

UDC 616.37-006-021-071-092-089.168:364.62(02)
<https://doi.org/10.31612/2616-4868.4.2025.02>

CHOICE OF TACTICS FOR PALLIATIVE SURGICAL TREATMENT OF PATIENTS WITH UNRESECTABLE PANCREATIC HEAD CANCER COMPLICATED BY OBSTRUCTIVE JAUNDICE IN CASES OF HIGH SURGICAL AND ANESTHETIC RISK

Borys H. Bezrodnyi, Ihor V. Kolosovych, Ihor V. Hanol, Viktor P. Slobodanyk, Ihor V. Cherepenko, Pavlo V. Chemodanov, Yevhenii O. Nesteruk

Bogomolets National Medical University, Kyiv, Ukraine

Abstract

Introduction. The disadvantages of open operations to eliminate biliary obstruction and duodenal obstruction in patients with unresectable pancreatic head cancer are a high incidence of postoperative complications (up to 40%) and mortality (up to 15–20%). When installing self-expanding metal stents (SEMS), the incidence of complications and mortality varies within 1–3%. However, during surgical bypass operations, effective drainage of the biliary system and stomach lasts for more than a year, and SEMS are subject to obstruction with the development of cholangitis 6 months after installation.

Aim. To improve the results of palliative surgical treatment of patients with unresectable pancreatic head cancer complicated by obstructive jaundice in cases of high surgical and anesthetic risk.

Materials and methods. The results of palliative surgical treatment of two groups of patients with unresectable pancreatic head cancer complicated by obstructive jaundice with a physical status of ASA-PS III were analyzed. The retrospective cohort (comparison group) included 18 patients who underwent biliary-digestive drainage by open surgical operations. The prospective cohort (main group) included 26 patients who underwent endoscopic stenting of the biliary system with SEMS.

Results. The treatment strategy for patients consists of gradually eliminating biliary and duodenal obstruction, and managing multiorgan failure by implementing an individualized treatment plan for patients developed by specialists from multidisciplinary medical groups. In cases of diagnosis of acute carcinomatous pancreatitis in patients with signs of hypertension of the main pancreatic duct, it is advisable to perform its transpapillary drainage with stenting of the common bile duct. In patients with physical status of ASA-PS III and Karnofsky index ≥ 70 (2 points on the ECOG scale), chemotherapy with gemcitabine tended to increase survival by 28.2% ($p=0.16$).

Conclusions. 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 52.6% ($p=0.0007$) and mortality by 31.2% ($p=0.01$).

Keywords: cancer of the pancreas, obstructive jaundice, prosthetics of the biliary system, biliary stenting, stenting of the biliary system, SEMS, bilio-digestive bypass

INTRODUCTION

The goal of palliative surgical treatment of patients with unresectable pancreatic head cancer (PCH) is to eliminate complications of the cancer process – biliary obstruction and duodenal obstruction. These tasks are solved by biliodigestive, gastrodigestive or double biliogastrodigestive bypass surgery, or stenting of the

common bile duct and duodenum with self-expanding metal stents (SEMS) [1]. Serious disadvantages of open surgical operations are the high frequency of postoperative complications (up to 40%) and mortality (up to 15–20%) [2, 3]. In operations with the installation of SEMS, the percentage of complications and mortality varies within 1–3% [1, 4]. Therefore, such minimally invasive interventions have gained priority. However, surgical

bypass operations provide effective drainage of the biliary system and stomach and a satisfactory quality of life for patients lasting more than a year. SEMs are subject to obstruction, deformation with a decrease in the ability to evacuate bile and the development of cholangitis within 6 months after installation, which reduces the quality of life and requires repeated hospitalizations and reconstructive interventions [2, 4]. With the introduction of the latest cancer treatment technologies, patient survival after surgical palliation can exceed one year, which maintains the value of classical surgical interventions with bypass anastomoses as the operations of choice [2].

AIM

To improve the results of palliative surgical treatment of patients with unresectable pancreatic head cancer complicated by obstructive jaundice in cases of high surgical and anesthetic risk.

