Evaluation of Risk factors for Recurrent Common Bile Duct Stone in Patients with Cholecystectomy

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I submit this thesis as the Master's thesis
in Medical Sciences

February, 2018

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The Master's thesis of Eun Soo Yoo in Medical Sciences is hereby approved.

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December, 22nd, 2017

- **Abstract -**

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Objectives : Recurrence of primary common bile duct (CBD) stone commonly occurs after complete removal of CBD stones in patients with cholecystectomy. This study aimed to investigate potential risk factors for the recurrence of primary CBD stones after endoscopic treatment.

Patient and Method : Between January 2005 and December 2015, the endoscopic retrograde cholangiopancreatography (ERCP) database of our medical center was retrospectively reviewed; information regarding eligible patients who had recurrent CBD stones with a history of previous cholecystectomy was collected. The characteristics of the bile duct, stones, and ERCP-related factors were analyzed.

Results : The recurrence rate of CBD stone was 12.9% (115/894) after endoscopic treatment in patients with cholecystectomy. In univariate analysis, number of CBD stones (≥2), CBD stone diameter (>10 mm), stone composition, stone consistency, diameter of CBD (>15mm), pattern of bile duct dilatation, sharp angulation of bile duct, balloon dilatation, endoscopic mechanical lithotripsy, endoscopic sphincterotomy and endoscopic papillary balloon dilatation alone method were significant between nonrecurrence and recurrence groups. However, in multivariate

analysis (based on the binary logistic regression method), the number of stones (≥2) (adjusted odd ratio [AOR] 1.844; 95% confidence interval [CI] 1.195–2.847; *p*=0.006), CBD stone diameter (>10 mm) (AOR 1.773; 95% CI 1.077–2.919; *p*=0.024), muddy stone (AOR 2.166; 95% CI 1.394–3.364; *p*=0.001), and sharp bile duct angulation (<145°) (AOR 1.738; 95% CI 1.129–2.675; *p*=0.012) were independent risk factors of CBD stone recurrence.

Conclusion : The number of CBD stones, CBD stone diameter, muddy stone, and sharp bile duct angulation are associated with primary CBD stone recurrence after cholecystectomy.

Key Words: Choledocholithiasis, Recurrence factor, Endoscopic retrograde cholangiopancreatography, Multivariate analysis, Cholecystectomy

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I. Introduction

After endoscopic extraction of common bile duct (CBD) stone, subsequent cholecystectomy is recommended to prevent biliary colic, cholecystitis, or CBD stone recurrence in patients with gallbladder stones [1]. With the present low mortality of elective cholecystectomy, primary operation is likely to carry a lower mortality than the nonoperative treatment [2].

However, recurrence of CBD stone is one of the bewildered problems even after cholecystectomy. Concerning frequency, some literature suggested that an incidence of CBD stone recurrence after endoscopic sphincterotomy (EST) was ranging from 4 % to 24% [3,4,5]. Recurrent CBD stones are generally considered to be stones that are detected 6 months or more after endoscopic stone removal [6]. Many studies exist about the incidence and the risk factors of CBD stone recurrence after endoscopic extraction. However, conclusions were different from study to study. D. Keizman et al. claimed that the risk factors for recurrent CBD stones were acute CBD angulation (smaller than 145 ^{o} on cholangiography), CBD dilatation (CBD diameter >15 mm), history of previous cholecystectomy, and presence of periampullary diverticulum (PAD) [6], whereas Kim et al. claimed that sustained dilation of the bile duct even after complete removal of stones and location of the papilla on the inner rim or deep within a diverticulum were independent risk factors for recurrent CBD stones. Kim CW et al. suggested that recurrence of CBD stones was more related to PAD type I compared to PAD type II or III [7]. They also suggested that the sizes of PAD were not related to the recurrence of CBD stones. The sizes of PAD were measured by CT or MRCP (axial and coronal images) using electronic calipers on the workstation [7]. This study aimed to evaluate risk factors for the recurrence of CBD stone in patients who underwent cholecystectomy after endoscopic removal of CBD stones.

II. Materials and Methods

Between January 2005 and December 2015, 894 consecutive patients underwent endoscopic extraction of common bile duct (CBD) stones and subsequent cholecystectomy at Ajou University Hospital in Suwon, South Korea. These cases were retrospectively reviewed from a prospectively designed endoscopic retrograde cholangiopancreatography (ERCP) database. Radiologic findings were reviewed with a radiologist. Although this study was a retrospective study, the recurrence of CBD stone was confirmed by telephone, and patients not identified were excluded from the study. In the retrospective design of the study, we assumed that ERCP was a common procedure and not limited to specific patients. The study was approved by the institutional review board.

