Responsiveness of the VISA-P scale for patellar tendinopathy in athletes

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ABSTRACT

Background Patient-reported outcome measures are increasingly used in sports medicine to assess results after treatment, but interpretability of change for many instruments remains unclear.

Objective To define the minimum clinically important difference (MCID) for the Victorian Institute of Sport Assessment scale (VISA-P) in athletes with patellar tendinopathy (PT) who underwent conservative treatment.

Methods Ninety-eight athletes with PT were enrolled in the study. Each participant completed the VISA-P at admission, after 1 week, and at the final visit. Athletes also assessed their clinical change at discharge on a 15-point Likert scale. We equated important change with a score of ≥3 (somewhat better). Receiver-operating characteristic (ROC) curve analysis and mean change score were used to determine MCID. Minimal detectable change was calculated. The effect of baseline scores on MCID and different criteria used to define important change were investigated. A Bayesian analysis was used to establish the posterior probability of reporting clinical changes related to MCID value.

Results Athletes with PT who showed an absolute change greater than 13 points in the VISA-P score or 15.4–27% of relative change achieved a minimal important change in their clinical status. This value depended on baseline scores. The probability of a clinical change in a patient was 98% when this threshold was achieved and 45% when MCID was not achieved.

Conclusions Definition of the MCID will enhance the interpretability of changes in the VISA-P score in the athletes with PT, but caution is required when these values are used.

INTRODUCTION

Patellar tendinopathy (PT) is a common overuse injury in sports, especially among basketball and volleyball players.[1] PT pathology can be studied using ultrasound, although the correlation between imaging results and clinical symptoms is rather poor.[2] Therefore, the patient's perception of change is essential when assessing the clinical course in daily practice, and the use of patient-reported outcomes (PROs) is justified.[3–5]

To assess the severity of symptoms in athletes with PT, the Victorian Institute of Sports (Australia) developed the VISA-P scale,[6] which consists of eight items and is a self-administered outcome measure. Six items rate pain level during daily activities and functional tests on a numeric pain-rating scale (0–10) and two items provide information on sporting participation. The maximum possible score is 100 points, which corresponds to an asymptomatic active athlete. The theoretical minimum score is 0 points. The VISA-P score, which has become the most widely used PRO to measure changes in athletes with PT,[7] has been established as a valid and reliable instrument with adaptations to several languages available.[8–12]

PROs used to detect clinical changes in health status must be interpretable.[13] If the score of an athlete with PT has increased by 11 VISA-P points since the first visit, then what does that mean to the therapist? Clinical studies with large numbers of patients allow reporting small differences in outcome that reach statistical significance without evidence that these are clinically relevant for patients.[14]

An important characteristic of PRO validity is responsiveness that accurately and specifically indicates how well an instrument measures clinically significant changes.[3 4 15] The study of responsiveness can help determine the minimum clinically important difference (MCID), which is the smallest change, that is, meaningful to the patient for an outcome measure.[15] MCID estimation uses an anchor-based method that reflects the patient's perception, and is expressed in the same units as the studied scale, which facilitates the interpretation of the clinical relevance of score changes after an intervention.[16]

To date, a few isolated data of responsiveness have been reported for the VISA-P scale by using distribution-based approaches.[11 12] Only the German adaptation study provide information in the same units of the scale by standard error (SE) of measurement (SEM) and minimal detectable change (MDC).[11] We found no reports in the literature describing the MCID from anchor-based approaches for the VISA-P scale. Because of the widespread use of the VISA-P scale in sports medicine, responsiveness must be explored and reported in a clinically applicable manner. We aimed to calculate the MCID values for the VISA-P scale in the case of athletes with PT and test if these values depend on the baseline scores and the selected cut-off points on external anchor, to define minimal clinical significance.

