

ISSN 2786-5584 PRINT
ISSN 2786-5592 ONLINE

Ukrainian
Peer-Reviewed Scientific
and Practical Medical Journal

2 (13) | 2025

GENERAL SURGERY

ЗАГАЛЬНА ХІРУРГІЯ

Antimicrobial resistance
of combat-related infections

Clinical-epidemiological
characteristics and etiological
structure of benign mechanical
jaundice syndrome:
an 11-year single-center study

Clinical approach to the treatment
of metastatic skin melanoma



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¹ Інструкція для медичного застосування лікарського засобу Дексалгін® саше від 03.03.2023 р. № 428, РП № UA/9258/01/01. ² Інструкція для медичного застосування лікарського засобу Дексалгін® саше від 03.03.2023 р. № 428, РП № UA/9258/02/01. ³ Інструкція для медичного застосування лікарського засобу Дексалгін® ін'єкт від 18.10.2023 р. № 1808, РП № UA/3764/01/01. ⁴ Sanchez-Carpena J, et al. Comparison of dexketoprofen trometamol and tramadol in the treatment of renal colic. Clin Drug Invest 2003, 23:139-152. ⁵ Barbano MJ, et al. Clinical pharmacokinetics of dexketoprofen. Clin Pharmacokinet 2001, 40:245-262. ⁶ Marenco 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. ⁷ Metscher B, et al. Dexketoprofen-trometamol and tramadol in acute lumbago. Fortsch Med Orig 2001, 118:147-151. ⁸ 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. ⁹ 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, 1-8. ¹⁰ 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.

*Показання: Симптоматичне лікування гострого болю від легкого до помірного (Дексалгін® і Дексалгін® саше) і від помірного до сильного (Дексалгін® ін'єкт) болю.

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Тел: +38 (044) 494 33 88.
UA-Dex-03-2024-V1-Press. Останній перегляд 26.01.2024.

Ukrainian
Peer-Reviewed Scientific and Practical Medical Journal

2 (13) | 2025

GENERAL SURGERY

Founded in May 2021
Quarterly journal

Заснований у травні 2021 року
Виходить 4 рази на рік

ЗАГАЛЬНА ХІРУРГІЯ

Український рецензований науковий спеціалізований медичний журнал

The journal is registered as a professional edition of scientific research in the field of medicine and approved as a «B» list journal by the Ministry of Education and Science of Ukraine Order of the Ministry of Education and Science of Ukraine No 1166 as of December 23, 2022, Appendix 3

Журнал включено до Переліку наукових фахових видань України з медичних наук. Категорія «Б»
Наказ МОН України № 1166 від 23.12.2022 р., Додаток 3

Indexed in | Журнал індексується в міжнародних наукометричних базах та каталогах
Index Copernicus, CrossRef, Vernadsky National Library of Ukraine, Google Scholar, OUCI, Scilit, WorldCat

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State registration

Register of entities in the field of media

Media ID R30-03941

Decision of the National Council of Ukraine on Television and
Radio Broadcasting No 1440 dated April 25, 2024

Approved for printing by the Academic Council
of Bogomolets National Medical University
Protocol No 11 signed June 26, 2025

Publishing

VIT-A-POL limited liability company
Office 3, 19a Academician St. Yefremov, Kyiv, 03179
Tel. +38096 70-21-152. E-mail: vitapol3@gmail.com
Certificate of publishing business entity
DK No 4757 granted August 5, 2014

Project manager Bernyk O. M.
Translation and editing Sachuk O. V.
Design Mamchych V.

Signed for printing July 29, 2025
Circulation 500 copies
Printed by Pro Format Ltd.
45b, Kubanska Ukrayiny str., off. 16, 02166, Kyiv
Certificate of publishing business entity
DK No 5942 granted January 11, 2018

 Printed on acid-free paper

Healthcare professionals are the intended audience for this journal

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Сусак Я. М. (Київ)

Заступник головного редактора

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радіомовлення № 1440 від 25.04.2024 р.

Рекомендовано Вченою радою Національного
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Протокол № 11 від 26.06.2025 р.

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Свідоцтво суб'єкта видавничої справи
ДК № 4757 від 05.08.2014 р.

Менеджер проекту Берник О. М.
Переклад та редагування тексту Сачук О. В.
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Підписано до друку 29.07.2025 р.
Наклад 500 прим. Ум. др. арк. 8,60
Друк ТОВ «Про Формат»
02166, Київ, вул. Кубанської України, 456, оф. 18
Свідоцтво суб'єкта видавничої справи
ДК № 5942 від 11.01.2018 р.

 Надруковано на безкислотному папері

Видання призначено для фахівців в галузі охорони здоров'я

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ДО УВАГИ АВТОРІВ

To the 100th anniversary of Ivan Tanasienko: in memory of a teacher, scientist, and surgeon

The article commemorates the 100th anniversary of the birth of Ivan Denisovich Tanasienko (1925—1998), an outstanding Ukrainian surgeon, teacher, scientist, and medical education organizer. The article highlights the key stages of his life, professional development, and scientific activity. I. D. Tanasienko began his career in the post-war period as a doctor at a peripheral hospital and rose to the rank of professor at the Kyiv Medical Institute, dean of the faculty, and head of the Department of Surgery. His scientific interests encompassed a wide range of issues related to abdominal, vascular, endocrine, and emergency surgery. He was among the first in Ukraine to adopt contemporary methods of diagnosing and treating obstructive jaundice and diseases of the stomach, biliary tract, and pancreas. He authored over 100 scientific papers, spearheaded clinical innovations, and supervised 16 candidate's and 2 doctoral theses. Ivan Denisovich, a remarkable lecturer and mentor, influenced students' knowledge as well as their perspective, instilling strong ethical standards in medicine. His contributions to medicine were recognized with the State Prize of Ukraine. The bright memory of I. D. Tanasienko lives on in the hearts of his students, colleagues, and grateful patients.



Ivan Denisovich Tanasienko was born on June 16, 1925, in the village of Ustye, Bershadsky district, Vinnytsia region, to a poor peasant family. In 1946, he entered the Vinnytsia Medical Institute, from which he graduated in 1951. While still a student, he drew his teachers' attention to his abilities and keen interest in surgery. After graduating from the institute, I. D. Tanasienko worked for 3 years in the medical department of the Chita Railway, and then at the railway hospital in the city of Kozyatyn, Vinnytsia region. Ivan Denisovich developed his surgical and clinical skills while working at remote

hospitals. Those small medical facilities provided the basis for his initial patient interactions, practical skills, and doctor's worldview. The first surgical interventions, communication with more experienced colleagues, and outpatient admission of patients marked the start of the future professor's medical career.

From 1954 to 1965, I. D. Tanasienko worked as a junior researcher in the Department of Clinical Surgery at the Ukrainian Research Institute of Clinical Medicine, named after Academician M. D. Strazhesko. Within the confines of this clinic, he grew into a highly qualified surgeon under the guidance of the outstanding surgeon O. L. Phakadze. At that time, patients with various surgical pathologies were treated in the surgical department of the institute. Commissurotomy was performed for mitral stenosis, lung resection for nonspecific diseases and tumours, and surgical interventions were conducted for gastric and duodenal ulcers, pathologies of the small and large intestines, liver and extrahepatic bile ducts, peripheral vessels, breast and superficial tumours. Surgeons actively operated on urgent pathologies, and the clinic provided emergency care. The clinic was among the first in Ukraine to administer endotracheal anesthesia, which replaced the imperfect mask anesthesia. I. D. Tanasienko played the most active role in this multifaceted clinic activity. For 10 years, Ivan Denisovich collaborated with associate professor O. L. Phakadze to not only comprehensively master thoracic and abdominal surgery, as well as the basics of anesthesiology and resuscitation, but also to shape his clinical thinking. At the same time,

the inefficiency and inaccuracy of medical and diagnostic methods and techniques prompted him to recognize the necessity of conducting scientific research, particularly in the challenging area of gastric and duodenal surgery. In 1963, I. D. Tanasienko defended his PhD thesis titled «The effect of gastric resection on iron metabolism in patients with gastric and duodenal ulcers».

Ivan Denisovich's subsequent activities had a tight relationship with the Kyiv Medical Institute. In December 1964, I. D. Tanasienko began working as an acting and later associate professor at the Department of Hospital Surgery, which was headed by Professor M. M. Kovalev, whom he regarded as his second teacher. At that time, the clinic was one of the leading in Ukraine. Its scope of practice included surgery of the liver and extrahepatic biliary tract, stomach, intestines, peripheral vessels, and breast. Treatment of patients with purulent surgical pathology accounted for a large amount of work. Several days a week, the clinic was on duty in the ambulance, receiving an extensive number of urgent patients (up to 100 ambulance carriages per day) from the right bank of Kyiv. In such circumstances, Ivan Denisovich clearly demonstrated his abilities as an outstanding clinician, teacher, and scientist. In 1971, I. D. Tanasienko defended his doctoral dissertation on «Clinic, diagnostics and surgical treatment of obstructive jaundice of non-neoplastic origin». This fundamental scientific work and subsequent research on this topic put him in the first ranks of surgeons and scientists studying such a complex problem. A system for categorizing obstructive jaundice of non-neoplastic origin was proposed, as well as the tactics and characteristics of surgical interventions in this patient population.

Percutaneous transhepatic cholangiography was one of the earliest methods used in Ukraine to diagnose jaundice, and it was implemented in the clinic of the Department of Surgery at the Faculty of Sanitary and Hygienic Sciences, which was later headed by I. D. Tanasienko.

In 1973, Ivan Denisovich was awarded the academic degree of Doctor of Medical Sciences. In the same year, he was appointed Professor of the Department of Hospital Surgery of the Kyiv Medical Institute. From 1972 to 1976, he served as the dean of the First Medical Faculty of the Kyiv Medical Institute. Many students of that time are still grateful to their strict but fair dean. Ivan Denisovich helped capable and hardworking students in every way, yet he was merciless to future doctors who truanted.

In December 1974, he was awarded the academic title of Professor. From 1974 to 1994, Professor I. D. Tanasienko headed the Department of Surgery

of the Sanitary and Hygienic (later Medical and Preventive) Faculty at the Kyiv Medical Institute (later the National Medical University). From 1994 to 1998, he worked as a professor at this department (later the Department of General Surgery No. 2 of the National Medical University).

Ivan Denisovich's activities as a teacher and lecturer were also well-known. When giving lectures on general surgery or surgical diseases to third and fourth-year students, he necessarily included demonstrations of thematic patients. Moreover, the students prepared in advance by their teachers and postgraduates reported on the patients during the lectures. In particular, several patients were shown to have acute appendicitis, including simple, phlegmonous, gangrenous, and gangrenous-perforative types. The combination of a conversation with the patient, their objective examination, a well-voiced audience, and a demonstration of slides, tables, and drawings made a strong impression on the students and contributed to their better assimilation of the material.

The presentation of films from various sections of surgery was also required as part of the lecture procedure. Professor I. D. Tanasienko's practical classes evolved not only into a command of knowledge and practical skills, but also into discussions about life and philosophy, which formed the worldview of the future doctor, citizen, and patriot.

In 1988, I. D. Tanasienko was awarded the State Prize of Ukraine for the cycle of works «Scientific development and introduction into wide practice of health care methods of diagnostics, surgical treatment, and prevention of diseases of the endocrine glands».

Ivan Denisovich's scientific and surgical interests were extremely diverse. His numerous publications cover the surgical treatment of mitral stenosis, diseases of the stomach, duodenum, small and large intestines, pancreas, liver, gallbladder and extrahepatic bile ducts, pathology of the breast, peripheral vessels, and issues of purulent surgery. His unique research distinguishes him not only as a highly qualified surgeon but also as an inquisitive scientist.

Under the leadership of I. D. Tanasienko, the clinic dealt with the issues of thyroid surgery, gastric and duodenal ulcers and associated complications. He proposed numerous inventions and rationalizations, implemented innovative surgical techniques and interventions. Some of them included methods of valve formation in gastrocystoanastomosis in patients with pancreatic cysts, probes and bougies for treating extrahepatic bile duct diseases. 107 scientific works were published in both national and international journals. Under his supervision, 16 candidate's and 2 doctoral dissertations were defended.

Ivan Denisovich organized and participated in many congresses, conferences, and plenums of the Scientific Society of Surgeons.

I. D. Tanasienko's wife, Natalya Rodionovna Skaletska (died 1996), was the daughter of famous composer and folklorist Rodion Andriyovych Skaletsky. The family always maintained a spirit of goodwill and creativity, engaged in interesting medical and philosophical discussions and singing Ukrainian songs. Ivan Denisovich's house was frequently visited by friends and colleagues, including Prof. M. M. Kovalev, Prof. G. V. Burenko, associate professors P. F. Demydyuk, M. S. Khalabuda, A. V. Vovchenko, V. M. Mellin, Y. O. Suprun, writer V. Yukhymovych, and many others.

Ivan Denisovich Tanasienko passed away on March 27, 1998, and was buried in the Forest Cemetery in Kyiv. He will always be remembered fondly by friends, colleagues, students, and grateful patients.

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До 100-річчя Івана Танасієнка: пам'яті вчителя, вченого, хірурга

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Стаття присвячена 100-річчю з дня народження Івана Денисовича Танасієнка (1925—1998) — видатного українського хірурга, педагога, вченого та організатора медичної освіти. Висвітлено ключові етапи його життя, професійного становлення та наукової діяльності. Розпочавши трудову діяльність у повоєнний період, І. Д. Танасієнко пройшов шлях від лікаря периферійної лікарні до професора Київського медичного інституту, декана факультету та завідувача кафедри хірургії. Його наукові інтереси охоплювали широкий спектр проблем абдомінальної, судинної, ендокринної та невідкладної хірургії. Він одним із перших в Україні впровадив сучасні методи діагностики та лікування обтураційних жовтяниць, захворювань шлунка, жовчних шляхів та підшлункової залози. Автор понад 100 наукових праць, ініціатор клінічних нововведень, науковий керівник 16 кандидатських і 2 докторських дисертацій. Відомий як блискучий лектор та наставник, Іван Денисович формував не лише знання, а й світогляд студентів, прищеплював високі етичні стандарти професії. Його внесок у медицину відзначено Державною премією України. Світла пам'ять про І. Д. Танасієнка зберігається в серцях його учнів, колег і вдячних пацієнтів.

Clinical-epidemiological characteristics and etiological structure of benign mechanical jaundice syndrome: an 11-year single-center study

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Benign mechanical jaundice (BMJ) is a common condition in gastroenterological and surgical practice. Despite its clinical significance, most studies involve mixed etiologies (benign and malignant), complicating the assessment of the features specific to benign forms. Data on the seasonality, trends in hospitalization frequency, and clinical-demographic characteristics of patients with BMJ remain limited.

OBJECTIVE – to analyze the etiological structure, demographic profile, clinical presentation, hospitalization trends, and seasonality of benign mechanical jaundice based on 11 years of single-center data.

MATERIALS AND METHODS. A retrospective-prospective single-center study was conducted involving 1,187 patients diagnosed with BMJ and hospitalized at Kyiv City Clinical Hospital of Emergency Care between 2013 and 2024. The diagnosis was based on clinical, laboratory, and imaging findings, with malignant pathology excluded. Descriptive, correlation, regression, and variance statistics were applied.

RESULTS. The most common cause of BMJ was choledocholithiasis (73.6%), followed by indurative pancreatitis (7.7%), major duodenal papilla stenosis (7.1%), and Mirizzi syndrome (2.9%). Females predominated (57.8%), and the mean age was 64.7 ± 14.3 years. Seasonal variation was statistically significant ($p < 0.001$), with peaks in January, May, and November. A moderate positive correlation was observed between total bilirubin levels and time to hospitalization ($r = 0.482$; $p < 0.001$). A gradual increase in BMJ cases from 2014 to 2021 was noted ($R^2 = 0.47$).

CONCLUSIONS. Choledocholithiasis is the leading cause of benign mechanical jaundice. Patients typically present late, with higher bilirubin levels correlating with delayed hospitalization. A clear pattern of seasonality was identified, which may inform improved healthcare resource planning. This study is the first in Ukraine to provide a comprehensive analysis of benign mechanical jaundice in a large cohort with the exclusion of malignant cases.

KEYWORDS

benign mechanical jaundice, choledocholithiasis, benign biliary obstruction, seasonality, bilirubin, indurative pancreatitis.

ARTICLE • Received 2025-03-26 • Received in revised form 2025-05-07 • Published 2025-07-31

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Mechanical jaundice syndrome (MJS) is a clinical manifestation of impaired bile flow due to obstruction of the biliary tract, accompanied by elevated levels of direct bilirubin and characteristic symptoms of cholestasis. Obstructive jaundice can result from both malignant and benign causes; however,

most epidemiological and clinical studies fail to clearly differentiate between these forms, complicating the assessment of patient characteristics specific to benign mechanical jaundice [2, 4, 19, 22, 23, 30]. For instance, a population-based study conducted within the DISCOVER program [25]

reported the overall incidence of jaundice among adults over 45 years of age but did not distinguish between malignant and benign etiologies, significantly limiting the applicability of its findings for the analysis of MJS.

At the same time, benign mechanical jaundice (BMJ) – most often associated with choledocholithiasis [1, 15, 28], biliary strictures [5, 9], or external (extraductal) compression [12, 23, 27] – frequently requires urgent hospitalization in gastroenterology and surgical departments [21]. Despite its clinical relevance for prognosis and treatment planning, the population-level prevalence of BMJ remains insufficiently studied.

An increase in the frequency of BMJ is expected due to the rising incidence of choledocholithiasis, the leading cause of benign biliary obstruction. According to the literature, choledocholithiasis is diagnosed in 10–20% of patients with cholelithiasis (CL) [13, 18, 24]. The overall prevalence of cholelithiasis in the general population is estimated at 10–15% in developed countries [14], with some studies reporting a rate of 2,966.7 per 100,000 individuals as of 2021 [26]. A consistent upward trend in this indicator has been observed—for example, in the United States, the prevalence of cholelithiasis increased from 7.4% in the 1990s to 13.9% in 2020 [28]. Consequently, a projected increase in choledocholithiasis prevalence may lead to a corresponding rise in BMJ as one of its key complications.

The relevance of studying the clinical presentation, etiological structure, and seasonal variation of obstructive jaundice stems from its high incidence, the risk of serious complications, the need for timely and appropriate treatment decisions, and the scarcity of studies involving reliably confirmed benign etiologies. Moreover, most existing studies are limited in duration and do not analyze seasonal trends or temporal shifts in the etiological spectrum.

Given these limitations, a long-term study involving a large cohort of patients with clearly verified benign obstructive jaundice is warranted. Such research would allow for detailed analysis of demographic and clinical characteristics, changes in etiological patterns over time, seasonal fluctuations, and other features of the disease course. This approach is essential to improve patient stratification, optimize care pathways, and enhance the overall effectiveness of treatment.

OBJECTIVE – to analyze the etiological structure, demographic characteristics, clinical manifestations, seasonal variations, and trends in hospitalization frequency among patients with benign mechanical jaundice, based on 11 years of observations at a single specialized hospital.

Materials and methods

A retrospective-prospective single-center study was conducted involving 1,187 patients diagnosed with BMJ who were hospitalized at the Kyiv City Clinical Hospital of Emergency Care between January 1, 2013, and December 31, 2024.

Inclusion criteria

- Presence of clinical signs of jaundice (e.g., yellowing of the skin and sclera);
- Elevated total bilirubin level > 2.5 mg/dL (≈ 43 μ mol/L);
- Imaging-confirmed extrahepatic biliary obstruction (based on ultrasound, magnetic resonance cholangiopancreatography (MRCP), or endoscopic retrograde cholangiopancreatography (ERCP));
- Benign etiology of obstruction (e.g., choledocholithiasis, benign strictures, parasitic obstruction);
- Age ≥ 18 years.

Exclusion criteria

- Confirmed or suspected malignant obstruction (e.g., pancreatic head cancer, cholangiocarcinoma, Klatskin tumor);
- Intrahepatic causes of jaundice (e.g., hepatitis, cirrhosis, drug-induced liver injury);
- Incomplete clinical records (e.g., missing ultrasound or laboratory data);
- Age < 18 years.

The following data were collected for each patient:

- demographic information (age and sex);
- clinical data: primary complaints at the time of hospital admission;
- laboratory parameters, including total bilirubin level;
- imaging findings (results of abdominal ultrasound, MRCP, and/or ERCP);
- pre-hospital duration (time from symptom onset to hospitalization);
- hospitalization date (used to assess seasonal variation and annual trends).

The diagnosis of benign mechanical jaundice was established using a structured, stepwise diagnostic algorithm (Fig. 1). Patients were enrolled based on the following criteria:

1. Initial Clinical Screening

Patients were evaluated for clinical signs of jaundice, including:

- Yellowing of the skin and/or sclera
- Dark urine
- Acholic (pale) stools.

If any of these signs were present, further laboratory evaluation was initiated.

2. Laboratory Confirmation of Cholestasis

Laboratory tests included measurement of total and direct (conjugated) bilirubin.

Patients with direct bilirubin accounting for > 50% of total bilirubin and total bilirubin levels > 2.5 mg/dL (43 μmol/L) were considered suspected cases of mechanical (obstructive) jaundice.

3. Initial Imaging

All patients underwent abdominal ultrasound.

In cases where dilation of the bile ducts was observed (common bile duct diameter > 6 mm), extrahepatic obstruction was suspected.

If no bile duct dilation was found, intrahepatic causes were considered, and further testing was performed, including serological assays, liver function tests, MRCP, and, when indicated, liver biopsy.

4. Verification of Etiology

If imaging confirmed the presence of biliary calculi, the patient was referred for endoscopic papillotomy (EPT) with lithoextraction (LE) or laparoscopic choledocholithotomy (LCLT) with lithoextraction.

If no stones were detected, additional imaging (MRCP, CT, or endoscopic ultrasound (EUS)) was performed. When necessary, biopsy was used to rule out malignant processes.

Statistical analysis

Descriptive statistics were used to summarize the data. Quantitative variables are presented as mean ± standard deviation (M ± SD) or as median with interquartile range (25th–75th percentile),

depending on data distribution. Categorical variables are reported as absolute numbers and percentages.

The mean values were compared using Student's t-test. Spearman's rank correlation was employed to assess associations between continuous variables. To analyze hospitalization rates across different months, either the chi-squared (χ²) test or Fisher's exact test (for small sample sizes) was applied. Regression analysis was conducted to evaluate trends in annual hospitalization rates. A p-value of < 0.05 was considered statistically significant.

All statistical analyses were performed using IBM SPSS Statistics software.

Results

A total of 1,187 patients with benign mechanical jaundice were treated during the study period, including 501 men (42.2%) and 686 women (57.8%) (p < 0.001), with a mean age of 64.7 ± 14.3 years (range: 17–97 years) (Fig. 2).

Men were significantly younger than women: 62.0 ± 14.2 years vs. 66.5 ± 14.1 years, respectively (p < 0.001). The mean body mass index (BMI) was 25.3 ± 4.2 kg/m² (range: 18.1–36.4 kg/m²).

Primary hospital admission due to jaundice occurred in 1,092 patients (92.0%), while 95 patients (8.0%) were re-hospitalized. Since 2014, there was

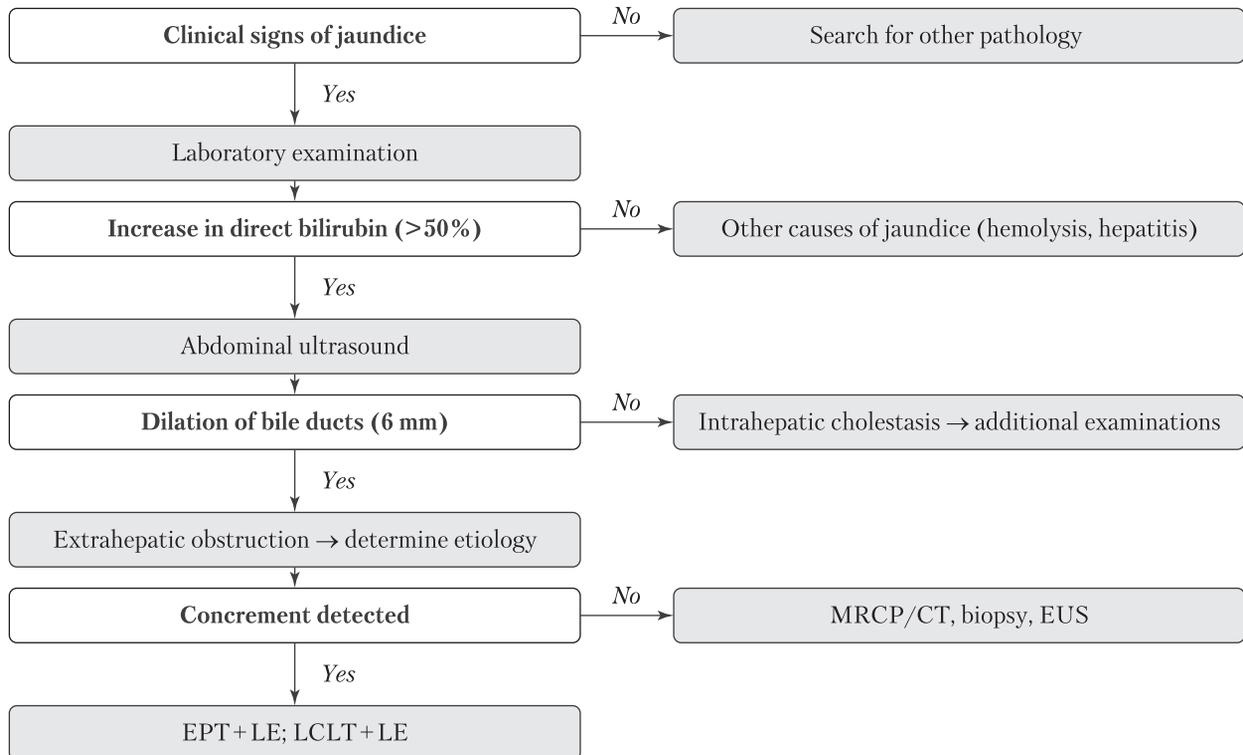


Figure 1. Step-by-step diagnostic algorithm for mechanical jaundice of benign origin

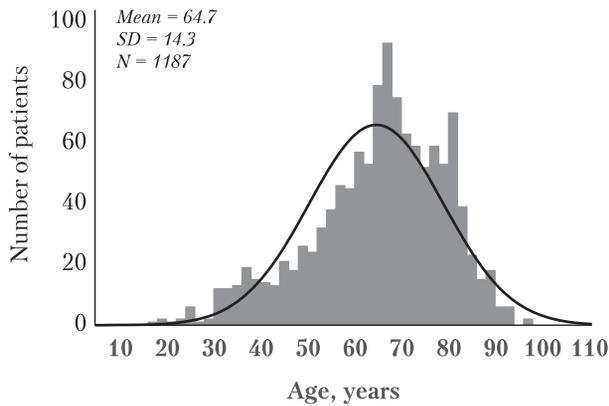


Figure 2. Age distribution of patients with benign mechanical jaundice overlaid with a normal (Gaussian) distribution curve

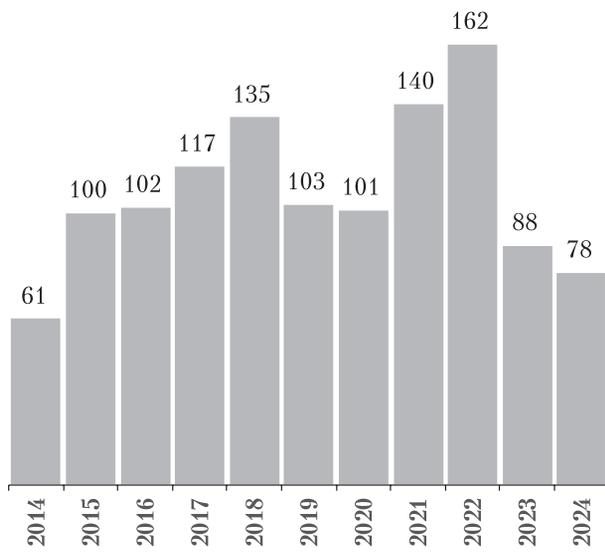


Figure 3. Annual distribution of hospitalized patients with benign mechanical jaundice from 2014 to 2024 (n = 1,187)

a steady increase in the number of hospitalizations for benign mechanical jaundice:

In 2014, 61 patients (5.1%) were hospitalized; by 2018, this number rose to 135 patients (11.4%).

During the COVID-19 pandemic, hospitalization rates declined to 103 patients (8.7%) in 2020 and 101 patients (8.5%) in 2021. In the following post-pandemic years, a marked increase was observed: 140 patients (11.8%) in 2022 and 162 patients (13.6%) in 2023.

However, during the period of martial law, there was a sharp decline in hospitalizations: in 2023, 88 patients (7.4%) were hospitalized, and in 2024, 78 patients (6.6%) (Fig. 3).

The regression analysis of hospitalization rates from 2014 to 2021 confirmed a significant upward trend. Data from 2022 to 2024 were excluded due to

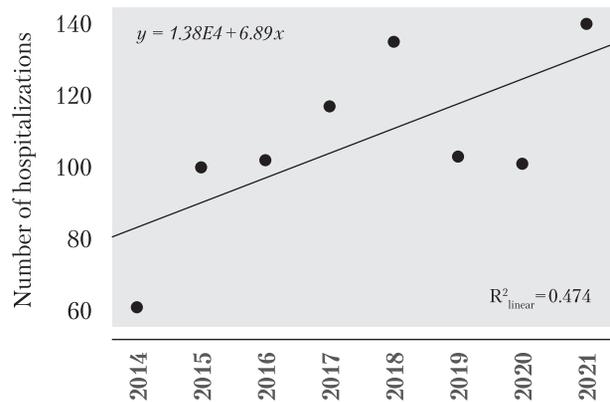


Figure 4. Linear regression analysis of hospitalization frequency for benign mechanical jaundice between 2014 and 2021

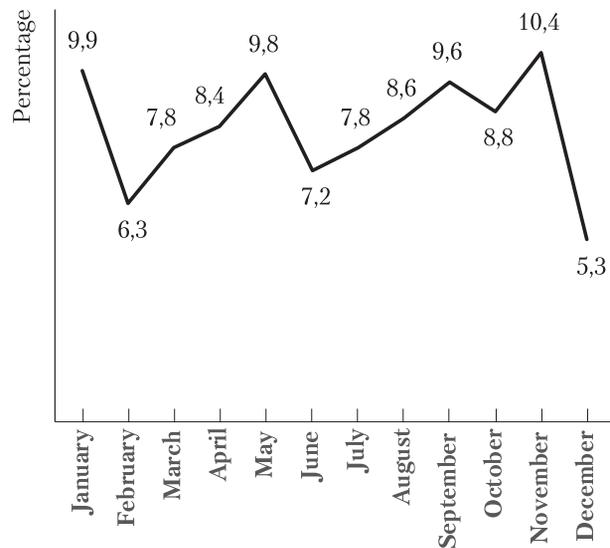


Figure 5. Seasonal distribution of hospitalizations for benign mechanical jaundice

extraneous variables, specifically the full-scale war in Ukraine and the COVID-19 pandemic, which could distort the trend and influence study outcomes. A linear regression of hospitalizations during 2014–2021 revealed a moderate positive trend ($R^2 = 0.47$), indicating a gradual increase in the incidence of benign mechanical jaundice. The average annual increase was approximately 6.9 cases per year (Fig. 4).

