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Validity of the FACT-H&N (v 4.0) among Malaysian oral cancer patients

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SUMMARY

To assess the cross-sectional construct validity of the Malay-translated and cross-culturally adapted FACT-H&N (v 4.0) for discriminative use in a sample of Malaysian oral cancer patients. A cross-sectional study of adults newly diagnosed with oral cancer. HRQOL data were collected using the FACT-H&N (v 4.0), a global question and a supplementary set of eight questions ('MAQ') obtained earlier in pilot work. Of the 76 participants (61.8% female; 23.7% younger than 50), most (96.1%) had oral squamous cell carcinoma; two-thirds were in Stages III or IV. At baseline, patients' mean FACT summary (FACT-G, FACT-H&N, FACT-H&N TOI, and FHNSI) and subscale (pwb, swb, ewb, fwb, and hnsc) scores were towards the higher end of the range. Equal proportions (36.8%) rated their overall HRQOL as 'good' or 'average'; fewer than one-quarter rated it as 'poor', and only two as 'very good'. All six FACT summary and most subscales had moderate-to-good internal consistency. For all summary scales, those with 'very poor/poor' self-rated HRQOL differed significantly from the 'good/very good' group. All FACT summary scales correlated strongly ($r > 0.75$). Summary scales showed convergent validity ($r > 0.90$) but little discriminant validity. The discriminant validity of the FHNSI improved with the addition of the MAQ. The FACT-H&N summary scales and most subscales demonstrated acceptable cross-sectional construct validity, reliability and discriminative ability, and thus appear appropriate for further use among Malaysian oral cancer patients.

Introduction

Oral cancer is the sixth most common cancer and can seriously affect sufferers' quality of life. Considering the important functional and social role of the oral cavity and its related structures (and anatomical location), oral cancer can be even more debilitating than other forms of cancer.[1] The most difficult challenge in managing oral cancer is the delicate balance between arresting disease progression and not compromising the patient's quality of life.[2] Thus, specialists must consider patients' perceptions and preferences before choosing the treatment regimen. Patients are often willing to accept a reduced lifespan rather than compromise their quality of life drastically, especially with speaking, eating, and swallowing.[3] Understanding the functional, socio-psychological and physical effects of oral cancer would assist medical and dental specialists in appreciating the value that sufferers attach to different aspects of their health-related quality of life.

In Malaysia, such information is lacking, and the condition appears to be silently borne by patients. There is therefore an urgent need for Malaysian dental and medical specialists to be better informed about their oral cancer patients' on-going health-related quality of life (HRQOL) at different stages of their illness, especially at diagnosis and after commencing treatment. Such information would greatly assist in managing such patients. In order to obtain it, patients' HRQOL measurement would need to be achieved using an instrument that is appropriate for Malaysia's multicultural society. The development of existing disease-specific HRQOL instruments has occurred using more homogenous populations in developed countries, and their suitability for use in Malaysia is untested.

The purpose of this study was to determine the cross-sectional validity of the cross-culturally adapted FACT-H&N (v 4.0) instrument for discriminative use among Malaysian oral cancer patients.

Patients and methods

In earlier work—using quantitative and qualitative evaluations by an expert group (18 medical, nursing, and dental specialists actively managing oral cancer patients throughout Malaysia)—the Functional Assessment of Cancer Therapy (FACT) scale[4] (v 4.0), a modular disease-specific instrument, was selected over both the European Organization of Research and Treatment for Cancer (EORTC)[5] and the University of Washington Quality of Life (UW-QOL)[6] instruments for use in Malaysia. The Malay-translated FACT-H&N (v 4.0) was pre-tested for face validity and content validity, then cross-culturally adapted for the Malaysian context in terms of its conceptual and operational equivalence. This pre-testing was

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undertaken using semi-structured, face-to-face in-depth interviews conducted among a purposive sample of 50 oral cancer patients of different ages, ethnicity, cancer staging and treatment status.

The current study was part of a longitudinal, prospective multicentre study on a patient cohort assessed at three data collection points (at diagnosis, and then 1 and 3 months after commencing treatment). Data reported here are from the baseline assessments (at diagnosis).

A consecutive clinical convenience sample was recruited (over a period of 4 months), comprising all newly diagnosed adult (age 18+ years) oral cancer patients who had yet to undergo any treatment. These included outpatients and inpatients with disease staging from I to IV. Mentally incoherent patients (verified from medical records) were excluded. Seven oral maxillofacial specialist clinics (in five general government and two teaching hospitals) throughout Malaysia were chosen as sampling points. These were chosen because of their roles as regional oral cancer referral centers and their patients' ethnic and cultural representativeness of three main regions in Malaysia. A formal sample size calculation was not undertaken for this study; rather, the sample size was determined by the number of patients presenting during the recruitment period.

