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Modern Aspects of Personalized Biliary Drainage in Malignant Mechanical Jaundice

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Abstract Malignant obstructive jaundice caused by hepatopancreatoduodenal tumors remains a major clinical challenge requiring prompt biliary decompression. This study justifies a differentiated approach to the use of minimally invasive drainage techniques (endoscopic and percutaneous) in 120 patients with inoperable malignancies. The results demonstrate that individualized selection of drainage method based on the level of obstruction significantly improves clinical efficacy, reduces complication rates, decreases the need for reinterventions, and enhances survival compared to uniform treatment strategies.

Keywords Obstructive jaundice, Malignant biliary obstruction, Endoscopic stenting, Differentiated approach

1. Introduction

Malignant (obstructive) jaundice of tumor etiology is a frequent and severe complication of malignant tumors in the hepatopancreatoduodenal zone. By the time jaundice manifests, most of these tumors are considered inoperable, and radical surgery becomes impossible. Without adequate bile drainage, patients quickly develop liver failure, cholemia, and the onset of cholangitis may lead to sepsis. Mortality without drainage is extremely high, making timely biliary decompression a vital part of palliative care for such patients.

The modern stage of surgical gastroenterology development is characterized by a shift towards minimally invasive interventions for biliary decompression. Traditional open surgical bypass anastomoses (choledocho- or hepaticojejunostomy) in the context of malignant obstruction are associated with a high complication rate (up to 30%) and perioperative mortality of 3-15%. In contrast, endoscopic and percutaneous drainage have proven to be effective and relatively safe methods, allowing for reduced bilirubin levels, elimination of cholemia, and prevention of purulent complications. Endoscopic transpapillary stenting (via ERCP) is considered the method of choice for distal biliary obstructions caused by tumors in the area of the Vater's papilla or pancreatic head. If the tumor is located high (hilar cholangiocarcinoma, Klatskin tumor), endoscopic drainage is difficult and often incomplete; in such cases, percutaneous transhepatic cholangiostomy (PTCS) is prioritized. Both approaches—endoscopic and percutaneous—are minimally invasive and collectively allow for effective jaundice relief in most patients. However, several unresolved questions remain regarding the optimal strategy. The main issue is the selection of the drainage method for a specific patient based on the anatomy of the tumor obstruction. A uniform approach (e.g., only external drainage or only endoscopic stenting for all patients) does not take into account the differences in the location of the block and the condition of the intrahepatic ducts. This can lead either to unjustified risks (attempts at endoscopic drainage of complex hilar strictures) or inadequate decompression (by draining only one lobe of the liver in the case of bilobar obstruction). It is known that incomplete drainage of all affected ducts leads to retention of obstruction in the liver lobe and the risk of purulent complications. Even with the success of the intervention, if a significant portion of the liver remains undrained, bile hypertension persists in these segments, often leading to cholangitis and deterioration in survival rates. On the other hand, overly aggressive tactics (such as the installation of multiple stents for multi-level strictures) increase the invasiveness of the procedure and may increase the risk of complications, such as duct injury, bleeding, and infection. Therefore, a balance must be struck between the volume of drainage and the safety of the procedure.

Optimizing palliative treatment of malignant jaundice consists of a differentiated approach—choosing the least traumatic and simultaneously sufficiently effective method of decompression for each patient. Literature shows that for proximal (hilar) tumor strictures, adequate improvement in bile flow is achieved by draining at least 50% of the functional liver volume. Drainage of >50% of liver volume correlates with significant bilirubin decline and fewer cholangitis episodes. This is usually achieved by installing two stents (bilateral drainage of the right and left lobes) in patients with Bismuth II-III tumors of the liver hilum, while

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for more complex strictures (Bismuth IV), drainage of three branches (right anterior, right posterior, and left lobe) may be required. However, draining inevitably non-perfused or atrophied liver segments is unfeasible, as it does not improve function and only increases the risk of infections. In cases of distal obstructions, it is sufficient to stent one common bile duct, restoring flow from the entire liver. Therefore, when planning an intervention, the shape and level of tumor obstruction (according to the Bismuth-Corlette classification and cholangiography data) should be considered, and the goal should be to achieve complete drainage of all functioning liver lobes.

