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REVIEW

Minimal clinically important difference of commonly used hip-, knee-, foot-, and ankle-specific questionnaires: a systematic review

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Abstract

Objective: Minimal clinically important difference (MCID) has become the most important psychometric factor for interpreting change in individual's responses over time from the patient's perspective, evaluating study results and planning sample sizes. The purpose was to synthesize and critically appraise MCID of the most frequently used hip-, knee-, foot-, and ankle-specific patient-reported outcomes (PROs).

Study Design and Setting: A search was conducted on PubMed, Cochrane Library, and Web of Science from each site's respective inception through January 2019 for MCID in 25 PROs. The studies reporting their results with anchor-based method were included.

Results: 228 full-text articles were assessed for eligibility, and 48 were included in the final evaluation. Our synthesis provides a comprehensive assessment of MCID for 16 disease or joint specific PROs. MCID of the Western Ontario and McMaster Universities Index (33.3%), International Knee Documentation Committee Subjective Knee Form (14.5%) and Knee Injury, and Osteoarthritis Outcome Score (14.5%) was found to be the most commonly presented PROs. The studies mainly (85%) used the receiver operating curve analysis to elicit MCID.

Conclusion: MCID is increasingly used as a measure of patient's improvement. However, MCID varied based on the analytic methods, study population, type of disease, the baseline status, change in values and treatments, and patient demographics. Therefore, it should be interpreted with caution.

Keywords: Minimum important difference; MCID; Lower extremity outcome scores; Patient-reported outcomes

1. Introduction

Patient-reported outcomes (PROs) are commonly used to assess symptoms, function, or any change in disability after treatment of patients. The PROs, including the patient's health, quality of life, or function associated with health care or treatment [1], are directly reported by the patient without interpretation of the patient's response by a clinician. The assessment of change in patients' symptoms and function over time is necessary for both clinical practice and research. Demonstration of any change in PROs measured before and after treatment is often interpreted as a treatment effect. Therefore, the properties of the PROs need to be assessed [2].

Recently, minimal clinically important difference (MCID) has become the most important psychometric parameter for interpreting the change over time or, in other words, a threshold value is defined for this change [3]. Various terminologies including minimum important change, minimal clinically important change, and minimal clinically important improvement have been proposed [4]. MCID is defined as the smallest difference in score from the domain of interest based on patients' perception as being beneficial [5]. For example, even if MCID for an outcome measure is 12 points and the patient records a 9-point change in that measure after treatment, this difference may not represent a detectable clinical change.

MCID can be determined with two general approaches: distribution-based and anchor-based methods. Although distribution-based approaches depend on the statistical characteristics of the data, anchor-based approaches translate the change in the outcome measure to the patients' perspective. The anchor-based approach has received much attention in the literature. In this approach, it is crucial to evaluate the relevance of anchors (external criteria) to quantify differences measured by an outcome instrument.

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What is new?

Key findings

- Minimal clinically important difference (MCID) is increasingly used to measure patient's improvement. Even if MCID is estimated in many lower extremity pathologies, it still needs to be reported for various pathologies. MCID varied based on the analytic methods, study population, type of disease, the baseline status, and treatments of the patients. Therefore, it should be interpreted cautiously.

What this adds to what was known?

- Our study presented that MCID has been established in only 16 of the 25 included PROs. Despite the same patient population, the same treatment regime, and follow-up time, a wide range of MCID values was reported for the same PRO. This is mainly related to the calculation method of MCID; therefore, the researchers should consider these methods for sample size calculation or the magnitude of clinical improvement in patients.

What is the implication and what should change now?

- To our knowledge, this is the first study to be presented to the readers on MCID that are estimated using a variety of methods and patient populations from the literature for 16 commonly used PROs. Searching for information about MCID is quite challenging for researchers and readers because the term MCID can be expressed in many different ways such as minimal clinically important change, minimal clinically important improvement, and so forth. Different methods have been used to determine the efficacy of different interventions in different pathologies. This review, which presents a generalized summary of the literature, will help researchers who need information about MCID and will enable them to reach more comprehensive information in a much shorter time. In addition, owing to the comprehensive nature of this study, the gaps in the literature will be easily found out. Therefore, it offers implications for several future studies for researchers who want to calculate MCIDs for new pathologies or determine effectiveness of different interventions.

However, external anchor can be varied, and there is no consensus regarding a cutoff point. The anchor-based method is independent of the sample size and is based on patients' decision of whether the sum of improvement after the intervention or therapy is meaningful to them [6].

As the number of studies using PROs has increased, certain limitations have been recognized for defining the statistically significant differences and the description of clinical importance had to be readdressed when interpreting study outcomes and making clinical decisions based on them. Previously, some authors have suggested that the method for reproducing clinically important outcome should be tailored to either the disease itself or the population under study [5]. Moreover, MCID is a very important instrument in calculating the sample size of a study. If patients are specifically diagnosed, then the reported specific MCID point for sample size calculation can be confidently used.

1.1. *Objectives*

This study aims to conduct a systematic review and to investigate MCID of the 25 most commonly used PROs in lower extremity pathologies using anchor-based approaches.

2. Methods

2.1. *Search strategy*

A search of the PubMed, PEDro and Cochrane Central Register of Controlled Trials and Web of Science databases from 1980 through January 10, 2019, was conducted. The literature search was extended via the OpenGrey database for unpublished studies in the gray literature and by manual searching of reference lists of the core articles.

