

## Endoscopic Retrograde Cholangiopancreatography: safety and acceptance in pregnancy

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### Abstract

To evaluate the indications, clinical features, safety in sedation, complications and minimum use of radiation during endoscopic retrograde cholangiopancreatography in pregnant patients of varying trimesters, a prospective case series was conducted at the endoscopy suite, Surgical Unit 4, Civil Hospital Karachi, from January 2007 to June 2011. Acquiring the desired goal through endoscopic therapy was considered technical success.

A total of 10 pregnant women (mean age  $25.5 \pm 4.8$  years) underwent 11 ERCP procedures. Three (30%) patients were in the first trimester, 4 (40%) in the second trimester, and 3 (30%) in the third trimester. Of the 10 women, 4 (40%) were primigravida and six (60%) multigravida. Mean fluoroscopy time was  $6.5 \pm 1.7$  seconds. Technically successful endoscopic therapy was performed in all the cases with no maternal or foetal adverse events. The delivery was full term in all cases with an Apgar score of more than 8, except in 1 (10%) with an uneventful continuing pregnancy.

It was concluded that endoscopic retrograde cholangiopancreatography, when indicated, is an effective and safe therapeutic procedure in pregnancy.

**Keywords:** ERCP, Pregnancy, Choledocholithiasis, Radiation safety.

### Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a contemporary and gold standard procedure for the pancreaticobiliary pathologies. Serious perinatal and maternal morbidity prevails when it comes to performing an ERCP in a pregnant patient with pancreaticobiliary disorders.<sup>1</sup> Hormonal changes during pregnancy increase the lithogenicity of bile and impair gallbladder

emptying, which create a favourable environment for gallstone formation.<sup>2</sup> The incidence of gallstones during pregnancy is as high as 12%,<sup>3</sup> and about 1 of every 1000 pregnancies is complicated by symptomatic biliary-tract disease.<sup>4</sup> Relapsing pattern of biliary pancreatitis and cholangitis occurs during pregnancy,<sup>5</sup> and the disease should be managed as in a non-pregnancy state.<sup>6</sup> However, in a country like Pakistan, the situation becomes more complicated and perplexed due to limited healthcare facilities, lack of expert interventional gastroenterologists and relatively low incidence of disease leading to sparse expertise. Since the advent of ERCP during pregnancy in 1990 with few case reports,<sup>6,7</sup> scanty number of case series have been published comprising only few hundred procedures. To date, this is the first study of its type from this part of the world. The intent was to evaluate the indications, findings and safety of ERCP in pregnancy.

### Patients and Methods

This case series was conducted at the Endoscopy Suite, Surgical Unit 4 of Civil Hospital, Karachi, between January 2007 and June 2011. More than 2000 procedures were performed during the study period. Of them, 10 were pregnant. An expert endoscopist with an annual procedure rate of 700 performed all the procedures. After detailed counselling about the risks, possible complications and alternative options, informed consent was obtained from all the patients. Patients with definite indication were admitted to the ward and routine lab tests, including complete blood count (CBC), liver function tests (LFT), prothrombin time (PT), and transabdominal (TA) ultrasonography were performed. Evaluation by an obstetrician was done before the procedure regarding maternal health and foetal wellbeing. Pre-procedure prophylactic antibiotic, intravenous cephalosporin, was administered to all and propofol was used for deep sedation by a senior anaesthesiologist. During the procedure, patients were monitored by continuous electrocardiography (ECG) and pulse

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oximetry. Foetal monitoring was not performed in any of the cases. In order to avoid decrease in uterine perfusion, left lateral recumbent position was used. Abdomen was shielded from all four quadrants by maternity lead aprons, minimising foetal radiation. ERCP was performed by employing the standard technique, using a therapeutic duodenoscope (TJF 180: Olympus Japan Inc.). Standard biliary sphincterotome was used for biliary cannulation, only brief fluoroscopy snapshots were taken to confirm deep biliary cannulation and to obtain contrast cholangiogram. The ionic contrast medium renograffin (diatrizoate meglumine and diatrizoate sodium) was used to opacify the bile and the pancreatic duct. Post-interventional assessment for the possible procedure-related complications was done in all the patients for 48 hours. They were evaluated by the primary team, and the severity was graded according to the Cottons definition.[8] Routine lab tests including serum amylase, was done on consecutive days and the patients were discharged within 24 hours post-procedure if there was no evidence of any complication. Indications, findings, therapies, safety, technical success and complications were assessed. ERCP indications were based on clinical symptoms; history, laboratory results, and radiological imaging studies (e.g., TA ultrasound).

Technical success of the procedure was defined as acquiring the desired goal by succeeding with the endoscopic therapy. The endoscopic and fluoroscopic findings, the therapeutic measures performed, and the complications were recorded for each patient. Term pregnancy was defined as at least 37 completed weeks of gestation. Foetal radiation exposure was not routinely measured. The first trimester corresponded to weeks 1 to 14, the second trimester to weeks 15 to 28, and the third trimester >29 weeks. Apgar scores at 1 and 5 minutes of all the neonates were inquired from the respective obstetricians of the patients via telephonic conversation and were duly recorded.

