

Validity and Reliability of the Hindi Version of the Patient Assessment of Constipation Quality of Life Questionnaire in Cancer Patients on Opioids for Pain Management at Tertiary Care Center, India

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Abstract

Background: Opioid-induced constipation (OIC) causes a significant worsening of quality of life (QOL). The patient assessment of constipation QOL questionnaire (PAC-QOL) is a validated scale in English language to assess the QOL in patients with chronic constipation and guide the management by measuring response to a targeted therapy. **Objective:** The objective of the study was to evaluate the validity and reliability of PAC-QOL questionnaire after translation in Hindi language for Indian cancer patients with OIC. **Materials and Methods:** This was a prospective observational cross-sectional study. Three hundred and thirteen adult cancer patients receiving opioid treatment for pain and experiencing self-reported symptoms of constipation were evaluated. The severity of constipation was assessed at baseline and at an interval of at least 2 weeks by the physician using constipation scoring system (CSS) and self-reported Hindi version of PAC-QOL questionnaire. **Results:** The data obtained from 313 patients were taken for analysis. The internal consistency of the tool was established with the favorable value of Cronbach's alpha coefficient (i.e., >0.70) obtained for all four subgroups and overall score. The intraclass correlation coefficient value of >0.70 also established good correlation between overall and subgroups scores of Hindi version of PAC-QOL, obtained at 1st and 2nd visit. It was observed from the result that a significant correlation existed between the overall and subgroups scores of Hindi version of PAC-QOL and CSS, thus establishing concurrent validity. **Conclusion:** It was concluded from the study results that Hindi version of PAC-QOL is both reliable and valid to assess the QOL in patients with OIC.

Keywords: Constipation scoring system, opioid-induced constipation, opioids, patient assessment of constipation quality of life, quality of life

INTRODUCTION

The opioids play a major role in the management of cancer pain.^[1] For moderate-to-severe cancer pain, initiating opioid therapy, along with nonopioid adjuncts, is advised by the World Health Organization analgesic ladder.^[2,3] Opioid-induced bowel dysfunction (OIBD), primarily a collection of gastrointestinal motility disorders, is the most common among the potentially debilitating side effects of chronic opioid use. The opioid-induced constipation (OIC) is the most commonly encountered OIBD.^[4]

In a systemic review that included 25 published prospective studies reporting adverse events of opioids, frequency of

OIC ranged from 5% to 97% in patients naïve for these opioids.^[2] The OIC has been defined as a change in bowel habits after initiation of opioid therapy, recorded over ≥ 7 days. It should be associated with any of the symptoms such as a

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reduction in the frequency of bowel movement, a feeling of incomplete evacuation, and increase force required to pass bowel movement due to hard stool.^[5]

OIC leads to a great impact on the quality of life (QOL).^[6] There are several subjective assessment scales and objective methods to assess the severity or to explore the pathophysiology of constipation.^[7] The Patient Assessment of Constipation QOL questionnaire (PAC-QOL) developed and validated in English language by Marquis *et al.* to assess the QOL in patients with constipation.^[8] The validity and reliability of this questionnaire has also been confirmed in various languages such as French, Dutch, Japanese,^[9] Turkish,^[10] and Persian.^[11] In this study, we validated a Hindi version of the PAC-QOL questionnaire and assessed its reliability and validity in cancer patients suffering from OIC

MATERIALS AND METHODS

Study design

This was an observational prospective cross-sectional study.

Setting

The study was done at the department of onco-anesthesia and palliative medicine in a tertiary care center. The study was completed within a span of 1 year from October 2017 to September 2018.

Ethical clearance

Ethical clearance for conducting the study was obtained from AIIMS Ethics Committee on September 1, 2017, vide Ref. No. IEC-415/04.08.2017, RP-40/2017.

Participants

The adult cancer patients presenting to palliative care clinic or admitted to palliative care unit, those on opioid treatment for more than 2 weeks for cancer pain, and meeting the criteria of OIC as suggested by consensus group^[5] were enrolled for the study after applying exclusion criteria. An informed written consent was obtained from all the participants. Demographic details and clinical profile containing malignancy, time duration, dose and type of opioid, adjuvant drugs, and use of laxatives were noted down.

Exclusion criteria

The patients aged <18 years, those with associated comorbidities (such as diabetes, Parkinson's disease, chronic idiopathic constipation, neurologic and neuromuscular disorders, metabolic derangements, constipation due to bowel obstruction or gut perforation, and malignancies arising from rectum or anal canal), patients on certain medications (e.g., iron supplements, antidepressants, antacids, antitussives, anticholinergics, antiemetics, neuroleptics, etc.) that lead to or exacerbate constipation, patients who were not able to read and write, not able to communicate properly, and mentally challenged were excluded from the study.

