

Multifactorial Evaluation of Patency of Metallic Stent in Percutaneous Transhepatic Biliary Drainage in Malignant Biliary Obstruction

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Abstract

Background: Malignant biliary obstruction can be caused by primary biliary malignancy, periampullary malignancy, gall bladder malignancy, hepatic malignancy, metastasis and metastatic portal nodes compressing or invading the hila, adjacent malignancy invading the biliary duct. Most of the biliary obstruction caused by the malignancy presents in the advanced inoperable stage with painless progressive jaundice. The delay may be because of delay by the patient, misdiagnosis as benign pathologies like hepatitis, gall stones, benign strictures and because of many alternative medicine treatment particularly in India. By the time the patient presents with jaundice most of the malignancy will be in advanced stage. Various methods to deal with the malignant obstruction can be surgical bypass, endoscopic biliary stenting, percutaneous biliary stenting.

Surgical bypass is not considered routinely as the morbidity and mortality of the procedure is relatively high and requires anaesthesia which adds to morbidity especially in old age with other comorbidities. Surgical bypass is otherwise done when patient is taken up for curative resection but found to be inoperable and when in addition to biliary bypass, gastrojejunostomy is also considered. Endoscopic stenting with plastic stent or SEMS is done if ampulla of Vater is not distorted and can be cannulated and only if the malignant stricture in distal CBD or hila is crossed. Percutaneous biliary drainage with stenting is possible only if IHBR, sectoral ducts are mildly dilated to access and able to cross the stricture with wire. In our study we studied the patency of stents with respect to diameter of stent, length of stricture and yield of stricture to dilatation, closed cell vs open cell stent, effect of balloon dilatation of stricture after stenting, patency in various Bismuth types, coverage of stent beyond the stricture proximally.

Materials and Methods: In this prospective interventional study, 139 [83 males/56 females] patients of malignant biliary obstruction due to various causes like hilar cholangiocarcinoma, gall bladder malignancy with biliary invasion and periampullary malignancy underwent percutaneous transhepatic biliary drainage with stenting from January 2015- June 2019. Patients were referred from

oncology department after tumor board meet decision for the procedure. Either right lobe IHBR/sectoral ducts or left lobe sectoral ducts or IHBR were accessed and rarely in some cases of type 4 hilar malignancy both lobe ducts are accessed, SEMS was placed across the stricture. After technical success of procedure, patients were assessed for clinical success and longevity of patency of stents. During this study various factors like diameter of stent, type of stent, type and length of malignant stricture, Bismuth type, ballooning before stenting was taken in to account to assess the longevity of patency.

Results: The patients were followed up for 1 year or until the death of the patient within a year. Patients who died because of stent obstruction were considered in the study and duration of patency is considered to be present from the day of procedure till the day presentation with obstructive features with increased direct bilirubin, cholangitis, pruritis. Patients who died due to other causes after the procedure were excluded from the study. Out of 132 patients, only 91 patients were considered in the study after exclusion.

Conclusion: Earlier occlusion of stents in hilar malignancy compared to periampullary malignancies and in advanced type 3, type 4 Bismuth compared to type 1, type 2 Bismuth hilar malignancies. Patency of stent is increased with increase in the diameter of stent, closed cell stent and balloon dilatation of stricture after stenting.

Key Word: IHBR –intrahepatic biliary radicles; CBD – common bile duct; CHD –common hepatic duct; SEMS – self expanding metal stent

Introduction

Malignant obstructive jaundice can be caused by such as cholangiocarcinoma, gallbladder malignancy, Periampullary, pancreatic, gastric cancer and hepatocellular carcinoma. The obstruction can range from sectoral ducts up to ampulla. However the obstruction involving the common hepatic duct and below present with clinically significant obstructive jaundice. Patient may present with painless jaundice, weight loss, anorexia, pruritus, fever because of cholangitis and liver

failure. Surgical resection is the primary curative treatment modality for malignant obstructive jaundice if operable, but patient usually presents in the advanced stage such that curative resection is not possible and palliative bypass surgery like choledochojejunostomy adds further morbidity. For such patients who are unable to undergo surgery or surgery carries more risk, early treatment is required to improve hepatic function to facilitate early chemotherapy treatment, hence endoscopic biliary drainage with stenting or transhepatic biliary drainage with stenting is the optimal choice. In patients with distorted ampulla or unable to pass the scope beyond pylorus or cannulate the ampulla, transhepatic biliary drainage is considered. The survival time of patients with obstructive jaundice depends on various factors like age, comorbidities, type of malignancy causing obstructive jaundice, but on average if not treated will be 3 months. Biliary drainage will be effective with clinical success if at least more than 25% of the liver is included in the drainage pathway. Drainage from atrophic lobe with prominent biliary ducts should not be done for ease and this will not be clinically successful. The clinical success is considered to be obtained if total serum bilirubin is reduced to less than or equal to 2mg/dl and this level is accepted for all chemotherapeutic regime. To achieve this level it takes between 3 weeks to 2 months which depends on the pre stent bilirubin level, percentage of liver drained by stent in type 3,4 Bismuth Hilar malignancies, Prothrombin time, liver metastasis

