Author's response to reviews

Title: Suture restriction of the temporal bone as a risk factor for acute otitis media in children: cohort study

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Author's response to reviews: see over
Dear professor Marchisio:

We are pleased to submit a revised version of our manuscript for consideration for publication in BMC Pediatrics (MS: 1839511783753245 entitled Suture restriction of the temporal bone as a risk factor for acute otitis medias in children: cohort study).

Words in bold below refer to editorial requests or reviewers’ comments, questions and suggestions for corrections; words in normal font are our comments and words in italics are the corrections made in the manuscript itself.

1) Please move your Funding’s information to the Acknowledgement’ section.
   Response: We have moved our Funding’s information to the Acknowledgement section (p.16; 1st sentence of the Acknowledgement section).

2) Please format your Authors’ contributions section according to our guidelines.
   Response: We have formatted our Authors’ contributions section according to your guidelines (p.16; Authors contributions section).

2) REVIEWER #1:
   Major compulsory: not necessary
   Minor revisions: no
   Discretionary revision: if we look to treatment of Otitis media children below the age of 6 years, the temporal bone is one major piece, this is right, but from an osteopathic perspective we find always more somatic dysfunctions than only the temporal bone e.g. venous congestion, C1,2 dysfunction, facial bone dysfunction and so on. So the question is if the temporal bone alone has so much influence in the development of otitis media. Could it be, that babies with temporal bone dysfunction develop other dysfunctions too? So perhaps the temporal bone dysfunction is only a key lesion but not the whole truth. A follow study must be done which compares babies with temporal bone dysfunction treated and non-treated, how is the development after 2 or three years.
   Response: We included in the introduction, method and discussion sections references to the other structures involved (such as the cranial base including occiput and sphenoid bone). In order to further elaborate on this aspect, we specified that: 1) the temporal bone might be one of the key structures involved in the pathogenesis
of AOM (p.5; last sentence of the 2nd paragraph of the introduction) and 2) “Suture restriction of other ET surrounding structures such as the occiput, the sphenoid or facial bones might also affect the ET maturation process.” (p.13; 19th sentence of the 1st paragraph of the discussion).

Level of interest: an article of outstanding merit and interest in its field

Quality of written English: acceptable

Response: We have done minor language corrections.

REVIEWER #2:

Major comments: Although the study is very interesting and of importance, I am sceptical to the use of ears as measuring unit and not child. It is well known that the heritability of OM is considerable, correspondingly it is difficult to control for such biases. I suggest the authors change their dependent variable to OM in children; n = 64. Another reason in since no specific criteria are used for the physician diagnosis of AOM. I hope the power calculations allow for the latter.

Response: In order to address this important comment, we further justify and explain hierarchical linear and nonlinear (multilevel) models commonly used in behavioural and social field. Since the terminology **hierarchical linear and nonlinear models** is more common than multilevel regression, we have changed for the former both in the abstract (p.2; last sentence of the 2nd paragraph of the abstract) and the article (p.10; 2nd, 13th and 17th sentences of the 1st paragraph, p.25; title of Table 3 and p.27; title of Table 4). We specified in the method section (p.10; 5th sentence of the 1st paragraph) that: “Since our data has a nested structure (2 ears that may have different characteristics nested into one child) a two-level model was used. The level one represents the relationships among the ear-level variables and the level two considers the influence of the child-level factors. Potential confounders and potential risk factors for AOM were associated with either the ear (level one) or the child (level two).” Indeed, with the use of hierarchical linear and nonlinear models, both the child and the ear variables are considered.

Moreover, we specified that we used specific criterias which are those currently included in guidelines of management of AOM for the physician diagnosis of AOM (p.9; 1st sentence of the 1st paragraph): “During the follow-up period (8 to 11 months), AOM had to be diagnosed by a physician (general practitioner, emergency room specialist or pediatrician) according to specific criterias currently included in guidelines of management of AOM. The diagnosis of AOM required 1) a history of acute onset, 2) presence of middle-ear effusion and 3) signs and symptoms of middle-ear inflammation.”

Minor essential revisions:

I suggest the authors focus on temporal bone results and leave out pacifier use and age, since the latter probably represents a confounder and pacifier use cannot be concluded upon based on a selected clinical sample.
Response: Age is not discussed in the article to keep the focus on the temporal bone results as suggested by reviewer #2. We have maintained information on elements that explained the occurrence of AOM in the final hierarchical linear and nonlinear (multilevel) model (p.11; 3rd sentence of the last paragraph of the results section): “In the final model, higher risk of developing AOM was explained by severe suture restriction of the temporal bone, use of pacifier and younger age.” The use of pacifier in our cohort (71.9%) was comparable to the use of pacifier (75%) in the Niemela et al (1995) cohort study done specifically on this risk factor. However, since the focus of our study is on the relationship between suture restriction of the temporal bone and AOM, we discussed its contribution only in the final model (statement above).

**Bias should be more thoroughly discussed, since a major weakness is the lack of standardization when population was recruited. In particular, what would the effect of a non-validated method for temporal bone… And non-specific OM diagnosis mean in terms of misclassification bias?**

*Response:* We further discussed bias of the study, and specifically selection bias, loss in follow-up and diagnosis misclassification (p.14; 3rd, 11th and 18th sentences of the strengths and weaknesses of the study discussion section).

**I suggest to shorten the introduction and focus only on temporal bone an ET information. Further, shorten method section and focus the discussion.**

*Response:* As requested by the first reviewer, we think that the temporal bone must be described in relation with its immediate environment, both in the introduction and method section in order to understand the specific impact of suture restriction of the temporal bone and for reproduction purposes. As described previously, we have discussed further bias in the discussion.

**Table 2 and 4 can be left out and cited in txt only, tb 3 shortened.**

*Response:* Those three tables are related to the hierarchical linear and nonlinear models concept. Specifically, Table 2 is required to understand and justify variables included in the level one (ear-level) and in the level two (child-level). As suggested by the reviewer #2, we shortened Table 3 (p.25). Table 4 present the most interesting results for readers: risk factors that explain the occurrence of AOM in the final model.

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

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

*Response:* We have revised the article for language corrections and changes.

As required, the electronic submission includes this presentation letter and a copy of the revised manuscript.

We hope this manuscript receives favourable consideration.

Yours sincerely,

The authors