Author's response to reviews

Title: Normative prosthodontic care need: does it impact the daily life of young Saudis with high level of oral diseases? a cross sectional study

Authors:

Maha El Tantawi (maha_tantawy@hotmail.com;mmmtantawy@iau.edu.sa)

Fahad Al-Harbi (falharbi@uod.edu.sa)

Version: 1 Date: 19 Jun 2017

Author’s response to reviews:

We thank the reviewers for going through our manuscript and their comments which help us improve it. The following are our responses to each comment:

Reviewer reports:

Haya Alayadi (Reviewer 1): This is an interesting domain to be assessed my only point is that the sample size calculation was not illustrated clearly

• Our response: we added more details in the first paragraph of the Materials and Methods (page 6 , lines 103-105) on how the sample size was calculated.

AlBandary AlJameel (Reviewer 2): Abstract

What does young adult mean? What was the youngest & oldest age (Line 18)

• Our response: In the 1st paragraph in Results (page 11, line 242), we indicated that 72.3% were less than 40. We also added the mean age in the Results of the Abstract (line 32). The youngest was 18.5, 83.4% were 45 year old and younger and 93% were 50 years old and younger and only 2.1% were 60+ years old (60-65).

The last sentence of abstract's conclusion does not fit well, also not related/supported by the study findings! (Line 44)

• Our response: we removed the sentence.

Material & methods
Regarding the risk factors in the "materials & methods" section, it would be better if justifications for recording variables into "binary" were provided!

- Our response: we added a justification (page 7, lines 144-146).

How was the variable "fluoride exposure" treated during analysis? What did the result reveal? (Line 103, 110)

- Our response: as shown in table 1, we used the “fluoride exposure” variable with its 3 categories (none, in tooth paste, others). We used this variable to describe the sample. The DAG did not identify it as a variable that should be adjusted as a confounder in the regression so we did not relate it to the outcome/s.

Questions of the impact of oral diseases on daily life, were they taken from validated questionnaire? If yes, why not mentioned? If no, how did you come up with such list of factors/items? Please provide explanation. (Line 112)

- Our response: all items in the questionnaire were based on the Basic Screening Survey questionnaire of the Association for State and Territorial Dental Directors as mentioned in page 6, line 106. This part applies to the 3 sections of the questionnaire.

Last paragraph need to be re-written/re-arranged to make it more readable! (Line 125)

- Our response: we rephrased the paragraph. We hope it is now more readable (page 8, lines 160-169).

The proposed conceptual framework was not easy to read and follow, especially the absence of links or suggested pathways. The author can massively improve this important part. (Line 133)

- Our response: we added a new figure (now Figure 1) to show the potential pathways between outcomes and exposures/ confounders. It represents the DAGs that were used to visualize the network of variables associated with the outcomes and to select those that should be adjusted as confounders in the regression analysis.

Results

Table 1, the number of lost teeth: mean & SD is 2.0 & 3.9 respectively, can you double-check it. Why SD is higher than the mean? Was there any skewed data?

- Our response: yes, the values reported in Table 1 are correct. Those who had lost at least one of their teeth represented 47.4% so that slightly more 50% had no teeth loss at all which skew the data.
It would be easier for the reader to follow your figure if you label it in the same order of information presented, so write Impact of untreated decay, need for periodontal care, and need for prosthetic care (adjusted & unadjusted) on daily life aspects. (Line 454)

If the text were better explained, may be I would understand the figure 1 more easily! Revise the arrows in the figure

May be you need to make it clear (probably two figures) factors that affect prosthetic care and then link it to its impact on daily life!

• Our response: we replaced this flow chart with the 2 DAGs (Figure 1 a and b) to show the direction of the association and at the same time show how the software helps select the confounders that need to be controlled in the models.

Discussion

You cannot generalize the statement for the whole adults in the Eastern Province; but you can say 46.7% of the study sample! (Line 225)

• Our response: rephrased as suggested, line 288.

Last sentence of the first paragraph "Our findings thus partly support the study hypothesis where higher disease level was associated with higher normative need for prosthetic care but not with impact on daily life" this might suggest that normative needs assessment could overestimate the treatment need as it is not affecting patients' quality of life, therefore treatment is not needed!! (Line 230)

• Our response: yes, we agree with the reviewer’s point of view and we raised a related point in Discussion (lines 315-318) and we also referred to other treatment approaches that aim at restoring function as opposed to restoring each lost tooth (lines 374-375).

