Reviewer’s report

Title: Birth weight by gestational age and congenital malformations in Northern Ethiopia

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Reviewer: Juliet Ndibazza

Reviewer’s report:

Comments to the Author

This is a useful study describing the prevalence and risk factors for low birth weight and congenital malformations in Ethiopia, studied between December 2011 and May 2013 in two district hospitals. Data on birth weight, congenital malformations and associated risk factors in African infants is scanty. Studies in different indigenous populations are vital for the development of cost-effective preventive antenatal interventions.

General comment

This manuscript makes an important contribution to the existing literature on the topic discussed, but its findings are perhaps not as widely generalisable because of the chosen study population.

Major compulsory revisions

The authors should clearly state which of birth weight or congenital malformations was considered the main outcome for this study, and the risk factors assessed. A consistent approach to these categories, in all sections of the report, would greatly enhance the presentation of this report.

Minor essential revisions

1. Title

The study design should be indicated in the title or abstract.

2. Abstract

Methods: the authors should include all relevant variables that were collected for the analyses in the study e.g. parity and antenatal care are missing here, but presented in the results.

Provide a systematic summary by clarifying the main outcome (?birth weight) and key risk factors (?gestational age and congenital malformations).

Results: Consider including the summary distribution measures for these e.g. mean (sd) for birth weight (pre-term vs term births) and gestational age, and proportions for congenital malformations, before detailing the observed results for the associations between outcome and risk factors. Then a mention of other significant risk factors such as parity, gender, antenatal care etc can follow.
Conclusion: this section can be improved to reflect the revisions made in the results section above.

3. Introduction
- State the hypothesis/objectives clearly.
- A paragraph on studies that have assessed the association between birth weight and gestational age in this population/other populations could be included in the background.
- Literature review on other known risk factors for low birth weight will provide a more comprehensive background for the reader.

4. Methods
More details should be provided in the methodology.
- Definitions: A definition of low and very low- birth weight, prematurity and small for gestational age should be included. As well as a definition of congenital malformations relevant to this study e.g. stating clearly that this included only malformations detected in the first xx hours, as this would give an indication of the malformations detected and missed/excluded.
- A description of the assessment of gestational age should also be included here.
- Study area: You make note of the very low proportion of deliveries in health facilities in this study area. This is a crucial point for selection bias and generalisability which should be expanded in the discussion section.
- Study population: i) Please state clearly whether this was a retrospective cohort using data from past records, or whether the study was initiated before the events (prospective study). ii) specify if this was a consecutive population or not. iii) Provide the total number of live births and stillbirths, and whether the latter were included in the analyses. Birth weight for stillbirths is often missed/not recorded, besides still births could contribute disproportionately to the number of births with congenital malformations. iii) Were any of the births assisted deliveries? v) For the reader not familiar with the services available, it could help to specify in the methodology that no prenatal screening by ultrasound was carried out during the antenatal period, if that was the case. Also, because ultrasound examinations during pregnancy could identify abnormal pregnancies (e.g. with neuro-tube defects), resulting in these being referred to the hospital, and creating a source of selection bias, and an artificially high prevalence of e.g. CNS malformations. vi) The details of the routine examination for the identification of congenital anomalies should be specified as it affects the rate of detection of specific birth defects. In numerous hospitals in Africa, infants are delivered by nurse midwives with limited skills and might miss a cleft palate or a hip dysplasia or an abnormal heart murmur. It is also most likely that no diagnostic testing was carried out for chromosome analysis. vii) Which medications did the mothers receive routinely or otherwise during the antenatal period? Was any assessment of the effect of these on birth weight and congenital malformations carried out?
- Statistical analyses: As mentioned for the results section in the abstract above, providing a clarification of the main outcome and risk factors assessed will provide the reader with a better understanding of your analyses. The confounders included in the final regression models should also be stated.

5. Results
- A descriptive table to show the number of births by hospital, and to provide an overall comparison of gender, mean birth weight, & proportions of congenital malformations should be considered before the detailed analyses & comparisons.
- Once again, a systematic reporting for the association between birth weight and gestational age, then for birth weight and congenital malformations, before other risk factors such as parity, would make this section an easier read. The tables and figures can then reflect the revised structure.

6. Discussion
- All key results should be summarised in the first paragraph, and then each result can be thoroughly discussed in the progressive paragraphs.
- The first sentence in this first paragraph is misleading. It suggests that the infants’ weight was measured prospectively after birth to assess an increase/decrease from the birthweight, by gestational age at birth. Please revise this to reflect the objectives of the study and results obtained.
- In the first paragraph the authors also report an association between the child’s gender and mother’s parity. How is this analysis related to the main objective?
- Results on birth weight are discussed in the second paragraph. It appears that the authors have also carried out a subgroup analysis by gender and parity for birth weight. This should be clearly stated in the methods section if preferred.
- The authors also suggest an association between birth weight and seasonal food availability. Considering that this study used data collected only over six months, probably this observation cannot be supported/disputed by this data, and this should be noted.
- The key limitation, a hospital based study in a region where only ~6% of the deliveries are attended in health institutions, should be aptly discussed, and a note on the generalisability of the results included. e.g. were these complicated pregnancies that were referred to hospital?

**Level of interest:** An article of importance in its field

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

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

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