Psychometric Properties of Postpartum Quality of Life Questionnaires: a Systematic Review and Meta-analysis Protocol

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Protocol

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Abstract

Background:

The postpartum quality of life refers to women's understanding of their standing in the postpartum crisis that differs depending on their health status, social support, cultural status and values, attitudes, goals and standards. The present systematic review will identify, describe, and critically assess the psychometric properties of postpartum quality of life questionnaires.

Methods/Design:

A systematic review will be conducted in databases including PubMed, Embase, Scopus, Web of Science, PsycINFO, and CINAHL from January 2000 to January 2020. The psychometric properties (validity and reliability) of the instruments used in the primary studies will be assessed, and the selection, methodological quality assessment and data extraction processes of the studies will be independently assessed by two reviewers with expertise in conducting systematic reviews, so as to minimize potential personal bias. Eligible resources are selected after any lack of consensus is put to debate. The risk of bias is assessed using the COSMIN RISK of Bias checklist, and to evaluate the quality of the studies, the protocol is written based on the PRISMA-P\(^1\) standards. The results of the studies will be judged based on good measurement properties, and the results of all the studies are qualitatively summarized to produce a reference for the general quality of the results. The general quality of the evidence will be determined using a modified GRADE method.

Discussion:

This study assessed the psychometric properties of questionnaires used for assessing postpartum quality of life and its results can be used to identify the most appropriate tool for health applications in measuring postpartum quality of life.

Systematic review registration:

reference number in PROSPRO CRD42020166301

Background:

Quality of life (QOL) refers to “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (1). According to the World Health Organization (WHO), quality of life consists of six domains: Physical health, psychological state, level of independence, social relations, environment, and spirituality/religion/personal beliefs. Quality of life is defined as the general health of people and societies and entails both positive and negative aspects of life and also life satisfaction, which includes satisfaction with physical health, family, education, occupation, wealth, religious beliefs, financial status and environment(2).

Maternal health is one of the main principles of socioeconomic well-being(3). The main health challenge of the 21st century is to improve quality of life and health, which can occur through the empowerment of the society for enabling greater control over personal health and ultimately its improvement. The postpartum periods consists of the first six weeks following childbirth (5) and, being a critical period for women, can lead to complications and impaired quality of life (6). The evaluation of postpartum quality of life allows women to assess their postpartum status and seek help from healthcare providers for herself and her child to improve their health.

Quality of life is a concept that is affected by the sociocultural system of each society (8) and is among the indicators that are affected after childbirth(9), and the evaluation of postpartum quality of life is essential to the promotion of
health in health planning. At present, the measurement of health-related postpartum quality of life has turned into an indispensable part of the health assessment process. In most studies, general instruments such as the SF-36 and WHOQOL-BREF are used to assess postpartum quality of life, and specific instruments such as MAPP-QIL, PQOL, and MGI are less commonly used.

Health-related quality of life questionnaires are constructs that cannot be directly measured, and due to their subjective nature, assessment techniques with favorable validity and reliability are highly important. Since health-related quality of life is an indisputable outcome in the assessment of the burden of diseases caused by health problems, it is important to use a valid instrument for its measurement. The present study seeks to find a good instrument out of the measurement instruments developed up to 2019 that is more suitable for assessing postpartum quality of life.

The preliminary search yielded a systematic review study (with no meta-analysis) by Mogos et al. (2012) conducted on general, pregnancy and postpartum quality of life assessment tools; however, none of them was in accordance with the current health model, meanwhile, specific postpartum quality of life tools have a highly credible role in maternal and neonatal health. Other studies have assessed postpartum quality of life using general quality of life instruments and have not had a systematic review design and have mostly been conducted to compare the correlation between a general quality of life instrument and a comparative instrument in postpartum women, and the results showed that although general instruments have lower sensitivity compared to specific instruments, they conceal the ability to detect small yet clinically significant changes in quality of life.

The present study will be conducted on primary studies. Based on the search carried out, there were no specific postpartum quality of life tools before 2002. This study will perform a comprehensive search for studies published from January 2000 to January 2020.

The study seeks to answer the following three questions:

1. How is the validity (construct validity and criterion validity) of the instruments used for assessing postpartum quality of life?
2. How is the reliability of the instruments used for assessing postpartum quality of life?
3. What are the critical appraisal and methodological quality of the studies regarding the measurement properties of the instruments used for assessing postpartum quality of life?

