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Responsiveness and Minimal Important Change of the IKDC of Middle-Aged and Older Patients With a Meniscal Tear

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Investigation performed at Department of Orthopaedic Surgery, OLVG Amsterdam, Amsterdam, the Netherlands

Background: Responsiveness and the minimal important change (MIC) are important measurement properties to evaluate treatment effects and to interpret clinical trial results. The International Knee Documentation Committee (IKDC) Subjective Knee Form is a reliable and valid instrument for measuring patient-reported knee-specific symptoms, functioning, and sports activities in a population with meniscal tears. However, evidence on responsiveness is of limited methodological quality, and the MIC has not yet been established for patients with symptomatic meniscal tears.

Purpose: To evaluate the responsiveness and determine the MIC of the IKDC for patients with meniscal tears.

Study Design: Cohort study (design); Level of evidence 2.

Methods: This study was part of the ESCAPE trial: a noninferiority multicenter randomized controlled trial comparing arthroscopic partial meniscectomy with physical therapy. Patients aged 45 to 70 years who were treated for a meniscal tear by arthroscopic partial meniscectomy or physical therapy completed the IKDC and 3 other questionnaires (RAND 36-Item Health Survey, EuroQol-5D-5L, and visual analog scales for pain) at baseline and 6-month follow-up. Responsiveness was evaluated by testing predefined hypotheses about the relation of the change in IKDC with regard to the change in the other self-reported outcomes. An external anchor question was used to distinguish patients reporting improvement versus no change in daily functioning. The MIC was determined by the optimal cutoff point in the receiver operating characteristic curve, which quantifies the IKDC score that best discriminated between patients with and without improvement in daily function.

Results: Data from all 298 patients who completed baseline and 6-month follow-up questionnaires were analyzed. Responsiveness of the IKDC was confirmed in 7 of 10 predefined hypotheses about the change in IKDC score with regard to other patient-reported outcome measures. One hypothesis differed in the expected direction, while 2 hypotheses failed to meet the expected magnitude by 0.02 and 0.01 points. An MIC of 10.9 points was calculated for the IKDC of middle-aged and older patients with meniscal tears.

Conclusion: This study showed that the IKDC is responsive to change among patients aged 45 to 70 years with meniscal tears, with an MIC of 10.9 points. This strengthens the value of the IKDC in quantifying treatment effects in this population.

Keywords: knee; meniscus; IKDC; measurement properties; clinimetrics

Different patient-reported outcome measures (PROMs) have been developed and validated for patients with meniscal injuries. Many reflect the patients' perception of knee-specific symptoms, functioning, and sports activities, such as the KOOS (Knee injury and Osteoarthritis Outcome Score), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Lysholm Knee Scoring Scale, the Western Ontario Meniscal Evaluation Tool, and the International Knee Documentation Committee (IKDC) Subjective Knee Form.[1] It is important to use high-quality PROMs to obtain outcomes that are trustworthy.[15] The quality of PROMs mainly depends on their reliability, validity, and responsiveness as described by the Consensus-Based Standards for the Selection of Health Measurements Instruments (COSMIN).[16] The IKDC, a 1-dimensional questionnaire as proven by confirmatory factor analysis, was previously shown to have the highest reliability and validity in measuring the functional outcome after treatment of meniscal injuries as compared with the KOOS and WOMAC.[14,27]

The responsiveness, however, of most PROMs, including the IKDC, is not well documented, and limited evidence is available in the specific population of patients with a meniscal tear.[1] The COSMIN initiative defines responsiveness as "the ability of a health related PROM

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to detect change over time in the construct to be measured."[16] Adequate responsiveness of a PROM is important to properly assess intervention effects in clinical trials.

