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Role of Early Endoscopic Retrograde Cholangiopancreatography (ERCP) In Management of Acute Biliary Pancreatitis

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Abstract

Acute pancreatitis is a common condition that has been the cause of extreme suffering, morbidity, and vast expenditure to the health care system worldwide. The incidence of 5-30 cases per 100,000 has been reported and is said to be increasing recently .One of the most common form of this disease is 'biliary pancreatitis' which is thought to result from temporary obstruction of the bile and pancreatic ducts, resulting in the reflux of bile and duodenal content and/or rise of hydrostatic pressure into the pancreatic duct .Usually, obstruction either can be constant (stone impaction in the ampulla) or intermittent (passage of multiple stones through ampulla). In those instances when gallstones are impacted at the ampulla of Vater, cholangitis and pancreatitis may develop, and timely extraction or removal is crucial for the improvement of patient's clinical condition. Outcome of the disease is therefore largely affected by the early resolution of obstructing stone.

The success rate for stone clearance in isolated ERCP (Endoscopic Retrograde Cholangiopancreatography) treatment is up to 87% to 97%, however up to 25% of patients require two or more ERCP treatment. Furthermore, complications such pancreatitis, haemorrhage, cholangitis, duodenal perforation (5% to 11%) are associated with ERCP and it accounts for mortality of up to 1% along with failure rates of 5% to 10%. Moreover, performing ERCP in the setting of acute pancreatitis can be especially challenging because at the said time patient's duodenum and ampulla are swollen and physical condition is compromised. Therefore, the role of early ERCP in acute biliary pancreatitis remains conflicted with a number of clinical trials and meta analyses producing contradicting results. In light of the somewhat confusing and partly conflicting outcomes of the various studies, we performed a review to determine whether there is consensus in published studies.

Keywords: ERCP, CBD stones, Acute Pancreatitis.

Introduction

The complicated presentation of acute pancreatitis is accountable for local injury, systemic inflammatory response syndrome (SIRS), and multiple organ failure. Acute pancreatitis is a common condition that has been the cause of extreme suffering, morbidity, and vast expenditure to the health care system worldwide. The incidence of 5-30 cases per 100,000 has been reported and is said to be increasing recently [1]. Apart from alcohol abuse, one of the most common form of this disease is 'biliary pancreatitis' which is thought to result from temporary obstruction of the bile and pancreatic ducts, resulting in the reflux of bile and duodenal content and/or rise of hydrostatic pressure into the pancreatic duct [2]. Usually, obstruction either can be constant (stone impaction in the ampulla) or intermittent (passage of multiple stones through ampulla). In those instances when gallstones are impacted at the ampulla of Vater, cholangitis and pancreatitis may develop, and timely extraction or removal is crucial for the improvement of patient's clinical condition. Outcome of the disease is therefore largely affected by the early resolution of obstructing stone [3]. Since most of the gallstones spontaneously proceed to the duodenum, majority of acute biliary pancreatitis are self-limiting and conservative treatment is sufficient. The success rate for stone clearance in isolated ERCP (Endoscopic Retrograde Cholangiopancreatography) treatment is up to 87% to 97%, however up to 25% of patients require two or more ERCP treatment [4]. Furthermore, complications such pancreatitis, haemorrhage, cholangitis, duodenal perforation (5% to 11%) are associated with ERCP and it accounts for mortality of up to 1% [5] along with failure rates of 5% to 10%. Also, when

patients proceed to ERCP, a significant number of them may not have stone. According to a study, rate of negative ERCP vary from 15% to 25% [6]. Moreover, performing ERCP in the setting of acute pancreatitis can be especially challenging because at the said time patient's duodenum and ampulla are swollen and physical condition is compromised. Therefore, the role of early ERCP in acute biliary pancreatitis remains conflicted with a number of clinical trials and meta-analyses producing contradicting results [7]. In light of the somewhat confusing and partly conflicting outcomes of the various studies, we performed a review to determine whether there is consensus in published studies.

