Original Article

ANATOLIAN CURRENT MEDICAL

DOI: 10.38053/acmj.1122657

Anatolian Curr Med J 2022; 4(3); 305-310

Management of difficult bile duct stones with temporary plastic stent and ursodeoxycholic acid treatment: 5 years of experience

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Cite this article as: Duran A, Çalta AF. Management of difficult bile duct stones with temporary plastic stent and ursodeoxycholic acid treatment. Anatolian Curr Med J 2022; 4(3); 305-310.

ABSTRACT

Aim: The aim of the study was to investigate the effect of temporary plastic stenting and ursodeoxycholic acid (UDCA) treatment on difficult choledochal stones that cannot be removed by basic ERCP techniques in patients who applied to our clinic with occlusion and underwent endoscopic retrograde cholangiopancreatography (ERCP).

Material and Method: Patients were scanned retrospectively using the hospital database. Patients who underwent ERCP due to malignancy, biliary tract injury and benign strictures were excluded from the study. 61 patients who were not successful with basic ERCP techniques such as endoscopic sphincterotomy (EST) and mechanical lithotripsy (ML) were included in the study. 750 mg/day UDCA was given to the patients for three months and plastic stent was applied. After the treatment, ERCP was tried again.

Results: Among the patients who underwent stent+UDCA, three (4.9%) patients had perioperative bleeding, one (1.6%) patient had peroperative perforation, four (6.6%) patients had postoperative pancreatitis, and one (1.6%) patient had mortality. The mean hospital stay was 1.96±2.1 days. Post-procedure total bilirubin and direct bilirubin values were observed to be lower than before the procedure (respectively, $p<0.001$ and $p<0.001$). The reduction in common bile duct diameter and stone size was found to be statistically significant in patients who underwent two procedures (respectively, $p<0.001$ and $p<0.001$). Although the reduction in stone size was statistically significant in patients who underwent three procedures, the decrease in the diameter of the common bile duct was not significant (p=0,090).

Conclusion: In our study, temporary plastic stenting and UDCA treatment were shown to be beneficial in common choledochal stones that could not be removed with basic ERCP techniques in the first ERCP session.

Keywords: Endoscopic retrograde cholangiopancreatography, choledocholithiasis, endoscopic sphincterotomy, ursodeoxycholic acid and bile duct stent

INTRODUCTION

Nearly 7-12% of patients undergoing cholecystectomy for gallstones are found to have stones in the common bile duct. Endoscopic retrograde cholangiopancreatography (ERCP) is widely used in the treatment of common bile duct stones ranging in size from a few mm to 3 cm (1,2). Although 85-90% of common bile duct stones can be successfully removed with standard techniques such as endoscopic sphincterotomy (EST), endoscopic papillary balloon dilation (EPBD), and mechanical lithotripsy (ML), additional ERCP procedures or surgical intervention are required in some cases (3). Large (>1.5 cm), multiple, and cylindrical stones as well as stones that cannot be removed due to surgically altered anatomy, narrowed or angled distal bile ducts, and periampullary diverticulum are defined as bile duct stones difficult for ERCP (4). These patients need ERCP methods that require more advanced techniques and equipment such as extracorporeal shock wave lithotripsy (ESWL), electrohydraulic lithotripsy (EHL), laser lithotripsy (LL), and endoscopic papillary large balloon dilatation (EPLBD) (5,6). Even if these methods are known to be effective, their use is restricted in patients with comorbidities because they are not available in all centers, are technically more difficult, have higher costs, and have longer procedure times (7).

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Received: 28.05.2022 **Accepted:** 22.06.2022

In cases where advanced ERCP techniques could not be applied, temporary stenting was performed and difficult bile duct stones were removed with repetitive ERCPs. It is not entirely clear by what mechanisms temporary plastic stents play a role in the removal of stones, but it is assumed that they are caused by mechanical friction. It has been argued that the addition of ursodeoxycholic acid (UDCA) to temporary stenting is beneficial (8,9). Ursodeoxycholic acid treatment has been used for many years in the liver, biliary tract, and digestive system diseases. It has been shown to be beneficial especially in dissolving cholesterol gallstones and preventing cholestasis, which is seen as a risk factor in the formation of bile duct stones (10). In this study, it was investigated whether UDCA and temporary plastic stenting are beneficial in the treatment of difficult choledochal stones that cannot be removed with primary ERCP techniques.

