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Position of the Ibero-American Society of Neurourology and Urogynecology (SINUG) on the urodynamics (UDS) in women undergoing surgical treatment for stress urinary incontinence (SUI)

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ABSTRACT

Introduction: Most clinical practice guidelines currently recommend not to necessary perform routine urodynamic studies (UDS) before surgery for female stress urinary incontinence (SUI). However, there is no consensus in the literature. Our objective was to evaluate the available evidence and to establish a position as a scientific society.

Methods: A search was conducted using PubMed, Web of Science and Scopus databases. Inclusion criteria were manuscripts in English with the terms "female urinary incontinence" and "urodynamics". The analysis included 25 studies.

Results: Regarding the usefulness of UDS in female undergoing SUI, two randomised, controlled trials have been published showing that preoperative UDS do not improve the results of SUI surgery. The review of data from different series on the surgical treatment of female SUI shows that up to 36% of patients undergoing surgery for SUI are complicated cases due to previous anti-incontinence surgery, pelvic prolapse that exceeds the hymen, radiotherapy or pelvic surgery. Moreover, the performance of UDS before treatment of SUI leads to a change in diagnostic orientation in 74% of patients with complicated SUI and 40% in the case of uncomplicated SUI. It should be noted that the UDS study modifies the proposed treatment in 23.8% and 11% of patients with complicated and uncomplicated SUI, respectively. A review by Serati et al. reported that the UDS results are congruent with the clinical diagnosis of SUI in 74.5% of cases. However, there is overactive detrusor in 10.6%, mixed urinary incontinence in 8% and the results of the UDS are inconclusive in 6.8% of cases. Therefore, it is estimated that UDS before surgery is more likely to change the management of SUI in 17% of patients.

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Conclusions: In women referring SUI, it is necessary to individualise the indication for UDS before surgical correction. UDS are complementary tests to be considered after non-invasive studies of the patient with a detailed clinical history, physical examination and other complementary tests such as a voiding diary, specific questionnaires and flowmetry with residual urine. We consider it necessary in cases of complicated or non-pure SUI.

1. Introduction

Urinary incontinence (UI) is defined by the International Continence Society (ICS) as any involuntary loss of urine [1,2]. UI is more common in women than in men, and its incidence increases with age [3]. Regarding prevalence, the EPINCONT epidemiological study conducted in a Norwegian county between 1995 and 1997 evaluated 27,936 women over 20 years, 25% of whom reported urine leakage [4]. Another study conducted in four European countries (France, Germany, UK and Spain) on 17,080 women over 18 years of age showed that 35% of them reported involuntary urine leakage in the previous 30 days [5]. UI in women is often classified as stress urinary incontinence, urge urinary incontinence and mixed incontinence [1,3]. According to the terminology recommended by the ICS, stress urinary incontinence (SUI) is defined as involuntary urine loss that occurs with physical exertion or exercise, including sporting activities, coughing or sneezing. Urgency urinary incontinence (UUI) is defined as involuntary urinary leakage associated with urgency. It is mixed urinary incontinence if there is both stress and urge urinary incontinence (involuntary urine leakage associated with urgency and also with physical exertion including sporting activities, coughing or sneezing) https://www.ics.org/glossary?q=INCONTINENCE [6].

After carrying out a clinical history and examination to determine the type of UI, treatment is considered depending on the type of incontinence, preferences, expectations and characteristics of the patient. Treatment alternatives range from conservative management to situations where surgery is required. Urodynamics (UDS) have been proposed as a complementary test that allows a functional assessment and can help predict the outcome of surgery in women undergoing surgical treatment for SUI [7]. However, there is no consensus in the literature about the timing and adequacy of performance of these studies in women undergoing surgery for the correction of SUI.

For the purpose of this review, it is useful to subclassify SUI in two group of patients: *uncomplicated SUI*, which are those patients with classic symptoms of leakage on effort or physical examination and negative responses to queries regarding symptoms of predominant urgency, incomplete emptying, overflow incontinence, functional impairment, and continuous leakage; and *complicated SUI*, when patients present with mixed UI, recurrent urinary tract infections, previous extensive or radical pelvic surgery, prior anti-incontinence surgery or complex urethral surgery, presence of voiding symptoms, presence of neurologic disease, symptoms of POP or genitourinary fistula, absence of urethral mobility and/or a post-void residual (PVR) urine volume greater than or equal to 150 ml [8]. Voiding dysfunction is defined by the presence of symptoms during the voiding phase, which may include a slow stream, intermittent flow, splitting or spraying, hesitancy, straining, or terminal dribbling. Uroflowmetry can confirm the diagnosis through findings of abnormally slow urine flow rates and/or elevated post-void residuals. In this situation, pressure-flow study can differentiate between detrusor underactivity and bladder outlet obstruction. Unfortunately, the definitions, cutpoints and nomograms established in males do not apply directly to women and further standardisation is still required to clearly establish those diagnoses in female patients. [6,9]. Therefore, the minimum evaluation in women with SUI includes history taking, urinalysis, physical examination, demonstration of SUI, assessment of urethral mobility, and measurement of PVR.

