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Endoscopic Necrosectomy for Infected Walled-off Pancreatic Necrosis: A Systematic Review and Meta-Analysis

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Aim: to evaluate the clinical success and complication rates of endoscopic step-up necrosectomy in patients with infected walled-off pancreatic necrosis, based on an analysis of contemporary scientific publications.
Material and methods. A systematic review and meta-analysis of 15 studies (total of 869 patients) published since 2020 and conforming to current treatment standards was conducted. The inclusion criteria were peer-reviewed original articles in Russian or English focusing on endoscopic step-up necrosectomy via a transluminally placed metal stent with a diameter greater than 1 cm in patients with confirmed infected walled-off pancreatic necrosis. A random-effects model was used for meta-analysis.
Results. The weighted mean clinical success rate of endoscopic step-up necrosectomy was 89.5 % (95% confidence interval (CI): 87.5–92.1 %). Considerable variability in outcomes was observed between studies (range: 61 to 100 %), with significant heterogeneity (I^2 = 89.2 %). The mean complication rate was 18.8 % (95% CI: 12.5–25.1 %). The most frequent complications were stent migration (5.2 %), bleeding (3.9 %), and stent obstruction (2.1 %). The analysis revealed significant variability in the criteria used to define clinical success across the studies.
Conclusions. Endoscopic step-up necrosectomy is a highly effective treatment for infected walled-off pancreatic necrosis with an acceptable safety profile. However, the lack of unified, standardized criteria for clinical success and the high heterogeneity of the data complicate comparative analysis. To improve the quality of evidence, it is necessary to develop standardized definitions of success and complications, as well as to conduct randomized controlled trials.
Keywords: pancreatic necrosis, infected pancreatic necrosis, walled-off pancreatic necrosis, endoscopic necrosectomy
Conflict of interest: the authors declare no conflict of interest.

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Эндоскопическая некрсеквестрэктомия при инфицированном отграниченном панкреонекрозе (систематический обзор и метаанализ)

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Цель: оценить клинический успех и частоту осложнений эндоскопической поэтапной некрсеквестрэктомии при инфицированном отграниченном панкреонекрозе на основе анализа современных научных публикаций.
Материал и методы. Проведен систематический обзор и метаанализ 15 исследований (всего 869 пациентов), опубликованных с 2020 г., соответствующих современным стандартам лечения. Критерии включения: рецензируемые оригинальные статьи на русском или английском языках, посвященные эндоскопической поэтапной некрсеквестрэктомии через транслюминально установленный металлический стент диаметром более 1 см у пациентов с подтвержденным инфицированным отграниченным панкреонекрозом. Использовалась модель случайных эффектов для метаанализа.
Результаты исследования. Средневзвешенный показатель клинического успеха эндоскопической поэтапной некрсеквестрэктомии составил 89,5 % (95%-ный доверительный интервал (95% ДИ): 87,5–92,1 %). При этом наблюдалась высокая вариабельность результатов между исследованиями (от 61 до 100 %) и значительная гетерогенность (I^2 = 89,2 %). Средняя частота осложнений составила 18,8 % (95% ДИ: 12,5–25,1 %). Наиболее частыми осложнениями были: миграция стента (5,2 %), кровотечение (3,9 %) и обтурация стента (2,1 %). Анализ выявил значительную вариабельность в критериях определения клинического успеха в разных исследованиях.
Выводы. Эндоскопическая поэтапная некрсеквестрэктомия является высокоэффективным методом лечения инфицированного отграниченного панкреонекроза с приемлемым профилем безопасности. Однако отсутствие единых стандартизированных критериев клинического успеха и высокая гетерогенность данных

затрудняют сравнительный анализ. Для улучшения качества доказательной базы необходима разработка унифицированных определений успеха и осложнений, а также проведение рандомизированных контролируемых исследований.
Ключевые слова: панкреонекроз, инфицированный панкреонекроз, отграниченный некроз поджелудочной железы, эндоскопическая некрсеквестрэктомия
Конфликт интересов: авторы заявляют об отсутствии конфликта интересов.

