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Original Research Article

Comparison of surgical biliary bypass and biliary metallic stents for palliation of incurable malignant distal bile duct obstruction: A prospective observational study

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ABSTRACT

Background: Management of obstructive jaundice from periampullary and pancreatic head malignancies is mostly palliative. With advancements in endoscopic and stent technology and instrumentation, endoscopic interventions are gaining popularity and acceptance over surgical relief of jaundice.
Objective: To study efficacy of surgical biliary bypass over biliary metallic stents for palliation of incurable malignant distal bile duct obstruction
Materials and Methods: Prospective observational study was carried out among 77 patients with incurable malignant distal bile duct obstruction. 45 of them chose to undergo surgical bypass while 32 agreed to undergo metallic stenting. Parameters like improvement in jaundice, procedure related morbidities, need for re-hospitalization, need for re-intervention, quality of life and survival were compared in two groups. Chi square test and t test were applied to compare two groups.
Results: There was prompt and good relief of jaundice in both groups. There was one procedure related mortality in each group. The morbidities were comparable. The stented patients were hospitalized for a cumulative mean period of 34.1 days compared to 14.2 days in the surgical bypass group (p= 0.0001). The global quality of life, pain, nausea, vomiting and appetite were significantly better in the surgical bypass group. There was significantly improved overall survival in the surgical bypass group (163.5 days vs. 150 days, p= 0.0001).
Conclusion: Surgical bypass offers safe and superior palliation to obstructive jaundice from inoperable periampullary and pancreatic head cancer.

1. Introduction

Malignant biliary obstruction from periampullary and pancreatic head lesions is common. Majority of them especially pancreatic head cancer, present at an advanced stage with vascular invasion. The patients also have high levels of bilirubin, advanced age with multiple co morbidities like diabetes, advanced stages of atherosclerosis, pulmonary diseases, poor performance status and poor nutrition.[1] All these factors make palliation of jaundice as the only feasible treatment in a large subset of patients. Before the mid 1980's, palliation was provided primarily through surgical bypass2. Cholecystojejunostomy and hepaticojejunostomy are established surgical biliary bypass procedures. Cholecystojejunostomy is shorter of the two procedures and can be done with a small sub costal incision under epidural or short general anesthesia. If the cystic duct is blocked by tumor as with very low insertion into common bile duct (CBD) or by nodal mass, the bypass becomes ineffective. Finding of white bile in gall bladder should raise suspicion for cystic duct block although occasionally a long standing high grade obstruction also can cause white bile. If on finding white bile a patent cystic duct cannot be demonstrated a choledochojejunostomy

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is indicated. The evolution of Endoscopic retrograde cholangiography (ERCP) with placement of larger plastic stents and later uncovered and covered metallic stents allowed this procedure to become a viable alternative to surgical palliation.[1]

The main advantage of ERCP is non operative technique and good patient acceptance. The disadvantage of plastic stents including stent block, stent migration have largely been addressed by the advent of self expanding metallic stents (SEMS).[2]

Self expanding metallic biliary stenting although popular has not been compared with palliative surgical bypass in any randomized study.[3] There is only one retrospective study comparing the efficacy of metallic stents with surgery.[4]

Hence with this background, present study was carried out to study efficacy of surgical biliary bypass over biliary metallic stents for palliation of incurable malignant distal bile duct obstruction

2. Materials and Methods

This prospective observational study was conducted at a government medical college hospital 'Karnataka Institute of Medical Sciences' Hubli, Karnataka, India. The prospectively collected data of 110 patients with distal common bile duct malignant obstruction in our center, between September 2010 and September 2019 was analyzed.

Institution Ethics Committee permission was obtained and written informed consent was taken from all eligible and willing patients for the present study. All standard protocols and procedures were followed.

2.1. Inclusion criteria

All patients with obstructive jaundice from lower end common bile duct obstruction of malignant etiology undergoing palliative treatment

The bilirubin should be more than 5 mg/dl

2.2. Exclusion criteria

Patients undergoing curative surgery for periampullary carcinoma.

