

## Percutaneous transhepatic biliary stenting: the first experience and results of the Hospital of Kaunas University of Medicine

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**Key words:** malignant biliary obstruction; percutaneous transhepatic biliary stenting.

**Summary.** Malignant biliary obstruction may be caused by cholangiocarcinoma and other nonbiliary carcinomas. At the time of diagnosis, 90% of patients with malignant obstructive jaundice may benefit from palliative treatment only. The objective of palliation is to relieve jaundice-related symptoms, prevent cholangitis, prolong survival, and improve quality of life. Percutaneous transhepatic biliary stenting is a well-established procedure used in patients with malignant obstruction of intra- and extrahepatic bile ducts.

Twelve patients (9 women, 3 men; mean age, 68 years; range, 44–88 years) with inoperable malignant biliary obstruction were selected for percutaneous transhepatic biliary stenting with metallic stents in the period from January to December 2007. Technical and clinical success rate in this patient series was 83% and 80%, respectively. Minor and major complications occurred in 17% and 8% of cases, respectively, which is in the range reported by the others. This is our first experience of percutaneous transhepatic biliary stenting at the Hospital of Kaunas University of Medicine and, to our knowledge, the first reported patient series in Lithuania.

These first results encourage expanding effective palliation by the employment of the percutaneous transhepatic biliary stenting in patients with nonresectable malignant biliary obstruction or in case of a recurrent disease after curative surgery. The cost effectiveness of percutaneous transhepatic biliary stenting against percutaneous transhepatic biliary drainage has yet to be evaluated in a prospective manner. However, immediate clinical benefits and positive short-term outcomes are unequivocal.

### Introduction

The incidence of biliary obstruction resulting from malignancies is increasing (1). Malignant biliary obstruction may be caused by primary biliary carcinomas (cholangiocarcinoma, gallbladder cancer invading the liver and/or hepatoduodenal ligament), and nonbiliary carcinomas (ampullary tumors, pancreatic, advanced gastric malignancies, periportal adenopathy in the hepatoduodenal ligament, hepatocellular carcinoma, or liver metastases) (2–6). Untreated biliary obstruction may lead to hyperbilirubinemia, pruritus, anorexia, cholangitis, septicemia, and liver failure.

At the time of diagnosis, 90% of patients with malignant obstruction of bile ducts may benefit from palliative treatment only and have a very poor prognosis (3, 7). Palliation of unresectable malignancies requires a multidisciplinary approach including medical oncologists, radiation oncologists, gastroenterologists, hepatobiliary surgeons, and interventional radiologists. The objective of palliation is to relieve

biliary obstruction-related symptoms, prevent cholangitis, prolong survival, and to improve quality of life (1, 8).

### Classification of bile duct obstruction

Biliary obstruction is classified into “low” and “high.” Low bile duct obstruction occurs below the usual insertion of the cystic duct. High bile duct obstruction occurs proximal to the cystic duct insertion and may be classified as suggested by Bismuth and Corlette (9) (Fig. 1):

