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Original Article

Short-Term Clinical Outcomes of Percutaneous Biliary Tract Interventions: Analysis of Success and Complication Rates

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Abstract

Introduction: Obstructive jaundice is a clinical syndrome that is commonly seen in gastroenterology. Endoscopic retrograde cholangiopancreatography (ERCP) has been recognized as a first-choice therapeutic approach, with percutaneous biliary interventions (PBIs) being a viable alternative. Recent data questions the performance and safety profile of PBIs.

Aim: The aim of the present study was to assess retrospectively the short-term clinical outcomes of PBIs in terms of technical and clinical success and adverse events (AEs) rate.

Patients and methods: This is a retrospective, single-center cohort study of 62 consecutive patients subjected to PBI between January 2019 and August 2022.

Results: Technical and clinical success rates of 97.10% and 79.40%, respectively were established. No PBI showed statistically significant superiority over the others. None of the evaluated factors showed significant influence on the therapeutic outcome and AEs. A total AE rate of 26.5% was calculated. All AEs were moderate to severe (grade III-IV according the Clavien-Dindo system). The mean hospital stay was 7.11±3.68 days. A total of 44.1% of the patients required multiple admissions.

Existing studies establish similarly high technical (75%-100%) and acceptable clinical (84%) success rates. Alarmingly high AEs incidence of almost 50% has been found in recently published studies. Infection was the most common adverse event we found in our study. Almost universally, PBIs are used as salvage techniques in patients with malignant disease, failed prior ERCP, and poor performance status.

Conclusion: PBIs remain a viable option to ERCP, but stricter patient selection and a gradual transition to EUS-guided draining procedures are likely required.

Keywords

biliary drainage, cholangiopancreatography, endoscopy, percutaneous, rendezvous, ultrasound

Abbreviations

AEs: adverse events
ECOG: Eastern Cooperative Oncology Group
ERCP: endoscopic retrograde cholangiopancreatography
EUS: endoscopic ultrasonography
EUS-BD: endoscopic ultrasound-guided biliary drainage
EUS-CDS: endoscopic ultrasound-guided choledochoduodenostomy
GB: gall bladder
GI: gastrointestinal
GSD: gallstone disease
ICU: intensive care unit
INR: international normalized ratio
PABS: percutaneous antegrade biliary stenting
PBIs: percutaneous biliary interventions
PC: percutaneous cholecystostomy
PEBD: percutaneous external biliary drainage
PS: performance status
PTBD: percutaneous transhepatic biliary drainage
PT-Rv: percutaneous rendezvous
SEMS: self-expandable metal stent
US: ultrasound

INTRODUCTION

Obstructive jaundice is one of the most challenging conditions to manage in the field of interventional gastroenterology. A variety of both benign and malignant diseases could serve as an underlying cause for such occurrences. Its social relevance is highlighted by real-life data claiming that about 80,000 new cases (8% of all cases of gallstone disease) of choledocholithiasis are established in the USA annually.[1] Furthermore, pancreatic cancer is the fourth most common cause of cancer-related death in Europe and the third most common in the USA, with its incidence expected to rise by 50% by 2035.[2,3] In about 70% of pancreatic cancer patients jaundice is the leading symptom, with about 80% of them being unfit for surgery at the time of diagnosis. To add on that, in the USA, there are about 7,000 to 8,000 cases of primary biliary tract tumors every year, most of them radically inoperable.[4]

The presented data underlines the importance of minimally invasive techniques aiming to restore adequate biliary drainage. Historically, surgical treatment of obstructive jaundice has been associated with a high rate of adverse events (5%–30%) and a somewhat high mortality rate (3%–10%).[5,6] These worrisome numbers lead to a gradual transition from surgical to endoscopic or percutaneous interventions as a primary treatment modality for biliary obstruction, especially in cases induced by unresectable gastrointestinal (GI) malignancies.

Currently, there are three pivotal techniques to obtain biliary drainage in the setting of obstructive jaundice:

1. Endoscopic retrograde cholangiopancreatography (ERCP).

Since its introduction in 1968 by William McCune[7], ERCP has become the first-line approach in the management of biliary obstruction. Achieving high success (90%-95%) and low adverse event (5.18-9.8%) rates, while preserving the anatomy and physiology of the GI tract, its value in the management of a broad spectrum of biliary disorders is enormous.[7-10] Unfortunately, achieving drainage via ERCP is impossible in about 3% to 10% of patients due to a variety of factors such as an inaccessible papilla, failure to cannulate, altered anatomy, and so on.[8,11]

2. Endoscopic ultrasound-guided biliary drainage (EUS-BD).

EUS-BD is a technique developed recently by Giovannini et al., who performed the first endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) in 2001, followed by hepaticogastrostomy in 2003.[12,13] This technique is predominantly used in patients with malignant diseases, although certain benign indications have emerged in recent years as well.[14] EUS-BD, albeit alternating the anatomy of the upper GI tract to a certain extent, still preserves the normal flow of bile in the GI lumen. Additionally, it has certain theoretical advantages over ERCP in terms of lower stent occlusion rate. While being acceptably safe (AEs – 29%)[15,16] and with a high success rate (>90%)[15], it is worth noting that this subset of procedures is rarely performed outside tertiary expert centers, and their general applicability in every-day clinical practice is still limited.

3. Percutaneous biliary interventions (PBIs).

PBIs is a general term that encompasses a number of interventions unified by access to the biliary tree through a percutaneous route. All of them can be performed under fluoroscopic or sonographic guidance, depending on local expertise. PBIs show high technical and clinical success rates for alleviating hyperbilirubinemia, varying between 90%–100% and 77%–98%, respectively, depending on etiology.[17] Unfortunately, the complication rate is considerably high (8%-30%), with a mortality rate of 0-3%.[17] Reinterventions are also an issue with such procedures and are needed in approximately 5%–25% of patients.[17,18] Other factors that are worth considering (at least for the external drainage procedures) include the persistent need for external drainage catheters, which worsen patients' quality of life, impair normal intestinal absorption and integrity, and lead to loss of fluid and electrolytes. The spectrum of PBI includes: 1. percutaneous external biliary drainage (PEBD); 2. percutaneous transhepatic rendezvous technique (PT-Rv); 3. percutaneous antegrade biliary stenting (PABS); 4. combined percutaneous and endoscopic techniques (hybrid techniques); and 5. percutaneous cholecystotomy (PC).

