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Modern Aspects of Personalized Biliary Drainage in Malignant Obstructive Jaundice

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ABSTRACT

Malignant obstructive jaundice caused by tumors of the hepatopancreatoduodenal region represents a significant clinical challenge and necessitates timely biliary decompression. This study substantiates a differentiated approach to the use of minimally invasive drainage techniques (endoscopic and percutaneous) in 120 patients with inoperable tumors. It has been demonstrated that the individualized selection of drainage methods based on the level of obstruction leads to higher effectiveness, reduced complication rates, decreased need for repeated interventions, and improved survival outcomes compared to standard, uniform strategies.

Keywords: *Obstructive jaundice, malignant biliary obstruction, endoscopic stenting, personalized approach.*

INTRODUCTION

Relevance

Mechanical (obstructive) jaundice of malignant etiology is a common and severe complication of tumors in the hepatopancreatoduodenal region. By the time jaundice manifests, most such tumors are deemed unresectable, and radical surgery becomes unfeasible. Without adequate bile drainage, patients rapidly develop liver failure, cholanemia, and secondary cholangitis, which can progress to sepsis. Mortality in the absence of drainage is extremely high; therefore, timely biliary decompression is a vital component of palliative care for these patients.

The current stage in the development of surgical gastroenterology is marked by a shift toward minimally invasive procedures for biliary decompression. Traditional open bypass surgeries (such as choledochojejunostomy or hepaticojejunostomy) in the context of malignant obstruction are associated with high complication rates (up to 30%) and perioperative mortality of 3–15%. In contrast, endoscopic and percutaneous drainage techniques have proven to be effective and relatively safe, allowing for bilirubin reduction, resolution of cholanemia, and prevention of purulent complications. Endoscopic transpapillary stenting via ERCP is considered the method of choice for distal biliary obstructions caused by tumors of the ampulla of Vater or the pancreatic head. When the tumor is located proximally (e.g., hilar cholangiocarcinoma or Klatskin tumor), endoscopic drainage is technically challenging and often incomplete; in such cases, percutaneous transhepatic cholangiostomy (PTC) is preferred. Both approaches—endoscopic and transhepatic—are minimally invasive and, together, can effectively relieve jaundice in the majority of patients. However, several unresolved questions remain regarding the optimal drainage strategy.

The primary challenge is the selection of an appropriate drainage method tailored to the patient's individual anatomical characteristics. A uniform approach (e.g., external drainage or endoscopic stenting for all cases) fails to consider differences in obstruction location and the condition of intrahepatic bile ducts. This can result in unjustified risks (e.g., attempting endoscopic drainage in complex hilar strictures) or insufficient decompression (e.g., draining only one hepatic lobe in bilobar obstruction). It is well established that incomplete drainage of all affected ducts leads to persistent obstruction in the undrained liver segments, increasing the risk of septic complications. Even when the procedure technically succeeds, failure to drain a significant portion of the liver results in ongoing bile hypertension and can provoke cholangitis and worsen survival outcomes. On the other hand, overly aggressive attempts to drain all segments (e.g., placing multiple stents in multilevel strictures) increase procedural invasiveness and the risk of complications, including ductal injury, hemorrhage, or infection. Therefore, a balance must be struck between drainage volume and procedural safety. Optimizing palliative treatment for malignant jaundice requires a differentiated approach—choosing the least invasive yet sufficiently effective decompression method for each patient. Literature suggests that in proximal (hilar) malignant strictures, effective bile outflow is achieved when at least 50% of the functional liver volume is drained. Drainage of >50% of liver volume correlates with significant bilirubin reduction and fewer episodes of cholangitis. This is typically accomplished by bilateral stenting of the right and left hepatic ducts in Bismuth types II–III hilar tumors; in more complex cases (Bismuth IV), drainage of three branches (right anterior, right posterior, and left) may be required. However, drainage of atrophic or non-perfused liver segments is not advisable, as it does not improve function and only increases the risk of infection. In distal obstructions, stenting of the common bile duct alone is usually sufficient to restore drainage from the entire liver. Thus, procedural planning should consider the morphology and level of the tumor-related obstruction (based on Bismuth-Corlette classification and cholangiography findings) and aim to achieve complete drainage of all functional liver segments.

