



Risk factors for the recurrence of stones after endoscopic minimally invasive cholecystolithotomy in China: a meta-analysis

Wenchao Li¹ · Pinzhu Huang² · Purun Lei² · Hui Luo³ · Zhicheng Yao¹ · Zhiyong Xiong¹ · Bo Liu¹ · Kunpeng Hu¹

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Abstract

Background The recurrence of stones after endoscopic minimally invasive cholecystolithotomy (EMIC) remains a hazardous problem in patients with cholelithiasis. We sought to evaluate the risk factors for recurrence after cholecystolithotomy and to provide a theoretical basis for the indication for cholecystolithotomy.

Methods We searched the Cochrane Library, PubMed, EMBASE, WanFang Data, CNKI and VIP Data to identify controlled trials related to cholelithiasis that were published between 2007 and 2016. The odds ratios (ORs) were calculated with 95% confidence intervals (CIs). Stata12.0 was used to test the heterogeneity and publication bias.

Results Eight studies involving 1663 participants were selected. No significant differences were observed in hazardous factors including advanced age, gender and diabetes mellitus compared with the control groups. However, family history of cholelithiasis, multiple calculi, gallbladder wall thickening (GBWT) over 3 mm, a preference for greasy food, dysfunction of the gallbladder and not taking oral ursodeoxycholic acid post-EMIC yielded pooled ORs (95% CI) of 3.28 (2.30, 4.66), 4.24 (2.76, 6.50), 18.4 (7.23, 46.83), 1.90 (1.20, 3.01), 26.16 (10.15, 62.34) and 2.90 (1.36, 6.15), respectively.

Conclusions A family history of cholelithiasis, multiple calculi, a GBWT ≥ 3 mm, a preference for greasy food, dysfunction of the gallbladder and not taking oral ursodeoxycholic acid post-EMIC are hazardous factors for stones and sludge after cholecystolithotomy.

Keywords Cholelithiasis · Gallbladder preserved · Stones recurrence · Risk factors · EMIC

Cholelithiasis is a common gastrointestinal disease with over 10% morbidity that is increasing significantly with the ageing of the population [1]. Cholecystectomy has been used to treat cholelithiasis for over 100 years since the first cholecystectomy was performed by Langenbuch [2]. However, many severe complications following cholecystectomy have

been reported in recent studies and listed as follows: duodenogastric reflux [3, 4], post cholecystectomy syndrome [5], bile duct injuries [6] and an increase in colonic cancer [7]. Additionally, with a deep understanding of the function of the gallbladder, surgeons now realize that the gallbladder not only concentrates and stores bile but also regulates the flow of bile. Moreover, not all patients are eligible for cholecystectomy, including the elderly and those at high risk. There may also be indications to preserve a useful gallbladder in younger patients with solitary or few stones and in whom stones may not recur [8].

In 1988, percutaneous cholecystolithotomy was first described by Kellett et al. [9] for the treatment of gallstones while leaving the gallbladder in situ. EMIC is a minimally invasive laparoscopic procedure that removes the calculi and preserves the gallbladder and was first described by BaoShan [10] in China. Given that EMIC can reduce residual gallstones and the recurrence of gallstones due to the application of endoscopic techniques and iconography, it is more mature than percutaneous cholecystolithotomy, which has become

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✉ Kunpeng Hu
hkpdhy918@126.com

¹ Department of General Surgery, The Third Affiliated Hospital, Sun Yat-sen University, Guangzhou, China

² Department of Gastrointestinal Surgery, The Sixth Affiliated Hospital, Sun Yat-sen University, Guangzhou, China

³ Department of Operating Room, The Third Affiliated Hospital, Sun Yat-sen University, Guangzhou, China

popular in China in recent years. A meta-analysis reported by Ye et al. including 14 RCTs about Endoscopic minimal invasive cholecystolithotomy versus laparoscopic cholecystectomy in treatment of cholecystolithiasis in china indicated that EMIC has shown significant less blood lost, shortened exhaust time and lower expense compared to laparoscopic cholecystectomy (LC), suggesting that Patients treated with EMIC have shown faster recovery and less complication than LC [11]. However, stone recurrence is a major problem associated with cholecystolithotomy, and there are few studies of the long-term outcomes of this approach with large numbers of cases. Risk factors for stone recurrence are a hotspot in current research. Therefore, this meta-analysis aimed to identify the risk factors for stone recurrence after cholecystolithotomy and to provide a theoretical basis for the indication of cholecystolithotomy.

