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Editorial

ERCP and pregnancy

Pregnancy represents a risk factor for the development of biliary lithiasis. It is estimated that 3 to 12% of pregnancies develop bile stones, and one in 1,000 to 1,200 presents lithiasis-related symptoms (1,2). In addition, choledocholithiasis during pregnancy represents a significant issue, as it may result in cholangitis or pancreatitis, potentially fatal complications for the mother and fetus. The management of both lithiasis and other conditions involving the bile ducts during pregnancy is challenging, since surgery under these conditions shows an increased risk for fetal compromise (3). For example, in a series of nine patients managed with open cholecystectomy and choledochal examination five fetal loss events occurred (4). However, recent series with laparoscopic surgery do not show such a complications rate (5,6), and it is recommended that procedures take place during the second trimester of pregnancy when possible (7). In this scenario, endoscopic management with ERCP represents an appealing alternative because of its, at least theoretically, lower morbidity and mortality. However, few papers on ERCP and pregnancy have been reported, and most depict isolated cases or series with low numbers of patients.

Since ERCP is the treatment of choice for choledocholithiasis, its application during pregnancy is of uncertain safety. First, risks stemming from the endoscopic procedure itself on a pregnant woman should be assessed, with a special focus on examination time and patient position. On the other hand, aspects regarding sedation should also be considered, particularly which drugs are to be used and by who. Finally and most importantly, there must be awareness on the risks that radiation exposure may pose on the fetus.

From the reported experience ERCP during pregnancy entails no higher risk of ERCP-related complications when compared to non pregnant patients (8-10). Nevertheless, it is recommended that during the virst trimester this technique be restricted to absolutely imperative, undelayable cases, since this in the period with a higher risk for fetal loss during pregnancy. It is also advised that the patient be positioned in left lateral decubitus, particularly during the third trimester, in order to avoid compression of the aorta and lower vena cava so as not to impair venous return (11). As regards sedation for pregnant women clinical practice guidelines recommend that an anesthesiologist be in charge (12,13). However, reported series include both cases sedated by anesthetists (14) and by endoscopists themselves (11) with no adverse events reported in relation to this. Regarding types of sedatives and their use during pregnancy, propofol is classified in category B, and midazolam in category D; among opiates, fentanyl belongs in C, and meperidine in B; on these ground guidelines recommend propofol. Again, reported papers include cases sedated with both types of drug, with no complications or differences in efficacy and safety between sedatives. Anyway, exposure in low doses and for shorter periods of time to any of them, as is the case during

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endoscopy, is unlikely to damage the mother or fetus (15). The primary source of concern on indicating ERCP in a pregnant woman is the potential risk of exposing the fetus to X rays (including delayed fetal growth, malformations, pediatric cancer, and death); however, radiation effects are solely known through both epidemiological and observational studies of exposed subjects following a nuclear explosion (16). The American College of Obstetricians and Gynecologists has established that fetal exposure below 5 rads or 50 mGy is not associated with miscarriage or fetal abnormalities (17). Unfortunately, the radiation doses a fetus may receive during ERCP are unknown. Various studies have estimated a dose of 0.1 to 3 mGy, far below those theoretically tolerated (10,15,18), whereas an additional study concluded that fetal exposure may on occasion exceed 50 mGy (19). The study by Tham and colleagues in 12 cases used fluoroscopy for an average of 3.2 minutes at a dose of 310 mrads, below the 5-10 rads considered to pose a risk for teratogenesis (20), with no resulting complications. However, no clear cut-off is known regarding radiation doses. Several reported studies used a lead-containing apron to shield the pelvis and thus reduce fetal exposure; however, this practice has not been proven effective (10).

For cases reported in the literature a careful endoscopic technique was used, guided cannulation was routinely applied, and the sphincterotome's appropriate position within the bile duct was checked using bile aspiration to avoid fluoroscopy. The latter was never employed in some series whereas others used it for limited periods of time, usually of a few seconds. Overall, stones were removed following sphincterotomy using a balloon. A plastic biliary prosthesis is routinely used in some sites in order to ensure drainage after stone removal or as sole therapeutic action, with stone removal being postponed until after delivery (21). However, this procedure has a number of drawbacks: in the absence of radioscopic monitoring the prosthesis may end up in a wrong position (the cystic duct or distal to residual stones, for instance), its use needs ultrasounds to check its location, and it also requires a second endoscopy for prosthesis withdrawal. On the other hand this prosthesis may become dysfunctional before delivery, which leads to an additional ERCP during pregnancy. From all this, these prostheses should logically be restricted to cases where they are strictly essential.

No relevant complications have been reported following ERCP in pregnant women. Fetal monitoring or the presence of a gynecologist during the exploration, although implemented in some hospitals, is considered unnecessary. In studies where it was specified, newborns had an Apgar score above 8 (14,15).

Given that, as previously discussed, the grestest concern in such cases is fetal exposure to X rays, the use of imaging techniques lacking ionizong radiation, including magnetic resonance imaging or echoendoscopy, has been posited prior to ERCP in order to clearly define lesions, and most particularly to avoid unnecessary examinations; in the case of endoscopic ultrasounds this might represent a semi-invasive procedure for the pregnant mother, as well as her exposure to sedatives. Also with the aim of precluding radioscopy choledochoscopies have been suggested to acknowledge bile duct status (22,23); however, this latter technique, while useful, is not available in all sites as yet, and also considerably prolongs examination time.

In the present issue of our *Spanish Journal of Gastroenteology,* J. García-Cano and colleagues present a multicenter, retrospective study representing the widest series ever reported in Spain, and where the most relevant aspects of ERCP in pregnant women are exemplified (24). On the one hand it shows that this technique is seldom performed: among 16 Spanish hospitals for a period of ten years only six had some experience, for a total of eleven cases. On the other hand, the reported technique included guided cannulation, bile aspiration to confirm the sphincterotome's proper

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positioning, and restricted fluoroscopy, which was only used in five procedures for a mean of 30 seconds. In these cases a lead apron was placed on the pelvis for shielding. Sedation was carried out using midazolam and opiates, and was controlled by the endoscopist. Ten sphincterotomies were performed with stone removal, and two biliary prostheses were implanted, which were eventually withdrawn following delivery. In four cases a gynecologist monitored the fetus, and in three a radiophysicist measured radiation doses received by the mother and fetus, although the results of such measurements are not reported. Finally, no complications arose and all pregnancies ended uneventfully at term.

To summarize the cumulative experience so far we may claim that ERCP during pregnancy is a safe, effective technique. However, it should be restricted to cases with a strict requirement, and non-invasive techniques such as MRI are first recommended in the remaining patients to avoid unnecessary examinations. Endoscopy is performed as usual with the patient in the left lateral decubitus. While bile aspiration is a fine method to confirm bile duct cannulation, there are no grounds on which to preclude a limited, judicious use of fluoroscopy as this allows to acknowledge proper cannulation, bile duct cleanliness, and correct prosthesis positioning, thus contributing to improve effectiveness and safety during the endoscopic procedure. When used, a low kilovoltage, maximum iris, and lead shielding are recommended (25). Sedation may be performed by anesthesiologists or other properly trained physicians, and no differences in safety are apparent between propofol or midazolam and opiates. Lastly, the presence of a gynecologist and routine fetal monitoring during the procedure are unnecessary.

To conclude, we can state that ERCP during pregnancy is an effective, safe procedure provided it is unequivocally indicated, and we should bear in mind that both during pregnancy and otherwise, the more uncertain its indication, the greater the risk for complications.

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