Ten-step procedure & outline for systematic review

In a systematic review of instruments Patient-Reported Outcome Measures (PROMs), an overview was given on the evidence available on each measurement property of the included instruments to come to an overall conclusion for each measurement property and to give recommendations for the most suitable instrument for a given purpose. The COSMIN guideline, consisting of a sequential ten-step procedure, was developed by the COSMIN steering committee and includes three parts: A, B and C. Figure 1

Step 1

OBJECTIVES:

The Main Objective:

1. Identification, description, and evaluation of the validity (construct and criterion validity) of instruments used for assessing postpartum quality of life.
Secondary Objectives:

1. The assessment of the reliability of instruments used for assessing postpartum quality of life.
2. The critical appraisal and methodological quality of studies regarding the measurement properties of instruments used for assessing postpartum quality of life.

Methods/design:

Type of Studies

This study will use all the primary studies investigating the psychometric properties of postpartum quality of life questionnaires (both specific and general instruments).

The design, implementation and reporting of this review will be based on the recommendations of the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative and the Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols (PRISMA-P) statement.

The protocol has been registered in PROSPERO database the under Temporary registration ID166301 (Awaiting reference number)

Type of Participants

All the primary articles conducted on women of reproductive age in the postpartum period.

Step 2

Inclusion Criteria:

1. All the primary studies investigating the psychometric properties of specific postpartum quality of life assessment instruments.
2. All the primary studies investigating the psychometric properties of general postpartum quality of life assessment instruments.
3. All the primary studies conducted between January 2000 and January 2020 will be included in the present study.
4. All the studies investigating the quality of life of women from one hour to one year postpartum using quality of life instruments will be included in the present study.
5. There will be no language restrictions for the included studies.

Exclusion Criteria:

1. Any studies using quality of life assessment instruments to investigate women's postpartum complications.
2. Any studies investigating women's quality of life and assessing the psychometric properties of non-postpartum quality of life assessment instruments.
3. Any studies containing only abstracts, books, research protocols, letters to the editor, and those with unavailable full texts.
4. Any studies with incomplete data and those with unavailable data, even after correspondence with the researcher.

Step 3

Search Strategy and Information Sources
An online search will be conducted in the following databases:

A systematic review will be conducted in electronic databases including PubMed, Embase PsycINFO, Scopus, Web of Science, and CINAHL for articles published from January 2000 to January 2020. The reference list of the original studies and gray literature will also be reviewed. In addition, a full search will be conducted in Proquest to find any relevant theses. The abstracts of conference papers retrieved through Scopus, Web of Science and other related websites will also be reviewed.

In this study, the search will be carried out using the COSMIN methodology for systematic reviews of PROMs, which recommends the use of four main components, including the construct, the population, the measurement properties, and the instrument(s) properties of interest(22). COSMIN has developed a comprehensive methodological search filter for PubMed with 97.4% sensitivity and 9.4% specificity in identifying studies on measurement properties (23). This filter has been translated for all the databases.

The preliminary search in PubMed will be carried out in the following steps. All the phrases and keywords will be selected from synonyms in MeSH and emtree and the examples in the search filters on the COSMIN website. Articles with relevant titles will be selected, and synonyms will be used to develop the keywords. The search strategy will first be carried out for PubMed. Then, the same strategy will be pursued for the other electronic databases. There are no language restrictions, but articles with non-English titles and abstracts will not be identified by a search in English. The search method is based on COSMIN guidelines and four key elements(24).

A draft of the search strategy is presented in Annex 2.
Table 1
Search terms and strategy used for the electronic databases included in our systematic review

<table>
<thead>
<tr>
<th>PubMed</th>
<th>Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>#5</td>
<td>date 2000/1/1:2020/1/1[dp]</td>
</tr>
</tbody>
</table>

After screening the articles, the reference list of the included articles will also be assessed in the selection stage.

**Study records**

**Data management**
The identified records will be pooled and automatically de-duplicated using Mendeley (Elsevier). Additional duplicates will be manually identified and compared based on the full texts.

Two reviewers will independently extract the relevant data from the included articles and record them in the data table(25). A third reviewer will assess these two tables. Disagreements between the reviewers and the research team will be discussed until the desirable outcome is reached. If no solution is found, for the final decision, the researchers will be referred to a third expert reviewer or will contact the authors of the article.

**Data items**

The following data are collected from each study: Title of the journal, authors’ names, publication year, country, data collection place and time, the study objectives, data collection instruments, subjects’ demographic details (gender, age, education, etc.), type of participants, number of participants, and type of study.

