

Fluoroscopy-Free Endoscopic Retrograde Cholangiopancreatography During Pregnancy

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ABSTRACT

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is an established therapeutic intervention for pancreatobiliary disorders; however, its use during pregnancy raises concerns regarding fetal exposure to ionizing radiation. Fluoroscopy-free ERCP offers an alternative approach that may avoid radiation exposure while providing effective biliary therapy. Evidence regarding its technical success and maternal and fetal safety remains limited.

Objectives: To assess the technical and clinical success of fluoroscopy-free ERCP in pregnant women requiring therapeutic ERCP and to evaluate procedure-related maternal complications and pregnancy/fetal outcomes. **Methods:** This hospital-based observational study included 30 pregnant women undergoing fluoroscopy-free therapeutic ERCP at tertiary-care centres in Raichur. Eligible participants were recruited consecutively. Demographic, obstetric, clinical, laboratory, imaging, procedural, and pregnancy outcome data were recorded. Biliary cannulation and therapeutic interventions were performed without fluoroscopy, with biliary access confirmed using non-radiological methods. Data were analyzed using IBM SPSS Statistics version 22.0, with a p value <0.05 considered statistically significant.

Results: The mean maternal age was 26.4 ± 4.8 years and mean gestational age at ERCP was 23.6 ± 7.1 weeks. Fluoroscopy-free biliary cannulation was successful in all patients, with no conversion to fluoroscopy. Overall technical and clinical success were each achieved in 96.7% of patients, while complete duct clearance at index ERCP was achieved in 86.7%. Significant post-procedural reductions were observed in total and direct bilirubin, AST, ALT ($p < 0.001$), and alkaline phosphatase ($p = 0.012$). ERCP-related complications occurred in 6.7%, comprising one case each of post-ERCP pancreatitis and post-sphincterotomy bleeding. No maternal mortality, immediate fetal distress, or procedure-related pregnancy loss occurred. All pregnancies resulted in live births; 10.0% were preterm deliveries.

Conclusion: Fluoroscopy-free ERCP appears to be a technically feasible and clinically effective therapeutic option during pregnancy, with favorable maternal and fetal outcomes when performed by experienced endoscopists with multidisciplinary support. Larger prospective multicentre studies are warranted to confirm its safety and effectiveness.

Keywords: Pregnancy; ERCP; fluoroscopy-free ERCP; choledocholithiasis; biliary obstruction; maternal outcomes; fetal outcomes.

INTRODUCTION

Gallstone disease is an important non-obstetric gastrointestinal problem encountered during pregnancy. Pregnancy promotes biliary sludge and gallstone formation because estrogen increases biliary cholesterol saturation, while progesterone reduces gallbladder motility and delays emptying.¹ Complicated gallstone disease may result in

choledocholithiasis, obstructive jaundice, acute cholangitis, or gallstone pancreatitis, for which endoscopic retrograde cholangiopancreatography (ERCP) may be required to achieve biliary decompression and ductal clearance.²

Globally, gallbladder stone disease during pregnancy has been reported in approximately 3.3–12% of women, while estimates for biliary sludge and

cholelithiasis range from 5–31% and 2–11%, respectively.³ Choledocholithiasis is considerably less frequent, with an estimated occurrence of approximately 1 per 1,000 pregnancies.³ In India, reliable population-level estimates specifically for choledocholithiasis requiring ERCP during pregnancy are lacking, and published Indian data on fluoroscopy-free ERCP in pregnancy remain particularly limited. This scarcity itself represents an important epidemiological and clinical evidence gap.

Conventionally, ERCP employs fluoroscopy to confirm biliary cannulation and guide therapeutic interventions. During pregnancy, however, exposure of the developing fetus to ionizing radiation is an important consideration, and radiation exposure should be kept as low as reasonably achievable. Fluoroscopy-free ERCP avoids fetal ionizing-radiation exposure by using techniques such as wire-guided cannulation, bile aspiration, endoscopic ultrasound, or other non-radiological methods to confirm biliary access and treatment success.^{2,4} Successful fluoroscopy-free procedures with favorable maternal and fetal outcomes have been described, including management of complex choledocholithiasis.^{2,4,5}

However, the available evidence is predominantly derived from case reports, small series, and retrospective experiences, with limited evidence from Indian tertiary-care settings.^{2,4,5} Consequently, systematic evaluation of technical success, procedure-related complications, and maternal and fetal outcomes is required. The present study was therefore undertaken to evaluate fluoroscopy-free ERCP during pregnancy in tertiary-care centres in India with the objectives to assess the technical and clinical success of fluoroscopy-free ERCP in pregnant women with an indication for therapeutic ERCP and to assess procedure-related maternal complications and pregnancy/fetal outcomes following fluoroscopy-free ERCP.

