

EVALUATIVE STUDY OF THE ERCP UNIT AT SAYED GALAL UNIVERSITY HOSPITAL IN COMPARISON WITH OTHER CENTERS

By

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Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems. 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 functioning unit. It takes many years to learn, and repeated practice, in order to master the skill of ERCP and to do it safely. The study evaluated the ERCP unit of Sayed Galal University according to safety, efficacy and complications in diagnosis and management of biliary obstruction by a retrospective study in comparison with other centers. This study was conducted on 318 patients with obstructive jaundice who fulfilling the designed inclusion criteria. The study was carried out in outpatient clinics of Tropical Medicine Department Al-Azhar University Hospitals (Sayed Galal Hospital), during the period from January 2012 to December 2016. The results showed the cannulation gave 94.3% good findings as 300 cases were successfully relieved the obstruction using either ES only, ES and stone extraction or stent application. The side effects were 16 (5%) cases making the ERCP relatively a safe procedure; however, with potential for severe life-threatening complications.

Key Word: Egypt, Patients, Endoscopic retrograde cholangiopancreatography

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) represents a monumental advance in the management of patients with pancreaticobiliary diseases, but is a complex and technically demanding procedure with the highest inherent risk of adverse events of all routine endoscopic procedures (Rustagi and Jamidar, 2015). Through the endoscope, the physician can see the inside of the stomach and duodenum, and inject dyes into the ducts in the biliary tree and pancreas so they can be seen on X-rays (Vitale *et al*, 2009).

ERCP is used primarily to diagnose and to treat the bile ducts conditions, including gallstones (Freeman, 1997), inflammatory strictures (scars), leaks (from trauma and surgery), and cancer (Costamagna and Mutignani, 2004). ERCP can be performed for diagnostic and therapeutic reasons, although development of safer and relatively non-invasive investigations such as magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound has meant that

ERCP is now rarely performed without therapeutic intent (Tham *et al*, 2007).

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 functioning unit. It takes many years to learn, and repeated practice, in order to master the skill of ERCP and to do it safely. It is important to understand the indications, contraindications, limitations, and complications of the individual procedures when offering ERCP to patients. Also, successful ERCP has replaced surgery as a treatment option for sum difficult pancreatic-biliary diseases; we have also seen problems and complications arising as a result endoscopic treatment. Prospective collection of data and selected randomized controlled studies with long-term follow-up are necessary to evaluate the true value of this technology in the overall care of the patients (Cotton *et al*, 2005).

The complications of ERCP can be divided into those potentially associated with the

type of the endoscopy, such as perforation, complications related to the use of sedative and narcotic analgesic drugs, and those particular to ERCP, such as pancreatitis and sepsis with regard to general complications (Iber *et al*, 2006).

The aim of the present study was to evaluate the ERCP unit of Sayed Galal University according to safety, efficacy and complications in diagnosis and management of biliary obstruction by a retrospective study in comparison with other centers.

Subject and Methods

This study included 318 patients with obstructive jaundice. All patients were applied for ERCP Unit of Sayed Galal University Hospital from January 2012 to December 2016. The records of the patients were retrospectively reviewed for age and sex, indications for ERCP, success rate, type and number of the additional therapeutic endoscopic procedures, complications and associated morbidity and mortality rate.

Study design: Clinical, laboratory data, ultrasound, ERCP reports and X-Rays of the cases coming to do ERCP were collected. These patients were already diagnosed as obstructive jaundice by clinical picture, laboratory, and ultrasonography, radiologic and referred to the ERCP Unit. The selected cases were 318 patients suffered from the obstructive jaundice.

Informed consent: The patients were made aware of whom operator would be, the specific benefits, the risks associated with procedures and possible alternatives during procurement of informed consent (Cotton *et al*,

1994).