METHODS

Participants

A sample of convenience was used. Data were collected from September 2008 to November 2011 at 10 sports physiotherapy clinics across Spain. Forty subjects within the sample were participants of a previous validation study of the VISA-P scale (VISA-P-Sp).[11] Athletes with PT who underwent physiotherapy treatment were eligible if they were over 18 years old, physically active at least three times a week, and were able to read and give

written informed consent. We only included patients who were clinically diagnosed with PT by ultrasound or those in whom tendinosis was verified using MRI and had a history of pain at the inferior pole of the patella (either continuous for at least 3 months or recurrent for at least 6 months).[17] In cases of bilateral symptoms only the most painful side was included. Patients with additional knee injuries, inflammatory conditions or a history of knee joint surgery, as reported by patients or detected by clinicians at baseline, were excluded. The minimum sample size for the ROC analysis was calculated for an area under the curve (AUC) of ≥0.9, (null hypothesis AUC=0.5), a type II error of 0.10, and a p value of <0.05. Power calculations indicated the need for a minimum of 19 subjects in each group (no change and improved).

Procedures

All athletes were clinically examined by a physiotherapist at their clinic. Participants completed the VISA-P-Sp scale three times: at the initial physical therapy visit (baseline), at 1 week (range 4–7 days) and at the final physiotherapy visit (range 25–120 days). Subjects were not assisted in completing the scales to avoid interviewer bias. The physical therapy treatments were not controlled, because the aim was to check responsiveness of the scale only. At discharge, the participants were asked to complete a global rating of change scale (GROC) and to respond to a question on the degree of perceived change on a 15-point-type Likert scale.[18] This scale is defined as the magnitude of an athlete's perceived change, ranking from −7 (very much worse) to +7 (very much better), with 0 indicating no change (appendix 1). The GROC asked a basic question: 'How are you today, in comparison with your first visit' We chose a global change score of ≥3 to represent a minimal important change, based on similar studies.[19–22]

The study protocol was approved by the Ethics and Experimental Research Committee of Miguel Hernandez University (DPC-SHS-001-08). All participants were informed about the study objectives and their informed consent was obtained before their participation in the study.

We studied responsiveness by assessing the following parameters:[23] the MCID, which is the minimum change in the score required to be considered clinically important by the patient,[19] and the $MDC_{95\%}$, which provides the lowest change, outside of error, that reflects actual change in a patients' condition.[3]

From previous studies,[22 24] we hypothesised that MCID depended on the baseline scores and the definition of 'important change' on GROC. Baseline scores were accounted during the MCID study through additional analyses using relative change scores, which were expressed as a percentage of change from baseline by dividing the change score by the baseline score.[25] To perform this analysis, it was necessary to recode the baseline score, so that higher scores indicated a higher level of pain and a lower level of sporting participation (ie, a VISA-P baseline score of 30 points would correspond to 70 for this calculation).

Likelihood ratios (LR) and postmeasurement probability of change were calculated.[21]

Additional analyses were conducted, equating important changes in the GROC scale with a score of ≥5, to assess the potential influence of different criteria when interpreting important changes in GROC.

Statistical analysis

Descriptive statistics were used to determine patient characteristics. Absolute and relative changes in VISA-P scores were calculated between the baseline and final assessments.

The MDC value was calculated as follows: $MDC_{95\%}=1.96\times\sqrt{2}\times SEM$, where 1.96 is the value associated with the 95% CI, and $\sqrt{2}$ accounts the error associated with taking two measurements.[25 26] SEM is an estimate of the expected variation in a set of stable scores, where one can assume that no real change has occurred.[13] It was calculated using the following formula: $SEM=SD\times\sqrt{(1-R)}$, where SD is the SD of the first assessment and R is the reliability coefficient for the questionnaire. The intraclass correlation coefficient (ICC) is a more appropriate reliability index than Cronbach's α.[27] Therefore the type 2,1 ICC was calculated, because in the Spanish cross-cultural adaptation study, only general ICC for overall sample was available.[12]