**Step 4**

**Selection process**

First, the titles and abstracts of all the studies will be listed and reviewed by two reviewers. Studies without an abstract and full text, those not matching the study objectives, duplicate articles, and those without the required data will be excluded. Then, the full text of the studies will be assessed in terms of the inclusion and exclusion criteria. Next, the selected studies will be divided into three groups: Relevant, irrelevant, and unclear. Irrelevant studies will be excluded. Then, the two reviewers will independently assess the remaining ‘unclear’ cases, and disagreements will be resolved through discussion. If no agreement is reached, a third expert reviewer will assess the case. In cases where the full text of the study is not available, it will be requested from the corresponding author by email.

**Steps 5-7**

**Appraisal of the methodological quality of the included studies (risk of bias assessment for each individual study)**

A new order is proposed for evaluating the measurement properties, as shown in Table 2. Content validity is considered the most important measurement property, because, first of all, it should be clear that the instrument items are relevant, comprehensive, and comprehensible in relation to the construct of interest and the target population(21). The instruments with high-quality evidence of inadequate content validity can be excluded from further assessment in the systematic review.

The methodological quality and details of the measurements will be assessed in each study using the COSMIN Risk of Bias Checklist, which examines whether the results are trustworthy based on the methodological quality of the study, and the main outcome of this study is to assess the psychometric properties of postpartum quality of life questionnaires(23). First, it should be determined which features of measurement will be assessed in each study.

The COSMIN Risk of BIAS checklist contains ten boxes (Table 2), each corresponding to one measurement property. The quality of each study should be separately assessed based on a measurement property using the relevant box in COSMIN. That is, it may not be necessary to complete the whole checklist when evaluating the quality of the studies described in an article. In accordance with the COSMIN taxonomy (16). Each case will be described on a four-point rating scale as ‘very good’, ‘adequate’, ‘doubtful’, and ‘inadequate’ and it will be determined whether appropriate statistical tests have been used or not and the overall quality score will also be ascertained for a particular measurement, taking into account the lowest score of each component(26).
In this study, we evaluate the following boxes, in respective order: Content validity, internal structure and remaining measurement properties (Table 2).

The findings pertaining to the development of the measurement instruments will be described narratively due to the lack of universally-accepted quality standards. Before the quality assessment and synthesis, the primary studies on reliability and validity will be stratified based on the methodological approach.

The results of each study will be assessed based on the criteria for good measurement properties and rated as 'sufficient' (+), 'insufficient' (−), or 'indeterminate' (±);(20, 27) For example, if the internal consistency of the QOL score is evaluated, at least low evidence for sufficient structural validity AND Cronbach's alpha(s) ≥ 0.70 for each unidimensional scale or subscale (Table 3).

The results of all the studies will be summarized so as to determine whether each measurement property of an instrument is sufficient (+), insufficient (−), inconsistent (±) or indeterminate (?). When the studies are inconsistent, the results from the pertinent sub-groups of the studies will be summarized to explain the inconsistency. If not possible, the overall quality will be determined based on the majority of the studies, and inconsistency will be accounted for in the third step.

The overall quality of the evidence will be rated using the modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach(26). Finally, the quality of the evidence will be downgraded when there is a risk of bias based on the COSMIN Risk of Bias Checklist.

**Table 2**

Boxes of the COSMIN Risk of Bias checklist

<table>
<thead>
<tr>
<th>Mark the measurement properties that have been evaluated in the article*.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content validity</strong></td>
</tr>
<tr>
<td>Box 1. PROM development**</td>
</tr>
<tr>
<td>Box 2. Content validity</td>
</tr>
<tr>
<td><strong>Internal structure</strong></td>
</tr>
<tr>
<td>Box 3. Structural validity</td>
</tr>
<tr>
<td>Box 4. Internal consistency</td>
</tr>
<tr>
<td>Box 5. Cross-cultural validity\measurement invariance</td>
</tr>
<tr>
<td><strong>Remaining measurement properties</strong></td>
</tr>
<tr>
<td>Box 6. Reliability</td>
</tr>
<tr>
<td>Box 7. Measurement error</td>
</tr>
<tr>
<td>Box 8. Criterion validity</td>
</tr>
<tr>
<td>Box 9. Hypothesis testing for construct validity</td>
</tr>
<tr>
<td>Box 10. Responsiveness</td>
</tr>
</tbody>
</table>

* If a box needs to be completed more than once, two or more marks can be placed.

