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PSYCHOMETRICS

Minimal Clinically Important Difference (MCID) for the Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire — IUGA Revised (PISQ-IR)

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ABSTRACT

Background: To put statistically significant changes in patient reported outcome measurement (PROM) questionnaires into a clinical perspective, the concept of the minimal clinically important difference (MCID) can be used.

Aim: To determine the MCID for the summary score for sexually active (SA) women of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR), a validated instrument which assesses sexual functioning (SF) for patients suffering from a symptomatic pelvic floor disorder.

Methods: Patients participating in a multicentre prospective cohort study comparing pessary therapy with surgery for a symptomatic pelvic organ prolapse (POP) filled in the PISQ-IR at baseline and 12 months' follow-up. We used both an anchor-based as well as a distribution-based method to calculate the MCID for both treatment groups. The Patient Global Impression of Improvement (PGI-I) questionnaire and PISQ-IR question 19a about satisfaction with sexual functioning were used as anchors. For the distribution-based approach we used the effect size (ES).

Outcomes: MCID for the SA summary score of the PISQ-IR.

Results: Data of 243 women were used to calculate the MCID. In the pessary group, Kendall's tau-b correlation coefficients between the PISQ-IR summary score and both anchors were below the cut-off of 0.21, which implies the anchors cannot be used to calculate an MCID. In our surgery group, the PISQ-IR question 19a met the anchor criteria and 0.31 points increase in the PISQ-IR summary score was equal to an improvement of 1 point on question 19a about satisfaction with sexual functioning.

Clinical implications: Future research on this subject should focus on clinical relevance of results rather than statistical significance only.

Strengths & Limitations: Our main strength is the fact that we used both anchor-based and distribution-based methods to determine our MCID. Secondly, we set out to determine an MCID for both treatment groups separately, which relatively enhances the generalisability of our results. A limitation is that we were not able to estimate an MCID for the pessary group. **Pruijssers B, van der Vaart L, Milani F, et al. Minimal Clinically Important Difference (MCID) for the Pelvic Organ Prolapse-Urinary Incontinence Sexual Function Questionnaire — IUGA Revised (PISQ-IR). J Sex Med 2021;18:1265–1270.**

Conclusion: We estimated the MCID for the PISQ-IR SA summary score to be 0.31 in our surgery group.

Key Words: Pelvic Organ Prolapse; Urinary Incontinence; Sexual Dysfunction; Minimal Clinically Important Difference; Surveys and questionnaires; Female

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INTRODUCTION

Pelvic organ prolapse (POP) is a common condition in women, which can cause bothersome symptoms like feeling or seeing a bulge in the vagina, urinary, and/or faecal incontinence and sexual dysfunction.[1,2] Treatment success is assessed using patient reported outcome measures (PROM). These PROM can be based on a single question reflecting reported improvement or on a validated disease specific quality of life questionnaire which covers a broader area of symptoms.

With respect to sexual functioning (SF), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR) is a reliable and validated instrument.[3] The PISQ-IR is currently the only questionnaire that addresses SF specifically for women with pelvic floor disorders, and is suitable for both sexually active (SA) as well as not sexually active (NSA) women.[4,5] The PISQ-IR consists of multiple domains that address different aspects of SF. The scores of the domains add up to a single over-all summary score for SA women only.[3,6] One of the most important aspects of PROMs is that the potential change they measure needs to be viewed in terms of clinical relevance, and not just statistical significance. For this purpose, the concept of the minimal clinically important difference (MCID) has been introduced.[7] The MCID is defined as the minimal change in PROMs scores that are actually meaningful and noticeable to patients in clinical practice.[7,8] Since an MCID for the PISQ-IR has not yet been established, the clinical implications of data using the PISQ-IR remain unclear. In many studies on urogynecological symptoms, SF is often underreported, in contrast to its importance. To be able to assess SF using a questionnaire with a clear cut-off for clinical relevance would therefore be most welcome. The aim of our study is to establish the MCID for the SA summary score of the PISQ-IR questionnaire, using a dataset from a large study on patients who are treated for a symptomatic POP.