Analysis of the hospitalization distribution among 1,187 patients with benign mechanical jaundice revealed significant seasonal fluctuations. The highest number of hospitalizations occurred in January, May, and November, while the lowest rates were observed in December, February, and June ($p < 0.001$) (Fig. 5).

Among the 1,187 patients, 53 (4.5%) were hospitalized within the first day of symptom onset (either

the onset of pain or jaundice). The majority of patients were admitted between the 2nd and 5th days (493 patients, 41.5%), followed by those hospitalized between the 6th and 10th days (560 patients, 47.2%). A smaller group of 81 patients (6.8%) was admitted more than 10 days after symptom onset. The average time from symptom onset to hospitalization was 5.87 ± 2.89 days (range: 1–19 days) (Fig. 6).

The clinical presentation of benign mechanical jaundice was typical in most patients, with cholestasis-related symptoms predominating. All patients (100%) exhibited yellowing of the skin and sclera. Other common symptoms included dark urine (86.8%), pale stools (79.2%), pruritus (61.2%), and right hypochondrial pain (83.0%). Additionally, some patients reported dyspeptic symptoms such as nausea, flatulence, and bitterness in the mouth; neurovegetative symptoms including irritability and insomnia; as well as allergy-like manifestations

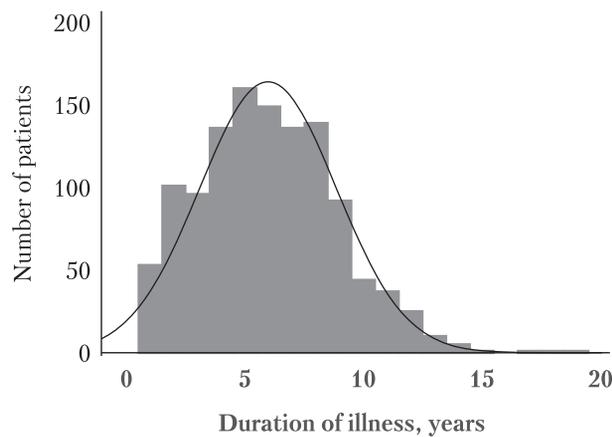


Figure 6. Distribution of patients by duration of illness prior to hospitalization, presented with an overlaid Gaussian (normal) distribution curve

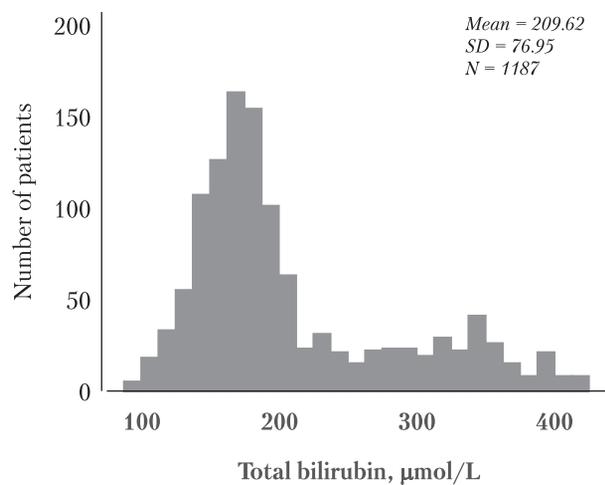


Figure 7. Distribution of patients with benign mechanical jaundice by total bilirubin level

such as skin rashes. These less frequent complaints highlight the systemic impact of bile stasis and may play a role in early diagnosis and differentiation from functional disorders (Table 1).

The total bilirubin level was 209.62 ± 76.95 $\mu\text{mol/L}$, ranging from 88.6 to 417.2 $\mu\text{mol/L}$ (Fig. 7). The direct bilirubin level was 120.68 ± 39.24 $\mu\text{mol/L}$, ranging from 39.4 to 254.2 $\mu\text{mol/L}$ (Fig. 8).

Table 1. Clinical complaints in patients with benign mechanical jaundice

| Indicator | Value |
|---|---------------|
| Main complaints | |
| Yellowing of skin and sclera | 1187 (100.0%) |
| Darkening of urine | 1030 (86.8%) |
| Pale stools | 940 (79.2%) |
| Itching of the skin | 727 (61.2%) |
| Pain in the right hypochondrium (paroxysmal or dull) | 985 (83.0%) |
| Mild | 363 (30.6%) |
| Moderate | 305 (25.7%) |
| Severe | 271 (22.8%) |
| Very severe | 46 (3.9%) |
| Right shoulder sign | 514 (43.3%) |
| Nausea, vomiting | 582 (49.0%) |
| General weakness, fatigue | 703 (59.2%) |
| Elevated body temperature > 36.9 °C | 552 (46.5%) |
| Body temperature in febrile patients, °C (M ± SD) | 37.9 ± 0.5 |
| Fever | 204 (17.2%) |
| Decreased appetite | 439 (37.0%) |
| Bitter taste and dry mouth | 415 (35.0%) |
| Additional complaints | |
| Postprandial heaviness; discomfort in the epigastric region or right side | 378 (31.8%) |
| Flatulence, abdominal bloating | 332 (28.0%) |
| Heartburn, belching, halitosis | 261 (22.0%) |
| Insomnia, irritability, anxiety | 249 (21.0%) |
| Unstable stool (alternating diarrhea and constipation) | 201 (16.9%) |
| Palpitations, blood pressure fluctuations | 142 (12.0%) |
| Skin rash, cholestatic dermatitis | 83 (7.0%) |

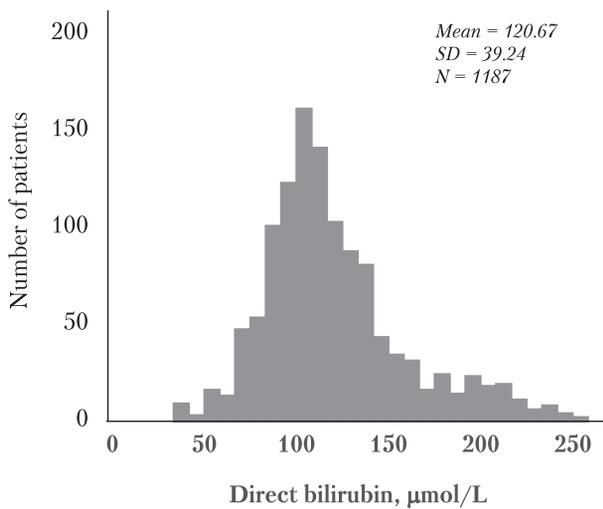


Figure 8. Distribution of patients with benign mechanical jaundice by direct bilirubin level

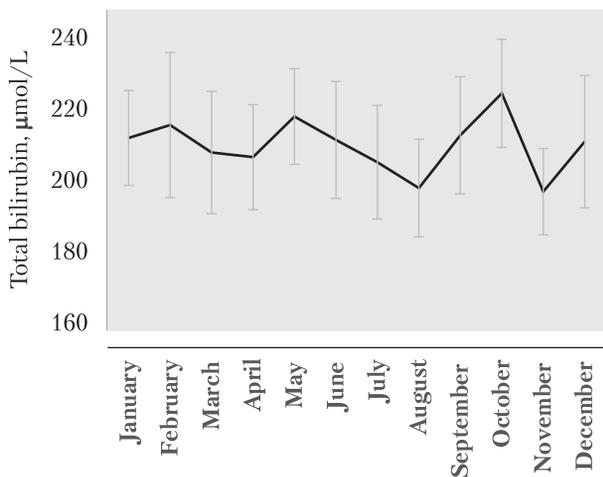


Figure 9. Mean total bilirubin levels with 95% confidence intervals, grouped by month of hospitalization

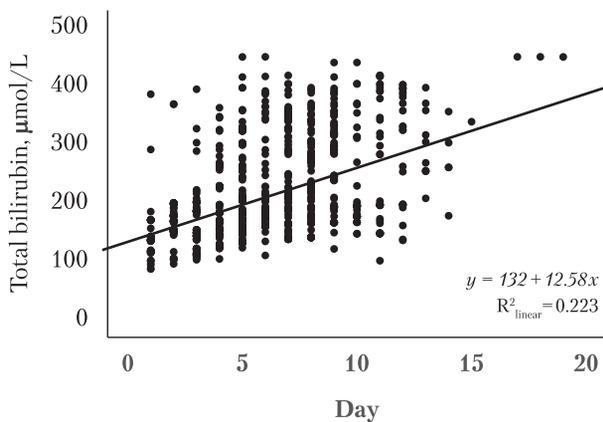


Figure 10. Linear regression analysis of the relationship between a total bilirubin level and illness duration prior to hospitalization

No statistically significant differences were observed in mean total bilirubin levels among patients hospitalized in different months (all $p > 0.05$) (Fig. 9).

The most common cause of mechanical jaundice was intraluminal obstruction, accounting for 73.6% of cases, primarily due to choledocholithiasis or other manifestations of cholelithiasis. Stenosis of the major duodenal papilla was responsible for 7.1% of cases.

External compression of the biliary tract was observed in 17.9% of patients, most frequently caused by indurative pancreatitis (7.7%), acute pancreatitis (6.7%), or Mirizzi syndrome (2.9%).

Parietal causes of biliary obstruction were rare, with strictures following surgical interventions identified in only 1.1% of cases (Table 2).

A statistically significant positive correlation was observed between a total bilirubin level and illness duration prior to hospitalization ($r = 0.482$; $p < 0.001$), with 22.9% of the variance in bilirubin levels accounted for by this factor ($R^2 = 0.229$) (Fig. 10).

Discussion

Mechanical jaundice of benign origin is a common condition encountered in gastroenterological and surgical practice. However, knowledge regarding its epidemiology, demographic characteristics, pathogenetic mechanisms, and seasonal variations remains incomplete. Most published studies analyze both benign and malignant causes of jaundice [1, 2,

Table 2. Etiological structure of biliary outflow obstruction causes in patients with benign mechanical jaundice (n = 1187)

| Cause of biliary obstruction | Number of patients |
|--|--------------------|
| Intraluminal | |
| Gallstone disease, choledocholithiasis | 874 (73.6%) |
| Stenosis of the major duodenal papilla | 84 (7.1%) |
| Parietal | |
| Post-op strictures | 13 (1.1%) |
| External | |
| Indurative pancreatitis | 91 (7.7%) |
| Pseudotumorous pancreatitis (IgG4-related) | 4 (0.3%) |
| Acute pancreatitis | 80 (6.7%) |
| Duodenal diverticulum (peripapillary) | 7 (0.6%) |
| Mirizzi syndrome | 34 (2.9%) |

4, 25, 30], complicating the understanding of the specific features and clinical course of benign cases.

Our study includes a large cohort of patients with mechanical jaundice ($n = 1,187$) of a clearly defined benign etiology. The mean age of patients at our center was 64.7 ± 14.3 years, which is higher than reported in other studies (ranging from 40.3 to 56.8 years) [1, 2, 4, 19]. Men were significantly younger than women (62.0 vs. 66.5 years, $p < 0.001$), suggesting potential differences in the natural history of the disease or disparities in healthcare access and screening.

Women predominated among patients with benign mechanical jaundice (57.8%), consistent with previous reports [1, 2, 4, 22]. This likely reflects the higher prevalence of the condition in middle-aged and elderly women [14, 17].

The clinical presentation was characterized by typical signs of cholestasis: jaundice was present in 100% of patients, dark urine in 86.8%, and acholic stools in 79.2%. A substantial proportion (83.0%) reported pain in the right hypochondrium of varying intensity, consistent with the findings of Asare et al. [4], who reported severe pain in 92.2% of cases, and Odongo et al. [19], who found that over 90% of patients experienced pain. Less frequent but clinically relevant symptoms included neurovegetative disturbances in approximately 21% of patients and skin rashes in 7%. These additional symptoms, often underestimated, may aid in early diagnosis and help differentiate mechanical jaundice from other conditions, such as viral hepatitis or pancreatitis without biliary obstruction.

The median time from symptom onset to hospitalization was 5.87 days, with only 4.5% of patients presenting within the first day. Similar findings were reported by Taylor et al. in the DISCOVER study, where over 60% of patients with jaundice sought medical care more than three days after symptom onset [25]. These data suggest that patients and healthcare providers may underestimate or fail to recognize symptoms promptly, contributing to delays in diagnosis.

A statistically significant positive correlation was observed between total bilirubin level and duration of illness before hospitalization ($r = 0.482$; $p < 0.001$). Although the coefficient of determination ($R^2 = 0.229$) indicates a partial relationship, this finding highlights the critical importance of early diagnosis and timely hospitalization to prevent progression of hyperbilirubinemia and associated complications.

The analysis of the etiological structure confirmed the predominant role of choledocholithiasis, consistent with previous reports [8, 22, 25]. Notably,

its prevalence in our cohort was higher (73.6%) compared to other studies reporting frequencies of 60.3% [1], 57.8% [2], and 51% [22].

Indurative pancreatitis, acute pancreatitis, and Mirizzi syndrome accounted for 7.7%, 6.7%, and 2.9% of cases, respectively, which aligns with proportions reported in other studies (6%–8%) [1, 2, 20, 22]. These conditions are often associated with a more severe clinical course, increased risk of infectious complications, and typically require a multidisciplinary management approach. This underscores the importance of stratifying patients not only based on clinical symptoms but also according to the likely etiology of biliary obstruction, to enable timely selection of treatment strategies—whether conservative, endoscopic, or surgical.

It is noteworthy that stenosis of the major duodenal papilla (7.1%) was identified as a distinct nosological entity in our study. This differentiation is not consistently made in other studies, where similar lesions are often grouped with functional or post-inflammatory stenoses or benign strictures of the distal common bile duct [1]. However, several authors advocate recognizing this pathology as a separate entity with specific indications for endoscopic intervention [7, 10].

The hospitalization trends indicate a gradual increase in benign mechanical jaundice cases from 2014 to 2018, likely reflecting improved diagnostic capabilities, an aging population, and a rising incidence of choledocholithiasis, which affects approximately 10–20% of the adult population in developed countries [14, 28]. The COVID-19 pandemic and the full-scale war in Ukraine from 2022 to 2024 significantly disrupted this trend, highlighting the impact of systemic external factors on healthcare delivery.

Hospitalization rates exhibited a distinct seasonal pattern, with peaks in January, May, and November, and troughs in December, February, and June ($p < 0.001$). This seasonal variation is likely multifactorial. It has been shown that increased consumption of foods rich in fat, protein, and cholesterol during winter and spring holiday periods contributes to enhanced bile lithogenicity and exacerbation of cholelithiasis [29]. Additionally, reduced physical activity in winter and seasonal fluctuations in hormonal levels and immune function may indirectly influence biliary system tone and predispose to biliary obstruction [16].

The decline in hospitalizations observed in December may reflect socio-behavioral factors, such as patients' reluctance to seek medical care before the holidays. Similarly, the decrease in June hospitalizations corresponds with the start of the vacation

season, leading to a delayed accumulation of symptoms and increased hospital admissions in August and September [3, 11]. These findings suggest a seasonal sensitivity of benign mechanical jaundice, warranting further investigation incorporating dietary habits, behavioral patterns, and climatic influences.

Clinically, understanding this seasonality could aid in optimizing hospital resource allocation during peak periods, refining preventive strategies, and implementing targeted active case-finding during high-risk months.

This study has several limitations. Its single-center design restricts the generalizability of the findings to other regions or countries. The absence of a comparative group with malignant jaundice limits the ability to evaluate the differential diagnostic value of specific symptoms or biomarkers. Partial retrospective data collection may introduce information bias and result in incomplete medical records. Additionally, the lack of consideration of therapeutic approaches – such as the type of surgical intervention or endoscopic techniques – may have influenced the severity and clinical outcomes reported.

Conclusions

Benign mechanical jaundice is most commonly caused by choledocholithiasis. Patients typically present late for hospitalization, which correlates with elevated bilirubin levels. A distinct seasonality in hospital admissions was identified, offering potential opportunities for optimizing healthcare resource planning. This study is the first in Ukraine to comprehensively analyze a large cohort of patients with benign mechanical jaundice, explicitly excluding malignant cases.

DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

Funding. This study received no external funding.

AUTHORS CONTRIBUTIONS

M. V. Maksymenko: conception and design, acquisition, analysis and interpretation of data, statistical analysis, drafting the article, critical revision of the article; Y. M. Susak: conception and design, critical revision of the article; V. M. Dorosh: critical revision of the article; O. M. Lobanova, R. O. Havryliuk: acquisition, analysis and interpretation of data, statistical analysis, drafting the article, critical revision of the article.

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Клініко-епідеміологічні характеристики та етіологічна структура синдрому механічної жовтяниці доброякісного генезу: 11-річне одноцентрове дослідження

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Синдром механічної жовтяниці доброякісного генезу (СМЖДГ) часто трапляється в гастроентерологічній і хірургічній практиці. Попри високу клінічну значущість, у більшості досліджень розглядають змішану етіологію (доброякісну та злоякісну), що ускладнює оцінку особливостей перебігу доброякісних форм. Дані про сезонність, динаміку частоти госпіталізацій і клініко-демографічні характеристики пацієнтів із СМЖДГ недостатньо вивчено.

Мета — провести аналіз етіологічної структури, демографічних характеристик, клінічних виявів, динаміки та сезонності госпіталізацій пацієнтів із СМЖДГ за даними одного центру за 11 років.

Матеріали та методи. Проведено ретроспективно-проспективне одноцентрове дослідження 1187 пацієнтів із СМЖДГ, госпіталізованих у Київську міську клінічну лікарню швидкої медичної допомоги в 2014—2024 рр. Діагноз установлювали на підставі клінічних, лабораторних та інструментальних даних після заперечення злоякісної патології. Для обробки отриманих даних застосовували описову, кореляційну, регресійну та варіаційну статистику.

Результати. Найчастішою причиною СМЖДГ був холедохолітиаз (73,6%), рідше — індуративний панкреатит (7,7%), стеноз великого дуоденального сосочка (7,1%) і синдром Міриззі (2,9%). Серед пацієнтів переважали жінки (57,8%). Середній вік пацієнтів — (64,7 ± 14,3) року. Сезонні коливання госпіталізацій були статистично значущими (p < 0,001): піки відзначено в січні, травні та листопаді. Виявлено статистично значущу кореляцію між рівнем білірубіну та тривалістю СМЖДГ до госпіталізації (r = 0,482; p < 0,001). Установлено поступове зростання частоти СМЖДГ з 2014 до 2021 р. (R² = 0,47).

Висновки. Доброякісна механічна жовтяниця найчастіше спричинена холедохолітиазом. Характерна пізня госпіталізація, що корелює з вищим рівнем білірубіну. Установлено чітку сезонність госпіталізацій, що може бути використано для поліпшення планування медичної допомоги. Уперше в Україні узагальнено дані про СМЖДГ у великій когорті із виключенням злоякісних випадків.

Ключові слова: механічна жовтяниця, холедохолітиаз, доброякісна обструкція, сезонність, білірубін, індуративний панкреатит.

FOR CITATION

■ Maksymenko MV, Susak YM, Dorosh VM, Lobanova OM, Havryliuk RO. Clinical-epidemiological characteristics and etiological structure of benign mechanical jaundice syndrome: an 11-year single-center study. *General Surgery (Ukraine)*. 2025;(2):8-16. <http://doi.org/10.30978/GS-2025-2-8>.

The effectiveness of laparoscopic choledochoduodenostomy for management of persistent common bile duct stones and advanced malignant obstructive jaundice

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Endoscopic clearance of common bile duct (CBD) stones and stenting for distal biliary obstruction are standard treatments, but can fail in cases of large calculi or advanced malignancy. Laparoscopic choledochoduodenostomy (LCCD) offers an internal bypass of the obstructed bile duct.

OBJECTIVE – to evaluate the safety and effectiveness of LCCD in patients with persistent CBD stones after failed endoscopic clearance and in those with advanced malignant obstructive jaundice.

MATERIALS AND METHODS. We reviewed 55 patients who underwent LCCD at our center between 2018 and 2024. Of these, 26 patients had large CBD stones not cleared by endoscopic retrograde cholangiopancreatography, and 29 had unresectable distal malignant obstruction (pancreatic or ampullary carcinoma). All procedures were performed laparoscopically using five trocars, with a longitudinal choledochotomy and duodenotomy, a side-to-side biliary–enteric anastomosis hand-sewn with absorbable barbed sutures (V-Loc™ 3-0), and concurrent cholecystectomy. Perioperative outcomes, complications, and follow-up results were analyzed.

RESULTS. LCCD was completed successfully in all 55 patients with no conversions to open surgery. The mean operative time was 76 minutes (range: 55–110 minutes). There were no major postoperative complications or 30-day mortality. The average hospital stay was 5.2 ± 2.1 days. Stone patients had 92% clearance of CBD stones with no residual obstruction or recurrent cholangitis observed over a follow-up of up to 5 years. In the malignant group, jaundice was effectively palliated in all cases, with no patient requiring repeat biliary bypass surgery during their remaining life span.

CONCLUSIONS. Laparoscopic choledochoduodenostomy proved to be a safe and effective procedure for both complex CBD stones after failed endoscopic retrograde cholangiopancreatography and for palliative relief of malignant obstructive jaundice. The technique achieved durable biliary drainage with minimal morbidity and short hospital stay. LCCD should be considered as an alternative when endoscopic management is unsuccessful or not feasible, offering definitive resolution of CBD stones and excellent palliative outcomes in advanced malignancies.

KEYWORDS

laparoscopy, choledochoduodenostomy, common bile duct stone, malignant obstructive jaundice, biliary bypass, endoscopic retrograde cholangiopancreatography failure.

ARTICLE • Received 2025-02-26 • Received in revised form 2025-06-07 • Published 2025-07-31

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Choledochoduodenostomy (CDD), the surgical creation of a side-to-side anastomosis between the common bile duct (CBD) and the duodenum, has long been recognized as an effective internal drainage procedure for obstructed bile ducts [5].

Historically, open CDD was frequently employed for large or recurrent CBD stones and distal biliary obstructions before the endoscopic era [10]. However, with the advent of endoscopic retrograde cholangiopancreatography (ERCP) and improvements

in laparoscopic CBD exploration, the use of CDD declined, and its indications became more limited. ERCP with endoscopic sphincterotomy and stone extraction is now the first-line therapy for choledocholithiasis, achieving CBD clearance in the majority of cases [1]. Nevertheless, ERCP can fail in a significant subset of patients – approximately 5–10% in various series – due to factors such as large or impacted stones, challenging anatomy, or inaccessible papilla. Furthermore, ERCP itself carries risks (e.g., pancreatitis, bleeding, perforation), and stones may recur in up to 4–24% of patients after endoscopic treatment [3, 15].

In cases where ERCP fails to clear the duct, surgical intervention becomes necessary to prevent ongoing biliary obstruction and cholangitis. Traditionally, open surgical options include choledocholithotomy with T-tube drainage or biliary-enteric bypass. In the minimally invasive era, laparoscopic approaches to the CBD have been developed [2]. Laparoscopic choledochoduodenostomy (LCCD) is one such approach that can serve as a salvage procedure for difficult CBD stones that cannot be removed endoscopically [5, 6]. Proponents of LCCD note that it provides a definitive, internal drainage solution for multiple or large stones and benign distal strictures while avoiding the morbidity of open surgery and the repeated instrumentation associated with multiple ERCP attempts [9, 10]. CDD creates a wide stoma between the dilated CBD and duodenum, which can facilitate the passage of small residual stones and prevent future stone impaction. Reports have demonstrated low rates of recurrent cholangitis or «sump syndrome» following CDD, particularly when the gallbladder and cystic duct are removed and the anastomosis is constructed with an adequate diameter [8, 11]. Recent studies and case series confirm that laparoscopic CDD is feasible and safe in experienced hands, suggesting this technique is a viable alternative for difficult or failed endoscopic cases [8].

Malignant distal biliary obstruction is another challenging scenario. Pancreatic head carcinoma and ampullary carcinoma can cause advanced malignant obstructive jaundice (AMOJ) in patients who are often not candidates for curative resection due to locally advanced disease or metastases. Endoscopic biliary stenting (via ERCP or EUS-guided approaches) is the preferred palliative treatment for malignant obstructive jaundice, but stent placement is not always successful or sustainable [7]. Tumor bulk or prior surgical anatomy may prevent successful stenting, and even when placed, stents have a limited patency and frequently require re-intervention due to occlusion. Surgical biliary bypass

(such as hepaticojejunostomy or choledochojejunostomy) offers more durable relief of jaundice, at the cost of open surgery [17, 22]. A laparoscopic biliary bypass, if achievable, could combine the long-term patency of surgical anastomosis with the lower morbidity of minimally invasive surgery. Laparoscopic choledochoduodenostomy has been explored as an alternative palliative method for distal malignant obstruction, effectively creating an internal drainage route that bypasses the tumor [18]. Unlike hepaticojejunostomy, a CDD keeps bile flow in the upper gastrointestinal tract and avoids an entero-enteric anastomosis, making it a simpler and more physiological bypass in distal obstruction cases. Early reports (mostly from high-volume centers in recent years) indicate that laparoscopic biliary bypass for malignancy is associated with high success in jaundice relief, low complication rates, and no need for external drainage tubes [18, 20].

Despite these potential advantages, LCCD remains a specialized procedure that is not yet widely adopted. The technical challenge of intracorporeal suturing for a biliary-enteric anastomosis has been a barrier, but advances such as barbed sutures and increased laparoscopic expertise are overcoming this hurdle. To date, most published experience with LCCD has been limited to small series or case reports [5, 8, 12]. In this context, we present our single-center experience with LCCD in two distinct patient groups: (1) those with large or refractory CBD stones after failed ERCP and (2) those with advanced malignant obstructive jaundice due to unresectable tumors. We report the perioperative outcomes, long-term follow-up, and clinical effectiveness of LCCD in these populations.

OBJECTIVE – to evaluate the safety and effectiveness of LCCD in patients with persistent CBD stones after failed endoscopic clearance and in those with advanced malignant obstructive jaundice.

Materials and methods

Study Design and Patients: This study is a retrospective analysis of all patients who underwent LCCD at our tertiary referral center between 2018 and 2024. A total of 55 patients were identified. Indications for LCCD fell into two categories. Group 1 (Benign Stones): 26 patients had persistent choledocholithiasis (CBD stones) that could not be removed via ERCP. These cases typically involved large (giant: 25–35 mm) CBD stones or multiple stones in a dilated duct, where endoscopic extraction had failed due to stone size, impaction, or challenging anatomy (such as a diverticulum or stricture preventing papilla access). Group 2 (Malignant Obstruction):

29 patients had advanced malignant obstructive jaundice caused by distal bile duct compression from unresectable malignancies. This group included patients with pancreatic head carcinoma and those with ampullary carcinoma with distal CBD involvement. All malignancies were confirmed via imaging and/or biopsy, and a multidisciplinary tumor board had deemed them unsuitable for curative resection. In these patients, palliative biliary bypass was indicated either due to failed endoscopic stenting or because a surgical bypass was preferred for longer-term relief of jaundice.

Preoperative Preparation

All patients underwent preoperative laboratory evaluation and imaging. The presence of CBD dilation was confirmed in all cases (a dilated biliary tree was a prerequisite for CDD to ensure a sizeable anastomosis). In Group 1, the mean stone size and number varied (data not shown); many had stones > 15 mm or multiple stones. In Group 2, the level of obstruction was distal (no hilar tumors were included), and some patients had plastic stents placed during prior ERCP attempts, which were either ineffective or had occluded. Patients with cholangitis received antibiotics and, if necessary, temporary percutaneous biliary drainage before definitive surgery. All patients provided informed consent for laparoscopic surgery with the understanding that conversion to open surgery could be required if difficulties arose.

Surgical Technique

All procedures were performed under general anesthesia with the patient in the supine position. A standard 4-trocar configuration was used in all cases (including epigastric, subcostal, and right flank ports to allow optimal access to the hepatic hilum and duodenum). First, a laparoscopic cholecystectomy was performed (in patients with a gallbladder *in situ*) as part of the procedure. Cholecystectomy serves two purposes: it prevents potential future gallstone issues and eliminates the cystic duct, thereby reducing the risk of sump syndrome from an undrained gallbladder remnant. Next, the hepatoduodenal ligament was carefully dissected to expose the dilated CBD. The first part of the duodenum was mobilized only if needed. In our series, a full Kocher's maneuver was not routinely required because the duodenum was typically reachable for anastomosis without extensive mobilization.

A longitudinal choledochotomy approximately 2–3 cm in length was made on the anterior wall of the CBD, usually just above the duodenum. A matching longitudinal duodenotomy was created

on the anterior wall of the duodenum (first or second portion) adjacent to the CBD incision. In Group 1 (stones), before proceeding to the anastomosis, we ensured clearance of stones from the CBD. Stones were removed through the choledochotomy by using a flexible choledochoscope and graspers/baskets as needed, or by flushing saline through the cystic duct stump or choledochotomy. In some instances, very large stones were fragmented using a lithotripter device for removal. Once the duct was cleared of calculi, attention turned to creating the bilio-duodenal anastomosis.

The CDD anastomosis was fashioned in a side-to-side manner. We performed a single-layer hand-sewn anastomosis using a running barbed suture (absorbable 3–0 V-Loc™). A continuous posterior row of suturing was done first: the suture was started at the rightmost end of the incision (proximal side) and ran toward the leftmost end (distal side) to approximate the posterior walls of the CBD and duodenum. After completing the posterior wall, the suture was tied or locked. A second continuous suture was then used for the anterior wall in a similar fashion, creating a watertight anastomosis. We found that the barbed suture allowed effective tissue approximation without the need for frequent knot tying, streamlining the construction of the anastomosis. Care was taken at the corners of the incisions to avoid leakage (adding an extra stitch or two at the ends if necessary). The resulting anastomosis was roughly the full length of the choledochotomy (approximately 2 cm), providing a wide stoma. A closed-suction drain (Jackson-Pratt) was placed near the anastomosis in all cases as a precaution to detect any early bile leak.

