Multi-language translation and cross-cultural adaptation of the OARSI/OMERACT measure of intermittent and constant osteoarthritis pain (ICOAP)


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Summary

Aim: To conduct a multi-language translation and cross-cultural adaptation of the Intermittent and Constant OsteoArthritis Pain (ICOAP) questionnaire for hip and knee osteoarthritis (OA).

Methods: The questionnaires were translated and cross-culturally adapted in parallel, using a common protocol, into the following languages: Czech, Dutch, French (France), German, Italian, Norwegian, Spanish (Castillian), North and Central American Spanish, Swedish. The process was conducted following five steps: (1) — independent translation into the target language by two or three persons; (2) — consensus meeting to obtain a single preliminary translated version; (3) — backward translation by an independent bilingual native English speaker, blinded to the English original version; (4) — final version produced by a multidisciplinary consensus committee; (5) — pre-testing of the final version with 10–20 target-language-native hip and knee OA patients.

Results: The process could be followed and completed in all countries. Only slight differences were identified in the structure of the sentences between the original and the translated versions. A large majority of the patients felt that the questionnaire was easy to understand and complete. Only a few minor criticisms were expressed. Moreover, a majority of patients found the concepts of constant pain and pain that comes and goes to be of a great pertinence and were very happy with the distinction.

Conclusion: The ICOAP questionnaire is now available for multi-center international studies.

Key words: Osteoarthritis, Hip — osteoarthritis, Knee — Pain — ICOAP — Translation.

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Osteoarthritis (OA) is a common, degenerative joint disease characterized by progressive destruction of cartilage, affecting large weight-bearing joints, such as the hip and knee. The pain and disability associated with hip and knee OA have a significant impact on the patients’ health-related quality of life. As the frequency of knee and hip OA increases as a result of the aging of the population, this disorder will become an increasingly major health problem. Thus, it is important to optimize treatment and evaluation of interventions that might prevent or delay the progression of the disease. Structural variables are usually used in clinical trials to assess the rate and extent of the cartilage breakdown. However, the clinical relevance of the results obtained remains debatable. Interest exists, therefore, in identifying a valid, dichotomous outcome variable that reflects the natural history of OA. In particular, interest has grown in using the requirement of total joint replacement as a “hard” outcome measure. Limitations exist, however, in the use of such an outcome, in particular variability in the decision to perform surgery. Thus, a better alternative might be to change the criteria “time to total joint replacement” to “time to fulfill the criteria for total joint replacement”. In this context, an international working group was created under the auspices of OARSI (Osteoarthritis Research Society International) and OMERACT (Outcome Measures in Rheumatology Clinical Trials) in order to create a composite index that could define states of severity and theoretical requirement for total joint replacement in knee and hip OA, for use in clinical trials evaluating potential disease-modifying drugs in OA. It was decided that the domains of pain, physical function and joint structure on X-Rays would be combined as a significant measure of outcome. As a first step, three working subgroups were constituted, to determine which instrument should be used to evaluate these domains.

Based on prior studies and experience, the “pain group” considered that the pain experience of people suffering from knee and hip OA was not adequately captured by existing measures and suggested the need for a new OA pain measure. Focus groups were conducted in order to obtain detailed description of hip and knee OA pain, from early to late disease, and identified two distinct types of pain, i.e., an aching and fairly constant background pain, and a less frequent but more intense and often unpredictable pain, the latter having a greater impact on quality of life, particularly if unpredictable. Using the data from the focus groups, a new pain instrument, the Intermittent and Constant Osteoarthritis Pain (ICOAP) measure, was developed. The ICOAP is an 11-item questionnaire, divided into two domains, a first 5-item scale for constant pain; and a 6-item scale for intermittent pain (so-called “pain that comes and goes”). Each domain captures pain intensity as well as related distress and the impact of OA pain on quality of life. Preliminary data have suggested the new measure to be valid and reliable. The ICOAP is not copyrighted and is available on the OARSI website.

Due to the increase in large multi-center international studies and the requirement for globally meaningful epidemiologic and/or therapeutic study results, there is a need for cross-cultural adaptation and validation of health status measures. The cross-cultural adaptation process may require translation and adjustment of cultural words, idioms and colloquialisms, when the instrument will be used in a country with a different language and culture than the country in which it has been developed, or just adaptation when it is aimed to be used in a country with the same language but a different culture. This process may involve substantial transformation of some items to fully capture the essence of the original concepts.

