

## ENDOSCOPIC METALLIC STENTING VERSUS SURGICAL BYPASS IN CASES OF INOPERABLE PANCREATIC HEAD CARCINOMA

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### ABSTRACT:

**Aim:** To compare endoscopic stenting with surgical bypass in palliation of patients with inoperable pancreatic head carcinoma.

**Patients and methods:** This prospective study included consecutive patients with obstructive jaundice due to inoperable pancreatic head carcinoma that were admitted to The Department of General Surgery, Minia University Hospital between July 2007 and September 2008.

**Results:** Endoscopic stenting was successful in 14 of 15 patients (93.3%) of the endoscopy group. Surgical bypass was done in 15 patients. There is no significant difference as regard the success of relieve of jaundice between the two groups ( $P>0.05$ ). The mean hospital stay was significantly shorter in endoscopy group, ( $P<0.05$ ). The mean cost of endoscopic stenting was significantly high. The complication rate was significantly lower in endoscopy group versus the surgical group ( $3.2\pm 1.4$  vs.  $7.4\pm 3.2$ ), ( $P<0.05$ ). The incidence of complications was significantly higher in cholecystojejunostomy than choledochojejunostomy.

**Conclusion:** Both endoscopic and surgical therapies are equally effective in term of palliation of obstructive jaundice. Endoscopic drainage is characterized by low morbidity, low mortality and short hospital stay. However, it is associated with high cost. In terms of surgical bypass, choledochojejunostomy is better than cholecystojejunostomy due to low complication rate.

### KEY WORDS:

Endotherapy

Surgical palliation

Malignant obstructive jaundice

### INTRODUCTION:

Among cancers of the gastrointestinal tract, carcinoma of the head of the pancreas is the third most common malignancy and the fifth leading cause of cancer-related mortality<sup>1</sup>. It is difficult to diagnose in its early stages. About 60%-80% of patients with periampullary carcinoma are inoperable either due to distant metastasis or local vascular invasion<sup>2</sup>.

Despite advances in understanding the pathology and biology of the disease, as well as improved diagnostic imaging and staging studies,

overall 5-year survival rate is less than 5%. Even with the most effective standard therapies, the collective median survival time of all patients is 4-6 months<sup>3</sup>. Because curative outcomes or long-term remissions are not likely to occur in a disease so biologically aggressive, most patients are in need for effective palliative techniques with a low morbidity and associated mortality and which are usually considered as more a hope than standard for most patients<sup>4</sup>. Before the mid-1980s, palliation was provided primarily through surgical bypass<sup>5</sup>. As early as 1980, attempts were made to

place stents in the biliary tree, first through the percutaneous transhepatic route and subsequently through endoscopic retrograde cholangio-pancreatography (ERCP)<sup>6</sup>. The results of some studies showed that endoscopic drainage offers effective short-term relief of jaundice and low morbidity and mortality rates as compared to surgical drainage<sup>7-8-9</sup>. However, the results of other studies are in favor of surgical palliation<sup>2</sup>.

Purpose of this prospective study is to compare endoscopic stenting with surgical bypass in palliation of patients with inoperable pancreatic head carcinoma and to evaluate the primary outcome; the success and effectiveness, secondary outcome as; mean procedure time, hospital stay, intensive care unit (ICU) stay, cost, morbidity and mortality.

#### **PATIENTS AND METHODS:**

This prospective study included consecutive patients with malignant obstructive jaundice due to inoperable pancreatic head carcinoma that were admitted to The Department of General Surgery, Minia University Hospital in period between July 2007 and September 2008. *Written informed consent was given from all included patients.*

Patients were subjected to complete clinical, laboratory, and radiological investigations. All patients were diagnosed by the use of abdominal CT guided biopsy, raised levels of CA 19-9. All the included patients were for palliation. The inoperability was determined by the presence of metastatic pancreatic cancer by the documentation of liver metastasis on imaging studies, or local vascular invasion. Suitability for general anesthesia was determined and the possibility of gastric outlet