After ensuring hemostasis and clean irrigation, all port sites were closed. No T-tube or internal stent was used across the anastomosis in our series (unlike some techniques that use a T-tube as a bridging stent, we relied on meticulous suturing and omental coverage of the anastomosis to prevent leakage). The gallbladder specimen and any retrieved stones were removed through an enlarged umbilical port incision using a specimen bag.

Postoperative Care and Follow-up

Patients were typically extubated in the operating room and sent to the surgical ward. Standard postoperative management included analgesia and early mobilization. The nasogastric tube (if placed) was removed at the end of surgery or on the first postoperative day. A liquid diet was started on postoperative day 1 or 2 once bowel function resumed. The abdominal drain was monitored and removed within 2–4 days if no significant bile leakage was

observed. Liver function tests were checked daily for the first few days to monitor bilirubin trends. Criteria for discharge included adequate pain control with oral analgesics, tolerance of diet, and no signs of complications.

Patients in the malignant group were also monitored by the oncology service for any further adjuvant therapies or hospice care, but importantly, we tracked whether any biliary re-intervention was needed post-LCCD. All patients had scheduled follow-up visits at one month post-surgery, then at three-month intervals for the first year, and every 6–12 months thereafter (stone patients continued long-term follow-up up to 5 years, whereas malignant patients often had follow-up until death). At follow-up, clinical status, liver function tests, and ultrasound or CT imaging (when indicated) were reviewed to assess the patency of the biliary-enteric anastomosis. We defined a successful outcome as relief of biliary obstruction without the need for additional biliary drainage procedures. Any complications were classified using the Clavien-Dindo grading system for surgical complications.

Results

Patient Characteristics

A total of 55 patients underwent LCCD during the study period (38 women and 17 men). The overall mean age was 67.8 ± 8.6 years (range 50–85 years), reflecting an older patient population in both groups. Table 1 summarizes the baseline demographics and characteristics of the two patient groups. Patients in the stone group (Group 1, $n = 26$) had a mean body mass index (BMI) of 28.4 ± 4.5 kg/m², whereas those in the malignant group (Group 2, $n = 29$) had a slightly lower mean BMI of 26.5 ± 3.5 kg/m². The gender distribution showed a female predominance in both groups, more pronounced in the benign

stone group (approximately 77% female), consistent with the higher incidence of gallstone disease in women. In the malignant group, about 62% were female. The diagnoses in the malignant cohort included pancreatic head carcinoma (the majority of cases) and ampullary carcinoma; all had distal CBD obstruction causing significant jaundice. Prior to LCCD, 26/26 stone patients had one or more failed ERCP attempts at stone extraction, and 19/29 malignant patients had attempted endoscopic stenting that was unsuccessful or not durable (the remaining malignant cases proceeded directly to surgical bypass due to tumor anatomy or recurrent stent occlusion). All patients had dilated CBD on imaging, with a median CBD diameter of $\sim 19 \pm 3$ mm in the stone group (due to chronic obstruction by stones) and 22 ± 5 mm in the malignant group (due to distal tumor blockage). There were no significant differences in age between the groups. Comorbid conditions (such as cardiovascular disease or diabetes) were common given the age range, but these were well-managed and did not preclude laparoscopic surgery.

Intraoperative Findings

All 55 procedures were completed fully laparoscopically, with no conversions to open surgery. The laparoscopic exposure of the CBD and duodenum was generally straightforward, given the prior biliary dilation; adhesions from cholangitis were present in a few cases but were manageable. In the stone group, multiple CBD stones were encountered in 12 patients, while single large stones were observed in 14 patients. Successful stone clearance was achieved in 24 out of 26 cases through choledochotomy using choledochoscopic guidance and retrieval tools. In two cases, a large stone was fragmented *in situ* to facilitate removal. The duodenum was accessible for all anastomoses without needing a full Kocher mobilization

Table 1. Baseline patient characteristics by group

| Characteristic | Stones group (n = 26) | Malignant group (n = 29) | All patients (n = 55) |
|--|---|---|-----------------------|
| Age, years (mean \pm SD) | 66.1 \pm 9.5 | 69.3 \pm 7.8 | 67.8 \pm 8.6 |
| Female | 20 (76.9%) | 18 (62.1%) | 38 (69.1%) |
| Male | 6 (23.1%) | 11 (37.9%) | 17 (30.9%) |
| Body mass index, kg/m ² (mean \pm SD) | 28.4 \pm 4.5 | 26.5 \pm 3.5 | 27.4 \pm 4.0 |
| Diagnosis/Indication | Large CBD stones after failed ERCP (100%) | Distal malignant biliary obstruction (100%) | – |
| Pancreatic carcinoma | – | 20 (69%)* | – |
| Ampullary carcinoma | – | 9 (31%)* | – |

Note. * Breakdown of malignancy types in Group 2 (approximate proportions; all had distal CBD involvement).

in our series, which helped save operative time. Anastomosis construction was smooth in all cases – the use of continuous barbed sutures enabled secure closure without difficulty. There were no intraoperative complications such as significant bleeding or injury to surrounding structures. Estimated blood loss was minimal (median ~50 mL, none exceeding 200 mL). No patients required intraoperative transfusions. All patients had a cholecystectomy completed; in several malignant cases, the gallbladder was distended (Courvoisier's sign) and filled with bile, which was removed without incident.

The mean total operative time for the entire cohort was 76 minutes (range: 55–110 minutes). This reflects the streamlined nature of the combined procedure (cholecystectomy + CDD) in our hands. Group-wise, the operative times were not markedly different – stone cases involved time for stone extraction, but malignant cases occasionally involved more time dissecting around a tumor; overall, both groups averaged roughly 1 hour to 1 hour 20 minutes. As experience was gained, later cases were on the shorter end of the range, with some LCCD procedures being completed in under 60 minutes.

Postoperative Outcomes: Recovery was generally rapid and uneventful. There were no major postoperative complications (defined as Clavien-Dindo grade III or above) in this series (0% major morbidity). In particular, no anastomotic leaks were detected: drain outputs were minimal and not bilious, and no patient developed peritonitis or required re-operation. Two patients (3.6%) experienced minor complications: one patient had a mild ileus that prolonged their nasogastric decompression by one day, and another developed a superficial port-site infection managed with antibiotics and local care. Importantly, there were no instances of postoperative cholangitis or pancreatitis. All patients had improved liver function tests after surgery; in the malignant group, serum bilirubin levels declined dramatically within the first week post-op as bile flow was restored internally. The average length of hospital stay was 5.2 ± 2.1 days. This phase included routine post-surgical observation; many patients (especially those with stones) were fit for discharge by postoperative days 3–5. Malignant cases sometimes stayed a day or two longer for optimization or arrangement of follow-up care, but there was no significant difference in the mean stay between groups.

There was no 30-day mortality in this series. All 55 patients survived to hospital discharge. One elderly patient in the malignant group (with metastatic pancreatic cancer) died 3 months later due to progression of cancer, but had no biliary issues in the interim.

Follow-up Results

All patients underwent postoperative follow-up to assess long-term effectiveness. In Group 1 (CBD stones), follow-up duration ranged from 6 months for the most recent cases up to 5 years for those operated on in 2018 (mean follow-up was 3 years). None of the stone patients had any recurrence of CBD stones or cholangitis during follow-up. They remained symptom-free (no jaundice, no biliary pain). Follow-up imaging (ultrasound or MRCP in some cases) showed a patent CDD with no dilation of intrahepatic ducts. Notably, no patient in the stone group developed evidence of «sump syndrome» or biliary gastritis. The surgical anastomosis provided durable drainage, with no late strictures observed in the CDD anastomosis. One patient in the stone group did have an unrelated issue (a ventral hernia repair) two years later, but their biliary tract remained healthy.

In Group 2 (malignant obstructive jaundice), follow-up was limited by the patients' overall prognosis. Nonetheless, the palliative benefit of LCCD was maintained in all 29 patients until the end of follow-up. Jaundice and pruritus resolved in all cases after surgery and did not recur, indicating sustained biliary decompression. No patient required a repeat biliary intervention, such as another bypass or stenting. Three patients lived beyond one year post-surgery (survival of 15, 19, and 26 months, respectively, with diagnoses of ampullary carcinoma or slower-progressing pancreatic cancer). These longer-term survivors had no episodes of cholangitis or biliary obstruction; the LCCD anastomosis remained functional throughout. The majority of the malignant group (particularly those with pancreatic head cancer) succumbed to their disease within 7–13 months of surgery due to tumor progression or systemic causes, but critically, none suffered recurrent biliary obstruction. For the time they survived, they were free of the need for external biliary drains or repeat hospitalizations for stent occlusions. This outcome underscores that LCCD provided an effective one-time solution for biliary drainage in this palliative context.

Overall, the results demonstrate that LCCD achieved its intended goals in both groups: definitive clearance of stones and prevention of cholangitis in the failed-ERCP patients, and sustained relief of jaundice in the advanced malignancy patients, with very low complication risk (Table 2). Both the stone and malignant groups benefited from the minimally invasive approach, with short hospital stays and avoidance of more morbid open surgeries or external drainage devices. The high success rates and lack of major complications in our series support LCCD as a reliable technique in these challenging situations.

Table 2. **Surgical outcomes for patients undergoing LCCD (combined results)**

| Indicator | Result |
|---|--|
| Operative time, minutes | 76 (range: 55–110) |
| Conversion to open surgery | 0 patients |
| Intraoperative blood loss, mL | ~50 median (none > 200) |
| Postoperative hospital stay, days (mean ± SD) | 5.2 ± 2.1 |
| Major complications (Clavien ≥ 3) | 0 |
| Minor complications (Clavien 1–2) | 2 (3.6%) – no bile leaks, no cholangitis |
| 30-day mortality | 0 patients |
| Stone clearance rate (Group 1) | 92% (24/26 patients) |
| Jaundice relief rate (Group 2) | 100% (29/29 patients) |

Discussion

This study highlights the efficacy of LCCD as a versatile solution for two complicated clinical scenarios: refractory bile duct stones and palliative management of distal malignant obstruction. Our key findings were that LCCD achieved a 100% rate of biliary decompression in both contexts. Moreover, this was accomplished with zero perioperative mortality and no major complications, attesting to the safety of the procedure in experienced hands. The mean operative time (~76 minutes) and hospital stay (~5 days) in our series indicate that LCCD can be performed efficiently with a quick postoperative recovery. These outcomes compare favorably with historical results from open surgery and align with other recent reports of laparoscopic biliary bypass. For instance, P. Senthilnathan et al. [19] reported that laparoscopic CBD exploration with CDD was safe and effective after failed ERCP, yielding stone clearance in all patients with a median hospital stay of 5 days. Our findings reinforce that laparoscopic CDD is a reliable salvage technique when endoscopic stone extraction is unsuccessful.

One of the remarkable aspects of this study is the absence of bile leaks or anastomotic complications. Biliary-enteric anastomosis, especially to the duodenum, traditionally raised concerns for leak or fistula. However, with careful technique, we observed no leaks; this mirrors other laparoscopic series where leak rates have been low (on the order of 3% or less) and typically managed conservatively [8, 9, 11]. In our practice, several technical factors likely

contributed to secure anastomoses: the use of a longitudinal incision (~2 cm) on both the CBD and duodenum to create a wide stoma, a tension-free alignment of the two structures (a key principle to prevent leaks/strictures), and the use of continuous barbed sutures which provided even distribution of tension and a water-tight seal. We also routinely placed an omental patch over the completed anastomosis (by laying a tongue of the greater omentum between the CBD and duodenum) to augment healing, similar to strategies reported by T. Lianyuan et al [14]. These steps likely minimized the risk of leakage. Our zero leak rate is comparable to the report by T. Lianyuan et al. [14] on laparoscopic bridge CDD for malignant jaundice, where only 1 out of 35 patients (2.8%) had a bile leak, which was controlled nonoperatively. The low complication profile of LCCD in our series and others underscores that, far from being an experimental procedure, it is a mature and safe technique when performed by surgeons adept in advanced laparoscopy.

In the context of persistent choledocholithiasis (Group 1), our results demonstrate that LCCD offers a definitive one-stage solution. All 26 patients who had failed ERCP for large CBD stones were rendered stone-free in 24 patients, with no evidence of recurrent stones on follow-up. By creating a side-to-side biliary outflow tract into the duodenum, LCCD effectively prevents future stone impaction by giving any new stones a large conduit to pass into the intestine. This is an advantage over simple T-tube drainage or repeat ERCP attempts. The long-term patency of the CDD in our series (no strictures or sump syndrome up to 5 years) is consistent with prior studies that found very low rates of recurrent cholangitis or sump syndrome after CDD [8, 13]. Sump syndrome – characterized by stagnation of debris in the distal bile duct remnant – was historically a concern, but in practice it appears to be quite rare with modern surgical technique [4]. In our patients, removal of the gallbladder and cystic duct and creation of a wide stoma likely mitigated any tendency for debris accumulation. Literature supports that properly performed CDD has a < 5% incidence of recurrent cholangitis [10], and our experience of 0% cholangitis reinforces that. Additionally, we did not observe any case of duodenal content reflux causing symptoms. Some degree of biliary-enteric reflux is inevitable, but it did not translate into clinical cholangitis in our cohort, echoing other reports that found reflux cholangitis to be uncommon and often related more to anastomotic stricture than to the reflux itself.

Compared to alternative surgical approaches for difficult stones (such as laparoscopic trans-cystic or

trans-ductal exploration with T-tube), LCCD has the benefit of providing an internal drainage route with no external appliances. Patients avoid the discomfort and infection risk of a T-tube and do not require a second procedure for tube removal. Our findings support that when ERCP fails (which happens in about 4–10% of CBD stone cases) [16], proceeding to a laparoscopic surgical solution can be done in the same hospital stay with excellent outcomes. Importantly, none of our stone patients needed any further ERCP or surgery after LCCD – a testament to the durability of the procedure. This spares patients the cycle of repeat endoscopic attempts or chronic interventions. Other authors have reported similarly that LCCD definitively resolves choledocholithiasis in challenging cases, with one review noting a 100% CBD clearance and only ~1% recurrence in mid-term follow-up [11, 19]. Thus, our study adds to the growing evidence that laparoscopic CDD is an effective permanent cure for choledocholithiasis in the subset of patients where standard endoscopic methods are insufficient.

In the malignant obstructive jaundice group, LCCD functioned as a palliative bypass with excellent results. Relief from jaundice was universal and maintained until patient deaths or the last follow-up, without any need for stent placements or reoperations. This is particularly noteworthy because managing biliary obstruction in advanced cancer can often be a recurrent challenge due to stent occlusions. By performing a surgical bypass, we essentially eliminated the issue of stent clogging. Our outcomes mirror those reported by recent studies on laparoscopic biliary bypass for malignancy. For example, a two-center study from China [14, 23] on 35 patients with advanced malignant jaundice found that laparoscopic CDD had a 100% technical success rate, with significant bilirubin reduction postoperatively and no instances of delayed cholangitis or anastomotic stricture during follow-up. They concluded LCCD is a safe and efficient palliative surgery for these patients. Our series, with 29 malignant cases, represents one of the larger single-center Western experiences and reinforces those conclusions. The avoidance of external biliary drains in these often frail patients is a major benefit of LCCD – external drainage via percutaneous catheters can lead to electrolyte imbalances, infection, and decreased quality of life with a catheter in place. In contrast, internal drainage via LCCD allowed our patients to be free of tubes, eat normally, and have stable biliary decompression.

It is worth comparing LCCD to the more conventional surgical bypass for distal biliary obstruction, which is a hepaticojejunostomy (HJ) or

choledochojejunostomy. While HJ is a well-established operation, doing it laparoscopically is complex, and open HJ carries significant morbidity in the context of advanced cancer. LCCD, by anastomosing to the duodenum, is less invasive – no intestinal anastomosis or Roux-en-Y limb is required [18]. This makes the procedure shorter and potentially lowers the risk of postoperative complications like delayed gastric emptying. Indeed, our mean operative time of ~76 minutes for LCCD is far shorter than typical times reported for open surgical bypass (often 2–3 hours). Even within our series, the malignant cases had average operative times around or under 1 hour once the surgical team was past the initial learning curve, which is remarkably efficient for a biliary bypass. T. Lianyan et al. [14] described that after about 13 cases, their operative time plateaued around 60 minutes as well. Thus, once the learning curve is overcome, LCCD can be completed in roughly an hour, making it very competitive with endoscopic or percutaneous alternatives in terms of procedure time, but with the advantage of a one-time, durable fix. Furthermore, we had no conversions to open, reflecting that with proper patient selection (distal obstruction, dilated duct) and technique, laparoscopic access is sufficient to perform the bypass in essentially all cases.

Our study also underlines the importance of concomitant cholecystectomy during LCCD. We removed the gallbladder in all patients to eliminate the possibility of the gallbladder acting as a reservoir for bile and stones (so-called «sump»). Some older series of open CDD noted sump syndrome, particularly when the gallbladder and cystic duct were left *in situ* [10]. By doing cholecystectomy, we likely contributed to the zero incidence of sump-related problems. Additionally, removing the gallbladder addresses any gallstones that might be present (and indeed, in many of our stone-group patients, cholecystectomy was indicated due to cholelithiasis). This comprehensive approach aligns with modern surgical teaching that any biliary bypass for benign disease should include cholecystectomy to prevent future issues.

While interpreting the positive outcomes of LCCD, it is important to consider patient selection and limitations. The success of CDD hinges on having a distal obstruction (whether stone or tumor) with a sufficiently dilated proximal duct. We did not include patients with hilar cholangiocarcinoma or small nondilated ducts, as those are not suitable for CDD. In high biliary obstruction, other techniques like hepaticojejunostomy or multiple stents would be needed. Also, our malignant group was limited to distal lesions, so our results specifically

support LCCD in that context. Patients with very short life expectancy (just a few weeks) might still be better served with a quick endoscopic or percutaneous stent rather than surgery; however, all our malignant patients were expected to live at least a couple of months and had either failed stenting or were deemed likely to benefit from a longer-term solution. The threshold for choosing surgical bypass over stents in malignant cases remains individualized: factors include predicted survival, performance status, and local expertise. Our data suggest that if a patient is a reasonable surgical candidate and has a life expectancy beyond a few months, performing an LCCD can spare them recurrent endoscopic procedures and maintain biliary patency throughout their remaining life. This is supported by studies indicating that surgical bypass has superior long-term patency compared to stents, especially if survival exceeds 6–12 months [20].

We acknowledge some limitations of this study. It was a retrospective analysis without a control group. We did not directly compare LCCD outcomes to alternative treatments (such as repeat ERCP, open surgery, or percutaneous drainage) in a randomized fashion. However, given the scenarios (failed ERCP or unresectable cancer), randomization would have been ethically difficult; our patients received the treatment deemed necessary after standard care had failed or was not an option. Another limitation is the relatively small sample size, especially for subgroup analyses. While 55 patients is a respectable series for this uncommon procedure, subgroup comparisons (e.g., minor differences in operative time or hospital stay between stone vs. malignant cases) were not statistically analyzed. Nonetheless, the uniform success across all patients is a strength in itself. Follow-up for the stone group was robust (up to 5 years), confirming durability, but follow-up for malignant patients was inherently shorter due to their disease – we cannot comment on anastomosis patency beyond 2 years in malignancy, since few survived that long. That said, in the palliative setting, maintaining patency for the duration of patients' lives (as we achieved) is the relevant measure of success.

In summary, LCCD proved to be an effective, safe, and durable solution for persistent biliary obstruction in both benign and malignant contexts. It essentially converted what would otherwise be chronic problems requiring multiple interventions into a one-time fix. The procedure leveraged the advantages of minimally invasive surgery – less postoperative pain, quick recovery, and short hospitalization – without compromising on the effectiveness of biliary drainage. Given our positive

experience, we advocate that LCCD should be considered more often, especially at centers with advanced laparoscopic expertise, when confronted with large irretrievable CBD stones or when facing a distal biliary obstruction that cannot be stented. The surgical community's initial reservations about laparoscopic biliary-enteric anastomosis are being dispelled by results like ours and those in the literature. As techniques continue to improve, we anticipate that LCCD and similar minimally invasive biliary bypasses will become standard alternatives in the algorithm of biliary disease management.

Conclusions

Laparoscopic choledochoduodenostomy is a safe and minimally invasive procedure that provides effective internal biliary drainage in patients with complex CBD stones and malignant obstruction. In our series of 55 patients, LCCD achieved high success rates without major complications or the need for reintervention. Its durability and rapid recovery support its use as a definitive option when endoscopic methods fail. LCCD should be considered a valuable alternative in the surgical management of difficult biliary conditions.

ACKNOWLEDGEMENTS

The authors would like to thank the surgical and nursing staff at the Odesa National Medical University Hospital for their assistance and support during the procedures.

DECLARATION OF INTERESTS

The authors declare no conflicts of interest relevant to this manuscript.

Funding. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

ETHICS APPROVAL AND WRITTEN INFORMED CONSENT STATEMENTS

This study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of Odesa National Medical University. Written informed consent was obtained from all patients prior to their participation in the study.

AUTHORS CONTRIBUTIONS

V.V. Grubnik: study concept and design, critical revision of the manuscript, supervision; Y.V. Grubnik: data analysis and interpretation, manuscript editing; V.V. Ilyashenko: data collection, literature review, manuscript drafting; M.Y. Grubnik: data analysis, manuscript drafting, and revision; V.V. Grubnyk: clinical procedures, patient follow-up, critical revision of the manuscript.

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Ефективність лапароскопічної холедоходуоденостомії при лікуванні каменів у загальній жовчній протоці, що персистують, і прогресуванні злоякісної обструктивної жовтяниці

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Ендоскопічне видалення каменів із загальної жовчної протоки (ЗЖП) та стентування при дистальній біліарній обструкції є стандартними методами лікування, але можуть бути неефективними у випадках великих конкрементів або злоякісного процесу, що прогресує. Лапароскопічна холедоходуоденостомія (ЛХД) є альтернативним методом, що забезпечує внутрішнє шунтування жовчної протоки з обструкцією.

Мета — оцінити безпечність та ефективність ЛХД у пацієнтів із каменями в ЗЖП, що персистують після невдалого ендоскопічного лікування, та у хворих зі злоякісною обструктивною жовтяницею, що прогресує.

Матеріали та методи. Проаналізовано післяопераційні результати, ускладнення та дані спостереження 55 пацієнтів (38 жінок та 17 чоловіків, віком 50–85 років (середній вік — $67,8 \pm 8,6$) року), яким було виконано ЛХД у нашому центрі в період із 2018 до 2024 р., із них 26 мали великі камені в ЗЖП, які не вдалося видалити за допомогою ендоскопічної ретроградної холангіопанкреатографії, 29 — нерезектабельну дистальну злоякісну обструкцію (рак підшлункової залози або ампули Фатера). Усі операції проводили лапароскопічно з використанням п'яти троакарів, подовжньої холедохотомії та дуоденотомії, бічного холедоходуоденального анастомозу, виконаного вручну розсмоктувальними швами (V-Loс™ 3–0), та одночасної холецистектомії.

Результати. Усі 55 операцій успішно виконано лапароскопічно без необхідності переходу до відкритої операції. Середній час операції становив 76 хв (від 55 до 110 хв). Серйозних післяопераційних ускладнень або летальності протягом перших 30 днів не зафіксовано. Середня тривалість госпіталізації становила $(5,2 \pm 2,1)$ доби. У пацієнтів із каменями в ЗЖП досягнуто 92% очищення протоки без залишкової обструкції або рецидиву холангіту протягом 5-річного періоду спостереження. У групі пацієнтів зі злоякісною обструкцією жовтяницю ефективно куповано в усіх випадках. Жодному не знадобилося повторного хірургічного втручання на жовчних шляхах.

Висновки. Лапароскопічна холедоходуоденостомія є безпечним та ефективним методом лікування як у складних випадках холедохолітіазу після невдалої ендоскопічної ретроградної холангіопанкреатографії, так і для паліативного усунення злоякісної обструктивної жовтяниці. Ця методика забезпечує тривале біліарне відведення з мінімальною кількістю ускладнень і коротким періодом госпіталізації. Лапароскопічну холедоходуоденостомію слід розглядати як альтернативу за неможливості або неефективності ендоскопічного лікування, оскільки вона забезпечує остаточне вирішення проблеми обструкції та якісну паліативну допомогу при онкологічних захворюваннях.

Ключові слова: лапароскопія, холедоходуоденостомія, камені в загальній жовчній протоці, злоякісна обструктивна жовтяниця, біліарне шунтування, невдача ендоскопічної ретроградної холангіопанкреатографії.

FOR CITATION

■ Grubnik VV, Grubnik YV, Ilyashenko VV, Grubnik MY, Grubnyk VV. The effectiveness of laparoscopic choledochoduodenostomy for management of persistent common bile duct stones and advanced malignant obstructive jaundice. General Surgery (Ukraine). 2025;(2):17–26. <http://doi.org/10.30978/GS-2025-2-17>.

Endoscopic transluminal interventions and percutaneous drainage in acute infected necrotizing pancreatitis: experience of a specialized center

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Acute infected necrotizing pancreatitis is a life-threatening complication. Over the past 25 years, the introduction of minimally invasive techniques has significantly improved treatment outcomes. However, variations in disease progression, anatomical characteristics, and the need for optimal personalized invasive strategies remain subjects of ongoing debate.

OBJECTIVE – to evaluate and compare the treatment outcomes of acute infected necrotizing pancreatitis with peripancreatic and combined (parenchymal + peripancreatic) lesions, using endoscopic transluminal interventions versus the traditional «step-up» approach.

MATERIALS AND METHODS. A retrospective study involving 67 patients (mean age – 50.5 ± 10.9 years) was conducted from 2021 to 2024. Group 1 ($n=28$) underwent endoscopic transluminal interventions (ETI), including endoscopic necrosectomy when necessary, while Group 2 ($n=39$) was treated using the traditional «step-up» approach, which involved percutaneous drainage (PD) and open necrosectomy if indicated. There were no significant differences between the groups in baseline characteristics or in the size of the walled-off pancreatic necrosis (WON). Clinical success was categorized as complete, partial, or absent. Statistical analysis was performed using χ^2 and the Mann-Whitney U test.

RESULTS. The ETI group required fewer repeat procedures: a single procedure was sufficient for 50 % of patients in Group 1, whereas in Group 2, the majority of patients needed ≥ 3 interventions ($p=0.013$). Complete clinical success was achieved in 64.3 % of patients in Group 1, compared to only 25.6 % in Group 2 ($p=0.004$). External pancreatic fistulas occurred only after PD (12.8 %, $p=0.049$). The mortality rate in the ETI group was lower (10.7 % vs. 23.1 %), although this difference was not statistically significant ($p=0.193$). Additionally, Group 1 had a shorter average hospital stay (56.2 ± 27.2 days) compared to Group 2 (63.4 ± 23.7 days).

CONCLUSIONS. Endoscopic transluminal interventions within a multidisciplinary «step-up» approach are safer and more effective than isolated percutaneous drainage. ETI reduce the need for repeat interventions, lower the incidence of complications, and contribute to improved clinical outcomes in cases of acute infected necrotizing pancreatitis. PD and ETI are not mutually exclusive and can be incorporated into hybrid treatment strategies.

KEYWORDS

acute infected necrotizing pancreatitis, localized necrotic collection, endoscopic transluminal necrosectomy, percutaneous drainage.

ARTICLE • Received 2025-03-25 • Received in revised form 2025-04-23 • Published 2025-07-31

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In approximately 20 % of cases, acute pancreatitis is complicated by necrosis, and secondary infection develops in 30–70 % of these cases [16, 17, 26]. Acute infected necrotic pancreatitis (AINP) is associated with a high mortality rate (up to 30 %) and requires

prompt invasive treatment. Although open surgical necrosectomy remains an effective treatment option, it is frequently associated with severe complications such as organ dysfunction, pancreaticocutaneous fistulas, and prolonged hospitalization [32].

The contemporary management of AINP has evolved from open necrosectomy to a minimally invasive «step-up» approach, beginning with initial drainage followed by necrosectomy if indicated [2, 5, 8, 31]. Percutaneous drainage (PD), a minimally invasive procedure, was widely adopted in the early 2000s [7, 27]. Between 2009 and 2012, endoscopic transluminal interventions (ETI) gained increasing adoption as part of this treatment paradigm [10, 22].

Currently, PD and ETI form the basis of the modern «step-up» approach for AINP, significantly reducing complication rates and mortality compared to open surgical procedures [2, 6, 15, 21, 31]. However, the choice of the optimal minimally invasive method remains a subject of ongoing debate. For instance, M. Jagielski et al. [14] reported that PD as monotherapy is successful in 44–56% of patients but is associated with complications in 28–71% of patients. Conversely, cohort analysis have demonstrated higher effectiveness of ETI as an initial treatment approach (72.7%) [13]. Additionally, some experts recommend a combined strategy (PD + ETI), particularly in cases of large or centrally located necrotic collections [19].

The choice of a minimally invasive approach depends on factors such as anatomical localization, the stage of necrosis evolution, and technical accessibility of the necrotic focus. Therefore, conducting clinical studies in specialized centers is essential for optimizing treatment strategies.

OBJECTIVE – to evaluate and compare the treatment outcomes of AINP with peripancreatic and combined (parenchymal + peripancreatic) lesions, using endoscopic transluminal interventions versus the traditional «step-up» approach.

Materials and methods

A total of 67 patients were included in the study 38 men (56.7%) and 29 women (43.3%), with mean age of 50.5 ± 10.9 years, who were treated for AINP at our medical institution between 2021 and 2024.

Based on the treatment approach, patients were divided into two groups. The main group (Group 1, $n = 28$) underwent endoscopic transluminal drainage and/or necrosectomy, while the comparison group (Group 2, $n = 39$) was treated with the traditional «step-up» strategy, which included ultrasound-guided PD, if necessary, followed by open necrosectomy without the endoscopic stage.

