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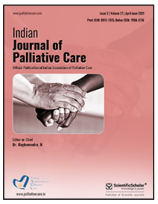

Original Article

Development and Validation of Total Pain Scale for Evaluation of Total Pain in Cancer Patients

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ABSTRACT

Objectives: Cancer pain has all the components of total pain such as physical, social, psychological, and spiritual. These components contribute to the overall pain experience in cancer patients. Many instruments have been developed till date to assess the effect of pain in cancer patients but none of the instruments include all components of total pain. In this article, we describe the development and validation of the total pain scale (TPS) for the evaluation of total pain in cancer patients with pain. This study aimed to develop and validate a questionnaire for the evaluation of total pain in cancer patients with pain.

Material and Methods: This study included a review of existing pain questionnaires for cancer pain for item pool generation. Items were generated in the Hindi language by six stakeholders to create 23 items to develop TPS. TPS was applied to 300 Hindi-speaking cancer patients. Bivariate correlation was used to reduce the number of items as well as construction of the domain followed by factor analysis to finalise TPS. Confirmatory factor analysis (CFA) was performed for testing the validity and reliability of TPS.

Results: TPS is an 18-item scale composed of four domains (physical, social, spiritual and psychological domain). The internal consistency of TPS and its subscales was found to be very good (α = 0.84–0.88). CFA and structural equation modeling Goodness of fit has confirmed that model 4 is the best fit as it yielded a lesser root-mean-squared error of approximation value of 0.062 and a greater comparative fit index, Tucker-Lewis index value of 0.944. The convergent and divergent validity of TPS and its domain was good.

Conclusion: This study reports TPS to be a brief (18-item), valid, and reliable questionnaire in the Hindi language for assessment of all components of total pain in cancer patients with pain.

Keywords: Cancer pain, Total pain scale, Validation, Reliability

INTRODUCTION

The incidence of cancer is rapidly increasing; globally it is 14.1 million new cases annually with cancer-related deaths that estimates to 8.2 million deaths/year.[1] As per the estimates of the World Health Organization in India, around 2.4 million people are suffering from cancer, of which more than 1 million new cases of cancer occur annually, and more than 80% are present at Stages III and IV.[2] Severe pain and other symptoms are commonly observed in advanced-stage cancer patients. It is estimated, of all cancer patients in India, about two-thirds are expected to be suffering from pain.[3]

In 1967, Dame Cicely Saunders first used the term 'Total Pain.' She explained total pain in terms of the physical, psychological, social and spiritual effects of pain on a patient's life. Cancer pain has all the components of total pain, such as physical, social, psychological, and spiritual.[4,5] These components contribute to the overall pain experience in patients with cancer referred to as total pain as shown in [Figure 1]. This study will focus on the concept of total pain which has received insufficient attention in the literature.

Several scales McGill Pain Questionnaire (MPQ) long and short form, brief pain inventory (BPI), and the pain thermometer for the assessment of various aspects of pain

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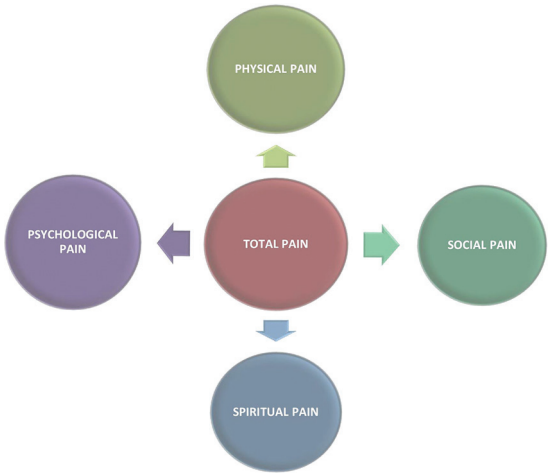

Figure 1: Conceptual model of total pain.

are found in the literature. However, these scales tend to cover total pain only partially, while their specific relevance to the Indian palliative care context may be questionable since most of these scales are primarily self-administered and in the English language. Translation of these scales in the Indian regional language brings sociocultural challenges. This causes an issue with the validity of that scale.[6,7] As a result, at present, there is no commonly accepted instrument to assess total pain due to cancer, in the pain and palliative care setting in India. Therefore, there is a strong need to develop a scale that encompasses this comprehensive multidisciplinary approach.

The instrument that is to be developed should include all components of total pain that impact patients' lives. The objective of the present study was to develop as well as validate a brief self-reported questionnaire for the evaluation of total pain in cancer patients.

MATERIAL AND METHODS

The study was done at Dr BRA Institute Rotary Cancer Hospital, AIIMS New Delhi, India, after approval of the Institute Ethics Committee of the tertiary care hospital. Eligibility criteria included any patient (a) diagnosed with cancer-related pain, (b) patients willing to provide written informed consent, (c) older than 18 years, (d) understanding Hindi language and (e) patients should be able to communicate effectively with the study personnel regarding the nature of their pain and patients of cancer with severe mental or cognitive disorders were excluded. Each participant was explained about the study and written consent was taken.

Study design

The study was conducted in two phases to develop a total pain scale (TPS) as shown in [Figure 2].

Phase 1: Development of first version of TPS (V_1), pilot testing and finalisation of TPS

Generation of item pool

In Phase 1, we performed a literature review using PUBMED and Google Scholar searching the keywords 'Cancer pain,' 'Physical pain,' 'Social pain,' 'Spiritual pain,' 'Physiological pain' and 'assessment of total pain in cancer patients.' The literature review was intended to gather a list of relevant cancer pain assessment questionnaires and previous cancer pain assessment guidelines.

