

Efficacy and safety of endoscopic retrograde cholangiopancreatography in pregnancy: A high-volume study with long-term follow-up

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ABSTRACT

Background/Aims: Pancreaticobiliary diseases are observed more frequently in pregnancy due to increased biliary stone formation. There are some concerns about the use of endoscopic retrograde cholangiopancreatography (ERCP) because of potential fetal exposure to radiation and serious adverse events, such as post-ERCP pancreatitis, which increases fetal or maternal morbidity and mortality. The aim of this study was to evaluate the efficacy and safety of ERCP during pregnancy and to present our experience.

Materials and Methods: This study included 25 pregnant patients who underwent ERCP due to biliopancreatic pathologies between 2010 and 2017. Indications for ERCP were choledocholithiasis (n=12), biliary pancreatitis (n=9), and acute cholangitis (n=4). ERCP procedures were performed using fluoroscopy (n=18) and the non-radiation technique (n=7). The duration of fluoroscopy was recorded in all cases. Fetal and maternal complications were both assessed.

Results: The mean age of patients was 29.4 (range, 21–40) years, and the mean duration of pregnancy was 19.9 weeks. All the 25 ERCP procedures were performed successfully. Biliary sphincterotomy was performed in all patients, and 18 patients with choledocholithiasis underwent stone extraction. The average procedure duration was 11 min, and the average duration of fluoroscopy was 6 s. There were no major complications in any patient. After the deliveries, the newborns were apparently healthy during the follow-up period of 1–7 years.

Conclusion: Either conventional or non-radiation ERCP procedures can be performed successfully in pregnancy, with no increase in the number of fetomaternal complications when performed by experienced endoscopists.

Keywords: Choledocholithiasis, endoscopic retrograde cholangiopancreatography, pancreatitis, pregnancy, radiation

INTRODUCTION

Physiological hormonal changes may increase the risk of cholelithiasis in pregnancy due to increased bile lithogenicity, smooth muscle relaxation, and bile stasis (1,2). The incidence of cholelithiasis has been reported to be 10% in the general population, whereas the incidence of cholelithiasis and biliary sludge in pregnancy has been reported to be up to 12% and 30%, respectively (3,4). Common bile duct stones are rarely observed during pregnancy and have been reported to occur at the rate of 1 in 1200 deliveries (5,6), and this condition may cause cholangitis and biliary pancreatitis prone to relapse during pregnancy (6). Although endoscopic retrograde cholangiopancreatography (ERCP) has been widely used in recent years, there are some concerns regarding potential fetal exposure to radiation and serious adverse events, such as post-ERCP pancreatitis, which increases fetal or maternal morbidity and mortality (7). Therefore, ERCP is currently used only for therapeutic intentions (7): choled-

ocholithiasis, cholangitis, biliary pancreatitis, and bile duct injury (8,9).

If possible, ERCP should be avoided in the first trimester of pregnancy. Fetal exposure to ionizing radiation during the period of organogenesis may cause fetal death, growth retardation, malformations, and childhood cancers (10,11). According to the International Commission on Radiological Protection, specific calculations about the fetal radiation exposure are advised when doses are suspected to exceed the threshold of 0.01 Gy (12), and the overall maximum allowed dose of radiation for the fetus is 0.005 Gy (11). The most appropriate time for ERCP is the second trimester, but it can be performed safely throughout gestation in the presence of emergency indications (13).

The aim of this study was to evaluate the efficacy and safety of ERCP during pregnancy and to present our experience that involved 25 pregnant patients.

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MATERIALS AND METHODS

Patients

The present study included a total of 25 pregnant patients who were evaluated and who underwent ERCP due to biliopancreatic pathologies in our endoscopy unit between 2010 and 2017. The results were retrieved retrospectively. The average age was 29.4 (range, 21–40) years, and the mean duration of pregnancy was 19.9 weeks. The demographic and clinical characteristics of the patients are summarized in Table 1. Six patients were in the first trimester, 12 patients were in the second trimester, and seven patients were in the third trimester.

All patients were assessed by abdominal ultrasonography, and two patients underwent further assessment by magnetic resonance cholangiopancreatography due to insufficient ultrasonographic examination. Indications for ERCP included biliary pancreatitis (n=9), choledocholithiasis (n=12), choledocholithiasis+cholangitis (n=1), and cholangitis (n=3), and they are listed in Table 2. Two patients previously underwent ERCP, along with cholecystectomy due to choledocholithiasis. One patient with cholangitis had undergone this procedure in the first trimester of the same pregnancy, and the other patient with choledocholithiasis was operated 2 years before the current pregnancy.