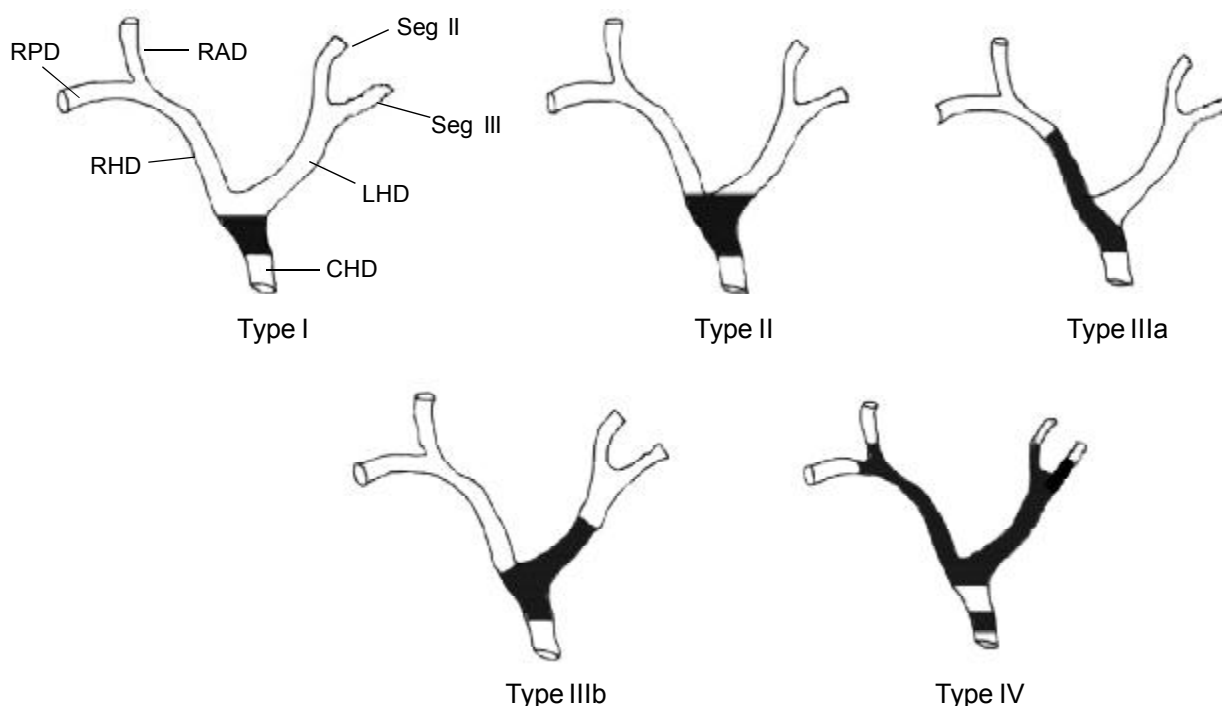
Type I, obstruction below the confluence;

Type II, obstruction confined to confluence;

Type IIIa, obstruction with an extension into right hepatic duct;

Type IIIb, obstruction with an extension into left hepatic duct;

Type IV, multicentric tumors or tumors that involve the secondary confluence on the right or/and left side.



**Fig. 1. Bismuth-Corlette classification of high bile duct obstruction**

CHD – common hepatic duct, RHD – right hepatic duct, LHD – left hepatic duct, RPD – right posterior division, RAD – right anterior division, Seg II – segment II duct, Seg III – segment III duct (modified from De Palma et al., 2007 (7)).

#### ***The treatment options in malignant biliary obstruction***

Malignant biliary obstruction may be managed by surgery, percutaneous transhepatic biliary drainage, or stricture stenting.

**Surgery** has been traditionally considered the treatment of choice in patients with biliary malignancies. Surgical approach to malignant biliary obstruction includes a curative resection or palliative procedure. Patients with Bismuth type I and II lesions are candidates for curative surgery. Surgery of a type III lesion often requires a major resection. Only minority of these patients eventually undergoes surgery. Type IV lesions are generally considered to be unresectable (6). Approximately 80% to 90% of these patients will be found unresectable (3, 7, 10, 11). Prognosis of latter patients is dismal. Among these patients, some will survive only a few weeks, most will die within six months, but some may survive in a fairly good condition for one or even several years (12). Reported median survival is 3–10 months (3, 8, 11, 13).

**Percutaneous transhepatic biliary drainage (PTBD)** is an effective preoperative risk-reducing modality and an effective palliative procedure in patients who are not surgically drainable (14). However,

an external catheter has a major potential for infection and dislodgement, and it is associated with catheter maintenance problems as well as with discomfort for the patient. There is a need for regular catheter flushing and dressing. Bile leakage, infection, and pain at the catheter entry site may also occur (15).

**Endoscopic stenting** in patients with low biliary obstruction is the preferred method (16). However, high obstructions, bilateral or multiple strictures, as well as previous upper gastrointestinal tract surgery may render endoscopic stent placement difficult or impossible (13).