Material and Methods

This prospective study was carried out on patients in Department of interventional radiology at Tamilnadu government multispeciality hospital, Omandurar estate, Chennai from January 2015 till June 2019. A total 139 subjects (83 male and 56 females) ranging in age from 42 years to 87 years were included in the study

Study Design: Prospective observational study

Study Location: This was a tertiary care hospital based study done in Department of interventional radiology at Tamilnadu government multispeciality hospital, Omandurar estate, Chennai.

Study Duration: January 2015 to June 2019

Sample size: 139 patients.

Subjects & selection method: Known patients of malignant biliary obstruction who were referred from medical, surgical and radiation oncology department after approval in tumor board meeting in Tamilnadu multispeciality hospital, Omandurar estate, Chennai. Patients referred from outside hospitals are referred to tumor board meeting for approval before procedure

Inclusion criteria:

- Known case of malignant biliary obstruction proved by biopsy and imaging
- Either sex
- Ultrasonically demonstrable IHBR / sectoral duct dilatation

Exclusion criteria:

- Severely moribund patient with multiple liver secondaries/ multiple system secondaries
- Moderate to massive ascites
- Severe coagulopathy

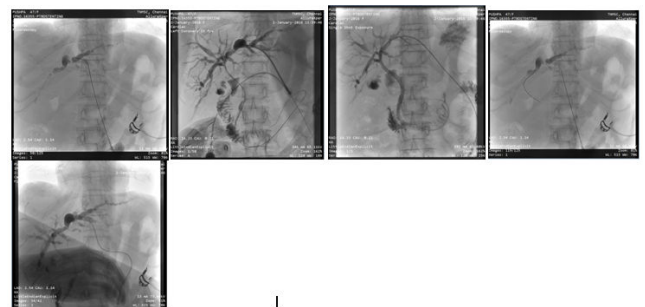
Procedure methodology

All the patients were assessed with ultrasound for IHBR or sectoral duct dilatation. The bilirubin value should be such that the direct bilirubin should be at least 2/3 of the total bilirubin and total bilirubin should be at least around 8mg/dl and biliary radicles should be visibly dilated. The coagulation profile of the patient should be within normal limits. If prothrombin time is such that INR > 1.5, inj. vitamin K iv for 3 days given and INR is reduced less than <1.5. If platelet count is less than 50,000, Platelet transfusion is given before and during the procedure if required. If there is mild to moderate ascites, ascitic fluid is drained such that there is no fluid interface between liver and abdominal wall. Patient preoperative images are evaluated for site of obstruction and to plan right lobe or left lobe access to achieve maximum volume of liver to be drained.

Informed written consent is obtained

Under sterile precaution, Under local anaesthesia with or without sedation, Using ultrasound guidance IHBR or second degree sectoral duct punctured with 22g chiba needle, once bile drains through the chiba needle, cholangiogram is done gently. Then using Neff percutaneous access set [Cook] over the cope mandril wire, 0.018 inch system converted to 0.035 inch system. Then using 4F Kumpe catheter and 0.035 inch terumo wire through outer sheath of Neff set, stricture negotiated and entered into duodenum. 0.038 inch Amplatz wire exchanged for glide wire and 6F sheath replaced with Neff set sheath, through which ballooning, stenting done over the Amplatz wire. Internal external drainage catheter placed after stenting. The internal external biliary drainage catheter is removed after a week

Case-1



Case-2

Type1: hilar cholangiocarcinoma, sector 2 duct approach



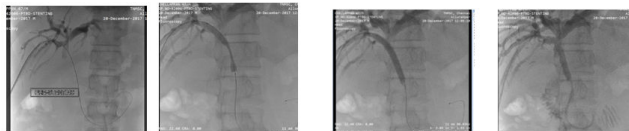
Case-3

Type 3/4 hilar cholangiocarcinoma , sector 5 duct approach



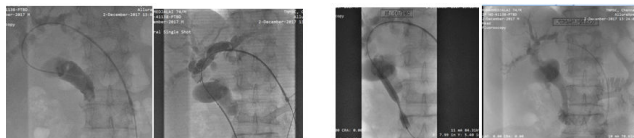
Case -4

CBD metastasis , sector 3 duct approach



Case -5

Type 1 hilar cholangiocarcinoma , sector 5 duct approach



Periampullary growth , sector 2 duct approach

Statistical analysis

H0: There is no difference in the mean duration of patency between the patients due to different diameters of stent.

