Endoscopic Common Bile Duct Stone Clearance during Pregnancy: Challenges and Solutions A Retrospective Cohort Study

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Abstract

Background: Pregnancy is associated with a higher risk of common bile duct stones. Currently Endoscopic Retrograde Cholangiopancreatography (ERCP) is the treatment of choice for symptomatic choledocholithiasis. However, ERCP during pregnancy is associated with the hazard of radiation exposure, as well as challenging patient positioning and anaesthesia.

Objectives: The present trial aimed to overcome the challenges associated with endoscopic clearance of symptomatic common bile duct stones during pregnancy, without adding risks or hazards either on foetus or mother.

Patients and methods: This was a retrospective analysis of endoscopic CBD clearance in 27 pregnant patients with symptomatic choledocholithiasis between February 2019 and February 2023. Sedation and anaesthesia were performed safely by a senior anaesthetist, and the endoscopic procedure was performed in left lateral decubitus instead of the prone position. The gravid uterus was kept away from the monopolar electrocautery current pathway. Radiocontrast injection and fluoroscopy were deleted and replaced by transabdominal US and endoscopic bile aspiration. The data were collected, tabulated, and analysed by SPSS ver. 26.

Results: Patient age ranged from 18 to 36 years (mean: 25 years). The mean duration of gestation ranged from 7-32 (mean 15 weeks), 17 patients were in the first trimester, 8 patients were in the second trimester, and two patients were in the third trimester. Therapeutic ERCP was successfully performed in all patients. The duration of the procedure ranged from 19 to 45 minutes (mean: $27\pm$ 13 minutes). As regards post-ERCP complications, one patient (3.7%) developed pancreatitis post-ERCP and was treated successfully with conservative treatment, and one patient (3.7%) with minor bleeding. All procedures were performed without any maternal adverse events immediately or during follow-up. There were no signs of foetal distress during any of these cases, and no foetal complications were noted upon delivery or at the 30-day follow-up.

Conclusion: Endoscopic clearance of symptomatic common bile duct stones during pregnancy can be achieved safely without fluoroscopy. Adjunct US and endoscopic bile aspiration can overcome the absence of fluoroscopy. Careful positioning of the patient, proper positioning of the monopolar cautery pad, and judicious anaesthetic modification are all crucial for patient and foetal safety.

Keywords: Non-Radiation, ERCP; Pregnancy; Guide Wire Cannulation; Choledocholithiasis. **DOI:** 10.21608/SVUIJM.2024.288209.1856

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Introduction

Pregnancy is associated with an increased of gallstones frequency and related complications. Hormonal changes during pregnancy are known to predispose patients to biliary disease and promote cholelithiasis. The incidence of gallstone disease during pregnancy has been reported to be 3.2-12.2% of all pregnancies (Luo et al., 2017; Xu et al., 2015). This risk increases with each pregnancy, and multiparous women are 10 times more likely to develop biliary complications (Toosi al., et 2011). Symptomatic choledocholithiasis occurs in less than 10% of symptomatic patients (Chan et al., 2012). Common bile duct stones are serious complications of gallstones that can lead to gallstone pancreatitis, cholangitis, sepsis, and even foetal and maternal death and require urgent therapeutic intervention (Goldschmiedt et al., 1993).

ERCP has been the standard minimally invasive technique and procedure of choice for the treatment of common bile duct stones (Friedel et al., 2014). In addition to the usual risks associated with ERCP, ionizing radiation might also carry teratogenic risks foetus during pregnancy. the to Additionally, the risk of pancreatitis is not limited to only exposure to radiation but also to medication and anaesthesia. The risk of pancreatitis is greater in pregnant patients (16%) than in nonpregnant patients (Smith et al., 2013; Magno-Pereira et al., 2017).

Radiation might cause foetal anomalies and preterm labour, particularly when ERCP

is performed in the first trimester (Magno-Pereira et al., 2017). Therefore, many groups have advocated for the complete exclusion of radiation to decrease foetal risk by using no radiation ERCP (NR-ERCP).

Since no radiation ERCP during pregnancy was first reported in 1990, it has been shown that ERCP can be conducted safely without necessitating fluoroscopic use **(Binmoeller et al., 1990)**.