Materials and methods

Search strategy

The medical databases of the Cochrane library, PubMed, EMBASE, WanFang Data, CNKI and VIP Data were searched for relevant articles published from 2007 to 2016 using the terms ‘gallbladder preserved’, ‘cholelithiasis’ and ‘cholecystolithotomy’. The included research was limited to human subjects. Potentially qualified studies were also identified by searching the reference lists of the selected studies. These processes were performed repeatedly until no additional articles could be identified. The details of Search Strategy were presented in Online Appendix 1. The searching tasks were conducted independently by four of the authors. (Purun Lei, Hui Luo, Zhicheng Yao and Zhiyong Xiong).

Selection criteria

All included studies were about the risk factors related to the recurrence of stones after EMIC. EMIC was defined as laparoscopic cholecystolithotomy involving calculi removal and gallbladder preservation via a laparoscope combined with a choledochoscope, and studies of percutaneous cholecystolithotomy, percutaneous cholecystostomy and percutaneous cholecystostomy were excluded.

The following selection criteria were applied for this meta-analysis: (1) the studies were cohort studies, (2) the studies investigated the risk factors related to the recurrence of stones after EMIC, and (3) the modus operandi was limited to endoscopic minimally invasive cholecystolithotomy.

Studies were excluded if they met the following criteria: (1) case report studies and reviews, (2) studies without a set control group, (3) studies that reported insufficient

information about the outcome of interest, or the outcome of interest was impossible to calculate and (4) the number of participants was less than 50.

Procedure of laparoscopic cholecystolithotomy

Preoperative ultrasonography (US) was performed to fully probe the gallbladder’s size, thickness of gallbladder wall, gallstone number and so on. Patients with Satisfactory gallbladder function and single calculi are more suitable for laparoscopic cholecystolithotomy. Under general anesthesia, the patient were turned to antitrendelenburg position with the head and right trunk elevated. Three position of ports were the same as those of the ports of LC, and CO₂ pneumoperitoneum was settled between 12 and 15 mm Hg. One more incision was made in the surface localization of the gallbladder fundus. Placing a gauze under the gallbladder, an appropriate length of incision in the fundus of gallbladder was made by trocar depending on the size of gallstones. Aspirator was used to suck out the bile, then 0.9% saline combine with gentamicin was used to lavage the gallbladder cavity by choledochoscope or cholecystoscope. The gallstones were taken out though the lithotomy forceps, stone baskets or aspirator (for small stones). Choledocholithotomy with laparoscope and choledochofiberscope, T tube drain or primary suture were used when the patient combined with choledocholithiasis. After removing all the stones, choledochoscope and ultrasonography were used to detected residual gallstones or choledocholithiasis. Biopsy of gallbladder mucosa was necessary so as to exclude the malignant biliary tumour. The incision at the bottom of the gallbladder was sutured with an 4–0 absorbable thread.

Data extraction

Two reviewers assessed the publications independently using a predefined data extraction form. Disagreements were resolved by discussion with a third reviewer. Studies that met the inclusion criteria were included for further analysis. General descriptive data (such as sample size, recurrence rate, follow-up time, hazards, etc.) are listed in Table 1. Nine hazards were included in the final meta-analysis.

Assessment of the methodological qualities of the included studies

The methodological qualities of the included studies were assessed according to the Newcastle–Ottawa scale (NOS) [12] independently by two of the authors (Hu and Li). This scale consists of three factors: patient selection, comparability of the study groups and assessment of the outcome. The eligible studies were classified as low-quality studies (0–4), moderate-quality studies (5–6) and high-quality studies

Table 1 Main characteristics of all eligible studies

First author	Year	Samples	Follow-up time(M)	Recurrence rate (%)	Included risk factors	NOS
Liling S	2016	168	24–48	42.26	Age, sex, family history, hypertension, hyperlipaemia, DM, adiposity, stones number, dietary habits	7
Shuai L	2015	641	36–72	4.5	Age, sex, family history, region, stones size, stones number, chronic disease	7
Quanfu L	2015	272	6–84	25	Age, sex, family history, adiposity, dietary habits, gallbladder function	7
Chao C	2015	167	6–65	8.98	Age, sex, family history, adiposity, stones type, submucosal calculi, exercise habits, ursodeoxycholic acid	7
Jianbin G	2014	122	52–63	21.3	Age, sex, GBWT, hypercholesterolaemia, hyperlipaemia, DM, stones number, gallbladder polyps	7
Wei S	2013	168	12–36	8.3	Family history, adiposity, dietary habit, gallbladder function, stones type	7
Jianping Z	2012	60	–	38.3	Family history, GBWT, DM, gallbladder function, stones number, ursodeoxycholic acid	6
Jian K	2011	65	6–120	38.5	Age, sex, family history, GBWT, DM, gallbladder function, stones number, ursodeoxycholic acid	7

M month, *DM* diabetes mellitus, *GBWT* gallbladder wall thickening, *NOS* Newcastle–Ottawa scale

(7–9). The NOSs of the eligible studies are summarized in Table 1. Online Appendix 2 was applied for presenting the criteria of methodological qualities while Online Appendix 3 showing the NOS of the included studies.