**Percutaneous transhepatic biliary stenting (PTBS)** is a well-established interventional radiology procedure used in patients with malignant biliary obstruction for decompression of intra- and extrahepatic bile ducts (3, 6, 13). Successful biliary drainage alleviates jaundice, improves liver function, and has a positive impact on quality of life (12, 16). It may also have positive influence on survival as these patients are more likely to receive chemo- or radiotherapy (3, 17, 18). The aim of this paper is to report our experience and results of the first patient series of PTBS in malignant biliary obstruction at the Hospital of Kaunas University of Medicine.

**Indications for PTBS**

Indications for PTBS are not precisely defined. PTBS is recommended in patients with nonresectable tumors or poor general condition when surgery is not recommended, as well as in patients with an obstruction due to recurrent malignant biliary obstruction (4, 6, 11, 16). PTBS in distal bile duct obstruction is a secondary tool and is in general reserved for cases where endoscopic retrograde cholangiopancreatography (ERCP) fails or is technically not feasible (13, 16). In hilar obstruction, both PTBS and ERCP are used as primary drainage modalities at different institutions (6, 14).

**Contraindications for PTBS**

The few contraindications of percutaneous bile duct stenting include clinically significant coagulopathy and voluminous ascites (16). The procedure is relatively contraindicated in obese and uncooperative patients.

**Complications of PTBS**

Immediate morbidity following PTBD (bleeding, septicemia, and bile leakage) is rare (1–5%) (19–22). PTBS-related morbidity is slightly higher, and complications are assorted based on outcome. *Major complications* result in admission to a hospital for therapy,

an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. *Minor complications* are not associated with any significant morbidity; they may require nominal therapy or a short hospital stay for observation (16). Rates of minor and major complications are in the range of 8–23% and 2–20%, respectively (13, 20). Minor complications include mild hemorrhage, biliary-venous fistula, bile leakage, subcapsular biloma (20, 23). Sepsis, hemorrhage (requiring blood transfusion), abscess, peritonitis, cholecystitis, pancreatitis, pneumothorax, fluid collection, death are described as major complications (3, 16, 20, 23) (Table). The recommended overall procedure threshold for all major complications of percutaneous transhepatic biliary stenting is 10%. Patients with coagulopathies, cholangitis, stones, malignant obstruction, or proximal obstruction will have higher complication rates (16). Most complications can be treated conservatively, and procedure-related mortality is less than 3% (3).

**Materials and methods**

All stents were placed by the team consisting of the radiologist and the abdominal surgeon. The procedures were performed with sonographic and fluoroscopic guidance, with the patient under local anesthesia and conscious sedation. Prophylactic

**Table. Complications of percutaneous transhepatic biliary stenting**

Type of complication	Rate of complication		
	N=154 (20)	N=130 (17)	N=76 (3)
Major	–	11% (14/130)	14.5% (11/76)
Hemobilia	6.4% (10/154)	3% (4/130)	2.6% (2/76)
Cholangitis	18% (28/154)	–	–
Cholecystitis	–	–	1.3% (1/76)
Pancreatitis	–	–	5.2% (4/76)
Abscess	–	3.8% (5/130)	1.3% (1/76)
Sepsis	–	–	2.6% (2/76)
Massive hemorrhage	5.8% (9/154)	–	–
Pneumothorax	–	0.7% (1/130)	1.3% (1/76)
Bile duct rupture	–	2.3% (3/130)	–
Stent migration	0.6% (1/154)	–	–
Stent dislocation	2.1% (3/154)	–	–
Stent obstruction	18% (28/154)	–	–
Minor		9% (12/130)	8% (6/76)
Mild hemorrhage	5.8% (9/154)	–	3.9% (3/76)
Biliary-venous fistula	2.1% (3/154)	–	2.6% (2/76)
Subcapsular biloma	2.4% (3/154)	–	1.3% (1/76)
Other data			
30-day mortality	9% (14/154)	11% (14/130)	13% (10/76)
Reintervention rate	15% (23/154)	–	–
Procedure-related mortality	–	–	2.7% (2/76)

intravenous antibiotics (gentamicin 5 mg/kg/24 h, ampicillin 2 g/24 h, and metronidazole 1 g/24 h) were routinely administered 12 h before the procedure and for 48–72 h afterwards (16). Coagulation tests were performed before the procedure, and stent placement was not performed, if clinically significant coagulopathy (international normalized ratio (INR) >1.5) was present.

