Reviewer’s report

Title: Characteristics and outcomes of patients with eclampsia and severe pre-eclampsia in Ndala Hospital, Tanzania

Version: 1 Date: 31 January 2014

Reviewer: Caitlin Shannon

Reviewer’s report:

Review

The paper summarizes data from a maternity audit on severe pre-eclampsia and eclampsia in a Tanzanian rural district hospital. Data show that among women with either eclampsia or severe preeclampsia both maternal and perinatal mortality are high (CFR of 11% and about 30%, respectively), even though burden is quite low (less than 3% of maternity cases). Authors give suggestions on treatment and management in a resource restricted setting, based on this audit. Approaches to effectively managing hypertensive disorders in resource restricted settings are lacking and data on experience and outcomes of high value.

Major comments:

1. Introduction –
   a. Additional information on the public health importance of hypertensive disease in pregnancy would strengthen the introduction and justification for the importance of this paper. For example, it would be helpful to include more information regarding the burden of hypertensive disease in pregnancy globally, as well as locally, if possible. Estimates are that hypertensive disorders complicated between 2 and 10% of pregnancies. In addition, regional data regarding MMR, skilled delivery, ANC and PNC would be useful in describing the context. Some of this information is provided in the first paragraph of the methods, but is better suited for the introduction.

   b. The research objective should be clarified including specification that data were part of a retrospective chart review / maternity audit. This should also be clearly stated in the title and abstract.

2. Methods -
   a. Ethics – Whether or not chart reviews require ethical review and / or the informed consent of patients is well-established and practices are inconsistent. Most ethics boards would require IC where identifying information will be abstracted. In order to waive IC, committees typically would require specific procedures be in place so that such information will not be extracted. In addition, best practice is to have data extraction done by external researchers, to preserve confidentiality. It appears that authors have considered these ethical issues and described them in the paper. However, best practice would have been to seek
ethical review and allow the review committee to independently determine whether IC is required. Additionally, authors should clarify ethics procedures, including what efforts were made to ensure that data were de-identified and that it was not possible to link the data to the patient.

b. Statistics – it is recommended that authors report confidence intervals for summary statistics, such as CRF.

c. Data management and missing data – it is unclear the quality of the data. Additional information on the extent of missing data would be useful to help the readers assess data quality. Medical record review is notoriously incomplete, especially outside of traditional research studies such as audits of medical records. Authors report that records were rechecked where discrepancies and missing data were found, but who did this secondary review? How much data was missing?

d. Diagnosis and inclusion in the study – it is unclear to what extent evidence of HELLP was used to diagnose eclampsia and whether presence of oedema or other symptoms were used for diagnosis of severe preeclampsia. Table one suggests signs were part of the diagnostic criteria, but what signs? It would be essential to provide a reference for the diagnostic criteria used.

3. Results

a. If data are reported to be extracted from charts in the methods they should be reported in the results. For example, there is no data on blood pressure presented, though it is specifically mentioned that BP data would be extracted – at admission, at 24 hours after admission, 72 hours after admission and at discharge. It would be useful to the reader to know these data and/or the extent to which they were missing – as they are essential to management and treatment and could help inform a better way forward in respect to management and treatment.

b. Tables –

i. Table one is not needed; can integrate case descriptions into text.

ii. Table two – some key data on patient characteristics should be described in text.

iii. Table five is not needed; can also integrate into text of results.

4. Discussion

a. This study was an audit or retrospective chart review and not an observational cohort study.

b. The authors should be careful not to overstate their conclusions, in light of the validity and reliability of the data.

c. It would be helpful to discuss more in-depth treatment with respect to delivery – when to induce and when to perform cesarean in the context of globally accepted guidelines. Authors do well to describe that women can be expectantly managed and a trial of labor attempted, and this is important to practitioners in similar settings, especially where cesarean may not be an option or is more risky
compared to when it’s performed in a tertiary facility. In addition, assisted delivery was common, but it’s not well described the risk/benefit of cesarean delivery in terms of outcomes for mother and perinate. As perinatal death was quite high, would more frequent recourse to cesarean in these cases lead to better outcomes for the perinate and the mother? If so when and in which cases? The author’s suggestions with respect to these questions and in light of their data and experience would be invaluable to readers.

d. Additional research – given this data, what additional research would be useful to improve management and outcomes among mothers with severe pre-eclampsia and eclampsia.

Minor comments for revision:

1. Title – I would suggest including wording to indicate that this was a retrospective chart review / audit.

2. Abstract –
a. Report total number of pregnancies (denominator for prevalence of severe preeclampsia and eclampsia).
b. When you report incidence, you should report the time period and the total number of pregnancies.

3. Introduction –
a. It would be helpful to break into multiple paragraphs.

4. Methods
a. Pg 5, para 1 – patients were not analyzed, their data were.
b. Treatment – it would be helpful to add citations for treatment guidelines. While the guidelines described follow globally accepted practice, readers—especially non- or inexperienced clinicians—may find utility in a clear reference.

5. Results
a. It would be helpful if authors could include data on the frequency of maternal death, stillbirth and early neonatal death among the 3398 deliveries during the study period. It would put the results in better context in terms of attributable risk. Or the MMR / NMR and stillbirth rate for the district, which could be reported in the introduction.
b. Pg 7, 2 para. Describe pertinent characteristics of the cases and not just what the table contains.
c. Table 2 –
i. Consider combining tables 2 and 3.
ii. GA should be reported as mean weeks. Also it would be useful to report n (%) delivered before 34 weeks.
d. Table 3 -
i. For induction, report n (%) of all women not just those delivered; number of
women delivered on admission is reported in Table 2. A footnote should be used to indicate that all inductions were with misoprostol (regimen would be useful), unless different methods were used for induction, in which case report in table n for each method. Also is it possible to report on labor augmentation, for those in spontaneous labor who were not progressing? The assumption underlying the data as reported is that those induced were not in spontaneous labor.

ii. For antihypertensive treatment, report frequency of nifedepine (oral), methyldopa (oral) and hydralazine (IV, oral).

e. Table 4 – include maternal outcomes; LBW is standardly reported as 2.5kg or less; VLB as 1.5kg or less. If data cannot be disaggregated in this way, then it would be important to explain that in the methods. Also, I might suggest that the data are reported as stillborn, died before maternal discharge. For mean BW, please report SD.

6. Discussion

a. I would suggest a clearer summary of the salient results before diving into a comparison to the literature and a discussion of strengths or weaknesses. This will help the reader focus on what the authors believe to be the most relevant findings.

b. I would avoid presenting results in the discussion not presented in the results, e.g., data on blood pressure.

c. Limitations

i. I would discuss how having an unreliable measure for protein urine may have affected the diagnosis of severe pre-eclampsia and eclampsia, and thus the findings for this study.

d. Pg. 10, first sentence – please provide reference to data from HIC.

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

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

'I declare that I have no competing interests