Statistical analysis

The statistical analyses were performed using STATA 12.0 (StataCorp, College Station, TX, USA). The odds ratios (ORs) with the 95% confidence intervals (CIs) were used to compare the quantitative statistical analyses for the dichotomous variables with fixed or random models. Heterogeneity among included studies was examined using the chi-squared-based Q test and the I^2 test [13, 14]. Heterogeneity differences were regarded as significant when $I^2 > 50%$ or $P < 0.1$ in the Q test. According to the Cochrane review guidelines, if severe heterogeneity was present at $I^2 > 50%$, random effect models (DerSimonian Laird method) were chosen; Otherwise, fixed effect models (Mantel–Haenszel method) were used to calculate the summary OR. Moreover, sensitivity analysis was conducted by deleting each study individually to evaluate the quality and consistency of the results. Publication bias was assessed with Egger's test.

Results

Literature search and study characteristics

According to the PRISMA statement [15], a flow diagram summarizing the literature search is presented in Fig. 1. A total of 851 studies were identified through the database search and other resources. Seven hundred forty-six studies

remained after the duplicates were removed, and 571 studies were excluded based on the titles and abstracts. The remaining 45 full-text publications were assessed for eligibility. Eventually, eight publications including 1663 patients were included in the present meta-analysis.

The patients in all the included studies [16–23] underwent EMIC and were selected according to similar inclusion criteria. The definition of EMIC is mentioned above. Nine hazards were eventually included in this meta-analysis as mentioned above. Four studies described advanced age, six studies described gender, five studies described a family history of cholelithiasis, seven studies described multiple calculi, four studies described diabetes mellitus, three studies described gallbladder function pre-EMIC, three studies described whether the patients took oral ursodeoxycholic acid post-EMIC, three studies described the thickness of the mucous membrane of the gallbladder and three studies described the patients' dietary habits. The risk factors, including adiposity, hyperlipaemia, a lack of regular exercise and intramural calculi of the gallbladder pre-EMIC, were mentioned in only two studies, and these studies included a small number of participants, so we were unable to estimate the effects of these indices on the hazards.

