Osteoarthritis and Cartilage

Editorial

The minimal clinically important difference re-considered

In an important contribution to *Osteoarthritis and Cartilage*, Mackay *et al.* report a systematic review of estimates of the minimal clinically important difference (MCID) for the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire in patients who underwent total hip or total knee replacement[1]. In this well conducted review, the authors observed a wide range of MCIDs across studies. This observation confirms findings in earlier reviews, which also reported a wide range of MCIDs for various outcomes measures, interventions and patient groups[2–4]. It is generally accepted that the MCID will vary depending on the intervention and the patient group. As noted by MacKay *et al.*[1], it is interesting that very large differences in MCIDs occur even within the context of a single intervention with a relatively predictable result (i.e., total hip or total knee replacement) in a specific patient group (i.e., patients with end stage osteoarthritis). This wide variation inevitably invites the conclusion that at present the MCID is not fit for purpose.

MacKay *et al.*[1] found that a wide range of methods were used to determine the MCID, including variation in the wording of the anchor question and response scale, variation in the time frame studied, and variation in the statistical approaches used when calculating the MCID. Again, these findings confirm earlier observations[2–4]. In order to remedy the problem of variation in MCIDs the general recommendation has been to standardize and refine methods used to determine the MCID[1–4]. The underlying expectation is that standardization of methods will lead to a uniform MCID. I will argue that standardization is unlikely to remedy existing problems and that a fundamental reconsideration of the conceptualization and methodology used to determine the MCID is required.

The MCID was originally defined as 'the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management'[5] (p. 408). In a further update, the MCID (or Minimal Important Change (MIC)) was defined as 'the smallest change in score in the construct to be measured that is perceived as important by patients, clinicians or relevant others'[6] (p. 258). What a patient identifies as important depends on a wide range of factors. If we take pain as an example, the MCID of pain is likely to depend on the baseline score of pain[7]; on the success of previous pain treatment (if previous treatments were not successful, even a small reduction in pain might be important); on the expected success of treatment (if treatment is expected to lead to a large reduction in pain, the patient is likely to identify only a large reduction as important); on the availability of other treatment options (if no other options are available, the patient might be happy with even a small reduction in pain); on clinician—patient interactions (if only a limited reduction of pain is possible, the patient is more likely to accept and see this

as important if the patient trusts the clinician) and finally, on a wide range of other psychological factors (a timid patient might be happy with only a small pain reduction, while a more demanding patient may expect a larger reduction). My hypothesis is that the variation in observed MCIDs is to a large extent due to these factors, in addition to the variation in methods used to determine the MCID.

If this line of reasoning is correct, standardization of methods to determine the MCID is unlikely to result in a uniform MCID. As a host of other factors are hypothesized to contribute to the MCID, standardization of all factors might not be feasible. More importantly, the concept of 'the' MCID becomes meaningless if the score is dependent on so many factors: instead of a single MCID, a wide range of different MCIDs would apply, with a different MCID depending on the baseline score, success of previous treatment, availability of other treatment options, *etc.*

Notwithstanding, it remains important to identify the smallest change in an outcome that a patient perceives as important (that is, the MCID). This is important at the level of an individual patient and at the level of a group of patients. At the individual level, the clinician and patient need to discuss and agree on the intended outcome of treatment, including the minimal improvement to be achieved for the treatment to be considered successful. At the group level, in a clinical trial it is essential to define the minimal level of improvement that will be considered important (that is, clinically significant), as opposed to looking at statistical significance alone. Because the MCID is so important, means of determining the MCID need to be better than those currently available.

In developing better methods it is important to realize that the MCID is, in fact, a statement of a value. What constitutes the smallest change in an outcome that a patient identifies as important expresses what the patient wishes to achieve, that is: a value. Both at the level of the individual patient and at the group level, patients need to define a minimal desired treatment outcome. I would argue that the consensus method[8–10] enables patients to directly state that value (that is, the MCID). At the level of the individual patient, the patient and the clinician should together discuss and reach consensus on the treatment plan and the minimal desired outcome. At patient group level, a panel can be used to reach consensus on the MCID for clinical trials. In a modern version, a panel could consist of patients, clinicians, researchers, and policy makers: based on their respective expertise and background, participants discuss and reach consensus on what constitutes a realistic MCID for a particular treatment in a specific group of patients. While the consensus method has been previously used to support clinicians in establishing the MCID[10], I now propose to use the consensus method to enable patients to define the MCID.

Currently, most experts recommend the anchor-based method to derive the MCID[8], an empirical approach to determining the

MCID. Relative to an external criterion (the anchor), patients indicate whether or not they perceive important improvements after having received treatment. These responses are then compared to scores on the outcome measure; this yields a cut-off on the outcome measure that defines the MCID. Instead of enabling patients to directly state what change they consider important, using the anchor other patients are surveyed regarding the treatment outcome. The responses relative to the anchor are used to calculate the MCID. This anchor-based method differs fundamentally from the consensus method proposed here.

Awareness that the MCID is a statement of a value and the conviction that patients should be allowed to define that value themselves are the fundamental characteristics of the proposed consensus method that distinguish it from the anchor-based method. The individual patient or panel makes a statement on what minimal change is important enough to mandate treatment. In doing so, they need to take into account information on the disease, the treatment and other factors they consider relevant. In the clinical setting the clinician provides this information, thereby enabling the patient to make an informed decision (see also[11]). In the research setting, panel members including representatives of patient organizations, clinicians, researchers, and policy makers provide that information, leading to an informed recommendation regarding the MCID. The individual patient or the panel considers disease, treatment, and other relevant factors (such as the availability of other treatment options) and makes an informed decision on what is considered the minimal desired treatment outcome. They directly state the minimal desired treatment outcome, as opposed to a researcher-led survey of patient evaluation of treatment outcome, which is then regarded as empirical evidence underpinning the formulation of a MCID.

Mackay et al. report on estimates of the Patient Acceptable Symptom State (PASS) for the WOMAC questionnaire, in addition to estimates of the MCID[1]. Although based on fewer studies, the cut-offs for the PASS showed variation as well. Similar to the MCID, factors such as success of previous treatment and availability of other treatment options can be assumed to affect the PASS, in addition to the variation in methods used to determine the PASS. Without going into details, I suggest to use the consensus method to enable patients to define the PASS, analogous to the MCID.

To conclude, I argue that (1) the current method of determining the MCID is not fit for purpose, as it yields a very wide range of estimates regarding the MCID (2) the MCID is a statement of a value (i.e., the minimal desired treatment outcome), and patients should be allowed to define that value themselves, and (3) the consensus method can be used to help patients to directly state that value, that is — to directly define the MCID. I therefore call on professional bodies, such as Osteoarthritis Research Society International (OARSI), to further develop the consensus method in order to derive recommendations for realistic MCIDs.

Author's contribution

JD conceived, wrote and approved this editorial.

Competing interests
None.

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