We retrieved and focussed our review on advanced cancer patients distress scale,[8] Cost-Prom Patient-reported outcome measure,[9] palliative outcome scale,[10] hospital anxiety and depression scale,[11-14] MPQ,[15] short form MPQ (SF-MPQ-2),[16-18] and revised SF-MPQ-2,[19] Brief Pain Inventory (BPI),[20] and Hindi Brief Pain Inventory,[21] Edmonton symptom assessment schedule,[22,23] The European Organization for Research and Treatment of Cancer (EORTC QLQ-C30),[24,25] Functional Assessment of Chronic Illness Therapy-spiritual well-being scales (FACIT-Sp 12)[26] and cancer pain assessment scales. In addition, we also reviewed the unidimensional scale, visual analogue scale,[27-29] numeric rating scale[30,31], and verbal rating scale.[28] Further details of these questionnaires were provided in Table 1. The review led us to develop a conceptual framework for total pain in cancer. We conceptualised total pain in cancer patients as a multidimensional phenomenon that includes patient's self-evaluation of the impact of their physical capabilities, psychological state, social life, and spirituality.

Based on the conceptual framework for TPS, palliative care experts framed 23 items in the Hindi language based on the review of available pain questionnaires and formal interviews of stakeholders (patients, caregivers, and healthcare professionals, with at least 15 years of experience).

A team of pain and palliative care experts (two doctors from the department of Onco-anaesthesia and palliative medicine) and health-care professionals, (one from the department of surgical oncology, one from the department of radiology, one from the Neuro-anaesthesiology department and one from biostatistics department) reviewed these questions for duplication and relevance in terms of total pain in cancer patients. Items were modified as per the suggestions of the team members.

All items were represented on a horizontal line as a numerical rating scale from 0 to 10, with 0 being not at all and 10 being the worst possible the patient can imagine, 1–3 corresponds to mild, 4–6 as moderate, and 7–9 as severe pain. The questionnaire was 'self-administered.' Caregivers were allowed to help if required.

TPS was developed with 23 items followed by pilot testing on 107 cancer patients. Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity was applied to test sampling