2.2. *Selection of studies*

The search was conducted by two independent reviewers and limited to peer-reviewed studies performed on adult populations in the English and Turkish languages. The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [7]. Medical Subject Headings terms and selected keywords used in the search strategy are provided in Appendix. After removing duplicates, the identified study titles were screened and abstracts were obtained for those presumed appropriate, followed by full-text retrieval for relevant articles. The articles were then screened in terms of inclusion criteria. References were also screened for other relevant articles that may have been missed during the search. The searching and selection processes are demonstrated in the PRISMA flow chart in Fig. 1.

2.2.1. *Inclusion criteria*

Studies were eligible for inclusion if

- The article reported MCID values;
- Studies estimated MCID with anchor-based approach;
- MCID of the PROs reported for orthopedic pathologies.

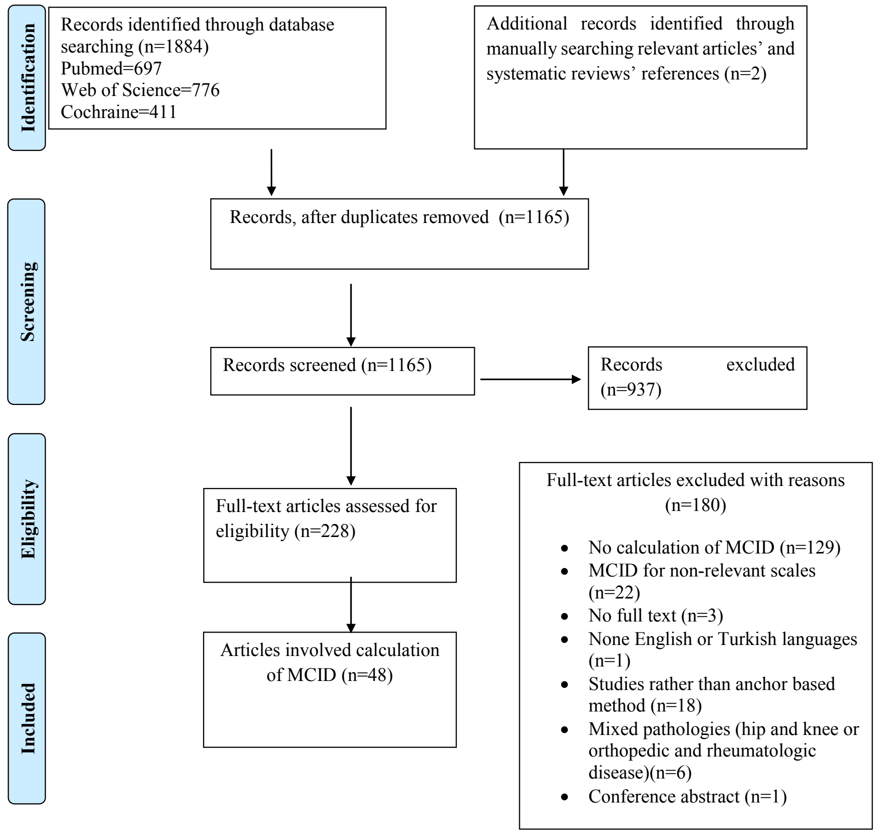

Fig. 1. Flow diagram. MCID, minimal clinically important difference.

2.2.2. *Exclusion criteria*

- Conference abstracts,
- Non-English or non-Turkish articles,
- Study protocol,
- Patients aged below 18 years,
- MCID defined for mixed hip and knee pathologies.

3. Data extraction

Two reviewers (D.C. and O.C. worked on each article) independently assessed inclusion or exclusion criteria for each article, and, in case of any disagreements, another reviewer (O.K.) resolved the issue. The first author extracted the following information from each article: author names, year of publication, pathology of the patient population, sample size, intervention received, length of follow-up, MCID values, anchor, and methods.

3.1. *Anchor-based approach of MCID*

The anchor-based method requires the use of an independent objective criterion to distinguish a threshold value for MCID. This is measured by the receiver operating curve (ROC) analysis, mean change method, or regression models. In the ROC method, the anchors functioned as gold standards, classifying patients as being importantly improved (somewhat better or better) or not improved (unchanged, very small change, somewhat worse, or worse) [4,8−10]. The ROC curve identifies a threshold of change in the PROs that discriminates between improved and nonimproved patients. Area under the curve indicates the change score between two patient groups [3,4]. The ROC cutoff point was based on the maximum of Youden's index, identified as −1 with equal weight for sensitivity and specificity. The Youden's index is accepted to be a good quantitative estimate of a cut point [11]. The other method was the 80% specificity rule because MCID has the best sensitivity for response while obtaining at least 80% specificity [12].

The mean change method introduced by Jaeschke et al. is the change score of patients who improved and therefore determines its cutoffs as patients who were identified to have a small, moderate, or large change [13]. MCID equals the mean change in the PROs of the improved patients, in other words, the mean change score of the patients who reported themselves as having a minimum change in the global rating of change scale after intervention. Redelmeier presented the specific self-assessment transition question that is most frequently used "How is your health today (at follow-up) compared with baseline?" There are 5 Likert response options available: "much better," "slightly better," "about the same," "slightly worse," and "much worse." The score differences (baseline to follow-up) were assessed for PROs and compared for the transition response categories. Therefore, MCID for progression is equal to the mean score difference of the "slightly better" minus the "about the same" groups [14].