With the advent of new EUS-guided drainage techniques, the application of PBIs to ensure biliary drainage is increasingly debated. The clinical outcomes and adverse

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event rate are under discussion. Little is known about the individual performance of the different types of PBIs. The influence of certain factors such as etiology and level of obstruction, patient's performance status (PS), and access route on the outcomes has hardly been investigated. Information on the number of interventions needed to achieve and maintain drainage, hospital admissions, and the total duration of hospital stay, which might be considered important surrogates of procedure efficiency, is lacking.

AIM

The primary endpoint of the current paper was to evaluate the short-term outcomes of PBIs in terms of technical and clinical success rates and AEs in general and specifically for each type of percutaneous intervention. As a secondary endpoint, we aimed to evaluate the influence of certain factors including type of procedure, utilized access route, etiology, level of obstruction, and patient's performance status on the outcomes.

ETHICS

Prior to the procedures, oral and written informed consent was obtained, and the patients and their relatives were thoroughly informed about the possible clinical outcomes, adverse events, and complications, as well as the valid alternatives. The study was conducted in accordance with the Declaration of Helsinki and approved by the Local Ethics Committee for studies involving humans.

PATIENTS AND METHODS

The study included 68 patients treated with PBIs for various biliary tract disorders at the University Hospital's Gastroenterology Department between January 2019 and August 2022. The research is designed as a single-center, retrospective cohort study. A total of 92 procedures were analyzed.

Patient selection

Inclusion criteria: age ≥18 years; interventional treatment with any type of PBI (PEBD, PT-Rv, PABS, hybrid techniques, PC) was considered the chief inclusion criterion; follow-up of at least 30 days post-procedure or until death; and competence to give informed consent was also required.

Exclusion criteria: patients lost to the follow-up were excluded from analysis; also, refusal to participate in the study was considered an exclusion criterion.

The patient selection process is shown in **Fig. 1**.

Methods

A standard pre-procedure assessment was performed for all patients. It included evaluation of the complete blood count, concentration levels of C-reactive protein, bilirubin, alkaline phosphatase, gamma-glutamyl transferase, alanine aminotransferase, aspartate aminotransferase, amylase, lipase, serum protein, albumin, and electrolytes, and the coagulation status, which included the international normalized ratio (INR) and the activated partial thromboplastin time. Adequate correction of coagulation status was mandatory with target values of INR <1.5 and thrombocyte count >50,000/mm^3.

Abdominal ultrasonography (US) was performed the day before and immediately prior to the procedure and the findings were thoroughly recorded. Preprocedural US was used to select the optimal therapeutic approach and, as a baseline technique, to screen for subsequent complications. The US machine used was Hitachi Aloka Alpha 7 combined with a standard convex transducer UST-9123.

All PBIs were executed under general anesthesia controlled by certified specialist using a combination of fentanyl, midazolam, sevoflurane, suxamethonium (Lysthenon), atracurium besylate (Tracrium), and propofol. All patients received prophylactic antibiotics (ceftriaxone 2.0 g i.v. and metronidazole 2×500 mg i.v. prior to the procedure and at least 3 days after). In case of an established infectious agent, a treatment according to antibiotic sensitivity was initiated. In all cases, an Hitachi Aloka Alpha 7 US device coupled with a standard convex transducer and a reusable needle guide were used. Patient's position was determined by the optimal approach to the desired duct, with supine position being generally preferable to left lateral position.

US examination was conducted and the desired duct was selected. In general, as peripheral duct as possible was selected to reduce the risk of bile leakage. Puncture of the extrahepatic ducts was avoided. The needle direction was oriented towards the hilum of the liver to alleviate subsequent guidewire advancement and manipulation. The access point of the needle could be either transabdominal or intercostal. Transabdominal approach was first choice and presumed safer. An 18 Ga puncture needle (Urothech GmbH, Rohrdorf, Germany) was used. Upon puncturing the bile duct, the stylet was removed. A spontaneous leak of bile was awaited to confirm correct positioning, and if not observed, gentle suction with a 5-ml syringe prefilled with 2 ml of 0.9% NaCl was performed. Only small amount of bile was aspirated to avoid rapid decompression of the biliary tree and consequent loss of position. If bile leakage didn't occur, gentle repositioning of the needle under US guidance was performed with repeated aspiration. In case of failure, the needle was retracted and the manipulation repeated. In rare cases with suspected purulent cholangitis, cautious irrigation with saline was done prior to reaspiration. Once in the target duct, cholangiography was performed. A C-arm machine (Philips BV Pulsera C-arm, Philips, Best, The Netherlands) was used for fluoroscopy

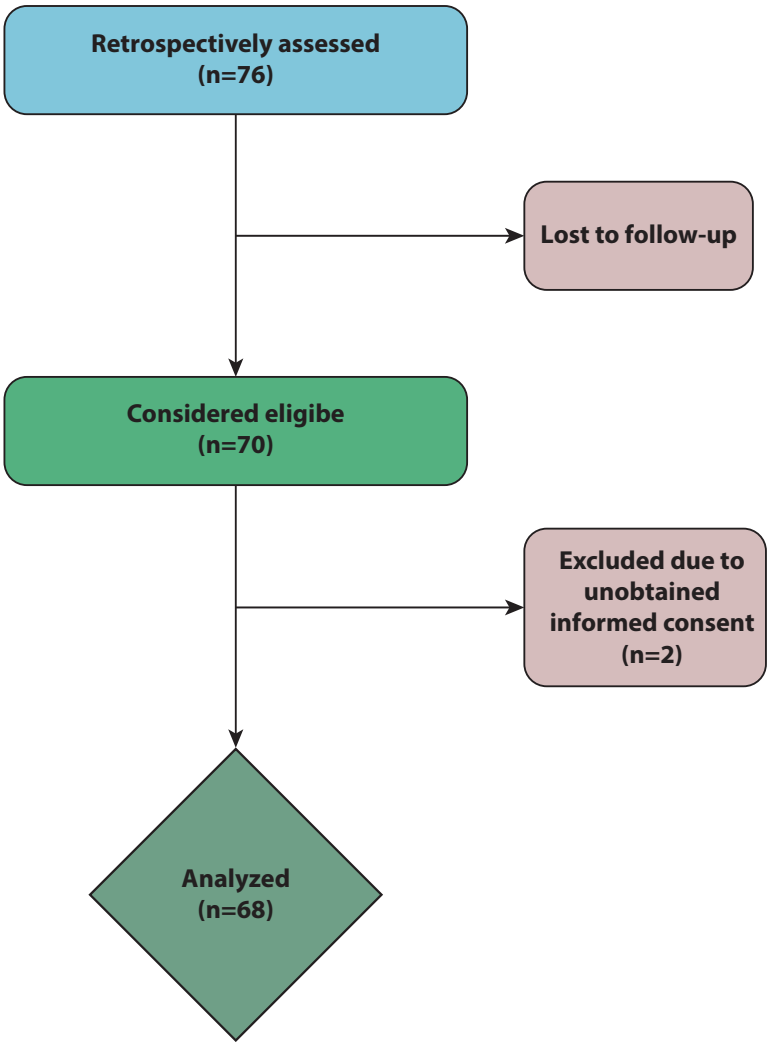

Figure 1. Patient selection process.