MATERIALS AND METHODS

The bidirectional, cohort, observational study, which consisted of a retrospective and prospective cohort, included 44 patients with unresectable pancreatic head cancer complicated by obstructive jaundice with

physical status according to the American Society of Anesthesiologists Physical Status III (ASA-PS-III) classification, who were treated in the clinics of the Department of Surgery No. 2 of Bogomolets National Medical University for the period 2015–2023. Of these, 18 patients who underwent biliodigestive drainage through open surgical interventions were included in the retrospective cohort (comparison group). Out of the total, 26 patients who underwent endoscopic transpapillary SEMs stenting of the biliary system were included in the prospective cohort (main group). The inclusion criteria for the study were: patients with unresectable, metastatic pancreatic head cancer stage IV (T1-4N0-2M1, complicated by obstructive jaundice, elderly and senile male and female individuals (according to the WHO age classification) with a physical status of ASA-PS III. Histologically, the tumors in all patients were identified as ductal adenocarcinomas. The prevalence and resectability of pancreatic tumors were determined according to the NCCN (2015–2024) and ESMO (2019–2023) recommendations based on a comparison of clinical, laboratory, and radiographic examination data. The groups were representative in terms of age, sex, comorbid pathology, level of hyperbilirubinemia, extent of cancer, histological characteristics of tumors, and indications for surgical treatment ($p > 0.05$) (Table 1).

Table 1

Main clinical characteristics of patients with pancreatic head cancer upon hospitalization

Indicators	Comparison group (n=18)	Main group (n=26)	p
Age, years	67.3±7.42	68.4±8.17	0.65
Sex			
Men	12 (66%)	17 (65.38%)	0.96
Women	6 (34%)	9 (34.62%)	0.96
Duration of jaundice, days	21.8±0.26	23.5±0.35	<0.0001
Total serum bilirubin, $\mu\text{mol/l}$	257.4±19.5	264.1±22.8	0.31
Hemoglobin, g/l	108±7.11	112±9.26	0.13
Albumin, g/l	31±4.32	30±4.96	0.49
Creatinine, $\mu\text{mol/L}$	146.3 ± 20.71	167.1 ± 21.35	0.002
Comorbidities			
Ischemic heart disease	18 (100%)	26 (100%)	1.0
Chronic obstructive pulmonary disease	6 (33.3%)	9 (34.6%)	0.92
Diabetes mellitus	12 (66.3%)	19 (73.1%)	0.63

The surgical treatment strategy in the study groups was based on the use of individual multi-stage treatment programs, which were created and implemented by specialists of multidisciplinary medical groups taking into account the specifics of the health status of each patient. The first step was to determine the severity of the health status and the risk of surgical intervention for each patient (Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM) scale [5]. The treatment program was divided into four consecutive stages, the implementation of each stage was a preparation for the next one.

The organization and volume of medical care at the first stage of treatment of patients in both groups were

the same. All patients were hospitalized to the intensive care unit. A detailed examination was performed, along with correction of homeostasis disorders and preparation for anesthesia and surgery. The diagnostic program included determining the localization and spread of the cancer process, the level, degrees of obstruction of the biliary system and the severity of secondary acute liver failure (ALF) (according to the criteria of the European Association for the Study of the Liver, 2023), cholangitis (ACh) (according to the criteria of the Tokyo Guidelines, 2018), the severity of comorbid pathology (according to the Charlson comorbidity index), the presence of hepatorenal and hemorrhagic syndromes, duodenal stenosis (DS), carcinomatous pancreatitis (CP), portal hypertension (PH) [3, 6, 7]. The main syndromes that

determined the severity of the patients' health condition were ALF, and ACh. Moreover, ALF and ACh were diagnosed in all patients in both groups.

The main differences in surgical tactics were that after preoperative preparation, patients in the comparison group (18 people) underwent preoperative biliary drainage (second stage of treatment). Minimally invasive procedures were used, namely, percutaneous, transhepatic cholangiostomy was performed in 12 patients, and transpapillary stenting of the common bile duct with 8-mm-diameter plastic stents was performed in 6 more patients after endoscopic retrograde cholangiopancreatography (ERCP). The next (third) stage of treatment for patients in the main group, was aimed at stabilizing the general health status, eliminating ACh and the phenomena of multiorgan dysfunction/insufficiency that were exacerbated in the case of postdecompression syndrome, which was diagnosed in 12 patients (66.7%) of the main group. After 18–23 days, the patients underwent the fourth stage of treatment – biliodigestive bypass surgery. In particular, 12 patients underwent biliodigestive bypass by performing a retrocaval cholecystojejunostomy with an isolated Brown's jejunal loop. Another 6 patients underwent end-to-side Roux-en-Y hepaticojejunostomy with an isolated Roux-en-Y jejunal loop up to 50 cm in length and end-to-side interloop jejunojejunal anastomosis.

