Author's response to reviews

Title: Clinical evaluation of error in saturation-readings taken through a skin-protective covering

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Author's response to reviews: see over
Reviewer’s report
Clinical evaluation of error in saturation-readings taken through a skin-protective gauze. Title:
1 25 November 2004 Version: Date:
Alexander Dullenkopf Reviewer:
Reviewer’s report:
General
The authors James et al. present a study to show that pulse oximetry readings taken through a skin protective gauze do not differ from readings taken from skin directly. Their objective is to protect the delicate skin of newborns from pressure-induced damage by using adult pulse oximetry probes. However, the study is conducted on adult volunteers because of ethical considerations.
The study done in neonates is being presented now
The reviewer personally has no experience in monitoring pulse oximetry through protective gauze and can only speculate about how widespread the method is (pulse oximetry or saturation combined with gauze shows no hits in medline). However, the authors address a topic related to patient safety in a straight forward planned study. Nevertheless, there are some drawbacks in the methodology of the presented study.
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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
Statistics
Paired t-test was used to show that pulse oximetry readings through two different types of gauze do not differ from direct measurement. There are no statistically significant differences between the methods in heart rate recordings, but in oxygen saturation readings. The authors declare the differences as not clinically relevant. Even if the two intervention groups are not tested against a gold standard (blood gas analysis) in my opinion the intervention groups should be compared to the reference group (direct pulse oximetry) by Bland-Altman plots with estimation of bias and precision rather than by paired t-test (Bland, Altman. Lancet 1986).
This has been done now
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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Please, replace saturation monitoring by pulse oximetry throughout the text.
Done
Please, provide page numbers.
Done
Methods
(p4): the machine will compensate by increasing its light output: as this is not the case for all pulse oximeters, the authors should specify, which machine they talk about. (p4): TurboStellar monitor: please give more details (manufacturer, City, Country).
Done
(p4): last para: this para should be shifted to the discussion in the limitations of the study section.
There should also be stated, that the two intervention groups were not tested against the gold standard but against the standard method. (p5): first para, last sentence: ?
Done
Results
(p5): It is stated twice in this section that differences were not clinically relevant. As these are statements and not results, please shift to discussion.
Done
Discussion
(p6): first sentence: please shift to results section.
Done
Please add a para - In conclusion, … - at the end of the discussion
Done
Legend to figure
Please delete – showing –
Done
Some typos:
Abstract
Edges of the adult finger clips … sometimes produces: Please delete – the - and change to – produce –
Done
There are also some minor layout errors to be corrected.
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Discretionary Revisions (which the author can choose to ignore)
Unable to decide on acceptance or rejection until the authors have responded to the
What next?:
major compulsory revisions
An article of importance in its field Level of interest: Acceptable Quality of written English:
No Statistical review:
Declaration of competing interests:
I declare that I have no competing interests’

Reviewer’s report
Clinical evaluation of error in saturation-readings taken through a skin-protective gauze. Title:
1 26 November 2004 Version: Date:
amir kugelman Reviewer:
Reviewer’s report:
General
This article evaluates the accuracy of pulse oximetry readings taken through a skin-protective gauze or micropore adhesive tape.
The authors try to convince that using adult clips in neonates are essential and economic in developing countries.
However, the study has significant technical and statistical limitation and the methods of evaluating accuracy of pulse oximetry are not appropriate.
The study was repeated in neonates and Bland Altman plots were employed
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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1. Technical limitations: the study is performed on adults. The authors justify that they have an ethical limitation in doing the study on infants. However, as the aim is to use it in infants, as pulse oximetry is not invasive and side effects are negligible, it is crucial to have data from infants. Furthermore, pulse oximetry is dependent on technical limitations, and using an adult clip on a newborn has to be tested specifically.

   The study was repeated in neonates

2. Pulse oximetry was checked comparing means of 3 measurement in 3 methods. It is not clear what means (how did they choose to 3 measurements), and the measurements were not done simultaneously. Thus, it is difficult to accept this evaluation.

   Dr Kugelman also suggested that the 3 methods could be measured simultaneously. To do this we would have to use pulse oximetry oxygen saturation monitors and we would introduce errors due to differences inherent in the different machines. We have therefore opted to use a single machine and take the readings sequentially in the same neonate – a technique sanctioned by Bland and Altman in their original studies on peak flow meters and saturation monitors.

3. Healthy adults were evaluated. The accuracy of pulse oximetry needs to be checked on a wide range of oxygen saturation. It is especially important to evaluate accuracy on the low saturation range, and this was not done. The gold standard of arterial blood gas oxygen saturation is not reported.

   Blood gas as the gold standard was considered but not utilized because the new study utilizes Bland Altman plots. According to Bland and Altman, ‘New methods can be compared to an established technique rather than with the true quantity. If the new method agrees sufficiently well with the old the old may be replaced’.

   The gold standard is needed for ‘calibration’ (Bland JM and Altman DG Statistical methods for assessing agreement between two methods of clinical measurement Lancet. 1986 ;1(8476):307-10.)

4. Statistical analysis: I suggest that the authors will show the bias (mean difference) and precision (standard deviation of the difference) of the measurements, an its linear regression and correlation coefficient to a valid standard. Comparing means is not adequate enough.

   Done

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. The title has to mention: "pulse oximetry oxygen saturation" and not only "saturation readings". It is only mentioning skin gauze and not the micropore adhesive tape. I would suggest to use a more general term for protective measures.

2. Abstract: Again: pulse oximetry oxygen saturation is not specified and the authors use the term: saturation only.

3. Introduction: the use of an adult clip in a neonate was not the purpose of reference 1.

4. Materials and methods: there is no reason to explain the principles of pulse oximetry in the section of materials and methods.

5. Results: The authors should reference a 2% acceptable range. As they used healthy adults with very narrow range of saturations it is not meaningful. In line 4 they refer to table 1. They got statistical difference between direct and micropore which they claim to be clinically insignificant. Needs to be discussed. They do not mention the results of table 2.

6. Discussion: the paragraph on the spectopotometry is not convincing as this is a possible additive error. The authors can only speculate on avoiding trauma by using the protective measures as they did not check it in a controlled study. The economical benefits should be refrained, if possible in dollars (most of the readers can not appreciate Indian money value). I suggest to conclude at the end of the study.

Discretionary Revisions (which the author can choose to ignore)
Reject because scientifically unsound

What next?: An article of limited interest

Level of interest: Not suitable for publication unless extensively edited

Statistical review: Yes

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

I was involved in a study that evaluated the use of reflectance pulse oximeters in newborns and infants, but I have no financial issues regarding this oximeter and it has no connection to the reviewed manuscript in any case.