The European Association of Urology (EAU) Guidelines on Non-neurogenic Female Lower Urinary Tract Symptoms (LUTS) version 2024 stated that UDS may help select the optimum surgical procedure, but the evidence suggests that performing UDS in patients with uncomplicated SUI is not necessary. However, its role in complicated SUI is still under debate, and the EAU Guidelines recommend to carefully consider it in complicated cases (associated storage symptoms, when the type of UI is unclear, when voiding dysfunction is suspected, associated POP or prior surgery for SUI) [3,10].

The American Urological Association (AUA)/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Guidelines on the Surgical Treatment of Female SUI version 2023, indicate that UDS are not necessary in patients with SUI and otherwise healthy to determine outcomes after surgery. They based their recommendation on the results of Value of Urodynamic Evaluation (VALUE) trial [11–13], which will be discussed later. However, the suggest to consider UDS in those patients with history of prior anti-incontinence surgery, prior pelvic organ prolapse surgery, mismatch between subjective and objective measures, significant voiding dysfunction, significant urgency, UUI, overactive bladder (OAB), elevated post-void residual, unconfirmed SUI, or neurogenic lower urinary tract dysfunction [11,12].

Nonetheless, key opinion leaders in Functional Urology and Urogynaecology have raised their concerns about the unjustified and misguided decline in routine use of UDS in Europe driven by various factors [14,15]. The objective of this review is to establish a position as a scientific society on the usefulness and indications for performing UDS prior to surgery for SUI in women based on the available evidence.

2. Material and methods

A literature review has been carried out on the recommendations for performing UDS prior to surgery for SUI in women. A web search was conducted in December 2023, using PubMed, Cochrane Library, Web of Science and Scopus databases for articles published between January 1979 and December 2023. Inclusion criteria were manuscripts in English reviewing the usefulness and necessity of performing UDS prior to surgery for SUI in women. Randomised controlled trials (RCTs), prospective, retrospective and observational studies were included. Given the paucity of studies on this topic, a broad search using the terms “female urinary incontinence” and “urodynamics” was used. Exclusion criteria were case studies and studies that did not estimate the need for or utility of UDS in the evaluation of SUI in women prior to surgery. The PICO question was Patients (adult women undergoing surgery for stress urinary incontinence), Intervention (urodynamic study prior to surgery), Control (no urodynamic study prior to surgery) Outcome (functional outcomes after stress urinary incontinence surgery).

The literature search found 147 studies. After removing duplicates and those that did not address the objective of the review, 43 full text articles were assessed of which only 25 were included. The 18 studies were excluded because they did not assess the usefulness and effect of performing UDS prior to SUI surgery as a primary or secondary objective (Fig. 1).

Based on the available evidence, the board of the Ibero-American Society of Neurourology and Urogynaecology (SINUG) established a position on the recommendations (see Tables 1 and 2).