Patients not willing for either surgical bypass or stenting.

Out of these 110 patients treated at our institute for surgical obstructive jaundice from periampullary lesions during this period, 77 patients were included in the present study based on their informed consent and eligibility criteria. They were explained in detail about the two modes of therapy for surgical biliary bypass and biliary metallic stents for palliation of incurable malignant distal bile duct obstruction and given the choice to undergo the treatment. 45 of them agreed to undergo surgical bypass while 32 agreed to undergo metallic stenting.

The diagnosis was established by a multiphase computed tomography scan in the presence of obstructive jaundice. Additional tests like CA19.9, side viewing endoscopy and biopsy were done. Those patients who were considered unsuitable for curative resection either because of locally advanced growth, metastasis or poor general condition and co morbidities precluding major resection were offered palliative biliary drainage if the bilirubin was high (>5 mg/dl). All treatment options, palliative metallic stenting, surgical Cholecystojejunostomy or choledochojejunostomy and supportive care alone were extensively discussed with the patient and relatives including risks, complications and costs.

Patients selected for stenting underwent uncovered metallic biliary stent using side viewing endoscope under fluoroscopic guidance, a 10 mm wall stent (Boston Scientific Corporation, Natick, MA) either 6 or 8 cm was used according to stricture location and length. Sphincterotomy was performed at the discretion of endoscopist.

Patients opting for palliative surgery underwent Cholecystojejunostomy to a proximal loop of jejunum, using two layer anastomosis. The stoma was 2 cm wide, performed at or near the fundus of gall bladder. In patients where in white bile was found in the gall bladder, cholecystectomy with choledochojejunostomy was done. Gastrojejunostomy was performed when duodenal obstruction was evident. Patients who did not want any procedure were given supportive care only.

The patients were followed up at regular intervals for three months. For those who did not come to hospital, a telephonic follow up was done. The relief of jaundice was monitored. The re hospitalization for different indications like pain, cholangitis, decreased oral intake were determined. The European Organization for Research and Treatment of Cancer Quality of Life - 30 questionnaires (EORTC - QLQ30)[5] was administered at three months after the procedure. The five function domains assessed were physical, role, emotional, cognitive and social function, the nine symptom domain were fatigue, nausea and vomiting, pain, dyspnea, anorexia, constipation, diarrhea and economic difficulty as well as one question on general health situation.

2.3. Statistical analysis

Statistical analysis was performed using Open Epi software version 3.01. Continuous variables were tested using independent student t test, categorical variables using chi square test, Survival was compared using Kaplan Maier plots and Log rank test. The quality of life parameters were compared using Chi square test. P value less than 0.05 was considered as statistically significant.

3. Results

1. On initial recruitment = 110 patients
2. Eligible and willing = 77
3. Surgical bypass group = 45 and metallic stenting group = 32 (Table 1)
4. One from each group had procedure related mortality (surgical bypass group=44 & metallic stenting group=31) [Table 2]

Twenty-two patients underwent surgery with curative intention. Two of them were found un-resectable due to locally advanced disease and underwent palliative roux en Y choledochojejunostomy and gastrojejunostomy. Thirty-eight patients were selected for ERCP and biliary stenting. In six patients stenting could not be done for technical reasons, one for scope could not be passed due to deformed duodenum and in five due to failure of cannulation (13%). These six patients along with 37 patients underwent palliative surgical biliary drainage. Thirteen patients received supportive therapy only. Among patients undergoing surgical bypass seven (15.5%) underwent cholecystectomy with choledochojejunostomy and gastrojejunostomy. The other 38 (84.4%) had Cholecystojejunostomy alone. All procedures were done under either epidural or general anesthesia.

hows patient characteristics. The patients who underwent stenting (n=32) and those who had palliative surgical bypass (n=45) were comparable with regard to age, gender; mean bilirubin, type of tumor, co morbidities and American society of anesthesiology scores (ASA).