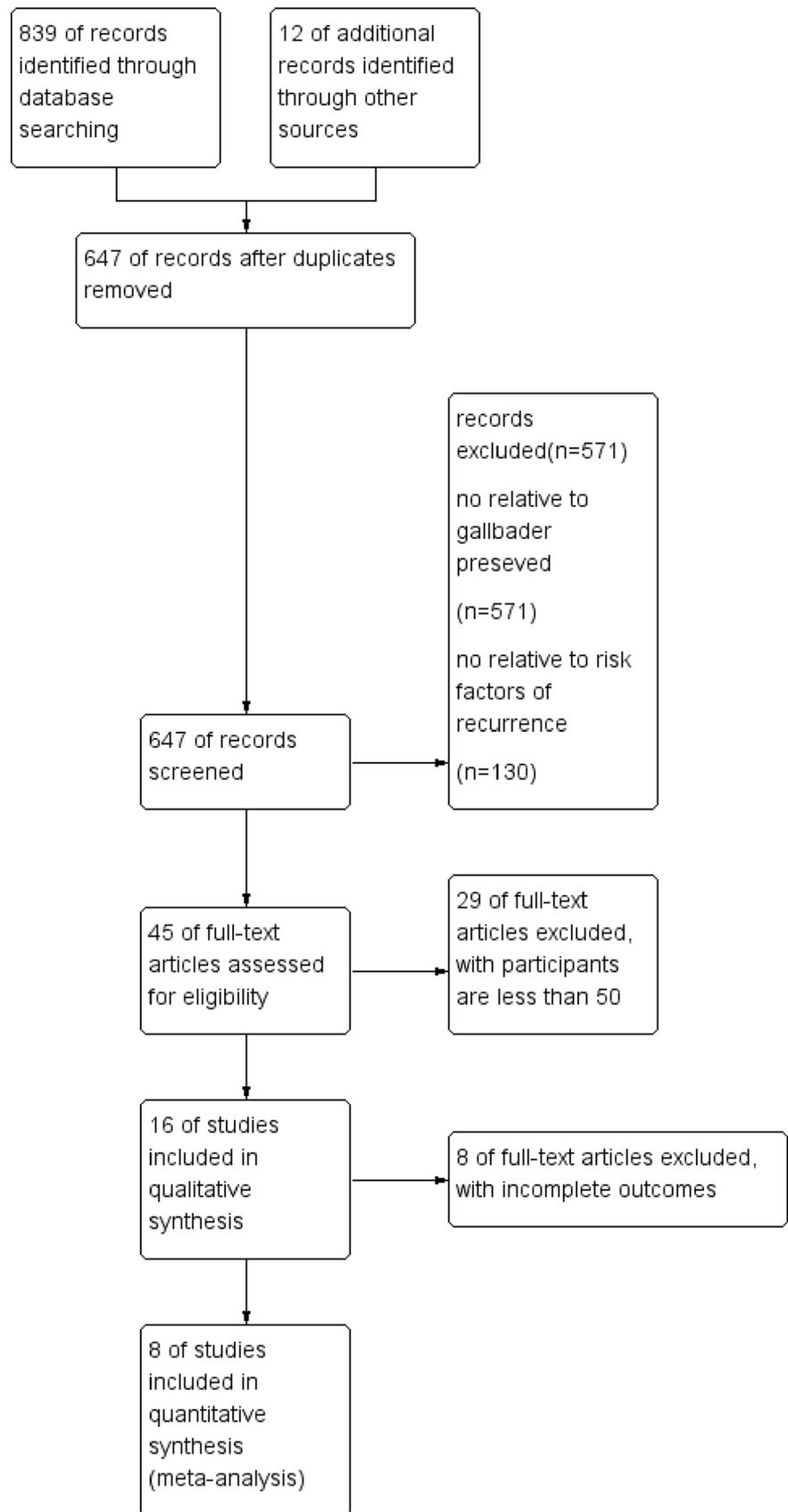
The follow-up times were reported as ranging from 6 months to 10 years in eight studies. The rate of stone recurrence was reported in all the included studies.

Primary hazards

Advanced age

Four of the included studies reported advanced age indices, and there was no heterogeneity among the studies ($I^2 = 0%$,

Fig. 1 Flow diagram of literature search and study selection



$P=0.62$). Thus, in the fixed-effects model (OR 1.00, 95% CI 0.65, 1.53, $P=0.99$; Fig. 2), no association was revealed between advanced age and stone recurrence (P value >0.05).

Gender

Six of the included studies reported the gender index, and no heterogeneity was presented ($I^2=0\%$, $P=0.65$), and there was no statistical significance in terms of the gender index (OR 1.02, 95% CI 0.74, 1.39, $P=0.62$; Fig. 2).

Family history of cholelithiasis

Six of the included studies reported the family history index. When all the studies were analysed, a family history of cholelithiasis was found to increase the risk of stone recurrence (OR 3.60, 95% CI 2.57, 5.05, $P<0.00001$).

However, a significant heterogeneity among the studies ($I^2=60\%$, $P=0.03$) was observed. The sensitivity analysis revealed that the study by Chao et al. [16] contributed the most to the heterogeneity. After the exclusion of this study, the heterogeneity was significantly decreased ($I^2=26\%$, $P=0.24$), and in the fixed-effects model (OR 3.28, 95% CI 2.30, 4.66, $P<0.00001$; Fig. 3), a family history of cholelithiasis was found to increase the rate of stone recurrence.

Multiple calculi

Seven included studies reported the multiple calculi index, and there was no significant heterogeneity among the studies ($I^2=4\%$, $P=0.39$). Therefore, using a fixed-effects model (OR 4.24, 95% CI 2.76, 6.50, $P<0.00001$), multiple calculi were found to increase the risk of stone recurrence compared with the control group, and the difference was statistically significant (P value <0.05 ; Fig. 3).