The use of multiple methods has been recommended for the study of MCID, followed by triangulation to report a small range of values.[23] We studied MCID by calculating the mean change score (MCS) and performing the ROC curve analysis.[15 28] The MCS was defined as the mean change in athletes who reported themselves as 'somewhat better' on the anchor (GROC=3).[19 23] ROC curves were created by considering the VISA-P change as a diagnostic test for discriminating between improved and not-improved patients, and the external criterion (GROC) as a gold standard. Athletes were dichotomised in those who did and did not have minimal important change, based on external criterion. AUC represents responsiveness and can be interpreted as the probability of correctly distinguishing improved patients from those without any change on GROC. AUC ranges from 0.5 (no accuracy in distinguishing improved from unchanged patients) to 1.0 (perfect accuracy). The optimal cut-off point was estimated by choosing the point that maximises the sum of specificity (ability to detect the absence of a clinical change when the change does not exist) and sensitivity (ability to detect a clinical change when it exists) and minimises the total error misclassification.[29] This point was considered as an expression of MCID at individual level. AUCs between 0.7 and 0.8 were considered to have acceptable discrimination, whereas values higher than 0.8 have excellent discrimination. Values of sensitivity and specificity ≥0.80 were considered acceptable.[30] The SE and 95% CI were also used to describe ROC results.

The positive LR (LR+) was calculated as SN/1-SP, and the negative LR (LR−) as 1-SN/SP. An LR+ >10 and LR− <0.20 were considered strong.[31]

Using LRs, we employed Bayesian analysis to determine the probability that an individual similar to the study cohort would experience an improvement in the symptoms. This was based on whether the individuals did or did not achieve the associated MCID for the VISA-P scale. This probability was calculated by multiplying the prior probability odds by correspondent LR.[21]

A Spearman rank correlation coefficient was calculated to determine whether the changes in the VISA-P and the GROC score were related.[32]

SPSS V.17.0 and MedCalc V.12.1.4 software were used.

RESULTS

Of the 98 subjects enrolled in the study, there were eight patients who dropped out of the follow-up. Three participants showed injuries on the lower limb during the course of the treatment (ankle sprain, plantar fasciitis and knee contusion), two moved away, and three did not complete the questionnaires. Characteristics of the remaining 90 participants are presented in table 1. Of these participants, 4 (4.4%) reported no change in GROC (levels 0 and 1), 28 (31.1%) reported mild improvement (GROC >1 to 3) and 58 (64.4%) reported a moderate-to-large

improvement (GROC >3–7). Specifically, 13 subjects rated 3 on GROC (14.4%). There were no cases of worsening. Table 2 shows the mean VISA-P scores from the three assessments, ICC, SEM and $MDC_{95\%}$. Tables 3 and 4 present the values for the MCID as estimated by the ROC and MCS methods, respectively. The sensitivity and specificity of the best cut-off point in the ROC curves, the LRs and postmeasurement probabilities of change related to the MCID, are all summarised in table 5.

Figure 1 shows ROC curves with the best cut-off point for defining the MCID (white dot) by using absolute and relative change scores at 2 selected levels of the 'minimal important change' definition (GROC, ≥3 and ≥5).

A high correlation was observed between the changes in the VISA-P and GROC score (Spearman r′=0.852; p<0.001).

DISCUSSION

To our knowledge, this is the first study that investigated the external responsiveness of the VISA-P scale. We combined anchor-based (MCS and ROC curve) and distribution-based approaches (SEM and MDC) to study responsiveness.[13]

In the German VISA-P adaptation study, $MDC_{95\%}$ was 12.6 and SEM was 4.54.[11] We obtained similar values. The estimated MCID exceeds $MDC_{95\%}$. Therefore we are confident that the differences in the VISA-P score represent a real change in the condition of the patient and not a measurement error.[3]

An anchor-based approach, which includes the global impression of change question as an external criterion, was used to establish the MCID score.[13] This external criterion was determined by asking the patient to rate the change that has occurred after treatment, for which a GROC scale is often used.[18] The participant's viewpoint is essential for this process. They decide if the amount of change is meaningful, providing more relevant information than group-level statistics, such as effect size or standardised response mean.[13]

Revicki *et al*[32] recommended a correlation threshold of ≥0.30–0.35 between self-rated studied outcome and the anchor used for estimating MCID, a condition that was met in this study.