"Our results show that almost all those with teeth loss (47.4%) needed prosthetic care (46.7%) indicating that they have not sought care to replace their loss" (Line 243); might also mean that normative need assessment is overestimating the treatment need and should not be considered as a main indicator of treatment need (we should also consider the perceived or expressed need).

• Our response: yes, again we agree with the reviewer’s point of view and we referred to the same idea as mentioned before in lines 315-318).

"In our study, neither prosthetic care need nor the numbers of lost teeth were independently associated with daily life aspects although some effect was due to the underlying diseases" (Line 284); the absence of association might be a result of location of lost teeth. Losing one or two posterior teeth while having a sufficient function (chewing, speaking, not affecting the appearance) might not have any negative impact on daily activities and this could explain your case! Have you collected any data on the location of lost teeth?
Our response: again we agree with the reviewer. We did not assess the location of lost teeth and we acknowledged that this may be the reason why our results where there was no association differed from other who studied the relation with respect to location of lost teeth (lines 360-363).

"Our results can thus be generalized to young populations with high levels of oral diseases in spite of the accessibility of health care services" (Line 300); that is difficult to confirm as the sampling did not explain the randomization process of selecting your participants although you mentioned "A random sample was selected stratified by gender" (Line 83) more details are needed here

Our response: we based the generalizability statement on the sample profile as described in Results and in Table 1. We directly used the findings that the mean age was 33 years with 72% younger than 40 years, more than 60% had untreated decay and need for periodontal care at the same time that all Saudis have access to health care under universal coverage.

Erin Masterson (Reviewer 3):

I appreciate the careful approach taken by the authors, specifically inclusion of a conceptual framework, but think the framework needs further development and more critical evaluation of the role of covariates in each analysis. These considerations may result in needing to re-analyze the data. The definition of the primary variable, "need for prosthetic care", should be articulated clearly and early on in the manuscript and incorporation of other oral health conditions should be cautiously incorporated into analyses given the relationship between caries or perio with tooth loss.

Our response: we responded in details to the Reviewer’s comments in the following sections.

Abstract

- define "need for prosthetic care" and "normative" -use "normative" consistently if it has implications on the definition of prosthetic care; otherwise delete

Our response: we defined the “need for prosthetic care” in the 2nd paragraph of Methods (lines 108-116). We believe it has implications since the level and impact are expected to differ if patient perspective is used and we commented on this in lines 315-318.

- "young" in Background, then "adult" in Methods and Results sections - clarify (perhaps "young adults" or explicitly state age range of study sample)

Our response: we added the mean age in the Results of the Abstract (line 32).
- Background suggests focus is on "need for prosthetic care" but Results report other oral health outcomes --> revise Methods to reflect approach

  • Our response: In Methods, we indicate that there were two outcomes: need for prosthetic care and its impact on daily life. We explained that we studied the association of these outcomes with several potential risk factors and confounders. In Results, we report respectively on the outcome (1st line of Results in Abstract), then on the association between outcomes and risk factors. We postponed the reporting on the prevalence of these risk factors and confounders to the Results itself rather than the Results of the Abstract.

- include exposures assessed and specific outcomes (oral health, and 6 daily life aspects);

  • Our response: we added “exposures” in the Methods of the Abstract (lines 23 and 24). The outcomes are already specified in line (originally 27-29).

- "impact on daily life" = "quality of life"?

  • Our response: Yes, we modified to make sure this term was used all through the manuscript except when we referred to specific terms used in other studies.

Intro

- P4L51: specify definition of "prosthetic care" in first sentence

  • Our response: we added the definition as suggested (lines 52 and 53)

- P4L52-53: seems obvious, but should include access to care/ability to pay/time to seek care as important factors in obtaining treatment

  • Our response: added “access to care” to the sentence. It covers issues of affordability and time (line 62).

Methods

- P5L88: target ___(sample size?)___ ..... 

  • Our response: yes, this is the sample size. We explained later in Results how much of this became actually available for analysis (line 236).

- upper age limit inclusion criteria to ensure young adult pop?

  • Our response: there was no upper age limit. The present study was conducted along another larger one (line 91). In that main study, adults (>18 years old) were included. We used
the data available from that study and the population (representing the Saudi population) was mostly young with 72.3% less than 40 years of age.

- P6L100: suggest "demographic variables"
  - Our response: changed as suggested (line 131).