guidance. Only mild opacification of the bile duct was conducted to be used as a roadmap, with overextension of the biliary tree generally considered unfavorable.

Percutaneous external biliary drainage (PEBD)

If external drainage was the first choice treatment, a 0.035 J-type Lunderquist guidewire (Urothech GmbH, Rohrdorf, Germany) was introduced in the biliary tree. On the other hand, if PEBD was used as a rescue technique in failed PT-Rv or PABS, usually 0.035 inch by 450 cm straight ERCP guidewire (JagWire Revolution^{TM}; Boston Scientific; Marlborough, MA, USA) was utilized. Next a dilation of the fistulous tract was performed with a 7 Fr and 10 Fr plastic dilators (Urotech GmbH, Rohrdorf , Germany). A careful fluoroscopic guidance was mandatory when using ERCP guidewire since dislocation was considered highly possible. Upon dilation, a 7 Fr or 10 Fr (Urotech GmbH, Rohrdorf, Germany) plastic 'pig tail' drainage catheter was advanced along the guidewire and positioned as distally as possible in the bile ducts. Drainage catheters with locking mechanism (only 10 Fr available) were preferred. Eventually, the drain was fixed to the skin with two sutures. Trans-drainage cholangiography was performed at the end of the procedure to verify the position and exclude bile leakage in the peritoneal cavity or inadvertent puncture of a blood vessel.

Percutaneous transhepatic rendezvous (PT-Rv)

Once in the desired duct, a 0.035-inch straight guidewire was advanced along the needle towards the common bile duct. In the ideal case scenario, the guidewire was passed transpapillary without the need for further instrumentation. If impossible, the guidewire was looped in the CBD and the needle removed. A 7 Fr dilation was performed and a 5 Fr metal tip cannula (Endo-flex GmbH, Voerde, Germany) advanced along the guidewire. With the cannula deep in the bile duct, subsequent manipulations with the guidewire or opacifications were performed to gain transpapillary access. Once well-looped in the duodenum, a standard duodenoscope Olympus TJF-160VR (Olympus, Hamburg, Germany) was advanced. A standard position "en face" with

the papilla was assumed and the guidewire grasped with a 10 mm snare. The guidewire then was extracted through the working channel of the endoscope and used to obtain deep biliary access with a standard sphincterotome. The guidewire was finally removed through the sphincterotome. Subsequent interventions (sphincterotomy, stone extraction, stenting) were performed in the traditional manner.

Percutaneous antegrade biliary stenting (PABS)

PABS was the method of choice in patients with inaccessible papilla (duodenal obstruction, altered anatomy, etc.). Once transpapillary position was achieved with a guidewire, dilation of the fistulous tract with a 10 Fr dilation catheter was performed. If a high grade biliary stenosis was evident, stricture dilation with a small caliber balloon (4-6 mm) was performed. A self-expandable metal stent (SEMS) (WallFlex TM; Boston Scientific; Marlborough, MA, USA) (in all but one case) was advanced through the stricture in antegrade fashion, percutaneously and transpapillary. In complex strictures, more than one stent could be introduced in a T-shape or Y-shape manner to achieve better drainage. Eventually, a temporary percutaneous drainage catheter (7 Fr or 10 Fr) was also placed for at least 7 days. Contrast media was injected trough the catheter to verify the patency of the inserted SEMS.

Hybrid techniques

They encompass a spectrum of procedures usually performed in the setting of complex (hilar) strictures in which a combination of percutaneous and endoscopic approach is utilized. Most commonly a combination of ERCP + PEBD (in accordance with the described technique) was used. A variation is the combination of ERCP + PABS. In this technique, initially an access to one of the liver lobes was ensured in the traditional manner through ERCP. Subsequently, percutaneous puncture of the contralateral ductal system was done and an ERCP guidewire advanced across the stricture and transpapillary (see PABS). Finally, two UC-SEMS were introduced and simultaneously released to achieve bilateral drainage. This technique was valued when bilateral cannulation was impossible endoscopically or when the common bile/hepatic duct was too narrow to introduce two SEMS consecutively.

The steps of combined percutaneous and endoscopic stenting are presented in **Figs 2-4**.

Percutaneous cholecystostomy

Under US guidance, the gall bladder was punctured with an 18 Ga needle. Extrahepatic (directly in the gall bladder) and transhepatic punctures were used, with the transhepatic preferred when possible. Aspiration of bile was conducted to verify position. No fluoroscopy was used. A 0.035-inch Lunderquist guidewire was advanced and the fistula dilated to 10 Fr. A 10 Fr plastic 'pig tail' catheter with locking mechanism was introduced along the guidewire in the GB. The GB content was drained entirely. US was performed at the end of the procedure to verify correct position of the catheter and the absence of leakage. The drain was then fixed to the skin with two sutures.