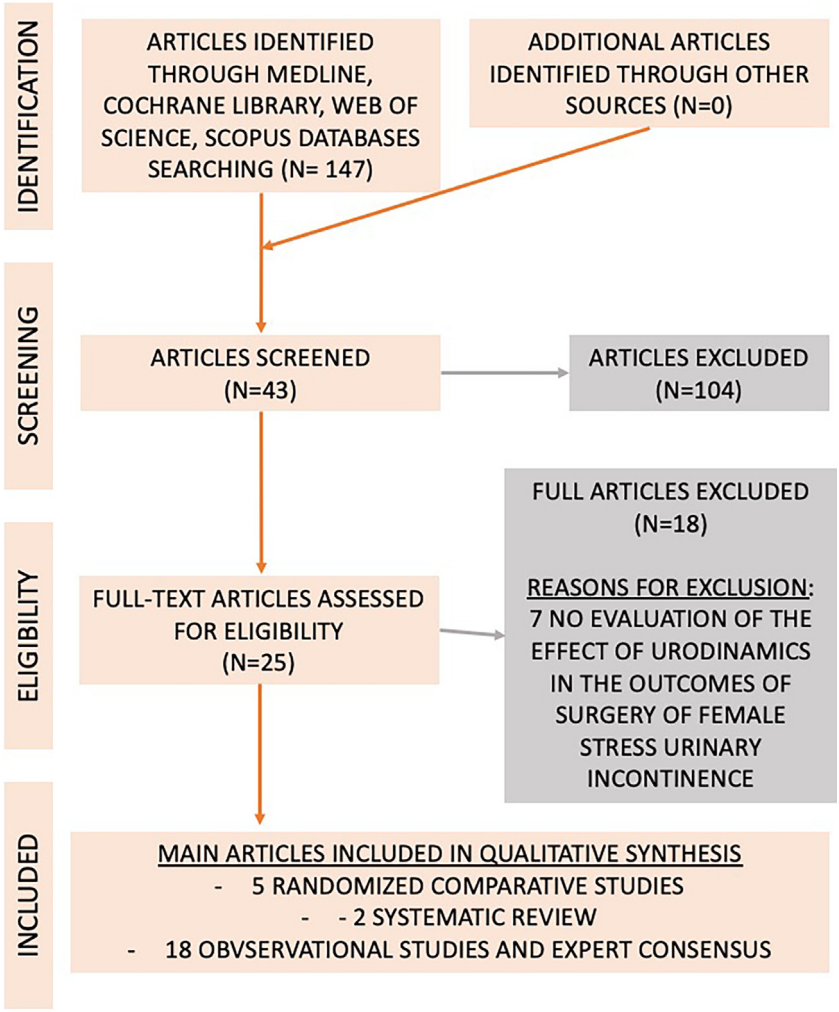

Fig. 1. Flowchart with the number of publications evaluated and included in the analysis, according to the PRISMA guidelines.

3. Results

3.1. Main studies evaluating the impact of UDS on outcome of SUI surgery

Regarding the usefulness of UDS in female patients undergoing surgery for SUI, 2 randomised, multicentre, non-inferiority, controlled trials (RCTs) have been published showing that preoperative UDS does not improve the results of stress incontinence surgery [13,18–20]. The VUSIS (Value of Urodynamics prior to Stress Incontinence Surgery) trial includes 59 women with SUI refractory to conservative treatment diagnosed with voiding diary, specific questionnaires and physical examination with UDS prior to surgery. Women were assessed with the UDI scale (urinary incontinence subscale of the Urogenital Distress Inventory) at 12 months after treatment. The mean difference in improvement was 14 in favour of the group without UDS confirming the predetermined non-inferior margin. However, this conclusion is limited by the low recruitment observed in the study [19]. The Value of Urodynamic Evaluation (ValUE) trial randomised 630 women with demonstrable uncomplicated SUI to undergo preoperative office-based evaluation with or without UDS. The primary outcome was treatment success at 12 months, defined as a ≥70% reduction in UDI score and a response of "very much better" or "much better" on the Patient Global Impression of Improvement scale (PGI-I). The results of the ValUE study showed that the omission of UDS in the pre-surgical assessment of women undergoing surgery for uncomplicated SUI did not cause inferior success in either per-protocol analysis (76.9% success if UDS vs 77.2% success if no UDS) or intention-to-treat analysis (76.5% success if UDS vs 77.4% success if no UDS) [13,20,21]. It is important to mention that exclusion criteria, defined as complicated SUI, included: previous surgery for incontinence, pelvic organ prolapse overpassing the hymen, or PVR greater than 150 ml. Nevertheless, review of the ValUE study data and reports from different series of surgical treatment of female SUI shows that up to 36% of patients undergoing surgery will have complicated SUI [14,22]. On the other hand, UDS prior to UI treatment leads to a change in diagnostic orientation in 74% of patients with complicated SUI and 40% in uncomplicated SUI [23].

In 2015, Rachaneni and Latthe conducted a systematic review and meta-analysis that asked the question: "Does preoperative UDS improve outcomes in women undergoing surgery for SUI?" After identifying 388 relevant articles, the authors included three RCTs in their analysis [16]: the VUSIS and ValUE trials and another small single-centre study. There were no statistical significant differences in the risk ratio for subjective cure, objective cure or complications, such as voiding dysfunction or urinary urgency, between women with and without UDS before surgery [13,17,19].

