

Evaluation of Therapeutic and Diagnostic uses of Endoscopic Retrograde Cholangiopancreatography in Surgical Practice

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Abstract

Background: Endoscopic Retrograde Cholangiopancreatography is direct contrast study of hepatobiliary system by combining the use of endoscopy and fluoroscopy. It has added advantage of allowing duodenoscopy and pancreatography which are helpful in diagnosis of Ampullary and Periampullary anomalies. This procedure can be performed in presence of ascites and hepatic malignancies. At present Endoscopic Retrograde cholangiopancreatography is more commonly used as therapeutic tool rather than diagnostic tool. **Method:** The present study was undertaken at a tertiary referral centre for duration of two years. A total of 40 cases, who underwent ERCP for various indications were included. Once patient was in the procedure room, baseline vital signs are recorded and an intravenous line started. Antibiotic prophylaxis was given at this time. ERCP performed with the patient on the x-ray table with radiological equipment and fluoroscopy at hand. **Result:** Choledocholithiasis 36% was the most common indication for ERCP. Successful extraction of CBD calculi was done in 78.57% cases. Biliary sphincterotomies was done in 92.5% (37) of the patients for successful drainage. Overall complication rate of ERCP was 12.5%. During this study Sensitivity of the biopsy was 57% while that of brush cytology was 40% and combined sensitivity was 60%. **Conclusion:** ERCP is effective

for the palliation of malignant biliary obstruction, for which self - expanding metallic stents have longer patency than plastic stents. It helps in diagnosis, identification and palliation of post operative biliary leaks. Morbidity and mortality following ERCP biliary drainage is low as compared to surgical biliary drainage.

Keywords: Endoscopic Retrograde Cholangiopancreatography; Hepatobiliary system; Pancreas; Diagnostic; Therapeutic

Introduction

Endoscopic Retrograde Cholangiopancreatography was first described in 1968 by William McCune [1]. It is direct contrast study of hepatobiliary system by combining the use of endoscopy and fluoroscopy.

A more recent analysis from the redesigned Nationwide Inpatient Sample dataset reported continued decline in the use of ERCP, driven by a >75% decrease in the rate of diagnostic ERCP between 1998 and 2013 [2].

This procedure is performed as outpatient procedure under Sedation (rarely under General Anaesthesia). Using a side - viewing endoscope duodenal papilla is identified and manipulated. The scope contains a working channel through which flexible instruments are passed in to bile ducts and / or pancreatic ducts to diagnose treat the diseases. A successful ERCP requires the co-ordination and co-operation of dedicated and committed team of endoscopists, nurses and assistants, as well as an organized and functional unit. It is useful in both diagnosis and treatment of diseases of hepatobiliary system and pancreas like -

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Diagnostic- Obstructive jaundice due to various causes, Chronic Pancreatitis, Gallstones with dilated common bile ducts, Bile duct injuries traumatic or iatrogenic, Sphincter of Oddi Dysfunction, Pancreatic malignancies

Therapeutic- Removal of gallstones from CBD, Dilation of biliary strictures, Drainage of pseudocyst of Pancreas, Biliary drainage in case of Obstructive jaundice, Diagnosis and treatment of pancreatic duct leak.

Endoscopic Retrograde cholangiopancreatography has added advantage of allowing duodenoscopy and pancreatography which are helpful in diagnosis of Ampullary and Periampullary anomalies. This procedure can be performed in presence of ascites and hepatic malignancies.

Endoscopic Retrograde cholangiopancreatography is however not without risk and serious complications have been reported. Acute pancreatitis remains the important complication of this procedure in 5-10% of patients and even after simple duct cannulation.

This diagnostic and therapeutic modality has impacted significantly in management of patients with many different benign and malignant diseases of pancreato - biliary system. Many different technologies are being developed to shorten the time of procedure by improving the access and success with selective deep cannulation thus minimizing manipulation of ductal system. At present Endoscopic Retrograde cholangiopancreatography is more commonly used as therapeutic tool rather than diagnostic tool.

Embryology

The liver develops from an endodermal bud that arises from the ventral aspect of the gut, at the point of junction between foregut and midgut. This bud grows into ventral mesogastrium and passes through it into septum transversum. It divides into pars hepatica and pars cystica. The pars cystica of the hepatic bud gives origin to the gall bladder and to the cystic duct. The bile duct at first opens on ventral aspect of the developing duodenum. As a result of differential growth and rotation of duodenal loop, it comes to open on dorsal medial aspect of duodenum along with ventral pancreatic bud.

