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SAFETY AND EFFICACY OF ERCP IN OUR INSTITUTION: REVIEW OF 168 CASES

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Abstract: - Background and aims: The objectives of our study were to evaluate the efficacy and safety of this technique performed by two endoscopists with basic training in a center of this nature.

Patients and methods: Single center retrospective study of the 168 ERCP performed in our hospital and comparing them with the quality standards proposed in the literature.

Results: In this trial, a total of 168 ERCP procedures performed in 153 patients at the endoscopy department of our hospital between January 2010 and December 2010, were retrospectively evaluated. The age, gender, complaints, pre-procedure diagnosis, the radiologic and clinical results, number of procedure repetitions and the final diagnosis were assessed. During the procedure basic patient monitoring was performed. The patients were those admitted to our hospital or referred from other healthcare centers.

Conclusions: the results obtained after performing 168 procedures support the ability to practice ERCP in University Clinical Centre of Kosova obtaining levels of efficacy and safety in accordance with published quality standards.

Keywords: Expert biliary endoscopist; repeated ERCP; cannulation; sphincterotomy; ERCP diagnosis; biliary cannulation; learning curve.

Introduction

Endoscopic retrograde cholangio-pancreatography (ERCP) is an important diagnostic and therapeutic technique in patients with hepatobiliary and pancreatic diseases. The success of this technique depends on a number of factors including the primary pathology, availability of the good endoscopic equipment and accessories, the endoscopist's skill and experience and well trained support [1]. Successful and safe cannulation of the choledochus represents the most considerable step of the diagnostic and therapeutic procedures [2-4].

Cannulation procedure is reported to achieve a success rate of 80-95% when performed by experienced endoscopists [5-8].

In cases where selective cannulation is not feasible, generally precut papillotomy techniques are performed. However, ERCP has potential serious complications, such as pancreatitis, bleeding, cholangitis and perforation that are more common upon the use of precut techniques [5, 9-11]. But, in experienced hands the rate of these complications increases significantly and is safe and very effective method in decompression of the biliary and pancreatic ducts.

To increase the safety and reduce the ERCP-associated complication risk, it is important to have an experienced endoscopist, avoid unnecessary procedures, make adequate preparation before the procedure and operate cautiously [11]. The failure rate for cannulation of the duct of interest at ERCP ranges from 5% to 15% [12,13]. Successful cannulation rate in our study was 91.1 %. Depending on clinical indications, a failed first attempt may lead to a repeat examination, an alternative diagnostic test, or follow-up clinical evaluation.

Material and Methods

This retrospective study was performed in endoscopy surgery department in University Clinical Centre of Kosova. A total of 168 ERCP procedures performed in 153 patients between January 2010 and December 2010, were retrospectively evaluated. The age, gender, complaints, pre-procedure diagnosis, the radiologic and clinical results, number of procedure repetitions and the final diagnosis were assessed. All of the procedures were performed by the same team of endoscopists with compatible levels of ERCP experience (mean 5 years). The ERCP procedures were performed under deep sedation and basic monitorisation standards by anesthesiologists.

The prophylactic antibiotic was given before the procedure. Before starting, the ERCP we made a double estimation of the number of procedures that could be performed annually at our center. On the one hand, considering the formula published by British authors indicating ERCP averaging 0.9 per 1,000 inhabitants/year [14]; and on the other, comparing ERCP performed by other hospitals of similar size and assigned population in our setting. In both cases, the estimated ERCP per year was more than 100 procedures, which would allow each endoscopist practicing at least 40 annual sphincterotomies [15] or 50 ERCPs/year [16-18]. In our clinic average 200 ERCP per year. To meet these needs, it was decided to assign two endoscopists, one nurse and one nursing assistant to perform the explorations, radiologist and radiologist assistant.

According to the technical complexity we started to perform those with lower difficulty (level I according to Schutz scale, Table I) and gradually we performed more complicated explorations (levels II, Table 1). The only complex maneuver we used from the beginning in case of difficult cannulation was the precut technique. We have designed a protocol for patients who are candidates for ERCP: Both individuals hospitalized as outpatients are evaluated by a gastroenterologist before proceeding who confirmed adequate indication of the test, a preoperative study (hemogram, PT/INR, electrocardiogram and chest radiograph) and are evaluated by an anesthesiologist. Information on each patient was recovered by performing a retrospective chart review and included in a database.

