Author’s response to reviews

Title: Reliability and validity of measuring scale for postoperative complications in third molar surgery

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EDITOR COMENTS AND ANSWERS

Reviewer reports:

Franz Josef Strauss (Reviewer 1): The manuscript submitted by Aravena et al assessed the reliability and validity of a scale designed to quantify and measure postoperative complications after third molar extraction. The paper is interesting, well written and deals with an interesting issue, relevant for oral surgery. However, there are some concerns, requiring a revision of the paper, therefore it is not acceptable for publication in its present form, unfortunately.

It seems that authors have chosen to report a cross-sectional (which need to follow the STROBE guidelines of reporting). Several items seem missing.

RESPONSE (R): We thank the reviewers for their interesting comments. We attach STROBE Checklist in “Supplementary material”. We answer your comments below and highlight changes in yellow on the text.

Introduction: Line 60, empty space after (9).

R: Corrected

Affiliation: carlos.manterola @ufrontera.cl (there is an empty space between the last name and @)

R: Corrected
Keywords: Be consistent with typing, for example in Keywords: Postoperative Complications; Oral surgery, Third molar, etc.

R: Corrected

Materials and methods: Sample size calculation. Please provide additional info on subject selection. How many patients from each hospital were included? Please provide a table with sociodemographic characteristics of the subjects. Did the patients receive antibiotics or a rinse after surgery?

R: In relation to the sample size, the purpose of this study was to design a new measurement instrument of postsurgical complications in third molar surgery and the number of participants was based on the recommendations of Streiner and Norman (reference nº20), who postulated a minimum number of 10 observations per item. In this context, a non-random and voluntary selection of the participants was proposed. According to the authors, a minimum of 50 patients is required to evaluate 5 items.

In relation to the subjects’ characteristics, we have made a new table adding these for each hospital that participated in the study (Table 1)

According to the surgical protocol of Chilean hospitals, all patients receive antisepsis with a 0.12% chlorhexidine mouthwash before surgery. As a protocol, we added the following postoperative indications: “After surgery, the following postoperative medication was prescribed: an antibiotic of amoxicillin 500 mg every eight hours for 5 days and 400 mg ibuprofen sodium taken orally every eight hours for pain relief”.

Results:

Please revise the format in Table 1, it is impossible to see all the scores. Also in Table 3, Observer 2, Media? n?. In the same table, authors state that suppuration and erythema do not show statistical significance, that statement is inconsistent with the table, for instance, Suppuration = 0.012, it is not statistically significant? Why not? Please justify. With regards to the structural equations model please provide more information, a table would be nice. In table 5 please include the p values and the statistical test.

R: We thank you for all the suggestions. We have corrected the format of Tables 1 and 3.

According to the level of statistical significance of “Suppuration”, the analysis of the structural equations model used establishes the choice of those items that present a statistical significance and standardized load over 0.5. The likelihood of statistical differences is positive, but does not meet the recommended factor load (equal to or greater than 0.5) based on the recommendations of Streiner & Norman (reference nº 20). This topic is mentioned at the bottom of the table with the following legend "Standardized loadings> 0.5 for selected items"
In relation to the structural equations model, we have written the method explaining the meaning of the linear structural relations model (LISREL). In turn, we have added Table 7, which confirms that the values used by the method exceed the recommended value for the fit model (reference nº 17).

Table 5 is an interpretation of the CART algorithm method. This algorithm has been chosen because it gives rise to interpretable segments. This method selects the variables that explain the complication by seeking out the greatest separability between groups. In other words, it is possible to detect the optimal number of groups and their composition solely on the basis of the similarity between cases according to the scores obtained from the scale with the degree of severity of complications recorded by expert observers.

In the item Discussion, we have added a brief explanation of the result of the CART method to understand the formation of groups of postoperative complications and the ranges of the assigned scores.

Discussion:

The authors do not discuss about the small sample, risk of bias and external validity. However, they mention the paper of Terwee et al 2007, which states that 100 subjects is the minimum to ensure stability of the variance. Furthermore, just 9 patients with complications are sufficient to validate a questionnaire? This weakness should be addressed in the paper.

R: We are concerned the low rate of complications could bias the numbering and score assignment of the new scale. However, here the RMSEA value, which estimates the overall amount of error in the model, indicates an adequate fit of the model, which speaks to the predictive capacity of the instrument with the score achieved in cases of complications according to the clinical diagnosis assigned by the experts. For a better explanation, we have rewritten the limitations items of the study.