Inclusion criteria for both groups

- Diagnosis of acute necrotizing pancreatitis that has progressed to an infected, localized necrotic collection (walled-off necrosis (WON) according to the Atlanta 2012 classification), confirmed by

abdominal contrast-enhanced computed tomography (CT) or abdominal magnetic resonance imaging (MRI), which directly contacts the stomach and/or duodenum.

- Duration of illness ≥ 4 weeks from the onset of abdominal pain (≥ 28 days).
- Clinical and laboratory indications for intervention.
- Age ≥ 18 years.

Inclusion criteria for the main group

- Underwent endoscopic transluminal drainage and/or necrosectomy.
- Prior single percutaneous drainage (PD) was not an exclusion criterion.

Inclusion criteria for the comparison group

- Underwent PD as the initial stage of treatment.
- No endoscopic intervention was performed.

Exclusion criteria from the study

- Isolated parenchymal necrotizing pancreatitis.
- «Dry» necrotizing pancreatitis.
- Post-traumatic necrotizing pancreatitis.
- Extensive necrosis with pericolic, pelvic, mediastinal, intra-abdominal spread, including the development of purulent peritonitis.
- Pancreatitis associated with malignancy.
- Severe concomitant diseases.
- Previous surgical interventions on the pancreas before inclusion.
- Lack of complete data on interventions.

Indications for ETI and PD

- Presence of a localized necrotic peripancreatic collection that, according to abdominal contrast-enhanced CT or abdominal MRI, directly contacts the stomach and/or duodenum.
- Duration of illness from the first attack of pain ≥ 4 weeks (≥ 28 days).
- Presence of external compression of the stomach and/or duodenum confirmed by esophagogastroduodenoscopy (EGD).

For diagnosis, a comprehensive assessment included general and biochemical blood tests, microbiological methods, ultrasonography, EGD, abdominal contrast-enhanced CT, or abdominal MRI. Given the complexity of the disease, patient management was multidisciplinary, involving surgeons, endoscopists, anesthesiologists, critical care physicians, radiologists, interventional ultrasound physicians, and other clinicians as needed (e.g., therapists, cardiologists, endocrinologists, and psychiatrists).

Characteristics of intervention in Group 1

Patients in Group 1 underwent ETI for drainage of the WON cavity, followed, if necessary, by endoscopic necrosectomy.

A duodenoscope Olympus TJF-150 (Japan) was used to create access and perform drainage, while a gastroscope Olympus GIF-Q150 (Japan), with a distal cap was used for direct necrosectomy. The procedures were performed under general anesthesia with endotracheal intubation, with patients placed in the supine position.

Access to the cavity was established at the point of maximal protrusion into the gastric lumen, and in one case, through a spontaneous cystoduodenal fistula. The fistulous tract was created using a cystotome or a needle papillotome with appropriate electrocoagulation settings, followed by dilation of the balloon catheter to 15–20 mm.

One to two double pigtail stents (10 Fr, 50 mm) were placed to ensure fistulous tract patency and facilitate endoscopic orientation during procedure.

The lavage of the WON cavity via transgastric access was performed with 1% hydrogen peroxide solution in volume up to 400 ml., with subsequent aspiration of the contents.

Direct necrosectomy was performed using an endoscopic tripod. Necrotic tissue that was tightly fixed was left for subsequent intervention. After each procedure, residual debris was documented for further evaluation.

During the clinical course in cases with prior PD, the irrigation of WON cavity was performed through a drain. In the absence of PD, at the end of intervention, a 7 Fr nasocystic drain was installed into the WON cavity for fractional irrigation. If necessary, balloon catheter dilation of the fistulous tract was performed again during the next procedure [18].

Characteristics of intervention in Group 2

Patients in Group 2 received treatment according to the «step-up» approach, starting with ultrasound-guided PD of the infected WON cavity. In some patients, PD was performed early in the course of acute pancreatitis (up to 28 days) in the presence of acute fluid collections, based on clinical indications (deterioration of the patient's condition, suspected or confirmed infection, abdominal compartment syndrome). If, after 28 days, the pathological process evolved into an infected WON, these patients were included in the study.

Interventions were performed under local anesthesia, with gradual dilation of the drainage canal in several stages based on clinical dynamics.

The drainage was inserted through the point of optimal access, taking into account the lesion topography as determined by CT or ultrasound data. Initially, a drain with a diameter of 9 Fr was used. If there was insufficient effectiveness or a large volume of contents, the drain was replaced or

sequentially dilated to larger sizes – 12–14 Fr (second procedure), 16–18 Fr (third procedure), and 22 Fr (fourth procedure). Fractional irrigation of the drains with a saline solution was performed every 6–8 hours to maintain patency and remove debris.

The goal of staged drainage was to reduce systemic toxicity, decrease purulent-necrotic content, and gradually form a separated cavity with subsequent debridement. In cases of multiple chambers of the WON cavity or insufficient effect, additional drains were placed in other anatomical zones.

If PD treatment was ineffective, if there was progression of sepsis, or in evidence of large, dense sequestra, open necrosectomy was performed.

A multidisciplinary team made decisions regarding surgical intervention in both groups.

Criteria for treatment effectiveness

The results of endoscopic transluminal drainage and/or necrosectomy were evaluated based on the degree of clinical success, which was classified as complete, partial, or absent clinical success. The technical success of the procedure was assessed by successful access to the WON cavity.

The main criterion for complete clinical success was the patient's discharge in satisfactory condition without the need for additional surgical interventions due to necrosectomy or complications.

Other criteria for treatment effectiveness at the time of discharge included:

- Absence or significant reduction of symptoms related to the primary disease (e.g., abdominal pain, hyperthermia, signs of compartment syndrome such as nausea, vomiting, and digestion problems).
- Imaging findings (ultrasound, contrast-enhanced CT, or MRI).
- Absence of fluid accumulations, or the presence of a cystic cavity < 3 cm that does not require surgical intervention.

Partial clinical success was defined as a reduction in pain syndrome, resolution of symptoms of gastric or duodenal obstruction, and/or reduction in hyperthermia, without significant improvement in the patient's overall condition. It also included cases where open surgical intervention was needed within the «step-up» strategy.

Absence of clinical success was defined as a fatal outcome, regardless of whether an open operation was performed within the «step-up» strategy.

Technical success of the endoscopic procedure was defined as the creation of a direct transluminal access to the WON cavity, which allowed for balloon catheter dilation of the created fistulous tract, placement of stents (drains), or passage of an endoscope into the WON cavity, regardless of the final

clinical treatment outcome. PD was considered successful if a pig-tail drain of the necessary diameter was installed into the WON cavity.

Complications were categorized into two groups: those directly related to necrosectomy (intraoperative complications) and those associated with the disease course that required surgical intervention (peritonitis, fistulas, and others).

Statistical analysis of the collected data was performed using IBM SPSS Statistics 22. Descriptive statistics were conducted. Quantitative data are presented as mean (M) \pm standard deviation (SD). For qualitative features, absolute numbers (n) and percentages were used. To assess the correspondence between observed and expected frequencies in categorical data, a one-sample χ^2 test was applied. Comparative analysis of quantitative variables was carried out using the Mann-Whitney U test. The null hypothesis of variable equality was rejected at $p < 0.05$.

Results

Patients in both groups exhibited no significant differences in the initial baseline parameters (Table 1).

Additionally, in both groups of patients no significant differences were found in clinical symptoms (Table 2) at the time of the initial procedure of endoscopic transluminal necrosectomy (ETN)

or percutaneous drainage (PD), when the disease had progressed to a morphological form of infected WON (not earlier than 28 days).

The average size of WON was assessed using diagnostic imaging methods (abdominal contrast-enhanced CT and, less frequently, abdominal MRI). The maximum dimensions of the cavity (conventional width and length) were measured separately in the axial and coronal planes. Four measurements were obtained, summed, and averaged (Figure). In Group 1, the average size of WON was 109.6 ± 32.9 mm; in Group 2, it was 114.5 ± 33.1 mm, $p = 0.518$.

Patients in Group 1 underwent a total of 48 endoscopic transluminal interventions, with half of the patients (50%) requiring only one procedure. In contrast, patients in Group 2 underwent 88 procedures in total, with the most common number of interventions being three per patient (43.6%), as detailed in Table 3.

The distribution of patients by the number of interventions showed a statistically significant difference between the groups ($p = 0.013$), indicating a greater need for repeat procedures in patients of Group 2, likely due to the lower initial efficacy of the treatment strategy.

The average intervals between successive procedures (1–2, 2–3, 3–4) did not show a statistically significant difference between the groups. However, these intervals were significantly shorter in Group 2 (Table 4).

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

| Characteristics | Total (n = 67) | Group 1 (n = 28) | Group 2 (n = 39) | p |
|--------------------------------|-----------------|------------------|------------------|-------|
| Males | 38 (56.7%) | 15 (53.6%) | 23 (59.0%) | 0.660 |
| Females | 29 (43.3%) | 13 (46.4%) | 16 (41.0%) | |
| Age, years (M \pm SD) | 50.5 \pm 10.9 | 52.6 \pm 12.5 | 48.9 \pm 9.4 | 0.184 |
| Time to admission, hours | | | | 0.936 |
| < 6 | 14 (20.9%) | 5 (17.9%) | 9 (23.1%) | |
| 6–24 | 15 (22.4%) | 6 (21.4%) | 9 (23.1%) | |
| 24–72 | 5 (7.46%) | 2 (7.1%) | 3 (7.7%) | |
| > 72 | 33 (49.3%) | 15 (53.6%) | 18 (46.2%) | |
| Hospitalization status | | | | 0.568 |
| First-time admission | 57 (85.1%) | 23 (82.1%) | 34 (87.2%) | |
| Readmission | 10 (14.9%) | 5 (17.9%) | 5 (12.8%) | |
| Pancreatitis etiology | | | | 0.642 |
| Gallstone disease | 39 (58.2%) | 15 (53.6%) | 24 (61.5%) | |
| Alcohol | 25 (37.3%) | 11 (39.3%) | 14 (35.9%) | |
| Hypertriglyceridemia | 2 (3.0%) | 1 (3.6%) | 1 (2.6%) | |
| Tumor (ampullary adenoma) | 1 (1.5%) | 1 (3.6%) | 0 | |
| Severity of acute pancreatitis | | | | 0.905 |
| Moderate | 46 (68.7%) | 19 (67.9%) | 27 (69.2%) | |
| Severe | 21 (31.3%) | 9 (32.1%) | 12 (30.8%) | |

Table 2. Primary conditions and symptoms in patients with infected walled-off necrosis at first treatment procedure

| Conditions and symptoms | Total (n = 67) | Group 1 (n = 28) | Group 2 (n = 39) | p |
|--|----------------|------------------|------------------|-------|
| Hyperthermia | 63 (94.0%) | 27 (96.4%) | 36 (92.3%) | 0.483 |
| Abdominal pain | 57 (85.1%) | 25 (89.3%) | 32 (82.1%) | 0.412 |
| Pronounced general weakness | 54 (80.6%) | 22 (78.6%) | 32 (82.1%) | 0.722 |
| Sepsis | 44 (65.7%) | 19 (67.9%) | 25 (64.1%) | 0.750 |
| Gastric outlet obstruction/vomiting | 42 (62.7%) | 17 (60.7%) | 25 (64.1%) | 0.777 |
| Pancreatic ascites | 33 (49.3%) | 15 (53.6%) | 18 (46.2%) | 0.549 |
| Loss of appetite and nausea | 34 (50.7%) | 14 (50.0%) | 20 (51.3%) | 0.918 |
| Sleep disturbances | 28 (41.8%) | 13 (46.4%) | 15 (38.5%) | 0.514 |
| Splenoportal thrombosis | 19 (28.4%) | 8 (28.6%) | 11 (28.2%) | 0.974 |
| Pleural effusion | 19 (28.4%) | 8 (28.6%) | 11 (28.2%) | 0.974 |
| Infection (positive bacteriological culture from WON aspirate) | 64 (95.5%) | 27 (96.4%) | 37 (94.9%) | 0.751 |

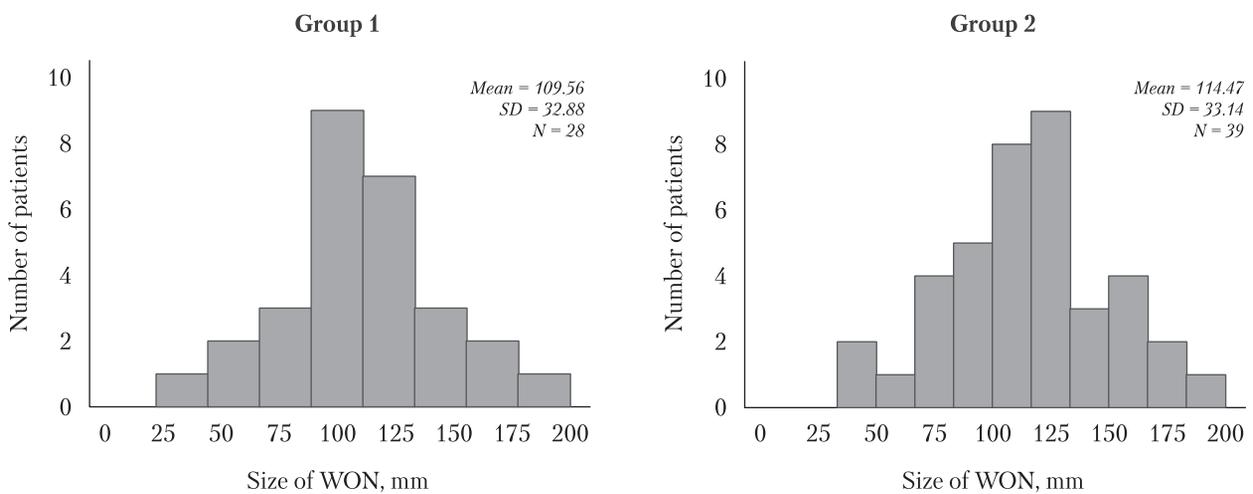


Figure. **Distribution of patients based on the average size of WON**

The initial intervention Group 1 was performed on average at 36.2 ± 16.1 days from the first episode of the disease, while in Group 2, it occurred at 30.6 ± 10.9 days ($p = 0.094$).

In Group 1, 14 (50%) patients underwent ultrasound-guided percutaneous pig-tail drainage (diameter of 9–12 Fr) in the area of the fluid-necrotic collection at an average of 7 (5–9) days from disease onset prior to ETI. Additionally, 15 (53.6%) patients underwent abdominal drainage for pancreatic ascites at different disease periods, and 8 (28.6%) patients had pleural drainage due to

Table 3. Distribution of patients by the number of procedures

| Number of procedures | Total (n = 67) | Group 1 (n = 28) | Group 2 (n = 39) |
|----------------------|----------------|------------------|------------------|
| 1 | 25 (37.3%) | 14 (50.0%) | 11 (28.2%) |
| 2 | 19 (28.4%) | 10 (35.7%) | 9 (23.1%) |
| 3 | 19 (28.4%) | 2 (7.1%) | 17 (43.6%) |
| 4 | 4 (6.0%) | 2 (7.1%) | 2 (5.1%) |

Table 4. Average intervals between procedures, days (M±SD (Min–Max))

| Procedures | Group 1 | Group 2 |
|------------|----------------|---------------|
| 1–2 | 7.0±2.2 (4–14) | 4.8±0.8 (4–6) |
| 2–3 | 7.0±1.4 (6–8) | 3.7±0.7 (3–5) |
| 3–4 | 6.5±0.7 (6–7) | 3.0±1.4 (2–4) |

Table 5. Treatment outcomes for acute infected necrotizing pancreatitis

| Clinical success | Total (n = 67) | Group 1 (n = 28) | Group 2 (n = 39) |
|------------------|----------------|------------------|------------------|
| Complete | 28 (41.8%) | 18 (64.3%) | 10 (25.6%) |
| Partial | 27 (40.3%) | 7 (25.0%) | 20 (51.3%) |
| No success | 12 (17.9%) | 3 (10.7%) | 9 (23.1%) |

exudative pleuritis. In Group 2, 24 (61.5%) patients underwent abdominal drainage for pancreatic ascites at various stages of the disease (p = 0.514), and 13 (33.3%) had pleural drainage for exudative pleuritis (p = 0.679).

The technical success was achieved in all patients.

In one patient of Group 1, experienced gastric wall bleeding during the first intervention, which was managed by balloon catheter compression. No complications requiring surgical intervention were observed.

Patients in Group 1 demonstrated significantly better treatment outcomes for AINP. Specifically, the rate of complete clinical success was significantly higher – 64.3% in the main group compared to 25.6% in the comparison group (p = 0.004) – with fewer patients exhibiting partial response or no clinical improvement.

The distribution of treatment outcomes (complete, partial, or no clinical success) between the groups differed significantly between the groups (p = 0.007), indicating the superiority of the strategy used in Group 1 (Table 5).

Although the mortality rate was lower in the main group (10.7%) compared to the comparison group (23.1%), this difference did not reach statistical significance (p = 0.193). In Group 1, complete success was primarily achieved after 1–2 procedures (44.4% and 38.9%, respectively), whereas in Group 2, it was mainly achieved after 2–3 procedures (30.0% and 60.0%, respectively; Table 6).

In both groups, all cases of absent clinical effect occurred after 1–2 interventions, with a higher frequency after the first procedure. Overall, the data suggest a preference for a smaller number of interventions to achieve complete success in Group 1, reflecting a higher initial effectiveness of treatment in this cohort. However, worth noting, that 14 (50%) patients in this group received ultrasound-guided 9–12 Fr percutaneous drainage into the area of fluid-necrotic accumulation, on average, on the 7th day (range 5–9 days) from disease onset, prior to ETI.

A key advantage for Group 1 was the absence of external pancreatic fistulas, which were observed in 5 (12.8%) patients in Group 2 (p = 0.049).

Table 6. Distribution of patients by treatment outcomes and the number of endoscopic procedures

| Clinical success | Total | Number of procedures | | | |
|------------------|-------|----------------------|------------|------------|-----------|
| | | 1 | 2 | 3 | 4 |
| Group 1 | | | | | |
| Complete | 18 | 8 (44.4%) | 7 (38.9%) | 1 (5.6%) | 2 (11.1%) |
| Partial | 7 | 4 (57.1%) | 2 (28.6%) | 1 (14.3%) | 0 |
| No success | 3 | 2 (66.7%) | 1 (33.3%) | 0 | 0 |
| Total | 28 | 14 (50.0%) | 10 (35.7%) | 2 (7.1%) | 2 (7.1%) |
| Group 2 | | | | | |
| Complete | 10 | 0 | 3 (30.0%) | 6 (60.0%) | 1 (10.0%) |
| Partial | 20 | 6 (30.0%) | 6 (30.0%) | 7 (35.0%) | 1 (5.0%) |
| No success | 9 | 5 (55.6%) | 0 | 4 (44.4%) | 0 |
| Total | 39 | 11 (28.2%) | 9 (23.1%) | 17 (43.6%) | 2 (5.1%) |

Despite longer intervals between procedures in Group 1, the average length of hospital stay was shorter (56.2 ± 27.2 days) compared to Group 2 (63.4 ± 23.7 days), mainly due to the reduced need for open surgery and a shorter postoperative course. However, this difference did not reach statistical significance ($p = 0.183$).

Discussion

Over the past two decades, approaches to the treatment of infected necrotizing pancreatitis have undergone a significant transformation—from open surgical interventions to minimally invasive techniques focused on a gradual, stepwise approach. As early as 1998, P. C. Freeny et al. [9] demonstrated the effectiveness of PD in critically ill patients, achieving a mortality reduction to 12%, which laid the foundation for further research supporting PD as the initial intervention.

The results of the multicenter PANTER study confirmed the advantages of the «step-up» approach with initial PD, allowing nearly half of the patients to avoid open surgery [30]. Contemporary literature reviews indicate that the success rate of PD alone in AINP ranges from 44% to 56%, representing a relatively high success indicator in clinical practice [14, 27]. However, PD has significant limitations, including the prolonged presence of external drains, risk of external fistula formation, incomplete debridement of central necrosis, and the need for subsequent necrosectomy [2, 7, 8, 31].

Since 2009, endoscopic transluminal interventions have been actively introduced into clinical practice. The pioneering study by N. Seifert et al. [22] was the first to demonstrate the efficacy of endoscopic necrosectomy, achieving a clinical success rate of over 80% in multicenter research. Subsequently, numerous randomized studies and meta-analyses, including the study by O.J. Bakker et al. [3], the TENSION trial [28], and C.M. Haney et al. [12], confirmed the advantages of the endoscopic «step-up» approach over surgical and traditional PD. Advantages include a reduction in the recurrence of organ failure, pancreatic fistulas, hospital stay, and the need for additional interventions, all while maintaining comparable mortality rates. Our results are consistent with these findings. Thus, in the ETI group, patients required fewer procedures and shorter hospital stay, had no external pancreatic fistulas and a tendency toward reduced mortality (10.7% vs. 23.1% in the PD group). Notably, 50% of patients in the ETI group required only a single procedure, which aligns with data from A. A. Siddiqui et al. [23] and D. Y. Bang et al. [4], who demonstrated the high efficacy of single-procedure

debridement when using modern lumen-apposing metal stents (LAMS). The absence of external pancreatic fistulas in the ETI group aligns with the findings of T. V. Gardner et al. [10], S. M. van Dijk et al. [29], and the TENSION trial [28], which confirmed that internal endoscopic drainage significantly reduces the risk of this complication compared to percutaneous approaches.

The strategy of delayed interventions used in our study also aligns with current best practices. The POINTER trial [8] demonstrated that postponing interventions for ≥ 28 days allows for a reduction in the number of procedures without compromising safety and efficacy. In our research, the average time to the first endoscopic intervention was 36.2 ± 16.1 days, which may have positively impacted treatment outcomes.

Furthermore, it is important that 50% of patients in the ETI group had prior PD, reflecting the concept of dual-modality drainage described by A. S. Ross et al. [20]. This approach combines the benefits of rapid initial decompression through PD with effective debridement of organized necrosis through ETI at a later stage.

Regarding mortality, the difference between the groups in our study did not reach statistical significance. A similar trend was observed in studies by S. M. Haney et al. [12] and R. Tang et al. [24], where complication and hospitalization rates were significantly lower in the ETI group, while mortality rates did not differ significantly. These findings highlight the advantages of the endoscopic approach primarily in reducing complications and enhancing patients' quality of life, rather than an impact on survival.

Overall, our results are consistent with current international guidelines from ESGE [2], AGA [6], ACG [25], which recommend: (1) if possible, delaying intervention until the formation of WON (about 4 weeks), (2) favoring endoscopic transluminal drainage and/or necrosectomy when access to WON from the stomach or duodenum is feasible, and (3) reserving necrosectomy for cases where drainage alone is ineffective.

Regarding timing, we, like T. H. Baron et al. [6], believe that PD can be performed as needed during the early acute phase (within 2 weeks of disease onset). In contrast, endoscopic transluminal interventions are reasonably performed after ≥ 4 weeks, once a «capsule» of WON has formed, which reduces the risk of complications. PD should also be considered as an adjunct to endoscopic drainage in cases where WON extends deeply into the paracolic spaces and/or the pelvic area. Additionally, PD may be used as a supplementary therapy after endoscopic or surgical necrosectomy if residual necrotic masses are present [6].

Based on our experience, when performing transluminal access to WON, even for endoscopic drainage, it is necessary to dilate the created fistulous tract using a 15–20 mm balloon catheter rather than placing transluminal drains alone. This approach enables passage of an endoscope into the WON cavity during the initial procedure to assess its size and contents. If needed, immediate necrosectomy can be performed within accessible limits. Additionally, this approach facilitates more effective planning of further management. It also enhances conditions for debriding the necrotic tissue within the gastric lumen during active lavage of the WON cavity, whether through an existing percutaneous drain(s) or a nasocystic drain placed endoscopically.

Conclusions

The data obtained confirm that endoscopic transluminal interventions, particularly within a multidisciplinary «step-up» approach, are safe and effective for patients with peripancreatic or combined (parenchymal + peripancreatic) lesions. Their application is associated with reduced invasiveness, fewer procedures, reduced complication rates, and improved clinical outcomes. Overall, ETI and PD in the paradigm of minimally invasive approaches should be viewed as complementary rather than competing methods.

DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

AUTHORS CONTRIBUTIONS

Y. M. Susak: conception and design, manuscript writing, critical revision of the article; N. V. Puzyr: acquisition of data, analysis and interpretation of data, manuscript writing.

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Ендоскопічні транслюмінальні втручання та перкутанне дренування при гострому інфікованому некротичному панкреатиті в умовах спеціалізованого центру

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Гострий інфікований некротичний панкреатит є ускладненням, що становить загрозу для життя. Упровадження малоінвазивних технологій за останні 25 років суттєво поліпшило результати його лікування. Проте варіабельність перебігу захворювання, анатомічні особливості та потреба індивідуального вибору оптимальної інвазивної тактики в кожному клінічному випадку залишаються предметом дискусії.

Мета — оцінити ефективність ендоскопічних транслюмінальних втручань (ЕТВ) порівняно з традиційною тактикою «step-up» із перкутанним дренуванням (ПКД) у лікуванні хворих з гострим інфікованим некротичним панкреатитом у спеціалізованому центрі.

Матеріали та методи. Проведено ретроспективне дослідження 67 пацієнтів (середній вік — $(50,5 \pm 10,9)$ року), пролікованих у 2021—2024 рр. Група 1 ($n = 28$) отримала ЕТВ з можливістю ендоскопічної некроектомії, групу 2 ($n = 39$) лікували за традиційною тактикою ПКД із відкритою некроектомією за потреби. Групи не відрізнялися за вихідними характеристиками та розміром обмежених некротичних скупчень. Клінічний успіх оцінювали як повний, частковий або відсутній. Статистичний аналіз виконували з використанням χ^2 та U-критерію Манна—Уїтні.

Результати. У групі ЕТВ виникла потреба в меншій кількості повторних процедур: одного втручання було достатньо в 50 % пацієнтів групи 1, тоді як у групі 2 найчастіше потрібно було ≥ 3 сеансів ($p = 0,013$). Повного клінічного успіху досягнуто в 64,3 % пацієнтів групи 1 та лише в 25,6 % у групі 2 ($p = 0,004$). Зовнішні панкреатичні нориці виникали лише після ПКД (12,8 %, $p = 0,049$). Летальність у групі ЕТВ була нижчою (10,7 порівняно з 23,1 %), але різниця не досягла рівня статистичної значущості ($p = 0,193$). Середній ліжко-день у групі 1 був меншим ($(56,2 \pm 27,2)$ і $(63,4 \pm 23,7)$ доби).

Висновки. Ендоскопічні транслюмінальні втручання в межах мультидисциплінарного підходу «step-up» є безпечнішими та ефективнішими порівняно з ізольованим ПКД, зменшують потребу в повторних інтервенціях, частоту ускладнень і сприяють кращим клінічним результатам при гострому інфікованому некротичному панкреатиті. Перкутанне дренування та ЕТВ не є взаємовиключними, їх можна поєднувати в комбінованих тактиках лікування.

Ключові слова: гострий інфікований некротичний панкреатит, обмежене некротичне скупчення, ендоскопічна транслюмінальна некроектомія, перкутанне дренування.

FOR CITATION

■ Susak YM, Puzyr VN. Endoscopic transluminal interventions and percutaneous drainage in acute infected necrotizing pancreatitis: experience of a specialized center. *General Surgery (Ukraine)*. 2025;(2):27-35. <http://doi.org/10.30978/GS-2025-2-27>.

Minimally invasive techniques in stage I–II chronic hemorrhoids: outcomes and prioritization

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Various minimally invasive techniques are widely used in the treatment of stage I–II chronic hemorrhoids (CH), including rubber band ligation (RBL), transanal hemorrhoidal dearterialization (THD), laser vaporization (LV), among others. Bipolar vaporization (BPV) is a novel and promising method of thermal tissue destruction using the EK-300M (*Svarmed*, Ukraine) bio-welding generator. Its effectiveness compared to other techniques remains insufficiently studied.

OBJECTIVE – to compare the outcomes of treating complicated stage I–II CH using four minimally invasive techniques (BV, LV, THD, RBL) and to determine their priority ranking.

MATERIALS AND METHODS. The study included 118 patients (67 men and 51 women, aged between 19 and 70 years; the mean age was 43.1 ± 12.5 years) with symptomatic stage I–II CH resistant to conservative therapy. Patients were divided into four groups according to the applied method: BPV ($n=32$), LV ($n=21$), THD ($n=23$), and RBL ($n=42$). The following parameters were assessed: duration of the procedure, frequency of intraoperative complications, dynamics of symptoms (pain, prolapse, bleeding, itching, soiling), recurrence rate, and patient satisfaction at 12-month follow-up.

RESULTS. All techniques demonstrated an adequate level of effectiveness and safety. The 12-month recurrence rates were BPV – 3.1%, LV – 4.8%, THD – 13%, and RBL – 26.2%. The highest satisfaction level (8–9 points) was observed in the BPV and LV groups (> 90% of patients). BPV and LV showed the best clinical efficacy and stability of outcomes. THD ranked third in terms of effectiveness, while RBL had the lowest priority due to the high recurrence rate.

CONCLUSIONS. Considering clinical outcomes, availability, and cost, bipolar vaporization can be recommended as a priority method for the treatment of stage I–II CH. Further multicenter studies are needed to confirm its long-term efficacy.

KEYWORDS

chronic hemorrhoids, bipolar vaporization, minimally invasive techniques, transanal dearterialization, laser vaporization, rubber band ligation, treatment outcomes.

ARTICLE • Received 2025-05-25 • Received in revised form 2025-06-19 • Published 2025-07-31

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Chronic hemorrhoidal disease (CH) remains one of the most common anorectal conditions worldwide. According to a national epidemiological study in China, the standardized detection rate of hemorrhoids was 17.7% among men and 43.7% among women [17]. The prevalence varies across different countries: in the USA, recent data indicate a rate of 13–16% of the population [9, 12, 20], while in Austria it reaches 39% [30]. The highest incidence is observed in the 45–65 age group; up to 50% of individuals over 50 years old have experienced

symptoms of hemorrhoidal disease [15, 30]. Additionally, screening colonoscopies detect hemorrhoids in 38–39% of patients, with more than half of these cases (55%) being asymptomatic [27, 30].

According to the Goligher classification [7, 16], the majority of patients present with stage I (72.89%) or stage II (18.42%) CH, while stages III and IV are much less frequent, accounting for 8.16% and 0.53% of cases, respectively [30].

