonstrated cardinal transformations. The proportion of patients who did not undergo open surgical intervention increased

from 26.8 % (11/41) to 52.8 % (19/36),  $\chi^2 = 5.52$ ;  $p = 0.047$ . The most significant reduction occurred in staged open operations, which declined from 58.5 % (24/41) to 22.2 % (8/36),  $p = 0.001$ . In contrast, the frequency of emergency operations remained stable: for infection, 26.8 % vs. 27.8 % ( $p = 0.925$ ); for haemorrhage, 7.3 % vs. 2.8 % ( $p = 0.363$ ); for peritonitis, 4.9 % vs. 8.3 % ( $p = 0.532$ ).

Kaplan-Meier analysis of time to first surgical intervention revealed no statistically significant difference in median values between groups (30 vs. 32 days, log-rank  $\chi^2 = 0.041$ ;  $p = 0.839$ ). However, the distribution of timing differed markedly: the 25th quartile was 5 [2–23] days in the comparison group vs. 26 [18–32] days in the main group, indicating a five-fold delay in early surgical interventions.

### Predictors of surgical interventions

Poisson regression for operation count ( $R^2 = 0.437$ ) identified OF development in the late phase of acute pancreatitis as the most powerful predictor of multiple interventions with IRR (incidence rate ratio) = 4.70 (95 % CI: 1.67–13.24;  $p = 0.001$ ). The pattern-oriented approach showed a trend toward a 33 % reduction in total operations (IRR = 0.67; 95 % CI: 0.34–1.31). However, the result did not reach statistical significance ( $p = 0.236$ ).

Cox regression analysis for time to surgery indicated that classic severity predictors (age, BMI,

Table 4. Organ failure characteristics in the study groups

Parameter	Group 1 (n = 41)	Group 2 (n = 36)	OR (95 % CI)	p
OF development				
Any OF	41 (100.0 %)	24 (66.7 %)	–	<0.0001
Persistent OF	37 (90.2 %)	18 (50.0 %)	0.11 (0.03–0.37)	<0.0001
Transient OF	22 (53.7 %)	18 (50.0 %)	0.86 (0.36–2.08)	0.745
Multiorgan OF	13 (31.7 %)	2 (5.6 %)	0.13 (0.03–0.60)	0.004
Number of OF episodes				
1	13 (31.7 %)	19 (52.8 %)		
2	12 (29.3 %)	13 (36.1 %)		0.051†
3	6 (14.6 %)	4 (11.1 %)		
$\geq 4$	10 (24.4 %)	0		
ICU Utilisation				
ICU admission	8 (19.5 %)	15 (41.7 %)	2.94 (1.08–8.00)	0.034
ICU duration, days*	5.0 [1.0–9.0]	2.5 [0.0–7.0]	–	0.136

Note. \* Fisher's exact test for distribution; Median [Q1–Q3].  
OR: odds ratio; CI: confidence interval.

BISAP) did not enter the final model. Instead, the time of complication type determined the timing of intervention: emergency operations for peritonitis had HR (hazard ratio) = 2.70 (95% CI: 0.59–12.47;  $p = 0.203$ ), infectious complications – HR = 1.83 (95% CI: 0.87–3.85;  $p = 0.110$ ), while staged open operations demonstrated a protective effect with HR = 0.75 (95% CI: 0.20–2.84;  $p = 0.672$ ).

### Intensive care resource utilisation

Paradoxical dynamics were observed in the requirement for ICU admission. The frequency of ICU admissions increased from 19.5% to 41.7% (OR = 2.94; 95% CI: 1.08–8.00;  $p = 0.034$ ), while the median duration of stay decreased from 5.0 [1.0–9.0] to 2.5 [0.0–7.0] days ( $p = 0.136$ ). These findings suggest a shift from a reactive model, characterised by prolonged ICU stays for patients with established complications, to a proactive model involving short-term monitoring of high-risk patients.

### Local Complications

The frequency of necrotising pancreatitis remained comparable between the groups (80.5% vs. 77.8%,  $p = 0.770$ ). Infected pancreatic necrosis showed a trend toward reduction from 46.3% to 30.6% ( $p = 0.152$ ). Acute peripancreatic fluid collections were observed in 85.4% and 75.0% of cases, respectively ( $p = 0.248$ ). The frequency of infected peripancreatic collections increased from 17.1% to 36.1%. However, this difference did not reach statistical significance. Walled-off necrosis was rare in both groups (2.4% vs. 2.8%,  $p = 0.929$ ).

### Mortality

Hospital mortality decreased from 12.2% (5/41) to 8.3% (3/36). However, this difference did not reach statistical significance due to the small number of events (OR = 0.66; 95% CI: 0.16–2.71;  $p = 0.579$ ). The clinical significance lies in the absolute reduction in death risk of 3.9%, corresponding to an NNT of 26 to prevent one death.

### Sensitivity analysis

A comprehensive sensitivity analysis was conducted to confirm the reliability of the findings and to exclude the influence of random factors (Table 5). This approach facilitates the assessment of the stability of group differences across various data analysis approaches.

A comparison of all study patients, based on the intention-to-treat principle, revealed a statistically significant reduction in hospitalisation duration for the group receiving enhanced treatment (group 2) compared to the group receiving traditional treatment (group 1). The median hospital stay was 27 days (mean  $30.2 \pm 21.2$  days) in group 2 vs. a median of 35 days (mean  $44.1 \pm 28.5$  days) in group 1. The reduction in hospital stay ranged from 8 to 14 days ( $p = 0.015$ ), indicating that the improved algorithm decreased patient hospitalisation by nearly two weeks.

Excluding patients with fatal outcomes from the analysis (5 cases in group 1 and 3 cases in group 2) further accentuates the advantages of the improved approach. The difference in hospitalisation duration increases to 15 days ( $p = 0.012$ ). The treatment effect remains moderate (effect size  $r = 0.352$ ), with a 67.6% probability that a randomly selected patient from group 1 will have a longer hospitalisation. Statistical analysis of anomalous values indicates that the longest hospitalisation (116 days) is not a statistical outlier, and the exclusion of extreme values minimally affects the results.

The practical value of the improved approach was assessed by calculating the number of patients who required treatment using the proposed algorithm. For OF prevention, the NNT (Number Needed to Treat) was 3 patients; for persistent OF prevention, the NNT was 2.5 patients; and for death prevention, 26 patients required treatment, respectively.

These indicators demonstrate the high effectiveness of the proposed approach, particularly in preventing the development and progression of OF.

Table 5. Sensitivity analysis for the primary endpoint

Analysis	Group 1 (n = 41)	Group 2 (n = 36)	Difference	p
Main analysis (ITT), days (Median [Q1-Q3], Mean $\pm$ SD)	35 [23–65] 44.1 $\pm$ 28.5	27 [15–33.25] 30.2 $\pm$ 21.2	–8 –13.9	0.015
Excluding deaths, days (Mean $\pm$ SD)	45.0 $\pm$ 29.7 (n = 36)	29.9 $\pm$ 22.0 (n = 33)	–15.1	0.012
Outlier analysis (Grubbs criterion)*	–	–	–	0.155

Note. ITT: intention-to-treat (analysis of all study patients).

\*  $G = 3.002 < G_{crit} = 3.292$ .

## Discussion

### Interpretation of the main results

The study demonstrates that personalisation of SAP treatment through early identification of OF patterns leads to clinically and economically significant improvements in outcomes [1, 5, 18, 23]. A reduction in median hospitalisation by 8 days (22.9%) exceeds the minimal clinically important difference and aligns with recent studies on personalised medicine in critical conditions.

A key outcome is the prevention of OF in 33.3% of high-risk patients (NNT = 3). Thus, for every three patients treated according to the differentiated protocol, one patient completely avoids the development of OF. Considering that OF is the main determinant of mortality in pancreatitis, this preventive effect is highly significant for improving survival rates.

Heterogeneity of treatment effects based on OF pattern is confirmed by a highly significant interaction in the ANCOVA model ( $p < 0.0001$ ), which validates the central hypothesis regarding the necessity of personalised treatment. Notably, the model accounts for 30.3% of the variability in hospitalisation duration without incorporating traditional severity predictors such as age or BMI, underscoring the fundamental role of OF patterns in determining disease trajectory [13].

The effectiveness of the pattern-oriented approach is based on three interconnected mechanisms. First, early stratification within the first 24 hours enables the initiation of preventive measures before irreversible pathophysiological changes occur. In contrast to the traditional reactive approach, which initiates interventions after complications manifest, the proactive model allows for modification of the natural disease course. Second, optimising the timing of interventions according to each pattern's expected trajectory prevents both premature operations with elevated complication risk and delayed interventions during necrosis progression. Third, differentiated therapy intensity avoids unnecessary interventions in favourable variants while ensuring adequate aggressiveness in unfavourable ones. This staged, physiology-guided strategy is consistent with broader surgical principles of damage control [17].

A reduction in persistent OF frequency from 90.2% to 50.0% (OR = 0.11) suggests effective interruption of the pathophysiological cascade. This outcome results from pattern-specific interventions, including aggressive early drainage of ascites-peritonitis in the early respiratory-renal pattern, an absolutely conservative approach in the

late respiratory pattern, and readiness for emergency interventions in the early multisystem pattern. The complete absence of patients with multiple OF episodes in the main group, compared to 24.4% in the retrospective cohort, further demonstrates the approach's capacity to prevent recurrent episodes of organ dysfunction.

The late respiratory pattern, which had the most severe natural course (a 61-day hospitalisation) demonstrated the maximum response to pattern-oriented therapy, achieving a 44% reduction in hospitalisation duration. This finding aligns with POINTER trial data, which indicate that delayed interventions are most effective for patients experiencing late complications [3, 4]. These patients typically have sufficient time for preventive measures, with a median manifestation period of 38.5 days. Employing conservative tactics until day 14, followed by a step-up approach, corresponds to this pattern's natural evolution, in which necrosis develops slowly and often remains sterile with adequate supportive therapy. The findings expand upon this concept by demonstrating the feasibility of prospectively identifying such patients.

The early multisystem pattern showed comprehensive improvements, with overall hospitalisation reduced by 47.2% and ICU stay by 45%. This variant is characterised by a fulminant onset and early multiorgan dysfunction, which is traditionally associated with the worst prognosis. Implementation of aggressive early therapy and continuous emergency intervention readiness enabled effective control of the multiorgan dysfunction cascade. The complete elimination of multiple OF episodes ( $\geq 4$ ) in this group further supports the effectiveness of the selected treatment tactics.

The paradoxical worsening of results for the early respiratory-renal pattern, evidenced by a 31.3% increase in hospitalisation duration, warrants critical evaluation. In the retrospective cohort, this variant exhibited the shortest natural treatment duration of 23.6 days, suggesting a relatively favourable prognosis. Potential contributing factors include: (1) impact of early frequent invasive interventions; (2) disruption of natural compensatory mechanisms; (3) inaccurate stratification in the small subgroup ( $n = 8$ ). Importantly, in the historical group, this pattern had the shortest hospitalisation duration (23.6 days), further indicating a relatively favourable natural course that did not require treatment intensification. These findings underscore the need for personalisation, not only by intensifying interventions, but also by considering reductions in their number and type.

The present findings expand upon the step-up approach paradigm established in the landmark

PANTER and TENSION trials [14, 19, 20]. While these studies proved the advantage of minimally invasive staged interventions over primary open necrosectomy for all patients, the current study highlights the need for personalisation within the step-up protocol. The observed reduction in new multi-organ failure frequency from 31.7 % to 5.6 % exceeds the PANTER trial results, where this indicator decreased from 40 % to 12 % [16, 21]. This improvement may be explained by the universal approach's failure to account for population heterogeneity, whereas pattern-specific tactics enable optimisation of intervention timing for each clinical variant.

It is important to note that this study does not position the pattern-oriented approach in opposition to the classic step-up method, but rather integrates personalisation into the existing paradigm [7, 22]. For the late respiratory pattern, the standard step-up protocol was effectively applied, yielding the most favourable outcomes for this variant. These findings indicate that the limitation lies not in the step-up approach itself, but in its universal application without consideration of individual course features.

The restructuring of surgical activity reflects a fundamental shift from surgery as the main treatment method to its use as a reserve option when conservative and minimally invasive therapies fail. A 62 % reduction in staged open operations, alongside stable emergency intervention rates, suggests an optimisation of surgical indications rather than mere avoidance of surgery. Additionally, a five-fold increase in the 25th quartile time to first operation, from 5 to 26 days, demonstrates abandonment of the early surgical debridement concept in favour of maximum delay.

The identification of OF in the late phase of AP (after day 14) as the most powerful predictor of multiple surgical interventions with IRR = 4.70 ( $p = 0.001$ ) has important practical implications. Patients who develop OF after day 14 have an almost five-fold higher risk of requiring repeated operations. Paradoxically, classic severity predictors at admission (BISAP, age, BMI) did not enter the model, underscoring the advantage of dynamic monitoring over static risk stratification.

### Paradigm shift in intensive care

The increase in ICU admission frequency from 19.5 % to 41.7 %, accompanied by a simultaneous reduction in median length of stay, reflects a shift in intensive care philosophy regarding the management of severe pancreatitis. Rather than relying on a reactive model in which patients are admitted to the ICU with established complications for extended periods, a proactive strategy of involving early,

short-term monitoring of high-risk patients has been adopted. Although this approach temporarily increases ICU burden in the short term, the overall reduction in intensive care bed-days and prevention of severe complications justify this approach.

### Clinical and economic implications

From a practical viewpoint, implementing the pattern-oriented approach requires reorganisation of the treatment process. Staff must be trained in the stratification algorithm within the first 24 hours to ensure round-the-clock readiness for emergency interventions in cases of the multisystem pattern and to optimise patient routing between departments. However, the potential savings of 589 bed-days per 77 patients and the reduction in the need for surgical interventions justify these organisational efforts.

The economic effectiveness of this approach, demonstrated by an NNT of 3 for the prevention of OF, makes it particularly attractive for healthcare systems with limited resources. Considering that the treatment cost for a patient with persistent multiorgan failure can exceed \$100,000, preventing one such case for every three patients treated results in substantial cost savings. Additionally, the reduction in the frequency of staged open operations allows operating resources to be allocated to other patients.

### Future perspectives and directions for development

The results justify the need for a multicentre randomised controlled trial to definitively validate the pattern-oriented approach. It is essential to modify protocols for early respiratory-renal patterns to incorporate less aggressive tactics. The integration of machine learning can enhance the accuracy of early stratification, particularly for cases that are borderline between patterns [12, 24]. Additionally, developing biomarker panels represents a promising direction for determining objective patterns and monitoring therapeutic responses.

### Conclusions

A differentiated approach to SAP treatment, guided by early determination of OF patterns, significantly reduces hospitalisation duration by 22.9 % and prevents OF development in one out of three high-risk patients.

The effectiveness of pattern-oriented therapy is heterogeneous: the greatest reduction in hospitalisation duration is observed in late respiratory (44 %) and early multisystem (47 %) patterns, whereas the early respiratory-renal pattern requires protocol modification.

Implementing a differentiated approach restructures surgical activity, resulting in a 62 % reduction in staged operations while maintaining a stable frequency of emergency interventions, which suggests more optimised surgical treatment indications.

A proactive monitoring strategy in intensive care units increases ICU admission frequency but reduces the overall duration of intensive care and helps prevent the development of persistent multiorgan failure.

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## DECLARATION OF INTERESTS

The authors declare no conflict of interest.

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## AUTHORS CONTRIBUTIONS

H. O. Levitskyi: conceptualization, methodology, investigation, data curation, formal analysis, writing – original draft. V. D. Sheiko: supervision, validation, writing – project administration, review, editing.

## STATEMENT ON THE USE

### OF GENERATIVE ARTIFICIAL INTELLIGENCE

the authors confirm that no generative AI systems were used to generate or interpret the content of this manuscript (text, figures, or data). Standard office tools (e.g., spelling/grammar checks in word processors) were used only for formatting and language polishing without content generation. No AI systems developed by the aggressor state were used.

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## Диференційований підхід до лікування тяжкого гострого панкреатиту залежно від патерну органної недостатності

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Тяжкий гострий панкреатит (ТПП) з органною недостатністю (ОН) асоціюється з летальністю 15–40%. Хоча підхід step-up довів перевагу над первинною некректомією, його універсальне застосування не враховує гетерогенності клінічного перебігу. Рання стратифікація пацієнтів на основі варіантів перебігу ОН може забезпечити персоналізовані протоколи лікування.

**Мета** — оцінити ефективність диференційованого підходу до лікування тяжкого гострого панкреатиту на основі варіантів перебігу органної недостатності порівняно зі стандартною тактикою.

**Матеріали та методи.** Проведено квазіекспериментальне дослідження з історичним контролем за участю 77 пацієнтів із ТПП або високим ризиком його розвитку. Група порівняння ( $n = 41$ , 2014–2019) отримувала стандартне лікування з ретроспективно підтвердженим розвитком ОН. Основна група ( $n = 36$ , 2022–2024) підлягала проспективній стратифікації за прогностичною моделлю протягом 24 год після госпіталізації з визначенням трьох патернів ОН: ранній респіраторно-ренальний, пізній респіраторний та ранній мультисистемний. Застосовували патерн-специфічні протоколи: агресивне раннє дренивання для раннього респіраторно-ренального патерну, максимально консервативний підхід для пізнього респіраторного патерну, інтенсивний моніторинг з готовністю до екстрених втручань для раннього мультисистемного патерну. Первинна кінцева точка – тривалість госпіталізації, вторинні – розвиток ОН, переведення у відділення інтенсивної реанімації, хірургічні втручання, летальність.

**Результати.** Медіана госпіталізації знизилась з 35 [23–65] до 27 [15,00–33,25] днів ( $p = 0,015$ ), тобто на 22,9%. Розвиток ОН попереджено у 33,3% пацієнтів із групи високого ризику ( $NNT = 3$ ). Частота ОН, що персистує, зменшилась з 90,2 до 50,0% (відношення шансів – 0,11, 95% довірчий інтервал – 0,03–0,37;  $p < 0,0001$ ), мультисистемної недостатності – з 31,7 до 5,6% ( $p = 0,004$ ). Ефект лікування значуще залежав від патерну ( $p < 0,0001$ ): пізній респіраторний патерн – зменшення тривалості госпіталізації на 44,4% (з  $(61,1 \pm 27,2)$  до  $(34,0 \pm 23,6)$  дня,  $p = 0,005$ ), ранній мультисистемний патерн – на 47,2% (з  $(50,2 \pm 32,8)$  до  $(26,5 \pm 19,3)$  дня,  $p = 0,042$ ), ранній респіраторно-ренальний патерн – незначуще збільшення (+31,3%,  $p = 0,870$ ). Частота проведення етапних відкритих операцій зменшилася з 58,5 до 22,2% ( $p = 0,001$ ) без впливу на частоту екстрених втручань. Летальність знизилась з 12,2 до 8,3% ( $p = 0,579$ ).

**Висновки.** Патерн-орієнтоване лікування ТПП вірогідно зменшує тривалість госпіталізації та запобігає розвитку ОН у третини пацієнтів із групи високого ризику. Ефективність терапії відрізняється залежно від патерну з максимальною користю для пізнього респіраторного та раннього мультисистемного варіантів. Запропонований підхід трансформує хірургічну парадигму з реактивної на проактивну, оптимізуючи терміни втручань на основі прогнозованої клінічної траєкторії. Необхідно провести багатоцентрову валідацію для підтвердження результатів.

**Ключові слова:** панкреатит, мультисистемна недостатність, гострий некротизувальний панкреатит, тривалість госпіталізації, результат лікування, оцінка ризику, запалення.

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# Bipolar vaporization of hemorrhoidal nodes in stage III chronic hemorrhoids: a single-centre comparative study involving laser hemorrhoidoplasty, transanal dearterialization, and Longo surgery

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**OBJECTIVE** – to compare the effectiveness and safety of bipolar vaporization (BPV) of hemorrhoidal nodes with laser hemorrhoidoplasty (LHP), transanal dearterialization (THD), and stapled hemorrhoidopexy (Longo surgery) in patients diagnosed with stage III chronic hemorrhoids.

**MATERIALS AND METHODS.** A single-centre, prospective, comparative study was conducted involving 63 patients (35 women and 28 men) with symptomatic stage III chronic hemorrhoids treated between 2021 and 2024. The mean age was  $45.3 \pm 11.1$  years, the mean body mass index was  $26.8 \text{ kg/m}^2$ , and the mean disease duration was  $10.3 \pm 6.7$  years. Patients were allocated to four groups based on the treatment method: BPV ( $n=18$ , 28.6%), LHP ( $n=15$ , 23.8%), THD ( $n=16$ , 25.4%), and Longo surgery ( $n=14$ , 22.2%). Bipolar vaporization was performed according to the author's method using the biowelding generator EK-300M (Svarmed, Ukraine) with multi-cycle vaporization of the node. Outcomes assessed included symptoms, complications, recurrences, patient satisfaction, duration of surgery, and length of hospital stay.

**RESULTS.** The mean duration of surgery was  $45.2 \pm 6.3$  minutes in the BPV group,  $44.5 \pm 7.5$  minutes in the LHP group,  $43.4 \pm 6.2$  minutes in the THD group, and  $41.1 \pm 4.9$  minutes in the Longo surgery group ( $p > 0.05$ ). Blood loss ranged from 10.4 to 16.4 ml across all groups ( $p > 0.05$ ). The incidence of submucosal hematomas did not exceed 35% in any group. All techniques resulted in a significant reduction in hemorrhoid symptoms postoperatively ( $p < 0.05$  within groups). At one year post-surgery, recurrence rates were 5.6% for BPV, 6.7% for LHP, 18.8% for THD, and 21.4% for Longo surgery ( $p = 0.422$ ). Patient satisfaction scores at 12 months ranged from 7.7 to 8.1 points.

**CONCLUSIONS.** Bipolar vaporization demonstrates effectiveness comparable to other minimally invasive techniques for the treatment of grade III chronic hemorrhoids, with minimal trauma and a short postoperative recovery period. The method is cost-effective due to the use of reusable electrodes. Bipolar vaporization is recommended for broader adoption in proctological practice, particularly in resource-limited settings.

## KEYWORDS

stage III hemorrhoids, bipolar vaporization, laser hemorrhoidoplasty, THD, Longo surgery, minimally invasive proctology.

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Stage III chronic hemorrhoids (CH) are among the most frequent reasons for referral to a coloproctologist, accounting for approximately 40% of all proctological pathologies [20, 25].

For most patients with stage III disease, conservative therapy is ineffective, while traditional hemorrhoidectomy is associated with significant trauma

[26, 27]. Consequently, minimally invasive technologies have been developed to eliminate pathologically altered hemorrhoidal nodes with minimal tissue damage and to facilitate rapid patient recovery.

Current treatment modalities include laser hemorrhoidoplasty (LHP) [14, 18], transanal dearterialization (THD/HAL-RAR) [11, 16, 19], stapled

hemorrhoidopexy (Longo surgery) [23, 26], and other energy-based methods such as ultrasonic or radiofrequency coagulation [9]. However, the majority of these techniques require costly equipment or disposable instruments, limiting their accessibility in middle-income countries.

Currently, there are no well-substantiated recommendations for selecting optimal treatment strategies for patients with stage III hemorrhoids. The international Delphi consensus highlights the necessity for a unified outcome assessment system but does not specify the superiority of any particular technique [30].

Systematic reviews further indicate that none of the existing procedures, including transanal dearterialization, stapled hemorrhoidopexy, or laser coagulation, demonstrate a definitive advantage regarding effectiveness, safety, or recurrence rates for stage III hemorrhoids [7, 13]. As a result, the selection of treatment methods in clinical practice is often influenced not only by clinical indications but also by the clinic's technical resources, equipment costs, and surgeon experience.

Bipolar vaporization of hemorrhoidal nodes (BPV), developed by a Ukrainian research group, represents a novel approach that offers ease of implementation, low cost, and consistent morphological outcomes [1, 2]. In contrast to laser technology, BPV utilizes reusable electrodes and a tissue biowelding generator, EK-300M (Svarmed, Ukraine), which produces a controlled zone of coagulation necrosis without carbonization [2]. Morphometric analyses have demonstrated that the necrosis zone following a single vaporization cycle is ellipsoidal, measuring approximately 3.9 mm in length, ensuring predictable depth and uniformity of thermal exposure [1].

**OBJECTIVE** – to compare the effectiveness and safety of bipolar vaporization (BPV) of hemorrhoidal nodes with laser hemorrhoidoplasty (LHP), transanal dearterialization (THD), and stapled hemorrhoidopexy (Longo surgery) in patients diagnosed with stage III chronic hemorrhoids.

## Materials and methods

The study cohort comprised 63 patients diagnosed with stage III chronic hemorrhoids, including 35 women (55.6%) and 28 men (44.4%), aged 28 to 71 years (mean age  $45.3 \pm 11.1$  years), who received treatment between 2021 and 2024. The mean body mass index (BMI) was  $26.8 \text{ kg/m}^2$  (range:  $19.8$  to  $37.0 \text{ kg/m}^2$ ). The mean duration of the disease was  $10.3 \pm 6.7$  years (range: 2 to 40 years).

The primary indications for surgical intervention, in addition to hemorrhoidal prolapse,

were persistent bleeding from the nodes of varying intensity in 59 patients (93.7%), perineal pain in 51 (81.0%), hemorrhoidal thrombosis in 30 (47.6%), anal canal itching in 33 (52.4%), and soiling in the perianal area in 27 (42.9%).

Patients were allocated to four treatment groups based on the intervention received: bipolar vaporization (BPV) using the original method (18 patients, 28.6%), laser hemorrhoidoplasty (LHP; 15 patients, 23.8%), transanal hemorrhoidal dearterialization (THD; 16 patients, 25.4%), and stapled hemorrhoidopexy (Longo surgery; 14 patients, 22.2%).

**Bipolar vaporization** was performed using the biowelding generator EK-300M. The technique for introducing a bipolar electrode into the hemorrhoidal node is described in detail for the treatment of stage I–II hemorrhoids [2]. Our previous studies have demonstrated that the necrosis zone after a single intratissue BPV is consistently ellipsoidal, with a characteristic thickening in the middle and an average length of approximately 3.93 mm [1]. Because stage III hemorrhoidal nodes exceed the length of a single vaporization zone, a **sequential multi-cycle technique** was employed. The electrode was introduced 2 mm below the proximal apex of the node for the initial vaporization cycle. It was then withdrawn 4 mm distally, and the procedure was repeated until the node was completely destroyed.

**Laser hemorrhoidoplasty** was performed according to a standard protocol [31] using a diode laser with a wavelength of 980–1470 nm. A laser fibre probe was introduced into the lumen of the hemorrhoidal node to achieve sequential coagulation of the cavernous tissue. This technique results in reduced node size and decreased blood supply due to thermal exposure.

