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Стеноз желчных протоков при гепатолитиазе: характерные особенности и факторы риска резидуального холангиолитиаза

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Цель: определение факторов, влияющих на наличие остаточных камней после холедохоскопии и литотрипсии.
Материал и методы. В нашем ретроспективном исследовании принял участие 201 пациент с гепатолитиазом и стенозом желчных протоков. С января 2018 г. по декабрь 2020 г. все пациенты перенесли холедохоскопическую литотрипсию с рассечением или без рассечения паренхимы и резекцией печени в отделении гепатобилиарной хирургии в больнице VietDuc University (Ханой, Вьетнам). Были собраны демографические данные, выявлены клинические особенности, получены результаты лабораторных исследований, установлен тип операции и особенности стеноза желчных протоков (локализация, число, степень выраженности). Основным критерием оценки была частота полного удаления камней в послеоперационном периоде.
Результаты. У 82,6% пациентов был выявлен один участок стеноза, у 49,8% – несколько участков. Частота полного удаления камней после холедохоскопической литотрипсии составила 43,2%, а в сочетании с резекцией печени или рассечением паренхимы – 75,3%. Использование нескольких методов лечения и тип внутрипеченочных камней являются двумя факторами, влияющими на наличие остаточных камней после операции.
Заключение. Холедохоскопия является эффективным способом диагностики желчных камней и выявления особенностей желчных протоков. Резекция печени и рассечение паренхимы в сочетании с холедохоскопической литотрипсией представляют собой безопасный и эффективный метод лечения, повышающий частоту полного удаления камней при гепатолитиазе и стенозе желчных протоков. В осложненных случаях, связанных с внутрипеченочными камнями, необходимо комплексное и интенсивное лечение.

Ключевые слова: *желчные протоки; гепатолитиаз; стеноз; стриктура; холедохоскопия; литотрипсия; резекция печени; остаточный камень*

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Авторы заявляют об отсутствии конфликта интересов.

Bile duct stenosis in hepatolithiasis: a detailed characteristics and predictors for stone clearance

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Our aim is to identify the prognostic factors for post-operative residual stone.
Methods. Our retrospective study recruited 201 participants with hepatolithiasis and bile duct stenosis who underwent choledochoscopic lithotripsy with or without parenchyma incision and hepatic resection in Department of Hepatobiliary surgery, VietDuc University hospital, Hanoi, Vietnam from 1/2018 to 12/2020. Demographic information, clinical features, laboratory results, type of operation, bile duct stenosis characteristics (site, number, severity) were collected. Our primary endpoint was the post-operative stone clearance rate.
Results. 82.6% had one stricture site, 49.8% had a severe stricture. The stone clearance rate after CEHL was 43.2, and combined hepatectomy/parenchymal incision was 75.3%. Multiple approaches and type of intrahepatic stone are two associated factors for residual stone.
Conclusion. Choledoscopy is a valuable tool in finding gallstones and acquiring bile duct characteristics. Hepatectomy and parenchymal incision, along with choledoscopic lithotripsy, is a safe and effective method for increasing the

clearance rate for hepatolithiasis and bile duct stricture. Comprehensive and aggressive treatment is needed in complicated intrahepatic stones.

Keywords: *hepatolithiasis; bile duct stenosis; choledochoscopic lithotripsy; hepatectomy; residual stone; predictors*
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Abbreviations

CCA	Cholangiocarcinoma
CEHL	Choledochoscopic electrohydraulic lithotripsy
CT	Computed tomography
ERCP	Endoscopic retrograde cholangiopancreatography
MRI	Magnetic resonance imaging
OP	Operation
PI	Parenchyal incision
PTCS	Percutaneous Transhepatic Cholangioscopy
US	Ultrasound

Introduction

Gallstones is a common disease in South East Asia, accounting for approximately 10% of the population, in which, half of these are hepatolithiasis [1, 2]. Risk factors are well determined, including infection, behavior, socio-economic status, and congenital [2–4]. Two main pathogenesis of hepatolithiasis are infection-induced cholestasis and defection of cholesterol metabolic regulation [3, 5]. The disease often co-exists with cholangitis and causes some complications, such as pancreatitis, bile duct stenosis, pyogenic liver abscess, and biliary cirrhosis. 2–10% of hepatolithiasis will further develop cholangiocarcinoma with poor survival outcomes [6–8]. The objective of cholelithiasis treatment is to remove the stones, manage comorbidities (bile duct stricture, liver abscess, liver atrophy), and prevent stone recurrence [9, 10]. Some figures showed that intrahepatic duct stenosis occurs in up to half of these cases, and is considered as a potential risk factor for residual stone [9, 11]. Thus, a comprehensive treatment is required.