The logistic regression analysis is the third approach for estimation of MCID. In this method, the transition responses are used (zero = almost equal and one = slightly better) as the dependent variable. The difference of score and possible confounders were considered as independent variables. The resulting odds ratios indicate the relative probabilities of being in the "slightly better" rather than in the "about the same" group [15]. The linear regression method is another quantification method. The score difference between baseline and follow-up can be further modeled on the basis of the transition item. The transition item is coded as 1 for "slightly better" and 0 for "almost the same" [3].

4. Results

4.1. Search results

The literature search identified 1884 potentially related articles. References of all relevant articles were also evaluated and two potential articles were identified. After excluding duplications ($n = -721$) 228 articles remained for testing against inclusion criteria. However, 129 studies were omitted because they did not mention MCID analysis, 22 studies calculated MCID for nonrelevant scales, 18 studies reported MCID using an analysis method different from the anchor-based approach, 1 study was not in English or Turkish, six studies reported MCID with mixed hip and knee pathologies, full text could not be accessed for 3 articles, and 1 study was only a conference paper. Finally, 48 studies were eligible for review (Fig. 1). MCID results were detected in 16 (64%) of the 25 PROs. Tables 1–4 summarize the studies. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Injury and Osteoarthritis Outcome Score (KOOS), and the International Knee Documentation Committee Subjective Knee Form (IKDC) were the most frequently used PROs to assess MCID in patients with lower extremity pathologies.

4.1.1. MCID of patient-reported hip outcomes

MCID of the Hip Outcome Score (HOS), Harris Hip Score (HHS), and Oxford Hip Score (OHS) was reported in seven studies where a mixed group of hip pathologies including osteoarthritis (OA) and femoral acetabular impingement (FAI) was evaluated [16–22]. (Table 2). In these studies, patients were followed up for a period of 6 to 24 months. MCID of the HOS was reported between 5 and 14.5 points depending on pathology, intervention, and follow-up period [16–18,22]. MCID of the OHS was reported in three studies. MCID values were very similar to those at 6-month follow-up in patients with hip arthroplasty and FAI surgery [19,20,23] (Table 2). The HHS or modified HHS was reported in four studies. Hoeksama et al. followed up their patients in 5 weeks and MCID was found to be 4 points [21]. The follow-up period was longer in the remaining three studies. MCID was reported to be around eight points [17,18].

MCID of the WOMAC was reported mostly in hip surgeries, and patients were followed up for 4 weeks to 2 years. MCID values, estimated by the ROC analysis, were reported between 19 and 45.87 points [20,24-26,28]. Only the study by Tubach et al. used the mean change method for estimation of MCID and the authors reported lower MCID values (7.9 to 21.1) after conservative treatment of hip OA [27]. MCID of Hip Disability and Osteoarthritis Outcome Score was presented in two studies including total hip arthroplasty and arthroscopic surgery [18,29] (Table 2).

4.1.2. MCID of patient-reported knee outcomes

MCID of the Oxford Knee Score was reported in four studies with different methods [19,30–32]. Patients were treated with total knee arthroplasty or nonsurgical treatment and followed up for 3 and 12 months. MCID reported at 1 year (MCID = 9) was higher than that reported at 6-month follow-up (MCID = 6.5). Clement et al. used the linear regression method for estimation of MCID after total knee arthroplasty. The authors reported lower MCID values (4.3 to 5) at 1-year follow-up. The mean change method was used by Harris et al., and the MCID values were found to be higher than those of other methods; also, the patients were treated nonsurgically and followed up for 3 months (Table 3). MCID of the Knee Society clinical rating system (KS) was analyzed by Lee et al. using the linear regression method with two anchor questions. In patients who declared improvement, MCID of the KS function and KS knee scores was reported to be 6.4 and 5.9, respectively [33] (Table 3).

A wide range of MCID was reported for the WOMAC to evaluate the results of surgical or conservative treatment of patients diagnosed with OA or focal articular cartilage defects [9,27,28,34–42]. MCID of the WOMAC for total knee arthroplasty was presented in five studies, and the patients were followed up for 6 to 12 months [9,28,36,40,41]. MCID was estimated either with the ROC analysis or mean change method. Although Escobar et al. and Chestworth et al. used the ROC analysis and followed up their patients for 1 year, Chestworth et al. reported higher MCID values (Table 3). The mean change method was used in two studies, presented by Escobar et al. MCID values were higher when transition questions were used [40,41]. Nonsteroidal anti-inflammatory drugs were used in two studies as a conservative treatment for knee OA and patients were followed up at 4 weeks. In both studies, MCID

Table 1. The patient-reported outcomes included in this review and the number of studies in which their MCID was calculated

Outcome instrument	Abbreviation	Number of studies
Oxford Hip Score	OHS[a]	3
Hip Outcome Score	HOS[a]	4
Hip Disability and Osteoarthritis Outcome Score	HOOS[a]	2
Harris Hip Score/Modified Harris Hip Score	HHS, mHHS[a]	4
The International Knee Documentation Committee Subjective Knee Form	IKDC[a]	7
The Lower Extremity Functional Scale	LEFS[a]	4
The Western Ontario and McMaster Universities Index	WOMAC[a]	16
Knee Injury and Osteoarthritis Outcome Score	KOOS[a]	7
Oxford Knee Score	OKS[a]	4
The Victorian Institute Of Sports Assessment Patellar Tendinosis	VISA-P[a]	1
Kujala Anterior Knee Pain Scale	Kujala[a]	1
Foot and Ankle Outcome Score	FAOS[a]	1
Foot and Ankle Ability Measure	FAAM[a]	2
The Victorian Institute Of Sports Assessment Achilles Questionnaire	VISA-A[a]	1
American Orthopedic Foot Ankle Society	AOFAS[a]	2
Knee Society Clinical Rating System	KS[a]	1
The Western Ontario Meniscal Evaluation Tool	WOMET	
The Anterior Cruciate Ligament Quality Of Life Questionnaire	ACL-QOL	
Knee Outcome Survey	KOS	
The Foot Function Index	FFI	
The Foot And Ankle Disability Index Score	FADI	
The Lysholm Knee Scale		
Tegner Activity Scale		
Marx Activity Rating Scale		
Achille Tendon Total Rupture Score	ATRS	

