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Percutaneous Metallic Stent Placement Effectiveness Compared to ERCP in Hilar and Lower Malignant biliary obstruction

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ABSTRACT— The management of malignant biliary obstruction of the liver is a challenging clinical problem. Because achieving a complete cure is rare and life expectancy is usually short, palliation of symptoms is often the best option for patients with this condition. Biliary decompression can be achieved through surgical bypass or nonsurgical methods. Recent advances in therapeutic endoscopy and interventional radiology have generally replaced surgical treatment, with its high operative risks. These effective and relatively non-invasive modalities have become the standard of care for palliation of malignant obstructive jaundice. To highlight the role of percutaneous stenting in management of malignant biliary obstruction. This study was conducted in Theodor bilharz research institute (TBRI), Egypt in collaboration with radiology department in Ain Shams University. Twenty-four patients who are referred with clinically suspected and diagnosed with malignant obstructive jaundice. This study included patients from the period between from September 2019 to September 2021. The results of this study demonstrate that, in patients with malignant obstructive jaundice, initial ERCP and initial percutaneous transhepatic stenting result in similar rates of successful biliary decompression with comparable adverse event rates. Specifically, with the initial procedure, there was no difference in the procedural success, incidence of cholangitis, and other procedure related complications. The percutaneous approach for stent insertion should be considered as the initial method of palliation for patients with advanced and difficult Bismuth types III and IV HC because of its higher procedural success rate and comparable clinical outcomes.

KEYWORDS: Percutaneous Metallic Stent, Endoscopic retrogradecholangio-pancreatography, Hilar and Lower Malignant biliary obstruction

1. INTRODUCTION

Malignant biliary obstruction is commonly due to pancreatic carcinoma, cholangiocarcinoma, or metastatic disease. Other causes include gall bladder carcinoma, hepatocellular carcinoma, lymphoma, and advanced gastric or duodenal cancer [1].

In patients with malignant obstructive jaundice, percutaneous stenting play an important role in their overall management. Drainage or stenting of an obstruction can relieve symptoms and restore serum biochemistry to normal. This optimizes the clinical condition of the patients for receiving palliative chemotherapy or radiotherapy, bringing about an improvement in their quality of life.

Percutaneous stenting can be used as an alternative to endoscopic retrogradecholangio -pancreatography (ERCP) or when ERCP is unavailable or unsuccessful due to anatomical variations or technical difficulty [2].

Percutaneous stenting is an invasive technique and has associated complications. These include bleeding, infection and bile leak. Procedure related death is reported as 0.6%–5.6% [3].

1.1 AIM OF THE WORK

To highlight the role of percutaneous stenting in management of malignant biliary obstruction.

2. PATIENTS AND METHODS

Patients: This study was conducted in Theodor bilharz research institute (TBRI), Egypt in collaboration with radiology department in Ain Shams University.

Twenty four patients who are referred with clinically suspected and diagnosed with malignant obstructive jaundice.

This study included patients from the period between from September 2019 to September 2021.

The study protocol was approved by the ethical committee of Ain Shams university. Also, a written informed consent was obtained from all patients' prior recruitment to study.

Inclusion Criteria: Patients clinically proven and/or imaging evidence of malignant biliary obstruction and agreement to complete the study requirement and fulfilment of requirements of general anaesthesia will be considered.

Exclusion Criteria: Patients on anticoagulation therapy, associated contraindication to the procedure such as massive ascites or post endoscopic pancreatitis, contraindications to general anaesthesia and all Cases were subjected to:

Thorough detailed history taking, Meticulous clinical examination and laboratory investigations including: CBC, liver function tests, kidney function tests and coagulation profile (PT and INR).

Imaging investigations including: abdominal US in all cases. CT or MRI / MRCP will be done in some cases when ultrasound is not conclusive and confirmation of the problem is needed.

Routine preparation before the procedure was fasting for 6 hours before the procedures, control blood pressure, blood sugar and anesthesia consultation.

Data were collected in the patient's radiologic files. Follow-up data after the end of the biliary procedure were collected from the patients' radiologic, clinical files and during follow up visits during and after completion of the treatment protocol.

Methods: All procedures were done by an experienced team consisted of an expert consultant, an assistant lecturer, a radiology resident, a nurse and technician, under general anesthesia or mild sedation with standardized techniques using seimens artis zee interventional angiography system with dyna CT device.