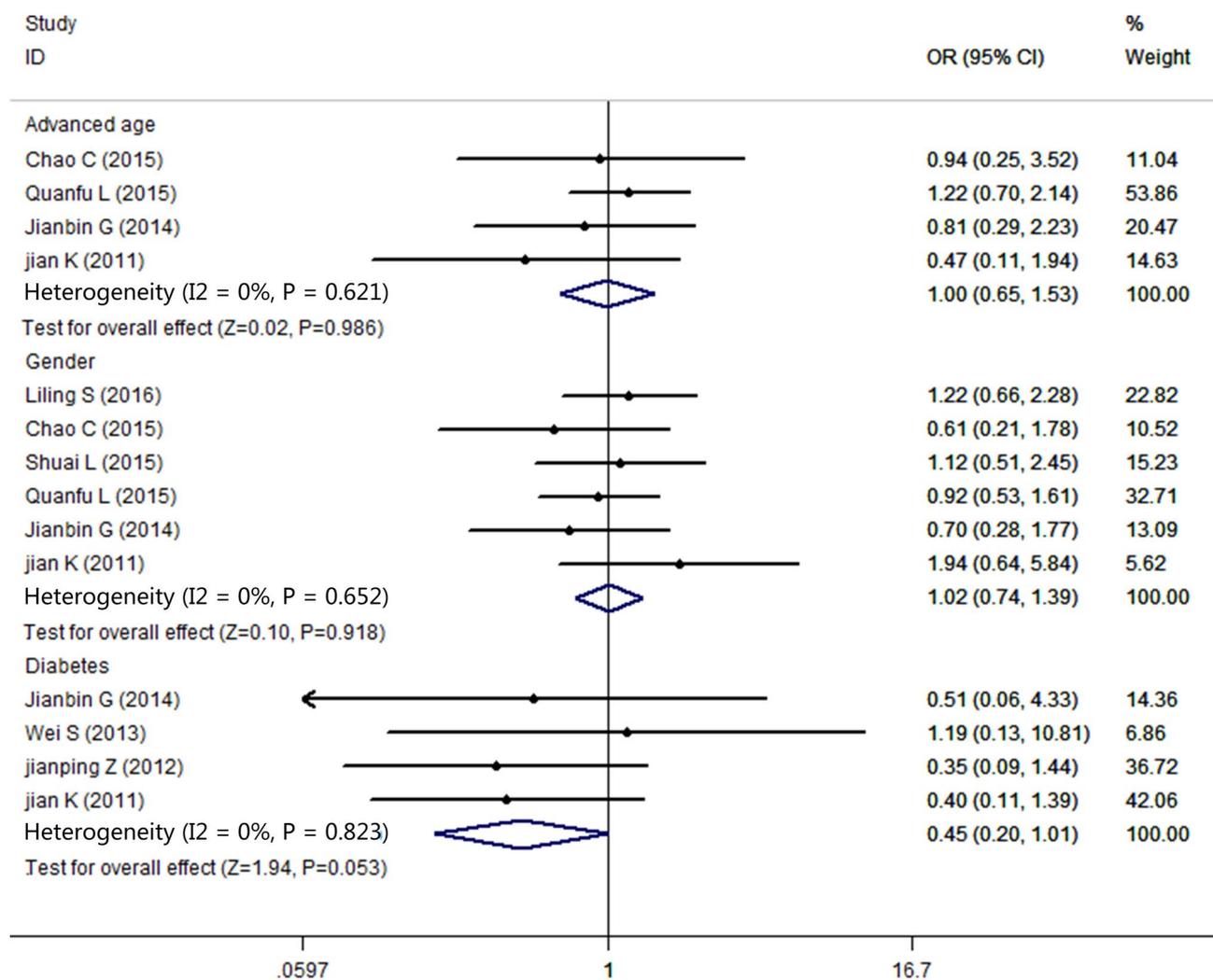


Fig. 2 Forest plot of the associations of advanced age, gender and diabetes with stone recurrence after EMIC