In the era of minimal invasive therapy, endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTCS) have been increasingly used [12, 13]. But, its efficacy in managing stricture and bilateral stone is limited. Besides, the risk of hemobilia, bile duct perforation, retrograde cholangitis, residual stones increases [14]. Open/laparoscopic surgery is a more effective option with higher stone clearance rate, the ability to resect damaged hepatic lobe, cancer... [8, 15, 16]. The intraoperative choledochoscopy and lithotomy along with hepatectomy or parenchymal incision have been advocated as a useful approach [17]. Clearance rate could reach 90% after hepatic resection and 98% after second intervention [18].

Though it is a matter of concern, predictors of stone clearance rate among patients with bile duct stricture after lithotripsy have not been well documented. Thus, the aim of our work was to determine the prognostic factors for post-operative residual stone.

Materials and Methods

Study population

This was a retrospective study conducted at the Department of Hepatobiliary surgery, Viet Duc University hospital in Hanoi, Vietnam. We recruited 201 participants whose surgery was peformed between January 1st, 2018 and December 31st, 2020. These patients were diagnosed with hepatolithiasis and bile duct stenosis and treated by open choledochoscopic lithotripsy (CEHL) with or without other interventions (parenchymal incision, hepatic resection). Patients without fully detailed characteristics of strictured bile duct were excluded.

Routine bile duct exploration was performed with Olympus® CHF-P20 Choledochoscopes (fig. 1). CEHL was served with three main aims: provide a direct view of the biliary tract, detect and remove the gallstones, and dilate the strictured duct. The operations were managed by experienced surgeons. Hepatectomy was indicated in patients having segmental atrophy, resectable cholangiocarcinoma and severe-strictured bile duct. Parenchymal incision was conducted when stones lie beneath the liver surface, preventing viewing from the choledochoscopy. The treatment protocol was further demonstrated in fig. 2.

Data collection

We collected demographic information, history of gallstones diseases and surgery, clinical symptoms, and laboratory results. Cholangitis was diagnosed and classified based on the 2018 Tokyo Guidelines [19]. Intra-operative lesions (atrophy, pancreatitis, pyogenic cholangitis/liver abscess, cholangiocarcinoma, and peritonitis) and type of operation were also recorded. Bile duct stenosis characteristics (site, number of strictures) were collected. The type of intrahepatic stone was classified into “A”, “B”, “C” according to the Cheon’s classification, based on information of stone distribution and associated bile duct strictures [9]. The degree of stricture was categorized as “mild” or “severe” following the Takada classification via 5-mm diameter choledochoscope [11].

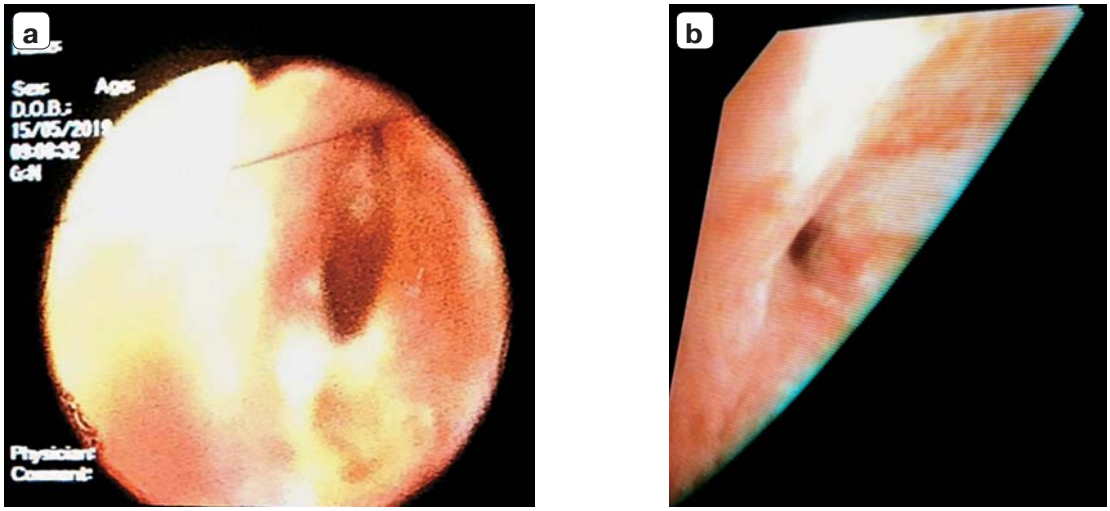

Fig. 1. Image of biliary stricture through choledoscopy: **a** – left lateral; **b** – posterior.
Рис. 1. Эндофото. Стриктура желчных протоков при холедохоскопии: **a** – вид сбоку; **b** – вид сзади.

