ABSTRACT

Background and aims: ERCP during pregnancy is always challenging for the entire team performing the endoscopic intervention. In this study techniques and different interventional aspects used at several centres about the clinical experience on ERCP in pregnant women are analyzed.

Patients and methods: the practice on ERCP in pregnant women in six centres during a period of ten years is reported.

Results: eleven patients were included in the study. Mean age was 30.6 years. Indication for ERCP was always symptomatic common bile duct stone (CBDS) disease. Before the procedure abdominal ultrasound was performed at all times and magnetic resonance cholangiopancreatography in four occasions. Conscious sedation by means of midazolam and fentanyl or meperidine was applied. Sphincterotomes and guidewires were used for biliary cannulation. Sometimes, rapid exchange platforms with short-length guidewires controlled by the same endoscopist were employed. Biliary cannulation was confirmed in 9 occasions by bile aspiration. In five procedures, a mean of 30 seconds of fluoroscopy was used, both to verify cannulation and to corroborate complete CBDS clearance. These patients had the pelvic zone protected with a lead shield and radiation dose was measured. Ten biliary sphincterotomies were performed followed by CBDS extraction. Two plastic stents were inserted. Relief of biliary obstruction was attained in all circumstances. Only one patient had hyperamylasemia after ERCP. All pregnant women had healthy foetuses with normal deliveries.

Conclusions: with experience, ERCP appears to be a safe technique during pregnancy. With simple measures fluoroscopic time can be diminished or even abolished. It seems that ERCP during pregnancy is underused in our working areas, although it has shown to be a useful technique for relieving biliary obstruction.


INTRODUCTION

It is known that hormonal changes during pregnancy increase bile lithogenicity and decrease gallbladder emptying. These facts contribute both to gallstone formation and to suffer from their complications. Cholecystolithiasis prevalence in pregnant women is in the range between 3 and 12% (1). Risk of gallstone cholecystitis during pregnancy is as high as 8 per 10,000 pregnancies and it is the second most common cause of emergency admission for non-obstetric causes after acute appendicitis. Symptomatic common bile duct stone (CBDS)–cholangitis, pancreatitis, jaundice, colicky pain– may occur up to one in every 1,200 pregnancies (2). Acute pancreatitis during pregnancy is usually secondary to biliary causes (3) and it has been related with increased mortality risk for the mother and foetus (4).

Traditionally, in these circumstances, treatment of gallstone disease complications has been conservative, because surgery may be associated with problems such as preterm labour and spontaneous abortion (5,6).

Since the advent of endoscopic retrograde cholangiopancreatography (ERCP) as a minimally invasive procedure and treatment of choice for the majority of biliary obstructions (7) it has also been applied for common bile duct conditions such as symptomatic CBDS during pregnancy (8).

In our country, there are few and isolated references (9,10) on ERCP during pregnancy. Therefore, we decided to conduct a multicenter study on its use.
PATIENTS AND METHODS

A survey was sent to 16 Spanish hospitals about the experience in each centre of ERCP in pregnant women in the last 10 years. Ten hospitals had no experience. Four of these centres had no obstetric departments.

Patients presented in the Emergency Department with symptoms related to bile duct obstruction (colicky pain, cholangitis, jaundice, pancreatitis). Transcutaneous abdominal ultrasound was the first imaging test performed, followed in some cases, by magnetic resonance cholangiopancreatography (MRCP). Endoscopic ultrasound (EUS) was not performed in any patient. Neither abdominal radiographs nor computed tomography (CT) scans were taken. Generally, patients were admitted in Digestive departments, although its evolution was followed also by obstetric specialists.

For ERCP patients were placed in left lateral decubitus (as for normal gastroscopy). The prone position was avoided because of the discomfort resulting from the volume of pregnant uterus. Besides, this position appears to increase uterine blood perfusion.

