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SURGICAL TREATMENT CHOICE FOR PATIENTS WITH NON-RESECTABLE PANCREATIC HEAD CANCER

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Abstract

Introduction. Due to the late diagnosis of the pancreatic head cancer, up to 80% of patients are subjected only to palliative surgical treatment to eliminate complications, i.e., obstructive jaundice and stenosis of the duodenum by a tumor, through a hepaticojejunostomy or transpapillary stenting of the common bile duct with self-expanding metal stents (SEMS). The disadvantages of open surgery include a high incidence of postoperative complications and mortality, and those of the transpapillary stenting – obstruction of up to 40% of stents in 6-8 years after implantation. With modern polychemotherapy, the survival rate of patients exceeds a year, when the drainage function of stents is impaired, and surgical bypass functions without complications. Therefore, it is relevant to personalize the choice of treatment for the patients.
Aim. To improve the results of palliative surgical treatment of patients with unresectable pancreatic head cancer, complicated by obstructive jaundice, by improving the choice of methods and techniques of surgical interventions.
Materials and methods. The randomized prospective study is based on the analysis of the obstructive jaundice treatment outcomes after the Roux hepaticojejunostomy with prophylactic gastrojejunostomy (main group, 53 patients) or transpapillary stenting of the common bile duct with SEMS (study group, 54 patients) were performed. The authors evaluated the effect of multiple organ failure and the Karnofsky index on the choice of patient treatment strategy, on the immediate and remote results, as well as the quality of life of patients in the postoperative period, using the EORTC QLQ-C30 V.3 and EORTC QLQ-PAN26 questionnaires.
Results. The use of self-expanding metal stents for internal drainage of the biliary system, compared with open surgery of double bypass reduces the incidence of postoperative complications by 29.9% ($\chi 2$=13.7, 95% CI 14.38-44.08, p=0.0002), and mortality by 7. 5% ($\chi 2$=4.16, 95% CI – 0.05-17.79, p=0.04). However, the course of the remote postoperative period (from 8 to 11 months) is complicated in 11.1% of cases by acute, in 37.1% by chronic recurrent cholangitis, and in 7.4% of cases an obstructive duodenal obstruction develops, which deteriorates the quality of patients' lives, and requires re-hospitalization and reconstructive interventions.
Conclusions. With a Karnofsky index <80, it is advisable to perform stenting of the common bile duct with SEMS, with a Karnofsky index >80, double biliodigestive and prophylactic gastrodigestive bypass surgery should be performed. When multiorgan dysfunction and cholangitis develop against the obstructive jaundice, the treatment consists of two stages, the first – transpapillary biliary drainage with plastic stents, the second – elective surgical intervention.

Keywords: **pancreatic head cancer, obstructive jaundice, stenting of the biliary system**

INTRODUCTION

Due to the late diagnosis of pancreatic head cancer, up to 80% of patients with it are only subjected to palliative surgical treatment, to eliminate complications: obstructive jaundice and duodenal stenosis caused by a tumor, either by hepaticojejunostomy surgery or by transpapillary stenting of the common bile duct with self-expanding metal stents (SEMS) [1, 2, 3]. The stenting of the common bile duct with SEMS has become a priority technology, as it is associated with a lower incidence of postoperative complications, lower mortality, and high

economic efficiency [1, 3]. However, in 4-6 months after stenting, in 20-40% of cases, obturation of stents by the tumor, bile acid salts, bacterial biofilms, as well as recurrent jaundice and acute cholangitis may develop, which reduces the life quality of patients, interferes with chemotherapy treatment, requires repeated hospitalization and complex reconstructive interventions [1, 4, 5]. In addition, regarding high efficiency of modern polychemotherapy (FOLFIRINOX, NAB-paclitaxel/gemcitabine, gemcitabine/capecitabine, liposomal irinotecan, etc.), and the use of multimodal treatment technologies, patients' survival after palliative interventions has increased from 6-7 to 8-12 months [6, 7]. Therefore, it is relevant to compare the results of open surgical operations with minimally invasive technologies of the common bile duct and duodenum transpapillary stenting.

AIM

To improve the results of palliative surgical treatment of patients with unresectable pancreatic head cancer by improving the choice of strategy and techniques of surgical interventions.

MATERIALS AND METHODS

The randomized prospective study included a total of 107 patients with locally advanced and unresectable pancreatic head cancer, complicated by obstructive jaundice, without signs of duodenal obstruction. The patients were treated in the clinics of the Department of Surgery No. 2 of the Bogomolets National Medical University during 2016-2023. They were diagnosed with the pancreatic head cancer, the stage determined by the recommendations of the National Comprehensive Cancer Network (NCCN, 2015-2023), the European Society for Medical Oncology (ESMO, 2019, 2022), and classifications of the American Joint Committee on Cancer (American Joint Committee on Cancer [AJCC], editions VII-VIII, 2016-2022). According to these documents, stage III head cancer (T1-3N2M0 and T4N0-2M0) was verified in 75 patients and stage IV (T1-4N0-2M1) – in 32 patients. The cancer was histologically identified as ductal adenocarcinoma in all patients (WHO, 2000). The authors determined the resectability of the head tumors comparing the data from clinical, laboratory and radiological examination, according to the recommendations of the NCCN (2015-2023) and ESMO (2019, 2022). At the present moment, spiral multidetector contrast computed tomography (CT) of the abdominal cavity, chest and pelvis, including the late arterial and portal venous phases and thin axial sections, is the best method for diagnosing and staging of ductal adenocarcinoma.

According to the treatment strategy (open surgical interventions, or endoscopic operations with transpapillary stenting of the biliary system using SEMS), the patients were randomized into the main group (53 people) or the study group (54 people). At the time of hospitalization, the patients of both groups did not differ significantly in terms of age and gender characteristics, level of hyperbilirubinemia, cancer spread, indications for surgical treatment, comorbid pathology, and histological characteristics of tumors ($p>0.05$) (Table 1).