Methods

All patients were counseled by the obstetrics department during both the pre- and post-procedure periods. Written informed consent was obtained from patients who participated in this study. The procedures were performed by experienced endoscopists in our endoscopy unit, where approximately 2000 ERCP procedures are performed per year, using a Olympus TJF-150 Actera Video Duodenoscope (Olympus Medical Systems Corporation, Shinjuku, Tokyo, Japan) and Philips BV Libra fluoroscopy device (Philips Medical Systems, The Netherlands), under propofol sedation given by the anesthesiology team. Because

some patients refused to give their consent to undergo the ERCP procedure using fluoroscopy due to concerns regarding fetal radiation, the procedure for these patients was performed using the “non-radiation technique.” This technique can be briefly described as cannulation of the main bile duct with a catheter and verifying the access to the bile duct by the bile aspiration, which then allows for sphincterotomy and stone extraction techniques as performed in conventional ERCP. Thus, the ERCP procedures for 18 patients were performed using fluoroscopy, and those for seven patients were performed using the non-radiation aspiration technique. Cannulations were performed using fluoroscopy in 18 patients, whereas for seven patients, they were performed and confirmed by aspiration and/or direct visualization of the bile, labeled as “non-radiation technique,” which is described above. After cannulation of the common bile duct, standard biliary sphincterotomy with monopolar cautery was performed in all patients, and extraction balloons were used in patients with biliary stones. After biliary sphincterotomy, when the biliary stone matching with the one reported in the imaging studies was extracted, we concluded that the stone that we were targeting was removed. This procedure was repeated a few times in some patients, when the extraction of the expected stone failed. The fetal radiation exposure was not calculated during any of the procedures. Patients were assessed for fetal and maternal complications.

Complete blood count, C-reactive protein, liver function tests, serum amylase, and bilirubin levels, and tests indicating the haemostasis status were routinely performed on a daily basis before and after ERCP for every patient. Standard biliary sphincterotomies with monopolar electrocautery were performed in all cases, and standard extraction balloons were used in patients with biliary stones. The fetal radiation exposure was not calculated during any of the procedures, but the total duration and the total radiation energy output created by the fluoroscope generator were recorded. Patients were assessed and monitored for fetal and maternal complications in

Table 1. Characteristics of the patients

Characteristics	No
Mean age in years (range)	29 (21–40)
Mean duration of pregnancy (weeks)	19.9 (4–36)
Number of patients	25
• First trimester	6 (24%)
• Second trimester	12 (48%)
• Third trimester	7 (28%)

Table 2. Indications of ERCP

Number of patients	25
Biliary pancreatitis	9
Choledocholithiasis	12
Choledocholithiasis+cholangitis	1
Cholangitis	3
ERCP: endoscopic retrograde cholangiopancreatography	

the post-ERCP period. Post-procedure maternal complications were evaluated according to consensus definitions (14) for post-ERCP pancreatitis, bleeding, or fever. Possible fetal complications were assessed by obstetricians after the ERCP procedure and during the post-delivery period for a follow-up of 1–7 years.

RESULTS

A total of 25 ERCP procedures were performed, and the cannulations were successful and uneventful in all cases. Biliary sphincterotomy was performed in all patients, and 18 patients with choledocholithiasis underwent stone extraction. No biliary stent was applied. Of four patients who underwent a previous cholecystectomy, three had choledocholithiasis and underwent re-sphincterotomy along with stone extraction. The other patient had cholangitis and underwent sphincterotomy and bile duct irrigation. The therapeutic procedures are presented in Table 3.

The average duration of fluoroscopy was 6 s, and the average procedure time defined by scope-in and scope-out was 11 min. Of note, although the radiation absorbed by the mother could not be measured, the total radiation energy output created by the fluoroscope generator was between 11.3 and 146 mGy, which might be only partially absorbed by the mother and the fetus, because of lead aprons placed under the mother's abdomen to reduce the effect of the given radiation. There were no major complications in any patient, except one patient who was in the 18th gestational week and had vaginal bleeding 3 days after the ERCP procedure, which led to abortion. In this patient, who previously had undergone both ERCP and cholecystectomy due to choledocholithiasis in her first trimester, the pre-ERCP evaluation had revealed fetal hydrocephalus and hydronephrosis. The fetal loss was

related merely to her obstetrical problems, which had already existed. The ERCP-related complications observed in this study are presented in Table 4.