[a] The minimal clinically important difference of the outcomes reported in this study.

was estimated by either logistic regression or ROC analysis [27,39] (Table 3). There were three studies that estimated MCID in conservative treatment of OA, and patients were followed up from 4 to 12 weeks [34,37,42]. MCID was analyzed by two different ROC analysis methods by Williams et al. MCID was lower in Youden's index method than the maximized specificity method (Table 3). Although MCID accepted 16% increase of total WOMAC scores estimated by the ROC analysis in the study by Hmamouchi et al., the mean change method used by Angst et al. MCID values were reported between 7.09 and 20.24 points for WOMAC subscales at 3-month follow-up [37,42]. MCID was calculated in only 1 study for the surgery of focal articular cartilage defects, and higher MCID values were found in longer follow-up [35] (Table 3). A 12-item reduced version of the WOMAC (ShortMAC) reported by Abbot et al showed 12.1-point MCID with larger change in patients receiving nonsurgical intervention for osteoarthritis [38].

Seven studies reported MCID of the IKDC [35,43–48]. The IKDC was used to evaluate anterior ligament injury, meniscus injury, focal articular defects, and variety of other knee pathologies in these studies. The patients were followed up from 12 weeks to 28 months. The ROC analysis was used in all studies and the lowest MCID was found to be 6.3 for surgery for focal cartilage defects at 6-month follow-up. The highest MCID (17) was reported in patients with a articular cartilage defect treated surgically and followed up for 2 years (Table 3).

Three studies reported MCID of the Lower Extremity Functional Scale for knee pathologies. The patients were treated conservatively and followed up between 4 weeks and 12 months [34,49,50]. Wang et al. reported very detailed analysis of MCID, which was derived from sex, symptoms' acuity, age, and the functional score of the patients. Negahban et al. found an MCID of 4.5 in patellofemoral pain syndrome (Table 3). In the study by Williams et al., MCID was analyzed by two different ROC analysis methods. MCID was higher when the maximized specificity method was used (Table 3). MCID for patellar tendinopathy was calculated in two outcomes [51]. In both studies, patients were treated conservatively and MCID was estimated by ROC analysis. Sanchez et al. reported that if patient satisfaction was more than 5, MCID of the Victorian Institute of Sports Assessment Patellar Tendinosis was found to be 15, and if more than three, it was

Table 2. Minimal clinically important difference of patient-reported hip outcomes

Authors	PROs	MCID		Anchor/methods	Pathology	Intervention (*n*)	Follow-up
Martin 2008	HOS-ADL	9		[e]GROC (7-point)	Hip pathologies	Hip arthroscopy (*n* = 126)	7 mo
	HOS-Sport	6					
Nwachukwu 2017	HOS-ADL	8.3		[e]GROC (7-point)	FAI syndrome	Surgery (*n* = 364)	1 y
	HOS-Sport	14.5					
Nwachukwu 2018	HOS-ADL	7.9		[e]GROC (7-point)	Residual FAI syndrome	Revision hip arthroscopy (*n* = 49)	1 y
	HOS-Sport	13.1					
Kemp 2013	HOS-ADL	5		[e]GROC (5-point)	Intra-articular hip lesions	Hip arthroscopic surgery (*n* = 50)	12 to 24 mo
	HOS-Sport	6					
Beard 2015	OHS	7.5		[e]GROC (5-point)	Hip pathologies	Hip arthroplasty (*n* = 82.415)	6 mo
Impelizzari 2012	OHS	6		[e]GROC (5-point)	FAI syndrome	FAI surgery (*n* = 102)	6 mo
Fernández 2017	OHS	7		[f]Anchor (5 point)	Hip OA	Hip arthroplasty (*n* = 361)	6 mo
Impelizzari 2012	WOMAC			[e]GROC (5-point)	FAI syndrome	FAI surgery (*n* = 102)	6 mo
	Pain	28					
	Stiffness	25					
	Function	21					
	Total	22					
Monticone 2017	WOMAC			[e]Global perceived Effect (7-point)	Hip fractures	Surgery and rehabilitation (*n* = 106 patients)	2 mo
	Pain	35					
	Stiffness	44					
	Function	24					
	Total below 88	21					
	Total above 88	29					
Chesworth 2008	WOMAC			[e]GROC (7-point)	Not defined	Total hip replacement (*n* = 1,131)	1 y
	Pain	41					
	Function	34					
Quintana 2012	WOMAC	1st, 2nd, and 3rd tertile		[e]Transition question (5-point)	Hip OA	Total hip arthroplasty ([a]*n* = 573) ([b]*n* = 333)	6 mo
	Pain	19-25-25					
	Function	26.4-39-40					
Quintana 2005	WOMAC	6 mo	2 y	[e]Anchor (4 point)	Hip OA	Total hip arthroplasty (*n* = 469)	6 mo-2 y
	Pain	41.99[c]-29.26[d]	44.78[c]-33.13[d]				
	Function	41.08[c]-26.54[d]	45.87[c]-25.93[d]				
	Stiffness	40.10[c]-25.91[d]	44.92[c]-33.20[d]				
Tubach 2005	WOMAC	Absolute	Relative	(GROC 5 point)	Hip OA	NSAIDs (*n* = 211)	4 wk
Ornetti 2011	WOMAC (0-100) Global state Functional state	 14.17 13.34		[e]Anchor (4-point)	Hip OA (n=305)	NSAIDs	1 month