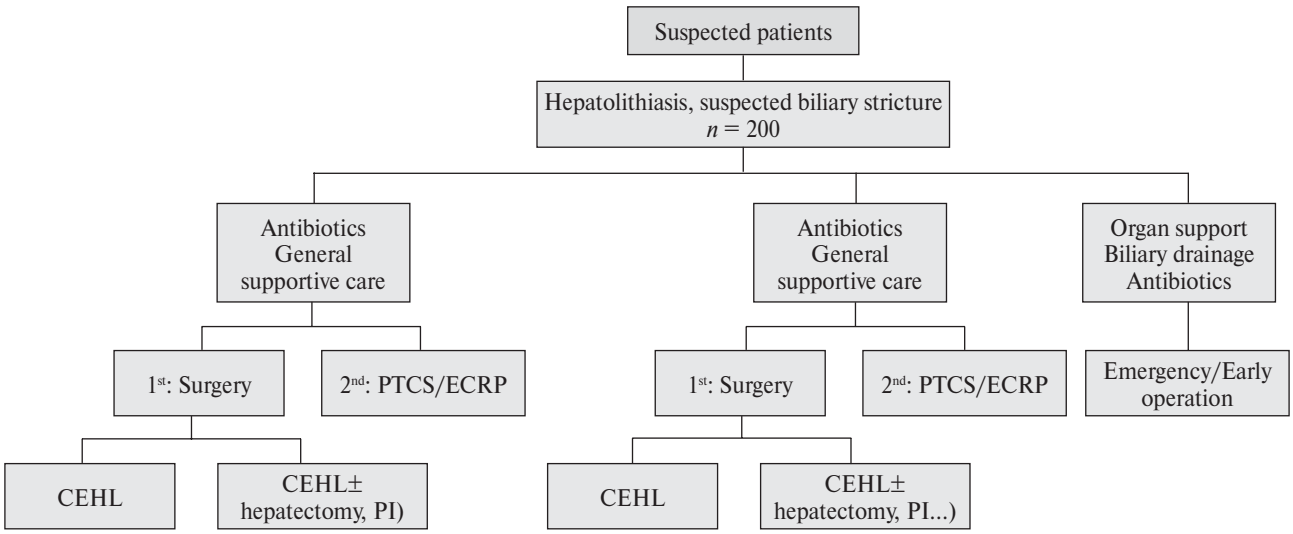

Fig. 2. Study protocol. CCA – Cholangiocarcinoma, CEHL – Choledochoscopic electrohydraulic lithotripsy, CT – Computed tomography, ERCP – Endoscopic Retrograde Cholangio Pancreatography, MRI – Magnetic resonance imaging, OP – operation, PI – Parenchyal incision, PTCS – Percutaneous transhepatic cholangioscopy, US – ultrasound.
Рис. 2. Протокол исследования.

Residual stone was the primary endpoint, which was determined via ultrasound (US) and T-tube cholangiography 7 days after the operation.

Statistical analysis

Demographic, clinical, and laboratory characteristics were compared between patients with and without residual stones using the chi-square test. To explore the factors associated with residual stones, we fitted multivariable regression models with different sets of variables, chosen based on literature review and personal experience of their clinical significance. The models included model 1 (age, sex), model 2 (model 1 + type of treatment), model 3 (model 2 + number of stricture), model 4 (model 2 + intrahepatic stone type), model 5 (model 2 + number of stricture, intrahepatic stone type), and model 6 (model 5 + previous intervention, cholangitis, liver abcess, liver enzymes and total bilirubin). Because residual stones were a common outcome (cumulative incidence >15%), we utilized log-binomial regression instead of logistic regression. In case the log-binomial regression model failed to converge, Poisson regression with robust variance estimation was used to approximate the log-binomial model [20]. The final model was the one with lowest Akaike information criterion (AIC).