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Statistical methods: IBM SPSS statistics (V. 26.0, IBM Corp., USA, 2019) was used for data analysis. Date were expressed as median and percentiles for quantitative non-parametric measures in addition to both number and percentage for categorized data.

The following tests were done: Comparison between two groups for non-parametric data using Wilcoxon Rank Sum test, wilcoxon signed rank test for comparison between two groups for non-parametric data, chi-square test to study the association between each 2 variables or comparison between 2 independent groups as regards the categorized data and the probability of error at 0.05 was considered sig., while at 0.01 and 0.001 are highly sig.

3. RESULTS

A total of 24 patients (11 females and 12 males; age, 32– 76 years; mean age, 47 -+38 y) were referred for biliary procedures between sept 2019 and sept 2021 (Table 2). There were no statistically significant difference between the two groups with respect to age or sex.

Table (1): Showing the demographic distribution of the patients of all groups

			I	II	Total
Sex	**F**	**Count**	6	5	11
		%	50.0%	41.7%	45.8%
	M	**Count**	6	7	13
		%	50.0%	58.3%	54.1%
Total		**Count**	12	12	24
		%	100.0%	100.0%	100.0%

The underlying causes of malignant obstructive jaundice included cholangiocarcinoma in 10 patients (41.6%), duodenal masses in 3 patients (8.6%), pancreatic masses in 9 patient (42.9%), metastatic in 1 patient (2.9%) and undiagnosed 1 patient (4.1%). (Table 2)

Table (2): Showing the underlying causes of malignant obstructive jaundice

			I	II	Total
Pathology	**Undiagnosed**	**Count**	1	0	1
		%	8.3%	0.0%	4.1%
	CholangioCA	**Count**	1	9	10
		%	8.3%	75.0%	41.6%
	duodenal adenoCA	**Count**	2	1	3
		%	16.7%	8.3%	12.5%
	pancreatic adenoCA	**Count**	7	2	9
		%	58.3%	16.7%	37.5%
	pancreatic adenoCA+ METS	**Count**	1	0	1
		%	8.3%	0.0%	4.1%
Total		**Count**	12	12	24
		%	100.0%	100.0%	100.0%

12 patients initially underwent percutaneous stenting, the procedure was successful in each case. Left sided approach was done in 1 patient where the dilatation was more prominent at the left biliary tree and it was easier to cross from the left access. Right sided approach was done in 11 patients where the dilatation was more prominent at the right biliary tree. Across the two groups, total of 12 patient received 8mm stent

(50%) and total of 12 patients received 10 mm stent (50%) (Table 4).

The procedure related complications were cholangitis, pancreatitis and bleeding. Only 2 patients among the two groups had cholangitis (11.4%), one patient in group I (8.3%), another one in group II (8.3%) (Table 3). Two patients developed pancreatitis in the first group only (5.7 %) (Table 6). No bleeding events or deaths detected during or after the procedures in the study group.

Table (3): Showing the prevalence of cholangitis among two groups.

			I	II	Total
Cholangitis	**no**	**Count**	11	11	22
		%	91.7%	91.7%	88.6%
	yes	**Count**	1	1	2
		%	8.3%	8.3%	11.4%
Total		**Count**	12	12	24
		%	100.0%	100.0%	100.0%

Table (3): Showing the prevalence of pancreatitis among all groups

			I	II	Total
Pancreatitis	**no**	**Count**	10	12	22
		%	91.7%	100.0%	88.6%
	yes	**Count**	2	0	2
		%	8.3%	0.0%	11.4%
Total		**Count**	12	12	24
		%	100.0%	100.0%	100.0%

Laboratory Parameters: Laboratory parameters included liver, kidney function tests HB level, WBCS count, platelets and coagulation profile.

All these parameters were measured at base level (pre- intervention) and after completion of treatment protocol.

Comparing median pre-intervention bilirubin levels among the two groups, were 18.6 mg/dl in group I and 19.65 mg/dl in group II. P- value of 0.275 (statistically insignificant).

Compared to 3 mg/dl in group I and 3.35 mg/dl in group II post-intervention with P- value of 0.238 (statistically insignificant). Individually among each group pre and post bilirubin levels are of high significant. p value of 0.002 in group I and II.