MATERIAL AND METHOD

The study was initiated with the approval of the Bandırma Onyedi Eylül University Faculty of Medicine Clinical Researches Ethics Committee (Date: 09.05.2022, Decision No: 2022-67). In the study, 585 patients who underwent ERCP for obstructive jaundice in the General Surgery Department of Bandirma Onyedi Eylül University Faculty of Medicine between 2016-2021 were retrospectively analyzed.

Data Collection and Patient Selection

Patients who presented to our clinic with obstructive jaundice between the specified dates and underwent ERCP were scanned retrospectively using the hospital database. 55 patients who underwent ERCP due to malignancy, biliary tract injury, and benign strictures were excluded from the study. Stone extraction with EST and ML, technically applied in our clinic, was planned for 530 patients with common bile duct stones. Bile flow was achieved by successful stone extraction in 450 patients in the first ERCP session. A temporary plastic stent was placed in 61 patients and 750 mg/day UDCA treatment was initiated. In the remaining 19 patients, common bile duct cannulation could not be performed during ERCP. Twelve of these patients underwent surgical intervention, and 7 patients were referred to centers where advanced ERCP techniques could be applied, considering their general condition was not suitable for surgical intervention.

Pre-Operative Evaluation and ERCP Procedure

Before the procedure, all patients were evaluated in terms of anesthesia, and necessary medical treatments were planned to reduce mortality and morbidity. Oral intake was stopped 6-8 hours before the procedure and the patients were taken to the ERCP unit after prophylactic antibiotic administration. They were then placed in the left lateral decubitus and semi-prone position; topical local anesthetic spray [3-5 puffs (10 mg/puff) 10% lidocaine spray]was applied before the procedure. The procedures were performed under deep sedation [intravenous midazolam (0.05 mg/kg) and/or propofol (0.5 mg/kg) and/or fentanyl (0.5-1 µr/kg)]. After evaluating the esophagus and stomach, the second part of the duodenum was reached by passing through the pylorus. Following visualizing the ampulla vatery, the papillae facing position was provided. Selective bile duct cannulation was attempted by entering the sphincterotomy from the papilla orifice at the 11 o'clock orientation. In our clinic, guidewire supported cannulation is generally applied; however, in cases where cannulation cannot be performed in this way, selective cannulation is preferred with contrast-assisted cannulation and deep cannulation techniques. Similarly, the selective bile duct cannulation technique with guidewire support to the pancreas is also applied primarily in cases where bile duct cannulation cannot be performed and pancreatic cannulation can be performed. After the biliary tract is cannulated with the selective bile duct cannulation technique, the bile ducts are filled with contrast material and the biliary tract is visualized with C-arm scopy. After evaluating the bile duct pathologies, biliary sphincterotomy (EST) is performed by cutting the papilla between 11 o'clock and 1 o'clock directions with the help of a sphincterotomy and electrocautery. The upper border of the incision forms the point where the intraductal part of the papilla intersects with the duodenal wall. In cases where the bile duct cannot be cannulated selectively, the pre-cut method can be used. Biliary and pancreatic sphincters are exposed by cutting the papilla mucosa and submucosa starting from the orifice with a needle-pointed sphincterotomy or using the fistulotomy technique from the upper part of the orifice, and EST is performed after the bile duct is cannulated. Following that, the detected pathology is treated. Before or after the EST procedure, endoscopic papillary balloon dilatation (EPBD) and ML techniques can be applied for common bile duct stones. The ML consists of a mechanical lithotripter, a reinforced wire basket used to attach the stone to the bile duct, a metal sheath, and a handle in which the trapped stone and the basket are pulled back against the metal sheath, thus exerting a crushing force. Stone removal procedures with EPBD and ML techniques were planned for our patients. In case of failure, surgery was planned or a temporary plastic stent (8.5 Fr or 10 Fr) was placed to provide bile flow, and treatment was started with UDCA 750 m/day. Then, as long as there was no clinical deterioration, the ERCP procedure was repeated every three months. During this period, UDCA treatment was continued. In patients with clinical deterioration, surgical treatment or referral to centers where advanced ERCP techniques are performed was considered.

Follow-up

When the patients were evaluated in the recovery room after the procedure, some of them were discharged on the same day while some were taken to the service for follow-up purposes, according to their clinical status. Patients who were found to have abdominal pain during the physical examination were followed closely in terms of possible pancreatitis or perforation, and complete blood count, liver function tests, and amylase values were checked in the follow-ups.