MATERIALS AND METHODS

Study Design and Setting

This hospital-based observational study was conducted in the Departments of Obstetrics and Gynecology and Medical Gastroenterology at Raichur Institute of Medical Sciences (RIMS), Raichur, and OPEC/RGSSH, Raichur, over a two-year period from 2024 to 2025. Pregnant women with a clinical indication for therapeutic endoscopic retrograde cholangiopancreatography (ERCP), in whom the procedure was attempted without fluoroscopic guidance, were included in the study.

Study Population

The source population comprised pregnant women attending or admitted to the participating tertiary-care hospitals with suspected or confirmed pancreatobiliary disease requiring therapeutic ERCP. The study population consisted of eligible pregnant women who

underwent fluoroscopy-free ERCP during the study period and provided written informed consent for participation.

Eligibility Criteria

Inclusion Criteria: Pregnant women of any gestational age were eligible for inclusion if they had a clinical indication for therapeutic ERCP, including confirmed or strongly suspected choledocholithiasis, biliary obstruction, acute cholangitis, or gallstone pancreatitis with persistent biliary obstruction. Only women in whom fluoroscopy-free ERCP was attempted and who provided written informed consent were included.

Exclusion Criteria: Patients were excluded if they declined to provide consent; had no therapeutic indication for ERCP; had a contraindication to upper gastrointestinal endoscopy, sedation/anesthesia, or therapeutic ERCP; had severe hemodynamic or cardiorespiratory instability precluding endoscopic intervention; or had incomplete clinical records that prevented assessment of the predefined primary outcomes.

Sampling Technique and Sample Size

A consecutive sampling technique was employed. All eligible pregnant women undergoing fluoroscopy-free ERCP at the participating centres during the study period and satisfying the predefined inclusion and exclusion criteria were recruited consecutively. Because fluoroscopy-free ERCP during pregnancy is an uncommon procedure and reliable local prevalence data were unavailable, total enumeration of all eligible cases (30 cases) presenting during the predefined study period between 2024 to 2025 was adopted.

Sample Size Calculation

No formal a priori sample size calculation was performed because fluoroscopy-free ERCP during pregnancy is an uncommon procedure; therefore, all eligible consecutive cases available during the predefined study period were included.

Data Collection

After obtaining written informed consent, demographic, obstetric, clinical, laboratory, imaging, procedural, and outcome-related data were recorded using a predefined data-collection proforma. Variables collected included maternal age, parity, gestational age and trimester at presentation, presenting symptoms, indication for ERCP, liver-function tests, serum bilirubin levels, pancreatic enzyme levels where clinically indicated, ultrasonography and/or magnetic resonance cholangiopancreatography (MRCP) findings, and associated biliary complications.

ERCP Procedure

All ERCP procedures were performed by an experienced therapeutic endoscopist without the use of fluoroscopy. Biliary cannulation was performed using

standard wire-guided techniques. Successful biliary access was confirmed using non-radiological methods, including aspiration of bile and/or available endoscopic or ultrasonographic guidance.

Therapeutic interventions, including endoscopic sphincterotomy, stone extraction, balloon sweeping, and biliary stent placement, were performed according to the underlying clinical indication and the endoscopist's judgment. Maternal clinical status and fetal well-being were assessed in coordination with the Obstetrics and Gynecology team according to gestational age, clinical condition, and institutional practice.

Procedural and Clinical Outcomes

Procedural variables recorded included successful biliary cannulation, completion of the intended therapeutic intervention, duration of the procedure, requirement for conversion to fluoroscopy, and immediate procedure-related complications.

Technical success was defined as successful completion of the intended biliary therapeutic intervention without the use of fluoroscopy. Clinical response following the procedure was assessed based on improvement in presenting symptoms and relevant clinical and laboratory parameters.

Procedure-related and pregnancy-related adverse events were documented during the available follow-up period. These included post-ERCP pancreatitis, bleeding, perforation, cholangitis, sedation- or anesthesia-related complications, maternal clinical deterioration, fetal distress, pregnancy loss, preterm delivery, and other documented maternal or fetal adverse outcomes.

Primary and Secondary Outcomes

The primary outcome was technical success, defined as successful completion of the intended therapeutic biliary intervention without the use of fluoroscopy. Secondary outcomes included successful biliary cannulation, complete duct clearance at index ERCP, clinical and biochemical improvement, procedure duration, need for repeat ERCP, maternal procedure-related complications, pregnancy outcomes, fetal outcomes, and neonatal outcomes.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA)^{6,7}. Categorical variables were summarized as frequencies and percentages. Continuous variables were expressed as mean and standard deviation for normally distributed data and using appropriate measures of central tendency and dispersion for non-normally distributed data.