A p-value of <0.05 was considered statistically significant. The analysis was performed with SPSS® Statistics version 26.0 64 bit for Windows (IBM® Corporation, USA).

The study was conducted according to the Declaration of Helsinki, and it was approved by our ethical committee.

Results

Among 201 patients, 70.1% were older than 45, and 30.8% were men. 108 (53.7%) had undergone at least one intervention (surgery, ERCP or PTCS) for cholelithiasis. 145 (72.1%) had acute cholangitis, mostly grade II (table 1). In table 2, intra-operative findings and bile duct stenosis characteristics are presented. The most common site of bile duct stricture is the left side (71.6%), followed by the right side (33.3%). Almost 80% had one stricture and nearly 50% had "severe" bile duct stricture. 31.8% of patients underwent liver resection, mainly in the left lateral lobe, only one patient (0.5%) had S6 segmentectomy. 10 patients (5%) had intra-operative hemobilia, residual abscess was observed in 9.5% of pa-

Table 1. Preoperative data of the study population

Таблица 1. Предоперационные данные исследуемой группы больных

Variables	Categories	Residual		P-value
		No	Yes	
Age	<45	30	30	0.194
	45–60	35	36	
	⩾60	44	26	
Sex	Male	32	30	0.648
	Female	77	62	
Number of previous intervention	0	59	34	0.038
	1–2	44	48	
	>2	6	10	
Cholangitis classification	0, I	55	52	0.399
	II, III	54	40	
Laboratory results				
WBC (G/L)	<4	1	3	0.448
	4–10	62	54	
	⩾10	46	35	
Platelets (G/L)	<150	13	19	0.121
	⩾150	96	73	
PT (%)	<70	7	7	0.786
	⩾70	102	85	
AST/ALT (UI/L)	⩾100	28	31	0.276
	<100	81	61	
Total bilirubin (μmol/L)	⩾50	21	22	0.491
	<50	88	70	
Positive blood/ bile culture	Yes	99	84	1
	No	10	8	

WBC – White blood count, PT – Prothrombin time, AST – Serum aspartate transaminase, ALT – Serum alanine transaminase

Table 2. Intra-operative and bile duct stenosis characteristics

Таблица 2. Интраоперационные особенности и характер стеноза желчных протоков

Variables	Categories	Residual		P-value
		No	Yes	
Presentation	Acute cholangitis	145		–
	Liver segment atrophy	34		–
	Acute pancreatitis	12		–
	Pyogenic cholangitis/ liver abscess	43		–
	Cholangiocarcinoma	8		–
	Peritonitis	2		–
Intra-hepatic stone type	A	72	32	<0.001
	B	23	29	
	C	14	31	
Cholelithiasis site	Left/right lobe	44		–
	Left, right lobe	33		–
	Left/right lobe; CBD	55		–
	Left, right lobe; CBD	69		–
(Biliary) cirrhosis		137		–
Biliary stricture site	Segmental duct	6		–
	Anterior/Posterior hepatic duct	22		–
	Right hepatic duct	67		–
	Left hepatic duct	144		–
	Hilar	5		–
Number of stricture site	<2	95	63	0.002
	⩾2	14	29	
Stricture severity	Mild	54	47	0.888
	Severe	55	45	
Type of procedure	Choledochoscopic lithotripsy	201		–
	Hepatectomy	64		
	– Left lateral	58		–
	– Left lobe	4		
	– Segment VI/II	2		
	Hepatic parenchyma incision	5		–
	Bilioenteric anastomosis	6		–
Stone clearance rate	Lithotripsy ($n = 132$)	57		–
	Lithotripsy + others (resection, incision) ($n = 69$)	52		–
Complications	None	162		–
	Bile leakage	1		–
	Bleeding (intraabdominal, gastrointestinal)	2		–
	Hemobilia/Rupture bile duct	10		–
	Residual abcess	19		–
	Surgical site infection	7		–

Table 3. Predictors for residual stone after choledochoscopic lithotripsy
Таблица 3. Факторы риска оставления резидуальных камней после холедохоскопической литотрипсии