The results for the MCID definition were uniform when absolute changes were used with ROC and MCS methods. However, we found greater variability when relative change scores were considered.[25]

In the musculoskeletal field some studies have shown that MCID can depend on patient's initial scores.[15 22 24 33] The analysis using relative change scores showed that athletes with lower baseline VISA-P scores required more change units to report an important change.

Typically, a score of 3–5 on a 15-point GROC scale is used to indicate minimally important change.[21 22 33] We selected a cut-off score of ≥3 to define MCID level, based on previous studies.[21 34] Owing to the variability of cut-off points, we performed a secondary analysis, considering minimal important change at level 5 on the GROC scale. As expected, different levels yielded different MCID values. In future studies, the levels of GROC selected for minimal important change must be reported to facilitate data comparison.[22]

Sensitivity and specificity associated with the MCID are valuable when examining misclassifications. If sensitivity and specificity values are high, one can be more confident when determining clinically important change from the MCID change score.[34] In this study, all values of sensitivity and specificity were close to or more than 80% when absolute change scores were used, and these percentages have been reported as acceptable.[30] This was not observed when the relative scores were used, given that the variability involves consideration of the baseline scores in the sample (range 20–82).

The MCID value can be considered a context-specific value, because it can vary depending on intervention type.[22] We have only defined the MCID values for conservative treatment; thus, further studies are necessary to assess whether these values differ after surgical treatment.

In this study, we could not determine the method of interpreting patient clinical worsening on the VISA-P scale, and whether MCID for improvement was the same for deterioration.[35]

The difficulty to interpret scores from PROs is considered an important barrier when using these tools in routine practice.[20] A good way to circumvent this limitation is to use LRs and posterior probability of change derived from ROC analysis. LRs

Table 1 Baseline characteristics of the study population (n=90)

Variables	Mean (SD) or frequency (%)
Age (years)	25.9±5.4
Height (m)	1.8±0.9
Weight (kg)	79.4±12.6
Body mass index	23.5±2.1
Gender, n (%)	
Males	70 (77.8)
Females	20 (22.2)
Chronicity of tendon pain (months)	14.1±13.9
3–6	46 (51.1)
7–12	16 (17.8)
13–24	10 (11.1)
>24	18 (20.0)
Follow-up period (months)	1.8±0.8
Side of injury, n (%)	
Right	45 (50)
Left	33 (36.7)
Bilateral	12 (13.3)
First episode of injury, n (%)	
Yes	31 (34.4)
No	59 (65.6)
Training days/week	5.0±1.1
Hours training/day	2.7±1.0
Sport disciplines, n (%)	
Volleyball	34.4
Basketball	22.2
Handball	13.3
Athletics	10.0
Soccer	8.9
Others (tennis, cycling)	11.2

Data are presented as mean±SD or frequency.

Table 2 Mean VISA-P scores at three moments of assessment and distribution-based statistics for all sample (n=90)

Baseline	50.1±18.4
Retest	54.8±18.7
$ICC_{2,1}$	0.95 (0.93–0.97)
Discharge	70.4±15.2
SEM	4.0
$MDC_{95\%}$	11.1

$ICC_{2,1}$, a type 2,1 intraclass correlation coefficient; SEM, SE of measurement; $MDC_{95\%}$, minimal detectable change using a 95% CI.

