Safety of endoscopical procedures during pregnancy

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ABSTRACT

Introduction: Data on safety issues and therapeutic outcomes of endoscopy in pregnancy remains limited especially in the local context. The concerns are that of safety in sedation and radiation to the foetus, effects on the pregnancy, the need for special precautions on mother and foetus during the procedure and long-term foetal outcome. We report a case series on four pregnant women to address these concerns and outline their therapeutic approaches.

Methods: We reviewed four patients who underwent oral gastroduodenoscopy (OGD) endoscopic retrograde or cholangiopancreatography (ERCP) during their pregnancies. Lead aprons were used to shield the foetuses in all patients that underwent ERCP. Sedation was given when necessary, and an anaesthetist was employed in one case for close patient monitoring. Fluoroscopy was minimised and radiographs were taken only when essential.

Results: The mean patient age was 27.8 years (range 23-35 years). The mean gestation was 21.5 weeks (range 14-32 weeks), with two patients each being in their second and third trimesters. The indications for ERCP were cholangitis and pancreatitis (one), choledocholithiasis on ultrasonography (two), and that for OGD was persistent vomiting (one). Two patients underwent sphincterotomy and one had a biliary stent inserted. One patient was lost to followup. The other three had a full-term normal delivery and all babies were healthy at birth with good birth weight and normal Apgar scores.

<u>Conclusion:</u> Our series showed that endoscopic procedures in pregnancy are safe for both mother and foetus. However, these procedures should be restricted to cases with definite indications and radiation exposure should be minimised with additional safety precautions such as minimal radiation exposure and the use of lead shield when applicable.

Keywords: conscious sedation, digestive system, endoscopy, pregnancy, radiation safety

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INTRODUCTION

Pregnancy-related gastrointestinal (GI) problems (especially of the upper GI tract) are some of the most frequently-encountered conditions. It was estimated that gallstone diseases occur in up to 12% of all pregnancies⁽¹⁾. While many patients improved clinically with standard treatment, some of these conditions require further investigations, including blood tests and diagnostic or therapeutic endoscopical procedures. The concerns about such investigations are the possible effects affecting the safety of the foetus and the outcome of a successful pregnancy. Issues including the anaesthetic agents used for sedation, possible radiation-associated teratogenicity, as well as the need for special precautionary measures and long-term foetal outcome require careful considerations for both principal physician and the patient.

While there are a few reports on the safety issues of endoscopic procedure during pregnancy in the literature, we are not aware of any report or case series on our local population. We reviewed four of our patients at Tan Tock Seng Hospital (TTSH) admitted from 1997 to 2004 to address the issue of safety in diagnostic and therapeutic endoscopy during pregnancy.

METHODS

We conducted a retrospective review on four cases of upper gastrointestinal endoscopy during pregnancy from November 1997 to February 2004. Case records were traced through our medical records office and patients' particulars including age, obstetrical history,

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Correspondence to: Dr Quan Wai Leong Tel: (65) 6256 6011 Fax: (65) 6357 7588 Email: wai_leong_ quan@ttsh.com.sg gestational period, documented past medical and surgical history as well as their presenting medical problems, were extracted. Investigation results including blood investigations, ultrasonography, as well as the actual detailed endoscopical reports, were traced. Special effort was made to track the clinical progression of the patients from the start of hospitalisation until discharge, and all complications during the stay were documented.

We also paid particular attention to the processes carried out during these endoscopical procedures, especially on the issue of sedation, the agent used, and dosages and radiation exposure as well as the precautions taken to minimise possible risks to the patients and their foetuses. These include the employment of an anaesthetist when indicated, the positioning of patients in semi-prone or left lateral positions, the use of lead apron for all endoscopic retrograde cholangiopancreatography (ERCP) cases, the minimal use of fluoroscopy and snap-shots, and the use of bipolar current in sphincterotomy. Information on subsequent blood test results as well as the outcome and progression of the subsequent follow-up visits were noted. Telecommunication follow-up was made to patients to determine the health status of the patients as well as their child.

