

**STUDY ON ENDOSCOPIC PALLIATION OF  
MALIGNANT BILIARY OBSTRUCTION  
BY PLASTIC STENTS**

**DISSERTATION SUBMITTED FOR DM MEDICAL  
GASTROENTEROLOGY  
(BRANCH-IV)  
AUGUST- 2010.**



**THE TAMIL NADU DR.MGR MEDICAL UNIVERSITY,  
CHENNAI, TAMIL NADU.**

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# **CERTIFICATE**

**This is to certify that this dissertation entitled  
“A Study on Endoscopic Palliation of Malignant  
Biliary Obstruction by Plastic Stents” submitted by  
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Gastroenterology, The Tamilnadu Dr.MGR Medical  
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the requirement for the award of DM., Degree Branch IV  
(Gastroenterology) is a bonafide work carried out by him  
under my direct supervision and guidance.**

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**MASTER CHART**

**PROFORMA**

# **INTRODUCTION**

# **AIM OF THE STUDY**



**REVIEW OF  
LITERATURE**

# **MATERIALS & METHODS**

# **OBSERVATION**

# **DISCUSSION**

# **CONCLUSION**

# **BIBLIOGRAPHY**

# **MASTER CHART**

## **INTRODUCTION**

Malignant biliary obstruction comprises of malignancies causing proximal malignant obstruction like Gallbladder carcinoma, hilar cholangiocarcinoma, node causing obstruction and malignancies causing distal malignant biliary obstruction including pancreatic malignancy, ampullary adenocarcinoma, distal cholangiocarcinoma and duodenal adenocarcinoma.

Most of the patients present in the late inoperable stage where palliation alone is possible. Palliation of jaundice is done by 3 methods.

- (1) Endoscopic stenting.
- (2) Surgical drainage
- (3) Percutaneous drainage

Endoscopic method is the most preferred because of the ease, physiologically least disturbing, with high success rate and negligible morbidity and mortality. Surgical drainage and percutaneous drainage are used in select situations, usually when the endoscopic stenting fails.

Endoscopic stenting in the preoperative setting is controversial. While some studies suggest negative benefit, it is generally accepted in



select circumstances like anticipated delay in surgery, cholangitis, renal failure, pruritis.

Both plastic and metallic stents are available for endoscopic palliation. SEMS are the standard in patients in whom expected life expectancy more than 6 months, plastic stents are preferred in patients whose life expectancy is less than 6 months and also in preoperative setting, due to low cost, but the disadvantage is frequent clogging and subsequent need for stent exchanges. To overcome this either 3 monthly exchange or demand exchange is advocated. Most experts would agree for demand exchange because upto 50% of patients may die without restenting.

# **REVIEW OF LITERATURE**

## **EPIDEMIOLOGY**

The incidence of pancreatic and biliary malignancies increases with age and, in fact, these tumors are rarely seen before the age of 45. Epidemiological surveys have shown that the median age of diagnosis approximates 70 years.

Diabetes, chronic pancreatitis, pernicious anemia, inherited disorders such as familial adenomatous polyposis, and high fat and meat intake have been cited as risk factors for pancreatic cancer. Patients with hereditary and familial pancreatic cancer have upto 40% life time risk of pancreatic cancer<sup>1</sup>.

The majority of cases of cholangiocarcinoma have no identifiable underlying etiology.

Choledochal cysts are associated with a 10% lifetime incidence of cholangiocarcinoma; there is a 1% per year risk which plateaus after 15-20 years.

Cholangiocarcinoma is also rarely seen in association with cirrhosis and has been weakly linked to hepatitis C infection.

Tumors at the biliary confluence of the liver are the most common and comprise 40-60% of the total. Middle third and distal third tumors comprise 17-20% and 18-27%, respectively. A small percentage of patients (<10%) have diffuse tumors involving the entire extrahepatic bile duct.

Among neoplasms involving the biliary tree, carcinoma of the gallbladder has the poorest prognosis with a 5 year survival ranging between 0% and 10% in most reported series<sup>2</sup>.

Cholelithiasis is thought to be an important risk factor for gallbladder cancer. Other risks factors such as the presence of a porcelain gallbladder, gallbladder polyps, an anomalous pancreatocobiliary junction and obesity have also been suggested in epidemiological studies<sup>3</sup>.

### **Natural History**

The most common malignancy causing distal biliary malignant obstruction is pancreatic cancer accounting for more than 90% of cases followed by gallbladder cancer, malignant lymphadenopathy and cholangiocarcinoma, the latter being relatively uncommon in Western countries.

Except for extrinsic compressions caused by enlarged lymph nodes in the case of hematological malignancies such as Non-Hodgkin's

lymphomas and for ampullary tumors, the majority of patients are found with unresectable disease have a median survival of 3-5 months<sup>4</sup>.

### **Clinical Features**

The most common presenting symptoms of pancreaticobiliary malignancies are painless jaundice, anorexia and weight loss. If pain occurs it is often located in the epigastric region or right upper quadrant, and may radiate to the back. Back pain usually indicates retroperitoneal infiltration by the tumor and therefore probable unresectability. Other symptoms may include dark urine, pale stools and pruritus. As many as 80% of patients with pancreatic cancer will present with impaired glucose tolerance or frank diabetes mellitus. Carcinoma of the body and tail of the pancreas presents with similar features, although jaundice is usually absent or develops very late in the course of the disease. A complete physical examination, including assessment for abnormal lymph nodes, jaundice, hepatomegaly, palpable gallbladder, or mass should be performed. Chest radiograph may be appropriate to exclude pulmonary metastases. Obtaining serum tumor markers such as CA 19-9 and CEA may be appropriate. Once there is a clinical suspicion of a pancreaticobiliary malignancy, further investigation with abdominal imaging studies is appropriate.

## **Most prevalent distal pancreaticobiliary Malignancies**

- Ampullary adenocarcinoma
- Pancreatic adenocarcinoma (Head)
- Cholangiocarcinoma (non hilar)
- Metastatic disease

### **Ampullary Carcinoma**

Ampullary carcinoma is suspected based upon the demonstration of obstructive jaundice, often with dilation of the pancreatic and biliary ducts seen on abdominal imaging studies. A discrete mass may or may not be identifiable by using standard transabdominal US (TUS) or helical computerized tomography (CT) scanning. ERCP allows for direct identification and biopsy confirmation, although the diagnostic accuracy of biopsy is not 100%. MRCP may allow identification of the lesion and obviate diagnostic ERCP. Endoscopic ultrasound (EUS) allows for more accurate diagnosis and staging of these lesions than CT, and also allows for fine needle aspirate (FNA) tissue sampling. EUS also may facilitate the selection of patients who can undergo local resection instead of pancreaticoduodenectomy (Whipple operation). Once the lesion is identified and staged, the choice of operative resection for cure or some

form of jaundice palliation are similar to treatment options for carcinoma of the pancreatic head.

### **Pancreatic malignancies**

The approach to the patient with pancreatic carcinoma involving the pancreatic head is different from the patient with body/tail lesions in terms of accessibility, curative potential, and palliation.

Most patients with cancer of the pancreatic head present with obstructive jaundice. Radiological imaging studies are performed allowing for (a) detection of the tumor, (b) determination of tumor respectability, and (c) tissue acquisition under imaging guidance.

TUS will suggest biliary obstruction by the demonstration of biliary ductal dilation. It may also identify the presence of obvious liver metastases. However, standard TUS is operator dependent and has a poor sensitivity for detecting small neoplasms of the pancreatic head. Recent advances in TUS, such as color Doppler US, US angiography, harmonic imaging (tissue harmonic imaging and contrast harmonic imaging), and three-dimensional US, may improve the usefulness of this modality in the staging of pancreatic cancer. Nonetheless, more information regarding

staging and extent of disease, and possible nodal or vascular involvement is obtainable with other imaging modalities.

Helical CT of the abdomen with fine cuts through the pancreas during the arterial and portal phases of contrast enhancement has a high sensitivity and specificity for the detection of pancreatic carcinoma. It allows for the determination of tumor extension, liver metastases, and invasion of vascular structures, and thus, resectability. Multislice (multidetector) CT has been introduced and may improve on the accuracy of helical CT. If the CT findings are found to be highly suggestive of a resectable pancreatic carcinoma in the appropriate clinical setting, and the patient is felt to be an operative candidate, a reasonable approach is to then refer the patient directly for an attempt at surgical resection (pancreaticoduodenectomy) with or without further imaging (depending on local availability and expertise) or diagnostic testing. Transabdominal or CT-guided biopsy of the pancreatic mass rarely may result in tumor seeding at the needle track or within the peritoneum and has been reported to increase the risk of postoperative recurrence. If the CT scan reveals overt evidence of unresectable pancreatic cancer or the patient is a nonoperative candidate because of co-morbid medical conditions, non-operative palliation of obstructive jaundice should be performed at

ERCP. If a definitive tissue diagnosis is required for the administration of chemotherapy and/or radiation therapy, tissue acquisition can be performed at the time of the palliative ERCP. If a tissue diagnosis cannot be made at that time, then EUS-guided FNA of the mass or metastatic sites should be performed.

Magnetic resonance imaging (MRI) of the pancreas may include MRI, MR cholangiopancreatography (MRCP), or magnetic resonance angiography. Standard abdominal MRI appears to be an accurate modality for staging pancreatic carcinoma, though it does not appear to be more specific or sensitive than helical CT. In addition, it is more expensive and more time consuming to perform than CT.

If expertise in EUS is readily available, it should be used as a preoperative staging modality in patients with suspected pancreatic cancer. This is particularly important in patients with equivocal findings on CT or those with co-morbidities and, therefore, at higher risk for intra operative or postoperative complications. EUS allows identification of vascular invasion as well as sampling of suspicious-appearing lymph nodes, which, if positive, may change the treatment approach as it alters prognosis. EUS appears to be complementary to helical CT, with EUS better at detecting small (<3 cm) masses, staging the portal vein, and detecting lymph node



metastases, while helical CT is superior for staging arterial involvement and distant metastases. An EUS-guided FNA biopsy specimen allows for a definitive tissue diagnosis of a pancreatic mass when results on other biopsy methods are negative but pancreatic cancer is suspected. If EUS suggests resectability, EUS-guided biopsy of the mass is not necessary before proceeding with operative resection, although this point remains controversial. Advantages of needle biopsy of the mass include identification of alternative diagnoses to primary pancreatic adenocarcinoma (lymphoma, islet cell tumors and metastatic disease). It also allows for preoperative patient counselling. Potential disadvantages of preoperative EUS-guided FNA include the risks of pancreatitis, bleeding, and, theoretically, tumor seeding. The latter has never been reported and appears to be inconsequential in most cases since the needle path usually lies within the resected specimen. Ideally, EUS should be performed before ERCP and stent placement since the latter may interfere with the accuracy of EUS staging and EUS findings of unresectable carcinoma allow improved patient selection for placement of a self-expanding metallic stent. In patients with unresectable cancer, EUS-guided celiac plexus neurolysis has been shown to control disabling abdominal pain.

