

Title:

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DOI: 10.17235/reed.2020.7288/2020 Link: <u>PubMed (Epub ahead of print)</u>

Please cite this article as:

Peñaloza Ramírez Arecio, Rodríguez Tello Dumar, Murillo Arias Andrés, Barreto Pérez Jonathan, Aponte Ordóñez Pedro. Endoscopic Retrograde Cholangiopancreatography Results 3 Days After a Failed Pre-cut . Rev Esp Enferm Dig 2020. doi: 10.17235/reed.2020.7288/2020.

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OR 7288 inglés

Endoscopic retrograde cholangiopancreatography results three days after a failed pre-cut

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Received: 19/06/2020

Accepted: 3/7/2020

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Conflict of interest: the authors declare no conflict of interest.

ABSTRACT

Introduction: deep cannulation of the common bile duct is essential in endoscopic retrograde

cholangiopancreatography (ERCP). However, cannulation is not possible in approximately 20 %

of the cases with the usual techniques. Pre-cutting is an alternative that allows cannulation in

difficult cases although its success is not guaranteed. Repeating the ERCP within three days of a

failed pre-cut is an acceptable option.

Objective: to determine if an ERCP performed three days after a failed pre-cut papillotomy

allows the bile duct to be cannulated without increasing complication rates.

Patients and methods: patients who underwent an ERCP plus pre-cut were included, in whom

the common bile duct could not be cannulated and who also underwent a new ERCP three days

after the initial pre-cut. The primary objective was a successful biliary cannulation in the second



ERCP and the secondary objective were the complications of the initial pre-cut.

Results: forty patients with an average age of 65 years were identified and 57 % were male. The indications for ERCP were choledocholithiasis in 95 %, biliary fistula in 2.5 % and pancreatic neoplasia in 2.5 %. The ERCP was repeated three days later in 92.5 % of the cases and the biliary cannulation was successful in 78.3 %.

Conclusions: a new ERCP performed within three days of a failed pre-cut is justifiable since it has a significant success rate. Bile duct cannulation is achieved in three out of four patients, with an acceptable percentage of complications.

Keywords: Endoscopic retrograde cholangiopancreatography. Endoscopic sphincterotomy. Bile duct. Catheterization.

INTRODUCTION

Deep cannulation of the common bile duct is essential in endoscopic retrograde cholangiopancreatography (ERCP). However, it is not possible to cannulate the bile duct with the usual techniques in approximately 20 % of cases. This occurs in spite of the development of new endoscopic accessories and in centers where there is expertise in performing ERCP (1). The technique of pre-cut papillotomy is a useful alternative that allows selective biliary cannulation in difficult cases. Even so, access to the bile duct cannot be guaranteed.

Currently, there are alternatives to access the common bile duct such as percutaneous transhepatic biliary drainage (PTBD), therapeutic ultrasonography techniques and surgery (2-4). Unfortunately, these techniques are either invasive and involve a considerable morbidity and mortality or are not widely available in all hospitals. An accepted option (5) is access to the bile duct when repeating the ERCP after a failed pre-cut. On these occasions, the orifice of the bile duct appears to be better exposed due to a decrease in the inflammation caused by the procedure. Thus, access to the bile duct is facilitated with success rates that are close to 80 % (5-10). The objective of this study was to determine if an ERCP performed three days after a failed pre-cut papillotomy allows the bile duct to be cannulated without an increase in complication rates.



PATIENTS AND METHODS

A prospective cohort study was performed of all the ERCPs undertaken at a tertiary referral center between September 2015 and September 2018. Clinical, endoscopic, and radiological data were collected from patients for whom access to the bile duct had not been achieved after an ERCP with a pre-cut was performed. A new ERCP was performed three days after the initial pre-cut. The pre-cut was performed early using a needle papillotome after three unsuccessful attempts to cannulate the bile duct. Two techniques were used. The pre-cut papillotomy (freehand) was performed by starting the incision from the papillary orifice and extending it cephalically to the roof of the papilla, whereas the fistulotomy or infundibulotomy was performed starting from the papilla dome in an ascending or descending direction based on its orientation and creating a choledochoduodenal fistula. In both cases, targeted cuts were made between the 9 o'clock and 11 o'clock positions. The incision was made using pulses of 1-2 mm with a depth of no more than 3 mm. The pre-cut technique was chosen based on the operator's criteria.

ERCPs that were repeated at a time interval other than three days, patients with a history of surgical or endoscopic manipulation of the papilla of Vater or those with an alteration in the digestive tract as a result of previous surgical procedures were excluded. All procedures were performed by two gastroenterologists with more than 15 years of experience in therapeutic endoscopy and had performed more than 1,500 ERCPs. Every patient agreed to undergo the procedure and signed the informed consent.

