Chapter 18
ERCP in Pregnancy

Jaclyn Kagihara and Larissa Fujii-Lau

Case Report

A 34-year-old woman who is 24 weeks pregnant with her first child presents to the emergency room with a 2-week history of right upper quadrant abdominal pain. She initially attributed her discomfort to acid reflux as the pain was primarily postprandial, but the use of over-the-counter H2 blockers provided no symptom relief. On presentation, she noted a 3-hour episode of persistent pain, associated with nausea, non-bloody emesis, and generalized fatigue. She denied fevers and jaundice.

In the emergency room, she was found to have temperature 98.5 °F and pulse 114 beats per minute (bpm). Labs were significant for aspartate transaminase 159, alanine transaminase 210, alkaline phosphatase 280, and total bilirubin 1.2. On transabdominal ultrasound, the visualized portions of the extrahepatic bile duct were seen to be dilated to 8 mm (Fig. 18.1) with sludge seen in the gallbladder (Fig. 18.2). Her heart rate improved to 86 bpm with the administration of normal saline fluids. Both gastroenterology and general surgery were consulted.

J. Kagihara · L. Fujii-Lau (✉)
University of Hawaii, Queens Medical Center, Honolulu, HI, USA
e-mail: llau@queens.org

D. K. Mullady (ed.), *Dilemmas in ERCP*,
https://doi.org/10.1007/978-3-030-12741-1_18

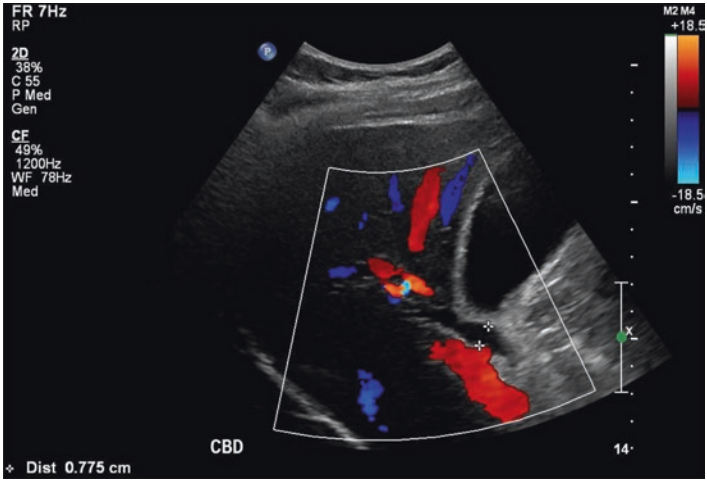

FIGURE 18.1 Transabdominal ultrasonography revealing a dilated common bile duct (8 mm) but no choledocholithiasis

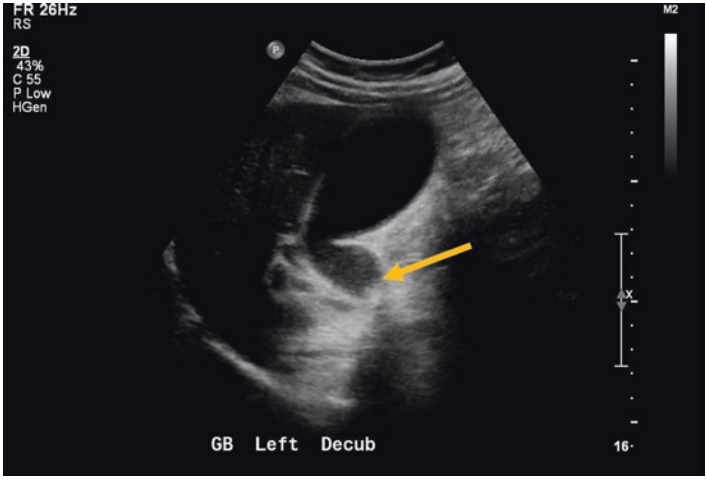

FIGURE 18.2 Transabdominal ultrasonography revealing shadowing sludge within the gallbladder neck (arrow)

The patient's case posed a handful of dilemmas in management:

- Is an endoscopic retrograde cholangiopancreatography (ERCP) indicated?
- Is immediate action necessary or can the patient be medically managed with therapeutic intervention delayed until after delivery?
- Should a confirmatory test be performed to determine if the patient has choledocholithiasis, if so should it be a magnetic resonance cholangiopancreatography (MRCP) or endoscopic ultrasound (EUS)?
- What risks does ERCP pose to the mother and the fetus?
- How must standard ERCP techniques be tailored in a pregnant patient?