A follow-up US was performed post-procedurally in all patients to search for complications. In patients with prior biliary interventions, bile was aspirated and sent for micro-

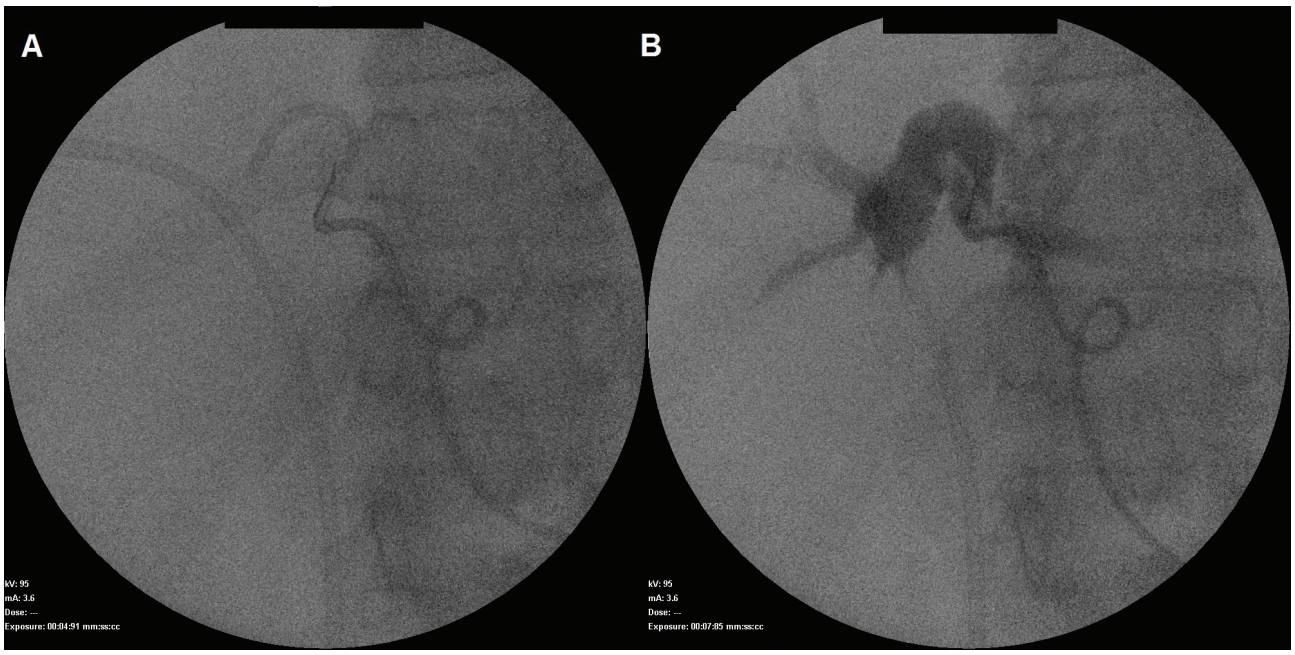

Figure 2. A. Previously placed plastic stent and percutaneous catheter for type II proximal biliary obstruction. **B**. Trans-drainage cholangiography.

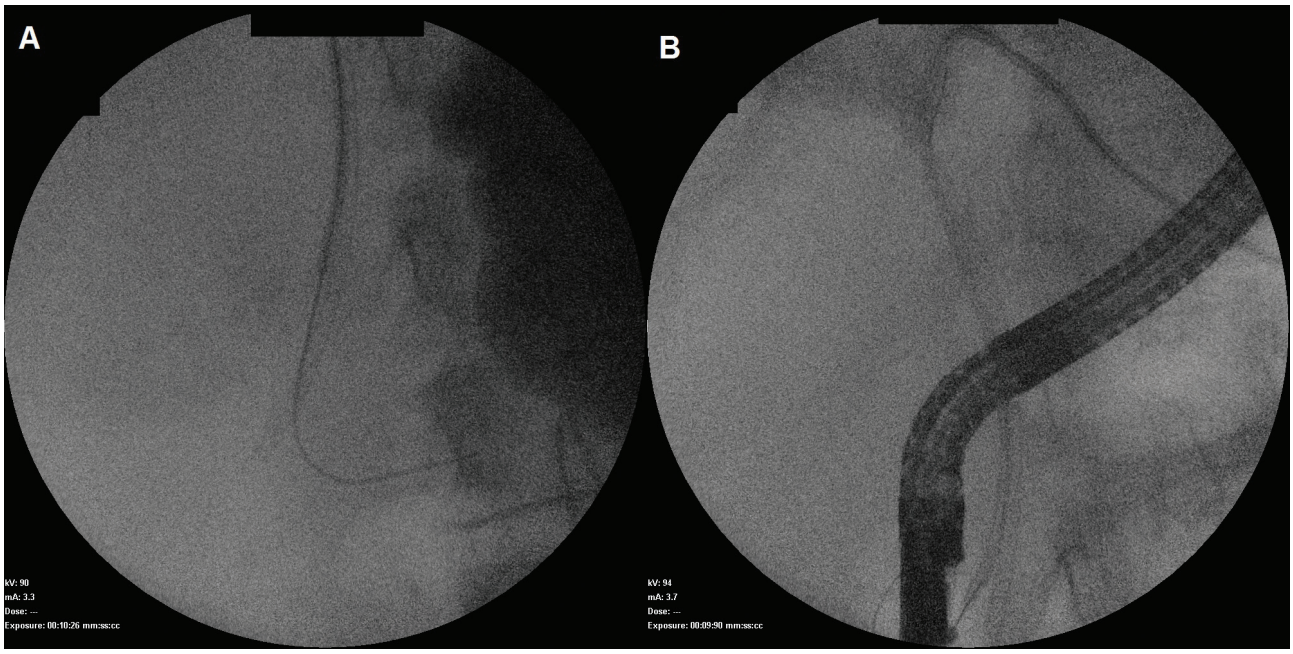

Figure 3. A, **B**. PT-Rv to obtain access to the left ductal system.

