Reliability & Validity of The Hindi Functional Assessment of Cancer Therapy For The Gallbladder Cancer

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ABSTRACT

Background and objective The efforts to monitor quality of life (QOL) are increasing. However, the non-availability of a valid and reliable tool in the local language is a common problem. Cross-culturally sensitive tools enable the researchers to compare different patient populations and identify cultural differences and variations. The present study was carried out to, validate and test for reliability a reliable QOL tool for the gallbladder cancer patient population in a tertiary care hospital in IMS,BHU, Varanasi India.

Key words Cronbach's α-gallbladder cancer - quality of life - reliability – validity.

Introduction : - In developing country when Quality of life is increased the survival of patient Suffering with the gallbladder cancer is also improved[1]. Patients with cancer of the gallbladder have adverse effect on their quality of life{2}. Patient is physically unfit to do his routine activities he/she feels to be cut off from his socio cultural activity, recreation and sexual functioning[3]. The disease is indigenous progresses very slow patient can not be assessed in initial period with minor symptoms[4.19] and he/she (patient) used to take symtomatic treatment

from available near by locality. Patient came for treatment in late stages have been found to have numerous problems at diagnosis and significant post-treatment morbidity compared to patients with other cancers[5,6]. Among these, physiological derangements like Upper abdominal pain, nausea and vomiting, loss of appetite, fatigue, loss of taste, jaundice and pain are of paramount importance. Impaired psychosocial functioning and psychological distress are also reported with worry, anxiety, mood disorder, fatigue, and depression as the main problems. Of all sub-sites, patients with the gallbladder cancer are reported to have the worst health related QOL(HRQOL)[7,8,9,]. Gender and age differences are evident with females showing poorer emotional functioning compared to males, and older patients showing better emotional and social functioning than younger patients.QOL research in the gallbladder cancer patients can be considered to be in its inicial stage[10]. Food digestion and eating have been identified as predictors of QOL in Cancer of the gallbladder and stage of the disease appears to have the strongest relationship with HRQOL, even though site and stage specific studies are very few. One of the reasons is the non-availability of valid local language tools[11,12,17]. Translating well-documented and established questionnaires has the advantages in terms of time saved on tool development. It also provides a scope for cross-cultural validity studies, and identifying cross-cultural QOL differences [2,7]. The Functional Assessment of Chronic Illness Therapy (FACIT).Measurement system's QOL tools for cancer, the Functional Assessment of Cancer Therapy (FACT), have shown substantial scope as a cross-cultural instrument in the Indian setting[28]. Despite the fact that the disease specific FACT tools contain the core General tool (FACT-G) as the generic QOL measure, the inclusion of the "Additional Concerns" subscale makes it a population specific tool that requires reliability studies in specific populations. The FACT-Hep (Hepatobilliary)Verson-4 is a 45 item questionnaire divided into five domains (4 non-specific an1specific). [8,9,10,11]

The present study was undertaken to validate and test for reliability a QOL tool for the gallbladder cancer patient population in a tertiary care hospital in north east India. The study was approved by ethical committee of the university. The test was administered and scored in accordance with the instructions in the manual for the version 4 of the FACIT measurement system16. Demographic variables were recorded at the time of interview while the disease and treatment variables were extracted from the case records. Statistical analyses were carried out by using product moment correlation. Reliability was estimated using Cronbach's α. [11,]

Material & MethodsA prospective cohort study from Nov 2011 toJune 2012 was carried out in a tertiary care hospital in IMS,BHU, Varanasi India among 65 cancer of the gallbladder patients who were undergoing or underwent curative treatment.

The Hindi version of the Functional Assessment of Cancer Therapy, Version 4 (FACTHep) was used. The study was approved by the Institution ethical committee (IAC). Written informed consent was obtained from all the participants. The test was administered and scored in accordance with the instructions in the manual for the version 4 of the FACIT measurement system. Statistical analyses were carried out by using product moment correlation. Reliability was estimated using Cronbach's α.[11.14,18]

Table1. Mean, range, standard deviation(SD), Cronbach's α of the total scores of Hindi FACTHep(versoin4)

Scale/Subscale	Chronbach's alpha	Range	Minimum	Maximum	Mean	Std. Deviation
Physical wellbeing(7)	0.738	24	2	26	16.68	5.271
Social wellbeing(7)	0.588	18	10	28	19.69	3.230
Emotional wellbeing(6)	0.782	16	5	21	13.63	4.182
Functional wellbeing(7)	0.566	22	2	24	12.55	5.163
FACT-G Total(27)	0.467	51	17	68	41.68	10.667
Additional concern Hep(18)	0.704	94	56	150	103.77	20.659
Total Of scale (45)	0.851	61.00	41.00	102.00	64.9538	12.08360
Valid N (listwise)	65					