Preparation: Preparing a patient for ERCP differed from other ones, as in hypertension and/or diabetic patients it was recommended to take the usual medications, but in a patient with cardiac and/or with blood disease special precautions should be taken. However, all patients must be fasting as least 8 hours prior to the endoscopy. Prior to starting the procedure, endoscopist should review the indication carefully, taking into account the latest radiological and laboratory information (Cotton *et al*, 1991).

ERCP procedures: An aseptic technique is maintained throughout the procedure. Some patients are at high risk of developing post ERCP septic complications; this is avoided by proper sterilization and disinfection of the endoscope and associated equipments by first removal of physical depress and then chemical neutralization of all microbiological agents in addition to the use of prophylactic antibiotic that is secreted in the bile before ERCP by 48 hours and after ERCP for 5 days (Cotton *et al*, 2009).

Endoscopic management: ERCP managed patient with proper Sphincterotomy either using the Sphinctrotome or needle knife for the missed stones, stone extraction was done either by balloon extraction, or by basket for stricture in some cases retension cholangiogram was used (Balloon was introduced in CBD, inflated and dye was injected under pressure). Dilatation only was done for some cases and others needed stent was applied as well. Patients without managed complications by ERCP were referred to surgery.

Results

The results are given in tables (1, 2, 3, 4, 5, 6, 7, 8 & 9).

Table 1: Age range of patients:.

Age distribution	Number	Percent
<60	240	75.47
>60	78	24.53

Table 2: Sexes of patients:

No. of cases = 318	Male		Female	
	<60	>60	<60	>60
Number	70	24	200	24
Percent	74.47	25.53	89.2	10.8

Table 3: Indications of ERCP in group was enumerated.

	Indications	<60 (%)	>60 (%)
1	Dilated CBD and/or high serum bilirubin level	90 (28.3)	91 (28.6)
2	Mild dilatation of CBD with mild elevation of S. Bil, GGT & ALP	60 (18.86)	60 (18.86)
3	Normal bilirubin level with mild elevation of GGT & ALP	10 (3.2)	0
4	Typical biliary colic with markedly distended calcular G.B.	5 (1.6)	0
5	Choledochal cyst	1 (0.3)	0
6	Pancreatic cyst	1 (0.3)	0

Table 4: Abdominal U/S:

Finding	<60 (%)	>60 (%)
C.B.D		
a- Normal C.B.D	8 (2.5)	0
b- C.B.D Stone	120 (37.7)	30 (9.4)
c- Malignancy	5 (1.6)	55 (17.2)
d- Dilated with apparent cause	75 (23.6)	25 (7.8)
Liver		
a- Normal	200 (62.8)	40 (12.5)
b- Enlarged	26 (8.1)	20 (6.2)
c- Cirrhotic	12 (3.7)	20 (6.2)
d- FHL	5 (1.6)	15 (4.7)
Spleen		
a- Normal	250 (78.6)	36 (11.3)
b- Enlarged	5 (1.6)	25 (7.8)
c- Splenectomy	2 (0.5)	0
Ascites	5 (1.6)	13 (4.1)

Table 5: Endoscopic sphincterotomy and stone extraction with a balloon or a wire basket successful in over 90% of cases, Precut or needle knife papillotomy necessary:

Variant	<60 (%)	>60 (%)
Stone extraction	130 (86.6)	5 (3.4)
Plastic stent without extraction	12 (8)	3 (2)

Table 6: Complications of ERCP

Complication	<60 (%)	>60 (%)
Total number and percent of complicated cases	6 (1.8)	10 (3.2)
Acute pancreatitis	3 (18.7)	4 (25)
Bleeding	1 (6.2)	2 (12.3)
Perforation	0	2 (12.3)
Acute cholangitis	0	2 (12.3)
Major premedication problems	1 (6.2)	0
Death	1 (6.2)	0

Table 7: Success and failure

Item	Success		Failure	
	<60 (%)	>60 (%)	<60 (%)	>60 (%)
Number	200	100	8	10
Percent	62.9	31.4	2.5	3.1

In failure, percutaneous trans-hepatic catheterization or drainage was successful up to 95% of cases, and a stent internalized eventual, depended on patients' prognosis. Use

of self-expanding metallic stents with prolonged patency (272 days vs. 96 days) associated with decreased hospitalization costs compared to plastic stents.

