Oral Diseases - Manuscript ODI-04-19-OM-7089

From: Oral Diseases (onbehalfof@manuscriptcentral.com)

To: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com

Cc: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com; taufan-b@fkg.unair.ac.id; rahul.nair@adelaide.edu.au; ankur.singh@unimelb.edu.au; drkaushiksengupta@gmail.com

Date: Wednesday, 24 April 2019 at 11:56 am GMT+7

24-Apr-2019

Dear Dr Hariyani,

Your manuscript entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia" has been successfully submitted online to Oral Diseases.

Your manuscript ID is ODI-04-19-OM-7089.

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Yours sincerely,

Michael Willis
Editorial Assistant
Oral Diseases

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Oral Diseases - Decision on Manuscript ODI-04-19-OM-7089

From: Oral Diseases (onbehalfof@manuscriptcentral.com)

To: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com

Cc: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com; taufan-b@fkg.unair.ac.id; rahul.nair@adelaide.edu.au; ankur.singh@unimelb.edu.au; drkaushiksengupta@gmail.com

Date: Monday, 5 August 2019 at 05:07 am GMT+7

04-Aug-2019

Dear Dr Hariyani,

Manuscript ODI-04-19-OM-7089, entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia", which you submitted to Oral Diseases, has now been reviewed. The comments of the reviewer(s) are included at the foot of this letter.

The reviewer(s) have suggested some major revisions to your manuscript. Therefore, I invite you to respond to the reviewer(s)' comments and revise your manuscript accordingly, if possible within the next 90 days, although there is no guarantee of acceptance of the revised manuscript, i.e., it will need again to go through full peer review.

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You are welcome to send to the editorial office any feedback you may have about the editorial and peer review process.

Once again, thank you for submitting your manuscript to Oral Diseases and I look forward to receiving your revision in due course.

Yours sincerely,

Giovanni Lodi, DDS, PhD
Editor-in-Chief, Oral Diseases

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
Dear authors,

Thank you for your submission of the manuscript ODI-04-19-OM-7089 titled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia". This is a very interesting study which aimed to demonstrate the relationship between the prevalence of RAS and depression in the Indonesian population using a nation-wide questionnaire (IFLS) and CES-D scale. The grammar, clarity, and structure of the manuscript was excellent and the analysis and discussion was very interesting as well. Included below are some issues pertaining to the manuscript:

Major issue:
1.Page 5, line 15 to 17 " presence of absence of RAS was self-reported by the respndents based on their experience of the disease in the past four weeks".

Based on the information above, there is minimal evidence to support whether there were firstly any oral lesions, and if so, how does the self-reported survery support a specific diagnosis of a condition such as RAS, which is a recurring/episodic ulceration of the oral mucosa (typically non-keratinized)? Is there is a sample questionnaire to support specific questions asked which favor a diagnosis? These could be ulcers of other etiologies such as infection (Herpes Simplex Virus), vesicubullous disorders, trauma, chemical burns, or medications. Ulcer itself can often be misreported as erosions or even dysesthesias (in the absence of clinical findings).

Additional data to support diagnosis of RAS or oral ulcers is important to support evidence of this otherwise well-written manusript.

Minor issue: (more to help direct structure of introduction)
Introduction
Recommend structuring the introduction to include:
Parapgraph 1- Introduction to RAS, global burden, pathophysiology and treatment
Paragraph 2- Literature on the association of RAS and prevalence studies.
Paragraphs 3- Literature on the association of RAS and depression studies.
Paragraph 4- Gap of knowledge, hypothesis, and objective.

Thank you for your submission of this rather interesting manuscript.

Sincerely yours.

Reviewer: 2

Comments to the Author
Some of the statements made are not supported by the cited references. Examples:
- Page 4 line 8-13: Natah et al. did not mention parafunctional habits nor depression in their publication in relation to RAS. This concept is repeated on page 10 in the discussion citing older references. Furthermore, the authors should carefully review their cited references in regards to the proposed role of trauma and RAS, specifically Akintoye and Greenberg (2014), which is cited multiple times elsewhere in the manuscript.
- Page 4 line 13-24: No references cited.