## Results

A total of 10 pregnant women (mean age  $25.5 \pm 4.8$  years; range 19 to 34 years; median age 25.5 years) underwent 11 ERCP procedures. The distribution of these 10 women gestational ages were; first trimester 3 (30%), second trimester 4 (40%) and third trimester 3 (30%). Four (40%) were primigravida and six (60%) were multigravida.

Indications included obstructive jaundice in 9 (90%) and stent exchange in 1 (10%). Only 1 (10%) patient had a repeat ERCP, while rest of the patients had it once. Clinical features included right upper quadrant pain in 9 (90%), nausea in 6 (60%), vomiting in 4 (40%), clinical jaundice in 3 (30%) and epigastric pain in 2 (20%). The mean fluoroscopy time was  $6.5 \pm 1.7$  seconds (range, 4 to 9s). Mean haemoglobin was  $11.69 \pm 1.0$ g/L (range: 10.5 to 13.1g/L); mean bilirubin was  $2.57 \pm 0.58$ mg/dL (range: 1.80 to 3.7mg/dl), mean direct bilirubin was  $1.91 \pm 0.49$ mg/dl (range: 1.20 to 2.90mg/dl) and mean alkaline phosphatase was  $407 \pm 89.8$ units/L (range: 290 to 514units/L). Ultrasound findings were common bile duct (CBD) stone in 9 (90%), dilated CBD and cholelithiasis in 5 (50%) and stent in CBD in 1 (10%) patient. ERCP revealed CBD stone in 9 (90%) and a plastic biliary stent in 1 (10%), successful cannulation was achieved in all. Biliary sphincterotomy was done in 9 (90%) and stones were extracted in 8 (80%) patients smoothly. One (10%) patient in third trimester had a large biliary stone (>15mm), and a plastic biliary stent was placed to ensure bile drainage while preventing stone impaction. After the delivery of a healthy full-term baby, ERCP was performed again and the stone was extracted successfully. Technically successful endoscopic therapy was performed in all the procedures. No maternal or foetal adverse events were noted immediately after any of the procedures or on follow-up. The delivery was full term in all the cases with an Apgar score of more than 8, except in one with an uneventful continuing pregnancy.

## Discussion

In a developing country like Pakistan, ERCP is still in the elementary phase of development. When it comes to performing an ERCP in a pregnant woman, it becomes more challenging and imposes more responsibility on the endoscopist. Symptomatic choledocholithiasis and gallstone pancreatitis is the most common pancreaticobiliary disease during pregnancy and is detrimental for both mother and foetus. Cholangitis in pregnancy carries a high rate of mortality and morbidity and ERCP is the gold standard procedure for prevention of the dreaded complication.<sup>2</sup> Since the advent of ERCP in pregnancy, its safety and efficacy has been proved and affirmed in many case series.<sup>1,2</sup> We report the first case series from Pakistan.

Intervention in gestational stages can lead to spontaneous abortion, foetal abnormalities,

premature labour, and even death. In case of any intervention, first trimester is the most precarious with a lower rate of term pregnancy (73.3%), the higher rate of pre-term delivery (20%) and low-birth-weight (21.4%). Generally, the second trimester is related to the lowest risk of interventions.<sup>9</sup> In our series, although with a limitation of low numbers, we did not encounter any complication to the mother or the foetus.

Radiation exposure to the foetus during an ERCP is of prime concern. Effects of ionising radiation on the embryo include miscarriage, foetal growth restrictions, congenital malformations, mental retardation and increased risk for childhood cancer.<sup>10,11</sup> Non-radiation techniques have been tried and are comparable to the standard techniques.<sup>12,13</sup> These include cholangioscopy<sup>1</sup> or transcatheter ultrasound monitored,<sup>2</sup> guide-wire-assisted cannulation. According to the American College of Obstetricians and Gynaecologists, exposure of less than 5 rad or 50 mGy does not appear to be associated with an appreciable increased rate of foetal anomalies or pregnancy loss.<sup>14</sup> Epidemiologic and observational studies have shown a threshold conceptus dose of 100-200 mGy leading to these complications<sup>15,16</sup> and the ERCP requires substantially less dose, particularly when the foetus is away from the primary beam.<sup>17-19</sup> As per Tham et al,<sup>20</sup> we also tried to reduce the radiation dose by limiting fluoroscopy time, shielding the pelvis with lead and avoiding hard copy radiographs, acquiring equally good results.

Biliary sphincterotomy in pregnancy has been reported by many authors in different large series with substantially good results.<sup>21,22</sup> Most of the patients in our study were of symptomatic choledocholithiasis, sphincterotomy, and balloon sweep was performed and stones were successfully removed in eight cases. One patient had a large stone (>1.5cm). Stent was placed with good drainage and a repeat procedure was done after the delivery. Stent was removed and duct was cleared by stone extraction. There was a single case of stent exchange. The patient had a post-laparoscopic cholecystectomy, Type A biliary injury<sup>23</sup> before pregnancy. She had a stent exchange before pregnancy and another one afterwards in the first trimester due to a persistent leak.

## Conclusion

The current series reinforces the previous data that ERCP in pregnancy, when performed by an

experienced endoscopist for a strong indication and therapeutic intent, is safe and effective. However, the radiation exposure and the timing of the procedure should be minimised as much as possible to attain maximum benefit. A multi-disciplinary team approach is required where obstetricians, biliary endoscopists and anaesthetists should work side by side in close coordination for the transcendent management, making the procedure impervious to any complications.

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