Table 8: Sixty-five stents applied with 28 plastic stents and 37 metal stents.

Item	Plastic stents		Metal stents	
	<60 (%)	>60 (%)	<60 (%)	>60 (%)
Number	25	3	7	30
Percent	38.46	4.61	10.77	46.15

Table 9: In ERCP failure, only solution PTD gave very high success rates 94.4%.

Item	Success		Failure	
	<60 (%)	>60 (%)	<60 (%)	>60 (%)
Number	5	12	0	1
Percent	27.7	66.6	0	5.6

Discussion

ERCP is particularly useful in the management of the jaundiced patient suspected of having biliary obstruction. Since its introduction in 1968, endoscopic retrograde cholangiopancreatography (ERCP) has become a commonly performed endoscopic procedure. The diagnostic and therapeutic utility of the ERCP was well demonstrated for a variety of disorders, including the management of biliary malignancies and the evaluation and treatment of benign and malignant disease of the pancreas (Mallery *et al*, 2003). ERCP has become popular worldwide because it can provide significant benefit in many clinical contexts. Sadly, it caused considerable harm in a small number of patients. Thus, it is crucial for practitioners and potential patients to understand the predictors of benefit, and of risk. Defining positive and negative outcomes has been a significant challenge, but much useful information has been gathered from increasingly sophisticated studies over the last 2 decades (Cotton, 2002).

NIH (2002) reported that in choledocholithiasis diagnosis, magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and ERCP have comparable sensitivity and specificity. Patients underwent cholecystectomy did not require ERCP preoperatively if there was low probability of having choledocholithiasis. Laparoscopic common bile duct exploration and postoperative ERCP were both safe and reliable in clearing common bile duct stones. ERCP with endoscopic sphincterotomy (ES) and stone removal was a valuable therapeutic modality in choledocholithiasis with jaundice, dilated common bile duct, acute pancreatitis, or cholangitis. In patients with pancreatic or biliary cancer, the principal advantage of ERCP was palliation of biliary obstruction when surgery was not elected. In patients who have pancreatic or biliary cancer and who were surgical candidates, there was no established role for preoperative biliary drainage by ERCP. Tissue sampling for patients with pancreatic or biliary cancer not

undergoing surgery might be achieved by ERCP, but this was not always diagnostic. ERCP is the best means to diagnose ampullary cancers. ERCP has no role in the diagnosis of acute pancreatitis except when biliary pancreatitis was suspected. In patients with severe biliary pancreatitis, early intervention with ERCP reduces morbidity and mortality compared with delayed ERCP. ERCP with appropriate therapy proved beneficial in selected patients who have either recurrent pancreatitis or pancreatic pseudocysts. Patients with type I sphincter of Oddi dysfunction (SOD) responded to endoscopic sphincterotomy (ES). Patients with type II SOD must not undergo diagnostic ERCP alone. If sphincter of Oddi manometer pressures are >40 mmHg, ES is beneficial in some patients. Avoidance of unnecessary ERCP is the best way to reduce the number of complications. ERCP should be avoided if there is a low likelihood of biliary stone or stricture, especially in women with recurrent pain, a normal bilirubin, and no other objective sign of biliary disease. Endoscopists carrying out ERCP should have good training and expertise before performing advanced procedures. With newer diagnostic imaging technologies emerging, ERCP was evolving into a predominantly therapeutic procedure. The complication rate associated with these techniques was reflecting greater technical difficulties (Maydeo and Bhandari 2007).