The primary outcomes were incidence and risk factors of recurrence of CBD stones. The recurrence of CBD stones was defined as the development of CBD stones after 6 months or later from the endoscopic stone removal and subsequent cholecystectomy. The patients were classified into two groups: recurrence and nonrecurrence groups. CBD stone and CBD-related characteristics and other ERCP-related factors were evaluated.

Several variables were evaluated for all patients. First, factors associated with patients were evaluated such as sex and the presence of PAD. PAD refers to extraluminal outpouchings of the duodenum arising within a radius of 2–3 cm from the ampulla of Vater [8]. PADs were classified into three different types according to the location of the major papilla: for type I, the major papilla was located inside of the diverticulum; type II, the major papilla was located in the margin of the diverticulum; and type III, the major papilla was located outside of the diverticulum [7]. The factors associated with ERCP for stone removal such as endoscopic mechanical lithotripsy (EML) and ampulla manipulation methods were also evaluated. Ampullary manipulation methods were classified into five groups:

EST alone, EST combined with endoscopic papillary balloon dilatation (EPBD), EST combined with endoscopic papillary large balloon dilation (EPLBD), EPBD alone, and EPLBD alone.

The factors associated with CBD stone were also evaluated, such as number, size (the size of CBD stones was measured basing on the diameter of the largest stone in multiple CBD stones, classified based on 10 mm diameter), gross composition (cholesterol stone or pigment stones), and the stone consistency (muddy or hard stones). The characteristics of the bile duct were also evaluated such as CBD diameter (the most dilated site, classified based on 15 mm diameter), patterns of the bile duct dilatation (diffused form or tapered form), and bile duct angulation (less than 145 ° or not).

The categorical variables were analyzed using chi-squared tests. Stepwise logistic regression analysis was used to identify the independent risk factors for the recurrence of CBD stone with cholecystectomy. The odds ratio and 95% confidence intervals were calculated. Univariate and multivariate analyses were used to determine the significant risk factors. Statistical Package for the Social Sciences (SPSS, version 21.0; ⓒ Copyright IBM SPSS Corporation) was used to perform univariate analysis and multivariate analysis to determine the relationship between each risk factor and the recurrence probability. By choosing the factors that had *p*-values less than 0.05, the significant risk factors were narrowed down.

III. Results

From January 2005 to December 2015, the endoscopic extraction of CBD stone with subsequent cholecystectomy was performed in 894 patients. Among the 894 patients, the recurrence of CBD stone occurred in 115 patients during the follow-up period. The mean follow-up period was 47 (1~252) months. The recurrence rate was 12.9% (115/894). All patients were classified into two groups: recurrence and nonrecurrence. No statistically significant differences were observed between the recurrence and nonrecurrence groups in patients' characteristics such as sex, existence of PAD, and types of PAD (Table 1).

Table 1. Patient characteristics

		Recurrence group n=115 (12.9%)	Nonrecurrence group n=779 (87.1%)	*p*-value
Sex (male/female)		54/61	418/361	0.18
PAD(yes/no)		49/66	275/504	0.129
Type of PAD				0.185
	None	66	504	
	I	5	26	0.966
	II	23	90	0.762
	III	21	159	0.608

Abbreviations: PAD = Periampullary diverticulum

On univariate analysis, significant differences were noted between groups in terms of CBD stone-related factors; number of stones (≥2) (p<0.001), CBD stone diameter (>10 mm) (p<0.001), cholesterol stone (p=0.001), and muddy stone (p<0.001). Also, significant differences in characteristics of CBD between the two

groups were observed: CBD diameter larger than 15 mm (p<0.001), diffuse pattern of bile duct dilatation (p=0.014), sharp angulation of bile duct (p<0.001). ERCP-related factors such as balloon dilatation ((p<0.001), EML for the CBD stone removal (p=0.007) and performed EST (p<0.001) also showed significant differences between the two groups (Table 2). In addition, statistically significant differences were also observed between recurrence and nonrecurrence groups when EST-alone method (p=0.002) or EPBD alone method (p=0.032) was chosen for the ampullary manipulation method (Table 3).

