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Research Article

# Survey on the plastic biliary stent in the management of large or multiple common bile duct stone

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## Abstract

***Background:*** One of the common treatments for patients with multiple or large gallstones is ERCP and plastic biliary stent placement. In this study, we aim to identify plastic biliary stent efficacy and potential factors in treatment failure in patients with multiple or large gallstones.

***Methods:*** This cross-sectional study was conducted during 2018-2019 on patients undergoing ERCP in Rouhani Babol Hospital. The patient records were obtained before the procedure, and the patients were monitored in the hospital for 24 hours afterwards. After discharge, they were followed up twice (6-8 weeks and 12-16 weeks later) to reassess the indication for ERCP and possible complications.

***Results:*** Among the 70 studied patients, the success rate of the plastic biliary stent was 88.6 percent. Stent failure was more common in patients with larger stone sizes (20.50 ± 1.29 vs 14.57 ± 3.63 millimeters, p=0.001) and longer duration of ERCP (16.25 ± 6.29 vs 9.70 ± 5.73 minutes, p=0.04). In multivariate logistic regression analysis, body mass index (BMI) (OR: 1.84, 95% CI: 1.06-3.17, p=0.02) and stone size (OR: 2.32, 95% CI: 1.01-5.32, p=0.04) were identified as risk factors for stenting failure.

***Conclusion:*** According to the results of this study, the common bile duct stenting using plastic biliary stent has a high success rate. Also, the plastic biliary stent failure was more common in patients with larger stone sizes and higher BMI.

***Keywords:*** Bile ducts, Gallstones, Endoscopic Retrograde Cholangiopancreatography, Stents.

## Introduction

Gallstones are the most common gastrointestinal disorder in the field of endoscopic treatment which manifests in the form of obstructive icterus and cholestasis pattern and mostly biliary pain. What is essential in these patients is to control symptoms and prevent complications such as cholangitis, pancreatitis, and secondary biliary cirrhosis. In order to remove the stones, Endoscopic Retrograde Cholangiopancreatography (ERCP) is needed to establish biliary drainage (1).

Special endoscopy technique is important for examining the pancreaticobiliary system, which is increasingly used in the digestive and liver centers. With the improvement and progress in imaging, such as endosonography and Magnetic Resonance Cholangiopancreatography (MRCP), the therapeutic role of ERCP has become more prominent. So that currently, more than five hundred thousand ERCP treatments are performed yearly in the United States of America. Performing ERCP is accompanied by some complications directly related to the severity and complexity of the operation (2, 3). One of the common treatments for patients with multiple or large gallstones is ERCP and biliary stent implantation. In the following session, the stone will be removed. In some of these patients, the biliary stent loses its function by displacing or obstructing the stent duct (4). While the alternative method has developed and the covered metal stent has been introduced, studies have not yet proven it superior.

Temporary plastic biliary stenting is a safe and recommended method for biliary drainage. These stents provide adequate performance until the subsequent intervention to remove stones in high-risk patients who have not been successful in the initial ERCP and have various co-morbidities (5, 6); the effect of ERCP and biliary stenting in elderly patients is known. Failure in plastic stent treatment results in stent displacement, frequent cholangitis, recurrence of symptoms, and stent removal (7).

Based on the literature review, the success rate of biliary stenting has been reported differently in various studies; hence the necessity of conducting this research is more apparent (8-10). We aim to identify the effective factors in the failure of plastic biliary stent treatment in patients with large or multiple gallstones who are candidates for stenting.



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## Methods

*Study design & setting*

This cross-sectional study was conducted in Rouhani Babol Hospital in 2018-2019 on patients undergoing ERCP. Eligible patients were over 18 years old whose indication for ERCP was stone. Also, patients with high-risk stones and chronic and systemic disease (CVA, CAD, COPD, etc.) who did not tolerate long-term intervention, patients who underwent open surgery, patients with juxta-ampullary or interpupillary diverticulum, biliary structure or bile duct malformation preventing sphincterotomy, were not included in this study. Patients who had incomplete files and we could not follow up, or did not refer to us, were also excluded from the study.