A right intercostal and/or left epigastric approach was chosen depending on the size and location of a tumor. An initial percutaneous transhepatic bile duct puncture was performed under ultrasound guidance using a 21-G needle. A 0.038" guide wire was then passed centrally in the biliary system and into the common bile duct and duodenum. Using angiographic methods, a cannula sheath and guide wire were introduced percutaneously across the hepatic parenchyma into the biliary ducts and advanced through the area of bile duct stricture into the duodenum. Stent insertion was then performed over a guide wire. Self-expandable metallic (stainless steel or nitinol) uncovered stents were used in all cases. After successful stent placement, a 6-Fr external drainage catheter was optionally placed proximally to the stent for drainage and flushing. The catheter was clamped the following morning for 6–24 hours and removed when clinical findings confirmed adequate drainage. A 6-Fr external bile drainage catheter was positioned in all cases when transhepatic stent placement was not technically feasible.

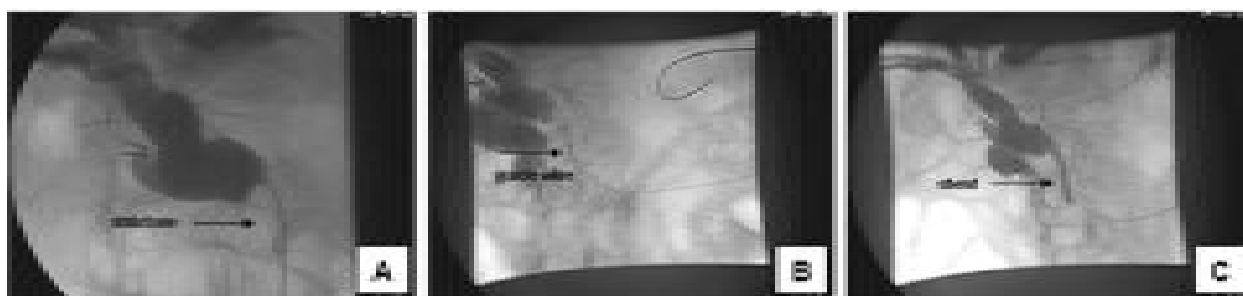
Technical success, clinical success, and complication rates were recorded. Technical success was defined as a successful deployment of a stent in an appropriate position resulting in drainage of stented bile ducts. Clinical success was defined as a decrease in serum bilirubin level not less than 10–15% relative to baseline within next 2–3 days after stent insertion (20).

## Results

Twelve patients (9 women, 3 men; mean age, 68 years; range, 44–88 years) with inoperable malignant biliary strictures were selected for percutaneous transhepatic placement of metallic stents in the period from January to December 2007.

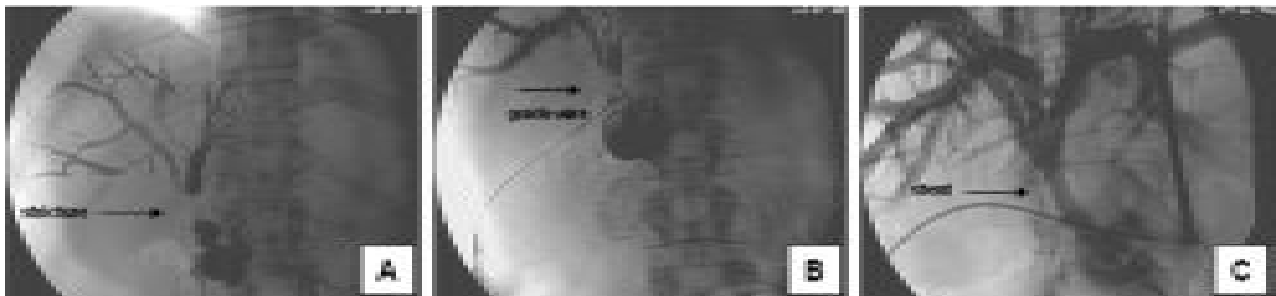
The etiology of biliary obstruction was cholangiocarcinoma (n=3), gallbladder carcinoma (n=1), pancreatic carcinoma (n=5), recurrent gastric cancer invading the hepatoduodenal ligament (n=2), and *Echinococcus alveolaris* (n=1). The diagnoses were based on imaging studies, i.e. computer tomography, endoscopic and percutaneous transhepatic cholangiography. Pathology confirmation was obtained by image-guided core needle biopsy whenever technically feasible.