Associations between categorical variables were assessed using the Chi-square test and independent t test was used to compare quantitative variables

between two groups. P value <0.05 was considered as statistically significant.

The study was initiated after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment. The clinical indication for ERCP was determined independently on the basis of the patient's medical condition, and participation in the study did not determine the need for the procedure.

All procedures were undertaken with appropriate multidisciplinary involvement of the Medical Gastroenterology and Obstetrics and Gynecology teams. Patient confidentiality and privacy were maintained throughout data collection, analysis, and reporting, and study-related information was used solely for the purposes approved by the Institutional Ethics Committee.

RESULTS

A total of 30 pregnant women undergoing fluoroscopy-free ERCP were included in the study. The mean maternal age was 26.4 ± 4.8 years. Twelve (40.0%) participants were primigravida, whereas 18 (60.0%) were multigravida. Regarding the timing of ERCP, 5 (16.7%) procedures were performed during the first trimester, 15 (50.0%) during the second trimester, and 10 (33.3%) during the third trimester, with a mean gestational age at ERCP of 23.6 ± 7.1 weeks. Abdominal/right upper quadrant pain was the most common presenting symptom, occurring in 26 (86.7%) patients, followed by jaundice in 19 (63.3%), nausea/vomiting in 14 (46.7%), and fever in 5 (16.7%). The most frequent indication for ERCP was uncomplicated choledocholithiasis/biliary obstruction in 19 (63.3%) patients, followed by acute cholangitis with choledocholithiasis in 5 (16.7%), gallstone pancreatitis with persistent obstruction in 4 (13.3%), and other biliary indications in 2 (6.7%). Imaging demonstrated common bile duct (CBD) stones in 25 (83.3%) patients, CBD dilatation in 24 (80.0%), and gallbladder calculi in 26 (86.7%). The mean CBD diameter was 9.8 ± 2.6 mm. Magnetic resonance cholangiopancreatography (MRCP) was performed in 22 (73.3%) patients, while endoscopic ultrasonography (EUS) was performed in 6 (20.0%) patients (Table 1). Successful biliary cannulation without fluoroscopy was achieved in all 30 (100.0%) patients. Endoscopic sphincterotomy was performed in 27 (90.0%) patients, balloon/basket stone extraction in 25 (83.3%), and biliary stent placement in 7 (23.3%). Bile aspiration was used to confirm biliary cannulation in 26 (86.7%) cases, while ultrasound/EUS-assisted confirmation was employed in 8 (26.7%). The mean procedure duration was 28.6 ± 9.4 minutes, and none of the procedures required conversion to fluoroscopy (0.0%). Fluoroscopy was therefore completely avoided in all 30 (100.0%) procedures. Overall technical success and completion of the intended therapeutic intervention

were achieved in 29 (96.7%) patients each, while complete duct clearance at the index ERCP was achieved in 26 (86.7%). Clinical improvement following ERCP was observed in 29 (96.7%) patients and biochemical improvement in 28 (93.3%). Failure of the intended therapeutic intervention occurred in 1 (3.3%) patient, and 2 (6.7%) patients required repeat ERCP (Table 2).

There was a significant improvement in hepatobiliary biochemical parameters following fluoroscopy-free ERCP. Mean total bilirubin decreased from 3.8 ± 2.1 mg/dL before ERCP to 1.7 ± 0.9 mg/dL after ERCP ($p < 0.001$), while mean direct bilirubin decreased from 2.6 ± 1.5 mg/dL to 1.0 ± 0.6 mg/dL ($p < 0.001$). Similarly, mean aspartate aminotransferase (AST) declined from 112.5 ± 68.4 U/L to 58.6 ± 31.2 U/L ($p < 0.001$), and mean alanine aminotransferase (ALT) decreased from 128.7 ± 76.3 U/L to 65.4 ± 36.8 U/L ($p < 0.001$). Mean alkaline phosphatase also decreased significantly, from 238.6 ± 105.2 U/L before the procedure to 181.3 ± 82.7 U/L after the procedure ($p = 0.012$). Thus, statistically significant post-procedural reductions were observed across all evaluated laboratory parameters (Table 3).

