

A comparative study of one minute versus five seconds endoscopic biliary balloon dilation after small sphincterotomy in choledocolithiasis

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Abstract

Background: Limited sphincterotomy and endoscopic papillary balloon dilation (EPBD) is a low-risk method for the treatment of choledocolithiasis. Traditionally one minute ballooning time (BT) is applied; however, the effective BT is not clear. In this study, we compare five seconds and one minute ballooning time.

Materials and Methods: In this single-blind, randomized, clinical trial 60 patients with common bile duct (CBD) stones documented in ultrasonography or magnetic resonance cholangiopancreatography (MRCP), with no severe hepatic, biliary or systemic diseases, enrolled in the study. The patients were randomly assigned to receive EPBD with either five seconds ($n = 31$) or one minute ($n = 29$) ballooning time (BT) after endoscopic retrograde cholangiopancreatography (ERCP) and small sphincterotomy. Then stones were retrieved with an extractor balloon. The patients were followed for 48 hours to check the possible complications.

Results: Successful CBD stone removal was the same in the five-second and one-minute BT groups (93.5% vs. 96.6%; $P = 0.594$). Pancreatitis occurred in three (9.7%) patients in the five-second BT group and in six (20.7%) patients in the one-minute BT group ($P = 0.233$). No hemorrhage or perforation was noted.

Conclusions: After a small sphincterotomy, EPBD in the five-second and one-minute BT groups had a similar efficacy. Small sphincterotomy combined with very short BT is a safe and effective method for CBD stone removal.

Key Words: Ballooning Time, choledocolithiasis, endoscopic papillary balloon dilation, small sphincterotomy

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INTRODUCTION

Endoscopic techniques for common bile duct (CBD)

stone clearance include sphincterotomy and/or endoscopic papillary balloon dilation (EPBD) followed by stone extraction.

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However, both these procedures are associated with complications. The acute complications of endoscopic sphincterotomy (EST) are pancreatitis, perforation of the duodenum or bile duct, bleeding, and infection; and long-term complications include permanent loss of sphincter function, stone recurrence, papillary stenosis, cholangitis, and probable carcinogenic risks following sphincterotomy. These concern endoscopists,

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particularly when performed in younger patients who will live many years after EST.^[1-6]

Acute events such as perforation and hemorrhage are less likely with EPBD, hence, it is the preferable method, especially in patients with conditions of high risk for perforation or hemorrhage, such as, duodenal diverticula or thrombocytopenia, respectively. Also the preserved biliary sphincter function may result in the elimination of long-term complications due to reflux of gastroduodenal contents, particularly in younger patients.^[7-10] The success rates of stone extraction may be less than EST, especially larger stones, and the rate of pancreatitis is higher in EPBD than EST.^[11,12] Hence, EPBD has not emerged into widespread use.

Some endoscopists utilize the advantages and overcome the limitations of both EST and EPBD with a combination of small or limited sphincterotomy followed by large balloon dilation. This evolving technique increases the success rate while decreases complications. In recent times this technique has been used worldwide. However, the precise method is not clear. With regard to this issue the question is about the duration of sphincter dilation. Thirty seconds to five minutes of ballooning time have been evaluated in various literatures, but the results are not similar.^[13-19] We believe that effective dilation will be achieved immediately after waist disappearance and longer BT only causes more complications. In the previous literatures, very short BT has not been evaluated. We wanted to answer the question of whether EPBD for a very short time after a small EST can be effective as longer BT, with lesser complications. In this study we compare the effectiveness and complications of five-second and one-minute EPBDs after a small EST in the treatment of choledocolithiasis.

MATERIALS AND METHODS

This unicentric, single-blind, randomized clinical trial was conducted at the Al-Zahra Hospital of the Isfahan University of Medical Sciences in the winter and spring of 2013. The Medical Ethics Committee of the Isfahan University of Medical Sciences approved the study protocol. Also this trial was registered in the Iranian Registry of Clinical Trial at www.IRCT.IR (Irct ID: IRCT2013033112877N1).