Aside from the responsiveness of a PROM, the interpretation of the changed score is essential in clinical practice. When changed scores are interpreted, the emphasis should be on the important change as perceived by the patient, represented by the minimal important change (MIC).[7] MIC is a measure that quantifies the smallest change score that patients perceive to be important.[4,6,7] It is relevant to know whether a measurement instrument is able to detect changes as small as the MIC value. This depends on the reliability and measurement error, often quantified as the smallest detectable change (SDC). When the SDC exceeds the MIC, an instrument cannot detect the MIC at the individual level on the basis of single measurements; when the SDC is smaller than the MIC, an instrument may detect statistically significant changes that lack clinical relevance. To ensure that observed changes are both statistically significant and clinically relevant, the change values have to exceed both the SDC and the MIC.[5]

Devji and colleagues[6] acknowledged the importance of the MIC in the interpretation of a treatment effect. The MIC for the IKDC is not yet determined for patients with an isolated meniscal tear.[1] Knowledge of both the responsiveness and the MIC in this patient population is important for designing clinical trials and to discriminate between responders and nonresponders with regard to the treatment. Unknown responsiveness and MIC severely hamper the interpretation of clinical trial results and might explain why the preferred choice of treatment for meniscal tears is still a topic of debate, despite several randomized controlled trials, systematic reviews, and meta-analyses comparing arthroscopic partial meniscectomy with physical therapy.[13,14,24,26]

Because the IKDC has high reliability and validity for patients with a meniscal tear, this study focuses on the other main measurement property, responsiveness, and the measure of interpretability, the MIC.[14,27] Specifically, we evaluated the responsiveness and MIC of the IKDC among middle-aged and older patients with meniscal tears.

METHODS

Population

This study was part of the ESCAPE trial, a noninferiority multicenter randomized controlled trial comparing arthroscopic partial meniscectomy with a nonoperatively treated control group receiving physical therapy.[24,25] Between July 2013 and October 2015, 321 patients between 45 and 70 years of age with a symptomatic, nonobstructive, degenerative meniscal tear (confirmed per magnetic resonance imaging) were included. Exclusion criteria consisted of severe osteoarthritis (Kellgren-Lawrence 4), body mass index >35 kg/m^2, locking of the knee, prior knee surgery, and knee instability attributed to anterior or posterior cruciate ligament rupture. Previous knee injuries (eg, anterior cruciate ligament rupture) that can interfere with the treatment outcome were assessed on magnetic resonance imaging and excluded from the trial. Further details can be found in the study protocol.[25] The ESCAPE trial was approved by the Medical Ethical Committee (NL44188.100.13). All patients provided written informed consent for participation.

Treatment

Patients randomized to arthroscopic partial meniscectomy underwent surgery within 4 weeks after enrollment. The arthroscopic partial meniscectomy procedure started with a general assessment of the joint, whereupon the affected meniscus was partially removed, resulting in a stable and solid meniscus. Patients received standard written postoperative instructions. Participants were referred to physical therapy after arthroscopic partial meniscectomy if rehabilitation was not going according to the guideline of the Dutch Orthopaedic Association.[23]

Physical therapy started 1 to 2 weeks after randomization. Patients in the physical therapy group participated in a supervised progressive exercise program consisting of 16 sessions of 30 minutes each (Appendix Table A1, available in the online version of this article).[25]

Data Collection

Patients received self-administered questionnaires at baseline and 6 months after enrollment. Patients completed the questionnaires at home, either online or on paper. In the online questionnaires, no data were missing, as completion of each item was required to move on to the next item. When an item was missing in the paper-based questionnaires, the missing item was obtained by telephone. To enhance the response rate, up to 3 response reminders were sent to the patients. Details on patient inclusions, randomization, and follow-up are available in Appendix Figure A1, available online.

