Can Trainees Safely Perform Endoscopic Treatments for Common Bile Duct Stones?  
A Single-center Retrospective Study

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Abstract:

Objective There are no reports on whether or not trainees can safely carry out endoscopic procedures for the removal of common bile duct (CBD) stones. The aim of this study was to investigate the efficacy and safety of endoscopic treatments for CBD stones by trainees.

Methods Endoscopic retrograde cholangiopancreatography (ERCP) was performed in 1,016 consecutive patients at our institution during the 6-year study period. The endoscopically treated patients with CBD stones were included in this study. Physicians who had experienced ≥300 ERCP procedures were defined as experts, while those who had experienced <300 procedures were defined as trainees. The trainees were replaced by an expert when they could not achieve the established criteria. Patients were divided into the following three groups to retrospectively examine the patients’ backgrounds, details of endoscopic treatments, and intra-/post-operative complications: Group A, completed by trainees under supervision of an expert; B, treated by an expert who switched in for a trainee in the middle of the procedure; and C, completed by an expert.

Results A total of 325 patients with CBD stones underwent endoscopic treatments. The number included in Groups A, B, and C was 176, 102, and 47, respectively. The bile duct catheter insertion successes rates for Groups A, B, and C were 99.0%, 97.1%, and 100% (p=0.09), and the complete stone removal rates were 94.2%, 94.8%, and 100%, respectively (p=0.07), showing no significant difference among the three groups. Furthermore, the frequency of intra-/post-operative complications was not significantly different among the three groups (p=0.48, p=0.12, respectively).

Conclusion This study showed that trainees could safely perform endoscopic procedures in accordance with our facility’s criteria during ERCP.

Key words: endoscopic retrograde cholangiopancreatography (ERCP), endoscopy, common bile duct, stone, trainee

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Introduction

Common bile duct (CBD) stones are a frequently encountered disease in clinical practice and constitute a gastrointestinal emergency disease, as they result in cholangitis and sepsis. The endoscopic management of CBD stones has been regarded as less invasive than surgery (1-3). Endoscopic treatments are therefore considered the first choice for the management of CBD stones.

In recent years, the Tokyo Guideline derived from international meetings in 2007 (4) and updated in 2013 (5) was published for the diagnosis, classification, and treatment of acute cholangitis. Although treatment is defined by severity in the Tokyo Guideline, endoscopic treatment has an important role in all severities.

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Endoscopic retrograde cholangiopancreatography (ERCP) is a relatively difficult procedure, and whether or not trainees can perform it safely remains unclear (6-8). Furthermore, no reports have described whether or not trainees can safely carry out procedures for the removal of CBD stones. The aim of this study was to investigate the efficacy and safety of endoscopic treatments for CBD stones performed by trainees.

**Materials and Methods**

**Patients**

ERCP was performed in 1,016 consecutive patients at our institution during a 6-year period (January 2009 to December 2014). The endoscopically treated patients were included in this study. The study design was approved by the local ethics committee, and all patients signed a standard informed consent form before undergoing the endoscopic procedure.

**Endoscopic procedure**

First, physicians who had experienced ≥300 ERCP procedures were defined as experts, while those who had experienced <300 procedures were defined as trainees. ERCP was performed by an expert operator (H.K.) and three trainees (T.I., H.S., and Y.N.) under the supervision of the expert. Physicians who had been mainly in charge of patients started the endoscopic procedure regardless of difficulty level. Trainees started the procedure and switched with the expert physician when they were unable to achieve viewing from the front of the papilla within 5 minutes, cannulation within 15 minutes, and completion within 60 minutes from 30 minutes after starting the procedure.

Pentazocine and midazolam (MDZ) were administered intravenously for conscious sedation under monitoring of peripheral oxygen saturation and blood pressure throughout the procedure. The initial dosages of pentalozine and MDZ were 15 mg and 1.25-2.5 mg, respectively, and the dose was adjusted according to the condition of the patient. Oxygen supplementation through nasal cannulae was used as necessary. Vital signs, dosages of sedatives, and the responses of patients were recorded in detail by nurses during the procedure.