Another factor is the patient's overall condition and comorbidities. In weakened patients with high operative risk, the least invasive method should be preferred. Typically, endoscopic stenting is better tolerated than external drainage with catheter placement through the skin. Internal stents avoid the continuous loss of bile outside, electrolyte imbalances, and the inconvenience of caring for a drainage tube. Therefore, when technically feasible, endoscopic stenting is preferred, especially in elderly patients and those with significant comorbidities. On the other hand, in cases of severe cholangitis, markedly enlarged intrahepatic ducts, or after gastrectomy (disrupted anatomy for ERCP), percutaneous methods are more direct and faster for decompression.

Thus, the relevance of the problem lies in the need to develop an algorithm for selecting the method of minimally invasive bile drainage, taking into account the individual characteristics of the tumor obstruction. A differentiated approach should improve treatment efficacy—reduce drainage failure rates, decrease complications (especially purulent ones), and enhance the quality of life for patients. Furthermore, adequate biliary decompression is a prerequisite for subsequent chemotherapy and radiation therapy, which may prolong the lives of patients with advanced tumors. Therefore, substantiating the optimal strategy for minimally invasive drainage in malignant jaundice is of great clinical interest and practical significance.

Study Objective. To justify a differentiated approach to the application of minimally invasive biliary drainage techniques in patients with inoperable malignant tumors of the hepatopancreatoduodenal zone complicated by mechanical jaundice.

2. Materials and Methods

The study was conducted at the departments of abdominal surgery and endoscopy and included 120 patients with mechanical jaundice caused by malignant tumors of the hepatopancreatoduodenal region (pancreatic head cancer, distal cholangiocarcinomas, tumors in the BDS area, proximal cholangiocarcinomas, and others). Inclusion criteria were as follows: clinical and laboratory signs of obstructive jaundice (total bilirubin >50 μmol/L, cholestatic syndrome), the presence of an inoperable tumor (based on imaging methods—CT/MRI—locally advanced or metastatic tumor deemed unresectable by a consensus), and technical feasibility for minimally invasive drainage. Patients with benign strictures, resectable tumors (planned for radical surgery), or previously drained bile ducts were excluded.

All patients signed informed consent for the intervention. The patients were randomized into two groups, each with 60 participants. The main group included patients for whom the biliary drainage strategy was determined individually based on the level of blockage and tumor characteristics (differentiated approach). The comparison group included patients who underwent standardized drainage (without considering the differences in obstruction anatomy). The average age of patients was 64±9 years, with 65 (54.2%) men and 55 (45.8%) women.

In the main group, the following protocol was applied. For distal obstructions (tumors of the ampulla or pancreatic head), the first step was performing endoscopic retrograde cholangiostomy with the installation of an internal stent in the extrahepatic bile ducts (via endoscopic retrograde cholangiopancreatography, ERCP). Self-expanding metallic stents with a diameter of 8–10 mm were used; the choice of metallic stents was due to their larger lumen and longer patency in oncological patients. For proximal tumors (hilar cholangiocarcinoma), preference was given to percutaneous transhepatic drainage under ultrasound and X-ray control. The Bismuth classification was applied: for types II–III, bilateral stenting was performed for the left and right systems (through separate punctures) to ensure drainage from both liver lobes; for type IV, three sectors (left lobe, right anterior, and right posterior sectors) were drained with the installation of three stents. A combination of endoscopic and percutaneous methods was allowed in one patient (so-called combined drainage)—for example, in a Klatskin tumor, an endoscopic stent was first placed in the left duct, followed by percutaneous drainage of the segmental ducts of the right lobe. If endoscopic intervention was technically unsuccessful (inability to catheterize the ducts due to complete obstruction, BDS stenosis, post-gastrectomy status, etc.), the patient was switched to percutaneous drainage (thus, the method was changed to a more suitable one within the framework of a differentiated strategy). In all cases, the goal was to achieve decompression of as much functioning liver parenchyma as possible. Full drainage was considered if total bilirubin decreased by >50% from baseline within two weeks.