Table 1

The main clinical characteristics of patients in the study and main group

Characteristics	Main group (n=53)	Study group (n=54)	p
Age (M±m)	67.3±5.4	68.1±4.9	0.42
Gender 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
Histological diagnosis	Pancreatic adenocarcinoma 53 (100%)	Pancreatic adenocarcinoma 54 (100%)	-
TNM stage Stage III (T1-3N2M0 and T4N0-2M0)	 38 patients	 37	 -
IV stage (T1-4N0-2M1)	15 patients	17	-
Associated diseases			
Hypertensive disease	53 (100%)	53 (98.1%)	0.31
Diabetes	19 (35.8%)	16 (30.2%)	0.53
COPD	2 (3.8%)	2 (3.7%)	0.97
CVA – cerebrovascular accident;	3 (5.6%)	2 (3.7%)	0.64
IHD – ischemic heart disease	27 (50.9%)	29 (53.7%)	0.77

Abbreviation: COPD – chronic obstructive pulmonary disease; CVA – cerebrovascular accident; IHD – ischemic heart disease.

During the examination at hospitalization, eleven patients of the main group and eight patients of the study group were diagnosed with multiple organ failure (hepatorenal and hemorrhagic syndromes), therefore, the surgery was performed in a two-stage strategy. The first stage involved endoscopic transpapillary stenting of the choledoch with plastic stents, followed by intensive therapy of the patients. After stabilization of the clinical condition and correction of homeostasis, planned surgical interventions were performed.

Obstructive jaundice was corrected in patients of the main group by Roux-en-Y «end-to-side» hepaticojejunostomy, on endobiliary drainage with a Roux-isolated loop of the jejunum, up to 50 cm long, and preventive retrocolic, isoperistaltic gastrojejunostomy «side-to-side», and an interloop isolating sphincter «end to side». A probe for enteral nutrition entered the jejunum through a Witzel-Stamm-Kader gastrostomy. We performed hepatojejunoanastomoses with knotted sutures of 4.0 PDS or Vicryl, using careful technique, considering the mucous membranes of the bile duct and jejunum, to prevent their local swelling, bile duct obstruction, biliary hypertension, and anastomotic sutures failure. During the open surgical interventions, eight patients, who did not respond well to pharmacological pain treatment, underwent intraoperative «chemical splanchnicectomy» by 50% alcohol blockade of the abdominal ganglion, according to Lillemoe K. D. [8]. The patients in the study group underwent transpapillary stenting of the common bile duct using SEMS performed by Boston Scientific WallSTENT Biliary Uncovered 10-60 mm. If correction of duodenal stenosis was necessary, we used HANAROSTENT Duodenum/ Pylorus NDSL20-140-230 stents. Then we compared the intraoperative adverse events incidence (surgical errors and complications during operations), postoperative complications, mortality and patient survival. The incidence of intraoperative adverse events was classified according to Satava R. M., 2005 [9], postoperative complications and mortality – according to the Clavien–Dindo classification [10, 11, 12], modified by Strasberg S. M., 2009 [13]. The study evaluated complications of the early, late and remote postoperative period.

The assessment of the patients' quality of life (QL) is the main criterion for determining the effectiveness of medical care in palliative medicine. Hence, we analyzed the data from the questionnaires of the European Organization for Research and Treatment Cancer EORTC QLQ-C30 V.3, in patients of both groups [14] and EORTC QLQ-PAN26 [15, 16, 17]. The obtained results were generalized according to Wilson-Mann-Whitney. Tables 3 and 4 contain values of the life quality of both groups. Depending on the Karnofsky index and the corresponding values of the ECOG (Eastern Cooperative Oncology Group) scale [18, 19], we analyzed the effectiveness of the patient treatment strategy. The research data were statistically treated using Microsoft Excel and the analysis software SPSS 20.0. The reliability of the differences between the average values was evaluated using non-parametric criteria: for related populations – the Wilcoxon test, for independent ones – Wilson-Mann-Whitney; $p<0.05$ was considered the reliability criterion.

RESULTS

After the comparative analysis of the surgical treatment outcomes in both groups (Table 2), the specific gravity of early postoperative complications in the main group was 37.3% against 7.4% in the study group ($\chi2=13.2$, 95% CI 14,38-44.08, $p=0.0002$). In the main group, complications developed in 20 people, of which 14 cases were the classes I-III (mild complications that were effectively eliminated by pharmacotherapy and minimally invasive procedures): suppuration of the postoperative wound, pneumonia, intestinal paresis with gastrostasis, mild gastrointestinal bleeding, urinary retention, etc.). In 6 patients, the complications were classes IV-VI – severe complications, as a result of which 4 (7.6%) patients died, due to the acute liver failure (2), myocardial infarction (1), and pulmonary embolism (1). The other 2 patients were diagnosed with hepaticojejunal anastomosis suture insufficiency, which required re-laparotomy and drainage.

In the study group, complications (acute cholangitis) were observed in 4 (7.4%) patients. They were assigned to class II, as they required only pharmaceutical endoscopic and medical treatment (intravenous corrective therapy, antibiotic therapy). If the mortality among the patients of the main group was 7.5%, the study group showed zero mortality ($\chi2=4.16$, 95% CI –0.55-17.73, $p=0.04$). Thus, all complications of the early postoperative period in patients of the study group were mild.

During the analysis of intraoperative adverse events, the authors defined that in the main group, the reasons for the hepaticojejunoanastomosis suture insufficiency were excessive mobilization of the common bile duct, which led to ischemia and local necrosis of its wall. Postoperative intestinal paresis with enterohepatic reflux also contributed to the insufficiency of anastomotic sutures. Therefore, the surgeons should carefully operate the hepatoduodenal ligament, minding the anatomical characteristics. Complications of the late postoperative period, which required re-hospitalization within 90 days after surgical correction, were observed only among patients in the main group (6 patients, 11.4%). Intraoperative chemical «splanchnicectomy» of the abdominal ganglion, performed on 8 patients in the main group, achieved 100% effectiveness. A clinically significant reduction in pain intensity was observed within 9-10 weeks after the procedure. With the Karnofsky index <80 (status of 2 points according to ECOG), the life expectancy of patients in the main group was 5.91±2.32 months, the study group was 5.37±1.48 months ($p=0.15$), and with the Karnofsky index >80 (0-1 ECOG points) patients' survival times were 9.23±2.66 and 8.21±2.93 months, respectively ($p=0.06$). After surgery for obstructive jaundice, according to the recommendations of the chemotherapist, 57.1% (28/49) of patients of the main group and 66.6% (36/54) of patients of the study group underwent chemotherapy treatment (in 52 cases monochemotherapy with gemcitabine was used, in 12 – with gemcitabine plus oxaliplatin).