ERCP-related maternal complications occurred in 2 (6.7%) patients, while 28 (93.3%) experienced no procedure-related complications. Post-ERCP pancreatitis occurred in 1 (3.3%) patient and post-sphincterotomy bleeding in 1 (3.3%). No cases of cholangitis, perforation, sedation/anesthesia-related complications, or procedure-related maternal mortality were observed. With respect to immediate fetal and pregnancy outcomes, there were no cases of immediate fetal distress or procedure-related pregnancy loss, and pregnancy continued without an immediate fetal complication in all 30 (100.0%) patients. Regarding

delivery and neonatal outcomes, 27 (90.0%) women delivered at term and 3 (10.0%) had preterm delivery before 37 weeks of gestation. All 30 pregnancies resulted in live births (100.0%), with no stillbirths or identified congenital anomalies. Neonatal intensive care unit (NICU) admission was required in 2 (6.7%) neonates. The mean gestational age at delivery was 37.8 ± 1.9 weeks, and the mean birth weight was 2.86 ± 0.42 kg (Table 4).

When outcomes were stratified according to trimester at the time of fluoroscopy-free ERCP, technical success was achieved in 5/5 (100.0%) first-trimester, 14/15 (93.3%) second-trimester, and 10/10 (100.0%) third-trimester procedures, corresponding to an overall technical success rate of 29/30 (96.7%). Clinical success showed the same distribution, occurring in 100.0%, 93.3%, and 100.0% of patients in the first, second, and third trimesters, respectively, with an overall rate of 96.7%. The single case of post-ERCP pancreatitis occurred in the second trimester (1/15; 6.7%), whereas the single episode of post-sphincterotomy bleeding occurred in the third trimester (1/10; 10.0%). No immediate fetal distress was observed in any trimester. Preterm delivery occurred in none of the first-trimester patients (0.0%), 1/15 (6.7%) second-trimester patients, and 2/10 (20.0%) third-trimester patients, giving an overall preterm delivery rate of 10.0%. All pregnancies resulted in live births, with rates of 100.0% in each trimester and an overall live-birth rate of 30/30 (100.0%). As no inferential p-values for comparisons across trimesters were provided, these trimester-specific findings should be interpreted descriptively rather than as evidence of statistically significant differences between trimester groups (Table 5).

Table 1. Baseline demographic, obstetric, clinical, and diagnostic characteristics of study participants (N=30)

Characteristic	n (%) / Mean $\pm$ SD
Demographic and obstetric characteristics	
Maternal age (years)	26.4 $\pm$ 4.8
Primigravida	12 (40.0)
Multigravida	18 (60.0)
Trimester at ERCP	
First trimester	5 (16.7)
Second trimester	15 (50.0)
Third trimester	10 (33.3)
Gestational age at ERCP (weeks)	23.6 $\pm$ 7.1
Clinical presentation	
Abdominal/RUQ pain	26 (86.7)
Jaundice	19 (63.3)
Nausea/vomiting	14 (46.7)
Fever	5 (16.7)
Primary indication for ERCP	
Uncomplicated choledocholithiasis/biliary obstruction	19 (63.3)
Acute cholangitis with choledocholithiasis	5 (16.7)
Gallstone pancreatitis with persistent obstruction	4 (13.3)
Other biliary indication	2 (6.7)
Imaging characteristics	

CBD stone demonstrated on imaging	25 (83.3)
Dilated CBD	24 (80.0)
Gallbladder calculi	26 (86.7)
Common bile duct diameter (mm)	9.8 ± 2.6
MRCP performed	22 (73.3)
EUS performed	6 (20.0)

Table 2. Procedural characteristics and technical and clinical success of fluoroscopy-free ERCP (N=30)

Procedural characteristic/outcome	n (%) / Mean ± SD
Procedural characteristics	
Successful biliary cannulation without fluoroscopy	30 (100.0)
Endoscopic sphincterotomy	27 (90.0)
Balloon/basket stone extraction	25 (83.3)
Biliary stent placement	7 (23.3)
Bile aspiration used to confirm cannulation	26 (86.7)
US/EUS-assisted confirmation	8 (26.7)
Procedure duration (minutes)	28.6 ± 9.4
Conversion to fluoroscopy	0 (0.0)
Technical and clinical outcomes	
Fluoroscopy completely avoided	30 (100.0)
Overall technical success	29 (96.7)
Intended therapeutic intervention completed	29 (96.7)
Complete duct clearance at index ERCP	26 (86.7)
Clinical improvement after ERCP	29 (96.7)
Biochemical improvement	28 (93.3)
Failure of intended therapeutic intervention	1 (3.3)
Repeat ERCP required	2 (6.7)

Table 3. Comparison of laboratory parameters before and after fluoroscopy-free ERCP (N=30)

Laboratory parameter	Pre-ERCP Mean ± SD	Post-ERCP Mean ± SD	p-value
Total bilirubin (mg/dL)	3.8 ± 2.1	1.7 ± 0.9	<0.001*
Direct bilirubin (mg/dL)	2.6 ± 1.5	1.0 ± 0.6	<0.001*
AST (U/L)	112.5 ± 68.4	58.6 ± 31.2	<0.001*
ALT (U/L)	128.7 ± 76.3	65.4 ± 36.8	<0.001*
Alkaline phosphatase (U/L)	238.6 ± 105.2	181.3 ± 82.7	0.012*