Hepatic Ducts

The intrahepatic segmental bile ducts unite to form lobar ducts, which in turn coalesce to form the - right and left hepatic ducts that represent the

beginning of the Extrahepatic biliary tract. The intrahepatic and ventrocranial branches form the right hepatic duct. It enters the left duct with a sharp curve, which accounts for the fact that Extrahepatic biliary calculi are less commonly found in this segment. The left hepatic duct is longer than the right and has a greater propensity for a sequence of distal obstruction. The junction of right and left hepatic ducts occurs extrahepatically in almost all instances but incision and dissection of the fibrous tissues at the hepatic plate may be necessary to expose this junction. The common hepatic duct, which begins at the confluence of the right and left hepatic ducts, is 3 to 4 cm in length. It is joined by the cystic duct to form the common bile duct.

The Gall Bladder

The gall bladder is located in the bed of the liver, in line of the anatomic division of that organ into right and left side. It is pear shaped and has an average capacity of 50 ml, and is divided into four anatomic portions: fundus, corpus, infundibulum, and neck. The fundus represents the blind end and that normally extends beyond the liver edge and is covered with peritoneum. It contains most of the smooth muscles of the organ, in contrast to the corpus, which is most of the major storage area and contains most of the elastic tissue. The body is covered extrahepatically with peritoneum and tapers into a neck which is funnel shaped, in the free border of hepatoduodenal ligament or lesser omentum. The convexity of the neck may be distended and dilated known as the infundibulum, or Hartmann's Pouch.

The wall of the gallbladder is made up of smooth muscle tissue, and the lumen is lined with high columnar epithelium that contains cholesterol and fat globules. The mucus secreted into the gallbladder originates in the tubular glands and the goblet cells of the mucus lining of the body and neck.

The gallbladder enters the common hepatic duct system by cystic duct that has variable length, averaging 2-3 cm, at an acute angle, and the right branch of the hepatic artery resides immediately behind it. Variations in the point of union between the cystic duct and the common hepatic duct are surgically important. The cystic duct may be parallel to the common hepatic duct and actually be adherent to it for a variable length. It may be extremely long and unite with the hepatic duct near the duodenum. On the other hand, the cystic duct may be absent or very short, and there may be an extremely high union with the hepatic duct. At times the cystic duct enters the right hepatic duct.

In some instances, the cystic duct may spiral either anteriorly or posteriorly in relation to the common hepatic duct and join the common hepatic duct from the left side. The segment of the cystic duct adjacent to the gall bladder bears a variable number of mucosal folds that have been referred to as valves of Heister but do not have valvular function.

Common Bile Duct

The common bile duct is approximately 8.5 cm in length. The normal external diameter ranges between 4 and 10 mm. Leshe has shown that at diameters of 10.2 mm or above, the probability of obstructive pathology is 50 percent. The upper portion is situated in the free edge of the lesser omentum to the right of the hepatic artery and anterior to the portal vein. The middle third of the common duct curves to the behind the first portion of the duodenum, where it diverges from the portal vein and hepatic arteries. The lower third part of the common bile duct curves more to the right of the pancreas, which it grooves, and enters Ampulla of Vater, where it is frequently joined by the pancreatic duct. The portions of the duct have been named after their relationship to the intestinal viscera; supraduodenal, intraduodenal, intrapancreatic. And intraduodenal length of each of these segments is 2, 2.5, 3 and 1 cm respectively. The pancreatic portion of duct is partially covered in 30 percent of cases. The final intraduodenal or intramural portion of the duct passes obliquely through the duodenal wall the pancreatic duct and follows one of three patterns. The structures may unite outside the duodenum and traverse the duodenal wall and papilla; they may join within duodenal wall and have a common short, terminal portion; or they may exit independently into the duodenum.

Distal common bile duct at the Ampulla of Vater is regulated by a sphincteric mechanism that originally was named sphincter of Oddi, but was more accurately described by Boyden who had described a complex of four sphincters of circular or spiral smooth muscle fibers surrounding the intramural portion of common bile duct and pancreatic ducts. The common duct exits duodenum at papilla of Vater.

Objective: To evaluate various therapeutic and diagnostic uses of Endoscopic Retrograde Cholangiopancreatography in Surgical practice.

