SESSION 19 - FEMALE STRESS URINARY INCONTINENCE

Abstracts 273-284
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Chair: Dr Rufus Cartwright (United Kingdom)

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MISCONCEPTIONS OF THE MINIMAL IMPORTANT DIFFERENCE ANALYSIS OF PATIENT-REPORTED OUTCOMES RELATED TO FEMALE URINARY INCONTINENCE: PRELIMINARY RESULTS OF A SYSTEMATIC REVIEW

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HYPOTHESIS / AIMS OF STUDY
Many results related to the effectiveness of surgical and non-surgical procedures for treating urinary incontinence (UI) are reported in the literature. Following the principles of evidence based-practice, besides the interpretation of study results based on statistical significance, authors should consider evaluating the clinical relevance of treatment effects in this field.

The minimal important difference (MID) of clinical outcomes could be used to assess the clinical relevance of interventions. MID is defined as “the smallest difference in score in the domain of interest that patients perceive as important, either beneficial or harmful, and which would lead the clinician to consider a change in the patient’s management”[1]. One common way to obtain MID for outcomes of interest is by using anchor-based methods. These methods apply one anchor that analyzes the change in the patient's health status according to the patient’s perception.

However, MIDs should be provided according to appropriate calculations and methods and based on the definition of a MID. However, there are a lot of misconceptions and misunderstandings related to the MID. These misunderstandings have led to incorrect reports of these values. Moreover, it is still not known which criteria the authors considered during the analysis of the MID in the Women’s Health area. Therefore, with this preliminary report, we aimed to identify and report all anchor-based methods to estimate MIDs for outcomes measures related to UI available in the literature; and analyze which concepts and levels of improvement in the health status of the patient have been considered by the authors to calculate the MID.

STUDY DESIGN, MATERIALS AND METHODS
This systematic review was conducted according to PRISMA guidelines. The study protocol was registered in the PROSPERO database (CRD42022299686). A systematic search was performed using Ovid Medline, Embase, Web of Science, and Scopus from May to June 2021. Any study generating MIDs for UI that included women with more than 18 years, stress urinary incontinence (SUI), urgency urinary incontinence (UUI) and/or mixed urinary incontinence (MUI) was included. The primary outcome was the MID for outcomes related to UI. No limits were applied on the databases for the date, language or publication range.

Studies were classified into three categories according to the level of improvement in health status assessed by the anchor and considered by the authors during the MID calculation: 1) slight improvement: if authors included participants that evaluated their health status as “a little better” in their analysis; 2) moderate improvement: if authors considered women that reported a “better” or a “much better” status of the condition; or 3) strong imporvement: if all patients that improved (“very much better” or if authors grouped all the patients that improved in one single category) were considered in one group against other group that did not report any improvement. After classifying the papers, we counted and reported how many studies were considering only the minimal level of improvement to reported the MID, according to previous definition and recommendation.

RESULTS
The initial electronic search resulted in a total of 1,662. After removing duplicates (n = 719), 943 were screened, and at the end of the selection stages, nine papers that reported anchor-analysis were included in this preliminary report. Seven studies included women with SUI (total sample size = 2,436), while one study included only women with UUI (n = 307), and the other one evaluated women with SUI and MUI (n = 288). Six studies analyzed data and provided the MID after a non-surgical treatment of UI, while three analyzed the results after surgery to correct UI. Eleven different questionnaires to measure the patient-related outcomes related to UI with their MIDs were identified. All the tools were related to measuring the impact, distress, or quality of life of women with UI.

Different anchors were used to analyze MID, including scales that evaluated the improvement and satisfaction of the patient, and the visual analogue scale, measures of urinary leakage and questionnaires that measure the severity and impact of UI. The MID of six tools was determined according to the smallest difference detected by the patients, using the Patient Global Impression of Improvement questionnaire and the self-reported satisfaction to assess the change of the condition. Most of the MIDs (n = 28, 80%) were miscalculated considering a moderate or a strong improvement of the patients, and not a minimal improvement as suggested by the literature (Table 1).