Independent t test

Table 4. Maternal complications and pregnancy/fetal outcomes following fluoroscopy-free ERCP (N=30)

Outcome	n (%) / Mean ± SD
Maternal procedure-related complications	
Any ERCP-related complication	2 (6.7)
Post-ERCP pancreatitis	1 (3.3)
Post-sphincterotomy bleeding	1 (3.3)
Cholangitis	0 (0.0)
Perforation	0 (0.0)
Sedation/anesthesia-related complication	0 (0.0)
Procedure-related maternal death	0 (0.0)
No procedure-related complication	28 (93.3)
Immediate fetal/pregnancy outcomes	
Immediate fetal distress following ERCP	0 (0.0)
Procedure-related pregnancy loss	0 (0.0)
Continued pregnancy without immediate fetal complication	30 (100.0)
Delivery and neonatal outcomes	
Preterm delivery (<37 weeks)	3 (10.0)
Term delivery	27 (90.0)

Live birth	30 (100.0)
Stillbirth	0 (0.0)
Congenital anomaly identified	0 (0.0)
NICU admission	2 (6.7)
Gestational age at delivery (weeks)	37.8 ± 1.9
Birth weight (kg)	2.86 ± 0.42

Table 5. Technical, clinical, maternal, and pregnancy outcomes according to trimester at fluoroscopy-free ERCP (N=30)

Outcome	First trimester (n=5)	Second trimester (n=15)	Third trimester (n=10)	Total (N=30)
Technical success	5 (100.0%)	14 (93.3%)	10 (100.0%)	29 (96.7%)
Clinical success	5 (100.0%)	14 (93.3%)	10 (100.0%)	29 (96.7%)
Post-ERCP pancreatitis	0 (0.0%)	1 (6.7%)	0 (0.0%)	1 (3.3%)
Post-sphincterotomy bleeding	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (3.3%)
Immediate fetal distress	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Preterm delivery	0 (0.0%)	1 (6.7%)	2 (20.0%)	3 (10.0%)
Live birth	5 (100.0%)	15 (100.0%)	10 (100.0%)	30 (100.0%)

DISCUSSION

The baseline demographic and clinical characteristics of our cohort are broadly consistent with the established epidemiology of gallstone disease during pregnancy. The mean maternal age was 26.4 years, and 60.0% of patients were multigravida. Pregnancy predisposes women to biliary sludge and gallstone formation through several physiological mechanisms, particularly estrogen-induced cholesterol supersaturation of bile and progesterone-mediated reduction in gallbladder motility and delayed emptying¹⁻³. These hormonal and physiological alterations provide an important biological basis for the occurrence of symptomatic gallstone disease and its complications during pregnancy.

The procedural outcomes observed in the present study demonstrate that fluoroscopy-free therapeutic ERCP can achieve a very high rate of technical success in appropriately selected pregnant patients. Selective common bile duct (CBD) cannulation was achieved in 100% of patients, while the overall technical success rate was 96.7%. These results are comparable to, and in some respects exceed, those reported in previous Indian studies. Gupta et al.⁸ evaluated 18 pregnant women undergoing therapeutic ERCP and demonstrated high technical success using techniques such as EUS and bile aspiration to facilitate radiation-free management. Similarly, Sharma and Maharshi⁹ reported 100% technical success using a two-stage approach in which a temporary plastic biliary stent was inserted without fluoroscopy during pregnancy, followed by definitive stone extraction and duct clearance after delivery.

An important finding of the present study is that complete CBD clearance was achieved during the index ERCP in 86.7% of patients. This suggests that, in experienced hands, a single-stage definitive fluoroscopy-free approach is feasible in the majority of

pregnant patients with choledocholithiasis. In contrast to a planned two-stage strategy involving temporary stenting followed by postpartum ERCP⁹, successful clearance during the initial procedure can avoid the need for a second intervention and may consequently reduce additional hospitalization, procedural anxiety, financial burden, and repeated anesthetic or sedation exposure. Nevertheless, temporary biliary stenting remains an important alternative when definitive duct clearance cannot be achieved safely during the index procedure.

Our technical results also compare favorably with international experience. Akcakaya et al.¹¹ reported 100% technical success in a Turkish series involving six pregnant patients undergoing seven ERCP procedures using wire-guided cannulation and bile aspiration. Similarly, Smith et al.¹² reported a technical success rate of 97.1% in a larger US cohort of 35 pregnant patients managed using a modified low-radiation technique. The 96.7% technical success observed in our cohort therefore falls within the upper range of previously reported outcomes and supports the feasibility of performing therapeutic ERCP without fluoroscopy when appropriate alternative methods of confirming biliary access are used.