obstruction in all the patients was excluded by endoscopy. Patients were randomly assigned to endoscopic group or surgical group. The random assignments were made using a list of sealed envelopes. Each procedure was explained in detail to patients and *written informed consent was* obtained from all the patients before each procedure. Patients of endoscopy (15 patients) were subjected to ERCP under general anesthesia and nasal endotracheal intubation, with the patient lying in the left lateral position using a therapeutic side viewing duodenoscope (Olympus, model TJF-140, Melville, NY) with an accessory channel diameter of at least 4 mm. A 9-Fr introducer system was used - under fluoroscopic guidance- upon which the stent was held, compressed and elongated by a cylindrical rolling membrane (the outer sheath), Figure 1. The delivery catheter had three markers: one at a first-proximal portion (the proximal marker), the second at the actual stent length position (the stent length marker), and the third at the distal position of the loaded stent (the distal marker). Stent deployment was accomplished by withdrawing the outer sheath while fixing the inner catheter. The metallic stents which were used had an intrinsic expanding force "self expandable" Wallstent (Schneider). Abdominal radiograph was taken at the end of the procedure to detect the start of its expansion. Patients of surgical group (15 patients) were subjected to surgical bilio-enteric bypass; cholecystojejunostomy or choledochojejunostomy according to the state of gallbladder, distended or not. Roux-en Y choledochojejunostomy was constructed. .

Absorbable 3-0 Vicryl sutures were used to establish the anastomoses. In cholecystojejunostomy, the 1<sup>st</sup> loop of jejunum was brought up to the

fundus of the gall bladder, and an incision was made in each with side-to-side anastomosis constructed. The data were collected and compared between the two groups as regard the; the success and effectiveness of the procedure, mean procedure time, hospital stay, intensive care unit (ICU) stay, cost, morbidity and mortality.

Follow-up evaluation included clinical assessment, assessment of serum bilirubin and liver enzyme levels and imaging of the biliary tract immediately before and after stent placement or surgical intervention and at 1, 3, 6 months after each.

#### Statistical analysis:

Collected data were tabulated. Numerical data were expressed by the mean  $\pm$  standard deviation and categorical data were expressed as number and percent (%). T-student test was used to compare numerical data, and Chi-square test was used to compare categorical data. P value was considered to be significant if it was  $<0.05$ .

#### RESULTS:

Thirty patients were included in the study, 20 males (66.6%) and 10 females (33.4%), with mean age  $60.2 \pm 11.6$  years.

The demographic data of patients undergoing endoscopic metallic stenting (endoscopy group) or surgical bypass (surgical group) are shown in table 1. Endoscopy group included 15 patients, 10 males (67%) and 5 females (33%), with mean age of  $60.2 \pm 11.9$  years. Surgical group included 15 patients, 11 males (73%) and 4 females (27%), with mean age of  $60.7 \pm 8.9$  years.

Clinically, all patients of both groups were seen to present with

malignant obstructive jaundice. The other associated manifestations are comparable in both groups.

Pancreatic adenocarcinoma was diagnosed by CT guided biopsy in 9 patients (5 patients were in endoscopy group, and 4 patients were in surgical group). Elevated CA 19-9 and abdominal CT were diagnostic in 21 patients (10 patients were in endoscopy group, 11 patients were in surgical group).

Inoperability was due to local vascular invasion in 17 patients (56.6 %) and liver metastases in 13 patients (43.4 %). In endoscopy group, it was due to local vascular invasion in 9 patients (60%) and liver metastases in 6 patients (40%) while in surgical group it was due to local vascular invasion in 8 patients (53%) and liver metastases in 7 patients (47%),  $P > 0.05$ .

Endoscopic stenting and deployment was successful in 14 of 15 patients (93.3%) of the endoscopy group, table 2. This was confirmed by serial measurements of serum bilirubin, table 3, and serial plain radiographic imaging of the abdomen. The mean bilirubin level decreased from  $25.1 \pm 11.3$  mg before the procedure to  $12.9 \pm 4.3$  mg/dL at the 2 weeks follow-up, and this difference was statistically significant ( $P < 0.05$ ). Failed procedure was encountered in one patient. He was due to very tight stricture with failure to be negotiated by the guide wire and was treated by percutaneous route.

Bilio-enteric bypass was done in patients of surgical group. Cholecystojejunostomy was done in 10 patients (7 males and 3 females). Choledochojejunostomy was done in the remaining 5 patients (4 males and 1

female). Gastrojejunostomy was done in 4 patients.

