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The use of the Core Outcome Measures Index (COMI) in patients undergoing total knee replacement

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ABSTRACT

Background: The Core Outcome Measure Index (COMI) is a very short outcome instrument used in spine patients. The aim of this study was to examine the utility of a knee version of the COMI in patients undergoing total knee arthroplasty (TKA) by assessing the reproducibility, construct and discriminant validity, and responsiveness.

Methods: Preoperatively, 224 patients completed the Oxford Knee Score (OKS), EuroQoL (EQ-5D) and the COMI-Knee; 189 (84) % also completed the questionnaires at follow-up and 73 patients completed preoperatively the COMI-knee twice.

Results: The weighted kappa values for the COMI-knee single items ranged from 0.80 to 0.89 and the ICC for the COMI-knee (composite score), 0.86. The absolute SEM for COMI-knee was 0.4 points, i.e. four percent of the maximum value (10 points) and six percent of the average value (6.6 points). The Area Under the Curve derived from the Receiver Operating Characteristic method for the COMI-knee was 0.97 (95% CI, 0.93 to 0.99), with a cut-off value for indicating a "good" result of 2.3 (100% specificity, 87% sensitivity). Correlations between the COMI-knee and the OKS were −0.72 at baseline and −0.87 at six months. The correlations between the change scores for the COMI-knee and the change scores for the OKS and EQ5D index were 0.77 and 0.69, respectively.

Conclusions: The measurement properties of the COMI-knee satisfy international quality criteria and hence support its use in assessing patients undergoing TKA.

1. Introduction

For patients undergoing knee replacement, the treatment should relieve pain and improve daily function, work capacity, and quality of life. To assess these domains in the research or clinical setting, the use of so-called patient-rated outcome measures (PROMs) is recommended. These are considered to be the optimal way of evaluating the efficacy and effectiveness of treatments from the patient's perspective. For a comprehensive evaluation, both generic and disease-specific instruments should be administered. However, the use of different and lengthy instruments can increase the patient and administrative burden, thus reducing the feasibility of using sets of PROMs in the routine and systematic evaluation of patient outcome.

To overcome similar problems in the field of spine disorders, a brief set of core outcome measures was recommended for use by a group of international experts [1,2]. This group proposed an instrument now known as the Core Outcome Measures Index

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(COMI), which is a parsimonious set of single items for assessing pain, function, quality of life and disability. Subsequently an item for evaluating the "overall quality of life" (from the World Health Organization Quality of Life BREF questionnaire) was added. By taking the average of the single item scores, a summary index score (in addition to the single item scores) is obtained giving an aggregate of all domains. The COMI has been used in several studies as well as international registries [3,4]. Although initially developed for spine problems, the COMI has been adapted and proven to be valid for use in patients with other orthopedics disorders such as neck pain, hip osteoarthritis and femoroacetabular impingement, in addition to inguinal hernia [5,6]. The wide external validity of the instrument may be explained by the domains covered by the COMI, which are relevant to all orthopedic patients. This may minimize issues concerning content validity, with the instrument not having being developed with patient involvement.

The availability of a short instrument such as the COMI (six items) has several advantages. Its brevity makes it particularly suitable for the routine collection of patient-rated outcomes in the clinical setting. Further, if its wider use were to be adopted, it could be considered a "common denominator" facilitating comparisons between investigations and institutions, and even between different orthopedic disorders, in multicenter studies. Indeed, being a brief questionnaire that does not substantially increase the administrative/patient burden, it would allow individual centers to add the COMI alongside their routinely administered PROMs.

The aim of this study was to examine the validity of an adapted version of the COMI (COMI-knee) in patients undergoing total knee arthroplasty (TKA) by evaluating its reproducibility, construct and discriminant validity and responsiveness. Validity was examined by assessing its relationship with a well-established, validated questionnaire for TKA, i.e. the Oxford Knee Score [7,8] and a generic quality of life questionnaire used in previous COMI validation studies, the Euroqol — Five Dimensions (EQ-5D) [9–12].

2. Material and methods

In total, 224 patients undergoing surgery for TKA participated in this prospective study. All completed pre-operative questionnaires (see below) and 189 patients (84%) also completed the follow-up questionnaires. Preoperative questionnaires were completed by the patient at home and returned on the day of admission to hospital. After six months, the questionnaire booklet was sent out by post to those who had returned a preoperative questionnaire and had not undergone any surgery on the lower extremities in the preceding four months, with the request to complete it and return it using the stamped addressed envelope provided. Reliability was calculated on a subsample of 73 consecutive patients who were asked to complete the COMI again

Table 1
Description of the original and adapted items of the Core Outcome Measure Index.

Original COMI item	COMI-knee
(1) Pain symptoms Item max of two item values: "How severe was your back pain in the last week?" and "How severe was your leg/buttock pain in the last week?"	How severe was your **knee** pain in the last week? — response categories: numeric scale from 0 (no pain) to 10 (worst pain that I can imagine)
(2) Function "During the past week, how much did your back problem interfere with your normal work (including both work outside the home and housework)?"	During the past week, how much did your **knee** problem interfere with your normal work (including both work outside the home and housework)? — response categories: 1) not at all; 2) a little bit; 3) moderately; 4) quite a bit; 5) extremely
(3) Symptom-specific well-being "If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it?"	If you had to spend the rest of your life with the symptoms you have right now, how would you feel about it? — response categories: 1) very satisfied; 2) somewhat satisfied; 3) neither satisfied nor dissatisfied; 4) somewhat dissatisfied; 5) very dissatisfied
(4) General well-being "Please reflect on the last week. How would you rate your quality of life?"	"Please reflect **on the last week**. How would you rate your quality of life?" — response categories: 1) very good; 2) good; 3) moderate; 4) bad; 5) very bad
(5) Disability a) Social disability: During the past 4 weeks how many days did you cut down on the things you usually do (work, housework, school, recreational activities) because of your back problem? b) Work disability: During the past 4 weeks how many days did your back problem keep you from going to work (job, school, housework)?	During the last 4 weeks, how many days did you cut down on the things you usually do (work, housework, school, recreational activities) because of your **knee** problem? — response categories: 1) none; 2) between 1 and 7 days; 3) between 8 and 14 days; 4) between 15 and 21 days; 5) more than 21 days During the last 4 weeks, how many days did your **knee** problem keep you from going to work (job, school, housework)? — response categories: 1) none; 2) between 1 and 7 days; 3) between 8 and 14 days; 4) between 15 and 21 days; 5) more than 21 days *Added response option*: not applicable[a]

Scoring: the pain scale is scored 0–10, while the 5 response options of the category scales (items 2–6) are scored as 0, 2.5, 5.0, 7.5, 10.0 (for responses 1 to 5, respectively). The average of the two disability items (items 5 and 6) forms the score for the domain "disability". The five domain scores for pain, function (item 2), symptom-specific well-being (item 3), general quality of life (item 4) and "disability" (average of items 5 and 6) are then averaged to give a COMI score from 0 to 10. No missing answers are allowed.

[a] For patients who are retired or do not work; changes from the original COMI are marked bold.

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