In case of ERCP failure, percutaneous trans-hepatic catheterization or drainage is successful in up to 95% of cases, and a stent was internalized eventual, depending on the patients' prognosis. As in endoscopic approach, the use of the self-expanding metallic stents with prolonged patency (272 days vs. 96 days) was associated with decreased hospitalization costs when compared to plastic stents.

Combined percutaneous approach showed 80% success rate but was associated with 30% complications as pain, hemorrhage, perforation, cholangitis and bile leaks, but

rarely used (Dowsett *et al*, 1989).

Endoscopic bile duct stents have a role in the treatment of both malignant and benign biliary strictures, as well as; in the post-operative bile duct injuries or leaks (Vitale and George, 2009).

In the present study, the cumulative study of 318 patients underwent ERCP reported success rate of 94.3 % and failure rate of 5.7 %, international measures required for a trainee to acquire a level of competence in diagnostic and therapeutic ERCP is at least 180 procedures which allows deep cannulation of the bile duct in 70% to 80% of cases, but, below the optimal standard of 90-95% success rate when performed by experts (Chutkan *et al*, 2006). This agreed with nine conferences with hands-on ERCP training, including 124 patients, were held at 7 endoscopy centers. There were no significant differences in the sex ratio, age, indication, and therapeutic intervention between patients for hands-on training (n=124) and controls (n=124). Success rates and overall complications were similar between groups (91.9% vs. 92.7%, respectively, P = .811; 12.9% vs. 9.7%, respectively, P = .422).

In the present study, ERCP was presented as the dilated CBD and/or high serum Bilirubin level was in 181 patients (56.9%), mild dilatation of CBD with mild elevation of serum bilirubin, GGT and ALP was in 120 patients (37.7%), normal bilirubin level with mild elevation of GGT and ALP was in 10 patients (3.2%), typical biliary colic with markedly distended calcular gall bladder was in 5 patients (1.6%), Choledochal cyst was in one patient (0.3 %) and pancreatic cyst was in one patient (0.3%).

The present patients showed dilated CBD as general in 310 patients and normal in 8 patients. More over intrahepatic biliary radicals (IHBR) was dilated in 191 patients (60 %) and normal in 127 patients (40%).

The ultrasonographic indications of ERCP was reported in table 8 as showed 150 CBD stone that presents 47.2 % of all cases, malignancy in 60 patients (18.8%), dilated

CBD without detection of the cause in 100 patients and 8 normal CBD with clinical symptoms that indicates ERCP need.

The chief advantages in US were the least expensive and invasive imaging technique available. In addition, it allows for the evaluation of adjacent structures such as the kidney and aorta. It can detect calculi in the gallbladder with 98% sensitivity and 93.5-97.7% specificity (Cooperberg and Burhenne, 1980). It can detect the presence of obstruction with a sensitivity and specificity as high as 91% & 95%, respectively.34 A dilated common bile duct (CBD) (more than 5mm) was diagnostic of extrahepatic obstruction. The only caveat is post cholecystectomy and liver transplant patients, who may have a slightly dilated common duct without obstruction. Sensitivity is lower (75%) for detecting choledocholithiasis, partly due to overlying duodenal gas (Laing *et al*, 1984). US are less accurate than CT or ERCP in determining the cause and site of obstruction according to a prospective study of 220 patients (Pasanen *et al*, 1993). Other disadvantage was that US operator locally used and not available at all hospitals 24 hours a day. This agreed with Williams *et al*. (2007) who found that ultrasonography was a non-invasive technique and a primary scanning procedure in cases of jaundice and in detection of biliary tract dilatation with assessing the kevek of obstruction. They also stated that ultrasonography defines the level of obstruction in 95% of cases.

Endoscopic sphincterotomy and stone extraction with a balloon or a wire basket is successful in 90% of cases, Precut or needle knife papillotomy may be necessary, else, plastic stent application was necessary for drainage of retained mud and pus until another solutions is done as retrial with ERCP or surgical interference.