** Not considered a measurement property, but taken into account when evaluating the content validity (26)
<table>
<thead>
<tr>
<th>Measurement property</th>
<th>Rating</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| **Structural validity** | +      | CTT:  
CFA: CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08^2  
IRT/Rasch:  
No violation of unidimensionality^3: CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08  
AND  
no violation of local independence: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3’s < 0.37  
AND  
no violation of monotonicity: adequate looking graphs OR item scalability > 0.30  
AND  
adequate model fit: IRT: $\chi^2$ > 0.01  
Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > -2 and < 2  
  
? CTT: Not all information for ‘+’ reported  
IRT/Rasch: Model fit not reported  
- Criteria for ‘+’ not met |

<table>
<thead>
<tr>
<th>Internal consistency</th>
<th>+</th>
<th>At least low evidence^4 for sufficient structural validity^5 AND Cronbach's alpha(s) ≥ 0.70 for each unidimensional scale or subscale^6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>?</td>
<td>Criteria for “At least low evidence^4 for sufficient structural validity^5” not met</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>At least low evidence^4 for sufficient structural validity^5 AND Cronbach's alpha(s) &lt; 0.70 for each unidimensional scale or subscale^6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reliability</th>
<th>+</th>
<th>ICC or weighted Kappa ≥ 0.70</th>
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<tbody>
<tr>
<td></td>
<td>?</td>
<td>ICC or weighted Kappa not reported</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>ICC or weighted Kappa &lt; 0.70</td>
</tr>
<tr>
<td>Measurement property</td>
<td>Rating1</td>
<td>Criteria</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Measurement error</strong></td>
<td>+</td>
<td>SDC or LoA &lt; MIC&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>?</td>
<td>MIC not defined</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>SDC or LoA &gt; MIC&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Hypotheses testing for construct validity</strong></td>
<td>+</td>
<td>The result is in accordance with the hypothesis&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>?</td>
<td>No hypothesis defined (by the review team)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>The result is not in accordance with the hypothesis&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Cross-cultural validity\measurement invariance</strong></td>
<td>+</td>
<td>No important differences found between group factors (such as age, gender, language) in multiple group factor analysis OR no important DIF for group factors (McFadden's R&lt;sup&gt;2&lt;/sup&gt; &lt; 0.02)</td>
</tr>
<tr>
<td></td>
<td>?</td>
<td>No multiple group factor analysis OR DIF analysis performed</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Important differences between group factors OR DIF was found</td>
</tr>
<tr>
<td><strong>Criterion validity</strong></td>
<td>+</td>
<td>Correlation with gold standard ≥ 0.70 OR AUC ≥ 0.70</td>
</tr>
<tr>
<td></td>
<td>?</td>
<td>Not all information for ‘+’ reported</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Correlation with gold standard &lt; 0.70 OR AUC &lt; 0.70</td>
</tr>
<tr>
<td><strong>Responsiveness</strong></td>
<td>+</td>
<td>The result is in accordance with the hypothesis&lt;sup&gt;7&lt;/sup&gt; OR AUC ≥ 0.70</td>
</tr>
<tr>
<td></td>
<td>?</td>
<td>No hypothesis defined (by the review team)</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>The result is not in accordance with the hypothesis&lt;sup&gt;7&lt;/sup&gt; OR AUC &lt; 0.70</td>
</tr>
</tbody>
</table>

Adapted from Prinsen et al. (Prinsen et al., 2016a) under a Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/); (20, 21, 27)

AUC area under the curve, CFA confirmatory factor analysis, CFI comparative fit index, CTT classical test theory, DIF differential item functioning, ICC intraclass correlation coefficient, IRT item response theory, LoA limits of agreement, MIC minimal important change, RMSEA root mean square error of approximation, SEM standard error of measurement, SDC smallest detectable change, SRMR standardized root mean residuals, TLI Tucker–Lewis index, + sufficient, − insufficient, ? Indeterminate

A: To rate the quality of the summary score, the factor structures should be equal across the studies

B: Unidimensionality refers to a factor analysis per subscale, while structural validity refers to the factor analysis of a (multidimensional) PROM

C: As defined by grading, the evidence according to the GRADE approach

D: This evidence may come from different studies
e: The criteria “Cronbach alpha < 0.95” was deleted, as this is relevant in the development phase of a PROM and not when evaluating an existing PROM.

f: The results of all the studies should be taken together, and it should then be decided if 75% of the results are in accordance with the hypotheses.

**Data collection process (data extraction):**

The data to be extracted include the study objectives or questions, data related to publication, including authors’ names, year, assessment of psychometric properties, country, language of measurement, study design, study setting, and suitability of assessment, sampling method and instruments used in studies on postpartum quality of life. The measurement properties of some studies that are repeated several times may be based on different subgroups or the use of more than one metric, and subgroups of these studies, will be information about the following cases:

- Subgroups’ details (including clinical details, women's mean age, and interval of measurement of postpartum quality of life from one hour to one year postpartum).
- The study results and analysis details (correlation, validity, and reliability).
- Reported results (values related to an appropriate metric or a narrative statement of results).