ERCP was performed with conscious sedation using midazolam, fentanyl or meperidine administered by the same endoscopist. Buscopan was sometimes used to reduce duodenal motility. Patients were monitored by pulse oximetry. Electrocardiography and blood pressure measurements were occasionally done during the procedure. Only in some hospitals the foetus was monitored during and after the ERCP.

When fluoroscopy was employed, patient’s abdomen and pelvis was covered with lead aprons. The upper abdomen was spare from lead shield to allow bile duct examination during endoscopic intervention. Occasionally, radiation amount was measured by personnel from the Radiophysics Department.

For the procedure a therapeutic duodenoscope was advanced into the papillary area (Fig. 1). Biliary cannulation was performed with sphincterotomes and guidewires. Sometimes, rapid exchange platforms and devices were employed with short-length guidewires controlled by the same endoscopist. After inserting the sphincterotome in the papilla of Vater, in the theoretical part of the common bile duct, the guide was advanced. Easy passage of the guide was a sign that correct cannulation had been achieved (Fig. 2). The sphincterotome was slid over the guidewire inside the bile duct and bile was aspirated. When fluoroscopy was not used, this was the single method to confirm that biliary cannulation had been satisfactory. Afterwards, biliary sphincterotomy was performed in the usual manner in the majority of patients (Fig. 3). The sphincterotome was subsequently withdrawn, leaving the guidewire inside the common bile duct. An extraction balloon was passed over this guidewire and several sweeps were made in the bile duct in an attempt to remove all possible CBDS. After that, to ensure complete biliary drainage, a plastic biliary stent was occasionally inserted (Fig. 4). In these cases, a new ERCP was performed after delivery to complete bile duct clearance.

Following the procedure patients were monitored to rule out complications such as acute pancreatitis, bleeding, cholangitis or perforation.

RESULTS

In the 6 hospitals that responded affirmatively to the survey, a total of 11 ERCP (1.83 per hospital) were performed in 11 pregnant women. Patients’ mean age was 30.6 years. ERCP indication was always symptomatic CBDS, such as biliary colicky pain, cholestasis and obstructive jaundice in 10 cases and cholangitis/pancreatitis in another one. Before ERCP transcutaneous abdominal ultrasound was performed in all cases and MRCP in four. Common bile duct cannulation was achieved in all ERCP. In nine cases biliary cannulation was confirmed exclusively for bile aspiration (Table I). In one occasion the sphincterotome was used for cannulation without a guidewire. Nine times CBDS extraction was complete with a single procedure. Another ERCP after delivery was performed in two patients to extract plastic stents and complete stone extraction. One of these patients presented with multiple gallstones and had to undergo in the third trimester a laparoscopic cholecystectomy. In another patient with pancreatitis, cholecystolithiasis, CBDS, gallbladder hydrops and a splenic vein thrombosis, was treated with low molecular weight heparin, which was discontinued for ERCP.

In four occasions a gynecologist was present in the procedure for foetus monitoring. In three ERCP the amount of radiation, both foetal and maternal, was measured by personnel from the Radio physics Department. Fluoroscopy was used in total in five interventions for an
average time of 30 seconds (range 6-48). After ERCP hyperamylasemia was noted in only one patient. All pregnant women gave birth healthy foetuses with normal deliveries.

DISCUSSION

In this study, ERCP rate in pregnant women is very small. For example, in one participating hospital in which it was possible to know precisely the number of births in the whole health district covered, ERCP was performed 1 per 8,500 pregnancies at term. The highest rate was reported by Tang et al. (2) with 1 ERCP per 1,415 births.

It is possible that many of these pregnant women in our area had been treated conservatively without gastroenterologist consultation.

Due to the retrospective nature of our study, it is not possible to know precisely the number of births in the different participating hospitals during the study period and who did not undergo ERCP.

The first report on ERCP in pregnant women was published in 1990 (3). Since then, isolated cases have been reported (8-13) and some series (Table II) that, together, do not reach the number of 300 procedures during pregnancy.