The ICOAP was developed in the English language. It is a new, promising, and original questionnaire, which may be used in international studies. Thus, there is need for translation and cross-cultural adaptation in numerous languages and countries. The aim of the present study was to conduct such a multi-language translation and adaptation.

Methods

The questionnaires were translated and cross-culturally adapted in the following languages: Czech, Dutch, French (France), German, Italian, Norwegian, Spanish (Castillan), North and Central American Spanish, Swedish. Translations and cross-cultural adaptations were conducted in parallel under the responsibility of a local investigator, so-called the key in-country person, using a common protocol and according to recommendations for translation and cross-cultural adaptation. The process was conducted in five steps.

It was not necessary to contact the developer of ICOAP (GH) since she belonged to the working group. The key in-country person responsible for each translation process was native in the target language and was resident in the target country. In the first step, two or three persons (at least one rheumatologist or orthopedist and one teacher of English, all as bilingual as possible, of whom at least one was fully bilingual), native in the target language and living in the target country, translated independently the English version into the target language. In the second step, a group meeting was held, in which the translated version was obtained during a simple consensus meeting with the 2–3 translators.

In the third step, a backward translation was performed by an independent bilingual native English speaker, blinded to the English original version. In the fourth step, a multidisciplinary consensus committee was formed, to ensure that the translations were fully comprehensive, and to check cross-cultural equivalence of the source and final versions. The committees included the initial 2–3 translators, at least two rheumatologists (who may also be translators), if possible one orthopedic surgeon, one person very familiar with cross-cultural adaptation, and at least one patient fluent in English. During this meeting, the groups compared the initial version and the back translation, discussed the phrasing of the target-language version, and by consensus produced a final version.

During this whole process, the translators, as well as the members of the committee were instructed to keep in mind that the final wording needs to be understood by lay people including individuals with low levels of education. Due to a feasibility issue, it was not possible to organize a harmonization meeting involving the project manager, all key in-country persons, and all back-translators, but during the whole process, the key in-country persons had the possibility to join the project manager and the developer to discuss on conceptually problematic items. In a fifth step, the final version was pre-tested for cognitive debriefing with 10–20 target-language-native patients. These patients completed the questionnaire in the presence of a physician and a study nurse, and each question was discussed with the patient, to check whether it was easy understandable for all items and whether the patients had problems with the formulation. The cognitive debriefing results were reviewed by the key in-country investigators, the project manager and the developer of the questionnaire, when appropriate, the initial translation was modified accordingly. Finally, when all the final translations were available, the project manager homogenized the presentation of the questionnaires, then sent the questionnaires to the key in-country investigators who checked and corrected any spelling, diatrical, grammatical, or other errors. A second check was asked to key in-country persons just prior to submission of the article.

Results

Invitations to participate were sent in February and March 2007. All contacted investigators agreed to participate. The protocol could be followed and completed in all participating countries. The translated and adapted questionnaires were used in international studies. Thus, there is need for translation and cross-cultural adaptation in numerous languages and countries. The aim of the present study was to conduct such a multi-language translation and adaptation.
an example, the subtle differences between “pain, aching and discomfort” do not exist in French or in Dutch. Thus, the local committees preferred to translate to “douleur ou gêne” and to “verschillende soorten pijn, waaronder onge- mak” which best correspond to the original concept. The Spanish committee changed the sentence “pain in the area of the hip” to “pain in the groin and buttock area” since in Spanish, hip usually means the pelvic rather than the joint area. The possible translations for “past week” in German language do not clearly specify if this means the last 7 days or the time between Monday and Sunday of the previous week. The German committee chose the term “letzte Woche” and considered that it did not make a difference which time interval is referred to by the patient. The Dutch committee discussed the response “not at all”, particularly for constant pain. The question was whether such a response could mean “I have no constant pain” or “I have constant pain but am not bothered by it”.