3.2. Impact of the ValUE and VUSIS-II studies in the UDS use before SUI surgery

The effect of the recommendation made by the ValUE and VUSIS-II studies was reviewed by Mengerink et al. showing that in 2010 in the Netherlands, UDS was routinely performed in women prior to surgery for SUI in 37% of the departments [17]. decreasing to a 7% in a survey carried out in 2015 over 308 urogynecologists treating female

Table 1
Characteristics of the main studies evaluating the usefulness of UDS before surgery for SUI.

	Nager CW, et al. 2012	van Leijsen SAL, et al. 2012 [10]	Agarwal A, et al. 2014 [16]	Leandro A, et al. 2021 [17]	Serati M, et al. 2016 [14]
Type of Study	Multicenter non-inferiority randomised controlled trial	Multicenter non-inferiority randomised controlled trial	Prospective & Randomised	Retrospective	Retrospective
Primary outcome	Reduction in the score on the UDI of 70%	Clinical reduction of complaints as measured with the Urogenital Distress Inventory urinary incontinence subscale (UDI-UI) at 12 months after treatment.	Reduction in the score on the UDI	Evaluation of type of SUI as uncomplicated or complicated	Evaluation of type of SUI as uncomplicated or complicated
Intervention strategy	UDS vs no UDS before SUI surgery	UDS vs no UDS before SUI surgery	UDS vs no UDS before SUI surgery		
Inclusion criteria	Women with uncomplicated SUI	Women with SUI or mixed urinary incontinence (MUI) with predominant symptoms of SUI	Women presenting with predominantly SUI	Women with SUI derived from UDS prior to the surgical treatment	Women with SUI derived from UDS prior to the surgical treatment
Number of patients	630 (315 UDS & 315 no UDS)	59 (31 UDS & 28 no UDS)	60 (31 UDS & 28 no UDS)	792 patients	2053 patients
Notes		The trial was stopped prematurely because of slow inclusion	Patients with complicated SUI were excluded	39,5% SUI were considered uncomplicated and 60,5% as complicated SUI	36% SUI were considered uncomplicated and 64% as complicated SUI

- MUI: Mixed urinary incontinence
- SUI: Stress Urinary Incontinence
- UDS: Urodynamics
- UDI-UI: Urogenital Distress Inventory – Urinary Incontinence.

Table 2
Findings in randomised studies evaluating the usefulness of UDS before surgery for SUI.

	Nager CW, et al. 2012		van Leijsen SAL, et al. 2012 [10]		Agarwal A, et al. 2014 [16]	
	Without UDS	UDS before SUI surgery	Without UDS	UDS before SUI surgery	Without UDS	UDS before SUI surgery
Improvement on the UDI-UI	77.2%	76.9%	48 +/−22 (Mean and SD)	34 +/−22 (Mean and SD)	60.0% (Mean change 40)	86.7% (Mean change 50.3)
Subjetive Global Improvement	82.2%	79.5%	96%	87%	ND	ND
Subjetive Global Cure	ND	ND	79%	65%	ND	ND
Subjetive Cure – Stress test negative	72.9%	69.4%	82%	81%	86.6%	96.7%
Subjetive Global Cure - 48-h Voiding diary	ND	ND	86%	81%	ND	ND

- MUI: Mixed urinary incontinence
- SUI: Stress Urinary Incontinence
- UDS: Urodynamics
- UDI-UI: Urogenital Distress Inventory – Urinary Incontinence
- ND: No described.

UI, with a response rate of 41% [24]. Similarly, a US study showed a reduction in pre-surgery UDS use of 70% in the years 2008–2009 and 41% in 2014-2016 [25]. The same trend was confirmed in a review conducted in Virginia between 2011 and 2016, showing a change in the percentage of pre-surgical UDS from 68% to 58% [24].

3.3. Predictive UDS finding that may affect the outcomes of SUI surgery

The predictive effect of UDS parameters on the outcome after SUI surgery was reviewed by Nager et al. as a secondary objective of the SISTEr study, which evaluated the finding of SUI on preoperative UDS, the presence of involuntary detrusor contractions and Valsalva Leak Point Pressure (VLPP) as outcome predictors. The results showed a not statistically significant trend towards a greater success if urodynamic SUI was present (odds ratio (OR) 2.26; 95% CI 0.99, 5.17). Detrusor overactivity did not show differences in success, nor did VLPP using 90 cm H_20 as the cut-off point (55% vs. 54%) [21].