Table 1. Levels of difficulty in ERCP (modified from Chutkan et al.) (15).

Level I: Diagnostic cholangiogram
Diagnostic pancreatogram Biliary brush cytology Pancreatic cytology Standard sphincterotomy Removal of bile duct stones < 10 mm Stricture dilatation / stent / nasobiliary drain for extrahepatic stricture or bile leak
Level II: Diagnostic cholangiogram with Billroth II anatomy
Diagnostic pancreatogram with Billroth II anatomy Removal of bile duct stones > 10 mm Minor papilla cannulation Stricture dilatation / stent

The procedure was established as follows: the nurse helped the main endoscopist (who performed the procedure) while the other endoscopist remained always in the same room to improve its learning curve. The following devices that we are using for ERCP and other endoscopic procedures: Olympus UES-10, Olympus TJF 240, and Storz Autocon 50 electrocauters, with various ERCP, sphincterotomes, catheters, balloons, lithotripters, forceps and coagulation electrodes.

Ambulatory patients were admitted for 24 hours in the hospital, being discharged the day after the trial in the absence of complications; after discharge all individuals were reviewed in Outpatient Gastroenterology and Endoscopy surgery, 4 weeks later, to confirm adequate clinical course.

Results

In this trial, a total of 168 ERCP procedures performed in 153 patients who required repetition of 15 ERCP procedures, at the endoscopy department of our hospital between January 2010 and December 2010, were evaluated. The age range was 20 to 89 years old and the mean age was 62.33. The 48.4% of the cases were females (n=74) while 51.6% were males (n=79). We analyzed our results in demographic, clinical and technical characteristics (Table 2, 3, 4, 5).

Table2. Demographic characteristics of patients

Gender		**Age (mean)**
Female (n, %)	74 (48.8)	38.9
Male (n, %)	79 (51.2)	50.5

Table 3. Distribution of the pre-ERCP diagnosis (clinical characteristics)

Pre-ERCPdiagnosis (n=410)	**N**	**%**
Choledocholithiasis	49	29.1
Sd.Postcholecistectomy	28	18.3
Biliary Malignancy	3	1.94
Papillary tumor	8	5.19
Pancreatic head cancer	5	3.25
Klatskin tumor	4	2.59
Other indications	71	39.57

The review of the preliminary diagnosis of 154 cases revealed 49 patients with the most common indications choledocholithiasis: 29.1 % (including biliary colic, acute cholangitis or acute pancreatitis), postcholecitectomy 18.3 %,

tumors: 14.5 % [patients with biliary malignancy (1.94 %), 4 patients with Klatskin tumor (2.59 %), 8 patients with papillary tumor 5.19 %, 5 patients with pancreatic head cancer (3.25 %)] and other pathologies: 39.57 % [benign biliary stenosis, chronic pancreatitis or biliary leaks] (Table 3).

The papillotomy, balloon and/or basket catheter, pre-cut papillotomy, biliary stent application, and biopsies, were performed, respectively in 136 (80.9 %), 110 (71.9 %), 21 (13.7%), 17 (10.1%), 20 (11.9%). (Table 3.).

Additional therapeutic endoscopic procedures were performed including endoscopic sphincterotomy or papillotomy in 136 patients (80.9%), precut sphincterotomies were needed in 21 patients (13.7%), biliary balloon application in 110 (71.9%), biliary stone extraction in 53 (31.5%), biliary stenting in 17 (10.1%) (main indications:, biliary malignancy, biliary stenosis or biliary leakage), biliary basket lithotripter application in 8 (5.2%), taking biopsies 20 (11.9 %) (Table 4).