H1: There is difference in the mean duration of patency between the patients due to different diameters of stent.

Stent type	N	Mean	Std. Deviation	p value
8mm	16	143.81	128.700	0.023*
9mm	29	205.90	119.226	
10mm	46	241.11	119.040	
Total	91	212.78	124.657	

Interpretation:

The above table shows that the 8mm diameter stent were used in 16 cases in this study and the mean duration of patency is 143.83 ± 128.70 (Mean \pm SD), the 9mm diameter stent were used in 29 cases in this study and their mean duration of patency is 241.11 ± 119.04 and similarly the 10mm diameter stent were used in 46 cases in this study and their mean duration of patency is 205.90 ± 119.23 which conveys that there is statistically significant difference in the mean duration of patency between the patients due to different diameters of stent since their p value is 0.023 which is less than the 0.05 level of significance.

Now, to know which stent type has significant patency days than others we use multiple comparisons.

Multiple Comparisons					
(I) Stent type	(J) Stent type	Mean Difference (I-J)	Std. Error	Sig.	
8mm	9mm	-62.084	37.619	0.102	

	10mm	-97.296*	35.061	.007*
9mm	8mm	62.084	37.619	0.102
	10mm	-35.212	28.643	0.222
10mm	8mm	97.296*	35.061	.007*
	9mm	35.212	28.643	0.222

*. The mean difference is significant at the 0.05 level.

The above table shows that the 10mm stent has performed better than 8mm stent type in patent days of stents whereas, 9mm and 10mm seems almost similar in patent days.

H0: There is no difference in the mean duration of patency between the patients due to type of malignancy.

H1: There is difference in the mean duration of patency between the patients due to type of malignancy.

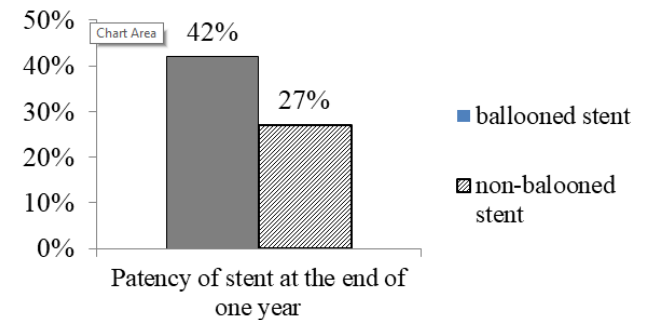
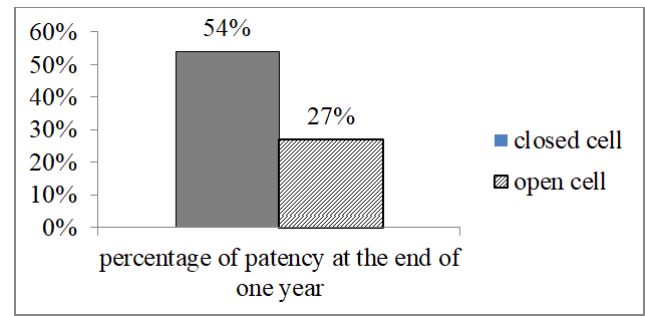
Type of malignancy	N	Mean	Std. Deviation	p value
Type 1/Type 2	31	230.77	117.294	0.003*
Type 3/Type 4	27	141.81	112.014	
GBMALIGN ANCY/ METASTASIS	19	242.84	123.324	
PERIAMPULLARY	14	269	117.14	
Total	91	212.78	124.657	

Interpretation

The above table shows that there is statistically significant difference in the mean duration of patency between the patients due to type of malignancy.