Alexandra Stähli (Reviewer 2): Material and methods:

The patient groups are not precisely characterized. Could the authors include a table with patient characteristics. Could the authors elaborate more about the different items of the scale according to which the patients were selected and distributed.

R: We added a new table with the sociodemographic characteristics of the patients (Table 1).

Regarding the selection of patients, all those who agreed to participate and who returned to the control on the 7th postoperative day were included. According to these criteria, among the three hospitals only 62 returned to the postoperative control and completed the study protocol.
For the reader it would be helpful to elaborate more about the surgical technique. How was the
wound closure performed? Did the surgeons use a drain? Was a primary closure performed?
What suture material was used?

R: We added details about the surgical protocol:

“Before all extractions, patients were given standard postoperative instructions. Initially,
extraoral antisepsis was performed with 2% chlorhexidine gluconate and intraoral antisepsis with
0.12% chlorhexidine gluconate mouthwash for one minute. Anesthesia was done by a standard
inferior alveolar nerve block and buccal blocks with 1:100,000 (Xylonor 2%, Septodont®). A
triangular mucoperiosteal flap was designed with an incision from the anterior border of the
mandibular ramus to the distal surface of the distobuccal cusp of the mandibular second molar
with a relieving vertical incision. Buccal osteotomy and tooth sectioning were carried out when
necessary with a round bur under copious irrigation with 0.9% sterile saline, following the
extraction performed. The flap was closed with interrupted 4-0 silk suture for the primary
closure”.

What postoperative procedure did the patients follow? Were the patients instructed to rinse with
chlorhexidine solution? Furthermore, it would be interesting to know if the patients received
postoperative antibiotics. Could the authors provide further detail about the postoperative
procedure.

R: We added details about the postoperative protocol:

“After surgery, the following postoperative medication was prescribed: an antibiotic of
amoxicillin 500mg every eight hours for 5 days and 400 mg ibuprofen sodium taken orally every
eight hours as pain relief.”

Next, as a reader it is not obvious how the complications were rated. Could the authors give
further information (maybe with pictures) how a complication was defined and according to
which parameters the patients were attributed to different scales? Furthermore, the authors
should be consistent with the definitions: without or mild complications appear in the manuscript
as one term.

R: We appreciate the reviewer's suggestion. The purpose of the scale is so the instrument can
discriminate the type of postoperative complication through the numerical allocation of the signs
and symptoms that the patient presents in the postoperative control. This purpose is verified by
the statistical model RMSEA that, by comparing the scores assigned by MFS and surgical trainee
with the clinical diagnosis assigned to the complication (Table 2), the instrument can assign the
type of complication.

However, the CART algorithm analysis classified “no complication” and “mild complication” as
only one category, according to the relationship between the summarized score of the scale and
diagnosis criteria of the experts.
For a better understanding of this explanation, we have added a paragraph with the detail of the diagnosis observed by the experts and their association with the classification assigned on the scale.

Results: Table 1 needs improvement. Please show all scores

R: Corrected

Discussion and Conclusion: Could the authors elaborate more about the ability of the scaling system to predict complications or was this not an issue?

R: Like previous suggestions, we have provided a text that explains the predictive method of the scale and the semiological and diagnostic characteristics that patients must have for their classification.

Next one wonders how the scaling system was in accordance with the patient’s perspective? Was there an accordance found? It should be discussed more in detail whether this small number of patients showing complications is really statistically solid to draw any conclusion about the validating system. This issue remains to be discussed.

R: As mentioned previously, one of the limitations was the number of participants who were able to complete the study, mainly due to the high demand for attention in the hospital centers. Nevertheless, the purpose of the study was to rely on the observation of experts who, in order to analyze interobserver reliability, had two observers per patient in the application of the scale. In turn, the number of complications (14.5%) is within the range of rates commonly reported in this type of surgery, which, according to the RMSEA analysis, was highly significant among the predictive capacity of the preliminary scale designed (Table 2) and its diagnostic criteria (Table 3) assigned by the experts (RMSEA fit value over 0.9 for predictability capacity of scale design). These topics are explained in the item “Discussion” for a better understanding.

Finally, we hope that this review has clarified the reviewers’ concerns and we are open to any comments that help improve the quality of this article.