The terms of chemotherapy initiation after the surgery did not differ significantly between the groups (42.0±9.8 days vs. 39.1±6.7 days, p=0.06). The overall survival of patients in the main group averaged 8.5±1.7 (range 5-11) months, compared to 7.9±1.9 (range 5-10) months in patients in the study group, i.e., without a significant difference in survival between both groups (p=0.08). However, among 21 patients in the main group and 18 patients in the study group, who did not receive chemotherapy, the average survival was 7.5±0.6 and 6.8±0.7 months, respectively.

Table 2

Complications of the early postoperative period and mortality according to the Clavien–Dindo classification in the modification of SM Strasberg, (according to Severity Grading System scale, 2009)

Indicators	Main group (n=53)	Study group (n=54)	p
Postoperative complications (according to Severity Grading System scale)			
Total number of complications	20 (37.3%)	4 (7.4%)	0.0002
Class I	8 (15.1%)	–	0.002
Class II	4 (7.5%)	4 (7.4%)	0.98
Class III	2 (3.8%)	–	0.15
Class IV	2 (3.8%)	–	0.15
Class V	–	–	–
Class VI	4 (7.5%)	–	0.04
Treatment of complications			
Relaparotomy, revision of hepaticojejunal anastomosis	2 (3.8%)	–	0.15
Drainage of the abdominal cavity under ultrasound and CT control	4 (7.5%)	–	0.04
Sanitation and drainage of the postoperative wound, antibiotic therapy	4 (7.5%)		0.04
Intensive therapy in ICU conditions	4 (7.5%)	4 (7.4%)	0.98
Terms of hospitalization (M±m), days	14 ±2.1	3 ±0.8	<0.0001
Re-hospitalization within 90 days after discharge (number of patients)	6 (11.3%)	–	0.01
Postoperative mortality	4 (7.5%)	–	0.04

Chemotherapy treatment of 28 out of 49 patients of the main group (57.1%) and 36 out of 54 patients (66.6%) of the study group corresponded to the survival during 9.31±0.98 and 8.9±0.81 months, against the aforementioned 7.5±0.6 and 6.8±0.7 months without chemotherapy. In this way, chemotherapeutic treatment contributed to an increase in the survival of patients, but it should be remembered that the development of acute cholangitis or duodenal obstruction violated the regimens of chemotherapy administration. The survival in both groups, depending on the method of the obstructive jaundice management and application of chemotherapy, is shown in Figures 1 and 2.

Analysis of the results of surgery in both groups during the late and remote postoperative period (from 4 to 11 months) revealed that in patients of the main group, the biliodigestive and gastrodigestive bypasses functioned without incidents, for the remainder of their lives. However, in 6 (11.1%) patients after stenting of the biliary system using SEMS, in the period from 8 to 11 months after stenting, recurrences of jaundice and acute cholangitis were observed (according to the TG18 criteria). During the treatment of four of them, we performed repeated endoscopic stenting of the biliary system, in two cases the health condition was stabilized by endoscopic recovery of stents and antibiotic therapy, regarding the sensitivity of the bile microflora to antibiotics. In other 19 patients, in the period from 8 to 11 months after surgery, recurrent pain in the right hypochondrium with subfibrillation, tachycardia, loss of appetite, skin itching, relapsing jaundice with subicteric sclera were observed (hyperbilirubinemia ranged from 40.51 to 58, 3 μmol /l). Alkaline phosphatase activity increased by 26.8-33.67%, and ultrasound visualized an increase in the size of the liver, moderately enlarged, deformed intrahepatic bile ducts with thickened walls, which together with SEMS visualization corresponded to the diagnostic criteria of recurrent cholangitis [20, 21].

Intensive corrective therapy, antibiotic therapy, and endoscopic stent disinfection provided a positive, albeit short-term, effect (metastatic liver damage progressed). In 4 (7.4%) patients from the study group, the course of the disease was complicated by nausea, vomiting, feeling of heaviness in the epigastrium, and the progression of cachexia. According to the results of X-ray and fibrogastroduodenoscopy, the patients were diagnosed with stenosis of the duodenum due to a tumor of the pancreatic head. This complication was eliminated by intestinal stenting with duodenal SEMS. Thus, the procedure of stenting with SEMS in the biliary system during the remote postoperative period was complicated by acute cholangitis in 11.1% of cases, recurrent cholangitis in 37.1%, and obstructive duodenal obstruction in 7.4% of cases.

The data on the patients' quality of life are presented in Tables 3 and 4. As follows from Table 3, before surgical treatment, the indicators of the patients' life quality in the main group and the study group (assessment of the general health condition, five functional and eight symptomatic scales and one item, which refers to the financial consequences of the disease, did not differ significantly (p>0.05). We surveyed the patients 6 months after the surgical correction of obstructive jaundice, and established that 2 patients of the main group and 2 patients of the study group died from the cancer progression.

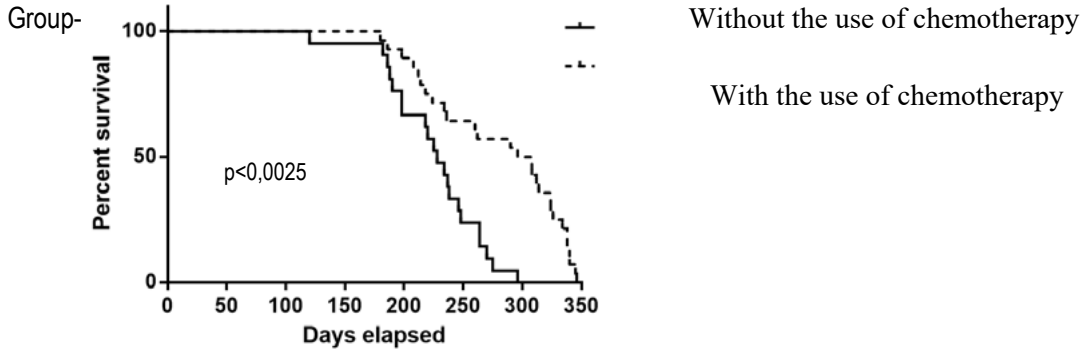

Figure 1. Survival of patients in the main group depending on chemotherapy.

