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SELECTION OF PALLIATIVE BILIARY DECOMPRESSION STRATEGY IN UNRESECTABLE PANCREATIC HEAD CANCER BASED ON PREDICTED POSTOPERATIVE OUTCOMES

Borys H. Bezrodnyi, Ihor V. Kolosovych, Ihor V. Hanol, Roman A. Sydorenko, Andrii M. Tsyhanok, Pavlo V. Chemodanov, Denys S. Kondratiev

Bogomolets National Medical University, Kyiv, Ukraine

Abstract

Introduction. Current recommendations are focused mainly on determining the indications for systemic therapy and consider biliary decompression as a stage of preparation for its implementation. However, existing scales mainly assess the prognosis of survival and tolerability of chemotherapy, but do not allow predicting the immediate results of decompression intervention.
Aim. To develop a differentiated approach to the selection of tactics and methods of biliary decompression in patients with unresectable pancreatic head cancer complicated by obstructive jaundice, based on the prognosis of early postoperative outcomes.
Materials and methods. The study included the results of treatment of 107 patients with unresectable pancreatic head cancer complicated by obstructive jaundice, who were divided into two groups depending on the chosen treatment tactics: the group of open biliary-digestive bypass operations (comparison group, n = 53) and the group of endoscopic transpapillary SEMS placement (main group, n = 54).
Results. Early postoperative outcomes are determined by the balance between the traumatic nature of the intervention and the patient's functional reserve, which justifies the need for a risk-based choice of biliary decompression method. The use of SEMS biliary stenting procedures to restore the biliary-digestive passage compared with traditional surgical biliary-digestive bypass is accompanied by a reduction in the complication rate by 13.3% (p = 0.03) and mortality by 7.5% (p = 0.04). Generally accepted prognostic scales (ASA, P-POSSUM, ACS NSQIP) have limited prognostic value for determining the immediate results of biliary decompression, since they do not take into account cholestasis-induced organ dysfunction.
Conclusions. The developed local scale provides reliable prediction of postoperative complications and mortality and allows stratifying patients according to the level of surgical risk. For the prediction of severe complications, the threshold was ≥ 9 points (sensitivity 100%, specificity 85.1%), for the prediction of mortality – ≥ 12 points (sensitivity 100%, specificity 93.9%).

Keywords: **cancer of the pancreas, obstructive jaundice, biliary stenting**

INTRODUCTION

Late diagnosis of pancreatic head cancer leads to the fact that up to 80% of patients are ineligible for radical surgical treatment and require palliative interventions aimed at relieving obstructive complications – obstructive jaundice, duodenal stenosis, and pain syndrome. Restoration of the biliary passage is carried out in two fundamentally different ways: open biliarydigestive bypass or endoscopic placement of self-expanding metal stents (SEMS) [1].

Biliodigestive anastomoses provide long-term decompression of the biliary tract (more than 14-16 months), but are accompanied by a risk of postoperative complications of up to 10% and a mortality rate of 5-7% [2]. Endoscopic stenting is characterized by a lower incidence of early complications (5-7%) and minimal mortality, but in 30-40% of cases, recurrent stent obstruction occurs within 6-7 months due to tumor progression, biliary sludge, and bacterial colonization with the development of cholangitis and recurrent jaundice [3]. Given modern systemic therapy, which extends survival to 14-16 months, the insufficient duration of functioning of self-expanding metallic stents (SEMS) has become a clinically significant problem.

Current recommendations (National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO), Eastern Cooperative Oncology Group (ECOG) scale) are focused mainly on determining indications for systemic therapy and consider biliary decompression as a stage of preparation for its implementation [4]. However, the implementation of the oncological protocol is possible only if jaundice is safely resolved and organ dysfunction is stabilized. Existing scales mainly assess survival prognosis and chemotherapy tolerability, but do not allow predicting the immediate results of decompression intervention. In clinical practice, most of these patients are treated in general surgical hospitals, where another key question is determining which procedure a particular patient can tolerate without developing postoperative decompensation of vital systems and multiple organ failure. Therefore, the choice between surgical bypass and endoscopic stenting is often made empirically, based on the doctor's clinical experience, which causes significant variability in treatment results.