Sixty consecutive hospitalized patients with a documented CBD stone, by ultrasonography (US) or magnetic resonance cholangiopancreatography (MRCP), eligible for endoscopic treatment, were enrolled. All patients met the following inclusion criteria: The patients were 16 to 90 years old, with no severe hepatic or systemic disease, no history of gastric

or choledochal surgery (except cholecystectomy), no active pancreatitis, no previous sphincterotomy, no biliary stricture, no choledochal cyst, no addiction, and no coagulopathy/thrombocytopenia (International Normalized Ratio (INR) less than 1.3 and platelet count more than 50000 in a microliter). Patients were excluded under the following conditions: Precut sphincterotomy, failure of cannulation of the common hepatic duct, no stone in the endoscopic retrograde cholangiopancreatography (ERCP) or lack of consent to cooperate in the trial. A written informed consent and agreement was signed by all the patients.

On the day before treatment, blood samples were obtained and sent to the laboratory for a complete blood count, liver enzymes, INR, and amylase and lipase levels. Under close monitoring and observation of an anesthesiologist, the patients were sedated with intravenous midazolam (1 - 2 mg), fentanyl (50 micrograms), ketamine (20 milligrams), and infusion of propofol (1.5 to 4.5 mg/kg/hour). For suppression of duodenal peristalsis; Hyoscine N-Butyl Bromide 20 mg intravenous was used.

Endoscopic retrograde cholangiopancreatography was performed with a side-view duodenoscope (EVISEXERA TJF-145; Olympus Optical, Tokyo, Japan). An electrocautery generator (KAVANDISH System; MATIN Mega1, Iran) with an automatically controlled cut-out system and biliary sphincterotomy (Cook®, TRI-25M, Tri-Tome PC® Triple Lumen Sphincterotomes) were used for EST. After selective cannulation and insertion of the guide wire (Hydra Jagwire™ High Performance Guide Wire 0.89 mm; Boston Scientific) into the CBD, cholangiography was done by injection of a diluted contrast medium. The largest CBD diameter, stones sizes, and count were calculated on the fluoroscopic image. Small sphincterotomy (but not complete unroofing) up to the proximal fold of the papilla was done. Then patients were assigned randomly to five seconds or one minute BT groups by using a table of random numbers generated by the statistician. Through the scope (TTS) a balloon (CRETM Wire-guided Esophageal/Pyloric/Colonic; 12, 13.5, 15 mm or 10, 11, 12 mm) was used for dilation according to the maximal size of the CBD. The ballooning time started when the waist disappeared under the vision of fluoroscopy. Then extractor balloon was inserted and removed to retrieve the stones. The procedure was successful if stone retrieval was complete. Two hours after terminating the procedure, serum amylase and lipase were checked. The patients were evaluated for complications, fever (oral temperature more than 38°C), and abdominal pain every six hours, up to 48 hours. Pancreatitis was defined as a combination of the post ERCP serum amylase level, three times above the upper limit of normal and more than 24 hours of persistent

abdominal pain, suggestive of pancreatitis. Pancreatitis was graded by days of admission, according to the 1991 consensus guidelines.^[17,20-22] Hemorrhage was considered if hematemesis or melena occurred. Cases suspicious of perforation, according to the history and physical examination, were documented with an abdominal x-ray or computed tomography scan (CT scan) if the x-ray was normal.

Continuous data were evaluated for normal distribution by using the Kolmogorov-Smirnov test and then compared, as appropriate, with the unpaired Student's t or Mann-Whitney tests. Corrected X2 or two-sided Fisher's exact tests, as appropriate, were used for comparison of the categorical variables. The criterion for statistical significance was $P < 0.05$. SPSS version 15.0 was utilized in this trial.

RESULTS

In the winter and spring of 2013, out of 96 consecutive patients assessed for ERCP, 73 patients fulfilled the inclusion criteria and 13 were excluded [Figure 1]. A total of 60 patients were recruited and randomized to one minute ($n = 29$) and five seconds ($n = 31$) BT after ERCP and EST. The patients demographics and procedural findings are illustrated in Table 1.