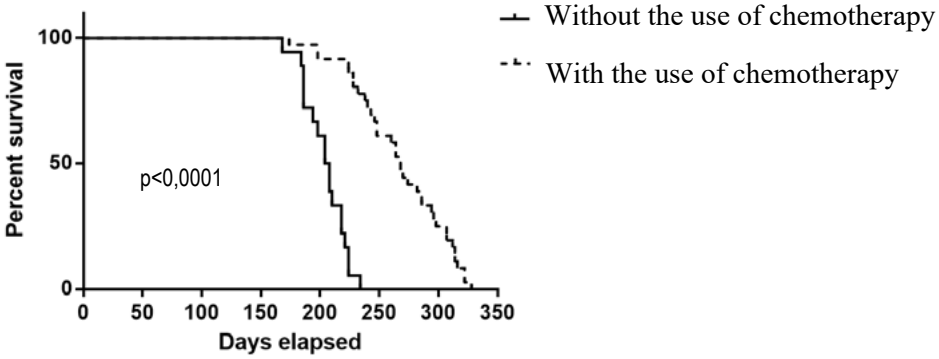

Figure 2. Survival of patients in the study group depending on chemotherapy.

Table 3

Assessment of the quality of life in patients of the main group and the study group, according to the data of the EORTC QLQ-C30 V.3 questionnaire

Indicators	Before surgical treatment	Terms after surgical treatment								
		6 months		8 months		9 months		10 months		
	Surgical intervention (n=53)	Stenting (n=54)	Surgical intervention (n=47)	Stenting (n=52)	Surgical intervention (n=25)	Stenting (n=26)	Surgical intervention (n=19)	Stenting (n=17)	Surgical intervention (n=14)	Stenting (n=9)
	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m
GHS/Ql Global health status/QoL	39.16±4.6	42.83±5.1	61.31±4.6	57.72±4.3	44.33±3.8	39.25±3.2	31.06±3.2	29.31±3.7	29.04±3.1	26.37±8.2
Functional scales										
PF2 Physical functioning	39.52±5.3	41.65±7.3	63.51±4.8	60.34±4.8	42.12±4.7	39.18±4.3	29.27±3.3	26.11±3.6	27.16±9.4	25.26±7.3
RF2 Role functioning	34.96±7.3	38.21±6.7	64.11±6.4	63.27±5.1	52.24±5.6	54.29±4.7	43.68±3.9	54.29±4.7	41.92±4.2	39.14±5.3
EF Emotional functioning	49.51±5.2	56.34±5.1	71.24±7.3	76.33±6.8	61.35±6.3	65.83±5.3	42.52±5.3	41.13±8.3	37.43±6.7	32.13±7.3
CF Cognitive functioning	58.65±4.3	63.4±5.5	69.37±5.8	71.34±5.2	51.43±4.9	59.16±6.4	48.36±4.1	42.93±7.4	43.19±5.6	39.27±6.5
SF Social functioning	44.17±4.9	48.96±4.1	67.15±5.1	69.01±6.3	48.12±5.3	43.72±5.9	39.11±3.2	22.16±4.9	25.62±7.3	21.14±5.8
Symptomatic scales and individual indicators										
FA Fatigue (10,12,18)/3	55.53±5.4	49.11±3.9	29.71±2.1	32.09±2.5	61.536±6.3	69.33±4.1	67.83±5.7	75.26±6.4	76.85±5.7	79.19±6.2
NV Nausea and vomiting (14,15)/3	34.18±4.6	37.85±6.3	17.43±1.4	25.34±1.9	29.22±3.4	47.19±3.8	33.16±6.7	52.16±4.5	39.28±3.5	61.16±5.9
PA Pain (9,19)/3	41.22±5.2	40.57±5.3	34.65±2.9	36.17±3.8	53.17±.3.6	56.25±5.3	57.24±.4.8	58.33±.5.9	59.37±.5.1	62.17±.7.5
DY Dyspnea (8)/3	49.83±4.3	52.81±4.9	35.74±3.1	37.32±4.9	46.32±5.1	44.37±4.9	49.36±6.1	51.83±7.3	48.19±8.3	56.74±6.5
SL Insomnia (11)/3	55.56±7.9	51.36±6.1	31.17±4.8	36.82±3.4	57.28±8.3	59.65±3.6	59.31±8.9	68.19±9.4	64.18±9.3	73.23±9.8
AP Appetite loss (13)/3	68.93±5.6	62.62±7.3	44.21±3.9	41.36±3.8	71.11±7.4	74.37±3.4	74.23±8.3	81.25±8.6	83.92±9.4	89.35±8.1
CO Constipation (16)/3	55.51±7.9	48.91±6.4	37.94±2.7	38.43±3.8	36.18±2.9	37.85±3.7	31.47±4.8	34.94±6.7	36.28±4.3	38.82±6.9
DI Diarrhea (17)/3	41.92±4.7	44.8±4.3	32.81±3.1	41.74±4.6	54.34±3.9	61.11±5.8	65.94±4.2	69.13±8.5	69.24±6.9	71.61±6.7
FI Financial difficulties (28)/3	42.67±8.5	39.17±7.1	41.24±6.3	40.63±5.4	43.16±4.3	37.48±3.8	29.93±3.7	33.27±3.9	31.17±3.7	28.36±5.8

Table 4

Evaluation of the quality of life in patients of the main group and the study group in the remote postoperative period, according to the data of the EORTC QLQ – PAN26 questionnaire (in points)