Materials and Methods

The present study was undertaken at a tertiary

referral centre for duration of two years. A total of 40 cases, who underwent ERCP for various indications were included in this study. All patients were explained the procedure and its probable complications in details and a valid, informed written consent was taken for the procedure including likely therapeutic interventions.

Selection Criteria

Inclusion Criteria

Patients attending surgical OPD complaining yellowish discolouration of skin, clay coloured stools with or without pain in abdomen.

Patients presenting with post cholecystectomy complications.

Patients with suspected malignant conditions of hepatobiliary system.

Exclusion Criteria

Patients not fulfilling above criteria, Pregnant females, Patients with coagulopathies and deranged coagulation profile, Patients with comorbid medical conditions, Patients with severe immunodeficiency and sepsis, Patients with past history of gastric bypass surgery or Billroth Surgery.

Preoperative Preparation

All cases underwent routine workup on outpatient basis which include a complete haemogram, liver function test, renal function test, fasting & postprandial sugars, coagulation profile, chest radiogram and ECG. Patients who were diabetics, their diabetic status was controlled pre-procedure. Patients on anticoagulants like aspirin were asked to discontinue the drug 7 days prior to the procedure. Patients were admitted one day prior to the chosen day of procedure. Patients were kept fasting overnight except hypertensives who received their usual dose of antihypertensive in morning on the day of procedure with sips of water. Morning dose of oral hypoglycaemics and / or insulin was omitted on the day of procedure. Patients also received sedative - anxiolytic in form of Tab. Calmpose 10 mg night before procedure. For hospital inpatients, dentures removed if present and patient was transported to endoscopy suite on cart, accompanied by medical personal and relevant x - rays.

Once patient was in the procedure room, baseline vital signs are recorded and an intravenous line

started. Antibiotic prophylaxis was given at this time. Premedication were given including paraneural sedation, and often atropine (0.4 mg). A topical anaesthetic agent such as Xylocaine spray was applied to the pharynx.

Technique

ERCP performed with the patient on the x-ray table with radiological equipment and fluoroscopy at hand. Following premedication patient was placed in left lateral decubitus position. The duodenoscope passed by mouth through the anesthetized pharynx, and in to the oesophagus, stomach, and duodenum. A rapid visual examination of these segments was made. Once the instrument has reached the second portion of the duodenum, ampulla of Vater is located, often on the medial wall; the periampullary region is carefully inspected. Often injection Buscopan was given to reduce the duodenal motility and facilitate the visualization. The inner catheter (containing contrast dye) then advanced from the lateral port of the endoscope and guided in to the orifice. Once the ampulla has been engaged, the catheter is advanced several millimeters in to the duct and small volume of contrast injected. The dye filling pattern was visualized under fluoroscopy ("the test shot") to determine the orientation. In this manner the pancreatic duct and bile duct may be selectively cannulated and imaged separately with contrast. Fluoroscopy can use as needed to assure proper catheter orientation. Formal spot radiographs are taken of contrast filled ducts for permanent record. At times X -ray table adjustments and patients repositioning may be necessary particularly if the gallbladder is imaged. Delayed films were also obtained following removal of duodenoscope since contrast material normally remains in the ductal system for minutes.

In addition, suspicious periampullary and ductal lesions may be biopsied and cytological brush samples obtained. "Blind" biopsies of the ducts and / or pancreas may be taken at physician discretion. A variety of therapeutic procedures, mentioned earlier, may be performed.

Post Procedure Care

The patient was kept at strict bed rest and observed carefully in the recovery room. Vital signs were monitored frequently to look for any complications that may arise. If the patient had tolerated the procedure well, he was shifted to the ward once sedatives effect had worn off. Patient is kept nil by mouth until gag reflex had returned, then oral sips followed by clear liquids for 24 hours. Any patient undergoing a therapeutic procedure was observed overnight in the hospital. All the patients were given report card and follow up schedule. Data collected was tabulated and statistically analyzed.