Variables		Residual stone (%)	Univariate		Multivariable	
			RR (95%CI)	P-value	RR (95%CI)	P-value
Sex	Male Female	48.4 44.6	Ref 0.86 (0.47–1.57)	 0.62	Ref 0.99 (0.73–1.33)	 0.94
Age	<45 45–60 ⩾60	50.0 50.7 37.1	Ref 1.03 (0.52–2.05) 0.59 (0.29–1.19)	 0.94 0.14	Ref 1.01 (0.72–1.41) 0.72 (0.49–1.06)	 0.95 0.09
Intrahepatic stone type	A B C	30.8 55.8 68.9	Ref 2.84 (1.43–5.64) 4.98 (2.34–10.61)	 **0.003** **<0.001**	Ref 1.67 (1.14-2.45) 1.72 (1.19-2.47)	 **0.004** **0.009**
No. of past intervention	0 1–2 >2	36.6 52.2 62.5	Ref 1.43 (1.02–1.99) 1.71 (1.07–2.72)	 **0.036** **0.024**	–	
Stricture severity	Mild Severe	46.5 45.0	Ref 0.97 (0.72–1.31)	 0.83	–	
Cholangitis grading	0,1 2,3	48.6 42.6	Ref 0.88 (0.65–1.19)	 0.39	–	
No. of stricture	1 >1	33.9 67.4	Ref 3,12 (1.53–6.37)	 **0.002**	–	

tients. In univariate analysis, comparing to patients without residual stones, patients with residual stones had higher rate of complicated stone type, higher previous interventions as well as less-aggressive surgical treatment ($p < 0.05$) (table 3). In multivariate analysis, the model 4 (with sex, age, intrahepatic stone type, and type of treatment) with AIC of 322.12 was chosen. We found a significant difference in residual stone rate when hepatolithiasis is more complicated and when combined treatment (CEHL with hepatectomy, parenchymal resection) is applied.

Discussion

The stone clearance rate was just 53.2%, compared to some figures of more than 80% regardless of bile duct stenosis [8]. When the intrahepatic stone was more complicated, the risk for residual stone increased approximately 70%. The clearance rate was higher when in hepatectomy and parenchymal incision group. Among 64 patients with hepatectomy, 15 patients had residual stone (23.4%), but 10 patients were bilateral hepatolithiasis with residual stone occurs in the unresected sides, so the truly residual rate after hepatectomy might be as low as 7.8%. A detailed report regarding the bile duct stenosis and the role of surgery for this condition has not been frequently published. The outcome is comparable to the published paper [8, 18]. Cholangiocarcinoma has been reported in patients with hepatolithiasis. 4% of our study population was diagnosed with cholangiocarcinoma, similar to Lorio et al. [8, 21]. The rate is even higher in recurrent stone or bilateral liver atrophy groups, which proposed a thorough treatment and follow-up.

Bile duct stricture might be a risk factor for residual stone, recurrent cholangitis. More than half of the study population had at least one previous intervention, making the diseases more complex. Most patients had one stricture, and mostly in the left hepatic duct, similar to previous articles [11, 22]. Bile duct stricture appears after cholangitis and inflammatory responses, which then triggers fibrosis and lumen narrowing [23, 24]. Another consideration is the degree of associated cholangitis. We followed the 2018 Tokyo Guidelines for pre-operative management, with antibiotics and general care in grade I and II cholangitis. Among 3 grade III cholangitis patients, which normally require urgent biliary drainage before surgery, 2 of them had low platelets but could not be cured by platelets tranfusion, thus biliary drainage could not be performed. One patient underwent emergency laparotomy after successful resuscitation due to cardiac arrest.

In patients with hepatolithiasis and suspected biliary stricture, we favored operation over PTCS/ERCP because of its efficacy. Though there is not any available literature relating each procedure's efficacy in bile duct stenosis group, surgery appears to have a higher success rate and lower recurrent rate [8, 9, 25]. PTCS is also a good option for patients with high surgical risk, history of biliary surgery and without hepatotrophy [26]. A novel approach using laser ablation to treat biliary stricture has been published with encouraging results [12], but further studies with a larger sample should be done to find the efficacy of the method. While PTCS could provide a good recovery and also the direct view of the bile duct via choledoscopy, it could not examine the liver condi-