The main evaluation criteria were success when repeating the ERCP three days later to gain biliary access and the complications during the initial pre-cut, mainly acute pancreatitis, hemorrhage or retroduodenal perforation.

Statistical analysis

Descriptive statistical parameters were applied for categorical variables, reported as frequencies and percentages in the statistical analysis. Continuous variables are summarized using central tendency and dispersion measurements (means and standard deviations or medians and IQR).



The Stata 13® program was used. This study was approved by the Ethics and Research Committee of Hospital de San José.

RESULTS

Over a period of three years, 798 ERCP were performed. In 40 cases, pre-cut papillotomy was performed without achieving biliary access in the first ERCP. The therapeutic indications for ERCP were choledocholithiasis in 95 % of cases, biliary fistula in 2.5 % and cancer of the head of the pancreas in 2.5 %. The average age of the cohort was 65 years (range 34-92) and 57 % were male (Table 1). Of the 40 patients, 37 (92.5 %) underwent a new ERCP within three days of a pre-cut or failed fistulotomy and a successful biliary cannulation was achieved in 28 (75.6 %). Regarding the technique of the procedure used, pre-cut papillotomy was performed in 80 % of cases and infundibulotomy was performed in 20 % of the patients. The success of biliary cannulation with a pre-cut starting from the papillary orifice was 71.8 % and 62.5 % with infundibulotomy. An intradiverticular and peridiverticular papilla was found in 17 % of the cases. Of these, cannulation of the bile duct was successful in 85 % within three days of the initial precut.

Access to the bile duct during the second ERCP was not achieved in nine (24.4 %) patients using the usual cannulation techniques. On one occasion, it was possible to cannulate the bile duct with a second pre-cut, which would increase the success rate of the second ERCP to 78.3 %. Seven underwent cholecystectomy plus open bile duct exploration. Another patient underwent a laparotomy and an unresectable mass in the head of the pancreas was found. The final diagnosis for the nine patients for whom the second ERCP was unsuccessful was choledocholithiasis (88 %) and cancer of the head of the pancreas (12 %).

Complications after an initial pre-cut papillotomy were 7.5 %. One patient presented bleeding (2.5 %) and required endoscopic treatment with a 1:10000 adrenaline solution and transfusion of two units of red blood cells. Two patients developed moderate post-ERCP pancreatitis (5 %) that was resolved with a conservative management.

DISCUSSION



The pioneering ERCP study reported bile cannulation in 25 % of cases (11). The development of the technique along with training of the operators and the improvement in the equipment and accessories have considerably increased success rates. Cannulating an intact papilla is considered to be difficult after either five attempts, more than five minutes without success or unwanted cannulation of the pancreatic duct (12). In these cases, an early pre-cut papillotomy should be considered in any of the techniques (from the papillary orifice, fistulotomy or transpancreatic pre-cut, among others), in order to reduce the risk of post-ERCP pancreatitis, with biliary cannulation rates that are similar to persistent attempts (12).

The technique of pre-cut papillotomy is a useful technique to gain access to the bile duct in difficult cases. However, success cannot be guaranteed in all cases. Repeating ERCP three days after a failed pre-cut is an alternative that should be considered. After this length of time, it seems that as the inflammation decreases, the identification of the bile orifice rises and its cannulation becomes easier. With this practice, success rates close to 80 % have been reported (5-10). Another alternative for cannulating the bile duct as a rescue therapy is PTBD. The success of this procedure depends on the dilation of the bile duct. Related adverse events are not negligible, as bleeding, infection, bile fistula and possible tumor growth in the bile duct occur in up to 33 % of cases (2). Endoscopic ultrasonography guided access to the bile duct is another attractive and minimally invasive technique. In a review of 1,127 cases, the average rates of technical success were 91 % and of clinical success were 88 %. However, the average rate of complications was 26 %, with a mortality of 0.4 % (4/1,127 patients). In addition, it is expensive and its availability is limited (13).

Treatment of choledocholithiasis can be performed with open or laparoscopic cholecystectomy plus exploration of the bile duct. When comparing open or laparoscopic surgical exploration of the bile duct with ERCP in the management of choledocholithiasis, stone removal, morbidity and mortality rates are similar (3). However, surgical exploration has been reported to be associated with an increased risk of biliary fistula and long-term complications such as stenosis. Surgical exploration of the bile duct requires personnel with specific training and experience (3). When they have the resources available, 86 % of surgeons prefer to do a preoperative ERCP.



In our study of 40 patients, the success rate of bile duct cannulation three days after a failed pre-cut was 75.6 %. In all cases, standard cannulation techniques were used without the need for additional pre-cutting. When the initial pre-cut was extended, the success rate rose to 78.3 %. Our results are comparable with retrospective studies that evaluated the same practice with different time intervals and reported success rates between 68 % and 78 %. Some authors used techniques such as extending the initial pre-cut (Table 2).