Standard duodenoscopes (JF-260V and TJF-240; Olympus Medical Systems, Tokyo, Japan) were used for the procedures. Furthermore, we used 2T-Q260M and CF-Q240AI (Olympus Medical Systems) for patients who had undergone gastric surgery.

Guidewire cannulation was used for bile duct catheter insertion (9). When a biliary approach failed using a standard method, a precut technique using a needle knife (Boston Scientific, Tokyo, Japan) was attempted as a rescue technique. Endoscopic sphincterotomy (EST) (2), endoscopic papillary balloon dilation (EPBD) (10), or endoscopic papillary large balloon dilation (EPLBD) (11) was performed to facilitate stone removal in most cases. While EST (medium incision or larger) was carried out for the first papillotomy, EPBD was selected depending on the use of anti-thrombotic drugs and the condition of the periamplullary diverticulum. EPLBD was selected for patients with 3 or more stones and with a sufficiently dilated bile duct from the lower bile duct to the hiliar bile duct, even if the stones were 12 mm or longer or about 10 mm in diameter.

For stone removal, standard techniques (basket, balloon catheter, mechanical lithotripsy) were applied. A mechanical lithotriptor was used to crush stones too large to retrieve intact. Extracorporeal shock wave lithotripsy (ESWL) was used for large stones that could not be crushed by mechanical lithotripsy. Essentially, complete duct clearance was attempted at each procedure. The need for repeat endoscopy was determined on discussion with the patient considering the stability of his/her general condition during the previous procedure and the likelihood of complete duct clearance. When complete stone extraction was not achieved, a 7.0-Fr straight or double-pigtail catheter (Flexima™ Biliary Stent System, Boston Scientific, Marlborough, USA) was positioned for bile duct drainage. Stent exchange was performed only when acute cholangitis recurred.

After the procedure, we administered 0.2-0.5 mg flumazenil. As a preventive measure against pancreatitis after ERCP, a sufficient amount of replacement fluid was given in addition to administration of protease inhibitors and ulinastatin in all cases. Furthermore, immediately after ERCP procedures, patients received 25-50 mg diclofenac suppositories depending on the judgment of the operator.

**Examination items**

The proportion who underwent an endoscopic procedure, number of patients by group, patient background [age, sex, Eastern Cooperative Oncology Group performance status scale (PS), presence or absence of concomitant diseases/cholecystectomy/perianmpullary diverticulum/history of previous treatments/gastrectomy/anti-thrombotic drugs], details of endoscopic therapy (complete removal rate of CBD stones, procedure time, procedure number, dose of MDZ, long diameter of CBD, short diameter and number of stones, papillary treatment, use of a pancreatic duct guidewire, and placement of a pancreatic duct stent), and complications were reviewed based on medical charts and films. We investigated the complications that occurred during and after ERCP. Complications during the procedure were cardiopulmonary suppression, and those after procedure were pancreatitis, cholangitis, and bleeding. Cardiorespiratory suppression was defined as peripheral oxygen saturation <90% and/or systolic blood pressure <90 mmHg observed at any time during the procedure. Post-ERCP pancreatitis (PEP), cholangitis, bleeding and their severities were determined according to the 1991 consensus guidelines by Cotton et al. (12)

The above-mentioned items were examined by dividing patients into the following three groups: Group A, treated by
This retrospective study aimed to evaluate whether or not
trainees could safely perform endoscopic treatment for CBD stones under experts’ instruction. Our data showed that trainees could safely perform endoscopic treatment for CBD lack of a significant difference in the success rate of the bile trainees could safely perform these procedures according to EST
MDZ (mean) (range) 5.8mg (1.25-20) 6.5mg (1.25-17.5) 5.3mg (1.25-12.5) 0.048
Procedure time (mean) (range) 36 min (10-90) 46min (19-118) 30min (15-108) <0.0001
Long diameter of CBD (mean) (range) 9.4mm (4.6-20.1) 9.7mm (4.8-14.8) 9.8mm (5.2-32.0) 0.94
Number of CBD stones (median) (range) 1 (0-12) 2 (0-10) 2 (0-12) 0.48
Short diameter of CBD stones (median) (range) 7.0mm (2.5-19.5) 7.5mm (2.8-20.5) 6.8mm (3.4-34.0) 0.57
Presence/ Absence + + - + -
Only ENBD tube inserted (%) 5.1 94.9 4.9 95.1 0 100 0.36
Procedures for the papillia (%) 70.5 29.5 84.3 15.7 68.1 31.9 0.02
EST (%) 56.8 43.2 68.6 31.4 57.4 42.6 0.14
EPBD (%) 11.9 88.1 14.7 85.3 10.6 89.4 0.78
EPLBD (%) 6.2 93.8 11.8 88.2 0 100 0.10
Pre-cut (%) 0 100 2.9 97.1 0 100 0.053