METHODS

Study design

This is an ancillary analysis of a multicentre prospective cohort study comparing the effect of pessary therapy vs surgery in women suffering from a symptomatic pelvic organ prolapse (METC UMCU approval number 14/533). Patients were included in twenty-two different Dutch hospitals. Inclusion criteria were women with symptomatic POP-Q stage 2 or higher. Exclusion criteria were: Prior pessary therapy or POP surgery, considerable probability of future childbearing, insufficient knowledge of the Dutch language, co-morbidity causing increased surgical risks at the discretion of the surgeon or major psychiatric illness. Patients in our study made their own treatment choice and could choose either surgical intervention or pessary therapy. We used either a ring or occlusive pessary, since both have proven to be effective.[9] Decision on which surgery technique was performed was left to the discretion of the gynaecologist. No vaginal mesh surgery was allowed. All patients gave written informed consent and were followed-up at 6 weeks and 12 months.

Outcomes

Participants completed questionnaires concerning SF at baseline and after 12 months of treatment. SF was evaluated using the PISQ-IR. The PISQ-IR consists of 10 individual domains (6 for SA women, 4 for NSA women) and an overall summary score.[3,6] The overall summary score can only be calculated for SA women and therefore we decided to calculate the MCID for SA women only.[6] The 6 domains for SA women are: Arousal and orgasm, partner related, condition specific, global quality, condition impact and desire. The PISQ-IR SA summary score is calculated as followed: The sum of the response values is divided by the number of questions answered. This results in a summary score range from 1 − 4.6 when a sexual partner is present, and from 1− 4.71 without a sexual partner. Increase in score indicates improvement in SF.[6] For the purpose of our analyses the change in SF was assessed by calculating the difference in mean summary score between baseline and 12 months' follow-up. At 12 months, a questionnaire regarding the perceived improvement in symptoms, the Patient Global Impression of Improvement (PGI-I) scale was filled in. The PGI-I is a 7-point Likert scale single question, in which patient describes improvement in symptoms, with scores ranging from 1 (very much better) to 7 (very much worse), The PGI-I was validated for women with POP.[10]

MCID

With respect to the MCID there are 2 approaches to calculate its value. First, the anchor-based approach uses the correlation of the instrument of interest (in this case the PISQ-IR) with another patient-reported or clinical indicator of change (ie, anchor). In this approach the anchor is the Gold standard that is used to determine what is of minimal clinical relevance, and to assess the mean change on the questionnaire that is to be evaluated. Secondly, the distribution-based method assesses the MCID using statistical measures of magnitude of the effect and variability in these results. In practice, effect sizes (ES), standard deviations (SD) and/or standard error of the mean (SEM) are all used for this purpose.[11,12] The anchor-based approach is considered to be the most relevant method, because it reflects patient experience rather than statistical characteristics.[11] This means the distribution-based MCID is meant to support the anchor-based outcome, rather than to be used as primary method. However, distribution-based approaches could also be used to estimate an MCID if no anchor-based methods are available, or if the anchors proved to be unreliable.[11] In the ideal situation, an MCID is based on triangulation (converging multiple approaches into range of values or single value) of both methods, primarily based on the anchors with support of distribution-based estimates.[11,13] Based on literature, our anchor-based

estimate received a weight of two-thirds, our distribution-based estimate received a weight of one-third.[14] Because the MCID might vary across different treatment groups, we calculated an MCID for our pessary and surgery groups separately.[15]

Statistical analysis

Differences in baseline characteristics between treatment groups were calculated using Mann-Whitney tests or independent samples *t*-test when variables were continuous, categorical variables were compared using X^2 tests. IBM SPSS Statistics version 26 was used. A p-value of $P < .05$ was considered statistically significant.