**Transanal hemorrhoidal dearterialization (THD/ HAL-RAR)** was performed using a proctoscope equipped with a Doppler sensor to identify branches of the superior rectal artery, which were then stitched and ligated. In cases of severe prolapse, mucopexy was also performed. The procedure followed the widely accepted technique described by P. Dal Monte et al. [5].

**Stapled hemorrhoidopexy (Longo surgery, PPH machine)** was performed using a standard circular stapler. A purse-string suture was applied 2–4 cm above the dentate line, followed by resection of a circular strip of mucosa and simultaneous suturing, in accordance with the classic Longo description [17, 23].

**Inclusion criteria** comprised symptomatic stage III chronic hemorrhoids according to the Hollinger classification [4, 8], age  $\geq 18$  years, absence of severe concomitant pathology (ASA 4), and provision of written informed consent for surgical treatment and outpatient monitoring during the postoperative period.

*Exclusion criteria* included a history of infectious or undifferentiated colitis within six months prior to screening, malignant neoplasms of the rectum and anal canal, inflammatory diseases of the rectum, exacerbation of chronic gastroenterological diseases (such as pancreatitis, cholecystitis, hepatitis, gastritis, or colitis), logistical issues such as failure to appear for examination within established deadlines, and non-compliance with the diagnostic and treatment plan.

*Treatment effectiveness* was evaluated using the indicators recommended for hemorrhoidal disease in the international Delphi study [30] (Table 1).

Statistical analysis was conducted using IBM SPSS Statistics v. 22.0.

Comparisons between two independent samples were performed using the Student t-test for normally distributed data or the Mann–Whitney U-test for non-normally distributed data. For two dependent samples, either the paired t-test or the Wilcoxon signed-rank test was applied. Quantitative indicators across more than two groups were analysed using analysis of variance (ANOVA) with a post hoc Bonferroni correction. Qualitative indicators were compared using the  $\chi^2$ -test or Fisher's exact test. Mean values are presented as  $M \pm SD$ , and relative values as  $n (\%)$ .

The null hypothesis was rejected at  $p < 0.05$ .

The study was conducted in accordance with the principles of the Declaration of Helsinki (2013) and was approved by the local ethics committee (No. 21-E/2021, dated 12/15/2021).

## Results

Baseline patient characteristics across the study groups were comparable. No statistically significant differences were observed between the groups regarding age, sex, BMI, disease duration, frequency

of thrombosis in the anamnesis, or severity of hemorrhoid symptoms (all  $p > 0.05$ ). These findings indicate that the samples were homogeneous with respect to initial parameters (Table 2).

Analysis of the primary intraoperative and postoperative indicators revealed specific characteristics associated with each method (Table 3).

A comparison of the primary intraoperative and postoperative indicators revealed no statistically significant differences across any of the parameters studied.

The average surgical intervention duration ranged from 41 to 45 minutes, with no significant differences between the groups. This finding suggests comparable technical complexity and procedure duration for all techniques performed by a standardized surgical team. Intraoperative blood loss was minimal (10–16 ml) and did not differ significantly between the groups, further supporting the low-traumatic nature of all interventions.

The incidence of submucosal hematomas ranged from 22.2% to 35.7% across the groups. However, this difference was not statistically significant ( $p = 0.852$ ). This result may be attributed to the small sample size and the limited clinical significance of these complications. Postoperative pain, as measured by the average ketorolac doses administered during the first three days, also did not differ between groups (all  $p > 0.05$ ), indicating comparable postoperative comfort regardless of the technique used.

The hospital stay (2.8–3.3 days) and temporary disability (5.4–5.9 days) were similar across all groups, reflecting a rapid recovery after minimally invasive interventions.

All techniques (BPV, LHP, THD, and Longo surgery) produced comparable outcomes regarding key intraoperative and postoperative parameters,

Table 1. **Criteria for evaluating the effectiveness of treatment**

Endpoints	Indicators	Assessment method	Time frame
<b>Primary</b> Symptoms of hemorrhoids	Pain, prolapse, itching, soiling, bleeding	Scale 0–9 points; frequency (%)	Basic level, 7 days, 6 months, 1 year
	Incontinence	Wexner scale [19]	1 year
<b>Secondary</b> Complications	Abscess, anal stenosis	Physical examination	7 days (abscess), 1 year (stenosis)
	Urinary retention	Ultrasound	7 days
	Fistula	MRI in case of questionable clinical data	1 year
<b>Patient satisfaction</b>	Subjective patient assessment	Scale 0–9 points	Basic level, 7 days, 6 months, 1 year
<b>Recurrence</b>	Recurrence of symptoms	Patient complaints	6 months, one year

Table 2. **Baseline characteristics of patients with stage I–II chronic hemorrhoids**

Parameter	BPV (n = 18)	LHP (n = 15)	THD (n = 16)	Longo surgery (n = 14)	Total (n = 63)
Age, years	46.5 ± 12.5	51.0 ± 11.9	42.9 ± 9.1	40.5 ± 8.0	45.3 ± 11.1
Males	19 (59.4%)	11 (54.4%)	23 (54.8%)	14 (60.9%)	28 (44.4%)
Females	13 (40.6%)	10 (47.6%)	19 (45.2%)	9 (39.1%)	35 (55.6%)
BMI, kg/m <sup>2</sup>	27.5 ± 3.8	27.5 ± 3.3	28.1 ± 4.1	24.5 ± 4.3	27.0 ± 4.1
Disease duration, years	9.5 ± 8.9	12.7 ± 6.2	9.2 ± 4.8	10.1 ± 6.0	10.3 ± 6.7
Deep venous thrombosis in the anamnesis	8 (44.4%)	8 (53.3%)	7 (43.8%)	7 (50.0%)	30 (47.6%)
<b>Hemorrhoid Symptoms</b>					
Pain	15 (83.3%)	12 (80.0%)	13 (81.3%)	11 (78.6%)	51 (81.0%)
points	3.5 ± 1.2	3.3 ± 1.0	3.7 ± 1.8	3.8 ± 1.7	3.5 ± 1.4
Prolapse	18 (100%)	15 (100%)	16 (100%)	14 (100%)	63 (100%)
Itching	9 (50.0%)	8 (53.3%)	9 (56.3%)	7 (30.4%)	33 (52.4%)
points	6.2 ± 1.5	5.0 ± 1.0	6.1 ± 1.8	5.8 ± 3.2	5.8 ± 1.7
Soiling	8 (44.4%)	7 (46.7%)	6 (37.5%)	6 (42.9%)	27 (42.9%)
points	4.1 ± 1.0	3.7 ± 1.1	4.6 ± 1.6	4.0 ± 0.8	4.1 ± 1.2
Bleeding	18 (100%)	14 (93.3%)	14 (87.5%)	13 (92.9%)	59 (93.7%)
points	5.2 ± 0.3	5.1 ± 0.4	5.4 ± 0.7	5.4 ± 0.4	5.3 ± 0.6

Note. Categorical variables are presented as the number of cases and percentage, while quantitative indicators are presented as M ± SD. The average scores were determined based on the number of patients exhibiting the corresponding symptoms. Across all baseline parameters, there were no statistically significant differences between the study groups (all p > 0.05).

Table 3. **Comparison of the main intraoperative and postoperative outcomes in patients with stage III chronic hemorrhoids by surgical technique**

Parameter	BPV (n = 18)	LHP (n = 15)	THD (n = 16)	Longo surgery (n = 14)	p
Duration of surgery, min	45.2 ± 6.3	44.5 ± 7.5	43.4 ± 6.2	41.1 ± 4.9	> 0.05
Intraoperative blood loss, ml	10.4 ± 4.2	10.9 ± 4.2	16.4 ± 4.5	13.9 ± 5.3	> 0.05
Frequency of submucosal hematomas	4 (22.2%)	4 (26.4%)	5 (31.3%)	5 (35.7%)	0.852
Average doses of ketorolac					
Day 1	2.9 ± 0.7	2.7 ± 0.7	2.8 ± 0.8	3.0 ± 0.7	> 0.05
Day 2	2.0 ± 0.5	2.0 ± 0.4	2.4 ± 0.5	2.0 ± 0.1	> 0.05
Day 3	0.9 ± 0.3	0.7 ± 0.6	0.9 ± 0.6	0.8 ± 0.8	> 0.05
Average length of hospital stay, day	2.8 ± 0.7	2.9 ± 0.7	3.2 ± 0.7	3.3 ± 0.9	> 0.05
Average duration of disability, days	5.4 ± 0.8	5.7 ± 0.7	5.9 ± 0.9	5.8 ± 1.6	> 0.05

Note. Categorical variables are presented as the number of cases and percentage, while quantitative indicators are presented as M ± SD. p-value is based on ANOVA results, or  $\chi^2$ -test.

supporting their safety and effectiveness for treating stage III chronic hemorrhoids.

A comparative analysis of the dynamics within the «Hemorrhoid symptoms» cluster identified distinct characteristics among the groups (Table 4).

A comparative analysis of the progression of primary clinical symptoms (pain, prolapse, itching, soiling, and bleeding) in patients with stage III chronic hemorrhoids revealed no statistically significant differences between treatment groups at any observation point ( $p > 0.05$  according to  $\chi^2$  or Fisher's exact test).

**Pain syndrome.** Prior to surgery, 78–83% of patients reported pain across all treatment groups. One week post-intervention, the incidence of pain decreased by more than twice in all groups (44–63%), and the mean visual analogue scale score ranged from 1.25 to 1.80, with no significant differences between methods. At 6 and 12 months postoperatively, pain frequency remained low, not exceeding 15–20%, indicating a sustained long-term effect irrespective of the surgical technique.

**Prolapse of nodes.** Complete resolution of prolapse occurred in all patients within the first

Table 4. **Postoperative dynamics within the «Hemorrhoid symptoms» cluster**

Parameter	BPV (n = 18)	LHP (n = 15)	THD (n = 16)	Longo surgery (n = 14)	p
<b>Pain</b>					
Before surgery	83.3%	80.0%	81.3%	78.6%	0,988
7 days	8 (44.4%)	7 (46.7%)	10 (62.5%)	8 (57.1%)	0,697
6 months	1 (5.6%)	2 (13.3%)	2 (12.5%)	2 (14.3%)	0,847
12 months	1 (5.6%)	2 (13.3%)	3 (18.8%)	3 (21.4%)	0,578
<b>Prolapse</b>					
Before surgery	100%	100%	100%	100%	1
7 days	0	0	0	0	1
6 months	0	0	6.3%	7.1%	0,736
12 months	11.1%	13.3%	18.8%	21.4%	0,849
<b>Itching</b>					
Before surgery	9 (50,0%)	8 (53.3%)	9 (56.3%)	7 (30.4%)	0,964
7 days	27.8%	33.3%	25.0%	28.6%	0,965
6 months	11.1%	20.0	18.8%	21.4%	0,863
12 months	16.7%	20.0%	18.8%	21.4%	0,988
<b>Soiling</b>					
Before surgery	8 (44,4%)	7 (46.7%)	6 (37.5%)	6 (42.9%)	0,985
7 days	50,0%	60.0%	56.3%	42.9%	0,802
6 months	16.7%	20.0%	18.8%	21.4%	0,988
12 months	16.7%	20.0%	18.8%	21.4%	0,988
<b>Bleeding</b>					
Before surgery	18 (100%)	14 (93.3%)	14(87.5%)	13 (92.9%)	0,094
7 days	0	6.7%	12.5%	7.1%	0,521
6 months	5.6%	13.3%	6.3%	7.1%	0,847
12 months	11.1%	13.3%	12.5%	14.3%	0,994

Note. p between the groups – according to the results of  $\chi^2$  or Fisher's exact test.

postoperative week. Isolated recurrences (6–21 %) were observed at 12 months, primarily following THD and Longo surgery, but these differences were not statistically significant. These findings support the comparable effectiveness of all four methods in correcting prolapse.

**Itching and soiling.** The incidence of anal itching and soiling declined progressively over the year in all groups, with no significant differences between groups ( $p > 0.8$ ). In most patients, these symptoms either resolved or were minimal, indicating improved quality of life following minimally invasive interventions.

**Rectal bleeding.** Prior to surgery, bleeding was the predominant symptom in 88–100 % of patients. One week postoperatively, bleeding either resolved completely or persisted only in isolated cases (up to 12 %). At 6–12 months, the incidence of bleeding remained low (6–14 %) and did not differ significantly between methods, demonstrating reliable hemostasis across all intervention types.

In summary, all evaluated methods (BPV, LHP, THD, and Longo surgery) demonstrated comparable clinical effectiveness in resolving the primary symptoms of chronic hemorrhoids during both early and late postoperative periods. Therefore, selection of a specific technique may be guided primarily by the clinic's technical resources, cost considerations, and patient-specific factors.

The mean values of the «Satisfaction» cluster score also did not differ significantly between groups at any time point during the study (Table 5).

A comparison of the mean «Satisfaction» cluster scores over time shows that all four surgical methods for treating stage III chronic hemorrhoids achieve high levels of postoperative comfort and patient satisfaction.

Seven days following the intervention, the mean satisfaction scores ranged from 6.3 to 7.1, with no statistically significant differences between groups ( $p > 0.05$ ). The highest scores were observed in the BPV and LHP groups, potentially attributable to reduced postoperative pain and more rapid resumption of daily activities.

At six months postoperatively, all groups showed a further increase in satisfaction scores (7.3–8.1), reflecting sustained positive functional outcomes and reduced recurrent symptoms. Nevertheless, no statistically significant differences were observed between the surgical methods ( $p > 0.05$ ), indicating comparable long-term effectiveness.

At twelve months, the mean satisfaction scores decreased slightly (to 6.7–7.7), possibly reflecting partial recurrence of minor symptoms or individual variation in outcome perception. Despite this, satisfaction levels remained high in all groups, consistently exceeding 6 points.

In summary, irrespective of the surgical method employed, most patients rated their treatment outcomes as good or very good. The lack of statistically significant differences between groups suggests that all four methods are comparable in terms of clinical and subjective effectiveness in managing stage III chronic hemorrhoids.

Analysis of hemorrhoid recurrence rates in the long-term postoperative period revealed that, at six months post-treatment, symptom recurrence occurred only in isolated cases (6.3–7.1 %) following LHP, THD, and Longo surgery, with no recurrences observed after BPV. No statistically significant differences were identified between groups ( $p = 0.736$ ), indicating comparable effectiveness among the methods during the early follow-up period (Table 6).

One year following the intervention, all groups exhibited a modest increase in recurrence rates. The lowest recurrence rates were observed in the BPV (5.6 %) and LHP (6.7 %) groups, whereas higher rates were reported in the THD (18.8 %) and Longo surgery (21.4 %) groups. However, these differences did not reach statistical significance ( $p = 0.422$ ).

All studied methods demonstrated sustained effectiveness over one year. However, vaporization technologies, including bipolar and laser methods, were associated with a trend toward lower recurrence frequency. This outcome may result from more uniform coagulation of the hemorrhoidal plexus

Table 5. Average values for the «Satisfaction» cluster by group across assessment dates

Period	BPV (n = 18)	LHP (n = 15)	THD (n = 16)	Longo surgery (n = 14)	p
7 days	7.1 ± 0.8 (5–8)	6.9 ± 0.9 (5–8)	6.3 ± 1.6 (4–9)	6.4 ± 1.4 (4–9)	>0.05
6 months	8.1 ± 1.0 (6–9)	8.0 ± 1.8 (4–10)	7.3 ± 1.5 (4–10)	7.6 ± 1.4 (4–10)	>0.05
12 months	7.7 ± 1.4 (5–10)	7.5 ± 1.6 (4–10)	6.7 ± 2.1 (3–10)	7.0 ± 0.9 (3–10)	>0.05

Note. Indicators are presented as M ± SD (min–max).

Table 6. Distribution of patients within the «Recurrence» cluster during the long-term postoperative period across the study groups

Period	BPV (n = 18)	LHP (n = 15)	THD (n = 16)	Longo surgery (n = 14)	p
6 months	0	1 (6.7%)	1 (6.3%)	1 (7.1%)	0.736
1 year	1 (5.6%)	1 (6.7%)	3 (18.8%)	3 (21.4%)	0.422

vessels, which avoids the development of ischemic areas or excessive scarring.

Bipolar and laser vaporization offer effectiveness comparable to other methods, with a tendency toward improved long-term outcomes. These techniques also maintain minimal invasiveness and facilitate a short recovery period.

No complications anticipated within the relevant clinical domain were recorded in any group during the study. However, one patient (7.1%) experienced urinary retention on the first postoperative day following the Longo procedure.

## Discussion

Minimally invasive technologies for the treatment of stage III chronic hemorrhoids represent an optimal balance between therapeutic effectiveness and patient safety [6, 10, 12].

Transanal dearterialization (THD/HAL-RAR), stapled hemorrhoidopexy (Longo surgery), and laser hemorrhoidoplasty (LHP) are among the most widely recognized methods globally. However, despite their technical advancements, these procedures are costly and require disposable instruments, which restricts their widespread adoption in public healthcare settings [6, 7, 29].

THD reduces arterial inflow to the corpora cavernosa but does not remove existing hemorrhoidal nodes. The recurrence rate after one year is reported to be 10–20% [7, 11].

The Longo procedure provides a good initial effect; however, safety remains the key argument of critics of the technique. A systematic review of 78 studies (14,232 patients) showed a wide range of complications, 3.3–81%, including bleeding, sepsis, stenosis, severe pelvic pain, and 5 fatal cases [22]. According to Ravo B, in 1,107 patients the complication rate was 15%, including bleeding (4.2%) [24], which occurs suddenly and requires immediate surgical revision [21].

Laser hemorrhoidoplasty results in minimal tissue trauma but is associated with high procedural costs. Additionally, precise control over the depth of coagulation remains challenging [18, 28].

Bipolar vaporization of hemorrhoids is technically

simpler and more cost-effective, enabling localized intratissue necrosis and subsequent reduction of cavernous tissue [1, 2].

Utilization of the EK-300M generator enables the formation of a stable coagulation zone without increasing the risk of mucosal perforation or excessive thermal injury [2].

Morphometric studies have demonstrated that the depth of coagulation can be effectively controlled, thereby preserving intact mucosal areas [1].

The recurrence rate one year after BPV was 5.6%, which was lower than that observed after THD (18.8%) and the Longo procedure (21.4%). However, this difference did not reach statistical significance, likely due to the limited sample size.

Patient satisfaction following BPV was the highest across all follow-up periods. Additionally, the durations of hospital stay and disability were the shortest, at 2.8 and 5.4 days, respectively.

BPV enables targeted treatment of each node, avoids mucosal resection, and is associated with a low risk of bleeding and hematoma formation. The use of reusable electrodes further reduces the overall cost of the intervention.

In contrast to laser coagulation, bipolar energy produces uniform tissue heating and permits multi-cycle treatment of large nodes in stage III chronic hemorrhoids [1, 2].

The present findings align with previous studies that highlight the effectiveness of intratissue thermo-coagulation methods, including radiofrequency, infrared, and bipolar techniques, in reducing complication rates and preserving anal canal anatomy [3, 9, 15].

Despite its positive results, this study has several limitations, including its single-centre design, small sample size, and absence of randomization, which may introduce selection bias. Nevertheless, group homogeneity and the use of a standardized methodology help mitigate these limitations.

Although various minimally invasive approaches are available, there is a lack of conclusive evidence-based recommendations for selecting the optimal treatment for stage III chronic hemorrhoids. The present results support the feasibility of conducting comparative research on BPV and other methods to establish unified clinical protocols.

## Conclusions

Bipolar vaporization demonstrates effectiveness comparable to other minimally invasive treatments for stage III chronic hemorrhoids, while offering minimal trauma, a brief postoperative recovery, and reduced costs through the use of reusable electrodes. This technique is suitable for broad adoption in proctological practice, particularly in settings with limited resources.

## DECLARATION OF INTERESTS

The authors declare no conflict of interest.

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## AUTHORS CONTRIBUTIONS

L. S. Bilianskyi: conception and design, critical revision of the manuscript; I. V. Voloshyn: acquisition, analysis and interpretation of data, statistical analysis, drafting, critical revision of the manuscript.

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## Біполярна вапоризація гемороїдальних вузлів при хронічному геморої III стадії: одноцентрове порівняльне дослідження з лазерною вапоризацією, трансанальною деартеріалізацією та операцією Лонго

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**Мета** — порівняти ефективність та безпечність біполярної вапоризації (БПВ) гемороїдальних вузлів із лазерною вапоризацією (ЛВ), трансанальною деартеріалізацією (ТНД) та степлерною гемороїдопексією (операцією Лонго) у хворих на хронічний геморої III стадії.

**Матеріали та методи.** Проведено одноцентрове проспективно-порівняльне дослідження 63 пацієнтів (35 жінок та 28 чоловіків) із симптомним хронічним гемороєм III стадії, пролікованих у 2021—2024 рр. Середній вік пацієнтів становив  $(45,3 \pm 11,1)$  року, індекс маси тіла —  $26,8 \text{ кг/м}^2$ , тривалість захворювання —  $(10,3 \pm 6,7)$  року. Пацієнтів розподілили на чотири групи залежно від методу лікування: БПВ — 18 (28,6%), ЛВ — 15 (23,8%), ТНД — 16 (25,4%), операція Лонго — 14 (22,2%). Біполярну вапоризацію виконували за авторською методикою з використанням біозварювального генератора «ЕК-300М» («Свармед», Україна) із багатоцикловою вапоризацією вузла. Оцінювали симптоми, ускладнення, рецидиви, задоволення результатом, тривалість операції та госпіталізації.

**Результати.** Середня тривалість операції становила  $(45,2 \pm 6,3)$  хв у групі БПВ,  $(44,5 \pm 7,5)$  хв у групі ЛВ,  $(43,4 \pm 6,2)$  хв у групі ТНД,  $(41,1 \pm 4,9)$  хв у групі операції Лонго ( $p > 0,05$ ). Крововтрата — 10,4—16,4 мл у всіх групах ( $p > 0,05$ ). Частота підслизових гематом не перевищувала 35%. Усі методики сприяли значному зниженню симптомів геморою після операції ( $p < 0,05$  усередині груп). Через рік після операції рецидиви зареєстровано в 5,6% пацієнтів після БПВ, у 6,7% — після ЛВ, у 18,8% — після ТНД, у 21,4% — після операції Лонго ( $p = 0,422$ ). Оцінка задоволеністю результатом через 12 міс становила 7,7—8,1 бала.

**Висновки.** Біполярна вапоризація забезпечує ефективність, порівнянну з такою при використанні інших малоінвазивних методик лікування хронічного геморою III ст., мінімальну травматичність, короткий післяопераційний період. Цей метод має низьку вартість через можливість застосування багатополозових електродів. Біполярна вапоризація може бути рекомендована для широкого впровадження в проктологічну практику, особливо в умовах обмежених ресурсів.

**Ключові слова:** геморої III стадії, біполярна вапоризація, лазерна вапоризація, трансанальна деартеріалізація, операція Лонго, малоінвазивна проктологія.

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# Association between rs571312 MC4R and rs3810291 TMEM160 single-nucleotide polymorphisms and metabolic surgery outcomes

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**OBJECTIVE** – to determine the association between the SNP *rs571312 MC4R* and SNP *rs3810291 TMEM160* genes and the results of metabolic surgery.

**MATERIALS AND METHODS.** A prospective, observational, monocentric cohort study was conducted at the Department of General Surgery No2 of Bogomolets National Medical University. A total of 112 patients with surgical indications were offered bariatric surgery. Patients who agreed to undergo bariatric surgery ( $n=53$ ) comprised the main group. Those who refused surgical treatment ( $n=59$ ) formed the control group. The main group underwent bariatric interventions, including laparoscopic gastric bypass and laparoscopic sleeve gastrectomy, whereas patients with  $BMI \geq 50$  kg/m<sup>2</sup> had a two-stage surgical treatment involving intragastric balloon placement for a period of 6 months, followed by gastric bypass within 14 days after balloon removal. The results for both groups were evaluated one year after the start of treatment. In the control group, 59 patients suffering from obesity received conservative treatment. Before the start of treatment, all patients underwent anthropometric examinations and analysis of buccal epithelial scrapings. Genetic studies included DNA collection and isolation, as well as genotyping to determine polymorphisms of the *rs571312 MC4R* and *rs3810291 TMEM160* genes.

**RESULTS.** A strong correlation was found between bariatric surgery outcomes and the presence of *rs571312 MC4R* and *rs3810291 TMEM160* gene polymorphisms in the study group ( $r=0.622$ ;  $p \geq 0.001$ ). There was no significant association between the degree of gene dominance and bariatric surgery outcomes ( $r=0.112$ ,  $p \geq 0.5$ ).

**CONCLUSIONS.** In the studied cohort, a relationship was found between the effectiveness of bariatric procedures and the presence of the *rs571312 MC4R* ( $r=0.465$ ) and *rs3810291 TMEM160* ( $r=0.55$ ) polymorphisms, as well as the concurrent presence of both polymorphisms ( $r=0.622$ ). The detection of these polymorphisms is associated with bariatric surgery outcomes, regardless of the degree of their genetic dominance ( $r=0.467$ ).

## KEYWORDS

treatment, excess weight loss, gene, polymorphisms.

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Nowadays, metabolic surgery is the safest and most effective method of obesity treatment in most countries throughout the world. According to the IFSO 8th Global Registry Report, 480,970 bariatric surgeries were performed worldwide in 2023.

The study of polymorphisms of certain genes has considerably improved disease prediction in many cases. To date, a significant number of studies have proven that genetic factors play a key role in the development of obesity. However, it remains insufficiently studied whether certain genetic factors affect the process of obesity treatment and its results.

According to the literature data, there is a relationship between obesity and the detection of polymorphisms of certain genes.

Lu Liu et al. carried out a meta-analysis involving 11,569 patients with stage III obesity and identified polymorphisms of the *FTO*, *TMEM18*, *NRXN3*, *MC4R*, *SEC16B*, *GNPDA2*, *TNNI3K*, *QPCTL*, and *BDNF* genes in 7,334 (63.4%) patients, indicating an association between polymorphisms of these genes and obesity [9].

M. C. Y. Ng et al. studied the association between single-nucleotide polymorphisms of the *MC4R* gene

and obesity in a multicentric study involving 8,860 patients. It was determined that the *MC4R* gene is a codon for melanocortin receptor proteins, which are agonists of leptin, a hormone that acts as a regulator in the circuit of humoral regulation of hunger and satiety. As a result, 59.1% (5,236) of obese patients demonstrated an association between the detection of *MC4R* gene polymorphisms and obesity [12].