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Introduction

Acute pancreatitis remains one of the most challenging problems in modern emergency surgery. In 15–20 % of cases, the disease follows a severe course, characterized by the development of pancreatic necrosis and systemic complications [1]. Despite advances in diagnosis and treatment, pancreatic necrosis continues to pose a serious threat to patients' life, requiring a multidisciplinary approach and an individualized management strategy. Pancreatic necrosis is associated with multiple organ failure, sepsis, abscesses and other life-threatening conditions, the incidence of which reaches up to 40 % in the infected variant of the disease, making it one of the most severe conditions in abdominal surgery [2]. Despite the widespread adoption of minimally invasive treatment methods (endoscopic, percutaneous, and laparoscopic interventions) in recent years, a unified algorithm for the management of infected walled-off pancreatic necrosis still does not exist. This leads to variability in outcomes and necessitates further investigation into optimal strategies [3, 4].

Aim: to evaluate clinical success and complications associated with endoscopic step-up necrosectomy for infected walled-off pancreatic necrosis, based on contemporary research.

The study results may be used to optimize the choice of management strategies for pancreatic necrosis, develop evidence-based clinical guidelines, and predict postoperative complications.

Thus, the investigation of treatment outcomes for pancreatic necrosis remains a relevant task, the resolution of which could significantly improve treatment results and patient quality of life.

Material and methods

When conducting the systematic review, we included studies published from 2020 onward to analyze the most current data corresponding to modern standards of endoscopic treatment for pancreatic necrosis. This temporal selection is consistent with the PRISMA 2020 guidelines for rapidly evolving medical fields, as this period marks the introduction of new clinical protocols [5]. The exclusion of earlier studies was justified by their non-compliance with current clinical practice, methodological heterogeneity, and the obsolescence of many conclusions due to technological progress in interventional endoscopy.

This systematic review and meta-analysis was registered in the international prospective register of systematic reviews PROSPERO under the number CRD42025107331.

To unify the analyzed data, the review included studies based on the revised Atlanta classification of acute pancreatitis. This approach ensures the comparability of results and minimizes discrepancies in the interpretation of clinical cases. According to this classification, infected walled-off pancreatic necrosis (IWOPN) is defined as an encapsulated, heterogeneous collection that persists for more than 4 weeks and contains a fluid component with areas of necrosis and/or sequestra [6].

Studies published in the eLIBRARY.RU scientific electronic library adhere to the classification of the Russian national clinical guidelines [7]. Consequently, the data were interpreted according to the revised Atlanta classification. It should be noted that Russian-language publications were not included in the data synthesis, which did not affect the results of the statistical calculations.

The systematic review included studies focusing on the endoscopic treatment of patients with a confirmed diagnosis of IWOPN. The studies had to involve a step of transluminal placement of a metal stent with a diameter greater than 1 cm, followed by minimally invasive endoscopic step-up necrosectomy (ESN) via the established access. The analysis incorporated the following parameters: demographic characteristics (number of patients), intervention efficacy indicators (clinical success), and data on procedural complications.

Inclusion criteria:

- thematic relevance: studies directly addressing key aspects of the research problem were selected;
- scientific validity: only peer-reviewed original articles indexed in Scopus, Web of Science, PubMed, and eLibrary were considered;
- study design: both prospective and retrospective cohort studies (multicenter and single-center) were analyzed;

• data sufficiency: publications were required to contain comprehensive information for methodological quality assessment and inclusion in the meta-analysis;

• accessibility: only studies with full open-access text were considered;

• timeframe: studies published from 2020 onward were reviewed;

Exclusion criteria:

• individual case reports and descriptive studies;

• studies focusing on the cost-effectiveness of treatment;

• publications with restricted access to the full text;

• studies published before 2020.

Given the absence of randomized controlled trials on this topic, observational studies (without a control group) were included in the review. This approach is justified by several key factors: the need to analyze real-world data of clinical practice to assess the effectiveness of specialized procedures; and its compliance with contemporary methodological guidelines (PRISMA 2020, GRADE), which permit the synthesis of non-randomized data when studying specific interventions. To ensure the reliability of the results, we applied strict study selection criteria (e.g., the use of protocols, objective outcome and complication criteria), which minimized potential systematic biases while maintaining the relevance of the conclusions for clinical practice. The treatment protocols used in the included studies were based on the updated American Gastroenterological Association guidelines for the management of pancreatic necrosis and the consensus guidelines for the diagnosis and treatment of pancreatic pseudocysts and walled-off necrosis by a Chinese multidisciplinary expert group [1, 8].

During the literature screening, the identified systematic reviews and meta-analytic studies underwent a detailed methodological analysis (study design, data synthesis criteria, assessment of the primary studies' reliability, data presentation, and meta-analysis methods); however, they were not used for integration into the primary analysis.

The conducted assessment included three key areas: analysis of the study design's compliance with modern methodological standards, evaluation of the completeness and reliability of the presented information, and an expert analysis of the correctness of the results interpretation.