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TABLE 1
Hypotheses With Expected and Calculated Correlations[a]

	Hypothesis	Expected *r*	Calculated *r* (95% CI)	*P* Value
1	The change in total IKDC score shows at least a very strong positive correlation with the change on the PCS of the RAND-36.	≥0.7	0.74 (0.67 to 0.81)	<.001
2	The change in the items for activity of the IKDC (questions 8 and 9) shows a very strong positive correlation with the change on the dimension for PCS of the RAND-36.	≥0.7	0.70 (0.61 to 0.78)	<.001
3	The change in the items for activity of the IKDC (questions 8 and 9) shows a very strong positive correlation with the change on the dimension for physical function of the RAND-36.	≥0.7	0.72 (0.63 to 0.79)	<.001
4	The change in the items for pain of the IKDC (questions 1-3) shows a very strong negative correlation with the change in VAS for pain during weightbearing.	≤–0.7	–0.68[b] (–0.76 to −0.59)	<.001
5	The change in the items for pain of the IKDC (questions 1-3) shows a moderate to strong positive correlation with the change on dimension for bodily pain of the RAND-36.	0.3≤ *r* <0.7	0.59 (0.51 to 0.69)	<.001
6	The change in VAS for pain at rest shows at least a moderate to strong negative correlation with the change in IKDC.	−0.3≥ *r* >−0.7	–0.55 (–0.60 to −0.40)	<.001
7	The change in VAS for pain during weightbearing shows a moderate to strong negative correlation with the change in IKDC.	–0.3≥ *r* >−0.7	–0.70[b] (–0.77 to −0.60)	<.001
8	The change in EQ-5D-VAS shows moderate to strong moderate positive correlation with change in IKDC.	0.3≤ *r* <0.7	0.35 (0.21 to 0.43)	<.001
9	The change in total IKDC score shows a poor positive correlation with the change on the dimension for general health of the RAND-36.	<0.3	0.04 (–0.06 to 0.17)	.49
10	The change in total IKDC score shows a poor positive correlation with the change on the MCS of the RAND-36.	<0.3	–0.11[b] (–0.123 to 0.11)	.07

[a]EQ-5D-VAS, EuroQol–5 Dimension–Visual Analog Scale; IKDC, International Knee Documentation Committee; MCS, Mental Component Scale; PCS Physical Component Scale; RAND-36, 36-Item Health Survey; VAS, visual analog scale.
[b]Hypothesis not confirmed.

Outcome Measures

Four PROMs that were evaluated were all translated and validated for the Dutch population.[8,27,28,31] Sociodemographic information (age, sex, and body mass index) was collected at baseline. At follow-up, the same PROMs were administered, and an anchor question was added about the patients' assessment of change of functioning in daily activities.

The IKDC was developed to measure knee-specific symptoms, function, and sports activity for patients with ligament or meniscal injuries.[10] The IKDC consists of 19 items, of which 18 are converted into a total score. The answer to question 10a is not used for the overall score. Factor analysis confirmed the single dimension in a similar population.[27] The sum of these 18 items is converted into an IKDC score, ranging from 0 to 100 points. The minimum score of 0 points indicates that the patient is very limited in daily and sports activities, and the maximum score of 100 points indicates no restriction in functioning.[10] The IKDC was validated for patients with meniscal tears.[2,27]

The RAND 36-Item Health Survey (RAND-36) is a general health questionnaire that consists of 8 dimensions with a total of 36 questions.[31] From these 8 dimensions, 2 aggregated scores are calculated: the physical and mental component scores. These scores can be compared with the Dutch population with an average score of 50 points, in which higher scores represent better health. A study on its psychometric qualities concluded sufficient reliability and validity.[31]

The EuroQol–5 Dimension–5 Level (EQ-5D-5L) is a generic measure of health often used to assess quality of life.[9] The questionnaire consists of 5 questions on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Additionally, patients were asked to rate their general health on a visual analog scale (EQ-5D-VAS) for a score between 0 and 100, with 0 indicating the worst possible health status as perceived by the patient and 100 indicating the best. The EQ-5D-VAS is responsive for patients undergoing knee arthroscopy[17] and was the only EQ-5D item that we used for further analysis.