M. Bandstein et al. identified 7 single-nucleotide polymorphisms: *PTBP2*, *NUDT3*, *TEAP2B*, *ZNF608*, *MAP2K5*, *GNPDA2*, and *MTCH2* associated with obesity in 238 obese patients who underwent laparoscopic gastric bypass and found an 11% higher percentage of excess body weight loss (%EWL) in patients who had at least one of the seven single-nucleotide polymorphisms compared to patients who did not have *SNPs* in the indicated genes in their genome [3].

S. Z. Lutz et al. identified a correlation between the presence in the genome of obese patients of single nucleotide polymorphisms (*SNPs*) *rs2235543*, *rs12565406*, and *rs4844880* of the *HSD11B1* gene, which is a regulator of fat metabolism in liver cells) and non-alcoholic fatty liver disease in obese patients ( $r=0.64$ ) [11].

Thus, there is a certain relationship between the detection of gene polymorphisms, namely *SNP rs571312* of the *MC4R* gene and *SNP rs3810291* of the *TMEM160* gene, and the occurrence of obesity, regardless of gender and race. However, the relationship between these polymorphisms and obesity treatment outcomes has not yet been investigated and is extremely relevant. Therefore, this study aimed to determine the association between the *rs571312 MC4R* and *SNP rs3810291 TMEM160* gene polymorphisms and obesity treatment outcomes.

**OBJECTIVE** – to determine the association between the *MC4R SNP rs571312* and *SNP rs3810291 TMEM160* genes and the results of metabolic surgery.

## Materials and methods

The study method is a prospective, observational, monocentric cohort study conducted at the Department of General Surgery No2 of Bogomolets National Medical University.

A total of 112 patients were included in the study (clinical characteristics of the patients are presented in Table 1). All patients had indications for surgical treatment determined by International Federation for the Surgery and Other Therapies for Obesity (IFSO), namely body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup> regardless of the presence and severity of comorbidities or BMI 30.0–34.99 kg/m<sup>2</sup> and the presence of concomitant comorbidities. Patients included in the study were offered metabolic surgery. 53 patients who agreed to undergo the bariatric procedure were included in the main group. 59 patients who refused surgical treatment and underwent conservative treatment formed the control group. The study result was evaluated one year after the start of treatment. The main group underwent bariatric interventions, including laparoscopic gastric bypass ( $n=20$ ; 37.7%) and laparoscopic sleeve gastrectomy ( $n=17$ ; 32.2%). Patients with BMI  $\geq 50$  kg/m<sup>2</sup> ( $n=16$ ; 30.1%) had a two-stage surgical treatment. The first stage involved placing an intragastric balloon for 6 months, followed by gastric bypass within 14 days after balloon removal. The final result was assessed 12 months later. The control group consisted of 59 obese patients treated conservatively, namely with diet therapy, psychological support sessions, lifestyle correction, and dosed physical activity.

Before treatment, both groups underwent anthropometric measurements, routine general clinical observations, and analysis of buccal epithelium scrapings. Genetic research included DNA collection, isolation, and genotyping. DNA isolation was performed using reagents from the DNA kit (NeoPrep DNA, Ukraine). The manipulations were

Table 1. Clinical characteristics of the patients

Parameter	All the patients (n = 112)	Main group (n = 53)	Control group (n = 59)
Age, years	48 ± 9 (27–68)	48 ± 9 (23–68)	49 ± 10 (29–67)*
Body mass, kg	144.8 ± 15.7 (110.1–210.2)	148.0 ± 18.4 (110.1–210.2)	141.8 ± 12.2 (117.2–172.2)*
Height, cm	166 ± 13 (150–188)	165 ± 12 (152–188)	166 ± 13 (150–185)
Initial BMI, kg/m <sup>2</sup>	45.1 ± 6.1 (35.2–75.3)	48.6 ± 7.4 (35.2–75.3)	41.6 ± 3.1 (35.5–50.5)*
Ideal body mass, kg	62.2 ± 7.2 (51.5–74.5)	62.6 ± 7.1 (52.8–73.3)	61.2 ± 6.8 (51.1–74.5)*
Excess weight, kg	100.2 ± 19.0 (65.9–144.6)	101.5 ± 22.3 (70.5–144.6)	99.8 ± 18.5 (62.3–132.7)*

Note. The difference between the main and the control groups for all parameters is statistically insignificant ( $p > 0.05$ ).

\* In one or both groups, the data distribution differed from normal; the analysis was performed using the Wilcoxon T-test.

carried out in accordance with the protocol and step-by-step instructions provided with the kit.

All DNA samples were genotyped using allelic discrimination analysis on a Fast Real-Time PCR device (System 7500, USA) using TaqMan probes. For the isolation of *SNP rs571312 MC4R* and *SNP rs3810291 TMEM160*, pre-assembled TaqMan® genotype assays (Applied Biosystems, USA) were used.

To assess treatment outcomes, BMI parameters and the percentage of excess weight loss (%EWL) were used.

## Results

Before treatment, the main group had an average BMI of  $48.6 \pm 20.1$  kg/m<sup>2</sup>, while the control group had an average BMI of  $41.6 \pm 16.0$  kg/m<sup>2</sup>. After treatment, the average BMI in the main group reduced to  $29.5 \pm 5.4$  kg/m<sup>2</sup>, but in the control group it decreased insignificantly to  $40.2 \pm 13.8$  kg/m<sup>2</sup> (Table 2).

After 12 months of observation, the main group's average %EWL was  $59.21\% \pm 23\%$ . The highest %EWL was 77.2%, while the lowest %EWL was 49.9%. The control group had a significantly lower average %EWL –  $9.92 \pm 7.25\%$ . The interval between the highest and lowest %EWL was 19.45% and 2.2%, respectively. The average %EWL in obese patients varied depending on the surgical treatment method used. Patients who underwent Roux-en-Y gastric bypass had the highest average %EWL –  $69.71 \pm 20.0\%$ , while those who underwent sleeve gastrectomy had an average %EWL of

$51.57 \pm 5.9\%$ . After two-stage surgical treatment, patients had an average %EWL of  $51.7 \pm 7.92\%$ .

During genotyping analysis, we revealed the distribution of single-nucleotide polymorphisms *rs571312* of the *MC4R* gene and *rs3810291* of the *TMEM160* gene in the main and control groups.

The distribution of results by the presence of polymorphisms of the genes studied had the following characteristics. Among all patients included in the study (n = 112), the studied single-nucleotide polymorphisms were detected in 23.2% (n = 26), and the remaining 76.8% (n = 86) of patients did not have *SNP rs571312 MC4R* and *SNP rs3810291 TMEM160* in the studied samples. The distribution of single-nucleotide polymorphism detection by patient groups is presented as follows. The *rs571312 MC4R* polymorphism was detected more often in the main group – 19.5% (n = 10, where n is the number of patients) than in the control group – 14.6% (n = 8) (p = 0.007). The *rs3810291 TMEM160* polymorphism was detected more often in the main group – 9.75% (n = 5) than in the control group – 5% (n = 3), (p < 0.01). The presence of both polymorphisms was found only in the main group – 7.3% (n = 3) (Table 3).

The distribution of genotype dominance was significant (Fig. 1). The G/G genotype of the *SNP rs571312* polymorphism of the *MC4R* gene was detected in 15 (83.4%) patients with detected polymorphisms (p ≤ 0.01). The T/G genotype of the *SNP rs571312* polymorphism of the *MC4R* gene was detected in 3 (16.6%) individuals out of all patients in whom this polymorphism was observed

Table 2. **BMI dynamics in both groups depending on the treatment method, kg/m<sup>2</sup>**

Treatment method	Before treatment	After treatment	p
Roux-en-Y Gastric bypass	47.8 ± 10.1 (35.2–75.3)	28.5 ± 6.2 (26.2–30.1)	< 0.001
Sleeve gastrectomy	42.2 ± 7.4 (35.4–48.6)	30.1 ± 5.5 (29.2–31.0)	< 0.001
Intragastric balloon + RYGB	52.2 ± 6.4 (50.1–54.4)	28.3 ± 6.0 (26.1–30.5)	< 0.001
BMI in the main group	48.6 ± 20.1 (35.2–75.3)	29.5 ± 5.4 (26.1–31.0)	< 0.001
Conservative treatment	43.6 ± 16.2 (35.5–50.5)	40.2 ± 13.8 (33.4–47.0)	0.06

Table 3. **Distribution of single nucleotide polymorphism detection by patient groups**

Group	SNP rs571312 MC4R	SNP rs3810291 TMEM 160	Dual polymorphism presence	Polymorphism absence	p
Main (n = 53)	10 (19.5%)	5 (9.75%)	3 (7.3%)*	38 (70.75%)	0.007
Control (n = 59)	8 (14.6%)	3 (5.0%)	0	48 (82.97%)	< 0.01

Note. \* n = 3 among patients in whom both polymorphisms were detected (n = 26).

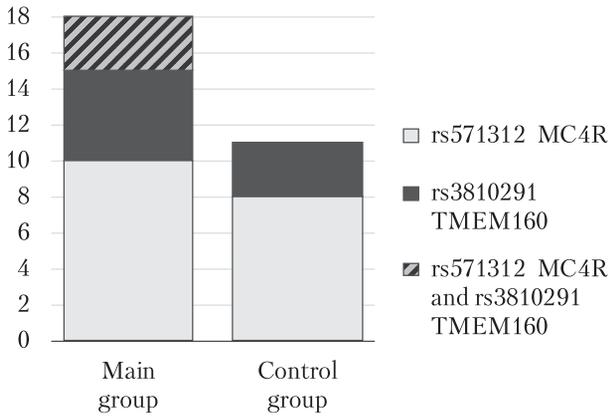


Figure 1. Distribution into study groups depending on the available gene polymorphism

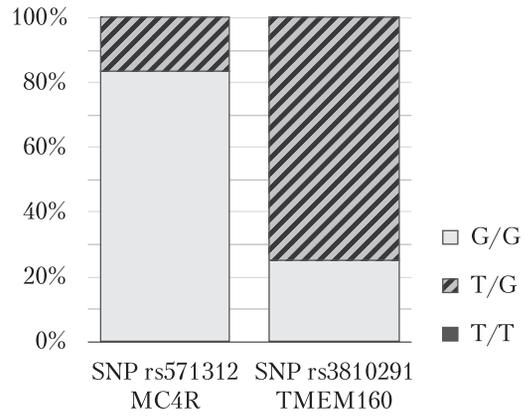


Figure 2. Distribution of the genetic dominance

( $p=0.0087$ ), and has no statistical significance. The T/T genotype was not detected in any of the patients. The G/G genotype of the *SNP rs3810291* polymorphism of the *TMEM160* gene was detected in 2 patients (25%) out of all identified carriers of this polymorphism, and has no statistical significance ( $p=0.0077$ ). The T/G genotype of the *SNP rs3810291* of the *TMEM160* gene was detected in 6 carriers of this polymorphism (75%) ( $p \leq 0.01$ ). The T/T genotype was not detected in any of the patients (Fig. 2).

During the statistical processing of the obtained data by the rank correlation method, no relationship was found between the degree of gene dominance and the effectiveness of bariatric procedures ( $r=0.112$ ). Detection of the polymorphism *rs571312* of the *MC4R* gene and *rs3810291* of the *TMEM160* gene is strongly correlated ( $r=0.467$ ;  $p \leq 0.05$ ) with the effectiveness of surgical treatment of obesity, regardless of the degree of their genetic dominance.

In the main group, patients with single-nucleotide polymorphisms in their genome that were the subject of this research had an average %EWL of  $60.47 \pm 3.4\%$  and a decrease in BMI by  $40.4 \pm 15.4\%$  compared to the initial one 12 months after surgery. In the control group, such patients demonstrated a significantly lower average %EWL –  $11.5 \pm 1.5\%$  – and a decrease in BMI by  $7.8 \pm 2.1\%$  after 12 months of conservative therapy, which was not statistically significant.

Treatment outcomes were distributed by patient group as follows: average %EWL, BMI decrease, and the presence of single-nucleotide polymorphisms of the genes *rs571312 MC4R* and *rs3810291 TMEM160*. In the main group, patients with none of the studied SNPs ( $n=38$ ) had an average treatment efficacy index for %EWL of  $52.9 \pm 2.7\%$  and a BMI decrease of  $33.3 \pm 9.8\%$  12 months after treatment. However, patients in the control group ( $n=48$ ) achieved a %EWL of  $10.2 \pm 1.1\%$  and a BMI decrease of  $7.5 \pm 1.1\%$  after conservative therapy. In the main group, patients with the *SNP rs571312*

Table 4. Treatment outcomes by average percentage of excess weight loss, BMI reduction, depending on gene polymorphisms

Gene polymorphism	Main group		Control group	
	%EWL, %	BMI decrease, %	%EWL, %	BMI decrease, %
No SNP	$52.9 \pm 2.7$	$33.3 \pm 9.8$	$10.2 \pm 1.1$	$7.5 \pm 1.1$
SNP rs571312 MC4R	$55.4 \pm 0.8$	$47.5 \pm 12.2$	$9.96 \pm 1.25$	$8.1 \pm 1.4$
SNP rs3810291 TMEM160	$55.7 \pm 1.4$	$45.5 \pm 8.5$	$10.5 \pm 1.3$	$9.1 \pm 1.5$
Dual SNP presence	$68.4 \pm 4.2$	$50.1 \pm 10.2$	0	0
p	$\leq 0.05^*$		$< 0.01^*$	

Note. \* In one or both groups, the data distribution differs from normal; a comparison was performed using the Wilcoxon T-test. Comparison was performed between patients of the main and control groups.

*MC4R* (n = 10) had an average treatment efficacy index for %EWL of  $55.4 \pm 0.8\%$  and a BMI decrease of  $47.5 \pm 12.2\%$  after treatment. In the main group, patients with *SNP rs3810291 TMEM160* (n = 5) demonstrated an average %EWL of  $55.74 \pm 1.4$  and a BMI decrease of  $45.5 \pm 8.5\%$ . Patients with both studied gene polymorphisms had the highest average treatment efficacy index for %EWL of  $68.4 \pm 4.2\%$  and a BMI decrease of  $50.1 \pm 10.2\%$ . In the control group, all obese patients with the studied gene polymorphisms had a low average treatment efficacy for %EWL of  $11.5 \pm 1.5\%$  and an insignificant BMI decrease of  $7.5 \pm 1.05\%$ . Patients with *SNP rs571312 MC4R* (n = 8) had %EWL indicators of  $9.96 \pm 1.25\%$  and a BMI decrease of  $8.1 \pm 1.4\%$ . Patients with *SNP rs3810291 TMEM160* (n = 3) demonstrated an average %EWL of  $10.5 \pm 1.3\%$  and a BMI decrease of  $9.1 \pm 1.5\%$  after treatment. In the control group, no patients had both studied gene polymorphisms (Table 4).

Statistical analysis using the method of linear correlation revealed a positive correlation ( $r = 0.467$ ;  $p \leq 0.05$ ) between the detection of polymorphisms *rs571312* of the *MC4R* gene and *rs3810291* of the *TMEM160* gene and treatment efficacy for %EWL, and a weak correlation ( $r = 0.191$ ) between the absence of the studied polymorphisms in the sample and treatment efficacy for %EWL. A correlation was also found between the detection of *SNP rs571312* of the *MC4R* gene in the study group and the effectiveness of the treatment by %EWL ( $r = 0.443$ ). A correlation was found between the presence of *SNP rs3810291* of the *TMEM160* gene in the main group and treatment efficacy for %EWL ( $r = 0.5$ ). A strong correlation was noted between the presence of both studied polymorphisms in the main group and treatment efficacy for %EWL ( $r = 0.608$ ). The presence of the studied polymorphisms in the control group does not affect treatment efficacy for %EWL ( $r = 0.097$ ).

During the statistical processing of the obtained data using the rank correlation method, no relationship was found between the degree of gene dominance and the effectiveness of bariatric procedures ( $r = 0.112$ ;  $p \leq 0.05$ ), which indicates that the detection of polymorphisms *rs571312* of the *MC4R* gene and *rs3810291* of the *TMEM160* gene is strongly correlated ( $r = 0.467$ ;  $p \leq 0.05$ ) with the effectiveness of surgical treatment of obesity, regardless of the degree of their genetic dominance.

## Discussion

During the course of the study, some patterns were identified. The polymorphisms that were the subject of this research, including *SNP rs571312* of the

*MC4R* gene and *SNP rs3810291* of the *TMEM160* gene, were investigated to assess their association with metabolic surgery outcomes.

P. K. Thanos et al. in their study analyzed the genetic risk score in patients who underwent bariatric surgery, with the aim of using it as a predictive factor for weight loss parameters one year after surgery. Thirty patients were assessed using the Genetic Obesity Severity Scale (GARS), which analyzes neurogenetic polymorphisms associated with food addiction. Genetic and psychosocial data collected before surgery were compared with weight loss data, including weight change, BMI, and %EWL [16].

I. Ntalla et al. found that several genetic loci were associated with BMI and obesity. The aim of the study was to examine the impact of known loci associated with BMI in adults. For this purpose, 34 variants were selected for study among 7,787 adolescents of Greek origin. The cumulative impact of the variants was assessed by calculating a genetic risk score (GRS-34) for each participant. Variants at the *FTO*, *TMEM160*, *FAIM2*, *RB1*, *ZNF608*, and *QPCTL* loci demonstrated nominal evidence of association with BMI and/or risk of overweight ( $p < 0.05$ ) [15].

The results showed correlations between the «risk» alleles of individual genes, weight data after 1 year, and psychosocial indicators. Spearman correlation showed that the *OPRM1* gene polymorphism (*rs1799971*) had a significant negative correlation with weight at 1 year ( $r_s = -0.4477$ ,  $p < 0.01$ ) and BMI ( $r_s = -0.4477$ ,  $p < 0.05$ ). In addition, the risk allele of the *DRD2* gene (*rs1800497*) had a negative correlation with BMI at 1 year ( $r_s = -0.4927$ ,  $p < 0.05$ ), indicating that the presence of one copy of the «risk» allele was associated with lower BMI. However, this allele had a positive correlation with weight change ( $r_s = 0.4077$ ,  $p < 0.05$ ) and %EWL ( $r_s = 0.5521$ ,  $p < 0.05$ ) at 1 year after surgery. This suggests that people with a higher genetic risk of obesity are more likely to have better outcomes in obesity treatment, especially in the case of the *DRD2* polymorphism.

Therefore, research on the association between genetic factors and surgical treatment efficacy for obesity is extremely relevant.

## Conclusions

An association was found in the studied group of patients between the metabolic surgery outcomes and the presence of polymorphism of the genes *rs571312 MC4R* ( $r = 0.465$ ); *rs3810291 TMEM160* ( $r = 0.55$ ); and the presence of both polymorphisms ( $r = 0.622$ ;  $p \leq 0.05$ ).

The degree of gene dominance has no relationship with bariatric surgery outcomes ( $r = 0.112$ ).

The detection of polymorphisms *rs571312* of the *MC4R* gene and *rs3810291* of the *TMEM160* gene is associated ( $r = 0.467$ ;  $p \leq 0.05$ ) with the metabolic surgery outcomes, regardless of the degree of their genetic dominance.

## DECLARATION OF INTERESTS

The author declares no competing financial interests.

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# Асоціація одонуклеотидних поліморфізмів генів rs571312 MC4R та rs3810291 TMEM160 з результатами метаболічної хірургії

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**Мета** — визначити зв'язок генів *SNP rs571312 MC4R* та *SNP rs3810291 TMEM160* з результатами метаболічної хірургії.

**Матеріали та методи.** Проспективне обсерваційне когортне моноцентричне дослідження проведено на кафедрі загальної хірургії № 2 Національного медичного університету імені О. О. Богомольця за участю 112 пацієнтів із показаннями до хірургічного лікування, яких розділено на дві групи. Основну групу становили 53 пацієнти, які погодилися на бариатричну процедуру, контрольну — 59 пацієнтів, які відмовилися від хірургічного лікування та отримали консервативне лікування. Результати оцінювали через рік після початку лікування. В основній групі було проведено такі бариатричні втручання: лапароскопічне шунтування шлунка, лапароскопічну рукавну резекцію шлунка, пацієнтам з індексом маси тіла  $\geq 50$  кг/м<sup>2</sup> — двохетапне хірургічне лікування (установлення внутрішньошлункового балона на 6 міс і шунтування шлунка протягом 14 днів після видалення балона). До початку лікування проводили антропометричні обстеження та дослідження зішкрібків букального епітелію. Генетичні дослідження передбачали виділення ДНК, а також генотипування для визначення поліморфізмів генів *rs571312 MC4R* і *rs3810291 TMEM160*.

**Результати.** Виявлено кореляцію між позитивними результатами бариатричних процедур і наявністю поліморфізмів генів *rs571312 MC4R* та *rs3810291 TMEM160* ( $r = 0,622$ ,  $p \geq 0,001$ ). Ступінь домінування генів не мав зв'язку з результатами бариатричної хірургії.

**Висновки.** У досліджуваній групі пацієнтів виявлено зв'язок між ефективністю проведених бариатричних процедур та наявністю поліморфізмів генів *rs571312 MC4R* ( $r=0,465$ ); *rs3810291 TMEM160* ( $r=0,55$ ); наявністю обох поліморфізмів ( $r=0,622$ ). Виявлення досліджуваних поліморфізмів пов'язане з результатами бариатричної хірургії, незалежно від ступеня їх генетичної домінантності ( $r=0,467$ ).

**Ключові слова:** лікування, втрачена надлишкова маса тіла, ген, поліморфізми.

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# Palliative laparoscopic hepaticojejunostomy: a single-centre prospective series

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**OBJECTIVE** – to assess the safety and efficacy of palliative laparoscopic hepaticojejunostomy in the management of distal bile duct obstruction.

**MATERIALS AND METHODS.** This single-centre prospective cohort study included 22 patients with inoperable tumour-related distal bile duct obstruction. Most participants were men ( $n=17$  (77.3%)) with a mean age of  $66.7 \pm 9.6$  years. Bile duct obstruction was caused by pancreatic head adenocarcinoma ( $n=18$ ), Vater's papilla adenocarcinoma ( $n=2$ ), cholangiocarcinoma ( $n=1$ ), and duodenal melanoma ( $n=1$ ). A total of 13 (59%) patients had a history of percutaneous transhepatic cholangiostomy, and 3 (13.6%) had unsuccessful endobiliary stenting attempts. All patients underwent palliative laparoscopic procedures, including Roux-en-Y hepaticojejunostomy (side-to-side or end-to-side) and entero-enteric anastomosis. The primary endpoint was biliodigestive anastomosis patency without reintervention until death or end of observation. Secondary endpoints included 30-day mortality, complications classified according to the Clavien–Dindo system, bile leakage defined by the International Study Group of Liver Surgery (ISGLS), length of hospitalization, time to resumption of enteral nutrition, and overall survival.

**RESULTS.** The average duration of the operation was  $354.5 \pm 110.1$  minutes with an average blood loss of  $58.3 \pm 43.1$  ml. Complications occurred in 8 (37.5%) patients, including bile leakage in 7 cases (ISGLS B – in 6, ISGLS C – in 1 with biliary peritonitis), and one Clavien–Dindo IIIb event (torsion of the small intestine around the entero-enteric anastomosis). No cases of wound infection or postoperative bleeding were recorded. The average length of hospitalization was  $10.3 \pm 5.3$  days (range, 4–24 days). Most patients ( $n=19$  (86.3%)) were mobilized on the 1st postoperative day, and oral nutrition was initiated on the 2nd day. During the follow-up period (median – 8.5 months, IQR 6.8–12.0), no recurrences of bile duct obstruction or need for repeated drainage were observed. Two episodes of acute cholangitis were managed conservatively. No deaths occurred within 30 days postoperatively.

**CONCLUSIONS.** Laparoscopic hepaticojejunostomy appears to be a feasible and effective palliative procedure for distal biliary obstruction in selected patients. This approach maintains anastomotic patency without the need for reintervention, is associated with low blood loss, and enables rapid resumption of enteral nutrition. The complication profile is primarily characterized by manageable bile leakage, with rare Clavien–Dindo grade IIIb adverse events. This method may be considered as an alternative to stenting when stenting is not possible or has failed, or in patients with a life expectancy  $> 6$  months who are scheduled for chemotherapy.

## KEYWORDS

laparoscopic hepaticojejunostomy, palliative surgery, malignant bile duct obstruction, pancreatic head cancer, biliodigestive anastomosis, bile leakage, Clavien–Dindo classification, ISGLS, endobiliary stenting, internal biliary drainage.

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Pancreatic head cancer is among the most aggressive gastrointestinal malignancies and is frequently diagnosed at an inoperable stage due to local invasion or distant metastasis. In these cases, the primary objective is palliation of mechanical jaundice, which substantially reduces quality of life and causes such

symptoms as pruritus, cholangitis, coagulopathy, and liver failure [1, 24].

Endoscopic stenting via endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound-guided biliary drainage (EUS-BD), and percutaneous transhepatic biliary drainage (PTBD)

are the primary palliative approaches for managing biliary obstruction. These interventions rapidly reduce bilirubin levels and shorten hospitalization, but are limited by risks such as reobstruction, cholangitis, and the need for repeated procedures [3, 13, 20]. The European Society of Gastrointestinal Endoscopy (ESGE) and American Society for Gastrointestinal Endoscopy (ASGE) recommend that the choice between endoscopic and surgical drainage should be guided by the patient's expected survival and functional status [2, 6].

For patients with preserved general health and functional reserves, surgical biliodigestive anastomosis remains a viable alternative, offering longer-term internal biliary drainage and a lower rate of reintervention compared to stenting [15, 24]. Recent studies demonstrate that palliative surgical interventions can be effective even in resource-limited settings. For example, in the study by FL Mutombo *et al.* (2025) involving 53 patients with inoperable pancreatic cancer, the failure rate of palliative operations following biliodigestive bypass was 22.6%, and most patients were able to resume oral nutrition [15].

Advancements in minimally invasive technologies have expanded the possibilities for palliative interventions. Laparoscopic hepaticojejunostomy (LHJ) provides physiological drainage with reduced trauma, decreased blood loss, and shorter hospital stays. Recent analyses by R. Wu *et al.* (2025) and M. Masood *et al.* (2025) indicate that laparoscopic techniques are associated with acceptable complication rates and sustained long-term patency of the anastomosis in cases with palliative indications [14, 24].

The selection of an optimal drainage strategy, whether endoscopic or surgical, remains a topic of debate. Consequently, evaluating the safety, efficacy, and durability of laparoscopic interventions for palliative management of inoperable pancreaticobiliary cancer with distal bile duct obstruction is of ongoing importance.