In the comparison group, all patients underwent standard single-stage drainage following the protocol previously adopted in the clinic: percutaneous transhepatic cholangiostomy with the installation of an external drainage system in one of the liver systems. Typically, the expanded right hepatic duct was punctured, followed by drainage of the right lobe; for left-sided tumors, the left hepatic duct was punctured. Endoscopic intervention was not performed at this stage in the comparison group. Thus, the strategy did not involve mandatory bilateral or combined drainage; most patients in this group had only one liver lobe drained (unilateral bile drainage). After external drainage and bilirubin reduction, internal stents were placed in the comparison group if necessary (via the formed fistula track, the "rendezvous" method), but for the purpose of the analysis, the initial results were evaluated only after the first stage (primary decompression).

Patients in both groups were monitored dynamically. Laboratory parameters (bilirubin levels, alkaline phosphatase, transaminases) were evaluated before and after the intervention (on the 1st, 3rd, 7th days, and 2 weeks). The technical success of the procedure was defined as the installation of the drainage system in the bile ducts with restoration of bile flow. Clinical success was defined as the reduction in the severity of jaundice and intoxication in the following 1–2 weeks, confirmed by a reduction in bilirubin >50%. All complications related to the intervention were recorded: acute cholangitis, acute pancreatitis (for endoscopic procedures), bleeding (intraluminal or into the cavity requiring blood transfusion), peritonitis or abdominal abscesses, incorrect stent placement or migration, early stent occlusion, and fatal outcomes within 30 days after the intervention. In the long-term period (the average follow-up period was 10 months), the frequency of recurrent obstruction (restenosis or stent occlusion), the need for repeated interventions (stent replacement in case of occlusion or displacement, installation of additional drains in case of obstruction progression), and overall patient survival (6- and 12-month survival) were assessed. Kaplan-Meier method was used to evaluate survival, and survival curves were compared using the log-rank test. Statistical processing was performed using StatTech® software; group comparisons were made using χ^2 and Student's t-test, with a significance level of $p<0.05$. The ethics committee approved the study, and it adhered to the Helsinki Declaration.

Figure 1. Schematic of Differentiated Drainage Tactics

The algorithm takes into account the accessibility of the papilla for endoscopy and the level of obstruction. For a patent BDS and predominantly distal obstructions, endoscopic stenting is performed; for high strictures, percutaneous drainage is applied immediately. CDS – choledochoduodenostomy (endoscopic transpapillary stenting), HGS – hepaticogastrostomy (percutaneous transhepatic stenting, EUS-drainage terminology). This approach minimizes invasiveness (avoiding external drainage in distal blocks) and ensures adequate bile drainage from all necessary liver lobes in the case of hilar strictures.

3. Results and Discussion

Both groups were comparable in basic characteristics. In the main group, the average age was 64.3±8.7 years, with 32 men (53%), while in the comparison group it was 63.5±9.1 years, with 33 men (55%) ($p>0.5$). The etiology of obstruction was as follows: pancreatic head cancer – 25 cases (42%) in the main group and 26 (43%) in the comparison group; proximal cholangiocarcinoma (liver hilum tumor) – 18 (30%) vs 17 (28%); ampullary cancer (Vater's papilla tumor) – 6 (10%) vs 7 (12%); gallbladder carcinoma with cholangiocathesis – 5 (8%) vs 4 (7%); metastatic biliary tree lesions (lymph nodes of the hilum, stomach cancer, etc.) – 6 (10%) vs 6 (10%). The level of biliary tract blockage: distal obstruction (below the confluence of the hepatic ducts) was noted in 34 (57%) and 35 (58%) patients in the main and comparison groups, respectively; hilar obstruction (Bismuth II–IV) – in 26 (43%) vs 25 (42%) patients. No statistically significant differences were found between the groups for these indicators ($p>0.1$), confirming the correctness of the comparison.