Results

Table 1: Indications of EECF

Sr. No.	Indication	No. of Cases	Percentage
1	Choledocholithiasis	14	36%
2	CBD injury	2	5%
3	Choledochocyst	2	5%
4	Cholangiocarcinoma	7	18%
5	Chronic pancreatitis	2	5%
6	Peri - ampullary carcinoma	10	26%
7	Post CBD exploration	1	2%
8	AUPBD	1	3%

The commonest indication for ERCP during the study period was choledocholithiasis (36%). (Table 1)

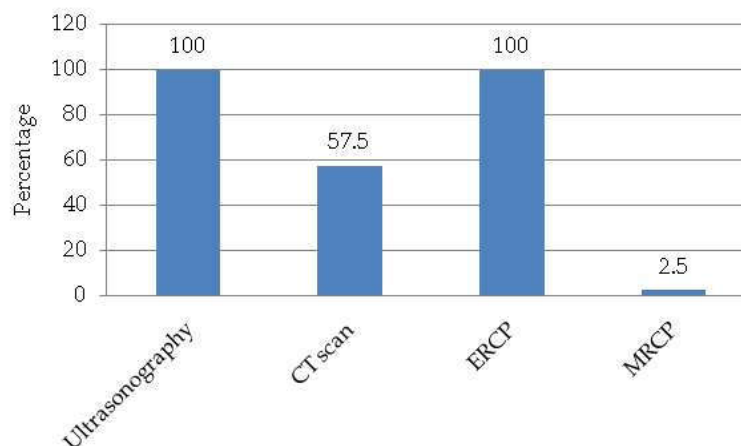


Fig. 1:

Fig. 1 shows various investigations done, USG was done for all the patients, and depending on clinical, USG findings and availability further investigations were carried out. CT scan was done for 57.5% of patients along with ERCP. MRCP was done for one patient with hepatic duct calculi along with CBD calculi.

Table 2: Detail Analysis of ERCP Study

	CBD cal	CBD injury	Choledochal cyst	CBD cholangio Ca	Chronic pancreatitis	Periampullary Ca	Post CBD expl	AUPBD	Pancreatic Anomaly	Total
No. of patients	14	2	2	7	2	10	1	1	1	40
Stone Extraction	11						1			12
Failed Extraction	3									3
Sphincterotomy	14	2		7	2	10	1	1		37
Stenting	14	2		7		10	1	1		35
Failed Cannulation					1					1
Biopsy + Br. Cytology				7		10				17
Successful drainage	14	2		7		10	1	1		35
Pancreatitis	2									2
Cholangitis			1							1
Bleeding				1		1				2

Majority of patients were found for CBD cal (14) followed by Periampullary Ca (10). Most of the cases are from Sphincterotomy followed Stenting and drainage (Table 2).

Table 3: Summary of ERCP Study

ERCP Procedure	No. of Cases	Percentage
Total ERCP's attempted	40	100
CBD calculus extraction	11	27.5
Failed extraction of CBD calculus	03	7.5
Total Sphincterotomy performed	37	92.5
Stenting of CBD	35	87.5
Biopsies for tissue diagnosis	17	42.5
Failed cannulation	01	2.5
Complication rate	05	12.5
Successful internal drainage achieved	35	87.5

It was observed that, CBD calculus extraction was done in 11 cases out of total attempted 14 cases with success rate of 78.5%. Sphincterotomies were required in 37 patients (92.5%) and post procedure stenting was done in 35 (87.5%) patients. Out of 35 patients who underwent stenting, in 17 (48.57%) patients stenting was done as a palliative option

to relieve the obstruction in cases with terminal CBD cholangiocarcinoma and peri - ampullary carcinomas with metastasis. Overall success rate of ERCP in achieving the internal drainage was 87.5%, where as eRCP failed in 3 cases (7.5%) (Table 3).

Table 4: Diagnostic And Therapeutic ERCP

Sr. No.	Indication for ERCP	No. of Cases	Diagnostic, Therapeutic, Palliative
1	Choledocholithiasis	11	T
2	CBD injury	02	D + P
3	Choledochal cyst	02	D
4	Cholangiocarcinoma	07	D + P
5	Chronic Pancreatitis	02	D
6	Peri - ampullary carcinoma	10	D + P
7	Post CBD exploration	01	T
8	AUPBD	01	D + P
9	Pancreatic anomaly	01	D

ERCP was used purely as a diagnostic in 5 cases, while it was used as therapeutic in 12 cases (11 with CBD calculus and 1 post CBD exploration). ERCP was used as diagnostic and palliative in 20 cases, with successful internal drainage. ERCP was failed in 3 cases of CBD calculi. Thus it is found that ERCP is of therapeutic in 11 cases of choledocholithiasis, while it was diagnostic and palliative in cases of obstructive jaundice due to malignancies and also useful for tissue diagnosis of malignant conditions.