Introduction

Pregnancy is a known risk factor for developing gallstones. During pregnancy, elevated levels of estrogen and progesterone increase bile lithogenicity and decrease gallbladder wall motility, favoring the formation of gallstones [1–3]. These physiologic alterations in pregnancy can even provoke the recurrence of biliary tract disease in patients who have already undergone cholecystectomy [4].

Pancreaticobiliary disease is estimated to complicate as many as 3.3–12.2% of pregnancies [5, 6]. In a prospective study, sludge and/or stones were found by ultrasound in 5.1% and 7.9% of pregnant women by the second trimester and third trimester, respectively, as well as in 10.2% of women by 2–4 weeks postpartum [7]. Fortunately, most pregnant women remain asymptomatic, such that the frequency of disease requiring therapeutic intervention has been reported be as few as 1 in 1200 deliveries [8]. Furthermore, in the postpartum period, sludge and stones are spontaneously cleared in 61% and 28% of women, respectively, as hormone levels

return to their prepregnancy state [9]. Despite this phenomenon, significant complications of cholelithiasis including acute cholecystitis, cholangitis, and pancreatitis can still develop in up to 10% of symptomatic pregnant females and may lead to potentially life-threatening consequences for both the mother and the fetus. Surgery, once considered to be the mainstay in management for gallstone disease, is now understood to carry an increased risk of maternal and fetal compromise [10]. ERCP, therefore, has emerged as the treatment of choice, and interventional endoscopists treating pregnant patients need to be experienced and comfortable with this procedure. In this chapter we review the special considerations that should be reviewed when ERCP is considered for a pregnant patient.

Diagnosis/Assessment

Indications for ERCP

The role of ERCP in pregnancy is strictly therapeutic. The primary indications are similar to those in nonpregnant patients and are listed in Table 18.1. In rarer instances, ERCP has been performed in pregnant patients with choledochal cysts [11], parasitic infection of the biliary tree [12], and pancreatic adenocarcinoma [12].

Justifying the need for ERCP in a pregnant patient begins with the appropriate diagnosis. Transabdominal US has tradi-

Table 18.1 Indications for ERCP during pregnancy

Symptomatic choledocholithiasis
Cholangitis
Gallstone pancreatitis
Obstructive jaundice
Biliary or pancreatic ductal disease (i.e., leak, stricture)

tionally been the initial imaging study of choice in patients with suspected choledocholithiasis, but its use may be limited when considering the changes in body habitus and the anatomy that occur in pregnancy. The use of MRCP and EUS to confirm the presence of choledocholithiasis prior to ERCP has recently been gaining popularity. However, due to the limited studies on the use of MRI during pregnancy, the International Commission on Non-Ionizing Radiation Protection recommends avoiding this as much as possible during the first trimester of pregnancy [13]. They state that MRI should only be pursued after critical risk-benefit analysis has been undertaken for each individual patient. Data supports the use of EUS prior to ERCP, especially in cases where transabdominal US and/or MRCP are nondiagnostic and the clinical suspicion for CBD stones remains high. Several studies have emphasized the utility of EUS-guided ERCP in patients with suspected choledocholithiasis as up to 40% of ERCPs may be avoided by the lack of biliary pathology seen on initial EUS [14–16].

Ultimately, treatment should not be delayed for patients with a clear diagnosis that requires intervention. In a retrospective study, patients managed conservatively for symptomatic gallstones were more likely to develop recurrent symptoms, require emergency room or hospital visits, and undergo cesarean section operations than those treated with either ERCP and/or cholecystectomy [17]. For patients in whom an indication is not straightforward, the decision to undergo ERCP should be individualized, based on the clinical status of the mother and the fetus and expert opinions of the endoscopist, anesthesiologist, obstetrician, and surgeon.