**OBJECTIVE** – to assess the safety and efficacy of palliative laparoscopic hepaticojejunostomy in the management of distal bile duct obstruction.

## Materials and methods

This single-centre prospective cohort study included 22 patients with inoperable tumour-related distal bile duct obstruction. Most participants were men ( $n = 17$  (77.3%)) with a mean age of  $66.7 \pm 9.6$  years.

### Inclusion criteria

- Patients presenting with malignant obstructive jaundice characterized by a distal biliary obstruction;

- Absence of carcinomatosis or significant ascites;
- Satisfactory overall health status permitting laparoscopic intervention;
- For patients with prior percutaneous cholangiostomy, the presence of asthenia resulting from bile loss and a sustained preference to avoid external drainage;
- Provision of written informed consent for surgical intervention.

### Exclusion criteria:

- Presence of severe hypoalbuminemia or decompensated systemic conditions;
- Anatomical unsuitability, such as tumour masses or metastatic lymph nodes in the hepatoduodenal ligament region;
- Marked venous collateralization in the hepatoduodenal ligament secondary to tumour invasion of the portal vein.

Bile duct obstruction was caused by pancreatic head adenocarcinoma ( $n = 18$ ), Vater's papilla adenocarcinoma ( $n = 2$ ), cholangiocarcinoma ( $n = 1$ ), and duodenal melanoma ( $n = 1$ ).

A total of 13 (59%) patients had a history of percutaneous transhepatic cholangiostomy, and 3 (13.6%) had unsuccessful endobiliary stenting attempts.

All patients underwent palliative laparoscopic procedures, including Roux-en-Y hepaticojejunostomy (RYHJ) (side-to-side or end-to-side) and entero-enteric anastomosis (EEA).

**The laparoscopic surgical technique involved** the use of combined anesthesia, specifically endotracheal anesthesia in conjunction with epidural blockade. The patient was positioned supine with legs apart on the operating table. For procedures in the upper abdominal cavity, such as cholecystectomy and hepaticojejunostomy, the table was adjusted to the Fowler position. During interventions below the mesocolon, including excision of the Roux loop and creation of a jejunojunctional anastomosis, the table was placed in a moderate Trendelenburg position.

A total of six trocars were used (see figure): two 10-mm trocars for the camera positioned at the umbilicus and as an auxiliary port 5–6 cm cranial and 4–5 cm to the right of the umbilicus; one 12-mm trocar placed along the lateral edge of the left rectus abdominis muscle at the umbilical level; and one 5-mm trocar in the epigastrium, 1–2 cm to the left of the midline at the level of the round ligament of the liver, approximately 5–6 cm below the xiphoid process, designated for the needle holder. A 30° laparoscope was employed. The liver was elevated using a Nathanson retractor positioned in the right costoxiphoid angle.

The Roux-en-Y loop was created by transecting the small intestine 35–40 cm distal to the ligament of Treitz using a 45 mm stapler, followed by division of the mesentery to its root. In cases of a short mesentery, when additional length was required, the second or third jejunal artery was divided at the mesenteric root while preserving collateral blood flow. The Roux-en-Y loop was positioned retrocolically, to the right of the midcolonic vessels and duodenum, or, when technically necessary due to tumour size, through the lesser omentum.

In 18 of 22 cases, the hepaticojejunostomy was formed side-to-side with a diameter of 7–10 mm, without circular mobilization or transection of the common bile duct. A 15–20 mm segment of the anterior wall of the common bile duct was used. The anastomosis was completed using either knotted or continuous sutures with 5/0 or 4/0 monofilament absorbable material; in three patients, a V-lock suture (Opusmed, 15cm, 4/0 cutting, 17 mm, 1/2 circle round) was employed.

The jejuno-jejunal anastomosis was created in an isoperistaltic fashion using a 45 mm × 3.5 mm stapler. The mesenteric defect, including the Petersen space, was left unclosed.

When feasible, a biopsy was obtained from the liver (8 cases). If this was not possible, a laparoscopic trephine biopsy of the pancreatic head was performed (6 cases), although 3 of these were uninformative. Selection of the optimal access for the latter procedure required a detailed analysis of preoperative computed tomography data.

After completion of RYHJ, a stapled EEA was initiated. The enterotomy was closed with a double-row continuous suture, primarily using V-lock 3/0 suture material.

Percutaneous cholangiostomy, previously placed in 13 patients (59 %) for severe mechanical jaundice, was closed on postoperative day 3 and removed on days 4 or 5 following laparoscopic surgery.

A video of the procedure is available at: <https://youtu.be/S0C93hF6t2A?si=pd-FfbkDdoYG6jj9>

The study endpoints included a primary endpoint of anastomotic patency without reinterventions and secondary endpoints of 30-day mortality, complications classified according to the Clavien–Dindo system [4], bile leakage defined by the International Study Group of Liver Surgery (ISGLS) [22], length of hospital stay, time to resumption of enteral nutrition, and overall survival.

Statistical analysis was conducted using IBM SPSS Statistics (version 22.0). Quantitative variables were described using the arithmetic mean (M), standard deviation (SD), and range (minimum to maximum). For variables not normally distributed,

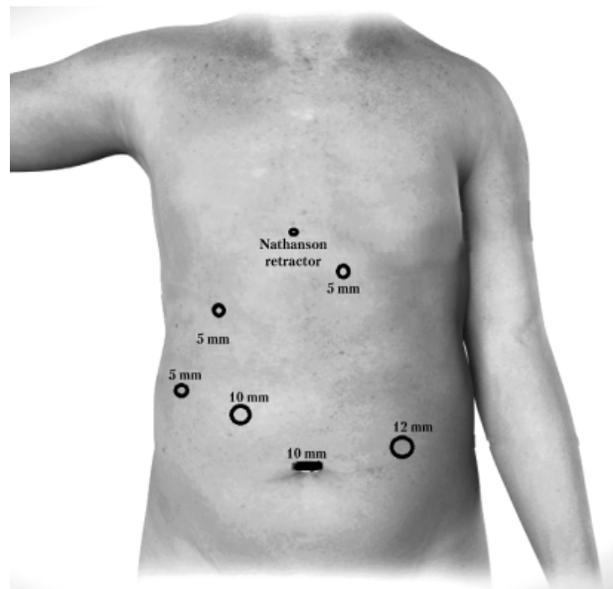


Figure. **Diagram of trocar placement**

data were presented as median (Me) and interquartile range (IQR, 25th–75th percentiles).

Normality of data distribution was assessed using the Shapiro–Wilk test. Comparisons of pre- and postoperative indicators were performed using the paired Student's t-test for normally distributed data or the Wilcoxon test for non-parametric data. Categorical variables were reported as absolute numbers and percentages.

A p-value of <0.05 was considered statistically significant.

## Results

**Intraoperative indicators.** All surgical procedures were performed laparoscopically, and no cases required conversion to open surgery. In 12 patients (54.5 %), the anastomosis was created using a continuous suture, while in 10 patients (45.5 %), a knotted suture was utilized. The mean operative time was  $354.5 \pm 110.1$  minutes (range: 140 to 670 minutes), and the mean intraoperative blood loss was  $58 \pm 43$  ml (range: 30–120 ml). In three cases of subcompensated duodenal stenosis, a Roux-en-Y gastroenterostomy was additionally performed anterior to the colon, without the formation of a Brownian fistula.

Following surgery, most patients ( $n = 19$ ; 86.3 %) were transferred to the surgical ward and mobilized the day after surgery. Oral nutrition with liquid food was commenced 24 hours postoperatively. In three patients, oral nutrition was initiated one day later.

Postoperative bilirubin levels demonstrated a significant decrease. Prior to surgery, the mean total bilirubin concentration was  $79.3 \pm 71.1$   $\mu\text{mol/l}$

(range: 10.0 to 260.0  $\mu\text{mol/l}$ ), which declined to  $34.1 \pm 35.3$   $\mu\text{mol/l}$  before hospital discharge ( $p = 0.011$ ). Additionally, patients with prior percutaneous transhepatic cholangiostomy experienced a reduction in bilirubin levels from  $54.8 \pm 43.4$  to  $25.0 \pm 13.4$   $\mu\text{mol/l}$  ( $p = 0.026$ ), suggesting that HJ provides more favourable conditions for bile outflow compared to percutaneous transhepatic cholangiostomy. Overall, the mean total bilirubin level decreased by  $46.1\% \pm 5.1\%$  (range: 90.6% to 0.0%).

Postoperative complications were observed in 8 patients (37.5%), including bile leakage in 7 patients (31.8%) and torsion of the small intestine around the EEA in 1 patient (4.5%).

Among patients with bile leakage, 6 cases were classified as ISGLS B and were managed with drainage or observation without further intervention. One case was classified as ISGLS C (Clavien–Dindo IIIb) and presented with biliary peritonitis due to partial HJ insufficiency, necessitating laparotomy and debridement without intervention at the anastomosis (Table). Following abdominal cavity debridement and placement of drains to the anastomosis, the patient's condition stabilized, enteral nutrition was resumed, and bile leakage through the drains gradually decreased over the subsequent 12 days.

The mean duration of bile leakage was  $14.6 \pm 1.7$  days, ranging from 8 to 20 days.

A torsion of the small intestine involving the EEA (Clavien–Dindo IIIb) was managed surgically by untwisting the EEA during laparotomy.

No cases of wound infection or bleeding were observed. Patients with percutaneous transhepatic cholangiostomy underwent preoperative bile cultures with an antibioticogram. Standard antibiotic prophylaxis was administered (cefazolin 2 g or an alternative antibiotic based on sensitivity, 40 minutes before surgery and again 3 hours later), and antibiotics were discontinued postoperatively. Antibiotic therapy was required only in the case of peritonitis (one patient).

The mean duration of hospitalization was  $10.4 \pm 5.5$  days, with a range of 4 to 22 days. In the absence of bile leakage, patients were discharged between days 4 and 9, with a mean of  $7.1 \pm 1.3$  days, considering the complexity of home transfer. When bile leakage through drains was present, most patients in satisfactory condition were discharged home for observation, with an average duration of  $16.0 \pm 4.9$  days. Drains were removed on an outpatient basis after cessation of bile leakage.

During the observation period (median 8.5 months [IQR 6.8–12.0]), no recurrence of bile duct obstruction or need for repeated drainage was observed. Two episodes of acute cholangitis were recorded (after 50 days, one associated with chemotherapy),

Table. **Patient characteristics, operative course and follow-up outcomes**

Parameter	Value
Number of patients	22
Male/female	17/5
Age, years (M $\pm$ SD; range)	$66.8 \pm 10.5$ 50–86
Main disease (nosological structure)	
Adenocarcinoma of the head of the pancreas	18
Adenocarcinoma of the Vater's papilla	2
Cholangiocarcinoma	1
Duodenal melanoma	1
Reasons for inoperability	
Distant metastases	15
Locally advanced forms with substantial vascular involvement or invasion	7
Prior decompression of the biliary tract (percutaneous cholangiostomy)	13 (59.1%)
Interventions performed	
Laparoscopic hepaticojejunostomy	19
Hepaticojejunostomy + gastrojejunostomy	3
Liver biopsy (laparoscopic)	8
Percutaneous biopsy of the pancreatic head (of which uninformative)	6 (3)
Lymph node biopsy	1
Intraoperative indicators	
Duration of surgery, min (M $\pm$ SD; range)	$354.5 \pm 110.1$ 140–670
Blood loss volume, ml (M $\pm$ SD; range)	$58 \pm 43$ 30–120
Postoperative complications (overall)	8 (37.5%)
Clavien–Dindo IIIb	3 (13.6%)
Cholestasis, SGLS B/SGLS C	6/1
Bile leakage, days (M $\pm$ SD; range)	$14.6 \pm 1.7$ 8–20
Torsion of the jejunio-jejunal anastomosis	1 (laparotomy, repeat EEA)
Biliary peritonitis	1 (laparotomy, debridement, drainage)
Wound infection/intra-abdominal collections	0
Postoperative hospital stay, days (M $\pm$ SD; range)	$10.3 \pm 5.3$ 4–24
Recurrence of biliary obstruction or repeated percutaneous transhepatic cholangiostomy during follow-up (months [IQR])	Not reported (8.5 [6.8–12.0])
30-day mortality, %	0

both managed conservatively without intervention on the anastomosis. No deaths occurred within 30 days (see Table). Prolonged hospitalization and extended bile leakage were primarily observed in elderly patients, during the initial phase of technique development, and in one patient with liver failure due to prior chemotherapy and prolonged jaundice. These factors may be partially preventable.

## Discussion

Hepaticojejunostomy is commonly used as an effective method for internal drainage of the biliary tract in cases of malignant obstruction of the distal common bile duct. This procedure is indicated following unsuccessful endoscopic retrograde cholangiopancreatography, biliary obturation, stent migration, intraoperative identification of an inoperable tumour, or after prior external drainage, with the primary aim of improving patient quality of life [5, 17, 18, 21].

In the past two decades, reports documenting the successful use of laparoscopic HJ in patients with inoperable distal biliary obstruction have increased [8, 10, 23]. This technique represents a minimally invasive alternative to open HJ or endoscopic stenting.

The findings indicate that laparoscopic hepaticojejunostomy is a safe and highly effective approach for palliative restoration of biliary outflow in patients with inoperable distal biliary obstruction of malignant origin. The lack of conversions, mortality, and recurrent obstruction aligns with contemporary studies that report a high success rate for laparoscopic HJ and a low incidence of severe complications [5, 10].

In this series, bile leakage (31.8%) did not result in significant clinical manifestations and was primarily managed conservatively. These findings align with those of FL Mutombo *et al.* (2025), who reported an overall complication rate of 38% and a mortality rate of 0% in 37 patients undergoing laparoscopic or open palliative bypass [15].

Compared with endoscopic stenting, LHJ provides a longer period of patency and a reduced need for reinterventions [11, 17, 21]. Cohort studies report that jaundice recurrence after self-expanding metal stents (SEMS) occurs in approximately 17–37% of patients within 3–6 months [16]. Plastic stents demonstrate a median patency of 3–6 months, which is associated with frequent reinterventions and recurrence of jaundice during this period [9]. In the present study, no recurrence of bile duct obstruction or requirement for re-drainage was observed during the follow-up period (median 8.5 months [IQR 6.8–12.0]). Furthermore, the laparoscopic approach reduces surgical trauma and lowers

the incidence of infections and bleeding compared with open surgery [8, 17].

The present findings are consistent with those of M. Masood *et al.* (2025), who reported in their review that laparoscopic palliative interventions for inoperable pancreatic cancer are safe and associated with lower complication rates and shorter hospital stays compared with open surgery [14].

GEM Rizzo *et al.* (2023) emphasize that when selecting between endoscopic and surgical palliative methods, consideration should be given to life expectancy, patient condition, and resource availability. The authors note that surgical biliodigestive anastomoses offer prolonged drainage, whereas endoscopic approaches are preferable for patients with limited survival prognosis [19].

From a technical perspective, side-to-side anastomosis has several advantages over end-to-side, including shorter operating time, reduced risk of bleeding and injury to the hepatoduodenal ligament, and a lower likelihood of ischemic stricture. Concerns regarding the development of blind sac syndrome (Sump syndrome) in Roux-en-Y LHJ are not supported by recent evidence. Contemporary publications report only isolated cases occurring 10 to 20 years after open procedures, which lack clinical significance in patients with malignant pathology [7, 12].

LHJ offers the combined benefits of minimal invasiveness and physiological internal drainage. The present study confirms its feasibility as a preferred method for patients with inoperable pancreatic head cancer who have an expected life expectancy exceeding 3 to 6 months.

Several limitations of our study should be considered when interpreting the results. First, the single-centre prospective design and relatively small sample size ( $n = 22$ ) reduce statistical power and limit the generalizability of our findings. Second, the absence of a control group, such as patients who underwent endoscopic or open palliative intervention, precludes direct comparison of the effectiveness of different methods. Third, the heterogeneity of the nosological composition (adenocarcinoma of the pancreatic head, adenocarcinoma of the Vater's papilla, cholangiocarcinoma, and duodenal melanoma) may influence outcomes, particularly survival and complication rates. Fourth, the median follow-up duration of 8.5 months is insufficient to assess long-term anastomotic patency and the occurrence of late complications, such as strictures or blind sac syndrome. Additionally, bile leakage and postoperative events were evaluated clinically, based on drain output, without routine use of control cholangiography or magnetic resonance cholangiopancreatography

(MRCP), which may have resulted in underestimation of minor leakage frequency.

To validate these findings, multicentre prospective studies with larger sample sizes, standardized patient selection criteria, and a unified protocol for assessing complications according to the Clavien–Dindo and ISGLS classifications are necessary. Future research should compare LHJ with endoscopic stenting and open palliative interventions in terms of quality of life, duration of anastomotic patency, reintervention rates, and overall survival. Additionally, the influence of technical variants of the anastomosis (side-by-side versus end-by-side) on the incidence of bile leakage and stricture formation warrants investigation. The combination of LHJ with laparoscopic gastroenterostomy should be examined separately, considering the potential for duodenal stenosis over time and evaluating the role of LHJ in comprehensive palliative treatment, including the early initiation of chemotherapy.

Expanding the sample size, standardizing the methodology, and extending the observation period will facilitate a more objective evaluation of the long-term efficacy and safety of LHJ.

## Conclusions

Laparoscopic hepaticojejunostomy represents a safe and effective approach for internal biliary drainage in patients with inoperable pancreatic head cancer following unsuccessful endobiliary stenting or external drainage.

In this study, the procedure was completed without conversions or fatalities. The incidence of serious complications (Clavien–Dindo i IIIb) was 13.6 %.

The anastomosis maintained complete patency of the biliary tract throughout the observation period, with no recurrence.

Laparoscopic hepaticojejunostomy enables the collection of histological material during a single intervention, thereby facilitating subsequent oncological management.

In selected patients without carcinomatosis or ascites and with adequate functional reserves, laparoscopic hepaticojejunostomy may be considered as an alternative to endoscopic stenting.

## DECLARATION OF INTERESTS

The Authors declare no conflict of interest.

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## AUTHORS CONTRIBUTIONS

O. V. Ivanko: conception and design, drafting the article; V. V. Skyba: critical revision of the article; A. V. Homan: acquisition of data, analysis and interpretation of data.

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## Паліативна лапароскопічна гепатикоєюностомія: одноцентрова проспективна серія

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**Мета** — оцінити безпечність та ефективність паліативної лапароскопічної гепатикоєюностомії при дистальному блокуванні жовчних протоків.

**Матеріали та методи.** В одноцентрове проспективне когортне дослідження було залучено 22 хворих із неоперабельним дистальним блоком жовчних протоків пухлинного генезу. Серед них переважали чоловіки (17 (77,3%)). Середній вік — (66,7±9,6) року. Причинами обструкції жовчних протоків були аденокарцинома головки підшлункової залози (n = 18), фатерового сосочка (n = 2), холангіокарцинома (n = 1), меланома дванадцятипалої кишки (n = 1). В анамнезі черезшкірну черезпечінкову холангіостомію проведено 13 (59%) хворим, невдалі спроби ендобілярного стентування — 3 (13,6%). Усім пацієнтам виконано паліативні операції з лапароскопічного доступу: гепатикоєюоанастомоз за типом бік-у-бік чи кінець у бік на Ру-петлі та ентеро-ентероанастомоз. Первинна кінцева точка — патентність (прохідність) біліодигестивного анастомозу без реінтервенцій до смерті/кінця спостереження, вторинні — 30-денна смертність, ускладнення за класифікацією Клав'єна — Діндо, жовчні витоки за ISGLS (Міжнародна дослідницька група з хірургії печінки), тривалість госпіталізації, термін відновлення ентерального харчування, загальна виживаність.

**Результати.** Середня тривалість операції — (354,5±110,1) хв, об'єм крововтрати — (58,3±43,1) мл. Ускладнення зареєстровано у 8 (37,5%) пацієнтів: жовчні витоки — у 7 (ISGLS B — у 6, ISGLS C — в 1 із жовчним перитонітом, Клав'єна — Діндо IIIb — в 1 (перекрут тонкої кишки навколо ентеро-ентероанастомозу). Інфекції ран/кровотечі після операції не зафіксовано. Середня тривалість госпіталізації — (10,3±5,3) доби (4—24 доби). Більшість пацієнтів (19 (86,3%)) активізовані в 1-шу добу, пероральне харчування розпочато з 2-ї доби. За період спостереження (медіана — 8,5 міс (IQR 6,8—12,0)) рецидивів обструкції жовчних протоків або необхідності повторного дренивання не спостерігали. Два епізоди гострого холангіту проліковано консервативно. Випадків смерті упродовж 30 днів не було.

**Висновки.** Лапароскопічна гепатикоєюностомія є здійсненою та ефективною паліативною операцією при дистальному блокуванні у відібраних пацієнтів: збережена прохідність анастомозу без реінтервенцій, низька крововтрата та швидке відновлення ентерального харчування. Профіль ускладнень зумовлений переважно керованими жовчаними витоками, небажані події IIIb рівня трапляються рідко. Метод можна розглядати як альтернативу стентуванню у випадках його неможливості/невдачі або за очікуваної тривалості життя > 6 міс із плановою хіміотерапією.

**Ключові слова:** лапароскопічна гепатикоєюностомія, паліативна хірургія, злаякісна обструкція жовчних протоків, рак головки підшлункової залози, біліодигестивний анастомоз, жовчні витоки, класифікація Клав'єна — Діндо, ISGLS, ендобілярне стентування, внутрішнє дренивання жовчних шляхів.

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# The role of minimally invasive diagnostic techniques in optimizing treatment strategies in patients with colorectal cancer

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**OBJECTIVE** – to improve staging accuracy and optimize therapeutic strategies in patients with colorectal cancer by performing minimally invasive diagnostic procedures, specifically diagnostic laparoscopy with peritoneal lavage and cytological examination, and mediastinoscopy with targeted lymph node biopsy, in cases where conventional imaging methods (computed tomography [CT], magnetic resonance imaging [MRI], positron emission tomography combined with computed tomography [PET-CT]) yield equivocal or inconclusive results.

**MATERIALS AND METHODS.** This ambispective (retrospective–prospective) study was conducted from 2023 to 2025 and included 37 patients with colorectal cancer who had inconclusive standard imaging results regarding distant metastases or peritoneal carcinomatosis. Patients were allocated into two groups: 22 patients with suspected peritoneal carcinomatosis underwent diagnostic laparoscopy with peritoneal lavage, peritoneal biopsy, and cytological analysis, while 15 patients with suspected mediastinal lymph node involvement underwent cervical mediastinoscopy with targeted lymph node biopsy. Diagnostic accuracy, the impact of findings on subsequent therapeutic management, and procedural safety were evaluated.

**RESULTS.** Peritoneal carcinomatosis was morphologically confirmed in 19 of 22 patients (86.4%), and metastatic involvement of mediastinal lymph nodes was confirmed in 11 of 15 patients (73.3%). Verification of the pathological process resulted in a change in therapeutic strategy for 29 of 37 patients (78.4%). Specifically, 27 patients (73.0%) received systemic chemotherapy, 7 patients (18.9%) underwent radical surgical procedures, 2 patients (5.4%) underwent palliative resection, and 1 patient (2.7%) declined further treatment. No serious intraoperative complications were observed. Minor postoperative events, including pain at the puncture site, subcutaneous emphysema, and transient fever, occurred in 8 patients (21.6%) and did not require additional treatment.

**CONCLUSIONS.** Incorporating diagnostic laparoscopy and mediastinoscopy into the colorectal cancer staging algorithm yields high diagnostic accuracy, supporting personalized treatment planning. The application of minimally invasive methods reduces unnecessary surgical interventions, shortens the time to initiation of systemic therapy, and may improve prognosis in patients with advanced disease.

## KEYWORDS

colorectal cancer, diagnostic laparoscopy, carcinomatosis, mediastinoscopy, staging, metastasis, NCCN.

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Colorectal cancer (CRC) is one of the most prevalent malignant neoplasms and a leading cause of cancer-related mortality worldwide [10]. Prognosis is closely linked to the stage at diagnosis. Early-stage detection is associated with improved survival rates and the potential for radical treatment, whereas distant metastases significantly reduce the likelihood of favourable outcomes [10]. The National Comprehensive Cancer Network (NCCN) guidelines for Colon and Rectal Cancer (version 2.2024) underscore the importance

of accurate staging in selecting optimal therapeutic strategies [1]. Digital imaging modalities, including computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography combined with computed tomography (PET-CT), are routinely used to assess primary tumour size, regional lymph node involvement and the presence of distant metastases. Despite their widespread use, these imaging techniques have limited sensitivity for detecting microscopic lesions, such as occult peritoneal

carcinomatosis, and for evaluating non-regional lymph nodes, including mediastinal lymph node involvement [5, 10]. CT scanning, in particular, has low sensitivity for identifying peritoneal metastases < 5 mm in diameter [11]. Furthermore, hypermetabolically active mediastinal lymph nodes observed on PET-CT may be reactive, resulting in false-positive findings [4]. Tumours have traditionally been considered the primary consumers of glucose in the body, a concept that underpins PET-CT tumour visualization using a radioactive glucose tracer to identify regions of elevated glucose metabolism. However, recent studies indicate that tumours are highly heterogeneous and consist of various cell types. Research conducted by a team of American investigators has shown that immune cells, specifically macrophages and T cells, are the primary consumers of glucose within tumours, rather than malignant cells. In contrast, tumour cells utilize glutamine and fatty acids as their principal energy sources. This finding represents a significant advancement and may substantially influence future approaches to cancer diagnosis and treatment [6].

The primary disadvantage of PET-CT includes undetected (false negative) peritoneal carcinomatosis in patients with CRC, potentially resulting in exploratory or palliative surgery. Conversely, a false positive PET-CT result may prevent patients from receiving potentially beneficial radical bowel resection. In these controversial cases, morphological verification of suspicious changes is required [5].

The NCCN guidelines recommend the use of minimally invasive diagnostic techniques when imaging data are inconclusive [1]. Specifically, diagnostic laparoscopy with peritoneal lavage for cytology is advised for suspected peritoneal carcinomatosis, while mediastinoscopy is recommended for patients with CRC who present with enlarged mediastinal lymph nodes [1]. These procedures provide direct morphological



Figure 1. **Enlarged paratracheal lymph nodes**

verification. Laparoscopy enables assessment of the macroscopic condition of the peritoneum and collection of peritoneal lavage samples for cytology and biopsy. Mediastinoscopy facilitates the acquisition of histological samples from a suspicious lymph node. Previous studies have shown that in localized CRC, positive peritoneal lavage cytology serves as an independent negative prognostic marker associated with a high risk of peritoneal recurrence [3]. Incidental confirmation of mediastinal metastases by imaging alone has been reported only in isolated clinical cases [2], underscoring the necessity for histological confirmation.