As part of this study, a comprehensive search for scientific publications was performed in the following leading international and Russian bibliographic databases:

• The Russian scientific electronic library eLIBRARY.RU;

• The PubMed database of medical publications (U.S. National Library of Medicine);

• International platforms — Scopus (Elsevier) and Web of Science (Clarivate Analytics).

The search for relevant publications was conducted in both Russian and English using specially developed search queries. These queries included key terms such as "infected pancreatic necrosis", "walled-off necrosis", "endoscopic necrosectomy", and their Russian-language equivalents. To optimize the results, Boolean operators (AND, OR) were used in combination with additional terms ("transgastric drainage", "minimally invasive approach", "treatment outcomes"), allowing for the most comprehensive coverage of existing studies on the topic.

The initial screening of scientific databases identified 256 publications potentially relevant to the study. After removing duplicate records and sequentially applying the selection filters (according to the established criteria), 63 articles were selected for further analysis. The assessment procedure was conducted in two stages: first, the titles and metadata (including information about the authors, year of publication, and research centers) were analyzed, followed by a detailed review of the abstract content, study methodology, and presented results. Upon completion of this process, the final sample included 15 methodologically sound publications, which formed the basis for the meta-analysis (the complete selection process is illustrated in Figure 1). The remaining sources were used exclusively for comparative analysis and interpretation of the obtained data.

The systematic review included studies presented in Table 1.

Data accumulation (study database) and descriptive statistics were calculated using Microsoft Excel 2016.

The meta-analysis was conducted in accordance with the Cochrane Handbook and was based on a random-effects model. Cochran's Q-test (χ^2) was used to assess the statistical significance of heterogeneity; a p-value < 0.05 was considered significant. Egger's test was performed to statistically evaluate bias. A Z-test was used to assess significance, with a p-value < 0.05 indicating high statistical power of the results. While these meta-analysis parameters are not mandatory for non-randomized observational studies, they were calculated for the preliminary assessment of the results and for the standardized planning of future randomized trials.

Meta-analytical data processing was performed using the freely distributed software RevMan 5.4 (The Cochrane Collaboration) and the Python 3.9 programming environment with the StatsModels and Meta libraries. Both approaches yielded similar results, confirming the absence of significant discrepancies between them.