The biliary stents were placed in a one-step procedure in 5 patients. In the remaining 7 patients, an external PTBD with 6-Fr pigtail catheter was established, whereas the lesion was stented 3–10 days later. Successful deployment of the stent at the appropriate position was achieved in 10 out of the 12 patients (83% technical success rate). Percutaneous transhepatic insertion of metallic stents was performed either via the right (n=4) or via the left liver lobe (n=6). Single stent placement was adequate to pass the stricture in 9 patients (90%) (8 patients with type I and 1 patient with type II stricture according to Bismuth-Corlette classification). Bilateral stenting with 2 stents was employed in 1 patient with type IV stricture. Radiological data and main stages of the stent placement are depicted in Fig. 2–5. The technical failure in both cases was due to hilar cholangiocarcinoma with multiple intrahepatic strictures and non-identifiable passage to the extrahepatic biliary tract. Clinical success with a mean 12% decrease in serum bilirubin level within 48–72 hours after PTBS (from



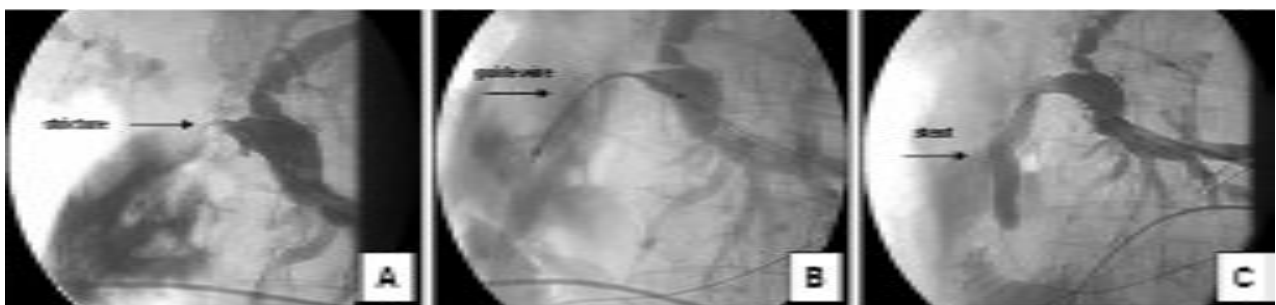
**Fig. 2. Bismuth-Corlette type I stricture**

Straight arrow indicates the localization of the site of biliary obstruction (A), passage of the guide wire through the stricture and into the duodenum (B), stent insertion over a guide wire and dilatation of the stricture (C).



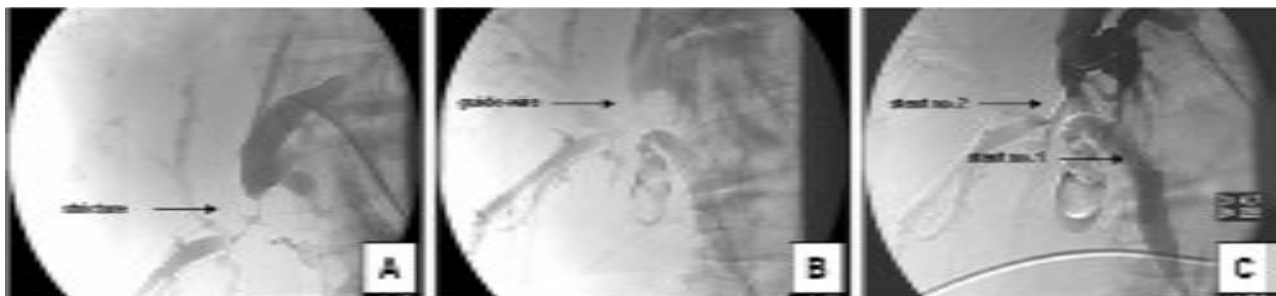
**Fig. 3. Bismuth-Corlette type II stricture**

Straight arrow indicates the localization of the site of biliary obstruction (A), passage of the guide wire through the stricture in the place of hepaticojejunostomy and into the small intestine limb (B), stent insertion over a guide wire and dilatation of the stricture (C).