Table 3 Results from the ROC curve analysis with clinical relevance set at two different levels on the external anchor (GROC scale)

	Improved n	No change n	ROC cut-off point (MCID)	AUC	SE	AUC 95% CI Lower bound	AUC 95% CI Upper bound	Sensitivity (95% CI)	Specificity (95% CI)
Equating important change with a GROC ≥3									
Absolute change score	71	19	>13	0.921*	0.03	0.845	0.968	78.7 (67.6 to 87.7)	94.7 (74.0 to 99.9)
Relative change score			>15.4	0.745*	0.06	0.643	0.831	94.4 (86.2 to 98.4)	47.4 (24.4 to 71.1)
Equating important change with a GROC ≥5									
Absolute change score	51	39	>15	0.924*	0.02	0.848	0.969	82.3 (69.1 to 91.6)	92.3 (79.1 to 98.4)
Relative change score			>50	0.763*	0.04	0.662	0.846	51.1 (36.6 to 65.2)	92.3 (79.1 to 98.4)

AUC, area under the curve; GROC, global rating of change; MCID, minimum clinically important difference; ROC, receiver-operating characteristic curve.
*p<0.001.

Table 4 MCID values with 95% CI for the VISA-P-Sp scale estimated by MCS method

	MCID set at GROC ≥3		MCID set at GROC ≥5	
	MCS (SD)	95% CI	MCS (SD)	95% CI
Absolute change score	12.6 (2.2)	11.4 to 13.8	16.0 (4.7)	13.2 to 18.8
Relative change score	27.0 (12.0)	20.5 to 33.5	32.4 (19.1)	21.1 to 43.7

GROC, global rating of change; MCID, minimum clinically important difference; MCS, mean change score; VISA-P, Victorian Institute of Sport Assessment.

associated with an MCID value can be a measure of accuracy of a self-reported scale change score when detecting the occurrence of a minimal clinically important change.[21] A larger LR+ and smaller LR− indicate the likelihood that an important change has been achieved when the outcome measure score is equal to or greater than the MCID value.[26] We used the LRs to estimate the posterior probability of change if MCID was or was not achieved. These results suggest that a patient with a baseline of 35 points would require a change corresponding to greater than 13 points (when taking absolute changes into account with the ROC methodology) to define MCID (GROC, ≥3), or a change greater than 15.4% of the baseline (in an inverted scale, ie, 65) if relative change scores are used. This percentage increases to 27% when MCS is considered. Furthermore, in a patient with a VISA-P baseline score of 55 points, we could interpret a change of 14 points in the VISA-P score as a 98% chance of experiencing a minimal clinically important change. If this patient had a change of 9 points after treatment, the probability of clinically important change would be 45%. Therefore, we can be more confident a minimal important change has been achieved if the VISA-P change associated with MCID is achieved.

These results could help clinicians on how to interpret the VISA-P changes after non-surgical therapeutic intervention. However, caution is needed when using these thresholds because they are not free of methodological limitations. First, the study was not blinded during data collection, and this may have influenced the GROC values. The participants could attempt to please their physiotherapist by indicating some improvement, which is a limitation of the self-reported rating of change.[36] In the future, a clinician's assessment or a prognosis scale of change could be included to add new perspectives.

The use of a single global rating as an external criterion presents additional problems because the psychometric properties of this 15-point Likert scale remain unclear and difficult to measure.[32] Despite being the most common method,[25] the use of this anchor is somewhat controversial when it is based only on an athlete's perception of change,[32] given that two patient-reported outcomes are compared, which introduces subjectivity and potential recall bias.[19 36] However, the GROC scale is commonly used in clinical research[18] and is used by patients to assess their own recovery in clinical practice.[33] In the absence of a 'gold standard', it is an accepted method for estimating MCID.[15 22 34] To interpret the VISA-P changes, alternative

Table 5 Likelihood ratios and posterior probabilities of change related to MCID considering important change at levels 3 and 5 on the GROC scale