Table 5: Yield of Brush Cytology and BIOPSY

Procedure	No. of Cases	Diagnostic	Non Diagnostic	Sensitivity (%)
Brush cytology	5	2	3	40%
Biopsy	7	4	3	57%
Brush cytology + Biopsy	5	3	2	60%

Out of 17 cases of malignancy, brush cytology was done in 5 cases, biopsy done in 7 cases and combined brush cytology biopsy was done in 5 cases. Thus the sensitivity of combined biopsy and brush cytology is more than the independent procedure.

Table 6: Complications of ERCP

Complication	No. of Cases	Severity	Outcome
Heamorrhage	02 (5.0%)	Mild	Managed conservatively
Pancreatitis	02 (5.0%)	Mild	Managed conservatively
Cholangitis	01 (2.5%)	Mild	Managed conservatively
Total	05		

The overall complication rate was 12.5%

(05 cases), while it more when sphincterotomy (11.76%) was done than without (5.8%). No death that directly attributed to complications related to ERCP procedure was found in this study. All the complications which occurred during the study were mild in severity and were managed conservatively (Table 6).

Analysis of Biliary Decompression with ERCP

A) CBD CALCULI (Total 14 cases):

Majority of CBD calculi diagnosed on Ultrasound were extracted using ERCP guided procedure, i.e. of 11 patients accounting for 78.57%. The rest of the patients required open CBD exploration.

Table 7: Reason for CBD exploration

Sr. No.	Reason For CBD Exploration	No. of Cases
1	Failed extraction during ERCP	01
2	Large stone >2 cm in diameter	01
3	Multiple impacted stone with grossly dilated CBD	01

There was one patient who has been operated for open CBD exploration for CBD calculi, who again came with recurrent CBD calculi. ERCP was done in that patient with complete clearance of CBD. Thus in CBD calculus mainstay of treatment is nowadays via endoscopic route and surgical role is limited to small no of cases in which ERCP fails to extract calculi, with larger size of calculi or in a case with impacted calculi. (Table 7).

B) PERI- Ampullary Carcinoma and CBD Cholangiocarcinoma (Total 17 Cases) -

In all the cases with peri - ampullary carcinoma and CBD cholangiocarcinoma ERCP was done along with sphincterotomy, biliary stenting and brush cytology or biopsy.

There was no any case with failure of ERCP in this group.

- 10 Patients (58.8%) were fit for radical surgery. Prior ECRP was done.
- 02 Patients (11.76%) underwent palliative bypass. Prior ERCP was done
- 05 Patients (29.4%) Presented with metastasis and surgery was contraindicated. ERCP with stenting was the only option.

C) CBD Injury

During the study there were 2 cases of CBD injury out of which in 01 case CBD injury occurred during open cholecystectomy and in another case it was traumatic injury of CBD leading to large biloma formation in rt. Lobe of liver. In both the cases ERCP showed evidence of biliary leakage from rt. Hepatic duct. In first case it was managed with stenting followed by definitive surgery and in second case stenting followed by pigtail drainage of Bilioma.

Discussion

In present study, out of 40 attempted ERCP, 39 patients could undergo the cholangiogram with success rate of 97.5%.

Sphincterotomy was required in 37 patients (92.5%) while stenting was done in 35 patients (87.5%). Internal biliary drainage was successfully achieved in 35 patients (87.5%). Complication rate was 12.5% with no death directly related to ERCP procedure.

In trial conducted by Frey CF, found sensitivity and specificity of ERCP in diagnosing CBD calculi 90% and 97% respectively, while in our study 14 cases of CBD calculi diagnosed by ultrasonography were accurately diagnosed by ERCP with sensitivity and specificity of 100% respectively [3].

The sensitivity rate for ERCP - directed brush cytology or biopsy is 30% to 50%, with a combination achieving sensitivity rates of 65% to 70% [70]. In our study sensitivity rate for ERCP directed brush cytology and biopsy were 40% and 57% respectively while combined procedure had sensitivity rate of 60%.

In P. B. Cotton et al study, 1921 patients who underwent endoscopic sphincterotomy had a complication rate of 5.8% with 0.2% fatality rate [4]. In our series, endoscopic sphincterotomy had a complication rate of 11.6% with no fatality. In Rabenstein et al., rate of mild and severe pancreatitis was 4.1% and 0.6% [5]. In our study mild pancreatitis was seen in two cases with rate of 5%. No any medications were given prior to ERCP. The risk factor identified for developed of pancreatitis was due to difficult cannulation in both the cases as per Cheng CL [6].