Results from these reports show that ERCP is an effective and safe technique for treating symptomatic biliary obstruction during pregnancy. Our data are consistent with these previous experiences. Biliary obstructive disease in our patients was always due to symptomatic CBDS which-together with acute cholecystitis, is the most common cause of bilio-pancreatic illness in pregnant women (22). The possible radiation damage to the foetus is one of the key issues of concern in this type of procedures. The effects of radiation on intrauterine development derived primarily from observational studies in atomic bomb survivors. Animal studies have also been reported. It appears that doses below 5 rad or 50 mGy have no deleterious effects (23). Tham et al. (18) observed a maximum dose of 3 mGy to the foetus during 3 minutes of fluoroscopy. Kahaleh et al. (19) showed a maximum of 1.8 mGy in their group of patients. It seems that the radiation threshold for foetal malformations can start at the dose of 100 mGy (24). These figures are rare in diagnostic radiology. Besides, in ERCP the foetus is not in the centre of the radiation beam. Still radiographs produce more radiation than fluoroscopy and should be avoided.

However, in many cases endoscopists prefer not to use radiation and concentrate solely on the technique (20). One reason may be to avoid psychological pressure that fluoroscopy time measurement may have. Especially, if the same endoscopist should be aware of other important...
aspects such as patient sedation. In our series, more than half of ERCP (6 of 11) were successfully performed without fluoroscopy. Perhaps it should be desirable that another doctor, different from the endoscopist performing the ERCP could be responsible for sedation. Often this is not possible and in almost all of our series, the same physician had to deal with both aspects.

Non-fluoroscopic techniques are facilitated by the use of guidewires to cannulate the papilla of Vater and the employ of rapid exchange devices that allow the endoscopist to control the guide in case there are not trained endoscopist assistants (25).

For patient sedation it can be employed regular medication: midazolam, meperidine, fentanyl, or propofol. Buscopan is also used to reduce duodenal motility. Occasionally, ERCP can be done with general anaesthesia (20).

The U.S. Food and Drug Administration (FDA) classifies benzodiazepines as a category D, i.e. unsafe during pregnancy. Some of these drugs may cause defects such as cleft palate. However, sedation with midazolam has been used in many reported cases and it seems that specific doses used for ERCP have not shown any foetal problems.

None of our patients underwent EUS, although the technique was available in some hospitals. CBDS diagnosis was made by abdominal ultrasound and MRCP. EUS is a highly specific method to diagnose CBDS, but it can prolong the time required for sedation if EUS is followed by

<table>
<thead>
<tr>
<th>Trimester of pregnancy</th>
<th>Third (6)</th>
<th>Second (4)</th>
<th>First (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERCP interventions</td>
<td>Biliary sphincterotomy and CBDS extraction (9)</td>
<td>Biliary sphincterotomy, CBDS extraction and plastic stent insertion (1)</td>
<td>Plastic stent insertion alone (1)</td>
</tr>
<tr>
<td>Use of fluoroscopy</td>
<td>To confirm cannulation and CBDS extraction (1)</td>
<td>To confirm CBDS extraction (4)</td>
<td>Without fluoroscopy (6)</td>
</tr>
</tbody>
</table>

The number of patients in each group is shown between brackets. CBDS = common bile duct stones.