Pain was assessed through 2 visual analog scales of 100 mm. Patients were asked to rate their pain at rest and during weightbearing activities in the previous week. The amount of pain was scored by marking on a line of 100 mm, with 0 indicating no pain and 100 indicating severe pain.

The external anchor question "How did your function in daily activities change since the surgery/treatment of your knee?" was administered at 6 months after enrollment to determine the patient's perception of change in knee function after the treatment.[12] The question was scored on a 7-point Likert scale, ranging from very much worsened to very much improved.

Responsiveness

Responsiveness of the IKDC was assessed with hypothesis testing based on the correlations of absolute changed scores, as recommended by the COSMIN panel.[19] Ten hypotheses were formulated (see Table 1): 5 before data collection

TABLE 2
Scores at Baseline and 6-Month Follow-up and the Changed Scores[a]

PROM: Subscale	Baseline	6-mo Follow-up	Changed Scores	Percentage Changed Scores
IKDC: total	45.7 ± 15.1	66.7 (50.6 to 78.2)	19.5 (3.5 to 31.3)	44.6 (7.1 to 82.8)
RAND-36				
PCS	37.7 ± 8.4	49.5 (41.8 to 54.2)	9.4 ± 9.6	25.8 (4.9 to 49.9)
MCS	52.9 (47.3 to 60.4)	55.3 (48.6 to 58.5)	–0.4 (–4.6 to 4.2)	–0.4 (–7.4 to 8.1)
PF	60 (45.0 to 75.0)	80.0 (60.0 to 90.0)	15.0 (0 to 30)	22.6 (0 to 70)
BP	42.9 (32.7 to 44.9)	77.6 (67.4 to 89.8)	32.7 (13.8 to 46.9)	77.3 (33.3 to 120)
GH	70.0 (60.0 to 80.0)	72.5 (65.0 to 85.0)	5 (–5 to 15)	6.5 (–6.7 to 25)
VAS for pain				
Rest	30.1 (15.8 to 56.1)	6 (0.0 to 24.1)	–18.9 (–36.9 to −1.9)	–82.0 (–100 to −17.5)
Weightbearing	60.9 (42.0 to 78.1)	16.5 (4.6 to 51.4)	–30.2 ± 32.8	–61.9 (–90.2 to −17.4)
EQ-5D-VAS	78.1 (64.3 to 88.1)	82.6 (69.3 to 90.4)	3.1 (–7.6 to 11.6)	–3.8 (–8.9 to 15.7)

[a]Data are reported as median (interquartile range). For normally distributed data, values are reported as mean ± SD. BP, bodily pain; EQ-5D-VAS, EuroQol–5 Dimension–Visual Analog Scale; GH, general health; IKDC, International Knee Documentation Committee; MCS, Mental Component Scale; PCS Physical Component Scale; PF, physical functioning; PROM, patient-reported outcome measure; RAND-36, 36-Item Health Survey; VAS, visual analog scale.

(hypotheses 1, 3, 5, 9, 10) and 5 after data collection but before data analysis (hypotheses 2, 4, 6-8). The expected correlations were predetermined per current literature, clinical experience, and consensus among the authors. Correlations were categorized as very strong ($r \geq 0.7$), strong ($0.5 \geq r < 0.7$), moderate ($0.3 \geq r < 0.5$), and weak ($r < 0.3$). The hypotheses were tested with the Pearson correlation coefficient for normally distributed data and the Spearman rank correlation coefficient for nonnormally distributed data. To demonstrate good responsiveness, ≥75% of the hypotheses should be confirmed.[16]

Minimal Important Change

The MIC was defined as the smallest change in outcome in the domain of interest as perceived beneficial by the patient.[4] The MIC value was established with an "anchor-based MIC distribution method," a blending of 2 methodologies: Specifically, an anchor-based method uses an external criterion to determine what patients consider important,[3] which is especially helpful in a study based on score distribution, given that distribution-based methods lack information on whether the observed changes are minimally important.[4]