Common Bile Duct stone removal was achieved in 28 (96.6%) patients in the one-minute group and 29 (53.5%) patients in the five-second group; they were statically similar ($P = 0.594$). In the one-minute group, the CBD and stone sizes were 14 and 12 mm, respectively; retrieval with a balloon failed because of the cuboid shape, as it could not be cached with a basket. In the five-second group, one of patient's CBD and stone sizes were 15 mm, hence the instruments could not be passed, and in another patient, the CBD was 25 mm and stone size was 13 mm.

Pancreatitis occurred in six (20.7%) patients in the one-minute BT group and three patients (9.7%) in the five-second group. The pancreatitis rate was two times longer in the BT group; however, both groups were the same statistically ($P = 0.233$). Also, no significant differences were observed in the mean serum amylase and lipase levels in both groups after the procedure.

Abdominal pain was seen only in patients with pancreatitis and the others did not suffer significant pain.

The mean days of admission did not differ between the groups, statistically. However pancreatitis of more than one day admission after the procedure was numerically two times more in longer BT. Severe pancreatitis (10 days admission or more; according to consensuses of 1991) occurred in one patient in this study in short BT.^[22] The results are summarized in Table 2.

We had no patients with perforation of lumen, significant or clinical hemorrhage or cholangitis. There was a patient in the five-second BT group with post-ERCP fever and four days of admission, but the fever was not related to any hepatobiliary problem.

DISCUSSION

In the endoscopic treatment of choleducolithiasis, CBD clearance rate and fewer complications are the most important issues.

Table 1: Patients demographic and procedural findings in one-minute and five-second BT

	Ballooning time		P value
	One minute (n=29)	Five seconds (n=31)	
Gender			0.206
Male	14 (51.7%)	10 (32.3%)	
Female	15 (48.3%)	21 (67.7%)	
Age	54.97±19.83	55.74±20.70	0.856
Maximum CBD diameter (mm)	12.86±4.80	12.97±4.54	0.829
Maximum stone size (mm)	8.10±3.65	7.74±2.96	0.850
≤ 10 mm	25 (86.2%)	26 (83.8%)	
> 10 mm	4 (13.8%)	5 (16.1%)	0.544
Balloon size (mm)	12.22±2.08	12.22±2.16	0.969
Mean stone count	1.38±0.72	1.13±0.42	
1	22 (75.9%)	28 (90.3%)	0.265
2	3 (10.3%)	2 (6.5%)	
3	4 (13.8%)	1 (3.2%)	
Pre ERCP amylase (U/L)	113.41±171.87	101.61±115.35	0.953
Pre ERCP lipase (U/L)	113.21±228.56	126.94±310.04	0.842

CBD: Common bile duct, ERCP: Endoscopic retrograde cholangio pancreatography, BT: Ballooning time