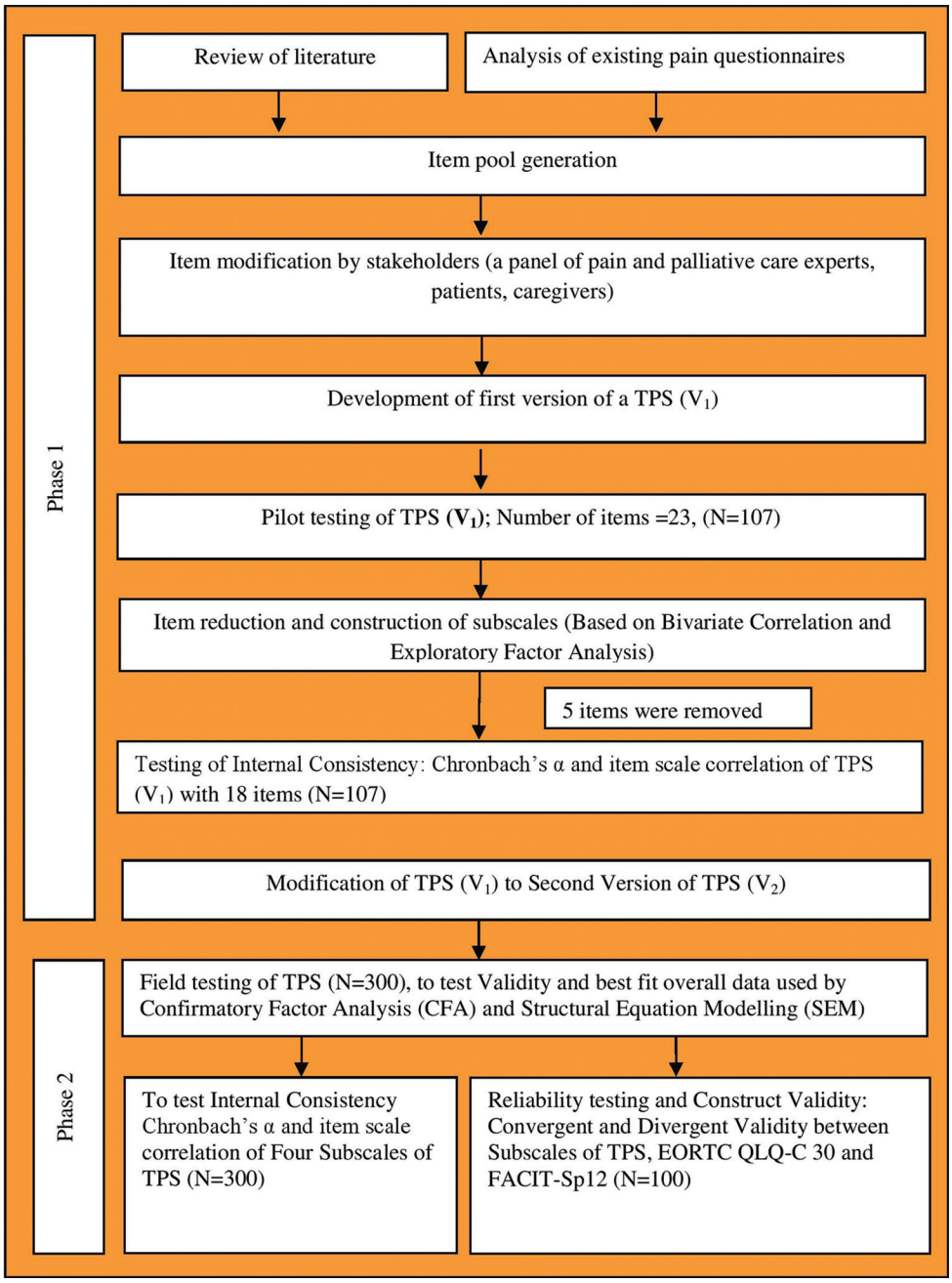

Figure 2: Flow chart of development and validation of total pain scale in cancer patients in Indian setup. TPS: Total pain scale, EORTC QLQ-C30: The European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire, FACIT Sp-12: Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being.

adequacy and strength of the item association. Bivariate correlation was used for item reduction if Pearson's correlation coefficient (r) was either too low (≤0.30) or too high (≥0.85). The principal component analysis followed by the varimax rotational method was used to extract factors from the pooled data. The maximum likelihood method and orthogonal varimax rotation were used with factor structure to improvise item loading around factors. Any item with a loading value of more than 0.4 and factors with an Eigenvalue of more than 1 was considered relevant.[32] The extracted factor was subjected to confirmatory factor analysis (CFA) to assign domains. Internal consistency of the TPS and extracted domains was tested by Cronbach's coefficient alpha (α). The α value of >0.7 has been recommended as

Table 1: Validated Tools used in the development of total pain scale (TPS).

S. No.	Tools	First author and year of validity	Validated in palliative care
1.	ACPDS	Sabine Fischbeck *et al.* 2012[8]	Sabine Fischbeck *et al.* 2012[8]
2.	COST-PROM	Jonas A *et al.* 2014[9]	Jonas A *et al.* 2014[9]
3.	POS	Julie Hearn *et al.* 1999[10]	Julie Hearn *et al.* 1999[10]
4.	HADS	Lloyd-Williams M *et al.* 2001[11] Bjelland I *et al.* 2002[12] Snaith RP *et al.* 2003[13]	Le Fevre *P* 1999[14]
5.	McGill (MPQ)	Melzack 1975[15]	Dudgeon *et al.* 1993[16] De Conno *et al.* 1994[17]
6.	SF-MPQ	Melzack 1987[18]	Melzack 1987[18]
7.	SF-MPQ-2	Robert H.Dworkin *et al.* 2009[19]	NA
8.	BPI	Twycross *et al.* 1996[20]	Twycross *et al.* 1996[20]
9.	BPI-H	Abha Saxena *et al.* 1999[21]	Abha Saxena *et al.* 1999[21]
10.	ESAS	Bruera E *et al.* 1991[22] Chang VT *et al.* 2000[23]	Bruera E *et al.* 1991[22]
11.	EORTC QLQ-C 30	Aaronson NK *et al.* 1993[24]	Aaronson NK *et al.* 1993[24] Kaasa S *et al.* 1995[25]
12.	FACIT-Sp 12	Peterman AH *et al.* 2002[26]	Peterman AH *et al.* 2002[26]
13.	VAS	Scott & Huskinsson 1976[27] Jensen *et al.* 1986[28] Price *et al.* 1994[29]	De Conno *et al.* 1994[17]
14.	NRS	Jensen *et al.* 1986[28] Jensen *et al.* 1993[30] Jensen *et al.* 1994[31]	De Conno *et al.* 1994[17]
15.	VRS	Jensen *et al.* 1986[28]	De Conno *et al.* 1994[17]

the stringent criteria for good internal consistency.[32] As an outcome, we modified and reduced the number of items and extracted the domains. As a result, we finalised the TPS.

Phase 2: Field testing of TPS to test its validity and reliability

In the Phase 2 study, field testing was done on another 300 cancer patients with pain. From all the 300 patients who had filled out TPS, 100 patients were randomly selected to fill EORTC QLQ C-30 version 3.0 and FACIT-Sp12 version 4.0 along with TPS, Permission was obtained from copyright holders to use both these questionnaires in the present study. EORTC QLQ-C30 evaluates patients' quality of life[24] and FACIT-Sp 12 stands for Functional Assessment of Chronic Illness Therapy-spiritual Well-being scales.[26]

CFA was used to test the construct validity of the TPS. First, we fit the confirmatory model in 4 domains obtained by factor analysis. The goodness of fit of the model was tested using various fit indices, like the Chi-square statistic as well as the Chi-square/degrees of freedom ratio, root-mean-squared error of approximation (RMSEA), Tucker-Lewis index (TLI) and Comparative Fit Index (CFI). The models with RMSEA values that are at or <0.08 are considered to be adequate and the value of TLI and CFI ≥ 0.95 is considered indicative of a good fit.[33]

In addition, we also fit three other models based on factor analysis. A better fit is indicated by a lower Chi-square and Akaike's information criterion (AIC) when comparing these models with our final four-factor model. Model 1 represented a one-factor model, in which 18 items were used as one factor; model 2 represented as two-factor model in which 18 items were divided into two factors one with 12 items and one with six items according to factor analysis. Model 3 was a three factors model in which items were divided into three factors - 10 items, 4 items and 4 items, respectively, based on factor analysis. Model 4 was a four-factor model in which items were divided into four factors- with the first two factors (Physical and Spiritual factors) having four items each and the other two (Psychological and Social factors) with five items each.