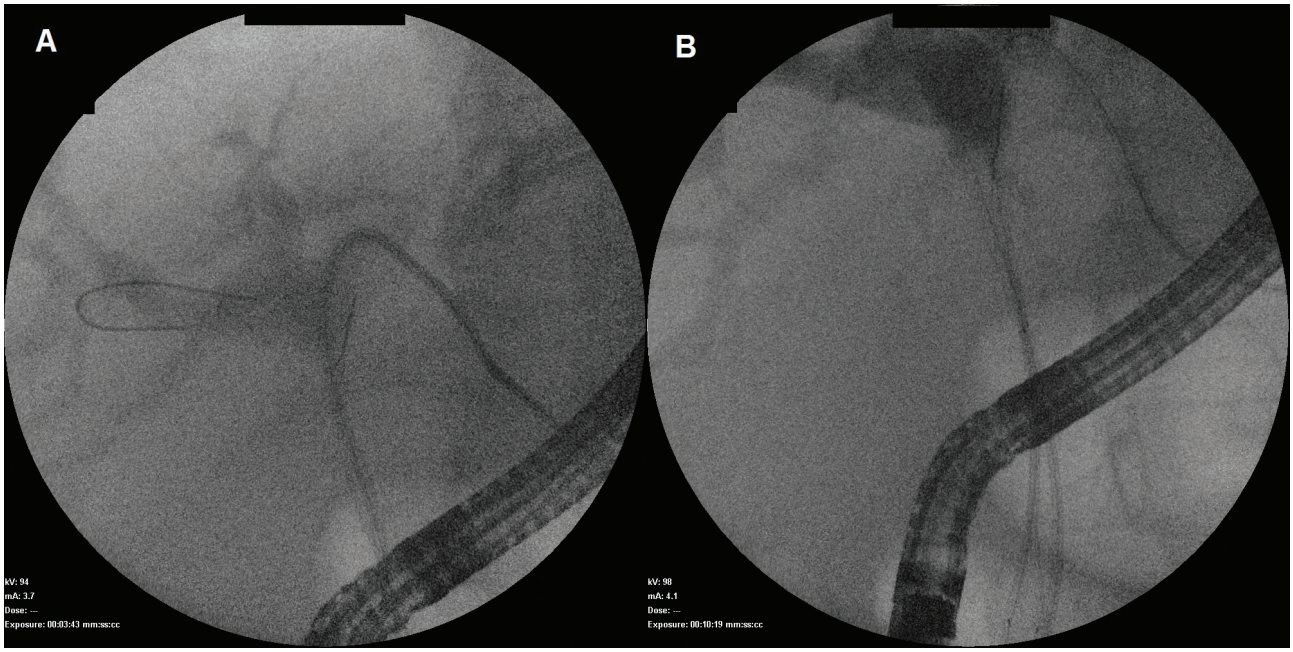

Figure 4. A. Trans-papillary cannulation of the right ductal system. **B**. Simultaneous advancement (endoscopic and percutaneous) of two FC-SEMS (8/100 mm).

biological testing. All patients underwent ultrasonography and lab testing on post-procedure day 1 and were discharged on day 2 if no imaging, laboratory, or clinical signs of inflammation or biliary obstruction were found. Follow-up ultrasonography and lab testing were performed two and four weeks after the procedure and as per necessity thereafter.

Technical success was defined as successful completion of the planned intervention – placement of stent or drain in the desired duct or gall bladder, or achieving transpapillary cannulation with a guidewire in PT-Rv. Clinical success was defined by resolution of jaundice and pruritus and improvement of lab abnormalities (50–75% decrease of bilirubin levels on week 2). Short-term adverse events are recorded at 30 days and are defined and classified according to the Clavien-Dindo system (see appendix, **Table A1**).

Statistical analysis

The data were analyzed using the SPSS v. 27.0 (SPSS Inc., Chicago, IL, USA). The majority of the variables were cat-

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egorical or ordinal and were summarized in terms of frequencies and percentages. Using the chi-square test (for variables with more than two categories) and Fisher's exact test (for variables with two categories), associations between target variables were determined. Continuously measured variables (e.g., age, hospital stay in days) were tested for normality using the Shapiro-Wilk test, and mean values and standard deviations were reported if normality was observed. A t-test for independent samples was used to compare the means of two groups. All statistical analyses were two-tailed, and a type I error alpha of 0.05 was considered statistically significant (p<0.05).

RESULTS

Background and clinical data

The study included 68 patients between the ages of 46 and 89 years, with a mean age of 68.11±11.43 years, including 72.10% men and 27.90% women. The mean ages of the men and women were 67.42±11.70 and 69.89±10.8, respectively (p=0.429).

All patients underwent PBIs. The decision for PBI was clinically based in 45.60% of the cases, in 26.50% on unsuccessful cannulation, 19.10% on altered anatomy, 5.90% on an inaccessible papilla of Vater, and 2.90% on the presence of prior percutaneous interventions.

External drainage was the most common treatment, applied to 52.90% of patients. Reintervention was needed in 35.30% (n=24), including 17.60% with PTBD, 11.80% with ERCP, and 5.90% with surgical treatment. Of these, 22.10% had one reintervention, 7.40% had two interventions, and 5.90% had three reinterventions.

According to the etiology of the obstruction, the most frequent types were perihilar cholangiocarcinoma (26.50%), pancreatic cancer (19.10%), hilar lymphadenopathy (14.70%), and choledocholithiasis (13.20%). Metastasis constituted 17.60% of the cases. Transabdominal access was utilized in the majority of cases (83.8%), while intercostal access was utilized in 16.20% of cases.

The clinical data is summarized in **Table 1**.

Technical and clinical success of the percutaneous biliary interventions

The technical success rate of the procedure was 97.10% (n=66), with two patients experiencing failure (2.90%). The treatment was clinically successful in 54 (79.40%) of the technically effective procedures, whereas in 12 (17.70%) cases, clinical effectiveness was not achieved. The four most frequent treatment procedures (external drainage, rendezvous, antegrade stenting, and hybrid techniques) did not show a significant association with the technical success rate (p=0.671) or the clinical success rate (p=0.117). Because of the small number of cases, cholecystostomy and

Table 1. Clinical information about the patients

Variables	Statistics
Type of procedure	N (%)
External drainage	36 (52.90%)
Rendezvous	14 (20.60%)
Antegrade stenting	7 (10.30%)
Hybrid techniques	6 (8.80%)
Cholecystostomy	4 (5.90%)
Cholangiography	1 (1.50%)
Decision for PTBD	N (%)
Clinically based	31 (45.60%)
Unsuccessful cannulation	18 (26.50%)
Altered anatomy	13 (19.10%)
Inaccessible papilla of Vater	4 (5.90%)
Prior interventions	2 (2.90%)
Prior interventions	N (%)
None	21 (30.90%)
PTBD	10 (14.70%)
ERCP	29 (42.60%)
PTBD + ERCP	8 (11.80%)
Reinterventions	N (%)
None	44 (64.70%)
PEBD	12 (17.60%)
ERCP	8 (11.80%)
Surgical treatment	4 (5.90%)
Number of reinterventions	
None	44 (64.70%)
One	15 (22.10%)
Two	5 (7.40%)
Three	4 (5.90%)
Etiology	
Perihilar cholangiocarcinoma	18 (26.50%)
Pancreatic cancer	13 (19.10%)
Lymphadenopathy	10 (14.70%)
Choledocholithiasis	9 (13.20%)
Carcinoma of ampulla of Vater	2 (2.90%)
Chronic pancreatitis	1 (1.50%)
Metastasis	12 (17.60%)
Other etiology	3 (4.40%)
Level of stenosis	N (%)
Proximal	34 (50.0%)
Distal	23 (33.80%)
Choledocholithiasis	10 (14.70%)
Other levels	1 (1.50%)
Access route	N (%)
Transabdominal	57 (83.80%)
Intercostal	11 (16.20%)
Performance status (ECOG classification)	N (%)
1	7 (10.30%)
2	25 (36.80%)
3	26 (38.20%)
4	10 (14.70%)

cholangiography were excluded from the statistical analysis but are included in **Fig. 5**.