There is a major design flaw in the reporting of the results using the shortened 10-question CES-D. In materials and methods the authors divide the scores of the CES-D into different groups to categorize the severity of depression (page 5, line 34) , however that is not how CES-D is used or described in the literature. The cutoffs reported in the literature are to determine whether the patient may have depression or not. A score of 2 does not mean that the subject has low level depression, rather the subject does not score high on the evaluation of depressive symptoms. The mean and range of CES-D scores for the subjects who scored > 10 was also not given; the upper limit of the shortened CES-D is 30. Another design flaw was the self-reported stress. To adequately reduce this confounding factor a validated questionnaire such as the perceived stress scale would have been more appropriate. The self-reporting of RAS is another major design flaw and it is not clear how this was asked of the subjects. Particularly, if the subjects were given any literature, pamphlet, or any reading material and/or pictures to explain what RAS is and improve self-reporting reliability. An indicator of this issue concerning the reliability is the age range up to 97 years of age.

The statement that “our findings supports this theory as RAS among Indonesian may be one type of somatic symptoms caused by depression” (page 11, line 22) is inadequate.

Oral Diseases - Manuscript ODI-04-19-OM-7089.R1

From: Oral Diseases (onbehalfof@manuscriptcentral.com)

To: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com

Date: Tuesday, 3 September 2019 at 05:33 pm GMT+7

03-Sep-2019

Dear Dr Hariyani,

Your revised manuscript entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia" has been successfully submitted online and is presently being given full consideration for publication in Oral Diseases.

Your manuscript ID is ODI-04-19-OM-7089.R1.

Please mention the above manuscript ID in all future correspondence or when calling the Editorial Office with questions. If there are any changes in your postal or e-mail addresses, please log onto ScholarOne Manuscripts at https://mc.manuscriptcentral.com/odi and edit your user information accordingly.

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Your manuscript will first be checked by our editorial office staff to ensure that it complies with our author guidelines. Following this it will be sent back to the handling Associate Editor who will consider it further and decide whether or not to send it back to the original peer reviewers. We will send a decision to you as soon as we can, and usually within four weeks.

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Yours sincerely,

Michael Willis
Editorial Assistant
Oral Diseases

Oral Diseases - Decision on Manuscript ODI-04-19-OM-7089.R1

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Date: Thursday, 26 September 2019 at 09:21 pm GMT+7

26-Sep-2019

Dear Dr Hariyani,

Manuscript ODI-04-19-OM-7089.R1, entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia", which you submitted to Oral Diseases, has now been reviewed. The comments of the reviewer(s) are included at the foot of this letter.

The reviewer(s) have suggested some major revisions to your manuscript. Therefore, I invite you to respond to the reviewer(s)' comments and revise your manuscript accordingly, if possible within the next 90 days, although there is no guarantee of acceptance of the revised manuscript, i.e., it will need again to go through full peer review.

To revise your manuscript, log onto https://mc.manuscriptcentral.com/odi and enter your Author Centre where you will find your manuscript title listed under "Manuscripts with Decisions". Under "Actions", click on "Create a Revision". Your manuscript number has been appended to denote a revision.

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You are welcome to send to the editorial office any feedback you may have about the editorial and peer review process.

Once again, thank you for submitting your manuscript to Oral Diseases and I look forward to receiving your revision in due course.

Yours sincerely,

Giovanni Lodi, DDS, PhD
Editor-in-Chief, Oral Diseases

Associate Editor
Comments to the Author:
(There are no comments.)

Reviewer(s)' Comments to Author:

Reviewer: 1

Comments to the Author
Hariyani et al have submitted an interesting manuscript on an Indian population-based self-survey study investigating the association between depression and recurrent aphthous stomatitis. The comments made in the previous version appear to have been addressed.

Reviewer: 2

Comments to the Author
Unfortunately, some flaws within the study persist.
1. The reliability of RAS self-reporting. The authors report that the questionnaire implies recurrent ulcers consistent with the diagnosis of RAS. The fact that it is implied and not explicitly stated is worrisome. Without knowing the exact verbiage and details in the questionnaire used, it is not possible to determine the reliability of the questionnaire and, consequently, if the authors are effectively measuring what they intended on measuring in this study.
2. The inadequate description of CES-D results. The authors cannot assume depression when an appropriate cutoff has not been validated and this study cannot establish that they are indeed clinically depressed, as no clinical evaluation for depression was performed to confirm it. The purpose of a cutoff would be to answer the “yes/no” question of clinically depressed or not. The CES-D does not to categorize the severity of depression. Therefore, to divide the groups into different levels of depression is inappropriate. It is more appropriate to report these as depressive symptoms and describe the groups in such terms as well as adjusting the title of the manuscript.
3. The statement on page 11 line 54 “Our findings suggest that RAS among Indonesians may be one of the somatic symptoms caused by depression” remains inadequate. It would be more appropriate to add “in susceptible individuals” as other oral findings could be a result of parafunctional habits such as morsicatio, fibromas, and frictional keratoses.

Oral Diseases - Manuscript ODI-04-19-OM-7089.R2

From: Oral Diseases (onbehalfof@manuscriptcentral.com)

To: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com

Date: Sunday, 13 October 2019 at 03:02 pm GMT+7

13-Oct-2019

Dear Dr Hariyani,

Your revised manuscript entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia" has been successfully submitted online and is presently being given full consideration for publication in Oral Diseases.

Your manuscript ID is ODI-04-19-OM-7089.R2.

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Yours sincerely,

Michael Willis
Editorial Assistant
Oral Diseases

Oral Diseases - Decision on Manuscript ODI-04-19-OM-7089.R2

From: Oral Diseases (onbehalfof@manuscriptcentral.com)
To: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com
Cc: ninuk_hariyani@yahoo.co.id; ninukhariyani@gmail.com; taufan-b@fkg.unair.ac.id; rahul.nair@adelaide.edu.au; ankur.singh@unimelb.edu.au; drkaushiksengupta@gmail.com
Date: Wednesday, 5 February 2020 at 06:08 pm GMT+7

05-Feb-2020

Dear Dr Hariyani,

It is a great pleasure to accept your manuscript entitled "Depression and recurrent aphthous stomatitis – evidence from a population-based study in Indonesia" in its current form for publication in the journal Oral Diseases.

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You are welcome to send to the editorial office any feedback you may have about the editorial and peer review process.

On behalf of both Senior Editors of Oral Diseases, we thank you again for your fine contribution, and we look forward to your continued contributions to the journal and its increasing global reputation.

Yours sincerely,

Giovanni Lodi, DDS, PhD
Editor-in-Chief, Oral Diseases

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26th August 2019

Giovanni Lodi, DDS, PhD,
Editor-in-Chief,
Oral Diseases

Dear Dr. Giovanni Lodi,

We are very grateful to you for the opportunity to revise our manuscript, and we acknowledge the time spent by the editors and reviewers in commenting on this paper. Please find below a point-by-point reply to the reviewers' comments. We hope that we have now addressed the concerns raised and believe that the manuscript has been substantially improved.

Thanking you.

Yours sincerely,

Ninuk Hariyani (Corresponding Author)

Lecturer and researcher
Department of Dental Public Health
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Reviewer: 1

Comment 1:- This is a very interesting study which aimed to demonstrate the relationship between the prevalence of RAS and depression in the Indonesian population using a nation-wide questionnaire (IFLS) and CES-D scale. The grammar, clarity, and structure of the manuscript was excellent and the analysis and discussion was very interesting as well.

Response:- Thank you very much for your positive feedback on our manuscript.

Comment 2:- Page 5, line 15 to 17 "presence of absence of RAS was self-reported by the respondents based on their experience of the disease in the past four weeks". Based on the information above, there is minimal evidence to support whether there were firstly any oral lesions, and if so, how does the self-reported survey support a specific diagnosis of a condition such as RAS, which is a recurring/episodic ulceration of the oral mucosa (typically non-keratinized)? Is there a sample questionnaire to support specific questions asked which favour a diagnosis? These could be ulcers of other etiologies such as infection (Herpes Simplex Virus), vesiculobullous disorders, trauma, chemical burns, or medications. Ulcer itself can often be misreported as erosions or even dysesthesias (in the absence of clinical findings). Additional data to support diagnosis of RAS or oral ulcers is important to support evidence of this.

Response:- This study was a secondary data analysis from a nation-wide study. The question about RAS was asked in Indonesian language using a term that is a common term for RAS among lay persons. Among Indonesians, it is not a common practice to seek dental care for RAS. However, the term for RAS in the Indonesian language used in the questionnaire implies recurrent ulcer, consistent with the diagnosis of RAS. We have now added the explanation of this measurement in page 5 line 108-110. We also note this as a limitation of our study (page 12 line 274-277).

Comment 3:- Recommend structuring the introduction to include: Paragraph 1- Introduction to RAS, global burden, pathophysiology and treatment

Response:- Thank you for the suggestion. We have revised the introduction section accordingly (page 3 line 54-58).

Comment 4:- Recommend structuring the introduction to include: Paragraph 2- Literatures on the association of RAS and prevalence studies.

Response:- Due to the fact that there are variations in RAS prevalence caused by ethnic and socioeconomic groups of samples and the prevalence measure used (cited in page 3 line 59-61), the RAS prevalence studies presented here were limited to studies that were comparable and meaningful.

Comment 5:- Recommend structuring the introduction to include: Paragraphs 3- Literature on the association of RAS and depression studies.

Response:- Thank you for the suggestion. Corresponding changes are incorporated in the revised introduction (page 4 line 72-76).

Comment 6:- Recommend structuring the introduction to include: Paragraph 4- Gap of knowledge, hypothesis, and objective.

Response:- Thank you for the suggestion. The suggested change is incorporated in paragraph 4 of the introduction section (page 4 line 90-91).

Reviewer: 2

Comment 1:- the statements made are not supported by the cited references. Page 4 line 8-13: Natah et al. did not mention parafunctional habits nor depression in their publication in relation to RAS. This concept is repeated on page 10 in the discussion citing older references.

Response:- Thank you very much for identifying this wrong citation. It has been revised on page 4 line 77-80.

Comment 2:- the authors should carefully review their cited references in regards to the proposed role of trauma and RAS, specifically Akintoye and Greenberg (2014), which is cited multiple times elsewhere in the manuscript.

Response:- Thank you for suggesting this. The proposed role of trauma and RAS have now been added in the discussion section (page 10-11 line 243-246) and in the reference list (page 20 line 409-411).

Comment 3:- the statements made are not supported by the cited references. Page 4 line 13-24: No references cited.

Response:- Thank you. The appropriate reference has been added in the introduction session (page 4 line 80-81) and included in the references list (page 18 line 343-344).

Comment 4:- There is a major design flaw in the reporting of the results using the shortened 10-question CES-D. In materials and methods the authors divide the scores of the CES-D into different groups to categorize the severity of depression (page 5, line 34), however that is not how CES-D is used or described in the literature. The cut offs reported in the literature are to determine whether the patient may have depression or not. A score of 2 does not mean that the subject has low level depression, rather the subject does not score high on the evaluation of depressive symptoms. The mean and range of CES-D scores for the subjects who scored > 10 was also not given; the upper limit of the shortened CES-D is 30.

Response:- Thank you for the suggestion. The method for calculating the CES-D data (previous file on page 5, line 34; in the current file, page 5, line 114-121) followed protocols advised previously (Tampubolon, G., & Hanandita, W. (2014). Poverty and mental health in Indonesia. *Social Science & Medicine, 106*, 20-27. doi: 10.1016/j.socscimed.2014.01.012). We justify the use of different cut offs in page 5-6 line 121-129. The mean and range of CES-D scores for the subjects who scored > 10 has now also been added in the descriptive result (page 7 line 161-162).

Comment 5:- Another design flaw was the self-reported stress. To adequately reduce this confounding factor, a validated questionnaire such as the perceived stress scale would have been more appropriate.

Response:- This study was a secondary data analysis of a nation-wide study. Due to the nature of large-scale study, a single item global measure of stress was used here. Prior study has found the use of such a question valid and reliable for such a scenario (Littman, A. J., White, E., Satia, J. A., Bowen, D. J., & Kristal, A. R. (2006). Reliability and validity of 2 single-item measures of psychosocial stress. *Epidemiology*, 398-403). This is now added to the discussion (page 12 line 278-279) and in the reference list (page 19 line 362-363). This limitation is also been added to the text on limitations of this study (page 12 line 279-281).

Comment 6:- The self-reporting of RAS is another major design flaw and it is not clear how this was asked of the subjects. Particularly, if the subjects were given any literature, pamphlet, or any reading material and/or pictures to explain what RAS is and improve self-reporting reliability. An indicator of this issue concerning the reliability is the age range up to 97 years of age.

Response:-

Please see our response to Reviewer 1 Comment 2:

> This study was a secondary data analysis from a nation-wide study. The question about RAS was asked in Indonesian language using a term that is a common term for RAS among lay persons. Among Indonesians, it is not a common practice to seek dental care for RAS. However, the term for RAS in the Indonesian language used in the questionnaire implies recurrent ulcer, consistent with the diagnosis of RAS. We have now added the explanation of this measurement in page 5 line 108-110. We also note this as a limitation of our study (page 12 line 274-277).

Comment 7:- The statement that "our findings supports this theory as RAS among Indonesian may be one type of somatic symptoms caused by depression" (page 11, line 22) is inadequate.

Response:- Thank you. The sentence now has been rephrased on page 11 line 267-268.

Department of Dental Public Health

Faculty of dental medicine
Universitas Airlangga

Ninuk Hariyani
Lecturer and Researcher

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ninuk.hariyani@adelaide.edu.au

13th October 2019

Giovanni Lodi, DDS, PhD,
Editor-in-Chief,
Oral Diseases

Dear Dr. Giovanni Lodi,

We are very grateful to you for the opportunity to revise our manuscript, and we acknowledge the time spent by the editors and reviewers in commenting on this paper. Please find below a point-by-point reply to the reviewers' comments. We hope that we have now addressed the concerns raised and believe that the manuscript has been substantially improved.

Thanking you.

Yours sincerely,

Ninuk Hariyani (Corresponding Author)

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ninuk.hariyani@adelaide.edu.au

Reviewer: 1

Comment 1:- Hariyani et al have submitted an interesting manuscript on an Indonesian population-based self-survey study investigating the association between depression and recurrent aphthous stomatitis. The comments made in the previous version appear to have been addressed.

Response:- Thank you very much for your positive feedback on our manuscript.

Reviewer: 2

Comment 1:- The reliability of RAS self-reporting. The authors report that the questionnaire implies recurrent ulcers consistent with the diagnosis of RAS. The fact that it is implied and not explicitly stated is worrisome. Without knowing the exact verbiage and details in the questionnaire used, it is not possible to determine the reliability of the questionnaire and, consequently, if the authors are effectively measuring what they intended on measuring in this study.

Response:- We recognize that the reviewer is concerned regarding the self-reporting of RAS in this study as well as the reliability of the applied tool in the original survey. Given that RAS is a recurrent form of ulceration (an oral manifestation associated commonly with pain and discomfort), it is unlikely that participants will report it inaccurately. Additionally, as it is an ulceration, the self-report of exposure (depression) and the outcome doesn't imply presence of dependent measurement error. With regard to the exact verbiage and details in the questionnaire, we can only back translate the question from the local Indonesian language to English. We have provided the Indonesian verbiage used in the questionnaire in the manuscript (page 5 line 108-110). As noted, this is a secondary analysis of existing data we are limited with the available data to us. Finally, even if RAS was measured inaccurately this will only be a form of non-differential misclassification of outcome (as outcome measure is non-dependent on exposure measurement) which is likely to bias our estimate towards the null. Hence, our findings may only be an underestimation of true association. These have been added when discussing our limitations (page 12 line 280-284).

Comment 2:- The inadequate description of CES-D results. The authors cannot assume depression when an appropriate cutoff has not been validated and this study cannot establish that

they are indeed clinically depressed, as no clinical evaluation for depression was performed to confirm it. The purpose of a cutoff would be to answer the "yes/no" question of clinically depressed or not. The CES-D does not to categorize the severity of depression. Therefore, to divide the groups into different levels of depression is inappropriate. It is more appropriate to report these as depressive symptoms and describe the groups in such terms as well as adjusting the title of the manuscript.

Response:- Thank you for the comment. We agree with specifying that the people are "depressed" is overstating the abilities of the scale. CES-D was developed and implemented as intended (1). Here it is not a diagnostic tool, but a screening tool. The initial scale was used as a continuous scale. Later descriptive analysis with Raskin Depression Scale among a small sample of psychiatric inpatients suggested a cut off of 16 for the 20-item inventory and an approximation of 10 to be useful for the short-scale (2). The assumptions of scale-building are valid as well, where higher CES-D scores were correlated with higher depression. Thus, the continuous and categorized scores were similarly valid. This was also found in the current study where all analyses were carried out with continuous and categorized scores and there was a congruence among these scores. The category of 10 or higher is also maintained here, and this lends to easy comparison to any other study as well. We have change the depression term into depression symptoms throughout the text.

1. Craig, T. J., & Van Natta, P. (1973). Validation of the community mental health assessment interview instrument among psychiatric inpatients: working paper B-27a. Rockville, MD: Center for Epidemiologic Studies.
2. Weissman, M. M., Sholomskas, D., Pottenger, M., Prusoff, B. A., & Locke, B. Z. (1977). Assessing depressive symptoms in five psychiatric populations: a validation study. American journal of epidemiology, 106(3), 203-214.

Comment 3:- The statement on page 11 line 54 "Our findings suggest that RAS among Indonesians may be one of the somatic symptoms caused by depression" remains inadequate. It would be more appropriate to add "in susceptible individuals" as other oral findings could be a result of parafunctional habits such as morsicatio, fibromas, and frictional keratoses.

Response:- Thank you for the suggestion. The changes have been made in the sentence (page 11 line 269-270)