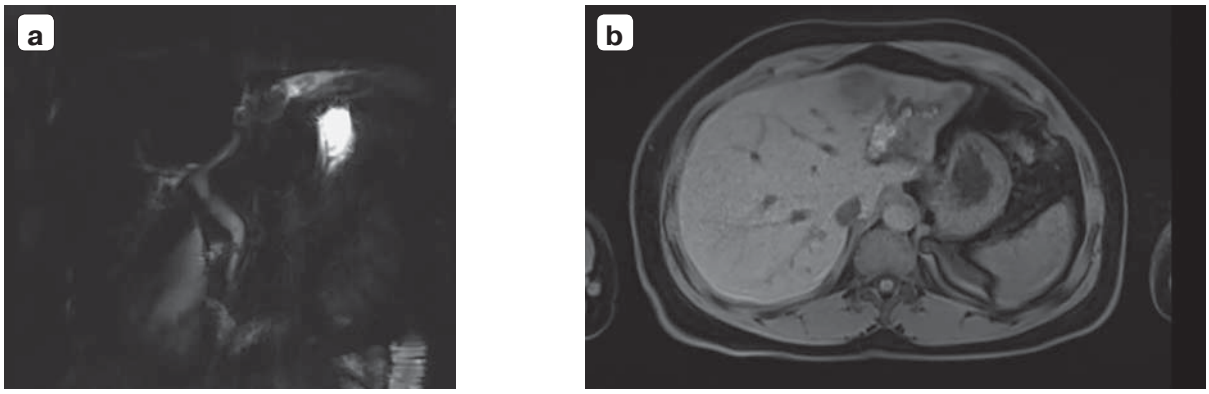

Fig. 3. Image of biliary stricture in imaging: **a** – magnetic resonance cholangiopancreatography (MRCP); **b** – magnetic resonance imaging (MRI) axial.

Рис. 3. Стеноз желчных протоков: **a** – МР-холангиопанкреатикограмма; **b** – магнитно-резонансная томограмма.

tions (atrophy, cirrhosis, cancer)... Another reason is that only 50% of hepatectomy is determined before the surgery, while other was decided during the laparotomy [27]. New surgical approach using parenchymal incision with clearance rate of 88.2% has also been applied in our study, and also showed promising results [28]. Although we only performed hepatectomy for segmental atrophy, resectable cholangiocarcinoma and severe-strictured bile duct (fig. 3), we suppost that hepatectomy or parenchymal incision could apply to other patients to reduce the residual stones [10, 29].

We routinely did left lateral hepatectomy, but not right hepatectomy due to higher risk of infection and post-operative liver failure. This topic is still controversial. Jeng et al. supposed that outcomes after left lateral segmentectomy (the most commonly affected side) was satisfied and the risk of complication was lowered [30]. But recent data identified that if the degree of hepatectomy is equivalent to the affected segment or when the remnant liver is sufficient, then the outcomes of bilateral hepatectomy is justified [10, 31]. With the advancement of hepatic resection techniques as well as management of gallstones, we supposed that right hepatectomy could be technically feasible.

In the minimally invasive era, while open surgery might be a matter of concern, laparoscopic surgery could be a good candidate for replacement [13, 25, 32, 33]. The strengths of laparoscopy are reduced pain, the ability to perform hepatectomy and cholecystectomy [27]. Laparoscopic hepatectomy for intrahepatic stone has been increasingly reported, with comparable efficacy and similar or lower morbidity than open surgery [13]. Although there are some technical challenges, laparoscopy has the potential to make a strong influence in the treatment of gallstones and could be the cornerstone of minimally invasive gallstones treatment in the future.

To be concluded, our study shows that bile duct stricture is truly complicated comorbidity of hepatolithiasis. Nearly half of our patients were classified as "severe" stricture and in grade B/C regarding intrahepatic stone distribution-stricture relationship, with later one a significant predictor for clearance outcome. The residual stone rate was 50% lower in hepatectomy or parenchymal incision was applied.

Our study has some limitations. Firstly, our study population was solely in the surgical group. And secondly, we did not routinely do pre-operative biliary drainage, right hepatectomy, and ductal stenting. To the best of our knowledge, our study provides one of the most comprehensive data regarding the characteristics of hepatolithiasis and bile duct stricture. The data could be used as a useful tool for clinicians to determine the optimal treatment for the patient.

Conclusion

82.6% had one stricture site and nearly half had a severe stricture. Hepatolithiasis with bile duct stenosis is a complicated co-morbidity, with the stone clearance rate of 54.2%. Choledoscopic in combination with hepatectomy is a safe and useful method. Combined approach and the type of intrahepatic stone are two associated factors for residual stone.

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Authors contributions

Dang Do Hai – design the study, write the manuscript.

Lan Nguyen Thi – collect the data, analyze the data.

Khiem Nguyen Thanh – revise the manuscript.

All authors have read and approved the final version of the manuscript.

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