4. DISCUSSION

The results of this study demonstrate that, in patients with malignant obstructive jaundice, initial ERCP and initial percutaneous transhepatic stenting result in similar rates of successful biliary decompression with comparable adverse event rates. Specifically, with the initial procedure, there was no difference in the procedural success, incidence of cholangitis, and other procedure related complications.

This suggests that initial percutaneous transhepatic stenting is a safe and effective initial procedure for

malignant obstructive jaundice that offers very palatable option for relief of biliary obstruction. As the long-term outcomes for patients with malignant obstructive jaundice is quite poor, it is of critical importance to maintain quality of life and to ensure that the most appropriate initial procedure is offered to patients.

Several endoscopic guidelines recommend percutaneous drainage rather than endoscopic drainage for unrespectable advanced HC of Bismuth type III or higher [4]. This recommendation is equally applicable for preoperative biliary drainage in perihilar cholangiocarcinoma and periampullary masses [5].

However, the endoscopic approach has certain advantages over percutaneous stenting: it is more comfortable for the patient, and it requires a shorter hospital stay. Therefore, endoscopic stenting is initially attempted in patients with malignant obstructive jaundice. In the early 2000s, the success rate for adequate endoscopic biliary drainage of malignant obstructive jaundice specially hilar tumors was reported to be 55–81% [6], but the success rate of endoscopic stent insertion has been gradually increasing because of modifications to stents and accompanying devices, as well as advances in endoscopic stenting skills [7].

However, in cases of advanced high up cholangiocarcinoma / Klatskin tumors, the success rate of endoscopic stenting is still lower than that of percutaneous stenting [8].

A multicenter retrospective study found that percutaneous procedures have significantly higher success rates and a lower risk of cholangitis than endoscopic drainage [9].

The results of the present study are important because if we can identify patient factors that may predict failure of endoscopic stenting before attempting the procedure, we can reduce unnecessary ERCP procedures and thereby prevent the related complications.

The most common reasons for failure of endoscopic stenting were failure of the guide-wire to pass through the stricture.

In high up hilar cholangiocarcinoma, the obstruction pattern is more complex because it is tighter, longer, and more tortuous, and it involves more liver segments. Unlike percutaneous biliary stenting, in which precise lobar selection is possible for drainage, endoscopic biliary drainage has only one retrograde direction and manipulation of devices is more difficult through the long channel [10].

No differences in clinical results, were detected in the current study between endoscopic and percutaneous stent insertions for biliary drainage in patients with malignant obstructive jaundice. There were no significant differences in procedure-related complications, stent patency time, or patient survival time between groups.

These results are similar to those of prior studies including [9], [8] who gives the upper hand to the percutaneous method in reduced procedure related complications.

Although statistically insignificant, the complication rate was lower in the percutaneous group than in the endoscopic group.

The occurrence of cholangitis was equal (8.3%) in the percutaneous group II and endoscopic group I. The results of this study differ from those of previous studies in which Born et al. reported that complications were more common with percutaneous drainage.

The advantages of percutaneous approach are as follows: [4] stated that manipulation of the devices is easier; and Precise lobar or segmental selection for drainage is possible; [11], [3] stated various stent designs are available (T-configured or X-configured); [12] stated less congestion of stents occurs at the stricture site, enabling easier re-intervention; and stent patency can be evaluated before removing the external drainage catheter.

This study has several strengths, including its comparison of biliary stenting alone, using either an endoscopic approach or percutaneous approach and follow-up period.

5. CONCLUSION

In conclusion, the percutaneous approach for stent insertion should be considered as the initial method of palliation for patients with advanced and difficult Bismuth types III and IV HC because of its higher procedural success rate and comparable clinical outcomes.