Post-ERCP pancreatitis or preterm labor was not observed. Five patients had hyperamylasemia and short duration of pain lasting less than 24 h. The remaining patients had normal deliveries and healthy newborns. After the deliveries, the newborns were apparently healthy for a follow-up period of 1–7 years.

DISCUSSION

Symptomatic pancreaticobiliary diseases are relatively common due to increased gallstone formation during pregnancy (1,2). The incidence of choledocholithiasis may reach up to 12% in the pregnant population, and it increases with gestational age (15). Untreated gallstone pancreatitis during pregnancy has a high maternal and fetal mortality of 37% and 38%, respectively (16), and without intervention, biliary pancreatitis recurs more frequently in pregnant patients than in non-pregnant population (70% vs. 20%–30%) (17).

Tiwari et al. (18) reviewed 19 studies involving ERCP procedures in pregnant women. The most common indication for performing ERCP were abnormal liver function tests (75%), and the other indications included gallstone pancreatitis (29%), choledocholithiasis (20%), and cholangitis (23%). In our study, the indications for ERCP were biliary pancreatitis (n=9), choledocholithiasis (n=12), choledocholithiasis+cholangitis (n=1), and cholangitis (n=3).

It has been demonstrated that prophylactic sphincterotomy during ERCP can reduce the risk of recurrent biliary pancreatitis and cholangitis during pregnancy (19). Sphincterotomy was performed in all our patients (n=25) to reduce that risk, but we intentionally did not place plastic stents to avoid putting the patient at stake, as they may occlude during pregnancy, which might lead to

Table 3. Results of ERCP

Procedures (n)	25
• Bile duct cannulation	25
Fluoroscopy	18
Bile aspiration	7
• Sphincterotomy	25
Stone extraction	18
Stent	0
Procedure time	
• Average duration of fluoroscopy (sec)	6
• Average procedure time (min)	11
ERCP: endoscopic retrograde cholangiopancreatography	

Table 4. Complications

Complications	n=4
Vaginal bleeding	2
Uterine contraction (medical treatment+normal labor)	1
Preterm labor	0
Abortion	1
Post-ERCP pancreatitis	0
ERCP: endoscopic retrograde cholangiopancreatography	

cholangitis and be a second reason for biliary occlusion, if the stent did not migrate intraluminally, at best. There were no major complications in any patient, except one patient who had vaginal bleeding 3 days after the procedure and had an abortion, which was found to be primarily related to her obstetrical problems that had existed before the ERCP procedure.

Tang et al. (19), in their series, reported that term pregnancy was achieved in 53 of 59 patients (89.8%). They concluded that hepatobiliary diseases during the first trimester were associated with the highest risk of preterm delivery (20.0%). In contrast to their study, we did not observe any preterm delivery or fetal distress. In the literature, preterm birth has been reported in 4.6% of patients, and the other procedure-related complications included post-ERCP pancreatitis (4.6%), spontaneous abortion (0.9%), and fetal distress (0.6%) (18). Vaginal bleeding (n=1) and uterine contractions (n=1) were the uneventful complications observed in our patients, which improved with medical treatment. Post-sphincterotomy bleeding, cholangitis, or post-procedure pancreatitis was not detected with either fluoroscopic or non-fluoroscopic interventions in any of our cases. Only post-ERCP hyperamylasemia and short duration of pain lasting less than 24 h were observed in five of our patients. The reason for these favorable findings may be that we did not encounter problems such as difficult bile duct cannulations and inadvertent pancreatic canal cannulations or that we did not perform balloon dilatation to naive papilla, which may increase the risk of post-ERCP pancreatitis. However, we might have observed post-ERCP pancreatitis if we had incorporated a higher cumulative number of pregnant patients, including the most difficult cases that necessitate repetitive cannulations, inadvertent pancreatic duct cannulations, and so forth. In addition, both the high-volume of procedures performed in our department, which is approximately 2000 ERCP procedures annually, and the performance of these procedures by advanced trained endoscopists might account for the low complication rates found in this study.

Although no procedure-related maternal or fetal complications were observed in their study, Tang et al. (19) reported a fluoroscopy time of up to 7.2 min (median, 1.45 min) and a post-ERCP pancreatitis rate of 16%. This high rate of pancreatitis may be due to repeated cannulation of the papilla and thermal injury of electrocautery during sphincterotomy. Young age, female gender, a history of pancreatitis, sphincter of Oddi dysfunction, difficult cannulation, and precut sphincterotomy were declared as risk factors for post-ERCP pancreatitis (20). Furthermore, a

prolonged fluoroscopy duration may make the procedure more controlled and safer, and this condition may be the reason for the lower rate of complications than those reported in the literature.