A standard side-viewing Olympus duodenoscope performed the entire procedure in a semi-lateral or prone position. Also, in all patients, 10 French (Fr) stents in the bile duct, the proximal end above the top of the common bile duct (CBD) stone, and the left distal end in the duodenal lumen were used (2). 100 mg of diclofenac was given rectally to patients to prevent pancreatitis after ERCP. Patients were hospitalized for at least 24 hours after ERCP and were examined for clinical and biochemical symptoms. Incidents such as cholangitis, cholecystitis, and pancreatitis were recorded. If there were no complications, the patients were discharged and were followed up for possible symptoms in the next 6-8 weeks. They were referred to the ERCP unit with the request for liver biochemical tests, and their bilirubin, alkaline phosphatase, and CBC were recorded. They were also followed up during the following 12-16 weeks in person for the need for ERCP. Biochemical and clinical findings of patients with recurrence and stent replacement were compared with patients with successful biliary drainage.

*Statistical methods*

The data were analyzed with SPSS V.22 software. Categorical and continuous data were reported as frequency, percentage, mean, and standard deviation. Chi-square tests have been used to examine the relationship between categorical variables. After checking the normality, we used Independent T-test or Mann-Whitney test for continuous variables and revealed their relationship with categorical variables. In this study, logistic regression was also used to check the prediction of patients affecting failure of biliary stent. The significance level was less than 0.05.

## Results

Among the 70 examined patients, the average age was 66.66 ± 14.48 years (the youngest was 25, and the oldest was 91 years). Among these patients, 32 (45.7%) were male, and 38 (54.3%) were female. The average body mass index was 27.13 ± 2.12 kg/m2, with a minimum of 23.05 and a maximum of 33.00 kg/m2. In the investigation of complications caused by ERCP, 8 (11.4%) patients suffered from pancreatitis and 15.7% (11 patients) suffered from cholangitis. The stent was placed in the common bile duct in all patients. One stent was placed in 69 patients (98.6%), and two stents were placed in one patient (1.4%). The most common symptom of the patients when visiting was abdominal pain with 25 patients (35.7%) and abdominal pain with jaundice with 14 patients (20.0%). On average, the size of the stone was



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about 15 mm, and we used stents between 6 and 12 cm to perform the procedure, which took about 10 minutes on average. Also, the stents were in place for an average of more than 50 days (Table 1).

**Table 1:** Mean and standard deviation, minimum and maximum continuous variables of study participants

| Variables | Mean ± SD | minimum | maximum |
|---|---|---|---|
| Stone size (millimeter) | 14.91±3.80 | 8 | 22 |
| Total bilirubin (umol/L) | 9.5±3.4 | 4.9 | 18.9 |
| Direct bilirubin (umol/L) | 4.37±5.98 | 0.1 | 45 |
| ALP (U/L) | 681.31±435.51 | 23 | 2491 |
| AST U/L) | 99.59±111.72 | 4 | 607 |
| ALT U/L) | 119.97±109.66 | 10 | 550 |
| HB (g/dl) | 11.91±1.61 | 8.2 | 15 |
| Platelet (Mcl) | 223204.29±76055.35 | 9300 | 480000 |
| WBC (thousand per microliter of blood) | 11226.43±9730.14 | 5300 | 87000 |
| Stent length (centimeter) | 7.53±1.12 | 6 | 12 |
| Duration of stent placement (day) | 53.71±36.08 | 14 | 255 |
| Duration of ERCP (minutes) | 10.07±5.92 | 5 | 30 |

ALP; Alkaline phosphatase, AST; Aspartate Aminotransferase, ALT; Alanine aminotransferase, HB; Hemoglobin, WBC; Wight blood cell, ERCP; Endoscopic retrograde cholangiopancreatography

Among the 70 patients studied, 27 (38.6%) had not taken any antibiotics, and 43 (61.4%) had used antibiotics. 23 people (32.9%) used ciprofloxacin and metronidazole and 11 people (15.7%) used ceftriaxone and metronidazole. After 6 to 8 weeks, the patients were followed up for possible symptoms, and only eight patients (11.4%) needed to perform ERCP again and replace the stent, the average time of which was nearly 11 minutes. In other words, the success rate of the plastic biliary stent was 88.6%. After 3 to 4 months, the patients were followed up again, and only one patient (1.4%) needed ERCP again, the average time of which was 5 minutes.