A large majority of the patients felt that the questionnaire was easy to understand and complete. They also felt that the content was good and that the questions fit with their feelings. Only a few minor criticisms were expressed by the patients. Interestingly, those criticisms were not related to a particular country or language. Most were related to the concepts of constant pain and pain that comes and goes. Some patients asked how to reply if they did not have constant pain, or did not have pain that comes and goes. A few patients were somewhat irritated by the two different questionnaire sections, of which one was dealing with a problem they did not have. A minority found it difficult to understand the differences in the concepts of constant pain and pain that comes and goes, or to discriminate the characteristics of both pains. However, in most of them, the problem was solved by explaining the concepts of constant pain and pain that comes and goes. Moreover, a majority of patients found the concepts of constant pain and pain that comes and goes to be of a great pertinence and were very happy with the distinction. A few patients found the questionnaire to be rather extensive and/or were annoyed by redundancies in the phrasing.

Following these comments, and further testing in the original language, minor modifications were made to improve the succinctness of questionnaire section framing, and to better explain the response option “not at all”. As the changes made were relatively minor and mainly constituted delimitations, it was decided during an investigators’ meeting that they did not necessitate repeating the whole translation and cross-cultural adaptation process. There was no need to make other changes to one translation to accommodate feedback from another one.

Discussion

In this study, the new ICOAP questionnaire was translated and cross-culturally adapted to several languages. A strength of this work is that the multinational process was conducted in parallel and following a common protocol; prior translations of measures have generally been conducted language by language, independent from one another, and using different protocols. The second strength is that the multi-translation process was planned very early, i.e., several months prior to the publication, with the authors of the original ICOAP questionnaire, allowing us to adapt the original ICOAP in accordance with the comments from the multi-language translation and to use the ICOAP questionnaire in international studies very early after development in English.

One could wonder why two different processes were conducted for Spanish. An instrument used in a country other than that in which it was developed may require adaptation if the population concerned have another culture with similar language. The committee considered that there are sufficient differences between the Spanish cultures on one hand, North and Central America on the other hand, to justify these processes. On the contrary, a cross-cultural adaptation to British English was not conducted since the ICOAP questionnaires were developed in several countries including England, and since some British rheumatologists considered that such a process was not needed.

The study was conducted following standardized guidelines for translation and cross-cultural adaptation. It is usually considered that the quality of the translation increases when it is performed by at least two independent translators, who should translate into their mother tongue. The translators included at least one person aware of the objectives underlying the material and the concepts involved (the rheumatologist or orthopedic surgeon) and one who was not aware (the teacher of English). The back translation helps the quality of the final version, since it can amplify and reveal some misunderstandings or ambiguities. It was performed by people translating in their mother tongue, as proposed, but by only one translator. Some have recommended conducting as many backward translations as forward translations, but there is a lack of consensus on this point, and there is no data to suggest that increasing the number of back translations increases the quality of the work. Conducting such a work in parallel in nine countries can lead to feasibility issues, thus it was preferred to perform only one back translation in order to increase the feasibility. The committees were multidisciplinary, including the translators, physicians experts in the field of OA, and patients. The pre-testing ensured that all items were correctly understood, and suggested an excellent face validity.

The metrological properties of the translated questionnaires, in particular validity, reliability and responsiveness, have not been evaluated. One can consider that the metrological properties can be modified by the process. On the other hand, it can be considered that when the translation and cross-cultural adaptation has been conducted using a correct protocol, the metrological properties are not altered and do not necessitate a re-evaluation. Although the response to this particular question is not clear, it was decided that the metrological properties of the translated and adapted ICOAP questionnaires would be further evaluated separately by all local investigators. These evaluations are ongoing.

In conclusion, the ICOAP instrument is now available for multi-center international studies. It is currently used in the ongoing OMERACT/OARSI study which aims to elaborate a set of criteria defining theoretical requirement for total joint replacement for knee or hip OA, for use in clinical trials evaluating potential disease-modifying drugs in OA.

Conflicts of interest

JF Maillefert received in 2007 speaker honorarium from Abbott, Bristol Myers Squibb, and Wyeth laboratories, for less than 10,000 US dollars.

L Punzi received in 2007 speaker honorarium from Fidia and Wyeth laboratories, for less than 10,000 US dollars.

S Lohmander received in 2007 speaker or advisory board honoraria from AstraZeneca, Carbylan, Lilly, Pfizer, SanofiAventis, Seikagaku, and Tigenix, for less than 10,000 US dollars.
M Kloppenburg, L Fernandes, KP Günther, E Martin Mola, K Paveika, MA Lopez-Olivo, M Dougados, GA Hawker these authors do not have conflict of interest.

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Supplementary material
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References