Indicators	Before surgical correction	Terms after surgical correction								
		6 months		8 months		9 months		10 months		
	Surgical intervention (n=53)	Stenting (n=54)	Surgical intervention (n=47)	Stenting (n=52)	Surgical intervention (n=25)	Stenting (n=26)	Surgical intervention (n=19)	Stenting (n=17)	Surgical intervention (n=14)	Stenting (n=9)
	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m	M±m
Pancreatic pain	33.28±3.4	36.74±4.1	24.19±4.6	25.17±3.9	42.21±3.8	46.37±3.1	43.19±4.6	52.74±6.3	44.81±4.1	53.45±5.6
Digestive symptoms	45.71±3.9	46.38±5.7	25.48±3.4	29.17±4.8	44.62±5.8	48.93±5.6	40.98±4.3	56.94±4.8	41.98±7.3	43.94±6.8
Altered bowel habit	43.09±4.1	50.14±5.3	31.23±4.7	34.16±3.4	37.23±4.7	43.16±3.4	40.23±4.7	48.16±3.9	43.81±7.1	48.94±6.7
Hepatic symptoms	58.43±4.3	61.35±5.9	21.14±2.9	34.26±3.7	26.38±3.1	48.17±4.3	41.72±4.9	57.27±4.6	28.17±6.3	72.24±6.6
Body image	48.68±3.9	45.33±4.8	41.25±4.5	38.94±4.8	43.59±6.4	47.19±4.2	48.16±7.4	47.69±5.7	47.13±6.5	44.28±9.1
Health care satisfaction	59.14±7.3	61.14±7.3	67.23±6.9	64.16±5.9	57.82±8.4	70.25±6.9	61.82±8.4	63.25±6.9	59.16±7.1	63.24±8.4
Sexuality	46.17±3.9	44.25±4.7	38.24±3.6	41.15±6.4	42.39±8.7	43.26±9.8	32.18±9.7	33.24±8.7	33.72±9.1	34.17±8.6

During this observation period, biliodigestive bypasses and stents effectively drained the biliary system. At the time of the survey, the level of total bilirubin in the main group and the study group was 26.4±2.9 and 38.2±8.7 μmol/l, respectively. The results of the questionnaire testified to the improvement of the quality of life of patients in both groups. In particular, the general condition of health was assessed by the main group as that one which improved by 56.4% ($\chi2$=41.2, 95% CI 41.45-68.86, p<0.0001), and in the study group – by 35.7% ($\chi2$=23.25, 95% CI 22.47-49.03, p<0.0001), which was classified as «significant» positive changes. The life quality values, according to functional scales, have also improved. In particular, in the main group and the study group, respectively, values of physical functioning increased by 61.5% ($\chi2$=46.62, 95% CI 46.44-73.39, p<0.0001) and 46.3% ($\chi2$=32.23, 95% CI 32.05-59.39, p<0.0001), role functioning by 88.2% ($\chi2$=82.83, 95% CI 74.98-94.39, p <0.0001) and 68.5% ($\chi2$=55.73, 95% CI 53.66-79.30, p<0.0001), emotional functioning by 43.0% ($\chi2$=28.87, 95% CI 28.87-56.35, p<0.0001) and 35.7% ($\chi2$=23.25, 95% CI 22.47-49.03, p<0.0001), cognitive functioning by 18 .9% ($\chi2$=10.95, 95% CI 8.20-31.39, p=0.0009) and 12.7% ($\chi2$=7.25, 95% CI 3.43-24.10, p=0.007), social functioning by 52% ($\chi2$=36.89, 95% CI 37.23-64.85, p<0.0001) and 37.5% ($\chi2$=24.69, 95% CI 24 .06-50.83, p<0.0001). Positive changes in the life quality were also observed by the symptomatic scales and individual values. Thus, in the main and study groups, respectively, fatigue values decreased by 47.3% ($\chi2$=32.52, 95% CI 32.82-60.46, p<0.0001) and 34.7% ($\chi2$ =22.46, 95% CI 21.59-48.02, p<0.0001), nausea and vomiting – by 17.0% ($\chi2$=9.75, 95% CI 6.68-29.24, p=0.001) and 10% ($\chi2$=5.63, 95% CI 1.36-20.83, p=0.01), pain – by 17.1% ($\chi2$=9.75, 95% CI 6 .68-29.24, p=0.001) and 10.8% ($\chi2$=6.1, 95% CI 1.97-21.81, p=0.01), shortness of breath – by 28.6% ($\chi2$=17.52, 95% CI 16.2-41.88, p<0.0001) and 28.8% ($\chi2$=18.0, 95% CI 16.5-41.96, p<0.0001), insomnia – by 43.6% ($\chi2$ =29.27, 95% CI 29.41-56.93, p<0.0001) and 29.4% ($\chi2$=18.44, 95% CI 17.01-42.58, p<0.0001).

The feeling of reduced appetite decreased by 35.3% ($\chi2$=22.5, 95% CI 21.98-48.75, p<0.0001) and 33.9% ($\chi2$=21.83, 95% CI 20, 89-47.21, p<0.0001), bowel movement disorders decreased by 30.9% ($\chi2$=19.18 95% CI 18.16-44.27, p<0.0001) and 20.4% ($\chi2$=12.15, 95% CI 9.53-32.93, p=0.0005), diarrhea by 21.9% ($\chi2$=12.91 95% CI 10.63-34.71, p= 0.0003) and 6.8% ($\chi2$=3.76, 95% CI-1.07-16.76, p=0.05), financial problems related to the disease did not change significantly. From the above materials, we conclude that the patients who survived 6 months after the recovery of the physiological bile passage noted an improvement in the quality of life, according to the values of all questionnaire scales, regardless of the type of surgical intervention that drains the biliary system. That is, the recovery of the physiological passage of bile determined the improvement of the physical condition, social function and mental health status of the patients. In eight months after the surgical correction, 25 patients of the main group and 26 patients of the study group survived. Changes in the values of the functional scales during this period, compared to the 6-month period of the survey, showed a deterioration of the general health condition by 27.9% ($\chi2$=7.94 95% CI 8.8-47.47, p= 0.004) and 31.6% ($\chi2$=9.57 95% CI 12.22-50.81, p=0.002), respectively.