In the main group, the planned drainage was performed in 58 out of 60 patients (96.7%). Two patients required a change of method: in one case, during the attempt to perform ERCP stenting for the tumor in the lower third of the choledochus, catheterization of the papilla failed due to infiltration of the duodenal wall, and the patient was successfully drained percutaneously; in another case, with a Bismuth IV hilar tumor, after two stents were installed, obstruction of a segmental duct remained, requiring additional puncture drainage. In the comparison group, the technical success of the primary procedure was achieved in 54 out of 60 patients (90%): 6 patients were unable to drain the bile ducts on the first attempt due to technical difficulties (severe cholangitis, obstruction of the duct lumen with pus, inability to pass the guide through the tumor) – they underwent repeated attempts, counted as complications. The difference in technical success (96.7% vs 90%) was not statistically significant ($p=0.12$), but the trend in favor of the differentiated approach was evident.

Clinical success (significant reduction in jaundice in the following 14 days) was observed in 55 (91.7%) patients in the main group, which was significantly higher than 48 (80%) in the comparison group ($\chi^2=4.0$; $p=0.045$). Thus, the differentiated approach allowed for full biliary decompression in nearly 92% of patients. In the comparison group, one in five patients did not achieve sufficient effect from the first intervention (high bilirubinemia persisted), requiring additional measures.

The main cause of incomplete clinical effect in the comparison group was inadequate liver volume drainage. For proximal strictures, when only one half of the biliary tree was drained (e.g., only the right duct), several patients still had obstruction in the contralateral lobe, leading to persistent hyperbilirubinemia and episodes of cholangitis. In the main group, thanks to bilateral drainage in the same situations, bile flow from both the right and left lobes was ensured (complete bile drainage). As a result, the proportion of patients with full decompression (defined as drainage of ≥50% of liver parenchyma) in the main group significantly exceeded that in the comparison group (92% vs 80%, see above).

Following the interventions, a significant reduction in total bilirubin levels was observed in most patients in both groups (Figure 2). Initially, the average serum bilirubin concentration was 256±98 µmol/L (main group) and 249±105 µmol/L (comparison group), p=0.74. By day 3 after drainage, bilirubin reduction in the main group was more pronounced: to 152±80 µmol/L vs 180±95 µmol/L in the comparison group (p=0.08). By day 7, bilirubin levels in the main group decreased by an average of 71% from baseline and reached 74±45 µmol/L, while in the comparison group, the decrease was 55%, to 112±60 µmol/L, p=0.04. In 11 patients from the comparison group, significant hyperbilirubinemia (>100 µmol/L) persisted after a week, while in the main group, this was seen in only 5 patients. Bilirubin normalization (<20 µmol/L) was achieved in 40 patients (67%) in the main group and 32 (53%) in the comparison group. Similar dynamics were seen for alkaline phosphatase (ALP) and GGT levels: in the main group, the average ALP decreased to 280 U/L after 2 weeks, in the comparison group to 400 U/L (initially ~600–650 U/L in both groups). Therefore, the individualized strategy led to a faster resolution of cholestasis.

In the early postoperative period (30 days), complications were recorded in 12 patients (20%) in the main group, while in the comparison group, complications were observed in 21 patients (35%, p=0.08). The structure of complications is presented in Table 3. The most common was acute cholangitis – 6 cases (10%) in the main group compared to 15 (25%) in the comparison group. The development of cholangitis was usually associated with residual obstruction of a liver lobe or infection due to incomplete bile drainage. In the comparison group, 10 patients with bilobar obstruction who underwent unilateral drainage developed purulent cholangitis in the opposite lobe within 3–5 days after the procedure. This required antibiotics and additional drainage of the second lobe (these cases were counted both as complications and as forced reinterventions). In the main group, cholangitis occurred in only 2 patients with multifocal (Bismuth IV) obstruction, in whom even the installation of 2–3 stents did not ensure full drainage of all segments – episodes of fever and bacterial growth in blood were observed. Notably, with adequate bilateral drainage, the incidence of cholangitis is minimal – in our data, about 5%, which matches the reports in the literature.

Acute post-procedural pancreatitis – a characteristic complication of endoscopic retrograde procedures – occurred in 3 out of 36 patients in the main group who underwent ERCP (8.3%). In two cases, it was mild and was treated conservatively; in one, it was moderate, requiring 6 days of intensive therapy, with recovery. In the comparison group, no endoscopic procedures were initially performed, so no pancreatitis was noted (0%, p=0.08 when comparing groups). Bleeding occurred in 2 patients in the main group (3.3%) and 3 patients in the comparison group (5%). All were intraluminal (gastrointestinal) – likely from the papillotomy site or the tumor node – and were stopped conservatively without the need for blood transfusions.

