OPEN PEER REVIEW

Open Peer Review (OPR)

As a new feature for progressing towards transparency, we decided to open a new window for all of our editors as well as authors titled "**Open Peer Review**". We hope by this new facility, our reviewers will be more motivated and authors will be more satisfied with the review process. We believe that publishing our peer review reports could make a transparent and clear environment for all our efforts within a journal, but not all reviewers tend to publish their comments.

What is "Open Peer Review" process?

An "Open Peer Review" process is making the details of all review process (including reviewers, associate editors, and EICs comments) as "Public" as it is agreed by EIC, Authors, and reviewers.

Advantages of "Open Peer Review" process

- More transparency, constructiveness and tactful comments of the peer review process: leads to an increase in the quality of reviews
- More motivations for all involved roles in the review process
- Authors' satisfactions from the review process: Increases honesty between authors and reviewers
- Education of both authors and new students
- Prevents reviewers from following their individual agendas and leading to the detection of reviewers' conflicts of interests

You can find out more at:
https://sites.kowsarpub.com/kowsar/knowledgebase/category/tree.html#opr.html

International Journal of Cancer Management
Article DOI: 10.5812/ijcm.96157
Published in: International Journal of Cancer Management: 13(3); e96157

Peer Review Report for "The Validation of Functional Assessment of Cancer Therapy-Breast Symptom Index (FBSI) Among Iranian Women with Breast Cancer"

Author(s): Hadi Zamanian, Mona Daryaafzoon, Mohammadali Amini-Tehrani, Zahra Taheri-Kharameh, Sahar Foroozanfar

Review Timeline:

Submit Date: 8 Jul 2019
Revised Date: 31 Jan 2020
Accepted Date: 5 Feb 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (0) 14 Sep 2019

Dear AE,
This manuscript is interesting but there are several mistakes in the writing of the manuscript. It needs minor revision. There is some point by point recommendation that may help the improvement of the quality of the manuscript:
- It would better that the authors used “Mesh keyword, the keywords are not Mesh.
- The introduction section please refer to research necessity and purpose, this study what dose benefit compare to previous studies?
- What are the criteria for the diagnosis of advanced cancer?
- Despite the importance of the age, the age range is not included in the entry criteria? Why?
- Please mention to the assumptions for statistical test.
- Please at the beginning of the discussion section, refer to the findings, briefly.
- Not mentioned to the method of sample size determination.
- Is it unimportance the state of breast cancer in state of psychology in patients?
- Vancouver’s style has not considered in some section.

- Please explain the reliability of the questionnaire with mentioning the reference.
- Please write the acknowledgment after conflict of interest if applicable.
- Some errors in grammar, diction, and sentence structure exist in the paper, which impede reading.

Thanks.

REFEREE: Associate Editor | **Revision** (0) 16 Sep 2019

Dear EIC,

According to the comments of the reviewer the manuscript needs revision.

Thanks.

REFEREE: EIC | **Revision** (0) 16 Sep 2019

Dear Author,

Please revise your manuscript according to the comments of the reviewers and resubmit again.

Thanks

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Reviewer,

Author(s) appreciate your kind effort and the time taken for reviewing the manuscript, which indeed contributes to the improvement of the quality of the manuscript. Please, find our responses and revised text according to each comment below.

#1 It would better that the authors used "Mesh keyword, the keywords are not Mesh.

R. The keywords were reconsidered. The "Patient-reported outcome" is replaced by the Mesh term, "Patient Outcome Assessment", and the "Validation" by the "Psychometrics".

#2 In introduction section please refer to research necessity and purpose, this study what dose benefit compare to previous studies?

R: The last two paragraph of the "Introduction" section were subjected to a major change. Please find the revised text below, which includes the necessity and purpose, as well as what the current study aimed at adding to the literature.