Pregnancy Testing

Rapid pregnancy testing is commonplace and should be considered standard of care prior to ERCP in any woman of childbearing age. The importance of pregnancy screening is highlighted in a case series on the safety and efficacy of standard ERCP in pregnancy in which 3 out of 23 women did not know they were pregnant at the time of ERCP [8].

Consent

As with any intervention, a thorough informed consent process is mandatory prior to ERCP. All patients should be told of available alternatives in management, the proposed plan for ERCP, along with any potential adverse events. In addition to the immediate risks of ERCP to the patient and the fetus, the possible long-term risk of radiation exposure to the fetus should be discussed with the patient [18].

Fetal Monitoring

Prior to ERCP, an obstetrician consultation is required for assistance in the perioperative care of the patient and the fetus. Their support should also be readily available throughout the procedure in the event there is fetal or patient distress. The decision to monitor fetal heart rate should be individualized based on the recommendation of the obstetrician, which is typically guided by gestational age of the fetus and available resources. Before 24 weeks gestation, Doppler confirmation of the presence of an adequate fetal heart rate before and after the procedure is sufficient. After 24 weeks gestation, simultaneous monitoring of electronic fetal heart and uterine contraction should be performed before and after the procedure [19].

Timing

There is scarce evidence in regard to the optimal timing of ERCP in pregnancy. The second trimester of pregnancy theoretically provides the safest opportunity [19]. In the first trimester, the fetus is undergoing organogenesis and is therefore most susceptible to the teratogenic effects of ionizing radiation [20]. Studies from atomic bomb survivors suggest that the effects of radiation on the central nervous system are highest during weeks 8–15 of gestation [21]. In the third trimester, the mother's gravid uterus may present anatomic

alterations that make it difficult for even the most skilled endoscopists to access the ampulla.

In a retrospective review, patients who underwent ERCP in the first trimester had the lowest percentage of term pregnancy (73.3%), highest risk of preterm delivery (20.0%), and highest-risk low-birth-weight newborns (21.4%) [22]. The authors suggested that the adverse outcome in those undergoing first-trimester ERCP was attributed more to the hepatobiliary disease itself rather than the ERCP procedure itself. Reassuringly, none of the 59 patients in this study experienced adverse events such as stillborn or fetal malformations.

Sedation and Antibiotics

Sedation is high risk in pregnancy and therefore should be administered under the guidance of an anesthesiologist. All agents should be used with great caution and vigilance and given in slow titration and at the lowest dose to avoid hemodynamic and respiratory changes in the mother and the fetus.

Physiologic changes to the respiratory system during pregnancy include a 20% increase in oxygen consumption and a 20% decrease in pulmonary function residual capacity, which can lead to a rapid decrease in partial pressure oxygen in situations with maternal apnea [23]. Furthermore, airway protection is of concern in pregnant patients, as swelling of the oropharyngeal tissues and a decreased caliber of the glottic opening can make intubation challenging. Additionally, progesterone causes relaxation of the lower esophageal sphincter, thereby increasing the risk of aspiration in an unconscious pregnant patient [24]. Noteworthy hemodynamic changes during pregnancy include a 40% increase in blood volume and cardiac output and a 20% dilutional decrease in hematocrit, rendering the fetus sensitive to maternal hypoxia and hypotension [23]. Great care, therefore, must be taken to avoid oversedation of pregnant patients [19].

The risk of drug teratogenicity in the fetus is related to the inherent toxicity of the medication, the dosage and the dura-

tion of exposure, and the period of fetal development when introduced [25]. Recommendations are based on scant data from case series and reports and from the Food and Drug Administration (FDA) drug categorization. Since 2014, the FDA no longer uses the five categories (A, B, C, D, and X) to determine the safety of over-the-counter and prescription drugs in pregnancy. Because most information about drug safety during pregnancy came from animal studies, uncontrolled studies, and postmarking surveillance, the old FDA classification system led to confusion and difficulty applying available information to clinical decisions. In 2015, the FDA enlisted a new labeling of all drugs in a consistent format called the "Pregnancy and Lactation Labeling (Drugs) Final Rule (PLLR)." The information required by the FDA has three subsections: pregnancy (8.1), lactation (8.2), and females and males of reproductive potential (8.3) [26]. A summary of the commonly used sedative drugs using the new FDA classification is provided in Table 18.2.

