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Development and validation of the Gothenburg Trismus Questionnaire (GTQ)

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SUMMARY

Objectives: To develop and validate a comprehensive, self-administered questionnaire for patients with limited ability to open the mouth, trismus.

Materials and methods: We derived the Gothenburg Trismus Questionnaire (GTQ) from empirical evidence in the medical literature and interviews with medical experts as well as patients. The draft version was tested in a pilot study ($n = 18$). Patients with a maximal incisal opening (MIO) of $\leqslant 35$ mm were included. The study comprised patients with benign jaw-related conditions ($n = 51$), patients treated for head and neck (H&N) cancer ($n = 78$) and an age- and gender-matched control group without trismus ($n = 129$).

Results: The GTQ instrument was well accepted by the patients, with satisfactory compliance and low rates of missing items. After item reduction, due to items not being conceptually relevant and/or low factor loadings, the GTQ demonstrated high internal consistency (Cronbach's alpha 0.72–0.90), good construct validity and known-group validity.

Conclusion: We developed a trismus-specific self-administered questionnaire, the GTQ, that showed good psychometric properties. We suggest this questionnaire, that has clear clinical relevance, to be adopted and used in clinical practice and in research, acting as a screening tool as well as an endpoint in intervention and jaw physiotherapy/rehabilitation studies.

Introduction

Trismus is defined as a limitation in the mouth/jaw-opening ability due to a reduced mandible mobility.[1,2] Trismus can occur from benign jaw related conditions, often referred to as temporomandibular disorders (TMD). According to a NIH consensus panel, TMD refers to "a collection of medical and dental conditions affecting the temporomandibular joint (TMJ) and/or the muscles of mastication, as well as contiguous tissue components".[3,4] It can also result from local or metastatic tumor growth of head and neck (H&N) tumors, and more importantly, as a debilitating side-effect to H&N oncology treatment, especially radiotherapy.[5] An objective measure of trismus is the limited ability to open the mouth, maximal incisal opening (MIO), $\leqslant 35$ mm.[1,6] Trismus affects many important aspects of daily life, such as chewing, diet normalcy, difficulties in eating, an inability to practice effective oral hygiene, pain, speech and overall health related quality of life (HRQL).[4,7]

In Sweden, approximately 1200 patients are diagnosed with H&N cancer every year. Of these, 90% receive radiotherapy and/or chemotherapy and the remaining 10% undergo surgery and/or additional radiotherapy.[8] In this patient category, the etiology of trismus can be the result of tumor growth and/or a side-effect of treatment damaging critical structures of chewing, such as the masseter and pterygoid muscles, damage to nerve or supportive tissue or to the TMJ.[9] The incidence of trismus is particularly increased after chemoradiotherapy[10] and external beam radiation therapy to the area.[11] There is a steep dose–effect relationship with increased probability of trismus with increasing radiation doses.[12] Magnetic resonance imaging after radiotherapy demonstrates abnormalities in several structures involved with chewing which suggests multi factorial mechanisms behind this condition.[13]

The prevalence of post treatment trismus ranges between 5% and 45%[7,14] varying because of different treatment strategies, as well as diverse and inconsistent manners of assessing trismus attributed to the lack of uniform criteria.

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Patient reported outcome (PRO) instruments are becoming more and more important because reliable measures of how the patients' experience their symptoms can be considered equally important in clinical research as survival and mortality. Although several H&N specific HRQL questionnaires exist today,[15] no questionnaire has specifically addressed trismus. Some of the existing questionnaires only partially cover relevant questions, and most do not take the pain aspect into account.

Due to the paucity of PRO questionnaires specifically addressing trismus, the present study was initiated with the aim to develop and validate a comprehensive, trismus specific self-administered questionnaire, the Gothenburg Trismus Questionnaire (GTQ). This questionnaire could serve as a screening tool and endpoint in intervention and jaw physiotherapy/rehabilitation studies in trismus patients.

Methods

GTQ development

The GTQ was developed in two stages: (1) input from an expert panel, literature review and patient interviews, to elicit and evaluate items (content validity); and (2) evaluation of the instruments' measurement properties (including reliability, validity, and responsiveness).