Statistical Analysis

SPSS (Statistical Package for the Social Sciences) 25.0 package program was used for the statistical analysis of the data. Categorical measurements were expressed as numbers and percentages while continuous measurements as mean and standard deviation. Chi-square and Fisher's exact tests were used to compare categorical expressions. Shapiro-Wilk test was used to determine whether the parameters in the study showed a normal distribution. Mann Whitney U test was used for the parameters that did not show normal distribution. Wilcoxon ranks test was used to examine the differences between pre-and post-process values. The statistical significance level was considered as 0.05 in all tests.

RESULTS

In the study, a total of 585 ERCP patients were evaluated. 55 patients were directly excluded from the study because they were treated for malignancy, benign stenosis, and postoperative bile leakage. In the remaining 530 patients, stones were detected in the common bile duct, and stones were successfully removed in 450 (84.9%) in the first ERCP session. Twelve (2.26%) of 80 (15.1%) patients who were considered to have difficult common bile duct stones were scheduled for surgery, and seven patients (1.32%) were referred for advanced ERCP techniques. A temporary plastic stent was placed with ERCP in 61 patients (11.5%) and UDCA treatment was started. It was determined that the presence of concurrent malignancy (p=0.023) and preoperative bleeding (p=0.021) findings were observed more frequently in patients who underwent ERCP and went to surgery directly. It was observed that the stone size (p=0.004) and common bile duct diameter (p=0.038) values were higher in patients who underwent ERCP and went directly to surgery. Among the patients who underwent stent+UDCA, three (4.9%) patients had perioperative bleeding, one (1.6%) patient had preoperative perforation, four (6.6%) had postoperative pancreatitis, and one (1.6%) had mortality. The mean hospital stay was 1.96±2.1 days (**Table 1**). The clinical and demographic data of the patients who received a temporary plastic stent after ERCP and were started on UDCA treatment are presented in **Table 2**.

Table 1. Clinical and demographic data of patients with difficult bile duct stones

	Stent + UDCA (n=61) n (%)	ERCP + Surgery (n=12) n (%)	pa
Gender			0.314
Female	30 (49.2)	4 (33.3)	
Male	31 (50.8)	8 (66.7)	
Heart disease	38 (62.3)	7 (58.3)	0.796
Kidney disease	8 (13.1)	2 (16.7)	0.744
Lung disease	8 (13.1)	2 (16.7)	0.744
Central nervous system disease	4 (6.6)	1 (8.3)	0.824
History of malignancy	-	1 (8.3)	0.023*
Pre-op bleeding	3 (4.9)	3 (25.0)	0.021*
Pre-op perforation	1 (1.6)	-	0.655
Post-op bleeding	-	-	-
Post-op pancreatitis	4 (6.6)	-	0.362
Mortality	1 (1.6)	-	0.655
	Stent + UDCA (n=61) Median	**ERCP + Surgery (n=12) Median**	**pb**
Age (year)	67.0	67	0.841
Stone Size (mm)	9.8	16	0.004**
Bile duct diameter (mm)	14	16	0.038*
Pre-op bilirubin (mg/dL)	0.9	2.25	0.512
Pre-op direct bilirubin (mg/dL)	0.4	1.55	0.627
Post-op bilirubin (mg/dl)	0.70	2.6	0.255
Post-op direct bilirubin (mg/dl)	0.30	1.75	0.277
Pre-op amylase (IU/L)	45.0	52	0.404
Post-op amylase (IU/L)	47.0	45	0.623
Duration of procedure (min)	15	27.5	0.365
Leukocyte (ų/L)	7.4	8.25	0.376
Length of stay (day)	1	1	0.825

* p<0.05, **p<0.001, a: chi-square and fisher exact test, b: Mann Whitney U test

Table 2. Clinical and demographic data of patients with stent insertion and UDCA treatment started for difficult bile duct stones

	Frequency (n)	Percentage (%)
Gender		
Female	30	49.2
Male	31	50.8
Heart disease	38	62.3
Kidney disease	8	13.1
Lung disease	8	13.1
Central nervous system disease	4	6.6
History of malignancy	-	-
	Mean±sd	**Median**
Age (year)	64.5±17.0	67.0
Stone size (mm)	9.5±2.4	9.8
Bile duct diameter (mm)	13.8±4.3	14
Pre-op bilirubin (mg/dl)	2.35±3.2	0.9
Pre-op direct bilirubin (mg/dl)	1.86±2.9	0.4
Post-op bilirubin (mg/dl)	1.81±2.7	0.70
Post-op direct bilirubin (mg/dl)	1.44±2.5	0.30
Pre-op amylase (IU/L)	107±389.3	45.0
Post-op amylase (IU/L)	124.8±281.5	47.0
Duration of procedure (min)	20.3±11.4	15
Leukocyte (ų/L)	8.3±5.4	7.4
Number of procedure (times)	2.2±0.5	2