The primary goal of NR-ERCP is to achieve biliary cannulation without radiation exposure, through either empirical guidewire cannulation or through the use of imaging tools (such as ultrasound or choledochoscopy) guidance (Shelton et al., 2007).

Excluding fluoroscopy has many drawbacks, such as failed cannulation or incomplete bile duct cannulation and the possibility of failing to remove all biliary stones or sludge (Simmons et al., 2004).

There are limited studies published in the literature regarding the efficacy of abdominal ultrasound (US) as an adjunct to endoscopy to ensure successful cannulation of the guide wire to the CBD. Most of the data are from case reports and small series. Many researchers have reported their experiences using endoscopic biliary stenting without fluoroscopy or imaging guidance.

In this study, we retrospectively present our trial to overcome the challenges associated with endoscopic clearance of symptomatic common bile duct stones during pregnancy.

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Patients and methods

In the present study, the authors retrospectively analysed the data of **27** pregnant women who presented with symptomatic common bile duct stones in a tertiary care hospital between February 2019 and February 2023. Exclusion criteria were patients refusal, coagulopathy malignant jaundice, patients with acute pancreatitis, and incomplete file records.

Approval for the study was obtained from the local institutional ethical committee of South Valle University, Egypt, with IRB Number (SVU-MED-SUR11-4-23-3-601). The study was registered in clinical trials.com with identifying number: NCT06092905. The registration page found ClinicalTrials.gov PRS: Record at: Summary NCT06092905. This work has been reported in line with the STROCSS criteria (Mathew and Agha, 2021).

The extracted data included gestational age, clinical presentations, and routine laboratory examinations, including serum bilirubin level, alkaline phosphatase level, liver enzymes, coagulation profile, and white blood cell count before and 24 hours after the intervention.

The data also included the results of abdominal US, the diameter of the CBD, the number and size of CBD stones, and the presence or absence of intrahepatic biliary dilation. Magnetic resonance cholangiopancreatography (MRCP) was performed to confirm the presence of stones in the CBD if an abdominal ultrasonography examination revealed gallbladder stones and suspicion of CBD stones.

Preoperative ultrasound and/or MRCP were used to measure the size of the tones and the size of the CBD.

The primary end point of the recurrent study was successful relief of biliary obstruction in pregnant women without use of fluoroscopy, either by endoscopic CBD stone clearance or endoscopic biliary stenting.

Methods

The risks, complications, and alternatives of the endoscopic procedure were explained to the patients. Formal written consent was obtained from all the studied patients. The patients were assessed by an obstetrician for well-being and foetal bv an anaesthesiologist for general anaesthesia and endotracheal intubation. The patients fasted for approximately 8 hours before the procedure. A prophylactic antibiotic was administered. The procedure was performed under general anaesthesia with cuffed endotracheal intubation in the left lateral decubitus.

A senior anaesthetist conducted the anaesthesia. Medications were calculated as follows: Propofol, 1.5 mg/kg; Atracium, 0.5 mg/kg for induction of anaesthesia; and 0.1 for maintenance. mg/kg А cuffed endotracheal tube was inserted. and isoflurane was subsequently used for maintenance of anaesthesia. Reversal was achieved through the administration of 50 ug/kg neostigmine plus 0.02 mg/kg atropine. Pethidine (25 mg) was given. Intraoperative monitoring, non-invasive BP, ECG, and capnography were used.

Endoscopic procedures were conducted via a duodenoscope with side viewing. (Olympus side-viewing endoscopes TJF-160VR were used.) After the advancement of the duodenoscope into the duodenum, the papilla was localized and cannulated with a standard hydrophilic guide wire (280 cm, 0.035"; Cook Medical, Inc., Winston-Salem, USA). After CBD cannulation, we confirmed successful common bile duct cannulation by aspiration of bile and abdominal US (**Fig.1**).

All cases were by same endoscopist and same radiologist and same senior anaesthetist.

As regard of sphincterotomy. We used conventional methods in most of cases and

if there were difficult, we used precut sphincterotomy



Fig.1. Ultrasonography showing the guidewire in the common bile duct

Endoscopic sphincterotomy was carried out in all cases by bipolar current to facilitate extraction of stones by balloon and Dormia basket, and successful clearance was confirmed by US (Fig.2).