**Fig. 4. Bismuth-Corlette type III stricture**

Straight arrow indicates the localization of the site of biliary obstruction (A), passage of the guide wire through the stricture and into the duodenum (B), stent insertion over a guide wire and dilatation of the stricture (C).



**Fig. 5. Bismuth-Corlette type IV stricture**

Straight arrow indicates the localization of the site of biliary obstruction (A), passage of the guide wire through the stricture and into the duodenum (B), stent insertion over a guide wire and dilatation of the stricture, second stent was employed to connect the left and the right hepatic ducts (C).

322±134 µmol/L preoperatively to 284±108 µmol/L postoperatively) was recorded in 8 out of the 10 patients (80%). Minor complications were encountered in two patients (17%): subcapsular biloma (1 case) and biliary-venous fistula (1 case) that required no specific management. Major complication – acute cholangitis and septicemia – has developed in one patient (8%). There was no procedure-related or in-hospital mortality.

### Discussion

Percutaneous transhepatic insertion of metallic stents is an established palliative modality to relieve malignant biliary obstruction. Majority of groups have reported a 95–100% technical success rate in dilated bile ducts and 75% in nondilated bile ducts, with satisfactory biliary decompression and symptom relief in 88–96% of cases (3, 17). It is of interest that partial liver drainage may appear as effective as a complete

liver drainage. Drainage of as little as 30% of the functional parenchyma may be adequate in patients with noncirrhotic liver and in those who have not received chemotherapy (24).

Success rates and complication rates for both endoscopic and percutaneous transhepatic biliary stenting are operator dependent, and it may influence the choice of a specific technique at different institutions (6). However, PTBS have a distinct advantage over ERCP, as one or more appropriate segments for drainage can be chosen. Ultrasound guidance during PTBS is extremely useful in such patients and significantly increases the rates of successful biliary drainage in case of malignant biliary strictures (6, 16).

Metallic stents have been found to be superior to plastic stents, with longer patency rates, better symptom-free survival time, and improved quality of life for the patients, as well as lower complication rates and an overall lower cost (13, 24, 25). Their design allows a small track through the liver parenchyma, which should reduce the complications associated with the percutaneous procedure. Once in place, the stents extend to their large lumen, which might reduce the re-occlusion rates, as the patency of a stent should be directly related to the stent diameter. The internal lumen of metallic stents is 20–30 times larger than the lumen of plastic stents. The open wire mesh allows drainage of biliary side-branches and plays an important role in the management of hilar obstructions. The variety of different combinations allows treatment of complicated strictures and effective drainage of several isolated hepatic ducts, which should reduce the risk of cholangitis and septicemia. The small surface area of the wire mesh might also reduce bacterial growth and encrustation. Multiple stent placements in both liver lobes can be achieved via uni-, bi-, or multilateral percutaneous approaches, and the stents may be arranged side-to-side, one through the struts of the other, or two or even three into one. There are also several anatomic configurations that may be managed by the percutaneous technique only. Moreover, the lumen of metallic stents can be evaluated with ultrasonography and computed tomography (26, 27).

The most common causes of occlusion of an uncovered metallic stent are sludge formation, proximal and distal tumor overgrowth, tumor ingrowth, and stone formation (28, 29). To prevent tumor overgrowth,

a safety margin of at least 2 cm should be left at each end of the upper and lower margins of the stricture (overstenting) (30, 31). The obstruction rates for uncovered stents in previous studies varied from 5% to 100% during a 1- to 19-month period following stent placement (13). The symptom-free period for these patients ranges from 2 weeks to 13 months (median of 10 weeks), and majority of the patients die from malignant disease before occurrence of stent dysfunction (13). It should also be noted that patients with high postintervention bilirubin levels ( $>68.4$  mmol/L) and with Bismuth type IV tumors have 3.64–4.84 times greater risk of death than other patients (3).