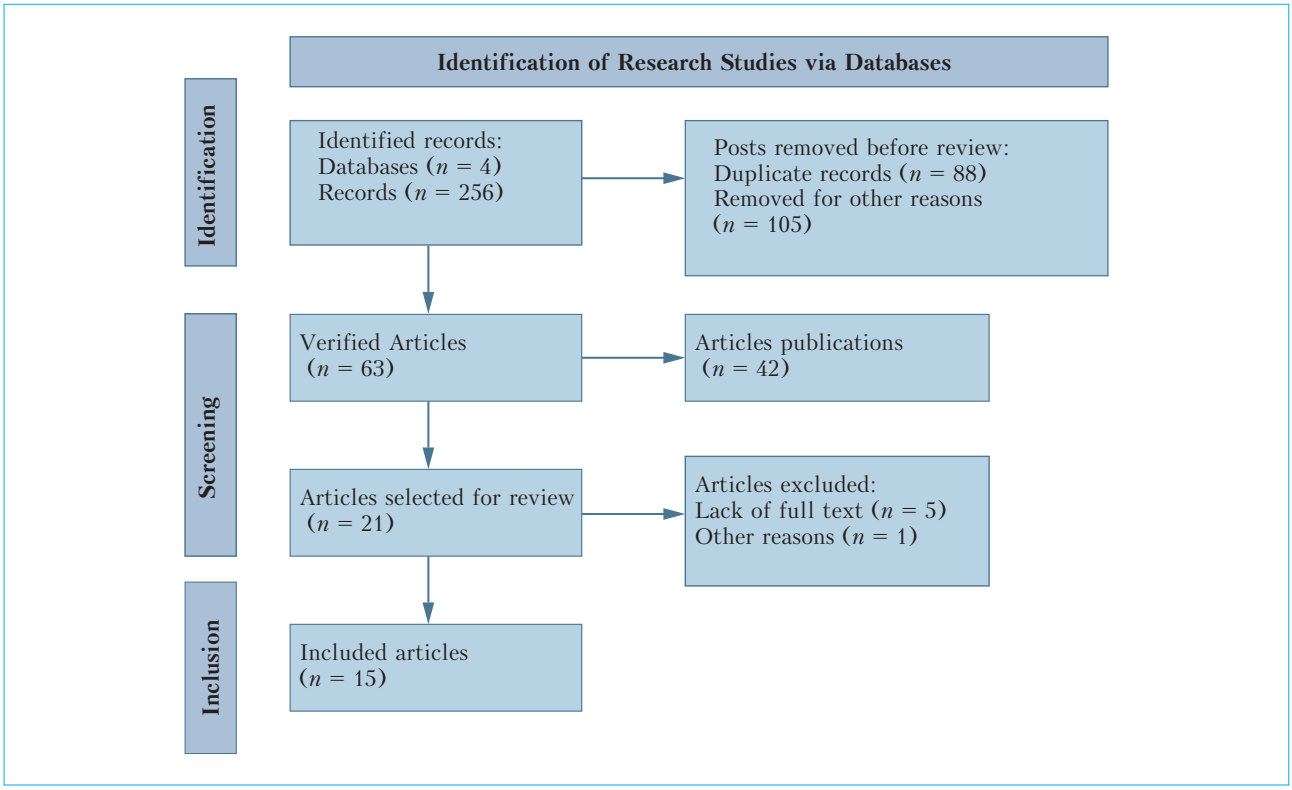

Figure 1. The method of filtering scientific publications used in this study
Рисунок 1. Методика фильтрации научных публикаций, примененная в данном исследовании

Table 1. Characteristics of studies included in the systematic review
Таблица 1. Характеристика исследований, включенных в систематический обзор

First author, year	Study design	Number of patients, *n*	Clinical success, %	Complications, %
Siddiqui A., 2021 [9]	Multicenter retrospective cohort	387	95.6	14.72
Moon J.H., 2024 [10]	Multicenter randomized prospective	25	92	40.0
Luangsukrerk T., 2022 [11]	Multicenter prospective cohort	31	100	6.45
Pattarapuntakul T., 2023 [12]	Single-center retrospective cohort	34	100	23.52
Pawa R., 2022 [13]	Single-center retrospective cohort	37	92	13.51
Kim Y.S., 2021 [14]	Multicenter retrospective cohort	60	85	45.0
Valentin C., 2024 [15]	Multicenter retrospective cohort	41	80.5	29.26
Mehta V., 2025 [16]	Single-center retrospective cohort	95	92.63	no dat
Xu N., 2024 [17]	Single-center retrospective cohort	22	90.5	13.63
Olsen G.A., 2024 [18]	Single-center retrospective cohort	20	90	35.0
Dhillon A., 2020 [19]	Single-center prospective cohort	41	80	2.43
Khodakaram K., 2024 [20]	Single-center retrospective cohort	36	61	8.3
Dorrell R., 2025 [21]	Single-center retrospective cohort	70	94	12.85
Mangiafico S., 2024 [22]	Single-center prospective cohort	18	100	27.7
Seicean A., 2020 [23]	Multicenter retrospective cohort	47	87	34.04

Graphical representations (forest plots, etc.) were generated in Python 3.9 using the statsmodels, meta, and metafor libraries.

Since aggregated data from publications were used, approval from an ethics committee was not required.

Results

Overall efficacy and heterogeneity

The study of ESN efficacy in IWOPN is an important area in modern pancreatology, as this method represents a minimally invasive alternative to open surgical interventions, which are associated with high trauma and postoperative mortality. The weighted mean clinical success rate was 89.5 % (95% CI: 87.5–92.1 %); Z-test: 12.45, $p < 0.001$. Heterogeneity analysis revealed considerable variation in clinical success rates across studies, ranging from 61 % (Khodakaram, 2024) to 100 % (Luangsukrerk, 2022; Mangiafico, 2024). Quantitative assessment of heterogeneity yielded an I^2 statistic of 89.2 % (high heterogeneity, $p < 0.001$), indicating that 89.2 % of the variability is attributable to real differences between studies rather than random chance. Egger's test indicated statistically non-significant asymmetry ($t = 1.87$, $p = 0.08$).

A forest plot was constructed for visual assessment of the clinical success rates across the studies (Fig. 2).

Subgroup analysis

In light of the significant heterogeneity, we conducted a subgroup analysis, stratifying the studies by their design (Table 2).

Multicenter and prospective studies demonstrated slightly higher success rates. The best outcomes (>95 %) were observed in studies with rigorous patient selection (standardized protocols) and experienced specialists.

