Questions and Answers session – 10th September 2020

Please note that the following text is not an accurate reproduction of the minutes of the online session. They have been extensively edited to make it more informative and useful to readers.

Was this a cohort study?

The paper stated that this study was a cohort study because the participants started off with the exposure (acute cholecystitis) and these participants were followed through time to measure outcomes which in this case was composite maternal fetal complications. However, we suggested that this may actually be a cross sectional study.

How do they know that the diagnosis of cholecystitis using coding has picked up a homogenous cohort? Is there much variation in how people define cholecystitis or differentiate it from other conditions such as bilary colic?

The study used a set of simple codes that they used as the basis of the inclusion criteria but there is no spectrum of variability that they can account for because they don't have the data to do so. The definition was purely based on the code. There were different codes used for different conditions such as chronic/ acute cholecystitis and biliary colic. They also exclude any other symptomatic biliary disease.

For any database study the question is how good is the quality of the data collected. Are there other studies that attest to the validity of the NRD? Have the authors employed any validation procedures with regards to both the diagnosis and the outcomes collected?

As far as we are aware, the authors did not employ any further measures to validate the results collected from the database. We would say that this is one of the limitations of the study – as it the data collected depends on if the coding was correct and there is no way of checking that. The NRD is audited but the authors do not carry out any further checks of this.

Did the authors do any further analysis to explain why the majority of patients did not have surgery (despite very clear guidelines that indicate that if you have acute cholecystitis during pregnancy then patients should be considered for operative treatment) and if there were any significant differences between centres or between surgeons looking after these patients?

As mentioned in the talk, patients of lower socio-economic groups may not be insured in the US and so may not necessarily have access to surgical facilities. The study looked for and corrected for some of the variables in the data such as hospital size, rural vs teaching hospitals and hospital ownership. They did not identify any statistically significant differences between those groups.

There are 3 interventions within the intervention group although cholecystostomy does not seen as though it should be an operative intervention. Did the study look at difference in maternal fetal outcomes between the 3 different interventions?

We agree that we were surprised that cholecystostomy were included. A cholecystostomy does not really seem like an operative intervention and is normally only used when other surgical interventions have failed.

The study does not report data on how the 3 interventions each affected the maternal fetal outcomes. The numbers for the cholecystostomy group were very small – around 5% in each trimester. The study only mentioned which surgical procedures were implemented not if it was related to any particular outcomes.

Patients who were discharged and were then operated on later were placed into the non-operative group for the study. Should these patients not have been allocated into the operative group?

We agree that this should have been the case and were also puzzled as to why these patients were in the non-operative group. The study also does not mention how delayed the surgery was – for example did the patient just want to go home to recovery for a few days or did the hospital have a set pathway whereby the patients come for the operation in a few days' time.

What were the overall conclusions? Are the authors purposing any further research? How would you take this forward?

The overall conclusions were that most pregnant women admitted with acute cholecystitis were managed nonoperatively, which is contrary to many clinical guidelines and this is associated with increased maternal-fetal complications.

The authors of the study have said that they do not think a randomised control trial (RCT) is feasible. They suggest that a strong cohort/ observation study would be the way forward. However, we feel that the data they start with is a bit dubious, especially with the issue with gestational age and because we don't have a reliable picture of the patient's level of unwellness, these results do not seem very reliable.

Why is an RCT considered not feasible?

In theory an RCT would be conducted. Although this may be a more complicated population/ situation, RCT's have in the past been done in complicated situations such as emergency settings, A and E departments, ITU etc. There is ethically nothing wrong with conducting this RCT – as long as clinical equipoise exist.