- P6L100: suggest "sex" instead of "gender"
  - Our response: change as suggested, here and all through the manuscript (line 131).

- P6L103: these are not risk factors for all oral diseases, consider re-phrasing to be more accurate
  - Our response: rephrased as suggested (line 135).

- P6L107: suggest "brushing habits"
  - Our response: modified as suggested (line 140).

- P6L109: suggest "sugar sweetened beverages"
  - Our response: modified as suggested (line 141).

- P6L110: suggest "topical fluoride" since ingested fluoride is not included in the description
  - Our response: modified as suggested (line 142).

- P6L114: suggest "if each of these problems" if this is accurate
  - Our response: modified as suggested (line 149).

- Describe clinical exam before Questionnaire since the "need for prosthetic care" is the focus of the study
  - Our response: modified as suggested, clinical exam now comes first (lines 116-123).

- the definition of "need for prosthetic care" or "normative need for prosthetic care" is not included in the Materials and Methods section - the description (currently under Conceptual Framework P7L135-140) should be moved to the beginning of the paragraph that starts on P6L116 since this is the primary outcome of interest/focus of the study
  - Our response: moved it as suggested, definition is now in lines 108-116.

- consider simplifying the definition of "need for prosthetic care" to simply stating criteria #1 from citation 16 (how were "ill fitting or not esthetically acceptable" assessed in order to exclude criteria #2 anyway?)
Our response: we showed how the cited study defined the need then how it was modified based on our sample so that we don’t attribute to them a definition they did not use. The percentage of those with criterion #2 was very small and would make no difference either way. For those who had an appliance, we clinically examined and asked if there were problems, such as ill-fitting or esthetical acceptability.

- Revise P6L116-124 so that, First, the primary outcome/condition of focus is defined ("need for prosthetic care", per prior bullet). Next, describe the exam that generated the two variables for determining "need for prosthetic care" (prosthetics and missing teeth). Third, note that additional oral health measures were included in the exam (decay and perio).

- move content in the Conceptual Framework section (P7L140-150) to Background and include citations for established associations/relationships between variables

- P7L142: suggest rephrasing sentence - "in turn" seems to suggest that these things result from caries whereas you mean to say the opposite

- P7L145: specify "Some of these factors"

- the Conceptual Framework section should address if/how covariates are related to the exposures and outcomes of primary interest (need for prosthetic care, impact on quality of life)

- Our response: we added the DAG (Figure 1 a and b) showing these associations instead of the flow chart we previously used.

- P8L150: need citation for statement "known to increase as the number of lost teeth increases."

- P8L160: too much reliance on black box/computerized approach to selecting covariates in models and their roles in the relationships of interest, such as confounders or for statistical precision (eg, P8L168: "The software suggest"). Additionally, distinction should be made between associations and established causal relationships. Daggity could be used and cited as a tool for developing the conceptual framework but the extensive description on P8L160-169 (and such a heavy reliance on its output) is not warranted
Our response: we agree with the reviewer that variables should not be included in a model just because software can accommodate them or marks them for inclusion regardless of their relevance to the study question. We revised the manuscript to remove any undue mention of causality since ours is a cross sectional study and all the tested relationships are associations. We rephrased the parts that implied we blindly followed the software since this did not happen (lines 178-180 and 210, 215-219). We also reduced the focus in this paragraph on the software and added the graph itself showing the frameworks for the models and how the graphs helped us select the confounders that should be controlled in the models. The other variables in the networks shown in the DAG would not confound the associations we studied and therefore, do not need to be included in the models.

- Revise DAG: should have one direction as noted in Analysis subsection (PP8L156), suggest referencing the work of Judea Pearl when making these revisions. Specifically, suggest making arrows go from left to right or from top to bottom, show how the covariates are related to the outcomes (need for prosthetic care, quality of life)

Our response: The DAGs (Figure 1 a and b) with arrows showing direction of association are added.

- P9L174: adjust for age when "need for prosthetic care" is outcome (you state this association in your Intro/Background section)

Our response: yes, we agree with the Reviewer that age is a potential confounder for the “need for prosthetic care” along with several other variables. Its inclusion, however, was not warranted by the DAG analysed since its inclusion/exclusion does not bias the association between outcome and exposure in the presence of the other variables in the DAG network. This is why we explained in the manuscript that it is important to identify the confounders that should be adjusted in the regression analysis for reliable estimates to be obtained. We do not deny that age and several other factors are potential confounders. The major idea behind our analysis plan was how we selected the variables to control as opposed to including all potential confounders.