AIM

To develop a differentiated approach to the selection of tactics and techniques of biliary decompression in patients with unresectable pancreatic head cancer complicated by obstructive jaundice, based on the prognosis of early postoperative outcomes.

MATERIALS AND METHODS

The work was carried out during 2016-2023 at the Department of Surgery with the course of abdominal surgery of Bogomolets National Medical University and was approved by the Commission on Bioethical Expertise and Ethics of Scientific Research. The study included the results of treatment of 107 patients with unresectable pancreatic head cancer complicated by obstructive jaundice. Exclusion criteria were resectable pancreatic head tumors, previous reconstructive surgery on the biliary tract, the presence of duodenal obstruction, and the spread of cancer to the anatomical structures of the liver hilum. Diagnosis and staging of cancer were performed in accordance with the recommendations of the NCCN and ESMO using the American Joint Committee on Cancer (AJCC) classification (7-8 editions) [5]. There are 75 patients had stage III disease (T1-3N2M0, T4N0-2M0), 32 had stage IV (T1-4N0-2M1). In all cases, pancreatic ductal adenocarcinoma was histologically confirmed. Tumor resectability was assessed based on clinical examination and multidetector contrast-enhanced computed tomography in the arterial and portal phases according to the NCCN and ESMO recommendations [6].

The hypothesis of the study was based on the assumption that the immediate results of palliative biliary decompression are determined not by the type of intervention (biliodigestive shunting or SEMS), but by the balance between surgical load and functional reserve of the patient. Therefore, risk stratification according to the specialized local scale we created will provide a more accurate prediction of postoperative outcomes than universal clinical scales (American Society of Anesthesiologists (ASA), Portsmouth-Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (P-POSSUM), National Surgical Quality Improvement Program (ACS NSQIP), ECOG), and allow for personalization of surgical treatment strategies.

Patients were divided into two groups depending on the chosen treatment approach: a group of open biliary-digestive bypass operations (comparison group, n = 53) and a group of endoscopic transpapillary SEMS installation (main group, n = 54). Thus, in the comparison group, open biliary-digestive bypass was performed – hepaticojejunostomy on an isolated Roux-en-Y loop of the jejunum with prophylactic gastrojejunostomy. The anastomosis was formed with knotted sutures (PDS 4-0 or Vicryl 4-0) with precise comparison of the mucous membranes. According to indications (pain syndrome), 8 patients underwent intraoperative chemical splanchnicectomy (coeliac plexus blockade with 50% ethanol according to Lillemoe). Also, in 11 (20.8%) patients, preoperative biliary drainage was performed as the first stage (percutaneous, transhepatic cholangiostomy in 6 (11.3%) patients and in 5 (9.4%) patients after endoscopic retrograde cholangiopancreatography, transpapillary stenting of the common bile duct with plastic stents with a diameter of 8 mm was performed. In the SEMS group, decompression of the biliary tract was performed by transpapillary placement of a self-expanding metal stent (Wallstent Biliary Uncovered, Boston Scientific). Upon admission, there were no significant differences between the two groups in terms of age, sex, bilirubin level, spread of the tumor process, concomitant pathology and indications for decompression of the biliary tract ($p > 0.05$) (Table 1).

In the studied groups, a comparative analysis of the incidence of intraoperative adverse events (surgical errors and complications during operations), postoperative complications, 30-day mortality and patient survival was conducted. The incidence of intraoperative adverse events was classified according to R. M. Satava, 2005, postoperative complications and mortality were assessed according to the Clavien–Dindo classification as modified by S. M. Strasberg, 2009 [7].

Statistical analysis of the obtained research results was performed using Microsoft Excel and the statistical analysis package IBM SPSS Statistics 22.0. The significance of differences between mean values was assessed using nonparametric criteria: for related populations – Wilcoxon test, for independent populations – Mann-Whitney. The criterion for significance of differences was considered to be $p < 0.05$.