Fig. 2. Ultrasonography showing the dilated common bile duct after clearance of the stones

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In addition, if a missed stone was suspected, a stent was inserted by guidance of endoscope and direct visualization, but we confirmed the proper insertion of the stent inside CBD by US instead of radiological C arm. Sonographic guidance was a substitute of non-visualization of the inside of CBD due to lack of fluoroscopy guidance (**Fig.3**), and plastic stents (10-French, 10 cm; Cook Medical, Winston-Salem, USA) were used with good bile flow.

A missed stone was suspected when CBD clearance cannot be confirmed by US due to gases masking CBD, and when the number of stone that removed is less than what detected on MRCP or Preoperative US.



Fig. 3. Ultrasonography showing a stent inserted in the common bile duct

In the case of no visualization of the wire by US, another trial of wire manipulation was conducted to ensure proper positioning of the wire inside the CBD using the least invasive technique. The procedure time was calculated from the time at which the duodenoscope was introduced from the mouth until its removal.

Follow-up: The follow-up serum amylase and lipase levels were measured 24 hours

after the procedure. Endoscopic complications, including bleeding, perforation, pancreatitis, fever, cholangitis, or evidence of foetal compromise, were assessed. Fetal complications were also assessed before discharge, at delivery, and one month after delivery. Patients with failed CBD stone clearance were arranged for another ERCP trial 3 months after delivery.

Statistical analysis

Data were collected, tabulated and analysed by SPSS program (Statistical Package for the Social Sciences ver. 26, SPSS Inc, Chicago, Illinois, USA). The collected data include Demographic and Preoperative Data of Pregnant Women Included in the Study, as well as the endoscopic findings, outcomes, and complications of the procedure.

Results

The patients' ages ranged from 18 to 36 years (mean: 25 years). The mean duration of gestation ranged from 7-32 (mean 15 weeks), 17 patients were in the first trimester, 8 patients were in the second trimester, and two patients were in the third trimester. Seventeen women were in their first pregnancy; the other ten women were in their second pregnancy. Before the procedure, choledocholithiasis was identified via radiologic studies in all patients (22 patients with abdominal US and 5 patients with MRCP). There were 15 patients with single stones, 5 patients with Tahle 1 D

two stones, and 7 patients with multiple CBD stones. The maximum stone diameter from 4-12 ranged mm, measured preoperatively by US. All patients had dilated CBD, the diameter of which ranged from 7 to 14 mm. Elevated liver enzymes to various degrees were noted in all patients (Table.1). Three patients had acute cholecystitis clinically, and one patient had acute cholangitis.

All the patients had jaundice; most of them presented with right upper quadrant pain (biliary colic), and three patients had The total serum bilirubin fever. concentration ranged from 2.5 to 8.9 mg/dL (mean: 5.2 mg/dL); the direct serum bilirubin concentration ranged from 2.3 to 7.5 mg/dL (mean: 3.2 mg/dL); the ALT concentration ranged from 54 to 967 U/L (mean: 250 U/L); the aspartate transaminase (AST) level ranged from 55 to 910 U/L (mean: 115 U/L); and the serum amylase concentration ranged from 23 to 150 U/L (mean: 69 U/L) (Table.1).

able 1. Demographic and Preoperative Data			a of Pregnant Women Included in the		e Study
	Parameters		Valu	es mean	

Parameters	Values mean	
Maternal age (in years)	18-36 Mean (25)	
Gestational age (in weeks)	7-32 Mean (15)	
Clinical presentations:		
– Jaundice	27 patients	
– Right upper quadrant pain	27 patients	
– Fever	4 patients	
Laboratory data:		
– Total bilirubin (mg/dL)	2.5 to 8.9 mg/dL (mean: 5.2	
 Direct bilirubin (mg/dL) 	mg/dL)	
– AST	2.3 to 7.5 mg/dL (mean: 3.2 mg/Dl)	
– ALT	54-967 U/L (mean: 250 U/L)	
 Alkaline phosphatase (IU/dl) 	55-910 U/L (mean: 115 U/L)	
- Total leukocyte count (cells/mm)	404.6±424.6	
– Amylase (U/L)	7.2 (4–15.4)	
- · · ·	23-150 U/L (mean: 69 U/L)	
Ultrasound and MRCP findings:		
- Single CBD stone	15 patients (55.5%)	
– Two stones	5 patients (18.5%)	
- Multiple CBD stones	7 patients (25.9%)	