This study examined the impact of diagnostic laparoscopy with cytological analysis and mediastinoscopy with targeted lymph node biopsy on initial treatment planning and the consistency between clinical and morphological data.

**OBJECTIVE** – to improve staging accuracy and optimize therapeutic strategies in patients with colorectal cancer by performing minimally invasive diagnostic procedures, specifically diagnostic laparoscopy with peritoneal lavage and cytological examination, and mediastinoscopy with targeted lymph node biopsy, in cases where conventional imaging methods (computed tomography [CT], magnetic resonance imaging [MRI], positron emission tomography combined with computed tomography [PET-CT]) yield equivocal or inconclusive results.

## Materials and methods

**Study design.** This retrospective-prospective clinical study was conducted from 2023 to 2025 and included 37 patients with colorectal cancer (CRC).

**The inclusion criteria** for patients in this study required the presence of suspicious radiological signs indicating potential metastasis to the peritoneum or mediastinal lymph nodes. Specifically, these signs included ascites, peritoneal thickening, or enlarged (> 11 mm) mediastinal lymph nodes of undetermined origin (Fig. 1).

**Methods.** All patients underwent standard imaging, which included CT of the chest, abdomen, and pelvis. Intravenous contrast was administered when indicated. If imaging results suggested possible peritoneal carcinomatosis or mediastinal lymph node involvement, a minimally invasive procedure was performed (diagnostic laparoscopy or mediastinoscopy, respectively). Patients were then preliminarily divided into two groups: those with suspected peritoneal carcinomatosis (n = 22) and those with suspected mediastinal lymph node involvement (n = 15).

All procedures were conducted under general anaesthesia. For suspected peritoneal carcinomatosis, diagnostic laparoscopy with peritoneal lavage or ascites

aspiration was performed. When ascites volume exceeded 500 ml (Fig. 2), aspiration was followed by cytological examination of the fluid. In the absence of ascites, 400 ml of saline was injected and then aspirated, as recommended by cytologists. The collected washings were analyzed using standard cytological techniques to detect tumour cells in the peritoneal fluid.

Patients with suspected mediastinal lymph node involvement underwent standard mediastinoscopy by the technique of Carlens.

Following mediastinal examination, targeted biopsies were obtained from all enlarged lymph nodes (> 11 mm) or those deemed suspicious. The biopsy specimens were submitted for histological analysis.

**Outcomes Evaluation.** The main endpoints included: (1) changes in treatment strategy after obtaining cytology/histology data (e.g., transition from possible (according to non-invasive diagnostic methods) radical surgery to palliative therapy or vice versa); (2) correlation between cytology/histology results and primary imaging data (confirmation or refutation of initial clinical suspicion); (3) safety of procedures (frequency and severity of complications).

Statistical analysis was performed using descriptive statistical methods, including the number and percentage for categorical variables and the arithmetic mean with standard deviation for continuous values.

The study was conducted in accordance with the principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants.

## Results

Histological and/or cytological analysis confirmed metastatic peritoneal involvement in 19 of 22 patients (86.4%) who were diagnosed with peritoneal carcinomatosis using non-invasive diagnostic techniques (Fig. 3). Morphological confirmation of metastasis to mediastinal lymph nodes was achieved in 11 (73.3%) of 15 (86.4%) patients with mediastinal lymphadenopathy identified by CT or PET-CT.

The findings allowed for personalized adjustment of further treatment strategies. Specifically, 27 (72.9%) patients who underwent diagnostic laparoscopy or mediastinoscopy and were confirmed to have stage IV disease received chemotherapy, since surgical intervention was inappropriate. The remaining patients, who didn't present with metastases in the mediastinal lymph nodes and peritoneal carcinomatosis, underwent radical surgery. In two (5.4%) cases, palliative intestinal resection was performed for urgent indications (acute intestinal obstruction). One (2.7%) patient declined further treatment.

No intraoperative complications occurred during laparoscopy or mediastinoscopy. The duration of

hospital observation ranged from 24 to 48 hours. Mild postoperative pain, isolated seromas at the surgical wound site, and a transient increase in body temperature to 37.8 °C were observed in 8 (21.6%) patients.

A summary of the study results is presented in Table.

## Discussion

The study demonstrates that minimally invasive techniques, including diagnostic laparoscopy with peritoneal biopsy and cytological analysis of fluids and mediastinoscopy with biopsy, provide high diagnostic efficiency and clinical value in patients with suspected peritoneal carcinomatosis or metastatic involvement of mediastinal lymph nodes in CRC. Among patients with suspected peritoneal carcinomatosis (n = 22), cytology and histology did not confirm the lesion in 3 patients (13.6%), allowing for safe radical surgery and avoiding unnecessary palliative interventions and PCT. In contrast, 19 patients (86.4%) with confirmed peritoneal carcinomatosis required systemic therapy. For patients with suspected mediastinal lymph node involvement (n = 15), 4

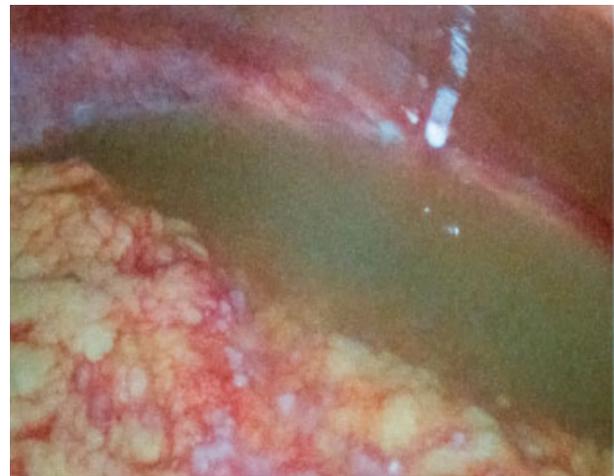


Figure 2. Ascites in the abdominal cavity (> 500 ml)



Figure 3. Confirmed peritoneal carcinomatosis

Table. **Clinical results of the study**

Group	n	Procedure	Result
Suspected peritoneal carcinomatosis (Group A)	19 (86.4%)	Laparoscopy + histological examination + peritoneal lavage/ascites aspiration (fluid cytology)	Confirmed carcinomatosis. Scheduled or palliative polychemotherapy (PCT) (n = 17) and palliative surgery (n = 2) were prescribed.
Suspected peritoneal carcinomatosis (Group B)	3 (13.6%)	Laparoscopy + histological examination + peritoneal lavage/ascites aspiration (fluid cytology)	Carcinomatosis was not confirmed. Planned radical surgery was performed (left or right hemicolectomy depending on the location of the tumour).
Suspected metastatic involvement of mediastinal lymph nodes (Group C)	11 (73.3%)	Mediastinoscopy + biopsy	Metastatic involvement of mediastinal lymph nodes was confirmed. Systemic chemotherapy was prescribed (n = 10). One patient declined treatment.
Suspected metastatic involvement of mediastinal lymph nodes (Group D)	4 (26.7%)	Mediastinoscopy + biopsy	Metastatic involvement of mediastinal lymph nodes was not confirmed. Planned radical surgery (left or right hemicolectomy depending on tumour location) was performed

patients (26.7%) showed no metastatic cells in their histological samples, allowing for radical surgical treatment. In the remaining patients (73.3%), histological confirmation of metastases resulted in upstaging to stage IV and necessitated PCT.

The present findings are consistent with previous research, which supports both financial and clinical feasibility of laparoscopy and mediastinoscopy for staging colorectal cancer. Notably, multicenter studies have shown that positive cytology of peritoneal washings serves as an independent negative prognostic marker, correlating with a higher risk of peritoneal recurrence and reduced survival [3]. The reported 20–30% frequency of false-positive PET-CT results in the mediastinum (20–30%) highlights the need for histological verification in cases of mediastinal lymphadenopathy [11].

The safety of these procedures was confirmed by the absence of serious complications: patients underwent laparoscopy and mediastinoscopy without significant adverse events, which is consistent with the literature data on the low risk of postoperative complications in minimally invasive interventions [7]. Furthermore, these methods offer the advantage of direct visualization and assessment of lesions, a benefit not achievable through digital imaging techniques alone.

The primary limitations of this study include a relatively small sample size and a mixed retrospective-prospective design, which may limit the generalizability of the results. Nevertheless, the findings confirm the practical diagnostic value of minimally invasive techniques for cancer staging and establish a foundation for further multicenter studies to evaluate their impact on long-term survival and patient quality of life.

## Conclusions

Diagnostic laparoscopy with histological examination, peritoneal lavage followed by cytological analysis, and mediastinoscopy with biopsy provide valuable and informative adjuncts to standard imaging modalities in the diagnosis of colorectal cancer.

The application of these techniques enhances the accuracy of clinical cancer staging, particularly in cases with suspected metastatic tumour spread.

Negative findings from these studies support the feasibility of safe radical surgery, whereas positive findings facilitate timely referral to systemic therapy for stage IV disease.

The implementation of an integrated approach reduces the risk of unnecessary surgical interventions and addresses potential limitations in existing treatment strategies. This approach is consistent with current recommendations from the National Comprehensive Cancer Network (NCCN) and the European Society for Medical Oncology (ESMO) for optimizing CRC treatment.

The findings support wider adoption of minimally invasive procedures within CRC detection protocols and promote the development of improved recommendations grounded in multidisciplinary diagnostic strategies.

## DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

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## AUTHORS CONTRIBUTIONS

O.A. Danylenko: concept and design, methodology, clinical data collection, participation in minimally invasive diagnostic procedures, statistical analysis, drafting of the manuscript; O.O. Piskorsky: scientific guidance and

methodological support, clinical coordination, analysis and interpretation of the findings, participation in minimally invasive diagnostic procedures, critical revision of the manuscript.

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# Роль малоінвазивних діагностичних методик в оптимізації лікувальної тактики у хворих на колоректальний рак

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**Мета** — підвищити точність стадіювання та оптимізувати лікувальну тактику у пацієнтів з колоректальним раком шляхом застосування малоінвазивних діагностичних втручань — діагностичної лапароскопії з перитонеальним лаважем і цитологічним дослідженням, а також медіастиноскопії з прицільною біопсією лімфатичних вузлів при сумнівних або непереконливих результатах візуалізаційних методів обстеження КТ (комп'ютерна томографія), МРТ (магнітно-резонансна томографія), ПЕТ-КТ (позитронно-емісійна томографія, поєднана з комп'ютерною томографією).

**Матеріали та методи.** Це ретроспективно-проспективне дослідження 2023—2025 років, залучено 37 пацієнтів із колоректальним раком, у яких стандартні методи візуалізації не дали змоги однозначно визначити наявність віддалених метастазів або перитонеального канцероматозу. Пацієнтів розділено на дві групи: 22 хворих із підозрою на канцероматоз очеревини, яким виконано діагностичну лапароскопію з лаважем черевної порожнини, біопсією очеревини та цитологічним аналізом; 15 хворих із підозрою на ураження медіастинальних лімфатичних вузлів, яким проведено цервікальну медіастиноскопію з прицільною біопсією. Оцінювали діагностичну точність, вплив отриманих результатів на подальшу лікувальну тактику та безпечність виконаних процедур.

**Результати.** Перитонеальний канцероматоз морфологічно підтверджено у 19 із 22 (86,4%) пацієнтів, метастатичне ураження медіастинальних лімфатичних вузлів — у 11 із 15 (73,3%) пацієнтів. За результатами верифікації патологічного процесу лікувальна тактика була змінена у 29 (78,4%) пацієнтів: 27 (72,9%) отримали системну хіміотерапію, 7 (18,9%) — радикальні оперативні втручання, у 2 (5,4%) виконано паліативну резекцію, 1 (2,7%) відмовився від подальшого лікування. Серйозних інтраопераційних ускладнень не зафіксовано; незначні післяопераційні явища (біль у ділянці проколу, підшкірна емфізема, короткочасна лихоманка) спостерігалися у 8 (21,6%) пацієнтів і не потребували додаткового лікування.

**Висновки.** Включення діагностичної лапароскопії та медіастиноскопії до алгоритму визначення стадії колоректального раку забезпечує високу діагностичну інформативність і сприяє персоналізації лікування. Застосування малоінвазивних методів дозволяє уникнути необґрунтованих хірургічних втручань, скоротити час до початку системної терапії та покращити прогноз у пацієнтів із поширеними формами хвороби.

**Ключові слова:** колоректальний рак, діагностична лапароскопія, канцероматоз, медіастиноскопія, стадія, метастазування, NCCN.

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# Analysis of risk factors associated with complications after laparoscopic gastric bypass in patients with obesity

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Global data indicate that complications after laparoscopic gastric bypass occur in 5.8 to 12.4 % of patients. Recent studies identify prior abdominal surgeries, chronic liver diseases, arterial hypertension, chronic lung diseases, and repeated bariatric procedures as primary risk factors for postoperative complications.

**OBJECTIVE** – to determine the primary risk factors associated with complications in obese patients after laparoscopic gastric bypass.

**MATERIALS AND METHODS.** A retrospective analysis was conducted on data from 556 obese patients, as defined by IFSO criteria, who underwent laparoscopic gastric bypass surgery between 2011 and 2025 at the Department of General Surgery No 2, Bogomolets National Medical University. Of these patients, 261 (46.3 %) were men and 295 (53.7 %) were women. The mean body weight was 151.88 (95 % CI: 135.5–168.1) kg, and the mean body mass index was 46.73 (95 % CI: 43.93–49.52) kg/m<sup>2</sup>. The surgical and anesthetic risk, assessed using the ASA scale, was 3.42 (95 % CI: 3.31–3.53). Two groups of patients were established: a control group (2011–2019) and an experimental group (2019–2024), to evaluate the impact of the new strategy on the incidence of complications.

**RESULTS.** Univariate logistic regression analysis identified seven factors with a significance level of <0.1: duration of surgery, postoperative pain level, early mobilization, chronic obstructive pulmonary disease, gastroesophageal reflux disease, sleep apnea, and diabetes mellitus. To determine the minimum set of factorial features associated with the occurrence of complications in obese patients after laparoscopic gastric bypass, a multivariate logistic regression analysis was employed. This analysis identified five factorial features associated with complication risk: «duration of surgery», «postoperative pain level», «delayed mobilization», «sleep apnea syndrome», and «diabetes mellitus».

**CONCLUSIONS.** The factors influencing the development of postoperative complications in obese patients after laparoscopic gastric bypass surgery included the duration of surgery, postoperative pain level, delayed mobilization, sleep apnea syndrome, and diabetes mellitus.

## KEYWORDS

complications, gastric bypass, marginal ulcer, gastro-gastro fistula, Petersen's hernia, bleeding.

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Selecting appropriate surgical strategies for obese patients requires a multidisciplinary approach and individualized adaptation of established clinical protocols and recommendations. A key element in this process is the assessment of risk factors that may contribute to adverse outcomes or complications, as well as their timely diagnosis and management.

In 2007, E.J. DeMaria et al. developed a scale to assess the risk of negative outcomes after bariatric surgery, incorporating five main criteria: body mass index > 50 kg/m<sup>2</sup>, male gender, arterial

hypertension, risk factors for pulmonary thromboembolism, and age > 45 years [2]. Subsequent revisions expanded the scale to include additional risk factors and re-evaluated the original criteria. D. R. Flum et al. found that only a body mass index > 50 kg/m<sup>2</sup> was associated with increased rates of complications and mortality after bariatric surgery, with higher indices correlating directly with greater severity. The remaining four factors did not influence complication and mortality rates in this study [4].

U.K. Coblijn et al. (2016) applied this scale to obese patients undergoing laparoscopic gastric bypass. The criteria referenced above had no effect on the risk of death or complications. Repeated bariatric surgery was the only factor associated with an increased risk of complications or mortality [1].

Laparoscopic gastric bypass is considered among the most effective treatments for morbid obesity. According to the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) (8th Global Registry Report, 2023), 480,970 bariatric surgeries were performed in 2022, with laparoscopic gastric bypass accounting for 28.8% of initial procedures [13].

Global data indicate that complications after laparoscopic gastric bypass occur in 5.8 to 12.4% of patients [1].

Recent studies identify prior abdominal surgeries, chronic liver diseases, arterial hypertension, chronic lung diseases, and repeated bariatric procedures as primary risk factors for postoperative complications [7].

**OBJECTIVE** – to determine the primary risk factors associated with complications in obese patients after laparoscopic gastric bypass.

## Materials and methods

A retrospective analysis was conducted to identify risk factors associated with complications after laparoscopic gastric bypass. The study included 556 patients who underwent laparoscopic gastric bypass at the clinical base of the Department of General Surgery No2, Bogomolets National Medical University between 2011 and 2025 (Table 1).

The observation period ranged from 6 to 65 months. The analysis focused exclusively on complications related to laparoscopic gastric bypass, including bleeding, marginal ulcers, suture failure, intestinal obstruction, and ineffective weight loss. All complications were classified using the Clavien-Dindo scale (Table 2).

Beginning in 2019, the management of obese patients before, during, and after laparoscopic gastric bypass was modified based on findings from our previous studies and the Enhanced Recovery After Surgery (ERAS) protocol. Consequently, two groups of patients were established: a control group (2011–2019) and an experimental group (2019–2024), to evaluate the impact of the new strategy on the incidence of complications.

According to the new strategy, preoperative preparation included catheterization of the epidural space and establishment of central venous access under ultrasound guidance. Additionally,

saline laxatives and a carbohydrate mixture (5% glucose, 200 ml) were administered 12 hours and 4 hours before surgery, respectively. Dexamethasone (8 mg) was administered intravenously 10 minutes before the incision, and antibiotic prophylaxis was provided 30 minutes before surgery. Intraoperatively, local infiltration anesthesia was given at the trocar insertion sites, and pneumatic compression of the lower extremities was used instead of elastic compression to prevent thrombosis. Cassettes for gastroenteroanastomosis and entero-enteric anastomosis were replaced, using the TriStaple technique. Paracetamol was administered intravenously at the beginning of the skin suturing procedure. At the conclusion of surgery, 5 ml of tranexamic acid was administered 12 and 24 hours after surgery. Postoperatively, the urinary catheter was removed immediately, the nasogastric tube was withdrawn within one day, and drains were removed 2–3 days after surgery. Early patient mobilization was implemented during the postoperative period. Oral fluid intake commenced 6 hours after surgery, with a stepwise increase in volume and a corresponding decrease in infusion therapy. On postoperative day 4, all patients without complications underwent contrast gastrography to assess the capacity of the gastroenteroanastomosis.

The study adhered to modern bioethical standards. Statistical analysis was performed using IBM SPSS Statistics Base software (version 26). Univariate and multivariate logistic regression models were applied. Results with  $p < 0.05$  were considered statistically significant.

The results of univariate logistic regression models (Table 3) identified seven factors with a significance level  $< 0.1$ : duration of surgery, postoperative pain level, early mobilization, chronic obstructive pulmonary disease (COPD), gastroesophageal reflux disease (GERD), sleep apnea, and diabetes mellitus. To determine the minimum set of factorial features associated with the occurrence of complications in obese patients after laparoscopic gastric bypass, a multivariate logistic regression analysis was conducted. Five factorial features were found to be significantly associated with the probability of complications: «duration of surgery», «postoperative pain level», «delayed mobilization», «sleep apnea syndrome», and «diabetes mellitus» (Table 4).

A logistic regression model analysis identified the risk factors for bleeding, marginal ulcers, and intestinal obstruction in obese patients after laparoscopic gastric bypass. Arterial hypertension (OR = 1.78, CI: 1.03–3.04;  $p = 0.05$ ), COPD (OR = 2.35, CI: 1.06–5.2;  $p = 0.034$ ), and diabetes mellitus (OR = 17.26, CI: 3.72–80.1;  $p < 0.001$ )

Table 1. **Complications observed in obese patients after laparoscopic gastric bypass**

Complication	Number
Bleeding	14 (2.51 %)
Intraluminal	13 (2.33 %)
Intraperitoneal	1 (0.17 %)
Marginal ulcer complicated by	12 (1.07 %)
Perforation	1 (0.17 %)
Penetration	1 (0.17 %)
Bleeding with iron deficiency anemia	4 (0.71 %)
Uncomplicated	6 (1.07 %)
Ineffective weight loss	1 (0.17 %)
Strangulated hernia of Petersen's space	1 (0.17 %)
Gastro-gastro fistula	1 (0.17 %)
Splenic vein thrombosis with splenic infarction	1 (0.17 %)
Postoperative strangulated umbilical hernia	1 (0.17 %)
Acute adhesive small intestinal obstruction	1 (0.17 %)
<b>Total</b>	<b>32 (5.75 %)</b>

Table 2. **Classification of complications according to the Clavien-Dindo scale**

Degree	Number
I	0
II	12 (37.5 %)
IIIa	1 (3.1 %)
IIIb	19 (59.4 %)
IVa	0
IVb	0

were associated with an increased risk of postoperative bleeding. The use of NSAIDs (OR = 3.89, CI: 1.23–12.68;  $p < 0.001$ ), diabetes mellitus (OR = 4.45, CI: 1.39–14.19;  $p < 0.001$ ), and elevated postoperative pain levels (OR = 1.6, CI: 1.01–2.52;  $p < 0.001$ ) were linked to a higher incidence of marginal ulcers. Additionally, duration of surgery (OR = 1.04, CI: 1.23–12.68;  $p < 0.001$ ), diabetes mellitus (OR = 8.77, CI: 1.57–48.79;  $p < 0.001$ ), delayed mobilization (OR = 1.9, CI: 1.01–2.6;  $p = 0.012$ ), and sleep apnea syndrome (OR = 10.2,

CI: 1.83–57.07;  $p = 0.008$ ) were significant predictors of intestinal obstruction. Duration of surgery (OR = 1.03, CI: 1.00–1.07;  $p = 0.013$ ), the presence of comorbid conditions (OR = 1.2, CI: 1.02–1.43;  $p = 0.028$ ), arterial hypertension (OR = 1.56, CI: 1.03–2.35;  $p = 0.03$ ), diabetes mellitus (OR = 4.03, CI: 1.5–10.81;  $p = 0.006$ ), delayed mobilization (OR = 1.97, CI: 1.01–2.91;  $p < 0.001$ ), and sleep apnea syndrome (OR = 2.8, CI: 1.00–7.86;  $p = 0.05$ ) were all associated with an increased risk of early complications within 30 days after surgery.

The control group consisted of 178 patients treated between 2011 and 2019, including 86 (48.3 %) men and 92 (51.7 %) women. The mean body weight was 144.8 (95 % CI: 142.7–146.8) kg, and the mean body mass index (BMI) was 45.44 (95 % CI: 44.67–46.22) kg/m<sup>2</sup>. The surgical and anesthetic risk, as measured by the ASA scale, was 3.36 (95 % CI: 3.25–3.47). The study group comprised 378 patients treated between 2019 and 2024. Both groups were comparable in terms of age, sex, height, body weight, BMI, and total number of participants. The overall incidence of postoperative complications was 23 cases (12.9 %) in the control group and 9 cases (2.38 %) in the experimental group. This reduction in complications was statistically significant ( $p < 0.05$ ).

## Discussion

Laparoscopic gastric bypass is one of the most effective methods for treating obesity and comorbid conditions associated with it. Timely identification of the principal risk factors minimizes the likelihood of complications after laparoscopic gastric bypass and provides a faster effect from the operation.

Since 2007, numerous risk assessment scales have been proposed to assess the risk of complications after laparoscopic gastric bypass. They are updated and improved annually with data from various bariatric centres.

The study identified several factors influencing the incidence of complications after laparoscopic gastric bypass: duration of surgery (OR = 1.06, CI: 1.02–1.1;  $p < 0.001$ ), postoperative pain level (OR = 2.39, CI: 1.52–3.76;  $p < 0.001$ ), delayed mobilization (OR = 1.99, CI: 1.02–2.95;  $p < 0.001$ ), sleep apnea syndrome (OR = 4.23, CI: 1.45–12.34;  $p = 0.008$ ), and diabetes mellitus (OR = 6.98, CI: 2.36–20.6;  $p < 0.001$ ).

