Reviewer's report

Title: Pregnancy outcome following gestational exposure to azithromycin

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Reviewer: Aruna Mittal

Reviewer's report:

The title ?Pregnancy outcome following gestational exposure to azithromycin? of the manuscript is not appropriate since the authors have enrolled only 18% women out of 123, received azithromycin for genitourinary infections, which is not satisfactory number to reach to the conclusion hence it should be modified. Overall the manuscript has grammatical errors and not very clearly written. My specific comments are as follows:

Abstract
· Methods
For this study authors have divided pregnant women into 3 groups:
Group 1: Women who took azithromycin.
Group 2: Women exposed to non-teratogenic antibiotics for similar indications Group 3: Women exposed to non-teratogenic agents.
The basis on which groups were made is very confusing. Women in group 2 and 3 were exposed to Non-teratogenic agents, it is not clear how these two groups are different from each other. In Group 2 ?similar indication? What does author mean by this is not clear.
· Results
n=369, Is it the total number of women enrolled for the study? Nothing is mentioned in this context in the main text of the manuscript.
Authors didn?t found statistically significant differences among the three groups in the rates of major malformations; 3.4% (exposed) versus 2.3% (disease matched) and 3.4% (non teratogen). Here again the bases on which these groups are made is not clear and not even matched with the groups mentioned in method section of the manuscript.
What are the ?endpoints? authors had examine?

Introduction
1st paragraph last line ?Recently, a large study examining treatment of trachomas (almost 1000 people) was published, that documented that the prevalence and intensity of infection fell dramatically and remained low for two years after one treatment.? Reference should be mentioned.
2nd page first paragraph of introduction ?There were 11 reported exposures to azithromycin during the first trimester, resulting in one elective abortion, one ectopic pregnancy and 10 healthy, full-term babies.?
How this is possible, out of 11 women studied 2 already had abortion and ectopic pregnancy and remaining 9 should gave birth to healthy babies and not 10 (as mentioned in the manuscript). The statement should be corrected accordingly.

Patients and Methods
4th paragraph: In the abstract authors mentioned 3 groups for study. However, in this section 2 groups are mentioned. Comparisons among the groups were very confusing. Azithromycin exposed women were compared with other non-tratogenic drug exposed women having matched disease and unmatched diseases.
What all are ?matched disease??
?Over-the-counter medications?, what dose this means?
Non-teratogenic drug or Non-teratogenic agents. Either use drug or agent and consistency should be maintained.

Results
Description of other drugs in the exposure time should be included in the study.

1st Paragraph last line, ?There were no differences in the maternal characteristics between the study group and the two comparison groups.? With ?maternal characteristics? what does authors mean by this should be clearly mentioned. In the abstract, authors have mentioned that the disease is matched between two groups and not with the third group.

Discussion
It should be written clearly. Involvement of STD pathogen other than Chlamydia has not been included in the text. Since azithromycin is also used in the treatment of Neisseria gonorrhoeae, authors should also mentioned importance of the study in relation to other STD pathogens.
In addition in vivo animal study should be done to conform these findings.
The baseline rate of malformations is 1%-3%, is this parameter given by authors or it is published data (then please mentioned the reference).

Legends
Not included in the manuscript

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1) Title of the manuscript should be more appropriate to the study.
2) Discussion should be rewritten in the light of study design and result obtained.
3) Number of women enrolled and their further grouping should be the same in all the sections of the manuscript and data should be re-evaluated accordingly.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
1) Legend missing
2) Grammatical mistakes in abstract, methods and results should be rectified.
3) Reference with respect to trachoma study (1st paragraph last line) is missing and added in the text and list of references.
4) Introduction, 2nd page first paragraph. Out of 11 women studied 2 already had abortion and ectopic pregnancy and remaining 9 should gave birth to healthy babies and not 10 (as mentioned in the manuscript) The statement should be corrected accordingly.

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes

Declaration of competing interests:
I declare that I have no competing interests.