The indications for antibiotics are the same in pregnant and nonpregnant patients. Antibiotics are often given prophylactically during ERCP particularly if contrast is used to decrease the risk of infection of inadequately drained contrast. In general, penicillins, cephalosporins, erythromycin, and clindamycin are considered to be safe during pregnancy and lactating, while quinolones and tetracyclines should be avoided in all trimesters [19]. Metronidazole should not be used in the first trimester, and sulfonamides and nitrofurantoin should not be given to pregnant patients in their third trimester. During breastfeeding, sulfonamides, quinolones, and metronidazole should be avoided.

Treatment/Management

Positioning

The optimal position for pregnant women undergoing ERCP should minimize fetal radiation exposure (discussed further below) and avoid vascular compression. In the second and

Table 18.2 Sedative medication for ERCP during pregnancy. (From the FDA website for each medication)

Drug	Old FDA pregnancy safety category	PLLR	
		Pregnancy (8.1)	**Lactation (8.2)**
Meperidine (DEMEROL®)	B	Available data with meperidine are insufficient to inform a drug-associated risk for major birth defects and miscarriage Formal animal reproduction studies have not been conducted with meperidine Meperidine administration to pregnant hamsters during organogenesis reportedly caused neural tube defects (exencephaly and cranioschisis) at a dose 0.85 and 1.5× the recommended human dose, 1200 mg/day	Meperidine appears in the milk of nursing mothers receiving the drug
Fentanyl citrate	C	Available data with fentanyl are insufficient to inform a drug-associated risk for major birth defects and miscarriage Fentanyl administration to pregnant rats during organogenesis has been shown to be embryocidal at doses within the range of the recommended human dose	Fentanyl appears in the milk of nursing mothers receiving the drug Infants exposed to fentanyl through breast milk should be monitored for excess sedation and respiratory depression

(continued)

Table 18.2 (continued)

Drug	Old FDA pregnancy safety category	PLLR	
		Pregnancy (8.1)	**Lactation (8.2)**
Midazolam (VERSED®))	D	Available data with midazolam are insufficient to inform a drug-associated risk for major birth defects and miscarriage Midazolam administration to pregnant rabbits and rats showed no evidence of teratogenicity at doses 5 and 10× the recommended human dose, 0.35 mg/kg	Midazolam appears in the milk of nursing mothers receiving the drug
Diazepam (VALIUM®)	D	Available data with diazepam are insufficient to inform a drug-associated risk for major birth defects and miscarriage Diazepam administration to pregnant mice and hamsters during organogenesis has been shown to cause cleft palate and encephalopathy at a dose 8× the recommended human dose, 1 mg/kg/day	Diazepam appears in the mild of nursing mothers receiving the drug

Propofol (DIPRIVIAN®)	D	Available data with propofol are insufficient to inform a drug-associated risk for major birth defects and miscarriage Propofol administration to pregnant rats either prior to mating, during early gestation, or during late gestation and early lactation has been shown to cause decreased pup survival and increase maternal mortality at a dose less than the recommended human dose, 15 mg/kg/day	Propofol appears in the mild of nursing mothers receiving the drug

third trimester, patients should avoid being placed in the supine position as the gravid uterus can compress the aorta or the vena cava, resulting in maternal hypotension and inadequate placental perfusion [19]. In most studies, patients are placed in the left lateral position with a wedge or pillow placed under the patient's right hip to help maintain safe orientation.

Electrocautery

Amniotic fluid can serve as a conduit for electrical current to the fetus [27]. When sphincterotomy is used, the uterus should not lie in the path between the sphincterotome and the grounding pad. Placement of the grounding pad on the posterior thoracic wall therefore is more ideal than placement on the thigh. If available, monopolar electrocautery can be used to avoid the need for a grounding pad and decrease the risk of current passing through the gravid uterus [19].

Radiation Exposure and Risk

The consequences of radiation exposure during standard ERCP with fluoroscopy are a major and highly debated concern. Knowledge regarding the effects of radiation are largely derived from epidemiologic and observational studies from exposed human populations and animal studies. Radiation harm to the fetus can be divided into two types. Deterministic effects of radiation include malformation and disturbances in growth and development, the likelihood and severity of which are proportional to the radiation dose. Stochastic effects include disturbances in genetics and cancer, which follow a "no-threshold" model regardless of radiation dose [28].