- Diameter CBD (mm)	7 -14 mm (average 11 mm)
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With regard to the endoscopic technique, successful biliary cannulation was achieved by sphincterotome in 22 patients and by precut in 5 patients. Stones were removed by balloon in 13 patients and by Dormia basket in 8 patients. Extraction failed in two patients, but no stones were extracted in four patients; however, MRCP confirmed the presence of stones, which most likely spontaneously passed, and we inserted a biliary stent in 6 patients (22.22%) (two patients with failed clearance and 4 patients for whom no stones were found, most likely passed stones).

Selective cannulation of the CBD was successful in all patients and was confirmed by an abdominal US scan of the CBD to visualize the wire. After the extraction of stones, free bile flow was at once achieved. The duration of the procedure ranged from 19 to 45 minutes (mean: 27 ± 13 minutes).

Among the complications, one patient (3.7%) with minor bleeding was treated by washing with epinephrine, and the bleeding

stopped. One patient (3.7%) developed mild post ERCP acute pancreatitis, with Ranson's score 2 (Ranson et al., 1976).. Clinically, the patient suffered from nausea, epigastric and back pain about 12 hours after ERCP. Laboratory investigations revealed only raised WBCS count (18000/ml), raised AST (286 U/ML), and high serum amylase (460 U/L), otherwise, normal other laboratory findings. Abdominal US revealed normal findings. The patient was treated successfully with conservative treatment in the form of intravenous fluids, analgesics, and proton pump inhibitors (Table.2). Both minor bleeding during the procedure and pancreatitis post ERCP mild were encountered precut sphincterotomy in patients.

Regarding the 5 patients in whom precut sphincterotomy was used, one patient with 2 CBD stones had minor bleeding during the procedure, another patient with multiple CBD stones developed post ERCP mild pancreatitis.

Outcomes	Values	
Successful papilla cannulation:	27 patients (100%)	
- Sphincterotomy	22 patients (81.5%)	
– Precut	5 patients (18.5%)	
Successful wire placement in the	27 patients (100%)	
CBD	13 patients (48.14%)	
Extraction by balloon	8 patients (29.62%)	
Extraction by Dormia basket	2 patients (7.4%)	
Failed clearance	4 patients (14,8%)	
Passed stones (clear CBD)	6 patients (22.22%)	
Successful stent placement		
Operative time (min):		
– Range	19-45 minutes	
– Mean	27±13 min	
Clinical success/Resolution of	27 patients (100%)	
symptoms:		
Postoperative complications:		
 Acute pancreatitis 	One patient (3.7%)	

.Table 2. Endoscopic findings, outcomes, and complications

- Minor bleeding	One patient (3.7%)
- Acute cholangitis	0/27 patients
– Perforation	0/27 patients
- Obstetric/fetal complications	0/27 patients
0/10	

Biliary colic, abdominal pain, jaundice, and fever were markedly improved in the majority of the patients. Total bilirubin levels became normal after a median of 8 days (range 5–15 days). All patients were discharged from the hospital within 24 hours, except one patient who developed mild acute pancreatitis and was discharged 5 days after improvement of the pain, tolerance of oral diet, open bowel, and after obstetrician consultation.

No maternal or foetal adverse events or complications were detected after the procedures or during the follow-up period. The course of pregnancy was, in each patient, entirely normal with the delivery of a healthy child at term. None of the patients had symptoms of choledocholithiasis or cholangitis during the follow-up period.

Discussion

Biliary disease is considered the second most common gastrointestinal disorder requiring surgery during pregnancy after appendicitis (Parangi et al., 2007). The migration of gallstones to the common bile duct may cause various complications, such as cholangitis and biliary pancreatitis, which can be life-threatening for both the mother and the foetus (Cappell, 2011). ERCP is currently the standard technique for treating symptomatic common bile duct stones during pregnancy, but it has many adverse effects, as radiation exposure, and sedation and procedural medications may be harmful to the foetus and pregnant women, as they may induce foetal teratogenicity and premature labour and abortion (Gorson et al., 1977).