(*Continued*)

Table 2. Continued

Authors	PROs	MCID		Anchor/methods	Pathology	Intervention (*n*)	Follow-up
	Function	7.9	21.1	Logistic regression			
Hoeksama 2003	HHS	4		[e]GROC (6-point)	Hip OA	Physical therapy (*n* = 75)	5 wk
Nwachukwu 2017	mHHS	8.2		[e]GROC (7-point)	FAI syndrome	FAI surgery (*n* = 364)	1 y
Nwachukwu 2018	mHHS	7.9		[e]GROC (7-point)	Residual FAI	Revision hip arthroscopy (*n* = 49)	1 y
Kemp 2013	mHHS	8		[e]GROC (5-point)	Intra-articular hip lesions	Hip arthroscopic surgery (*n* = 50)	12 to 24 mo
Kemp 2013	HOOS			[e]GROC (5-point)	Intra-articular hip lesions	Hip arthroscopic surgery (*n* = 50)	12 to 24 mo
	Pain	9					
	Symptoms	9					
	ADL	6					
	Sport, recreation	10					
	QOL	11					
Lyman 2018	HOOS			[e]GROC (6-point)	Not defined	Total hip arthroplasty (*n* = 2323)	2 y
	Pain	36					
	Symptoms	20					
	ADL	14					
	QOL	13					

Abbreviations: ADL, activities of daily life; FAI, femoral acetabular impingement; OA, osteoarthritis; HHS, Harris Hip Score; HOS, Hip Outcome Score; HOOS, Hip Disability and Osteoarthritis Outcome Score; mHHS, Modified Harris Hip Score; OHS, Oxford Hip Score; QOL, quality of life; WOMAC, The Western Ontario and McMaster Universities Osteoarthritis Index; MCID, minimal clinically important difference; GROC, Global Rating of Change Scale; PROs, patient-reported outcomes; mo, month; y, year; w, week.

Score ranges: WOMAC (0-100), OHS (0-48), HHS (0-100), mHHS (0-100), KOOS (0-100), HOOS (0-100), 0 = Worst, 100 or 48 = Best.

[a] Cohort 1.
[b] Cohort 2.
[c] A great deal of better.
[d] Somewhat better.
[e] ROC analysis.
[f] Mean change.

found to be 12.6. The Kujala Patellofemoral Scale showed 9.5-point MCID at 4-week follow-up [49] (Table 3).

Seven studies investigated MCID of KOOS with many pathologies such as anterior cruciate ligament (ACL) surgery, osteochondral lesions, and osteoarthritis [10,32,45,48,52–54]. In these studies, patients were followed up for a period of 20 days to 52 weeks. In these studies, MCID was estimated by ROC analysis, mean change method, or both. The lowest MCID was reported for the KOOS symptoms subscale (MCID = 0.5) after 10 weeks of postoperative ACL rehabilitation [54]. The highest MCID was found for the KOOS quality of life subscale (MCID = 27.3) after ACL reconstruction [52] (Table 3).

4.1.3. MCID of patient-reported ankle and foot outcomes

There are 5 foot and ankle PROs analyzed in this review. Chan et al. and Dawson et al. reported their results of hallux valgus surgery with the American Orthopedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score. Two years after surgery, a high MCID with a value of 29 was found [55]. Dawson et al. followed up their patients at 1 year after hallux valgus surgery. The AOFAS Ankle-Hindfoot Score showed the lowest MCID [56] (Table 4). Different foot and ankle pathologies were treated conservatively and assessed with Foot and Ankle Ability Measure (FAAM) [57,58]. After 4 weeks of follow-up, the authors reported that MCID was eight points for FAAM activity of daily living and nine points for FAAM sports subscales. Hung et al. reported the lowest MCID at above 6 months of follow-up (MCID = 17.2) [58]. In the study by McCormack et al., patients with insertional Achilles tendinopathy treated conservatively were assessed by LEFS and the Victorian Institute of Sports Assessment Achilles questionnaire (VISA-A) scores. Twelve-week follow-up showed that MCID values of the LEFS and VISA-A were 12 and

Table 3. Minimal clinically important difference of patient-reported knee outcomes