It is well known that the current treatment strategy for CH is based on a stepwise approach – from

conservative to surgical interventions [5, 10, 12, 34]. While conservative therapy remains a mandatory component for all stages of CH, most patients with stage I–II disease who fail to achieve stable results with medical management require minimally invasive procedures.

Among the most commonly used minimally invasive techniques are rubber band ligation (RBL) [29], sclerosing injections (SI) [14], transanal hemorrhoidal dearterialization (THD) [35], endovascular embolization of the superior rectal artery (Emborrhoid therapy) [6], and various thermal tissue destruction methods, including infrared photocoagulation [32], laser coagulation [22, 23], radiofrequency ablation [21, 22], and bipolar coagulation [31].

These techniques aim to reduce the vascularity of hemorrhoidal tissue, remove excess tissue, and minimize prolapse through ablation or fixation of hemorrhoidal cushions to the rectal wall. Despite their proven clinical efficacy, most of these techniques have certain limitations, including the potential for postoperative pain, the need for repeat procedures, risk of recurrence, technical complexity (particularly in THD and Emborrhoid therapy), and high equipment costs [5, 9, 10, 13, 33].

The lack of consensus regarding the optimal treatment modality for stage I–II CH necessitates further clinical research in this area.

Among new approaches, tissue vaporization techniques have attracted growing interest. They are already widely used in urology [8, 18], gynecology [3], and in the treatment of lower limb varicose veins [1]. Due to their technical characteristics and method of energy delivery, this approach could potentially be effective in the treatment of hemorrhoidal disease. However, according to the available literature, experience with the use of vaporization specifically in proctology has not yet been documented, which underscores the relevance of further research in this area.

OBJECTIVE – to compare the outcomes of treatment for complicated stage I–II chronic hemorrhoidal disease using minimally invasive techniques, including bipolar vaporization, and to determine the priority ranking of these methods.

Materials and methods

The study included 118 patients with complicated chronic hemorrhoidal disease (CH) resistant to conservative treatment: 41 patients with stage I CH (34.7%) and 77 patients with stage II CH (65.3%). The cohort consisted of 67 men and 51 women, aged between 19 and 70 years; the mean age was 43.1 ± 12.5 years. The distribution of patients by treatment method and CH stage is shown in Table 1.

There were no statistically significant differences between the study groups in the distribution of CH stages ($p = 0.586$).

An original method for bipolar vaporization of hemorrhoidal nodes was applied in this study, using the EK-300M bio-welding generator developed in Ukraine («Svarmed») [5].

Inclusion criteria:

- symptomatic stage I–II chronic hemorrhoidal disease according to Goligher's classification [7, 16], resistant to conservative treatment;
- age ≥ 18 years;
- absence of severe comorbidities (ASA class IV);
- signed informed consent for surgical treatment and outpatient follow-up during the postoperative period.

Exclusion criteria:

- history of infectious or undifferentiated colitis within the last 6 months prior to screening;
- malignancies of the rectum or anal canal;
- inflammatory diseases of the rectum; exacerbation of other chronic gastrointestinal diseases (pancreatitis, cholecystitis, hepatitis, gastritis, colitis) or acute surgical conditions;
- logistical issues (missed follow-up appointments), non-compliance with the planned diagnostic and treatment schedule.

The effectiveness of bipolar vaporization of hemorrhoidal nodes was assessed based on parameters defined for hemorrhoidal disease treatment in the international Delphi study [34].

The **primary endpoint** was the «Hemorrhoid Symptoms» domain, which included pain, prolapse, itching, soiling (minor discharge of mucus, liquid stool, or perianal skin soiling), and bleeding (presence of blood in the stool during defecation).

Secondary endpoints included «Complications» (fecal incontinence, abscess, urinary retention, anal stenosis, and fistula), «Recurrence», and «Satisfaction» (patient satisfaction with surgical outcomes).

Table 1. **Distribution of patients by treatment method and CH stage**

| Group | Stage I CH | Stage II CH | Total |
|--|------------|-------------|-------|
| Bipolar vaporization | 10 (31.3%) | 22 (68.8%) | 32 |
| Laser vaporization | 6 (28.6%) | 15 (71.4%) | 21 |
| Rubber band ligation | 18 (42.9%) | 24 (57.1%) | 42 |
| Transanal hemorrhoidal dearterialization | 7 (30.4%) | 16 (69.6%) | 23 |
| Total | 41 (34.7%) | 77 (65.3%) | 118 |

The «Hemorrhoid Symptoms» domain was assessed using a 0–9 point scale (0 – no symptoms, 9 – maximum severity), as well as by the frequency of occurrence in the study groups. In the baseline characteristics (preoperative), both the symptom score and frequency were presented. During follow-up, only the frequency was reported due to the low incidence of symptoms at later time points, which made it inappropriate to calculate mean scores.

The «Complications» domain was assessed as follows: fecal incontinence – using the Wexner Scale [19]; abscess and anal stenosis – based on physical examination findings; urinary retention – diagnosed by ultrasound; fistula – diagnosed by MRI in cases of inconclusive physical examination.

The «Satisfaction» domain was evaluated on a 0 to 9-point scale (0 – no satisfaction with the surgery, 9 – maximum satisfaction with surgical outcomes).

The «Recurrence» domain was defined as the re-appearance of the patient's initial symptoms.

The timing of assessments for the «Symptoms» and «Satisfaction» domains was preoperatively (baseline) and at 7 days, 6 months, and 12 months post-procedure. Abscess and urinary retention were assessed at 7 days post-procedure; anal stenosis, fecal incontinence,

and fistula – at 12 months. The «Recurrence» domain was evaluated at 6 and 12 months post-procedure.

Statistical analysis was performed using IBM SPSS Statistics 22.0.

For comparison of two independent samples, Student's t-test was used for normally distributed variables, and the Mann–Whitney U test was used for non-normally distributed variables. For paired (dependent) samples, the Wilcoxon signed-rank test was used. For comparison of quantitative variables across more than two groups, analysis of variance (ANOVA) was applied. Categorical variables were compared using the chi-square (χ^2) test or Fisher's exact test, as appropriate.

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

Results

The baseline characteristics of the patients were compared across the study groups. No statistically significant differences were found in age, sex, BMI, disease duration, history of thrombosed hemorrhoids, or severity of hemorrhoid-related symptoms (all $p > 0.05$), confirming the homogeneity of the groups at baseline (Table 2).

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

| Parameter | BPV (n = 32) | LV (n = 21) | RBL (n = 42) | THD (n = 23) | Total (n = 118) |
|-----------------------------------|--------------|-------------|--------------|--------------|-----------------|
| Age, years | 43.3 ± 14.7 | 45.0 ± 8.8 | 41.0 ± 11.5 | 44.7 ± 13.9 | 43.1 ± 12.5 |
| Male | 19 (59.4%) | 11 (54.4%) | 23 (54.8%) | 14 (60.9%) | 67 (56.8%) |
| Female | 13 (40.6%) | 10 (47.6%) | 19 (45.2%) | 9 (39.1%) | 51 (43.2%) |
| BMI, kg/m ² | 27.4 ± 3.8 | 23.7 ± 3.3 | 25.7 ± 7.6 | 25.3 ± 5.4 | 25.7 ± 5.8 |
| Disease duration, years | 6.8 ± 4.5 | 9.0 ± 3.9 | 7.6 ± 3.1 | 9.3 ± 4.4 | 7.9 ± 3.9 |
| History of thrombosed hemorrhoids | 14 (43.8%) | 6 (28.6%) | 16 (38.1%) | 11 (47.8%) | 71 (60.2%) |
| Hemorrhoid symptoms domain | | | | | |
| Pain | 18 (56.3%) | 16 (76.2%) | 31 (73.8%) | 15 (65.2%) | 80 (67.8%) |
| Pain score | 2.7 ± 1.4 | 2.8 ± 1.3 | 2.6 ± 1.3 | 2.7 ± 0.9 | 2.7 ± 1.2 |
| Prolapse | 22 (68.8%) | 11 (52.4%) | 30 (71.4%) | 13 (56.5%) | 76 (64.4%) |
| Prolapse score | 4.6 ± 1.3 | 3.5 ± 0.5 | 4.3 ± 1.3 | 4.5 ± 1.3 | 4.3 ± 1.2 |
| Itching | 9 (28.1%) | 5 (23.8%) | 11 (26.2%) | 7 (30.4%) | 32 (27.1%) |
| Itching score | 2.8 ± 0.7 | 3.2 ± 0.8 | 3.5 ± 0.7 | 3.1 ± 0.7 | 3.2 ± 0.7 |
| Soiling | 8 (25.5%) | 6 (28.6%) | 12 (28.6%) | 6 (26.1%) | 32 (27.1%) |
| Soiling score | 3.1 ± 0.8 | 3.3 ± 0.8 | 3.3 ± 0.6 | 3.4 ± 0.6 | 3.3 ± 0.6 |
| Bleeding | 32 (100.0%) | 21 (100.0%) | 42 (100.0%) | 23 (100.0%) | 118 (100.0%) |
| Bleeding score | 4.7 ± 1.1 | 4.3 ± 1.1 | 4.6 ± 1.2 | 4.7 ± 1.4 | 4.6 ± 1.2 |

Note. Categorical variables are presented as the number of cases and percentage, while quantitative indicators are presented as $M \pm SD$. Symptom scores were calculated for patients with the respective symptoms. No statistically significant differences were observed between groups for any baseline parameters (all $p > 0.05$).

Analysis of key intraoperative and postoperative indicators revealed certain specific features associated with each of the four surgical techniques (Table 3).

The duration of surgery was significantly shorter in the RBL group (8.5 ± 7.2 min), which is expected given the technical simplicity of this procedure. For the other techniques (BPV, LV, THD), the average duration ranged from 41.1 to 44.3 minutes, with no significant differences between these groups ($p < 0.001$ vs. RBL).

Intraoperative blood loss was also minimal in the RBL group (1.6 ± 1.4 mL) due to the absence of tissue dissection and the controlled mechanical effect on hemorrhoidal tissue. BPV, LV, and THD showed comparable blood loss levels (6.5–8.3 mL), which were not clinically significant and did not require additional hemostatic measures ($p < 0.001$ vs. RBL).

The incidence of submucosal hematomas ranged from 9.5% to 34.8%, with no statistically significant differences between groups ($p = 0.115$), indicating a favorable safety profile for all techniques when performed with proper technique.

Postoperative analgesic requirements were moderate across all groups. The number of ketorolac doses administered during the first and second postoperative days did not differ significantly between groups ($p > 0.26$), indicating comparable levels of postoperative pain.

It is noteworthy that both the average length of hospital stay and the duration of temporary disability were significantly lower in the RBL group (0.4 ± 0.5 days and 2.6 ± 0.5 days, respectively), consistent with the outpatient nature of this procedure. In the BPV, LV, and THD groups, these values were approximately 2.1–2.3 days for hospitalization and 5.6–5.8 days for temporary disability ($p < 0.001$ vs. RBL).

Thus, the analysis of intraoperative and postoperative outcomes demonstrates that all techniques offer a favorable safety and low-trauma profile. RBL ensures the shortest intervention time and fastest recovery of work capacity, although further evaluation is needed regarding its long-term outcomes.

A comparative analysis of the dynamics of the «Hemorrhoid Symptoms» domain revealed certain differences between the treatment groups (Table 4).

Thus, in the long term, bipolar vaporization and laser vaporization provided the best control of this key symptom of chronic hemorrhoids, showing more stable results in preventing recurrent bleeding compared to RBL and THD.

The dynamics of the «Satisfaction» domain indicators demonstrated a clear positive trend in all groups (Figure).

At one week post-treatment, mean satisfaction scores were comparable across all groups (6.7–7.1 points, $p = 0.084$), reflecting minor between-group differences in the early postoperative period.

At 6 months, a clear trend toward increasing satisfaction was observed in all groups, with the highest mean scores recorded in the LV group (8.7 ± 0.5 points) and the BPV group (8.3 ± 0.7 points), significantly exceeding the scores in the RBL group (7.7 ± 1.5 points, $p = 0.010$). The distribution of scores showed that in the BPV group, 43.8% of patients rated their satisfaction at the maximum level (9 points), with an additional 46.9% rating it at 8 points, whereas in the RBL group, only 33.3% of patients gave a score of 9 points.

At 12 months, this dynamic remained stable: the highest scores were again observed in the BPV group (8.3 ± 0.7 points) and the LV group (8.2 ± 1.0 points), with significantly lower scores in the RBL

Table 3. Comparison of key intraoperative and postoperative parameters in patients with stage I–II chronic hemorrhoidal disease according to surgical technique

| Parameter | BPV (n = 32) | LV (n = 21) | RBL (n = 42) | THD (n = 23) | p (overall) |
|--|--------------------|------------------|-----------------------|------------------|-------------|
| Duration of surgery, min | $44.3 \pm 7.1^*$ | $42.4 \pm 6.5^*$ | 8.5 ± 7.2 | $41.1 \pm 3.8^*$ | < 0.001 |
| Intraoperative blood loss, mL | $8.3 \pm 3.7^{*#}$ | $8.1 \pm 3.0^*$ | 1.6 ± 1.4 | $6.5 \pm 3.2^*$ | < 0.001 |
| Submucosal hematomas | 7 (21.9%) | 5 (23.8%) | 4 (9.5%) [#] | 8 (34.8%) | 0.115 |
| Number of ketorolac doses | | | | | |
| Day 1 | 1.4 ± 0.9 | 1.8 ± 0.5 | 1.9 ± 1.7 | 1.5 ± 0.5 | 0.268 |
| Day 2 | 1.8 ± 0.8 | 1.9 ± 0.6 | 2.0 ± 0.8 | 1.7 ± 0.5 | 0.310 |
| Hospital stay, days | $2.3 \pm 0.5^*$ | $2.1 \pm 0.4^*$ | 0.4 ± 0.5 | $2.2 \pm 0.7^*$ | < 0.001 |
| Duration of temporary disability, days | $5.8 \pm 0.7^*$ | $5.6 \pm 0.7^*$ | 2.6 ± 0.5 | $5.7 \pm 0.8^*$ | < 0.001 |

Note. p-value (overall) – based on ANOVA or chi-square test.

* The difference from the RBL group is statistically significant ($p < 0.05$).

The difference from the THD group is statistically significant ($p < 0.05$; Bonferroni correction).

Table 4. Frequency of «Hemorrhoid Symptoms» domain indicators over time (by treatment group and control time points), %

| Symptom | BPV (n = 32) | LV (n = 21) | RBL (n = 42) | THD (n = 23) | P |
|-----------------|-----------------|----------------|-----------------|-----------------|-------|
| Pain | | | | | |
| Preoperative | 56.3 | 76.2 | 73.8 | 65.2 | 0.334 |
| 1 week | 65.6 | 61.9 | 69.0 | 60.9 | 0.904 |
| 6 months | 0.0* | 4.3* | 14.3 | 4.3* | 0.034 |
| 12 months | 0.0* | 4.3* | 26.2 | 13.0* | 0.018 |
| Prolapse | | | | | |
| Preoperative | 68.8 | 71.4 | 57.1 | 69.8 | 0.568 |
| 1 week | 0.0 | 0.0 | 0.0 | 0.0 | 1.000 |
| 6 months | 0.0* | 4.8 | 14.3 | 4.3* | 0.034 |
| 12 months | 3.1 | 4.8 | 26.2 | 13.0 | 0.018 |
| Itching | | | | | |
| Preoperative | 28.1 | 23.8 | 26.2 | 30.4 | 0.964 |
| 1 week | 9.4 | 14.3 | 16.7 | 17.4 | 0.802 |
| 6 months | 0.0* | 0.0* | 21.4 | 4.3 | 0.002 |
| 12 months | 9.4 | 14.3 | 31.0 | 13.0 | 0.080 |
| Soiling | | | | | |
| Preoperative | 25.0 | 28.6 | 28.6 | 26.1 | 0.985 |
| 1 week | 31.3 | 33.3 | 35.7 | 26.1 | 0.883 |
| 6 months | 3.1* | 4.8 | 14.3 | 4.3 | 0.245 |
| 12 months | 3.1* | 4.8 | 26.2 | 13.0 | 0.018 |
| Bleeding | | | | | |
| Preoperative | 100.0 | 100.0 | 100.0 | 100.0 | 1.000 |
| 1 week | 0.0* | 0.0* | 2.4 | 0.0* | 0.610 |
| 6 months | 0.0* | 0.0* | 16.7 | 8.7* | 0.026 |
| 12 months | 3.1 | 4.8 | 21.4 | 8.7 | 0.054 |

Note. p-values between groups calculated using χ^2 test or Fisher's exact test.

* The difference from the RBL group is statistically significant ($p < 0.05$).

Table 5. Recurrence rate by groups at 6 and 12 months post-procedure

| Time point | BPV | LV | RBL | THD | p |
|------------|-------------|-------------|---------------|--------------|-------|
| 6 months | 0 | 0 | 6 (14.3%) | 1 (4.3%) | 0.034 |
| 12 months | 1 (3.1%) | 1 (4.8%) | 11 (26.2%) | 3 (13.0%) | 0.018 |

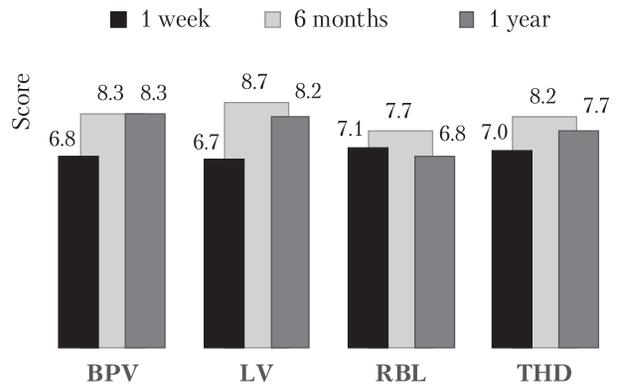


Figure. Mean «Satisfaction» scores over time in the study groups

group (6.8 ± 2.0 points, $p = 0.001$). The analysis of score distribution further confirmed these trends: in the BPV group, 43.8% of patients maintained the maximum satisfaction score (9 points), and another 46.9% rated their satisfaction at 8 points, while in the RBL group, only 28.6% of patients gave a score of 9, and more than 30% of patients reported scores of ≤ 6 points.

Thus, the analysis of patient satisfaction demonstrates that bipolar vaporization and laser vaporization provide the highest and most stable level of subjective satisfaction in the long-term follow-up period. Despite the rapid recovery of work capacity after RBL, a significant proportion of patients reported lower satisfaction scores, which is likely associated with the higher rate of symptom recurrence. Analysis of hemorrhoid recurrence rates at 6 and 12 months post-treatment revealed clear inter-group differences (Table 5).

At 6 months, no recurrences were observed in the BPVP and LV groups (0%), while the THD group had 1 case (4.3%), and the RBL group had a recurrence rate of 14.3% ($p = 0.034$ between groups).

At 12 months, the trend remained consistent: the lowest recurrence rates were seen in the BPVP (3.1%) and LV (4.8%) groups, with the THD group showing 13.0% and the RBL group demonstrating the highest rate at 26.2% ($p = 0.018$ between groups). Thus, RBL showed the highest recurrence rate, reflecting the lower long-term clinical stability of this technique for treating stage II hemorrhoids.

Overall, the results confirm that bipolar vaporization and laser vaporization provide the most durable effect in preventing symptom recurrence, while THD delivers intermediate results, and RBL carries a significantly higher risk of recurrence in the long-term follow-up. It should be noted that no complications specified in the corresponding domain were recorded in any of the groups during the study.

Discussion

Chronic hemorrhoids remain a significant medical and social issue due to their high prevalence and considerable impact on patients' quality of life [12, 17, 30]. The majority of patients present with stage I (72.9%) or stage II disease (18.4%), while stage III–IV cases are relatively rare [30]. Patients with persistent symptomatic stage I–II CH who are refractory to conservative therapy typically require minimally invasive treatment [5, 35].

In modern clinical practice, methods such as RBL, SI, THD, and emborroid therapy are commonly employed for stage I–II CH [11, 24, 28, 35]. While these techniques show high efficacy, they are associated with certain limitations, including post-operative pain, recurrence risk, need for repeated procedures, and, in some cases, the requirement for advanced technical equipment (THD, emborroid therapy) [11, 24, 28, 35].

Thermal destruction techniques – laser coagulation, radiofrequency ablation, and bipolar coagulation – achieve good outcomes in reducing prolapse and vascularization of hemorrhoidal tissue but require costly equipment and carry risks of complications such as scarring and stenosis [10, 23, 25]. Infrared photocoagulation demonstrates relatively modest long-term efficacy (75–80% at 1 year) [4, 26].

A novel thermal destruction technique – BVP using the EK-300M – was recently introduced for the treatment of stage I–II CH [5]. In the present study, we conducted a comparative analysis of BPV versus other popular techniques: LV, THD, and RBL.

All studied methods demonstrated an acceptable safety profile. Procedure time was shortest in the RBL group, while the most stable symptom dynamics were observed in the BPVP group. At 12 months post-treatment, residual pain, prolapse, itching, and bleeding were less frequent in the BPV group than in the THD and RBL groups and comparable to LV. Recurrence rates were lowest in the BPV group (3.1%) and LV group (4.8%), whereas higher rates were observed in the THD group (13%) and especially in the RBL group (26.2%), consistent with published data on the elevated recurrence risk following RBL [24].

Patient satisfaction was highest in the BPV and LV groups, with more than 90% of patients reporting scores of 8–9 at 12 months. Compared to literature reports on other thermal destruction methods [10, 23, 25], the outcomes for BPV were comparable or superior, with minimal blood loss (8.3 ± 3.7 mL), short postoperative recovery, and sustained symptom resolution.

Importantly, in terms of clinical efficacy, BPV is at least equivalent to LV, and given the lower cost of equipment and consumables, as well as the simplicity of the technique and availability of devices, it offers a higher potential priority for wider clinical implementation.

According to our findings, THD ranks third in priority, providing good clinical results but at a higher cost and technical complexity. In contrast, among the techniques analyzed, RBL demonstrated the lowest priority for stage I–II CH due to the highest recurrence rate, despite its technical simplicity and brief procedural duration.

Conclusions

The data obtained support the potential of BPV as an effective and safe method for treating stage I–II CH. In our study, BPV appears highly suitable for broader clinical use due to its balance of efficacy and accessibility.

All evaluated minimally invasive methods (BPV, LV, THD, RBL) provided an adequate level of efficacy and safety for stage I–II CH. BPV and LV showed the best clinical outcomes, with low recurrence rates and high patient satisfaction. Considering its lower cost, ease of use, and availability, BPV can be recommended as a first-line option for the treatment of stage I–II CH. THD ranks third in priority based on our data.

RBL should be considered a lower priority method for this patient category due to its higher recurrence rate. It should be noted that this study has limitations – a relatively small sample size per group, a single-center design, and a 12-month follow-up period. Further multicenter studies with larger patient cohorts and longer follow-up are required to definitively establish the role of BPV in the comprehensive management of CH.

DECLARATION OF INTERESTS

The authors declare no conflict of interest.

Funding. This study was conducted as part of the research plan of the Department of Surgery No 1 at Bogomolets National Medical University «Development and improvement of diagnostic, surgical treatment, and rehabilitation methods for patients with digestive tract and perineal pathology.» The authors received no additional financial support for this study.

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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Малоінвазивні методики лікування хронічного геморою I—II стадії: результати застосування та пріоритетність

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У сучасній клінічній практиці застосовують такі малоінвазивні методики лікування хронічного геморою (ХГ) I—II ступеня, як лігування латексними кільцями (ЛК), трансанальна гемороїдальна дезартеріалізація (ТГД), лазерна вапоризація (ЛВ) тощо. Біполярна вапоризація (БПВ) є новою перспективною методикою термічної деструкції тканин із застосуванням біозварювального генератора «ЕК-300М» («Свармед», Україна). Її ефективність порівняно з іншими методами досі недостатньо вивчена.

Мета — порівняти результати лікування ускладненого ХГ I—II ступеня за допомогою чотирьох малоінвазивних методик (БПВ, ЛВ, ТГД, ЛК) і визначити їхній ранг пріоритетності.

Матеріали та методи. У дослідження було залучено 118 пацієнтів (67 чоловіків і 51 жінка віком від 19 до 70 років, середній вік — $(43,1 \pm 12,5)$ року) із симптоматичним ХГ I—II ступеня, резистентним до консервативної терапії. Пацієнтів розподілили на чотири групи залежно від застосованої методики: БПВ ($n = 32$), ЛВ ($n = 21$), ТГД ($n = 23$), ЛК ($n = 42$). Оцінювали тривалість втручання, частоту інтраопераційних ускладнень, динаміку симптомів (біль, пролапс, кровотеча, свербіж, забруднення), частоту рецидивів, рівень задоволеності лікуванням через 12 міс.

Результати. Усі методики забезпечили достатній рівень ефективності та безпечності. Частота рецидивів через рік становила: у групі БПВ — 3,1 %, у групі ЛВ — 4,8 %, у групі ТГД — 13 %, у групі ЛК — 26,2 %. Рівень задоволеності був найвищим (8—9 балів) у групах БПВ і ЛВ (> 90 % пацієнтів). Методи БПВ та ЛВ продемонстрували найкращу клінічну ефективність і стійкість результатів. За ефективністю ТГД посіла третє місце, а ЛК — найнижче через високу частоту рецидивів.

Висновки. З урахуванням клінічних результатів, доступності та вартості біполярна вапоризація може бути рекомендована як пріоритетна методика для лікування ХГ I—II ступеня. Необхідно провести багаточентрові дослідження для підтвердження тривалої ефективності.

Ключові слова: хронічний геморою, біполярна вапоризація, малоінвазивні методики, трансанальна дезартеріалізація, лазерна вапоризація, лігування латексними кільцями, результати.

FOR CITATION

■ Bilianskyi LS, Voloshyn IV. Minimally invasive techniques in stage I–II chronic hemorrhoids: outcomes and prioritization. General Surgery (Ukraine). 2025;(2);36–43. <http://doi.org/10.30978/GS-2025-2-36>.

Clinical-anamnestic characteristics and quality of life in patients with the Cajal subtype of chronic slow-transit constipation

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The Cajal subtype of chronic slow-transit constipation (CSTC) is associated with Cajal cell deficiency and is considered the most resistant to conservative therapy. Its diagnosis requires histological analysis of all layers of the intestinal wall, which involves invasiveness and carries the risk of complications. Therefore, the clinical phenotype of this subtype remains insufficiently studied.

OBJECTIVE – to evaluate the clinical-anamnestic characteristics and quality of life in patients with the Cajal subtype of chronic slow-transit constipation following colectomy.

MATERIALS AND METHODS. Over the past 12 years, the Cajal histological subtype of CSTC was diagnosed in 21 patients after colectomy (group O). The comparison group included 70 patients of similar age and sex who did not exhibit signs of CSTC (group R). The study groups did not differ significantly regarding gender, mean age, or body mass index. Clinical-anamnestic data and quality of life were assessed using the PAC-QOL scale in both groups.

RESULTS. Women predominated in both groups: 20 (95.2%) in the main group O and 65 (92.9%) in group R. The mean age was 33.9 ± 8.7 years in group O, compared to 41.5 years in group R. The clinical phenotype of patients with the Cajal subtype who required surgical treatment was characterized by early disease onset at a young age (8.67 ± 5.08 years), a high mean disease duration at presentation (25.24 ± 11.18 years; range 3–51), and genetic predisposition, with a positive family history in first-degree relatives in 50.5% of cases. These patients exhibited prolonged intervals between bowel movements (mean 12.2 ± 4.3 days) and lack of response to conservative therapy. Stool types 1 and 2 on the Wexner scale were observed in 71.4% and 28.6% of patients, respectively. Most patients required manual assistance during defecation (95.2%) and experienced pronounced pain syndrome (visual analog scale 2.8 ± 1.3). Quality of life, as measured by the PAC-QOL scale, showed a significant decline in group O compared to group R across all parameters. Physical discomfort worsened by 2.72 times (3.24 ± 0.44 vs. 1.19 ± 0.29); psychosocial discomfort by 2.19 times (1.84 ± 0.58 vs. 0.84 ± 0.18); anxiety by 2.66 times (2.05 ± 0.24 vs. 0.77 ± 0.24); satisfaction by 2.88 times (2.48 ± 0.59 vs. 0.86 ± 0.28); and the PAC-QOL score by 2.57 times (2.24 ± 0.25 vs. 0.87 ± 0.12), with $p < 0.05$ for all comparisons.

CONCLUSIONS. Our findings confirm the presence of severe clinical and functional disorders in patients with the Cajal subtype, identifying them as potential candidates for surgical treatment.

KEYWORDS

chronic slow transit constipation, Cajal subtype, quality of life, PAC-QOL scale.

ARTICLE • Received 2025-04-26 • Received in revised form 2025-06-03 • Published 2025-07-31

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Chronic constipation remains a significant medical and social problem. Recent reviews indicate that the prevalence of chronic idiopathic constipation in the general population is approximately 14%, with higher rates observed in women and elderly patients [6, 16, 18]. This condition is associated with increased

physical and psychosocial discomfort, imposes a substantial burden on healthcare systems, and significantly affects patients' quality of life [2, 5, 6, 15].

Morphological studies classify slow-transit constipation (CSTC) into four main histological subtypes: neuropathic, myopathic, histologically intact,

and the «Cajal» subtype. The latter is characterized by a reduction in the number of interstitial cells of Cajal (ICCs), which serve as the intestinal «pace-makers» [12]. ICCs generate and propagate electrical «slow waves» essential for coordinating peristalsis, and their deficit is associated with severe colonic hypomotility [18].

The clinical features of chronic constipation, specifically slow-transit constipation (STC), are characterized by prolonged colonic transit time and a significant reduction in coordinated colonic motility [1]. CSTC affects 2–4% of the general population and is often refractory to standard therapeutic approaches, resulting in a high functional burden [18].

Despite growing attention to the histological classification of slow-transit constipation, modern literature lacks comprehensive studies describing the clinical-anamnestic and morphological characteristics of patients based on their histological subtype [11]. This gap is primarily due to the challenges in verification, which requires histological analysis of the full thickness of the colonic wall. Particular attention should be paid to the clinical features of the Cajal subtype, as it tends to respond poorly to conservative treatment and may be a suitable candidate for surgery [7].

OBJECTIVE – to evaluate the clinical-anamnestic characteristics and quality of life in patients with the Cajal subtype of chronic slow-transit constipation following colectomy.

