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ORIGINAL ARTICLE

Retrospective Study

# Management of endoscopic biliary stenting for choledocholithiasis: Evaluation of stent-exchange intervals

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## Abstract

***AIM***

To evaluate the best management of plastic stents in patients with choledocholithiasis who were unfit for endoscopic stone removal or surgery.

***METHODS***

Between April 2007 and September 2017, 87 patients (median age 83.7 years) with symptomatic choledocholithiasis were treated with insertion of 7-Fr plastic stents because complete endoscopic stone retrieval was difficult, and their general condition was not suitable for surgery. Seventy of these patients agreed to regular stent management and stent exchange was carried out at every 6 mo (Group A, $n$ = 35) or every 12 mo (Group B, $n$ = 35). The remaining 17 patients did not accept regular stent exchange, and stents were replaced when clinical symptoms appeared (Group C). We evaluated the frequency of biliary complication and stent patency rate during follow-up periods.

***RESULTS***

The patency rate of biliary plastic stents was 91.4% at 6 mo (Group A) and 88.6% at 12 mo (Group B), respectively. Acute cholangitis occurred in 2.9% of Group A patients and in 8.6% of Group B patients. In Group C, median stent patency was 16.3 mo, and stent exchange was carried out in 70.6% of cases because of acute cholangitis or obstructive jaundice. Although a high incidence of acute cholangitis occurred, there was no biliary-related mortality.

***CONCLUSION***

Plastic stent exchange at 12-mo intervals is considered

a safe procedure for patients with choledocholithiasis. Long-term biliary stenting increases biliary complications, but it can be an acceptable option for select patients who are medically unfit for further invasive procedures.

**Key words:** Acute cholangitis; Endoscopic retrograde cholangiopancreatography; Stent exchange; Plastic stent; Biliary stenting



**Core tip:** Adequate management of plastic stents for choledocholithiasis was evaluated. Stent exchange was carried out at every 6 mo (Group A), every 12 mo (Group B) or on demand (Group C). The stent patency rates were 91.4% for Group A and 88.6% for Group B, respectively. In Group C, median stent patency was 16.3 mo, and stent exchange was required in 70.6% of patients. There was no biliary-related mortality. Although 12 mo is considered a safe interval for plastic stent exchange, long-term biliary stenting can be an acceptable option for selected patients who are medically unfit for further invasive procedures.

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## INTRODUCTION

Endoscopic biliary sphincterotomy with stone removal is the gold standard for the treatment of choledocholithiasis. In the case of difficult biliary stones, various approaches such as mechanical lithotripsy, electrohydraulic lithotripsy, laser lithotripsy, and extracorporeal shock wave lithotripsy have been used for stone extraction[1]. Although most common bile duct stones can be treated successfully by conventional endoscopic procedures, in cases where endoscopic stone removal has failed, surgery must be considered as a next step. However, in elderly patients with serious comorbidities and higher surgical risks, plastic stent placement could be an alternative treatment to surgery. In these cases, the principal aim of biliary stenting is to avoid acute cholangitis, which can progress to sepsis.

With the progressive increase in the elderly population, endoscopic biliary stenting is widely used as a safe approach for the management of choledocholithiasis[2]. However, there are complications, such as stent occlusion and migration[3,4], after stent implantation. The longer the stents are in place, the more likely stent-related complications such as obstructive jaundice and acute cholangitis are to happen. According to a previous report[5], the mean complication rate was 22.4% (0%-64%), and the biliary-related mortality rate was 3.5% (0%-21.1%) after plastic stent replacement. Although the optimal time for biliary plastic stent exchange has not yet been established, a standard type of polyethylene stent patency is approximately 3 mo[6]. Therefore, 3-6-mo intervals for plastic stent exchange have commonly been recommended. However, it is difficult for elderly patients with numerous comorbidities to follow the recommendation for further biliary stent exchange in such a short period. In the present study, we evaluated the adequate intervals for biliary stent exchange as a treatment for patients with choledocholithiasis.