RESULTS

All four patients were seen at the KK Women's and Children's Hospital (KKWCH) for their obstetrical condition. The mean patient age was 27.8 years (range 23-35 years). The mean duration of gestation was 21.5 weeks (range 14-32 weeks). Two patients were in the second trimester, and the other two in the third trimester. None of our patients were in their first trimester when teratogenicity due to sedation and radiation exposure would presumably exert its greatest impact. The indications for ERCP were cholangitis and pancreatitis (n=1), choledocholithiasis on ultrasonography (n=2), and that for oral gastroduodenoscopy (OGD) was persistent vomiting (n=1).

Sedation used included the usual intravenous (IV) midazolam (up to 5 mg) and IV fentanyl (up to 100 mcg). One patient received IV propofol (140 mg in total) administered by an anaesthetist. Other agents that have low teratogenic effects included IV hyoscine bromide and IV glucagon, and they are commonly used in routine ERCP cases⁽²⁾. There were no documented episodes of hypoxia, hypotension or bradycardia while employing these agents. The reversal of sedation for all patients was also uneventful. None of the four patients suffered from aspiration during and after the endoscopical

procedures. All patients were positioned in either left lateral or semi-prone posture to avoid any compromise in maternal venous return secondary to inferior vena cava compression by the gravid uterus. Lead aprons swere used for all three cases of ERCP to shield the foetus from radiation, and minimal fluoroscopy and radiographs were taken to avoid teratogenic effects on the developing foetus. The fluoroscopic screening fields were further modified and coned down to a smaller area to ensure the minimum possible dose of radiation being employed at any one time.

Two patients underwent sphincterotomy and one had a biliary stent insertion. Bipolar current were used during sphincterotomy to minimise stray current effect. No complications were encountered in all four cases during the procedures. All patients were observed overnight for fever and abdominal pain, and their vital signs were also monitored closely. None showed clinical evidence of pancreatitis or significant bleeding that could be linked to the procedure. In fact, the patient with cholangitis and pancreatitis due to strictures made clinical improvement after stenting.

Post-discharge reviews were done for three patients. Clinical and biochemical results were encouraging with normalisation of liver function tests in two of the three patients that underwent ERCP. One patient was lost to follow-up and did not turn up for her appointment. She remains uncontactable. Telephone follow-ups were made to all patients. However, only three were contactable and all three delivered at full- term via normal delivery. All babies' birth weights were normal (>3 kg) with a mean birth weight of 3.13 kg. The lowest Apgar score at 5 min was 9, with a mean score of 9. The oldest child is now attending pre-primary class (K2) and remains healthy.

DISCUSSION

We reported a local case series of four patients in their second and third trimester of gestation who had successfully undergone endoscopical procedures in the hospital. We found that endoscopical procedures in pregnancy need not necessarily be associated with a higher complication rate for both mother and child, as compared to the general population, if careful selection is made. In fact, we did not encounter any complications with all four of our patients. Other than one patient who was lost to follow-up, the remaining three patients had uneventful pregnancies and deliveries. All three babies were born fullterm with healthy birth weight and Apgar scores. However, our series is limited by its size which may not accurately reflect the actual outcome of this cohort of patients. Besides, long-term impact on the babies' development remains to be determined.

There are three other larger series on this topic in the medical literature which also demonstrated the safety of endoscopy during pregnancy. In the series by Sungler et al⁽¹⁾, five of 37 symptomatic or complicated gallstone disease cases were subjected to an ERCP for biliary pancreatitis or jaundice. All were in their 13th to 32nd gestational week. All patients delivered healthy full-term babies. There were no post-endoscopical complications encountered. In the second series by Jamidar et al⁽²⁾, 23 patients underwent ERCP for symptomatic pancreaticobiliary disease. Three patients had diagnostic ERCP and 20 had therapeutic ERCP including sphincterotomy and stent insertion procedures. One case was complicated by pancreatitis. There was one spontaneous abortion and one neonatal death, although a causal relationship to ERCP was not apparent. The third series by Tham et al⁽³⁾ reported a single centre's experience of ERCP during pregnancy. 15 patients with pancreaticobiliary disease were subjected to ERCP including sphincterotomy and stenting. One patient with sphincterotomy developed pancreatitis that was successfully managed conservatively. There were no reported adverse outcomes to either the foetus or the mother.