Table 2: Correlation matrix and significant of FACThep total score and subscale score with various parameters

	FACThep Total	Physical Wellbeing	Social wellbeing	Emotional wellbeing	Functional wellbeing	Additional Concern
Age	-.231	.072	.126	-.146	-.153*	-.022
Gender	.082	-.045	.069	.069	.194	-.022
Economic	-.018	.126	.086	.061	.042	-.038
Type of family	-.018	.299*	.150	-.082	-.014	-.010
Lymphatic involvement	-.056	-.010	.160	-.075	-.129	.029
Grade	.630**	.006	.015	.098	.-162	.019
Diet	-.164	-.122	-.166	.044	.004	-.171

Education	.455**	.271*	.124	.259*	.180	.437**
Pretreatment interview status	.555**	.362**	.143	.525**	.501**	.828**
During treatment	.476**	.-112	.-114	.273*	.315*	.510**

P*≤0.05,   P**≤0.01

Result

The result of 65 respondents were analyzed . the mean age is 53.95range is (25-80). Male female ratio is 1:2.6 , income category lower is 35.4%, middle is 30.8%, upper middle is 33.8%. Hindu were90.8% and Muslim were 9.2%. In family status joint is 35.4% and nuclear is 64.6%. In education illiterate are 30.8%. educated with primary education 30.8%, school level education is 16.9% patients received college level or professional education were 10.8%, having steady income stage. The total score of the individual respondent ranged from 41-102 with mean score 64.95. The cronbach's α for the subscales ranged from .566 to .782 while the cronbach α for the total FACT hep Hindi version 4 was .85 (Table1) Age was negatively correlated with FWB r-.156 p≤.021,gender, economic status, diet does not shows any significant correlation but type of family joint and nuclear shows positive correlation with PWB , lymphatic node involvement and grade have highly significant correlation with FACThep total scores r.630 p≤0.00. patients education shows significant correlation with EWB, additional concern and total FACThep scoring. In the pretreatment stage the FACThep score showed significantly positive correlation with PWB, EWB ,FWB, additional cocern and total FACTHep scores respectively r .362**   p≤ .003, r.525** p≤.0.00 , r.525** p≤.0.00, r .501**p≤.000, r .555 p≤ .000. During treatment FACTHep scores are highly positive correlation with Total FACThep, EWB, FWB, additional concern respectively r .476** p≤0.00 , r.273*   p≤.043,   r.273*   p≤.019,   r .510 p≤0.00.(Table2)

Discussion

FACIT The functional assessment of cronic illness therapy measurement system's QOL tools for cancer, not for hepatobilliary and gallbladder cancer but also available FACT B(breast cancer)[17] FACTH&N(head & neck) cancer[2]UW-QOLv4 for oropharangeal cancer[15] FACT.Pan(pancease)cancer these tools are available in different language and also in Indian national language Hindi[11]. The advantage of using Hindi developed version tool instead of developing a new one, is primarily save the amount of time needed to establish reliability for the translated tool . As the source tool is valid, and its characterastics(face, contant, construst, and factorial validity) are passed in to translated version as the items are same similar by content implication and structure. The cronbach α of the present study indicates high internal consistency for subscales and translated tool so Hindi version

of Fact hep can be consider a reliable QOL tool for the gallbladder cancer patients[2,18].

The present study shows effects of age on functional wellbeing, older age shows poor negative functional wellbeing. The type of family (joint and nuclear) the patient are active with small families having better PWB. Higher educational status of patient influence the QOL in gallbladder cancer patient these patients having better planned way of treatment patient shows better emotional stability. In pre treatment stage patients have better coping and adjustment scores, and in the active treatment stage patients were found to have better emotional and functional wellbeing, coping with the treatment and rehabilitation with disease.

In conclusion the Hindi FACT Hep version 4 was developed and its sensitivity was found to be satisfactory. This study also influence cross-cultural sensitivity of the tool. FACTHep version 4 questionnaires further can be used in long term follow up studied to identify the QOL determinants in eastern Indian gallbladder cancer patient population, and their change over time result of this study will assist in developing psychological and rehabilitation intervention programme to meet the specific requirements of the patients.

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