The technical success rate was not significantly associated with the etiology of the obstruction (p=0.690), the performance status of the patient (0. 232) or the access route (p=1.000). The use of reinterventions was not a significant factor for the technical efficacy of the procedure (p=0.121); however, the number of reinterventions significantly affected the success rate (p<0.001). The patients with three interventions showed 50% technical success compared to those with no or fewer interventions.

Similarly, clinical effectiveness was not significantly associated with the etiology of the obstruction (p=0.245), the performance status of the patient (0.862), the access route (p=0.437), or the use of reinterventions (p=0.222). The number of reinterventions was marginally associated with the clinical efficacy rate (p=0.050). The clinical success rate for patients who received three interventions was 25%, compared to 84.10% with no reinterventions, 80% with one reintervention, and 80% with two reinterventions.

Adverse events

Adverse events were observed in 26.50% (n=8) of the patients, the most frequent being cholangitis, which was registered in a total of nine cases – in five cases alone and in four cases together with another adverse event **(Fig. 6)**. We did not find a significant association between the type of procedure and the frequency of adverse events (p=0.998). Of the three cases of death, one had perihilar cholangiocarcinoma, and two had metastases. They all occurred in patients with reinterventions and transabdominal access. Two of them had a performance status (see Appendix, **Table A2**) of 3 and one of 4. Summary of AEs types and incidence is provided in **Fig. 6**.

The occurrence of adverse events was not significantly associated with the etiology of the obstruction (p=0.329), the performance status of the patient (0.302), the access route (p=0.265), or the use of reinterventions (p=0.121).

All documented AEs were classified as moderate or severe (Grade III-V according to the Clavien-Dindo system). **Table 2** illustrates the distribution of AEs depending on their severity.

Table 2. Severity of AEs according to the Clavien-Dindo classification

Grade	Number of patients	% of all adverse events
I	0	0
II	0	0
IIIa	4	22.20
IIIb	6	33.31
IVa	3	16.60
IVb	2	11.12
V	3	16.60

Hospital stay and number of hospitalizations

The mean hospital stay was 7.11±3.68 days, ranging between 3 and 20 days. According to hospitalizations, 55.90% (n=38) were hospitalized once, 20.60% (n=14) twice, 17.60% (n=12) three times, 4.40% (n=3) four times, and 1.50% (n=1) five times.

The length of the hospital stay was significantly related to the clinical success of the procedure. The patients with clinically successful interventions had a mean hospital stay

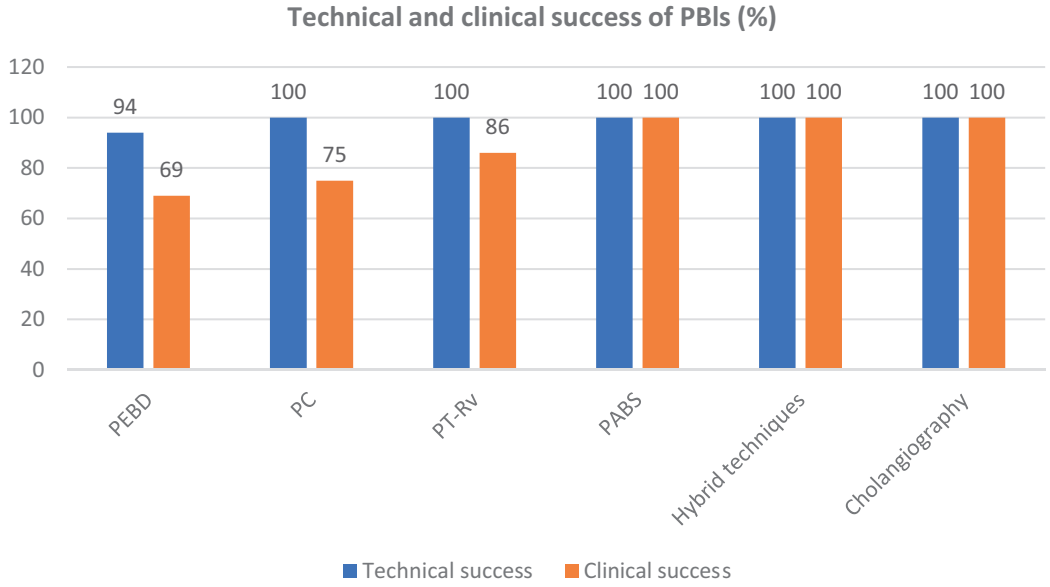

Figure 5. Technical and clinical success rates of PBIs. PEBD: percutaneous external biliary drainage, PC: percutaneous cholecystostomy, PT-Rv: percutaneous transhepatic rendezvous, PABS: percutaneous antegrade biliary stenting.