Criteria for clinical success

The definition of clinical success is paramount for evaluating the efficacy of different treatments for IWOPN. Our analysis revealed substantial variability in the criteria used by different authors:

1. **Necrosis resolution criteria.** Most studies (Moon et al., 2024; Xu et al., 2024; Seicean et al., 2020) defined success as a ≥ 50 % reduction in necrosis size or reduction below a specific threshold (e.g., 2 cm — in Pawa et al., 2022 and Dorrell et al., 2025; less than 3 cm — in Seicean et al., 2020). Khodakaram et al. (2024) and Dhillon et al. (2020)

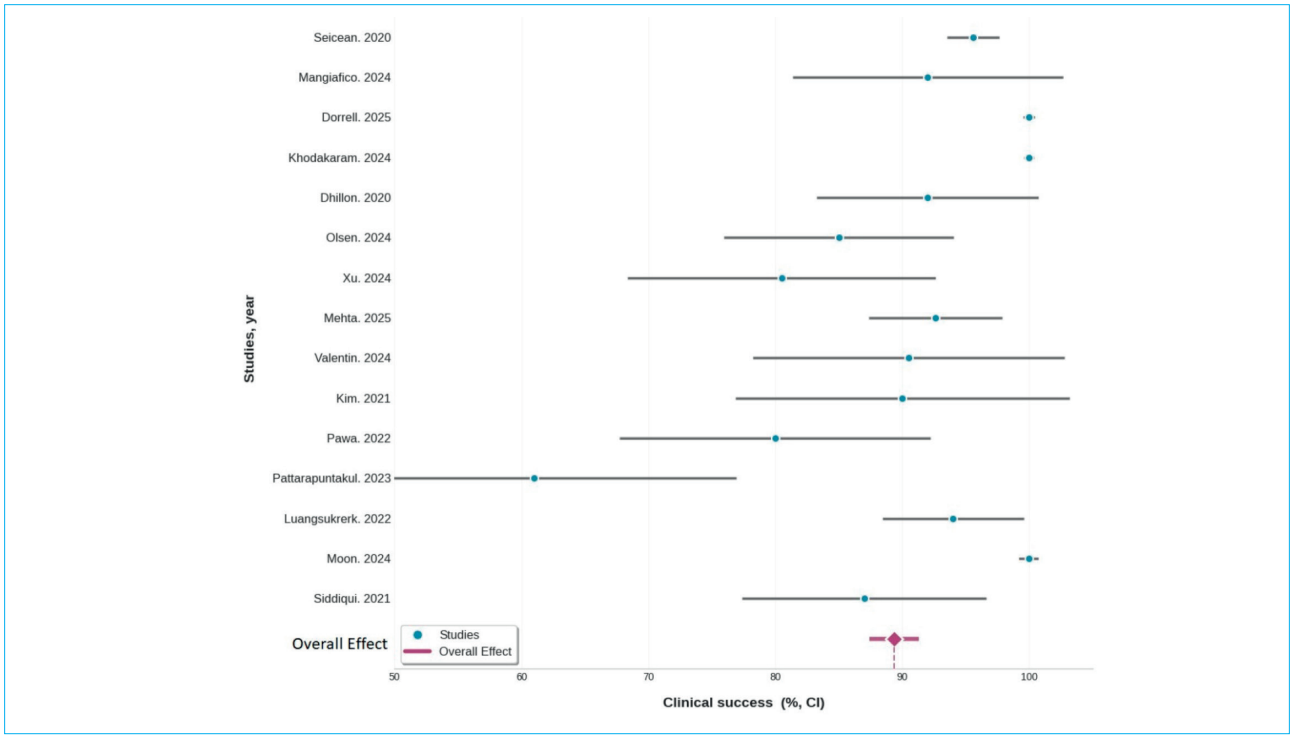

Figure 2. Meta-analysis of clinical success rates of endoscopic step-up necrosectomy in infected walled-off pancreatic necrosis across included studies: X-axis — clinical success rate (%); Y-axis — studies (first author)

Рисунок 2. Метаанализ клинического успеха применения эндоскопической поэтапной некрсеквестрэктомии при инфицированном отграниченном панкреонекрозе в различных исследованиях: ось X (горизонтальная) — процент клинического успеха (%); ось Y (вертикальная) — список исследований (первый автор)

Table 2. Subgroup analysis of studies by type
Таблица 2. Анализ в подгруппах в зависимости от типа исследования.