- P9L174: "MSA set" - actual measures should be listed here

Our response: the confounders were identified only after the DAG analysis. We considered it, therefore, part of Results and listed them when reporting the results of DAG (lines 254-258).

- P9L175-178: if there are multiple exposures considered, this should be reflected consistently throughout the manuscript; the Abstract and Intro suggest the interest is focused on how the need for prosthetic care influences quality of life. You could consider adding the influence of other oral conditions on quality of life as a sub-analysis. However, as you state on P8L148, you must also address the fact that the influence of oral diseases and need for prosthetics on quality of life are difficult to separate.

Our response: we agree with the review about the complexity of the network of variables and their association with the need for prosthetic care and how this affects daily life. Because of
their intertwining of factors, we used DAG to avoid adding unneeded factors that would result in spurious associations. The need for prosthetic care was not per se responsible for the impact on daily life but it was our main outcome not the other oral diseases. We added in the Aim of the Abstract (line 20) and also in Intro (line86 and 87) that we assessed the influence of need for prosthetic care in conjunction with the 2 diseases on impact on daily life.

- P9L178: "MSA set" - actual measures should be listed here; explain why are the "number of teeth lost" adjusted for? Is age associated with quality of life (P10L219 indicates age is only related to feeling pain)? If not, why is it adjusted for? Same questions apply to SES. Adjusting for factors only associated with the exposure will bias your results.

• Our response: we added the DAGs showing the network of factors that are associated with each other and with the outcome. The same DAGs show the variables that need to be included in the models and adjusted thus explaining the reason why we selected some factors but not others for inclusion in the model. The codes behind the DAGs are also included as a supplement to explain the logic behind the construction of the networks in the DAGs. The “number of teeth lost” should not be adjusted for since it was not identified by the DAG. Age is associated with feeling pain which is one of the aspects of daily life that may be associated with the outcome. We did not adjust only for factors that had significant association. In the first model, we adjusted for dental visits last year and health insurance and they were not significantly associated with the outcome. The factors selected to be included in the models and controlled are the minimal group that would block the confounding associations in the network. If these are adjusted, the confounding effect is removed.

- P9L180: statistics - address concern for multiple comparisons (6 outcomes by 3 exposures in the second analysis)

• Our response: we added further explanation (lines 229 and 230) that we adjusted for multiple comparisons across the 6 outcomes. For each outcome, the multivariable analysis already indicates that the exposures were simultaneously considered and adjusted for.

- P9L180: rephrase sentence on interpretation of statistical thresholds, rather than "set" perhaps state that p-values less than 0.05 were considered statistically significant

• Our response: rephrased as suggested (line 233).

Results

- given nearly 20% of the study sample has incomplete data, the existing data should be evaluated for selection bias to the extent possible

• Our response: we explained the reasons that some of the data were missing. We also added a sentence in the beginning of Results (lines 240 and 241) indicating that comparing the two subsets showed no evidence of selection bias.
- given the motivation for this paper was that little evidence for prosthetic need is available in younger (adult) populations with high prevalence of dental decay, it is confusing why nearly 30% of the study sample is over 40 years of age. If age is an effect modifier or risk factors for need for prosthetic care, should the analysis be stratified by age or should the analysis be restricted to the age bracket of interest (younger adults)?

- Our response: we explained that the data was collected along a larger study assessing the oral health of individuals in the Eastern Province. We did not, therefore, restrict inclusion to only those in a specific age range...just >18 years of age. Whereas 72.3% were less than 40 years old, 83.4% were 45 year old and younger and 93% were 50 years old and younger and only 2.1% were 60+ years old (what is known as older adults). Because of the small number of participants in age groups that are considered not young, it was not possible to stratify by age and we obtained unreliable estimates with huge confidence intervals. The participants in our sample were thus mostly young adults with a smaller percentage of adults/ middle aged adults....

- P9L192-195: suggest new paragraph to describe the oral health outcomes of the study sample; it would help readers to directly connect the relationship between missing teeth and prosthetic appliances with "needed prosthetic care". In this analysis, "need for prosthetic care" is essentially having at least one missing tooth (that hasn't yet been addressed with prosthetics)

- Our response: modified as suggested and shifted the clinical information to a new paragraph (lines 248-250).