The World Gastroenterology Organisation reported that patients were exposed to fluoroscopy for about 2–16 min during diagnostic ERCP, and this duration was significantly longer in therapeutic procedures (21). In the literature, the mean duration of fluoroscopy was reported to range between 8 s and 7.2 min in pregnant patients (18), and the ERCP-induced fetal radiation exposure was reported to range between 0.1 and 3 mGy per procedure (11,13,15,22–24).

The methods and the necessity of estimating the fetal radiation exposure during ERCP in pregnant patients are still controversial in the literature.

In this context, Kahaleh et al. (11) and Smith et al. (25) reported an average between 0.4 and <0.1 mGy fetal absorbed dose as 10% of the thermoluminescent dosimetry (TLD) dose recorded on the upper back of the patient in the primary beam. Based on these data, both authors proposed that measuring the fetal radiation exposure from the fluoroscopy time or measuring it via TLDs is unnecessary. In contrast, Samara et al. (22) stated that fetal absorbed radiation was primarily through scattered radiation from the mother's body and argued that the methods of Smith and Kahaleh may not be appropriate.

Tham et al. (15) used a non-anthropomorphic phantom to estimate the entrance skin dose and reported a fetal dose exposure of 3 mGy.

In a more recent study, Huda et al. (26) used TLDs to estimate the patient-absorbed dose and also performed Monte Carlo calculations using a three-dimensional computational phantom representing a 9-month pregnant patient to measure the fetal absorbed dose. They concluded that the lowest absorbed dose of the uterus and fetus was found to be 0.01 mGy to the fetal brain, and the largest absorbed dose was 0.13 mGy to the placenta. The spleen of the mother had the largest absorbed dose of 12.18 mGy because it was closest to the source of radiation. Thus, these results indicate that the amount of radiation to which organs are exposed changes according to the distance from the radiation source.

ERCP in pregnant patients should be carried out in a safe, quick, and effective manner, and the complication rate

must be low. Although non-radiation ERCP with the bile aspiration technique (13) appears to be a favorable method in this group of patients, sufficient definition of the biliary system cannot be obtained with this technique, and residual stones may be left in the common bile duct that may lead to recurrent pancreatitis or cholangitis (10).

Another option to perform non-radiation ERCP is the endoscopic ultrasound (EUS)-guided method, but this technique has some negative aspects such as a long procedure time, increased costs, and expertise requirements. Lachter et al. (27) reported that fetal complications occurred during examinations by endoscopists who had performed fewer than 300 EUS procedures. Unfortunately, the most common location of the EUS perforation is the duodenum, and the perforations mostly resulted from mechanical injury of the duodenal wall due to the rigid tip of echoendoscopes (28)

In addition, studies using ERCP with fluoroscopy have reported that exposed radiation doses were estimated under the limit of 0.005 Gy, which was defined as the overall maximum allowed dose of radiation for the fetus by the International Commission on Radiological Protection (11).

The suggestions to reduce the exposed radiation are the following: limiting the fluoroscopy time (25), using the anterior-posterior beam projection and lead apron shielding (12,20), and avoiding hard copy radiographs (10). The beam and patient position and the physician's experience are the primary factors that alter the absorbed dose significantly (26). In their series, Gupta et al. (29) presented their experience with therapeutic ERCP in 18 pregnant women and long-term follow-up of the babies born after ERCP. The median procedure time was 17 min, and the median fluoroscopy time was 8 s. Two of their patients had post-procedure complications. One patient had post-sphincterotomy bleeding, and the other had mild post-ERCP pancreatitis and preterm delivery. They contacted and obtained information about 11 of the 18 patients and their children who were of a median age of 6 (range, 1–11) years. All the patients had healthy children without any developmental or congenital abnormalities. In our study, we managed to contact and obtain information about 21 of 25 patients who had healthy newborns, and no developmental or congenital abnormalities were observed for a follow-up period of 1–7 years.

In conclusion, either conventional ERCP or non-radiation ERCP procedures can be performed successfully in pregnancy, without increasing the fetal and maternal com-

plications when carried by experienced endoscopists, in appropriate settings.

Ethics Committee Approval: N/A.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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