Reviewer's report

Title: Nonsynostotic plagiocephaly: a child health care intervention in Skaraborg County in Sweden

Version: 2 Date: 03 Oct 2018

Reviewer: Deborah A. McNeil

Reviewer's report:

Abstract

Aim: the sentence needs a period at the end

Results: unclear if the asymmetry reversal OR at 12 months for parent information was for all infants and what impact the intervention had on that OR. Unclear who were the non cases; non cases of what? Was it the infants who did not have brachycephaly at birth?

Conclusion what does benefitted reversal mean? Do the authors mean that those in the intervention group were more likely to have reversal of asymmetry?

Background

Nice definition of NSP. As I understand it the intervention was education of the nurses to follow the Guidelines that were developed and the key to that was educating the parents in prevention.

Methods

Page 4 lines 13 and 14 - Good attempt to address issues of "spill over" for nurses not providing the intervention by using nurses who did not attend the education program.

Pag4 lines 17 and 18 - Were the nurses who had not attended the education program but were in the intervention group provided with education? Was there anything done to assess intervention integrity? It would have been helpful to have more information about the distribution of the education and how many of the population of nurses attended the education program so we would know who many nurses by group were eligible to participate in the study. In looking at the supplemental material Consort chart for nurses, it identifies that all control group nurses received the intervention. This is at odds with what is written in the manuscript in the lines identified above. My sense is that the control intervention was routine care; it would help to explain this in the chart or change the wording to make it clearer. It would also have been helpful to know the infant/parent population eligible to participate. There is a brief description of drop outs but at this point it is unclear what the response rate was. I would have like to have seen a calculated percent of the drop outs in the manuscript. The consort flow chart is also difficult to understand as it
appears that all infants received the intervention. If the CONSORT flow charts remain as supplemental material there needs to be more in the text to clarify the above questions.

Page 4 Line 42- Please define what is meant by regularly. How often on average did nurses see infants?

Page 4 Line 56 - how frequent in the first few months on average were visits?

Page 5 lines 51-53 - Was the rating scale developed by the authors'? In what way was this validated and reliability and validity assessed? I do not believe that the next section on validation for 12 month measurements addresses the above question as this was for the blinded assessors and not for the nurses.

Page 6 lines 31 and 32 - References for the following statement is needed. "The natural course, parents' habits, and national recommendations can influence cranial shape of all infants".

Page 6 line 48 should be in past tense

Page 6 - line 49 please spell out AC2

Page 6 line 51 I believe there is an error in the P value and it should be < 0.05 not 0.50

The entire Statistical methods section requires more information. For instance what was compared for the Chi2 analysis. What odds were being modeled in the regression analysis. What approach was taken for the multivariable analysis. How were co-variates or independent variables chosen? How was the modeling carried out? Was there any model validation undertaken?

Results

In general the results section requires a significant amount of re-working. If there was statistical testing done then the p values should be displayed along with identifying the test that was used. I see that some results are reported in Tables 1 and 2 but it feels that there is a disconnect between what is in the text and the tables. Since there was statistical testing there should not be differences ascribed between groups unless there was a statistical difference. The number of
sub-analyses with small samples is a problem and should be justified as more exploratory and addressed as a limitation.

Page 7 lines 18 and 19 - It would be inappropriate to say that there was a greater proportion of infants with side preference as the p value was > 0.05. This needs to be reworded to reflect that there were not differences because they did not reach statistical significance.

Page 7 line 25. A more appropriate term than minimum - maximum is range.

Page 7 line 31- please identify if this is the result of a Kappa analysis and the Kappa statistic of if it is just an agreement percent

Page 8 line 25 - a description of how prevention failure was categorized would be helpful here based on cases and non-cases.

Page 8 line 29 - I am a bit concerned about analyzing the total NSF i.e. each group combined since there is a statement on page 8 line 42 that indicates that results were different among the groups which may indicate that the groups should not be combined and that the total analysis could attenuate the findings. There should be in the methods section or here the rationale for conducting a total of all three types analysis given the differences in trajectories found.

Page 8 line 33 and remainder of the paragraph - should be past tense: change "are" to "were"

Page 8 line 34 - I am assuming that the statistic used was Chi square, however due to the small numbers a more appropriate statistic would be Fishers Exact test.

Page 8 lines 35, 36 - The results are identified as lower but not statistically significant. The results should say there were no statistical differences not that the percent was lower in one group.
Page 8 lines 42,34 - Were these results statistically significant?

Page 8 lines 50,51 - Were the results statistically significant?

Page 9 line 30-44 - there are many causal statements that are beyond the scope of the analysis used. At best associations were found.

Page 9 line 31-32- The correct description of the OR should be that there were 4 x greater odds of NSP reversal from T1 to T2.

Page 10 line 0 - another example of claiming differences when not statistically different.

Page 10 lines 4-16 - unclear if these results are statistically significant or not.

Page 10 lines 22, 23 - this statement requires rewording to reflect the analysis. Suggest something like: … the intervention was associated with reversal and reduced risk… The key point is association and not causation. Suggest the investigators read Bradford Hill and criteria for causation. One recent article describes them for modern times (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589117/).

Page 11 lines 6- 11- This analysis should be in the methods and results. It seems an afterthought which is should not have been.

Conclusion

The results are overstated see above comments. The conclusion has much information about future research needed with which I agree . I would have liked to have seen a "So What" statement as in examining graphs and data by 12 months there was little difference between the control and intervention group which might be explained by the brachycephaly persistence. However, if there was little difference at 12 months is the intervention truly needed. How many babies would be helped and what are the impacts of a misshapen head at 12 months.
Tables 1 and 2

Requires more in the legend including as explanation of case and non-case and intervention failure. Unclear why the RR is reported since it is not mentioned in the methods or results but OR is identified in the text.

**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?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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