To compare the score among the domains to find the contribution of each domain out of the total score of all domains, we converted the aggregate of each domain in 0–100 score, the method of this conversion is as follows: To calculate subscale scores, the reported value of each item of a domain was added, divided by the maximum possible domain scores, multiplied by 100 to yield subscale score of 0–100 points, where higher value corresponds to worst pain. Similarly observed value of all items in all domains was added, divided by the maximum possible value of the total items multiplied by 100 that yields a summary score of the TPS at 0–100 points. Construct validity was assessed using Pearson's correlations between the subscales of TPS and subscales of EORTC QLQ C-30 and FACITSp-12. Statistical analysis was using the IBM SPSS Version 22.0 and STATA 12.0.

RESULTS

Phase 1 study

The demographics and clinical characteristics of 107 cancer patients who completed TPS (V_1) during pilot testing are shown in [Table 2], which shows the mean (standard deviation, SD) age of patients was 47.6 (12.2%) years and male patients were 56%, female patients were 44%. The most frequent cancer site was head and neck cancer (20.6%), followed by genitourinary cancer (19.6%), breast cancer (18.7%), and lung cancer (15.9%).

We did Pearson's correlation coefficient of 23 items of TPS (V_1) between items, five items were eliminated out of 23 items as three items were highly correlated with Pearson's correlation coefficient, ≥0.85[32] (Item number 7, 13, and 19 were eliminated) and two items were weak correlation (Item number 18 and 20) (Pearson's correlation coefficient, ≤0.30). Item no 1 and 7 were highly correlated (r = 0.921) as item number 7 represents a single construct that is, walking, while item number 1 represents a broad construct that is, general activity (e.g., standing, sitting, bathing, eating and drinking) therefore item number 7 (walking ability) was eliminated. Similarly, item numbers 5 and 13 were highly correlated (r = 0.955). Item number 13 (guilt) was eliminated because most of the patients could not understand the meaning of guilt but item number 5 (angry with god) was retained as it had a good correlation with other items of the scale and was simple to understand by patients. Item no 12 and 19 were highly correlated (r = 0.87). As item number 12 represented the frustration of patients due to cancer pain, while item number 19 represented anger, we opted to retain item no 12 as frustration was more associated with the disease while anger is a broad domain and it may be circumstantial. Both items 18 (Social isolation) and 20 (Fear of unknown) had a weak correlation (Pearson's correlation coefficient, ≤0.30) with the remaining items, and also patient could not understand the meaning of social isolation and fear of the unknown. Hence, we eliminated both items number 18 and 20 from TPS (V_1).

A significantly high KMO value (0.83) in the sphericity test revealed the adequacy of the factor analysis in the present study data. The number of factors was identified by the Scree test shown in [Figure 3].

After that exploratory factor analysis of 18 items in 107 patients yielded four-factor structures that explained

Table 2: Characteristics of patients who participated for pilot testing (N=107) and field testing (N=300).

	Pilot testing (N=107)		Field testing (N=300)	
Age (yrs.) Mean±S.D (range)	47.6±12.2 (18-75)		49.4±12.7 (18-75)	
Gender	N	%	N	%
Male	60	56.1	164	54.7
Female	47	43.9	136	45.3
Marital status				
Unmarried	6	5.6	20	6.7
Married	97	90.7	280	93.3
Widowed	4	3.7	0	0
Educational level				
Illiterate	25	23.4	87	29
5th class pass	26	24.3	46	15.3
10th class pass	26	24.3	80	26.7
12th class pass	9	8.4	29	9.7
Graduate or More	21	19.6	58	19.3
Occupation				
Employed	11	10.3	63	21.0
Unemployed	55	51.4	170	56.7
Homemaker	41	38.3	50	16.7
Other	0	0	17	5.7
Diagnostic category				
1. Head & Neck Cancer	22	20.6	63	21.0
2. Lung Cancer	17	15.9	61	20.3
3. Gastro Intestinal Cancer	10	9.3	41	13.7
4. Genitourinary Cancer	21	19.6	47	15.7
5. Breast Cancer	20	18.7	41	13.7
6. Soft Tissue Sarcoma	3	2.8	19	6.3
7. Leukaemia & Lymphoma	5	4.7	21	7
8. Others	9	8.4	7	2.3
NRS				
Mean±S.D. (range)	5.4±1.4 (0-10)		5.1±1.8 (0-10)	

70.0% of total variance with an Eigenvalue of more than 1, After applying maximum likelihood with four factors and orthogonal varimax rotation, loading of 18 items around four factors, but we kept all items above 0.4 cutoff mark shown in [Table 3].

The first factor contained five items that were general statements or were associated with the psychological circumstance of cancer pain; we called it the psychological or emotional domain. The second factor has five items that were related to social life called the social domain. The third factor consisted of four items that evaluate spiritual and religious activity; called the spiritual domain and the fourth factor consisted of four items that evaluate physical capabilities; called physical domains shown in [Table 4].