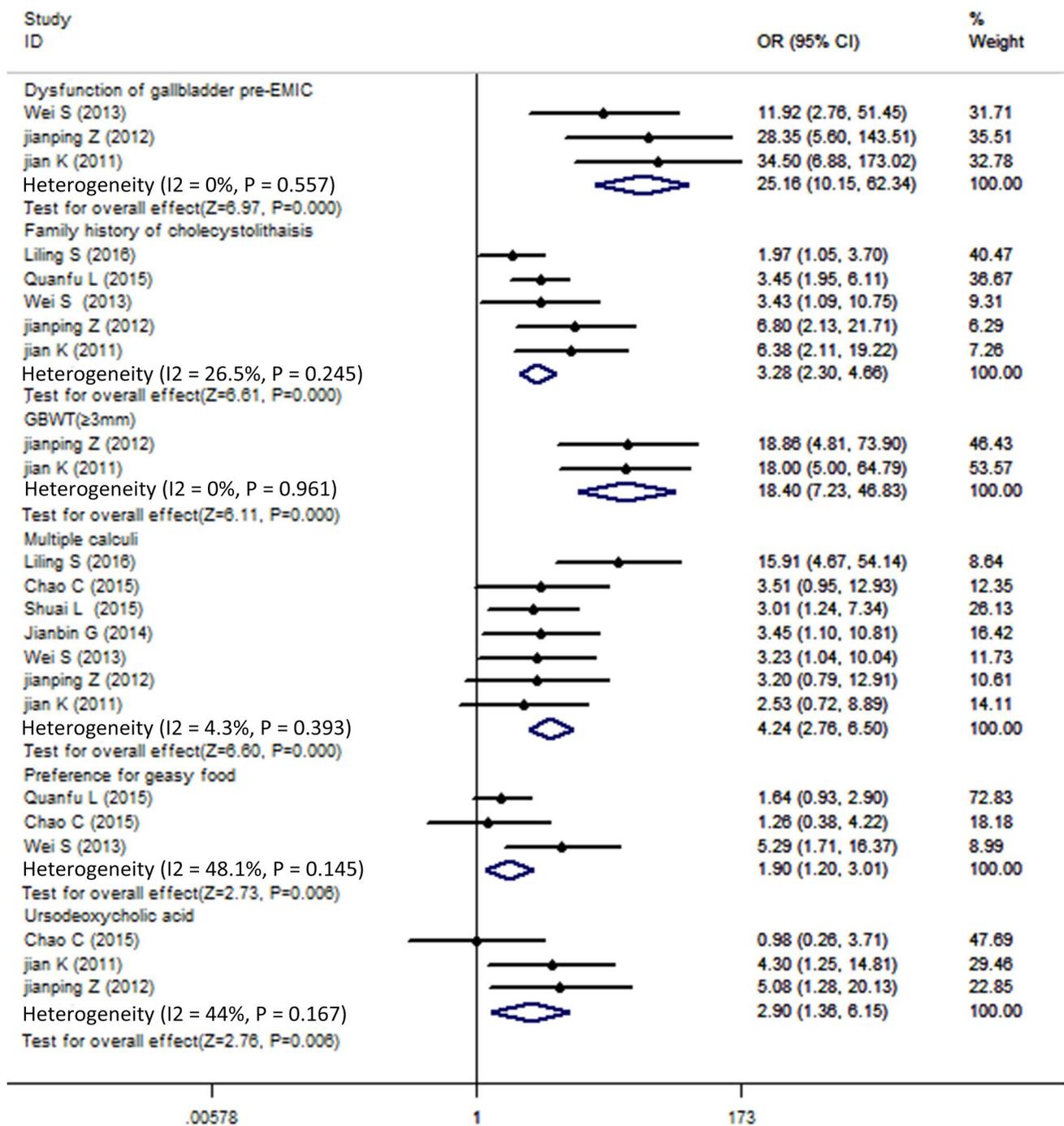


Fig. 3 Forest plot of the associations between gallbladder function, family medical history, GBWT, multiple calculi, dietary habit and ursodeoxycholic acid with stone recurrence after EMIC

Diabetes mellitus

Five included studies reported the diabetes mellitus index, and there was significant heterogeneity among the studies ($I^2 = 57\%$, $P = 0.06$). The sensitivity analysis revealed that the study by Liling et al. [23] contributed the most to the

heterogeneity. After the exclusion of this study, the heterogeneity was no longer significant ($I^2 = 0\%$, $P = 0.82$). Therefore, a fixed-effects model was applied (OR 0.45, 95% CI 0.20, 1.01, $P = 0.05$; Fig. 2), and no significant difference in stone recurrence was observed between those with diabetes mellitus and the control group.

GBWT \geq 3 mm

Three included studies reported the thickened mucous membrane of the gallbladder index, and there was significant heterogeneity among the studies ($I^2 = 74\%$, $P = 0.02$). The sensitivity analysis revealed that a study by Jianbin et al. [18] contributed the most to the heterogeneity. After the exclusion of this study, the heterogeneity was no longer significant ($I^2 = 0\%$, $P = 0.96$), and in the fixed-effects model (OR 18.4, 95% CI 7.23, 46.83, $P < 0.00001$; Fig. 3), a GBWT \geq 3 mm was found to increase the risk of stone recurrence, and the difference was statistically significant.