In our series, special attempts were made to minimise the radiation exposure to the foetuses, including use of lead shields, short duration of radiation exposure, coned-down fluoroscopical screening views, and no spot radiographs taken unless essential. We believe that such measures would be sufficient to minimise the radiation exposure to the foetuses to below teratogenic level. Such measures were also adopted by Tham et al⁽³⁾ and the calculated average foetal dose of radiation in his study was 310 mRads, which was substantially less than the level of approximately 10 Rads for teratogenesis. However, the dose of concern for childhood cancer is unknown.

There were a few interesting reports on treatment of bile duct stones in pregnant patients without radiation exposure^(4,5). Simmons et al⁽⁴⁾ described deep cannulation achieved directly with a guide wire advanced under endoscopy, deep into the duct followed by the catheter which was advanced over the wire into the duct. Bile was aspirated to confirm a biliary cannulation and sphincterotomy was done. Although biliary cannulation is almost certain when bile is observed in the catheter, one could not know whether the bile duct or cystic duct had been cannulated. As such, one might be sweeping the cystic duct instead of clearing stones from the common hepatic duct. The potential risk of retained proximal bile duct stone exist although not encountered in this study.

The issue of sedation to mother and foetus was not shown to be associated with negative outcome in our patients. Common agents such as IV midazolam, fentanyl and glucagon have been used in different series on pregnant patients without reported complications^(1,2,6,7). In the report described by Simmons et al⁽⁴⁾, all patients were given IV propofol, IV fentanyl as well as IV midazolam and/or meperidine and there were no known adverse event to both mother and foetus related to the sedation administered. In another case series reported by Tham et al⁽³⁾, there were also no medication-related complications such as hypoxia, arrhythmia and hypotension observed.

Of special interest is the use of propofol for sedation that is currently gaining popularity. This agent is classified under category B for use in pregnancy⁽⁸⁾. Although studies in animals (rats and rabbits) showed no teratogenic effects, there is no well-controlled study on its safety in pregnant women to date. However, this agent has been employed in caesarean sections with promising outcomes. Djordjevic et al⁽⁶⁾ have found propofol having less adverse effects during induction and maintenance in pregnant candidates as compared to thiopentone, although there was a significantly greater decrease in heart rate and blood pressure in the propofol group. The Apgar scores were also noted to be significantly higher in the propofol group. Hug et al⁽⁹⁾, with their data on 25,000 cases, found that the incidence of hypotension and bradycardia did not significantly affect the overall haemodynamics of patients clinically, if propofol is given according to protocol in non-pregnant patients. However, there are limited data on the use of propofol in non-caesarean pregnant patients in first and second trimesters especially with regard to long-term foetal outcome.

In our only patient with IV propofol administered, a total of 14 ml (140 mg) was given under the direct supervision of an anaesthesiology consultant. The patient did not develop any complications during and after ERCP and was well when discharged. However, patient is lost to follow-up and there is no available data on the foetal outcome in this case, despite attempts to contact the patient. The use of IV midazolam and fentanyl was not associated with any known complications with the other three patients.

In conclusion, our series supported the data that endoscopical procedures in pregnancy appear to be safe for both mother and foetus. Although only four patients were reported, our results were comparable to other published studies in the medical literature. However, it would be prudent on our part to ensure these procedures are restricted to cases with definite indications with additional safety precautions to minimise radiation exposure made available whenever needed. An experienced endoscopist is also advocated so as to minimise the duration of the procedure. This would translate to shorter radiation exposure and sedation time. Data on the long-term development of the children remain to be determined. Perhaps, a larger scale study in future would address the issue of long-term foetal outcome.

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