Anchor-based method

The first step in the anchor-based method was to calculate the overall association between the anchors and the PISQ-IR summary score. In order for the anchor to be usable, a medium correlation of at least Kendall's Tau-b (τ_b) $\geq$ 0.21 needed to be confirmed.[16]

Once such correlation was present, we proceeded to calculate the MCID using the anchors. For our anchor-based approach we decided to use the Patient Global Impression of Improvement (PGI-I) questionnaire and PISQ-IR question 19a. We considered these questions to be the most eligible because of their generic natures, as elaborated below. Participants filled in the PGI-I at 12 months' follow-up. Since the PGI-I is a global assessment of improvement of treatment for POP, it will also be influenced by other changes in urogenital functioning after treatment. For the PGI-I, we calculated the mean change in PISQ-IR summary score between all 7 categories of the PGI-I. We defined our anchor as the mean score in those who responded their symptoms to be "a little better" on the PGI-I, as it reflects the minimal change in score for a participant to report improvement.[11]

PISQ-IR question 19a is a question in which patients are asked to rate their satisfaction with current sex life on a 5-point scale ranging from 1 (satisfied) to 5 (dissatisfied).[3] Participants answered this question at baseline and at 12 months. We chose this question since it is the only one that specifically rates difference in satisfaction with sexual functioning. For PISQ-IR question 19a, we categorized the change in scores into 3 groups: A group of patients that reported no change in score after 12 months, one that showed improvement of 1 point in satisfaction with sex life (ie decrease of one point) and a group that showed improvement of at least 2 points in satisfaction with sex life (decrease of at least 2 points). We defined our anchor as a 12 months' improvement of 1 point on this scale because we considered this to be the minimally clinical improvement.

Distribution-based method

The MCID was also estimated with a distribution-based method. Effect sizes are a measure for magnitude of the effect, and are calculated by dividing the difference between baseline and follow-up assessments by the standard deviation of the baseline.[17] We used an ES of 0.5 since this is considered to be a medium effect size, which indicates moderate or a conservative *minimal* clinical relevance.[17,18,19] The MCID can also be defined as $^1/_2$ of the SD and the SEM of baseline scores, which are widely used methods to estimate the MCID.[17, 20] The SEM has shown to correlate with anchor methods and can be interpreted as the minimal change that exceeds error of measurement.[21] Since both $^1/_2$ SD and SEM are derived from baseline scores only, while 0.5 ES is based on change in scores after intervention, we chose to use only effect sizes as our distribution-based method.

RESULTS

Study population

Patients were included between February 2016 and December 2017. In our cohort, 326 SA women were analysed for baseline characteristics. Out of these 326 SA participants, 243 remained SA over the year, and answered enough PISQ-IR questions to compare pre- and post-intervention summary scores. The loss of 83 participants was because of 2 reasons: 53 patients did not respond to the questionnaires at 12 months follow-up, and 30 women became NSA during the 12 months of follow-up. At 12 months, out of these 243 participants, 242 women responded to the PGI-I and 239 women responded to question 19a of the PISQ-IR. Demographic data are provided in Table 1. Participants in the surgery group were significantly younger, were more often pre-menopausal and had a lower PISQ-IR SA summary score as compared to the pessary group, indicating worse SF.

Anchor-based MCID

There was a statistically significant, but weak negative association between change in PISQ-IR SA summary score and PGI-I in the pessary group (τ_b = -0.13, P = .04) and a weak and non −significant negative association in surgery group (τ_b = -0.14, P = .07). The association between change in PISQ-IR summary score and change in question 19a of PISQ-IR was not statistically significant and weak in the pessary group (τ_b =-0.04, P = .58). In the surgery group, there was a significant medium negative association between change in summary score and PISQ-IR question 19a (τ_b = -0.21, P = .006).

Only question 19a of the PISQ-IR in the surgery group fulfilled the association criteria for the anchor-based method. Therefore, we only presented the PISQ-IR SA summary scores for the different levels of change in satisfaction with SF, as measured with question 19a of the PISQ-IR, for patients in the surgery group (Table 2). With respect to our predefined anchor, women in this group who reported an increase of 1 point in satisfaction with their sex life after treatment, had a mean improvement in PISQ-IR SA summary score of 0.32 (0.28) points.

