



Case Report

Minimal clinically important improvement response in patients with severe osteoarthritis of the knee: Short report from a survey of clinicians

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ABSTRACT

The minimal clinically important improvement (MCII) is the smallest change that signifies an important improvement. Disease severity may complicate MCII. We developed an eight-question survey examining MCII in patients with severe knee osteoarthritis (Kellgren-Lawrence grade 4). Twenty-seven of 101 clinicians completed the survey. An MCII of 20% was selected most frequently for pain, function, and patient global assessment. Clinicians were divided on responder rate, selecting 20%, 30%, and 50% equally. These findings suggest a 20% MCII may be useful in patients with severe osteoarthritis, but that there is not enough evidence to support a responder rate in this population.

1. Introduction

Patient reported outcomes are frequently used in interventional trials of chronic pain such as osteoarthritis and rheumatoid arthritis. The responses to patient reported outcomes are often scores that are measured and analyzed as continuous variables. These results are difficult to interpret by clinicians, who prefer to know how many patients had a clinically relevant therapeutic response to treatment. The concept of minimal clinically important improvement (MCII) is defined as the smallest change that signifies an important improvement to the patient.¹

While the concept of MCII is well supported, there is no consensus on MCII cutoff values. The Outcome Measures in Rheumatology (OMERACT), an international network organizing consensus conferences on outcomes measures in rheumatology clinical trials, has focused several conference sessions on the MCII. Participants at the 2007 meeting reported strong agreement (88%) that the percent of improved subjects (MCII) should be reported in addition to continuous outcomes (such as mean change in pain).² However, only 40% agreed that they currently have enough data to propose a cut-off. A follow-up email survey was used to determine which of the following values were best for MCII: 10%, 15%, 20%, 30%, and 50%. Among 36 completed surveys, the MCII value most frequently chosen was 20%, for pain (40% of participants), patient global assessment (40% of participants), and function (54% of participants).²

The Initiative on Methods, Measurement, and Pain Assessment in

Clinical Trials (IMMPACT) advocates a provisional benchmark of 10–20% for minimally important improvement and $\geq 30\%$ for moderately important response to treatment in patients with chronic pain.³ The American College of Rheumatology definition of improvement that is widely reported is 20% (ACR20), reflecting a collective improvement in several core rheumatoid arthritis symptoms.⁴

Severity of chronic disease may affect what is considered a clinically important improvement. For instance, patients with osteoarthritis are typically graded using the Kellgren-Lawrence (KL) grading system, where grade 2 is minimal disease, grade 3 moderate, and grade 4 is severe disease.⁵ Patients with higher KL grade have previously been shown to yield lower response to treatment and lower change in WOMAC pain scores than patients with less severe KL grade.^{6,7} Because disease severity may complicate the cutoffs for MCII and responder rate, we aimed to develop and implement a survey to determine an appropriate MCII among patients with severe osteoarthritis.

2. Methods

A short, eight-question survey was developed to determine an appropriate MCII and response to intervention among patients with severe osteoarthritis defined by KL grade 4. Questions 1–3 were used to identify the clinician's specialty, years practiced, and whether they treat severe knee osteoarthritis. Questions 4–6 asked about MCII for pain, function, and PGA in patients with severe OAK. Question 7 asked about the responder rate in patients with severe osteoarthritis. The final

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Table 1
Results of the email survey of clinicians on MCII and responder rates.

Response categories	MCII pain, KL4 disease	MCII function, KL4 disease	MCII PGA, KL4 disease	Responder, KL4 disease	MCII pain, KL2,3,4
10%	14.3%	0%	4.8%	0%	0%
15%	0%	9.5%	0%	9.5%	14.3%
20%	42.9%	42.9%	47.6%	28.6%	33.3%
30%	28.6%	28.6%	19.1%	28.6%	28.6%
50%	14.3%	19.1%	28.6%	33.3%	23.8%

KL, Kellgren Lawrence. MCII, minimal clinically important improvement. Responder defined by the OMERACT-OARSI scenario D criteria.

question asked about the MCII for pain in patients with any disease severity osteoarthritis (KL2–4). The response categories were chosen based on the OMERACT 8 survey²: 10%, 15%, 20%, 30%, and 50%.

Clinicians were provided with definitions at the start of the survey: MCII = minimal clinically important improvement is the smallest change in an outcome that a patient would identify as important; severe OAK/KL4 = Kellgren Lawrence grade 4 is characterized by large osteophytes, marked joint space narrowing, severe sclerosis and definite bone deformity / bone on bone; responder rate = percent of patients treated with the drug having satisfactory effect according to the OMERACT/OARSI scenario D criteria.

Survey Monkey was utilized to design the survey, collect responses, and aggregate results (www.surveymonkey.com). The survey was emailed to 107 clinicians in the United States with experience in clinical trials. Four clinicians automatically opted-out and two surveys were bounced back. Surveys were sent to the remaining 101 clinicians via email a maximum of three times, including the initial survey and two follow-up reminder emails, sent one week apart.

3. Results

A total of 27 of 101 clinicians responded to the survey. There were 21 completed surveys and 6 partially completed surveys. All but one (96.3%) clinician had treated patients with severe osteoarthritis (KL4). The clinicians reported a range of specialties: 38% orthopedic, 33% rheumatology, 19% internal medicine, and 9% other. The majority (76%) of clinicians had been practicing in their specialty for at least 20 years, with the remainder having practiced between 10–20 years.

Questions 4–8 sought to determine best values for MCII and response rate (Table 1). In patients with severe osteoarthritis (questions 4–6), clinicians overwhelmingly selected a 20% MCII for pain, function and patient global assessment.

In comparison, there was less consensus when clinicians were asked about MCII in patients with any severity osteoarthritis (question 8): participants were equally likely to select an MCII of 20%, 30%, and 50%.

The participants were divided on responder rate in patients with severe osteoarthritis, and were equally likely to select a responder rate of 20%, 30%, and 50%.

4. Discussion

The primary findings from this survey demonstrate that the most frequent response was an MCII of 20% for pain, function, and PGA in patients with severe knee osteoarthritis. Taken together with the existing literature, a 20% minimal response to intervention appears to be well supported in patients with chronic pain to determine improvements that are clinically important and not just statistically significant.

These results support the MCII values identified by the OMERACT 8 group survey in patients with any disease severity: most participants selected an MCII of 20% (33% this survey, 40% OMERACT 8), followed by 30% (29% vs. 33%, respectively), and 50% (24% vs. 20%, respectively). While an MCII of 20% was most frequently selected for both the severe osteoarthritis population and the general osteoarthritis population (KL grades 2–4), there was greater consensus for a 20% MCII pain threshold in the severe osteoarthritis population and a shift towards a lower MCII of 20%.

Participants were more divided on responder rate than on MCII, selecting 20%, 30%, and 50% equally. The responder rate values selected were numerically greater than the MCII values selected, suggesting a higher threshold for responder rate may be necessary to be clinically meaningful.

In conclusion, there appears to be some consensus on MCII, which may be minimally impacted by disease severity, but there is not consensus on responder rate. Further research should determine appropriate level of response and whether the definition of response can be standardized across disease severity.

Conflict of interest

None.

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