Post-ERCP pancreatitis (PEP) remains one of the principal maternal complications of ERCP during pregnancy. Tang et al.¹³, in a retrospective US cohort of 65 pregnant women undergoing 68 ERCPs, reported PEP in 16.0% of procedures (11/68). In contrast, PEP occurred in only one patient in our cohort, corresponding to a rate of 3.3% (1/30). This compares favorably with the 5.6% rate (1/18) reported by Gupta et al.⁸ and the 5.7% rate (2/35) reported by Smith et al.¹². These findings indicate that omission of fluoroscopy does not necessarily result in an increased risk of pancreatitis when the procedure is performed using careful, standardized cannulation techniques.

The low incidence of PEP in our study may, at least in part, be related to strict use of wire-guided cannulation. Wire-guided biliary access can minimize unnecessary contrast injection into the pancreatic duct and reduce papillary or pancreatic duct trauma associated with repeated cannulation attempts. The importance of procedural technique and operator expertise is supported by the systematic review and meta-analysis by Azab et al.¹⁴, which included 1,307 pregnant patients. Although radiation-guided and non-radiation ERCP (NR-ERCP) did not differ significantly in fetal or pregnancy-related complications, maternal non-pregnancy-related adverse events were lower with NR-ERCP (7.6%) than with radiation-guided ERCP (14.9%)¹⁴. The authors emphasized that favorable outcomes with radiation-free techniques are closely associated with specialist expertise and procedural experience. This is particularly relevant to the present study, as all procedures were performed by a single highly experienced therapeutic endoscopist at dedicated tertiary centers.

Confirmation of successful CBD cannulation is a central challenge when fluoroscopy is completely omitted. In our cohort, bile aspiration was used in 86.7% of procedures, while transabdominal ultrasound and/or EUS was employed in 26.7%. This approach is consistent with previous experience reported by García-Cano et al.¹⁵, in whose Spanish multicenter study six of 11 patients were successfully managed without fluoroscopy using bile aspiration as the principal method of confirming biliary access. Bile aspiration is simple, rapid, inexpensive, and widely accessible; however, it may not always provide definitive anatomical confirmation of guidewire position. As highlighted by Smith et al.¹², reliance on aspiration alone may not completely exclude unintended cannulation of adjacent ductal structures. The selective incorporation of transabdominal ultrasound or EUS in our cohort therefore provided an additional means of confirming ductal anatomy and therapeutic success. Notably, none of the procedures required conversion to fluoroscopy.

The obstetric and fetal outcomes in the present study were also encouraging. All patients continued their pregnancies without immediate fetal distress or pregnancy loss, and the live-birth rate was 100%. Preterm delivery occurred in three patients, giving an overall rate of 10.0%. This compares favorably with outcomes described in previous cohorts, including the 11.4% preterm delivery rate reported by Smith et al.¹². Tang et al.¹³ reported less favorable pregnancy outcomes among women undergoing ERCP during the first trimester, including a 20.0% rate of preterm delivery and a 21.4% rate of low birth weight. The overall preterm delivery rate in our cohort was also comparable with that reported in the broader literature summarized by Azab et al.¹⁴.

Trimester-specific findings are particularly relevant because the first trimester represents the period of

organogenesis and therefore raises the greatest concern regarding unnecessary fetal exposure to ionizing radiation. In the present study, none of the five patients who underwent ERCP during the first trimester experienced fetal distress or subsequent preterm delivery. Although the small number of first-trimester procedures limits definitive conclusions, these findings provide reassuring preliminary evidence regarding the feasibility of a completely fluoroscopy-free approach when therapeutic intervention cannot safely be deferred.

The avoidance of ionizing radiation represents one of the major theoretical advantages of fluoroscopy-free ERCP during pregnancy. Available evidence and professional guidance indicate that fetal radiation doses associated with appropriately performed conventional ERCP are generally substantially below thresholds associated with deterministic fetal effects such as congenital malformations^{10,14}. Nevertheless, minimizing radiation exposure remains desirable, particularly because stochastic effects, including radiation-associated malignancy, are generally considered to lack a clearly established threshold below which risk is absolutely absent. A completely fluoroscopy-free approach therefore removes procedural fetal radiation exposure while still permitting effective biliary intervention, provided that biliary access and therapeutic completion can be reliably established using alternative techniques.