There are three possible sources of radiation during standard ERCP [29]. The first occurs when the X-ray source emits a focused beam of radiation directly toward a subject. The second form is the major source of exposure to the endoscopists and staff, as well as the fetus, as the X-ray "scatters" throughout the room. It occurs when a source emits a focused

beam of radiation that strikes an object and ricochets from its original path. The third form is often negligible and occurs when radiation escapes or "leaks" from the X-ray source.

Ionizing radiation can be quantified in a variety of ways [30]. The *absorbed dose* is the amount of energy per unit mass of tissue through which the radiation passed and is expressed in units of gray (Gy). The *effective dose* is expressed in units of sievert (Sv). It combines the amount of radiation absorbed and tries to estimate the effect of the radiation, based on radiation type and radiation-sensitivity of different organs. This measurement is used to assess long-term risk of radiation exposure, such as cancer. The *dose-area product (DAP)* or *kerma-area* product is a measure of radiation dose integrated across the entire exposed field. It is derived from the absorbed dose multiplied by the area irradiated and is expressed in units of gray per square centimeters (Gy/cm^2).

The 2017 American College of Obstetricians and Gynecologists Guidelines for Diagnostic Imaging During Pregnancy and Lactation state, "fetal risk of anomalies, growth restriction, or abortion have not been reported with radiation exposure of less than 50 mGy, a level above the range of exposure for diagnostic procedures." [20]

Several authors, therefore, have attempted to quantify radiation exposure during ERCP to both the mother and the fetus using different methodologies. Using thermoluminescent dosimeters (TLDs), Kahaleh et al. found mean estimated fetal radiation exposure to be 0.4 mGy (range 0.01–1.8 mGy) [31]. Another group used a non-anthropomorphic phantom to estimate the entrance dose and subsequently measured fetal dose exposure at 3 mGy (range 1.02–5.77 mGy) with a mean fluoroscopy time of 3.2 minutes (range 1.1–6.1 minutes) [32]. Samara et al. presented an intriguing model utilizing data obtained from 24 nonpregnant patients for estimating conceptus radiation dosage for a specific patient procedure [28]. The study was performed in two stages. The first step involved collecting data on technical and physical parameters for fluoroscopy and radiography. The second step involved the use of a Monte Carlo-N-particle code, a mathematical phantom, to

calculate the normalized conceptus dose for a range of exposure techniques, patient size, and gestational age. This model allows for a more accurate estimation of fetal radiation exposure when compared with traditional methods. Their data revealed that fetal dose exposure may occasionally exceed 50 mGy (range 3.4–55.9 mGy), above the level deemed "safe" by ACOG. Despite these authors' efforts and the recommendations laid forth by ACOG, a clear-cut safe or harmful radiation dose for ERCP in pregnancy is still unknown. We recommend the lowest dose of radiation necessary to complete the procedure successfully be used.

Because standard ERCP has the potential to deliver elevated doses, dose reduction techniques are of the utmost importance to protecting the mother and the fetus. Table 18.3 contains a list of general rules for safe and effective fluoroscopy use. Patients should be strategically positioned relative to the expected trajectory of the X-ray beam. Wagner et al. proposed that a posteroanterior projection of the X-ray beam would result in 3–7× less entrance dose compared to a lateral approach, as the mother has more tissue in this direction to provide shielding [33]. A lead should be used in all cases of ERCP with fluoroscopy. The use of a radiation-attenuated drape (made of heavy metals bismuths and antimony) hung