First, we analyzed the correlation between the changes in IKDC scores and the external anchor question. Next, if this correlation was >0.5, the study population was divided into *changed* and *unchanged* based on the external anchor question. The changed group comprised patients who reported to be very much, much, and slightly improved. The unchanged group included patients who reported to be unchanged. Patients who reported very much, much, or slight deterioration in daily functioning were excluded since we were comparing patients with and without important improvement.[4]

The receiver operating characteristic (ROC) curve was used because it searches for the optimal cutoff points, irrespective of how much misclassification occurs. A graphic display of the anchor-based MIC distribution was plotted, as well as the ROC curve.[3] Sensitivity and specificity were determined for all potential cutoff points. The MIC value was determined by the optimal cutoff point—that is, with the smallest value of the sum of the proportions of misclassifications: (1 – sensitivity) + (1 – specificity).[3] In other words, the MIC was quantified by the IKDC score that best discriminated between patients with and without clinically relevant improvement.

Statistical Analyses

We used descriptive statistics to analyze the patients' demographics and tested all data for normality with the Kolmogorov-Smirnov test. The mean and SD were calculated for continuous normally distributed data ($P > .05$, Kolmogorov-Smirnov) and the median and interquartile range for continuous nonnormally distributed data ($P < .05$, Kolmogorov-Smirnov). Frequencies and percentages were used for categorical data. We calculated the changed scores by subtracting the baseline scores from the follow-up questionnaire scores. The percentage change scores are reported in Table 2, as it takes into account the scores at baseline. All analyses were performed with SPSS (v 22; IBM Corporation).

RESULTS

In total, 321 patients were randomized in the ESCAPE study; however, 2 patients (1 in each treatment group) withdrew immediately after randomization. Of the remaining 319 patients, 298 (93.4%) returned the baseline and 6-month follow-up questionnaires. Baseline data of the 21 patients who did not complete the 6-month follow-up questionnaires were discarded. At baseline, the questionnaires (n = 298) contained 0.4% missing items. At follow-up (n = 298), 0.06% of the items were missing. Most patients (n = 279, 94%) completed both questionnaires online. Fifteen patients completed

TABLE 3
Baseline Characteristics[a]

	n (%) or Mean ± SD
Patients	298
Sex	
Male	148 (49.7)
Female	150 (50.3)
Age, y	57.5 ± 6.7
Body mass index, kg/m^2	26.9 ± 3.9
Treatment	
APM	151 (50.7)
PT	147 (49.3)
Affected knee	
Left	136 (45.6)
Right	162 (54.4)
MRI: affected meniscus	
Medial	245 (82.3)
Lateral	52 (17.4)
Both	1 (0.3)
Radiograph: Kellgren-Lawrence, n	281
0: No OA	29 (9.7)
1: Doubtful	147 (49.3)
2: Minimal	95 (31.9)
3: Moderate	10 (3.4)
4: Severe[b]	0 (0)

[a]APM, arthroscopic partial meniscectomy; MRI, magnetic resonance imaging; OA, osteoarthritis; PT, physical therapy.
[b]Kellgren-Lawrence grade 4 was an exclusion criterion.

both questionnaires on paper, and 4 patients completed the first questionnaire online and the second on paper. Patient characteristics are shown in Table 3, with the mean and changed scores of the PROMs in Table 2.

Responsiveness

Of 10 hypotheses, 7 (70%) were confirmed. The hypothesized and calculated correlation coefficients with the 95% CIs are shown in Table 1. For 2 unconfirmed hypotheses (hypotheses 4 and 7), the correlation coefficients deviated only slightly (≤0.02) from the predetermined threshold. Only hypothesis 10 differed from the predetermined direction, with a poor negative correlation while a poor positive correlation was expected.