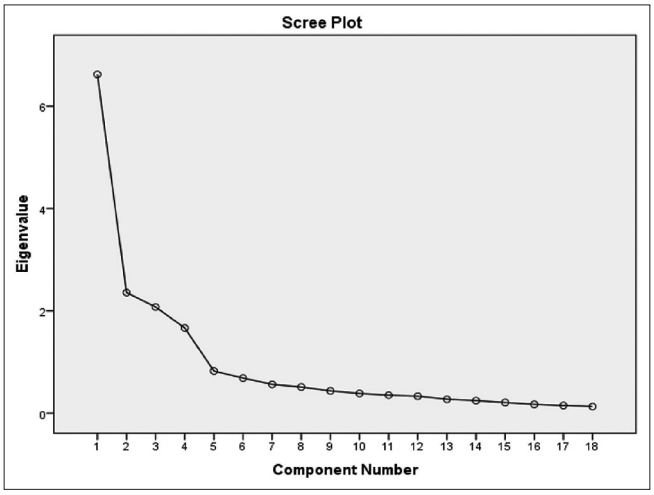

Figure 3: Scree plot of total pain scale (V1).

Chronbach's alpha coefficients for physical, social, spiritual, and psychological and TPS were 0.78, 0.80, 0.81, 0.92, and 0.89, respectively, thus depicting high internal consistency. TPS was finalised with 18 items and items were rearranged as per the domains. The final version of TPS is attached in Annexure 1 (Hindi Version) and to calculate the scoring of TPS and is linear transformation of Raw Score 0-100 provided in Annexure 2.

Phase 2 study

The demographics and clinical characteristics of patients (n = 300) who were recruited for field testing are shown in [Table 2]. Which SD age of patients in the field testing group was 49.4 (12.7) years and male patients were 164 (54.7%) and females were 136 (45.3%). 280 (93.3%) were married 20 (6.7%) were unmarried, while more than 50% of these patients had higher education. Out of these 47 (15.7) were employed, 205 (68.3) were unemployed and 48 (16%) were housewives.

Table 3: Loading of items on four factors.

	Variables	Factor 1	Factor 2	Factor 3	Factor 4
Q1	General activity (e. g . standing, sitting, bathing, eating, drinking) अपने दैनकि कार्यो पर असर (जैसे उठना,बैठना , घूमना, नहाना, खाना,पीनाआदि)	-0.020	-0.129	0.044	***0.627***
Q2	Impact on job/work (नौकरी/काम पर असर)	0.047	***0.819***	-0.011	0.039
Q3	Enjoyment of life (जीवन का आनंद लेने पर)	0.298	0.214	0.076	***0.769***
Q4	Worthless/hopeless नराश (उदासी महसूस होना)	***0.849***	0.182	0.126	0.142
Q5	Anger with God (भगवान से नाराजगी)	-0.029	0.264	***0.786***	0.257
Q6	Worried about future of family (परविार के भवष्यि की चति)	0.282	***0.701***	0.253	-0.099
Q8	Anxiety (feeling nervous) चति (घबराहट महसूस होना)	***0.869***	0.126	0.059	0.007
Q9	Regret to past activity (अपने कर्मो का पछतावा)	0.289	0.304	***0.704***	-0.029
Q10	Financial concern (इलाज के दौरान धन सम्बन्धी परेशानी)	0.168	***0.847***	0.176	0.096
Q11	Sleep (आपकी नींद पर)	0.101	0.172	0.128	***0.773***
Q12	Frustration (चड़िचड़िापन होना)	***0.811***	0.239	0.161	0.230
Q14	Loss of social status and role (समाज में आपकी भूमकिा और स्तर पर असर)	0.152	***0.778***	0.188	0.230
Q15	Relations with other people (परविार के अथवा समाज के लोगो से मलिने-जुलने पर)	0.080	0.181	0.103	***0.848***
Q16	Fear of suffering from diseases (बीमारी से होने वाली पीड़ा से डर)	***0.805***	0.061	0.260	0.089
Q17	Loss/Struggle with faith in God (भगवान पर आस्था/वशि्वास घटना)	0.185	0.057	***0.806***	0.224
Q21	Dependency-burden to family(परविार के भवष्यि की चति)	0.125	***0.814***	0.143	0.156
Q22	Depressed (feeling sad, hopeless) नराश (उदासी महसूस होना)	***0.850***	0.127	0.138	0.044
Q23	Fear of dying (मरने का डर)	0.219	0.069	***0.743***	-0.015

Loading of 18 items are shown in four factors. Loading of items with more than 0.4 are in bold and italics

[Table 5] represents that physical pain has the highest pain score average of 60.6 units with a 95% confidence interval (CI) (57.5–63.5), the lowest average pain score was 33 units found in the Spiritual domain with 95% CI (29.7–36.2) while social pain score was 49 units with 95% CI (45.6–52.09) and emotional pain score was 48 units with 95% CI (45.3–50.4) which were approximately equal. In this study, the total pain score is around 48 units in the 0–100 range with 95% CI (45.5–49.8).

The Cronbach's coefficient (α) of TPS was found to be 0.88 while α of four domains ranged from 0.84 to 0.88. Based on the summary scores, physical pain contributed 32% toward total pain, while non-physical factors such as social pain, psychological pain and spiritual pain contributed 26%, 25% and 17%, respectively, to the total pain shown in [Figure 4].

Construct validity of TPS

Construct validity was evaluated by CFA. We developed four models to investigate which represents the best fit for the overall data. According to the fit indices shown in [Table 6], Model 4 was a better-fitting model. Model 4 had an RMSEA value of 0.062, a CFI value of 0.944, and a significant change in Chi-square statistic (χ^2) with the change in the degree of freedom in comparison with Model 1, 2, and 3 ($\chi^2 = 278.09$, $P < 0.001$, for Model 4). Model 4 was the best suitable fit for the data and correlation and covariance within the domain and between the subscales as shown in [Figure 5]. The goodness of fit results of structural equation modeling (SEM) reveal that Model 4 provides better classification than the other three models, four domains obtained from 18 items are good for assessing the total pain of cancer patients.