INTERPRETATION OF RESULTS
Although previous systematic reviews have reported the psychometric properties of different questionnaires to measure UI outcomes, this is the first study to analyze methods of obtaining MIDs for UI outcomes from the patients perspective (anchor based methods). All the tools with their respectives MIDs were related to the impact, distress, and/or quality of life of women with UI. The use of these outcomes measures is in line with the associated impairments of social, psychological, financial, and sexual aspects of a women’s life produced by UI.

Most of the authors in this field did not consider the smallest difference identified by the participants to calculate the MID, which does not follow the original definition of MID proposed by Jaeschke et al.,1 This could generate underestimation or over-estimation of MID, which may directly impact the interpretation of the findings from the clinical trials[2] and biased interpretation of the results of the clinical significance from the interventions used to manage female UI. Therefore, the interpretation of the clinical significance related to UI outcomes should be done with caution.

CONCLUDING MESSAGE
Few studies that aimed to calculate the MID using anchor-based methods for outcomes related to female UI were found in the literature. Eleven different questionnaires to measure the outcomes related to UI with their MIDs were identified. However, most studies had not considered the smallest change of improvement (as perceived by the patients) in their analysis, which does not follow the definition of the MID. This could impact decision making. Future research should provide clear guidelines on how to calculate, report, and interpret MIDs in this field.

FIGURE 1

Table 1. Level of improvement used by the authors to group participants and to calculate the minimal important difference.

Questionnaires	Anchors	Level of improvement in health status considered by the authors to calculate MID
Urogenital Distress Inventory (UDI)	Patient Global Impression of Improvement questionnaire	Moderate
	Incontinence Severity Index	**Slight***
	Voiding diary	Moderate/Strong
	Global Perception of Improvement	Moderate
	Patient Satisfaction Questionnaire	Moderate
Urogenital Distress Inventory - Irritative Subscale	Voiding diary	Moderate
	Global Perception of Improvement	Moderate
	Patient Satisfaction Questionnaire	Moderate
Urinary Distress Inventory – Stress Subscale	Patient Global Impression of Improvement questionnaire	**Slight**
	Incontinence Severity Index	Moderate
	Voiding diary	Moderate
Urinary Impact Questionnaire (UIQ)	Patient Global Impression of Improvement questionnaire	**Slight***
	Incontinence Severity Index	Moderate
	Voiding diary	Moderate
Overactive Bladder Questionnaire (OAB-q) - Symptom Severity (SS)	Voiding diary	Strong
	Global Perception of Improvement	Moderate
	Patient Satisfaction Questionnaire	Moderate
Incontinence Quality of Life (I-QOL)	Patient Global Impression of Improvement questionnaire	**Slight***
	Pad Test	Strong
	Voiding diary	Strong
Pelvic Floor Impact Questionnaire (PFIQ)	Self-reported satisfaction	**Slight***
	Visual analogue scale	Moderate
Pelvic Floor Distress Inventory (PFDI)	Self-reported satisfaction	**Slight***
	Visual analogue scale	Moderate
International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF)	Patient Global Impression of Improvement questionnaire	**Slight**/Strong
	Satisfaction	Strong
	Pad test	Strong
	Voiding diary	Moderate/Strong
	Urogenital Distress Inventory	Strong
	Incontinence Impact Questionnaire	Strong
ICIQ-Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)	Patient Global Impression of Improvement questionnaire	Strong
	Satisfaction with the treatment	Strong
	Pad test	Strong
	Voiding diary	Strong
Australian Pelvic Floor Questionnaire	Patient Global Impression of Improvement questionnaire	**Slight***

Table 1. Level of improvement used by the authors to group participants and to calculate the minimal important difference.

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1. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials. 1989;10(4):407-415.
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