Table 2. Univariate analysis of the risk factors for recurrence of CBD stones

	Recurrence group (n=115)	Nonrecurrence group (n=779)	*p*-value
CBD stone-related factors			
CBD stone number of ≥2 (yes/no)	68/47	306/473	<0.001
CBD stone diameter (≥10 mm) (yes/no)	65/50	225/554	<0.001
Stone composition (cholesterol/pigment)	83/32	434/345	0.001
Stone consistency(muddy/hard)	68/47	303/476	<0.001
CBD-related factors			
Diameter of CBD (≥15 mm) (yes/no)	82/33	378/401	<0.001
Pattern of bile duct dilatation (diffuse/tapered)	49/66	428/351	0.014
Sharp angulation of the bile duct (<145°) (yes/no)	71/44	320/459	<0.001
ERCP-related factors			
Balloon dilatation (yes/no)	49/66	197/582	<0.001
EML (yes/no)	15/100	47/732	0.007
EST (yes/no)	72/43	303/476	<0.001

Abbreviations: CBD = Common bile duct; ERCP = Endoscopic retrograde cholangiopancreatography;

EML = Endoscopic mechanical lithotripsy; EST = Endoscopic sphincterotomy

Table 3. Univariate analysis of ampullary manipulation method

	Recurrence group	Nonrecurrence group	*p*-value
Ampullary manipulation method			
EST alone	59	525	0.002
EST+EPBD	7	55	0.078
EST+EPLBD	16	56	0.866
EPBD alone	4	47	0.032
EPLBD alone	14	47	0.424

Abbreviations: EST = Endoscopic sphincterotomy; EPBD = Endoscopic papillary balloon dilatation; EPLBD = Endoscopic papillary large balloon dilatation

Several significant factors on univariate analysis were evaluated using multivariate analysis. In the multivariate logistic regression analysis, multiple CBD stones (adjusted odd ratio 1.844; 95% confidence interval 1.195–2.847; p=0.006), CBD stone diameter (>10 mm) (adjusted odd ratio 1.773; 95% confidence interval 1.077–2.919; p=0.024), muddy stone (adjusted odd ratio 2.166; 95% confidence interval 1.394–3.364; p=0.001), and sharp angulation of bile duct (adjusted odd ratio 1.738; 95% confidence interval 1.129–2.675; p=0.012) were the independent risk factors for CBD stone recurrence (Table 4). In contrast to the univariate analysis, the multivariate analysis showed that stone composition, CBD diameter (>15 mm), pattern of bile duct dilatation, balloon dilatation, performed EML, performed EST, and ampullary manipulation method were not significant risk factors of CBD stone recurrence (Table 5).

Table 4. Multivariate analysis of the risk factors for recurrence of CBD stones

Variables	Odds ratio (95% CI)	*p*-value
CBD stone-related factors		
CBD stone number (≥2)	1.844 (1.195–2.847)	0.006
Diameter of CBD stone (>10 mm)	1.773 (1.077–2.919)	0.024
Stone consistency(muddy)	2.166 (1.394–3.364)	0.001
Composition of stone (cholesterol)	0.633 (0.397–1.010)	0.055
CBD-related factors		
Diameter of CBD (>15 mm)	1.525 (0.922–2.521)	0.1
Pattern of bile duct dilatation (diffuse)	0.814 (0.530–1.252)	0.349
Sharp angulation of the bile duct (<145°)	1.738 (1.129–2.675)	0.012
ERCP-related factors		
Balloon dilatation	1.299(0.716–2.357)	0.39
EML	1.224(0.614–2.439)	0.566
EST	0.587(0.323–1.064)	0.079

Abbreviations: CBD = Common bile duct; ERCP = Endoscopic retrograde cholangiopancreatography; EML = Endoscopic mechanical lithotripsy; EST = Endoscopic sphincterotomy

Table 5. Multivariate analysis of ampullary manipulation method

Ampullary manipulation method	Odds ratio (95% CI)	*p*-value
EST alone	0.635(0.293–1.376)	0.25
EST+EPBD	0.517(0.151–1.768)	0.293
EST+EPLBD	0.781(0.276–2.207)	0.641
EPBD alone	0.272(0.074–1.004)	0.051
EPLBD alone	0.752(0.281–2.011)	0.57

Abbreviations: Abbreviations: EST = Endoscopic sphincterotomy; EPBD = Endoscopic papillary balloon dilatation; EPLBD = Endoscopic papillary large balloon dilatation

