Author's response to reviews

Title: Intrahepatic cholestasis of pregnancy: observational study of the treatment with low-dose ursodeoxycholic acid

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Author's response to reviews: see over
Reviewer’s report
Title: Intrahepatic cholestasis of pregnancy: observational study of the treatment with low-dose ursodeoxycholic acid
Version: 2 Date: 4 March 2015
Reviewer: Chad Hall

Reviewer’s report:
Major Compulsory Revisions

1. Tables 1-3 should undergo statistical analysis to determine significance between patients who received UDCA and those who did not receive medication. P values should be included in figures where appropriate to show statistical significance.

We have made statistical analysis to determine significance between patients treated with UDCA and those who did not receive medication. P-values have been added to the figures, except fig 3, because a few number of the patients.

2. Please provide additional information on selection criteria for patients receiving treatment. How did you assess patient’s symptoms? Was a formal scale used to show improvement in pruritus? It is clear that the laboratory values decreased; however, did patients also experience a decrease in symptoms?

In paragraph four in material and methods.

3. The study showed that women receiving treatment were more likely to deliver pre-term due to severity of disease. Please provide reasons for delivery in the discussion. Also, what are the characteristics of patient’s who delivered preterm, for instance, what were their lab values and how did they respond to treatment? Were there any noticeable demographic differences in patients who had severe disease? Would these patients be considered a failure of medical management? Did you attempt to increase the treatment dose to avoid pre-term labor? More information is needed to prove the women who delivered pre-term actually had more severe disease.

Preterm deliveries and patients with severe ICP were analyzed separately lines 201-221.

In discussion preterm birth Lines 261-275.

Minor Essential Revisions
1. Please review the 2nd paragraph of the introduction, specifically line 100. The information trying to be given and the purpose of using this reference is not clear.

Corrected line 100.

Discretionary Revisions
1. Were patients with gallstones treated differently? Were these patients referred for cholecystectomy?

Lines 173-177.

Reviewer’s report:
This is an interesting and clear retrospective observational study comparing the characteristics of women with ICP treated with or without UDCA, and of their offspring.

Major revisions

- Please list all of the medication side effects (line 176-177) before asserting that medication tolerability and safety in your discussion

Lines 185-186

- Please add p values demonstrating whether the differences between UCDA and non-UCDA groups are different for all of the characteristics in Tables 1, 2 and 3. Without such demonstrated measurement of statistical difference (or similarity) these tables are somewhat meaningless.

We have made statistical analysis to determine significance between patients treated with UDCA and those who did not receive medication. P-values have been added to the figures, except fig 3, because a few number of the patients.

Minor revisions
- Gene names should be italicized
  Done.
- The authors may want to reconsider their use of interpretations of results within the results section.