The near-pathognomonic findings on ERCP of a pancreatic head cancer are strictures of the bile and pancreatic ducts with proximal dilation (the “double-duct” sign). While ductal abnormalities are almost invariably present in patients with adenocarcinoma, other imaging modalities (CT, MR, and EUS) have supplanted ERCP in the diagnosis of pancreatic cancer. Preoperative ERCP does not add further staging information and may result in complications that may make operative intervention more difficult and/or may considerably delay operative intervention, resulting in a decreased potential for curative resection. Furthermore, several studies suggest higher postoperative complications when a preoperative ERCP is done. However, if the patient suffers from cholangitis or severe pruritus, or if there is a substantial delay in operative resection, preoperative ERCP with biliary drainage should be performed.

### **Cholangiocarcinoma**

A primary tumor of the bile duct should be suspected based on clinical and imaging findings. Abdominal CT scans will show biliary dilation without an associated pancreatic mass or pancreatic ductal dilation, and the level of obstruction usually can be localized to a level above that of the pancreatic duct. The differentiation of hilar vs non-hilar tumors is important because of implications for both operative resection and

endoscopic palliation. The Bismuth classification of cholangiocarcinoma is useful for determining surgical resectability and type of surgery. If imaging studies map the level of obstruction below the bifurcation (Bismuth type 1 lesions), operative resection should be considered in fit patients without metastatic disease. If the patient is a poor operative candidate, palliation with plastic or metal stents, as with pancreatic carcinoma, should be undertaken.

### **Metastatic disease**

Metastatic disease may lead to biliary obstruction either intrinsically or extrinsically (porta hepatic involvement) anywhere from the level of the bifurcation to the ampulla. The diagnosis may be obvious, based upon known widespread malignancy, or more occult and discovered at the time of endoscopic evaluation or surgical resection. CT scan findings may mimic primary malignant disease of the bile ducts or pancreas. An MR examination may be useful in defining the presence of perihilar obstructive disease. If disease is widespread, palliation of obstruction is indicated as for primary malignancies.

## **Anatomical classification of Hilar Cholangiocarcinoma**

The extent of duct involvement by perihilar tumors may be classified as suggested by Bismuth and Corlette.

- A. Type 1 : tumors below the confluence of the left and right hepatic ducts (ceiling of the biliary confluence is intact; right and left ductal systems communicate);
- B. Type II : tumors reaching the confluence but not involving the left or right hepatic ducts (ceiling of the confluence is destroyed; bile ducts are separated);
- C. Type III : tumors occluding the common hepatic duct and either the right (IIIa) or left (IIIb) hepatic duct;
- D. Type IV : multicentric tumors or tumors involving the confluence and both hepatic ducts, the right one and the left one.

## **Malignant Hilar Strictures**

- Cholangiocarcinoma
- Gallbladder carcinoma
- Nodal mets at porta hepatis
- Hepatocellular carcinoma

- Hepatic metastases
- Metastasis to biliary tree

### **Criteria for unresectability in patients with hilar cholangiocarcinoma**

- Medical co-morbidities limiting the patient's ability to undergo major surgery.
- Significant underlying liver disease prohibiting liver resection necessary for curative surgery based on preoperative imaging.
- Bilateral tumor extension to secondary biliary radicals.
- Encasement or occlusion of the main portal vein.
- Lobar atrophy with contralateral portal vein involvement.
- Contralateral tumor extension to secondary biliary radicals.
- Evidence of metastases to N2 level lymph nodes.
- Presence of distant metastases.

### **Indications for Endoscopic Palliation**

Biliary decompression is indicated if there is cholangitis or pruritus in the face of advanced malignant biliary obstruction. Biliary stenting has also been shown to improve symptoms of anorexia and quality of life.

Routine preoperative drainage of an obstructed biliary system, however, has not been shown to benefit patients who will soon undergo a

surgical procedure, and may in fact be deleterious in some<sup>5,6,7</sup>. If preoperative drainage is indicated because of cholangitis or an anticipated delay to surgery in the face of clinically significant symptoms, such as pruritus, drainage has traditionally been performed using plastic stents.

### **Plastic endoprotheses**

Plastic stents are easy to insert, and can be removed if necessary. Their biggest advantage compared to metal stents is that their upfront cost is significantly lower (tenfold in many markets). A large variety of biliary plastic stents are available with internal diameters ranging from 5 to 11.5 French (Fr) gauge with lengths varying from 5 to 15 centimeters (cm). Straight plastic stents with flaps at both ends are the most commonly used. The disadvantage of plastic stents is early stent clogging. Recent investigations have focused on the importance of ingested fibre matter<sup>9</sup> and the production of bacterial biofilm<sup>10</sup> as the factors responsible for stent clogging.

### **Methods to overcome stent clogging.**

- (1) Size of the internal diameter.

The duration of patency for stents with an internal diameter of 10 Fr or greater is 21-32 weeks compared to 10-12 weeks for 7 or 8.5 Fr plastic

stents. Additionally, there may be a lower associated incidence of cholangitis with larger-caliber stents which is attributed to improved internal flow dynamics<sup>44</sup>. There is no conclusive evidence favouring 11.5F over 10F stents<sup>11</sup>.

(2) Plastic stent design.

Animal studies suggest straight stent may provide better drainage than pigtail stents<sup>8</sup>.

Pilot study has assessed a stent without a lumen, that may result in prolonged stent patency<sup>15</sup>.

(3) Position of the distal tip of the stent.

Stents were placed above papilla but stents placed above the papilla had higher stent migration rates<sup>12</sup>.

(4) Administration of choloretic agents and/or antibiotics.

Antibiotics may also be useful by inhibiting bacterial colonization of the stent. However, both classes of drugs, alone or in combination, have failed to demonstrate improvement in the duration of stent patency<sup>13,14</sup>. In addition, no improvement in survival has been noted.

## **Self-expandable metal stents**

SEMS are delivered into the bile duct while completely constrained by a sheath, allowing insertion as a small-circumference delivery system. SEMS differ in regard to the type of delivery system, structural composition, design, length and diameter. However, all achieve a much larger internal diameter and subsequent longer patency rate compared to plastic stents. The mechanisms of SEMS blockage include

- stent ingrowth
- over growth by tumor,
- mucosal hyperplasia.

More recently, polyurethane-covered SEMS have been developed in the hope of prolonging stent patency by presenting a physical barrier to tumor ingrowth. In the sole randomized comparative trial to date, the covered SEMS technology was associated with a significant increase in patency duration as compared to the uncovered SEMS. However the covered SEMS may occlude ductal branches, leading to complications such as cholecystitis, cholangitis, and pancreatitis.

SEMS are difficult to remove, they are reserved for patients with established, unresectable malignant disease, although recently, an



increasing number of endoscopists are describing removal of covered SEMS.

### **PLASTIC Vs METAL STENTS**

Factors	Plastic Stent	Metallic Stent
Cost	Cheaper	Costlier
Placement	Relatively easy	More expertise
Patency	2-4 months	6-8 months
Long term complication	Clogging	Tumor ingrowth, over growth
Management of stent obstruction	Stent exchange	Placement of plastic stent in SEMS

#### **Stent choices for palliation of malignant biliary obstruction**

The major decision that needs to be made is the type of stent to be placed (plastic or metal). Important measures for this decision include several

#### **Stent-related factors,**

- such as stent efficacy (relief of jaundice),
- stent patency,
- need for reinterventions, and costs.

#### **Patients-related issues, such as**

- the extent of disease and

- expected survival time, also need to be considered and influence the optimal and cost-effective choice of stent.

Plastic stents and SEMS both provide palliation of jaundice and improve liver tests after placement in over 95% of patients.

### **Median stent patency** ranges

(A) 2 to 5 months for plastic stent,

(B) 4 to 10 months for SEMS<sup>16</sup>.

Median patient survival ranges from 4 to 6 months after plastic or metallic stenting. The recent Cochrane systematic review, however, did not conclude on any survival benefits attributable to metal versus plastic stents.

Cost-effectiveness analyses have shown that the optimal choice of stent (plastic versus SEMS) is influenced by the ratio of the cost of stent to the cost of the ERCP, and the anticipated life expectancy of the patient. The greater the cost of the ERCP, the more likely the SEMS will be a cost-effective choice. Plastic stents may be preferred to SEMS in patients with large tumors (>3 cm) or liver metastases, both of which are poor predictors of survival, as plastic stents are cost-saving in patients surviving less than 3-4 months while SEMS are more cost-effective in patients expected to survive longer than 6 months<sup>17</sup>.

SEMS may be preferred in a patient who is non-complaint or resides in a remote area without medical access, despite an anticipated short life expectancy.

### **The optimal stenting strategy**

In a randomized trial, routine exchanges every 3 months were associated with longer symptom-free intervals for patients than exchanges at signs of stent occlusion, but there was no difference in overall survival<sup>17</sup>. Most cost effective stenting strategy is covered metallic stent and least cost effective method is routine 3 monthly replacement of plastic stents<sup>18</sup>.

Occluded SEMS are managed by a variety of methods. The most commonly used techniques include

- insertion of a plastic stent within the occluded SEMS,
- insertion of a second SEMS and
- mechanical cleaning of the occluded stent lumen.

Overall success rates for re-establishing biliary drainage are over 80%. Given the typical short median survival at the time of the first SEMS occlusion, treatment with a plastic prosthesis seems to be the most cost-effective method.

## **Percutaneous approach**

The disadvantages of external biliary drainage include the risk of spontaneous catheter dislodgment, inflammation and pain around the puncture site, leak of ascitic fluid and bile around the catheter, and loss of fluid and electrolytes.

Speer and colleagues conducted a prospective, randomized study comparing percutaneous and endoscopic drainage. While overall survival was not different between either arm, 30-days mortality, both by intention-to-treat and per-protocol, randomized study comparing percutaneous and endoscopic drainage. While overall survival was not different between either arm, 30-day mortality, both by intention-to-treat and per protocol analysis, was significantly lower in the endoscopy group and justified the early termination of the study<sup>19</sup>. A recent randomized controlled trial showed patients treated by percutaneous drainage had longer survival than patients treated by endoscopic drainage<sup>20</sup>.

At present, there is insufficient evidence in the literature to advocate the routine use of percutaneous drainage as the preferred approach in the palliation of patients with distal biliary obstruction other than for reasons of institutional expertise or availability.

## **Surgical palliation**

Historically, surgery was the favored method of palliation, but has been replaced by percutaneous and endoscopic insertion of stents<sup>14</sup>. The 30-day mortality after surgical palliation for pancreatic cancer and cholangiocarcinoma is significant, especially in the face of advancing age and metastatic disease. Recent studies have shown that gastrojejunostomy, in addition to biliary bypass may decrease the incidence late gastric outlet obstruction without higher morbidity or mortality. Surgery has the advantage of precluding multiple reinterventions, associated with less invasive procedure, namely endoscopic stenting. Most complications occurred in the first 30 days in the surgical group. In contrast to the endoscopy group, therefore numerically fewer late complications due to cholangitis or gastric obstruction. A meta-analysis performed with these three studies confirmed a higher likelihood of intervention in the stent group<sup>21</sup>. A recent, single-center, retrospective cost-analysis in the US also revealed a striking difference between endoscopic palliation and surgery despite the need for repetitive interventions and readmission in the endoscopic group<sup>22</sup>. Surgical bypass remains an excellent alternative and may be favored in patients with unresectable disease at the time of

laparotomy, and for those requiring concomitant gastrointestinal bypass and/or celiac nerve block for management of chronic pain.

### **Adjuvant therapy**

The role of chemotherapy in patients with unresectable disease is still limited.

An important breakthrough in the management of advanced pancreatic cancer occurred with the introduction of gemcitabine and other cytotoxic drugs which have been shown to improve major symptoms such as pain and weight loss, clinical benefit response, time to progression, and length of survival, but maintain an acceptable toxicity profile.

The effect of chemotherapy in the management of malignant biliary obstruction is unknown. Because tumor invasion into the biliary tree is unlikely to be relieved by chemotherapy alone, a procedure to palliate the obstruction is still necessary regardless of the administration and response to adjuvant therapy, and may in fact be required to improve liver tests and function prior to the initiation of this treatment. In contrast, addition of a chemotherapeutic regimen for the treatment of patients with unresectable disease could potentially result in an improvement in survival and influence the choice of palliation.

## **AN APPROACH TO THE MANAGEMENT OF PATIENTS WITH DISTAL BILIARY MALIGNANCIES**

If a pancreaticobiliary malignancy is suspected based on clinical and US findings, further imaging must be performed to obtain a diagnosis, stage the extent of the malignant process for respectability, and evaluate the appropriateness of possible palliative treatment. Identification of the level of obstruction is of importance since the differential diagnosis and therapeutic implications differ accordingly, conceptually, management may be stratified according to whether the biliary obstruction is proximal or distal. Patients with a distal CBD obstruction may be amenable to endoscopic or surgical drainage, whereas a more proximal blockage of the biliary tree may require a more complex intrahepatic anastomosis or percutaneous drainage. The optimal approach to patients with malignant biliary obstruction must take into account the performance characteristics of the different imaging modalities, the level and cause of the obstruction, the risk of cholangitis when opacifying an obstructed biliary tree, and the potential for curative versus palliative therapy. Recent data suggest that non-invasive biliary imaging may greatly assist endoscopic drainage and diminish septic complications that occur when there is a failed attempt at unilateral or bilateral drainage.

## **Curative Surgery**

Operable patients with a distal pancreaticobiliary neoplasm and no evidence of metastatic disease or local vascular invasion should be offered curative surgical resection. Unfortunately these patients account for only 10-20% of all presenting cases. Many elderly patients are not referred for consideration of surgery as they are judged unfit for surgery due to advanced age or the presence of unrelated co-morbidities. The first step towards potential resection should be laparoscopy to determine respectability and to prevent a lengthy hospital stay and prolonged convalescence associated with an unnecessary laparotomy,

Laparoscopy is used

- to detect peritoneal carcinomatosis,
- liver metastases,
- malignant ascites, and
- unexpected cirrhosis.

Despite an extensive preoperative work-up, 11%-53% of patients were found to be unresectable at the time of laparotomy. Most patients thus end up undergoing palliative treatment tailored to the symptomatology, i.e.



either a surgical bypass (biliary or biliary and gastric), or placement of a biliary stent.

## **Palliation**

The three most important conditions requiring treatment is patients with unresectable biliary and pancreatic cancers are

- cholestasis,
- pain, and
- gastrointestinal obstruction.

These may be due to of local tumor invasion into adjacent structures including the bile ducts, duodenum, and neural celiac plexus.

## **Background**

Endoscopic placement of plastic biliary stents were first described by Soehendra et al. as an alternative to surgical biliary bypass in high-risk and inoperable cancer. Self-expandable metal stents (SEMS) for use in the biliary system were introduced into clinical practice over a decade later. The ability to place a larger-diameter plastic stent is limited by the size of the endoscope accessory channel. SEMS were developed to overcome this limitation. They have the advantage of larger diameter stenting (upto 10mm) but are more costly than plastic stents.

## **Technique of stent implantation**

The options include draining only the left hepatic system, draining only the right hepatic system, or draining both systems. The decision whether to place a single biliary stent or multiple stents depends initially on the location of the stricture in the biliary tract. In patients who have strictures that do not involve the confluence of right and left hepatic ducts (Bismuth type I hilar strictures), jaundice can be palliated completely with a single biliary stent because both the right and left intrahepatic ductal systems are in communication.

In patients who have more complex strictures (Bismuth type II to IV strictures) the central question is whether adequate palliative relief of obstruction requires the placement of two endoprotheses, one to drain the left system and other the right, or if one prosthesis placed in either system will suffice.

Palliation of jaundice generally requires drainage of 1/4 to 1/3 of a healthy liver, or proportionally more in those with underlying dysfunction. Hence unilateral drainage is usually adequate, and many studies have reported good results using a single stent in about 80% of patients with type II and III tumors. No difference in efficacy has been shown between single stent placement in the left or the right system. Really, the necessity to

ensure the drainage of both systems, including additional endoscopic or percutaneous stent, if necessary, pertains more to the prevention of procedure-induced cholangitis caused by contrast injection in undrained biliary branches than to effective palliation. Generally, if both lobes are imaged with contrast during cholangiography bilateral stenting reduces the potential sequelae of cholangitis in contaminated but undrained areas. If contrast does not contaminate both sides then unilateral stenting should be sufficient. Patients with multiple intrahepatic strictures may not benefit from any type of drainage procedure if several segments ( $>1/4$ ) always remain undrained. In the absence of intractable symptoms, these patients should avoid endoscopic measures, as the risk of inducing cholangitis outweighs benefits from endoscopic drainage.

### **Patient preparation**

The patients should have an intravenous line for administration of sedatives, antibiotics and hydration. Antibiotic coverage is mandatory, particularly in those patients with more complex strictures (Bismuth type III and IV). Prophylaxis can be given as a single, adequate dose shortly before the procedure and should be continued for 4-5 days after the procedure. *Escherichia coli*, and to a lesser extent, *Klebsiella* spp. (gram-negative bacteria) and gram-positive *Enterococcus* spp. are the most

common organisms in bile. Therefore, antibiotics should be aimed mainly at gram-negative bacteria with good penetration in liver tissue and bile. Ciprofloxacin is currently the first choice of antibiotic. In case of cholangitis, piperacillin-tazobactam is advisable. Patients should be routinely sedated with diazepam or midazolam, sometimes combined with fentanyl or pethidine. The patients should be monitored by an assistant and by mechanical methods including pulse oximetry. Supervision by an anesthetist may be required.

### **MRCP and CT-guided stent implantation.**

Recent reports describe the utility of MRCP or CT imaging to guide selection of the target lobe for subsequent endoscopic stenting, often without use of contrast<sup>27</sup>. MRCP or CT images are used to confirm the diagnosis of Klatskin tumor to exclude other biliary diseases and to demonstrate the stenoses as well as dilation of proximal liver segments.

The left or right main hepatic duct is chosen for stent insertion, depending on the number of drainable liver segments. Subsequent to MRCP selective endoscopic retrograde contrast injection is deliberately limited to the distal end of the malignant tumor stenosis. Thereafter, sphincterotomy is generally performed, the papillotome or a catheter is advanced to the distal margin of the stricture and a guidewire (hybrid or

hydrophilic) is advanced, under fluoroscopic guidance, in the direction of the duct preselected for drainage based on prior imaging. Once the guidewire passes through the stricture, it is advanced as deeply as possible into that lobe. Then a catheter is advanced over the guidewire and through the stricture as far as possible, the guidewire is removed, and as much bile as possible is aspirated to decompress the accessed duct. Contrast is injected with the catheter and the unilateral cholangiogram is completed. Subsequently, a stiff guidewire is substituted for the initial guidewire and the catheter removed, leaving the guidewire in that duct for the remainder of the procedure until final stent deployment. Thereafter, if necessary, dilation of the malignant stenosis is performed using either balloon catheters or bouginages. If histological diagnosis is not already established, sampling is performed with a biopsy forceps and cytology brush. Finally a plastic or a metal stent is inserted to decompress the proximal ductal system. If bilateral stent placement was planned, immediately after insertion of the first guidewire a second guidewire is inserted into the contralateral side, stents are placed sequentially into the left and then the right hepatic ducts over dual guidewires.

### **Unilateral random stent implantation**

MRCP images are used to confirm the diagnosis of Klatskin's tumor, to exclude other biliary diseases, and to demonstrate the stenoses, as well as dilation of proximal liver segments. Contrast injection at ERCP is deliberately limited to the extrahepatic bile duct distal to the tumor. Then, sphincterotomy is performed in all cases, and a guidewire is subsequently advanced through the malignant stenosis into the duct that is technically easiest to access. A catheter is then passed over the guidewire and through the stenosis, and, after removal of the guidewire, a unilateral cholangiogram is completed. Finally, a single plastic or metallic stent is deployed<sup>26</sup>.

### **Contrast-free stent implantation**

Stents are placed in these patients under fluoroscopic guidance as follows: the stent assembly is passed over the guidewire above the suspected site of stricture and the stent is deployed at the desired site.