IV. Discussion

Commonly, CBD stones are secondary stones from gallbladder stones. However, in some patients, CBD stones recur after cholecystectomy. Even in some patients who underwent cholecystectomy, CBD stones recurred frequently after endoscopic removal of CBD stones. Several studies exist on the recurrence of bile duct stones after EST, and they indicated a wide range in the incidence of stone recurrence from 4% to 24% [3,9]. Primary CBD stones can recur after cholecystectomy because stones are formed in the bile duct due to bile stasis. A lot of papers have reported that bile duct stones are associated with bile duct stricture, papillary stenosis, periampullary diverticulum, reflux of the duodenal contents into the bile duct, and parasites or foreign bodies within the bile duct or other factors predisposing to stasis and encouraging bacterial overgrowth [10]. However, the risk factors are different from paper to paper.

Oak et al. reported that risk factors for recurrent bile duct stones after cholecystectomy were the presence of periampullary diverticulum type 1or 2 and multiple CBD stones. Multiple CBD stones were considered significant risk factors consistent with our study, but periampullary diverticulum was not a significant risk factor in our study [11]. Song et al. reported that risk factors for CBD stone after endoscopic clearance of bile duct stone were CBD diameter (>15 mm) and the presence of periampullary diverticulum [4]. In our study, CBD diameter (> 15mm) and the presence of periampullary diverticulum were not significant risk factors on multivariate analysis. Periampullary diverticula have been known to cause functional biliary stasis possibly because of compression of the distal CBD or also induce reflux of duodenal contents including bacteria into the bile ducts caused by the insufficiency of the choledochoduodenal sphincter [12,13]. However, the effect of PAD on bile stasis was thought to disappear after EST or EPBD for stone removal, so the presence of PAD or type of PAD may not induce the recurrence of

CBD stones after cholecystectomy. More studies are required to prove PAD effect on bile stasis after EST or EPBD for stone removal.

Some studies suggested that CBD dilation (>15 mm) can cause recurrent CBD stone after ERCP [9]. In the present study, patients with a dilated bile duct were especially possible to form new stones in the bile ducts [14]. Kim et al. reported that sustained bile duct dilation even after removal of stones might cause delayed bile drainage and be a potential risk factor for recurrence of CBD stones [15]. Although it is logical and generally believed, the association between biliary disease recurrence and a large bile duct with consequent bile stagnation has not been proven [14]. The unexplained unfavorable conditions to form stones such as bacterial status or bile composition after cholecystectomy need to be investigated.

The angulation of bile duct was considered as an independent risk factor consistent with our data [6]. The angulation along the course of the CBD may predispose to bile stasis and thus promote stone formation and recurrence. Stasis is thought to play an important role in the pathogenesis of cholesterol gallbladder stones for retention of cholesterol supersaturated bile in the gallbladder long enough to provide time for nucleation and precipitation of cholesterol crystals and retention of crystals to allow them to grow into stones [10]. In our data, duct angulation was evaluated in two-dimensional planes on cholangiography as other previous studies.

In the same reason, multiple and large CBD stones (>10 mm) may cause bile stasis more easily after extraction of the stone. Multiple and large CBD stones (>10 mm) indicate that stone feature is associated with medication or chronic inflammation. The primary CBD stone is associated with increase in the rate-limiting enzyme for cholesterol synthesis in the liver, hydroxymethyl coenzyme A reductase (HMG-CoA reductase), and a reduced concentration of the rate-limiting enzyme for degradation of cholesterol to bile acids, 7a-hydroxylase, has been found in the liver in some of these patients [10].

Muddy stones can be retained in the bile duct more easily after ERCP. Small stone fragments that have been missed by cholangiography may act as nidi for stone aggregation causing recurrence [16]. Muddy stones cannot be extracted simply during ERCP, so tiny fragments of stones can remain in the bile duct. However, little data is available regarding stone consistency, like whether it is muddy or has a hard feature. Therefore, clearance of stone fragments should be confirmed after lithotripsy to prevent recurrence of CBD stone [3].

Cholecystectomy is commonly recommended for all patients with CBD stones and symptomatic gallbladder stones, unless there are inappropriate specific reasons for considering surgery [17]. Subsequent cholecystectomy after CBD stone extraction can be helpful to avoid CBD stone recurrence [18]. Several previous trials recommended elective cholecystectomy after EST in cases of GB stones, preexisting cholangitis, acute pancreatitis, complete opacification of the GB during ERCP, and non-visualization of the GB after EST [1,4].