> Yost et al., (7) developed the functional assessment of cancer therapy-breast symptom index (FBSI), derived from the FACT-B, to assess symptoms in patients with breast cancer. The original study evaluated the validity of the early six-item version (7), and Lee et al., (8) confirmed the psychometric properties of the full-form index with eight items. However, these indices are not validated in breast cancer population of Iran.
>
> Although FACT-B provides various indices addressing different dimensions of QoL in patients with breast cancer, Iranian research on QoL of the patients rarely utilized the

instrument, as implied by a recent systematic review (9). It can be argued that research on QoL in this population requires exploration of various variables that influence the symptoms defining the QoL in such patients. Thus, it is necessary to incorporate different indices into studies to shed more light on the factors contributing to the patient's QoL, especially the symptoms. Besides, previous studies did not address how FBSI-6 and -8 indices indicate patients' mental status, compared to the previously introduced index of trial outcome index (TOI). Therefore, the present investigation aimed at evaluating the validity and applicability of both FBSI-6 and -8 indices in a sample of Iranian women with breast cancer.

#3 What is the criteria for the diagnosis of advanced cancer?

R: We asked about stage and grade of breast cancer in data collection based on reliable pathology and specialist diagnosis report; based on these reports, patients (who were included as breast cancer patients in study settings), were with stage 1 to 4 breast cancer. However, the current study does not consider any stage of cancer such as "advanced cancer" in data analysis. The reasons were: a) we had high missing data on cancer stage, which lead to not considering this variable in our study; b) Although cancer stage affects patients' outcomes and symptoms, but it has not significant effect on used reliability and validity tests in this study; as well, because of reason a, we have not considered cancer stage in Known-Group validity analysis. C) Because of this limitation, we suggested in the last paragraph of the manuscript:

Moreover, it is recommended that future researchers investigate the role of cancer stage in the FBSI's applicability and whether or not there is any difference due to cancer stage in patterns of relationship between FBSI and patients' psychological states.

#4 Despite the importance of the age, the age range is not included in the entry criteria? Why?

R. The inclusion and exclusion criteria missed some of the main points, including the least age for inclusion. Please find below the revised text, to which both the age criterion and the exclusion criteria are added.

The inclusion criteria were age 18 years or above, willingness to participate in the study, ability to communicate in Farsi language, having a diagnosis of any form of breast cancer, and being diagnosed for at least one weak. The patients with any metastatic brain diseases or history of psychiatric disorders were excluded.

#5 Please mention to the assumptions for statistical test.

R: The original work by Yost et. al (2005) used Spearman's correlation coefficient, which we followed in this manuscript. Accordingly, in this revised text, we considered non-parametric inferential statistic for analysis the data. Please note that the group comparisons were reanalyzed with Mann-Whitney U and Kruskal-Wallis test, to ensure the homogeneity of analysis approach and since the groups' data showed some divergence from normal distribution. The revised texts now read:

Analysis Approach:

Non-parametric inferential statistic was employed for data analysis, including the Spearman's rho for the correlations (7), and the Mann-Whitney U and Kruskal-Wallis tests for group comparisons. P-value <.05 was considered significant.

Known-group differences:

None of the target indices could distinguish between the known patients (p=.271 to .795 > .05). Also, there were no significant relationships between the target indices and time since diagnosis (p<.05).

#6 Please at the beginning of the discussion section, refer to the findings, briefly.

R: The following text is added to the beginning of the conclusion section, as a summary of the study findings:

The current study confirmed the validity of FBSI-6 and -8 among Iranian women with breast cancer. The study also showed the differences between FBSI and TOI in terms to stress and depression symptomatology, while they were relatively consistent in terms of anxiety symptoms. Also, only FBSI-6 showed acceptable internal consistency.

#7 Not mentioned to the method of sample size determination.

R: The sample size determination is included in "Analysis approach" section, which now reads:

The sample size was determined based on the formula of $N = [(Z_\alpha+Z_\beta)/C]^2 + 3$, suggested for correlational analysis (13), where Z_α refers to standard normal deviation for α=0.05 as 1.96,

Z_β indicates standard normal deviation for β=0.80 (the power) as 0.842, and C = 0.5 * ln[(1+r)/(1-r)] with r = 0.20 represents the least expected correlation. The minimum sample size was determined 194 that was reached in the current study (N=223).