### **Rendezvous technique**

An interventional radiologist passes a guidewire transhepatically down the bile duct and into the duodenum; this wire is then grasped by the endoscopist to place stents in the bile duct. The combined percutaneous-endoscopic approach has been reported by many groups. The rationale is

that the complications should be lower than those with a purely percutaneous approach, since only small catheters are passed through the liver, and rather briefly. However, the complication rates are not negligible.

## **AIM OF THE STUDY**

1. To Study the causes of Malignant Biliary obstruction
2. To Study the success rate of endoscopic stenting in patients with malignant biliary obstruction.
3. To Study the reason for failure in endoscopic stenting.
4. To Study the morbidity and mortality of endoscopic Biliary stenting.
5. To Study the effectiveness of 7F and 10F in endoscopic palliation of jaundice.
6. To Study the difference in patency rates of 7F and 10F plastic stent.
7. To Study the complication rate between 7F and 10F endoscopic stenting.



## **MATERIALS AND METHODS**

The Study was conducted in Department of Digestive Health and Disease (DDHD) a superspeciality department with rich heritage located in Government peripheral hospital, Anna Nagar, Chennai, attached to Government Kilpauk Medical College, Chennai.

The study was conducted in DDHD inpatients and patients referred from Government Kilpauk Medical College (Surgical GastroEnterology, General Surgery), Government Royapettah Hospital (Surgical Gastro Enterology, General Surgery), Government General Hospital (Surgical GastroEnterology, General Surgery).The study period was from December 2007 to December 2009.

Patients with Malignant Biliary obstruction were divided in to two groups

- (1) Proximal Biliary Obstruction
- (2) Distal Biliary Obstruction .

After ERCP stenting patients with 7F plastic stent were compared with patients with 10F plastic stents.

### **INCLUSION AND EXCLUSION CRITERIA :**

- All patients with Malignant biliary obstruction with informed consent were included.

- Candidates not willing were excluded.
- Candidates not fit for ERCP procedure were excluded.
- Patients in whom benign cause was suspected were excluded.

We used Duodenoscope of length 156cm working channel diameter of 4.2mm, field of view 110<sup>0</sup> (Model No.ED341C Batch No.A120052) with a PENTAX video processor EPK 150C input 100-240V-50/60HZ ranging 300 VA max.

We used ERBE endocut (Model ICC 200 EA INT) for Biliary sphincterotomy with cutting current 120 effect 3 without coagulation.

## **ACCESSORIES**

- Cannula (Triple Lumen with curved tip),
- Guidewire Zebra 0.035 450 cm (Bavarianwire – Mediglobe) X wire (0.025, 0.035 – Conmed),
- Wilson cook triple lumen bow sphincterotome, Triple lumen needle knife sphincterotome,
- Sohendra Biliary dilatation catheter (7F, 10F)
- OASIS 10 Fr. (One action Stent introduction system)
- Stent pusher for 7F stent

➤ Biliary Stent

- Size – 7F, 10F
- Model – Amsterdam (Straight), Pigtail
- Length – 7cm, 10 cm, 12cm

➤ Cholangiogram done using IOHEXOL USP equiv to 350 mg. of Iodine (Omnique)

**Statistical Methods**

The statistical software package SPSS for windows version 15 (SPSS Inc., Chicago, III) was used to analyse the data, mean, S.D. were used to summarise data for continuous variables whereas percentages were used for categorical variables.

Patients presenting with Malignant biliary obstruction were investigated with

- Complete hemogram
- Blood Sugar
- Urea creatinine
- Liver function test
- USG Abdomen
- CT Abdomen,

- MRCP,
- EUS

### **Preparation**

Injection Vitamin K was given for 3 days. Injection Ciprofloxacin and Metronidazole IV was given before the procedure and continued for 3 days. Intravenous Dextrose normal saline was given for 4 hours before the procedure at 150ml./hr. The procedure was explained in detail and informed written consent obtained. After overnight fasting patient was taken to ERCP theatre and placed in prone position.

Sedation and Premedication— Injection Pentazocine 25mg., Injection Promethazine 50 mg., Injection Hyoscine 2 amp., in midazolam 2 - 5 mg.

Duodenoscopy was done and ampulla visualized, if growth or ulceration visualized biopsy was taken then selective CBD cannulation was done using cannula or bow sphincterotome and 0.35 guidewire (in tight stricture 0.25 guidewire). If guidewire entered repeatedly into pancreatic duct, then pancreatic duct stent was placed and then cannulation of CBD was attempted. Then bow sphincterotomy was done.

Our endoscopists performed stenting by no contrast technique and unilateral random biliary stenting in most of the cases. If cholangiogram was necessary it was done using minimum of contrast.

After placing guidewire into right or left system using fluoroguidance, dilatation was done using 7F and 10F Sohendra Biliary dilators as required. Then 10F x 10 cm straight or double pigtail stent was placed using OASIS (One Action Stent Introduction System). For placing 7F stent stent pusher was used.

For most of the patients double pigtail stents were used. Our endoscopists felt straight stent may not be of adequate length to cross the stricture and the chance of migration was more compared to pigtail stents.

After placing the stent across the malignant stricture, bile flow was ensured. Stent position was confirmed fluoroscopically. Patients were monitored for any immediate post procedure complications. After 6 hrs. patients were given clear fluids and then diet was slowly advanced.

In the next 2 days patients were monitored for complications like post sphincterotomy bleeding, cholangitis pancreatitis, perforation, stent migration, and investigated accordingly.

After 1 week patients were reviewed as outpatient with clinical history for improvement in pruritis, jaundice, cholangitis and sense of well being. They were monitored objectively with liver function test and ultrasound abdomen.

Patients were said to have adequate drainage if S. Bilirubin fell by 0.5 mgs.% per day<sup>31</sup>. Serum Bilirubin was monitored 7 days after endoscopic stenting. Patients were observed till 30 days post procedure for any mortality.

Patients were discharged with advice to turn up for stent exchange if they developed increasing jaundice and fever with chills. Patients were not offered 3 monthly regular exchange. Long term follow up was done till the patient died or lost for followup

## **STUDY OUTLINE**

Number of Patients 60

Male 36

Female 24

M:F Ratio 3:2

Mean Age 58.6

Age Range 32-80

Age range in Males 35-80

Age range in Females 32-80

Ampullary malignancy 22

Head of pancreas growth 8

Distal cholangiocarcinoma 15

Gall bladder carcinoma 5

Hilar cholangiocarcinoma 8

Node causing obstruction 2

No of patients with Proximal Malignant Biliary Obstruction 45 (75%)

No of patients with Distal Malignant Biliary Obstruction 15 (25%)

Success rate of endoscopic plastic Stenting in all patients 68.33%

Success rate of stenting in proximal Malignant Biliary Obstruction 60%

Success rate of stenting in distal Malignant Biliary Obstruction 78.0%

Number of cases with 10F. Plastic stent 16

Number of cases with 7F. Plastic stent 25

Number of days of patency for 7F Plastic stent                      61 days  
Number of days of patency For 10F Plastic stent                      217 days  
Immediate Complication 6/60 10% (3 minor, 3 Moderate)  
30 day mortality    Nil  
Exchange 6/41 ,  
Follow up 13 patients mean 3.615 months



## **OBSERVATION**

### **Socioeconomic status :**

Most of the patients were from Government hospitals in Chennai. All were from lower socioeconomic status.

### **Risk Factor :**

Age group of patients range from 32-80. Mean age was 58.6. Age group of male 35-80, with mean age of 56.80. Age group of female range from 32-80 with mean age of 61.29. P value 0.132. Statistically not significant . M : F ratio of all patients was 3 : 2. The M F ratio of Gall Bladder carcinoma was also 3 : 2.

Among 8 patients with pancreatic carcinoma 5 patients were smokers. Chronic liver disease was seen in one patient with hilar Cholangiocarcinoma and one patient with distal cholangiocarcinoma.

Among the patients with Malignant Biliary Obstruction causes due to distal MBO were 45/60 and causes due to proximal MBO were 15/60.

Etiology were

Ampullary carcinoma	22 (36.6%)
Distal cholangiocarcinoma	15 (25%)
Head of Pancreas carcinoma	8 (13.3%)

Hilar Cholangiocarcinoma	8 (13.3%)
Gall Bladder Carcinoma	5 (8.3%)
Lymph node causing hilar obstruction	2 (3.3%)

### **Clinical features**

Commonest presentation was jaundice 100% (60/60). The other presentations were anorexia and loss of weight 54/60 (90%), pruritus 50/60 patients (83.3%), pale stools 45/60 patients (75%), abdominal pain 16/60 patients (26.6%), Cholangitis 9/60 (15%) and Malena 3/60 (5%).

Hepatomegaly was seen in 41/60 patients and gall bladder was palpable in 21/60 (35%). In patients with proximal Malignant Biliary Obstruction hepatomegaly was palpable in 30/45 patients compared with 11/15 in patients with distal Malignant Biliary Obstruction. In patients with distal Malignant Biliary Obstruction GB was palpable in 16/45 (35%) patients compared with 5/15 (35%) patients in proximal Malignant Biliary Obstruction. There was no statistical significance between these two groups.

### **Endoscopic stenting**

Among the 41 patients who were successfully stented 29 patients were stented in first sitting and 10 patients were stented in second sitting. In 2 patients stenting was successful only in third sitting.

Biliary Bow Sphincterotomy was done in 30 patients, needle knife Sphincterotomy used in 15 patients, pancreatic stent was placed in 5 patients.

### **Method of Stent placement**

Out of 41 patients stented contrast free stent implantation was done in 34 patients. Among these 34 patients MRCP assisted stenting was done in 7 patients. In rest of the patients fluoro assisted non contrast technique was used. In the remaining 7 patients cholangiogram was done.

Stenting was successful in 41/60 patients with overall success rate of 68.33%. Success rate for proximal MBO was (78.0%) 32/41 compared with success rate of (60%) 9/15 for distal malignant biliary obstruction, with P value of 0.423 (statistically not significant). Among the patients where endoscopic stenting failed, the causes of failure include

- Repeated entry of guidewire into pancreatic duct 6/19
- Tight stricture 5/19
- Non visualization of ampulla 3/19
- Anatomical defects 2/19
- Diverticulum 1/19
- Reason not known 2/19

## **Post procedure complications**

Immediate complication rate was 10% (6/60)

Most common complication was cholangitis (3) followed by pancreatitis (1), perforation (1) and stent migration (1). Stent migration was managed with repeat stenting 2 days later. All other patients were managed conservatively. One patient went against medical advice.