Table 18.3 Techniques to minimize radiation exposure in standard ERCP

Use short "taps" of fluoroscopy
Use the last-image-hold or fluoroscopy loop recording feature for image analysis
Use low-dose-rate setting Avoid recorded images
Avoid use of magnification
Collimate X-ray beam to the smallest field possible
Place the patient close to the image receptor and far from the radiation source
Use lead shielding

around the image intensifier in one study reduced radiation dose exposure to the endoscopists and the staff by ~90% [29]. Room setup is important and should be arranged so that the image receptor is kept as close to the patient as possible and the X-ray beam as far from the patient as possible. Endoscopists should use pulse (not continuous) fluoroscopy at a low-dose frame rate setting. If image noise becomes a problem at the low-dose frame rate, then endoscopists should collaborate with a medical physicist or work with a vendor service representative to adjust image processing settings to optimize image quality [34]. The number of recorded spot images should be limited, keeping in mind that digital image capture requires a lower dose compared with film radiography, if images are necessary. For image analysis the last-image-hold or loop recorder feature is useful. Magnification mode should be used sparingly as the radiation dose is compounded as the field of view decreases. Routine reminder of demagnification may be useful as endoscopist may have the habit of staying in magnification mode while preoccupied with other facets of ERCP [35]. Collimating the X-ray beam to the smallest field possible accomplishes several advantages including decreasing the amount of scatter radiation striking the fetus and image receptor, improving the fluoroscopic image quality, and reducing the chance of direct exposure to the fetus [34]. The importance of ERCP in pregnant patients being performed by skilled endoscopists in properly equipped and staffed healthcare institutions cannot be reinforced enough. It has been shown that radiation exposure is significantly higher with endoscopists who perform less than 200 ERCPs per year. In a study by Liao et al., the differences in median radiation exposure to patients essentially doubled when the procedure was performed by a low-volume endoscopist [36].

Non-radiation ERCP

The goal of non-radiation ERCP is to achieve biliary cannulation without radiation exposure, thereby negating the risks

of radiation to the patient and fetus. However, the lack of fluoroscopy may increase the risk of retained stones or missing biliary pathology (i.e., strictures, leak). Therefore, the benefit of the lack of fetal radiation exposure needs to be weighed against the risk of the more technically challenging ERCP. Multiple techniques have been suggested including needle-knife fistulotomy, two-stage process with biliary stenting, and bile aspiration. Further studies are needed to determine the role of each of these techniques in pregnancy.

In 1990, Binmoeller and Katon published a landmark case of NR-ERCP in a pregnant female with an impacted stone at the ampulla that caused displacement and obstruction of the papillary orifice, prohibiting standard papillotomy and biliary cannulation [37]. Using the needle-knife papillotome, a large choledochal-duodenal fistula was created allowing spontaneous passage of the stone. Several other authors have reported use of the needle-knife papillotome to facilitate biliary cannulation in patients that fail conventional methods [38, 39]. The needle-knife allows for flexibility in orientation and ease of maneuverability and can cut with little current. The authors note that the incision should be done over the calculus as this will function as a safety buffer. Safety of needle-knife was examined by Huibregtse et al. who found the rate of duodenal perforation to be less than that of standard endoscopic papillotomy with no difference in bleeding rates but a higher risk of pancreatitis with use of needle-knife [40].

Bile aspiration is another proposed technique for non-radiation ERCP. Uomo et al. first described this technique in 1994 where a catheter was inserted into the bile duct followed by aspiration of fluid [41]. The technique is based off the assumption that if bilious fluid is aspirated, then bile duct cannulation is confirmed. If clear fluid is seen, then placement in the pancreatic duct is presumed and cannulation is reattempted. Shelton et al. performed wire-guided cannulation and confirmed biliary cannulation by observing bilious fluid around the guidewire while moving the guidewire back and forth to facilitate fluid drainage [42]. The bile aspiration technique has several potential drawbacks. The method does not differentiate

between cannulation of the cystic duct versus the common hepatic duct, and it may be difficult to discern whether the duct has been cannulated beyond the level of obstruction. Additionally, confirmation that the biliary duct has been swept of all biliary stones or sludge is not always clear. Shelton et al. overcame this by performing choledochoscopy to confirm ductal clearance in five patients, while transabdominal ultrasound was performed after ERCP in another case series [43].

The use of stents in the setting of pregnancy is controversial. Axelrad et al. was the first group to implement prophylactic bile duct stenting in a pregnant patient with choledocholithiasis who had recurrent pain after sphincterotomy and balloon extraction [44]. Repeat ERCP demonstrated retained gallstones prompting placement of a CBD stent to prevent recurrence. Opponents of biliary stents as temporary treatment for choledocholithiasis in pregnancy argue that stent placement requires fluoroscopy and a second procedure to remove the stent, with the added potential complication of stent occlusion and cholangitis. Proponents, on the other hand, reason that it is a safe technique with minimal adverse events. In a case series of ten pregnant patients who underwent placement of a 10 Fr biliary stent without sphincterotomy, all the patients delivered healthy babies at term with postpartum ERCP with sphincterotomy and stent extraction [45]. In two patients, the stent remained in place for 7 and 8 months throughout gestation without cholangitis. Sharma et al. performed a similar study but opted for sphincterotomy plus stenting of a 7Fr double-pigtail CBD stent [46]. In the postpartum period, patients were subjected to definitive ERCP with stent removal, cholangiogram, and stone removal. One patient presented for her second ERCP 3 years after the first and in the interim had another asymptomatic pregnancy with normal delivery. Four patients were found to have completely blocked stents with bile drainage seen around the stent. The authors recommend therefore that a sphincterotomy be performed prior to stenting as it allowed drainage of the bile even in the event of stent occlusion, decreasing the risk of complications.

Imaging tool-guided ERCP entails the use of transabdominal US, EUS, or choledochoscopy to directly visualize the biliary duct to facilitate cannulation and clearance. Transabdominal US requires the patient to be moved from the left lateral position to supine with the ERCP equipment in place [47, 48]. This is time-consuming and difficult, making it not an optimal technique for ERCP. As discussed earlier, EUS before ERCP can determine the actual necessity of intervention. It can also provide information regarding the location, size, and number of stones present to directly guide biliary intervention. Vohra et al. used EUS to confirm the presence of choledocholithiasis prior to ERCP, and the number of stones extracted at ERCP matched the number of stones seen during EUS [15]. Two patients underwent direct peroral choledochoscopy to confirm stone clearance due to fragmentation of a stone during extraction. There were no immediate procedure-related complications, and no patient required a repeat procedure. A more recent trial by Netinatsunton et al., however, seems to yield more concerns and questions regarding the efficacy and safety of EUS-guided ERCP without fluoroscopy when compared to that of standard ERCP with fluoroscopy [49]. While the cannulation success rates, adverse event rates, and total procedure times were similar in both groups, the stone clearance rate in the EUS-guided ERCP group was inferior to that in the standard ERCP group. Peroral choledochoscopy provides direct visualization of the duct and is performed by insertion of a cholangioscope through the working channel of a duodenoscope. Few reports have utilized this technique; however a promising case series by Shelton et al. used the SpyGlass Direct Visualization System (Boston Scientific, Marlborough, MA) to confirm biliary cannulation and document stone clearance without the need for fluoroscopy [42]. The main limitations of choledochoscopy are its high cost and exhaustive technical and time demands, such that it should be used selectively in pregnant patients after conventional ERCP methods have been unsuccessful.

Outcomes

Adverse Events

Complications of ERCP whether performed during pregnancy or not include pancreatitis (2–9%), post-sphincterotomy hemorrhage (0.5–5%), cholangitis (<1%), and perforation (<1%) [50, 51]. Post-ERCP pancreatitis (PEP) is an important and potentially preventable complication of ERCP. Patient-related risk factors for PEP include young age and female gender. Procedural risk factors include difficult cannulation, need for precut sphincterotomy, and passage of a guidewire deep into the pancreatic duct.

A retrospective cohort study of the National Inpatient Sample compared standard ERCP outcomes among 907 pregnant women with 2721 nonpregnant women [52]. There was no difference in rates of perforation, infection, and bleeding between both groups. However, PEP occurred in 12% of pregnant women versus 5% of nonpregnant women. Pregnancy was an independent risk factor for PEP, even when controlling for the lower rate of pancreatic duct stent placement in the pregnant women. The authors proposed several theories to explain this including more difficult cannulation due to minimizing of radiation use and physician hesitancy to give large volumes of intravenous fluid and prophylactic rectal indomethacin. Muniraj and Jamidar et al. reviewed the outcomes of 11 large studies using standard ERCP in pregnancy and found PEP and post-sphincterotomy bleeding to comprise 9.5% and 1.0% of maternal complications, respectively [53]. There were no maternal deaths. Fetal complications included preterm birth (4.0%), spontaneous abortion (0.5%), and pre-eclampsia (1%). There was one neonatal death, but no clear causal relationship to the ERCP procedure was established.