No cases of duodenal perforation, biliary peritonitis, or life-threatening bleeding were observed. In one case in the comparison group, displacement (migration) of the external drain from the choledochus occurred on the first day, leading to bile leakage into the free peritoneal cavity and the need for urgent re-cholangiostomy – this case was categorized as a technical failure/complication.

The mortality associated with the procedure was 0% in the main group and 5% (3 patients) in the comparison group. All three deaths were due to severe septic cholangitis following incomplete drainage: these patients had widespread tumors of the liver hilum, and unilateral drainage did not prevent the rapid progression of the purulent process. Despite intensive therapy and reinterventions, these patients could not be saved. This result underscores the clinical importance of choosing the optimal drainage strategy for proximal malignant strictures.

During follow-up, it was noted that patients in the main group required fewer repeat hospitalizations and invasive procedures related to drainage function. Over the observation period (an average of 10 months), 11 patients (18%) in the main group required additional interventions on the bile ducts, while in the comparison group, 24 patients (40%, p<0.01). This category included: repeat drainage of another lobe in cases of incomplete decompression (2 cases in the main group vs 10 in the comparison group), stent/drain replacement or cleaning due to obstruction (8 vs 12 cases), and installation of a new stent when tumor obstruction progressed (e.g., tumor growth in the pancreatic head compressing the previously passable section of the choledochus; 5 vs 7 cases). The main cause of restenosis of drains was tumor progression and stent occlusion with tumor tissue or biliary sludge. The use of covered metallic stents in the main group slightly reduced the frequency of occlusions: the average time to repeat obstruction was ~5.5 months, while in patients with plastic stents (some of the comparison group received plastic endoprotheses) it was ~3 months, which agrees with known data. It should be noted that according to modern guidelines, uncovered metallic stents are preferred in palliative situations with hilar strictures, as they do not block the mouths of side branches. In our study, all patients with hilar cholangiocarcinoma had uncovered metallic stents installed, whereas in the comparison group, some patients received plastic stents after external drainage – this may have contributed to more frequent occlusions and repeat procedures in the comparison group.

By the time of the final observation (12 months), 18 patients (30%) in the main group were alive, while in the comparison group, 12 patients (20%) survived. The overall survival curves show a trend towards higher survival in the differentiated approach, though the differences did not reach statistical significance (log-rank p=0.15). The median survival was 9.8 months (95% CI 8.5–11.1) in the main group and 7.2 months (95% CI 5.9–8.5) in the comparison group. The most frequent cause of death in all cases was progression of the underlying disease (metastasis, tumor cachexia, multiple organ failure). It is important to emphasize that adequate biliary drainage allowed most patients to start systemic anti-cancer therapy: chemotherapy was received by 70% of patients in the main group and 55% in the comparison group. Some patients with hilar cholangiocarcinoma additionally underwent intraluminal photodynamic therapy (according to the oncologist's recommendations). Supportive treatment, including cholagogue drugs and antibiotic prophylaxis when necessary, was provided to all according to standards. Therefore, the survival differences, although not statistically significant, reflect a more favorable disease course with timely and complete biliary decompression.

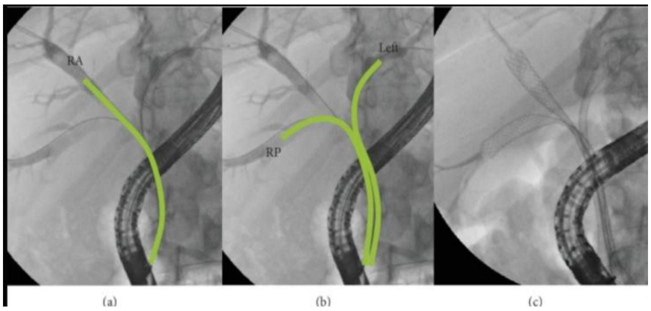

Figure 2. Fluoroscopy of the Stages of Endoscopic Drainage of Proximal Obstruction (Diagram of Three Images)