Complication rate in patients with proximal malignant biliary obstruction was (83.3%)5/6 compared to (16.7%)1/6 in patients with distal malignant biliary obstruction with P value 0.39163 ( not significant).

Complication following 7F stenting occurred in 3 patients compared to 1 patient following 10F stenting with P Value 0.699( not significant).

There was no mortality at 30 days in any group followed.

## **Review visit**

Mean Serum Bilirubin (total) before stenting was 14.44 mg% and after stenting was 7.19%. Drainage was obtained in all patients stented with 7F or 10F plastic stents.

Repeat Serum Bilirubin (total) at 7 days following 7F stenting and 10F stenting was 7.1mg% and 5.3mg% respectively.

## **Stent exchange**

Only 6 patients came for stent exchange among them 2 underwent stenting twice. The shortest duration of stent patency was 40days, longest duration of stent patency was 10 months

Mean no of days for 1<sup>st</sup> exchange was 61 days for patients with 7F stent and 217 days for patients with 10F stent P value <0.001 (significant)

Stent exchange was done in 2/45 in patients with distal obstruction compared with 4/15 in patients with proximal obstruction P value not significant.

## **Long Term Follow up**

13 patients had long term follow up, shortest duration was 1 month and longest duration was 15 months mean of 3.615 months. Among them 8 patients died with mean survival of 120 days.

**PROXIMAL MALIGNANT BILIARY OBSTRUCTION Vs  
DISTAL MALIGNANT BILIARY OBSTRUCTION**

	<b>Proximal</b>	<b>Distal</b>	<b>P Value</b>	<b>Significance</b>
Male	23	11	0.132	N.S.
Female	22	4		
Success	32	9	0.423	N.S.
Failure	13	6		
1 <sup>st</sup> sitting	26	10	0.64551	N.S.
2 <sup>nd</sup> sitting	17	5		
3 <sup>rd</sup> sitting	2	0		
<b>Hepatomegaly</b>				
palpable	30	11	0.630	N.S.
Non palpable	15	4		
<b>Gall Bladder</b>				
palpable	16	5	0.875	N.S.
nonpalpable	29	10		
<b>Comorbid Illness</b>				
GB Stone	2	0	0.49	N.S.
GB & CBD Stone	3	-		
HBV CLD	1	1		

### **7F VS 10F PLASTIC STENTS**

	<b>7 F Stent</b>	<b>10 F Stent</b>	<b>P Value</b>	<b>Significance</b>
<b>Complications</b>			0.699	N.S.
Cholangitis	2	1		
Pancreatitis	1	0		
<b>Number of Attempts for Endoscopic stenting</b>			0.65087	N.S.
1 <sup>st</sup> sitting	19	10		
2 <sup>nd</sup> sitting	5	5		
3 <sup>rd</sup> sitting	1	1		
<b>Stent Exchange</b>				
No. of Patients	5	3	0.001	Significant
Mean No. of Days	62	217		

## IMMEDIATE COMPLICATIONS AFTER STENTING

Cholangitis	3
Pancreatitis	1
Perforation	1
Stent Migration	1
Bleeding	Nil
TOTAL	6/60 ( 10%)

## LATE COMPLICATIONS AFTER STENTING

30 Day Mortality	Nil
Stent Clogging	6 Patients



## ETIOLOGY OF MALIGNANT BILIARY OBSTRUCTION

Ampullary Carcinoma	22 (36.6%)	Distal 45/60 (75%)
Distal Cholangiocarcinoma	15 (25%)	
Head of Pancreas Malignancy	8 (13.3%)	
Hilar Cholangiocarcinoma	8 (13.3%)	Proximal 15/60 (15%)
Gall Bladder Carcinoma	5 (8.3%)	
Lymph Node causing hilar obstruction	2 (3.3%)	

## **DISCUSSION**

In this study all patients were from lower socioeconomic status so the epidemiological aspect of this study will reflect a group of people from lower socio economic status.

M : F ratio in this study was 3 : 2. Age group of patients 32-80. Mean age was 58.6. Age group of male patients range from 35-80, with mean age of 56.80. Age group of female patients range from 32-80 with mean age of 61.29.

Randi G et al<sup>29</sup> in their study described mean age of patients with biliary tract cancer as 56.76. Yogesh Batra<sup>33</sup> described a M : F ratio of 0.36:1 in Gall Bladder carcinoma in their study. The M.F. ratio of Gall Bladder carcinoma in this study was 3 : 2. The difference could be due to fewer number of patients in this study.

Barbhuiya<sup>30</sup> (et al) described M : F ratio of 3 : 2 in their single centre study in central India. This was very similar to the observation in this study.

In this study 5 patients with pancreatic carcinoma had smoking history. Ghadirian<sup>24</sup> et al have described smoking as a risk factor for pancreatic carcinoma with two fold relative risk in their study.

In this study one patient with hilar cholangiocarcinoma and one patient with distal cholangiocarcinoma was associated with HBV related chronic liver disease. Shaib Y et al<sup>23</sup> have described chronic liver disease as one of the risk factor for cholangiocarcinoma.

In this study commonest cause of malignant biliary obstruction was ampullary carcinoma 22 (36.6%) followed by distal cholangiocarcinoma 15 (25%), hilar cholangiocarcinoma 8(13.3%), head of pancreas malignancy8 (13.3%),Gall bladder carcinoma 5(8.3%)and lymph node causing hilar obstruction2(3.3%)

Ibrahim A et al<sup>34</sup> in their study of 72 patients described incidence of cholangiocarcinoma (proximal and distal) in 31 patients 43%, pancreatic adenocarcinoma in 23 patients (31.9%), followed by Gall Bladder cancer in 5 patients(8.3%).In their study incidence of cholangiocarcinoma was similar to this study, whereas ampullary carcinoma was less common in their study, the increased incidence of ampullary adenocarcinoma in this study could be attributed to lack of biopsy confirmation in all patients.

In this study commonest presentation was jaundice 100% followed by anorexia and loss of weight 90%, pruritis 50/60 (83.3%), pale stools 45/60 75%, abdominal pain 16/60 (26.6%)and malena3/60(5%).

Giovanni D De Palma et al<sup>31</sup> described jaundice in 100%, pruritis (100%) anorexia and weight loss in 50%.

The increased incidence of anorexia and weight loss in this study could be attributed to the late presentation in the patients

In this study the sensitivity of Biliary Brush cytology was 25%. Hema Govil<sup>25</sup>, CJR Stewart<sup>39</sup> reported Biliary Brush cytology sensitivity of 68% and 59.8% with specificity of 100% and 98% respectively. The lower sensitivity in this study could be explained by fewer number of patients in this study and reused Biliary Brush Cytology forceps.

Overall success rate of patients undergoing endoscopic plastic stenting was 68.33% patients with distal malignant biliary obstruction had a success rate of (78.0%) and those with proximal malignant biliary obstruction had a success rate of (60%).

Ibrahim A et al<sup>34</sup> in their single centre experience described a overall success rate of (77.8%) which is similar to this study.

In more recent studies from west like the one by Giovanni D De Palma et al<sup>31</sup> success rate of 100% was described. This may be due to single use of accessories and relatively earlier presentation of patients to the endoscopic palliation.

In this study immediate complication rate was 10% (6/60), with cholangitis being the commonest with incidence rate of 5% (3/60), with no 30 day mortality. S.S. Saluja, Manpreet Gulati et al<sup>32</sup> have described in their study cholangitis rate of (11%).

Giovani D De Palma et al<sup>31</sup> in their study described no cholangitis and no 30 day mortality. The absence of cholangitis in their study could be attributed to no contrast technique in their study compared to usage of contrast in 7 patients in this study.

In this study mean serum total bilirubin was 14.44 mg.% before stenting and 7.19 mg.% after stenting. The mean serum total bilirubin after 7F plastic stenting was 7.64±3.6mg.% compared to mean serum bilirubin value of 5.31±2.13mg.% after 10 F plastic stenting.

Drainage occurred in all patients after 10F and 7 F stent in each group. Virendera Singh<sup>36</sup> and Sigh V<sup>37</sup> have described similar results in their study (100%) drainage.

Giovani et al<sup>31</sup> in their study described a mean serum total bilirubin value of 15.8 ± 9.2mg.% before stenting and a mean serum bilirubin value of 4.0 ± 2.1mg.% after stenting.

Among the patients whom underwent stent exchange once stent patency was 61 days for 7F stenting and 217 days for 10F stenting in this study which was statistically significant.

Moller Pedersen et al<sup>38</sup> in their observation described mean patency days for 7F as 67 days and 144 days for 10F stenting which was similar to the observation in this study.

A Speer et al<sup>28</sup> have described patency rate of 32 weeks for 10F compared with 12 weeks for 7F which is also similar to this study.

Complication rate among patients stented with 7F plastic stents and 10F plastic stents were similar in my study. However A Speer et al have described less complication rate 5% in patients stented with 10F plastic stents compared to 34% in patients stented with 7F plastic stents.

Moller Pedersen et al<sup>38</sup> have described immediate complication rate of 13.9% after 7F plastic stent, and 16.7% after 10F plastic stent. The reason for similar rate of complications between patients stented with 7F and 10F stent could be due to less number of patients in this study

## **CONCLUSION**

1. Most common cause of malignant biliary obstruction in this study was ampullary adenocarcinoma followed by distal cholangiocarcinoma, hilar cholangiocarcinoma, head of pancreas malignancy, Gall Bladder carcinoma and lymph node causing hilar obstruction .
2. Over all success rate of all patients with Malignant Biliary Obstruction was 68.6% with success rate of 78% for patients with distal Malignant Biliary Obstruction and 60% for patients with proximal Malignant Biliary Obstruction cases.
3. Most common reason for failure of endoscopic stenting in patients with malignant biliary obstruction was repeated entry of guidewire into pancreatic duct followed by tight stricture, nonvisualization of ampulla, anatomical difficulties and periampullary diverticulum.
4. Immediate complication rate was 10% with no mortality. Cholangitis being the commonest complication followed by pancreatitis, perforation, stent migration in one patient each.
5. Both 7F and 10F were equally effective in reducing jaundice in the short term.

6. Mean number of days of stent patency after 10F stent was 217 days and 61 days after 7F which was statistically significant.
7. Complication rate between patients treated with 7F Plastic stent and 10F plastic stent were similar.