Multiple Comparisons				
(I) type of malignancy	(J) type of malignancy	Mean Difference (I-J)	Std. Error	Sig.
Type 1/Type 2	Type 3/Type 4	88.959*	30.801	.005*
	GB malignancy/metastasis	-12.068	34.091	.724
	Periampullary	-38.226	37.677	.313
Type 3/Type 4	Type 1/Type 2	-88.959*	30.801	.005*
	GB malignancy/metastasis	-101.027*	35.038	.005
	Periampullary	-127.185*	38.536	.001*
GB malignancy /metastasis	Type 1/Type 2	12.068	34.091	.724
	Type 3/Type 4	101.027*	35.038	.005*
	Periampullary	-26.158	41.213	.527
Periampullary	Type 1/Type 2	38.226	37.677	.313
	Type 3/Type 4	127.185*	38.536	.001*
	GB malignancy/metastasis	26.158	41.213	.527

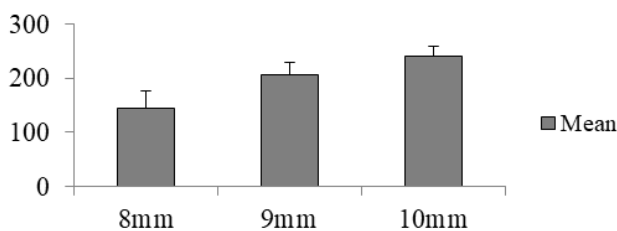
*. The mean difference is significant at the 0.05 level.



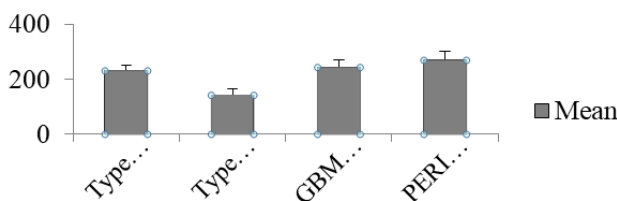
The above table shows that the (I) Type of malignancy is better than (J)Type of malignancy if it is significant and has positive value otherwise, (J)Type of malignancy is better than (I)Type of malignancy if it is significant and has negative value. Therefore, the table conveys that the malignancy type Type 1/Type 2, GBMALIGNANCY/METASTASIS and PERIAMPULLARY has better significant patent days than Type 3/Type 4.

Graphical Representation

Duration of patent days according to the stent type



Duration of patent days according to the type of malignancy



Result

139 patients [83 males and 56 Female] patients of malignant biliary obstruction with age range between 42 years and 87 years were considered for the procedure . The direct bilirubin level of the these patients ranged from 28mg/dl to 5mg/dl . Out of 139 patients,132 patients [78 males and 54 females] had successful procedure , 7 patients had technical failure . The reasons for the failure are severe respiratory distress in 1 patient such that access to the sectoral duct is failed due to gross movement of liver during respiration , 3 patients had minimal sectoral duct ,IHBR dilatation in which access is failed and in 3 patients stricture could not be crossed even after second attempt. Out of 132 patients, right lobe access was done in 73 patients and left lobe access in 54 patients and bilateral access was done in 5 patients. Out of 132 patients , 71 patients had hilar cholangiocarcinoma, 13 patients had gallbladder malignancy with bileduct invasion , 31 patients had periampullary carcinoma including pancreatic malignancy,17 patients with nodal metastasis/direct invasion by adjacent tumours at hila or CBD causing obstruction of confluence, CHD or CBD. Out of 137 stenting in 132 patients , 10mm diameter stents were used in 68 patients , 9mm stents were used in 43 stents , 8mms stents were used in 26 patients . Closed cell bare metal stent [Wall stent –Boston scientific]was used in 28 instances and open cell type stent[Absolute Pro –Abbott] were used in rest of the instances. Closed cell type was mostly used in periampullary carcinoma ,gall bladder malignancies with secondary CBD invasion ,in type 1 Bismuth hilar malignancies without crossing the confluence. Out of 71 cholangiocarcinoma , 6 patients had type 1 hilar cholangiocarcinoma , 27 patients has type 2 Bismuth , 38 patients had type 3 or type 4 . Ballooning of stent after deployment was done in 54 patients . Less than 1 cm proximal coverage of stent beyond the stricture was noted in 14 patients due to technical accuracy in deployment of self expanding stent and relatively shorter length of the stent. All the