## MATERIALS AND METHODS

### *Study design*

Only patients with difficulty of complete endoscopic stone retrieval by conventional endoscopic lithotripsy were eligible for participation in this study. These patients had multiple large stones and/or difficult anatomy after abdominal surgery. From Aril 2008 to September 2017, 87 patients (37 male/50 female; median age 83.7 years) with symptomatic choledocholithiasis who were not suitable for repeated endoscopic lithotripsy and for surgical procedures because of multiple comorbidities were treated with the insertion of 7-Fr biliary plastic stents. Among these, 70 patients received regular stent exchange at every 6 mo (Group A, $n$ = 35) or every 12 mo (Group B, $n$ = 35). They were divided into odd (Group A) and even numbers (Group B) taken from their medical chart. The remaining 17 patients did not accept the recommendation of regular stent exchange (Group C). In this group, we simply observed their conditions until any biliary-related symptom appeared, and stent exchange was carried out only when the onset of a clinical suspicion of stent blockage (*i.e.*, acute cholangitis or obstructive jaundice). After obtaining ethical approval from the Institutional Review Board of our institution, we conducted a retrospective review of medical records of patients. The main outcomes were the stent patency rate and frequency of stent-related complications, especially acute cholangitis. The diagnosis of all patients was based on symptoms, blood tests and imaging modalities. Acute cholangitis was diagnosed according to The Tokyo Consensus Meeting criteria[7].

### *Endoscopic procedure*

Before performing ERCP, informed consent was obtained from each patient and/or caregiver. All endoscopic procedures were performed under moderate sedation by giving intravenous injections of midazolam and pethidine hydrochloride. All patients underwent continuous monitoring by electrocardiogram and pulse

oximetry and received 2 L/min of oxygen through a nasal cannula throughout the endoscopic procedure. The straight type of plastic biliary stents (7 Fr diameter, Boston Scientific Japan) were routinely used for biliary drainage. The length of the stent was routinely 7 cm, but it varied depending on the patients' anatomic characteristics. After plastic stent were inserted, all patients and/or their caregivers received oral and written instructions about further biliary stent management.

### *Statistical analysis*

Various parameters were compared between Group A and Group B. Continuous variables with normal distributions were compared by two-sample *t*-test. Mann-Whitney *U* test was used for the comparison of continuous variables with skewed distributions. The $\chi^2$ test or Fisher's exact test was used for categorical variables as appropriate. *P*-values of 0.05 or less were considered statistically significant. All statistical analyses were performed using the EZR[8] (Saitama Medical Center, Jichi Medical University, Saitama, Japan, version 1.32), which is a graphical user interface for R (the R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander that was designed to add statistical functions frequently used in biostatistics.

## RESULTS

In this study, 87 patients with a high surgical risk, for whom it was not possible to completely remove biliary stones using conventional endoscopic lithotripsy, were included. Characteristics of Groups A and B are shown in Table 1. There were no significant differences between the two groups in age, sex, frequency of periampullary diverticulum, reasons for endoscopic stone removal failure, and median follow-up period. Stent patency in Groups A and B is shown in Table 2. Plastic stents were changed at scheduled intervals in 91.4% (32 of 35) of patients in Group A and 88.6% (31 of 35) of patients in Group B. In Group A, stents were changed prior to schedule (6 mo) in 3 cases because of stent occlusion ($n$ = 1) or migration ($n$ = 2), while 4 cases required stent exchange prior to schedule (12 mo) in Group B, due to stent occlusion ($n$ = 3) or migration ($n$ = 1). Acute cholangitis occurred in 2.9% of patients in Group A and 8.6% of patients in Group B.

Characteristics of Group C (stent exchange on demand) are summarized in Table 3. During the follow-up periods, plastic stent exchange was carried out in 70.6% (12 of 17) of patients in this group because of stent-related biliary complications (Table 4). Indications for stent exchange were acute cholangitis (35.3%, $n$ = 6), obstructive jaundice (23.5%, $n$ = 4) or liver dysfunction (11.8%, $n$ = 2). The median stent exchange interval was 16.3 mo (interquartile range 12.7-21.2 mo).