## **BIBLIOGRAPHY**

1. Villeneuve Pj, Johnson KC, hanley Al, et al. Alcohol, tobacco and coffee consumption and the risk of pancreatic cancer; results from the Canadian Enhanced surveillance system case-control project. Canadian cancer registries Epidemiology research group. Eur J cancer prev 2000; 9:49-58.
2. Piehler JM, Crichlow RW. Primary carcinoma of the gallbladder surg Gynecol Obstet 1978 ;147:929-942.
3. Chijjiwa K, Kimura H, Tanaka M.Malignant potential of the gallbladder in patients with and without choledochal cyst. Int surg 1995;80-61-64.
4. Nix GA, Dubbelman C, Wilson JH, et al. prognostic implications of tumor diameter in carcinoma of the head of the pancreas. Cancer 1991;67:529-535.
5. Sewnath ME, Karsten TM, Prins MH, et al. A meta analysis on the efficacy of preoperative biliary drainage for tumors causing obstructive jaundice. Ann surg 2002; 236:17-27.
6. Lai EC, Mok FP, Fan ST, et al . preoperative endoscopic drainage for malignant obstructive jaundice. Br J surg 1994;81:1195-1198.
7. Martignoni ME, wagner M, Krahenbunl L, et al. Effect of preoperative biliary drainage on surgical outcome after pancreatoduodenectomy. Am J surg 2001;181:52-59; discussion 87.
8. Scheeres D, O'Brien W, Ponsky L, et al . Endoscopic stent configuration and bile flow rates in a variable diameter bile duct mode. Surg Endosc 1990;4:91-94.

9. Van Berkel AM, Van Marle J, Groen Ak, et al. Mechanisms of biliary stent clogging: Confocal laser scanning and scanning electron microscopy. *Endoscopy* 2005; 37:729-734.
10. Libby ED, Leung JW. Prevention of biliary stent clogging : a clinical review. *Am J Gastroenterol* 1996;91:1301-1308.
11. Kadakia SC, Starnes E. Comparison of 10 French gauge stent with 11.5 French gauge stent in patients with biliary tract diseases. *Gastrointest Endoscopy* 1992;38:454-459.
12. Pedersen FM, Lassen AT Response. *Gastrointest Endosc* 2000; 51:117.
13. De Ledinghen V, Perosn B, Legoux JL, et al. prevention of biliary stent occlusion by ursodeoxycholic acid plus norfloxacin: a multicenter randomized trial. *Dig Dis Sci* 2000; 45:145-150.
14. Halm U, schiefke, Fleig WE, et al. ofloxacin and ursodeoxycholic acid versus ursodeoxycholic acid alone to prevent occlusion of biliary stents: a prospective, randomized trial. *Endoscopy* 2001; 33:491-494..
15. Raju GS, Sud R, Elfert AA, et al. Biliary drainage by using stents without a central lumen: a Pilot study. *Gastrointest Endosc* 1992; 24:391-394.
16. Moss AC, Morris E, Leyden J, MacMathuna P. Malignant distal biliary obstruction : a systematic review and meta-analysis of endoscopic and surgical bypass results. *Cancer Treat Rev* 2007; 33(2) :213-221.
17. Prat F, Chapat O, Ducot B, et al. A randomized trial of endoscopic drainage methods for inoperable malignant strictures of the common bile duct. *Gastrointestinal Endoscopy* 1998;47:1-7.

18. Da Silveria E, Waschke K, Barkum A, et al. Costeffectiveness decision analysis comparing covered to uncovered self expandable metal stents to elective or on-demand polyethylene stent changes in patients with distal biliary malignant obstruction, *Gastrointestinal Endoscopy* 2005;61:AB 203.
19. Speer AG, Cotton PB, Russell RC, et al. Randomised trial of endoscopic versus percutaneous stent insertion in malignant obstructive Jaundice. *Lancet* 1987;2:57-62.
20. Pinol V, Castells A, Bordes JM, et al. Percutaneous self –expanding metal stents versus endoscopic polyethylene endoprotheses for treating malignant biliary obstruction: randomized clinical trial. *Radiology* 2002: 225:27-34.
21. Martin RC, vitale GC, Reed DN, et al. Cost comparison of endoscopic stenting vs surgical treatment for unresectable cholangiocarcinoma. *Surg Endosc* 2002;16:667-670.
22. Shore S, Raraty MG, Ghaneh P, et al. Review article: Chemotherapy for pancreatic cancer. *Aliment pharmacol Ther* 2003;18:1049-1069.
23. Shaib Y, El-Serag HB. The epidemiology of cholangiocarcinoma. *Semin Liver Dis* 2004, 24; 1150125.
24. Ghadirian P, Lynch HT, Krewski D. Epidemiology of pancreatic cancer; an overview. *Cancer Deted Prev* 2003; 27; 87-93
25. Hema Govil, Vijaya Reddy, Brush Cytology of the Biliary tract Retrospective study of 278 cases with histopathologic correlation. *Diagnostic Cytopathology* 2002, Vol.26, Issue 5, Pages 273-277,

26. Hintze RE, Abou –Rebyeh H, Adler A, et al. Magnetic resonance cholangiopancreatography- guided unilateral endoscopic stent placement for klastskin tumors. *Gastrointestinal Endoscopy* 2001; 53:40-46.
27. De palma GD, Pezzullo A, Rerga M, et al. Unilateral placement of metallic stents for malignant Hilary obstruction: a prospective study. *Gastrointestinal Endoscopy* 2003;58:50-53.
28. Speer AG, Cotton PB, MacRae KD. Endoscopic management of malignant biliary obstruction: stents of 10F gauge are preferable to stents of 8F gauge. *Gastrointest Endosc* 1988; 34; 412-417.
29. Randi G. Epidemiology of biliary tract cancer an update. *Annals of oncology* 2009, 20, 146-159.
30. Barbuiya, T. Singh, S. Gupta, Gall Bladder Cancer in India, *Internet Journal of Epidemiology* 2009, Volume 7, No.2.
31. Giovanni D De Palma, Giovanni Lombardi, Maria Rega, Contrast-free endoscopic stent insertion in Malignant Biliary Obstruction. *World J Gastroenterol* 2007 August 7, 13(29); 3973-3976
32. S.S. Saluja, Manpreet Gulati, Endoscopic or Percutaneous Biliary drainage for Gall bladder cancer Randomised trial and quality of life assessment. *Clinical Gastroenterology and Hepatology*, August 2008; Vol.6, Issue 8, Page 944-950.
33. Yogesh Batra. Sujoy Pal, Gall Bladder cancer in India, a dismal picture. *Journal of Gastroenterology and Hepatology*, 2005, Vol.20, Issue 2, Pages 309 to 314.
34. Ibrahim A, Almogleh, Rashed S. Al Rashed, *Saudi Medical Journal*, 2003. Vol. 24 (12); 1360-1363.

35. S. Singh, A.K. Sachdev, Palliative surgical bypass for unrespectable periampullary carcinoma. *Hepatobiliary Pancreatic diseases International*, 2008, 7 : 308-312.
36. Virendra Singh, Gurpreet Singh, Contrast free Balloon assisted unilateral plastic stenting in Malignant hilar obstruction. A new method *Digestive endoscopy*, 2008. Vol.20, Issue 4, Pages 190-193.
37. Sing V, Singh G, Verma G.R. Contrast free unilateral endoscopic palliation in Malignant hilar biliary obstruction. New method. *J Gastroenterology & Hepatology*, 2004, May 19(5), pages 589-591.
38. Moller Pedersen. Endoscopic Management of Malignant Biliary Obstruction is stent size 10F better than 7F Scandinavian. *J of G* 1993, Vol.28; Pages 185-189.
39. CJR Stewart, PR Mills, Brush Cytology in the assessment of Pancreaticobiliary strictures a review of 406 cases. *J Clinpathol* 2001; 54 : Vol. 44, Pages 449-455.



## **Post procedure complication**

Cholangitis

Pancreatitis

Bleeding

Perforation

Other complication

## **Review visit at 7 days**

LFT, other tests

## **Stent Exchange**

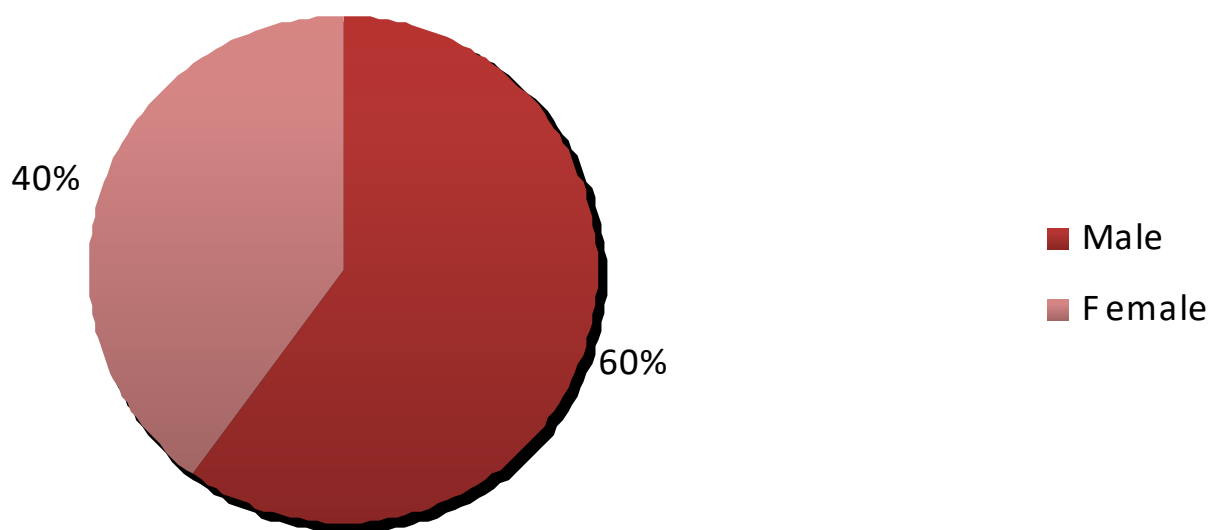
1.

2.