Subgroup	Number of studies	Mean success rate (%)
Multicenter studies	6	90.2
Prospective studies	5	90.5
Single-center studies	9	88.5
Retrospective studies	10	88.7

emphasized complete resolution of necrosis but used different timeframes (1 month vs. 3 months). Diagnostic methods also varied, including CT (Khodakaram et al., 2024) and ultrasound (Mehta et al., 2025).

2. **Clinical symptoms.** Resolution of symptoms was considered in nearly all studies, but with differing stringency. Moon et al. (2024) and Mehta et al. (2025) required complete resolution of symptoms, while Dorrell et al. (2025) and Seicean et al. (2020) accepted clinical improvement without strict quantitative assessment.

3. **Timeframe for assessment.** The follow-up duration varied significantly, from 4 weeks (Moon et al., 2024) to 6 months (Dorrell et al., 2025). A 3-month follow-up was most commonly used (Dhillon et al., 2020; Mehta et al., 2025).

4. **Additional success criteria.** Some studies included the absence of need for re-intervention (Xu et al., 2024; Seicean et al., 2020). Seicean et al. (2020) additionally considered the absence of fluid collection recurrence and postoperative complications.

Structure and frequency of complications

Analysis of the complication profile in the included studies is crucial for an objective assessment of the safety of ESN in IWOPN. Data from a total of 869 patients were used for this analysis.

The meta-analysis showed that the mean complication rate following ESN was 18.8 %, with a range of 2.4 to 45.0 %. The pooled effect (μ) was 18.8 % (95% CI: 12.5–25.1 %), indicating significant variability between the studies.

Figure 3 presents a funnel plot of the overall proportion of ESN complications in the analyzed studies. The plot demonstrates asymmetry, suggesting potential publication bias.

Due to the high heterogeneity in the overall complication data, we analyzed the studies by specific complication categories. Figure 4 presents a forest plot showing the distribution of procedure-related complications (directly associated with the endoscopic step-up necrosectomy technique) across the included publications, presented as percentages.

A total of 165 complications were recorded among 869 patients. The specific complication profile was as follows: bleeding — 3.9 % (n = 34), stent migration — 5.2 % (n = 45), stent obstruction — 2.1 % (n = 18), perforation — 1.5 % (n = 13), intestinal fistulae — 0.6 % (n = 5), gastroduodenal artery pseudoaneurysm — 0.2 % (n = 2), and other complications — 5.5 % (n = 48).

Study-specific distribution of complications:

1. **Bleeding:** the highest incidence was reported in the studies by Kim et al. (2021) — 9 cases, and Pattarapuntakul et al. (2023) — 7 cases.

2. **Perforation:** this complication was most frequently observed in the studies by Kim et al. (2021) — 3 cases, and Seicean et al. (2020) — 2 cases.

3. **Stent migration:** was prominent in the studies by Kim et al. (2021) — 8 cases, and Valentin et al. (2024) — 10 cases.

4. **Intestinal fistulae:** all registered cases (n = 5) were reported in a single study — Kim et al. (2021).

5. **Stent obstruction:** predominated in the studies by Moon et al. (2024) — 8 cases, and Dorrell et al. (2025) — 4 cases.

6. **Gastroduodenal artery pseudoaneurysm:** this rare complication was reported exclusively in the study by Seicean et al. (2020).

Only one study (Valentin et al., 2024) provided data on long-term complications beyond a 6-month follow-up period, including pancreatic endocrine and exocrine insufficiency, and portal hypertension. These long-term sequelae are not directly related to the endoscopic transluminal drainage and necrosectomy procedure itself but are rather consequences of the severe pancreatic necrosis (extent and location of necrotic tissue). Therefore, we deemed it inappropriate to include these specific long-term outcomes in the structured analysis of procedure-related complications for this systematic review.

Discussion

The findings presented should be interpreted in the context of potential biases. There is a risk of overestimating the overall clinical success rate due to the possible absence of small-scale studies with negative results, indicating potential publication bias. Furthermore, upon re-analysis, we identified several studies that reported superior outcomes for specific stents (naming manufacturers) over other seemingly comparable devices. In our opinion, the potential for conflicts of interest in such cases cannot be ruled out, which may have distorted the results and influenced the meta-analysis.