Table 1. Baseline characteristics SA patients (N = 326)

	N (%) or median (IQR)		
	Pessary (N = 199)	Surgery (N = 127)	*P* value
Age (y)	60 (55 – 67)	57 (51 – 64)	.04
BMI	25 (23 – 26)	25 (23 – 29)	.05
History of gynecologic surgery	35 (17.7%)	20 (15.7%)	.65
Family history of prolapse	51 (25.9%)	41 (32.3%)	.26
3rd/4th degree perineal tear	16 (9.8%)	8 (7.7%)	.66
Parity	2 (2 – 3)	2 (2 – 3)	.92
Menopausal state			
- Pre	18 (9.4%)	21 (18.1%)	.03
- Peri	10 (5.2%)	10 (8.6%)	
- Post	163 (85.3%)	85 (73.3%)	
POP-Q stage			
- 2	83 (41.7%)	61 (48.0%)	.38
- 3	112 (56.3%)	62 (48.8%)	
- 4	4 (2.0%)	4 (3.1%)	
Duration of complaints (mo)	12 (4 – 36)	12 (4 – 36)	.91
SA summary score*	3.39 (0.29)	3.29 (0.30)	.006

*Range from 1 – 4.6 when a sexual partner is present, 1 – 4.71 without a sexual partner. Higher score indicates better SF

Table 2. Mean change in PISQ-IR SA summary score in surgery group for categories of satisfaction with sex life

Change in response to question 19a in surgery group (satisfaction with sex life)	Respondents, N	Mean change, PISQ-IRSA summary score (SD)
Improvement in satisfaction with ≥2 points	9	0.35 (0.34)
Improvement in satisfaction with 1 point	20	0.32 (0.28)
No change in satisfaction	47	0.12 (0.25)
Deterioration in satisfaction	25	0.08 (0.36)

Distribution-based estimates

The distribution-based approach to calculate the MCID is shown in Table 3. In the pessary group, there was no change in PISQ-IR SA summary score from baseline to 12 months' follow-up, which led to an effect size of zero. In the surgery group, the distribution-based estimate of the MCID is 0.30 based on 0.5 effect size.

DISCUSSION

Findings

We set out to establish the MCID for the summary score of the PISQ-IR for SA women who underwent pessary therapy or surgery for a symptomatic POP. Since the PGI-I we had chosen to be an anchor failed to reach the threshold of correlation with the PISQ-IR in our 2 treatment groups, both $\tau_b < 0.21$, it cannot be used for MCID calculation.[16] In the pessary group, question 19a of the PISQ-IR was not a suitable anchor either. However, we were able to use question 19a as an anchor in our surgery group and determined the MCID for this group to be 0.32, based on a reported 1-point improvement in satisfaction with sex life after 12 months' follow-up. This estimate is supported by our distribution-based estimate of 0.30. After weighing both approaches, our final estimate of the MCID is 0.31 points. We were not able to determine a distribution-based MCID for our pessary group because the difference of the PISQ-IR SA summary score between baseline scores and follow-up scores was zero.

The MCID is defined as the minimal change in PROM scores that are actually meaningful and noticeable to patients in clinical practice.[7,8] Establishing an MCID for the summary score of the

Table 3. Distribution-based MCID calculation across treatment groups

PISQ-IR SA summary score	Difference pessary group (95% CI)	Difference surgery group (95% CI)
Mean change between baseline and 12 mo	0.00 (-0.04 – 0.05)	0.18 (0.11 – 0.24)
0.5 of the effect sizes	0.00	0.30

PISQ-IR questionnaire for sexually active women who undergo surgery for a symptomatic POP allows us to judge an effect of treatment from a clinical instead of statistical point of view. Any statistically significant effect of surgical intervention below the MCID of 0.31 has to be viewed with caution, since it could overestimate the clinical relevance. In addition, the MCID will allow researchers to calculate accurate sample sizes for single arm or comparative studies on the treatment of women with sexual dysfunction associated with POP and/or urinary incontinence.

Our study has several strengths. First, we were able to use both an anchor-based and a distribution-based method to determine an MCID for our surgery cohort arm. This is particularly important since the anchor-based method represents a direct assessment of the change in condition by the patient herself, whereas the distribution-based method is purely a statistical one. Both methods resulted in an MCID in close proximity of each other, which adds great strength to our final estimate.

Another strength was the fact that we used data from a large multicentre cohort of women who had surgery or pessary treatment for a symptomatic POP. These women made their own decision on which treatment options they preferred, thereby representing daily practice. According to current literature, we determined an MCID for both treatment groups separately.[15] This enhances the generalisability of our findings in each group, although the applicability of the results could be limited by the fact that our population was Dutch only and sexual functioning might affect female quality of life in a more or less severe way in other parts of the world. A third strength is the fact that we used the condition-specific PISQ-IR to measure sexual functioning and calculated its MCID instead of a more generic questionnaire like the Female Sexual Functioning Index (FSFI).[22] Women with a POP and/or incontinence will encounter specific sexual problems related to their condition, which will be more accurately assessed with a condition-specific instrument like the PISQ-IR.

One of the most important drawbacks of our study is the fact that we could not determine an MCID for our pessary group, because the anchors we had chosen proved to have a poor correlation with the change in PISQ-IR summary score. Since there was no improvement in SA summary score in our pessary study arm, we could not estimate an MCID based on a distribution-based method either. The main outcome of our prospective cohort study on the treatment of POP with pessary therapy or surgery is the relief of POP symptoms, with SF being a secondary outcome. The primary outcome is assessed with the PGI-I at 12 months' follow-up and score changes will be heavily dependent on the perceived improvement of POP symptoms. Due to the generic nature of the PGI-I we hoped that it would also capture changes in SF to a level it could be used for calculating the MCID of the PISQ-IR summary score. Unfortunately, considering the low correlation coefficients, it did not. This means improvement in sexual functioning does not necessarily lead to improvement in general well-being. The second anchor we used is one particular question (19a) of the PISQ-IR that assesses general satisfaction with SF. Because of the nature of this question, as well as being one of the questions of the PISQ-IR itself, we expected it to correlate well with the PISQ-IR summary score and it did show a medium correlation in our surgery group. A plausible explanation for this correlation on a moderate level is the fact that SF is complex and dependent on many factors. Although the PISQ-IR intends to capture these different factors in its scales, it may not capture all elements that are associated with satisfaction about SF. Furthermore, missing data of about 25% of our initial participants at 12 months' follow-up might have led to over-/underestimation of our results. However, similar studies with a follow-up of 12 months had a lower response rate compared to our study.[23,24]

Although we have chosen to estimate an MCID only for the summary score of the PISQ-IR, we want to stress the importance of evaluating changes in the different domains of which this summary score consists, as the separation of sexuality in different aspects is a major strength of the PISQ-IR.

To the best of our knowledge there is only one study that estimates the MCID for the PISQ-IR. Mamik et al estimated the MCID of the original PISQ total score to be 6 points.[25] As this previous version of the PISQ-IR has a total scoring range from 0 − 125, this MCID equals a change in score of 4.8%. Our estimate of the MCID for the PISQ-IR SA summary score (ranging from 1 − 4.6 or 4.71) represents a change in score of 8.4 − 8.6%. This difference could be explained by the fact that we determined an MCID exclusively for assessing the effect of surgical treatment on SF, while the MCID of the PISQ-IR is meant for all different intervention types.

CONCLUSION

This is the first study to estimate an MCID for the PISQ-IR. Our study estimated the MCID for the PISQ-IR SA summary score to be 0.31 points 1 year after undergoing surgery for a symptomatic POP. Future research on effectiveness of interventions on SF in women with POP will have to relate to this MCID. Our results can be used to calculate sample sizes as well as evaluate the clinical value of results in future research on this subject.

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STATEMENT OF AUTHORSHIP

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