The mean bilirubin level decreased from  $26.1 \pm 10.1$  mg before the procedure to  $11.1 \pm 3.6$  mg/dL at the 2 weeks follow-up, and this difference was statistically significant ( $P < 0.05$ ). There is no significant difference as regard the success of relieve of jaundice between the 2 groups, ( $P > 0.05$ ), table 3.

The mean procedural time was  $45 \pm 15$  minutes in endoscopy group, and  $90 \pm 39$  minutes in surgical group,  $P$  value  $< 0.05$ .

The mean hospital stay was significantly shorter in endoscopy group versus surgical group ( $3 \pm 1$  days vs.  $7 \pm 3$  days),  $P$  value  $< 0.05$ .

The mean ICU stay was significantly shorter in endoscopy group versus surgical group ( $2.1 \pm 1.4$  vs.  $5.4 \pm 2.9$  days),  $P$  value  $< 0.05$ .

The mean cost of endoscopic stenting was  $4000 \pm 300$  LE and for surgical drainage (including hospital stay and ICU stay) was  $2600 \pm 200$  LE,  $P$  value  $< 0.05$ .

The mean of complication rate was significantly lower in endoscopy group versus the surgical group ( $3.2 \pm 1.4$  vs.  $7.4 \pm 3.2$ ),  $P$  value  $< 0.05$ . In the endoscopy group, pancreatitis was diagnosed in 2 patients, cholecystitis in 2 patients and stent occlusion in 2 patients that needed endoscopic re-intervention. The cause of occlusion

was tumor ingrowth. The mean stent patency was  $190 \pm 56$  days, In the surgical group, wound infection was in 6 patients; abdominal wound dehiscence was in 1 patient, cholangitis in 3 patients, bile leak in 3 patients and biliary peritonitis in 1 patient with fatal outcome due to septicemia. The incidence of these complications was significantly higher in subgroup of cholecystojejunostomy than choledochojejunostomy,  $P < 0.05$ . All patients with cholangitis, bile leak, biliary peritonitis were seen in this subgroup.

There is no related mortality in the endoscopy group, while there was operative mortality in 3 patients of surgical group.

The mean duration of the follow up was  $6 \pm 3.1$  months. Reintervention due to gastric outlet obstruction was required in 4 patients; 2 in the endoscopy group and 2 in the surgical group. None of patients who had undergone Roux-en-Y choledochojejunostomy and simultaneously gastrojejunostomy required intervention later during the follow up.

During the follow up, 5 patients (33%) died in the endoscopy group, and 4 patients (26.6%) died in the surgical group,  $P > 0.05$ . The deaths were attributed to the patients' natural course of disease. The survival rates were similar in patients of both groups. The mean survival time was  $120 \pm 31$  days in the endoscopy group versus  $112 \pm 26$  days in the surgical group,  $P > 0.05$ .

**Table 1:** Characteristics of patients

Variable	Endoscopy group	Surgical group	P value
Mean age $\pm$ SD (years)	60.2 $\pm$ 11.9	60.7 $\pm$ 8.9	>0.05
Female/male	5/10	4/11	>0.05
Clinical presentation:			
Jaundice	15	15	>0.05
Pain	11	12	>0.05
Metastatic disease	6	7	>0.05
Local vascular invasion	9	8	>0.05

**Table 2:** Outcome measure

Outcome	Endoscopy group	Surgical group	P value
Success rate (%)	93	100	P>0.05
Mean survival time $\pm$ SD (days)	120 $\pm$ 31	112 $\pm$ 26	P>0.05
Mean hospital stay $\pm$ SD (days)	3 $\pm$ 1	7 $\pm$ 3	P<0.05
Mean ICU stay $\pm$ SD (days)	2.1 $\pm$ 1.4	5.4 $\pm$ 2.9	P<0.05
Mean procedure time $\pm$ SD (min)	45 $\pm$ 15	90 $\pm$ 39	P<0.05
Mean morbidity rate $\pm$ SD	3.2 $\pm$ 1.4	7.4 $\pm$ 3.2	P<0.05
Mortality related procedure (%)	0%	20%	P<0.05
Mean cost $\pm$ SD (LE)	4000 $\pm$ 300	2600 $\pm$ 200	P<0.05