Sphincterotomy was undergone by 83.9% (73 of 87) of patients before the insertion of the biliary stent. In the remaining patients, sphincterotomy was not carried out because of the presence of a large periampullary diverticulum ($n$ = 11) or continuous anticoagulant therapy ($n$ = 3). All 10 cases with acute cholangitis in this study improved with antibiotics and prompt biliary stent exchange. Although 1 case of acute cholangitis progressed into septic shock, the patient recovered within 7 d. There was no mortality related to biliary complication.

## DISCUSSION

Endoscopic biliary lithotripsy has been established as a gold standard for the treatment of choledocholithiasis. However, complete stone clearance is not feasible in some cases. Multiple large stones, stone impaction, and difficult anatomy after abdominal surgery are significant predictors for failure of endoscopic lithotripsy. If endoscopic stone removal attempts have failed, surgical procedures such as sphincteroplasty and/or choledochoduodenostomy are required. However, elderly patients with multiple comorbidities tend to be poor candidates for invasive surgery. In these cases, to avoid the onset of biliary complication, especially acute cholangitis, biliary stenting could be an alternative option.

The principal aim of this study is how to manage biliary stents in patients with choledocholithiasis for whom previous endoscopic lithotripsy had failed and who were medically unfit for surgery. According to previous studies[4,6,9], plastic stents should be exchanged within 3-6 mo to prevent later complications, such as acute cholangitis. Di Giorgia *et al*[9] evaluated 78 patients with biliary stenting for choledocholithiasis. They compared two groups as follows: Scheduled stent exchange *vs* stent exchange on demand. They suggested that the best way to prevent acute cholangitis was to change the plastic stent every 3 mo. Although plastic stent exchange within 3-6 mo is commonly advocated, it is too difficult for elderly patients with numerous comorbidities to undergo an ERCP in such a short period. In the present study, we attempted to define the best intervals for stent exchange for choledocholithiasis and planned plastic stent exchange at every 6 mo (Group A) or every 12 mo (Group B). Stent exchange prior to schedule was required in 8.6% of patients in Group A and 11.4% of patients in Group B. Li *et al*[10] evaluated 50 patients with biliary stenting for choledocholithiasis and reported that stent patency rates were 94% at 6 mo, 79% at 12 mo, and 58% at 24 mo. Slattery *et al*[11] analyzed stent patency rates of 201 patients with choledocholithiasis, and their results were 93.5% at 6 mo and 81.9% at 24 mo. Our results are similar to those of these reports. High stent patency rates at 12 mo in our study suggest that short-term plastic stent exchange is not always necessary.

**Table 1 Characteristics of patients who underwent regular stent exchange, *n* (%)**

| | Group A (*n* = 35) | Group B (*n* = 35) | *P* value |
|---|---|---|---|
| Stent-exchange schedule | 6 mo | 12 mo | |
| Age, yr | 82.9 (77-87) | 84.4 (76-89) | NS |
| Sex, male/female | 15/20 | 16/19 | NS |
| Periampullary diverticulum | 7 (20.0) | 8 (22.9) | NS |
| Sphincterotomy | 30 (85.7) | 29 (82.9) | NS |
| Post-ERCP pancreatitis | 1 (2.9) | 1 (2.9) | NS |
| Reason for endoscopic stone removal failure | | | |
| No. of stones | 16 (45.7) | 14 (40.0) | NS |
| Size of stones | 17 (48.6) | 18 (51.4) | NS |
| Anatomical difficulty | 2 (5.7) | 3 (8.6) | NS |
| Follow-up periods, mo | 27.3 (12-40) | 26.5 (14-37) | NS |

Continuous variables are expressed as median (interquartile range). Categorical variables are expressed as numbers. ERCP: Endoscopic retrograde cholangiopancreatography; NS: Not significant.

**Table 2 Stent patency of patients who underwent regular stent exchange, *n* (%)**

| | Group A (*n* = 35) | Group B (*n* = 35) | *P* value |
|---|---|---|---|
| Stent-exchange schedule | 6 mo | 12 mo | |
| Stent patency at scheduled time | 32 (91.4) | 31 (88.6) | NS |
| Stent exchange prior to schedule | 3 (8.6) | 4 (11.4) | NS |
| Details of stent troubles | | | |
| Stent occlusion | 1 (2.9) | 3 (8.6) | < 0.05 |
| Stent migration | 2 (5.7) | 1 (2.9) | NS |
| Acute cholangitis | 1 (2.9) | 3 (8.6) | < 0.05 |
| Biliary-related mortality | 0 | 0 | NA |

NS: Not significant; NA: Not available.