Neonatal outcomes in our cohort were similarly favorable, with a mean birth weight of 2.86 kg and NICU admission required in two neonates (6.7%). The neonatal admissions occurred in association with preterm delivery. Importantly, adverse obstetric outcomes in patients requiring ERCP may reflect not only the intervention itself but also the severity of the underlying biliary disease. Acute cholangitis, biliary pancreatitis, systemic inflammation, maternal infection, and related physiological stress can independently contribute to uterine activity, preterm labor, and adverse fetal outcomes^{8,13,14}. Thus, the three preterm deliveries observed in our study may plausibly have been influenced by the underlying severity of maternal biliary disease rather than being directly attributable to fluoroscopy-free ERCP.

Overall, the present findings demonstrate that completely fluoroscopy-free ERCP can provide high technical success, a high rate of definitive duct clearance, and favorable maternal and fetal outcomes when performed by an experienced therapeutic endoscopist. The combination of wire-guided cannulation, bile aspiration, and selective ultrasound or EUS confirmation appears to provide an effective strategy for avoiding radiation while maintaining procedural success. The 96.7% technical success rate, 86.7% index-procedure duct clearance rate, low PEP incidence of 3.3%, absence of conversion to fluoroscopy, and favorable pregnancy outcomes compare well with previously published Indian and

international experience^{8–15}. These findings support fluoroscopy-free ERCP as a feasible therapeutic option for appropriately selected pregnant patients, particularly in specialized centers with expertise in advanced biliary endoscopy. However, the relatively small cohort and limited number of first-trimester procedures should be considered when interpreting these results, and larger prospective multicenter studies are needed to establish the comparative safety and effectiveness of this approach.

Future Research

Future studies should include larger prospective multicentre cohorts with an appropriate comparison group undergoing conventional fluoroscopy-guided ERCP. Such studies should evaluate trimester-specific outcomes, standardized technical and clinical success criteria, procedure-related radiation exposure where applicable, maternal complications, and detailed neonatal outcomes. Longer-term follow-up of infants should also be incorporated to assess developmental outcomes. Multicentre studies involving endoscopists with different levels of expertise would help determine the generalizability and reproducibility of fluoroscopy-free ERCP during pregnancy.

Limitations

- This study has several limitations. First, the sample size was relatively small because fluoroscopy-free ERCP during pregnancy is an uncommon procedure, which limits the statistical power to detect uncommon maternal and fetal complications.
- The observational design and absence of a conventional fluoroscopy-guided ERCP control group preclude direct comparison of the safety, efficacy, and procedural outcomes of the two approaches.
- The study was conducted at two tertiary-care centres, and all procedures were performed by an experienced therapeutic endoscopist; therefore, the findings may not be directly generalizable to centres with different levels of expertise or procedural experience.
- The study included only five patients undergoing ERCP during the first trimester, limiting the ability to draw reliable trimester-specific conclusions.
- Potential selection bias cannot be excluded because only patients considered suitable for fluoroscopy-free ERCP were included.
- Long-term maternal and neonatal follow-up, including assessment of later childhood developmental outcomes, was not available.
- some outcomes, particularly pregnancy and fetal outcomes, may have been influenced by the severity of the underlying biliary disease rather than by the ERCP procedure itself.

CONCLUSION

The present study demonstrates that fluoroscopy-free endoscopic retrograde cholangiopancreatography (ERCP) is a technically feasible and clinically effective therapeutic approach for appropriately selected pregnant women with biliary indications requiring intervention. Successful biliary cannulation and completion of the intended therapeutic intervention were achieved in nearly all patients without the need for conversion to fluoroscopy. The procedure was associated with substantial clinical and biochemical improvement and effective duct clearance in most cases. These findings indicate that therapeutic ERCP can be performed without ionizing radiation during pregnancy while maintaining a high level of procedural effectiveness. The favorable outcomes observed across different trimesters further support the feasibility of this approach when intervention cannot be safely deferred.

Fluoroscopy-free ERCP also demonstrated a favorable maternal and pregnancy safety profile, with few procedure-related maternal complications and no procedure-related maternal mortality, immediate fetal distress, or pregnancy loss. Pregnancy continuation and neonatal outcomes were generally favorable, supporting the potential value of avoiding fetal radiation exposure during therapeutic ERCP. Nevertheless, the procedure should be performed only when clinically indicated and preferably in experienced tertiary-care centers by skilled endoscopists with multidisciplinary support from obstetric, anesthesia, and radiology teams. Pre-procedure imaging with non-ionizing modalities such as MRCP or EUS should be considered to confirm the indication and facilitate procedural planning. Appropriate maternal and fetal monitoring should be maintained before, during, and after the procedure. Larger prospective, multicenter studies with suitable comparison groups and long-term maternal and offspring follow-up are recommended to confirm safety, determine trimester-specific outcomes, and establish standardized protocols for fluoroscopy-free ERCP during pregnancy.