An additional factor is the patient's general condition and comorbidities. In debilitated patients with high operative risk, the least traumatic method is preferred. As a rule, endoscopic stenting is better tolerated than external drainage with a percutaneous catheter. Internal stents avoid continuous external bile loss, electrolyte disturbances, and the inconvenience of drain maintenance. Therefore, when technically feasible, endoscopic stenting is preferable, especially in elderly patients or those with significant comorbidities. Conversely, in cases of severe cholangitis, markedly dilated intrahepatic ducts, or post-gastrectomy anatomy (hindering ERCP), the percutaneous approach offers a more direct and expedient route for decompression.

In conclusion, the relevance of this issue lies in the need to develop a clinical algorithm for selecting a minimally invasive biliary drainage method tailored to the anatomical and clinical characteristics of malignant obstruction. A differentiated approach is expected to enhance treatment outcomes—reducing drainage failures, minimizing complications (especially infections), and improving patients' quality of life. Furthermore, effective biliary decompression is essential for initiating subsequent chemotherapy or radiotherapy, which can prolong survival in patients with advanced malignancies. Therefore, the rationale for optimal minimally invasive drainage strategies in malignant jaundice holds significant clinical interest and practical value.

Objective

To justify a differentiated approach to the use of minimally invasive biliary drainage techniques in patients with inoperable malignant tumors of the hepatopancreatoduodenal region complicated by obstructive jaundice.

Materials and Methods

The study was conducted in the departments of abdominal surgery and endoscopy and included 120 patients with obstructive jaundice caused by malignant tumors of the hepatopancreatoduodenal area (pancreatic head cancer, distal cholangiocarcinoma, tumors of the ampullary region, proximal cholangiocarcinoma, etc.). Inclusion criteria were: clinical and laboratory signs of obstructive jaundice (total bilirubin > 50 µmol/L, cholestatic syndrome), presence of an inoperable tumor (based on imaging—CT/MRI—indicating locally advanced or metastatic disease deemed unresectable by a multidisciplinary team), and technical feasibility of minimally invasive drainage. Exclusion criteria included benign strictures, resectable tumors (planned for curative surgery), or previously drained biliary systems.

All patients provided informed consent for the procedures. They were randomized into two groups of 60 patients each. In the main group, the drainage strategy was determined individually based on the level of obstruction and tumor characteristics (differentiated approach). In the control group, a standardized drainage protocol was used without considering anatomical differences. The mean patient age was 64±9 years; there were 65 males (54.2%) and 55 females (45.8%).

In the main group, the following protocol was applied:

For distal obstructions (tumors of the ampulla or pancreatic head), the first step was endoscopic retrograde cholangiopancreatography (ERCP) with placement of an internal stent in the extrahepatic bile ducts. Self-expanding metal stents (SEMS) with a diameter of 8–10 mm were used, selected for their superior patency and durability in oncological patients.

For proximal tumors (e.g., hilar cholangiocarcinoma), percutaneous transhepatic drainage under ultrasound and fluoroscopic guidance was preferred. The Bismuth classification was used to guide treatment: in types II–III, bilateral stenting of the left and right ductal systems was performed via separate punctures to ensure drainage of both hepatic lobes; in type IV, three sectors (left lobe, right anterior and right posterior segments) were drained with three stents.

A combined approach (both endoscopic and percutaneous) was allowed in selected cases—for instance, in Klatskin tumors, an endoscopic stent was placed into the left duct followed by percutaneous drainage of the right ductal system. If endoscopic intervention failed (due to complete obstruction, stenosis of the ampulla, or altered anatomy after gastrectomy), patients were switched to percutaneous drainage as part of the differentiated strategy. The goal in all cases was to decompress the largest possible volume of functioning hepatic parenchyma. Successful drainage was defined as a ≥50% reduction in total bilirubin within 2 weeks.

In the control group, all patients underwent standardized single-stage drainage per the clinic's previous protocol: percutaneous transhepatic cholangiostomy with external drainage of a single hepatic ductal system. Typically, the dilated right hepatic duct was punctured, followed by drainage of the right lobe; in left-sided tumors, the left hepatic duct was accessed. Endoscopic procedures were not performed at this stage. Thus, most patients in this group underwent unilateral drainage only. After external drainage and reduction in jaundice, internal stents could be placed via the existing tract using the "rendezvous" technique, but for the purpose of this analysis, only initial decompression outcomes were evaluated.