Out of 300 patients, 100 also filled the EORTC QLQ C-30 and FACITSp-12 besides TPS. Convergent validity was assessed using Pearson's correlation coefficient among similar domains of the TPS, EORTC QLQ C-30 and FACIT-Sp12 whereas divergent validity was tested between unrelated subscales of TPS, EORTC QLQ C-30 and FACIT-Sp12 shown in [Table 7]. The EORTC QLQ-C30 domains – physical, social and psychological highly correlated with the respective domains of the TPS with ($r = 0.574$, $r = 0.470$, and $r = 0.714$) and $P < 0.001$, respectively. The FACIT Sp-12 correlated well with TPS ($r = 0.466$, $P < 0.001$). Convergent and divergent validity of TPS and its domain was good as none of the domains of TPS had a high correlation with other domains of TPS and dissimilar domains of EORTC QLQ C-30 and FACIT-Sp12 ($r = 0.02$–0.48) while similar domains of TPS, EORTC QLQ C-30 and FACIT-Sp12 had high correlation ($r = 0.47$–0.71). The Pearson's correlation coefficient subscales of TPS, EORTC QLQ C-30 and FACIT-Sp12 were statistically significant ($P < 0.001$).

DISCUSSION

The TPS is a psychometrically established questionnaire that aims to detect total pain. The available standardised questionnaires do not cover all the dimensions of pain and they do not specifically cater to patients with advanced cancer stage. Fischbeck *et al.* stated that some questionnaires used in cancer pain do focus on psychological issues, such as depression and anxiety disorder, but do not cover all the concepts of pain.[8]

We emphasised self-administration of TPS unless patients were unable to read or write, in case one of the attendants was allowed to assist the patients to fill out the questionnaire. TPS is a new questionnaire, which has been designed to assess all the issues concerning palliative care patients in a self-reported mode, which serves as the most reliable source of information. The severity of pain is assessed with simultaneous assessment of pain in all the dimensions.

Table 4: More than 0.4 loading of items on 4 factors.

Factor	Construct Domains	Items No.
1	Psychologicaldomain	4,8,12,16,22
2	Socialdomain	2,6,10,14,21
3	Spiritualdomain	5,9,17,23
4	Physicaldomain	1,3,11,15

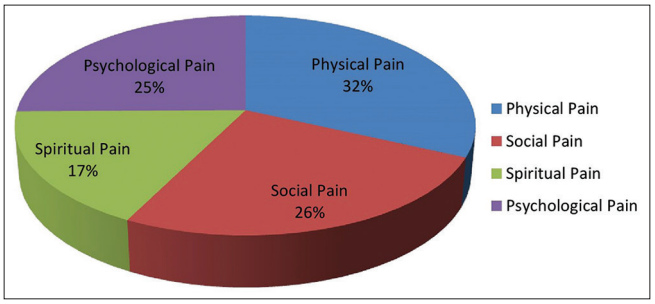

Figure 4: Total pain in cancer patients.

Table 5: Total pain on 0-100 scale (N=300).

Domains	Mean±S.D	Mean diff (95% CI)	Median	Range	Cronbach's coefficient (α)
Physical	60.55±26.06	(57.5-63.5)	62.5	0-100	0.85
Social	48.85±28.53	(45.6-52.09)	50	0-100	0.84
Spiritual	33.04±28.63	(29.7-36.2)	30	0-100	0.87
Psychological	47.93±22.43	(45.3-50.4)	48	0-100	0.84
Total Pain	47.68±18.72	(45.5-49.8)	50	0-100	0.88