The technical and clinical success rates are reported to be 90–100% in large patient series. In our hands, stents were successfully inserted in 83% of cases with an 80% clinical success rate in this patient series. These somehow lower success rates could be attributed to the learning curve, as this is our first experience of PTBS at the Hospital of Kaunas University of Medicine and the first reported patient series in Lithuania. The results are likely to improve with a better preoperative patient selection and increasing experience of interventional radiologists and surgeons (learning curve-dependent results). However, the overall procedure-related morbidity rate was in the range reported by the others, and only one patient in our series developed a major complication that needed specific therapeutic interventions and resulted in prolonged hospitalization. Our initial experience with PTBS seems promising in palliating patients with primary or recurrent nonresectable malignant biliary obstruction.

### Conclusion

Percutaneous stenting of the biliary tree is a safe and effective minimally invasive procedure. Percutaneous transhepatic biliary stenting provides equally adequate palliation in patients with proximal and distal bile duct obstruction. The technical and clinical success rates are satisfactory and are learning curve-dependent. The benefits of stenting must be evaluated considering poor survival prognosis in this patient group. The cost effectiveness of percutaneous transhepatic biliary stenting against percutaneous transhepatic biliary drainage has yet to be evaluated in the local setting; however, clinical benefits and positive short-term outcomes are undisputable.

## Perkutaninio transhepatinio tulžies latakų stentavimo pirmoji patirtis ir rezultatai Kauno medicinos universiteto klinikose

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**Raktažodžiai:** piktybinės tulžies latakų struktūros, transhepatinis tulžies latakų stentavimas.

**Santrauka.** Piktybinę tulžies latakų obstrukciją gali sukelti tulžies latakų ir kai kurie kitos kilmės navikai. Net 90 proc. pacientų, kuriems diagnozuojama tulžies latakų navikinio peraugimo sukelta mechaninė gelta, gali būti taikomas tik simptominis gydymas. Paliatyvus gydymo tikslas – palengvinti su mechanine gelta susijusius simptomus ir išvengti galimų komplikacijų, taip pat pagerinti pacientų išgyvenamumą bei gyvenimo kokybę. Perkutaninis transhepatinis tulžies latakų stentavimas yra minimaliai invazinė intervencija, atliekama kontroliuojant ultragarsu ir rentgenu, galinti padėti radikaliai pašalinti intrahepatinių ir ekstrahepatinių tulžies latakų obstrukciją.

KMUK Chirurgijos klinikoje 2007 m. sausio gruodžio mėnesiais perkutaninis transhepatinis tulžies latakų stentavimas metaliniais savaime išsiplečiančiais stentaais atliktas 12 pacientų, kuriems diagnozuota mechaninė gelta, sąlygota išplitusio navikinio proceso, dėl to radikalus chirurginis gydymas jau buvo negalimas. Pacientų grupėje komplikacijų dažnis neviršijo literatūroje nurodomo dažnio. Šioje pacientų grupėje techniškai sėkmingos buvo 83 proc. visų intervencijų, o geras gydomasis procesas – 80 proc. atvejų. Kiti autoriai, aprašantys dideles pacientų grupes, nurodo, jog perkutaninis transhepatinis tulžies latakų stentavimas sėkmingai gali būti atliekamas net 90–100 proc. atvejų. Tačiau tai yra pirmoji tokio intervencinio gydymo patirtis Kauno medicinos universiteto klinikose ir Lietuvoje, todėl galima manyti, jog rezultatai turėtų būti geresni, tobulėjant priešoperacinei pacientų atrankai ir didėjant chirurgų bei intervencinių radiologų klinicinei patirčiai.

Ši pirmoji patirtis parodė, jog perkutaninis transhepatinis tulžies latakų stentavimas yra saugi ir efektyvi minimaliai invazinė paliatyvi intervencija, kuri gali būti atliekama tais atvejais, kai diagnozuojama išplitusio navikinio proceso sukelta mechaninė gelta ir radikalus chirurginis gydymas negalimas. Tačiau, siekiant įvertinti vėlyvuosius šių intervencijų rezultatus ir nustatyti optimalias jų atlikimo indikacijas Lietuvoje, reikalingi tolesni perspektyvieji tyrimai.

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