Abbreviations

ERCP endoscopic retrograde cholangio-pancreatography
CBC complete blood picture
PT prothrombin time
MRI magnetic resonance imaging
MRCP magnetic resonance cholangio-pancreatography

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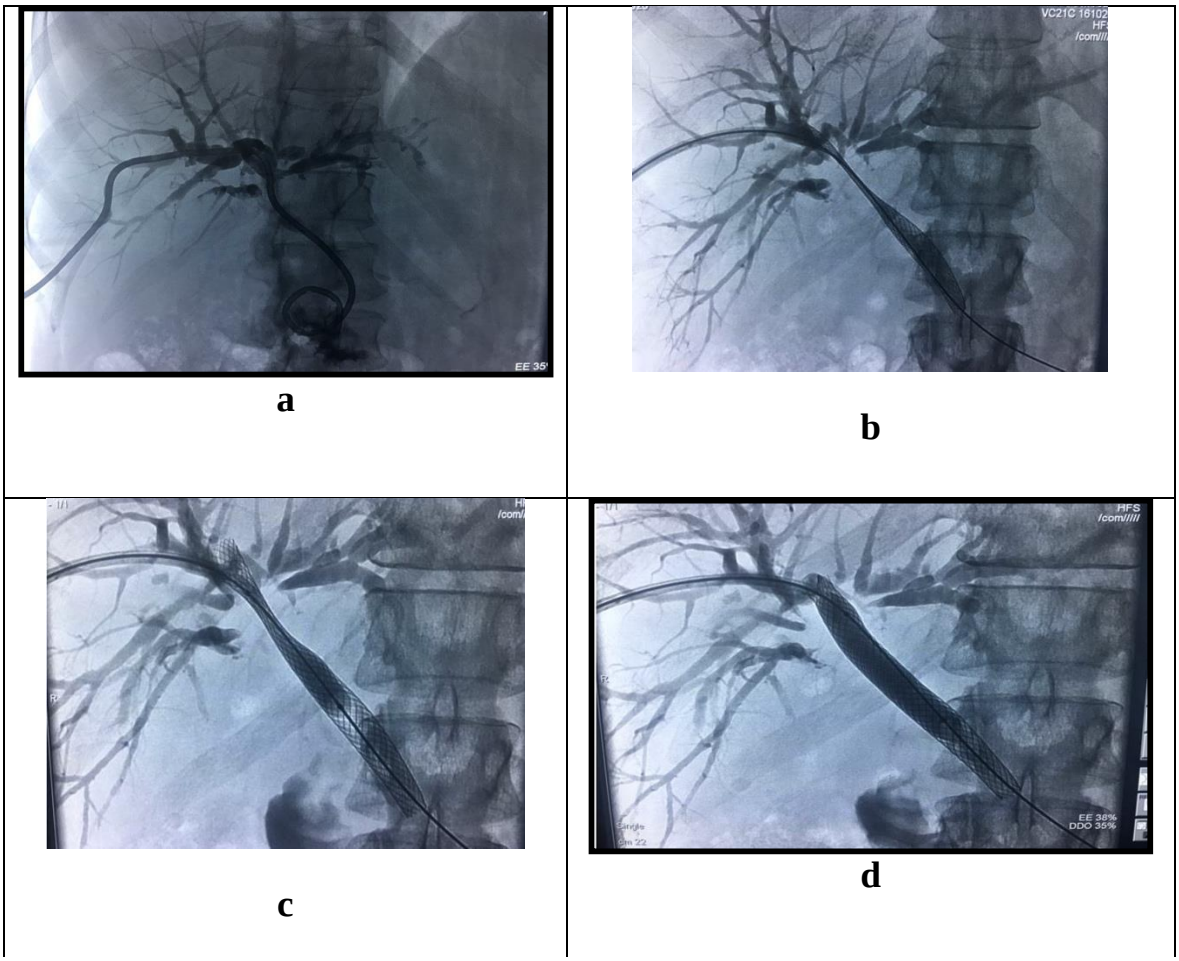

Figure 1. 60 years old female patient, diagnosed with cholangiocarcinoma complicated by malignant obstructive jaundice. (a) PTC using internal external catheter shows level of obstruction at the proximal CBD with subsequent right, left and common hepatic ducts dilatation is also noted. (b) DSA shows 8 mm metallic stent with balloon dilatation of the stenotic segment; (showing a small stenotic segment distal to

CHD (c) 8 mm balloon dilation over 0.035 inch super stiff guidewire. (d) full dilatation of the stenotic segment & repositioning of the balloon through the stent and stenotic segment.