Minimal Important Change

A strong correlation was found between the changed IKDC scores and the external anchor question ($r = 0.64$, $P < .001$). On the basis of the external anchor question, 217 patients (72.8%) reported to be changed and 48 (16.1%) unchanged. Patients who reported slight (n = 21, 7%), much (n = 7, 2.3%), or very much (n = 3, 1%) deterioration were excluded from the MIC analysis. Figure 1 shows the ROC curve. The optimal cutoff point was set at a sensitivity value of 79.7% and a specificity of 72.9%, resulting in an MIC of 10.9 points on the IKDC (range, 0-100 points). The anchor-based MIC distribution is displayed in Figure 2.

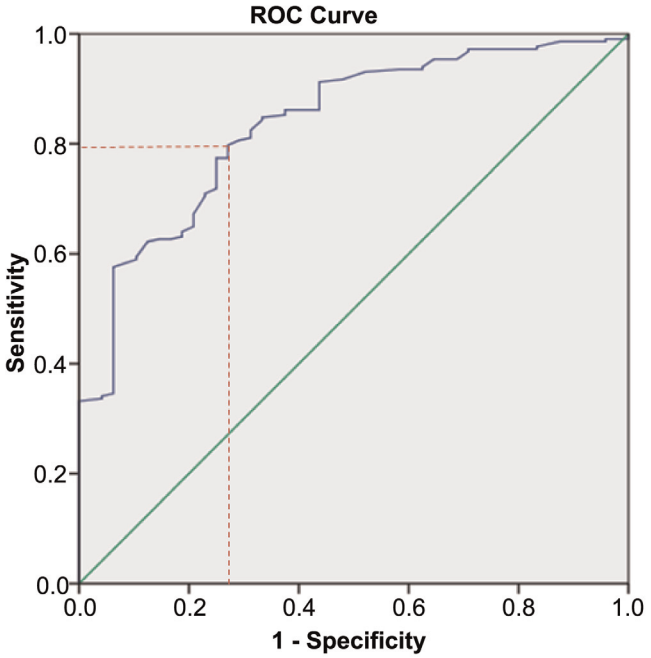

Figure 1. Receiver operating characteristic (ROC) curve, with optimal cutoff point.

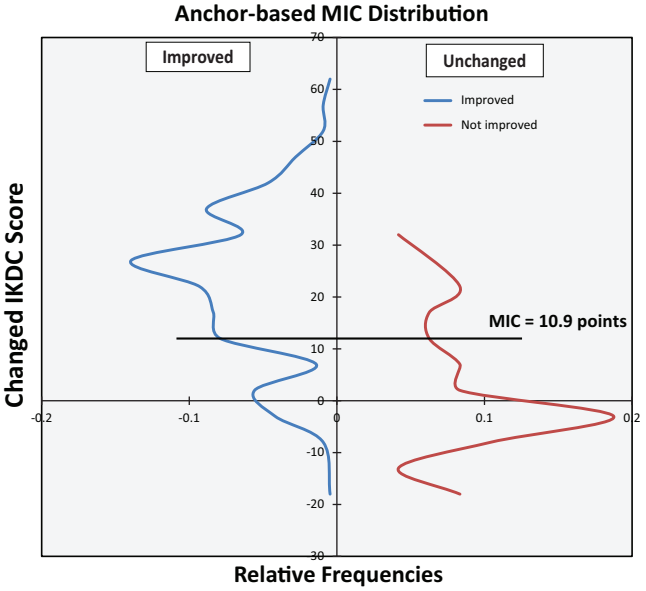

Figure 2. Anchor-based minimal important change (MIC) distribution. IKDC, International Knee Documentation Committee.