Table 1

Main Clinical Characteristics of Patients in the Study Groups

Indicators	Comparison group (n=53)	Main group (n=54)	p
Age (M±m)	67.3±5.4	68.1±4.9	0.42
Sex Men Women	 34 (64%) 19 (36%)	 32 (59.2%) 22 (40.8%)	 0.61 0.61
Total serum bilirubin (M±m) μmol/l	204.4±49.3	216.0±38.1	0.17
TNM Stage Stage III (T1-3N2M0 and T4N0-2M0)	38 (71.7%)	37 (68.5%)	0.71
Stage IV (T1-4N0-2M1)	15 (28.3%)	17 (31.5%)	0.71
Comorbidities			
Hypertensive disease	53 (100%)	53 (98.1%)	0.31
Diabetes mellitus	19 (35.8%)	16 (30.2%)	0.53
Chronic obstructive pulmonary disease	2 (3.8%)	2 (3.7%)	0.97
Cerebrovascular complications	3 (5.6%)	2 (3.7%)	0.64
Coronary heart disease	27 (50.9%)	29 (53.7%)	0.77

RESULTS

When comparing the results of surgical treatment of patients in both groups, it was found that the frequency of complications in the early postoperative period in patients in the comparison group was 18.9% versus 5.6% in the main group ($\chi 2 = 4.38$, 95% CI 0.64-26.32, $p = 0.03$), and 30-day mortality was 7.5% and 0% ($\chi 2 = 4.16$, 95% CI 0.55-17.79, $p = 0.04$), respectively (Table 2, 3).

Table 2

Postoperative Complications and Mortality According to the Clavien–Dindo Classification Modified by S. M. Strasberg (2009) in Patients in the Comparison Group

Indicators	Comparison group (n=53)	
	Single-stage surgical treatment (n=42)	Two-stage surgical treatment (n=11)
Postoperative complications (Accordion Severity Grading System scale)		
Total number of complications 10 (18.9%)	Number of complications 6 (14.3%)	Number of complications 4 (36.4%)
Class I	0	2 (18.2%)
Class II	0	0
Class III	2 (4.8%)	0
Class IV	1 (2.4%)	1 (9.1%)
Class V	0	0
Class VI	3 (7.1%)	1 (9.1%)
Treatment of complications		
Relaparotomy, revision of hepaticojejunal anastomosis	2 (4.8%)	0
Intensive care in ICU settings	4 (9.5%)	0
Hospitalization time (M±m), days	14 ±2.1	11.7±2.4
Rehospitalization within 90 days after discharge (number of patients)	6 (14.3%)	0
30-day mortality	3 (7.1%)	1 (9.1%)

Table 3

Complications of the Early Postoperative Period and Mortality according to Clavien–Dindo, Modified by S. M. Strasberg (2009) in Patients of the Main Group

Indicators	Main group (n=54)
Postoperative complications (Accordion Severity Grading System scale)	
Total number of complications	3 (5.6%)
Class I	0
Class II	3 (5.6%)
Class III	0
Class IV	0
Class V	0
Class VI	0
Treatment of complications	
Intensive care in ICU (number of patients)	3 (5.6%)
Hospitalization time (M±m), days	3.1 ±0.8
Rehospitalization within 90 days after discharge (number of patients)	0
30-day mortality	0

It was also found that the structure of complications in the studied groups differed significantly. Thus, after open biliary-digestive bypass, the most common complications were those associated with exacerbation/progression of hepatorenal dysfunction due to surgical trauma and anesthesia, and purely surgical complications, such as insufficiency of anastomotic sutures. While after endoscopic stenting, complications associated with the papillotomy procedure (bleeding, pancreatitis) prevailed. Severe postoperative complications (Clavien–Dindo IV-VI) were noted mainly in patients with progressive organ dysfunction at the time of intervention, regardless of its type. Mortality within 30 days was recorded only after open surgeries, while no fatalities were observed in the main group.