hows follow up parameters. One patient in the surgical arm died in the postoperative period due to respiratory infection and sepsis. One patient in the endoscopy and stent group developed severe acute pancreatitis with renal failure and could not be salvaged. The relief of jaundice was prompt in both groups. At 4 weeks following the procedure the average bilirubin was 3.5 and 4.3 in bypass and stent groups respectively. Two patients in the stent group had acute cholecystitis with empyema of gallbladder necessitating cholecystectomy, which could be done laparoscopically in both cases. After excluding admissions for chemotherapy and its complications like vomiting and diarrhea, patients undergoing stenting needed frequent hospitalization (p=0.005) mainly to treat repeated cholangitis, pain and dehydration. In all five patients in surgical bypass group and four patients in stent group took chemotherapy. The cumulated total length of hospital stay per patient including postoperative stay was significantly less for surgical bypass patients.

hows EORTC QLQ– C30 comparison at 3 months. Two patients in the stent group developed persistent vomiting due to gastric outlet obstruction and were given supportive care only as they were too frail to receive additional therapy either duodenal stent or gastric bypass. Patients on regular follow up received antacids, analgesics, multivitamins and anxiolytics. The quality of life EORTC questionnaire was completed by 63 patients at 3 months follow. The patients in surgical bypass group experienced significantly better overall global health status, nausea, pain and appetite.

The median overall survival was significantly better in the surgical bypass group compared to stented patients (163.5 days vs. 150 days) (Figure 1)

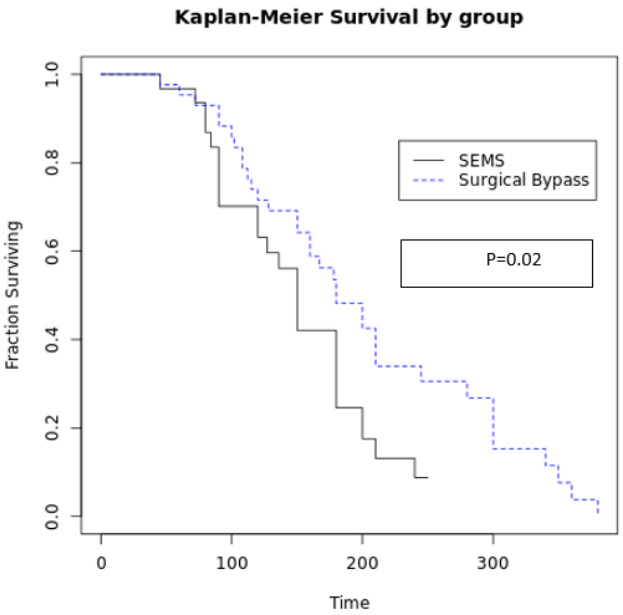

Fig. 1: Overall survival following surgical bypass and Self expanding metallic stent (SEMS). [Time- in days]

4. Discussion

Lower end common bile duct obstruction from periampullary carcinoma and pancreatic head cancers pose unique problem. The tumor is often un-resectable due to local spread or distant metastasis, or patient is medically unfit to undergo a major surgery. Palliation is often the only option available. The main goals of palliation are relief of jaundice, treatment of duodenal obstruction when present and pain management.

Relieving the biliary obstruction can be done by surgical bypass or by endoscopic biliary stenting either plastic or metallic. Duodenal obstruction can be palliated by either a surgical gastrojejunostomy or by endoscopic duodenal stenting.

With improvement in endoscopic technique and instrumentation and wider access to these procedures, and better patient acceptance for endoscopic palliation, endoscopic palliation is pushed more zealously over surgical palliation. There is still disagreement as to whether endoscopic or surgical palliation is associated with better outcome. Endoscopic techniques are being continuously refined in order to make up for its shortcomings, in the form