Pathophysiology

Eugene Opie put forward the common channel hypothesis in 1901 which proposed that a gallstone transiently lodged in the distal common channel of the ampulla of Vater allowed bile to reflux into the pancreatic duct [8]. More likely cause of ABP (Acute Biliary Pancreatitis) are said to be the biliary crystals or small stones which are more prone to negotiate cystic duct and papillary migration [9]. Another proposed theory is that passage of a stone through the sphincter causes transient incompetence of sphincter allowing duodenal fluid and bile reflux into the pancreatic duct. Relaxation of the papillary sphincter following the recent passage of stones which can obstruct the pancreatic juice flow or favour duodenopancreatic reflux, respectively [10]. A third possibility is obstruction of the pancreatic duct due to gall stones, leading to ductal hypertension. This causes minor ductal disruption, extravasation of pancreatic juice into the less alkaline interstitial of the pancreas, and promotion of enzyme activation. In cases where other etiological factors are not evident, there is still the possibility of finding microlithiasis, seen as birefringent crystals, on microscopy of bile [11]. This occult microlithiasis is probably responsible for up to half of those with idiopathic acute pancreatitis.

Distinguishing biliary from other forms of pancreatitis

Usually, diagnosis of acute pancreatitis is straightforward requiring at least 2 of 3 criteria to be fulfilled. Abdominal pain, typically located in the upper abdomen and often radiating to the back; serum amylase and/or lipase increased 3 times greater than the upper limit of normal (lipase is more sensitive, specific, and remains increased longer than amylase); and/or radiographic evidence of pancreatitis on Computed Tomography scan (CT) [12]. Although gallstone pancreatitis is the most common cause of pancreatitis, other aetiologies must be contemplated before initiating treatment. If ABP is not diagnosed in a timely fashion, the potential for benefit with endoscopic therapy may be lost. There's an increased number of patients with AP of the ages 40 to 49 years and older than 70 years. Alcoholic and hyper triglyceridemic AP is higher in patients younger than the age of 50 years, and biliary pancreatitis higher in patients older than 70 years [13]. Any previous history of biliary colic in the past may suggest a biliary cause, but laboratory studies and imaging are most helpful to establish the diagnosis of ABP. Serum alanine aminotransferase increase of at least 3 times the upper limit of normal has been shown to have a positive predictive value of 95% for ABP [14]. Appearance of gallstones on abdominal imaging further supports the diagnosis of gallstone pancreatitis.

The presence of choledocholithiasis on trans-abdominal ultrasound is relatively specific; however, the sensitivity of ultrasound for common bile duct (CBD) stones is low therefore, its role in the diagnosis of choledocholithiasis is less certain [15]. CT of the abdomen with contrast generally has a limited role in the initial evaluation of patients who have acute pancreatitis. However, CT may be helpful to rule out other important causes of abdominal pain and to identify mass and cystic lesions of the pancreas. Magnetic resonance cholangiopancreatography and endoscopic ultrasound may be helpful in some cases to diagnose choledocholithiasis but are of limited benefit for showing gallstones in the absence of choledocholithiasis [16].

Determining Ongoing Biliary Obstruction

Clinical condition of the patient and trend of laboratory values are the most helpful parameters for recognizing ongoing biliary obstruction. Unremitting pain and increasing liver function test abnormalities may indicate ongoing obstruction caused by an impacted stone. Acosta and colleagues [17] reported that decreasing severity of abdominal pain, decreasing serum bilirubin, and presence of bile in a nasogastric tube aspirate strongly suggested ampullary stone decompression. Diagnosis of choledocholithiasis (without ampullary stone impaction) is important but not with respect to the potential need for urgent intervention. Endoscopic ultrasonography has a high sensitivity for diagnosis of bile duct stones [18]. Clinical criteria and ordinary laboratory determinations are sufficiently accurate to discriminate between patients with ABP and those with other acute abdominal pathologies. Careful monitoring of patients' pain, quality of nasogastric aspirate, and serum bilirubin level can accurately identify the few cases with persistent ampullary obstruction. Those patients can then be selected for intervention to restore the ampullary patency and prevent progression of acute pancreatitis [19].

Estimating the likely severity of the attack

The revised Atlanta classification is used to define severity of pancreatitis as follows [20].

Mild acute pancreatitis

i. No organ failure or local or systemic complications.

ii. Most episodes of pancreatitis are mild and self-limiting, lasting less than 7 days.

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Moderately severe acute pancreatitis

i. Transient organ failure of less than 48 hours or local complications (peripancreatic fluid collection, pancreatic necrosis) or systemic complications (exacerbation of pre-existing disease).