Preference for greasy food

Three included studies reported the dietary habit index, and there was no significant heterogeneity among the studies ($I^2 = 48\%$, $P = 0.15$). Therefore, the preference for greasy food was demonstrated to increase the risk of stone recurrence in a fixed-effects model (OR 1.90, 95% CI 1.20, 3.01, $P = 0.006$; Fig. 3).

Gallbladder dysfunction pre-EMIC

Three included studies reported the gallbladder functional status index, and there was no significant heterogeneity among the studies ($I^2 = 0\%$, $P = 0.56$). Therefore, using a fixed-effects model (OR 26.16, 95% CI 10.15, 62.34, $P < 0.00001$), gallbladder dysfunction pre-EMIC was found to be associated with a higher rate of stone recurrence (P value < 0.05 ; Fig. 3).

Not taking ursodeoxycholic acid orally post-EMIC

Three included studies reported an index on the use of ursodeoxycholic acid after EMIC, and there was no significant heterogeneity among the studies ($I^2 = 44\%$, $P = 0.17$). Therefore, in a fixed-effects model (ORs 2.90, 95% CI 1.36, 6.15,

$P = 0.006$; Fig. 3), not taking oral ursodeoxycholic acid post-EMIC was demonstrated to increase the risk of stone recurrence compared to the control group, and the difference was statistically significant (P value < 0.05).

Publication bias and sensitivity analysis

The sensitivity analysis results for the primary hazards were mentioned above. Regarding the publication bias, an Egger's test indicated that there was no publication bias in our meta-analysis (P value > 0.05 ; Table 2).

Discussion

This study was a further meta-analysis of eight studies that sought to evaluate the risk factors for stone recurrence after EMIC. The present meta-analysis arrived at the following main findings: (1) no significant differences were found in relation to age, gender or diabetes mellitus after EMIC; (2) patients with a family history of cholelithiasis, those with multiple calculi, those with a GBWT \geq 3 mm, those with a preference for greasy food and those with pre-EMIC gallbladder dysfunction are at a high risk for the recurrence of stones after EMIC.

The main findings of our meta-analysis seem to be contradictory to a previous meta-analysis [24] (Chinese Article) that was performed to investigate the risk factors for the recurrence of stones after cholecystolithotomy. This previous meta-analysis included six studies, including four of the studies described here, which enrolled a total of 1002 patients and revealed that advanced age was a risk factor for the recurrence of stones after cholecystolithotomy. However, this previous meta-analysis included only a small number of studies and indicated significant heterogeneities in some outcomes. Additionally, our analysis did not include two studies that were included in the previous meta-analysis because the

Table 2 Summary of the meta-analysis

Hazards	Participants	Effect estimate			Heterogeneity		Publication bias	Statistical method
		ORs	95% CI	<i>P</i>	<i>I</i> ² (%)	<i>P</i>		
Advanced age	626	1.007	0.736 1.377	0.967	0	0.62	0.124	Fixed model
Gender	1435	1.079	0.849 1.371	0.533	0	0.652	0.192	Fixed model
Family medical history	900	4.528	2.528 8.112	0	59.8	0.029	0.091	Random model
Multiple calculi	1305	4.237	2.760 6.505	0	4.3	0.393	0.67	Fixed model
Diabetes	507	0.832	0.282 2.456	0.056	56.5	0.739	0.990	Random model
Preference for fatty food	607	1.9	1.198 3.014	0.006	48.1	0.145	0.716	Fixed model
GBWT \geq 3 mm	243	8.837	2.104 37.111	0.003	73.5	0.023	0.305	Random model
Dysfunction of gallbladder pre-EMIC	293	25.156	10.152 62.339	0	0	0.557	0.135	Fixed model
Not taking ursodeoxycholic acid	292	2.895	1.362 6.154	0.006	44	0.167	0.921	Fixed model

surgical procedures were percutaneous cholecystolithotomy, which did not meet the criteria for our meta-analysis.

EMIC has recently become popular and successful in China, but it has not been widely recognized in Europe and the Americas. Stone recurrence was the main problem that obstructed the development of cholecystolithotomy; indeed, recurrence had been reported to occur at a rate of 44% at 48 months after percutaneous cholecystolithotomy [25]. However, gallstone residuals and recurrences have markedly decreased due to the broad use of minimally invasive technologies, such as laparoscopy and choledochoscopy in clinics. In China, a long-term analysis of the gallstone recurrence rate after EMIC over more than 15 years reported a rate of 10.11% within both 10 and 15 years [26]. In our meta-analysis, we found a mean rate of stone recurrence of 24.8% in the pool estimation during an average follow-up time of 3 years. Additionally, a randomized, double-blind, placebo-controlled, multicentre clinical trial reported that ursodeoxycholic acid is a safe and effective drug for the treatment of gallstones [27]. In our analysis, not taking oral ursodeoxycholic acid post-EMIC increased the rate of stone recurrence compared with the control group (OR 2.90, 95% CI 1.36, 6.15, $P=0.006$). Therefore, we suggest that patients who undergo cholecystolithotomy take ursodeoxycholic acid orally to prevent the recurrence of stones.