**Table 3:** Laboratory data of patients before and after ERCP

	Before procedure		After 1 week		2 weeks		4 weeks		P value
	Endo	Surgical	Endo	Surgi	Endo	Surgical	Endo	Surgica	
Total Bil (mg%)	25 $\pm$ 11.3	26 $\pm$ 10.1	19 $\pm$ 6.7	19 $\pm$ 5.2	12 $\pm$ 4.3	11.1 $\pm$ 3.6	5 $\pm$ 2.1	4 $\pm$ 2.7	>0.05
Direct Bil (mg%)	23 $\pm$ 9.2	24 $\pm$ 8.4	15 $\pm$ 3.1	14 $\pm$ 4.1	8 $\pm$ 5.6	7 $\pm$ 3.9	3 $\pm$ 1.2	2 $\pm$ 1.4	>0.05
ALP (U/L)	576 $\pm$ 120	592 $\pm$ 150	360 $\pm$ 78	367 $\pm$ 97	227 $\pm$ 34	31 $\pm$ 29	98 $\pm$ 43	102 $\pm$ 32	>0.05

Bil: bilirubin,

ALP: alkaline phosphatase,

Endo: endoscopy.



**Fig.1: Metallic stent in the CBD (endoscopic view).**

**DISCUSSION:**

The majority of patients with pancreatic cancer are non-resectable and jaundiced at presentation. Methods of palliation in such patients with locally advanced disease comprise endoscopic placement of a biliary endoprosthesis or surgical bypass<sup>10</sup>. Although both surgery and endoscopy are equally effective options, endoscopic drainage with the insertion of a stent into the bile duct has been shown to significantly reduce the length of hospitalization and is associated with lower procedure morbidity and mortality<sup>11</sup>. In the present study, we have a similar result and both methods are equally effective in relieving of the jaundice.

Most endoscopic drainage procedures with the insertion of a metal stent are done as a same day procedure<sup>12</sup>. So, Endoscopic palliation is associated with shorter hospitalization than the surgical palliation. In our study, there was a prolonged hospitalization (mean of 3±1 days) in the endoscopy group, which is explained by the fact that all the patients were admitted to the hospital for laboratory, and radiological evaluation before randomization to either endoscopy or surgery. An additional factor is the repeated attempts of endoscopic stenting (needed in 3 patients).

Han et al<sup>13</sup> showed a lower incidence of the need for ICU admission after endoscopic biliary stenting in a randomized trial of endoscopic stenting versus surgical bypass in malignant bile duct obstruction. In our study, the endoscopic palliation was associated with a significant short ICU stay.

The surgical palliation of malignant obstructive jaundice due to

advanced pancreatic cancer has a high morbidity and mortality rates<sup>14</sup>. In the present study, we have similar results when compared with endoscopic palliation.

A randomized controlled trial comparing endoscopic therapy vs. surgical bypass in 50 patients with malignant biliary obstruction stated that survival rates were higher in the endoscopy group (22 ± 3 weeks vs. 16 ± 2 weeks)<sup>14</sup>. In the present study, the survival rate is similar in both groups and this may be attributed to diagnosis of the disease in an advanced stage.

Martin et.al.<sup>15</sup> performed a study about cost comparison of surgery and endoscopy in this issue. Results revealed that the cost of endoscopic drainage procedure is significantly less than the surgical procedure with shorter hospitalization and lower total cost of care. Our results do not support this evidence of low cost of endoscopic palliation. The reduction in mean length of hospital and ICU stay was not translated to low cost of the procedure. This is attributed to the high cost of the metallic stent itself.

Endoscopically treated patients demonstrated better quality of life compared with those who underwent surgical drainage procedure. Better patency rates are reported with metallic than with plastic stents though no effect on survival is noted. Plastic internal stents are cheapest but reportedly prone to migration<sup>16</sup>. The incidence of recurrent jaundice after biliary stenting has decreased with the use of expandable metallic stents compared with plastic stents, but still tumor ingrowths can cause late stent occlusion<sup>17</sup>. This was seen in two patients in our study.