Prolonged duration of surgery is associated with an increased risk of complications. P. Major et al. (2016) confirmed this relationship, reporting a higher incidence of complications with longer procedures (OR = 1.01; CI: 1.00–1.02;  $p = 0.003$ )

Table 3. Analysis of univariate logistic regression models for predicting bleeding in patients with morbid obesity during the postoperative period after laparoscopic gastric bypass

Factor sign	Value of the coefficient of the model, $b \pm mb$	Significance difference of the coefficient from 0, p	AUC (95 % CI)	Odds ratio indicator of the model, OR (95 % CI)	Significance difference of the OR from 0, p
Age, years	0.03 ± 0.02	0.067	0.59 (0.45–0.73)	1.03 (0.99–1.07)	0.067
Sex (1 – male, 2 – female)	0.35 ± 0.37	0.34	0.54 (0.44–0.64)	1.42 (0.68–2.93)	0.34
Weight, kg	0.008 ± 0.01	0.44	0.53 (0.44–0.62)	1.01 (0.98–1.03)	0.44
Height, cm	4.94 ± 2.03	0.015	0.5 (0.4–0.61)	140.4 (2.61–7542.65)	0.015
BMI, kg/m <sup>2</sup>	0.01 ± 0.04	0.7	0.48 (0.39–0.57)	1.01 (0.94–1.09)	0.7
Time of operation, min	0.05 ± 0.01	0.001	0.74 (0.67–0.81)	1.05 (1.02–1.08)	0.001
ASA, class	0.34 ± 0.24	0.16	0.57 (0.47–0.66)	1.41 (0.87–2.29)	0.16
Number of comorbidities	0.15 ± 0.06	0.01	0.54 (0.43–0.65)	1.16 (1.02–1.32)	0.01
Chronic obstructive lung disease (1 – yes, 0 – no)	0.23 ± 0.16	0.1	0.57 (0.47–0.67)	1.26 (0.91–1.76)	0.1
Chronic liver disease (1 – yes, 0 – no)	–0.06 ± 0.18	0.74	0.46 (0.35–0.58)	0.94 (0.65–1.36)	0.74
Arterial hypertension (1 – yes, 0 – no)	0.07 ± 0.16	0.66	0.49 (0.38–0.6)	1.07 (0.77–1.49)	0.66
Diabetes mellitus (1 – yes, 0 – no)	1.54 ± 0.37	<0.001	0.65 (0.55–0.766)	4.69 (0.2.25–9.77)	<0.001
Alcohol consumption (1 – yes, 0 – no)	0.01 ± 0.55	0.97	0.5 (0.39–0.6)	1.01 (0.34–3.02)	0.97
GERD (1 – yes, 0 – no)	0.77 ± 0.4	0.05	0.57 (0.46–0.67)	2.16 (0.98–4.77)	0.05
Delayed mobilization (1 – yes, 0 – no)	3.28 ± 0.49	<0.001	0.31 (0.2–0.42)	1.97 (1.91–2.06)	<0.001
Myocardial infarction in anamnesis (1 – yes, 0 – no)	–0.32 ± 0.75	0.66	0.46 (0.38–0.59)	0.72(0.16–3.15)	0.66
Deep vein thrombosis (1 – yes, 0 – no)	–1.49 ± 1.02	0.14	0.45 (0.35–0.55)	0.22 (0.03–1.68)	0.14
Chronic venous insufficiency (1 – yes, 0 – no)	0.21 ± 0.36	0.56	0.52 (0.42–0.62)	1.23 (0.6–2.51)	0.56
Sleep apnea (1 – yes, 0 – no)	1.14 ± 0.38	0.003	0.6 (0.49–0.71)	3.14 (1.46–6.73)	0.003
Cholecystectomy during surgery (1 – yes, 0 – no)	–0.89 ± 0.46	0.25	0.41 (0.32–0.5)	0.4 (0.16–1.01)	0.25
Non-steroid anti-inflammatory drug (1 – yes, 0 – no)	0.81 ± 0.74	0.27	0.62 (0.53–0.71)	2.26 (0.52–9.8)	0.27
Level of discomfort after operation, points	0.55 ± 0.14	<0.001	0.69 (0.6–0.78)	1.74 (1.3–2.32)	<0.001

Table 4. Multivariate logistic regression analysis of the development of postoperative complications in obese patients after laparoscopic gastric bypass

Factor sign	Value of the coefficient of the model, $b \pm mb$	Significance difference of the coefficient from 0, p	Odds ratio indicator of the model, OR (95% CI)
Time of operation, min	0.06 ± 0.02	< 0.001	1.06 (1.02–1.1)
Level of discomfort after operation, points	0.87 ± 0.23	< 0.001	2.39 (1.52–3.76)
Delayed mobilization (1 – yes, 0 – no)	4.42 ± 0.8	< 0.001	1.99 (1.02–2.95)
Chronic obstructive lung disease (1 – yes, 0 – no)	0.43 ± 0.24	0.046	1.54 (0.95–2.48)
GERD (1 – yes, 0 – no)	1.29 ± 0.55	0.19	3.66 (1.23–10.85)
Sleep apnea (1 – yes, 0 – no)	1.44 ± 0.54	0.008	4.23 (1.45–12.34)
Diabetes mellitus (1 – yes, 0 – no)	1.94 ± 0.55	< 0.001	6.98 (2.36–20.6)

[5]. According to E. Stenberg (2014), the influence of operative time was significant when surgeons had performed fewer than 100 bariatric operations (OR = 1.83; CI: 1.47–2.07;  $p < 0.001$ ). However, this effect was not observed when surgeons had completed more than 300 operations, and the operative time was less than  $99.2 \pm 45.63$  [12].

Diabetes mellitus not only increases the overall complication rate but also elevates the risk of specific postoperative events, including postoperative bleeding (OR = 17.26, CI: 3.72–80.1;  $p < 0.001$ ), marginal ulcers (OR = 4.45, CI: 1.39–14.19;  $p < 0.001$ ), intestinal obstruction (OR = 8.77, CI: 1.57–48.79;  $p < 0.001$ ), and early postoperative complications (OR = 4.03, CI: 1.5–10.81;  $p = 0.006$ ). E. Stenberg (2014) reported that diabetes mellitus affects the occurrence of all complications (OR = 1.47, CI: 1.31–1.64;  $p < 0.001$ ), but does not significantly influence the rate of serious complications (grade IIIB according to the Clavien-Dindo scale) – OR = 1.22, CI: 1.00–1.5;  $p = 0.053$  [12]. The same results were observed in patients with and without diabetes mellitus, suggesting that diabetes mellitus may not independently affect the occurrence of complications [5, 11, 13].

Previous studies indicate that sleep apnea syndrome does not affect the rate of complications [3, 5]. However, further investigation of this issue is warranted.

Postoperative bleeding represents the most common complication after laparoscopic gastric bypass, prompting a separate analysis of risk factors in this population. The present data identify three factors associated with an increased risk of postoperative bleeding: arterial hypertension (OR = 1.78, CI: 1.03–3.04;  $p = 0.05$ ), COPD (OR = 2.35,

CI: 1.06–5.2;  $p = 0.034$ ), and diabetes mellitus (OR = 17.26, CI: 3.72–80.1;  $p < 0.001$ ). A meta-analysis by H. Santos-Sousa et al. (2024) involving 232,488 patients confirmed the association between arterial hypertension and postoperative bleeding (OR = 1.33, CI: 1.02–1.73;  $p < 0.01$ ) [10]. Additional studies [7–9, 14] also demonstrated the influence of diabetes mellitus on postoperative bleeding. Currently, there is no evidence regarding the negative impact of chronic obstructive pulmonary disease on the occurrence of postoperative bleeding.

The adoption of a new patient management strategy contributed to a decrease in the number of complications from 23 (12.9%) to 9 (2.3%). The implementation of the ERAS protocol has been shown to reduce complication rates, length of hospital stay, and postoperative pain levels [6, 9]. In the study group, reduced postoperative pain and early mobilization likely contributed to the lower complication rate, consistent with the provisions of the ERAS protocol.

## Conclusions

The factors influencing the development of postoperative complications in obese patients after laparoscopic gastric bypass surgery were identified. They include duration of surgery, postoperative pain level, delayed mobilization, sleep apnea syndrome, and diabetes mellitus.

The factors associated with postoperative bleeding in obese patients after laparoscopic gastric bypass surgery were identified. They include arterial hypertension, chronic obstructive pulmonary disease, and diabetes mellitus.

The factors influencing the development of postoperative complications in obese patients during the

early postoperative period after laparoscopic gastric bypass surgery were identified. These factors comprise duration of surgery, presence of several comorbid conditions, arterial hypertension, diabetes mellitus, delayed mobilization, and sleep apnea syndrome.

A new management strategy for obese patients after laparoscopic gastric bypass was developed, integrating the ERAS protocol and new elements identified by us based on previous studies. The application of the new strategy reduced the rate of postoperative complications from 12.9% to 2.3% ( $p < 0.05$ ).

## DECLARATION OF INTERESTS

The authors, who participated in this study, stated that they had no conflicts of interest regarding this manuscript.

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## ETHICS APPROVAL AND WRITTEN INFORMED CONSENT STATEMENTS

In this study, the authors adhered to the Ethical Principles for Medical Research Involving Human Subjects outlined in the World Medical Association Declaration of Helsinki and current Ukrainian regulations. The study protocol was approved by the ethics committee of Bogomolets National Medical University. Written informed consent was obtained from all the patients.

## AUTHORS CONTRIBUTIONS

Work concept and design, data collection and analysis, responsibility for statistical analysis – V. O. Nevmerzhytskyi, M. S. Kryvopustov; writing the manuscript, critical review – V. O. Nevmerzhytskyi.

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## Аналіз чинників ризику ускладнень після лапароскопічного шунтування шлунка в пацієнтів з ожирінням

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За світовими даними, ускладнення після лапароскопічного шунтування шлунка виникають у 5,8—12,4% пацієнтів. Згідно з останніми дослідженнями, загальними чинниками ризику післяопераційних ускладнень вважають наявність абдомінальних операцій в анамнезі, хронічні захворювання печінки, артеріальну гіпертензію, хронічні захворювання легень і повторні бариатричні операції.

**Мета** — визначити основні чинники ризику ускладнень у пацієнтів з ожирінням, яким проведено лапароскопічне шунтування шлунка.

**Матеріали та методи.** Проведено ретроспективний аналіз даних 556 пацієнтів з ожирінням відповідно до критеріїв IFSO, яким виконано лапароскопічне шунтування шлунка в період з 2011 до 2025 р. на базі кафедри загальної хірургії № 2 Національного медичного університету імені О. О. Богомольця. Серед них був 261 (46,3%) чоловік і 295 (53,7%) жінок. Середня маса тіла становила 151,88 (95% довірчий інтервал (ДІ) — 135,5—168,1) кг, середній індекс маси тіла — 46,73 (95% ДІ 43,93—49,52) кг/м<sup>2</sup>. Хірургічний та анестезіологічний ризик за шкалою ASA — 3,42 (95% ДІ 3,31—3,53).

**Результати.** За результатами однофакторних моделей логістичної регресії було відібрано 7 чинників із рівнем значущості < 0,1: тривалість операції, рівень болю після операції, рання активізація, хронічне обструктивне захворювання легень, гастроєзофагеальна рефлюксна хвороба, нічне апное, цукровий діабет. Для відбору мінімального набору факторних ознак, пов'язаних із виникненням ускладнень у пацієнтів з ожирінням після лапароскопічного шунтування шлунка, використано метод багатофакторної логістичної регресії. Виділено 5 факторних ознак: «тривалість операції», «рівень болю після операції», «відсутність ранньої активізації», «синдром нічного апное» та «цукровий діабет».

**Висновки.** Визначено чинники впливу на розвиток післяопераційних ускладнень у пацієнтів з ожирінням після виконання лапароскопічного шунтування шлунка: тривалість операції, рівень болю після операції, відсутність ранньої активізації, синдром нічного апное та цукровий діабет.

**Ключові слова:** ускладнення, шунтування шлунка, маргінальна виразка, гастро-гастро нориця, грижа Петерсена, кровотеча.

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# Clinical case of surgical treatment of undifferentiated pleomorphic liver sarcoma

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Undifferentiated pleomorphic liver sarcoma (UPS), formerly known as malignant fibrous histiocytoma (MFH), represents a very rare primary hepatic tumour. It was first described by O'Brien and Stout in 1964. This type of tumour is the most prevalent malignant soft tissue tumour, which usually occurs in adulthood and affects the extremities, less commonly the retroperitoneum and abdominal organs.

**OBJECTIVE** – to present the treatment outcomes of a rare case of UPS of the liver. The article describes a clinical case of surgical treatment of a patient with UPS of the liver. Patient N., 36 years old, complained of pain in the right hypochondrium, fever, and general weakness. According to the results of instrumental examinations, the clinical diagnosis was made: primary liver tumour, tumour rupture, and intra-abdominal bleeding. After preoperative preparation, a right-sided hemihepatectomy, D2 lymphadenectomy, cholecystectomy, and abdominal drainage were performed. The histopathological and immunohistochemical features of the tumour cells were most consistent with undifferentiated pleomorphic liver sarcoma. According to the Federation Nationale des Centres de Lutte Contre le Cancer (FNCLCC) sarcoma grading system, a total score of 7 (G3) was assigned. The diagnosis was undifferentiated pleomorphic liver sarcoma, pT<sub>4a</sub>N<sub>0</sub>M<sub>0</sub> G3 stage III, grade 2. Six months later, a CT scan of the abdominal cavity revealed a tumour focus in the right subdiaphragmatic space with invasion of the right diaphragm dome, liver segment IV, and right kidney.

Surgical intervention was performed in volume: viscerolysis, atypical resection of the SgIV liver with right-sided nephrectomy and resection of the right dome of the diaphragm, aortocaval lymphadisection. Postoperative diagnosis: undifferentiated pleomorphic liver sarcoma pT<sub>4a</sub>N<sub>1(1/2)</sub>M<sub>0</sub> G3, R0, stage III, grade 2. Currently, the period of recurrence-free observation is 12 months after the second surgery.

## KEYWORDS

undifferentiated pleomorphic liver sarcoma, sarcoma, neoplasms.

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Undifferentiated pleomorphic liver sarcoma (UPS), formerly known as malignant fibrous histiocytoma (MFH), represents a very rare primary hepatic tumour. It was first described by O'Brien and Stout in 1964 [6]. This type of tumour is the most prevalent among soft tissue malignancies, typically occurring in adulthood and affecting the extremities, less commonly the retroperitoneum and abdominal organs [8]. The first case of UPS of the liver was described in 1985, but the disease remains poorly understood [1].

The main clinical sign observed in 78.4 % of cases was pain or discomfort in the right hypochondrium, followed by weakness, weight loss, jaundice, and fever. In 15 % of cases, no clinical manifestations were noted [5]. Overall, UPS ranks 4th among the most common soft tissue sarcomas. The incidence is 0.8–1.0 per 100,000 among the European race. In UPS of the liver, a solitary lesion with a size of 3.6–17.8 cm (average 9.7 cm) is observed [4, 7]. Abdominal ultrasound and contrast-enhanced CT combined with

trepan biopsy are the main diagnostic methods for verifying UPS of the liver [3, 9, 10]. A significant proportion of cases involving this pathology are misdiagnosed; specifically, 15% of patients with UPS are treated as having benign focal liver disease. The local recurrence rate is 19–31%, the metastasis rate is 31–35%, and the 5-year survival rate is 65–70% [2]. In China, a total of 76 cases were reported, with 50 cases involving men, resulting in a male-to-female ratio of 1.9:1. The average age of the patients was 51 years, with more than 85% being over 40 years old. Only 45 clinical cases of UPS of the liver have been described in the English-language literature.

In this paper, we present a clinical case of surgical treatment of a patient with UPS of the liver. Patient N., 36 years old, complained of pain in the

right hypochondrium, fever, and general weakness. Ultrasound examination revealed no free fluid in the pleural and abdominal cavities. In the right lobe of the liver, a solid mass with an indistinct contour, measuring 180 × 150 mm, occupied the entire right lobe of the liver.

The patient underwent a CT scan with IV enhancement: a tumour-like mass measuring 188 × 117 mm with areas of haemorrhage was detected in the parenchyma of the right liver lobe (Fig. 1).

This mass invaded the right hepatic vein and the right Glissonian pedicle, passing along the right contour of the middle hepatic vein. There were no signs of contrast extravasation at the time of the study. The patient underwent 3D modelling of the liver (CT volumetry and segmentation) (Fig. 2).

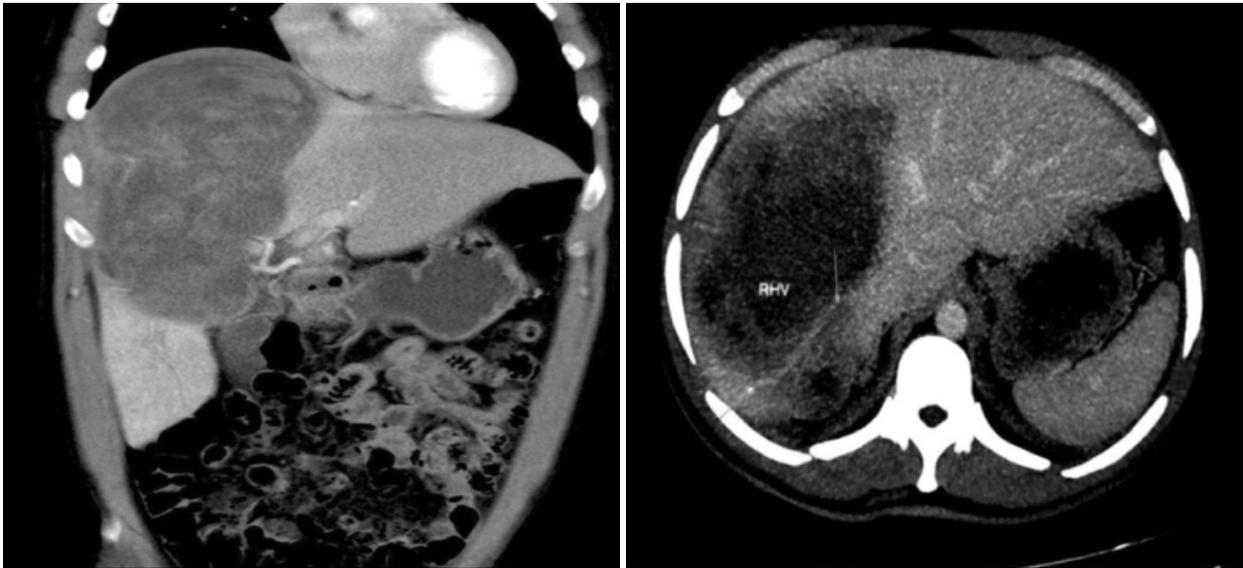


Figure 1. CT scan of the abdominal cavity

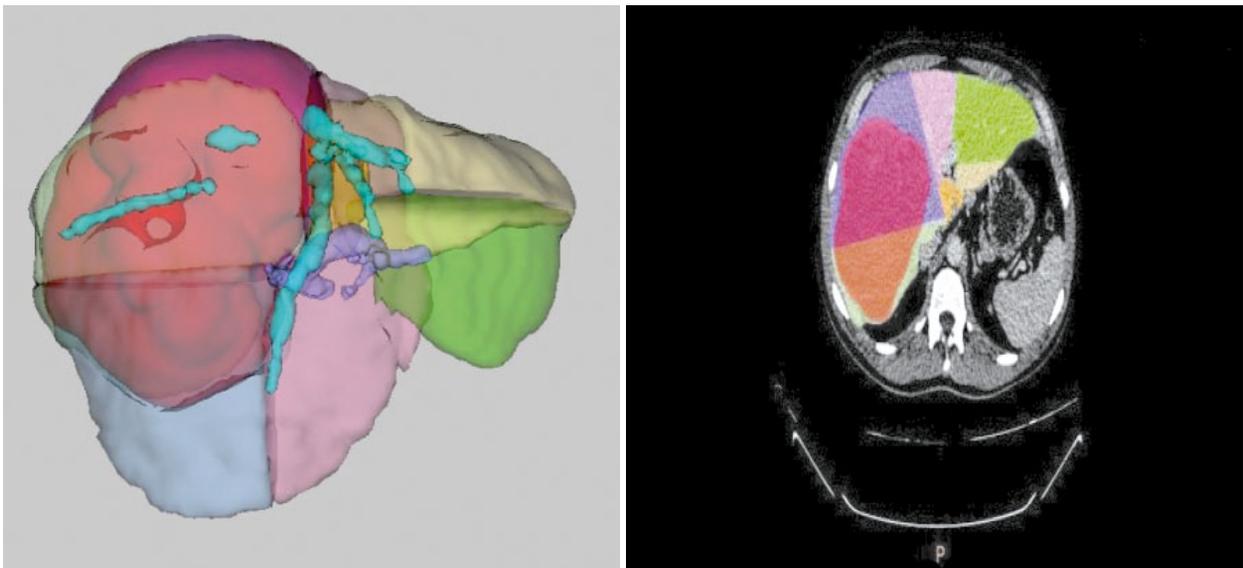


Figure 2. CT volumetry and liver segmentation

After the examination, the clinical diagnosis was made: primary liver tumour, tumour rupture, and intra-abdominal bleeding. After preoperative preparation, the patient underwent surgery, including right-sided hemihepatectomy, D2 lymphadenectomy, cholecystectomy, and abdominal drainage. The extent of D2 lymph node dissection included the removal of lymph node groups 12, 8, 13a, and 9 (Fig. 3).

Pathological diagnosis: Solid cystic liver mass morphologically similar to malignant neoplasia of mesenchymal origin (Fig. 4).

Immunohistochemical examination was performed. The tumour cells were diffusely positive for histone H3 with a K27M mutation, INI-1, and focally positive for desmin. A focal spot reaction to total cytokeratin and cytokeratin SAM 5.2 was observed. The tumour cells were positive for CD10 and partially positive for CD13, SALL4. The tumour cells were negative for NMV-45,

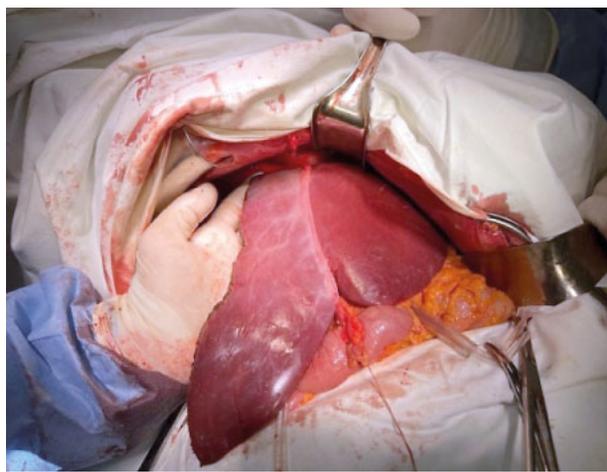


Figure 3. **Intraoperative photo**



Figure 4. **Macropreparation**

TFE3, inhibin alpha, GFAP, MDM2, MyoD1, myogenin, CD68, CD45, CD34, RAX-8, caldesmon, STAT6, S-100, SOX-10, CDK4, ERG, DOG-1, CD43, EMA, PLAP, synaptophysin, OST3/4, epithelial antigen Ber-EP4. Thus, this morphological picture and immunophenotype of the tumour cells are most consistent with undifferentiated pleomorphic liver sarcoma.

According to the Federation Nationale des Centres de Lutte Contre le Cancer (FNCLCC) sarcoma grading system, the tumour scored 3 points for differentiation, 3 points for mitotic activity (22 per 10 high-power fields at magnification  $\times 400$ ), and 1 point for necrosis (10%), resulting in a total score of 7 (G3). No signs of lymphatic, vascular and perineural invasion were found within the studied specimens. Macroscopically, the tumour was limited to the liver tissue, but had two growth loci (visceral surface and diaphragmatic surface) – multifocal growth and corresponded to an undifferentiated pT4aN0Mo G3 pleomorphic liver sarcoma.

The patient was discharged on the 25th postoperative day in satisfactory condition to continue combined therapy under the supervision of a clinical oncologist at his place of residence.

Three months after surgery, oncological screening and a contrast-enhanced CT scan of three anatomical regions were performed. No CT signs of disease progression were detected.

Six months following the prior examination, subsequent oncological screening identified a recurrence of the disease. A CT scan of the abdominal cavity revealed a tumour focus in the right subdiaphragmatic space, with invasion into the right dome of the diaphragm, segment IV of the liver, and the right kidney (Fig. 5).



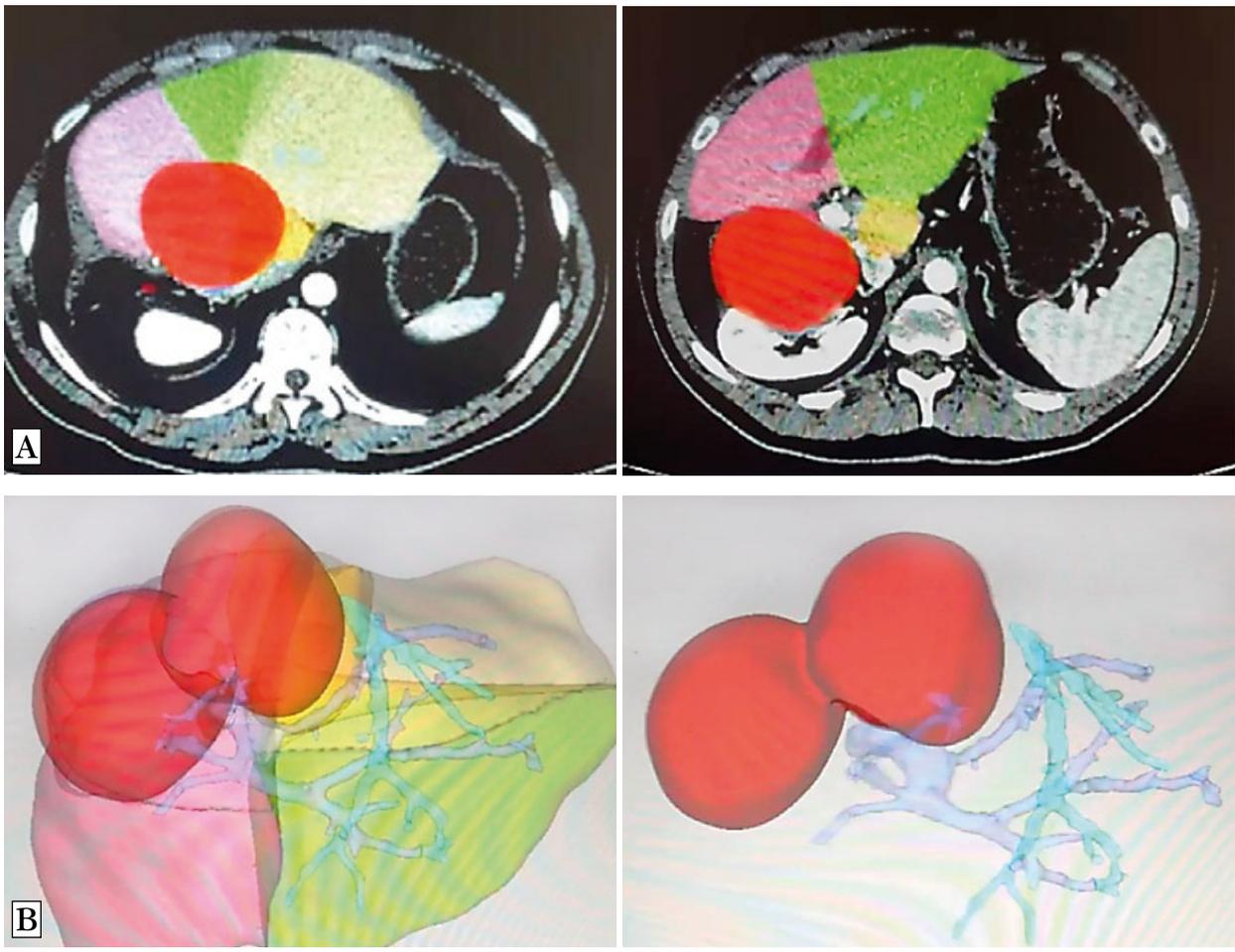


Figure 5. CT volumetry (A) and liver segmentation (B)

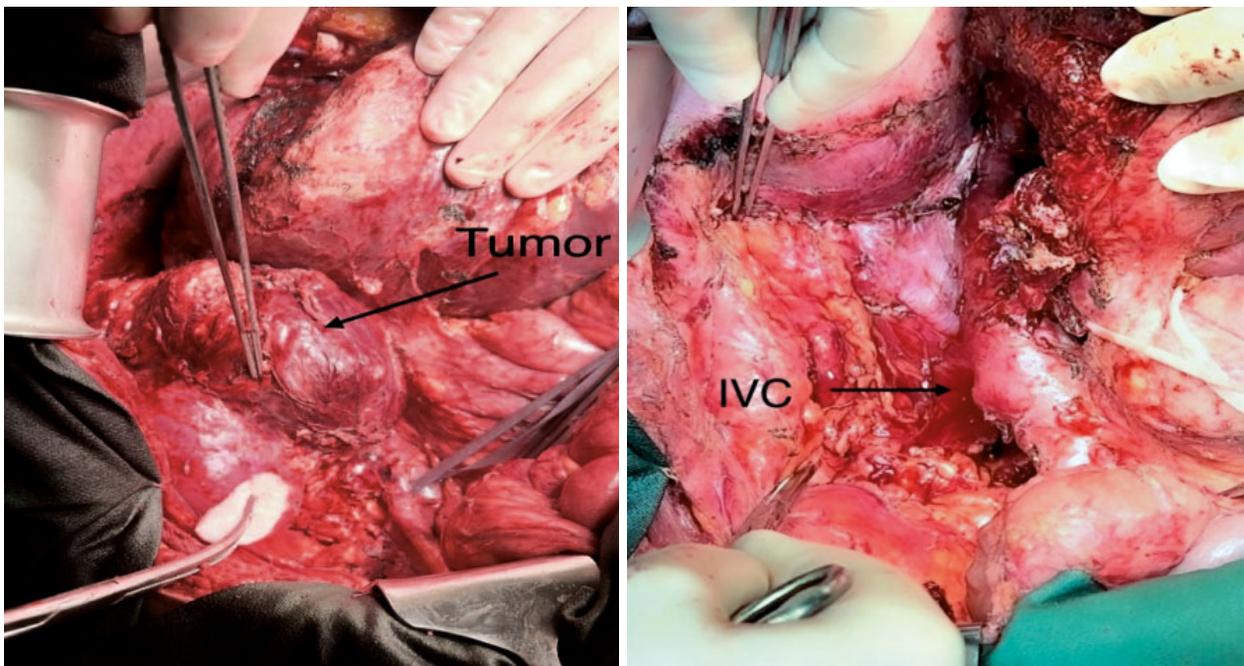


Figure 6. Intraoperative photo



Figure 7. **Macroscopic specimen of the tumour: recurrent tumour with SgIV in the liver and right kidney**

After preoperative preparation, the patient underwent surgery, which included viscerolysis, atypical SgIV liver resection with right-sided nephrectomy and resection of the right dome of the diaphragm, and aortocaval lymphadisection (Fig. 6, Fig. 7). The extent of lymph node dissection included the removal of lymph node groups 16a2, 16b1.