Multicenter and prospective studies demonstrated slightly higher success rates, likely attributable to more standardized patient management protocols

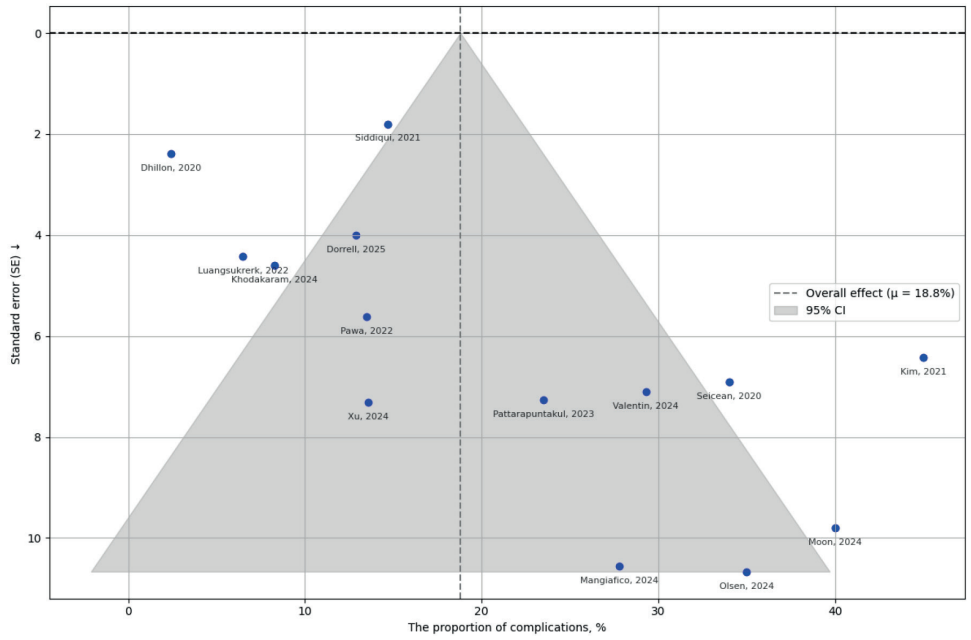

Figure 3. Funnel plot assessing publication bias of complication rates following endoscopic step-up necrosectomy in infected walled-off pancreatic necrosis: *X*-axis — complication rate (%), *Y*-axis — standard error (SE); the solid contour represents 95 % confidence intervals; the pooled effect (μ = 18.8 %) is shown as a vertical dashed line; blue dots represent individual studies (first author, year)

Рисунок 3. Воронкообразная диаграмма, оценивающая систематическую ошибку частоты осложнений после эндоскопической поэтапной некрсеквестрэктомии при инфицированном отграниченном панкреонекрозе: по оси *X* — процент осложнений, по оси *Y* — стандартная ошибка (SE); сплошной контур обозначает 95% ДИ; общий эффект (μ = 18,8 %) показан вертикальной пунктирной линией; синие точки — исследования (первый автор, год)

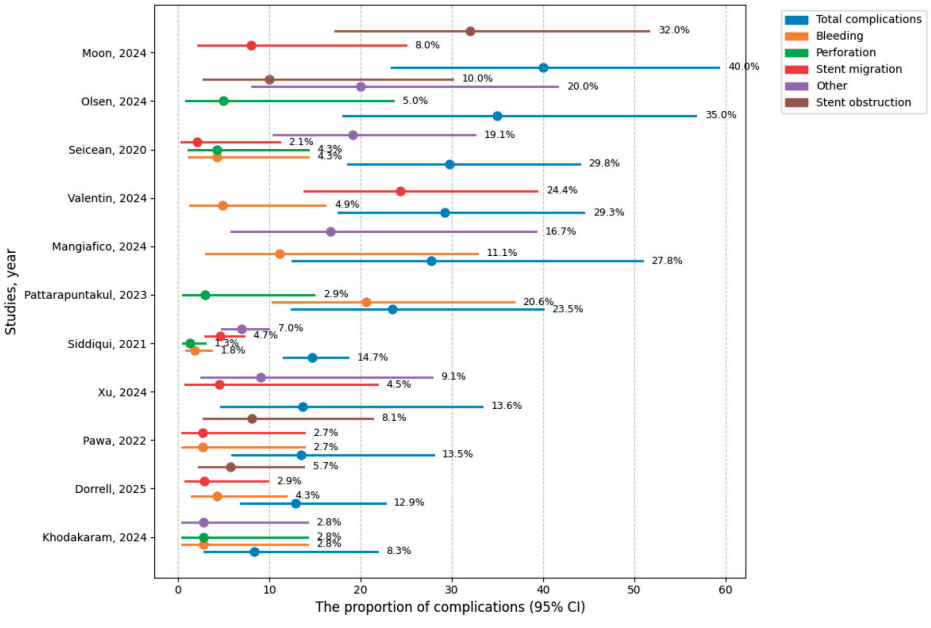

Figure 4. Forest plot of complication rates (with 95 % confidential intervals) following endoscopic step-up necrosectomy across included studies

Рисунок 4. Лесной график доли осложнений эндоскопической поэтапной некрсеквестрэктомии с 95% ДИ в исследованиях

for IWOPN. While retrospective data showed comparable efficacy, their interpretation requires caution due to inherent risks of selection and reporting bias.

