Reviewer’s report

Title: A randomized controlled double blind trial comparing the effects of the prophylactic antibiotic, Cefazolin, administered at Caesarean delivery at two different timings (before skin incision and after cord clamping) on both the mother and newborn

Version: 1 Date: 16 Jun 2016

Reviewer: Elizabeth Moore

Reviewer’s report:

I don't know if it was due to the conversion to a pdf, but there are numerous spacing errors throughout the manuscript. These should be corrected.

In the abstract, the authors state that the pre-incision group has longer hospital stay. This is not supported by the data. In fact, the abstract conclusion says the pre-incision decreased hospital stay significantly.

Page 5, line 27: I am not sure what the authors mean by "The data supporting their findings can be found at Neonatal Department." I am not sure what findings they are talking about and what the Neonatal Department is located or what it has to do with anything.

Page 5, line 47. It is not necessary to exclude preterm babies since the inclusion criteria required mothers to be at least 37 weeks gestational age at delivery.

Page 6: Why did the authors decide to recruit 1200 participants? Was this based on a sample size calculation? If yes, then the details needs to be provided. If not, the authors need to justify why this number was selected.

Page 6: The authors state block randomization was used, but do not describe what was blocked. In addition, they do not describe the randomization strategy used and how it was done.

The authors did not operationalize or justify many of the outcomes the reported in the results section. For example, What Apgar scores were considered "abnormal", what is meant by blood culture yes, what is "proven" sepsis, how were all the post op complications defined and diagnosed, etc. No where do the authors provide details on how these any of these outcomes were collected and determined. Who did the Apgar scores the nurse or neonatologist? Who diagnosed the post op complications; was it done by one individual? If not, how did then ensure the was consistency in the diagnoses?

The statistical analysis conducted on this study is very weak. First They say means and standard deviations were calculated for normally distributed data, but do not say how they determined if the data were normally distributed. In addition, for all the outcomes they placed the continuous variables into categories for analysis. There is no justification for doing this. This type of
analysis decreases the strength of the results. For example why would you compare hospital days between the pre-incision and post-incision groups using categories? Why not compare the actual number of days. If that was done, a much strong statistical test could be used. Also, the authors state they used chi-square tests for the analysis, but for many of the comparisons this is not appropriate because for several of the outcomes had less than give observations. The chi-square test is not appropriate in this situation. Instead, a Fisher's exact test should have been used. The authors also say a Levene's test for equality of variance was used, but this doesn't make sense because all the comparisons were conducted on categorical data so variance isn't an assumption for the statistical test.

Page 6, line 57: it should read, "...and all data were" not "...all data was".

Page 7, line 3: The first sentence, 1200 what? were recruited?

Page 8, line 3: The first sentence should be in the present tense.

Page 8, line 12 the second word in the sentence (Mean) should not be capitalized. The authors should provide the gestational age for both groups and give the results of the statistical test (p value) for the comparison. Did the authors look at maternal age? If yes, that information for both groups should be in the manuscript including the results of the statistical comparison.

Page 8, lines 25-27: Who determined the non-reassuring fetal heart status and how was this diagnosed? What is meant by "abnormal lie"?

Again, neonatal weight should not be compared in categories. Instead use the continuous variables and compare it using a more powerful statistical test.

The authors state there were not differences between the groups for demographics, but none of the results are presented. The p values for each of these should be included in Table 1.

There is not a reference to Table 2 in the text.

Page 9, line 12 (sentence starting "Mothers who received antibiotics...") This is an awkward sentence structure. Needs to be reworded.

Page 9, 27: The authors report the mean hospital days for the mothers, but then put the days into categories for the comparison between the groups, why?

Page 9, line 32: I am not sure how the authors justify the statement, "...delay was probably due to some infectious morbidity..." What is meant by infectious morbidity?

Page 9, line 34: The blood culture was positive for what?

Page 9, line 59: Give the non-significant p value.
For the comparison of post op complications, did the authors conduct post hoc tests to determine where the differences were among the different post op complications? It looks like the main difference is in SSI, but this needs to be verified with post hoc tests. In the discuss the authors state they had no difference in some of the post op complications as reported in other studies, but without the post hoc tests, they can't say that for sure. For all comparisons that had more than two categories that were statistically significant, post hoc tests should have been conducted.

Why did the authors not report the relative risk and confidence intervals for the results? These results should be provided.

Page 11, line 12: "Lesser" is not a word.

Nowhere in the discussion section do the authors discuss the limitations of their study. For example, is the study sufficiently for all the maternal and neonatal outcomes? It is likely, based on the incidence rates of some of the outcomes they looked at that the study does not have sufficient power to detect a difference. Without knowing this, they need to be careful making the conclusions they made. It is possible that a difference was not found between the groups because of a type II error.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

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