Patients in both groups were followed up dynamically. Laboratory parameters (bilirubin, alkaline phosphatase, transaminases) were assessed before and after the procedure (on days 1, 3, 7, and at 2 weeks).

Technical success was defined as the successful placement of a drainage system with restoration of bile outflow. Clinical success was defined as reduction of jaundice and intoxication within 1–2 weeks, confirmed by ≥50% decrease in bilirubin levels. All procedure-related complications were recorded: acute cholangitis, acute pancreatitis (in endoscopic cases), hemorrhage (intraluminal or intra-abdominal requiring transfusion), peritonitis or intra-abdominal abscesses, incorrect stent placement or migration, early stent occlusion, and 30-day post-procedure mortality.

In the long-term follow-up (mean duration 10 months), rates of recurrent obstruction (restenosis or stent occlusion), need for repeat interventions (e.g., stent replacement or additional drainage due to progression), and overall survival (6- and 12-month) were assessed. Survival was analyzed using the Kaplan–Meier method, and group comparisons were performed with the log-rank test. Statistical analysis was conducted using StatTech® software. Group comparisons employed the χ^2 and Student's t-tests, with a significance level set at $p<0.05$.

The study was approved by the institutional ethics committee and conducted in accordance with the Declaration of Helsinki.

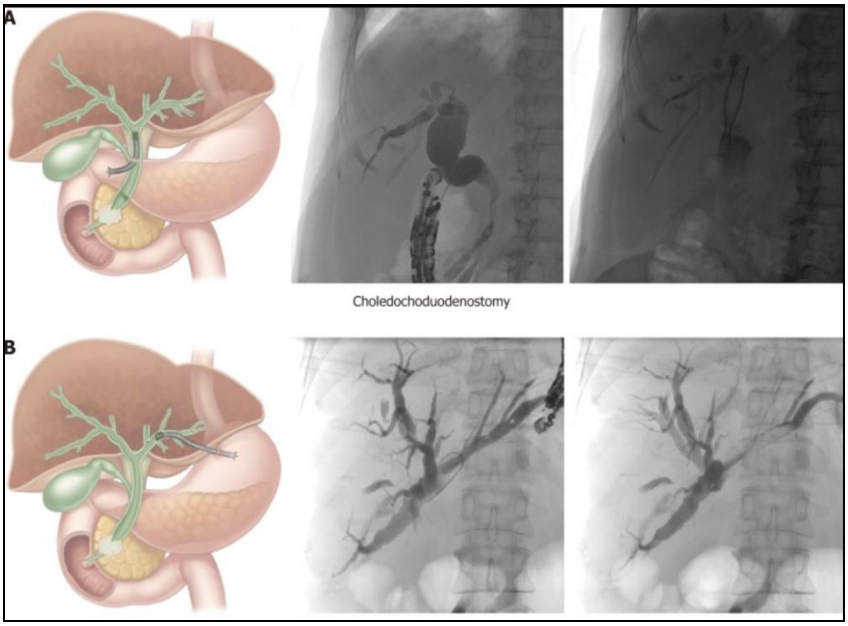

Fig. 1. **Diagram of a differentiated drainage strategy**

During the follow-up period, it was noted that patients in the main group required fewer rehospitalizations and invasive procedures related to drainage function. Over the observation period (average 10 months), 11 patients (18%) in the main group required additional biliary interventions, compared to 24 patients (40%, $p<0.01$) in the comparison group. These included repeat drainage of the contralateral lobe due to initial incomplete decompression (2 cases in the main group vs. 10 in the comparison group), replacement or clearance of clogged stents/drainage (8 vs. 12 cases), and the installation of a new stent in the event of tumor progression (e.g., pancreatic head tumor growth compressing the previously patent section of the common bile duct; 5 vs. 7 cases).

The primary cause of stent restenosis was tumor progression and obstruction of the stent with tumor tissue or biliary sludge. The use of covered metallic stents in the main group slightly reduced the incidence of stent occlusion: the average time to repeat obstruction was ~5.5 months, compared to ~3 months for patients with plastic stents (some comparison group patients had plastic endoprostheses), consistent with known data. Notably, current guidelines for palliative care recommend uncovered metallic stents for hilar strictures to avoid blocking the orifices of side branches. In our study, all patients with liver hilum cholangiocarcinoma in the main group received uncovered metallic stents, while some patients in the comparison group underwent plastic stenting after external drainage, which may have contributed to higher rates of occlusion and repeat procedures.