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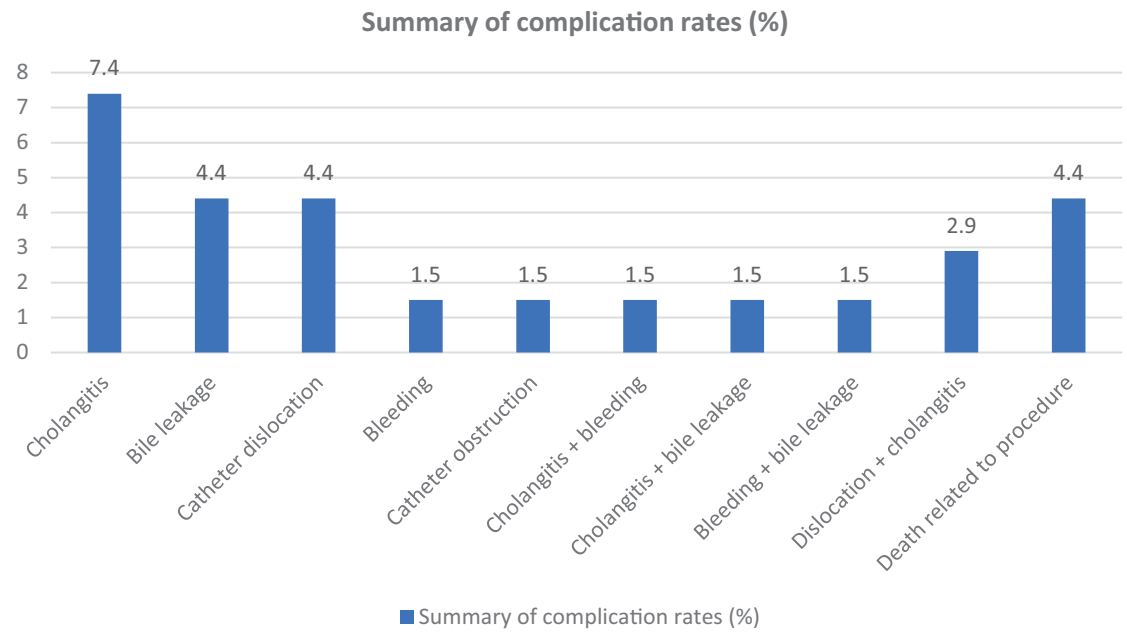

Figure 6. Adverse events.

of 6.33±2.71 days compared to 10.14±5.24 days for those with clinically unsuccessful procedures, p=0.019.

No significant association was found with the presence of adverse events and the utilization of reinterventions. The patients with adverse events had a mean hospital stay of 7.44±2.81 days versus 7.00±3.97 of those without adverse events (p=0.664). The patients without reinterventions had a mean hospital stay of 7.11±4.08 days compared to 7.12±2.89 days for those with reinterventions (p=0.990).

DISCUSSION

Obstructive jaundice is a clinical syndrome increasingly established in gastroenterological practice. Its incidence in the general population is estimated to be around 5-7 per 1000 people.[19] Therapeutic approaches in those patients are constantly evolving, which raises a continuous debate on the optimal management strategy. Treatment decision derives primarily from the etiology of obstruction. Benign causes, the most common of which is choledocholithiasis (54.1% of all cases of obstructive jaundice), are mostly managed non-surgically (endoscopically or percutaneously).[19] Malignant diseases, if radically operable, are amenable to surgical treatment. In unresectable cases, the emphasis is set on non-surgical methods. Evidently, the mini-invasive treatment is a hallmark of the management of obstructive jaundice. Traditionally ERCP was regarded as the "gold" standard, especially in low biliary obstruction, while percutaneous drainage was a valid alternative and sometimes preferable in the setting of proximal occlusion. The advent of EUS-guided drainage techniques, however, raised a debate on the optimal alternative to ERCP, more recently even being discussed as a first-choice therapy in selected patients.[20] Additionally, emerging data criticizes the safety profile of PBIs, questioning the benefit-to-risk ratio of the technique.[21]

The current research included 68 patients, of whom the men were significantly more than the women (72.10% vs. 27.9%). Those results seem contradictory to general data suggesting that obstructive jaundice is more prevalent in women (male:female ratio, 1.0:1.4).[22] This data, however, largely derives from the considerably higher incidence of GSD in women. PBI in our study (and in general) was rarely performed for choledocholithiasis. If only malignant indications are analyzed, our results are consistent with general knowledge suggesting that men with biliary obstruction are approximately twice as many as women.[23] In terms of age, we established a mean age of 68.5±11.1 years for the entire group. Again, if only patients with malignant etiology are considered, comparable results are established in other studies (age interval 61-82 years).[24]

As anticipated malignant obstruction was the primary indication for intervention, comprising 80.8% of all cases, 19.2% of the procedures were performed for benign indications, particularly choledocholithiasis and bile leakage. Similar results were obtained by other researchers.[21]

We considered the decision-making process to be particularly interesting for the subsequent analysis. Our data shows that PTBD was regarded as a first-choice modality in less than half of the patients (45.60%). More commonly, it was used as a 'salvage' technique. In other studies, PTBD was almost entirely an alternative to ERCP.[25] This data suggests that PBI are largely utilized in "difficult" patients, who would naturally be more prone to adverse events.

The primary endpoint of our study was to establish the short-term clinical outcomes of PBI in terms of technical

and clinical success and adverse events rate. A technical success rate of 97.1% for the entire group was established. Technical failure occurred in only two patients in the ED subgroup. This is understandable considering the fact that ED comprises the largest subgroup (52% of all cases). Clinical success was 79.40%, notably higher (but not statistically significant) for the methods associated with internalization of drainage (PABS, PT-Rv). Our results confirm the general finding that, technically, PBI are highly successful. (75%-100%).[26] Clinical success is also satisfactory, 82.4% on the average and 79.40% in our study.[26] Existing data on the best percutaneous drainage technique is somewhat inconsistent, but our research suggests that different techniques (at least in the presence of adequate expertise) have similar performance. Our research failed to establish good predictor of therapeutic success (etiology, intervention technique, access route, performance status, etc.). The need for subsequent interventions was consistently (and significantly) associated with decreased clinical response. We might conclude that patients with one or two clinically unsuccessful procedures might benefit from reassessment, preferably in the setting of multidisciplinary team.

In terms of adverse events, we established such in approximately ¼ of all patients (26.5%), the most common complication being cholangitis. More than one complication was established in 7.40% of all cases (38.5% of all adverse events). Notably, all complications were defined as moderate or severe (grade III-V according to the Clavien-Dindo system). No correlation between the adverse event rate and type of procedure was found. The performance status or utilized access route also showed no association with the complication rate. Other studies also failed to establish such a correlation.[21] It should be stated that the PS in our study was almost universally poor, with more than half of the patients having PS of 3 or 4. Fatal outcome directly associated with the procedure was seen in 3 patients (4.40%). They were all with advanced malignant disease, complex proximal stenosis, and poor PS.