The factors that determine stone relapse remain unclear. The predictive hazardous risk for stone relapse remains a topic of discussion in the literature. In the present meta-analysis, dysfunction of the gallbladder was found to be associated with a significant increase in the stone recurrence rate. The formation of a gallstone is mainly contingent on the function of gallbladder. Dysfunction of the gallbladder is mainly manifested as the prolongation of the time of gallbladder diastole and contraction, i.e. a decrease in the rate of relaxation and contraction. Consequently, bile emptying is delayed, and bile is detained, which leads to the formation of gallstones [28]. Furthermore, a GBWT ≥ 3 mm was associated with a high risk of stone recurrence after EMIC. The main mechanism may be as follows: the thickening of the gallbladder wall increases the absorption of cholate, which results in a decrease in the cholate concentration, and cholesterol is thus present in the supersaturated state, which easily precipitates and crystallizes. Additionally, the rough gallbladder wall causes the constituents of the bile to be easily deposited or to turn into stones with inflammatory cast-off cells as the cores. Therefore, treatment of gallbladder inflammation, which can recover the contractile function of the gallbladder after cholecystolithotomy, should be a key measure to prevent the recurrence of stones.

The rate of stone recurrence after EMIC was nearly 4.24 times higher in subjects with multiple calculi than in those with a solitary calculus in the present analysis. The main reason is not explicit; however, in addition to post-operative stone residue, some studies have suggested that

pronucleation may occur in gallbladders with stones, which can secrete a large amount of mucin glycoprotein to promote the formation of stones. Thus, patients with multiple stones have a high level of pronucleation that leads to precipitation and production of cholesterol and stones [29, 30].

The stones recurrence rate after EMIC was nearly 3.28 times higher among the patients with family histories of cholelithiasis in our analysis. This contributing factor probably exists due to similar dietary compositions and habits and inherent factors. Additionally, the preference for fatty food, which was found to increase the rate of stone recurrence (OR 1.90, 95% CI 1.20, 3.01, $P=0.006$), and low levels of consumption of high-fat foods may lead to increased hepatic cholesterol synthesis, increased serum cholesterol levels and the possibility of gallstone formation [31].

In this meta-analysis, we found no associations of age, sex or diabetes mellitus with the relapse of stones. Interestingly, in 2006, Dhiman et al. conducted two randomized and controlled trials to examine the relationship between oestrogen and gallbladder disease, and these authors confirmed that oral oestrogen is associated with gallbladder disease when used by postmenopausal women [31]. This contradiction may have resulted from the heterogeneity between the included studies and the small number of participants in our analysis.

Although the outcome measures mentioned above were comprehensively evaluated, this meta-analysis has several limitations. First, the main limitation is that all the included studies were retrospective, and we did not have specific individual data for all the trials. Thus, our statistical analyses could only be performed at the study level. Second, a single study may have influenced the overall results in the sensitivity analyses for multiple stones, diabetes mellitus and a GBWT ≥ 3 mm, which suggests that our study may be underpowered and unstable. Third, all subjects included in this study were Chinese, which may have resulted in a potential bias due to race. Finally, the inconsistencies between the included articles regarding the control of confounding factors may have influenced the accuracy of the results.

Conclusion

This meta-analysis demonstrated that multiple calculi, a family history of cholelithiasis, a GBWT ≥ 3 mm, a preference for greasy food and gallbladder dysfunction prior to EMIC were associated with the recurrence of stones after EMIC. Thus, patients with a single stone, normal gallbladder function, a gallbladder wall that is less than or equal to 3 mm and those without a family history of cholelithiasis can be considered for EMIC. Additionally, ursodeoxycholic acid should be used to prevent the recurrence of stones.

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Compliance with ethical standards

Disclosures Drs. Wenchao Li, Pinzhu Huang, Zhicheng Yao, Purun Lei, Hui Luo, Zhiyong Xiong, Bo Liu and Kunpeng Hu have no conflicts of interest or financial ties to disclose.

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