At the last follow-up (12 months), 18 patients (30%) in the main group were alive, compared to 12 patients (20%) in the comparison group. Survival curves indicate a trend towards higher survival with the differentiated approach, but the differences did not reach statistical significance (log-rank $p=0.15$). 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 common cause of death in both groups was disease progression (metastases, tumor cachexia, multi-organ failure). Importantly, adequate biliary drainage allowed most patients to start systemic anti-tumor therapy: 70% of patients in the main group and 55% in the comparison group received chemotherapy. Some patients with hilar cholangiocarcinoma also underwent intraluminal photodynamic therapy (as recommended by the oncologist). Supportive treatment, including cholagogues and, if necessary, antibacterial prophylaxis, was provided to all patients according to standards.

Thus, although survival differences were not statistically significant, they reflect a more favorable disease course with timely and complete biliary decompression.

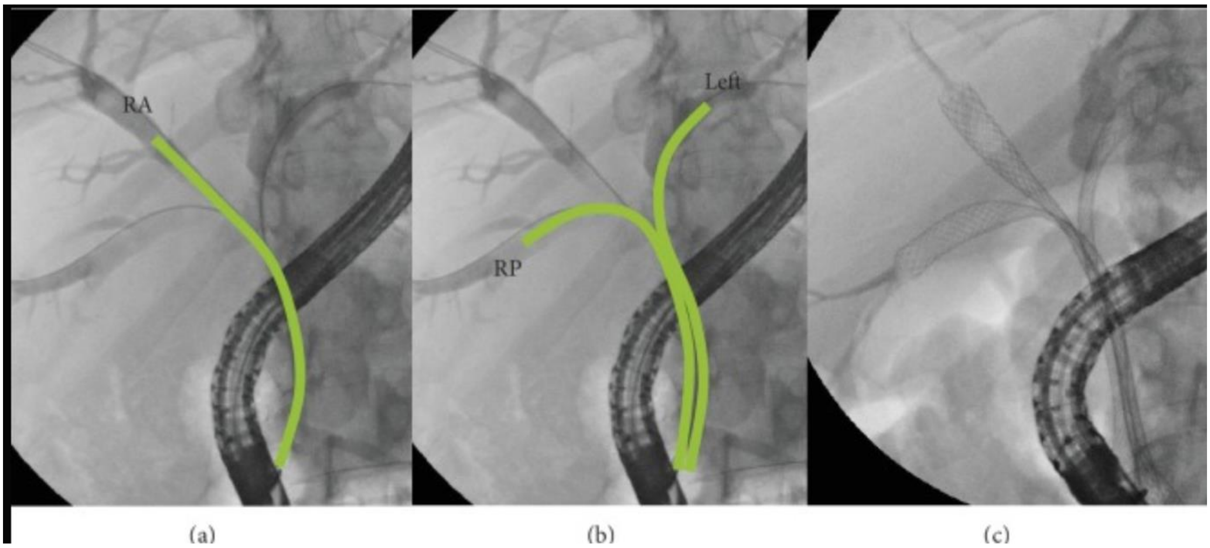

Fig. 2. **Fluoroscopy of the stages of endoscopic drainage for proximal obstruction (a three-image diagram)**

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

Table 1: Patient characteristics (distribution by diagnosis and level of obstruction)

Indicator	Main Group (n=60)	Comparison Group (n=60)
Mean age, years	64.3 ± 8.7	63.5 ± 9.1
Male/Female	32/28	33/27
Pancreatic head cancer	25 (42%)	26 (43%)
Proximal cholangiocarcinoma	18 (30%)	17 (28%)
Ampullary cancer (Vater's papilla)	6 (10%)	7 (12%)
Gallbladder cancer	5 (8%)	4 (7%)
Others (metastatic, other)	6 (10%)	6 (10%)
Distal obstruction	34 (57%)	35 (58%)
Hilar obstruction (II–IV)	26 (43%)	25 (42%)

Table 2: Methods and extent of drainage used in the groups

Parameter	Main Group (Differentiated)	Comparison Group (Standard)
ERCP stenting (internal stent)	36 patients (60%)	0 patients (0%)
PTBD (external/internal drainage)	24 patients (40%)	60 patients (100%)
Combined (ERCP + PTBD)	10 patients (16.7%)	0
Number of stents/drains placed	1 in 32 (53%); 2 in 22 (37%); 3 in 6 (10%)	1 in 50 (83%); 2 in 10 (17%); 3 or more – 0
Complete bilateral drainage in hilar strictures (Bismuth II–IV)	22/26 cases (85%)	8/25 cases (32%)
Use of metal 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 approach was external drainage.