Table 1. Patient Characteristics (Distribution by Nosology and Level of Obstruction)

Parameter	Main Group (n=60)	Comparison Group (n=60)
Average Age, years	64.3 ± 8.7	63.5 ± 9.1
Men/Women	32/28	33/27
Pancreatic Head Cancer	25 (42%)	26 (43%)
Proximal Cholangiocarcinoma	18 (30%)	17 (28%)
Ampullary Cancer (Vater's Papilla Tumor)	6 (10%)	7 (12%)
Gallbladder Cancer	5 (8%)	4 (7%)
Other (Metastatic, etc.)	6 (10%)	6 (10%)
Distal Obstruction	34 (57%)	35 (58%)
Hilar Obstruction (Bismuth II–IV)	26 (43%)	25 (42%)

Table 2. Methods and Volume of Drainage Used in Groups

Parameter	Main Group (Differentiated)	Comparison Group (Standard)
ERCP Stenting (Internal Stent)	36 (60%) patients	0 (0%) patients
Percutaneous Transhepatic Drainage (External/Internal Drainage)	24 (40%) patients	60 (100%) patients
Combined (ERCP + Percutaneous)	10 (16.7%) patients	0
Number of Stents/Drains Installed	1 in 32 patients (53%); 2 in 22 (37%); 3 in 6 (10%)	1 in 50 (83%); 2 in 10 (17%); 3 or more – 0
Full Bilateral Drainage for Hilar Strictures (Bismuth II–IV)	22/26 (85%) cases	8/25 (32%) cases
Use of Metallic Stents	40 patients (67%)	15 patients (25%)
Use of Plastic Stents	8 patients (13%)	12 patients (20%)
External Drainage Only	12 patients (20%)	45 patients (75%)

Note: In the comparison group, some patients later received internal stents, but the initial method was external. Self-expanding metallic stents were predominantly used in the main group as the primary method, whereas in the comparison group, they were used only secondarily or in cases of distal tumor spread after external drainage.

Table 3. Complications Related to Drainage (Within 30 Days)

Complication	Main Group (n=60)	Comparison Group (n=60)
Acute Cholangitis	6 (10%)	15 (25%)
Acute Pancreatitis Post-ERCP	3 (5%)	0
Gastrointestinal Bleeding	2 (3.3%)	3 (5%)
Displacement/Loss of Drainage	0	1 (1.6%)
Peritonitis, Perforation	0	0
Sepsis (Severe Cholangitis)	2 (3.3%)	5 (8.3%)
Total Patients with Complications	12 (20%)	21 (35%)
Mortality (30 Days)	0	3 (5%)

Note: Some patients had more than one complication (e.g., cholangitis progressing to sepsis). Each patient is counted once in the category of the most severe outcome.

This situation illustrates the necessity of a multimodal approach: sometimes the optimal solution is a combination of endoscopic and percutaneous methods for placing all necessary stents and ensuring complete bile drainage.

The Results Obtained Demonstrate the Advantages of a Differentiated, Individualized Approach to Biliary Drainage in Malignant Obstructive Jaundice. The main group, where the treatment method was selected based on the level of obstruction, showed a higher clinical success rate (92% vs 80%) and fewer complications compared to the group with a uniform approach. These data align with current views and are supported by the literature. A meta-analysis of 21 studies (1693 patients) showed that in low (distal) blockages, endoscopic stenting provides better clinical efficacy (better resolution of jaundice) compared to percutaneous drainage. In contrast, for high (hilar) obstructions, percutaneous access has a higher technical success rate and more effectively resolves jaundice than the endoscopic approach alone. The authors of that review conclude that the choice of method should be based on the level of obstruction: ERCP is recommended as the method of choice for distal biliary tree tumors, and percutaneous transhepatic drainage (PTH) is preferred for hilar strictures. Our differentiated algorithm aligns with this recommendation, which accounted for its high efficiency.