CBD: common bile duct, MDZ: midazolam, ESWL: extracorporeal shock wave lithotripsy, ENBD: endoscopic nasobiliary drainage, EST: endoscopic sphincterotomy, EPBD: endoscopic papillary balloon dilation, EPLBD: endoscopic papillary large balloon dilation

Table 2. Contents of Endoscopic Treatments.

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=176)</th>
<th>Group B (n=102)</th>
<th>Group C (n=47)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete removal of CBD stones rate (%)</td>
<td>94.2</td>
<td>94.8</td>
<td>100</td>
<td>0.07</td>
</tr>
<tr>
<td>Bile duct catheter insertion successes rate (%)</td>
<td>99</td>
<td>97.1</td>
<td>100</td>
<td>0.08</td>
</tr>
<tr>
<td>MDZ (mean) (range)</td>
<td>5.8mg (1.25-20)</td>
<td>6.5mg (1.25-17.5)</td>
<td>5.3mg (1.25-12.5)</td>
<td>0.048</td>
</tr>
<tr>
<td>Procedure time (mean) (range)</td>
<td>36 min (10-90)</td>
<td>46min (19-118)</td>
<td>30min (15-108)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Long diameter of CBD (mean) (range)</td>
<td>9.4mm (4.6-20.1)</td>
<td>9.7mm (4.8-14.8)</td>
<td>9.8mm (5.2-32.0)</td>
<td>0.94</td>
</tr>
<tr>
<td>Number of CBD stones (median) (range)</td>
<td>1 (0-12)</td>
<td>2 (0-10)</td>
<td>2 (0-12)</td>
<td>0.48</td>
</tr>
<tr>
<td>Short diameter of CBD stones (median) (range)</td>
<td>7.0mm (2.5-19.5)</td>
<td>7.5mm (2.8-20.5)</td>
<td>6.8mm (3.4-34.0)</td>
<td>0.57</td>
</tr>
<tr>
<td>Presence/ Absence</td>
<td>+ + - + -</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only ENBD tube inserted (%)</td>
<td>5.1</td>
<td>94.9</td>
<td>4.9</td>
<td>95.1</td>
</tr>
<tr>
<td>Procedures for the papillia (%)</td>
<td>70.5</td>
<td>29.5</td>
<td>84.3</td>
<td>15.7</td>
</tr>
<tr>
<td>EST (%)</td>
<td>56.8</td>
<td>43.2</td>
<td>68.6</td>
<td>31.4</td>
</tr>
<tr>
<td>EPBD (%)</td>
<td>11.9</td>
<td>88.1</td>
<td>14.7</td>
<td>85.3</td>
</tr>
<tr>
<td>EPLBD (%)</td>
<td>6.2</td>
<td>93.8</td>
<td>11.8</td>
<td>88.2</td>
</tr>
<tr>
<td>Pre-cut (%)</td>
<td>0</td>
<td>100</td>
<td>2.9</td>
<td>97.1</td>
</tr>
</tbody>
</table>

PS: Eastern Cooperative Oncology Group performance status scale
of the endoscopic procedure as an independent risk factor in their prospective study.

Nevertheless, we must consider that the safety and success of ERCP performed by trainees might vary depending on patients’ general condition and disease status, such as the malignancy status. We therefore focused on the safety of endoscopic treatment for CBD stones performed by trainees and evaluated the outcomes by dividing patients into Groups A (treated by trainees), B (experts switched in for trainees in the middle of the procedure), and C (treated by an expert). No previous study has conducted an investigation from this viewpoint.