Materials and methods

Over a 12-year period, the Cajal histological subtype of CSTC was diagnosed in 21 patients after colectomy [7]. This allowed for a retrospective analysis of the clinical-anamnestic features in patients with the Cajal subtype, supporting its consideration as a potentially distinct clinical form. These patients were included in the main group (Group O). The comparison group included 70 patients of similar age and sex who showed no signs of CSTC (reference group – R). The study groups did not differ significantly regarding gender, mean age, or body mass index. In both groups, females predominated: 20 (95.2%) in the main group O and 65 (92.9%) in the reference group R, $p = 0.486$. The Rome IV criteria were used to diagnose CSTC [3].

Inclusion Criteria

- Age over 18 years.
- CSTC that does not respond or poorly respond to modern conservative treatment methods for at least 6 months.
- Low quality of life (QoL).
- Consent to undergo surgical treatment.
- Consent to complete a QoL questionnaire.

Exclusion Criteria

- Age under 18 years.
- Severe comorbidities.
- Presence of mental disorders.
- Pregnancy.
- Oncological diseases.
- Harmful habits.
- Refusal to complete the QoL questionnaire.
- Proctogenic constipation.
- Irritable bowel syndrome and/or secondary constipation or constipation with a specific etiology (associated with an underlying condition).
- Drug-induced constipation.

Histological and immunological examinations

Samples were collected from various sections of the gastrointestinal tract, including the appendix, ileum, cecum, colon, and sigmoid colon. For our study, samples were taken from all sections of the colon and appendix, including at least three full-thickness sections from the transverse and longitudinal projections, each approximately 2 cm in length. The tissue specimens were fixed in 10% buffered formalin, wired in alcohol, and embedded in paraffin. Serial sections were stained with hematoxylin-eosin. Additionally, an immunohistochemical study was performed on the paraffin blocks using the Polyclonal Ra a-Hu CD 117 (c-kit) antibody (DAKO, Denmark) to detect Cajal cells via the imaging En-Vision™ FLEX System.

Pathohistological study

Microscopic examination was carried out using an Olympus CX23 (Japan) microscope with a nozzle. Morphometric measurements were performed using Olympus Stream (Japan) software. The histological examination focused on evaluating the intestinal wall structure, including the architectonics of glands and the cellular stroma composition within the mucous membrane. Parameters evaluated were total muscle layer thickness, the ratio of the thickness of different layers and the number of layers, the presence of lymphoid cell infiltration, the presence or absence of cytoplasmic inclusions in smooth myocytes, and their relative size. Meissner's plexuses were identified between the outer and inner muscle layers according to typical histological features. The glial cells were determined by their size, the presence of large vesicular nuclei, and Nissl substance. Their approximate number was calculated, and additional characteristics, including the presence or absence of dystrophic changes and lymphoid infiltrates, were assessed [12].

Quality of Life Assessment

The quality of life was evaluated using the disease-specific Patient Assessment of Constipation – Quality

of Life (PAC-QOL) questionnaire, developed and validated by Marquis et al. [14] in 2005. The questionnaire includes 28 items grouped into 4 subscales:

- Worries and concerns (11 items)
- Physical discomfort (4 items)
- Psychosocial discomfort (8 items)
- Satisfaction with treatment (5 items).

Each item is assessed using a 5-point Likert scale, ranging from 0 (not at all/never) to 4 (very much/all the time), reflecting the patient's experience over the previous two-week period. A higher score indicates a worse QoL due to constipation. Total PAC-QOL scores and subscale scores were calculated according to the original PAC-QOL documentation for each patient [14]. QoL was assessed before surgery and one year after surgery.

Before visiting the clinic, all patients had been undergoing conservative therapy, which gradually became less effective over time. The treatment involved a high-fiber diet (n = 21, 100%), pharmacological agents (n = 21, 100.0%), and cleansing enemas (n = 21, 100%).

21 (100%) patients underwent colectomy with low rectal resection.

The impact of the histological subtype of the colonic wall on the clinical course in patients with the Cajal subtype of CSTC was assessed retrospectively. This was done by comparing the histological findings of resected colonic specimens obtained after colectomy with preoperative questionnaire data and medical history.

Clinical characteristics of patients with the Cajal subtype of CSTC were analyzed in comparison with those of the reference group.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics, version 22. Descriptive statistics were calculated. Data normality was assessed using the Shapiro-Wilk test. Mean values were presented as $M \pm SD$. Categorical data were expressed as counts (%). The comparison of mean values for quantitative variables was performed using the Wilcoxon-Mann-Whitney. Comparisons of relative frequencies were performed using Pearson's chi-square test. The null hypothesis of equality of variables was rejected at $p < 0.05$.

Results

Women predominated in both groups: 20 (95.2%) in group O and 65 (92.9%) in group R. The mean age was 33.9 ± 8.7 years in group O, while in group R it was 41.5 years. The average age at disease onset in group O was 8.67 ± 5.08 years. The body mass index

(BMI) was 20.395 ± 2.29 kg/m² in group O and 22.2 ± 2.29 kg/m² in group R, with no statistically significant difference between the groups, $p < 0.05$.

The mean disease duration in group O was 25.24 ± 11.18 years (range: 3–51 years). Stool consistency assessed by the Wexner scale in group O respondents was type 1 in 71.4% and type 2 in 28.6%, whereas in the reference group R, stool types 4, 5, and 3 were observed in 54 (77.1%), 8 (11.4%), and 8 (11.4%) patients, respectively. The average interval between bowel movements in group O was 12.2 ± 4.3 days, whereas patients in group R had daily bowel movements.

A positive family history of chronic slow-transit constipation was observed in 50.5% of patients with the Cajal subtype in the first degree relatives. Manual assistance was required in 20 patients (95.2%) in group O, whereas manual assistance wasn't required in group R.

The mean intensity of abdominal pain, measured by the visual analog scale (VAS) from 0 to 10, was 2.8 ± 1.3 (range: 1 to 5) in group O respondents, with 14 patients (66.7%) reporting pain intensity greater than 3 points. In contrast, no pain syndrome was reported in group R.

The quality of life, assessed using the PAC-QOL scale, showed a significant decline in group O compared to the reference group across all parameters. Physical discomfort in group O worsened by 2.72 times (3.24 ± 0.44 vs. 1.19 ± 0.29); psychosocial discomfort by 2.19 times (1.84 ± 0.58 vs. 0.84 ± 0.18); anxiety by 2.66 times (2.05 ± 0.24 vs. 0.77 ± 0.24); satisfaction by 2.88 times (2.48 ± 0.59 vs. 0.86 ± 0.28); and the PAC-QOL score by 2.57 times (2.24 ± 0.25 vs. 0.87 ± 0.12), with $p < 0.05$ for all comparisons (Table).

Table. Values of PAC-QOL scores

| PAC-QOL scales | Group O | Group R |
|----------------------------|--------------------------------|----------------------------------|
| Physical discomfort | 3.24 ± 0.44 (2.00–3.75) | $1.19 \pm 0.29^*$ (0.25–1.75) |
| Psychosocial discomfort | 1.84 ± 0.58 (1.13–2.88) | $0.84 \pm 0.18^*$ (0.50–1.38) |
| Worries and concerns | 2.05 ± 0.24 (1.45–2.27) | $0.77 \pm 0.24^*$ (0.36–1.45) |
| Satisfaction and treatment | 2.48 ± 0.59 (1.0–3.4) | $0.86 \pm 0.28^*$ (0.20–1.60) |
| PAC-QOL | 2.24 ± 0.25 (1.86–2.71) | $0.87 \pm 0.12^*$ (0.61–1.18) |

* $p < 0.05$.

According to the results, the clinical phenotype of patients with the Cajal subtype of chronic slow-transit constipation is characterized by an early disease onset (mean age at onset 8.67 ± 5.08 years) and a prolonged disease course (25.2 ± 11.2 years). Women predominated in this group (95.2%), with a mean age at the time of surgery of 33.9 ± 8.7 years. Typical features include infrequent bowel movements (mean interval between defecations 12.2 ± 4.3 days) and hard stool consistency (type 1 in 71.4% and type 2 in 28.6% according to the Wexner scale), with manual assistance required in 95.2% of cases.

A positive family history of the disease in first-degree relatives was registered in 50.5% of patients. Abdominal pain syndrome was present in 66.7% patients, with pain intensity exceeding 3 points on the VAS (mean value 2.8 ± 1.3).

These findings confirm the presence of severe clinical and functional disorders in patients with the Cajal subtype, identifying them as potential candidates for surgical treatment.

Discussion

Constipation remains a significant challenge in modern medicine, with substantial healthcare expenses associated with ineffective conservative treatments, leading to reduced patients' quality of life. Current data indicate that CSTC affects 2–4% of the general population. It is frequently resistant to conservative treatment, resulting in a high healthcare and social burden [3].

In recent literature, the Cajal subtype of CSTC has been identified in 19.6% of patients who underwent surgery [13], aligning with previous reports of ICC deficiency in patients with CSTC [4, 10, 18]. ICCs are intestinal «pacemaker» cells, and their reduction leads to colonic hypomotility, supporting the classification of the Cajal subtype as a morphologically distinct form of STC [2, 6, 9, 10].

Despite a variety of medications and dietary recommendations, CSTC associated with ICC deficiency is mostly unresponsive to standard treatment. Prospective reviews indicate that medical therapy provides only temporary relief, and radical interventions are necessary in refractory forms of the disease [18]. In such cases, subtotal or total colectomy with ileorectal anastomosis is recognized as the most effective treatment for refractory CSTC. Retrospective studies report that 81–93% of patients experience significant improvements in bowel movement frequency, overall functional status, and sustained quality of life post-colectomy [4, 7, 8, 11, 17].

Our study aimed to provide a detailed comparison of clinical and anamnestic characteristics, as well as

quality of life (PAC-QOL) measures, in patients with the Cajal subtype of CSTC compared to the reference group. Thus, the typical clinical picture of patients with the Cajal subtype of chronic slow-transit constipation is that of a woman approximately 34 years old, with disease symptoms beginning in childhood (mean age at onset: 8.7 years) and a disease duration exceeding 25 years. Half of these patients (50.5%) have a positive family history of constipation in first-degree relatives. The average defecation frequency is once every 12 days, with hard stool consistency (type 1–2 on the Wexner scale). A need for manual assistance is reported in 95.2% of cases. Additionally, 66.7% of patients experience abdominal pain, and there is a significant reduction in quality of life across all PAC-QOL domains.

This study included only patients after colectomy due to a refractory course of the disease. Consequently, the findings do not represent the full spectrum of clinical variability of the Cajal subtype of CSTC, but rather focus on the most severe cases requiring surgical intervention. Further research is necessary to include patients with milder forms who respond to conservative therapy, in order to establish clearer diagnostic criteria for this phenotype and potentially predict the disease course.

The limitations of this study include a sample comprised solely of surgical cases and the absence of preoperative functional assessments of colonic motility.

Future research should focus also on patients with early-stage Cajal-type CSTC, compare the effectiveness of various therapeutic strategies according to morphological subtypes, and developing stratification algorithms for surgical decision according to clinical, anamnestic, and morphological data.

Conclusions

The clinical phenotype of patients with the Cajal subtype who required surgical treatment was characterized by early disease onset at a young age (8.67 ± 5.08 years). These patients exhibited a high mean disease duration at presentation (25.24 ± 11.18 years; range 3–51), with a genetic predisposition evidenced by a positive family history in first-degree relatives in 50.5% of cases. They also experienced prolonged intervals between bowel movements (mean 12.2 ± 4.3 days) and lack of response to conservative therapy (100% refractory cases). Stool types 1 and 2 on the Wexner scale were observed in 71.4% and 28.6% of patients, respectively. Most patients required manual assistance during defecation (95.2%) and reported pronounced pain syndrome (VAS 2.8 ± 1.3) and a significant worsening of the overall PAC-QOL score (by 2.57 times).

DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

Funding. This work was carried out in accordance with the research plan of the Department of Surgery with the Course of Emergency and Vascular Surgery, Bogomolets National Medical University: «Surgical treatment of chronic disorders of large intestinal transit». State registration number: 0124U001916. The authors received no additional financial support.

AUTHORS CONTRIBUTIONS

Conception and design — I. M. Leshchyshyn, L. Y. Markulan; acquisition, analysis and interpretation of data — I. M. Leshchyshyn, O. I. Okhotska, P. L. Byk; statistical analysis — L. Y. Markulan; drafting the article — I. M. Leshchyshyn; critical revision of the article — I. M. Leshchyshyn, O. I. Okhotska.

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Клініко-анамнестичні характеристики та якість життя пацієнтів із кахальним підтипом хронічного повільно-транзитного запору

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Кажальний підтип хронічного повільно-транзитного запору (ХПТЗ), асоційований із дефіцитом клітин Кажалія, вважається найбільш резистентним до консервативної терапії. Його діагностика потребує гістологічного аналізу всіх шарів кишкової стінки, що пов'язано з інвазивністю та ризиком ускладнень. Тому клінічний фенотип цього підтипу недостатньо вивчений.

Мета — оцінити клініко-анамнестичні особливості та якість життя пацієнтів із кахальним підтипом хронічного повільно-транзитного запору після колектомії.

Матеріали та методи. За останні 12 років кажальний гістологічний підтип ХПТЗ був верифікований у 21 пацієнта після колектомії (група О). Групу порівняння утворено із 70 пацієнтів аналогічного віку та статі без ознак ХПТЗ (група R). Групи суттєво не відрізнялися за статтю, середнім віком та індексом маси тіла. У всіх пацієнтів були проаналізовані клініко-анамнестичні дані та якість життя за шкалою PAC-QoL.

Результати. В обох групах переважали жінки: 20 (95,2%) у групі О та 65 (92,9%) у групі R. Середній вік у групі О становив ($33,9 \pm 8,7$) року, у групі R – 41,5 року. Клінічний фенотип пацієнтів із кахальним підтипом, які потребували хірургічного лікування, характеризувався початком захворювання в молодому віці ($(8,67 \pm 5,08)$ року), тривалим перебігом до встановлення діагнозу (від 3 до 51 року, у середньому – $(25,24 \pm 11,18)$ року), генетичною схильністю (сімейний анамнез у родичів першого ступеня споріднення в 50,5% випадків), значними інтервалами між дефекаціями (у середньому $(12,2 \pm 4,3)$ доби), відсутністю відповіді на консервативну терапію, типом калу 1 та 2 за шкалою Wexner у 71,4 та 28,6% пацієнтів відповідно, необхідністю ручної допомоги під час дефекації (95,2%) та виразним больовим синдромом (за візуальною аналоговою шкалою – $2,8 \pm 1,3$). Якість життя за шкалою PAC-QoL була статистично значущо нижчою в групі О порівняно з групою R за всіма показниками: фізичний дискомфорт – у 2,72 разу ($3,24 \pm 0,44$ та $1,19 \pm 0,29$), психосоціальний дискомфорт – у 2,19 разу ($1,84 \pm 0,58$ і $0,84 \pm 0,18$), тривожність – у 2,66 разу ($2,05 \pm 0,24$ та $0,77 \pm 0,24$), задоволеність – у 2,88 разу ($2,48 \pm 0,59$ і $0,86 \pm 0,28$), загальний бал за PAC-QoL – у 2,57 разу ($2,24 \pm 0,25$ та $0,87 \pm 0,12$). Усі відмінності були статистично значущими ($p < 0,05$).

Висновки. Отримані результати підтверджують наявність тяжких клінічних і функціональних порушень у пацієнтів із кахальним підтипом ХПТЗ, що дає підстави розглядати їх як потенційних кандидатів на хірургічне лікування.

Ключові слова: хронічний повільно-транзитний запор, кажальний підтип, якість життя, шкала PAC-QoL.

FOR CITATION

■ Leshchysyn IM, Markulan LY, Okhotska OI, Byk PL. Clinical-anamnestic characteristics and quality of life in patients with the Cajal subtype of chronic slow-transit constipation. General Surgery (Ukraine). 2025;(2):44-49. <http://doi.org/10.30978/GS-2025-2-44>.

Multifactorial assessment of the effectiveness of surgical treatment for obesity

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OBJECTIVE – to create a model for choosing the most effective method of surgical treatment of obesity.

MATERIALS AND METHODS. The study was conducted at the Department of General Surgery No 2, Bogomolets National Medical University. The study group included 53 patients who consented to the bariatric procedure. The control group consisted of 59 patients. The study group underwent bariatric interventions: laparoscopic gastric bypass (37.7%), laparoscopic sleeve gastrectomy (32.2%), and 30.1% underwent the installation of an intragastric balloon, followed by gastric bypass and outcome assessment after 12 months. The control group received conservative treatment for obesity. All patients underwent routine general clinical examinations, genotyping via the Fast Real-Time PCR System in TaqMan medium, and stool analysis using polymerase chain reaction to determine the parameters of the intestinal microbiome.

RESULTS. Statistical data processing showed that the chance of achieving an optimal outcome is highest in patients with a detected SNP MC4R, an unsatisfactory initial intestinal microbiota pattern, and an extensive family history of obesity, as well as those who underwent laparoscopic gastric bypass.

CONCLUSIONS. Laparoscopic gastric bypass is the preferred surgical technique for obesity treatment, yielding an optimal outcome. The presence of an unsatisfactory initial intestinal microbiota pattern, the detection of SNP MC4R polymorphism, and a family history of obesity influence the effectiveness of surgical treatment. The chance of achieving an optimal outcome is 3.6 times higher in patients with a detected SNP MC4R polymorphism.

KEYWORDS

treatment, polymorphisms, obesity, bariatric surgery.

ARTICLE • Received 2025-03-25 • Received in revised form 2025-04-29 • Published 2025-07-31

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Obesity is characterized by an excessive accumulation of adipose tissue in the human body, leading to the occurrence of many comorbidities and a decline in quality of life. Obesity increases the risk of diabetes, metabolic syndrome, arterial hypertension, ischemic heart disease, and acute cerebrovascular accidents. Obesity is associated with gallstone disease, colorectal cancer, non-alcoholic fatty liver disease, hiatal hernia, osteoarthritis, etc. Consequently, enhancing the effectiveness of obesity treatment is relevant.

Bariatric surgery is becoming more prevalent globally as an effective and safe treatment option for obesity. The IFSO 8th Global Registry Report [5] indicates that, in 2023, there were 480,970 bariatric operations performed worldwide. The most common metabolic interventions included sleeve gastrectomy (60.4%), Roux-en-Y gastric bypass (29.5%), mini-gastric bypass (4.3%), and other operations (5.8%).

Some scientific studies evaluated changes in the intestinal microbiota of individuals depending on their body weight and response [12] to bariatric interventions. The researchers also noted a correlation between obesity and polymorphisms in specific genes.

Jianhua Zhao et al. used a global population gene study (GWAS) to analyze the genetic material of 2,760 individuals with class III obesity, revealing polymorphisms in FTO, TMEM18, NRXN3, MC4R, SEC16B, GNPDA2, TNNI3K, QPCTL, and BDNF in 1,697 (61.4%) of the individuals, indicating a relationship between obesity and the human genome [15]. S. Z. Lutz et al. determined the correlation between the presence of the HSD11B1 gene (responsible for encoding the activator of 11 β -hydroxysteroid dehydrogenase, a regulator of cellular fatty acid metabolism) in the genome of obesity-associated single-nucleotide

polymorphisms (SNPs) rs2235543, rs12565406, and rs4844880 and non-alcoholic fatty liver disease in obese individuals [11]. M. Bandstein et al. identified seven single-nucleotide polymorphisms (PTBP2, NUDT3, TFAP2B, ZNF608, MAP2K5, GNPDA2, and MTCH2) associated with obesity in 238 patients undergoing laparoscopic gastric bypass. They discovered that patients who had any of the single-nucleotide polymorphisms had an 11 % greater percentage of excess weight loss (EWL) compared to those lacking these SNPs in all genomes [3].

Consequently, there exists a correlation between obesity, regardless of gender and race, and changes in intestinal microbiota patterns, as well as gene polymorphisms, namely SNP rs571312 of the MC4R gene and SNP rs3810291 of the TMEM160 gene.

Currently, a significant challenge in bariatric surgery is the creation of a decision-making model that enables the selection of the most successful surgical approach for obesity treatment in each case based on specific criteria.

OBJECTIVE – to create a model for identifying the most effective method for the surgical treatment of obesity based on the analysis of intestinal microbiome parameters and genetic markers associated with obesity.

Materials and methods

The monocentric prospective observational cohort study was conducted at the Department of General Surgery No 2, Bogomolets National Medical University.

The study included 112 patients (see Table 1 for their clinical characteristics). All patients met the IFSO criteria and required surgical treatment: BMI ≥ 35 kg/m² regardless of comorbidities or BMI 30.00–34.99 kg/m² with comorbid conditions. All patients in the study were offered surgical treatment. The study group included 53 patients

who consented to bariatric surgery. The control group consisted of 59 patients who refused surgical treatment and instead received conservative therapy. The findings were evaluated one year after the start of treatment. The study group underwent the following bariatric interventions: laparoscopic gastric bypass – 20 patients (37.7 %), laparoscopic sleeve gastrectomy – 17 patients (32.2 %), and 16 patients (30.1 %) with super-obesity who underwent two-stage surgical treatment, namely the installation of an intragastric balloon for 6 months as the first stage of the two-stage treatment, followed by gastric bypass within 14 days after balloon removal and outcome assessment 12 months after the two-stage treatment initiation [1]. The control group consisted of 59 obese patients who were treated conservatively, including diet therapy, psychological support sessions, lifestyle adjustments, and moderate physical activity.

At the beginning of treatment, both groups were prescribed anthropometric assessments, standard general clinical evaluations, genotyping via the Allelic Discrimination system using the Fast Real-Time PCR System (Applied Biosystems™, Life Technologies, USA) in TaqMan media, and stool analysis by PCR to determine quantitative and qualitative indicators of the intestinal microbiome.

The assessment of treatment effectiveness was conducted using the following multifactorial criteria:

1) Percentage of EWL. The American Society for Metabolic and Bariatric Surgery defines effective surgical treatment of obesity as achieving a EWL of no less than 50 % within 12 months postoperatively.

2) The intestinal microbiota patterns, specifically the *Firmicutes/Bacteroidetes* ratio (FBR) and *Bacteroidetes/Faecalibacterium* ratio (BFaR), represent the ratios of the dominant families of microorganisms that colonize the intestinal mucosa. The average normal values for the indicated colonies in Europe are 1–5 for FBR and 0.01–100.0 for BFaR [8].

Table 1. Clinical characteristics of study patients

| Indicator | All patients (n = 112) | Study group (n = 53) | Control group (n = 59) | p |
|--------------------------------|----------------------------|----------------------------|----------------------------|--------|
| Age, years | 48.2 ± 9.2 (27–68) | 47.7 ± 9.1 (23–68) | 48.9 ± 9.5 (29–67) | 0.286* |
| 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) | 0.085* |
| Height, cm | 166 ± 13 (150–188) | 165 ± 12 (152–188) | 166 ± 13 (150–185) | 0.818 |
| Initial BMI, kg/m ² | 45.1 ± 6.1 (35.2–75.3) | 48.6 ± 7.4 (35.2–75.3) | 41.6 ± 3.1 (35.5–50.5) | 0.256* |
| 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) | 0.362* |
| 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) | 0.321* |

Note. A comparison of data between the study and control groups.

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

3) The presence or absence of genetic markers associated with obesity includes polymorphisms SNPs rs571312 of the MC4R gene and SNP rs3810291 of the TMEM160 gene.

- 4) Comorbidity of diabetes.
- 5) Patient age.
- 6) Patient gender.
- 7) Family history of obesity.
- 8) Bad habits (alcohol, smoking).

Results

The average BMI of patients in the study group before surgery was 48.6 ± 20.1 kg/m². The average BMI among patients in the control group before treatment was 43.6 ± 16.0 kg/m². After surgery, the average BMI in the study group decreased to 29.5 ± 5.4 kg/m², while in patients in the control group, it was 40.2 ± 13.8 kg/m² (Table 2).

The study group exhibited an average EWL of $59.21\% \pm 23\%$ after 12 months of observation. The maximum EWL observed in the study group was 77.2%, while the minimum EWL was 49.9%. The control group exhibited a significantly lower average EWL of $9.92\% \pm 7.25\%$. The EWL range in the control group was 19.45% to 2.2%. The average EWL in patients undergoing bariatric surgery with various techniques differed. Patients who underwent gastric bypass using the Roux technique demonstrated the highest average EWL, at $69.71\% \pm 20.0\%$. In contrast, those who underwent sleeve gastrectomy had an average EWL of $51.57\% \pm 5.9\%$, while patients after two-stage surgical treatment achieved an average EWL of $51.7\% \pm 7.92\%$.

Analysis of the FBR and BFaR in the study group revealed an average FBR of 94.5 before surgical treatment. Only three patients in this group (5.67%) had FBR values within the reference range before treatment. The average BFaR in the

study group was 1708.5, with a significant range of minimum and maximum values, specifically 50000 and 0.0003, respectively. Before surgical treatment, BFaR was within reference values for two patients (3.77%).

The intestinal FBR in the control group was 52.5 ± 91.1 on average before treatment. Two patients in this group (3.38%) had average FBRs that varied within the reference values before treatment initiation. The average BFaR before treatment was 579.1. Reference values of BFaR before treatment were not detected.

Analysis of intestinal microbiota patterns revealed the following changes 12 months after surgery. The average FBR after surgical intervention for obesity was 2.84 ± 6.4 , with a range of maximum and minimum values of 7.19 and 0.79, respectively. The indicators attained reference values in 50 patients (94.33% of the cohort). Three patients (5.67%) exhibited no positive changes in FBR indicators, resulting in insufficient effectiveness of surgical treatment, with an average EWL of $49.52\% \pm 0.6$. The average BFaR indicator in patients under treatment after 12 months was 58.4, with the maximum and minimum values recorded at 121 and 0.256, respectively. In 49 patients (92.4% of the cohort), the indicators attained reference values. Four patients (7.6%) did not have intestinal microbiota markers return to reference values, resulting in insufficient effectiveness of surgical treatment, with an average EWL of $49.33\% \pm 1.1$.

In the control group, the average FBR indicator after treatment was 6.1 ± 22.2 , with a range of 0.2 to 22.4. Ten patients (16.9%) exhibited results within the reference values from the onset of treatment. The average BFaR indicators in treated patients were 130.2, with reference values achieved in 11 patients (18.6%) (Table 3).

The distribution of results was determined by the presence of polymorphisms in the studied genes.

Table 2. BMI dynamics in both groups depending on the treatment method, kg/m²

| Treatment method | Before treatment | After treatment | p |
|--|-------------------------|-------------------------|---------|
| RYGB | 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 implantation + gastric bypass | 52.2 ± 6.4 (50.1–54.4) | 28.3 ± 6.0 (26.1–30.5) | < 0.001 |
| Study group (total) | 48.6 ± 20.1 (35.2–75.3) | 29.5 ± 5.4 (26.1–31.0) | < 0.001 |
| Control group | 43.6 ± 16.0 (35.5–50.5) | 40.2 ± 13.8 (33.4–47.0) | 0.06 |

Note. Intragastric balloon implantation + gastric bypass – placement of an intragastric balloon as the first stage of treatment for patients with super-obesity, and performing gastric bypass 6 months after the start of treatment.

Table 3. Microbiome status depending on the treatment method, % of references

| Treatment method | Firmicutes/Bacteroidetes | | | Bacteroidetes/Faecalibacterium | | |
|--|--------------------------|-----------------|---------|--------------------------------|-----------------|---------|
| | Before treatment | After treatment | P | Before treatment | After treatment | P |
| RYGB | 5.00 | 95.00 | <0.001* | 10.00 | 95.00 | <0.001* |
| Sleeve gastrectomy | 0.00 | 94.22 | <0.001* | 5.82 | 94.28 | <0.001* |
| Intragastric balloon implantation + gastric bypass | 6.25 | 87.50 | <0.001* | 0.00 | 81.25 | <0.001* |
| Study group (total) | 5.67 | 94.33 | <0.001* | 3.77 | 92.40 | <0.001* |
| Control group | 3.38 | 16.90 | 0.06 | 0 | 18.60 | 0.07* |

Note. * In one or both groups, the data distribution differs from normal. A comparison was performed using the Wilcoxon T-test. *

The analyzed single-nucleotide polymorphisms were identified in 23.2 % (n = 26) of all patients included in the study (n = 112), while 76.8 % (n = 86) did not have SNP rs571312 MC4R and SNP rs3810291 TMEM 160 in the studied samples. The distribution of single-nucleotide polymorphisms among patient groups is presented as follows. The rs571312 MC4R polymorphism was detected more often in the study group compared to the control group (p = 0.007), while the rs3810291 TMEM 160 polymorphism was also more prevalent in the study group (p < 0.01). The presence of both polymorphisms was identified only in the study group, accounting for 7.3 % (n = 3) (Table 4).

The study group consisted of three subgroups depending on the chosen surgical treatment method and the presence of genetic markers associated with obesity: 20 patients underwent laparoscopic gastric bypass (nMC4R = 8, nNMEM160 = 3), 17 patients underwent laparoscopic sleeve gastrectomy (nMC4R = 2, nNMEM160 = 1), and 16 patients received two-stage treatment involving intragastric balloon placement followed by laparoscopic gastric bypass after 6 months (nMC4R = 3, nNMEM160 = 1). Among these subgroups, the highest treatment efficiency in terms of EWL was

Table 4. SNPs distribution in both groups

| SNP | Study group (n = 53) | Control group (n = 59) |
|--------------------|----------------------|------------------------|
| rs571312 MC4R | 10 (18.8 %) | 8 (13.5 %) |
| rs3810291 TMEM 160 | 5 (9.4 %) | 3 (5.1 %) |
| Both SNPs | 3* (5.6 %) | 0 |
| No SNPs | 38 (71.7 %) | 48 (81.4 %) |

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

observed in patients who underwent laparoscopic gastric bypass, achieving 69.7 %. Patients who underwent two-stage treatment had a EWL of 55.7 %, while those operated on by sleeve gastrectomy had the lowest EWL at 52.5 %.

In a significant cohort of patients undergoing surgery for obesity, initial assessments of intestinal microbiome patterns revealed unsatisfactory results. Specifically, the FBR was within reference values for only three patients (5.67 %), while the average BFaR met reference values in only two patients (3.77 % of the cohort) before surgery.