The assessment of the general health condition did not statistically differ from the preoperative level,

there was a decrease in emotional functioning by 14.1% ($\chi2$=3.71 95% CI –1.85-32.45, p=0.05) and 14, 5% ($\chi2$=3.98 95% CI –1.12-32.5, p=0.04), physical functioning by 33.3% ($\chi2$=9.78 95% CI 13.15-52.86, p =0.001) and 33.4% ($\chi2$=10.22, 95% CI 13.69-52.59, p=0.001), role functioning by 18.7% ($\chi2$=5.05, 95% CI 1, 64-37.69, p=0.02) and 12.3% ($\chi2$=3.34 95% CI –2.79-29.89, p=0.06), cognitive functioning by 26.1% ($\chi2$=7.35 95% CI 7.37-45.62, p=0.006) and 16.9% ($\chi2$=4.7, 95% CI 0.69-35.26, p=0.03), social functioning by 28.3% ($\chi2$=8.07, 95% CI 9.11-47.88, p=0.004) and 37.7% ($\chi2$=11.84, 95% CI 17.26-56, 74, p=0.0006). Analysis of the changes in the values of the symptomatic scales shows a deterioration in the quality of life due to an increase in pain syndrome in the upper abdomen, in particular in the subjects of the main group, from 34.65±2.9 to 53.17±.3.6 (p<0, 0001), i.e. by 55.9%, and in the study group from 36.17±3.8 to 56.25±5.3 points (p<0.0001), i.e. by 55.6%. The study also revealed an increase in the severity of indigestion (nausea, vomiting, decreased appetite, defecation disorders) and endogenous intoxication (weakness, lethargy, fatigue, insomnia).

The analysis of the specialized module EORTC QLQ-PAN26 (Table 4) helped to assess the effect of various surgical techniques for the bile flow recovery on changes in the digestive system, and the quality of life of patients. In particular, 6 months after recovery of the bile flow by both surgical intervention and biliary stenting procedures, a decrease in «pancreatic» pain syndrome was diagnosed (pain localized in the upper half of the abdomen and back, increased at night, not relieved by analgesics, provoked by eating), respectively by groups, by 27.3% ($\chi2$=16.59 95% CI 15.1-40.51, p<0.0001) and 30.55% ($\chi2$=19.29, 95% CI 17.99-43.78, p<0.0001); manifestations of indigestion symptoms decreased by 44.4% ($\chi2$=29.96, 95% CI 30.15-57.7, p<0.0001) and 36.9% ($\chi2$=24.2, 95% CI 23 .53-50.23, p<0.0001); the severity of symptoms of defecation disorders decreased by 38.7% ($\chi2$=25.19, 95% CI 24.99-52.14, p<0.0001) and 32% ($\chi2$=20.38, 95% CI 19.24-45.27, p<0.0001), «hepatic» symptoms decreased by 63.8% ($\chi2$=49.18, 95% CI 48.73-75.39, p<0.0001) and 44, 3% ($\chi2$=30.44, 95% CI 30.2-57.48, p<0.0001). At the same time, the values of the questionnaires regarding the attitude to one's body and treatment satisfaction did not show reliable changes. The issue of sexuality was ignored by 84.9% of patients in the main group and 77.7% in the study group. However, these data were not reliable. After surveying patients in both groups at 8, 9, and 10 months following surgical correction, and comparing the results with those from the 6-month survey, we found an increase in the «pancreatic pain» scale by 83.3% ($\chi2$=34.97, 95% CI 60, 29-93.18, p<0.0001) and 92% ($\chi2$=43.44, 95% CI 71.04-97.72, p<0.0001), the scale of indigestion symptoms by 38.7% ($\chi2$=11.75, 95% CI 17.62-58.04, p=0.0006) and 93.1% ($\chi2$=44.41, 95% CI 72.4-98.2, p<0,0001), the scale of «hepatic» symptoms by 33.3% ($\chi2$=9.78, 95% CI 13.15-52.86, p=0.001) and 91.8% ($\chi2$=43.27, 95% CI 70.79-97.63, p<0.0001). Thus, the most significant characteristics that manifested a decrease in the patients' life quality at the terminal stage of the disease were: the progression of pain syndrome, symptoms of indigestion and «hepatic» symptoms. Moreover, such changes were characteristic of patients who developed recurrent cholangitis after the biliary stenting. In the late postoperative period, the severity of «hepatic» symptoms in these patients was 3.3 times greater (p<0.0001) than during open surgical operations. In general, 31 patients of the main and 40 patients of the study group died within 7, 8 and 9 months after surgical interventions. 14 patients of the main group and 9 of the study group survived the 10th month. As of 11 months after the surgery for jaundice, only 7 patients of the main group were alive. None of the patients in the study group survived to 11 months after the surgery for obstructive jaundice.

DISCUSSION

In 2020, Fabian et al. [22] published a meta-analysis comparing double palliative surgical bypass with double stenting for malignant biliary and duodenal obstruction. In the early postoperative period, the clinical success of endoscopic biliary stenting was slightly higher than surgical interventions, but was accompanied by a more frequent need for repeated endoscopic interventions, and a greater number of complications in the long postoperative period. Surgical bypass has been shown to be a good option for patients with a relatively long-life expectancy [1, 2, 3]. However, important issues of tactics and techniques of open and endoscopic surgical interventions remained outside the scope of the study. First, this concerns the staging of surgical interventions. According to our observations, in 11 patients in the main group and 8 patients in the study group, long-term obstructive jaundice was complicated by liver-renal dysfunction and hemorrhagic syndrome. At the same time, three patients in the main group and five people in the study group were diagnosed with acute cholangitis. The indicated complications are regarded as manifestations of multiple organ failure, with the risk of developing biliary sepsis, and the possibility of acute liver failure. Surgical treatment in such cases consisted of two stages. The first stage was involved the endoscopic transpapillary drainage of the common bile duct with plastic stents, followed by a course of intensive therapy in ICU, and elective surgical interventions after correction of homeostatic disorders. The two-stage treatment strategy made it possible to save the lives of most of these patients, but in the postoperative period, one of them developed acute renal failure, which was lethal, in 2 cases – gastrointestinal bleeding due to erosive gastroduodenitis, in 1 case – pneumonia. That is,

