Author's response to reviews

Title: Prognostic factors of successful tympanoplasty in pediatric patients: a cohort study

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Version: 3  Date: 22 May 2012

Author's response to reviews: see over
Dear Dr. Neiman,

RE: MS: 1000402703691222

We submit our manuscript, entitled “Prognostic factors of successful tympanoplasty in pediatric patients: a cohort study” by Boronat Echeverría et al., for consideration for publication in BMC Pediatrics.

We have reviewed our manuscript and have added a paragraph concerning the limitations of the study design and all the possible limitation have been discussed.

**Responses to points:**

With respect to the definition of success, we mention: By incorporating a more functional definition of success (i.e., measured by means of three criteria: integrity of graft, hearing, and adequate air-filled space in the middle ear), the rate of success fell to 56.3%, compared to that (93.8%) found when only the integrity of the implant or closure of perforation was considered (Table 2). (Discussion pg. 10, p.1)

With relation to the point if this is the first article published on the validation of and index that predicts the result of tympanoplasty in children, we mention: To our knowledge, this is the first study to validate an index that predicts the result of tympanoplasty in children. (Discussion pg. 11; p 2)

On the age at time of surgery, we mention: It is important to point out that, in the present work, age at the time of surgery was excluded because this variable did not show sufficient weight in the model to predict the success of surgery. A limitation of this study would be the considering that the youngest patient included was five years of age. (Discussion pg. 11. P3)

When the definition of success was compared with the literature, we say: It is of note that, in that study, the definition of success was the same as the one used in the present study; one limitation of this definition is that the frequency of success is lower than when just one factor is considered. (Discussion pg. 12, p. 1)

With respect to the age of onset of chronic otitis, we mention: our study was small; however, the age of onset of chronic otitis media was associated with the success of tympanoplasty. (Discussion pg. 13, p.1)

When mention the patients with craniofacial dysmorphias ,we mention: Despite the small sample size in our study, this variable was related with the prognoses of the patients, one reason in this study would be that the increased technical difficulty encountered in performing tympanoplasty on patients with craniofacial dysmorphia tends to negatively affect the outcome of the surgery. (Discussion pg. 13, p2).
There are two paragraphs concerning limitations:
One limitation of this study was that, with the seven variables included in the predictive model, it was possible to predict only 81% of the successful outcomes. In the validation study, all patients with a successful evolution could be predicted. Nevertheless, the specificity was only 67%; therefore, it was expected that this model could not predict 33% of the failures. In the present study, 17% of the patients who had been predicted to have successful outcomes had, in fact, unfavorable post-surgical evolutions. However, the predictive model produced better results than did analyzing each variable separately. The model that included the three outcome criteria was the most equilibrated of these models was the one that incorporated all three parameters of success as the outcome criterion, because it predicted a greatest number of failures without affecting the percentage of predicted successes.
As mentioned above, the sample size of this study is its main limitation; thus, it will be necessary to include a greater range of patients in order to evaluate the benefit of the prognostic index presented here. As indicated by Sackett et al. [23], it is preferable to quantify the probability of success of a therapeutic intervention when explaining the intervention to a patient or to the patient's family members, because a calculated value provides them with a more objective tool with which to make a decision as to whether an intervention is appropriate or not. (Discussion pgs. 13 (p. 3)-14(p.1))

Reviewer comment

1. This journal is well designed paper. As described in the results the parameter used for the prognosis of success of tympanoplasty were not statistically significant except Craniofacial dysmorphia. (table I). It would be better the author explain the reason for that.

In the manuscript we comment in the discussion that: Despite the small sample size in our study, this variable was related with the prognoses of the patients, one reason in this study would be that the increased technical difficulty encountered in performing tympanoplasty on patients with craniofacial dysmorphia tends to negatively affect the outcome of the surgery (Discussion pg. 13, p.2)

2. Broken letter in the text.

~ With the modeling the $\beta$s were utilized to develop a predictive model of the

The symbol "$\beta$", which had been missing, has been inserted into Methods. (pg 7, p.3)

3. Why is the reason that the post op success of hearing results were evaluated with hearing gain decibels not with air-bone gap?
In the discussion we comment: Therefore, in this study, the auditory component of success was defined as a gain in auditory threshold of 10–20 dB, or more, and not as closure of the air-bone gap, the reason being that the latter is measured only by tonal audiometry, which was not possible to do with all the children in this study; we had technical problems with the children. For those cases in which tonal audiometry could not be done, those patients were assessed by using brainstem auditory evoked potentials. (Discussion pgs. 10 (p.1) & 11 (p.1))

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4. I agree with the key opinion of this paper the predictive model was better than analyzing each variable by separate. So I recommend the analysis of the failure cases(43.7%: in this study based on the three success outcome variables) with the 7 parameter. Because the surgeon might be interested with the most affecting factor for the results. For example) 30 failure cases mucosal infection (15%), age under ( %)

Inclusion of all patients with failed outcome would have resulted in an unwieldy table. In Table 4, we listed the clinical characteristics of the patients, in the validation study, who had failed outcomes

We have had the English reviewed throughout the manuscript and the formatting of our files revised.

We thank the reviewers for the comments and their advice.

We thank you in advance for your time in considering this article for publication in BMC Pediatrics.

Sincerely,

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