Study tools

Hindi version of the patient assessment of constipation quality of life

The Hindi version of Original PAC-QOL questionnaire was obtained by e-mail communication with the MAPI research trust organization that has the copyright to distribute the linguistically validated version of PAC-QOL questionnaire free of cost for the academic research purpose to individual or institutes. PAC-QOL had already undergone full linguistic validation process. Therefore, no formal linguistic validation by translation-retranslation method was done.

The PAC-QOL questionnaire comprises 28 questions that are divided into four subscales. The physical discomfort subscale comprises first four questions (question 1–4), psychosocial discomfort subscale includes next eight questions (question 5–12), worries/concerns subscale includes next 11 questions (question 13–23), and satisfaction subscale includes last five questions (question 24–28). Response score for each question ranged from 0 to 4. The rules mentioned in the PAC-QOL Information Booklet 1st Ed. provided by Mapi Research Trust (Copyright © 2005 Mapi Research Trust-All rights reserved) along with Hindi translated PAC-QOL questionnaire and copy of agreement were followed while calculation of scores, interpretation of missing data, etc.

Constipation scoring system

Constipation Scoring System (CSS)^[12] questionnaire comprises eight component questions that measure the symptomatic severity of constipation. The response score for each question ranged from 0 to 4 and overall score ranged from 0 to 30. The severity of constipation is directly related to the overall score.

After collecting the relevant patient data, physician-reported assessment of severity of constipation was documented using CSS.^[12] The assessment of QOL was documented by self-reported Hindi version of PAC-QOL^[8] questionnaire filled by the patients.

Re-assessments on the same tools were again documented on subsequent follow-up visits of the patients with at least an interval of 2 weeks.

Sample size

The sample size was calculated as ten times the number of component questions in the PAC-QOL. Number of patients = 10 × Number of questions in PAC-QOL^[9,10] Sample size for our study was targeted at a minimum of 280 patients. However, a total of 354 patients were included in the study, and data obtained from 313 patients were taken for analysis. Data from 41 patients were rejected due to incompletely filled questionnaire or inadequate data.

Statistical methods

The internal consistency and reproducibility of Hindi version of PAC-QOL were assessed to determine the reliability of the tool. The value of Cronbach's alpha was calculated for the total score and also for all four subscales of Hindi version of PAC-QOL to determine the internal consistency. The comparison of

scores of Hindi versions of PAC-QOL obtained at the first visit with those obtained at the subsequent visit of the patient was done using test–retest method to evaluate the reproducibility. Patients reporting no change in the severity of constipation in between the two visits were taken for test–retest analysis using intraclass correlation coefficient (ICC).

To determine the concurrent validity between the PAC-QOL scores and the CSS scores, Pearson’s correlation coefficients were calculated.

Statistical analysis

Data analysis was done using software STATA 14.0, College Station, Texas 77845, USA.

RESULTS

The sample consisted of 52.07% males and while 47.9% of females. The mean age was 49.5 ± 13.6 years and mean duration of opioid treatment was 8.2 ± 6.8 days [Table 1].

Reliability

Internal consistency of Hindi version of the patient assessment of constipation-quality of life

The Cronbach’s alfa coefficient was calculated for all four subgroups and overall score. Cronbach’s alpha value for the

overall PAC-QOL score was 0.86, while alpha value for four subscales ranged between 0.69 and 0.72 [Table 2]. The alpha values derived indicated that the Hindi version of PAC-QOL response scores was consistent for the overall questionnaire and also across all four subscales of the tool.

Test–retest reliability

For test–retest study, 101 patients were available. The mean interval between 1st and 2nd visit was 16 ± 3.2 days. ICC for overall score was 0.85, while ICC for subscales ranged between 0.74 and 0.91. The result established a good correlation between the Hindi version of PAC-QOL, overall and subgroups scores obtained at first and second visit [Table 3].

Concurrent validity

The concurrent validity was assessed between Hindi version of PAC-QOL scores and CSS scores obtained from all 313 patients. The value of Pearson’s correlation coefficient between the CSS score and overall Hindi version of PAC-QOL score ($r = 0.64, P < 0.0001$) and CSS and all four subscales of Hindi version of PAC-QOL, $r = 0.40$ for worries and concern, $r = 0.41$ for psychological discomfort, $r = 0.55$ for physical discomfort, and $r = 0.67$ for satisfaction were significant at $P < 0.0001$ level [Table 4].

DISCUSSION

The outcome of our study proved that Hindi version of PAC-QOL is both reliable and valid to assess QOL in Indian cancer patients with OIC. The self-reported questionnaire, PAC-QOL, was originally developed in English language and later on developed in many other languages.^[8] Till date, PAC-QOL has been formally validated in Japanese^[9] ($n = 295$), Turkish^[10] ($n = 154$), and Persian^[11] ($n = 100$) languages.