Table 1: Patient characteristics

Variables		Surgical Bypass group (n=45)	Metallic stenting group (n=32)	t/chi square value	p value
Age (years) mean+SD		62+12.3	64+11.4	t = 0.734	0.4654
Sex	Male	30 (66%)	22 (68%)	X^2 = 0.354	0.5516
	Female	15 (34%)	16 (32%)		
Bilirubin (mg/dl) mean+SD		14+5.7	12+5.3	t = 1.581	0.1183
Tumor cause	Pancreatic head	17 (37.7%)	12 (37.5%)	X^2 = 0.045	0.8307
	Periampullary	28 (62.3%)	20 (62.5%)		
Reason for inoperability	Locally un-resectable	15 (33.3%)	9 (28.1%)	X^2 = 0.867	0.833
	Poor clinical condition	24 (53.3%)	17 (53.1%)		
	Metastatic disease	3 (6.6%)	2 (6.2%)		
	Combination of above	3 (6.6%)	4 (12.5%)		
ASA Status	ASA-1	2 (4.4%)	4 (12.5%)	X^2 = 1.689	0.4297
	ASA-2	20 (44.4%)	13 (40.6%)		
	ASA-3	23 (51.2%)	15 (46.9%)		

Table 2: Follow up parameters

Variables		Surgical Bypass group (n=45)	Metallic stenting group (n=32)	t/chi square value	p value
Bilirubin (mg/dl) 4 weeks after procedure [mean+SD]		3.5+1.9	4.3+2.0	t = 1.7659	0.0821
Morbidity	Yes	4 (9.1%)	5 (16.1%)	X^2 = 0.299	0.5845
	No	41 (90.9%)	27 (83.9%)		
Hospital stay	Mean days	14.2+3.2	34.1+8.1	t = 13.185	**< 0.001**
30 day Mortality	Yes	1 (2.3%)	1 (3.2%)	X^2 = 0.2318	0.6302
	No	44 (97.7%)	31 (96.8%)		

Table 3: EORTC QLQ – C30 comparison at 3 months

	Surgical bypass(35) Mean (SD)	Metallic stent(28) (Mean and SD)	P
Global health status	69.20 (24.2)	56.43 (28.2)	**0.05**
Physical functioning	70.7 (23.2)	66.4 (24.3)	0.47
Role functioning	70.5 (32.8)	68.8 (30.2)	0.83
Emotional functioning	65.7 (24.6)	60.9 (26.7)	0.46
Cognitive functioning	85.1 (23.5)	86.2 (22.5)	0.85
Social functioning	72.2 (27.6)	74.1 (28.2)	0.78
Fatigue	34.1 (32.5)	45.4 (42.5)	0.23
Nausea and vomiting	8.0 (16.8)	18.0 (22.5)	**0.04**
Pain	27.0 (34.4)	45.4 (35.6)	**0.04**
Dyspnea	22.7 (29.3)	21.8 (24.9)	0.89
Insomnia	28.6 (30)	27.6 (34.5)	0.90
Appetite loss	20.20 SD(30.10)	36.40 (32.50)	**0.04**
Constipation	17.8 (24.5)	16.8 (23.3)	0.86
Diarrhea	4.5 (23.7)	7.3 (32.1)	0.69
Financial difficulty	52.4 (35.6)	57 (45.0)	0.65

SD: Standard Deviation

of multiple plastic stents, to uncovered to covered metallic stents.

The type of surgical palliation differs from studies. The very term palliation means as much less invasive procedure as possible. But in some studies compulsory hepaticojejunostomy[6] along with gastrojejunostomy is done in all patients[7] which is a far too big procedure compared to simple Cholecystojejunostomy in these often asthenic, sick patients, inviting higher morbidity and mortality.