in patients with multiorgan dysfunction or cholangitis, severe complications developed in 4 cases out of 19. Therefore, monitoring the severity of multiorgan dysfunction in such patients should be carried out daily, according to the SOFA scale. We found that the use of SEMS was accompanied by a decrease in the frequency of early postoperative complications by 29.9% ($\chi2$=13.7, 95% CI 14.38-44.08, p=0.0002), and a decrease in mortality by 7.5% ($\chi2$=4.16, 95% CI –0.05-17.79, p=0.04), compared to surgical bypass. Ying-bin Liu, 2020, Beger H. G., Büchler M. W., 2023 [1, 4] state that SEMS effectively drain the biliary system for 6 months, and later, due to obstruction of stents by a tumor, there is a risk of recurrent obstructive jaundice and acute cholangitis [1, 2, 4, 23].

The obtained data show that open surgical interventions with biliodigestive and preventive gastrodigestive bypass within 11 months from the observation onset were not associated with the bypass obstruction manifestations. At the same time, in the other group, in the period from 8 to 11 months after the stenting of the biliary system using SEMS, 6 (11.1%) cases were associated with a recurrent jaundice with acute cholangitis, 4 (7.4%) cases – with stenosis of the DPC by a tumor, and 19 (37.1%) – with recurrent cholangitis. These results are in line with the data of Scheufele F. and Friess H. [2], a meta-analysis of five randomized controlled trials, which proved that surgical bypass surgery is associated with a reduction in the recurrence of jaundice and cholangitis, compared with the biliary stenting procedure. Therefore, the choice of patient treatment strategy should rely on the prognosis of the expected survival of the patients, which we did by the Karnofsky index and the corresponding value of the ECOG scale. We found that with the Karnofsky index <80 (15 patients) during hospitalization in patients of the main group, their life expectancy was 5.91±2.32 months. With a Karnofsky index value >80 (38 patients), life expectancy was 9.23±2.06 months. Among the patients of the study group, the Karnofsky index <80 was determined in 14 people and their life expectancy was 5.37±1.48 months. With the Karnofsky index >80 (40 patients), life expectancy was 8.21±2.93 months. As the phenomena of SEMS obstruction developed in the period from 8 to 11 months of their functioning, and concerned 53.7% of patients, we can assume that with an expected survival of less than 5 months (Karnofsky index <80, 2 points on the ECOG scale), it is advisable to perform stenting of the common bile duct using SEMS; if the Karnofsky index >80 (0-1 points on the ECOG scale), which predicts survival for more than 8 months, it is advisable to perform double bypass surgery. Our study demonstrated that, regarding the medical indications and contraindications (comorbid pathology, multiple organ failure) and the patient's treatment refusal, chemotherapy was administered to 57.1% of patients in the main group and 66.7% in the study group. In chemotherapy, the survival rate of patients in both groups significantly increased.

Thus, the performance of double surgical bypass in the course of open surgical interventions made it possible to prevent the development of recurrent jaundice, cholangitis, duodenal obstruction, cachexia in the distant postoperative period, and to adhere to the protocols of chemotherapy treatment of patients. The quality of life of these patients, according to the EORTC QLQ-C30 and EORTC QLQ-PAN26 questionnaires, was better than that of patients in the study group, although no significant difference in survival was found. The use of minimally invasive technology for the correction of obstructive jaundice in patients of the study group demonstrated advantages over traditional technology due to decrease in early postoperative complications, short-term hospitalization, and quick recovery. However, this method of treating patients is also a double drainage technology, but delayed in time, since duodenal stenting was performed not as a preventive measure, but in cases of clear manifestation of duodenal obstruction (in 7.4% of patients). The results of the study indicate that both analyzed strategies for treating patients are successful. At the same time, surgical bypass, compared to the SEMS placement, in the distant postoperative period prevented the recurrence of jaundice and cholangitis, as well as the development of duodenal obstruction. The use of SEMS shows better results in the early postoperative period, but in 8 months after the stent placement 18.5% of patients developed complications: recurrent jaundice with cholangitis, duodenal obstruction, also, 37.1% of patients developed recurrent cholangitis. Current data show that in the case of sensitivity of a cancer tumor to polychemotherapy, even with palliative treatment of patients with pancreatic cancer, patient survival can increase to more than 12 months, and then the value of surgical bypass, given its better long-term results, becomes relevant.

According to the literature review and our own experience [1, 2, 3], we can conclude that unresectable cancer of the gastrointestinal tract is accompanied by the development of the following pathological syndromes: malignant mechanical jaundice (up to 97% of patients), obstruction of the gastric outlet (up to 25% of patients), bad-controlled pain syndrome (10%-15% of patients), which significantly worsens the quality of life of patients and provokes mortality. To eliminate these syndromes, both surgical and interventional methods of treatment are available, the use of which is regulated by the treatment strategy. Rehabilitation measures in the postoperative period should be aimed at correcting pain and symptoms of indigestion: nausea, vomiting, decreased appetite, defecation disorders, endogenous intoxication. The following conclusions can be drawn.

CONCLUSIONS

1. The choice of the surgical treatment strategy for the patients is based on the following factors: life expectancy, the presence of multiple organ failure syndrome, the severity of comorbid pathology, the possibility of complete combined treatment of patients.

2. When diagnosing patients with multiple organ failure syndrome (hepatic-renal and hemorrhagic syndromes) and cholangitis, surgical correction of obstructive jaundice is advisable in the last two stages, during the first of which endoscopic transpapillary drainage of the biliary system with plastic stents and correction through intensive therapy of homeostatic disorders are performed, the second stage involved the surgical treatment.