In examining the relationship between the two groups of plastic biliary stent success and failure, we also concluded that the larger size of the stone and the longer duration of ERCP, resulted in the need for stent replacement (respectively: P=0.001 and P=0.04) (Table 2).



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**Table 2:** Comparison of categorical variables studied between two groups of success and failure of plastic biliary stent

| Variables | No need to replace | Need to replace | P-value* |
|---|---|---|---|
| Age (year) | 67.95±15.68 | 56.63±20.10 | 0.13 |
| BMI (kg/m2) | 27.07±2.14 | 27.61±1.99 | 0.18** |
| Stone size (millimeter) | 14.57±3.63 | 20.50±1.29 | 0.001 |
| Total bilirubin (umol/L) | 9.51±3.55 | 9.40±2.22 | 0.79 |
| Direct bilirubin (umol/L) | 4.59±6.26 | 2.71±2.66 | 0.61 |
| ALP (U/L) | 692.81±436.93 | 703.08±431.84 | 0.06 |
| AST U/L) | 88.00±86.84 | 100.29±113.55 | 0.72 |
| ALT U/L) | 83.25±71.18 | 122.20±111.55 | 0.64 |
| HB (g/dl) | 11.90±1.62 | 12.15±1.57 | 0.76** |
| Platelet (Mcl) | 222731.82±76331.35 | 231000±81947.13 | 0.83** |
| WBC (thousand per microliter of blood) | 11359.85±1005.04 | 9025.00±1354.92 | 0.50 |
| Stent length (centimeter) | 7.50±1.14 | 8.00±0.81 | 0.17 |
| Duration of stent placement (day) | 53.62±37.11 | 55.25±9.50 | 0.44 |
| Duration of ERCP (minute) | 9.70±5.73 | 16.25±6.29 | 0.04 |

BMI; Body mass index, ALP; Alkaline phosphatase, AST; Aspartate Aminotransferase, ALT; Alanine aminotransferase, HB; Hemoglobin, WBC; Wight blood cell, ERCP; Endoscopic retrograde cholangiopancreatography

*Mann-Whitney test

**Independent T-test

Subsequently, we investigated the predictive effect of failure factors versus success factors using the logistic regression model with the Enter method, which entered the demographic and paraclinical variables into the model. Finally, stone size and body mass index have been significantly associated with increased biliary stent failure (Table 3).

**Table 3:** Multivariate logistic regression analysis to investigate failure factors in biliary stent

| Variables | OR | 95 % CI | P-value |
|---|---|---|---|
| History of cholecystectomy (yes) | 2.88 | 0.37-22.08 | 0.30 |
| Sonographic result (multiple) | 1.40 | 0.13-14.27 | 0.77 |
| History of antibiotic consumption (yes) | 0.61 | 0.08-4.60 | 0.63 |
| Age (year) | 0.94 | 0.89-1.00 | 0.06 |
| BMI (kg/m2) | 1.84 | 1.06-3.17 | **0.02** |
| Stone size (millimeter) | 2.32 | 1.01-5.32 | **0.04** |
| Total bilirubin (umol/L) | 1.07 | 0.82-1.40 | 0.59 |
| Direct bilirubin (umol/L) | 0.89 | 0.61-1.30 | 0.56 |
| ALP (U/L) | 0.99 | 0.99-1.00 | 0.08 |



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| | | | |
|---|---|---|---|
| AST (U/L) | 0.99 | 0.98-1.01 | 0.83 |
| ALT (U/L) | 0.99 | 0.98-1.00 | 0.49 |
| HB (g/dl) | 1.10 | 0.58-2.09 | 0.76 |
| WBC (thousand per microliter of blood) | 0.99 | 0.99-1.00 | 0.45 |
| Stent length (centimeter) | 1.38 | 0.65-2.89 | 0.39 |
| Duration of stent placement (day) | 1.01 | 0.97-1.02 | 0.93 |
| Duration of ERCP (minutes) | 1.16 | 0.99-1.34 | 0.05 |