The patient was discharged on the 11th postoperative day in satisfactory condition to continue combined therapy under the supervision of a clinical oncologist.

Pathological examination revealed the following findings:

1. The liver tissue contained a solid cystic mass composed of stellate, spindle-shaped, epithelioid and extremely pleomorphic multinucleated cells, forming solid layers around single duct-like structures lined with cylindrical epithelium. The tumour cells exhibited pronounced polymorphism. The morphological picture was most consistent with recurrent undifferentiated pleomorphic sarcoma. According to the FNCLCC sarcoma grading system, the tumour scored 3 points for differentiation, 3 points for mitotic activity (24 per 10 high-power fields at magnification  $\times 400$ ), and 2 points for necrosis (60%), resulting in a total score of 8 (G3). There were no signs of lymphatic, vascular or perineural invasion within the studied specimens. The largest tumour size measured 15.2 cm. Tumour invasion into the kidney tissue and the adjacent diaphragmatic flap was observed, corresponding to rpT3. The adrenal gland was not involved in the tumour process.

The resected margins of the ureter, renal vessels, paranephric adipose tissue, diaphragm, and

liver parenchyma showed no evidence of tumour involvement (R0).

2. Of the two examined lymph nodes, one demonstrated tumour metastasis with histological features similar to the primary liver tumour (1/2).

Postoperative diagnosis: undifferentiated pleomorphic liver sarcoma (G3) rpT<sub>3</sub>rpN<sub>1(1/2)</sub> R0.

Currently, the recurrence-free follow-up period is 12 months after the second surgery.

## Conclusions

Although UPS of the liver is a rare malignant mesenchymal tumour, it should be considered in the diagnosis of large liver lesions. The clinical manifestations and diagnostic features are variable, which makes preoperative identification challenging. Predictive factors include patient age, tumour size, histological grade, histological subtype, and anatomical location. Surgery remains the primary treatment strategy for undifferentiated pleomorphic liver sarcoma.

## DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

## ETHICS APPROVAL AND WRITTEN INFORMED CONSENTS STATEMENTS

All procedures were carried out in compliance with the current legislation of Ukraine on ethics, the principles of Good Clinical Practice (ICH 6CP), and the recommendations of the 2013 Helsinki Declaration.

## AUTHORS CONTRIBUTIONS

Y.P. Bakunets: critical review of the manuscript; Y.P. Bakunets, M. S., Zagriyuchuk I.A., Bryndak R.A. Samokishchuk: work concept, design, and critical review of the manuscript; F.O. Prytkov: work concept and design, data collection and analysis, and writing the manuscript; M.I. Korshunova: data collection, analysis, and writing the manuscript.

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## Клінічний випадок хірургічного лікування недиференційованої плеоморфної саркоми печінки

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Недиференційована плеоморфна саркома (НПС) печінки, раніше відома як злоякісна фіброзна гістіоцитоза (МФН), дуже рідко локалізується в печінці як первинна пухлина. Вперше описана в 1964 р. O'Brien і Stout. Цей тип пухлини є найпоширенішим серед злоякісних пухлин м'яких тканин, зазвичай виникає в дорослому віці та вражає кінцівки, рідше – заочеревинний простір й органи черевної порожнини.

**Мета** — представити результат лікування рідкісного випадку недиференційованої плеоморфної саркоми печінки.

Описано клінічний випадок хірургічного лікування пацієнта з НПС печінки. Пацієнт Н., 36 років, звернувся зі скаргами на біль у правому підребер'ї, підвищення температури тіла, загальну слабкість. За результатами інструментальних обстежень встановлено клінічний діагноз: первинна пухлина печінки, розрив пухлини, внутрішньочеревна кровотеча. Після проведення доопераційної підготовки виконано правобічну гемігепатектомію, лімфаденектомію D2, холецистектомію, дренажування черевної порожнини. Морфологічна картина й імунофенотип клітин пухлини найбільше відповідали НПС печінки. За системою градації сарком Federation Nationale des Centres de Lutte Contrele Cancer (FNCLCC) загальна кількість балів – 7 (G3). Встановлено діагноз: НПС печінки pT<sub>4a</sub>N<sub>0</sub>M<sub>0</sub> G3 III ст., 2 клінічна група. Через 6 міс за даними комп'ютерної томографії органів черевної порожнини виявлено пухлинне вогнище в правому піддіафрагмальному просторі з інвазією в правий купол діафрагми, IV сегмент печінки, праву нирку. Виконано оперативне втручання в обсязі: вісцероліз, атипична резекція SgIV печінки з правобічною нефректомією та резекцією правого купола діафрагми, аортокавальна лімфодисекція. Післяопераційний діагноз: НПС печінки pT<sub>4</sub>N<sub>1(1/2)</sub>M<sub>0</sub> G3, R0, III ст., 2 клінічна група. Тривалість безрецидивного спостереження становить 12 міс після повторного оперативного втручання.

**Ключові слова:** недиференційована плеоморфна саркома печінки, саркома, неоплазія.

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# The shape and volume restoration of the mammary glands in postoperative deformations

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This article is dedicated to modern methods of reconstructive and plastic breast surgery in women with postoperative deformities. Reconstruction of the mammary glands in cases of postoperative deformities relies on a variety of surgical techniques. The selection of an appropriate method depends on the morphological characteristics of the defect, tissue condition, prior surgical history, and the patient's overall somatic status. The article highlights the anatomical and aesthetic parameters of the mammary glands, the classification of postoperative deformities, and modern approaches to secondary reconstruction (implants, autologous tissues, lipofilling), the importance of preserving or restoring the nipple-areolar complex, as well as methods for objective measurement of breast shape and volume, including 3D scanning, magnetic resonance imaging (MRI), and mathematical models. The main approaches to reconstruction are discussed: implants, tissue expanders, autologous flaps (DIEP, TRAM, TDAP, SGAP, LICAP), and lipofilling as an additional or independent option for minor defects. Their advantages, disadvantages, and indications are analyzed. Special attention is given to breast symmetry, the influence of individual anatomical features of the patient, and the staging of surgical interventions. It is emphasized that early reconstruction after mastectomy contributes to better psychological rehabilitation, and the restoration of the breast's aesthetic units improves patients' quality of life. MRI is identified as the most accurate method for assessing breast volume, although less invasive and more accessible methods are preferred in routine practice. The article summarizes current approaches to the planning and execution of secondary reconstructive surgery for restoring breast shape, volume, and symmetry. The importance of an individualized approach is emphasized to achieve optimal aesthetic and functional outcomes.

## KEYWORDS

breast reconstruction, postoperative deformities, autologous flaps, breast symmetry, nipple-areolar complex, 3D breast imaging, MRI volumetry.

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According to official data from the American Society of Plastic and Reconstructive Surgeons, in 2019, 575,292 plastic surgeries were performed on the mammary glands (National Plastic Surgery Statistics 2022). The number of patients who underwent surgical intervention in the United States increased by 15 % between 2014 and 2019. Consequently, the number of postoperative complications, including pathological deformations of the mammary gland shape and volume, also increased.

Surgical interventions on the mammary gland alter not only its proportions but also affect the overall body balance, which is related to symmetry and aesthetics. The consequences of surgical

intervention must consider all potential postoperative effects, including scars and distortion defects in the form of asymmetry due to tissue removal.

Research conducted by silicone implant manufacturers indicates that within a decade, 22 % to 36 % of patients may require secondary surgical correction for shape and volume deformations, with this rate expected to increase to 35 %-47 % over time. Pathological deformation of the mammary glands following surgery was most often attributed to capsular contracture, ptosis, and mammary gland asymmetry [36].

The pursuit of effective, minimally invasive, and standardized methods motivated this study.

Specific parameters may change naturally or through external intervention over a woman's life, such as weight changes, hormonal fluctuations during and after lactation, and the aging process. These physiological changes are generally symmetrical. However, surgical interventions for medical or aesthetic reasons can modify any of the three primary parameters that determine breast shape, either individually or in combination.

To restore symmetry, beauty, and harmony, it is essential to adhere to the proportionality principle during both surgical planning and the intervention itself. Proportionality restoring of anatomical structures requires considering blood supply, skin innervation, and glandular tissue quality while also paying attention to supporting structures, biomechanical characteristics, glandular tissue dynamics, and connections with axillary structures and the vasculature of the pectoralis major and latissimus dorsi muscles [25].

Three main parameters that influence the shape of the mammary gland are the contact area with the chest wall (base), the skin surface area, and the breast parenchyma volume. Additional factors include the base shape, the ratio of structural elements in the composition of the breast parenchyma (ratio of glandular, adipose tissue, and connective tissue), and skin elasticity. The base size and shape of the mammary gland are often referred to as the 'breast footprint' in literature. The breast shape can be altered by modifying one or more of these parameters through surgical intervention.

According to surveys, breast asymmetry occurs in 5%-50% of women. From a surgical perspective, the most challenging situations arise when the nipple-areolar complex is located above the highest projection point of the breast.

Studies indicate that lateral displacement is of more concern to women than height differences. High nipple placement is typically regarded as abnormal. A volume difference exceeding 100–150 grams between breasts is noticeable when unclothed and may raise concerns for patients when wearing undergarments. The position of the inframammary folds is imperceptible in the horizontal plane if the difference is less than 1 cm. However, a discrepancy exceeding 2 cm may cause concern in women and is often a reason for aesthetic surgical interventions.

### **Standards of mammary gland shape, size, and volume**

The desire to describe an aesthetically acceptable mammary gland is not new. Defining aesthetic beauty becomes more feasible with measurable parameters and consideration of body proportions.

The female mammary gland is perceived as a spatial geometric shape resembling a hemisphere or a cone. Breast surgeries modify, reduce, or increase the breast volume, may reduce the skin surface area, and change the shape of the base. If the changes involve only one side, breast symmetry is disrupted, and the spatial relationships between the breasts change. A disproportionate increase or decrease in any measurable parameter leads to the loss of the aesthetic breast shape.

Aesthetic units and subunits of the breast are static. Functional anatomical landmarks, which border or overlap one another, are individually defined by the plastic surgeon. The shape and size of an aesthetic unit influence the surgical intervention goal, whether it is partial or complete breast removal, reconstructive or aesthetic surgery, including breast shaping, volume augmentation or reduction, or symmetry correction. Various interventions involve specific aesthetic units and subunits of the breast. Restoring an aesthetic unit is particularly relevant when it is located in an anatomically significant area. It is crucial to preserve or reconstruct the nipple-areolar complex, the lower pole profile, or the upper-inner quadrant of the breast. The complexity of a particular aesthetic unit is characterized by its blood supply, tissue structure, innervation, unit or subunit volume, surface profile, skin quality, and the proportion of incisions at unit borders to natural folds.

The aesthetic appearance of the breast is primarily determined by its proportion to the entire body. In human body proportions, the entire breast is an aesthetic unit from the anthropometric perspective. The aesthetic subunit of the breast is defined by the proportion of various anatomical landmarks. Aesthetic units can be divided into additional subunits: the nipple, areola and its immediate surroundings, the central chest area, and the upper, lower, inner, and outer poles of the breast. The upper-inner quadrant is a distinct aesthetic unit. This area, the *décolleté*, defines the visible attractiveness of the breast. Its preservation or restoration is one of the key challenges for surgeons practicing reconstructive plastic procedures. Significant discrepancies between body and breast size appear aesthetically unbalanced, such as an extremely large breast size in a slender woman or a small breast size in a woman with an endomorph body type. Breasts with proportions that differ from the norm, size mismatches, or asymmetry can affect a person's behavior, emotional well-being, and self-esteem.

An objective determination of individual breast beauty can be achieved by comparing the measurable parameters of its ideal shape and size. Plastic surgeons have attempted to define breast beauty, i.e., its ideal dimensions, based on clinical

experience, artistic canons, geometric and mathematical measurements. The proportions of an ideal breast and its measurable parameters include the ratio of the upper and lower breast poles, the nipple position on the breast meridian, the inframammary fold (IMF) and its distance from the nipple, the horizontal and vertical diameter of the breast base, and the angle of nipple deviation in the area of the greatest projection.

### Proportions of the ideal breast

Arithmetic measurements and geometric rules determine the individual proportions of the breast, anatomical landmarks, and lines necessary for definition.

#### *Parameters of a medium-sized breast*

- Distance between the suprasternal notch and the nipple is 18–21 cm.
- Horizontal diameter of the breast base is 11–14 cm.
- Vertical diameter of the breast is 11–14 cm.
- Nipple-areolar complex diameter is 2.8–5 cm.
- Distance between the inner pole and the nipple is 8–11 cm.
- Distance between the outer pole and the nipple is 9–11 cm.
- Distance between the upper pole and the nipple is 6–7 cm.
- Distance between the lower pole and the nipple is 7–9 cm.

The breast meridian is the vertical midline (from the inner third of the clavicle to the nipple, inframammary fold, descending toward the abdomen).

Horizontal breast lines are parallel circles between its base and the nipple.

The ideal ratio of the upper to lower breast poles is 45:55, and the optimal lower pole size from the nipple to the inframammary fold is 5.5–7.0 cm, averaging 6.8 cm according to Persichetti's studies.

Batik and Uzun have researched that the length of the lower pole is 5–7 cm from the lower edge of the areola to the inframammary fold when it is measured without skin tension. The distance between the inframammary fold and the nipple differs from the distance from the lower edge of the areola to the inframammary fold. The distance from the nipple to the inframammary fold is a more accurate measurement of the lower pole [22].

### The significance of the nipple-areolar complex in aesthetic and reconstructive breast surgery

In the aesthetic evaluation of the breast, the position, shape, and size of the nipple are of great importance. It is located at the highest curvature point, on the breast meridian, between the upper and lower poles (45:55), slightly above the midline. The nipple is tilted upward

by 20 degrees. The areola's diameter is proportional to the breast size, ranging from 2.8 to 5.0 cm.

On average, the areola is round, with a diameter of 3.8 cm, while the nipple diameter ranges from 0.8 to 1.5 cm. These parameters can vary depending on breast volume.

The presence or absence of the nipple or areola significantly affects the overall aesthetic appearance of the breast. The absence of a nipple reduces the aesthetic appeal of the breast and is perceived by patients as an imperfection in reconstructive procedures. Psychological studies indicate that reconstructive breast surgery can be considered complete only after the restoration of the nipple-areolar complex.

Differences in the diameter and shape of the nipple-areolar complex must be taken into account in nearly every case involving reconstruction with an expander, breast hypertrophy, or gigantomastia. Typically, nipples are positioned at different levels in the horizontal or vertical plane.

### Methods for measuring the mammary gland shape and volume

The measurement of breast volume has been a challenge for plastic surgeons for decades. Several methods have been developed to determine breast volume.

Direct mechanical measurements are based on **Archimedes' principle**. The simplest method involves submerging the breast in a container filled with liquid and measuring the volume of displaced fluid. However, this approach is inconvenient for the patient, and it is difficult to implement. Based on the same principle, an imprint of the breast is created using a thermoplastic material. Once it hardens, the mold is filled with liquid, which is then measured. A study published by Turkish authors described the use of a **ready-made device based on the fluid displacement principle**, which allowed measuring the difference in breast volume. However, these measurement methods did not gain popularity due to their inaccuracy and complexity in routine practice [34].

A group of Chinese authors attempted to develop a practical formula for calculating breast volume:

$$(\pi \cdot MP^2 \cdot (MR + LR + IR - MP))/3,$$

where: MR – medial radius (distance from the nipple to the medial border); LR – lateral radius (distance from the nipple to the lateral border); IR – nipple-inframammary fold length (distance from the nipple to the inframammary fold); MP – mammary projection.

The accuracy of such volume measurements is limited because the breast cannot be described using a simple geometric formula. Therefore, anthropometric measurement methods have not become widely adopted in daily practice.

Breast volume and ptosis can be accurately calculated using models described by B. Longo et al. The authors aimed to develop a unified predictive formula for assessing volume in both small and large breasts. Their study was based on anthropomorphic measurements and direct volume measurements of 108 mastectomy specimens received from 88 women. The authors performed multivariate regression analysis to develop a predictive volume assessment formula, which was then internally validated.

The mean breast weight was  $527.9 \pm 227.6$  g (range: from 150 to 1250 g). The most significant predictive parameters were:

- Distance from the sternal notch to the nipple;
- Distance from the inframammary fold to the nipple;
- Distance between the folds' projections.

The resulting BREAST-V formula showed a corrected r-value of 0.73. The expected deviation in volume estimation was 89.7 g (95 % CI: 62.4–119.1 g), and the expected relative deviation was 18.4 % (95 % CI: 12.9 %–24.3 %). The authors stated that BREAST-V is a reliable tool for objectively assessing small and large breast volumes and can be used as an additional tool in surgical planning.

An app called BREAST-V is now available for iOS and Android devices for free download on the App Store and Google Play Store [4].

### Other measurement methods

Similar anthropometric data can be obtained from breast and chest wall photographs or direct measurements.

The biostereometric measurement method is based on the same principle. Breast volume data can be obtained using computer calculations performed when studying images in standard projections.

Mammographic images have been used to determine breast volume, but due to inaccuracies, particularly related to compression, this method was deemed ineffective.

A more precise measurement of breast volume can be performed using a laser scanner. A laser beam scans the breast surface, and through computer processing, a model is created, followed by volume calculations.

Advantages of the laser scanning method:

- It allows scanning in a standing position, under physiological conditions.

Disadvantages:

- High device cost;
- It requires specialized laboratory and trained personnel;
- Inaccuracy in measuring ptotic breasts, as breast parenchyma casts a shadow, concealing part of the volume from the laser beam.

German and Japanese specialists have published several studies describing the practical application of this method.

### MRI- and CT-based volume measurement

The idea of determining breast volume using MRI and CT scans originated from neurosurgical diagnostics. In neurosurgery, it is crucial to determine the precise spatial localization of a brain tumor, its size, and its relationship with surrounding structures. Advances in diagnostic imaging and virtual modeling have enabled the use of these methods in other medical fields.

Software used for volume determination:

- FreeForm Concept
- ANSYS
- Geomagic Studio
- Amira
- Mimics
- Osiris
- AMIDE
- Sundera Vie Personal
- OsiriX
- ConQuest
- Ginkgo CADx
- XMedCon
- Mango
- UniPACS DICOM viewer
- ImageVis3D
- DicomWorks
- Slicer

MRI and CT volume measurements are typically conducted using specialized software programs commonly utilized in industrial settings. Segmentation is performed manually, generally requiring 40–60 slices, depending on the scanner's resolution.

While the segmentation process can be partially automated, the similar density of subcutaneous fat in the breast and chest wall often results in poor contrast at the boundaries, complicating accurate delineation of breast tissue from adjacent structures.

During segmentation, breast boundaries are manually marked using fixed points, reducing measurement errors due to subjectivity [24].

The authors of this section propose defining the sternal midpoint as the medial boundary. The lateral boundary is defined as a plane along the lateral edge of the pectoralis major muscle, built perpendicularly to the chest wall. The distal boundary is the inframammary fold, and the upper boundary is the beginning of the breast projection.

Computer programs generate voxels (volume units) from selected pixels on slices, and the total volume is quantitatively assessed. A spatial model can then be obtained from the voxel distribution.

*MRI as the most accurate measurement method*

A variety of programs are available for MRI-based volumetric analysis. While some options are expensive, free online versions can be accessed at [www.idoimaging.com](http://www.idoimaging.com).

MRI volume measurement is labor-intensive and expensive, making it less practical compared to other methods. However, it remains the most accurate measurement method according to the literature.

In 2015, H. Kim et al. published a study on MRI for breast reconstruction planning, including both autologous flap and implant-based reconstruction.

The study included 40 patients preparing for autologous reconstruction with DIEP flap and 30 patients preparing for implant reconstruction between 2011 and 2012.

In DIEP flap patients, the average weight of excised breast tissue after mastectomy had a stronger association with the MRI-estimated breast volume than with CT-estimated volume (Pearson's correlation: 0.928 vs. 0.782;  $p = 0.001$ ). MRI had a stronger correlation with final flap weight than CT (Pearson's correlation: 0.959;  $p = 0.001$ ).

For implant-based reconstruction patients, MRI-estimated volume closely correlated with the actual mean weight of removed breast specimens (0.937;  $p = 0.001$ ).

The average implant volume used for reconstruction was more closely related to the MRI-estimated breast volume than to the actual mastectomy tissue weight (0.893 vs. 0.880;  $p = 0.001$ ).

The authors concluded that MRI provides reliable information for determining implant volume and autologous tissue flap volume, ensuring optimal symmetry in breast reconstruction [20].

**Three-dimensional modeling based on surface scanning**

In recent years, three-dimensional (3D) visualization based on surface scanning has gained popularity due to its advantages, such as:

- Fast and simple analysis;
- Minimally invasive procedure;
- Ability to examine the patient in an upright position;
- No ionizing radiation;
- Safety.

3D scanning systems are relatively new and were first described by SJJ Daly and Hartmann in 1995. The authors used Moire topography to obtain surface scans. However, this method was limited in its ability to capture images and assess volume only in women with well-defined breast shapes and sizes.

J. M. Yip et al. used the Cyberware WBX (Cyberware, USA) system, which captures images

through scanning with four laser heads. The scanning process took an average of 15 seconds.

A. Losken et al. and B. Mailey et al. implemented scanning technologies using camera-based systems. These systems measure distortion of a light beam projected from an integrated light source (3DMD system, GA, USA, Losken) or analyze reflected light patterns (Portrait 3D, Axis Three, FL, USA, Mailey) [6].

These systems usually have a very short capture time (for example, 3DMD captures in  $\sim 50$  ms), which minimizes the effect of breathing and heart-beat movements during scanning.

*Validation of 3D imaging techniques*

In 2005, A. Losken et al. published a study evaluating the reliability of three-dimensional breast visualization methods. The authors emphasized that the potential for extrapolating precise data from 3D images to clinical practice is significant and that this method could greatly improve the accuracy of assessing shape, size, and volume in surgical planning.

*Study Details:*

- 19 three-dimensional images of breasts were obtained pre-mastectomy (14 patients).
- Breast tissue volume was determined intraoperatively using the water displacement method.
- Two independent studies calculated breast volume using 3D imaging and specialized software and compared the results with intraoperative volume measurements.
- The next step was to compare nipple-to-sternal notch distance measurements (20 breasts, 10 patients) in reality vs. on the 3D model.

*Key Findings:*

- Average breast volume is 500 ml.
- Measured volumes are 489 ml (first measurement) and 490 ml (second measurement).
- The relative difference between actual and calculated volume is  $\sim 2\%$ .
- Standard deviation is  $\pm 13$  to  $16\%$ .
- Study agreement coefficients are 0.80 (first study) and 0.92 (second study).
- The measurement correlation coefficient is 0.975.
- Average nipple-to-sternal notch distance is 26.1 cm (actual), 25.1 cm (first calculation), and 26.1 cm (second calculation).
- Relative difference in distance measurements is  $6\%$  (standard deviation:  $6-7\%$ ).

The authors concluded that objective breast volume assessment using 3D surface scanning is feasible and highly reproducible. Although subjectivity is always present in breast volume evaluation, 3D technology provides valuable information and is an extremely useful and convenient tool [23].

### Postoperative monitoring and virtual planning

3D scanning is also applicable for postoperative monitoring. Another significant advantage is that it allows segmentation of breast volume in virtual surgical planning.

However, surface scanning does not capture the full thickness of the breast down to the chest wall. Additionally, for large breast sizes, measurements may be inaccurate.

#### *Limitations of 3D Scanning:*

- High cost of the technology;
- Limited availability due to expensive equipment;
- Challenges in measuring large or ptotic breasts accurately.

#### *Systematic review of breast volume measurement accuracy*

In 2016, S. B. Choppin published a systematic review to evaluate the accuracy of various methods for measuring breast volume and their clinical utility.

The review included 15 studies, each with more than 10 participants, where the accuracy of volume measurement was compared against breast volume and weight after mastectomy [7].

#### Evaluated methods:

- Anthropometric analysis;
- Water displacement (Archimedes' principle);
- Breast molds;
- The Grossman-Rudnev cone method;
- CT- and MRI-based modeling;
- Mammography-based volume estimation.

#### Key Findings:

- All methods showed significant measurement errors (> 200 ml).
- Measurement errors were likely due to method execution rather than inherent flaws in the methods themselves.

#### *Reducing measurement errors*

To minimize errors, researchers emphasized the importance of:

- Consistent patient positioning;
- Standardized examination conditions;
- Uniform segmentation techniques to separate breast volume from the chest wall.

Clinicians must define an acceptable margin of error in breast volume measurement, as inaccuracies can lead to incorrect clinical decisions.