Content validity of the GTQ

The items of the GTQ instrument were developed based on a literature review of published trismus studies, non-validated trismus-related questions and the experiences of an expert panel consisting of two stomatognatic physiologists, one otolaryngologist and a behavioral scientist specialized in psychometrics. The initial draft of the GTQ instrument consisted of 43 items. A five-point Likert scale was used, except for certain items covering pain and limited mouth opening, for which a seven-point Likert scale was used. For most items the recall period was set to 1 week. For certain items covering pain and limited mouth opening however, the recall periods were set to one month or "right now".

Confirmatory interview study

Confirmatory individual interviews were conducted with 18 patients (9 with H&N cancer and 9 with TMD) to confirm the relevance and interpretability of the items. Patients were administered the GTQ instrument draft and were thereafter probed on, for example, how items were perceived, whether patients found any items to be missing and the length of time needed to fill in the questionnaire. Furthermore, a subset of patients was contacted for a semi-structured phone interview.

Exploratory psychometric validation phase

Study design and participants

Patients with benign TMD disorders seen by a stomatognatic physiologist were included at the Institute of Odontology, Gothenburg, Sweden at their first visit to the clinic. Patients with H&N cancer and trismus were included at the department of Otorhinolaryngology at Sahlgrenska University Hospital, Gothenburg, Sweden and at the department of Otorhinolaryngology, Karolinska University Hospital, Stockholm, Sweden. H&N cancer patients were identified and considered eligible for the study at oncology grand rounds or at follow-up visits after termination of treatment when there were clinical signs of trismus (MIO $\leqslant$ 35 mm). Patients with poor language comprehension and cognition were considered non-eligible. Instruments were distributed to patients at the clinic and mailed back. Patients who had not returned their instruments within 2 weeks were reminded once. The study also comprised an age- and gender-matched control group of patients from the department of Otorhinolaryngology at Sahlgrenska University Hospital, Sweden. The control patients denied trismus and had no clinical evidence of such and answered the questionnaire in clinic.

Overall, 138 patients with trismus were included: 51 patients with TMD and 78 patients with H&N cancer. Nine patients failed to return the questionnaire, giving a response rate of 93%. The control group consisted of 129 patients. Table 1 shows the sociodemographic and clinical characteristics of the participants.

References for validation

SF-36

The SF-36 is a widely used generic instrument for measuring HRQL, with a recall period of 4 weeks (standard version).[16,17] It contains 36 items in eight domains: physical functioning (PF), Role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), mental health (MH) and one question concerning perceived health during the last year. A score for each domain between 0 (worst) and 100 (best) HRQL is calculated using a standardized scoring system. The Swedish version has well-documented reliability and validity.[16]

EORTC QLQ-C30 and QLQ-H&N35

The EORTC QLQ-C30, assesses the physical and psychosocial functioning and symptom experiences of cancer patients in general.[18] To address additional symptoms associated specifically with H&N cancer and its treatment, the complementary 35-item module can be used, the QLQ-H&N35.[19,20] Recall period for both instruments is 1 week. Calculated scale scores range from 0 to 100. On the functioning and global QL scales a score of 100 corresponds to maximum functioning, whereas on the symptom scales and items a score of 100 means worst possible symptoms.[21] The core instrument[18] as well as the H&N cancer-specific module[20] have demonstrated satisfactory to excellent reliability and validity.

Statistics

Descriptive statistics was applied using standard methods. The psychometric qualities of the GTQ were assessed to determine reliability and validity. Scoring of the GTQ was carried out by calculating a mean for each domain, which is then transformed to a scale ranging between 0 and 100, where a higher score indicates greater perceived dysfunction due to trismus. Regarding missing items in a domain, non-missing items within that given domain were re-scaled to generate a value comparable to subjects responding to all items. If more than 50% of the items within the domain were missing, the domain score was also set as missing. Tests for comparing GTQ scores for patients and controls were performed using the Mann–Whitney *U*-test. For pairwise comparison between groups for sociodemographic and clinical characteristics, the following tests were applied: Fisher's Exact test for dichotomous variables; the Mantel–Haenszel Chi Square Exact test for ordered categorical variables, and the Mann–Whitney *U*-test for continuous variables. All tests were two-tailed and the significance level was set to 5% throughout.

Item reduction and subscale identification

As a first step, items with ceiling or floor effect with more than 40% of participants choosing the highest or the lowest response option, were considered for omission. If items had more than 5% missing responses, they were also considered to be removed.