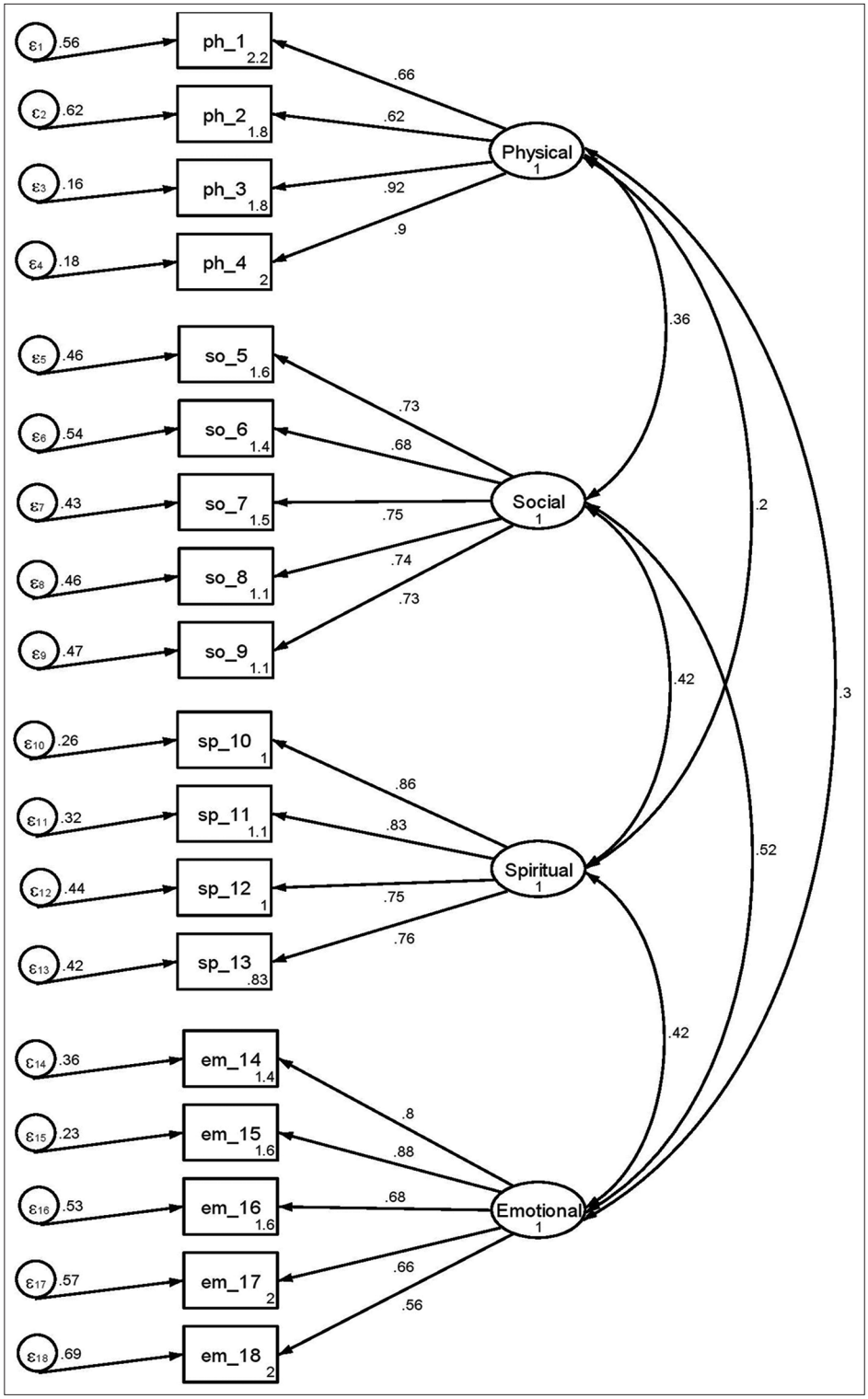

Figure 5: Confirmatory factor analysis and structural equation modelling for the four-factor model.

Despite the fact that patients were already experiencing pain due to cancer, they were able to report the pain using test version 1 of TPS. This is quite significant as the palliative care setting is a challenging area for the validation of questionnaires. Each of the four domains contained in TPS has shown high internal consistency (α = 0.89) and

Table 6: Fit indices for confirmatory factor models in overall sample.

Model	RMSEA	CFI	TLI	df	χ^2	χ^2/df	AIC	BIC	*P*-value
Model 1	0.186	0.473	0.402	135	1541.98		26757	26957	<0.001
Model 2	0.158	0.619	0.568	135	1151.72	390.26	26366	26566	<0.001
Model 3	0.111	0.818	0.790	132	616.28	535.44	25837	26048	<0.001
Model 4	0.062	0.944	0.934	129	278.09	338.19	25505	25727	<0.001

RMSEA: Root-mean-square error of approximation, CFI: Comparative fit index, TLI: Tucker–Lewis index, df: Degree of freedom, AIC: Akaike's information criterion, BIC: Bayesian information criterion

Table 7: Correlation matrix of four TPS Subscales with EORTC QLQ –C 30 and FACITSp-12 subscales (N=100).

		TPS				Total scale
	Subscales	Physical	Social	Psychological	Spiritual	
TPS	Physical	1	0.337**	0.212*	0.128	0.631**
	Social	0.337**	1	0.466**	0.274**	0.762**
	Psychological	0.212*	0.466**	1	0.392**	0.744**
	Spiritual	0.128	0.274**	0.392**	1	0.621**
	Total scale	0.631**	0.762**	0.744**	0.621**	1
EORTC QLQ-C30	Physical	0.574**	0.169	0.151	0.017	0.345**
	Social	0.243*	0.470**	0.486**	0.319**	0.549**
	Psychological	0.286**	0.531**	0.714**	0.303**	0.665**
FACIT Sp-12	Spiritual	0.219*	0.259**	0.401**	0.466**	0.479**

**Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed).

each domain also demonstrates a high internal consistency. Studies have demonstrated an acceptable good Chronbach's α of 0.84 for validation of EORTC QLQ-C30.[34]

The factor analysis confirms the psychometrically stable structure of the scale in both phases of the study and suggests that total pain consists of four domains that are physical, social, spiritual, and emotional aspects of pain. Our study proved very good reliability and consistency of construct validity in the phase two study. We choose two different instruments to establish construct validity EORTC QLQ-C30 (assessment of QOL) and FACITSp-12 (assessment of spirituality) and these two scales were used in the cancer population with proven validity and reliability.[34,35] Construct validity of TPS was found to be very good as there was a significant correlation between the related domain of TPS and EORTC QLQ-C30 depicting a good convergent validity. The EORTC QLQ-C30 domains physical, social and psychological are highly correlated with the respective domains of the TPS. Unrelated domains of TPS, EORTC QLQ-C30, and FACIT Sp-12 showed very low correlation confirming the divergent validity of TPS.