In the TOMUS study, 597 women were randomised to tension-free transobturator (TOT) or transvaginal-retropubic (TVT) mesh, but no differences were shown in either objective or subjective outcomes of surgery for SUI when differentiated by VLPP or maximal urethral closure pressure (MUCP) [26].

3.4. UDS may help to re-classify uncomplicated into complicated SUI

Agarwal et al. carried out a prospective randomised trial evaluating if preoperative UDS improve surgical outcomes in patients undergoing TOT procedure, excluding patients with detrusor overactivity (DO) and/or VLPP <60 cm H_2O and/or MUCP <20 cm H_2O [27]. The main difference with previous studies [10,21] is that, in the ValUE

study, the Medical, Epidemiologic, and Social aspects of Aging (MESA) questionnaire was used as a tool to define the predominant component between SUI and UUI in a semiobjective manner [28]. This way, SUI was considered predominant when the SUI symptom score was higher than UUI, resulting in only 683/4083 or 16% of patients referred for UI being included, which makes it difficult to apply the results of this study as a guaranteed generality. It is notable that, when assessing urgency through interview alone in 72 patients, significant differences in surgical outcomes are already apparent between those with and without prior stress urinary incontinence (SUI) [13,20,27].

Another study with a sample of 792 Argentinean women evaluated for SUI prior to surgical treatment, 39.5% had uncomplicated SUI and 60.5% had criteria for complicated SUI. The UDS showed a different diagnosis from the clinical evaluation in 52% of the patients [29]. In addition, the UDS revealed voiding dysfunction in 22.5% and 13.4% for the uncomplicated and complicated SUI group, respectively [23]. About 15%–20% of women with uncomplicated SUI at clinical evaluation showed detrusor overactivity. On the other hand, the use of the UDS modifies the proposed treatment in 23.8% and 11% of patients with complicated and uncomplicated SUI, respectively [14,23,30]. The review by Serati et al. over 263 women with SUI showed that the UDS was congruent with the clinical diagnosis in 74.5% of cases; however, there was overactive detrusor in 10.6% of cases, mixed urinary incontinence in 8%, and UDS results were inconclusive in 6.8%. Thus, they conclude that UDS may be useful to avoid surgery in patients with overactive detrusor who can be managed pharmacologically [31].

In order to answer the question of whether preoperative UDS improves outcomes, a study conducted in India on 72 patients who underwent SUI surgery and defining success with the same ValUE criteria (decrease in the urogenital distress inventory (UDI) and incontinence impact questionnaire (IIQ) score greater than 70%), the authors showed better results 12 months after surgery in those patients who underwent UDS than in those only assessed with clinical evaluation (80% and 53.3%, respectively) [15,27]

3.5. Effect of UDS from an economic point of view for health care systems

Routine UDS should be analysed from an economic point of view, recommending its use in selected cases [32]. The cost of preoperative UDS was determined in another secondary analysis of the ValUE trial. Using national reimbursement rates, the average cost of UDS was estimated to be $338.3 (USD). Extrapolating this cost to women like those enrolled in the ValUE trial, the authors determined that between $13 million and $33 million could be saved annually by not performing preoperative UDS [17].

3.6. Effect of UDS changing the management for SUI

The different studies have been evaluated in a systematic review of eight randomised studies showing that women who undergo UDS prior to surgery are more likely to have their management changed (17% vs. 3%) than those who do not undergo UDS and who change their management to use medical treatment [33,34]. The EAU clinical practice guidelines recognise the value of the UDS in choosing the optimal surgical treatment for patients with UI, therefore the performance of the UDS should aim to reproduce the patient's symptoms and should be accompanied by an adequate clinical evaluation. The information obtained from UDS can be of great value in discussing and managing expectations regarding invasive treatment of UI, but it does not avoid a proper clinical assessment [3].

4. Discussion

The UDS is a complementary diagnostic test that provides valuable information, if properly performed, and is essential for the pathophysiological understanding of SUI. Therefore, UDS should be performed in accordance with the recommendations outlined in the International Continence Society's (ICS) *Good Urodynamic Practices*, aiming to replicate the symptoms reported by the patient [2,32]. For patients presenting with SUI, the standard diagnostic approach involves a physical examination, including a stress test. According to the ICS *Good Urodynamic Practices*, routine UDS is not necessary prior to surgery for SUI in women. This recommendation is largely supported by the findings from the ValUE and VUSIS-II studies, which demonstrate that omitting preoperative UDS in this selective group of women does not negatively affect post-surgical outcomes when compared to those undergoing UDS [13,19,20]. Uncomplicated SUI is defined as having a duration of more than three months, a postvoid residual of less than 150 ml, a negative urine culture or urinalysis with no abnormalities, objectionable urethral hypermobility and a positive stress test [10,12].