Self-expanding metal stents were primarily placed in the main group as the initial method; in the comparison group, they were used only secondarily or in cases of distal tumor progression after external drainage.

Table 3: Drainage-related complications (within 30 days)

Type of complication	Main Group (n=60)	Comparison Group (n=60)
Acute cholangitis	6 (10%)	15 (25%)
Post-ERCP acute pancreatitis	3 (5%)	0
Gastrointestinal bleeding	2 (3.3%)	3 (5%)
Drain displacement/loss	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%)
30-day mortality	0	3 (5%)

Note: Some patients experienced more than one complication (e.g., cholangitis progressing to sepsis). In the table, each patient was counted only once, under the category of the most severe outcome.

The obtained results demonstrate the advantages of a differentiated, individualized approach to biliary drainage in malignant obstructive jaundice. The main group, where the treatment method was selected considering the level of obstruction, showed a higher clinical success rate (92% vs. 80%) and a lower complication rate compared to the group with a uniform approach. These data align with current concepts and are supported by the literature. A meta-analysis of 21 studies (1693 patients) showed that in cases of low (distal) obstructions, endoscopic stenting provides better clinical efficacy (more effective jaundice relief) compared to percutaneous drainage. On the contrary, in cases of high (hilar) obstructions, percutaneous access shows a higher technical success rate and more complete jaundice resolution 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 tumors of the distal biliary tract, while PTBD is preferred for hilar strictures. Our differentiated algorithm follows this recommendation, which accounted for its high efficacy.

A fundamental factor in complete decompression is the volume of the drained liver. It has been shown that drainage from at least one lobe of the liver (about 30% of the parenchyma) is necessary for clinical improvement, and optimally ≥50% of the volume, especially in patients with concomitant liver damage (cirrhosis). Tringali et al. (2019) note that draining >50% of the liver results in faster bilirubin reduction and less frequent cholangitis. Our data are consistent with this: in the main group, where most patients underwent bilateral or multi-segmental drainage when necessary, the incidence of cholangitis was only 10%, whereas in the control group it was 25%. Moreover, we observed that in patients with <33% drained parenchyma, the risk of cholangitis was maximal (about 30% of cases), while with >50% coverage, it was minimal (~5%), which closely matches the findings of Ohto et al., reporting 25% vs. 2.5% cholangitis in cases of incomplete versus complete drainage, respectively. Therefore, the drainage volume is a key predictor of success.

The differentiated approach allows for individually planning the necessary number of stents: for example, in Bismuth IIIa (obstruction of the right hepatic ducts), placing 2–3 stents instead of one improves outcomes. In the standardized drainage group, many patients were limited to a single drain, which was insufficient in complex lesions, leading to more repeat procedures and complications.

It is noteworthy that, according to some studies, more aggressive (multi-stent) drainage without subsequent chemotherapy does not improve long-term survival—the decisive factor is the ability to conduct systemic tumor treatment. In our study, more complete drainage in the main group indeed enabled earlier and more frequent initiation of chemotherapy (70% vs. 55% received systemic treatment). Presumably, this is why the survival curve of 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 instance, the median survival in unresectable pancreatic cancer is ~8–10 months even with chemotherapy, and for hilar cholangiocarcinoma ~12 months.