3

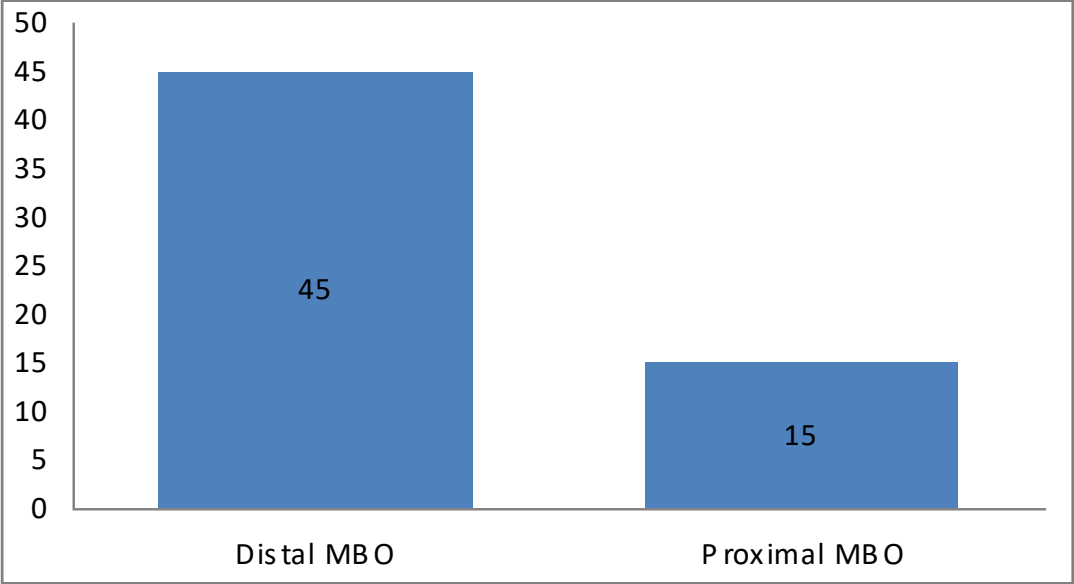
Follow up

# Sex Distribution

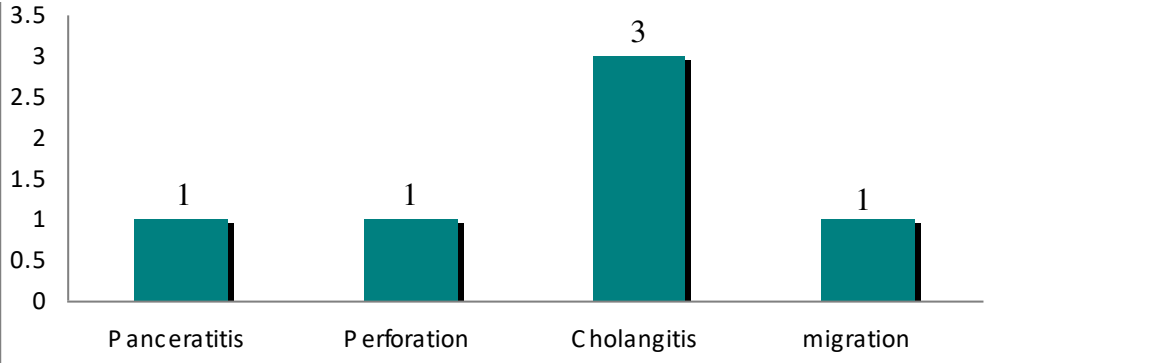




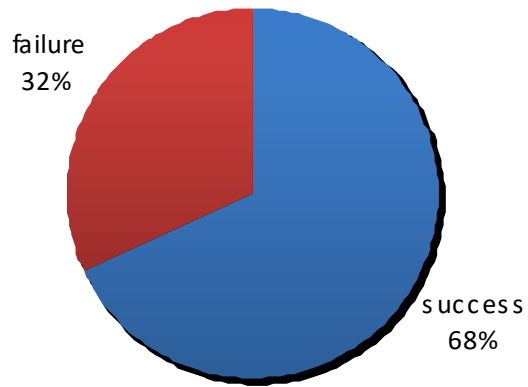
**NUMBER OF PATIENTS IN EACH GROUP OF MALIGNANT BILIARY OBSTRUCTION**



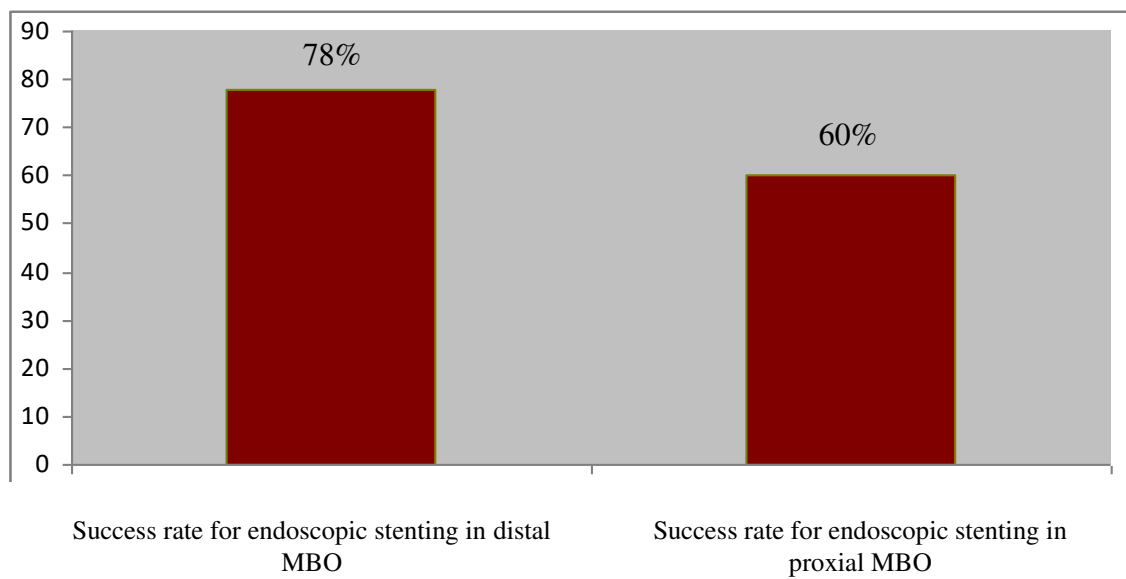
**IMMEDIATE COMPLICATIONS AFTER STENTING**



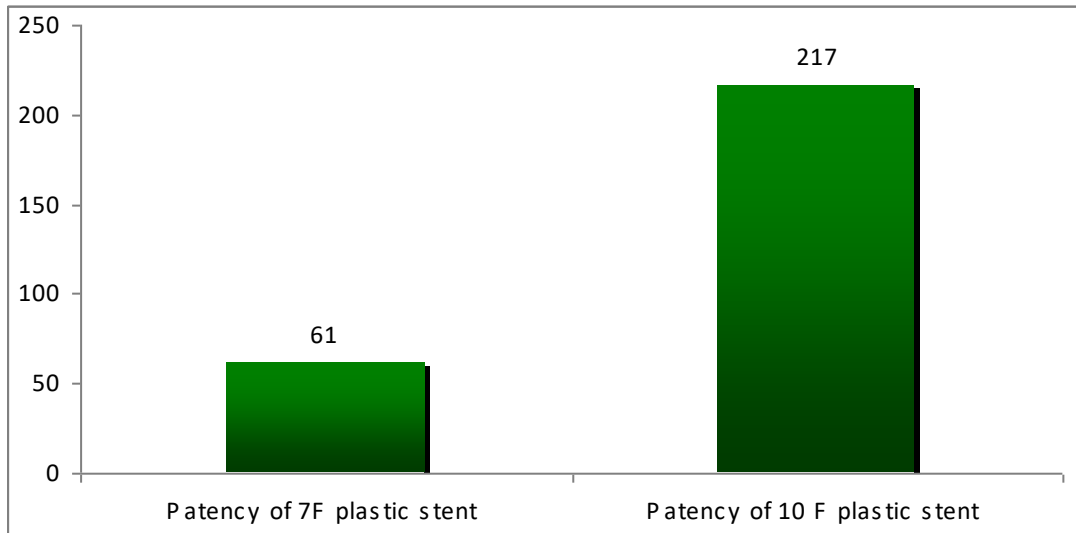
## PROCEDURAL SUCCESS RATE OF STENTING IN ALL PATIENTS



## SUCCESS RATE OF STENTING ACCORDING TO SITE

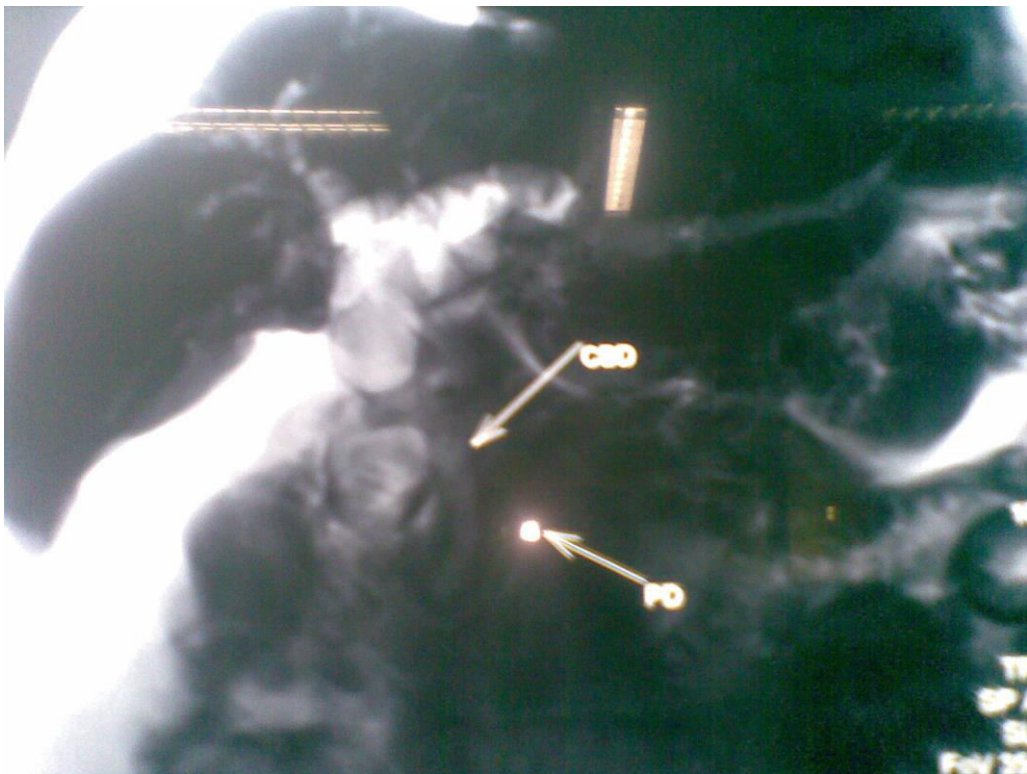