The fundamental factor in full decompression is the volume of the liver being drained. It has been shown that bile drainage from at least one lobe of the liver (about 30% of the parenchyma) is necessary for clinical improvement, and optimally, ≥50% of liver volume, especially in patients with concomitant liver damage (cirrhosis). Tringali et al. (2019) note that drainage of >50% of the liver leads to a more rapid reduction of bilirubin and is less likely to be accompanied by cholangitis. Our data are consistent with this: in the main group, where most patients underwent bilateral or multi-segmental drainage when needed, the incidence of cholangitis was only 10%, while in the control group, it was 25%. Moreover, we observed that in patients with <33% of liver parenchyma drained, the risk of cholangitis was highest (~30% of cases), while with >50% drainage, it was minimal (~5%), which nearly matches the results of Ohto et al., who reported 25% vs 2.5% cholangitis in incomplete vs complete drainage, respectively. Thus, the volume of drainage is a key predictor of success. The differentiated approach allows for individual planning of the necessary number of stents: for example, in Bismuth IIIa (right lobe duct obstruction), the installation of 2–3 stents instead of one improves the results. In the standardized drainage group, many patients were limited to a single drain, which was insufficient for complex lesions, leading to more repeated procedures and complications.

It is interesting to note that, according to some studies, more aggressive (multi-stent) drainage alone, without subsequent chemotherapy, does not improve long-term survival – the critical factor is the ability to proceed with systemic treatment of the tumor. In our study, more complete drainage in the main group did allow chemotherapy to be started more frequently and earlier (70% vs 55% received systemic treatment). This likely explains why the survival curve in the main group was higher, although the difference did not reach statistical significance due to the limited sample size. The absolute 1-year survival rates (30% vs 20%) are comparable to the literature: for inoperable pancreatic cancer, the median survival is approximately 8–10 months even with chemotherapy, and for hilar cholangiocarcinoma, it is about 12 months. Significant contributions to life prolongation may come from the use of local ablative technologies. In particular, photodynamic therapy (PDT) for tumor strictures combined with biliary stenting can significantly improve outcomes. According to D.Yu. Frantsev et al. (2019), in patients with inoperable hilar cholangiocarcinoma, the addition of PDT increased 12-month survival to 47.2% compared to 7.3% with stenting alone. Other studies have also confirmed that palliative PDT combined with drainage significantly increases overall survival in patients with cholangiocarcinoma (relative risk reduction ~3.15, $p<0.00001$). Another method is endobiliary brachytherapy – local irradiation of the stricture zone through installed catheters, which can prolong stent patency. In recent years, endoscopic radiofrequency ablation (RFA) of the biliary ducts has been developed: an endobiliary RF probe is passed through a cholangioscope or endoscope and burns the tumor tissue, slowing restenosis. Preliminary results are promising, but further studies are needed for RFA to be included in the standards.

As for the choice of stent type, a differentiated approach is also important. Plastic stents are cheaper but become occluded by biliary sludge quickly (within 3–4 months) and require replacement. Self-expanding metal stents (SEMS) have a much larger lumen diameter (8–10 mm versus ~3 mm for plastic) and last longer, with an average patency of 6–12 months. Therefore, in a palliative setting, primary use of SEMS is justified, despite their higher cost. An exception is cases where subsequent resection is expected (in which case plastic stents are preferred to avoid damage to the ducts by the metal stent). In our study, all patients received palliative (non-surgical) treatment, so all cases in the main group used metal stents. In the comparison group, however, some patients received plastic stents (especially during endoscopic phases after external drainage), which likely contributed to more frequent restenosis and shorter duration of effect. It is also important to note the specifics of hilar tumors: international guidelines (ESGE, 2018) do not recommend using covered stents in the bile duct hilum as they may obstruct the branches of segmental ducts, leading to abscesses in undrained segments. Only uncovered mesh stents are used, through which bile can also flow into side branches. We adhered to these principles, and no complications related to the choice of stent type were observed.