Authors	PROs	MCID	Anchor/methods	Pathology	Intervention (*n*)	Follow-up
Beard 2015	OKS	6.5	[c]GROC (5-point)	Knee pathologies	Knee arthroplasty (*n* = 94.015)	6 mo
Ingelsrud 2018	OKS	9	[c]GROC (7-point)	Not defined	Total knee replacement (*n* = 330)	1 y
Harris 2013	OKS OKS-PCS OKS-FCS	7.1[f] 17.3[f] 10.6[f]	[d]Transition rating (1-point)	Knee OA	Nonsurgical treatment (*n* = 134)	3 mo
Clement 2014	OKS Pain Function	 5 4.3	2 Anchor questions (5-point) Linear regression	Knee OA	Total knee arthroplasty (*n* = 505)	1 y
Lee 2016	KS-function score KS-knee score	Improvement / Satisfaction 6.1 / 6.4 5.3 / 5.9	2 Anchor questions (6-point) Linear regression	Knee OA	Total Knee Arthroplasty (*n* = 550)	2 y
Escobar 2013	WOMAC Pain Function	 20.5[a] 23.5[b] 24.2[a] 23.0[b]	[c]GROC (5-point)	Knee OA	Total knee arthroplasty ([a]*n* = 415) ([b]*n* = 497)	1 y
Escobar 2007	WOMAC Pain Stifness	6 mo / 12 mo 31[e] / 22.87[e] 27[e] / 14.52[e]	[d]Anchor (5-point)	Knee OA	Total knee arthroplasty *n* = 423 (6 mo), *n* = 364 (12 mo)	6-12 mo
Escobar 2014	WOMAC Pain Stiffness	Q1[e] Q2 Q3 Q4[e] Global 47.9 32.2 25.1 12.4 29.0 47.5 37.2 27.6 15.9 32.4	[d]Transition rating for pain and function (5-point)	Knee OA	Total knee arthroplasty (*n* = 923)	1 y
Ornetti 2011	WOMAC (0-100) Global state Functional state	 17.13 17.02	[c]Anchor (4-point)	Knee OA	NSAIDs (*n* = 881)	1 mo
Angst 2018	WOMAC Pain Function Standing/walking Stiffness	Regression model 8.74[d,f] 7.09 14.48[d,f] 11.25 10.20[d,f] 5.93 20.24[d,f] 16.24	Transition rating (5-point)	Knee OA	Rehabilitation (*n* = 190)	3 mo
Tubach 2005	WOMAC Function	Absolute / Relative 9.1 / 26.0	(GROC 5-point) Logistic regression	Knee OA	NSAIDs (*n* = 603)	4 wk
Williams 2012	WOMAC	2 mo / 6 mo / 12 mo 4.0[g] / 6.8[g] / 1.6[g] 8.8[h] / 6.8[h] / 12.0[h]	[c]GROC (15-point)	Knee OA	Conservative treatment (*n* = 168)	2, 6, and 12 mo
Hmamouchi 2012	WOMAC	%16	[c]Transition rating (5 point)	Knee OA	NSAIDs (*n* = 173)	6 wk
Greco 2010	WOMAC Pain Stiffness Function Total	6 mo / 12 mo 17.5 / 7.5 6.3 / 18.8 8.1 / 5.9 11.5 / 11.5	[c]GROC (7-point)	Focal articular cartilage defect	Surgery (*n* = 51)	6-12 mo
Maratt 2015	WOMAC Pain Stiffness Function	 31.25 25.00 26.93	[c]GROC (6-point)	Knee OA	Total knee arthroplasty (*n* = 2350)	2 y
Chesworth 2008	WOMAC Pain Function	 36 33	[c]GROC (7-point)	Not defined	Total knee replacement (*n* = 1578)	1 y

(*Continued*)

Table 3. Continued

Authors	PROs	MCID	Anchor/methods	Pathology	Intervention (*n*)	Follow-up
Abbot 2017	ShortMAC Pain/Function	Small change 7.9/9.3 Medium change 8.4/7.9 Large change 12.1/12.1	[c]GROC (15-point)	Knee OA	Nonsurgical interventions (*n* = 206)	9 wk
Greco 2010	IKDC	6 mo 12 mo 6.3 16.7	[c]GROC (7-point)	Focal articular cartilage defect	Surgery (*n* = 51)	6-12 mo
Wang 2018	IKDC	17	[c]Transition rating for physical function	Knee joint articular cartilage defect	Mosaicplasty or osteochondral allograft transplantation (*n* = 173)	2 y
Irrgang 2006	IKDC	11.5	[c]GROC (7-point)	Mixed knee pathologies	Surgery (*n* = 207)	19 mo
Grevnets 2107	IKDC	13.9	[c]GROC (6-point)	ACL injury	Surgery (*n* = 55)	4 mo
Ogura 2018	IKDC	9.8	[c]GROC (5-point)	Full-thickness osteochondral lesions	Osteochondral allograft transplantation (*n* = 86)	1 y
Huang 2017	IKDC	9.8	[c]GROC (15- point)	Knee injuries	Physical therapy (*n* = 173)	12 wk
Kummel 2018	IKDC	6.7	[c]Global treatment outcome (5-point)	ACL, meniscus, and/or cartilage injury	Surgery (*n* = 312)	6 mo
Negahban 2018	LEFS	4.5	[c]GROC (7-point)	Patellofemoral pain syndrome	Physical therapy (*n* = 233)	4 wk
Wang 2011	LEFS Total Sex Symptom acuity Age LEFS (0-33 points) LEFS (>33-42 point) LEFS (>42-51 point) LEFS (>51 point)	 12 6 to 14 6 to 17 5 to 12 14 12 5 5	[c]GROC (15-point)	Orthopedic knee pathologies	Rehabilitation (*n* = 6651)	—
Williams 2012	LEFS	2 mo 6 mo 12 mo 0.6[g] 7.5[g] 1.3[g] 6.3[h] 7.5[h] 12.5[h]	[c]GROC (15-point)	Knee OA	Conservative treatment (*n* = 168)	2, 6, and 12 mo
Negahban 2015	Kujala patellofemoral scale	9.5	[c]GROC (7-point)	Patellofemoral pain syndrome	Physical therapy (*n* = 233)	4 wk
Hernandez-Sanchez 2014	VISA-P	13 GROC>3 15 GROC>5	[c]GROC (15-point)	Chronic patellar tendinopathy	Conservative treatment (*n* = 98)	25-120 d
Mills 2015	KOOS Walking pain	26 wk 52 wk 11.5[g] 4[g] 18[h] 13[h] 20.06[e] 8.15[e] 14.95[f] 9.25[f]	Two anchors for walking and knee health (7-point)	Knee OA	Conservative treatment (*n* = 272)	26 wk 52 wk
	General knee pain	11.5[g] 4[g] 17[h] 12[h] 16.56[e] 4.3[e] 5.56[f] 4.03[f]				