sd: Standard deviation

Of the 61 patients with temporary plastic stent placement and UDCA treatment, 50 (81.96%) underwent two procedures, eight (13.11%) three procedures, and three (6.55%) four procedures. It was observed that the post-procedure total bilirubin ($p<0.001$) and direct bilirubin ($p<0.001$) values of the patients who underwent temporary plastic stent+UDCA were lower than before the procedure. There was no significant difference between the pre- and post- ERCP procedure findings of amylase value ($p>0.05$) (n=61). While a decrease was observed in total bilirubin and direct bilirubin values after all ERCP procedures, it was determined that the post-procedure total bilirubin values were lower in patients who had two procedures ($p=0.018$). On the other hand, direct bilirubin values were lower after the procedure in patients who had three procedures ($p=0.028$). The reduction in common bile duct diameter and stone size was found to be statistically significant in patients who underwent two procedures (respectively, $p<0.001$ and $p<0.001$). Although the reduction in stone size was statistically significant in those who underwent three procedures, the decrease in the diameter of the common bile duct was not significant (respectively, $p=0.011$ and $p=0.090$). In addition, although there was a numerical decrease in those who underwent four procedures, no statistically significant finding was observed (**Table 3**).

Table 3. Change in laboratory data in patients with stent + UDCA (n=61)

	Pre-operative Mean ± sd	Post-operative Mean ± sd	pa
Two procedures (n=50)			
Total bilirubin (mg/dL)	2.5±3.5	1.9±2.9	0.018*
Direct bilirubin (mg/dL)	1.9±3.2	1.6±2.6	0.066
Amylase (IU/L)	119.4±429.6	116.9±267.3	0.735
Bile duct diameter (mm)	16.5±3.4	13.6±4.2	<0.001**
Stone size (mm)	16.5±2.0	9.9±2.1	<0.001**
Three procedures (n=8)			
Total bilirubin (mg/dL)	2.4±1.8	1.4±1.0	0.063
Direct bilirubin (mg/dL)	1.9±1.9	1.0±1.1	0.028*
Amylase (IU/L)	47.6±26.5	204.1±415.6	0.237
Bile duct diameter (mm)	17.6±4.0	15.3±5.1	0.090
Stone size (mm)	16.4±3.0	7.3±2.9	0.011*
Four procedures (n=3)			
Total bilirubin (mg/dL)	1.9±1.6	0.6±0.6	0.180
Direct bilirubin (mg/dL)	1.5±1.6	0.15±0.07	0.180
Amylase (IU/L)	47±15.6	45.5±2.1	0.655
Bile duct Diameter (mm)	16.7±1.2	13.7±3.2	0.109
Stone size (mm)	16.8±1.3	7.4±2.8	0.109

* p<0,05, **p<0,001, a: Wilcoxon ranks test, sd: Standard deviation

DISCUSSION

Endoscopic retrograde cholangiopancreatography (ERCP) is an interventional method used in the diagnosis and treatment of pancreaticobiliary system pathologies. It has been used for many years in the treatment of common bile duct stones. With basic ERCP techniques that can be applied in many centers such as EST, ML, and EPBD, 85-90% of common bile duct stones can be treated. Bile duct stones that cannot be treated with these methods are called difficult bile duct stones and advanced ERCP procedures are needed. When these techniques are not available, surgical intervention or temporary biliary stenting techniques can be used (3,8,9,11).