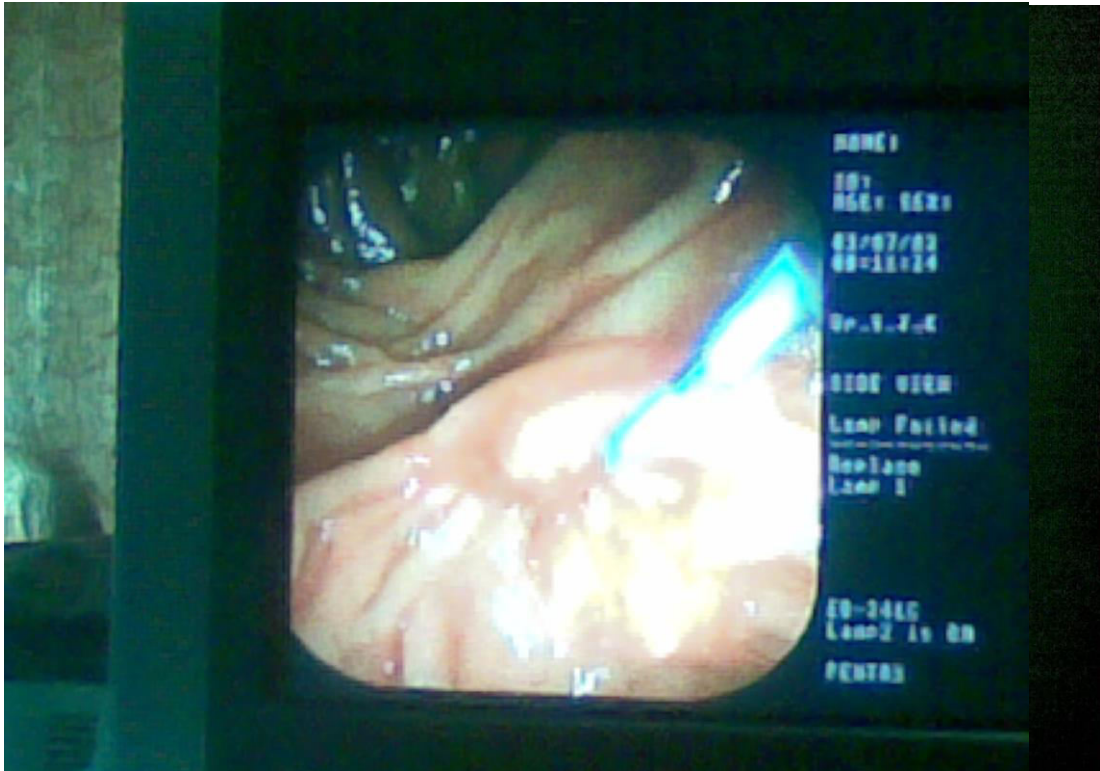
### MEAN NO OF DAYS OF STENT PATENCY



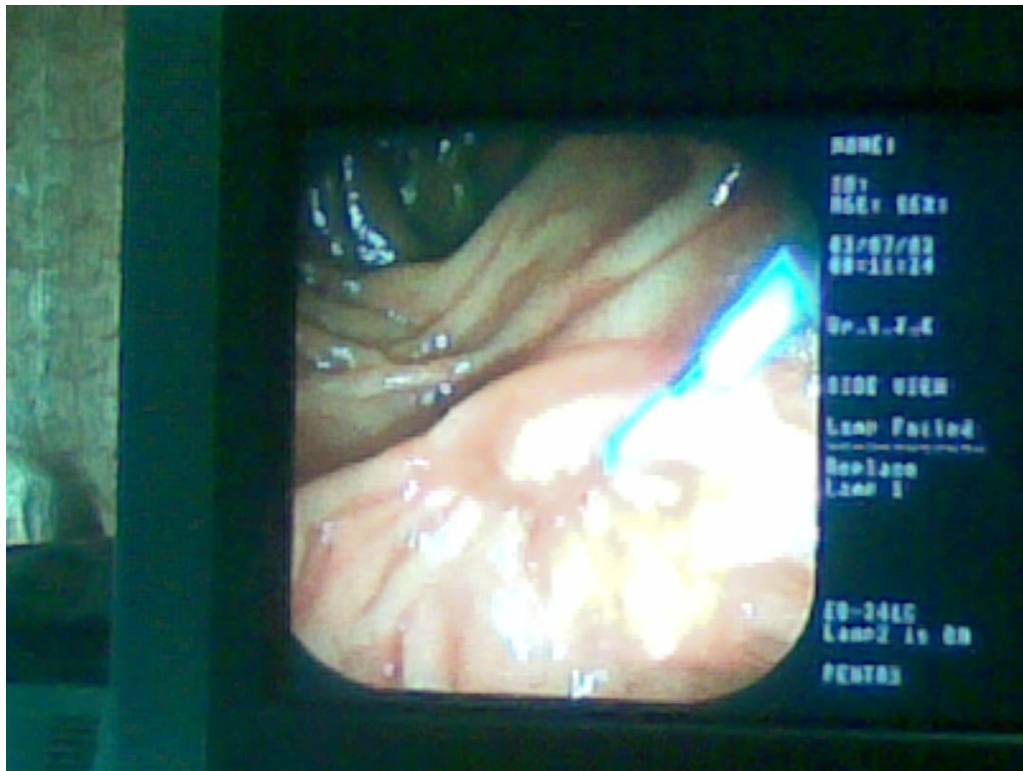


*MRI Abdomen showing Hilar Obstruction*

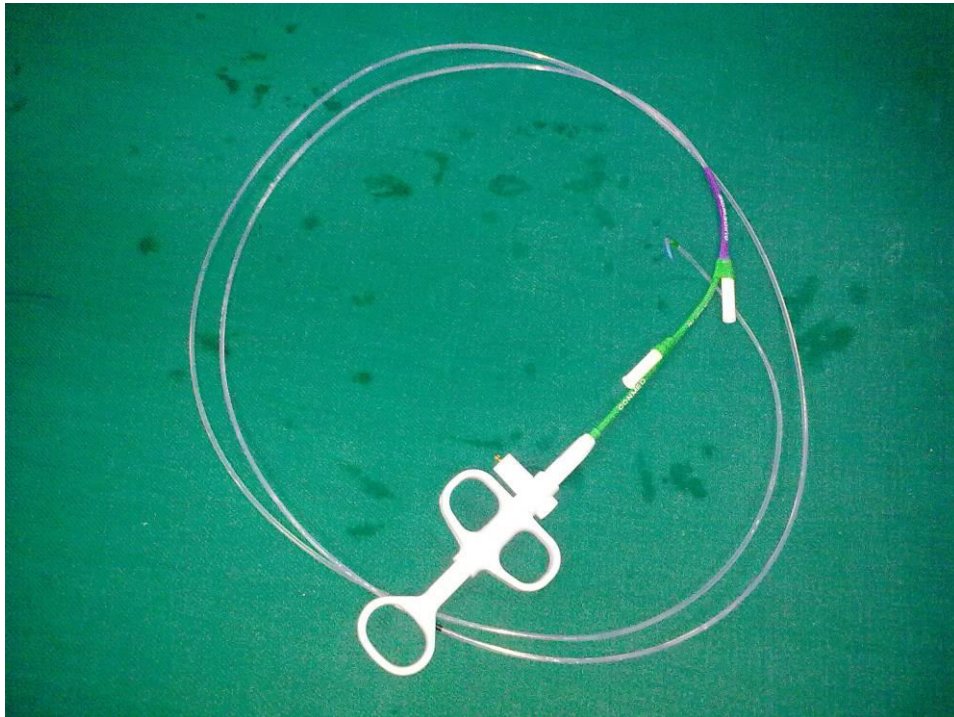




*Common Bile Duct Cannulation*







*Triple Lumen BOW Sphincterotome*



*7F Stent Pusher*





*10F OASIS*



*Sohendra Biliary Dilator*

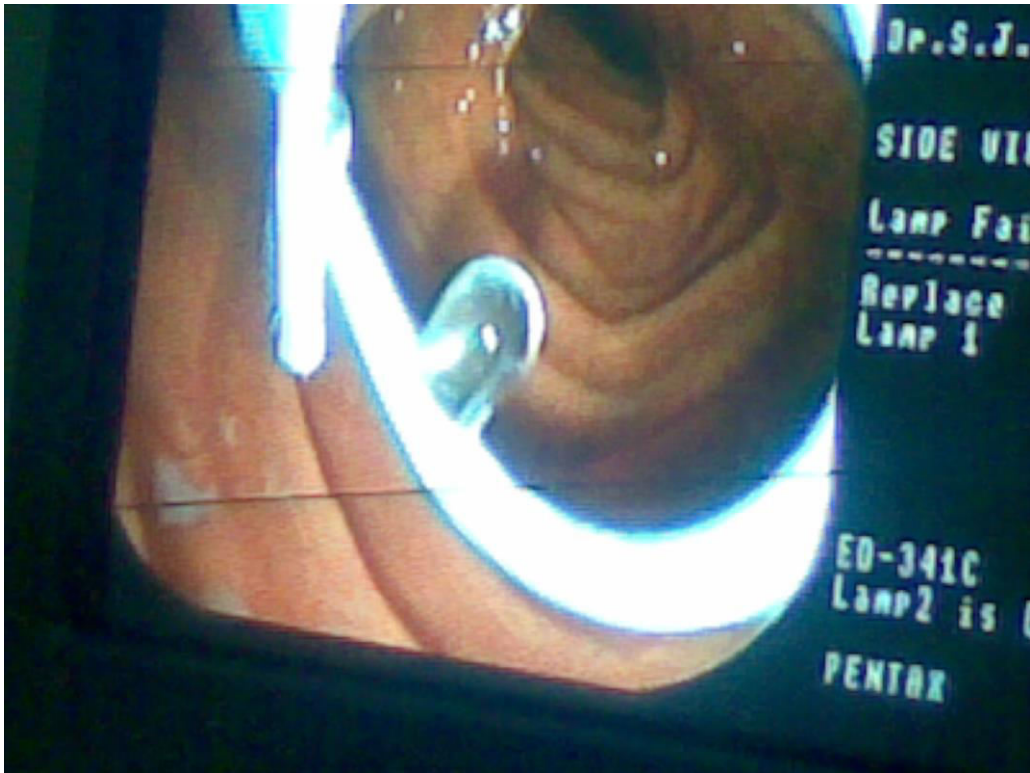


*7F Double Pigtail Stent*



*7F, 10F Straight Stent*





*7F Double Pigtail Stent in Position Draining white bile*