A significant contribution to prolonged survival can be made by applying local ablative technologies. In particular, photodynamic therapy (PDT) of tumor strictures combined with biliary stenting can significantly improve outcomes. According to D.Yu. Frantsev et al. (2019), in patients with unresectable hilar cholangiocarcinoma, adding PDT increased the 12-month survival rate to 47.2% compared to 7.3% with stenting alone. Other studies have also confirmed that palliative PDT combined with drainage significantly increases the overall survival of patients with cholangiocarcinoma (relative risk reduction of death ~3.15, $p<0.00001$). Another method is endobiliary brachytherapy—local irradiation of the stricture area through established catheters, which can extend stent patency. In recent years, the technique of endoscopic radiofrequency ablation (RFA) of the bile ducts has been developed: an endobiliary RF probe is introduced through a cholangioscope or endoscope to cauterize tumor tissue, slowing restenosis. Preliminary results are promising, but further studies are needed to include RFA in standards.

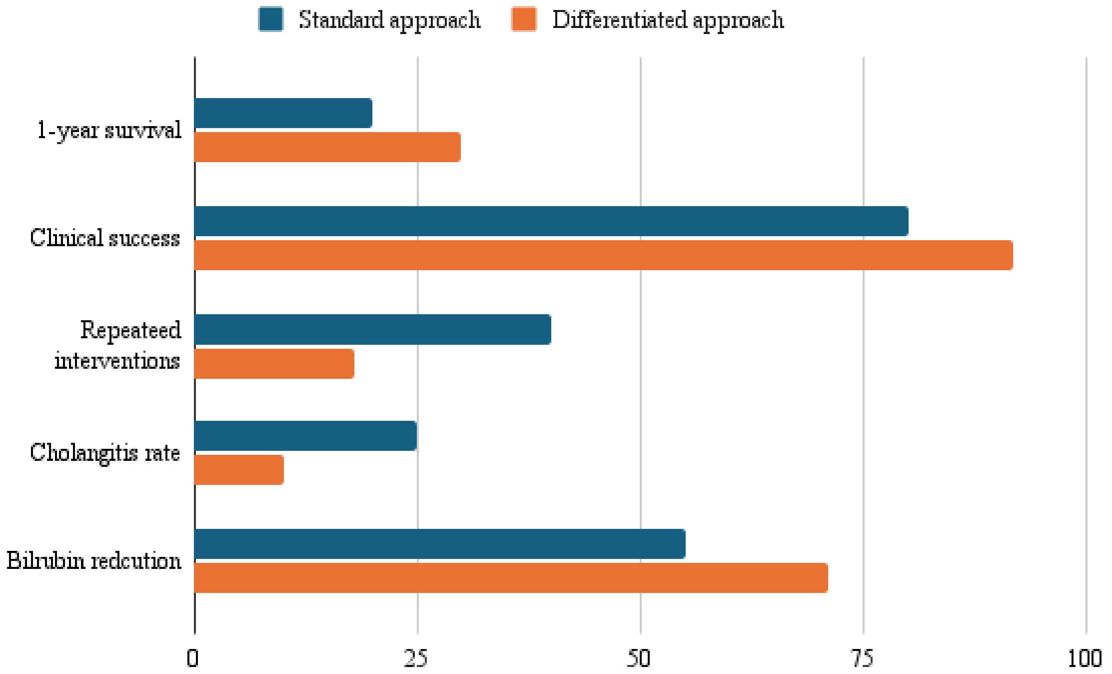

***Fig*. 3 Comparative analysis of key clinical and effectiveness indicators of the two drainage approaches**

Regarding the choice of stent type, a differentiated approach is also crucial. Plastic stents are cheaper but quickly (within 3–4 months) become obstructed by biliary sludge and require replacement. Self-expanding metal stents (SEMS) have a much larger lumen diameter (8–10 mm compared to ~3 mm for plastic) and last longer, with an average patency of 6–12 months. Therefore, in palliative situations, the primary use of SEMS is justified despite their higher cost. An exception is when subsequent resection is anticipated (in which case plastic is preferred to avoid duct injury by the metallic stent). In our study, all patients underwent palliative (nonoperative) treatment, so in the main group, metal stents were used in all cases. In the comparison group, however, some patients received plastic prostheses (especially during endoscopic stages after external drainage), which likely contributed to more frequent restenosis and reduced efficacy duration.

It is important to note the specificity of hilar tumors: international guidelines (ESGE, 2018) do not recommend using covered (Covered) stents in the liver hilum, as they can block segmental duct branches, leading to abscesses in undrained segments. Only uncovered mesh stents are used, allowing bile to pass through their openings into the side branches. We adhered to these principles—no complications related to stent type selection were noted.