OR; Odds ratio, CI; Confidence Interval, BMI; Body mass index, ALP; Alkaline phosphatase, AST; Aspartate Aminotransferase, ALT; Alanine aminotransferase, HB; Hemoglobin, WBC; Wight blood cell, ERCP; Endoscopic retrograde cholangiopancreatography

## Discussion

The main finding of the current research was that the plastic biliary stent's success rate is 88.6%. Biliary stenting through endoscopic retrograde cholangiopancreatography has dramatically improved the quality of patient care over the past 30 years (10). In a study conducted by Hormati et al., the success rate of the plastic biliary stent was 93.8% (8). A previous meta-analysis included 8 RCTs to compare multiple plastic stents verus self-expandable metal stents in treating benign biliary strictures (BBS) and revealed no difference in rate of stricture resoltion, but self-expandable metal stents required fewes ERCPs to achieve resolution (11). Another randomized trial by Ramchadani et al. compared multiple plastic stents versus a fully covered self-expanding metal stent in BBS due to chronic pancreatitis and reported similar efficacy and safety, with the latter requiring fewer ERCPs over two years (12).

Body mass index was shown to influence stent success rate in this study. Various similar studies reported obesity as a risk factor affecting the lack of proper biliary drainage over time (13-15). A previous study comparing ERCP efficacy and safety in obese and non-obese patients showed that the cannulation success rate was lower in obese patients compared to non-obese patients, but the complications did not differ significantly (16). This can be explained by the anatomical challenges that obesity presents, which complicates access to the biliary tree.

Another significant result in this study was the relationship between the success rate of the plastic biliary stent and stone size. Our study showed that a larger stone size more than doubles the chance of stenting failure and is considered a risk factor for stenting failure. Similaly, a retrospective cohort study conducted by Mendoze et al. reported the stone size to be most powerful bile duct stone disease outcome predictor in ERCP (17). The duration of ERCP was longer in patients who needed stent replacement. Based on the obtained results, a longer time to perform ERCP can be effective in the failure of stenting. Loperfido et al. also found in their study that the duration of ERCP is an essential factor in complications (18). The long duration of ERCP indicates the difficulty in stone removal, and can potentially predict procedure failure.

In investigating complications caused by the biliary stent in this study, 15.7% of cholangitis and 11% of pancreatitis were observed in the studied





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patients. In a prospective study by Pisello et al., mild early complications were observed in 28% of patients and late complications in 34% of patients. Cholangitis was the most common complication reported (19). In the study of Hormati et al. (9), in contrast our study, no cholangitis was reported, while pancreatitis occurred in 18.8%, which is nearly 9% more than our report. The difference in the rate of complications after biliary stenting seems to be due to the difference in the sample size, the different characteristics of the studied population, and the influence of confounding variables such as underlying disease. Pisello et al. reported in their study that during the follow-up, 11 patients died, and two of them (6.6%) were related to biliary causes. The endoscopic prosthesis as a definitive treatment is an effective method recommended over surgery in high-risk patients who have a short life expectancy (19).

This study has several strenghs and limitations. The study design was cross-sectional, so establishing casuality for the indentified factors for stent failure was limited. Another limitation was that potential confounders such as comorbid conditions were not fully controlled. The main strenghs of this study was consistent follow-up intervals and indentifying practical predictors of stent failure using logistic regression models.

## Conclusion

ERCP with plastic billiary stents have high efficacy in treating patients with large or multiple billiary stones. Large stone size, high body mass index and long duration of procedure are potential risk factors for failure in stenting procedure.

## Conflict of interests

The authors declare that they have no competing interests.

## Funding

This study was financially approved by Babol University of Medical Sciences, Babol, Iran.

**Ethics approval and consent to participate**

Babol University approved the study protocol for Medical Sciences (ethical code: IR.MUBABOL.REC.1398.125).

**Availability of data and materials**

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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