Severe acute pancreatitis

i. Persistent organ failure of greater than 48 hours.

ii. High mortality rate of 20%-30%.

During the course of acute pancreatitis, there are two peaks of mortality categorized as; early (within the first 2 weeks) and late. The mortality rate is strongly associated with the degree of multiorgan failure, but the causes in early and late mortality are different. During the early phase of AP relative mortality rates range from about one third to more than a half of the deaths [21], secondary to systemic inflammatory response. Infection of pancreatic necrosis leads to septic complications which in turn cause multi-organ dysfunction syndrome (MODS) and are the major cause of deaths lately [22]. It is essential to recognize patients at risk of developing severe acute pancreatitis at an early stage in order to optimize therapy and intensive monitoring. The Ranson score [23] is the most commonly used way to predict the severity of acute pancreatitis. The modified Ranson's criteria are used to assess gallstone pancreatitis, have a max score of 10. Five parameters assessed on admission and the other 5 at the 48-hour mark. Other grading systems, such as the Glasgow (or Imrie) score [24], may be more accurate in the specific case of gallstone pancreatitis. Unfortunately, both the Ranson and Glasgow systems take 48 h for full assessment to be completed. The APACHE-II (Acute Physiology and Chronic Health Evaluation II) and serum hematocrit both remain valid for assessment of severity at presentation [25].

Combining an obesity score with the APACHE-II seems to improve accuracy for prediction of severe or mild acute pancreatitis. obesity increases the severity of AP by amplifying the immune response to injury [26]. Serum hematocrit is an indicator of third spacing and volume depletion has proved to be useful in predicting the clinical course of acute pancreatitis. Low hematocrit on admission indicates a low risk of pancreatic necrosis (PNEC) in patients with acute pancreatitis. In contrast, an increase in creatinine within the first 48h is strongly associated with the development of PNEC. This finding may have important clinical implications and warrants further investigation. Nonspecific biomarkers, such as C-reactive protein (CRP) have also been studied as outcome predictors, but it has only been useful for predicting complications, namely necrosis [27].

ERCP in Mild acute Biliary Pancreatitis

Those patients with a predicted mild disease, the potential benefits of ERCP do not outweigh the risks for complications. Therefore, ERCP is not advocated in this group [28]. In certain exceptional scenarios ERCP might serve a role in patients with mild ABP. These include patients who are unfit or unwilling to undergo surgery. Even though it is a well-known fact that patients with GSP have a high rate of recurrence without cholecystectomy, ERCP with sphincterotomy is protective against recurrence of acute pancreatitis. However, because the gallbladder is left in situ, the rates of acute cholecystitis and biliary colic remain elevated [29]. ERCP is thus indicated in patients with ABP who cannot undergo cholecystectomy or will experience a prolonged delay before cholecystectomy.

ERCP in acute biliary pancreatitis with cholangitis

Urgent ERCP (within 24hrs) should be offered to patients with biliary AP complicated by cholangitis [30]. In the absence of cholangitis, the timing of ERCP for AP with persistent biliary obstruction is less clear. A total of 8 RCTs addressed the role of urgent ERCP in the management of patients with acute gallstone pancreatitis [31], Compared to conservative management, urgent ERCP had no impact on critical outcomes, such as mortality and multiple organ failure, and on important outcomes, such as single organ failure (eg, respiratory or renal), infected pancreatic and peripancreatic necrosis, and total rates of necrotizing pancreatitis. A recent systematic review by van Geenen et al. [32] clearly demonstrated that, despite numerous randomized trials, here is an obvious lack of consensus on the indications and timing of endoscopic retrograde cholangiopancreatography (ERCP) in ABP in meta- analyses and nationwide guidelines. Although demonstrated only in one study [33], it was found that there was a reduction in hospital length of stay for patients with ABP undergoing urgent ERCP. All the forementioned findings suggest that early ERCP is not beneficial in patients who have acute biliary pancreatitis without concomitant acute cholangitis. Other systemic review/meta-analyses also showed that regardless of the predicted severity of ABP, early ERCP does not provide benefit over conservative treatment for biliary pancreatitis in the absence of acute cholangitis [34].