In our study, the patients who underwent ERCP due to bile duct stones between the specified dates were examined and the clinical experience of temporary plastic stent application and UDCA treatment in patients who were accepted as having difficult bile duct stones was shared. While the first ERCP procedure was successful in 450 (84.9%) of 530 patients who were treated for bile duct stones, additional interventions were needed in 80 patients (15.1%) due to difficult bile duct stones. Our rate of detection of difficult bile duct stones was found to be compatible with the literature (3). Endoscopic sphincterotomy (EST), ML, and EPBD techniques can be used alone or in combination in the treatment of common bile duct stones. In a meta-analysis that compared EST and EPBD treatment, Park et al.(12) showed that stone clearance rates in the same session were better than EPBD in patients who underwent EST (EPBD vs. ES 0.59 odds ratio (OR) [0.36–0.94, 95% confidence interval (CI)]. There was no difference between EST and EST+EPBD (1.71 vs. 1.70 OR [0.92–3.17, 95% CI]). In another study involving 58 patients in whom EST was unsuccessful, EPBD was performed in addition to EST, and the procedure was successfully completed in 54 patients (93.1%). The remaining four patients (6.9%) needed ML (13). In cases where classical ERCP methods were not successful, advanced ERCP techniques were applied. In a study involving 44 patients with difficult bile duct stones, fully covered self-expandable stents (FCSEM) were used and became successful in 82% (14). In another study in which the efficacy and safety of EPLBD and EST were compared, Kogure et al. (15) demonstrated that EPLBD alone provided high success (EPLBD vs EST 90.7% vs. 78.8% $p=0.04$). In a study in which LL was used and 17 patients were treated, bile duct stones were cleared in the first session with a success rate of 94%. In another study involving 31 multicenter patients with LL, a success rate of 87% was achieved in the first session (16,17).

Temporary plastic stents can be used as another treatment method for difficult bile duct stones. This method can be used as a treatment method, as well as a bridge treatment until other interventions. Kedia et al. (18) used the multiple

plastic stent method in the management of difficult bile duct stones and showed that the stone size decreased and disappeared in some patients. A comparison was made between the patients with temporary plastic stent implantation and three-month replacement and patients in whom optional stent replacement was performed after stent insertion. Accordingly, the stone clearance rate was found to be higher in patients with frequent stent replacement. The rates of stent-related cholangitis were also found to be lower in the same group (19). It was shown that the addition of UDCA to temporary plastic stents leads to a reduction in stone size and ease of operation during stone removal (20). Similarly, UDCA treatment after stenting of the common bile duct was shown to be more effective than stenting alone (21). In another study conducted in our country, periodic stenting treatment was applied and a significant reduction in stone size was noted (22).

In our study, while the decrease in common bile duct diameter and stone size was statistically significant in patients who underwent two procedures, only the decrease in stone size was found to be significant in patients who underwent three procedures. Although there was a decrease in both stone size and diameter in patients who underwent four procedures, it was not statistically significant. This is thought to be due to the relatively low number of patients who underwent four procedures. However, Katsinelos et al. (23) emphasized that UDCA application after stenting did not significantly decrease the stone size in difficult common bile duct stones. Although there are different opinions in the literature, the general opinion is that stenting provides a clinical improvement in the disintegration of common bile duct stones by providing bile flow. It is not entirely clear how biliary stents can aid stone removal, but it is assumed that when the stents are left for a period of time, they cause mechanical friction against the stone and can lead to stone fragmentation, making it easier to clear in the subsequent ERCP. In addition, UDCA is known to dissolve bile duct stones by reducing intestinal cholesterol absorption and secretion of cholesterol into the bile (8,24,25). In the literature, success rates in the secondary ERCP procedure are given between 44-92%. It is reported that stone size is directly related to success (20). Similarly, in our study, successful results were obtained with two ERCP procedures in the majority of patients (81.96%). Successful stone extraction was performed in all patients, and mortality was observed in only one (1.6%) patient. There was a significant decrease in total and direct bilirubin values between the two ERCP procedures. Stone size and common bile duct diameter were found to be significantly higher in the group that went directly to surgery. This supports the literature in terms of emphasizing the importance of stone size. Our complication rates, such as bleeding and perforation, were found to be lower compared to the literature, while the length of hospital stay was consistent with the literature (25,26).

The main limitation of our study is that it was retrospective and could not be randomized with other ERCP techniques. The number of patients and the inability to make cost analysis can be described as other deficiencies.

CONCLUSION

In our study, temporary plastic stent application and 750mg/day UDCA treatment were shown to be beneficial in common bile duct stones that could not be removed with basic ERCP techniques in the first ERCP session. In the absence of any complications or emergency intervention, ERCP was performed at three-month intervals and common bile duct stones were successfully removed in all patients. On the other hand, our study is important because of being one of the few studies conducted on the issue in our country. In addition, considering the cost of advanced ERCP techniques, the lack of necessary equipment in every center, and the inaccessibility of patients to these applications, we think this practice is highly important.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was initiated with the approval of the Bandırma Onyedi Eylül University Faculty of Medicine Clinical Researches Ethics Committee (Date: 09.05.2022, Decision No: 2022-67).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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