Still there is controversy as regard the method of surgical biliary bypass. It can be done by cholecystojejunostomy, choledochoduodenostomy or hepaticojejunostomy. Operative morbidity and mortality are similar for both cholecystojejunostomy and hepaticojejunostomy, but the success rate in alleviating jaundice is higher for choledochojejunostomy or hepaticojejunostomy than for cholecystojejunostomy (97% vs. 87%)<sup>18</sup>. Also, the incidence of recurrent jaundice and cholangitis is 8% for cholecystojejunostomy and 0% for hepaticojejunostomy because of late obstruction of the cystic duct with tumor<sup>18-19</sup>. In the present study, 2 patients (13.3%) with cholecystojejunostomy developed recurrent jaundice as compared to none after hepaticojejunostomy. Another controversy over surgical bypass is whether gastric bypass should be done routinely or not. If gastrojejunostomy is not done at the time of biliary bypass, around 13%-21% of patients will require gastrojejunostomy and additional 20% of patients will die with some symptoms of duodenal obstruction,<sup>20</sup> A prospective randomized controlled trial also confirmed that prophylactic gastrojejunostomy should be done, otherwise 19% of patients require intervention for duodenal obstruction, when they are unfit for surgical procedure<sup>21</sup>. Many surgeons do not prefer prophylactic gastrojejunostomy<sup>22</sup> because of fear of higher morbidity but this was not found to be true in a prospective randomized controlled trial<sup>19</sup>. In the present study, prophylactic gastrojejunostomy was not done because of the fear of higher morbidity and mortality. However, combined biliary and gastric bypass is a practical option.<sup>21</sup>

In our study, the incidence of gastric outlet obstruction is low and this is explained by short life span in

those patients. Overall, our data reflect that endoscopic metallic stent palliation of malignant obstructive jaundice due to advanced cancer pancreas is better than open surgical bypass regarding the shorter hospital stay, low complication rate, low morbidity and low mortality. Its main concern is the high cost.

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## مقارنة بين دعامة القناة المرارية بالمنظار والجراحة التلطيفية في علاج الحالات المتأخرة من سرطان البنكرياس

أيمن حساين - عماد الصغير - معتصم الريدي

**الهدف:** يهدف البحث لعمل مقارنة بين دعامة القنوات المرارية و الجراحة التلطيفية في تلطيف الأعراض لمرضي الحالات المتأخرة من سرطان البنكرياس.  
**المرضى والأدوات:** لقد تضمنت هذه الدراسة المتقدمة مرضي انسداد يرقاني بسبب سرطان بنكرياس متأخر تم حجزها في قسم الجراحة العامة بمستشفى المنيا الجامعي في الفترة ما بين يوليو 2007 و سبتمبر 2008.

**النتائج:** نجح استخدام المنظار في وضع دعامة في عدد 14 من أصل 15 مريض بنسبة 93,3% بينما نجح عمل جراحة تلطيفية في 15 من أصل 15 مريض. وجد عدم وجود فرق بين الطريقتين في خفض نسبة الصفراء بالدم.

كانت فترة مكوث المريض بالمستشفى قصيرة بشكل ملحوظ في حالات المنظار بالمقارنة بحالات الجراحة.

كانت التكلفة الكلية أكبر في حالات المنظار بالمقارنة بحالات الجراحة حدوث مضاعفات كان أقل بكثير في حالات المنظار بالمقارنة بحالات الجراحة. حدوث مضاعفات كان أكثر في حالات التوصيل الجراحي بين المرارة والأمعاء عنه في حالات التوصيل الجراحي بين القناة المرارية و الأمعاء.

**الخلاصة:** يتساوي كل من الجراحة و الدعامة المرارية بالمنظار في خفض نسبة الصفراء بالدم في حالات سرطان البنكرياس المتأخرة و التي تتسبب في حدوث انسداد يرقاني.

ولكن يمتاز المنظار في هذه الحالات بأنه لا يتسبب في حدوث مضاعفات أو وفيات بنسبة كبيرة كحالات الجراحة كما أن مريض المنظار يتعافي ويخرج من المستشفى في وقت مبكر مقارنة بقرنائه ممن خاضوا جراحة تلطيفية وان كان المنظار أكثر تكلفة.

حدوث مضاعفات أكثر في حالات التوصيل الجراحي بين المرارة و الأمعاء عنه في حالات التوصيل الجراحي بين القناة المرارية و الأمعاء.