(*Continued*)

Table 3. Continued

Authors	PROs	MCID		Anchor/methods	Pathology	Intervention (*n*)	Follow-up
Mostafaee 2018	KOOS			[c]GROC (7- point)	ACL reconstruction	Post-op rehabilitation (*n* = 54)	10 wk
	Pain	11.5					
	Symptoms	1.5					
	ADL	0.5					
	Sport/recreation	17.5					
	QOL	22					
Huang 2017	KOOS			[c]GROC (15- point)	Knee injuries	Physical therapy (*n* = 173)	12 wk
	Symptoms	10.9					
	Pain	16.1					
	ADL	8.1					
	Sport/recreation	12.5					
	QOL	9.4					
Ingelsrud 2018	KOOS			GROC (7-point)	ACL injury	ACL reconstruction (*n* = 461-485)	Pooled data of 6, 12, and 24 mo
	Pain	13.9[c]	7.9[d,e]				
	Symptoms	5.4[c]	1.2[d,e]				
	ADL	5.1[c]	8.1[d,e]				
	Sport/recreation	2.5[c]	21.7[d,e]				
	QOL	21.9[c]	27.3[d,e]				
Monticone 2013	KOOS			[c]GROC (5-point)	Knee OA	Total knee arthroplasty rehabilitation (*n* = 148)	20 d
	Pain	16.7					
	Symptoms	10.7					
	ADL	18.4					
	Sport/recreation	12.5					
	QOL	15.6					
Ogura 2018	KOOS			[c]GROC (5-point)	Full-thickness osteochondral lesions	Osteochondral allograft transplantation (*n* = 86)	1 y
	Pain	16.7					
	Sport/recreation	25					
Harris 2013	KOOS			[d]Transition rating (1-point)	Knee OA	Nonsurgical treatment (*n* = 134)	3 mo
	Pain	12[f]					

Abbreviations: ACL, anterior cruciate ligament; ADL, activities of daily life; GROC, Global Rating of Change Scale; IKDC, The International Knee Documentation Committee Subjective Knee Form; KOOS, Knee Injury and Osteoarthritis Outcome Score; LEFS, The Lower Extremity Functional Scale; MCID, minimal clinically important difference; mo, months; OA, osteoarthritis; OKS, Oxford Knee Score; FCS, Functional Component Score; PCS, Pain Component Score; WOMAC, The Western Ontario and McMaster Universities Osteoarthritis Index; ShortMAC, Shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; VISA-P, The Victorian Institute of Sports Assessment Patellar Tendinosis; QOL, quality of life; KS, Knee Society Clinical Rating System; mo, month; d, day; y, year; Q, Quartile.

Score ranges: IKDC (0-100), OKS (0-48), WOMAC (0-100), LEFS (0-80), KOOS (0-100), VISA-P (0-100), shortMAC (0-100), Kujala Patellofemoral Scale (0-100), 0 = Worst; 100, 48, or 80 = Best.

[a] Cohort 1.
[b] Cohort 2.
[c] ROC analysis.
[d] Mean change.
[e] Mean change method by Jaeschke.
[f] Mean change method by Redelmeier.
[g] Youden's index.
[h] Maximized specificity method.

6.5, respectively [59]. Sierevelt et al. used both ROC analysis and mean change method for estimation of MCID. The patients with ankle and foot complaints treated surgically showed higher MCID score when the mean change method was used [60] (Table 4).

5. Discussion

The assessment of the improvement of the patient is a crucial part of clinical practice, and meaningful threshold change values of PROs are essential for decision-making regarding a patient's status. In this review, we identified 48 studies reporting MCID of the PROs used in lower extremity injuries in orthopedics. MCID values were calculated for a limited number of PROs and for a wider variety of patient population in hip, knee, foot, and ankle injuries.

MCID may vary based on the analytic methods, study population, disease severity/type, the observed baseline status, change in values and treatments, patient demographics, and generic or specific outcome instrument. Therefore, it is important to use caution while interpreting MCID and

Table 4. Minimal clinically important difference of patient-reported foot and ankle outcomes