Another alternative to standard drainage is endoscopic ultrasound-guided biliary drainage (EUS-BD), which has been developing in recent years. This technology combines endoscopy with a transhepatic approach: under the guidance of endoscopic ultrasound (EUS), the bile duct is punctured through the stomach or duodenal wall from the inside, and an internal stent is placed (e.g., hepaticogastrostomy). The

EUS-BD technique has shown high efficacy as a rescue procedure when traditional ERCP fails. Several studies have demonstrated that EUS drainage results are comparable to or even better than those of percutaneous transhepatic drainage: for example, Sharaiha et al. (2017) in a meta-analysis of 6 studies report equal technical success rates but a lower frequency of complications and repeat interventions with EUS-BD compared to percutaneous drainage. The advantages of the EUS-guided approach include the absence of external drainage (the stent is fully inside, as with ERCP) and the ability to drain hard-to-reach areas (for example, the left duct through the stomach). The drawbacks are the need for a highly qualified endoscopist, the availability of an endoscope with an ultrasound probe, and specialized tools; there is also a risk of intra-abdominal complications during puncture (bleeding, peritonitis). In our center, EUS drainage began to be implemented, but at the time of the study, it was used on a limited basis. It is promising that the differentiated approach can be expanded in the future to include EUS-BD as a third option: for instance, when ERCP is not feasible and there is a high risk of external drainage, endosonographic stenting could be used as an alternative. There are already algorithms suggesting that for malignant distal obstructions, EUS-CD (choledochoduodenostomy) should be performed immediately instead of ERCP in certain patient categories. While such recommendations are still under discussion, they are likely to be incorporated into practice in the near future.

Thus, the analysis of the literature and our data indicate that personalized treatment is the key to success in managing patients with malignant mechanical jaundice. A differentiated approach, which includes the optimal choice of drainage method, stent type and number, and the use of adjunct technologies (endoscopy, percutaneous interventions, EUS, local ablations), significantly improves immediate results and creates conditions for further anticancer therapy. Ultimately, this affects the survival and quality of life of patients. Considering the lack of a proven effect of drainage alone on long-term survival without subsequent tumor therapy, the main goal of biliary decompression should be to enable continued treatment – chemotherapy or radiotherapy. Only a comprehensive approach can ensure the longest duration and best quality of life for patients with this severe condition.

Our study had some limitations. First, the design was not blinded (the nature of the intervention could not be concealed), which could have introduced some subjectivity into postoperative management. However, objective laboratory and quantitative indicators minimize this effect. Second, the sample size (especially in survival analysis) was relatively small, making it difficult to detect statistically significant differences in long-term outcomes. Nevertheless, the trend in favor of the differentiated strategy is evident, and further studies with larger sample sizes are needed to confirm its impact on survival. Finally, tumor progression remains the decisive factor in prognosis; our data suggest that optimizing bile drainage should be seen as part of multidisciplinary treatment, including modern oncological methods (systemic chemotherapy, targeted therapy, etc.).

In general, the results of this study align with global trends and expand the evidence base in support of individualized strategies. The implementation of a differentiated approach in practice (algorithms for choosing a drainage method depending on the level of obstruction and the anatomy of the lesion) will improve treatment outcomes for patients with mechanical jaundice of oncological origin.

4. Conclusions

1. Individual selection of the drainage method (endoscopic, percutaneous, or their combination) based on the level and extent of the tumor obstruction results in clinical success in 91.7% of cases, significantly higher than the standardized strategy (80%, $p<0.05$).
2. In the differentiated approach, bile drainage from ≥50% of the liver volume was achieved in 92% of patients, while in the unilateral approach, this was only achieved in 80%. This leads to more rapid bilirubin reduction (1.3 times more pronounced on day 7) and significantly fewer purulent complications.
3. In the main group, complications occurred in 20% of patients, compared to 35% in the comparison group. Notably, the incidence of acute cholangitis decreased from 25% to 10%, with the relative risk reduced by 60%. There was also a trend towards a reduction in other complications, including early mortality (0% vs 5%).
4. The differentiated approach reduced the need for repeat drainage or stent replacement in the long term by two times (18% vs 40%, $p<0.01$). This facilitates patient management and reduces the burden on the hospital.
5. With the individualized approach, there is a trend towards increased survival: the median overall survival increased from 7.2 to 9.8 months, and 1-year survival increased from 20% to 30%. Although the difference did not reach statistical significance, it is clinically important and related to a wider use of chemotherapy after successful decompression.

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