However, there is a large proportion of women presenting with SUI that cannot be considered uncomplicated. In these patients, UDS should be considered before surgery for SUI, according to the recommendation by EAU, AUA/SUFU and CUA guidelines [3,11,12,35]. The review by Serati et al. suggests that only one-third of referred patients will present with uncomplicated SUI who can avoid the performance of UDS [23,36]. This means that, in actual practice, a large proportion of women with SUI can benefit from the information provided by the UDS, and that it can be very useful in discussing and managing the patient's expectations regarding invasive treatment. Moreover, many patients refer mixed UI or associate other urinary symptoms. Furthermore, it should be borne in mind that UDS leads to a change in management in 17% of patients, generally towards a more conservative approach, without limiting the possibility of surgery in the future [33].

It is of paramount importance to perform a correct clinical evaluation and physical examination in order to determine if SUI may be defined as uncomplicated or complicated (previous pelvic or anti-incontinence surgeries, pelvic irradiation, pelvic organ prolapse, ...) [23,36]. Therefore, when indicating the need for UDS, a thorough clinical evaluation and an adequate diagnostic work-up must be performed, following the recommendations of clinical practice guidelines [3,11,12,35]. The use of a voiding diary, uroflowmetry with measurement of PVR, urine sediment and specific questionnaires to rule out associated pathology are of paramount importance. Once the entire evaluation has been performed, we can classify SUI as uncomplicated or complicated [3,11].

The quality of the UDS is also a key element in clinical decision making, so it is essential to follow the ICS *Good Urodynamic Practice* [2,32]. If there is no congruence between the referred symptomatology and the UDS results, the patient's evaluation, the diagnosis and the established therapeutic plan should be reconsidered.

4.1. Position of the SINUG on the performance of UDS in women undergoing surgical treatment for SUI

According to the evidence available, the Ibero-American Society of Neurourology and Urogynecology (SINUG) supports that optimisation of preoperative UDS in women with SUI requires the introduction of objective detection/quantification tools for urgency that allow better clinical categorisation of the type of incontinence, improving the identification of those who do not require UDS. The potential presence of voiding dysfunction should be ruled out, as it may be present in up to 22.5% of women referred for SUI surgery and negatively impact their surgical outcomes; thus, UDS is an essential diagnostic tool when voiding dysfunction is suspected [16,23].

In patients with UI, a detailed evaluation is required, including clinical history with stress test, symptom assessment with validated

questionnaires, voiding diary, abdomino-pelvic physical examination (including pelvic floor assessment), urinalysis, uroflowmetry with PVR measurement, as well as specific questionnaires. These non-invasive studies represent the basis of the diagnostic study, which should allow the classification of SUI as complicated or uncomplicated. We also believe that it is in the group of patients with complicated SUI that the UDS can modify the proposed treatment, allowing optimisation of information on outcomes and expectations [23,37–39].

5. Conclusions

UDS describe the function of the lower urinary tract. In women who consult for SUI, it is necessary to individualise the indication for UDS prior to its surgical correction.

UDS is a complementary diagnostic test to be considered after a non-invasive study of the patient with a detailed clinical history, physical examination and other complementary tests such as a voiding diary, specific questionnaires and urine flow with residual urine. The indication must be contextualised and integrated into the clinical context of the patient.

We consider it necessary in cases of complicated SUI, patients of advanced age, neurogenic bladder, refractory SUI who have undergone previous surgery, patients with high PVR urine, suspicion of voiding dysfunction, with pelvic organ prolapse and in those situations in which the information from UDS could modify the therapeutic decision. If there is no congruence between the referred symptomatology and the UDS results, the patient's evaluation, the diagnosis and the established therapeutic plan should be reconsidered.

Ethics approval

The authors declare that this study involves Humans but ethics approval is not needed for the following reason: The study is a systematic review and does not affect the clinical practice

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Declaration of competing interest

The authors declare no conflict of interest.

The authors declare that generative artificial intelligence (AI) and AI-assisted technologies were not used to analyse or in the writing process.

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