The FACT summary scores include that of the general (FACT-G) and specific head and neck (FACT-H&N) module, the trial outcome index (FACT-H&N TOI), which is a combination of the functional, physical and head-and-neck subscales, and the head and neck symptom index (FHNSI), which is a subset of the specific head-and-neck module. The response options comprise a 5-point Likert scale ('not true at all', 'somewhat true', 'quite true', 'true' and 'very true', scored from 0 to 4, respectively), and higher FACT subscale and summary scores denote better HRQOL. The Malay-translated and cross-culturally adapted FACT-H&N (v 4.0) consisted of an additional set of eight items (identified as relevant to Malaysian oral cancer patients), termed 'the set of Malaysian questions' (MAQ; Table 1) and appended to the existing FACT-H&N (v 4.0). A global health-rated quality of life question was also included for assessing construct validity.

Data collection

Data collection (through face-to-face interviews by trained data collectors) was done for each patient within 1–2 weeks of diagnosis. Interviews took place in specialist clinics (out-patients) or in the wards (in-patients).

Statistical analyses

Data were analyzed using SPSS (version 12.0). Missing responses in particular subscales were managed by prorating these scores, as recommended in the FACT manual.[7] Raw FACT scores were computed using recommended scoring algorithms.[8] Derivatives of FACT scores were also calculated; these included the FACT-G (general module), FACT-H&N(TOI) (FACT-H&N-total index outcomes), and the FHNSI (FACT symptom-index score). Also calculated were the FACTHN-MAQ and the FHNSI-MAQ, respectively comprising the FACT-H&N and the FHNSI with the addition of the set of Malaysian questions.

Cross-sectional construct validity was assessed in terms of: (1) known groups validity; (2) convergent and discriminant validity; and (3) internal consistency. Analysis of variance (ANOVA) and post hoc testing using oneway ANOVA were used to compare summary and subscale mean scores (the alpha level was 0.05). Cronbach alpha coefficient was used to examine internal consistency and Pearson's *r* was used to assess correlation of normally distributed scores.

Table 1
Items added to the FACT-H&N (v 4.0).

The set of Malaysian questions (MAQ)[a]
Has your spiritual aspect of life/prayer life been affected by your illness?
Do you have difficulty in opening your mouth or limited mouth opening?
Do you have stiffness or limited movement of your shoulders?
Do you feel numbness in your body?
Do you experience a lack of appetite for food?
Have you chewed betel quid?
Are there bleeding or ulcers in your mouth?
Is there food stagnation in your mouth which makes oral hygiene care difficult?

[a] Higher FACT subscale and summary scores denote better HRQOL.

Results

Of the 76 patients, 47 (61.8%) were female. The average age was 58.2 years (sd, 13.4; range 21–86). There were 29 Indians (38.2%), 21 Malays (27.6%), 11 Chinese (14.5%), and the remaining 15 (19.7%) were mostly Indigenous people. Some 25 (32.9%) had no formal education; 46 (60.5%) were married, and 27 (35.5%) were widowed.

Clinical details

Almost all patients (96.1%) had oral squamous cell carcinoma, with the buccal mucosa (31.6% of cases) and tongue (28.9%) most commonly affected. The distribution of cases by cancer staging was Stage I (13.2%), II (19.7%), III (31.6%), and IV (35.5%). Just over half (52.6%) were to have surgery, 19.7% radiotherapy, 2.6% chemotherapy, and the remaining 25.0% were to have some combination of treatments.

Quality of life

In response to the global HRQOL item, ''How do you rate your health-related quality of life in the past 7 days?'' only two patients (2.6%) reported their quality of life as being 'very good'; 28 rated it as 'good' (36.8%) or 'average' (36.8%), and 18 (23.7%) as 'poor'. None rated it as 'very poor'.

Pre-treatment FACT summary and subscale scores are presented in Table 2. Patients' mean scores (summary and subscale) were found to be towards the higher end of the range for each scale and subscale.

Cross-sectional construct validity was assessed using (i) the known groups validity (ii) convergent and discriminant validity, and (iii) internal consistency. To assess (i), FACT summary and subscale mean scores were tabulated against three categories of the global HRQOL item ('very poor'/'poor', 'average', and 'good'/'very good'; Table 3). For each summary scale, there was a statistically significant gradient noted whereby the lowest scores were observed among patients with 'very poor/poor' HRQOL, the highest among those reporting 'good/very good' HRQOL. This pattern was seen for all the six FACT summary scales and for two of the subscales (the head and neck subscale and the set of Malaysian questions). It also occurred with the other subscales, but without statistical significance. For all FACT summary scales except the FHNSI-MAQ, the 'very poor/poor' self-rated HRQOL group differed significantly from those with 'good/very good' self-rated HRQOL. In contrast, for the FHNSI-MAQ summary scale, the head and neck domain and the set of Malaysian questions, the significant differences were between patients with 'very poor/poor' HRQOL and those with 'average' or 'good/very good' HRQOL.