**Table 3 Characteristics of patients who underwent stent exchange on demand, *n* (%)**

| Group C (*n* = 17) | |
|---|---|
| Age, yr | 84.1 (76-90) |
| Sex, male/female | 6/11 |
| Periampullary diverticulum | 4 (23.5) |
| Sphincterotomy | 14 (82.3) |
| Post-ERCP pancreatitis | 0 |
| Reasons for endoscopic stone removal failure | |
| No. of stones | 9 (52.9) |
| Size of stones | 6 (35.3) |
| Anatomical difficulty | 2 (11.8) |
| Reasons for rejecting scheduled stent exchange | |
| Cardiovascular diseases | 4 (23.5) |
| Stroke sequelae | 4 (23.5) |
| Age factors | 3 (17.6) |
| Dementia | 3 (17.6) |
| Malignancy | 3 (17.6) |
| Follow-up periods, mo | 24.8 (14-32) |

Continuous variables are expressed as median (interquartile range). Categorical variables are expressed as numbers. ERCP: Endoscopic retrograde cholangiopancreatography.

**Table 4 Stent patency of patients who underwent stent exchange on demand, *n* (%)**

| Group C (*n* = 17) | |
|---|---|
| Stent-exchange cases | 12 (70.6) |
| Indication for stent exchange | |
| Acute cholangitis | 6 (35.3) |
| Obstructive jaundice | 4 (23.5) |
| Liver dysfunction | 2 (11.8) |
| Details of stent troubles | |
| Stent occlusion | 10 (58.8) |
| Stent migration | 2 (11.8) |
| Duration of stent patency | 16.3 (12.7-21.2) |
| Biliary-related mortality | 0 |

Continuous variables are expressed as median (interquartile range).

Patients were instructed regarding the possible complications of delayed stent replacement and the necessity of regular stent exchange, but some patients or their caregivers did not accept the recommendation. In this study, 17 patients refused regular stent exchange (Group C) because of their serious conditions.

High incidence of acute cholangitis (35.3%) was seen in Group C. Sepsis due to acute cholangitis was seen in 23.5% (4 of 17) of patients in Group C, but all cases recovered with prompt stent exchange and antibiotics. There have been several studies regarding long-term biliary stenting for choledocholithiasis[5,10-13]. Ang *et al*[5] evaluated 83 patients with choledocholithiasis treated with long-term biliary stenting and found biliary complication in 34% of patients and acute cholangitis in 24% of patients. Bergman *et al*[12] analyzed 58 patients with choledocholithiasis and permanent biliary stenting; acute cholangitis was seen in 36% of patients, and the mortality rate related to biliary complication

was 16%. Pisello *et al*[13] reported on 30 patients with choledocholithiasis and long-term biliary stenting; late complications occurred in 34% of patients, and the mortality rate related to biliary complication was 6.6%. Slattery *et al*[11] reported on 201 patients with long-term biliary stenting for choledocholithiasis. According to their report, the frequencies of acute cholangitis (2.9%) and obstructive jaundice (8%) were significantly lower, and median stent patency (59.6 mo) was significantly longer than in other reports. They insisted that their superior stent patency was attributable to adequate sphincterotomy at the initial stent placement and attempts for partial duct clearance in all cases.

In the present study, rates of acute cholangitis in Group A (2.9%) and B (8.6%) were lower than we had estimated. When stents were exchanged at scheduled intervals, sludge occluded the stent lumen or adhered to the stent in 12 cases in Group A and 16 cases in Group B. However, most of these cases showed no signs of biliary obstruction. In these situations, bile duct patency is maintained by the bile drain mechanism around the stent. Moreover, even if the plastic stent becomes occluded, a clogged stent would have the potential to keep common bile duct stones from impacting. In the present study, we used plastic stents with a 7Fr diameter. We believe that stent diameter is not relevant to stent patency if adequate sphincterotomy was carried out. Regarding the migration of plastic stents, it was seen in only 5.7% (5 of 87) of patients. This might be because biliary stones stabilized the plastic stent inside the common bile duct and prevented stent migration.