Statistical analysis

The results of univariate logistic regression yielded a statistical model indicating that individual criteria can influence the chance of achieving an optimal outcome (EWL ≥ 65): the presence of the SNP MC4R genotype – OR 3.6 (95 %CI 1.45–5.65; p < 0.0001); unsatisfactory initial pattern of intestinal microbiota – OR 1.32 (95 %CI 2.11–6.15; p < 0.0001); family history of obesity – OR 1.8 (95 %CI 1.1–1.26; p < 0.0001); other criteria do not have a statistically significant effect on the chance of achieving an optimal outcome, as shown in Table 5.

The quality of the model, as indicated by the AUC values, was good (> 0.7) for SNP MC4R at 0.81 (p < 0.001), an unsatisfactory initial pattern of intestinal microbiota at 0.73 (p = 0.003), and a family history of obesity at 0.76 (p < 0.001). Other indicators yielded AUC values below the acceptable threshold, as shown in Table 6.

Discussion

Analysis of the obtained data revealed that the best outcomes in terms of EWL were achieved in patients who underwent laparoscopic gastric bypass surgery – 69.7 % (n = 20). Within this subgroup, the SNP MC4R polymorphism was most

Table 5. **Statistical analysis results**

| Parameter | Indicators | Model odds ratio (95 % CI) | p* |
|---|-------------|----------------------------|----------|
| SNP MC4R | 2.88 ± 0.48 | 3.60 (1.45–5.65) | < 0.0001 |
| SNP TMEM160 | 0.50 ± 0.76 | 1.10 (2.12–6.15) | 0.003 |
| Both SNPs | 0.26 ± 0.10 | 7.00 (2.53–19.3) | 0.002 |
| Unsatisfactory initial pattern of intestinal microbiota | 1.32 ± 0.17 | 3.1 (2.11–6.15) | < 0.0001 |
| Diabetes mellitus | 0.15 ± 0.10 | 10.10 (3.16–41.0) | 0.02 |
| Age | 0.38 ± 0.07 | 0.69 (0.77–1.36) | 0.0001 |
| Sex | 0.31 ± 0.02 | 1.19 (0.25–1.57) | 0.82 |
| Family obesity | 1.92 ± 0.74 | 1.80 (1.10–1.26) | < 0.0001 |
| Bad habits | 0.12 ± 0.03 | 0.49 (0.52–0.98) | 0.009 |

Note. * Significance level of the difference between the mean and mean values from 0.

Table 6. **ROC analysis of the obtained model**

| Parameter | AUC | Sensitivity, % | Specificity, % | Optimal border | p |
|---|------|----------------|----------------|----------------|---------|
| SNP MC4R | 0.81 | 65.0 | 98.0 | 0 | < 0.001 |
| SNP TMEM160 | 0.52 | 43.0 | 86.0 | 0 | < 0.001 |
| Both SNPs | 0.48 | 50 | 77.5 | 0.5 | 0.002 |
| Unsatisfactory initial pattern of intestinal microbiota | 0.73 | 72.2 | 96.0 | 0 | < 0.001 |
| Diabetes mellitus | 0.6 | 22.0 | 91.0 | 0 | 0.046 |
| Age | 0.49 | 50.0 | 81.0 | 14.0 | 0.002 |
| Sex | 0.5 | 11.0 | 60.0 | 0 | 0.838 |
| Family obesity | 0.76 | 69.0 | 88.0 | 0.5 | < 0.001 |
| Bad habits | 0.55 | 37.0 | 75.0 | 0 | 0.437 |

often detected (nMC4R=5), compared to patients who underwent sleeve gastrectomy (n=17, nMC4R=2), and those who received two-stage treatment (n=16, nMC4R=3). Statistical data processing showed that the chance of obtaining optimal outcomes is highest in patients meeting specific criteria for surgical treatment: the presence of SNP MC4R, unsatisfactory initial intestinal microbiota patterns, and an extensive family history of obesity. Given that the majority of these patients underwent laparoscopic gastric bypass surgery for obesity, it can be inferred that this surgical technique is a preferred treatment option for patients meeting the specified criteria. This hypothesis is confirmed by A. C. Gomes [7].

Multivariate analysis demonstrates that the selected criteria, including the detected SNP TMEM160, the presence of both gene polymorphisms, diabetes, age, gender, and bad habits, do not have a significant impact on achieving better surgical outcomes in patients with obesity.

Conclusions

An unsatisfactory initial pattern of intestinal microbiota, the presence of the SNP MC4R polymorphism, and a family history of obesity influence the effectiveness of surgical treatment as measured by EWL (p < 0.0001). Other criteria have little effect on the surgical outcomes as measured by EWL.

The chance of achieving an optimal outcome with EWL (i 65 %) is 3.6 times higher (95 % CI 1.45–5.65; p < 0.0001) in patients with a detected SNP MC4R polymorphism; 1.32 times higher (95 % CI 2.11–6.15; p < 0.0001) in patients with an unsatisfactory initial pattern of intestinal microbiota; and 1.8 times higher (95 % CI 1.1–1.26; p < 0.0001) in patients with an extensive family history of obesity.

Laparoscopic gastric bypass is the preferred surgical technique for obesity treatment to achieve an optimal EWL outcome (i 65 %) in patients with the MC4R SNP polymorphism, an unsatisfactory initial pattern of intestinal microbiota, and an extensive family history of obesity.

DECLARATION OF INTERESTS

The authors declare that they have no conflicts of interest.

Funding. This study received no funding from any specific public, commercial, or non-profit organization.

This study was conducted as part of a dissertation of P. A. Kobzar for a PhD degree «Multifactorial analysis of the bariatric surgery outcomes in patients with morbid obesity».

AUTHORS CONTRIBUTIONS

Ioffe OY: conception and critical revision of the manuscript; Kobzar PA: conception, design, data collection, analysis, and interpretation.

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Мультифакторна оцінка ефективності хірургічного лікування ожиріння

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Мета — створення моделі для вибору найефективнішого методу хірургічного лікування ожиріння.

Матеріали та методи. Дослідження проведено на базі кафедри загальної хірургії № 2 Національного медичного університету імені О. О. Богомольця. Досліджуваній групі пацієнтів (n = 53) виконували бариатричні втручання: лапароскопічне шлункове шунтування (37,7%), лапароскопічну рукавну резекцію шлунка (32,2%), установлення внутрішньошлункового балона із шунтуванням шлунка (30,1%). Результат оцінювали через 12 міс. Контрольна група – 59 пацієнтів з ожирінням, яких лікували консервативно. Усім пацієнтам виконували рутинні загальноклінічні обстеження, генотипування з використанням системи Fast Real-Time PCR System у середовищі TaqMan, аналіз калу за допомогою полімеразної ланцюгової реакції для визначення параметрів кишкового мікробіому.

Результати. Статистична обробка даних виявила, що шанс отримати ідеальний результат найвищий у пацієнтів із поліморфізмом SNP MC4R, які мають незадовільний патерн кишкової мікробіоти, обтяжений сімейний анамнез щодо ожиріння та яким виконано лапароскопічне шлункове шунтування.

Висновки. Лапароскопічне шунтування шлунка є оптимальним методом хірургічного лікування ожиріння для досягнення ідеального результату. Наявність незадовільного початкового патерну кишкової мікробіоти, виявлення поліморфізму SNP MC4R та ожиріння в членів родини впливають на ефективність хірургічного лікування. Шанс досягнення ідеального результату в 3,6 рази вищий у пацієнтів із поліморфізмом SNP MC4R.

Ключові слова: лікування, поліморфізми, ожиріння, бариатрична хірургія.

FOR CITATION

■ Ioffe OY, Kobzar PA. Multifactorial assessment of the effectiveness of surgical treatment for obesity. *General Surgery (Ukraine).* 2025;(2):50-55. <http://doi.org/10.30978/GS-2025-2-50>.

Clinical approach to the treatment of metastatic skin melanoma. Case study

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Melanoma is an aggressive disease that accounts for approximately 75 % of skin cancer-related deaths. The primary objectives of surgery in metastatic disease are symptom relief and debulking. As effective systemic treatment prolongs survival in a patient population with advanced disease, the role of local palliative therapy potentially increases. When considering palliative surgery, it is crucial to weigh the potential risks of surgical complications against the burden caused by the symptomatic lesions.

We present a case report of melanoma TxNxM1c metastasis to the skin in the right supraclavicular area with disintegration and bleeding, metastatic lesions in the cervical, axillary, and subpectoral lymph nodes bilaterally, and metastatic lesions in the left adrenal gland, stage IV. The patient was urgently hospitalized with manifestations of diffuse bleeding associated with tumor disintegration. According to the treatment history, the patient has been receiving targeted chemo-immunotherapy since 2022. The pain syndrome intensified, and periodic episodes of bleeding from the tumor were observed. Cytoreductive surgery tactics were discussed by the multidisciplinary team and agreed upon with the patient. The patient insisted on removing the tumor despite the risks of the operation. This clinical study deals with a controversial, yet clinically required, palliative care method for preserving and improving the quality of life with this diagnosis. This case highlights the aggressive nature of generalized melanosis, characterized by a rapid clinical course and limited response to traditional targeted chemo-immunotherapy. The difficulties encountered in the diagnosis and treatment of this aggressive form of metastatic melanoma underscore the need for early detection, tailored therapeutic approaches, and ongoing research efforts to improve treatment outcomes in such cases.

KEYWORDS

melanoma, metastasectomy, systemic therapy, surgery treatment.

ARTICLE • Received 2025-03-25 • Received in revised form 2025-04-22 • Published 2025-07-31

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Melanoma is a malignant neoplasm that develops from pigment cells (melanocytes) and most often affects the skin [6].

The annual incidence of malignant skin melanoma (MS) ranges from 3–5 per 100,000 population (Mediterranean countries) to 12–35 per 100,000 (Nordic countries), while in Australia and New Zealand it can reach 50 per 100,000 population. It is noted that the incidence of melanoma has been steadily increasing over the past 40 years, with a tendency to stabilize the mortality rate, except in elderly men. The peak incidence of cutaneous melanoma occurs at age 65, although the disease

can occur at any age. There is also an increase in the mortality-to-incidence ratio in Eastern European countries compared to Western European countries, which indicates the need to improve prevention measures and early detection of melanoma in Eastern European countries, in particular in Ukraine. In 2022, 330,000 new cases of melanoma were diagnosed worldwide, and almost 60,000 people died from this disease [1]. According to the National Cancer Registry, 5,051 cases of melanoma were registered in Ukraine in 2022–2023. As of 2023, 31,217 people with this disease were registered. Of those newly diagnosed, 33.9 % had stage

I of the disease, 43.4 % had stage II, 6.9 % had stage III, and 5.3 % had stage IV; in 10.4 % of patients, the stage was not determined. Treatment of metastatic melanoma is challenging. Overall 1-year survival for metastatic (generalized) melanoma depends on the stage of spread and is 62 % for stage M1a, 53 % for M1b, and 33 % for M1c [2]. Surgery for stage IV melanoma remains controversial, with systemic therapy being preferred. However, the need for rapid removal of life-threatening metastases and improved patient quality of life supports the need for surgical removal of the tumor, but it does not confer any survival advantage [3, 5].

Case report

Female patient, born in 1966.

Diagnosis: Non-pigmented melanoma TxNxM1c metastasis to the skin in the right supraclavicular area with disintegration and bleeding, metastatic lesions in the cervical, axillary, and subpectoral lymph nodes bilaterally, and metastatic lesions in the left adrenal gland, stage IV.

From the anamnesis: the diagnosis of non-pigmented melanoma was established in 2017, when a neoplasm in the right subscapular area was removed. The patient did not receive specific treatment in the postoperative period.

In 2022, the diagnosis was made: metastatic melanoma of the skin of the left breast, BRAF V600 mutated. 17 courses of radiation therapy (42.6 Gy) were performed, followed by 6 months of targeted therapy with encorafenib + binimetinib.

From March to May 2023, 4 courses of nivolumab immunotherapy were conducted.

In April 2024, the patient reported an enlargement of the supraclavicular and right cervical lymph nodes.

In July 2024, the patient began receiving pembrolizumab immunotherapy.

In October 2024, the patient was urgently hospitalized with manifestations of diffuse bleeding associated with tumor disintegration. The bleeding was stopped (Fig. 1).

The patient's general condition stabilized as a result of the treatment. Bandages with antiseptics were applied to the tumor, antibiotic therapy was administered based on bacterial culture results, and targeted therapy was prescribed according to the oncologist's recommendations (encorafenib + binimetinib).

Periodically, the patient had recurrent bleeding, which was stopped by tight tamponade and the use of hemostatic sponges. The pain syndrome intensified. Preoperative preparation was performed.

According to computed tomography (Fig. 2): Tumor mass in the right supraclavicular area with disintegration 160 × 161 mm, signs of vascular invasion of small branches of the right subclavian artery, invasion of the common, external, and internal carotid arteries, jugular vein, adjacent muscles, and the right lobe of the thyroid gland.

Metastatic lesions in the cervical, axillary, and subpectoral lymph nodes bilaterally; metastatic lesions in the left adrenal gland with tumor invasion of the left renal artery and vein; contact with the celiac trunk and left gastric artery.

Brain: No additional formations or foci of pathological density were detected. No additional formations or infiltrative changes in the lungs were detected. Mediastinal organs without visible pathology. Intrathoracic and axillary lymph nodes were not enlarged.

In November 2024, surgical treatment was performed in the following scope: Cytoreductive removal of skin melanoma in the right supraclavicular area. Plastic surgery with a skin-muscular flap on the vascular pedicle. The course of the postoperative period was of moderate severity. The postoperative wound healed with primary tension.

January 2025. Disease progression: a local metastatic lesion in the postoperative scar with compression of the tissues and organs in the neck. Tracheostomy. Symptomatic treatment. January 2025: death of the patient.



Figure 1. Preoperative appearance of the tumor

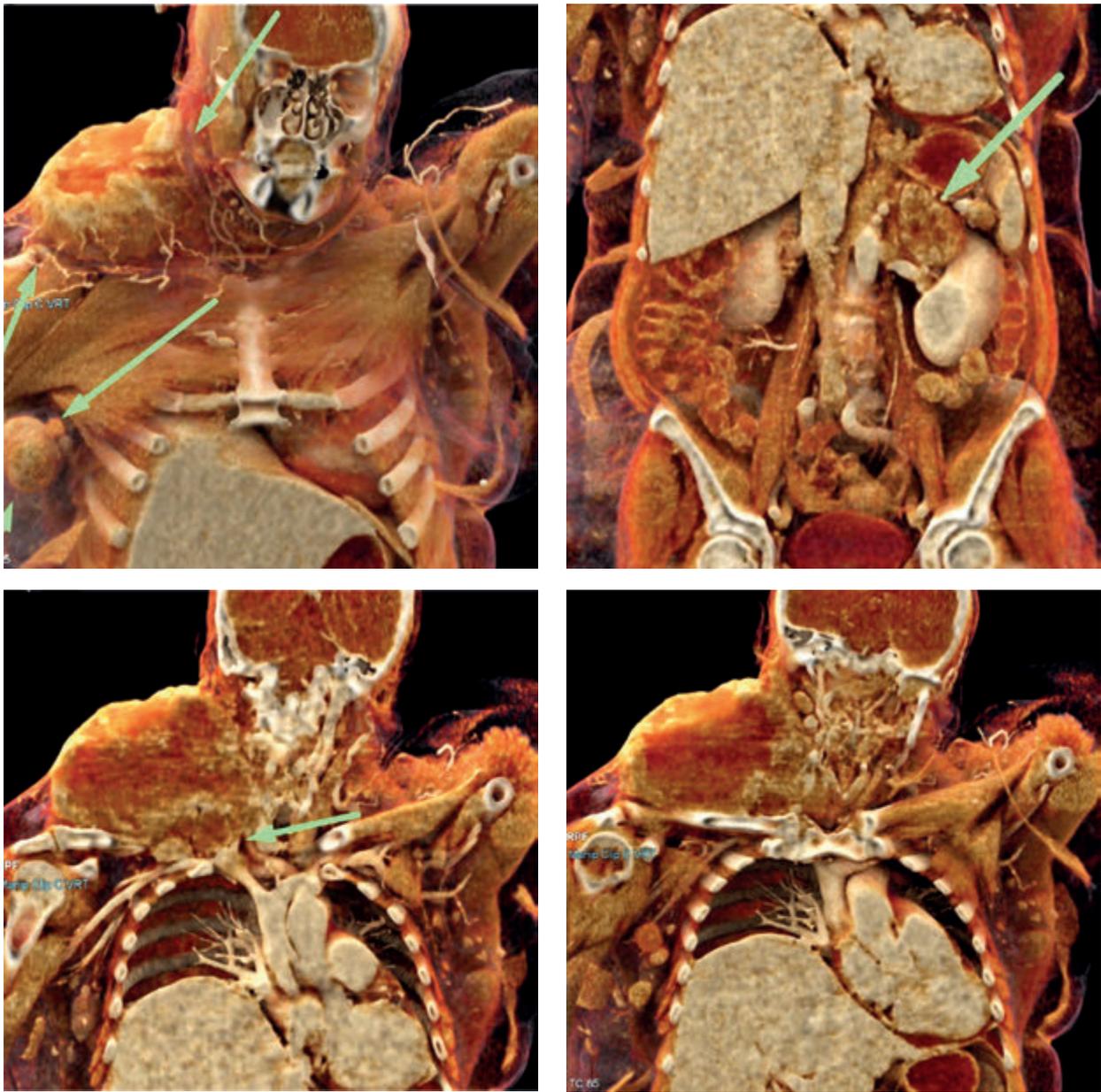


Figure 2. Preoperative computed tomography results

Discussion

This clinical case demonstrates a multifaceted approach to palliative treatment of skin melanoma, wherein systemic treatment serves as the primary therapeutic modality necessitating surgical intervention to eliminate the risk of blood loss and improve the patient's quality of life amidst the decay of necrotic tumor masses.

The role of metastasectomy in the treatment of melanoma varies depending on the site of metastasis and the patient's unique clinical presentation and may serve as an adjunct to systemic treatment of patients.

Approximately 50% of melanomas exhibit BRAFV600 mutations. The occurrence of BRAF

mutations varies depending on tumor location, with the highest frequency observed on the trunk (57%), extremities (46%), and face or scalp (28%).

Targeted therapies for melanoma with the BRAF V600E mutation have shown significant clinical results, although these are often temporary.

In addition, ongoing studies are investigating the combination of immune checkpoint inhibitors and targeted therapy, used simultaneously or sequentially [6].

Nivolumab is a human IgG4 monoclonal antibody that blocks the PD-1 protein. It is a type of immunotherapy that works as a checkpoint inhibitor, blocking the signal that prevents T cells from activating

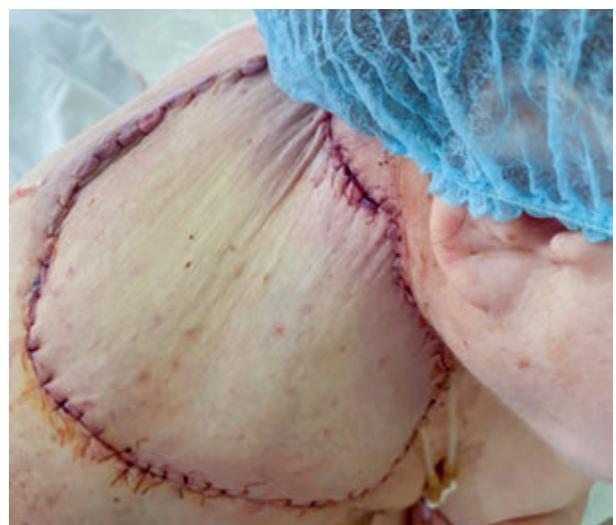


Figure 3. Macroscopic specimen of the tumor and postoperative appearance of the wound

against tumor cells. Nivolumab is used as a second-line drug for unresectable or metastatic melanoma after treatment with ipilimumab and, if the cancer has a BRAF mutation, a BRAF inhibitor [4].

Pembrolizumab is a humanized monoclonal antibody preparation against PD-1 (cell death protein 1), an immune checkpoint inhibitor that blocks the binding of PD-1 to the PD-L1 and PD-L2 ligands and thus restores the immune system's ability to attack and destroy cancer cells. Based on the results of the KEYNOTE-006 study, pembrolizumab was approved for use in unresectable and metastatic melanoma. Regarding the BRAF mutation, the results of the KEYNOTE 054 study showed that the efficacy of pembrolizumab was independent of the presence or absence of this mutation [8].

Encorafenib (BRAFTOVI) and binimetinib (MEKTOVI) were approved by the FDA in 2018 as a combination therapy based on results from the phase 3 COLUMBUS trial, which showed improved progression-free survival (14.9 months) in 577 previously untreated patients or those who have experienced disease progression at the start of or after prior first-line immunotherapy, compared with vemurafenib monotherapy (the mechanism of action of which is selective inhibition of mutant BRAF protein, with a particular focus on the V600E mutation, which is common in approximately 45% of melanoma cases) (7.3 months) with a median follow-up of 16.6 months and improved tolerability of the combination regimen. A subsequent interim analysis of overall survival with a median follow-up of 36.8 months showed a median OS of 33.6 months with encorafenib plus binimetinib versus 16.9 months with vemurafenib (HR= 0.61 [95% CI 0.47–0.79], $p < 0.0001$), demonstrating clinically meaningful efficacy and improved tolerability. Combined BRAF/MEK inhibition is the standard of care for advanced BRAF-mutated melanoma, especially with rapidly progressing and/or extensive metastases [7].

Surgery does not improve survival in patients with disseminated extracranial metastatic melanoma, but this tactic is important in most cases to preserve the patient's life and quality of life [3].

Conclusions

Palliative surgery for life-threatening metastatic skin melanoma is one of the methods of a multifaceted treatment strategy for this pathology.

DECLARATION OF INTERESTS

The authors declare no conflicts of interest.

ETHICS APPROVAL AND WRITTEN

INFORMED CONSENT STATEMENTS

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

AUTHORS CONTRIBUTIONS

O. I. Dronov: critical review of the manuscript; L. O. Roshchina, Y. P. Bakunets: work concept, design, and critical review of the manuscript; L. V. Levchenko: work concept and design, data collection and analysis, and writing the manuscript; V. I. Nahrebetskyi: data collection, analysis, and writing the manuscript.

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Клінічний підхід до лікування при метастатичній меланомі шкіри. Клінічний випадок

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Меланома – це агресивне захворювання, яке є причиною близько 75% смертей, пов'язаних із раком шкіри. Основні цілі хірургічного втручання при метастатичній меланомі – полегшення симптомів та зменшення об'єму пухлини. На тлі системної терапії, що демонструє поліпшення виживаності пацієнтів із цією патологією, роль локальної паліативної терапії потенційно зростає. Розглядаючи питання щодо застосування паліативної хірургії, важливо знайти баланс між потенційними ризиками хірургічних ускладнень і ризиками, спричиненими симптоматичними ураженнями.

Представлено клінічний випадок меланоми TхNхM1с. Метастази шкіри правої надключичної ділянки з розпадом та кровотечею. Білатеральне метастатичне ураження шийних, пахових, грудних лімфатичних вузлів, метастатичне ураження лівого наднирника, IV стадія. Пацієнтка госпіталізована в клініку в ургентному порядку з виявами дифузної кровотечі на тлі розпаду пухлини. З анамнезу лікування пацієнтки відомо, що з 2022 року розпочато прийом курсів таргетної хіміо-імунотерапії. Больовий синдром підсилювався, спостерігалися періодичні епізоди кровотечі з пухлини. Тактика лікування в обсязі циторедуктивного видалення пухлини обговорена мультидисциплінарною командою та узгоджена з пацієнткою. Пацієнтка наполягала на видаленні пухлини, незважаючи на ризики операції. Представлений кейс хірургічного лікування метастатичної меланоми є суперечливим, але водночас клінічно необхідним методом паліативного лікування для збереження та поліпшення якості життя пацієнтки. Цей випадок свідчить про агресивний характер генералізованого меланозу, що характеризується швидким клінічним перебігом та обмеженою відповіддю на основні рекомендовані схеми таргетної хіміо-імунотерапії. З огляду на труднощі діагностики та лікування цієї агресивної форми метастатичної меланоми, важливе значення мають раннє виявлення, адаптовані терапевтичні підходи й постійні дослідницькі зусилля для поліпшення результатів лікування таких пацієнтів.

Ключові слова: меланома, метастазектомія, системне лікування, хірургічне лікування.

FOR CITATION

■ Dronov OI, Roshchina LO, Bakunets YP, Levchenko LV, Nahrebetskyi VI. Clinical approach to the treatment of metastatic skin melanoma. Case study: General Surgery (Ukraine). 2025;(2):56-61. <http://doi.org/10.30978/GS-2025-2-56>.

A clinical case of surgical treatment of complicated chronic venous insufficiency using the principles of hemodynamic management

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Chronic venous disease is a widespread condition that involves telangiectasias, reticular veins, varicose veins, and venous ulcers. In addition to the well-known manifestations and complications, long-term persistent chronic venous insufficiency (CVI) can become a factor that contributes to the development of infectious processes in the skin and subcutaneous fat. If the inflammatory lesion spreads deeper, phlegmon and deep vein thrombosis may occur. 20% to 50% of patients suffering from deep vein thrombosis develop post-thrombotic syndrome.

A 59-year-old patient turned to the department of surgery with complaints of severe swelling of the right lower limb, darkening and thickening of the skin, the presence of several wounds from which pus periodically oozed, varicose veins, intermittent pain, and a feeling of distension in the affected limb. A year ago, she was hospitalized with recurrent erysipelas of the right lower limb, which was complicated by phlegmon and required surgery. Over the past year, she had noticed severe swelling of the limb, and the right lower leg had darkened considerably. During ultrasound Doppler mapping, we detected signs of past deep vein thrombosis with partial recanalization at the level of the popliteal vein, incompetence of the saphenofemoral junction, dilation of the great saphenous vein and its tributaries, and incompetence of the perforating veins in the lower third of the leg. The surgical intervention followed the principles of hemodynamic management. After ten and a half months, the patient was fully satisfied with the treatment outcomes. The limb showed no swelling, hyperpigmentation significantly decreased, and the chronic wounds completely healed.

For patients with complicated CVI, a history of inflammatory skin and subcutaneous fat diseases, and an incompetent deep venous system, hemodynamic conservative treatment or CHIVA (Cure Conservatrice et Hemodynamique de l'Insuffisance Veineuse en Ambulatoire) is the preferred option. This technique requires a detailed ultrasound Doppler mapping of the venous network and is personalized for each patient. This treatment approach can yield the most stable long-term results, the disappearance of all or most symptoms of CVI, and favourable cosmetic outcomes.

KEYWORDS

varicose disease, chronic venous insufficiency, hemodynamic management, post-thrombotic syndrome.

ARTICLE • Received 2025-03-25 • Received in revised form 2025-04-23 • Published 2025-07-31

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Chronic venous disease is a widespread, underdiagnosed condition that involves telangiectasias, reticular veins, varicose veins, and venous ulcers, which can require extensive treatment and hospitalization. The most common manifestation of chronic venous insufficiency (CVI) is varicose veins. Symptoms of CVI also include pain, skin changes, oedema, and ulceration [1]. Venous leg ulcers occur as a complication of CVI and represent the most common type of hard-to-heal wound in the lower extremity. They account for approximately 80% of all leg ulcers and

are commonly located on the medial one-third of the lower leg, anterior to the medial malleolus [1]. In addition to the well-known manifestations and complications, long-term persistent CVI can become a factor that contributes to the development of infectious processes in the skin and subcutaneous fat [6]. Non-necrotizing acute dermo-hypodermal infections are infectious processes that include erysipelas and infectious cellulitis, and are mainly caused by group A β -haemolytic streptococcus. The lower limbs are affected in more than 80% of cases,

and the risk factors are disruption of the cutaneous barrier, CVI, lymphoedema, and obesity [6, 10]. If the inflammatory lesion spreads deeper, phlegmon and deep vein thrombosis may occur. 20% to 50% of patients suffering from deep vein thrombosis develop persistent symptoms of venous system damage, called post-thrombotic syndrome [3, 4].

Today, there are many methods of treating CVI, including conservative drug therapy with venotonics, compression therapy, surgical techniques: stripping and miniphlebectomy, and well-known ablative techniques. Management of CVI requires an individualized approach, so a combination of individual techniques is most often used [1]. Hemodynamic conservative treatment of venous insufficiency in the ambulatory, known as CHIVA (Cure Conservatrice et Hemodynamique de l'Insuffisance Veineuse en Ambulatoire), is a good alternative to common procedures. It is associated with less bruising and nerve damage compared to stripping, saphenectomy, or ablation [2]. The main advantages include preservation of the saphenous vein, local anesthesia, low cost, low pain, and fast post-operative recovery. By adhering to all principles, this technique can be combined with various other methods, enabling a personalized approach to each clinical case [2, 5, 7].

Clinical case

A 59-year-old female patient presented to the department of surgery complaining of severe swelling of the right lower limb, darkening and thickening of the skin, the presence of several wounds from which pus periodically oozed, varicose veins, intermittent pain, and a feeling of distension in the affected limb.

According to the anamnesis, two years ago she first suffered from erysipelas of the right leg, was treated conservatively for about 10 days with antibiotic therapy, after which she noted significant improvement. However, the swelling of the limb persisted for a year. After a few months, the patient began to notice a slight darkening of the skin. A year ago, she was hospitalized again with a diagnosis of erysipelas and was prescribed antibiotic therapy, which did not give any results. The infectious process spread deeper, and 11 days after the onset of the disease, phlegmon of the right lower leg was diagnosed, for which surgical intervention was performed. After prolonged postoperative antibiotic therapy (about 3 weeks) and local treatment with the application of dressings, drainage of the wounds with antiseptics, she was discharged from the hospital with improvement. Over the past year, she had noticed severe swelling of the limb, which was present throughout the day, somewhat worsening in the

evening. The swelling prevented her from wearing regular clothes and shoes. The right lower leg had darkened considerably over the past year. The patient also reported that varicose veins first appeared more than 30 years ago, after her first pregnancy, but they did not bother her much. Over the past two years, the varicose veins and nodes had increased in size, and there had been a feeling of pain along the veins. The patient sought help at another clinic several months ago, but was denied surgery due to deep vein obstruction. She was prescribed phlebotonics and constant wearing of compression hosiery, which she did not wear due to discomfort.

On examination, the right lower calf was swollen, measuring 4.6 cm larger than the left one in the area of the middle of the lower leg. The skin was indurated with signs of lipodermosclerosis, and hyperpigmentation was present on the anteromedial surface of the lower leg. On the anterior surface of the lower leg along the tibia in the area of postoperative incisions, there were two wounds (fistulas) from which a scanty, whitish, odorless exudate came out. Varicose veins and nodes were outlined on the leg. A particular cluster of varicose nodes was observed on the upper third of the affected lower leg.

