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Use of the WOMAC questionnaire in Mumbai and the challenges of translation and cross cultural adaptation

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Abstract

Patient-reported outcome measures (PROMs) are disease specific questionnaires that are being increasingly used in clinical practice and research. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), is a widely used PROM in patients with hip or knee osteoarthritis. A validated WOMAC was used by us, and significant challenges were faced in administering it as several questions did not have a cultural connect. Functionally equivalent items in the Indian context had then to be used to complete the score. With greater emphasis today on the use of patient-reported outcome measures, and with data from multi-centric studies being pooled, cross-cultural adaptation becomes very important if the pooled data are to be really relevant. In India, with several languages being spoken, and a significant proportion of the population being illiterate, the physician and/ or the impartial witness must provide considerable explanation without attempting to influence the response. The key to the effective and correct use of PROMs thus lies not just in translation, but also in a stepwise validation of the questionnaire, and modification in the context of the country where it is used. Scores like WOMAC are often primary efficacy endpoints in clinical trials; are gaining greater importance to support label claims; have ethical implications, and directly impact regulatory decision making and thus, eventually, evidence-based practice.

Introduction

Patient-reported outcome measures (PROMs) are being increasingly used in clinical practice and research. These

are questionnaires that are to be completed by study participants and their use as important tools in clinical research is demonstrated by initiatives such as the Patient-Reported Outcomes Measurement Information System (1) as also the guidance paper by the United States Food and Drug Administration (US FDA) on the use of these measures (2). The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a disease-specific questionnaire, is a widely used PROM in patients with hip or knee osteoarthritis (OA) (3, 4). The WOMAC is self administered and multidimensional; it has 24 items grouped into three dimensions: pain (five items), stiffness (two items), and physical function (17 items). The pain subscale includes five questions on the degree of pain experienced with certain positions and activities; the function subscale includes 17 questions on the degree of difficulty experienced while completing activities while the stiffness subscale includes two questions on severity of stiffness. WOMAC produces one aggregate total score and scores for each of the subscales, with a higher score for each subscale indicating a worse condition.

The authors are currently part of a multi-centric study in India that is using the WOMAC as an index of efficacy in a study on osteoarthritis. The English language (United Kingdom) version of the WOMAC is being used, as also the linguistically translated and validated versions in Hindi and Marathi (the two most commonly spoken local languages in Mumbai) (5). In this communication, we present our experiences in using the translated versions of WOMAC in Mumbai.

Methods

At the point of writing this paper, the scale has been administered to seven patients, one of whom is illiterate. Two patients were administered the Hindi version, one the English language scale and the remaining four, the Marathi version.

Results

At the start of the study, we found that the time taken for completion of the WOMAC ranged from 15 minutes to 60 minutes (the latter being the time taken by the illiterate patient). The authors found that with the physical function subscale, several questions did not have a cultural connect. These included the putting on or taking off of stockings, getting in and out of a car, getting in and out of a bath tub, and the ease of using a Western toilet. Since completion of the entire score was envisaged as being necessary for evaluation, the authors themselves had to give functionally equivalent items relevant in the Indian context to explain to the patient, who then answered the question. For example, instead of "putting on or taking off of stockings" we asked about wearing a "churidar" which is an Indian type of leg hugging garment. We substituted "getting in and out of a car" with getting in and out of a "rickshaw" which is the common transport vehicle used by our patients. As illiterate participants were not excluded from this study, an impartial witness read out the translated version to our one illiterate patient, who then answered it with the physician attending the process.

Discussion

There is much emphasis today on using standardised and validated research instruments as these enable comparison of results both within and across countries. A patient-reported outcome (PRO) is an umbrella term that covers a whole range of potential types of measurement; it is used specifically to refer to measures that quantify a patient's state of health in terms of outcomes reported by himself/ herself. The common feature of PROMs is their grounding in the patient's perspective. PROMs are increasingly seen as complementary to biomedical measures and they are being incorporated more frequently into clinical trials and clinical practice. When they are used, there is the underlying assumption that the use of a validated instrument ensures that it increases the certainty with which the instrument accurately reflects what it is supposed to measure (6).

A review of literature on the use of the WOMAC, a patient-reported outcome, shows that while several authors have successfully used translated versions, others have faced difficulty (7, 8). Guermazi et al found that when the WOMAC was translated into Arabic from English, eight questions of the physical function subscale had insufficient psychometric properties and had to be excluded. They suggested the use of Sfax WOMAC, where the physical function subscale was modified for use in Tunisia (9). Our observations are similar to Guermazi and show that a previously validated instrument is not necessarily valid in another time, culture or context (10).