ERCP in ABP with biliary tract obstruction

At present there is limited literature to guide decision making of when non-urgent ERCP should be performed in hospitalized patients with ABP with persistent obstruction and no cholangitis. The Cochrane analysis concluded that ERCP should be performed within 72 hours, which associates with a non- significant trend toward reduction in local and systemic complications related to AP [35]. In support of this recommendation, Lee et al. [36] recently performed a retrospective comparison of outcomes in 73 patients with acute biliary pancreatitis with biliary obstruction without cholangitis treated with either urgent ERCP (<24 hours) or early ERCP (24-72 hours). Overall, timing of ERCP had no impact on hospital length of stay, post-ERCP complications, and complications due to pancreatitis, regardless of severity [36]. Practical and informative recommendations for designing future studies were offered in the AGA technical review. The timing of

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the ERCP intervention should be 24-48 hours after diagnosis (24 hours to allow spontaneous passage of stone and 48 hours to ensure that prolonged biliary obstruction does not occur) [37].

Fan et al. [38] evaluated the role of early ERCP in patients with acute biliary pancreatitis prior to the onset of complications, regardless of mild or severe presentation. Within 24 h of presentation, patients were randomized to early ERCP versus conservative treatment with selective ERCP. A significant reduction in progression to biliary sepsis was seen in the early ERCP patients. Interestingly, however, the incidence of local and systemic complications was not significantly different, which suggests that removal of the impacted stone may not reverse the damage already occurring in the pancreas during the first hours or days of the illness.

Acosta, J. M. et al in a prospective randomized clinical trial shows that there is a short period of time not longer than 48 hours from the onset of symptoms (perhaps shorter) when either spontaneous or operative dis-obstruction may prevent the progression of pancreatitis. Furthermore, it shows that, in patients whose obstruction remains at 24 hours, ERCP and ES benefit the outcome of ABP and these patients can accurately be identified on the basis of simple clinical, biochemical, and radiologic criteria [17]. Orı´a and colleagues [39] examined early endoscopic intervention compared with conservative management in patients with acute biliary pancreatitis and obstructive jaundice in one of the randomized, controlled trials. There were no significant differences observed with regard to mean organ failure scores, CT severity index, incidence of local complications, and overall morbidity and mortality. If acute cholangitis can be safely excluded, early endoscopic intervention is not mandatory and should not be considered a standard indication. A multicentre RCT comparing conservative treatment and early ERCP (i.e., within 72 h after symptom onset) for endoscopic papillotomy and removal of common bile duct stones showed that overall complication rates were similar, but complications were more severe in patients randomized to early ERCP [40]. Chang, L. et al. [41] in a prospective randomized trial preoperative versus postoperative ERCP in mild to moderate gallstone pancreatitis without cholangitis, selective postoperative ERCP and CBD stone extraction is associated with a shorter hospital stay, less cost, no increase in combined treatment failure rate, and significant reduction in ERCP use compared with routine preoperative ERCP [41]. Hence, it's evident that the importance of early ERCP ES to restore ampullary patency in patients with ABP, has been addressed in several randomized prospective studies. Despite that, the benefit of this approach remains controversial except for patients with associated cholangitis.

ERCP in Severe biliary pancreatitis without cholangitis or Biliary obstruction

Previous guidelines from 2005 recommended that all patients with severe biliary pancreatitis should have ERCP performed within 72 hours of presentation [42]. However, a recent Cochrane review and meta-analysis has shown that early ERCP does not affect mortality or complications in severe gallstone pancreatitis, and a benefit is only seen in patients with concurrent cholangitis or biliary obstruction [35]. The more recent guidelines both the IAP/APA and ACG guidelines recommending that ERCP should not be performed in all patients with severe biliary pancreatitis unless there is severe biliary pancreatitis with biliary tract obstruction [30,31].