The considerable variability in the definitions of clinical success across studies significantly complicates direct comparison of outcomes. Key discrepancies pertained to quantitative parameters (e.g., residual necrosis size of 2 cm vs. 3 cm vs. a 50 % reduction), follow-up durations (ranging from 1 to 6 months), and the combination of clinical and radiological criteria. This heterogeneity underscores the critical need for standardized definitions to enable more accurate data synthesis in future research. Therefore, the systematization and analysis of existing approaches to defining clinical success is a vital task that will facilitate the development of unified standards and enhance the quality of clinical studies in this field.

Consequently, this analysis substantiates the necessity of revising the clinical success criteria for the treatment of IWOPN. The authors propose that the key efficacy parameters should be: achievement of minimal necrosis size (less than 2 cm) confirmed by CT imaging, and absence of complications directly related to the progression of pancreatitis and sepsis.

This approach focuses on the primary goal of the intervention — sanitation of the infectious focus and creating conditions for the resolution of IWOPN — while distinguishing it from the technical risks inherent to ESN.

An important aspect of this proposed framework is the interpretation of a recurrence within 6 months not as a treatment failure, but as a manifestation of ongoing necrosis, which aligns with the prolonged natural course of walled-off pancreatic necrosis.

Furthermore, it is proposed that only those complications which necessitate a radical change in treatment strategy — specifically, the performance of an open surgery (laparotomy) — should be classified as clinical failure. Technical complications, such as stent migration or obstruction (e.g., by detritus), that were successfully managed endoscopically (via placement of an additional stent, stent clearance, or placement of a stent with a larger diameter), should not be considered criteria for ineffectiveness. This is because they do not reflect failure of the drainage method itself but rather represent issues addressed during its optimization.

To standardize outcome assessment, we propose establishing a follow-up period of 4 to 6 months. In our opinion, this duration is sufficient to evaluate the effectiveness of the primary intervention. An increase in the size of the residual cavity or the appearance of new sequestra occurring after this period should be classified as recurrences. The implementation of these unified criteria will enhance the consistency of results across different studies and enable a more objective comparative analysis of treatment efficacy for IWOPN.

ESN for IWOPN is accompanied by a range of complications, the most common being bleeding, stent migration, and stent obstruction. Bleeding and perforation are the most critical complications, requiring immediate intervention. It is important to note that in the analyzed studies, ESN was performed primarily using mechanical methods, most frequently with Dormia baskets and forceps. In some studies, cavity sanitation was performed using hydrogen peroxide. This variation in technique likely explains the reported differences in the frequencies of bleeding and perforation.

Stent migration is a frequent complication of ESN, which may be associated with technical aspects of stent placement or patient anatomy. In our view, it primarily depends on the endoscopist's experience. Most studies utilized LAMS (lumen-apposing metal stents) with a diameter greater than 1 cm. A rare complication such as gastroduodenal artery pseudoaneurysm underscores the necessity for careful patient monitoring after the intervention.

Conclusion

The study of endoscopic step-up necrosectomy efficacy in infected walled-off pancreatic necrosis represents an important area of modern pancreatology. This method serves as a minimally invasive alternative to open surgical interventions, reducing trauma and postoperative mortality. However, the lack of a unified definition of clinical success, potential conflicts of interest in publications, and variability in assessment criteria complicate data generalization and meta-analysis.

The results underscore the importance of an individualized approach for each patient and the necessity for further research to optimize the technique and reduce risks. The funnel plot revealed asymmetry in the overall proportion of procedure-related complications, which may indicate publication bias. While most studies clustered within the 95 % confidence interval, some fell outside its boundaries, potentially due to differences in methodology, center experience, or patient selection.

Therefore, to enhance the clinical effectiveness of endoscopic step-up necrosectomy, it is imperative to standardize definitions of clinical success and develop unified standards for complication assessment. This will improve the quality of clinical research and optimize surgical strategy in the treatment of infected walled-off pancreatic necrosis.

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