A recent systematic review (6) suggested that ERCP trainees might require experience with 70-400 procedures to achieve a certain level of success in bile duct catheter insertion (14-22). In reference to this review, in our facility, we defined physicians who had performed ≥300 ERCP procedures as experts.

In addition, the recent European Society of Gastrointestinal Endoscopy guideline (23) suggests that the supervisor should take over the procedure from the trainee when the papilla is deemed difficult to cannulate. Despite the lack of a precise definition for “difficult biliary cannulation”, a prospective multicenter study by Testoni et al. (24) showed a linear progression between ≤3 and 4-10 attempts and between 4-10 and >10 attempts. According to a previous meta-analysis (25), cannulation attempts of >10 minutes’ duration represented an independent risk factor with an odds ratio (OR) of 1.76 [95% confidence interval (CI): 1.13-2.74], and the pooled incidence of PEP increased from 3.8% to 10.8% compared with cannulation attempts of ≤10 minutes’ duration. A recent report also indicated that the appropriate cannulation time for trainees is 10 minutes (26). Based on these reports, the rule for switching from trainees to experts during ERCP in our facility was decided as follows: (1) viewing from the front of the papilla should be completed within 5 minutes, (2) cannulation should be completed within 15 minutes, and (3) the procedure should be completed within 60 minutes.

The present data suggested that trainees could safely perform ERCP for CBD stones under instruction by experts with our facility’s definition and switching rule. In clinical practice, many physicians in Group B were concerned about the clinical outcome (procedure time, complications associated with ERCP). Based on the patients’ background, Group B seemed to include many endoscopically difficult cases. It was therefore natural that Group B included a higher ratio of pancreatic duct pancreatic duct guidewire placement, higher dosage of MDZ, and longer procedure time than Groups A and C. However, no significant difference in the intra-/post-operative complication rate was observed among all groups, suggesting that our facility’s definition and switching rule are reliable for trainees performing ERCP for CBD stones.

Several limitations associated with the present study warrant mention. First, this was a single-center, retrospective study with a small number of enrolled patients. Second, there might be bias in patients’ background data, such as the significantly higher rate of patients with a history of cholecystectomy in Group C than in the other two groups. Third, we were unable to evaluate the cardiac function for all groups in detail, although there was no marked difference in the ratio of cardiac diseases among the groups.

In conclusion, this study demonstrated that trainees could safely carry out endoscopic treatment for CBD stones under our facility’s definitional switching rule. However, a multicenter prospective study will be required to confirm the validation of our educational system.

The authors state that they have no Conflict of Interest (COI).

References


Table 3. Adverse Events during or Post ERCP.

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=176)</th>
<th>Group B (n=102)</th>
<th>Group C (n=47)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during ERCPs (%)</td>
<td>7.4</td>
<td>9.8</td>
<td>12.8</td>
<td>0.48</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>post ERCPs (%)</td>
<td>13.1</td>
<td>20.6</td>
<td>8.5</td>
<td>0.12</td>
</tr>
<tr>
<td>Pancreatitis (All) (%)</td>
<td>11.4</td>
<td>14.7</td>
<td>8.5</td>
<td>0.57</td>
</tr>
<tr>
<td>Pancreatitis (Mild/Medium/Severe) (%)</td>
<td>9.7/1.7/0</td>
<td>8.8/3.9/2.0</td>
<td>6.4/0/2.1</td>
<td>0.28</td>
</tr>
<tr>
<td>Cholangitis (All) (%)</td>
<td>1.7</td>
<td>3.9</td>
<td>0</td>
<td>0.30</td>
</tr>
<tr>
<td>Cholangitis (Mild/Medium/Severe) (%)</td>
<td>1.7/0/0</td>
<td>2.0/2.0/0</td>
<td>0/0/0</td>
<td>0.18</td>
</tr>
<tr>
<td>Bleeding (All) (%)</td>
<td>0.6</td>
<td>3.9</td>
<td>0</td>
<td>0.06</td>
</tr>
<tr>
<td>Bleeding (Mild/Medium/Severe) (%)</td>
<td>0.6/0/0</td>
<td>2.0/2.0/0</td>
<td>0/0/0</td>
<td>0.20</td>
</tr>
</tbody>
</table>

ERCP: Endoscopic retrograde cholangiopancreatography

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