DISCUSSION

Responsiveness of the IKDC among patients 45 to 70 years old with symptomatic meniscal tears was confirmed in 7 of the 10 predefined hypotheses. One unconfirmed hypothesis demonstrated a weak negative correlation while a weak positive correlation was expected—namely, between

change in IKDC score and the Mental Component Scale of the RAND-36. Two unconfirmed hypotheses (4 and 7) deviated only slightly in magnitude from the expected correlation. Therefore, we concluded that the IKDC was responsive in our population. Furthermore, we calculated an MIC of 10.9 points reflecting the minimal change in IKDC score that a patient considers important. This value contributes to the interpretation of change scores as a result of the treatment of patients with meniscal tears.

Comparison With the Literature

Irrgang et al[11] established the MIC for the IKDC at 11.5 points and 20.5 points in a study population with various knee injuries, using the point on the ROC curve closest to the upper left corner. These values are both higher as compared with the MIC in our study. However, we determined the MIC as the optimal cutoff point, using the smallest value of the sum of the proportions of misclassifications. Furthermore, we found that the MIC exceeded the SDC of 8.8 points that was reported by Crawford et al.[2] Based on this SDC, there is 98% certainty that a change of 10.9 points was not due to measurement error.[21]

Responsiveness of the IKDC was previously reported by 2 studies. Crawford et al[2] analyzed responsiveness among 100 patients with meniscal injuries, and Irrgang et al[11] analyzed the responsiveness of 207 patients with a variety of knee disorders. Both studies concluded adequate responsiveness, using the effect size without predefined hypothesis as a measure of responsiveness. This is considered a less suitable method, since it measures magnitude of change rather than quality of the measurement.[1,5] Our results confirm that the IKDC is responsive to change based on recommended methodology.[18]

Strengths and Limitations

To our knowledge, this is the first study that determined the responsiveness and MIC of the IKDC among patients 45 to 70 years old with symptomatic meniscal tears, using predefined hypotheses with the expected magnitude and direction of the correlations. While previous studies investigating responsiveness with hypotheses testing used a general cutoff criterion of 0.5 for the expected correlations,[22,29,30] we defined more specific criteria to enhance the quality of our hypotheses. Another strength is that we utilized a large sample (n = 298) with >90% complete data. Third, with a relatively short interval (6 months), we are confident that patients could adequately recall any changes in physical functioning and that these changes were largely related to the treatment that they received. Fourth, we used the anchor-based MIC distribution for the calculation of the MIC to give more insight into the interpretation of the MIC.

There were also limitations to this study. First, the data were retrieved from a randomized controlled trial, which could have led to selection bias. Second, the anchor question was not a true reflection of the construct measured by the IKDC. The anchor question focused on functioning in daily living, and the IKDC measures knee-specific symptoms, functioning, and activities. However, we found a strong correlation ($r = 0.64$) between the anchor question and change in IKDC score. The results of our study apply specifically to patients 45 to 70 years old with degenerative meniscal tears and can be different for patients with traumatic meniscal tears or other knee pathologies.

Implications of the Study

The results of this study contribute to the evidence regarding the measurement properties of the IKDC among patients with meniscal tears; the IKDC is also responsive to change in this population and is valid and reliable. An MIC of 10.9 was established, which strengthened the value of the IKDC for assessing patient-reported knee function. The MIC of 10.9 points was determined on a group level. These results can therefore be used on a group level, whether by policy makers to determine treatment per recipient or by researchers to compare different treatments.[4,6,7] The distinctive character of the MIC between "changed" and "unchanged," on a group level, makes it highly relevant for developing clinical prediction models. Furthermore, based on the sensitivity and specificity levels (79.7% and 72.9%, respectively) and the probability of the measurement error (2%), the MIC of 10.9 can also be applied to individual patients.[4,6,7] However, one should take the patient's characteristics into account when applying the MIC on an individual level.[20]

CONCLUSION

The IKDC was responsive to change, with an MIC of 10.9 points for middle-aged and older patients with a meniscal tear. This study has shown that the IKDC has good measurement properties to evaluate the treatment effect on meniscal injuries. Therefore, we recommend the use of the IKDC for middle-aged and older patients with degenerative meniscal tears.

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