- A. Losken et al. suggested an acceptable measurement error of  $\pm 10\%$ .
- H. Probst et al. established a precision threshold of  $\pm 5\%$  and a volume tolerance of 25 ml.
- A 5–10% measurement error is considered clinically acceptable.

#### *Most accurate methods*

Among all imaging techniques, MRI scanning consistently demonstrated the highest accuracy.

Errors were less than 10% for different breast volumes:

- Small breasts (~250 ml);
- Medium breasts (~500 ml);
- Large breasts (~1000 ml).

#### *Conclusions*

- 3D surface scanning is an accurate, reproducible, and useful tool for breast volume assessment.
- MRI remains the most accurate method, but high costs and time-consuming analysis limit its widespread use.
- Acceptable measurement error for clinical decisions ranges from 5–10%.
- Standardized protocols for patient positioning and segmentation are necessary to improve accuracy [30].

### Incision lines on the breast

Conscious preoperative planning of incisions on the breast skin surface is essential. Periareolar, vertical, L-shaped, or T-shaped incisions are necessary for reducing or increasing breast volume or creating symmetry.

For tumor removal, classical mastectomy, or reconstructive breast surgeries, the following incisions should be used:

- Incisions around the nipple-areolar complex;
- Parallel incisions along the breast meridians;
- Vertical incisions on the lower pole.

Making an incision in the décolleté area should be avoided. Whenever possible, the incision should be placed along the natural curvature of the breast, at the border between the inframammary fold and the nipple-areolar complex.

#### *Radiation therapy's effect on scars*

Post-reconstruction radiation therapy does not worsen scar quality, regardless of skin incision direction. However, tissue fibrosis may lead to structural displacement.

#### *Preferred incision techniques*

- Incisions along relaxed skin tension lines;
- Parallel incisions outside breast aesthetic units;
- Incisions around the areola;
- Central horizontal breast incision with semi-circular extensions above or below the areola;
- Periareolar and vertical incisions on the lower pole of the breast.

From the areola, oblique and vertical incision lines are acceptable. Among these, the most favorable incision follows the central breast line.

### *Optimal incision direction*

The optimal incision direction is determined by:

- Relaxed skin tension line;
- Anatomical structure boundaries;
- Natural breast contours.

The goal of reconstructive or aesthetic breast surgery is not only to preserve the natural shape but also to achieve the best possible aesthetic result [28].

### *Incision placement impact on healing*

Incision lines corresponding to the boundaries of aesthetic units promote:

- Ideal wound healing;
- Normotrophic, minimally visible scars.

Reconstructing the aesthetic units of the breast helps restore the shape, volume, and symmetry of the entire body's external appearance.

## **Reconstructive and plastic surgery methods**

The goal of breast reconstruction is to correct the balance of three key measurable parameters:

- Partial or complete replacement of missing breast volume, achieved either by restoring volume on the affected side or reducing the volume of the contralateral breast.
- The missing volume can be restored using autologous tissue or implants.

One of the challenges in analyzing unsatisfactory surgical outcomes is the high variability among clinical cases, making it difficult to establish a universal treatment strategy for breast shape and volume deformities.

### *Modern oncoplastic approaches*

In contemporary breast surgery, the primary oncoplastic approach involves surgical planning based on breast aesthetic units and subunits, which determines incision lines for tumor removal.

- Surgical plans should be individualized, allowing for method adjustments during the procedure.
- Autologous tissue reconstruction provides a natural breast structure, making it biologically superior to foreign-body implants; however, the surgery is more complex and time-consuming.

In both early and delayed breast reconstruction, breast implants can yield excellent aesthetic results, reduce patient stress, and shorten treatment duration.

However, achieving full reconstruction of all breast aesthetic units generally requires at least three surgical procedures.

### *Skin surface replacement*

- Missing skin can be restored using flaps, which may be local or transferred from other anatomical areas.
- The most common and noticeable cause of asymmetry is a volume mismatch between the two breasts.

Recognizing and measuring this asymmetry is a key aspect of reconstructive plastic surgery [18].

Chest wall deformities or abnormal breast positioning can cause asymmetry without altering breast volume. Accurate volume discrepancy assessment is crucial for successful reconstruction.

### *Challenges in volume assessment*

• During reconstructive or aesthetic surgery, breast volume differences are typically assessed subjectively by the surgeon.

• Accuracy depends on the surgeon's individual experience.

• Plastic surgeon Aufricht (Hungarian by origin) stated in 1949:

«*Most surgeons rely solely on their eyes and hands during breast plastic surgeries.*» Unfortunately, this statement remains relevant today. Using objective volume measurement methods in reconstructive breast surgery provides significant advantages.

### *Runquist's formula for breast enlargement*

• Implants of the same base width but different heights will maintain the same inframammary fold position.

• High-profile implants may misposition the nipples, placing them below the highest point of anterior projection.

• The optimal nipple-to-IMF (inframammary fold) distance depends on implant width and skin elasticity.

Calculation example:

- Implant width 11 cm → Nipple-to-IMF distance:
  - 8 cm (firm skin)
  - 7 cm (elastic skin)
- Implant width 12 cm → Nipple-to-IMF distance: 8–9 cm
- Implant width 13 cm → Nipple-to-IMF distance: 9–10 cm

If the nipple-to-IMF distance exceeds 10 cm, it may indicate:

- Nipple position is too high.
- The lower pole curve is excessively long.
- Unfavorable lower-to-upper pole ratio.

To correct the proportions, options include:

- Redistributing glandular tissue;
- Removing excess skin via L- or T-shaped incisions [34].

### *Projection and proportion enhancements*

• Preserving glandular tissue in the central breast increases upper pole projection.

• Reducing breast footprint diameter while increasing projection improves upper-to-lower pole proportions.

- Upper pole volume can be enhanced through lipofilling.

#### *Structural Considerations for Breast Reconstruction*

- All aesthetic units of the breast may undergo reconstructive and aesthetic surgery.
  - The foundation of breast aesthetics includes:
    - Breast base (footprint);
    - Glandular tissue (parenchyma);
    - Skin envelope.

The juvenile mammary gland spot is a perfect circle, while the ratio of glandular to fatty tissue defines breast size and consistency.

- Skin quality, thickness, and elasticity influence breast shape and firmness.
- Surgical planning focuses on modifying the breast footprint by increasing or decreasing its diameter.

Breast reshaping and lifting can be achieved with:

- Parenchymal modeling (increasing or reducing volume);
- Skin removal or tightening;
- Carefully planned incision and excision techniques.

With age, the vertical breast footprint diameter shortens, and the upper pole shifts closer to the inframammary fold. Horizontal diameter decreases after reductive surgery [12].

#### *Techniques for breast volume and shape correction*

- Parenchymal volume can be reduced (breast reduction) or increased (implants).
- Mastopexy procedures modify breast shape and roundness without changing upper pole volume.
- Common incision types for breast correction:
  - Periareolar incision;
  - Round-block vertical incision;
  - Inverted-T incision

#### *Oncoplastic considerations*

- During oncoplastic surgery, excised breast tissue volume is measured, and the defect is reconstructed.
- Volume deficits between the two breasts are calculated to guide augmentation or asymmetry correction.

#### *The role of reconstruction in post-mastectomy recovery*

- Comprehensive surgical expertise is required for selecting the optimal reconstructive approach.
- Breast reconstruction after mastectomy is now a standard practice, but it was controversial for a long time.

Early critics believed that «sick women should be left alone» and opposed integrating post-mastectomy

breast reconstruction into routine plastic surgery, citing concerns about oncological safety.

However, medical practice has shown that delayed breast reconstruction significantly improves psychological recovery in women post-mastectomy.

Breast restoration provides:

- A chance for complete rehabilitation;
- Restoration of a normal appearance;
- Optimism and improved post-mastectomy quality of life.

This approach enhances both cancer treatment and psychological well-being [13].

#### *Breast reconstruction evolution since the 1980s*

Since the 1980s, breast reconstruction has been an integral part of breast cancer treatment.

Proven oncological safety and continuous advancements in surgical techniques have enabled:

- Successful restoration of breast shape and size;
- Improved clinical outcomes.

#### *Advancements in breast reconstruction techniques:*

- Submuscular placement of silicone implants;
- Innovations in textured and silicone gel implants;
- Borosilicate microspheres in implant design;
- Introduction of myocutaneous and myofascial flaps;
  - Refinement of microsurgical free tissue transfer techniques.

These methods apply to both primary and secondary breast reconstruction.

#### *The timing of breast reconstruction*

- Early reconstruction after mastectomy is preferred, as it helps avoid psychological trauma associated with breast loss.
  - If early surgery is not possible, secondary reconstruction is performed after 6–12 months to allow tissue recovery [23].

#### *Challenges in post-radiation reconstruction*

- Fibrosis is common in post-radiation patients, complicating simple implant placement.
  - Alternative reconstruction techniques (e.g., muscle or tissue flaps) may be required.
  - The optimal time for post-radiation reconstruction is typically one year after therapy.

#### *Achieving symmetry with contralateral breast adjustments*

Reconstructive surgical choice depends on post-mastectomy local tissue conditions.

Reconstruction techniques:

1. Silicone implant placement
  - Simple procedure
  - It requires sufficient soft tissue coverage
  - It is best for small breasts with firm tissue

2. Tissue expander technique
  - Gradual skin expansion to match contralateral breast size
  - Final implant selection based on preoperative markings
  - Ideal for large-breasted patients [38].

### Breast tissue expander

The technique involving tissue expansion and implant placement was primarily introduced into plastic and reconstructive surgery practice by Radovan in the 1980s, and it was further developed under the influence of Argenta's work. Today, this method is widely used in reconstructive breast plastic surgery. Earlier techniques required the mandatory use of skin (or musculocutaneous) flaps to replace the breast skin. Tissue expansion using expanders has significantly enhanced the capabilities of breast reconstructive surgery, particularly in early reconstruction procedures.

The tissue expanders used in the 1980s had a poor-quality surface. As a result, their displacement and even the formation of contractures that hindered proper tissue expansion were not uncommon. In the 1990s, Maxwell developed a new generation of textured expanders, which gave a significant boost to the development of reconstructive breast plastic surgery. The porous textured surface allows fibroblasts from the surrounding tissues to grow into the implant, providing the expander fixation in the desired position [25].

In general, tissue expansion with expanders is indicated for all women who have undergone mastectomy, where soft tissue quality is sufficiently good but its quantity is insufficient. From a technical standpoint, tissue expansion with expander usage is a less complex procedure than the alignment of a skin or muscle flap and is also not associated with scarring or deformational changes, which is an additional advantage for many women.

The use of expander tissue expansion tactics necessitates the need for secondary intervention aimed at the restoration of breast shape and size. Before the second stage of surgical correction can be performed, several preliminary check-ups are required, during which the expander must be gradually filled. This characteristic feature (the multi-stage nature of the correction) is inconvenient and even unacceptable for some women. Despite the advantages of reconstruction using autologous tissue, tissue expansion with expanders remains a standard method included in the set of breast reconstructive surgery procedures [18].

The size of the tissue defect after mastectomy is determined by measuring the horizontal and vertical dimensions of the healthy breast and projecting these

measurements onto the mastectomy area. When reconstructing the breast, it is important to take into account any interventions to eliminate damage and scar formation on the healthy side. This method allows for an accurate assessment of the amount of skin and tissue required for reconstructive surgery.

It is generally recommended to carry out the procedure in two stages. During the first stage, a tissue expander is implanted. In the second stage, after the soft tissue layer has been expanded, the expander is replaced with a standard implant. In some cases, reconstructive plastic surgery of small breasts is possible in one stage; after stretching the soft tissue layer, the expander is replaced with a standard implant.

In cases where the skin is too thin, it is advisable to attempt to increase the thickness of the covering layer over the expander using connective tissue from the chest wall or sections of surrounding muscles (such as the serratus anterior, rectus abdominis, or external oblique abdominal muscle).

The choice of expander depends on the size of the contralateral breast and must correspond to the dimensions of the chest wall. The volume of the expander should exceed the volume of the contralateral breast by approximately 100–200 ml. Expanders that are most commonly used are 12–16 cm in size with a volume of about 600 ml. Both single-chamber and dual-chamber expanders are available, with either integrated or external ports. The main advantages of an integrated port are that there is no need to form an additional pocket for the port, as well as it eliminates the risk of rotation after the expander is installed. The drawbacks include the risk of expander perforation due to improper needle insertion. Undoubtedly, a key aspect is that the textured surface of the expander ensures secure fixation to the surrounding tissues, preventing displacement once filled [19].

Before implantation, the expander is deflated and placed into the area of prior dissection (beneath the muscle layer). After restoring the integrity of the muscle layer by applying several interrupted sutures (using absorbable suture material), the expander is initially filled with 100–200 ml of sodium chloride physiological solution.

### Application of flaps in various modifications for breast shaping and volume restoration (gluteal flap, thoracodorsal flap, and LICAP flap)

Reconstruction with autologous tissue usage offers numerous advantages over implant-based reconstruction, including better aesthetic outcomes, a more natural breast shape, improved appearance over time, and fewer overall complications. Most

autologous breast reconstructions are based on the use of abdominal tissue as a donor site for flaps, which has proven to be reliable and is associated with good results and high patient satisfaction [16].

There are several alternative donor sites for autologous breast reconstruction in patients whose abdominal tissue is not suitable, often due to a thin abdominal wall or previous abdominal surgeries. These alternatives include the back, thighs, and buttocks [33].

Breast reconstruction using autologous tissue allows for the creation of a naturally shaped breast that is elastic, exhibits natural ptosis, and maintains normal skin temperature, which is rarely possible when using synthetic materials [5].

When there is sufficient area suitable for reconstruction and the required quality of soft tissues, a fairly good cosmetic outcome can be achieved. The use of a transposed abdominal skin flap provides enough skin surface for performing plastic procedures; however, upward displacement of the flap usually results in the formation of folds in the lateral areas (such defects are quite difficult to correct). Generally, the use of tissue expanders is necessary to achieve good cosmetic results [39].

Autologous breast reconstruction with anterior abdominal wall tissue usage is one of the surgical methods that began its history quite some time ago. Over the past 50 years, techniques for breast reconstruction with anterior abdominal wall tissue usage have reached a significant level of advancement. Historically, pedicled TRAM (Transverse Rectus Abdominis Myocutaneous) flap breast reconstruction was first described in the 1980s. The evolution from pedicled TRAM to free TRAM and then to DIEP (Deep Inferior Epigastric Artery Perforator) flap reconstruction reflects a transition from musculocutaneous flaps to perforator flaps that preserve the muscle.

Surgeons typically choose between pedicled TRAM and DIEP flap procedures based on their personal experience, comfort level with each technique, and the capabilities of their surgical equipment. It is important to note that the DIEP flap requires additional technical expertise [21].

The TRAM is a flap of the anterior abdominal wall that includes skin, subcutaneous fat, fascia, and the rectus abdominis muscle.

There are two types: pedicled TRAM (p-TRAM) and free TRAM (f-TRAM) flap.

DIEP is a flap based on the perforating branches of the deep inferior epigastric artery that includes skin and subcutaneous fat [10].

In recent years, the study of microsurgical techniques and the peculiarities of the blood supply to the subcutaneous fat tissue has led to the understanding

that the use of the rectus abdominis muscle is not a necessary component of the abdominal flap; the primary goal is to preserve the perforating vessels within the flap. The development of the deep inferior epigastric perforator (DIEP) flap technique has changed the approach to the use of anterior abdominal wall flaps in autologous breast reconstruction [14].

However, a major issue with these flaps is the risk of fat necrosis in the tissues due to the peculiarities of the blood supply to different areas of the transplant. Fat necrosis is caused by ischemia of the subcutaneous fat that leads to necrosis of adipose cells and subsequent scarring, which may clinically and radiographically mimic disease recurrence. On mammography, such damage may appear as heterogeneous tissue density and microcalcifications. According to the literature, the risk of fat necrosis using tissue complexes from the lower abdominal wall ranges from 3.0% (with TRAM flap transplantation) to 42.9% (DIEP flap) [12].

A meta-analysis of 13 studies conducted by X.-L. Wang and colleagues in 2014, involving data received from 1,843 patients, did not find a statistically significant difference in the overall complication rates between MS-TRAM and DIEP flaps.

The ideal candidate for a DIEP flap is a young, non-smoking woman with a normosthenic body type and excess tissue in the lower third of the abdomen, as well as a contralateral breast of small to medium volume [40].

In summary, breast reconstruction using DIEP and MS-TRAM flaps is a reliable and safe procedure. With a careful, differentiated approach, both methods can provide high-quality breast reconstruction results.

Over time, breast volume replacement procedures have evolved from using the entire latissimus dorsi (LD) muscle to pedicled perforator flaps that are available in the thoracic region, such as the thoracodorsal artery perforator (TDAP) flap, intercostal artery perforator flap, lateral flap, thoracic artery perforator flap, and serratus anterior artery perforator flap. The muscle-sparing LD flap (MS-LD) consists of a TDAP flap including a portion of the LD muscle to protect the perforators while preserving the nerves that innervate the rest of the LD muscle [28].

The TDAP flap is an effective and versatile tool that expands the arsenal of oncoplastic surgeons, combining the advantages of a perforator flap (minimal donor site pain) with the benefits of a pedicled flap (safety) and delivering satisfactory cosmetic results.

Among alternative options, the use of the superior gluteal artery perforator (SGAP) flap in autologous breast reconstruction is becoming increasingly popular among plastic and reconstructive surgeons.

First introduced by Allen and Tucker in 1995, the SGAP flap has since been used by several teams as a first-line alternative when the abdominal area is unsuitable as a donor site [1].

The superior gluteal artery and vein supply blood to the skin and fat of the upper buttock, while the inferior gluteal artery and vein supply the lower buttock. These vessels can be used to create the SGAP flap from the upper buttock and the inferior gluteal artery perforator (IGAP) flap from the lower buttock tissue. Scars from SGAP and IGAP flap harvesting are typically well concealed by clothing. However, since harvesting these flaps may result in undesirable contour changes in the buttock, we rarely perform these procedures and instead prefer alternative methods, such as the lumbar artery perforator (LAP) flap [8].

A retrospective comparative study comparing SGAP, LAP, and DIEP flaps in autologous breast reconstruction using the BREAST-Q scale, conducted by Opsomer et al., showed that patients who underwent breast reconstruction with the SGAP flap had similar satisfaction with the appearance of their breasts and similar overall satisfaction with the result compared to those who underwent DIEP flap reconstruction. However, satisfaction with the appearance of the donor site in the SGAP group tended to be lower, although not statistically significant ( $p = 0.061$ ), compared to the DIEP group. Commonly cited drawbacks of the SGAP flap include its technical complexity, due to prolonged intramuscular dissection of the pedicle and flap harvest, the need to change intraoperative position, and longer operation time [32].

In the context of autologous flap transplantation, it is also worth describing the LICAP (Lateral Intercostal Artery Perforator) flap. The lateral intercostal artery perforator (LICAP) flap is a versatile second-tier option in breast reconstruction. The flap is rotated from the redundant lateral thoracic fold on a pedicle that is easily dissected through a skin bridge without microsurgical intervention, often in an outpatient setting. It illustrates the safety and effectiveness of the LICAP flap for implant coverage when a muscle flap is unavailable or undesirable. In some cases, it is even possible to obtain sufficient soft tissue to reconstruct the breast mound without an implant [15].

A study by S. Hakakian and A. Ryan demonstrates the advantages of the LICAP flap in addressing various breast reconstruction challenges, including outpatient procedures, the absence of muscle damage, flap reliability, and a low risk of pathological changes at the donor site. These studies confirm that the LICAP flap reliably forms

a large skin-fat flap from the redundant tissue of the lateral chest fold with minimal complications, even after radiation therapy. The LICAP flap deserves close attention in breast reconstruction [29].

### Using implants for breast shaping and volume restoration

All women undergoing mastectomy should receive counseling regarding breast reconstruction options [9].

Subcutaneous mastectomy is becoming a standard procedure in many major centers, favoring surgical interventions that minimize additional skin incisions. Oncological indications for nipple removal include nipple involvement detected through clinical or radiological examination. From a plastic surgery perspective, nipple preservation is considered viable if the nipple can be positioned correctly anatomically after surgery. Previous breast incisions are not a contraindication to nipple-sparing mastectomy. The most common incisions include the inferolateral inframammary fold incision for better cosmetic outcomes. Full-thickness periareolar incisions are largely avoided to minimize nipple ischemia. Patients with grade I breast ptosis are universal candidates for subcutaneous mastectomy. Most patients with grade II breast ptosis are also excellent candidates; however, if they desire smaller, more elevated breasts, skin or areola adjustments may be preferred. In cases of severe grade II and III ptosis, several options for nipple preservation exist, depending on the surgical indications – whether for tumor removal with volume restoration or aesthetic procedures aimed at correcting breast volume and shape [35].

Implant-based reconstruction can be performed in one or two stages. In single-stage reconstruction, the final implant is placed during mastectomy, whereas in the two-stage approach, a tissue expander is initially placed and later replaced with the final implant during a second surgical procedure (tissue expander/implant).

According to the experience of M. Schefflan and A. Colwell, there is no difference in complication rates or revision frequencies between direct-to-implant and tissue expander/implant reconstructions [35].

Reconstruction directly with implants is considered for patients who wish to obtain an unchanged size of the mammary glands after the primary surgical intervention. Generally, these patients are healthy, with relatively symmetrical breasts and a volume of less than 900 cm<sup>3</sup>. The most critical component of successful single-stage silicone implant placement is the patient's health status and the vascularization of the skin flap post-mastectomy. Authors S. Colwell and M. Taylor note that

physical examination alone is sufficient to assess the flap; however, devices measuring tissue perfusion can also be used. To safely increase size in direct-to-implant reconstruction, the mastectomy technique must be precise in its ability to remove all breast tissue while leaving a well-perfused flap [35].

When using silicone implants for breast reconstruction, attention must be paid to options for soft tissue support and implant coverage. A meta-analysis of additional soft tissue coverage methods indicates that the ideal material should be flexible and soft yet durable for long-term soft tissue support. Moreover, the use of the material should not increase the risk of capsular contracture. Acellular dermal matrix is the most commonly used for breast implant coverage and meets the aforementioned requirements.

For successful implant interventions, a number of conditions must be met. Specifically, the contralateral breast should not be too large (maximum 300–400 g), the chest wall skin should be undamaged and capable of mobilization, and the pectoralis major muscle should be preserved. The maximum target breast sizes for which implant reconstruction can still be used are an average of 400–500 ml [26].

### Lipofilling in breast reconstruction surgery

The application of lipofilling in reconstructive plastic surgery for the rehabilitation of patients after the surgical stage of breast cancer treatment has been studied by the Institute of Pediatrics, Obstetrics, and Gynecology named after Academician O. M. Lukyanov of the National Academy of Medical Sciences of Ukraine and the Verum Medical Center. This meta-analysis did not demonstrate an increased recurrence rate in patients who underwent lipofilling after the surgical stage of breast cancer treatment compared to the group of patients without lipofilling, among more than 6,121 unique patients within 10 studies. The results confirm that this procedure can be performed safely on patients after the surgical stage of breast cancer treatment [29].

Lipofilling is an effective method for correcting aesthetic defects and improving the quality of life for patients who have undergone the surgical stage of breast cancer treatment. This method is also effective for correcting aesthetic defects and enhancing the quality of life of patients who have undergone subcutaneous mastectomies with simultaneous endoprosthesis placement [2].

According to scientific publications, lipofilling can be performed on elderly patients [3]. This method does not increase the risk of breast cancer development in patients undergoing surgery for aesthetic correction, regardless of the presence or absence of benign mammary gland pathology [11].

## Conclusions

The recent literature analysis underscores the unresolved challenges in the surgical restoration of breast shape and volume.

Essential components of secondary breast reconstruction surgery encompass skin repositioning, volume restoration at the breast defect site, inframammary fold restoration, reconstruction of the nipple-areolar complex, and simultaneous symmetry correction.

The application of flaps in the restoration of breast shape and volume provides an acceptable aesthetic outcome without the reliance on artificial substitute materials. However, these methods prolong surgical time and leave scarring at the donor site. These methods are widely used in routine reconstructive plastic surgery practice and require clear indications.

The issue of surgical restoration of breast shape and volume remains relevant and necessitates effective solutions. Potential avenues for research include the post-primary surgery analysis of breast deformation and the development of an updated algorithm for selecting a minimally invasive method during secondary surgery planning, aimed at optimizing outcomes related to aesthetic restoration and the psychological well-being of patients.

## DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

## AUTHORS CONTRIBUTIONS

The authors have contributed equally to conception and design, acquisition and interpretation of data, drafting the article.

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## Відновлення форми та об'єму молочних залоз після операційних деформацій

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Огляд присвячено сучасним методам реконструктивної та пластичної хірургії молочних залоз у жінок з післяопераційними деформаціями. Реконструкція молочних залоз при післяопераційних деформаціях ґрунтується на використанні різноманітних хірургічних технологій, вибір яких детермінується морфологічними характеристиками дефекту, станом тканин, історією попередніх втручань та загальним соматичним станом пацієнтки. У статті висвітлено анатомічно-естетичні параметри молочних залоз, класифікацію післяопераційних деформацій, сучасні підходи до вторинної реконструкції (використання імплантатів, аутологічних тканин, ліпофілінгу), важливість збереження або відновлення сосково-ареолярного комплексу, а також методи об'єктивного вимірювання форми та об'єму молочних залоз, включаючи 3D-сканування, магнітно-резонансну томографію (МРТ) та математичні моделі. Обговорено основні підходи до реконструкції: використання імплантатів, тканинних експандерів, аутологічних клаптів (DI-EP, TRAM, TDAP, SGAP, LICAP), а також ліпофілінгу як додаткового або самостійного варіанта при незначних дефектах. Проаналізовано їхні переваги, недоліки та показання. Особливу увагу приділено симетрії грудей, впливу індивідуальних анатомічних особливостей пацієнтки та етапам хірургічних втручань. Підкреслено, що рання реконструкція після мастектомії сприяє кращій психологічній реабілітації, а відновлення естетичних одиниць грудей покращує якість життя пацієнток. МРТ визнано найточнішим методом оцінки об'єму грудей, хоча в повсякденній практиці перевагу надають менш інвазивним і більш доступним методам. У статті узагальнено сучасні підходи до планування та виконання вторинної реконструктивної хірургії для відновлення форми, об'єму та симетрії грудей. Підкреслено важливість індивідуального підходу для досягнення оптимальних естетичних та функціональних результатів.

**Ключові слова:** реконструкція молочної залози, післяопераційні деформації, аутологічні клапті, симетрія грудей, сосково-ареолярний комплекс, 3D-візуалізація грудей, об'ємне МРТ-дослідження.

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