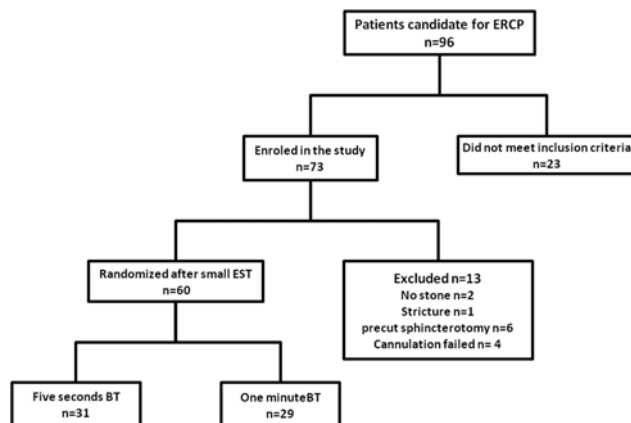


Figure 1: Patient selection diagram

Table 2: CBD stone removal and complications in one-minute and five-second BT

	Ballooning time			P value
	Total (n=60)	One minute (n=29)	Five second (n=31)	
CBD stone removal	57 (95.0%)	28 (96.6%)	29 (93.5%)	0.594
Pancreatitis	9 (15.0%)	6 (20.7%)	3 (9.7%)	0.233
Post ERCP amylase (U/L)	142.72±148.80	123.86±93.71	160.35±186.23	0.625
Post ERCP lipase (U/L)	198.24±371.39	189.31±267.95	206.61±451.78	0.636
Post ERCP amylase (U/L) ≥3×upper normal limit		3 (10.3%)	4 (12.9%)	0.538
Post ERCP lipase (U/L) ≥3×upper normal limit		8 (27.5%)	8 (25.8%)	0.876
Abdominal pain	9 (15.0%)	6 (20.7%)	3 (9.7%)	0.234
Days of admission	1.47±1.40	1.38±0.82	1.5±1.80	0.516
1	50 (83.3%)	23 (79.3%)	27 (87.1%)	
2-3	6 (10%)	5 (17.2%)	1 (3.2%)	
4-5	3 (5%)	1 (3.4%)	2 (6.4%)	
10	1 (1.7%)	0 (0%)	1 (3.2%)	
Fever	7 (11.7%)	4 (13.8%)	3 (9.7%)	0.620

CBD: Common bile duct, ERCP: Endoscopic retrograde cholangio pancreatography, BT: Ballooning time

This study compared the effectiveness and complications of EPBD with very short BT (five seconds) versus conventional BT (one minute), after a small sphincterotomy treatment of choledocolithiasis. Previous studies, in this aspect, have evaluated EPBD after EST in large or difficult-to-remove CBD stones.^[10,14,15,17-19] We applied this method for the endoscopic treatment of routine CBD stones. Also, in our study, EST was not complete and cutting progressed only up to the proximal fold of the papilla, not unroofing the CBD.

In our study, complete CBD stone clearance was similar in both BTs and failure of stone removal was not due to obstruction. Stones smaller than 10 mm were removed completely and larger stones retrieved equally in both groups. Post ERCP pancreatitis frequency was two times more in the longer BT group, but it was not significant statistically. The overall pancreatitis rate was 15% in this study, with 20.7 and 9.7% in one minute and five seconds, respectively. These frequencies are more than the global reports.^[1,4] It may be due to a trainee performing the procedure in an educational center. However, severe pancreatitis occurred only in one patient in the short-term group and other all pancreatitis patients were discharged two to five days after the procedure. We had no cholangitis, perforation or bleeding in patients.

In our experience, we have found that when the balloon waist disappears, the CBD roof and walls can be seen through a dilated sphincter, which we have referred to here as 'perfect dilation', after which the stones can be removed easily. Perfect dilation can be achieved in both the short and longer BT. However, the longer BT may only cause more injury and complications than benefit.^[12]

In this experience, EST was not complete and sphincter function could be preserved. Therefore, long-term complications of complete EST due to gastroduodenal reflux might be prevented. Also, acute complications, such as bleeding or perforation, were not seen. These advantages made this method a potential substitute for EST, especially in young patients and in those with a high risk for perforation or bleeding, such as, periampullary diverticula or thrombocytopenia. However, according to the high rate of pancreatitis, it could be supposed that small EST and EPBD should be used cautiously in patients with a high-risk for pancreatitis.

There were some limitations to our study. We did not evaluate the interfering factors such as cannulation of the pancreatic duct, multiple trials of cannulation, and ERCP duration. Also it was a unicentric and single-blind trial in a small number of patients. Therefore, the results could not be generalized.

CONCLUSION

Our study showed that in the treatment of CBD stones, EPBD with a five-second BT after a small EST was equal in efficacy to a one-minute BT. Complication rates were similar in both groups, as well. Therefore, it appears that a five-second dilation of the sphincter, after EST, is sufficient for stone removal.

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