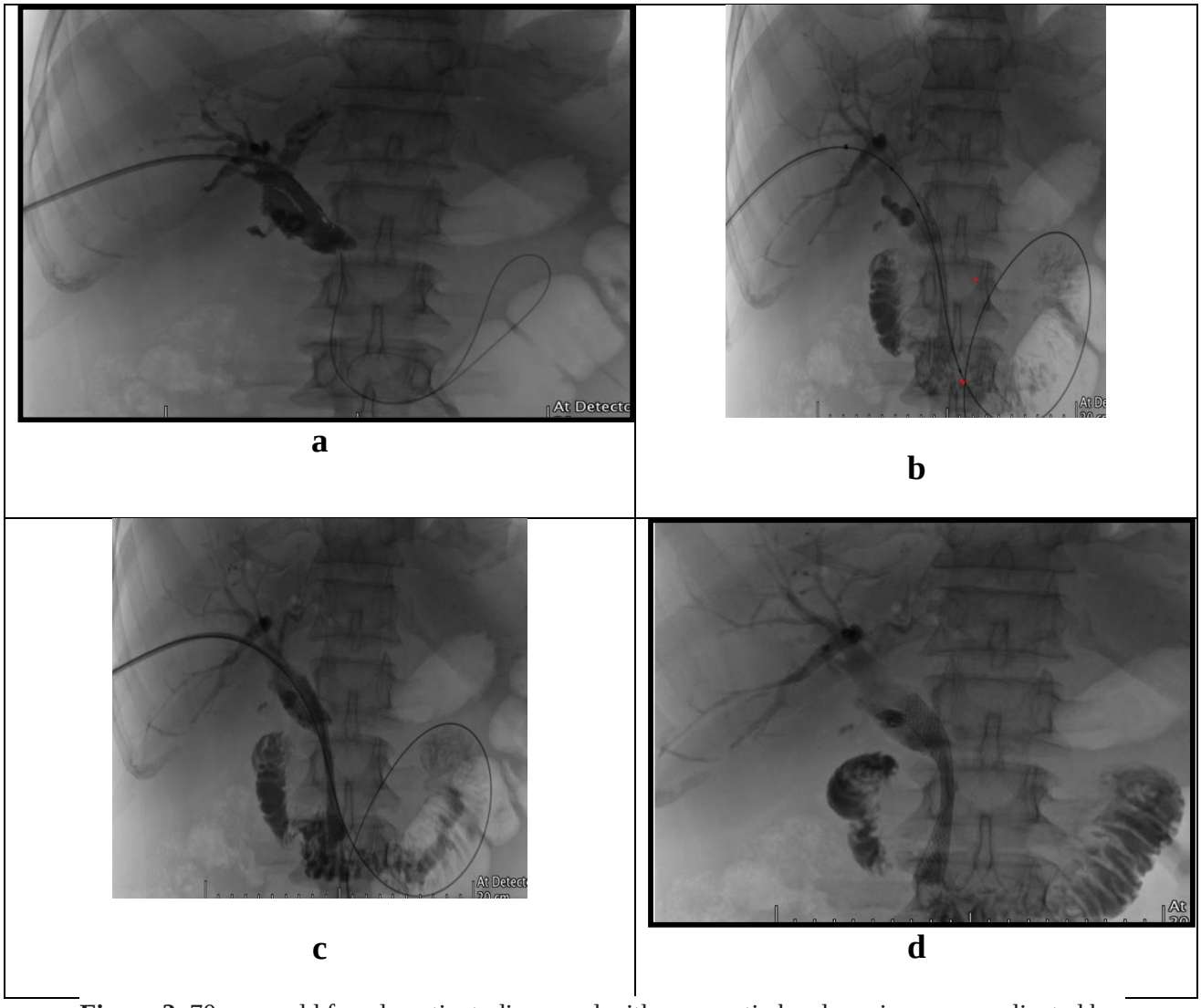

Figure 2. 70 years old female patient, diagnosed with pancreatic head carcinoma complicated by obstructive jaundice. (a) PTC shows no passage of contrast beyond the level of proximal CBD. Right, left IHBRs system dilatation also noted. (b) DSA shows 8 mm metallic stent insertion to the stenotic segment using 0.035 inch super stiff guidewire and (c) PTC showing good contrast flow through its lumen. (d) DSA shows final position of 8 mm metallic stent crossing the stricture site with its tip in the bowel loops.