Wu et al. analyzed the outcomes of 12 large studies of NR-ERCP in pregnancy [54]. The overall morbidity rate in the series was found to be 15.6%. Significant maternal complications included incomplete stone clearance (6.7%), hemorrhage (2.2%), stent occlusion (2.2%), PEP (1.1%), and stent

migration (1.1%). Fetal complications included preterm birth, intrauterine growth restriction, and spontaneous abortion at a rate of 2.6%, 2%, and 0.6%, respectively. There were no therapeutic abortions or postpartum infant deaths after ERCP, and with fetal mortality <1%, the procedure is seen to be relatively safe. Again, because the protocol for NR-ERCP eliminates ionizing exposure altogether, there is no need to consider the potential effects the fetus or child may experience.

Case Presentation Follow-up

In the presented case of the pregnant patient with complicated gallstones, an obstetrician was present to assist the patient and the fetus throughout the perioperative period. The patient was determined to be at indeterminate risk of choledocholithiasis based on ASGE guidelines and therefore underwent an EUS, which confirmed the presence of one stone within the bile duct (Fig. 18.3).[GIE 2010 71; 1] An

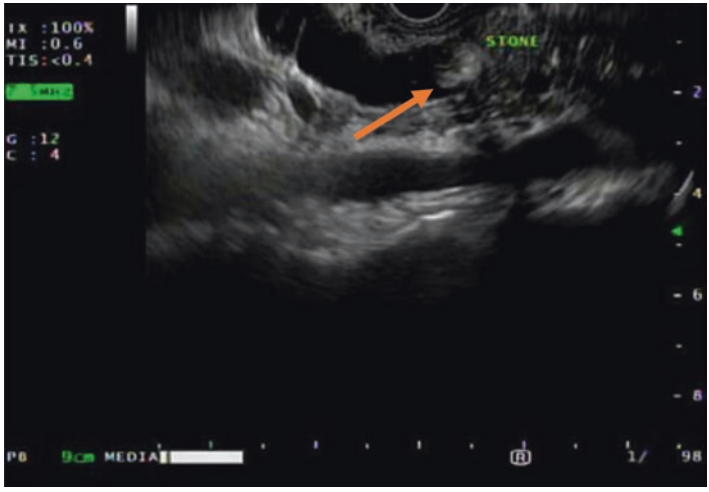

Figure 18.3 Endoscopic ultrasonography reveals a shadowing stone (arrow) in the distal common bile duct

immediate ERCP was performed with fluoroscopy used to only confirm biliary placement of the wire. A sphincterotomy was performed and the one stone was swept from the duct. Further balloon sweeps yielded nothing and were without resistance to suggest the presence of additional stones. The next day the patient underwent a laparoscopic cholecystectomy. She went on to have an uncomplicated pregnancy and delivered a full term baby without further biliary issues.

Conclusions

ERCP with or without the use of fluoroscopy is efficacious and safe in pregnant patients. It should be emphasized that this procedure be performed under the appropriate indications and when otherwise conservative management poses a life-threatening risk. Although the use of ERCP without fluoroscopy has the benefit of avoiding fetal exposure to radiation, the procedure becomes much more advanced and technically challenging. Therefore, each therapeutic endoscopist needs to have an arsenate of skill sets and should provide a comprehensive informed consent that includes the risks to both the patient and the fetus.

Pearls/Pitfalls

- ERCP with or without fluoroscopy is safe in all trimesters of pregnancy.
- ERCP should not be delayed in patients with a clear indication.
- EUS is theoretically preferred over MRCP for confirmation of bile duct pathology in the first trimester.
- Perioperative fetal monitoring and an obstetrician consultation should be considered in all patients.
- There is no known threshold for “safe” or “harmful” radiation to the fetus, so radiation reduction strategies should be employed in all patients.

- Non-radiation ERCP can be utilized in pregnant patients but makes the procedure more technically challenging.
- Therapeutic endoscopists with low ERCP volumes should consider transferring pregnant patients to a tertiary center with higher volumes.

Suggested Reading

The highly significant articles are marked in * in the reference section.

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