When assessing the predictive ability of the ASA, P-POSSUM, and ACS NSQIP scales to predict early postoperative complications and 30-day mortality during biliary decompression, it was found that the complication and mortality rates calculated using the P-POSSUM scale systematically exceeded the actual results, primarily in patients with low and moderate risk, while in patients with severe condition there was a tendency to underestimate them (Table 4).

A similar discrepancy between the prognosis and actual results was found when using the ACS NSQIP. The ASA scale demonstrated only a rough risk stratification without the possibility of quantitatively predicting the frequency of postoperative events. It was found that none of the studied scales provided sufficient correspondence between the predicted and actual treatment results across the entire range of clinical severity of patients. The discrepancies were most pronounced in the group of patients with moderate severity of jaundice, where the clinical decision on the choice of the decompression method is the most critical. Based on the analysis of the prognostic capabilities of classical universal scales and our own clinical material, a «local scale» for predicting the risk of early postoperative results in patients with pancreatic head cancer complicated by obstructive jaundice was formed (Table 5).

The prediction of the probability of complications and mortality was calculated using the logistic regression model formula:

$$P\,(event) = \frac{1}{1 + \exp[-(\alpha + \beta \cdot x)]},$$

where: P – probability of an event (complication, lethality), x – sum of local scale scores, α, β – model parameters.

To assess its discriminative ability, ROC analysis was performed. The area under the ROC curve (AUC) for the prediction of severe postoperative complications (Clavien–Dindo IV-VI) was 0.96 (95% CI 0.89-1.00), which was consistent with the high accuracy of the model. For the prediction of 30-day postoperative mortality, the AUC was 0.97 (95% CI 0.93-1.00). Optimal risk thresholds were determined using the Youden criterion. For the prediction of severe complications, the threshold was ≥ 9 points (sensitivity 100%, specificity 85.1%), for the prediction of mortality, ≥ 12 points (sensitivity 100%, specificity 93.9%). The frequency of postoperative events increased proportionally to the increase in the total score, which confirmed the presence of a monotonic relationship between the integral score of the scale and the risk of adverse outcomes (Figure 1).

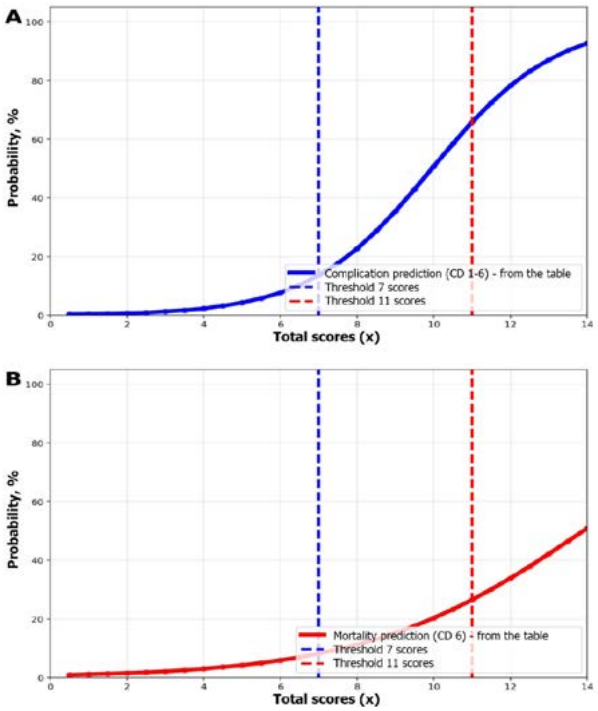

Figure 1. Graphs of the prediction of the frequency of complications (A) and mortality (B) in patients of the experimental group depending on the sum of points calculated according to the «local scale».
Note: number of patients – n=53, total complication rate: 18.9%, – mortality 7.54%.