Callahan et al in an interesting study analysed various quantitative measures of inflammatory activity and joint damage, including articular, radiographic, laboratory, questionnaire, and physical function measures, and correlated these measures with survival in patients with rheumatoid arthritis (RA) in a cohort of patients monitored in the mid-1980s and early 1990s. They found that the most significant marker for predicting premature mortality over five years in patients with RA was in fact a PROM that measured functional capacity rather than currently available laboratory tests, radiographs, or other imaging data (11). Sokka et al found that the Health Activity Questionnaire, a PROM that quantifies disabilities in activities of daily living predicted mortality both in patients with rheumatoid arthritis and community controls (12). Thus, in a country like India, instruments like the WOMAC have significant ethical implications for several reasons.

Linguistically translated versions are not the same as those that have undergone cross-cultural adaptation; the latter being needed when the scale is used in another country, language and setting (13). In India, there are 22 officially recognised languages. Data in multi-centric studies are ultimately pooled and, thus, cross-cultural adaptation is necessary for each one of these languages if the pooled data are to be really relevant. A large (17%) proportion of the population in the state of Maharashtra is illiterate (14) and thus, instruments do not truly become self-administered if the physician and /or impartial witness must provide considerable explanation without attempting to influence the response. The instruments are also primarily developed with the assumption of some baseline literacy and hence there is the risk that illiterate participants or those with low literacy are excluded from both development of the instrument and its ultimate application (15). Should we, for instance in this study, have at all administered the WOMAC to the illiterate patient given that every question was read out by the impartial witness and the questionnaire thus did not become truly patient-reported? On the other hand, excluding illiterate participants would lead to selection bias and also deny the benefits of participation to someone who wishes to participate. Yet another challenge is that investigators in India, though proficient in English, may not necessarily be proficient in all 22 languages spoken in the country with their multiple dialects; hence they accept the sponsor's translated version of the questionnaire and use it without much thought as to its cultural adaptation. Members of Institutional Review Boards (IRBs) that review the translations also tend to look at whether or not the language is likely to be understood by a lay person rather than whether the translated version matches the original in all respects.

Over the last 15 years, there has been discussion on how to interpret change in patient-reported outcomes and this has led to the development of methods for identifying a minimum important difference (MID). A MID is defined as the smallest change in respondent scores that represents clinical, as opposed to merely statistical, significance, and which would -- other things being equal -- warrant a change in a patient's care (16). In studies that use PROMs like the WOMAC

as a single or even key dependent variable, their measurement becomes vital. When used without cultural adaptation or in illiterate patients, the PROM does not really measure what it is supposed to measure, which can have serious consequences on the effectiveness of clinical interventions; decisions about appropriate patient care and policy and future research are driven by these measurements (17).

Where do we go from here? The key to the effective and right use of PROMs lies not just in translation, but a step-wise validation of the questionnaire and modification where necessary in the context of the country where it is used; and this has grown into a field of study in its own right. The American Association of Orthopedic Surgeons Outcomes Committee has laid down a five-step process for the cross-cultural validation of questionnaires (14). In the case of funded studies, sponsors often pay a considerable amount of money for obtaining these linguistically translated questionnaires. It is our recommendation that time, effort and money should also be spent by sponsors in cross-cultural adaptation which will then ensure that the instrument truly measures what it is supposed to measure. Also, then, data collected across wide geographic locations with disparate cultural contexts would become amenable to being pooled for analysis. In addition, for studies done in countries with low literacy rates or where illiterate patients are likely participants, a validated and culturally adapted audio recording can be made which the patient hears and subsequently answers. Both of these will then ensure that the US FDA's definition that a PROM "is a measure that comes directly from the patient without interpretation of the patient's response by the clinician or anyone else" is satisfied. We believe that the scenario would be similar in China and Latin America where large numbers of studies are now carried out. Finally, both investigators and IRBs need to realise that use of translations alone is not adequate and attempts should be made, wherever possible, to make the PROM culturally relevant. This is particularly important as patient related outcome measures like WOMAC are often primary efficacy endpoints in clinical trials; are gaining greater importance to support label claims; have ethical implications and directly impact regulatory decision making and thus, eventually, evidence based practice.

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