Several studies have confirmed the safety and efficacy of ERCP during pregnancy (Gorson et al., 1977; Tham et al., 2003; Kahaleh et al., 2004; Kahaleh et al., 2004).We can minimize radiation exposure by using external shielding of the foetus with a lead placed under the pelvis and lower abdomen to limit fluoroscopy time, reduce overall radiation exposure, and avoid taking hard copy X-ray films. With these precautions, foetal exposure was estimated to be well below the level needed to trigger radiation-induced teratogenesis (Tham et al., 2003; Kahaleh et al., 2004; Kahaleh et al., 2004; Johlin et al., 2002).

We can also avoid radiation risks by deleting fluoroscopy. ERCP without fluoroscopy during pregnancy was first described in 1990. A needle-knife sphincterotomy was performed to free an impacted stone at the ampulla of Vater (Binmoeller et al., 2002).

Since then, a few case reports and a small case series of radiation-free ERCP in pregnant women have been reported. The non-Radiation-ERCP technique can be classified as empirical bile aspiration or ultrasonic guidance cannulation. Bile duct cannulation was confirmed by bile aspiration or visualization of bile around the guidewire (Shelton et al., 2007; Akcakaya et al., 2009).

The main disadvantage of this technique is that bile aspiration cannot be used to distinguish between biliary and cystic duct cannulation, and stent might be inserted into the gallbladder (Cappell, 2011).

US was used to confirm guide wire bile duct cannulation and correct positioning of the papillotomy device; additionally, US is useful for identifying the position of a CBD stone and proving the clearance of stones within the common bile duct. Additionally, the use of a biliary stent under US guidance and proving that the stent is in a normal position (Parada et al., 1991; Freistühler et al., 1999).

Only recently, ultrasound (US)-guided endoscopic biliary stenting been reported by Sharma and Maharshi, who described a twostep procedure involving biliary sphincterotomy and stenting without fluoroscopy (Freistühler et al., 1999).

There are several drawbacks for US guidance: after sphincterotomy or balloon dilatation of the duodenal papilla, air flows into the bile ducts and obscures the ultrasonographic view of the biliary system. Irrigation with saline into the common bile duct can expel a portion of the air, but it is still difficult to obtain a satisfactory image of the bile ducts. Additionally, changing position to the supine position is required for satisfactory US examination (Llach et al., 2007).

With regard to patient position, ERCP is usually performed when non-pregnant patients are in the prone position to aid in selective bile cannulation and to provide better fluoroscopic imaging than when the patient is in other positions. However, this position is not safe during advanced pregnancy (second or third trimester) for many reasons: to avoid patient discomfort from the enlarged, gravid uterus pressing against the hard X-ray platform; to avoid decreased systemic and uterine perfusion from the enlarged gravid uterus compressing the aorta; and to avoid decreased venous return from the enlarged gravid uterus compressing the inferior vena cava (Llach et al., 2007). Additionally, sphincterotomy is best performed by bipolar diathermy, as recommended by the American Society for Endoscopy guidelines Gastrointestinal

(Qureshi et al., 2005); however, if this procedure is not used, we could use monopolar electrocautery, but we must place a return electrode (cautery pad) on the trunk or upper abdomen. This approach is used to ensure that the uterus is not between the active and return electrodes to avoid foetal effects, as amniotic fluid can conduct electrical current to the foetus (ASGE Standards of Practice Committee et al., 2012; Inamdar et al., 2016).

In the present study, we presented one of the largest series of pregnant patients who underwent no radiation ERCP because of symptomatic choledocholithiasis in various trimesters under transabdominal US guidance. Through biliary cannulation, we cannulated the bile duct with the assistance of a guidewire. Cannulation was confirmed by bile aspiration and/or visualization of the bile flow around the guidewire after cannulation, which was also confirmed by abdominal US. Afterward. biliary sphincterotomy and extraction of stones either by balloon sweeping of the biliary duct or Dormia basket extraction were performed.

