Author's response to reviews

Title: Paracetamol serum concentrations in preterm infants treated with paracetamol intravenously: a case series.

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Author's response to reviews: see over
To the Editor-in-Chief
Journal of Medical Case Reports
Professor Michael Kidd

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Concerning the Manuscript “Paracetamol serum concentrations in preterm infants treated with paracetamol intravenously: a case series of nine”.

Dear editor,

We would be grateful if you would consider our revised manuscript for publication. In this letter you will find a point-by-point response to the comments made by the reviewers.

1. The authors should further stress that the doses administered were ‘original’, off label and also ‘off-practice’, and likely due to a miscalculation (no conversion from propacetamol to paracetamol)

Response: Our doses were not due to miscalculation. We formulated this in the discussion section: ‘We accidentally administered i.v. paracetamol in a dose not supported by literature. The dose we used in preterm infants of less than 32 weeks gestation is being used in term infants, and is not a result of miscalculation due to the differences in formulations of propacetamol and paracetamol’.

2. Please also check the ‘loading’ dose and maintenance doses, since is strongly depends on the compound used. In its current form, the 3rd line of the discussion is not in line with what we have described and administered.

Response: We checked and adjusted the doses according to the referred article.

3. The authors should also integrate the reported problems with inadvertently dose administration of iv paracetamol (as communicated by the manufacturer).

Response: We contacted the manufacturer and incorporated their response in our discussion section.

On May 15th we received a further email with 2 remarks, made by the Deputy Editor.

1) In the Discussion section, the authors write: "We accidentally administered i.v. paracetamol in a dose not supported by literature.”

I felt that the authors were being too harsh on themselves. Their actions were not an accident but more a deliberate attempt to control pain using medication in an 'off-license' manner when no national evidence based and/or consensus guidance was available. So please would they consider revising this one sentence.

Response: we deleted the word “accidentally”.

2) In the Acknowledgements and Funding section the authors write:
"We would like to thank the parents of the infants who participated in our study for their consent. We would also like to state that our study was not funded in any way."

Was this case series part of a study? If so this should be made clear in the manuscript, as my impression from the manuscript (see Introduction) was that the collection of blood levels was not conducted as part of a formal study but more for safety reasons.

Response: we changed the acknowledgment section and stated that we “would like to thank the parents for their consent to publish the data”.

On May 20th we received further comments from the editorial team. Version 5 of the manuscript incorporates changes made to meet these comments:

1. Please alter your title to the following:
"Paracetamol serum concentrations in preterm infants treated with paracetamol intravenously: a case series"

Response: the title has been changed.

2. The Case Presentation section of the Abstract and the main Case Presentation section need to be reformatted to address each case in turn.

Response: the 9 cases are described separately in version 5 of the manuscript.

3. Please ensure you also include the ethnicity of the patient’s in the Case Presentation section of the abstract.

Response: the ethnicity is included in all of the 9 cases

4. Please remove the 'Author Information' section at the end of the manuscript.

Response: this section has been removed, and has been uploaded as a separate file

On May 31st we received a request for further adjustments concerning the format.

1. Please reformat the case presentation section of the abstract. It must be formatted to account for each of the 9 patients in turn, noting their age, sex and ethnicity. Please go to (http://jmedicalcasereports.com/info/instructions/#abstract) regarding instructions for authors. For you reference, we have included below an example of a case series. Please see the link below:

Response: we reviewed version 5 of the manuscript after studying the authors instructions again. We omitted the remarks made below the description of the 9 cases, as we felt this to be redundant information, given the presentation of each case separately and the overview of data provided by means of table 1.
We checked each case and noted that with every case age, gender and ethnicity is given. We looked at the example provided and could not find any data in our database of our patients that we did not describe in version 5 of our manuscript. Since NICU patients are transferred to general pediatric wards after the intensive care period and follow-up programs do not
concentrate on long term effects of neonatal pain or analgesia such long term outcome data is not available in our case. If the editors still feel this is not the correct format could you please provide us with detailed information on what is still missing or incorrect?

All changes are highlighted using the color yellow in the main manuscript (version 6).

Concerning the remark by one of the reviewers that our English was not suitable for publication we invited a native speaker to revise the manuscript. The only remark the native speaker had concerned omitting the word “at” from the last sentence.

We are looking forward to read your comment or decision on our manuscript.

Yours sincerely,

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