- P10L209-213: In your multivariate analysis, you have adjusted for causes of the tooth loss/exposure (which are also directly associated with quality of life/outcome) so you could expect that the relationship you observed between "need for prosthetic care" and quality of life would be attenuated. What is the question you want to answer? This should guide your analytic decisions: are you interested in the quality of life impact of the need for prosthetic care or on understanding how need for prosthetic care influences quality of life above and beyond the influence of oral disease?

- Our response: just like the Reviewer indicated: we wanted to say that in this young population with the profile we described, the need for prosth care itself would have an impact on daily life that is secondary to the diseases that caused this prosthetic need. This is why we concluded that it should be a priority to control the diseases which impact daily life and at the same time lead to need for prosthetic care rather than just focus on prosthetic need.

- Figure 2 - I find this very difficult to interpret, would prefer to see descriptions of the quality of life measures in Table 1 and a Table 3 with regression results (and numeric 95% CIs) for the assessment of need for prosthetic care --> quality of life

- Our response: we shifted the description of impact on daily life to a new table (Table 2) since adding the 3 levels of frequency of the 6 aspects would have increased table 1 by 18 more rows making it very lengthy and bulky. We also added a new table (Table 4) to show the regression estimates and CIs of the associations for the 2nd outcome.
Discussion

- address role of universal care coverage in findings, generalizeability to other populations

  • Our response: we added this in the generalizability statement (line 370).

- include a more detailed description of how other studies measure "need for prosthetic care"

  • Our response: we added examples of how others defined need for prosthetic care (lines 313-315).

- for next steps in this area of work, or if this were longitudinal data, what statistical approaches may have been more appropriate?

  • Our response: we added directions for future research in (lines 373-376). We suggested examining how the high level of caries and periodontal disease might affect the need for prosthetic care and how using the shortened dental arch approach might modify the impact on daily life. It might be interesting to follow up how the difference in the loss of teeth by time might reflect on the impact on daily life.

Conclusions

- P14L313-314: suggest reconsidering whether need for prosthetic care (or "tooth loss without prosthetics") truly has no negative impact on quality of life based the reported results (see comment above on multivariate analysis for need for prosthetics --> quality of life analysis)

  • Our response: we based our conclusion on the results we obtained which as the Reviewer previously indicated depended on the analysis plan we followed. Our point was that the need for prosthetic care is a symptom and that if resources are directed to symptomatic treatment where rehabilitative services are provided without addressing the preventive need, this downstream approach has little chance of addressing the roots of the problem. This argument, however, needs further testing in future studies and maybe clinical/field trial can help decide which approach should be followed. The various aspects (patients’ preferences, economic evaluation and health care system preparedness) need to be studied.

Throughout the manuscript:

- be careful with use of "effect" (implies causality) vs. "influence" or another term that does not imply causality when not warranted throughout

  • Our response: we revised and replaced as suggested.

- define what MSA means or eliminate acronym/terminology and just articulate the reason for including each covariate in the model
Our response: we removed the acronym MSA as suggested by the Reviewer and showed the DAGs and how it helped select the confounders that must be controlled in the models. Including all potential confounders carries the risk of introducing spurious associations. The focus of the analysis plan as in a DAG analysis was to select the minimum number of confounders that are associated with other variables as well as with the outcome and exposures so that by adjusting them, the risk of confounding bias is reduced if not eliminated. The reason these specific confounders were selected is related to how the structure of the network of associations in each model was made and is seen in both DAGs. These confounders—when controlled—would break the confounding associations seen in the network.

- be consistent in the research questions addressed (the evaluation of caries and periodontal disease is not mentioned until the end of the Methods section)

Our response: the main question of the study as indicated in the aim is to assess the need for prosthetic care, which factors are associated with it and how it is associated with daily life. We added untreated decay and need for periodontal care in the Aim (Abstract, line 20 and at the end of the Introduction, lines 86 and 87).

- if the only exposures of interest in the first analysis (risk factors for need for prosthetic care) are untreated decay and need for periodontal care, consider stating "oral disease and need for prosthetic care" (instead of generally referring to "associated factors", such as is done in the Abstract) as the focus of the study throughout; Alternatively, incorporate evaluation of other factors, perhaps including demographic and oral health risk factors.

Our response: the multivariable model (Table 3) includes other factors besides caries and periodontal disease, specifically education, dental visits last year and health insurance. We rephrased the aim of the Abstract and the Intro to include untreated decay and need for periodontal care.