Van Santvoort and colleagues [43] conducted a prospective observational multicentre study that evaluated a subset of patients with predicted severe ABP but without evidence of cholangitis. Patients who had an ERCP within 72 hours of symptom onset were classified as the early ERCP group and almost all (86%) underwent ERCP within 48 hours. Most patients (85%) in the ERCP group underwent therapy that included a biliary sphincterotomy. Patients who did not undergo ERCP or had ERCP later than 72 hours after onset of symptoms were in the conservative treatment group. Seven patients in the conservative group underwent an elective ERCP at a median of 5 days after symptoms (range 4-18 days). In patients with predicted severe ABP and concurrent cholestasis, early ERCP was associated with significantly fewer complications including pancreatic necrosis. Despite the study not being a randomized controlled trial, it still provides favourable observational data for the role of early ERCP in patients with severe ABP. Another multicentre randomised controlled trial by Nicolien at al. concluded that in patients with predicted severe gallstone pancreatitis but without cholangitis, urgent ERCP with sphincterotomy did not reduce the major complications or mortality, compared with conservative treatment. This study supports a conservative strategy in patients with predicted severe acute gallstone pancreatitis with an ERCP indicated only in patients with cholangitis or persistent cholestasis [44]. In a recent meta-analysis, De Coutinho, L. M. A. et al found no statistical difference between early ERCP and conservative treatment in patients with acute biliary pancreatitis, in terms of the occurrence of systemic adverse events, the development of acute cholangitis, and evolution to death [45]. However, the use of ERCP early in the treatment of acute biliary pancreatitis minimizes the occurrence of local adverse events, as well as decreasing the time to pain relief and to a reduction in axillary temperature. In addition, hospital stays were shorter among patients undergoing ERCP than among those undergoing clinical treatment alone. Furthermore, the use of early ERCP in patients with acute biliary pancreatitis could result in cost reductions, regardless of the level of severity.

Chen and colleagues evaluated the efficacy of early endoscopic intervention without fluoroscopy for severe ABP in the intensive care unit [46]. More than 70% of patients randomized to the endoscopic intervention arm underwent ERCP within 48 hours of symptoms; cannulation was reported to be more difficult when performed later. Biliary sphincterotomy with stone removal was completed in 80%. The remaining patients had suppurative

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cholangitis and were treated initially with nasobiliary drainage only. No patients in the conservative arm received ERCP. Patients in the endoscopic intervention group had a significant decrease in severity score at day 10; quicker relief of clinical symptoms including temperature, abdominal pain, and peritoneal irritation; and no mortality. There were 2 deaths in the conservative arm. A meta-analysis of eleven RCTs consisting of 1314 patients (conservative management=662, ERCP=652) were analysed demonstrates a significant decrease in complications in patients with severe ABP managed with early ERCP/ES compared with conservative management. As far as the mortality is concerned, there was a significant decrease was observed in mortality in severe GSP patients treated with early ERCP/ES [47]. In those with mild disease, a strong trend to decreased complications in the ERCP group was seen, however, this was not significant (OR 0.67; 95% CI, 0.43, 1.03; P=0.06) [47].

Currently, an adequately powered, randomized multicentre superiority trial is being conducted by the Dutch Pancreatitis Study Group to study the role of early ERC with sphincterotomy in patients with predicted severe biliary pancreatitis without cholangitis. (APEC trial, Current Controlled Trials number, ISRCTN97372133).

ERCP with sphincterotomy to prevent recurrent acute gallstone pancreatitis:

Cholecystectomy is the most effective method to prevent recurrent acute gallstone pancreatitis. In one of the RCT it was found that same-admission cholecystectomy reduces the risk of gallstone-related complications compared with interval cholecystectomy (risk ratio 0.28) [48]. In a prospective observational study, it was concluded that recurrent gallstone pancreatitis is rare after endoscopic sphincterotomy (ES), and the rate of recurrent pancreatitis was comparable between ES alone and ES with cholecystectomy (2.9% vs. 2.4%) [49]. A national database analysis showed that among patients without cholecystectomy, ERCP was associated with a lower rate of recurrent pancreatitis and severe pancreatitis. Therefore, ES may be an acceptable alternative to cholecystectomy for preventing recurrent gallstone pancreatitis if cholecystectomy is not feasible [50].

Conclusion

Acute pancreatitis is a common and potentially fatal disease. Ascertaining its aetiology on admission is vital for suitable treatment of the disease. Nearly half of the cases of acute pancreatitis are caused by gallstones or “sludge”. One of the first step in determining the biliary origin is by obtaining a detailed history and performing laboratory tests and transabdominal ultrasound. In the acute phase, elevated Amylase (>150 IU/L) is the most sensitive biomechanical marker. MRCP and EUS both have excellent diagnostic accuracy in detecting choledocholithiasis and can be used as second-line diagnostic tools. Early ERCP is only indicated in patients with proven biliary pancreatitis and concomitant cholangitis. It is not indicated in patients with a predicted mild disease course and its role is currently under investigation in those with a predicted severe disease course.

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