Considerable dispersity exists in the relevant literature on the AEs rate. Even the most optimistic results, however, show a complication rate of around 13%, which might be considered acceptable for patients with malignant disease and is largely comparable to the AE rate of ERCP.[27] A more recent Dutch study presents quite concerning results, establishing a complication rate of 50% and a mortality directly attributed to the procedure of 8.8%.[21] This study confirms our observation that infection is the most commonly seen complication. Notably, in the aforementioned study, percutaneous drainage was used as a rescue technique after failed ERCP and in subjects with poor PS. Those facts might at least partially explain the high prevalence of the unfavorable outcomes. Unfortunately, similar outcomes are found in other papers on the subject.[28,29] In 2016, well-designed Dutch RCT comparing the efficacy and safety of pre-operative drainage by ERCP versus PBI in perihilar cholangiocarcinoma was terminated prematurely because of increased overall mortality rates in the PBI group (3/27 (11%) vs. 11/27 (41%), respectively).[29] Cholangitis occurred in 59% in the PBI-group vs. 37% in the ERCP-group.[29]

Upon literature review, we established a tendency (at least in the articles published in the last decade) which is in line with our findings. A complication rate of approximately 30% is found in most papers on the subject. We are inclined to explain this worsening of the clinical outcomes (at least in our study, but we think that this conclusion might be generalized) with the gradual restriction of the indications for PTBD. With the increasing success rate of ERCP even for proximal strictures and the introduction of EUS-BD, PBIs are reserved for patients with advanced disease, poor PS, and limited life expectancy. Negative effects on patient's life quality is also a major concern.

Considering the life quality in the current study, we evaluated the number of hospital admissions and the mean hospital stay for the patients with PBI. We found that the need for multiple readmissions and continuous hospital in-stay has a profound negative impact on the patients' life quality, especially in those with advanced malignant disease. We found that half of the patients needed more than one hospitalization (range 2-5) and the mean hospital stay was 7.11±3.68 days (ranging between 3-20 days). About ¼ of all patients needed multiple interventions to achieve and/or sustain therapeutic effect. This data reflects the general opinion that PBIs (even when clinically successful) are impairing patients' life quality.

The current study has certain limitations. Although it includes consecutive patients, its retrospective nature obviously increases the risk of bias. The lack of control group (ERCP and/or EUS-BD) precludes ensuring of comparability of results. The discrepancy between the studied groups in terms of number of patients should be noted as well. On the other hand, it is our opinion that using hospital data as main source of information makes the results attributable to and quite adequately reflecting real clinical practice.

CONCLUSIONS

Management strategies for obstructive jaundice are constantly evolving. PBIs are still a valid option for resolution of biliary obstruction (particularly malignant one), showing acceptable technical and clinical success. Complication rate and life quality impact of PBIs are a major concern, which probably warrants more strict patient selection. ERCP and EUS-BD would likely result in better clinical outcomes. Well-designed prospective comparative studies evaluating ERCP, EUS-BD and PBI for relief of malignant biliary obstruction are needed to verify such statement.

Appendix A

Table A1. Clavien-Dindo classification of AEs

Grade	Definition of grades	Modes of therapy
Grade I	Any deviation from the normal postoperative course	No pharmacological or surgical treatment, endoscopic or radiological interventions were required. Acceptable therapeutic regimens are drugs such as anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. Wound infections or small abscess requiring incision at bedside are within this category
Grade II	Normal course altered	Pharmacological management other than Grade I. Blood transfusions and total parenteral nutrition are also included.
Grade III	Complications that require intervention of various degrees	Grade IIIa – complications that require an intervention performed under local anesthesia. Grade IIIb – interventions that require general or epidural anesthesia
Grade IV	Complications threatening life of patients (including CNS complications), requiring ICU support	Grade IVa – single organ dysfunction (including dialysis) Grade IVb – multi-organ dysfunction
Grade V	Death of patient	

AE: adverse event; ICU: intensive care unit

Table A2. ECOG performance status scale

Grade	ECOG performance status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

Authors contributions

Conceptualization: I.T. and Y.T.; methodology: I.T.; investigation: I.T.; resources: D.T. and I.T.; data curation: D.T.; writing – original draft preparation: I.T.; writing – review and editing: Y.T.; visualization: D.T.; supervision: Y.T.; project administration: Y.T.; funding acquisition: I.T.

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Informed consent was obtained from the subject involved in the study.

Data Availability Statement

Data are available on request due to privacy restrictions.

Conflicts of Interest

The authors declare no conflict of interest.

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Краткосрочные клинические результаты чрескожных вмешательств на жёлчевыводящих путях: анализ успешности и частоты осложнений

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Резюме

Введение: Механическая желтуха – это клинический синдром, который часто наблюдается в гастроэнтерологии. Эндоскопическая ретроградная холангиопанкреатография (ЭРХПГ) признана терапевтическим подходом первого выбора, а жизнеспособной альтернативой является чрескожное вмешательство на жёлчных протоках (ЧВЖП). Последние данные ставят под сомнение профиль эффективности и безопасности ЧВЖП.

Цель: Целью настоящего исследования было ретроспективно оценить краткосрочные клинические результаты применения ЧВЖП с точки зрения технического и клинического успеха и частоты нежелательных явлений (НЯ).

Пациенты и методы: Это ретроспективное одноцентровое когортное исследование с участием 62 последовательных пациентов, подвергшихся ЧВЖП в период с января 2019 года по август 2022 года.

Результаты: Установлены показатели технического и клинического успеха 97.10 % и 79.40 % соответственно. Ни одно ЧВЖП не продемонстрировало статистически значимого превосходства над другими. Ни один из оценённых факторов не оказал существенного влияния на терапевтический результат и НЯ. Была рассчитана общая частота НЯ 26.5 %. Все НЯ были от умеренной до тяжёлой степени (III-IV степени по системе Clavien-Dindo). Средняя продолжительность пребывания в больнице составила 7.11±3.68 дня. Многократную госпитализацию потребовали 44.1 % пациентов.

Существующие исследования устанавливают одинаково высокие технические (75–100 %) и приемлемые клинические (84 %) показатели успеха. В недавно опубликованных исследованиях была обнаружена тревожно высокая частота НЯ, составляющая почти 50 %. Инфекция была наиболее частым нежелательным явлением, обнаруженным в нашем исследовании. Практически повсеместно ЧВЖП используются в качестве метода спасения среди пациентов со злокачественными заболеваниями, неудачной предшествующей ЭРХПГ и плохим состоянием здоровья.

Заключение: ЧВЖП остаются жизнеспособным вариантом ЭРХПГ, но, вероятно, потребуются более строгий отбор пациентов и постепенный переход к процедурам дренирования под контролем ЭУЗИ.

Ключевые слова

жёлчный дренаж, холангиопанкреатография, эндоскопия, чрескожно, рандеву, УЗИ