Regarding complications, in our study, only patient (3.7%)developed mild one pancreatitis and was treated successfully with conservative treatment without any harms to the foetus or the mother; this number was within the range of that observed in the general population (1.6-15.7%), and one patient with minor bleeding during the procedure, which was treated by washing with epinephrine and bleeding, stopped and did not need any further intervention.

Additionally, it is noted that the usual post-ERCP complications, including post sphincterotomy bleeding, infection, pancreatitis, and perforation, can have greater consequences for pregnant women (Magno-Pereira et al., 2017). The incidence of pancreatitis ranged from 0 to 4% in three previous studies (Shelton et al., 2007; Sharma et al., 2008; Llach et al., 2007).

In the study by Shelton et al. (2007), post-ERCP pancreatitis was reported in one of 21 patients, which can be considered similar to the findings of our study. A recent study from China by **Huang et al. (2013)** reported the presence of PEP in one of 68 patients (1.5%).

Qureshi et al. (2005) reported 65 pregnant patients who underwent 68 ERCP procedures; as a result, they recommended the use of a no fluoroscopic technique, which can be performed safely during pregnancy; however, this procedure may be associated with a greater incidence of post-ERCP pancreatitis than in the general population, as noted in a previous study (16%) (Qureshi et al., 2005).

In comparison with our study, the lower incidence of pancreatitis might be attributed to the younger age of our patients and the use of US guidance during the procedure (Huang et al., 2013).

In many previous studies, the risk of post-ERCP pancreatitis was estimated to be 5%, increasing to approximately 16% in pregnant women (**Printen et al., 1978**).

In general, prolonged endoscopic manipulation, sphincterotomy, and pancreatic contrast agent injection are risk factors for post-ERCP pancreatitis (Tham et al., 2003).

Moreover, in a study of 58 pregnant patients undergoing ERCP, the risk of post-ERCP pancreatitis was estimated to be 12%; this increase in risk compared to that in nonpregnant patients (5%) was attributed to the limited use of fluoroscopy for guiding the wire during deep biliary cannulation (Huang et al., 2013).

The complication rate in our study was low, and maternal and foetal outcomes were favourable. Cannulation was successfully achieved in all patients; our results are similar to those of a study from China that proposed that transabdominal US-guided ERCP was preferred over other conventional non-radiation ERCP methods because of its greater stone clearance and lower complication rate (**Huang et al., 2013**).

The duration of the procedure ranged from 19 to 45 minutes (mean: 27 ± 13 min). This relatively long duration is comparable to that of conventional ERCP, mostly because of the time needed for abdominal ultrasonography to confirm successful cannulation and clearance and because of the time consumed in changing patient positions from the left lateral decubitus position to the supine position during US examination. Then, the patient was shifted to the left lateral position again. The time gained by deleting contrast agent injection fluoroscopic and evaluation were compensated by time used in US assessment and changing patient position.

With regard to biliary stents, in our study, a biliary stent was placed in 6 (22.22%) patients (two patients with failed clearance, and 4 patients did not have any stones during the procedure, most likely passed spontaneously). However, in a study by Abdo et al. involving 10 patients in Ismailia, Egypt, they reported a two-stage procedure involving the use of a biliary stent under US guidance; after 2 months, the delivery stent was removed, and the CBD stones were cleared under fluoroscopy (Abdo et al., 2021).

In our study, no cases of abortion or preterm delivery were documented, which might be related to the absence of fluoroscopy and its teratogenic effects and the shorter duration of the procedure, which can decrease the dose of anaesthetics needed and the use of safe anaesthetic medications.

Conclusion

Endoscopic clearance of symptomatic common bile duct stones during pregnancy can be achieved safely without fluoroscopy.

Adjunct US and endoscopic bile aspiration can overcome the absence of fluoroscopy. Careful positioning of the patient, proper positioning of the monopolar cautery pad, and judicious anaesthetic modification are all crucial to ensure patient and foetal safety. Note: This research has been posted as a preprint, it has not been peer reviewed by Journal (on 22 Dec, 2023, Springer Research Square platform, with doi: https://doi.org/10.21203/rs.3.rs-3782624/v1, the preprint present in Endoscopic Common Bile Duct Stones Clearance During Pregnancy: Challenges and solutions. A retrospective Cohort Study | Research Square).

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