3. The use of self-expanding metal stents for internal drainage of the biliary system compared to open surgery of double bypass (hepaticojejunostomy + gastrojejunostomy) reduces the incidence of postoperative complications by 29.9% ($\chi 2$=13.7, 95% CI 14.38-44.08, p=0.0002), and mortality – by 7.5% ($\chi 2$=4.16, 95% CI –0.05-17.79, p=0.04).

4. Restoration of the physiological passage of bile, regardless of the chosen correction technology (open surgery or endoscopic transpapillary stenting), improves patients' quality of life, which is manifested by improvement in physical condition, social function, and mental health status.

5. The procedure of stenting of the biliary system using SEMS in the remote postoperative period (8-11 months) in 11.1% of cases is complicated by acute cholangitis, in 37.1% by recurrent cholangitis, in 7.4% of cases obstructive duodenal obstruction develops. The treatment of these complications requires re-hospitalization, special examination, and intensive therapy, and in 7.4% of cases re-stenting of the common bile duct, and in other 7.4% of patients – stenting of the duodenum using SEMS.

6. The choice of biliodigestive bypass technology should be chosen depending on the predicted survival time of patients. If the prognosis of survival by the Karnofsky index <80 (2 points on the ECOG scale), which is less than 5 months, it is advisable to perform stenting of the common bile duct with self-expanding metal stents; if the Karnofsky index >80 (0-1 points on the ECOG scale), which predicts survival for more than 8 months, it is advisable to perform double biliodigestive and preventive gastrodigestive bypass surgery.

7. Complications in the postoperative period, such as acute or recurrent cholangitis and duodenal obstruction, prevent patients from adhering to chemotherapy treatment protocols.

8. In patients with poorly controlled pain syndrome, when undergoing open surgical interventions, it is advisable to perform intraoperative chemical «splanchnicectomy» of the abdominal ganglion using 50% alcohol.

Final statements. The choice of strategy of the palliative surgical treatment of patients to eliminate potentially debilitating syndromes through open, or minimally invasive, or combined surgical technologies acquires primary importance, as it is a prerequisite for the use of anticancer therapy.

Prospects for further research. Further research should combine the capabilities of known technologies to provide a long-term effect of the cancer complications management (obstructive jaundice and duodenal obstruction) with minimal trauma, thus creating conditions for chemotherapy treatment of patients, which should be effective, regardless of the stage of cancer spread.

COMLIANCE WITH ETHICAL REQUIREMENTS

The study was carried out in compliance with the main provisions of the Declaration of Helsinki of 1975, revised in 2000, the Council of Europe Convention on Human Rights and Biomedicine (2007) and the recommendations of the Bioethics Committee of the Presidium of the National Academy of Medical Sciences of Ukraine (2002). The Bioethics Commission of the Bogomolets National Medical University approved manipulations and other medical procedures. Clinical examination, surgical interventions were performed after patients signed the appropriate informed consent for surgical procedures.

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Резюме

ВИБІР ТАКТИКИ ХІРУРГІЧНОГО ЛІКУВАННЯ ХВОРИХ НА НЕРЕЗЕКТАБЕЛЬНИЙ РАК ГОЛОВКИ ПІДШЛУНКОВОЇ ЗАЛОЗИ

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Вступ. Через пізню діагностику до 80% хворих на рак головки підшлункової залози проводять лише паліативне хірургічне лікування з метою усунення ускладнень: обструктивної жовтяниці та стенозування пухлини дванадцятипалої кишки шляхом операції гепатикоєюностомії або транспапілярним протезуванням загальної жовчної протоки саморозширювальними металевими стентами (СМС). Недоліками відкритих операцій є висока частота післяопераційних ускладнень і летальність, а транспапілярних стентувань – обструкція до 40% стентів через 6-8 років після їх імплантації. При використанні поліхіміотерапії виживаність хворих перебільшує річний термін, коли дренажна функція стентів порушена, а хірургічні шунти функціонують без ускладнень. Тому актуальною є персоніфікація вибору тактики лікування хворих.

Мета. Покращити результати паліативного хірургічного лікування хворих на нерезектабельний рак головки підшлункової залози, ускладнений обструктивною жовтяницею, шляхом удосконалення вибору тактики та техніки хірургічних втручань.

Матеріали та методи. В рандомізованому проспективному дослідженні проведено аналіз результатів корекції обструктивної жовтяниці шляхом гепатикоєюностомії за Ру із профілактичним гастроєюноанастомозом (основна група, 53 хворих) або транспапілярним протезуванням загальної жовчної протоки СМС (група порівняння, 54 хворих). Оцінено вплив поліорганної дисфункції та індексу Karnofsky на вибір тактики лікування хворих, на безпосередні і віддалені результати та якість життя хворих у післяопераційному періоді за даними анкет EORTC QLQ-C30 V.3 та EORTC QLQ-PAN26.

Результати. Використання саморозширювальних металевих стентів для внутрішнього дренування біліарної системи, у порівнянні з відкритими операціями подвійного шунтування, знижує частоту післяопераційних ускладнень на 29,9% ($\chi2$=13.7, 95% ДІ 14.38-44.08, p=0,0002), а летальність – на 7,5% ($\chi2$=4.16, 95% ДІ – 0.05-17.79, p=0,04). Однак, перебіг віддаленого післяопераційного періоду (із 8 по 11 місяці) у 11,1% випадках ускладнюється гострим, у 37,1% – хронічним рецидивуючим холангітом, у 7,4% випадків розвивається обструктивна дуоденальна непрохідність, що погіршує якість життя хворих та вимагає повторної госпіталізації та реконструктивних втручань.

Висновки. При індексі Karnofsky <80 доцільно виконувати протезування загальної жовчної протоки СМС, при індексі Karnofsky >80 слід проводити хірургічні операції подвійного біліодигестивного і профілактичного гастродигестивного шунтування. При розвитку на тлі обструктивної жовтяниці поліорганної дисфункції і холангіту лікування проводять у два етапи, на першому – здійснюють транспапілярне дренування біліарної системи пластмасовими стентами, на другому – заплановане хірургічне втручання.

Ключові слова: **рак головки підшлункової залози, обструктивна жовтяниця, стентування біліарної системи**

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