Then, whether the subgroups' results have been collected or not is investigated, and if so, it will be examined how the pooling procedure and evidence of heterogeneity have been.

Data will be extracted by two independent reviewers. In the case of disagreement, the matter is referred to the third reviewer, and the reviewers will be contacted for further clarification.

**Risk of bias in individual studies**

**Missing Data:**

In the absence of full information, the relevant authors will be contacted, and if the missing data are not found, the study will be excluded.

**Heterogeneity Assessment:**

If the present study ends up performing a meta-analysis, the studies’ heterogeneity will be assessed using the $X^2$ test, and the $I^2$ index will be tested on the quantitative data. Where heterogeneity between the studies is high and analysis is not possible, the study will be reported in narrative form. The present study will assess the heterogeneity of the subgroups.

**Report of Bias Assessment:**

The Begg Plot, Egger Plot, and Funnel Plots will be used to assess Publication bias.

**Data Synthesis:**

First, data including comparisons, differences, and results are chronically collected from studies in a narrative form, and the best evidence related to the tools’ details will be identified using the COSMIN recommendations. The total score will be collected from the tools’ adequacy features as ‘Insufficient’ (−), ‘Sufficient’ (+), ‘Inconsistent’ (±), or ‘Indeterminate’ (?). After the collection and summarization of all the evidence based on the measurement properties using the modified GRADE approach, the quality of the evidence will be rated as ‘high’, ‘moderate’, ‘low’, or ‘very low’.

Moreover, in studies with sufficient data for meta-analysis, Stata (meta-analysis software) will be used.
Study strengths and limitations

The processes of selection, data extraction, and quality assessment were carried out independently by two reviewers experienced in systematic review methods in order to minimize personal bias.

To the researchers’ knowledge, only one systematic review article (with no meta-analysis) has been conducted (2012) on general and specific measurements used for pregnancy and postpartum, and that study found that none of the measurements matched the current health model (Mogos et al., 2013).

The included studies had no language restrictions, and there is therefore no language bias.

In the present study, the modified GRADE approach will be used to assess the quality of the evidence.

A meta-analysis may not be possible if only a few initial studies are found or have very different validity and reliability methods.

Discussion:

This systematic review will summarize and critically appraise the abundant literature pertaining to the reliability and validity of quality of life measurement instruments evaluated in postpartum women. High-quality systematic reviews can provide a comprehensive overview of the measurement properties of Patient-Reported Outcome Measures and support evidence-based recommendations in the selection of the most suitable PROM for a given purpose.

Physicians, Midwives, nurses and policy makers in healthcare often need to identify appropriate measurement instruments for different purposes, such as the observation of the natural history of a condition, the evaluation of the effectiveness of a treatment, and the assessment of the quality of care and life. This selection process can be complex, and systematic reviews of measurement properties serve as a component of the evidence-based framework for this purpose.

The present study is a systematic review of the assessment of the psychometric properties of studies conducted on postpartum quality of life. Researchers, physicians, and policy-makers in healthcare often need to identify and select appropriate quality of life measurement tools for various health purposes, and assessing the effectiveness of quality of life measurement tools in postpartum care is highly important for health assessment, maintenance, and interventions. This selection process can be complex, and a systematic review of the psychometric properties of quality of life tools will be used as the main component of an evidence-based framework for this purpose. The present study will provide evidence-based recommendations regarding the optimal use of postpartum quality of life tools with further assessments.

Abbreviations:

COSMIN: COnsensus-based Standards for the selection of health Measurement INstruments

PROM: Patient-Reported Outcome Measures

QOL: Quality Of Life

MAPP-QOL: Maternal Postpartum Quality of Life

PQOL: Chinese Postpartum QOL questionnaire
MGI: Mother-Generated Index

PRISMA-P: the Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols

AUC: Area Under The Curve

CFA: Confirmatory Factor Analysis

CFI: Comparative Fit Index

CTT: Classical Test Theory

DIF: Differential Item Functioning

ICC: Intraclass Correlation Coefficient

IRT: Item Response Theory

LoA: Limits of Agreement

MIC: Minimal Important Change

RMSEA: Root Mean Square Error of Approximation

SEM: Standard Error of Measurement

SDC: Smallest Detectable Change

SRMR: Standardized Root Mean Residuals

TLI: Tucker–Lewis Index

Declarations:

Ethics approval:

Code of Ethics received from Shahid Beheshti University of Medical Sciences: IR.SBMU.RETECH.REC.1397.1343

Consent for publication:

Not applicable.

Availability of data and materials:

The datasets used during the current study are available.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:

TM-G, NK, HSH-N, MA-D and MN all made substantial contributions to conception and design of the paper.

References:


