An assessment of the minimal clinically important difference for the pain disability quality-of-Life Questionnaire-Spine

Alycia Amatto [a,*], Ashley Smith [b,c], Bo Pan [d], Yazid Al Hamarneh [d], Taylor Burnham [e], Robert Burnham [a,b,f]

[a] *Division of Physical Medicine and Rehabilitation, Department of Medicine, University of Alberta, Edmonton, Alberta, Canada*
[b] *Vivo Cura Health, Calgary, Alberta, Canada*
[c] *Department of Clinical Neurosciences, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada*
[d] *Epicore Centre & Alberta SPOR Support Unit, Consultation & Research Services, University of Alberta, Edmonton, Alberta, Canada*
[e] *University of Utah, Department of Physical Medicine and Rehabilitation, Salt Lake City, UT, USA*
[f] *Central Alberta Pain and Rehabilitation Institute, Lacombe, Alberta, Canada*

ARTICLE INFO

ABSTRACT

Objective: The Pain Disability Quality-Of-Life Questionnaire-Spine (PDQQ-S) is a validated six question patient reported outcome measure designed for usage in minimally invasive spine intervention. The purpose of this study was to determine the Minimal Clinically Important Difference (MCID) for the PDQQ-S.
Design: Retrospective single arm cohort study involving 411 patients who had undergone lumbar facet and/or sacroiliac joint RFN and had completed pre-and 3-month post RFN PDQQ-S.
Methods: The MCID using both distribution and anchor-based ("Rebook RFN"; "Analgesic Requirements") methods were calculated.
Results: The distribution-based approach (using standard error of measurement) estimated the MCID to be −17.3 [PDQQ-S baseline mean (SD): 46.9 (7.9)]. This is supported by the anchor based approach, which calculated the MCID to be: −21.5 for rebook RFN; −11.3, -17.2 and −30.5 for mildly, moderately and dramatically decreased NSAID use respectively; and −11.7, -16.9 and −31.7 for mildly, moderately and dramatically decreased opioid use respectively. A moderate reduction in medication use was deemed to be clinically relevant.
Conclusion: The MCID value for the PDQQ-S is a score reduction of 17.

1. Introduction

Patient-reported outcome measures (PROMs) are helpful to interventional pain providers in determining patient care pathways, tracking progress and evaluating treatment effectiveness; however, PROMs are often underutilized because of time burden and difficulty in understanding clinically relevant results [1]. When discussing PROMs in the clinical setting, it is important to consider outcome measures in the context of statistical versus clinical significance. Classically, with statistical significance being classified as a p-value <0.05, there is a five percent probability that the observed pre-post treatment difference is due to chance alone [2]. In a clinical setting, the problem with utilization of statistical significance alone is that it does not necessarily predict whether there is a clinically relevant benefit for the patient or patient population. The importance of clinical relevance in the context of patient reported outcome measures is

well supported within the literature [3,4]. The Minimal Clinically Important Difference (MCID) was developed to detect the smallest change in an outcome measure between pre-and-post treatment that is perceived as beneficial by the patient [5]. There are multiple different strategies for calculation of an MCID value, as evidenced by Katz et al.'s assessment of the same in the context of various orthopedic conditions [2].

The Pain Disability Quality-Of-Life Questionnaire-Spine (PDQQ-S) is a short, six-question PROM exploring pain quality, disability, and quality of life (Fig. 1) designed as an efficient and easy-to-use PROM for minimally invasive spine interventions [6]. Previous psychometric evaluation of the Visual Analogue Scale version of the PDQQ-S confirmed favorable ease of use, reproducibility, validity, and responsiveness characteristics in spinal corticosteroid injections and radiofrequency neurotomy (RFN) [6]. The Numerical Rating Scale (NRS) version of the questionnaire used in this study is scored from 0 (meaning no pain, disability, and life

satisfaction/quality disruption) to 60 (maximal pain, disability, and life satisfaction/quality disruption). Although the validity and responsiveness of the NRS version of the PDQQ-S has recently been confirmed [7], the MCID remains to be defined. The objective of this paper is to determine the MCID of the NRS version of the PDQQ-S.

1.1. Materials and methods

Data were obtained from the electronic medical records of all patients treated with RFN for lumbosacral facet and/or sacroiliac joint pain (dual sensory block confirmed) at two interventional pain management clinics in Alberta, Canada (Central Alberta Pain and Rehabilitation Institute (CAPRI); Vivo Cura Health) by 3 physicians (2 physiatrists; one radiologist) between January 2019 -and July 2020. Both practices followed the same outcome data collection protocol. Specifically, on the day of the RFN, each patient completed the PDQQ-S based on their average pain experience over the prior week. At three months post RFN, each patient was emailed or snail mailed a follow-up PDQQ-S to be completed based on their average pain experience over the prior week. If the follow-up PDQQ-S was not received within one-two weeks, the patient was reminded electronically or by telephone call at one-week intervals for a maximum of 2 reminders. Additionally, at three months post-lumbosacral RFN, each patient indicated: a) if they wanted to rebook the RFN if/when their pain recurred (Yes/No) and b) the impact the RFN had on their analgesic requirement (non-narcotic [NSAID], narcotic) using a seven-item (dramatically, moderately, slightly increased or decreased, or no change) Likert scale questionnaire. Rebook response information was collected mainly to address a clinical need, that being to determine the need for a tentative future appointment for repeat RFN in the setting of long procedure waitlists. This information was chosen to be included in our study to provide further support for our MCID calculation. We defined an analgesic reduction of moderate or dramatic to be a clinically relevant change. These aforementioned measures were therefore operationally defined as anchors. Patients that did not complete all questionnaires (pre-and post RFN PDQQ-S, desire to rebook RFN, and change in analgesic requirements) were excluded from the study. The registry data protocol was approved by the Conjoint Health Research Ethics Board at the University of Calgary (Ethics ID#: REB20-0355).

2. Theory/calculation

Pain reduction scores were calculated as the difference between follow up and baseline score. Negative change represented improvement, and positive score represented deterioration. The statistical analysis method we employed was a combination of distribution-based (utilizing the standard error of measurement or SEm) and anchor-based methods. The anchor-based approach required patients to be categorized according to analgesic requirement and desire to rebook. MCID score was used as a cut-point for dichotomization in the receiver operating characteristics (ROC) curve analysis [8,9]. The distribution-based method uses a statistical approach to measure the variability within a sample and determine clinical importance. In this method, the MCID value was defined as the upper bound of the 95% confidence interval for the average change score [2]. Using the upper bound as MCID is based on the fact that MCIDs often turn out to be around 1 SEm or ½ Standard Deviation (SD) [2,3]. Effect size (difference in pre-post Rx means/SD of baseline score) cut-off point was selected. A linear mixed-effect model was used to estimate the average change of PDQQ-S score between pre- and three-month post-lumbosacral RFN with its 95% confidence interval adjusting patients' effort. Study methods were performed separately. The MCID estimates were calculated for each subgroup for the setting; "Analgesic Requirement" between mildly, moderately and dramatically decreased use as well as "Rebook RFN" response.

3. Results

Between January 2019 and July 2020, 601 patients underwent lumbar facet and/or SI joint RFN. Of these, 119 were excluded due to missing questionnaires, leaving 411 patients for analysis in the study. The mean(sd) age of the study cohort was 63.1 (11.9) years. Fifty-nine percent were female and 41% were male. Mean(95%CI) pre NRS score = 7.2(7.1–7.4) and post NRS score = 4.2(3.7–4.5). The calculated MCID varied depending on the calculation method and anchor employed. The distribution-based analysis (using SEm) of the entire cohort (n = 411) between baseline (Mean (SD): 46.86 (7.18)) and three months follow up estimated the MCID to be −17.3. Using the anchor-based method, the MCID values were as follows. A total of 324 patients responded affirmatively to the "rebook RFN question". Their Mean (95% CI) was −23.1 (−24.7 to −21.5). From the entire cohort, 153 and 121 patients reported using NSAIDS and opioids respectively. For "NSAID use", MCID values were −11.3, -17.2, and −30.5 for mildly, moderately and dramatically decreased use respectively (Moderate reduction: Mean (95% CI) −22 (−26.8, 17.2); Table 1). For "Opioid use", values were −11.7, -16.9, and −31.7 for mildly, moderately and dramatically decreased opioid use respectively (Moderate reduction: Mean (95% CI): −21.1 (−25.3- -16.9) (Table 1, Table 2). Taken together, PDQQ-S score reduction of 17 represented a consistent and clinically relevant MCID value for lumbosacral spine RFN. We identified that 49% of our data set reached MCID value of PDQQ-S change post RFN.

4. Discussion

The PDQQ-S is a validated, user friendly and efficient PROM that has utility in the domain of interventional pain medicine [4]. This paper aimed to determine the MCID value for this questionnaire. Based on our analysis, this was determined to be a PDQQ-S score reduction of 17. This MCID value provides a clinically relevant benchmark that helps put the calculation of statistical significance in a balanced context. Moving forward we can employ this MCID value clinically to inform patients of the probability of a clinically relevant improvement from a specific intervention and, in research, define the threshold of success for an experimental intervention.

As has been described, there are various methods that can be employed in order to calculate an MCID value, each with their own strengths and limitations [2]. Our chosen methodology utilized a combination of a distribution and anchor-based criteria. A distribution-based MCID calculation is defined mathematically and is not tied to patient-defined outcomes, which could limit the clinical relevance. Accordingly, we used a combination of distribution and anchor criteria (with a comparable outcome).

There are limitations to our study. We did not employ a traditional anchor like the Patient Global Impression of Change (PGIC) [10]. The PGIC subjectively quantifies a patient's impression of change post-treatment using a 7-point Likert scale ranging from "very much worse" to "very much improved". This type of anchor is sometimes termed a "subjective" anchor. Alternatively, we elected to use "Rebook RFN" and "Analgesic Requirements". These reflect changes in patient behavior presumably resulting from treatment effect and therefore have been described as "objective" anchors [3]. Because of the generous sample size (n = 411), the distribution based calculation used in our study provides the strongest level of evidence in support of our MCID value, and can stand alone as an estimate. Chung et al. performed a review of MCID related publications within the spine literature between 2011 and 2015. Of the 22 studies included describing independently calculated MCID values, six recommended distribution based methodology (either Standard Error of Measurement or Minimal Detectable Change). Among these six papers, five based their analysis on a sample size of between 45 and 61 patients, with the sixth study encompassing a larger sample size of 1055 [11]. In regards to articles more recently accepted for publication, Goudman et al. determined the MCID value (both distribution and anchor based calculations) for Medication Quantification Scale III and Morphine Milligram Equivalents in patients with Failed Back Surgery Syndrome who underwent spinal cord stimulation, and their sample size was 272 patients, with 12 month follow-up data available for 130 of the patients [12]. We acknowledge that the smaller sample sizes included in our Anchor based method is a limitation of our study. We chose to include this method as further support of

the findings of the distribution based calculation, given the remarkable similarity in resultant outcome value.

In our MCID calculation we have grouped together patients with both lumbosacral facet and SIJ procedures, with different procedural techniques. It is established within the literature that demonstration of MCID has less to do with selection criteria and procedural technique versus relevant clinical outcomes. Katz et al. [2] provide support to this, as they present multiple previous studies that combine population subtypes for the purposes of MCID calculation in various "painful orthopedic conditions". One such study by Farrar et al. [10] assesses the clinically important difference of the NRS through collection of "Data on 2724 subjects from 10 recently completed placebo-controlled clinical trials of pregabalin in diabetic neuropathy, postherpetic neuralgia, chronic low back pain, fibromyalgia, and osteoarthritis".

Nonetheless, questions remain, including whether reducing analgesic requirement and requesting to rebook truly reflect a clinically important improvement from the patient's perspective. Similarly, the threshold of a moderate reduction in analgesia was investigator determined. One could argue that any analgesic utilization reduction (i.e., even mild) would represent a clinically significant difference, and in that case, the PDQQ-S MCID would have been −11. However, we took a conservative approach and chose a moderate reduction of analgesic utilization as our MCID anchor criterion, as it aligned closely with the distribution method results. One disadvantage of using the "Analgesic Requirements" utilization anchor was that only 153 and 121 patients of the cohort of 411 reported using NSAIDs or opioids, respectively, which dramatically reduced the sample size for the MCID calculation.

In terms of future directions, we hope to further our analysis by calculating MCID using a traditional anchor-such as the Patient Global Impression of Change (PGIC). We have added Global Impression of Change to our routine outcome questionnaire in order to address this limitation of our study. Additionally, it is unclear if the MCID for lumbosacral RFN is similar for other spinal regions (i.e., cervical) or other interventional spine procedures (i.e., orthobiologic administration). Lastly, exploration of other psychometric properties of the NRS version of the PDQQ-S is warranted.

5. Conclusion

The PDQQ-S is a validated, short and easy to use outcome measure in interventional spine procedures. A PDQQ-S score reduction of 17 represents a consistent and clinically relevant MCID value in the context of lumbosacral radiofrequency neurotomy.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Appendices.

Interventional Procedure Follow-up Form

Name:_____ DOB:_____

Date of procedure:_____ Type of Procedure:_____

In order to help maximize the quality of your care, it is important that you fill out this form and return it to us.

Please fill out this form on or about the following date:_____, then deliver, mail or fax it back to our clinic.

Relating to your_____ pain, please record your scores in the 2nd column of this table, averaged for the past week:

	At the time of your procedure		3 months after your procedure	
Pain Intensity: how severe has your pain been? 0 = no pain; 10 = worst possible pain		/10		/10
Pain Frequency: how often has your pain been present? 0 = never present; 10 = always present		/10		/10
Disability: because of your pain, how difficult is it for you to do each of the following activities? 0 = no difficulty; 10 = completely unable to do it Difficulty for:		/10		/10
Difficulty for:		/10		/10
Satisfaction: if you had to live with the pain you have now for the rest of your life, how satisfied would you be? 0 = completely satisfied; 10 = completely unsatisfied		/10		/10
Quality of Life: how much has your pain disrupted the quality of your life? 0 = not at all; 10= completely ruined it		/10		/10
Totals:		/60		/60

Fig. 1. Pain Disability Quality-Of-Life-Questionnaire-Spine (PDQQ-S)

Table 1
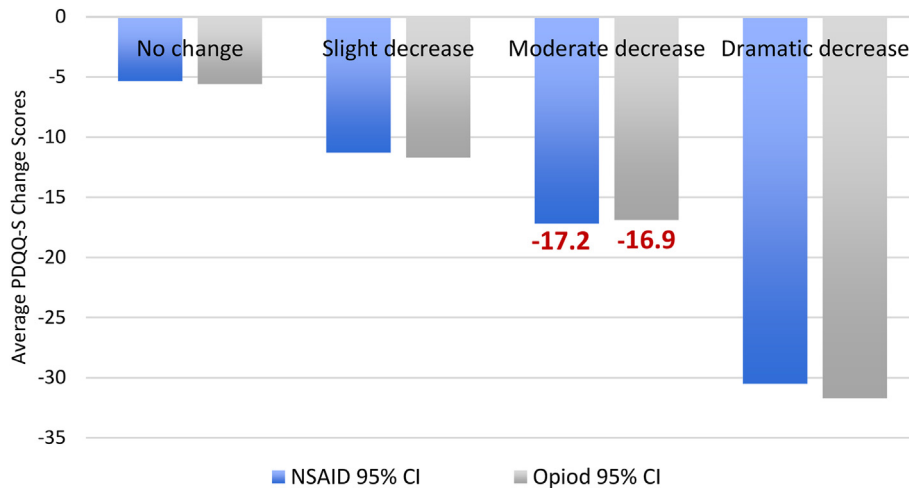Upper limit of 95% CI of average PDQQ-S change scores for levels of analgesic requirement change

Table 2
Results of MCID analysis including both distribution and Anchor-based approaches

Distribution-based method				
		Mean (95% Confidence Interval)	P-value	MCID
Difference of PDQQ		−18.85 (−20.39 to −17.31) (n = 411)	<0.001	−17.31
Anchor-based method				
NSAID	−3	−33.52 (−36.59 to −30.46) (n = 42)	<0.001	−30.46
	−2	−22 (−26.84 to −17.16) (n = 29)	<0.001	−17.16
	−1	−16.45 (−21.60 to −11.30) (n = 29)	<0.001	−11.30
	0	−9.24 (−13.13 to −5.34) (n = 38)	<0.001	−5.34
	1	−3.4 (−12.23–5.43) (n = 10)	0.407	
	2	−3.8 (−18.81–11.21) (n = 5)	0.521	
OPIOID	−3	−35.4 (−39.10 to −31.70) (n = 30)	<0.001	−31.70
	−2	−21.07 (−25.28 to −16.87) (n = 27)	<0.001	−16.87
	−1	−16.94 (−22.23 to −11.65) (n = 17)	<0.001	−11.65
	0	−11.13 (−16.68 to −5.60) (n = 36)	<0.001	−5.60
	1	−0.67 (−3.61 – 2.28) (n = 6)	0.586	
	2	−8 (−27.73–11.73) (n = 5)	0.323	
Rebook	Y	−23.10 (−24.71 to −21.49) (n = 324)	<0.001	−21.49
	N	−2.85 (−4.51 to −1.19) (n = 86)	<0.001	−1.19

References

[1] Holmes M, Lewith G, Newell D, Field J, Bishop F. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. Qual Life Res 2017;26(2):245–57.

[2] Katz N, Paillard F, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. J Orthop Surg Res 2015;10:24.

[3] Page P. Beyond statistical significance: clinical interpretation of rehabilitation research literature. Int. J. Sports Phys. Ther. 2014;9(5):726–36.

[4] Fleischmann M, Vaughan B. Commentary: statistical significance and clinical significance - a call to consider patient reported outcome measures, effect size, confidence interval and minimal clinically important difference (MCID). J Bodyw Mov Ther 2019;23(4):690–4.

[5] Rai S, Yazdany J, Fortin P, Aviña-Zubieta J. Approaches for estimating minimal clinically important differences in systemic lupus erythematosus. Arthritis Res Ther 2015;17(1):143.

[6] Burnham R, Stanford G, Gray L. An assessment of a short composite questionnaire designed for use in an interventional spine pain management setting. PMR 2012; 4(6):413–8.

[7] Burnham R, Amatto L, Smith A, Burnham T, Amatto A. An assessment of the validity and responsiveness of the numerical rating scale version of the pain disability quality-of-life questionnaire-spine. Inter. Pain Med. 2022;1(2). 2022.

[8] Maltenfort M, Diaz-Ledezma C. Statistics in brief: minimum clinically important difference—availability of reliable estimates. Clin Orthop Relat Res 2017;475(4): 933–46.

[9] De Vet H, Terwee C, Mokkink L, Knol D. Measurement in medicine: a practical guide. Cambridge University Press; 2011.

[10] Farrar J, Young Jr J, LaMoreaux L, Werth J, Poole M. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94(2):149–58.

[11] Chung A, Copay A, Olmscheid N, Campbell D, Walker B, Norman C. Minimum clinically important difference current trends in the spine literature. Spine 2017; 42(14):1096–105.

[12] Goudman L, Smedt A, Forget P, Moens M. Determining the minimal clinical important difference for medication quantification scale III and morphine Milligram Equivalents in patients with failed back Surgery Syndrome. J Clin Med 2020; 9(110):3747.