patients were followed up to 1 year .Clinical success was said to be attained when the total bilirubin is reduced by more than 20 % of total bilirubin within 7 days compared to the preprocedure total bilirubin level .Patency of the stent is followed up to 1 year . Patency duration is considered as duration from the time of SEMS insertion to occlusion of stent with rise in the direct bilirubin level or death of the patient due to occlusion of stent .Patients who died not because of rise in direct bilirubin were not considered for stent patency as they may falsely reduce the duration of patency. Out of 132 patients , 29 patients died because of non obstructive causes within a year and 12 patients lost follow up . In this 41 patients 17 patients had periampullary carcinoma, 11 patients had type 3/type4 hilar cholangiocarcinoma , 8 patients had metastatic disease, 3 patients with gall bladder malignancy and 2 patients had type 2 cholangiocarcinoma .Hence remaining 91 patients were considered for patency study for up to 1 year . The mean duration of patency is 144 days . The stent patency in type 1 and type 2 hilar cholangiocarcinoma is 146 days and 103 days in type 3 and 4. Mean duration of stent patency in periampullary carcinoma is 173 days and hilar /CBD metastatic disease/Gall bladder malignancy is 154 days . The stent patency at the end of 1year is 15% in type 3 and 4 Bismuth hilar cholangiocarcinoma , 39 % in type 1 and 2 bismuth Hilar malignancy ,42% in GB malignancy and metastatic disease with CBD,CHD involvement and 50% in periampullary malignancy. Mean patency of 10mm, 9mm and 8mm stent is 154 days , 134 days and 92 days and patency at the end of 1 year is 41%[19/47],31%[9/29] and 18%[3/17]respectively[93 stents in 91 patients] . Patency of closed cell stent is 54% [13/24] at the end of 1 year as against open cell stent which is 27%[18/67]. Ballooning of stent done in 54 Cases, Out of which 43 cases were in the follow up with patency at the end of 1 year is 42%[18/43] and without ballooning is 27%[13/48] .The incidence of cholecystitis due to cystic duct obstruction in patients in whom closed cell stent used is 16% as against open cell type where the incidence is 2.9%

Discussion

Malignant biliary obstruction may be caused by cholangiocarcinoma and non biliary carcinomas. The current treatment options for malignant obstructive jaundice include surgical, interventional therapy and endoscopic therapy. Surgery is primarily indicated in case of curative resection and in patients with both extrahepatic bile duct and duodenal /gastric outlet obstruction for surgical bypass .Surgery may be used to relieve jaundice in addition to removing lesions and peripheral vascular invasion . Elderly patients with a generally poor condition and associated comorbidities like diabetes, cardiovascular disease complications are not candidates for surgery. Non surgical endoscopic or percutaneous approach is the preferred treatment for such patients. The objective of palliative non surgical prodecures is to relieve jaundice-related symptoms, to prevent cholangitis and to improve quality of life . With the advent of technology and medical equipments , PTBD and stenting have exhibited good efficacy, with few complications and emerged as a crucial palliative treatment for malignant obstructive jaundice . The primary complications associated with PTBD and stenting

include the Drainage tube or biliary stent dislocation or fracture, obstruction with cholangitis, hemobilia because of adjacent vascular injury and pancreatitis . In our study out of 132 patients 41 patients were excluded from the study as some of them lost follow up and some of them died due to non obstructive causes after procedure . Within a year, out of 91 patients 27 patients died at the first instance of occlusion due to cholangitis and subsequent sepsis , 33 patients had repeat procedure for obstruction with plasty and /or restenting .In our study it is found that using longer stent, narrower stent , open cell stent and higher level malignant biliary obstruction is associated earlier occlusion of stent .Though the patency with closed cell stent is good , it is associated with more incidence of cholecystitis probably due to cystic duct obstruction and also incidence The increased duration of patency with closed cell stent may be because of less chances for the tumor ingrowth between the cells as compared to open cell stent in which cells are wide open .Though the patency percentage in periampullary malignancy is higher , it may be spuriously high as we used only closed cell stent and all are 10mm diameter and shorter length stents . The high incidence of occlusion in type 3 and type 4 Bismuth hilar cholangiocarcinoma may because of less volume of liver drained by stenting and longer length stent is used as stent has to extend up to and just beyond ampulla and also in some cases the proximal coverage of stent beyond malignancy is less due to stent length inadequacy. Longer patency duration in larger diameter stent may be because of tumor ingrowth to completely occlude the biliary lumen may be prolonged . Ballooning before or after stent placement compress the tumor against the biliary wall ,whereas in stenting without ballooning as stent expands ,the struts cut through the tumor as the tumour assuch is not compressed against the biliary wall and causes earlier occlusion especially in intramural type of growth.

Conclusion

Higher the level of biliary obstruction is associated with reduced duration of stent patency

Higher grade [Bismuth 3 and 4] associated with reduced patency duration compared with lower grade [Bismuth 1 and 2]

Stent patency is increased with larger diameter stent , closed cell stent

Balloon plasty of the malignant stricture before or after stent deployment increases the duration of patency of stent

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