Table 4

Predicted Risks of Complication Rates and Mortality according to the P-POSSUM, NSQIP and ASA Scales in Patients of the Comparison Group (N = 53) during Biliodigestive Bypass Surgery Depending on the Severity of Obstructive Jaundice and Treatment Tactics

Severity of jaundice	Physiological Assessment Scores P-POSSUM	Points for operational assessment P-POSSUM	Prediction of risk of complications				Mortality risk prediction			
			P-POSSUM (%)	ACS NSQIP (%)	ASA (%)	Actually (%)	P-POSSUM (%)	ACS NSQIP (%)	ASA (%)	Actually (%)
Mild (n=17) ASA 2E	19.3±0.98	14.1±1.12	12.4±2.11	10.8±1.67	Low up to 10%	11.7±1.96 (2 of 17)	2.46±0.29	1.1±0.17	up to 1%	0,0%
Medium (n=25) ASA 3E	26.8±2.13	13.7±1.02	31.3±2.91	13.9±1.11	Moderate up to 30%	8.0±0.89 (2 of 25)	7.62±0.63	1.47±0.15	up to 8%	0,0%
Severe (n=11) ASA4E, two-stage tactics 1st stage(n=11) **endoscopic**	40.5±5.72	7.1±0.46	Plastic stent 5.3±0.87	Plastic stent 2.8±0.33	Plastic stent Low up to 10%	Plastic stent 0.0%	Plastic stent 0.46±0.11	Plastic stent 0.40±0.1	Plastic stent up to 8%	Plastic stent 0,0%
2nd stage (n=11) ASA 3 **surgical**	27.1±1.28	15.5±0.93	41.9±5,37	44.6±4.9	High up to 50%	54.5±4.98 (6 of 11)	10.2±0.75	28.4±3.1	up to 25%	36.4±3.95 (4 of 11)
Severe (n=11) ASA 4E ***Hypothetically:*** *one-stage biliodigestive bypass surgery*	41.7±5.31	18.4±2.43	96.4±12.6	94.2±7.96	Critically high up to 100%	-	51.05±7.4	54.6±6.12	>50%	-

Table 5

Local Scale Indicators Are Defined to Predict the Risks of Complication Rates and Mortality in Palliative Surgical Treatment of Patients

	Indicator	Categories	Points
1.	Body mass index	< 18.5 (underweight, cachexia)	2
		18.5-24.9	0
		≥ 25	1
2.	Distant metastases	Distant metastases diagnosed	1
3.	Kidney failure	Creatinine > 200 μmol/L	1
4.	Heart failure	II-IV FC	1
5.	Albumin	< 28 g/l	2
		28-34 g/l	1
		≥ 35 g/l	0
6.	Total bilirubin	> 200 μmol/l	1
		≤ 200 μmol/l	0
7.	International normalized ratio	> 1.5	1
		< 1.5	0
8.	Cholangitis	Diagnosed	2
		Not diagnosed	0
9.	Alanine aminotransferase	Less than a twofold increase	0
		More than double the increase	1
10.	Age	> 75 years	1
		< 75 years	0
11.	Impaired consciousness, Glasgow Coma Scale (GCS < 15 points)	GCS < 15	1
		GCS 15 points	0

DISCUSSION

Treatment of patients with unresectable pancreatic head cancer has traditionally been viewed as a choice between surgical biliary bypass and endoscopic biliary stenting [8]. In most current guidelines, this choice is actually determined by the patient's general condition and the need to initiate systemic therapy as soon as possible [9]. However, the results of this study have shown that this approach is simplistic and does not reflect the real mechanism of postoperative complications.

The obtained data demonstrated that the immediate results of palliative decompression are determined not so much by the type of intervention as by the ratio of the traumatic nature of the procedure and the functional reserve of the patient. It was established that in patients with compensated or moderate organ dysfunction, open biliodigestive anastomoses are accompanied by an acceptable risk of complications and provide a long-term decompression effect. In contrast, in patients with severe multiorgan dysfunction, even minimally invasive interventions do not eliminate the high risk of adverse events, and decompression itself is only a stage of intensive therapy. Thus, biliodigestive shunting and SEMS are not alternative methods, but correspond to different levels of admissible surgical load.

Analysis of the prognostic capabilities of commonly used scales (ASA, P-POSSUM, ACS NSQIP) showed their poor suitability for predicting the outcome of biliary decompression [10]. These scales were developed to assess the risk of general surgical interventions and are based mainly on demographic, physiological and somatic parameters, while in patients with long-term obstructive jaundice, cholestasis-induced multiorgan dysfunction plays a key role [11]. As a result, the scales showed either an overestimation of risk or a lack of discriminatory power, especially in the SEMS group, where the event rate was low.

The developed «local scale», constructed using clinical and laboratory parameters directly related to biliary obstruction and multiorgan dysfunction, showed high discriminatory ability in predicting complications and mortality. The determined threshold values allowed not only to stratify patients by risk, but also to form a practical algorithm for choosing a decompression method. At low risk, biliodigestive bypass is advisable due to its long-term effect, while at high risk, endoscopic stenting is optimal as a less traumatic intervention. Thus, the choice of decompression method should be based not on the invasiveness of the procedure, but on the patient's predicted ability to tolerate it.

The clinical significance of the results obtained lies in the transition from empirical choice of palliative intervention to personalized treatment tactics. The proposed approach allows minimizing the risk of postoperative decompensation, preserving the possibility of systemic therapy and rationally using the potential of the long-term decompression effect of biliodigestive anastomoses.

The results obtained showed that the traditional opposition of open biliary-digestive bypass and endoscopic stenting as «more traumatic» and «less invasive» methods is clinically simplified. The frequency

of complications and mortality was determined not by the type of intervention, but by its correspondence to the patient's physiological reserve at the time of decompression. It was the exceeding of this reserve that led to the development of multiple organ failure and fatalities, while with an adequate ratio of the traumatic nature of the procedure and the patient's condition, even more extensive interventions were accompanied by acceptable results and provided a longer decompression effect. Thus, the obtained data allowed us to reject the null hypothesis and indicate that the choice of the biliary decompression method should be based on the prognosis of the tolerability of the intervention by a specific patient, and not on its formal minimal invasiveness. This justifies the use of a prognostically oriented approach as the basis of personalized treatment tactics.

CONCLUSIONS

1. Early postoperative outcomes are determined by the balance between the traumatic nature of the intervention and the patient's functional reserve, which justifies the need for a risk-based choice of biliary decompression method.

2. The use of the SEMS biliary system stenting procedure to restore the biliary-digestive bile passage, compared with the traditional surgical technology of biliary-digestive bypass, is accompanied by a reduction in the complication rate by 13.3% ($p = 0.03$) and mortality by 7.5% ($p = 0.04$).

3. Commonly accepted prognostic scales (ASA, P-POSSUM, ACS NSQIP) have limited predictive value for determining the immediate outcomes of biliary decompression, as they do not take into account cholestasis-induced organ dysfunction.

4. The developed local scale provides reliable prediction of postoperative complications and mortality and allows stratifying patients according to the level of surgical risk. For the prediction of severe complications, the threshold was ≥ 9 points (sensitivity 100%, specificity 85.1%), for the prediction of mortality – ≥ 12points (sensitivity 100%, specificity 93.9%).

Perspectives for further research. Further research should combine the capabilities of known technologies in order to provide a long-term effect of eliminating complications of the cancer process (obstructive jaundice and duodenal obstruction) with minimal trauma, thereby creating conditions for combined treatment of patients that should be effective regardless of the stage of cancer spread.

COMPLIANCE WITH ETHICAL REQUIREMENTS

he study was conducted in accordance with the main provisions of the Declaration of Helsinki of 1975, as revised in 2000, and the Council of Europe Convention on Human Rights and Biomedicine (2007). The Bioethics Commission of the Bogomolets National Medical University approved all medical procedures. All manipulations, endoscopic and surgical interventions were performed after the patients signed the corresponding informed consent for surgical treatment.