Another alternative to standard drainage is endoscopic ultrasound-guided biliary drainage (EUS-BD), which has been evolving in recent years. This technique combines endoscopy and percutaneous access: under endoscopic ultrasound (EUS) guidance, the bile duct is punctured through the stomach or duodenal wall from the inside, and an internal stent is placed (e.g., hepaticogastrostomy). EUS-BD has demonstrated high efficacy as a salvage technique after failed conventional ERCP. Some studies have shown that EUS-BD outcomes are comparable to or exceed those of PTBD: for example, Sharaiha et al. (2017) reported in a meta-analysis of 6 studies that both techniques had equal technical success, but EUS-BD had fewer complications and reinterventions compared to percutaneous drainage.

The advantages of the EUS-guided approach include the absence of external drainage (the stent remains entirely internal, as in ERCP) and the ability to drain hard-to-reach areas (e.g., the left duct via the stomach). Disadvantages include the need for a highly skilled endoscopist, specialized equipment (an endoscope with an ultrasound probe), and the risk of intraperitoneal complications during puncture (bleeding, peritonitis). In our center, EUS drainage has begun to be implemented, although its use was limited during the study. It is promising that the differentiated approach may be expanded in the future to include EUS-BD as a third option: for example, in cases where ERCP is not feasible and there is a high risk of external drainage, endosonographic stenting could be used as an alternative. Some algorithms already suggest opting for EUS-CD (choledochoduodenostomy) instead of ERCP in patients with malignant distal obstruction. Although these recommendations are still debated, they are likely to be adopted in clinical practice in the near future.

In summary, both literature data and our findings indicate that personalized treatment is key to successful management of patients with malignant obstructive jaundice. A differentiated approach that includes the optimal selection of drainage method, type, and number of stents, as well as the integration of complementary technologies (endoscopy, percutaneous interventions, EUS, local ablation), significantly improves immediate outcomes and provides conditions for subsequent antitumor treatment. Ultimately, this translates into improved survival and quality of life for patients.

Considering the absence of a direct impact of drainage alone on long-term survival without subsequent tumor therapy, the primary goal of biliary decompression should be to enable continued treatment—be it chemotherapy or radiotherapy. Only a comprehensive approach can maximize both the duration and 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 may have introduced a degree of subjectivity in postoperative management. However, objective laboratory and quantitative indicators minimized this effect. Second, the sample size (particularly in survival analysis) was relatively small, making it challenging to detect statistically significant differences in long-term outcomes. Nevertheless, the trend in favor of a differentiated strategy is evident, and further studies with larger cohorts are needed to confirm its impact on survival. Lastly, tumor progression remains the decisive prognostic factor; our data suggest that optimizing bile drainage should be viewed as part of multidisciplinary treatment, including modern oncological methods (systemic chemotherapy, targeted therapy, etc.).

Overall, the results of this study are consistent with global trends and expand the evidence base in favor of individualized strategies. Implementing a differentiated approach in practice (algorithms for selecting the drainage method based on the level of obstruction and lesion anatomy) will improve treatment outcomes for patients with malignant biliary obstruction.

Conclusions:

1. Individualized selection of the drainage method (endoscopic, percutaneous, or a combination) based on the level and extent of tumor obstruction achieves clinical success in 91.7% of cases, significantly higher compared to the standardized approach (80%, $p<0.05$).
2. The differentiated strategy enables bile flow from ≥50% of the liver volume in 92% of patients, whereas the unilateral approach achieves this in only 80%. This results in a faster bilirubin reduction (1.3 times more pronounced by day 7) and significantly lower rates of purulent complications.
3. In the main group, complications developed in 20% of patients, compared to 35% in the comparison group. A particularly notable reduction was observed in acute cholangitis incidence (from 25% to 10%, relative risk reduced by 60%). A trend towards reduction in other complications, including early mortality (0% vs. 5%), was also noted.
4. The differentiated approach resulted in half as many repeat drainage or stent replacement procedures in the long-term period (18% vs. 40%, $p<0.01$), facilitating patient management and reducing hospital burden.
5. The individualized strategy showed a trend towards improved survival: the median overall survival increased from 7.2 to 9.8 months, and 1-year survival from 20% to 30%. Although the difference did not reach statistical significance, it is clinically relevant and associated with more frequent chemotherapy following successful decompression.

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