This scale has an administration time of approximately 5 minutes which gives it an advantage over other pain assessment scales and has been designed to reflect the true nature of cancer-related pain in physical, social, spiritual, and psychological dimensions. It also demonstrated good validity and reliability in heterogeneous groups as well as in a sufficient sample size of cancer patients for verifying the psychometric properties of this 18-item scale. Our results are congruous with the findings of prior studies and recommendations.[35,36]

In our study, we had taken four models with each model with a different number of factors. However, it was found that our Model 4 which was a four-factor model had significant improvement over the rest of the models. Model 4 was described as the best fitting for the data because it was better than the three models and fulfilled all the criteria of goodness of fit. The goodness of fit results of SEM also revealed that Model 4 provided better classification than the other three models and the four domains obtained from 18 items are good for assessing the total pain of cancer patients. This procedure has been followed by the study of Atkinson who designed a three-factor model for BPI and found it to be best as it had high internal consistency.[37]

The strength of this instrument is that it contains all four components which are not available in any other questionnaire. We have applied SEM for CFA which further validates our scale in terms of assessing the total pain of cancer patients. In this study, TPS showed that 32% of physical pain and 68% of other factors (social, spiritual, and psychological) affect a patient's quality of life. Hence, now when the patient will come to the outpatient departments, we should not only treat physical pain but also counsel the patient emphasising psychosocial and spiritual well-being. Being a single-centre study is considered a limitation but this has its own advantage in

uniformity of data collection and evaluation. Most of the participants in Stage 4 are bedridden and disabled and therefore are unlikely to visit hospitals, and this was the major challenge this study faced.

The present study did not assess the cross-cultural validity of the TPS, albeit we are aware that differences are present in the cultural experiences of total pain in cancer patients.

Scope of future research

- Multi-centric studies should be undertaken to ensure the generalisability of the developed TPS
- It should be translated and validated into other Indian languages to expand its utility in a culturally vast country like India.

CONCLUSION

This study indicates TPS to be a brief, valid, and reliable questionnaire for the assessment of all components of total pain in cancer patients with pain. TPS and its domains (physical, social, spiritual, and psychological) demonstrated high internal consistency and good reliability. TPS was shown to have good convergent and divergent validity. Our scale would lead to a better understanding of the concept of total pain and the establishment of a treatment strategy for total cancer pain.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

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ANNEXURE

संपूर्ण दर्द का पैमाना

प्रश्न.	यह पैमाना आपसे पिछले सात दिनों में कैंसर के दर्द से आपके जीवन पर प्रभाव पूछता है। निचे दिए गए प्रश्नो में से कोई प्रश्न आपके लिए जरुरी भी नहीं हो सकता, पर आप सभी प्रश्नो के उत्तर देंगे। उस एक संख्या पर गोला लगाइए, जो यह वर्णन करती हो कि, कैंसर के दर्द की वजह से, पिछले एक सप्ताह के दौरान निम्नलिखित पर कितना असर पड़ा?											
1.	अपने दैनिक कार्यो पर असर (जैसे उठना, बैठना , घूमना, नहाना, खाना ,पीना आदि)	0 बिलकुल नहीं	1	2	3 थोड़ा सा	4	5	6 थोड़ा ज्यादा	7	8	9 बहुत ज्यादा	10 बहुत ही ज्यादा
2.	आपकी नींद पर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
3.	परिवार के अथवा समाज के लोगो से मिलने- जुलने पर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
4.	जीवन का आनंद लेने पर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
5.	परिवार के भविष्य की चिंता	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
6.	नौकरी/काम पर असर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
7.	इलाज के दौरान धन सम्बन्धी परेशानी	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
8.	निर्भरता /परिवार पर बोझ	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
9.	समाज में आपकी भूमिका और स्तर पर असर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
10.	भगवान से नाराजगी	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
11.	अपने कर्मो का पछतावा	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
12.	मरने का डर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
13.	भगवान पर आस्था / विश्वास घटना	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
14.	चिंता (घबराहट महसूस होना)	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
15.	निराश (उदासी महसूस होना)	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
16.	बीमारी से होने वाली पीड़ा से डर	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
17.	चिड़चिड़ापन होना	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा
18.	जीवन से निराश होना	0 बिलकुल नहीं	1	2	3	4	5	6	7	8	9	10 बहुत ही ज्यादा

प्रश्नावली किसके द्वारा भरी गई है : ☐

1. मरीज
2. देखभाल करने वाला
3. स्वास्थ्य देखभाल पेशेवर

Annexure 1: Total pain scale: Hindi Version.

Factor	Construct Domains	No. of Question	Items No.
1	Physical domain	4	1,2,3,4
2	Social domain	5	5,6,7,8,9
3	Spiritual domain	4	10,11,12,13
4	Psychological domain	5	14,15,16,17,18

TPS is composed of multi-item scales and single-item measures. These include four domains. Each of the multi-item scales includes a different set of items-no item occurs in more than one scale.

All of the scales and single-item measures range in score from 0 to 10. A high scale score represents a worst response level.

The principle for scoring these scales is the same in all cases 0 to 10:

1. Estimate the average raw score by adding the items contributed to respective domain.
2. Use a linear transformation to standardise the raw score, so that scores range from 0 to 100; a high score represent a higher ("worse") level of symptoms.

For all scales, the raw score of domain (RS). is the mean of the present in that domain.

Raw score=RS= $(I_1+I_2+\ldots\ldots+I_n)$ /n

I = Item in domain

N= Number of items in domain

Physical Domain= (RS)/Range×100

Examples:

Physical Factor

Raw Score = (Q1+Q2+Q3+Q4)/4
0-100 Transformation = (RS)/Range ×100
Range = Max-Min = 10-0 = 10

Range is the difference between the maximum possible value of RS and the minimum possible value.

Annexure 2: Scoring the total pain scale.