The treatment program of the main group of patients (26 people) differed in that the obstruction of the biliary system was relieved not by open surgical operations, but by endoscopic installation of transpapillary SEMs. Due to the peculiarities of the surgical anatomy of the duodenum, attempts to perform ERCP in two patients were unsuccessful. In these cases, the technology of biliodigestive prosthesis (choledochoduodenostomy) under EUS guidance (EUSCDS) was used. In addition, among the patients of the main group, in addition to

obstructive jaundice, 4 people were diagnosed with acute CP, and 5 people with DS. After preoperative preparation for urgent indications (within 24–48 hours after hospitalization), 20 patients after ERCP underwent transpapillary stenting of the common bile duct using SEMs (model Boston Scientific WallSTENT Biliary Uncovered, 10–60 mm). It should be noted that 5 of the 20 aforementioned patients developed progressive DS in the long-term postoperative period, due to which they underwent duodenal prosthesis with HANAROSTENT Duodenum/Pylorus NDSL20-140-230 stents.

In the studied groups, a comparative analysis of the frequency of intraoperative adverse events (surgical errors and complications during operations), postoperative complications, mortality and patient survival was conducted. The frequency of intraoperative adverse events was classified according to R. M. Satava, 2005, postoperative complications and mortality were assessed according to the Clavien–Dindo classification modified by S. M. Strasberg, 2009 [8, 9].

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

RESULTS

When comparing the results of surgical treatment of patients in both groups, it was found that the proportion of complications in the early postoperative period in patients in the comparison group was 83.3% versus 30.7% in the main group ($\chi^2=11.52$, 95% CI 22.96-70.50, $p=0.0007$), and mortality was 38.9% and 7.7% ($\chi^2=6.21$, 95% CI 6.37-54.36, $p=0.01$), respectively (Table 2).

Table 2

Postoperative complications and outcomes

Indexes	Comparison group (n=18)	Main group (n=26)	p
Surgical complications (Accordion Severity Grading System scale)			
Total number of complications	15 (83.3%)	8 (30.7%)	0.0007
Grade I	2 (11.1%)	3 (11.5%)	0.96
Grade II	5 (22.2%)	2 (7.7%)	0.17
Grade III	3 (16.6%)	1 (3.8%)	0.15
Grade IV	1 (5.55%)	0	0.22
Grade V	1 (5.55%)	1 (3.8%)	0.78
Grade VI	6 (33.3%)	1 (3.8%)	0.009
Management of complications			
Surgical revision of hepaticojejunostomy	1 (5.5%)	0	0.22
Surgical revision of postoperative wound	7 (38.9%)	0	0.0006
Radiological procedures	2 (11.1%)	0	0.08
Intravenous drip	4 (22.2%)	8 (30.7%)	0.53
Hospital stay (days)	17,4 ± 1,3	6,8 ± 0,53	<0.0001
Hospital readmission within 90 days	4 (22.2%)	5 (19.2%)	0.81
In hospital-mortality	7 (38.9%)	2 (7.7%)	0.01

Late postoperative complications requiring rehospitalization within 90 days after surgical correction of jaundice were observed in 4 (22.2%) patients in the comparison group and 5 (19.2%) patients in the main group ($\chi^2=0.058$, 95% CI $-19.84-28.36$, $p=0.81$). Patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 (19 patients) were indicated for gemcitabine monochemotherapy (4 patients in the main group and 15 in the experimental group). The remaining 16 patients with a status

of 3 (7 patients in the main group and 9 in the experimental group) were assigned palliative care. Chemotherapy treatment was started on the 5th week after correction of obstructive jaundice. As a result of a comparative analysis of the survival of patients in both subgroups depending on the fact of chemotherapy, it was found that in patients with a status of ECOG 2 points it was 4.32 ± 1.45 (range 3.81-1.93) months, compared to 3.37 ± 1.81 (range 2.80-4.23) ($T=0.31$, $p>0.4$) months in patients with a status of ECOG 3 points (Figure 1).

Survival proportions: Survival of Two groups

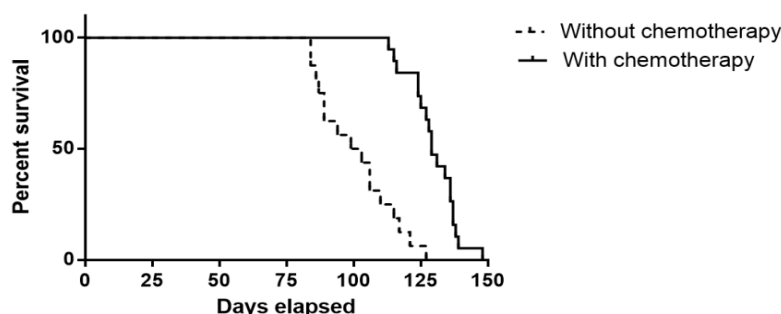


Figure 1. Survival of patients in two groups depending on chemotherapy.

DISCUSSION

In 2020, the results of a meta-analysis were published, which demonstrated the benefits of dual biliary and duodenal prosthesis in malignant biliary obstruction, including the use of two-stage technology [10, 11]. In our study, decompression of the biliary system was performed in all patients by surgical bypass or prosthesis with the installation of SEMs. Given the initial severe condition of the patients, surgical bypass was preceded by preoperative drainage of the biliary system. DS in patients in both groups was corrected exclusively by the installation of SEMs after the resolution of ALF manifestations. That is, a «hybrid» surgical technology was used (biliodigestive bypass and duodenal prosthesis). We found that the use of SEMs biliary stenting compared to traditional surgical technology was accompanied by a reduction in the complication rate by 52.6% ($\chi^2=11.52$, 95% CI 22.96-70.50, $p=0.0007$), and a reduction in mortality by 31.2% ($\chi^2=6.21$, 95% CI 6.37-54.36, $p=0.01$).

The prognosis of the expected survival of patients was determined by the Karnofsky index [12]. Literature data indicate that if the Karnofsky index < 80 , then the predicted survival of patients with pancreatic head cancer is 5.91 ± 2.32 months, and if the index > 80 – 9.23 ± 2.06 months [13]. In our study, among 35 patients who survived after correction of obstructive jaundice, 19 patients had a Karnofsky index $=70$ (corresponding to ECOG 2 points), and 16 had a Karnofsky index < 60 (corresponding to ECOG 3 points). At the same time, the actual survival in the first case was 4.32 ± 2.45 months, and in the second – 3.37 ± 1.81 months. Since in cases

of biliodigestive shunting, the drainage function of the anastomoses is preserved for more than a year, and in cases of transpapillary stenting with SEMs – for about 6 months, it becomes clear that in cases where the predicted life expectancy of patients is 5-6 months, it is justified to restore biliodigestive bile passage by transpapillary prosthesis of the common bile duct using SEMs or by EUS-guided choledochoduodenostomy.

In total, 35 patients (79.5%) out of 44 patients in both groups survived after surgery. When choosing chemotherapy as the first-line treatment for patients with metastatic pancreatic cancer and ECOG status of 2 points, in addition to gemcitabine (monotherapy regimen), its combination with capecitabine or erlotinib is possible [14]. Chemotherapy treatment for patients with ECOG status of 2 points was accompanied by a tendency to increase survival by 28.2% ($p=0.16$), which occurred due to a temporary slowdown in the growth rate of the cancer tumor and its metastases in 31.6% of patients.

CONCLUSIONS

1. The operation of choice in the surgical treatment of patients with unresectable pancreatic head cancer complicated by obstructive jaundice is the restoration of physiological bile passage by endoscopic stenting of the common bile duct with self-expanding metal stents.

2. In cases of diagnosis of acute carcinomatous pancreatitis in patients with signs of hypertension of the main pancreatic duct, it is advisable to perform its transpapillary drainage with stenting of the common bile duct using self-expanding metal stents.

3. The use of the biliary system stenting procedure with SEMS 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 52.6% ($p=0.0007$) and mortality by 31.2% ($p=0.01$).