DECLARATIONS

Consent for Publication

Written informed consent for publication of the study findings was obtained from the participants. No individually identifiable patient information is presented in this manuscript.

Availability of Data and Materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request, subject to institutional and ethical restrictions.

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributions

Anil Kumar G: study conception and design, methodology, clinical procedures, data collection, data analysis, manuscript drafting and critical revision. Vandana: obstetric assessment, pregnancy and fetal outcome evaluation, data interpretation, and critical revision of the manuscript. Sagar: data collection, literature review, data interpretation, and critical revision of the manuscript. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

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REFERENCES

1. Cappell MS. Gastrointestinal and hepatic disorders in pregnancy. In: Feldman M, Friedman LS, Brandt LJ, editors. *Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology, Diagnosis, Management*. 11th ed. Philadelphia: Elsevier; 2021. p. 1654-1681.
2. Kamani L, Mahmood S, Faisal N. Therapeutic endoscopic retrograde cholangiopancreatography without ultrasound or fluoroscopy in pregnancy. *Endoscopy*. 2012;44(Suppl 2 UCTN):E7-E8. doi: 10.1055/s-0031-1291761.
3. Vargas-Rubio R, Pinto-Saavedra OM. Endoscopic ultrasound and endoscopic retrograde cholangiopancreatography without fluoroscopy in the treatment of choledocholithiasis during pregnancy: report of two cases. *Rev Colomb Gastroenterol*. 2021;36(3):400-405. doi: 10.22516/25007440.667.
4. Burlen J, Amaral AC, Hussain WK, Han S. Cholangioscopy-directed basket extraction of bile duct stones in a pregnant patient. *Endoscopy*. 2023;55(Suppl 1):E813-E814. doi: 10.1055/a-2107-2735.
5. Gao Y, Kim JJ. S51 Procedural, Pregnancy, and Fetal Outcomes of Endoscopic Retrograde Cholangiopancreatography Performed During Pregnancy. *Am J Gastroenterol*. 2023 Oct;118(10S):S41. doi: 10.14309/01.ajg.0000949844.75704.91.

6. Yan F, Robert M, Li Y. Statistical methods and common problems in medical or biomedical science research. *Int J Physiol Pathophysiol Pharmacol*. 2017;9(5):157-163.
7. Panos GD, Boeckler FM. Statistical Analysis in Clinical and Experimental Medical Research: Simplified Guidance for Authors and Reviewers. *Drug Des Devel Ther*. 2023;17:1959-1961. doi: 10.2147/DDDT.S414599.
8. Gupta R, Tandan M, Lakhtakia S, Santosh D, Rao GV, Reddy DN. Safety of therapeutic ERCP in pregnancy - an Indian experience. *Indian J Gastroenterol*. 2005;24(4):161-163.
9. Sharma SS, Maharshi S. Two stage endoscopic approach for management of choledocholithiasis during pregnancy. *J Gastrointest Liver Dis*. 2008;17(2):183-185.
10. Krishnan A, Ramakrishnan R, Venkataraman J. Endoscopic intervention for symptomatic choledocholithiasis in pregnancy. *Clin Res Hepatol Gastroenterol*. 2011;35(12):772-774.
11. Akcakaya A, Ozkan OV, Okan I, Kocaman O, Sahin M. Endoscopic retrograde cholangiopancreatography during pregnancy without radiation. *World J Gastroenterol*. 2009;15(29):3649-3652.
12. Smith I, Gaidhane M, Goode A, Kahaleh M. Safety of endoscopic retrograde cholangiopancreatography in pregnancy: Fluoroscopy time and fetal exposure, does it matter? *World J Gastrointest Endosc*. 2013;5(4):148-153.
13. Tang SJ, Mayo MJ, Rodriguez-Frias E, Armstrong L, Tang L, Sreenarasimhaiah J, et al. Safety and utility of ERCP during pregnancy. *Gastrointest Endosc*. 2009;69(3 Pt 1):453-461.
14. Azab M, Bharadwaj S, Jayaraj M, Hong AS, Solaimani P, Mubder M, et al. Safety of endoscopic retrograde cholangiopancreatography (ERCP) in pregnancy: A systematic review and meta-analysis. *Saudi J Gastroenterol*. 2019;25(6):341-354.
15. García-Cano J, Pérez-Miranda M, Pérez-Roldán F, González-Carro P, González-Huix F, Rodríguez-Ramos C, et al. ERCP during pregnancy. *Rev Esp Enferm Dig*. 2012;104(2):53-58.