Initially, we performed a detailed ultrasound Doppler mapping of the venous system of the patient's lower extremities. The findings revealed the signs of past deep vein thrombosis. Specifically, the sural veins and popliteal vein were partially patent (with signs of partial recanalization), their walls were thickened, and the valve apparatus was not preserved. The femoral vein was patent, and the blood flow was satisfactory. The ostial valve was incompetent. The great saphenous vein was dilated to 16 mm in the middle third of the thigh. Varicose dilated anterior inflow of the great saphenous vein was also visualized. Severe varicose deformation with the formation of conglomerates in nodes was visualized in the posterior peripheral vein. Vertical reflux along the great saphenous vein system was recorded. Dilatation of the perforating veins in the lower third of the leg to 5.5–6.0 mm (Cockett's perforators) with registration of reflux and in the upper third of the leg to 4.2 mm (Boyd's perforators) was detected. During the ultrasound examination, no accumulations of pus were detected in the deep tissues. This patient was also referred for an X-ray and consultation with a traumatologist to ensure that there were no bone lesions.

Given the compromised deep venous system, the selected treatment approach for this patient was hemodynamic management in accordance with the CHIVA principles. We identified a type 1 shunt with a pathological discharge of blood from

the deep venous network through an incompetent saphenofemoral junction (escape point) into the cutaneous venous compartment, a segment of the great saphenous vein itself. Blood from the great saphenous vein returns to the deep venous system through the re-entry perforator (in this case, the main flow returns through Boyd's perforator), thus closing the pathological circle.

The surgical tactics were as follows: we eliminated the saphenofemoral junction, thus removing the escape point; we also performed a crosssectomy in the area of the saphenofemoral junction, the great saphenous vein was left intact, and the main flow was drained through Boyd's perforator (re-entry perforator). Using miniphlebectomy, we removed the anterior tributary of the great saphenous vein and the varicosely deformed posterior peripheral vein on the leg. We also eliminated the reflux-compromised perforators of the lower third of the leg – Cockett's perforators. Two days later, the patient was discharged from the surgical ward with recommendations to wear compression hosiery for 6 weeks. Follow-up examinations were scheduled

one week after surgery, along with suture removal, and one month after surgery. We evaluated the final treatment outcomes, including a detailed ultrasound Doppler mapping, 10.5 months after surgery.

Treatment outcomes

After ten and a half months, at the follow-up visit, the patient was fully satisfied with the treatment outcomes. Objectively: the limb was not swollen, only 0.5 cm thicker than the left one; hyperpigmentation significantly decreased along the entire length of the lower leg and chronic wounds completely healed. There were no varicose veins or nodes in the lower extremities. The patient reported the disappearance of pain or any discomfort, as well as complete satisfaction with the cosmetic result. During control ultrasound Doppler mapping, we determined a decrease in the diameter of the great saphenous vein to 10 mm in the middle third of the thigh; the draining flow went through the perforators towards the deep system without registering reflux. The results of the treatment are shown in Fig. 1 and Fig. 2.



Figure 1. **Extremity before treatment**



Figure 2. **Extremity 10.5 months after treatment**

Discussion

Inflammatory diseases of the skin and subcutaneous tissue, such as erysipelas and bacterial cellulitis, often occur in patients with CVI [6]. When the inflammatory process spreads to deeper tissues of the limb, lymphangitis, deep vein thrombosis, and phlegmon occur [3, 6]. Past acute deep vein thrombosis leads to persistent changes in the venous system, the so-called post-thrombotic syndrome, which worsens the already existing CVI [8]. Typical signs of post-thrombotic syndrome may include leg edema, redness, dusky cyanosis when the leg is in a dependent position, perimalleolar or more extensive telangiectasiae, new varicose veins, stasis hyperpigmentation, thickening of the skin and subcutaneous tissues of the lower limb known as lipodermatosclerosis, and in severe cases, leg ulcers, which may be precipitated by minor trauma [9, 11]. Post-thrombotic syndrome, in turn, can lead to recurrences of inflammatory diseases of the skin and soft tissues in the extremities, which will work like a vicious circle. For the treatment of post-thrombotic syndrome, compression stockings and medications are more often used than surgical interventions. Venous valve repair, venous bypass, and venous stents may have the potential to decrease post-thrombotic manifestations that are attributable to deep vein obstruction or valvular reflux in patients with post-thrombotic syndrome [6, 9, 11].

For patients with a compromised or completely obstructed deep venous system, hemodynamic conservative treatment of venous insufficiency in the ambulatory (CHIVA) is the preferred approach based on venous hemodynamics with deliberate preservation of the superficial venous system. This technique promotes normalization of distal venous pressure, reduction of the diameter of the venous wall in specific segments, and mitigation or complete disappearance of CVI symptoms [2, 5].

Conclusions

For patients with complicated chronic venous insufficiency, a history of inflammatory skin and subcutaneous fat diseases, and an incompetent deep venous system, hemodynamic management according to the CHIVA principles is the preferred surgical option. This technique can be performed after a detailed ultrasound Doppler mapping of the venous network and is personalized for each patient. This treatment approach can yield the most stable long-term results, the disappearance of all or most symptoms of CVI, and good cosmetic outcomes.

DECLARATION OF INTERESTS

The authors have no conflicts of interest to declare.

Funding. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

AUTHORS CONTRIBUTIONS

I. V. Kolosovych: work concept and design, critical review, final approval of the manuscript; K. O. Korolova: work concept and design, data collection and analysis, writing the manuscript;

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Клінічний випадок хірургічного лікування із застосуванням принципів гемодинамічної хірургії пацієнтки з ускладненою хронічною венозною недостатністю

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Хронічне захворювання вен, до якого відносять телеангієктазії, ретикулярні вени, варикозне розширення вен і венозні виразки, є поширеним явищем. Окрім загальновідомих виявів та ускладнень, хронічна венозна недостатність (ХВН), що тривало персистує, може стати чинником, що призведе до розвитку інфекційних процесів шкіри та підшкірної жирової клітковини. Якщо запальне ураження поширюється глибше, то можуть виникнути флегмона та тромбоз глибоких вен. Від 20 до 50 % пацієнтів після тромбозу глибоких вен страждають на посттромботичний синдром.

Пацієнтка, 59 років, звернулася до хірургічного відділення зі скаргами на сильний набряк правої нижньої кінцівки, потемніння та потовщення шкіри, наявність кількох ран, з яких виникають періодичні виділення, варикозне розширення вен, періодичний біль і відчуття розпирання в ураженій кінцівці. Рік тому вона була госпіталізована з рецидивом бешихового запалення правої нижньої кінцівки, яке ускладнилося флегмоною, з приводу чого проведено хірургічне втручання. Упродовж останнього року вона відзначала сильний набряк кінцівки, права гомілка значно потемніла. Під час ультразвукового доплерівського картування виявили ознаки перенесеного тромбозу глибоких вен із частковою реканалізацією на рівні підколінної вени, недостатність сафенофemorального співустя, розширення великої підшкірної вени та її приток, а також недостатність перфорантних вен нижньої третини гомілки. Хірургічне втручання проведено відповідно до принципів гемодинамічної хірургії. Через 10,5 міс пацієнтка була повністю задоволена результатом лікування. Кінцівка не набрякала, гіперпігментація значно зменшилася, а хронічні рани повністю загоїлися.

Для пацієнтів зі складною ХВН, запальними захворюваннями шкіри та підшкірної жирової клітковини в анамнезі й недостатністю глибокої венозної системи операцією вибору є гемодинамічна хірургія за принципами СНІВА. Ця методика може бути виконана після детального ультразвукового доплерівського картування венозної мережі. За допомогою персоналізованого підходу до лікування можна досягти максимально стабільного тривалого результату, зникнення всіх або більшості симптомів ХВН, а також доброго косметичного результату.

Ключові слова: варикозна хвороба, хронічна венозна недостатність, гемодинамічна хірургія, пост-тромботичний синдром.

FOR CITATION

■ Kolosovych IV, Korolova KO. A clinical case of surgical treatment of complicated chronic venous insufficiency using the principles of hemodynamic management. General Surgery (Ukraine). 2025;(2):62-66. <http://doi.org/10.30978/GS-2025-2-62>.

Antimicrobial resistance of combat-related infections. Literature review

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The article compiles information from scientific reports published between 2011 and 2024, indexed in both Ukrainian and international databases. The studies focus on the microflora of combat wounds and the antimicrobial resistance of primary pathogens responsible for purulent-septic complications in patients from conflict zones. We analyzed the etiological structure of common wound infections and their antibiotic resistance in military personnel with combat-related soft tissue injuries who were evacuated from the combat zone in eastern Ukraine.

A systematic review of approaches to addressing infection prevention and infectious complications in patients with combat-related soft tissue injuries has demonstrated the rational and justified use of antibiotics, as well as adherence to infection control protocols in developed countries. These measures effectively reduce the risk of surgical site infections. Since March 2022, the war in Ukraine has led to significant population migration and the evacuation of numerous patients from Ukrainian hospitals to medical facilities within European Union. Multidrug-resistant strains have been identified in patients from Ukraine. According to data from Ukrainian military and civilian hospitals, multidrug-resistant strains were prevalent in Ukraine between 2014 and 2024. *Acinetobacter baumannii* exhibited the highest resistance rates, with 92.5% of strains resistant to fluoroquinolones, 83.0% to aminoglycosides, and 67.9% to carbapenems. Resistance to carbapenems was observed in 55.6% of *Pseudomonas aeruginosa*, 42.9% of *Escherichia coli*, and 32.8% of *Klebsiella pneumoniae*. Microbial resistance emerged more frequently in Ukrainian military hospitals than in civilian hospitals and European medical institutions. The study provides epidemiological data on multidrug-resistant microorganisms isolated from patients evacuated from the combat zone in eastern Ukraine. To improve treatment options for Gram-negative bacterial infections, it is essential to identify additional phenotypic resistance profiles of multidrug-resistant microorganisms, especially those resistant to new antibiotic combinations.

KEYWORDS

microorganisms, infection, antibiotics, antibiotic resistance, combat-related injuries, armed conflict, Ukraine.

ARTICLE • Received 2025-04-26 • Received in revised form 2025-06-03 • Published 2025-07-31

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Antimicrobial resistance (AMR) is the ability of microorganisms to resist the action of antibiotics to which they were previously sensitive. This capability allows microorganisms to survive and reproduce despite antibiotic treatment. Microorganisms can develop AMR through various mechanisms, including mutation, horizontal gene transfer, and efflux pumps [4]. Antibiotic resistance is a significant global health concern [27, 30], posing a serious threat by reducing the effectiveness of treatments, increasing morbidity, and leading to higher mortality rates [9]. The World Health Organization (WHO) recognizes AMR as one of the top ten major threats to global health, with an estimated 700,000 deaths occurring annually [45]. In 2019, 1.27 million deaths

were attributable to AMR, surpassing the mortality associated with HIV/AIDS (864,000) and malaria (643,000) [40].

Furthermore, AMR prolongs hospital stays, causes disability due to infections [5], and increases economic costs. According to the World Bank, AMR could lead to additional healthcare expenditures of up to \$1 trillion by 2050 and result in annual losses to gross domestic product (GDP) ranging from \$1.0 to \$3.4 trillion by 2030 [13].

Key priorities in combating AMR include preventing infections that could lead to the inappropriate use of antimicrobial agents, ensuring universal access to quality diagnostics and proper treatment of infections, and promoting strategic initiatives

such as monitoring AMR and the consumption/use of antimicrobial agents. This also involves supporting research and development of new diagnostic tools and medicines [3]. Many diseases caused by antibiotic-resistant microorganisms underscore the urgent need for new prevention methods.

The ongoing conflict in Ukraine has exerted unprecedented pressure on the region's medical infrastructure and healthcare services [22, 25]. Following the full-scale invasion by Russian troops, the Ukrainian armed forces established efficient evacuation routes for wounded soldiers from the battlefield, drawing on both their own innovations and the experience of foreign medical services. Most injuries involve soft tissues of the torso and limbs. At all stages of evacuation and medical treatment, there is a significant risk of wound infection, which can complicate healing and pose a threat of infectious comorbidities.

It is well-known that gunshot wounds are associated with a high level of microbial contamination, particularly with opportunistic pathogens (OPs), which predispose patients to purulent-inflammatory infections. Given that a considerable number of wounded individuals develop infectious complications caused by multidrug-resistant strains of OPs, an urgent issue arises regarding appropriate antibiotic therapy and prophylaxis of these infections. The spectrum of microorganisms isolated from combat-related gunshot and mine-explosive wounds is continuously evolving. Understanding the predominant infections and their resistance to antimicrobial agents is crucial for effective patient management. However, in the existing national literature, the issue of antimicrobial resistance (AMR) in combat-related infections causing purulent-inflammatory complications is insufficiently addressed.

OBJECTIVE – to analyze data on the antibiotic resistance of primary combat-related infections in patients with soft tissue injuries evacuated from the zone of armed conflict in eastern Ukraine.

Materials and methods

A review of scientific reports published between 2011 and 2024 was conducted. The databases used in this study included PubMed, MEDLINE, and Cochrane, as well as the National Scientific Medical Library of Ukraine, the National Library of Ukraine named after V. I. Vernadsky, and the library of Bogomolets National Medical University. To find relevant materials, the following keywords were used: «antibiotics», «antibiotic resistance», «microorganisms», «infected combat-related injuries», «armed conflict», and «Ukraine».

Results and discussion

A total of 150 national and international scientific reports were reviewed, of which 46 met the criteria of our study. The analysis revealed significant differences in the etiology of wound infections and antibiotic resistance indicators, which varied depending on the timing and conditions of medical assistance provided at different stages of evacuating wounded military personnel. The battlefield presents serious challenges for the treatment of combat-related injuries, including frequent relocations of patients between facilities and medical teams, limited supplies in the combat zone, and difficulties encountered during long-distance medical evacuations [1, 2, 7].

The fundamental principle of military surgery is that any gunshot wound is considered microbiologically contaminated. Such wounds invariably contain mixed microbial flora, including OPs, as well as necrotic tissue foci, creating a favorable environment for the development of infectious and purulent-inflammatory conditions. WHO data indicate that 44–61 % of wounded individuals develop infectious complications [26]. In Ukraine, purulent-septic complications in gunshot wounds occurred in 50–75 % of cases [1, 2, 7], with a significant proportion of these infections caused by multidrug-resistant strains of OPs. A. Salmanov et al. [21] conducted a prospective multicenter study across 17 regional hospitals in Ukraine between 2019 and 2021, detecting surgical site infections in 15.3 % of patients. The main causative agents of these infections were *Escherichia coli* (21.3 %), *Enterobacter* spp. (12.9 %), *Klebsiella pneumoniae* (10.8 %), *Staphylococcus aureus* (9.1 %), and *Pseudomonas aeruginosa* (8.1 %), followed by *Enterococcus* spp. (7.3 %), *Proteus mirabilis* (6.8 %), *Acinetobacter baumannii* (6.1 %), *Stenotrophomonas maltophilia* (5.7 %), *Serratia marcescens* (5.3 %), and other microorganisms. Overall, 85.1 % of strains isolated from patients with infectious complications were multidrug-resistant. Methicillin resistance was identified in 41.2 % of *S. aureus* isolates (MRSA), resistance to vancomycin in 11.8 % of enterococci, resistance to third-generation cephalosporins in 48.4 % of all *Enterobacteriaceae*, and resistance to antimicrobials such as carbapenems in 71.3 % of all non-fermenting Gram-negative bacilli. Additionally, 25.1 % of the tested isolates were classified as multidrug-resistant. This study demonstrated that most hospitals are contaminated with multidrug-resistant hospital strains of OPs. A significant proportion of infectious complications among patients is associated with various factors, primarily the medical personnel, who can facilitate the transmission of resistant strains within healthcare institutions [34,

35], as well as prolonged medical evacuation of the wounded individuals.

In 2019, M. D. Zheliba et al. [1] conducted a study on the microbial landscape of combat wounds. The research was based on examinations and treatment of 262 victims of combat actions in eastern Ukraine, who received care at the Military Medical Clinical Center of the Central Region (Vinnytsia). Patients were admitted to the clinic 3–20 days after sustaining injuries. Throughout the evacuation process, all victims underwent surgical wound treatment and received antibiotics. Wound material was collected for microbiological examination on the day of hospitalization and during ongoing treatment. Microbiological analysis of biological material from the wounds revealed a predominance of Gram-negative non-fermenting OPs among bacterial cultures of gunshot wounds (68%), with *Acinetobacter* spp. accounting for 53% of cases and *Pseudomonas* spp. for 15%. Most of these strains (79.5%) were multidrug-resistant. Gram-positive OPs were represented by *Enterococcus* (10%) and *Staphylococcus* (14%). Staphylococci prevailed (36.8%) within the wound microflora during the first week after injury. Gram-negative OPs were isolated in 21.1% of cases. During the second week after injury, Gram-negative OPs became predominant. Between the second and fourth weeks, OP associations comprised *Acinetobacteria* and *Klebsiella* or non-fermenting bacilli and enterococci. The majority (79.5%) of strains exhibited multidrug resistance. The highest resistance levels were observed in strains of Gram-negative non-fermenting OPs. *Acinetobacter* spp. strains were resistant to most tested antibiotics but remained sensitive to polymyxin B and colistin. *P. aeruginosa* strains showed high antibiotic resistance (75%). All isolates of *Enterobacteriaceae* demonstrated 100% resistance to various generations of cephalosporins, penicillins, and fluoroquinolones. These strains were sensitive to amikacin, cefoperazone-sulbactam, and colistin, with moderate resistance observed to meropenem.

V. Kondratyuk et al. [25] conducted a microbiological study in four Ukrainian military hospitals from 2014 to 2020. A total of 813 microorganisms isolated from 162 patients were analyzed. All identified strains (*Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Klebsiella pneumoniae*) belonged to Gram-negative OPs. *A. baumannii* strains (92.5%) demonstrated the highest antimicrobial resistance level. Specifically, resistance was observed against fluoroquinolones (83.0%), aminoglycosides (70.2%), and carbapenems (67.9%). In contrast, resistance to carbapenems was 55.6% in *Pseudomonas aeruginosa*, 42.9% in *Escherichia*

coli, and 32.8% in *Klebsiella pneumoniae*. Multi-drug-resistant strains carried numerous antibiotic-resistant genes. *K. pneumoniae* co-produced class A and D β -lactamases, with one case producing blaNDM-1 and rmtC 16S rRNA methyltransferase. *A. baumannii* produced class A and D β -lactamases but did not produce metallo- β -lactamases. *P. aeruginosa* contained a wide range of β -lactamases from classes A and D, along with metallo- β -lactamases. Gram-positive cocci were susceptible to the tested antibiotics.

Additionally, research was carried out at the Communal Non-Profit Enterprise «Specialized Multidisciplinary Clinical Hospital of Kyiv». *K. pneumoniae*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* were the primary pathogenic strains that caused substantial concerns regarding antibiotic resistance, particularly resistance to reserve antibiotics [11].

Before the large-scale conflict in 2022, Ukraine provided surveillance data to the Central Asia and Europe antimicrobial resistance monitoring network, which indicated an increase in the prevalence of multidrug-resistant strains of OPs (<https://apps.who.int/iris/rest/bitstreams/1496762/retrieve>). This rise was especially notable among military personnel, likely due to the irrational use of antimicrobial agents and limited possibilities for prevention and control in the treatment of affected individuals after the annexation of Ukrainian regions by Russia in 2014 [25].

Previous reports from eastern Ukraine documented cases of infections caused by multidrug-resistant strains of OPs, including *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacteriales*, during the hospitalization of individuals with combat-related injuries [25]. These strains encompassed various clonal lineages, many of which carried carbapenemases, extended-spectrum β -lactamases (ES-BLs), and 16S methyltransferases [18]. A total of 32 *A. baumannii* isolates resistant to carbapenems and fluoroquinolones were obtained from patients with combat-related injuries sustained during the conflict in eastern Ukraine and treated in Bundeswehr hospitals in 2014 and 2015 [18].

More than a decade ago, resistant or even multidrug-resistant *A. baumannii* was described as a significant concern among patients with combat-related injuries [12, 33]. It remains a relevant issue today [10, 29, 38]. Typically, nosocomial (hospital-acquired) transmission is more likely in patients with combat wounds than auto-infection, due to prior colonization of *A. baumannii* [23, 39], with minimal or no impact from antimicrobial agents on the injury site [32]. Most international reports

of *A. baumannii* infections related to war are associated with armed conflicts in Iraq [21, 31, 46] and Afghanistan [19, 46]. Since the onset of the armed conflict in eastern Ukraine, cases of infectious complications caused by multidrug-resistant *Acinetobacter* spp. have been reported [42]. However, no studies have yet been conducted on species distribution. *Acinetobacter* spp. were particularly prevalent in wound flora during the later stages of wound consolidation, while Gram-positive bacilli dominated during the initial phase [42]. According to a multicenter study of Ukrainian hospitals conducted between 2013 and 2015, carbapenem resistance in *A. baumannii* isolates from blood samples is substantial, with a prevalence of 63.2% [37].

A recent study revealed that 78.6% of *A. baumannii* isolates causing healthcare-associated infections in intensive care units in Ukraine were resistant to carbapenems [36]. This poses a significant challenge for antimicrobial therapy. Ukrainian doctors have reported attempting desperate therapeutic measures, including the use of doxycycline, in cases of *A. baumannii* resistant to aminoglycosides. Furthermore, existing data on the primary mechanisms of carbapenem resistance in Ukraine remain limited, with most research focusing on *Enterobacteriaceae* rather than non-fermenting bacilli such as *A. baumannii* [20, 29].

H. Granzer et al. [17] detailed the epidemiology of carbapenem- and fluoroquinolone-resistant *A. baumannii* isolates obtained from patients with injuries sustained during the armed conflict in eastern Ukraine. These patients were treated in Bundeswehr hospitals in Berlin, Hamburg, Koblenz, and Ulm between 2014 and 2015. A total of 32 *A. baumannii* isolates resistant to carbapenems and fluoroquinolones were collected from 21 patients. Polymerase chain reaction (PCR) analysis revealed colonization or infection with multiple clones in some patients, indicating a high colonization pressure.

R. D. Zwittink et al. [47] reported the emergence of multidrug-resistant microorganisms in patients from Ukraine who have received treatment in the Netherlands since March 2022. The study included 58 patients and 75 isolates. Approximately half of these patients had been recently hospitalized in Ukraine. Genomic surveillance indicated that most multidrug-resistant strains of OPs belonged to widespread epidemic lineages found worldwide. Notably, 60% of these strains carried genes for metallo- β -lactamases (NDM) from New Delhi. Healthcare specialists should be aware of the increasing spread of such multidrug-resistant OP strains, which are associated with the medical evacuation of wounded

individuals from Ukrainian hospitals to medical facilities within the European Union, particularly the Netherlands [15]. The European Centre for Disease Prevention and Control (ECDC) recommends preemptive isolation of patients transferred from Ukrainian hospitals or those with a history of hospitalization in Ukraine within the past 12 months. Additionally, screening for multidrug-resistant OP strains is advised [14]. In Dutch hospitals, the primary multidrug-resistant pathogens causing purulent-inflammatory infections of gunshot wounds in admitted patients included *A. baumannii*, *E. cloacae*, *E. coli*, *K. pneumoniae*, *Proteus mirabilis*, *Providencia stuartii*, and *P. aeruginosa*.

According to WHO data, information collected from Ukrainian military and civilian hospitals indicates a high prevalence of multidrug-resistant microorganisms in Ukraine from 2014 to 2021 [25, 35, 44]. Reports have shown resistance rates of 17–84% to third-generation cephalosporins and carbapenems among *Enterobacteriales* and *P. aeruginosa*, as well as over 50% to carbapenems, fluoroquinolones, and aminoglycosides among *Acinetobacter* species [25, 35, 44]. European surveillance data for Ukraine indicate that 18% of *S. aureus* strains are MRSA, with 41% of methicillin-resistant strains associated with *S. aureus* infections related to healthcare settings [35, 44]. The multidrug-resistant strain of *A. baumannii* was recognized as a significant problem among US military personnel with combat-related injuries sustained in Afghanistan and Iraq in 2004. Similarly, in the UK, imported multidrug-resistant *A. baumannii* strains from Iraq and Afghanistan were identified as a potential source of severe hospital-acquired infections. The ability of *A. baumannii* to rapidly develop resistance to multiple classes of antibiotics has increased awareness of its clinical significance for hospital infections [24, 33].

A high prevalence of colonization was also observed among military personnel and civilian war victims transferred from Libya to German hospitals, notably a high frequency of multidrug-resistant strains of OPs [28]. Among 67 patients transferred during 2016–2017, MRSA and multidrug-resistant OPs were documented in 16% and 60%, respectively, with 37 isolates producing carbapenemases (such as New Delhi metallo- β -lactamase (NDM), (OXA)-48:15, OXA-23:9) [28].

Carbapenemases are β -lactamases, enzymes that often confer resistance to antimicrobial agents, particularly last-line antibiotics [28]. Among war victims in Syria requiring surgical intervention during 2011–2013, invasive surgical site infections involved 69% of cases with highly resistant strains of *A. baumannii*, *E. coli* producing extended-spectrum

β -lactamases (ESBL), and MRSA [41]. Studies conducted in Syria, neighboring countries, and European hospitals have found an increase in the number of carriers of multidrug-resistant microorganisms (MDRO), including *Enterobacterales* producing ESBL or NDM enzymes, and multidrug-resistant strains of *A. baumannii* in 33–83% of individuals [8].

Observations conducted during the war in Afghanistan (1979–1989) demonstrated contamination of gunshot wounds with Gram-positive aerobic microflora, spore-forming bacilli, *Clostridia*, non-spore-forming anaerobes, and coagulase-positive staphylococci from the moment of injury. Delays in evacuation or medical aid were associated with a shift in microflora towards Gram-negative bacilli. The microbiology of combat wounds sustained during US military operations in Iraq and Afghanistan (2001–2014) indicates a dominance of multidrug-resistant bacteria among wound pathogens. Specifically, this includes *A. baumannii*, *Enterobacteriaceae* such as *K. pneumoniae* and *E. coli*, which produce broad-spectrum β -lactamases, and MRSA [6]. Similar patterns were observed during the wars in Libya and Syria in 2011 and 2012, respectively. Combat-related injuries predominantly revealed Gram-negative non-fermenting bacilli and *Enterobacteriaceae*, with isolated strains exhibiting multidrug resistance to most antibiotics [16]. These findings support the presence of distinct bacteriological patterns related to changes in combat wounds.

Conclusions

Our research provided epidemiological data on multidrug-resistant microorganisms isolated from patients evacuated from the combat zone in eastern Ukraine. Additional phenotypic resistance profiles of multidrug-resistant microorganisms, particularly to new combinations of antibiotics, must be identified to expand therapeutic options for treating infections caused by Gram-negative bacilli.

To further elucidate these findings, it is necessary to conduct studies on the local epidemiology of antimicrobial-resistant pathogens responsible for purulent-inflammatory complications related to the medical care of wounded military personnel at various stages of evacuation.

DECLARATION OF INTERESTS

The author declares no conflicts of interest.

Funding. This research did not receive any grant or funding.

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Антимікробна резистентність збудників інфекцій бойових травм. Огляд літератури

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Стаття узагальнює дані наукових статей, опублікованих у період з 2011 до 2024 р. та індексованих в Україні й міжнародних базах даних, щодо мікрофлори бойових ран і антимікробної резистентності основних патогенів гнійно-септичних ускладнень лікування пацієнтів із зон збройних конфліктів. Проаналізовано етіологічну структуру основних збудників ранових інфекцій та їхню антибіотикорезистентність у військовиків із бойовими травмами м'яких тканин, евакуйованих із зони воєнного конфлікту на сході України.

Систематизація літературних джерел та підходів до вирішення проблеми профілактики інфікування пацієнта та лікування інфекційних ускладнень пацієнтів із бойовими травмами м'яких тканин виявила раціональне та обґрунтоване застосування антибіотиків у розвинених країнах і дотримання вимог інфекційного контролю, що сприяє мінімізації ризиків розвитку інфекцій ділянки хірургічного втручання. Починаючи з березня 2022 р., війна в Україні призвела до міграції частини населення та медичної евакуації великої кількості пацієнтів з вітчизняних лікарень до лікарень країн Європейського Союзу. У цих країнах спостерігалися випадки виділення мультирезистентних штамів у пацієнтів з України. Інформація, отримана з українських військових і цивільних шпиталів, свідчить про велику поширеність мультирезистентних штамів в Україні в 2014—2024 рр. Найвища резистентність виявлена в *Acinetobacter baumannii*: 92,5% штамів були резистентними до фторхінолонів, 83,0% — до аміноглікозидів, 67,9% — до карбапенемів. У *Pseudomonas aeruginosa* резистентність до карбапенемів становила 55,6%, у *Escherichia coli* — 42,9%, у *Klebsiella pneumoniae* — 32,8%. Частота виникнення резистентності серед досліджуваних патогенів в українських військових шпиталях була вищою, ніж у цивільних лікарнях та лікарнях європейських країн. Проведене дослідження дало змогу отримати епідеміологічну інформацію про організми з множинною лікарською стійкістю, виділені від пацієнтів зі східноукраїнської кризової зони. Необхідно визначити додаткові фенотипові моделі резистентності організмів із множинною лікарською стійкістю, зокрема до нових комбінацій антибіотиків, щоб розробити терапевтичні варіанти лікування інфекцій, спричинених грамнегативними бактеріями.

Ключові слова: мікроорганізми, інфекція, антибіотики, антибіотикорезистентність, бойові травми, збройний конфлікт, Україна.

FOR CITATION

■ Burakov OV. Antimicrobial resistance of combat-related infections. Literature review. General Surgery (Ukraine). 2025;(2);67-73. <http://doi.org/10.30978/GS-2025-2-67>.

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Acknowledgements (not obligatory). Acknowledge those who contributed to the manuscript providing technical help or writing assistance, or who provided general support.

Author contributions. Participation of each author in the manuscript writing (concept and design of the study; material collection, material processing, statistical data processing, writing text, and etc.)

Declaration of interests. Declare the presence or absence of a financial/personal interest or belief, consultant, institutional and other relationships that might affect the objectivity of the research.

Funding. All sources of funding must be acknowledged in the manuscript.

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