According to previous studies[14-17], the size of biliary stones decreases after plastic stent placement, and long-term stenting offers the possibility of complete stone elimination. In contrast, it has also been reported that long-standing biliary stents consequentially increase the risk of formation of biliary stones. The sphincter of Oddi functions as a mechanical barrier preventing the regurgitation of duodenal contents into bile duct. Therefore, lost sphincter of Oddi function results in bacterial growth in the bile duct by ascending infection and results in formation of brown pigment stones[18-20]. Sohn *et al*[21] reported that most cases of acute cholangitis after long-term biliary stenting occurred due to the development of brown pigment biliary stones. They suggested that biliary stents themselves could serve as the nidus for stone formation and development. In the present study, stone clearance was obtained in 5 patients (14.3%) from Group A and in 4 patients (11.4%) from Group B after repeated stent exchange. The mean period for stone clearance was 659 days in Group A and 718 d in Group B. However, significant stone growth also appeared in 2 patients (5.7%) in Group B and 3 patients (17.6%) in Group C (these data are not shown in the table). Our clinical data suggest that biliary stenting for choledocholithiasis could assist in subsequent biliary stone clearance, although it could also be related to stone formation and development, depending on the situation.

In this study, poor surgical candidates who underwent endoscopic biliary stenting showed low frequency of acute cholangitis and superior stent patency at 12 mo after stent implantation. In a progressively aging society, 1 year should be considered as an appropriate interval for plastic stent exchange in the treatment of choledocholithiasis. Although long-term biliary stenting increases the risk of biliary complication, it could also be an acceptable strategy for patients with limitations who are clinically unfit for invasive procedures. In this study, a small sample size may be one of the problems to support our definite conclusion. In addition, our study is retrospective evaluation, so it may be difficult to exclude any bias completely. Superior stent patency rate which are observed in this study may not hold true because of these limitations. Further studies with a large number of patients under prospective design will be required to confirm our results.

## ARTICLE HIGHLIGHTS

### *Research background*

In elderly patients with serious comorbidities, endoscopic biliary stenting is widely used as a safe approach for the management of choledocholithiasis. Although short intervals for plastic stent exchange have commonly been recommended to avoid acute cholangitis, it is difficult for elderly patients with numerous comorbidities to accept biliary stent exchange in such a short period. We evaluated the safe interval of endoscopic biliary stent exchange for choledocholithiasis.

### *Research motivation*

There has been limited data on the outcome of long-term biliary stenting for choledocholithiasis. In order to reduce the unnecessary medical procedures for high-risk patients, the optimal time for biliary stent exchange has to be established.

### *Research objectives*

The principal aim of this study is an evaluation of the adequate intervals for biliary stent exchange as a treatment for patients with choledocholithiasis. This research will contribute to the management of endoscopic biliary stenting for choledocholithiasis of high-risk patients.

### *Research methods*

Patients with symptomatic choledocholithiasis were treated with biliary plastic stents because complete endoscopic stone retrieval was difficult. Stent exchange was carried out at every 6 mo or every 12 mo. In the patients who didn't accept the recommendation of regular stent exchange, biliary stents were replaced when clinical symptoms appeared. The authors evaluated the frequency of biliary complication and stent patency rate during follow-up periods.

### *Research results*

Regarding the stent patency rate, there is no significant difference between the 6 mo stent exchange group and the 12 mo stent exchange group. Although a high incidence of acute cholangitis occurred in the on demand stent exchange group, there was no biliary-related mortality.

### *Research conclusion*

Although exchanges of plastic stent in short intervals have been recommended to avoid acute cholangitis, this study concluded that 12 mo is considered a safe interval for plastic stent exchange in choledocholithiasis. Long-term biliary stenting longer than 12 mo can also be an acceptable option for selected patients who are medically unfit for further invasive procedures, but we have

to observe these cases carefully because of the high frequency of acute cholangitis.

### *Research perspectives*

The authors' research findings contribute to the discussion about safe interval for plastic stent exchange in choledocholithiasis. The study design is retrospective and sample size is small, so further clinical trials in a large population under prospective design will be valuable.

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