Life expectancy was considered an important factor in deciding whether to do surgical or endoscopic palliation.[6] Endoscopic plastic stenting was recommended for those with poor prognosis and short life expectancy given the chance for stent block and stent migration in these patients. With metallic stenting this problem is reduced[8] hence the renewed interest for metallic stenting in patients with longer life expectancy.[3]

Cholecystojejunostomy is a simple procedure and can be done under epidural anesthesia especially in thin and frail patients with a small sub costal incision. The distended gall bladder is easily exposed and anastomosed to a proximal loop of jejunum. Because of simplicity and short duration of the procedure morbidity and mortality are low. Surgical bypass had good long term relief of jaundice and required no re intervention. The stent group had repeated hospitalizations (p=0.005) due to recurrent illnesses, low grade sepsis, pain and low oral intake and cholecystitis. The metallic stents were recommended over plastic stents due to larger size and less likelihood of blockage. The cholangitis in presence of patent metallic stents may be due to continuous reflux of bile through sphincter made incompetent by stent .The increase in pain in stent group may be due to stent induced cholangitis, and stretching of ampulla. Cholecystitis also contributes to the morbidity, reduced global health status, nausea and reduced appetite. As a permanent palliation, surgical bypass may be superior to metallic stenting, especially if the patient is expected to live longer.

In the absence of randomized study, bias in case selection and institutional expertise cannot be overlooked. A randomized study is not easily feasible and hence only cohort studies are possible with possible bias and lack of clinical significance. In the literature there is a lack of definition of palliation.[9] Some define palliation based on improvement in bilirubin,[10] while some define it by survival,[11] and some by quality of life.[12] As much as palliation is the goal of therapy, quality of life assessment using appropriate valid instrument is essential. In our setup where health care expenditure is personal and family problem, palliation has to be individualized based on economic status and expectations of family. Metallic stenting requires a high end setup and special expertise which is not easily available in small cities. A cost comparison will add to the value of the study. In a government hospital where care is highly subsidized and many things are free, cost comparison is difficult. The costs should include not only hospital costs and cost of consumables like stent, but also the cost of repeated hospitalization, lost working hours for the patient and attending relation.

Taylor MC et al[9] carried out a Meta analysis and stated that they could find only three randomized controlled trials eligible for inclusion in their Meta analysis. They observed that for comparison of failure of treatment in two procedures, the summary odds ratio could not be calculated as the three trials were heterogeneous. They also noted the odds of requiring more treatment sessions was 7.23 for stent group than the surgery group and found that the 30 day mortality was not significantly different in two groups which is comparable with the present study findings. They confessed that it is difficult to conclude as which treatment method is better as only few randomized controlled trials are existing and there is a need to carry out more randomized controlled trials.

Scott EN et al[7] studied 56 patients (endoscopic stenting group = 33 and surgical bypass group = 33) retrospectively and found that complications and mortality were comparable in two groups and this finding is in accordance with the present study. But they found that 39.4% of the stented group patients were re-admitted compared to only 13% from the surgical group which was statistically significant. They noted that the survival was significantly greater in surgical group compared to stenting group and we also observed similar finding.

Nikfarjam M et al[13] studied 69 patients retrospectively of whom 28 underwent surgical bypass and 41 biliary stenting. They found that the complications were significantly more in stenting group compared to bypass group. But we observed that the rate of complications or morbidities in two groups was comparable. The authors reported that requirement of further procedures was significantly increased in stent group compared to bypass group. They observed that the survival was comparable in two groups while we found that the survival was more in bypass group compared to stent group.

Ueda J et al[14] compared two groups of patients undergoing either bypass or stent and found that two patients died in stent compared to zero in bypass group. They also noted a greater morbidity in stent group while we found that the morbidities were comparable in two groups. They noted that the survival was comparable in two group but we observed that the survival was more in bypass group compared to stent group.

5. Conclusion

Surgical biliary bypass namely Cholecystojejunostomy offers superior palliation of malignant lower end biliary obstruction, and it can be used to palliate all patients

including those who are unsuitable for endoscopic procedure due to poor fitness and technical difficulty. The patients undergoing surgical bypass experienced lesser re hospitalization and lesser re interventions and had better quality of life. It can be done with minimal morbidity and mortality even in patients with poor performance status and also those who were unsuitable for endoscopic stenting due to technical difficulty. The metallic stenting being a high end procedure is not widely available in small towns and cities, in addition to cost considerations.

6. Source of Funding

None.

7. Interest of Conflicts

None.

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