	ROC cut-off point (MCID)	Prior probability meaningful change (%)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	Posterior probability of clinical change (%) if cut-off is achieved (95% CI)	Posterior probability of clinical change (%) if cut-off is not achieved (95% CI)
Equating minimal important change with a GROC ≥3						
Absolute change score	>13	78.9	15.0 (12.8 to 17.6)	0.22 (0.03 to 1.6)	98 (89 to 100)	45 (34 to 57)
Relative change score	>15.4	77.8	1.91 (1.2 to 3.0)	0.09 (0.03 to 0.3)	87 (81 to 91)	24 (10 to 50)
Equating minimal important change with a GROC ≥5						
Absolute change score	>15	56.7	10.7 (9.2 to 12.5)	0.2 (0.1 to 0.7)	94 (82 to 98)	20 (13 to 31)
Relative change score	>50	56.7	6.6 (5.0 to 8.8)	0.5 (0.2 to 1.6)	89 (73 to 96)	40 (33 to 47)

GROC, global rating of change; MCID, minimum clinically important difference; ROC, receiver-operating characteristic curve.

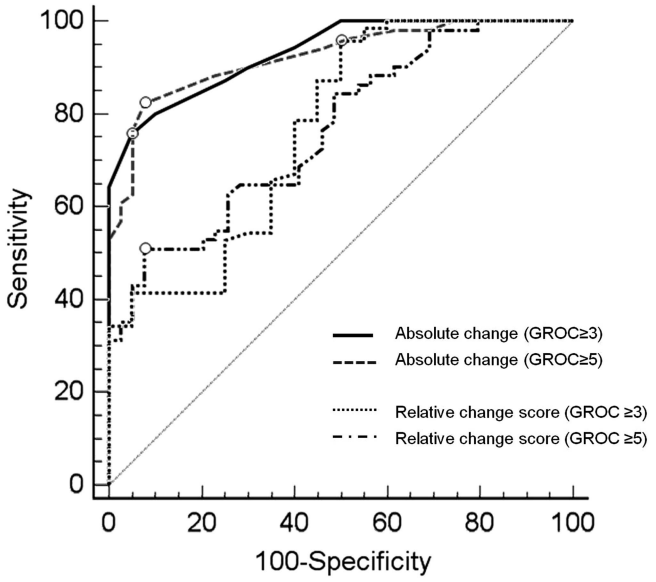

Figure 1 The receiver-operating characteristic curves resulting from the minimum clinically important difference (MCID) estimation using absolute and relative changes and for two levels of clinical significance on the global rating of change as external criterion. White dot represents the best cut-off point for each curve and it is considered an expression of the MCID at individual level.

methods of studying responsiveness are required alongside further studies.[25]

The ROC analysis seems to be more accurate than MCS, because it takes into account all data regarding changes observed in the entire group. However, due to the observed variability it could be problematic.[37]

There are no recommendations in the literature for the minimum sample size for studying MCID.[25] Larger samples are required to study the stability of reported MCID values and an additional study on female athletes is also necessary.

This analysis was performed using the Spanish version of the VISA-P scale, and the results could change if another population or alternative methodologies were used.

CONCLUSION

The estimated MCID for the VISA-P scale among athletes with chronic PT is a change greater than 13 points or an improvement of 15.4–27% of inverted baseline scores, although this retrospective estimation depends on baseline scores and the interpretation of a relevant change on GROC. These results could provide a reference to interpret clinical changes in the severity of symptoms for athletes with chronic PT who have undergone non-surgical treatment. Subjects with similar characteristics who have reported changes of at least MCID values in the VISA-P scale after therapy are more likely to experience a meaningful improvement in their symptoms than those who do not achieve these thresholds. The provision of MCID estimates will increase the applicability of the VISA-P scale but caution on their interpretation is needed due to the cited limitations.

What this study adds

- These results provide a reference for interpreting the clinical changes measured with the Victorian Institute of Sport Assessment scale (VISA-P) scale in terms of the severity of symptoms in a specific sample of athletes with chronic patellar tendinopathy. They would also help clinicians and researchers to determine the nature of the changes after therapeutic intervention. The minimum clinically important difference (MCID) values of the VISA-P could be used to estimate the sample size in future clinical trials.
- Caution is needed when interpreting the results of the responsiveness analysis because of the multiple factors that influence MCID values and for the methodological limitations that implies its study. Further research is necessary to obtain a stable range of MCID values for the VISA-P scale.

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