The time interval for repeating the ERCP is not defined. However, a retrospective study compared the repetition of the ERCP on day 1 with respect to those on days 2-3 or subsequent days. A significant difference in success rates was observed between the cases on day one (65.7%) and the combined cases for days two and three (88.2%) with a p = 0.027 (8). This fact supports our practice of repeating the ERCP three days after the initial pre-cut. It should be noted that a retrospective series reported that the only factor associated with the failure of the bile duct cannulation was the repetition of the ERCP less than four days after the initial pre-cut. In that study, the average ERCP repetition time was seven days. However, based on our data, this can be reduced, as it is possible to cannulate the bile duct on the third day with a similar success rate, with no increase in complications and a subsequent decrease in costs due to the days of hospitalization (5).

Our results suggest that the technique of pre-cut papillotomy has a better success rate (71.8 %) in bile duct cannulation than for infundibulotomy (62.5 %). However, these results are limited by the low number of patients included in the fistulotomy group. In a retrospective series of 274 patients comparing the different pre-cut techniques (pre-cut papillotomy, fistulotomy and transpancreatic papillotomy), no significant differences were seen in the success rate of bile duct cannulation among the three groups. However, the fistulotomy group showed a decrease in post-ERCP pancreatitis. Apparently, this finding is the result of the fact that there is neither thermal damage nor edema at the level of the pancreatic duct orifice and this preserves the flow after cannulation (15).

It is recommended that pre-cut papillotomy be performed by those specialists who manage to cannulate the bile duct in more than 80% of the cases using standard techniques (12). The length of time taken for the procedure and persistent attempts to cannulate increase the risk of



complications. Thus, an early pre-cut was performed after three unsuccessful attempts to cannulate the bile duct. This decreases the risk of post-ERCP pancreatitis (12). Pancreatitis after precut was reported in 5% and this is lower than what has been reported in similar studies (5-10). This data can probably be explained by the experience of the gastroenterologists (16). There are some limitations of our study, such as the low number of patients with malignant pathology (2.5%), which prevents us from drawing conclusions in this context. In addition, studies are needed that compare repeat ERCP performed within three days of a failed pre-cut with other techniques such as PTBD, ultrasonography or surgical exploration of the bile duct. In conclusion, performing a new ERCP three days after a pre-cut papillotomy or failed fistulotomy is justifiable in patients with choledocholithiasis, since it allows the bile duct to be cannulated in three out of four patients with an acceptable percentage of complications. This way, more invasive and probably more expensive treatments can be avoided. It is clear that each case must be individualized and medical judgment, experience and the availability of local resources must be taken into consideration.

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Table 1. Description of the study population

Total patients (n	= 40)
Average (IQR ²⁵⁻⁷⁵	5)
Age (years)	65 (34-92)
Sex (male)	23 (57.0 %)
Indications	
Choledocholithiasis	38 (95 %)
Biliary fistula	1 (2.5 %)
Pancreatic cancer	1 (2.5 %)
Cannulation technology	
Pre-cut	32 (80 %)
Fistulotomy	8 (20 %)
Description of the papilla	A 1
Normal	34 (82.5 %)
Peridiverticular	4 (10.0 %)
Intradiverticular	3 (7.5 %)
Complications	
Pancreatitis	2 (5.0 %)
Hemorrhage	1 (2.5 %)



Table 2. Studies, ERCP repetition after a failed pre-cut

Author	Country	Study	No.	Average time	Pre-cut technique	Successf	ul Complicat
			patients	for repeat		ERCP, 2 nd	i
				ERCP		attempt	2
Pavlides M	United	Retrospe	89	4 days	Pre-cut papillotomy	78 %	17 %
et al., 2014	Kingdom	ctive					
Kevans D et	Ireland	Retrospe	19	6 days	Fistulotomy	68 %	11 %
al., 2010		ctive			X \		
Donnellan F	Canada	Retrospe	51	7.7 days	Pre-cut papillotomy	75 %	4 %
et al., 2011		ctive					
Kim J et al.,	Korea	Retrospe	69	1 day	Pre-cut papillotomy	76.8 %	11.6 %
2012		ctive		2-3 days*			
Peñaloza et	Colombia	Prospecti	37	3 days	Pre-cut papillotomy	78.3 %	7.5 %
al.		ve			80 %		
				0	Fistulotomy 20 %		
Colan-	Spain	Retrospe	72 [†]	7 days	Pre-cut papillotomy	75 %	11.8 % [‡]
Hernández		ctive			66 %		4.4 % [§]
et al.					Fistulotomy 24 %		

*33 % were done on the first day, and 67 % on 2nd and 3rd days. [†]Initial pre-cutting was performed in 112 patients; ERCP was repeated on 72 patients. [‡]Percentage of adverse effects in 112 patients from initial pre-cut. [§]Percentage of adverse effects in 72 patients in the second ERCP.