Abdel Wahab *et al*. (2013) reported that regarding to the type of intervention, 14% of patients had endoscopic sphincterotomy but, 5.6% exposed to pre-cut papillotomy. Also, 7% had stent placement without sphinctero-

tomy or pre-cut, and 22% had stone extraction. Also, endoscopic sphincterotomy with stent placement constituted about 61% while pre-cut papillotomy with stent placement constituted 6%. Regarding the endoscopic sphincterotomy, about 52% were wide papillotomy while about 48% were small papillotomy. Regarding the stent placement, 99% were plastic stent, and a case (1%) was metallic stent from those 98% were single and only 2 cases (2%) were double stents, about 41% due to stones, 38 due to stricture and 2 cases (1.4%) due to bile duct injury post cholecystectomy. As to stone extraction, 31 cases (100%) were completely removed; 80% by balloon, 6.5% by basket and 13% by combined method (balloon and basket).

Complications of ERCP was collected and enumerated in the present study that gave a 16 overall complications as 5% of the cases, endoscopic approach was less in complications than Percutaneous approach and combined approach, Complications limited to pancreatitis (43.7% of overall complications) that was the most common complication (if dye was injected in the pancreatic duct), cholangitis (12.5% of overall complications) or bleeding (18.8% of overall complications) due to excessive sphincterotomy, infection, perforation or dead (1 patient) but the percutaneous approach and combined approach can cause more complications as pain, perforation, cholangitis and bile leaks. This agreed with Gurung *et al.* (2014) who stated that the commonest complication was acute pancreatitis in 17(4%), post-ERCP cholangitis 6(1.4%), bleeding 6(1.4%), duodenal perforation in 1(0.2%), arrhythmia in 1(0.2%) and one death (0.2%).

In the present study, the total number of stents applied was 65 stents with 28 plastic stents and 37 metal stents, the plastic stents were applied in cases of huge CBD stone or strictures until other surgical solution is done as CBD exploration and T-tube application or Choledocojejunostomy in cases of CBD injury, and metal stents were preferred in cases of cholangiocarcinomas, cancer

head of pancreases or FHL that causes pressure manifestations until other oncological solution done if available. This was in against Abdel Wahab *et al.* (2013) who stated that the stent placement, 99% were plastic stents, and I case (1%) was metallic stent from those 98% were single and only 2 cases (2%) were double stents, about 41% due to stones, 38 due to stricture and 2 cases (1.4%) due to bile duct injury post cholecystectomy. Liao *et al.* (2009) in China evaluated the success rate and complications of therapeutic ERCP among patients who participated in live demonstrations. All the patients who underwent therapeutic ERCP during live demonstrations at gastrointestinal endoscopy conferences in China between January 2002 and December 2007 were included. They concluded that although the success rate of therapeutic ERCP performed during live demonstrations was lower than that of routine procedures, the overall complication rate did not significantly increase. ERCP performed by visiting endoscopists was as safe as that done by local faculty in live demonstrations. Choudhary *et al.* (2014) in USA stated that the early precut technique for common bile duct cannulation decreases the trend of post-ERCP pancreatitis. El Nak-eeb *et al.* (2015) in Egypt evaluated the efficacy of intraoperative endoscopic retrograde cholangio-pancreatography (ERCP) combined with laparoscopic cholecystectomy (LC) for patients with gall bladder stones (GS) and common bile duct stones (CBDS). They concluded that hepatobiliary surgery proved to be an important field of surgery. Hepatobiliary surgeon must be acquainted with the operative ultrasound, endoscopy and ERCP as third hand to expand field of therapeutic options that might limit loss time in difficult biliary situations.

Conclusion

ERCP is a relatively safe endoscopic procedure; however, there was the potential for severe life-threatening complications. The overall complication was 5%. The commonest one was port-ERCP pancreatitis of com-

plicated cases (43.7%), post-ERCP cholangitis (12.5%), major medication problems (6.25%) and post-ERCP bleeding (12.5%).

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