Out of total 14 cases of CBD calculi 11 patients (78.57%) were treated by ERCP with sphincterotomy with stone extraction, while the remaining (21.5%) were treated with CBD exploration. Reflecting the high percentage of cases with choledocholithiasis,

ERCP guided extraction of CBD calculus followed by cholecystectomy was the most common procedure performed during the series. A total 3 (7.5%) cases required formal CBD exploration. These were the cases in which the ERCP route was failed or was not feasible.

A total of 17 cases presented with malignancy, radical resection was possible in 10 patients (58.8%), while 2 patients (11.76%) could undergo palliative resection (Bypass procedure). In 5 patients (29.4%). Surgery was contraindicated, so ERCP was done.

The present study also compares with the study by Proposito D et al., 118 which notes that two third of pancreatic cancer patients are still unsuitable for resection. Resectability rate was 18% with surgical palliation done in 34%, 58 underwent biliary bypass, 15 gastroenterotomies and 27 double bypass with mortality of 8.1% [7].

A study by Speer AG, Cotton P. B., Russell RCG showed that endoscopic biliary prosthesis successfully decompress the bile duct and relieve the symptoms in 70-80% of the patients with malignant obstruction. The method causes fewer complications than percutaneous route [8].

This matches with study done by Smith AC, Dowsett JE, Russell RCG et al that endoscopic drainage has lower morbidity and mortality than surgical palliative bypass [9].

Conclusion

ERCP is useful for both diagnosis and therapy of choledocholithiasis compared with USG or MRCP which are diagnostic only. Endoscopic sphincterotomy, stone extraction and stenting have replaced the traditional surgical bile duct exploration.

Ultrasonography remains the primary and initial diagnostic modality because of easy availability, cheap cost and non - invasiveness. USG still remains the most sensitive modality for diagnosing gall stones.

ERCP is effective for the palliation of malignant biliary obstruction, for which self - expanding metallic stents have longer patency than plastic

stents. The sensitivity of tissue diagnosis increases with combined use of brush cytology and biopsy.

ERCP helps in diagnosis, identification and palliation of post operative biliary leaks. Endoscopic therapy of postoperative biliary leaks and strictures should be undertaken as first - line therapy.

NSAIDs which are simple, cheap, and safe medication is recommended for preventing post - ERCP pancreatitis and reducing the incidence of post - ERCP pancreatitis before or probably immediately after ERCP in patients undergoing positive pancreatography.

References

1. McCune, WS, Shorb, PE & Moscovitz, H. Endoscopic cannulation of the ampulla of Vater, a preliminary report. *Ann Surg.* 1968;167:752-6.
2. Huang RJ, Thosani NC, Barakat MT, et al. Evolution in the utilization of biliary interventions in the United States: results of a nationwide longitudinal study from 1998 to 2013. *Gastrointest Endosc.* 2017 Jan 4 [Epub ahead of print].
3. Frey CF, Burbige EJ, Meinke WB, et al. Endoscopic retrograde cholangiopancreatography. *Am J Surgery.* 1982;144:109-114.
4. Cotton PB, Lehman G, Vennes J, Geenen JE, Russell RCG, Meyers WC, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc.* 1991;37:383-93.
5. Rabenstein T, Hahn EG. Post - ERCP pancreatitis: new momentum. *Endoscopy.* 2002;34:325-329.
6. Cheng CL, Sherman S, Watkins JL, Barnett J, Freeman M, Geenen J, et al. Risk factors for post - ERCP pancreatitis: a prospective multicenter study. *Am J Gastroenterol.* 2006;101:139-47.
7. Proposito D et al.: Palliative procedures in treatment of non resectable pancreatic tumours, *Annali italiani di Chirurgia.* 1998;69(2);185-93.
8. Speer, AG, Cotton, PB, Russell, RCG, Mason, RR, Hatfield, ARW & Leung, JWC et al. Randomized trial of endoscopic versus percutaneous stent insertion in malignant obstructive jaundice. *Lancet* 1987;2:57-62.
9. Smith, AC, Dowsett, JF, Russell, RCG, Hatfield, ARW & Cotton, PB. Randomised trial of endoscopic stenting versus surgical bypass in malignant low bile duct obstruction. *Lancet.* 1994;344:1655-60.