However, no definite guidelines are available for following up patients with removed CBD stone who underwent subsequent cholecystectomy. In fact, many patients visit the hospital for the management of symptoms of recurrent CBD stones. Therefore, identifying the risk factors for the development of recurrent CBD stones can be helpful. In patients with risk factors for bile duct stone recurrence, periodic surveillance can be recommended [4].

Geenen et al. reported that for patients with frequent CBD stone recurrences and without any obvious predisposing factors and even those patients who had no symptoms, annual ERCP surveillance is recommended to decrease the incidence of recurrent ascending cholangitis and its associated morbidity and mortality [19].

However, the main limitation of this study is related to the retrospective design, with potential bias due to patient selection, incomplete information, and the presence of clinical or endoscopic confounders. To minimize bias, a large number of consecutive patients were included in the study, and a prospectively designed

database with organized completion was used to record the demographic characteristics of patients and ERCP-related factors for comprehensive data collection. In addition, as endoscopy was used as the initial approach to a patient with CBD stones in our hospital, we thought there might be some bias in patient registration. Thus, logistic regression analysis was performed to control for potential clinical and ERCP-related confounders.

On the bias of the results and limitation of this study, we suggest that patients with multiple risk factors need more frequent follow-up assessment for early detection of recurrent CBD stones. Follow-up assessment can also be done by clinical follow-up assessment using MRCP and EUS. Abdominal CT or abdominal sonography is useful for surveillance, but tiny stones are more easily detected in MRCP or EUS. In general, patients with risk factors for recurrent CBD stones also need periodic liver function test evaluation in three or six-month intervals [20].

V. Conclusion

In conclusion, CBD stone number (≥2), CBD stone diameter (>10 mm), muddy stone, and sharp bile duct angulation (<145 °) are associated with recurrent common bile duct stones after cholecystectomy.

VI. Reference

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– 국문요약 –

담낭 절제술 이후 재발성 총담관담석의 위험 요소 분석

목적: 일차성 총담관담석의 재발은 처음 총담관담석을 완벽히 제거한 이후 담낭 절제술을 시행한 환자들에서 빈번하게 관찰된다. 이 연구는 내시경적 치료 시행 이후 일차성 총담관담석이 재발하는 환자들의 위험 요소에 대하여 분석하고자 하였다.

방법: 2005년 1월부터 2015년 12월의 기간 동안 아주대학교병원에서 내시경적 역행성 췌담관 조영술을 시행받은 환자들 중 담낭절제술을 시행받은 환자들을 대상으로 후향적으로 조사하였다. 총담관, 담석, 조영술과 관련된 인자들을 분석하였다.

결과: 내시경적 담석 제거술 이후 담낭절제술을 시행받은 환자들 중 총담관담석 재발률은 12.9%(115/894) 였다. 단변량분석에서 총담관담석의 개수, 담석의 직경, 담석의 성분, 담석의 점도, 담관의 확장 크기, 담관 확장 유형, 담관의 경사도, 풍선확장술 시행 여부, 내시경적 기계적 쇄석술 시행 여부, 내시경적유두

괄약근절개술 시행 여부, 내시경적유두풍선확장술 단독시행여부가 재발군이 대조군에 비해 유의하게 높았다. 그러나 다중 로지스틱 회귀 분석에서 담석의 개수가 2개 이상일 경우 (adjusted odd ratio [AOR] 1.844; 95% confidence interval [CI] 1.195–2.847; p=0.006), 담석 크기가 10m 이상일 경우 (AOR 1.773; 95% CI 1.077–2.919; p=0.024), 담석이 진흙 양상일 경우 (AOR 2.166; 95% CI 1.394–3.364; p=0.001), 담관 경사도가 145° 미만으로 예각일 경우(AOR 1.738; 95% CI 1.129–2.675; p=0.012)가 대조군보다 재발군에서 유의미한 요소로 확인되었다.

결론: 총담관담석의 개수, 총담관담석의 크기, 진흙양상의 담석, 예각인 담관 경사도가 담낭 절제술 이후 일차성 총담관담석 재발의 위험 요소로 확인되었다.

핵심어 : 총담관담석, 재발 인자, 내시경적 역행성 췌담관 조영술, 다변량 분석, 담낭 절제술