Authors	PROs	MCID	Anchor/methods	Pathology	Intervention (n)	Follow-up
McCormack 2015	LEFS	12	[a]GROC (15-point)	Insertional Achilles tendinopathy	Conservative treatment (n = 15)	12 wk
McCormack 2015	VISA-A	6.5	[a]GROC (15-point)	Insertional Achilles tendinopathy	Conservative treatment (n = 15)	12 wk
Chan 2017	AOFAS	29[a] 31[b]	Transition item 6-point	Hallux valgus	Surgery (n = 446)	2 y
Dawson 2007	AOFAS		[a]Anchor (5-point)	Hallux valgus	Surgery (n = 91)	1 y
	Halluks MTP-IP	17				
	Ankle hindfoot	2				
	Midfoot	5				
	Lesser toe MTP-IP	7				
Martin 2005	FAAM-ADL/Sport	8/9	[a]Anchor (7-point)	Foot and ankle pathologies	Physical therapy (n = 164)	4 wk
Hung 2018	FAAM-sport		[a]GROC (4-point)	Foot and ankle pathologies	Foot and ankle treatment (n = 3069)	3 to 6 mo
	3 mo	35.9				
	>3-mo	25.5				
	6 mo	33.9				
	>6-mo	17.2				
Sierevelt 2016	FAOS		Patients' global assessments (7-point)	Ankle and hindfoot complaints	Surgery (n = 145)	1 y
	Pain	15.3[a] 25.3[b]				
	Symptoms	7.1[a] 11.2[b]				
	ADL	17.6[a] 20.0[b]				
	Sport/rec	22.5[a] 36.8[b]				
	QOL	21.9[a] 32.7[b]				

Abbreviations: ADL, activities of daily life; GROC, Global Rating of Change Scale; AOFAS, American Orthopedic Foot and Ankle Society; FAAM, Foot and Ankle Ability Measure; FAOS, Foot and Ankle Outcome Score; MTP, metatarsophalangeal; IP, interphalangeal; LEFS, The Lower Extremity Functional Scale; VISA-A, The Victorian Institute of Sports Assessment Achilles Questionnaire; QOL, quality of life; y, year; wk, week.

Score ranges: FAAM-ADL (0-84); FAAM-sport (0-32); AOFAS (0-100); VISA-A (0-100); LEFS (0-80); FAOS (0-100); 0 = Worst; 100, 84, or 32 = Best.

[a] ROC analysis.

[b] Mean change method.

consider the available forecast for certain PROs. [61] We included only anchor-based approaches to define clinically meaningful MCID values for the 16 PROs. However, this review demonstrates that estimation of MCID with anchor-based approaches has some differences because the external anchors used in the included studies varied. Although it is accepted that anchors must be easily interpretable [62,63], there is no agreement with respect to appropriate anchors. In some studies, the minimum difference is the difference between patients who were "somewhat better" and "about the same." However, in some other studies, the minimum difference was defined as the difference between patients who reported their condition status as small improvement, medium improvement, large improvement, no change, or being worse. Consequently, maybe the actual minimum difference is unsatisfactory to reach. The other problem is patients' incapability to understand the state of improvement. For instance, in spite of patients being asked to report on changes from their previous status, they often report the current state of health as a comparison against expectations [64]. Moreover, these retrospective opinions are affected by recall bias as the patients fail to exactly remember the intrinsic nature of their previous condition [62].

More importantly, different MCID analysis methods resulted in quite different MCID values. The same PRO measures and different calculation methods yield variable MCID values that may have marked difference. Although some studies [3,4,13,42] recommend that mean change is the most widespread, accepted, valid concept, 85% of the authors used ROC analysis with two different methods in this systematic review. For instance, Williams et al. and Mills et al. estimated MCID for the LEFS and KOOS, respectively, and the maximized specificity method yielded higher scores than the Youden's index [10,34]. The mean change method was analyzed by either Jaeschke or Redelmeier. The MCID of the KOOS scale was analyzed by these two methods in the study by Mills et al., and MCID values were very distinct [10]. As we can see, the heterogeneity of published MCID values and inconsistency in the calculation of MCID have made interpretation and effective utilization of this potentially powerful metric increasingly difficult.

One of the most important methodological problems in most of the MCID studies is that the calculated values do not correspond to the concept of "minimal." Many studies also add the score differences of "much better" or "moderately better" to "somewhat better." Therefore, we reviewed the articles that we have included to determine if the values really reflect the "minimal." However, in most studies, the authors either included all positive responses as "minimal" or they gave insufficient information of what was accepted as "minimal." Therefore, it should be considered that the calculated values may not be "minimal."

We included disease or joint-specific PROs that are expected to be more responsive in defining change that is directly related to the condition. However, most of the studies have calculated MCID threshold for mixed pathologies rather than specific conditions such as hip pathologies and knee pathologies [9,16,43,50,59,65,66]. Nevertheless, we should consider that the established MCID specific to these mixed pathologies cannot be interpreted for specific pathologies. In addition, not only the MCID should be considered specific to pathologies but also determination of MCID must also consider different thresholds for different subsets of population. [67] For instance, compared with patients with a slight pain at pretreatment, those with prominent pain may need higher decrease in pain to perceive the treatment as rewarding.

5.1. Study limitations

We acknowledge some limitations. First, the search was restricted to studies in English and Turkish languages. Therefore, relevant studies in other languages could have been missed. There is large variation in terminology of MCID. We think that we have included the most commonly used terms, but we might have missed some terms.

In conclusion, we present existing data on MCID for commonly used PROs for lower extremity pathologies in orthopedics and discuss some of the methods used in the studies. A wide range of MCID values was reported for these instruments for each patient with hip, knee, foot, and ankle pathologies.

5.2. Future directions and conclusions

There is a need for studies of establishing MCIDs across several diseases on different patient populations to determine patient response to treatment. Lack of a universally accepted method makes it difficult to interpret results and apply it to help clinical decision-making process. In future studies, more work is needed to understand better method of calculation.

CRediT authorship contribution statement

Derya Çelik: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing - original draft, Writing - review & editing. **Özge Çoban:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology. **Önder Kılıçoğlu:** Conceptualization, Project administration, Writing - review & editing.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2019.04.017.

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