Limitations of Existing Literature on Laparoscopy in Pregnancy

Jonathan P Pearl, MD, FACS
Baltimore, MD

Raymond Price, MD, FACS
Salt Lake City, UT

Dimitrios Stefanidis, MD, PhD, FACS
Indianapolis, IN

We read with interest the article titled, "Cholecystectomy during the third trimester of pregnancy: proceed or delay?" by Fong and colleagues.[1] The authors should be congratulated; their article addresses an important issue: gallbladder disease during pregnancy, which poses a management dilemma for surgeons and patients alike. Using the California Office of Statewide Health Planning and Development database, the authors identified all women undergoing cholecystectomy during the third trimester of pregnancy (n = 403) and compared their perioperative outcomes with those of women who had the procedure within 3 months postpartum (n = 17,490). The authors identified longer length of stay, higher rate of readmission, and more preterm deliveries in the first cohort and concluded that composite maternal outcomes and procedure-related metrics were worse when cholecystectomy was performed during the third trimester of pregnancy and that, whenever possible, cholecystectomy should be delayed until the postpartum period.

In their discussion, the authors referenced the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guidelines for the use of laparoscopy during pregnancy,[2] and argued that revisions to the guidelines are necessary. They asserted that the SAGES guidelines statement that "laparoscopy can be safely performed during any trimester of pregnancy, when operation is indicated" is disputed by the findings of their study. We would like to emphasize that the SAGES guidelines committee follows a rigorous development process using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.[3] All guidelines are based on the best available evidence and are approved by the SAGES Board of Governors. Given that relevant literature often accumulates rapidly, our guidelines are updated every 3 to 5 years. Along those lines, the study by Fong and colleagues will be included in our next update and taken into consideration, along with other new relevant studies, for the formulation of updated recommendations.

In this letter to the editor, we wish to address a number of limitations of the study by Fong and colleagues[1] that will affect its appraisal during our updated evidence-based review. The study is based on a statewide database review that has numerous inherent limitations. Most relevant to this study, the severity of patient symptoms and indication for the cholecystectomy in the 2 cohorts is unknown. The authors cannot exclude the likelihood that patients operated on during the third trimester had exhausted all other measures before proceeding with surgery. The study also does not address whether patients had biliary pancreatitis or choledocholithiasis, which may have increased the urgency for operation. The finding that third trimester patients comprised only 2% of the total study population, and 98% of patients had their cholecystectomy in the postpartum period, suggests selection bias; it demonstrates that the standard followed by surgeons during the third trimester is nonoperative management and that cholecystectomy is chosen in highly selected cases. This indicates that only in cases in which nonoperative treatment was unsuccessful was surgery pursued, and implies that surgery patients likely had more severe disease. It is not surprising that patient outcomes were slightly worse when surgery was performed before delivery, albeit still very safe. Therefore, the findings of this study appear to support the SAGES guidelines statement that surgery can safely be performed at any trimester when operation is indicated.

It should also be noted that the study's finding that patient length of stay was longer in the third trimester group is further confounded by including the preoperative hospital time in the calculation. This group likely includes patients whose symptoms did not improve with nonoperative treatment and went to surgery during the same hospitalization. The authors' finding that outpatient procedures were less common in the third trimester surgery group (15% vs 37%) supports this argument. In addition, the higher rate of conversion to laparotomy in the third trimester group (13.6% vs 1.7%) further suggests that these patients had worse disease, in addition to any difficulty related to an enlarged uterus. The higher incidence of open cholecystectomies contributes to the increased length of stay and higher morbidity in this group. The SAGES guidelines state that laparoscopic cholecystectomy should be the treatment of choice in

the pregnant patient with symptomatic gallbladder disease.

The authors also identified a higher risk of preterm delivery in the third trimester group and emphasized the potential associated neonatal morbidity. The authors surmised that the prepartum cholecystectomy group had significantly worse cerebral, cardiac, and pulmonary complications. They also assumed an increase in fetal demise. There are no data presented in this report to support these conclusions. Furthermore, the authors did not evaluate the timing of preterm delivery. Spontaneous abortions, which could be induced by delay in treatment of a severe disease process such as severe cholecystitis and biliary pancreatitis, were not recorded. Other confounding factors include that the prepartum subset was slightly older and had a higher Charlson Comorbidity Index than their postpartum counterparts.

In summary, we would like to thank Fong and colleagues for bringing attention to this important topic. The limitations of the existing literature on laparoscopy in pregnancy have been clearly referenced in the SAGES guidelines and indicate the need for high quality studies that will enable guideline developers to provide meaningful advice to surgeons treating pregnant patients.

The SAGES Guidelines committee will continue critically analyzing and grading the published literature using the most robust methodology. Our committee has a task force dedicated to reviewing recent literature and assessing whether our published guidelines require amending or modification. Our detailed review of this article and its limitations do not support a change in our recommendations at this point. Surgeons should continue exercising caution when dealing with surgical diseases in the pregnant patient, but proceed safely with surgery when it is in the best interest of their patient.

REFERENCES

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Guideline Recommendations for Cholecystectomy in Pregnancy: Need for Emphasis on Neonatal Outcomes

In reply to Pearl et al

Zhi Ven Fong, MD, MPH, PhD,
David C Chang, PhD, MPH, MBA
Boston, MA

Henry A Pitt, MD, FACS
Philadelphia, PA

We thank Pearl and colleagues[1] for their interest in our article titled, "Cholecystectomy during the third trimester of pregnancy: proceed or delay?" First, we would like to acknowledge and thank the authors for their role in the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Guidelines Committee. These efforts are time consuming and costly, and these surgeons should be commended for taking on the necessary task of providing practitioners with guidelines to assist with everyday patient management. When their most recent guideline for surgery in pregnancy was updated,[2] existing data were not robust, especially with respect to neonatal outcomes.

As the authors point out, inherent biases exist in using administrative databases to address clinical questions, and this issue was acknowledged within our manuscript. Due to possible upcoding practices in patients with biliary colic, our study group deemed that using diagnostic ICD-9 codes would be unreliable, making the indication for cholecystectomy difficult to ascertain. That said, we accounted for disease severity by adjusting for setting (outpatient vs inpatient), urgency (scheduled vs unscheduled), and cholecystectomy approach (open vs laparoscopic). Additionally, we leveraged the longitudinal nature of the database to better define a more homogenous cohort by including only pregnant women who did not have any previous biliary-related hospital episodes before delivery. This subanalysis excluded potential failure of medical management in both third trimester and postpartum women. Analyses after adjustment for disease severity and previous admission both confirmed that preterm delivery was twice as common when operation was performed in the third trimester.