Table 1: Patients characteristics (n=313)

Patient variables	Observations (in mean ± SD or % (Percentage))
Age (years)	49.5±13.6
Gender (male:female)	163:150
Educational qualification (%)	
Primary	121 (38.7)
Middle school	53 (16.9)
High school	97 (30.9)
Graduate	42 (13.4)
Duration of opioid Rx (in weeks)	8.2±6.8
CSS	9.9±3.3
PAC-QOL score	
Physical discomfort score	1.326677±0.62
Psychosocial discomfort score	1.133778±0.43
Worries/concerns score	0.955852±0.36
Satisfaction score	1.894568±0.52
Overall score	1.327721±0.36

PAC-QOL: Patient assessment of constipation quality of life questionnaire, CSS: Constipation scoring system

Table 2: Internal consistency of Hindi version of the patient assessment of constipation quality of life questionnaire tool

Subgroups and overall	Cronbach’s alpha
Physical discomfort	0.7222
Psychosocial discomfort	0.6907
Worries and concerns	0.7711
Satisfaction	0.7025
Overall	0.8609

Table 3: Intraclass correlation values for tool subgroups and overall score

Subgroups	ICC	95% CI
Physical discomfort	0.783	0.694-0.848
Psychosocial discomfort	0.755	0.657-0.828
Worries and concerns	0.906	0.863-0.935
Satisfaction	0.738	0.635-0.816
Overall	0.847	0.781-0.894

ICC: Intraclass correlation coefficient, CI: Confidence interval

Table 4: Pearson’s correlation coefficients between the constipation scoring system score and subgroups and the overall patient assessment of constipation quality of life questionnaire score

Subgroups	Pearson’s correlation	P
Physical discomfort	0.5471	<0.00001
Psychosocial discomfort	0.4069	<0.00001
Worries and concerns	0.4007	<0.00001
Satisfaction	0.6661	<0.00001
Overall	0.6419	<0.00001

In contrast to original and subsequent studies in which study population were adult patients with a history of chronic primary constipation, our study population included patients with only drug (i.e., opioids) induced constipation, while patients with constipation due to other causes were excluded.

In our study, a strong internal consistency for the overall Hindi version of PAC-QOL score (i.e., Cronbach's alpha coefficient of 0.86) was observed. The Cronbach's alpha coefficient value for subgroup scores ranged from 0.70 to 0.77, also in favor of strong internal consistency. The result is comparable with the other published language versions of the questionnaire.^[8-11]

In terms of reproducibility of tool, a very good correlation was found between the overall and subgroup scores of Hindi version of PAC-QOL of first and second visit (i.e., ICC value ranged from 0.74 to 0.85) with a mean interval of 16 ± 3.2 days. The result of our study was comparable to the previous language versions^[8-11] except ICC for satisfaction subscale which is quite high in contrast to other studies (i.e., 0.74). Those patients not complaining in change of severity of constipation were included for the test-retest study; so unaltered severity of symptoms, also a short interval between visit, the similarity in response to questionnaire was expected and could be the reason for a strong correlation between all scores.

To determine concurrent validity, Hindi version of PAC-QOL overall score and subscale scores were compared to CSS scores. The severity of OIC was used by CSS in the present study. Pearson's correlation coefficient value ranges from 0.40 to 0.67 for all four subscales and overall score with $P < 0.00001$, showing a significant correlation between scores. The score is comparable to previous studies.^[9,10] Bengi *et al.*^[10] compared the PAC-QOL and CSS and found a correlation of 0.457 ($P < 0.001$) between the overall PACQOL and the CSS, while Nomura *et al.*^[9] found a correlation of 0.30–0.55 ($P < 0.001$) between the subscales and overall PAC-QOL and the CSS.

As the patients presenting to our pain and palliative clinic or ward, who required opioids for pain management, along with opioids, laxatives were often prescribed as per standard protocol for anticipated OIC. The CSS scores were usually on the lower side due to routine administration of laxative in these patients, average being just 9.9 ± 3.3 . In our study, we used this scale to just assess the severity of presenting symptoms of constipation.

The PAC-QOL questionnaire is valid and reliable to assess the QOL affected by the primary functional constipation and also in assessing responsiveness to targeted treatment strategies, as proved by the previous studies conducted in different language versions till date. From our study, it is now well established that the Hindi version, the present scale, can also be used to assess patients with constipation induced by causes other than primary

or functional. With a valid and reliable tool in a language that is easily understandable by most of our population, it can be used as a tool in routine clinical practice to evaluate the impact of constipation on QOL and also to measure the response to a constipation targeted pharmacotherapeutic regimen. As the PAC-QOL questionnaire has been validated in multiple international languages, it could be possible to compare our studies with international studies on constipation and to carry out further research work on constipation.

CONCLUSION

Hindi version of PAC-QOL has been proved to have reliability and validity to assess the QOL in cancer patients with OIC. It can also be used to assess the impact of a given therapeutic regimen for constipation and resulting improvement in QOL.

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Conflicts of interest

There are no conflicts of interest.

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