#8 Is it unimportance the state of breast cancer in state of psychology in patients?

R: The "state of breast cancer" seems a little unclear to us. As we have shown in table two, breast cancer symptoms (which are investigated via FBSI indices in our study) are highly correlated to emotional wellbeing (EWB) as a psychological outcome of cancer state. As well, "the breast cancer stage" is indeed a contributor factor to the psychological sate of the patients, as the reviewer correctly noted. About cancer stage, it is to be noted that because there were high missing data for cancer stage in the study sample, we could not rely on any further analysis. Therefore, this issue is included in the manuscript, indicating the need to be explored by future researchers. The revised text is as follows:

> Moreover, it is recommended that future researchers investigate the role of cancer stage in the FBSI's applicability and whether or not there is any difference due to cancer stage in patterns of relationship between FBSI and patients' psychological states.

#9 Vancouver's style has not considered in some section.

R: The reference style is checked and some minor changes are done in bibliography and in the text.

#10 Please explain about the reliability of the questionnaire with mentioning the reference.

R: The reliability of the target indexes is included in the "instrument" section as follows:

> Yost et al., (7) reported the Cronbach's alpha for FBSI-6 as 0.76 and 0.75 in two assessments over a 16-week period. Also, Lee et al., (8) reported the test-retest reliability of FBIS-6 and -8 as 0.75 and 0.77 respectively, during 30 days, using intraclass correlation coefficient.

Also, the internal consistency reliability of DASS-21 among the study sample is included, as follows:

> The Cronbach's alpha for depression, anxiety, and stress subscales among the study sample were 0.80, 0.71, and .080, respectively

Accordingly, the internal consistency reliability of both FBSI-6 and -8 indices is now reported in the revised manuscript. The "Analysis approach" section now entails the analysis procedure, as follows:

> Internal consistency reliability was assessed via Cronbach's alpha coefficient.

The "Results" section now includes a new subsection of "Reliability" reporting the Cronbach's alpha coefficient for both target indices, as follows:

> **Reliability**
>
> The Cronbach's alpha for FBSI-6 and -8 were 0.71 and 0.54, respectively. For FBSI-6, the results were similar to that of Yost et al. (7). However, the results for FBSI-8, including two items from breast cancer subscale, indicated the heterogeneity among the combined items.

In Abstract section, the results are also reported, as follows:

Cronbach's alpha for FBSI-6 and -8 indices were 0.71 and 0.54, respectively.

#11 Please write the acknowledgment after conflict of interest if applicable.

R: The "Acknowledgment" will be included in the final manuscript upon acceptation.

#12 Some errors in grammar, diction, and sentence structure exist in the paper, which impede reading.

R: The revised manuscript is grammatically rechecked by the Kowsarpub English language service, to ensure the readability of the text.

Best Regards,

Authors

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Associate Editor | **Revision** (1) 24 Jan 2020

Dear EIC
Based on the authors' answers to the reviewers' comments, the reviewer(s) have recommended publication.
Kind regards.

REFEREE: EIC | **Revision** (1) 24 Jan 2020

Dear Authors,
Thank you for submitting your manuscript to IJCM. There are some points that need consideration:
1. As we do not publish brief reports, please change the manuscript type to a research article and change the manuscript structure according to IJCM's guidelines, which can be found on the journal website.
2. Please make the abstract structured.
3. Define all abbreviations when they are used for the first time, both in the abstract and manuscript body.
4. Separate the result and discussion sections.
5. Try to expand the manuscript, so that we can publish it as a research article. The manuscript is rather short.
Thanks.

OPEN PEER REVIEW

Revision (2)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Reviewer,

Author(s) appreciate your kind effort and the time taken for reviewing the manuscript, which indeed contributes to the improvement of the quality of the manuscript. Please, find our responses and revised text according to each comment below.

#1 It would better that the authors used "Mesh keyword, the keywords are not Mesh.

R. The keywords were reconsidered. The "Patient-reported outcome" is replaced by the Mesh term, "Patient Outcome Assessment", and the "Validation" by the "Psychometrics".

#2 In introduction section please refer to research necessity and purpose, this study what dose benefit compare to previous studies?

R: The last two paragraph of the "Introduction" section were subjected to a major change. Please find the revised text below, which includes the necessity and purpose, as well as what the current study aimed at adding to the literature.

> Yost et al., (7) developed the functional assessment of cancer therapy-breast symptom index (FBSI), derived from the FACT-B, to assess symptoms in patients with breast cancer. The original study evaluated the validity of the early six-item version (7), and Lee et al., (8) confirmed the psychometric properties of the full-form index with eight items. However, these indices are not validated in breast cancer population of Iran.
>
> Although FACT-B provides various indices addressing different dimensions of QoL in patients with breast cancer, Iranian research on QoL of the patients rarely utilized the

instrument, as implied by a recent systematic review (9). It can be argued that research on QoL in this population requires exploration of various variables that influence the symptoms defining the QoL in such patients. Thus, it is necessary to incorporate different indices into studies to shed more light on the factors contributing to the patient's QoL, especially the symptoms. Besides, previous studies did not address how FBSI-6 and -8 indices indicate patients' mental status, compared to the previously introduced index of trial outcome index (TOI). Therefore, the present investigation aimed at evaluating the validity and applicability of both FBSI-6 and -8 indices in a sample of Iranian women with breast cancer.

#3 What is the criteria for the diagnosis of advanced cancer?

R: We asked about stage and grade of breast cancer in data collection based on reliable pathology and specialist diagnosis report; based on these reports, patients (who were included as breast cancer patients in study settings), were with stage 1 to 4 breast cancer. However, the current study does not consider any stage of cancer such as "advanced cancer" in data analysis. The reasons were: a) we had high missing data on cancer stage, which lead to not considering this variable in our study; b) Although cancer stage affects patients' outcomes and symptoms, but it has not significant effect on used reliability and validity tests in this study; as well, because of reason a, we have not considered cancer stage in Known-Group validity analysis. C) Because of this limitation, we suggested in the last paragraph of the manuscript:

Moreover, it is recommended that future researchers investigate the role of cancer stage in the FBSI's applicability and whether or not there is any difference due to cancer stage in patterns of relationship between FBSI and patients' psychological states.

#4 Despite the importance of the age, the age range is not included in the entry criteria? Why?

R. The inclusion and exclusion criteria missed some of the main points, including the least age for inclusion. Please find below the revised text, to which both the age criterion and the exclusion criteria are added.

The inclusion criteria were age 18 years or above, willingness to participate in the study, ability to communicate in Farsi language, having a diagnosis of any form of breast cancer, and being diagnosed for at least one weak. The patients with any metastatic brain diseases or history of psychiatric disorders were excluded.

#5 Please mention to the assumptions for statistical test.

R: The original work by Yost et. al (2005) used Spearman's correlation coefficient, which we followed in this manuscript. Accordingly, in this revised text, we considered non-parametric inferential statistic for analysis the data. Please note that the group comparisons were reanalyzed with Mann-Whitney U and Kruskal-Wallis test, to ensure the homogeneity of analysis approach and since the groups' data showed some divergence from normal distribution. The revised texts now read:

Analysis Approach:

Non-parametric inferential statistic was employed for data analysis, including the Spearman's rho for the correlations (7), and the Mann-Whitney U and Kruskal-Wallis tests for group comparisons. P-value <.05 was considered significant.

Known-group differences:

None of the target indices could distinguish between the known patients (p=.271 to .795 > .05). Also, there were no significant relationships between the target indices and time since diagnosis (p<.05).

#6 Please at the beginning of the discussion section, refer to the findings, briefly.

R: The following text is added to the beginning of the conclusion section, as a summary of the study findings:

The current study confirmed the validity of FBSI-6 and -8 among Iranian women with breast cancer. The study also showed the differences between FBSI and TOI in terms to stress and depression symptomatology, while they were relatively consistent in terms of anxiety symptoms. Also, only FBSI-6 showed acceptable internal consistency.

#7 Not mentioned to the method of sample size determination.

R: The sample size determination is included in "Analysis approach" section, which now reads:

The sample size was determined based on the formula of $N = [(Z_\alpha+Z_\beta)/C]^2 + 3$, suggested for correlational analysis (13), where Z_α refers to standard normal deviation for α=0.05 as 1.96,

Z_β indicates standard normal deviation for β=0.80 (the power) as 0.842, and C = 0.5 * ln[(1+r)/(1-r)] with r = 0.20 represents the least expected correlation. The minimum sample size was determined 194 that was reached in the current study (N=223).

#8 Is it unimportance the state of breast cancer in state of psychology in patients?

R: The "state of breast cancer" seems a little unclear to us. As we have shown in table two, breast cancer symptoms (which are investigated via FBSI indices in our study) are highly correlated to emotional wellbeing (EWB) as a psychological outcome of cancer state. As well, "the breast cancer stage" is indeed a contributor factor to the psychological sate of the patients, as the reviewer correctly noted. About cancer stage, it is to be noted that because there were high missing data for cancer stage in the study sample, we could not rely on any further analysis. Therefore, this issue is included in the manuscript, indicating the need to be explored by future researchers. The revised text is as follows:

> Moreover, it is recommended that future researchers investigate the role of cancer stage in the FBSI's applicability and whether or not there is any difference due to cancer stage in patterns of relationship between FBSI and patients' psychological states.

#9 Vancouver's style has not considered in some section.

R: The reference style is checked and some minor changes are done in bibliography and in the text.

#10 Please explain about the reliability of the questionnaire with mentioning the reference.

R: The reliability of the target indexes is included in the "instrument" section as follows:

> Yost et al., (7) reported the Cronbach's alpha for FBSI-6 as 0.76 and 0.75 in two assessments over a 16-week period. Also, Lee et al., (8) reported the test-retest reliability of FBIS-6 and -8 as 0.75 and 0.77 respectively, during 30 days, using intraclass correlation coefficient.

Also, the internal consistency reliability of DASS-21 among the study sample is included, as follows:

> The Cronbach's alpha for depression, anxiety, and stress subscales among the study sample were 0.80, 0.71, and .080, respectively

Accordingly, the internal consistency reliability of both FBSI-6 and -8 indices is now reported in the revised manuscript. The "Analysis approach" section now entails the analysis procedure, as follows:

> Internal consistency reliability was assessed via Cronbach's alpha coefficient.

The "Results" section now includes a new subsection of "Reliability" reporting the Cronbach's alpha coefficient for both target indices, as follows:

> **Reliability**
>
> The Cronbach's alpha for FBSI-6 and -8 were 0.71 and 0.54, respectively. For FBSI-6, the results were similar to that of Yost et al. (7). However, the results for FBSI-8, including two items from breast cancer subscale, indicated the heterogeneity among the combined items.

In Abstract section, the results are also reported, as follows:

Cronbach's alpha for FBSI-6 and -8 indices were 0.71 and 0.54, respectively.

#11 Please write the acknowledgment after conflict of interest if applicable.

R: The "Acknowledgment" will be included in the final manuscript upon acceptation.

#12 Some errors in grammar, diction, and sentence structure exist in the paper, which impede reading.

R: The revised manuscript is grammatically rechecked by the Kowsarpub English language service, to ensure the readability of the text.

Best Regards,

Authors

OPEN PEER REVIEW

Revision (2)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: EIC | **Revision** (2) 5 Feb 2020

Dear Author,
This is my pleasure to announce you that your article has been accepted by the editorial committee after peer review in the International Journal of Cancer Management (IJCM). Hopefully, it will be published in future issues.
Thanks.