4. In patients with ASA-PS III physical status and Karnofsky index ≥ 70 (2 ECOG points), chemotherapy with gemcitabine showed a trend toward an increase in survival by 28.2% ($p=0.16$).

Perspectives for further research. Further research should combine the capabilities of known technologies in order to provide a long-term effect in 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 progression.

COMPLIANCE WITH ETHICAL REQUIREMENTS

The 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. Before the research

began, all participants were given detailed information about the objectives, methods, possible risks, and benefits of taking part. All participants signed consent forms prior to the start of data collection. Participants had the right to withdraw from the study at any point without explanation. For studies involving minors or individuals with limited legal capacity, informed consent was obtained from their legal guardians. In accordance with confidentiality standards, all data was collected anonymously and processed in compliance with data protection regulations.

FUNDING AND CONFLICT OF INTEREST

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}

Slobodanyk V. P.^{E, B}

Cherepenko I. V.^{E, B}

Chemodanov P. V.^{E, B}

Nesteruk Y. O.^{B, C}

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Резюме

ВИБІР ТАКТИКИ ПАЛІАТИВНОГО ХІРУРГІЧНОГО ЛІКУВАННЯ ХВОРИХ НА НЕРЕЗЕКТАБЕЛЬНИЙ РАК ГОЛОВКИ ПІДШЛУНКОВОЇ ЗАЛОЗИ, УСКЛАДНЕНИЙ ОБСТРУКТИВНОЮ ЖОВТЯНИЦЕЮ, У ВИПАДКАХ ВИСОКОГО ХІРУРГІЧНОГО ТА АНЕСТЕЗІОЛОГІЧНОГО РИЗИКІВ

Борис Г. Безродний, Ігор В. Колосович, Ігор В. Ганоль, Віктор П. Слободяник, Ігор В. Черепенко, Павло В. Череданов, Євген О. Нестерук

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

Вступ. Недоліками відкритих операцій усунення біліарної обструкції та дуоденальної непрохідності у хворих на нерезектабельний рак головки підшлункової залози є висока частота післяопераційних ускладнень (до 40%) та летальність (до 15–20%). При встановленні саморозширюваних металевих стентів (Self-Expanding Metal Stents – SEMS) частота ускладнень та летальності коливається в межах 1–3%. Однак при операціях хірургічного шунтування ефективного дренивання біліарної системи і шлунку триває понад рік, а SEMS вже через 6 місяців після встановлення піддаються обструкції з розвитком холангіту.

Мета. Покращити результати паліативного хірургічного лікування хворих на нерезектабельний рак головки підшлункової залози, ускладнений обструктивною жовтяницею, у випадках високого хірургічного та анестезіологічного ризику.

Матеріали та методи. Проаналізовано результати паліативного хірургічного лікування двох груп хворих на нерезектабельний рак головки підшлункової залози, ускладнений обструктивною жовтяницею, із фізичним статусом градації ASA-PS III. До ретроспективної когорти (група порівняння), включено 18 хворих, яким білідигестивне дренивання виконано відкритими хірургічними операціями. До проспективної когорти (основна група) включено 26 пацієнтів, яким було виконано ендоскопічні операції стентування біліарної системи з використанням SEMS.

Результати. Тактика лікування хворих полягає у поетапному усуненні обструкції біліарної системи, поліорганної недостатності, дуоденальної непрохідності шляхом реалізації індивідуального плану лікування хворих, розробленого фахівцями мультидисциплінарних лікарських груп. У випадках діагностики у хворих гострого канцероматозного панкреатиту з ознаками гіпертензії головної панкреатичної протоки доцільно проводити її транспапілярне дренивання із стентуванням загальної жовчної протоки. У пацієнтів із фізичним статусом градації ASA-PS III і індексом Karnofsky ≥ 70 (2 бали за шкалою ECOG) і проведенням хіміотерапії гемцитабіном відмічена тенденція до збільшення виживаності на 28,2% ($p=0,16$).

Висновки. Використання з метою відновлення білідигестивного пасажу жовчі процедури стентування біліарної системи за допомогою SEMS у порівнянні із традиційною хірургічною технологією білідигестивного шунтування супроводжується зменшенням питомої ваги ускладнень на 52,6% ($p=0,0007$), а летальності на 31,2% ($p=0,01$).

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

Received: 28.02.2025

Accepted: 8.04.2025