Table 4: Distribution of invasive procedures (technical characteristics)

Invasive procedures performed	n	%
Applicationofballoonand/ orbasket catheter	110	71.9
Papillotomy	136	80.9
Biliary stone extraction	53	31.5
Pre-cut papillotomy	21	13.7
Applicationof biliarystent	17	10.1
Taking biopsies	20	11.9
Sclerotherapy	2	1.19
Mechanical lithotripsy	8	5.2

Generally more than one invasive procedure is applied on the same patient (for example: papillotomy + balloon and basket catheter application), so the numbers and percentages may be a bit confusing.There are 15 cases (8.9 %) who had repeated procedure due to infeasibility of cannulation. Among these 15 cases, the reasons for repeat procedure were as follows: 4 patient intolerance or premedication problems, 6 stenosis of pylorus or duodenal bulbs diverticuls, 1 complete papillary obstruction, and 4 papillary position abnormality (Table 5).

Table 5: Reasons for repeat ERCP (n=15)

Reasons for repeat ERCP(n=15)	n	%
Patient intolerance or premedication Problems	4	2.6
Stenosis of pylorus or duodenal bulbs Diverticuls	6	3.9
Complete papillary obstruction	1	0.65
Papillary position abnormality	4	2.61

Discussion

Successful cannulation of the pancreatic and bile ducts can be achieved in greater than 90% of cases in experienced hands. Failed cannulation happens even in experienced hands [12,13]. The reasons for failed ERCP in general include anatomic variation (eg Billroth II anastomosis), obstructive processes that preclude access to the duodenum and major papilla, complete obstruction of the duct of interest, inadequate patient sedation, poor

patient tolerance of endoscopy, and lack of endosopic expertise [19].In our study was unsuccessful cannulation were: patient intolerance or premedication problems, stenosis of pylorus or duodenal bulbs diverticuls, complete papillary obstruction, papillary position abnormality. When cannulation fails, patient management alternatives include; 1-omit ductography in management decisions, 2-obtain ductography via percutaneous route, 3-perform precut sphincterotomy,4-surgical exploration with intraoperative ductography, 5-repeat ERCP[20]. We have done the fifth one in these cases. The procedures of ERCP have been put into practice in 2002 at our institution and the number of cases undergoing these procedures is progressively increasing. Approximately 1900 ERCP procedures have been performed between January 2002 and the end of December 2012, average 200 ERCP/ year. In this trial, a total of 168 ERCP procedures performed in 153 patients who required repetition among 15 ERCP procedures at the endoscopy department of our hospital between January 2010 and December 2010, were retrospectively evaluated. The review of the preliminary diagnosis of 154 cases revealed 49 patients with choledocholithiasis, postcholecistectomy, 3 patients with biliary malignancy, 4 patients with Klatskin tumor, 8 patients with papillary tumor, 5 patients with pancreatic head cancer.

The review of the cases requiring repeated ERCP procedure patient intolerance or premedication problems, stenosis of pylorus or duodenal bulbs diverticuls, complete papillary obstruction, papillary position abnormality. The investigation of the interventional procedures performed revealed 136 papillotomy, 110 balloon and/or basket catheter, 21 pre-cut papillotomy, 17 biliary stent application, 20 taking biopsy. During the procedure, cannulation may not be feasible due to reasons related to duodenum or papilla. Duodenal diverticula is the most common cause among the cases requiring repetition with a rate of 3.57 %, followed by protrusion of papilla due to enclaved stone at a rate of 2.97%. In cases where drainage is blocked due to various reasons during cannulation, a biliary stent may be inserted. Various complications may develop during or after the ERCP procedure. Pancreatitis is a common complication occurring after ERCP. Hemorrhage, perforation, cholangitis, cholecystitis and cardiopulmonary complications may occur [21]. In our study the most common complication was acute pancreatitis, which was seen in 4 patients (2.38%). No patient died. The experience that the endoscopist and his/her team have, is of great significance. At our medical center, all of the procedures were performed by the same team of endoscopists with compatible levels of ERCP experience (Mean 6 years). Being a referral center itself, we did not have the option of sending patients to another ERCP-performing center, so we performed repeat ERCPs with the same crew resulting in satisfactory outcomes.

In conclusion, although this study has some limitations inherent to its retrospective nature, we believe that the practice of ERCP in our hospital reached adequate levels of efficacy and safety, consistent with quality standards proposed in the literature.

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