<table>
<thead>
<tr>
<th>Author</th>
<th>Year of publication</th>
<th>n</th>
<th>ERCP interventions</th>
<th>Mean time of fluoroscopy (seconds)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jamidar (14)</td>
<td>1995</td>
<td>23</td>
<td>14 BES, 1 Papilla minor, 4 PBS, 1 PPS</td>
<td>Not reported</td>
<td>1 preterm birth, 1 abortion, 1 infant born dead</td>
</tr>
<tr>
<td>Farca (15)</td>
<td>1997</td>
<td>10</td>
<td>1 BES, 11 PBS</td>
<td>45</td>
<td>None</td>
</tr>
<tr>
<td>Sungler (16)</td>
<td>2000</td>
<td>5</td>
<td>5 BES</td>
<td>Not reported</td>
<td>None</td>
</tr>
<tr>
<td>Howden (17)</td>
<td>2001</td>
<td>21</td>
<td>17 BES</td>
<td>93</td>
<td>1 preterm birth</td>
</tr>
<tr>
<td>Tham (18)</td>
<td>2003</td>
<td>15</td>
<td>6 BES, 1 PBS</td>
<td>192</td>
<td>1 post-ERCP pancreatitis</td>
</tr>
<tr>
<td>Tham (18)</td>
<td>2003</td>
<td>15</td>
<td>6 BES, 1 PBS</td>
<td>192</td>
<td>1 post-ERCP pancreatitis</td>
</tr>
<tr>
<td>Kahaleh (19)</td>
<td>2004</td>
<td>17</td>
<td>17 BES</td>
<td>14</td>
<td>1 post-ERCP pancreatitis, 1 bleeding for BES, 2 preeclampsia</td>
</tr>
<tr>
<td>Shelton (20)</td>
<td>2008</td>
<td>21</td>
<td>21 BES, 4 PBS, 6 PPS</td>
<td>Not used</td>
<td>1 post-ERCP pancreatitis, 1 foetus with intrauterine growth retardation</td>
</tr>
<tr>
<td>Akcaya (5)</td>
<td>2009</td>
<td>6 (7 ERCP)</td>
<td>6 BES, 1 PBS</td>
<td>Not used</td>
<td>None</td>
</tr>
<tr>
<td>Daas (21)</td>
<td>2009</td>
<td>10 (17 ERCP)</td>
<td>9 BES, 8 PBS 1 PPS</td>
<td>8</td>
<td>None</td>
</tr>
<tr>
<td>Tang (2)</td>
<td>2009</td>
<td>65 (68 ERCP)</td>
<td>64 BES, 15 PBS</td>
<td>85</td>
<td>11 (16%) post-ERCP pancreatitis</td>
</tr>
<tr>
<td>Current study</td>
<td>2011</td>
<td>11</td>
<td>10 BES, 2 PPS</td>
<td>30</td>
<td>1 hyperamilasemia</td>
</tr>
</tbody>
</table>

BES: biliary endoscopic sphincterotomy usually followed for common bile duct stone extraction manoeuvres by means of extraction balloons and Dormia baskets. PBS: plastic biliary stent. PPS: plastic pancreatic stent.
ERCP. A very promising therapeutic aspect of EUS is the ability to perform during the same session with the linear scan echoendoscope common bile duct cannulation, sphincterotomy and stone extraction (26).

Cholangioscopy through the working channel of the duodenoscope can also help to diagnose bile duct diseases in a non-fluoroscopic way. Besides complete CBDS removal can be verified (27). When fluoroscopy is not employed, CBDSs are considered completely removed if the extraction balloon is pulled out easily from the bile duct and does not break. If MRCP has been previously made, the number of CBDSs is known and it can be checked if they all have come out. In case of doubt about complete common bile duct cleaning or to ensure biliary drainage, plastic stents have shown to be a safe and temporizing measure (28) until, after delivery, by means of another ERCP a complete CBDS extraction can be achieved.

To avoid possible biliary sphincterotomy complications, some authors (15) have proposed to place plastic stents as the single drainage way at the initial ERCP during pregnancy. After delivery, sphincterotomy and extraction can be performed at another procedure. However, the majority of reported studies have shown sphincterotomy as an appropriate technique to complete treatment in one single intervention. Also in our series, only one ERCP was performed in 9 out of 11 patients.

Although in some of our reported cases a gynaecologist and Radiophysics personnel were present, it is not common practice (2) and ERCP can be performed solely with the endoscopy staff.

In conclusion, ERCP appears to be a safe and effective technique during pregnancy to relief bile duct obstruction. Fluoroscopy time can be reduced and even eliminated by simple measures. It seems, however, that in our working areas ERCP is underused during pregnancy.

REFERENCES