Study limitations. Limitations of the study include its single-center nature, the dependence of endoscopic outcomes on operator experience, and the small number of complications and the absence of mortality in the fatal event group in the SEMS group, which limits the accuracy of mortality estimates. Further external validation of the scale in independent samples is necessary.

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No benefit in any form has been received and will be received from a commercial party related directly or indirectly to the subject matter of this article. The authors declare no conflict of interest regarding the publication of this article.

AUTHOR CONTRIBUTIONS

Bezrodnyi B. H.[A, B, D, F]

Kolosovych I. V.[B, D, F]

Hanol I. V.[B, C, F]

Sydorenko R. A.[B, C, F]

Tsyhanok A. M.[B, F]

Chemodanov P. V.[B, F]

Kondratiev D. S.[C, F]

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Резюме

ВИБІР ТАКТИКИ ПАЛІАТИВНОЇ ДЕКОМПРЕСІЇ БІЛІАРНОЇ СИСТЕМИ ПРИ НЕРЕЗЕКТАБЕЛЬНОМУ РАКУ ГОЛОВКИ ПІДШЛУНКОВОЇ ЗАЛОЗИ НА ОСНОВІ ПРОГНОЗУ ПІСЛЯОПЕРАЦІЙНИХ РЕЗУЛЬТАТІВ

Борис Г. Безродний, Ігор В. Колосович, Ігор В. Ганоль, Роман А. Сидоренко, Андрій М. Циганок, Павло В. Чемоданов, Денис С. Кондратьєв

Національний медичний університет імені О. О. Богомольця, м. Київ, Україна

Вступ. Сучасні рекомендації орієнтовані переважно на визначення показань до системної терапії і розглядають біліарну декомпресію як етап підготовки до її проведення. Проте існуючі шкали оцінюють переважно прогноз виживаності та переносимість хіміотерапії, але не дозволяють прогнозувати безпосередні результати декомпресійного втручання.

Мета. Розробити диференційований підхід до вибору тактики і методів біліарної декомпресії у хворих на нерезектабельний рак головки підшлункової залози, ускладнений обструктивною жовтяницею, на основі прогнозу ранніх післяопераційних результатів.

Матеріали та методи. У дослідження були включені результати лікування 107 хворих на нерезектабельний рак головки підшлункової залози, ускладнений обструктивною жовтяницею, що були розподілені на дві групи в залежності від обраної тактики лікування: група відкритих біліодигестивних шунтуючих операцій (група порівняння, n = 53) та група ендоскопічного транспапілярного встановлення SEMS (основна група, n = 54).

Результати. Ранні післяопераційні результати визначаються балансом між травматичністю втручання та функціональним резервом пацієнта, що обґрунтовує необхідність ризик-орієнтованого вибору методу біліарної декомпресії. Використання з метою відновлення біліодигестивного пасажу жовчі процедури стентування біліарної системи SEMS у порівнянні із традиційною хірургічною технологією біліодигестивного шунтування супроводжується зменшенням питомої ваги ускладнень на 13,3 % (p = 0,03), а летальності на 7,5% (p = 0,04). Загальноприйняті прогностичні шкали (ASA, P-POSSUM, ACS NSQIP) мають обмежену прогностичну цінність для визначення безпосередніх результатів біліарної декомпресії, оскільки не враховують холестаз-індуковану органну дисфункцію.

Висновки. Розроблена локальна шкала забезпечує достовірне прогнозування післяопераційних ускладнень і летальності та дозволяє стратифікувати пацієнтів за рівнем хірургічного ризику. Для прогнозу важких ускладнень поріг становив ≥ 9 балів (чутливість 100 %, специфічність 85,1 %), для прогнозу летальності – ≥ 12 балів (чутливість 100 %, специфічність 93,9 %).

Ключові слова: **рак підшлункової залози, обструктивна жовтяниця, протезування жовчних проток**

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