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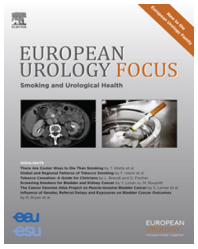

Review – Female Urology – Incontinence

Definition of Success after Surgery for Female Stress Incontinence or Voiding Dysfunction: An Attempt at Standardization

Maude E. Carmel[a,*], *Donna Y. Deng*[b], *Tamsin J. Greenwell*[c], *Philippe E. Zimmern*[a]

[a] *University of Texas Southwestern, Dallas, TX, USA;* [b] *University of California San Francisco, San Francisco, CA, USA;* [c] *University College London Hospitals, London, UK*

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Abstract

Context: There is currently no standardized definition of success for surgery for stress urinary incontinence (SUI) and voiding dysfunction (VD) in women.
Objective: To review the use of outcome measures (OMs) and definitions of success in the literature on SUI and VD surgery in women in an attempt to provide recommendations for future publications.
Evidence acquisition: A PubMed search of all English language full-text articles on SUI and VD surgery in women published between 2010 and 2015 was performed. A list of randomized trials and prospective and retrospective studies was obtained. Specific objective and subjective OMs used to define success were reviewed.
Evidence synthesis: Some 95 articles met the inclusion criteria for SUI surgery outcomes. Most trials reported outcomes at 12 mo after surgery. The majority ($n = 48$) reported their primary outcomes using both objective and subjective success measures, 24 defined success using subjective OMs alone, and 23 using objective OMs alone. The OMs most frequently used for objective success were a negative cough stress test (CST), a negative pad test, and the absence of retreatment for SUI. The definition of subjective success most often involved questionnaires. The questionnaires most frequently used were Patient Global Impression of Improvement (PGI-I), Urinary Distress Inventory (UDI)/UDI-6, International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) and Medical Epidemiologic and Social Aspects of Aging (MESA). Only 11 studies on OMs used for VD surgery were published between 2010 and 2015. The two most common criteria used for success were measurement of postvoid residual urine (PVR) and subjective resolution of VD symptoms.
Conclusions: There is great heterogeneity in the definition of success used after surgery for SUI or VD in women. For SUI surgery, we recommend use of the CST and a 1-h pad test for the definition of objective success, and of the UDI/UDI-6, Incontinence Impact Questionnaire (IIQ), King's Health Questionnaire (KHQ), ICIQ-SF, or PGI-I questionnaire for subjective success. For VD surgery, cure should include measurement of PVR and self-reported resolution of VD symptoms.
Patient summary: We looked at the definition of success used for surgery for stress urinary incontinence (SUI) and voiding dysfunction (VD) in women. We found that there is great heterogeneity among studies, making study comparison extremely difficult. According to the outcome measures used most frequently, we make recommendations regarding the definition of cure for SUI and VD in women to be used in future publications.

* Corresponding author. University of Texas Southwestern, 5323 Harry Hines Boulevard, Dallas, TX 75390-9110, USA. Tel. +1 214 6486333; Fax: +1 214 6488786.
E-mail address: maude.carmel@utsouthwestern.edu (M.E. Carmel).

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1. Introduction

There is currently no standardized definition of success for surgery for stress urinary incontinence (SUI) and voiding dysfunction (VD) in women. This makes it very challenging to compare different procedures owing to the wide heterogeneity among the outcome variables used. There have been a few recent attempts to develop both core and minimum outcome sets to be reported in every study to provide consistent evidence from which to draw meaningful conclusions. The last Cochrane review of minimally invasive midurethral sling operations for the treatment of SUI noted that the variable quality of evidence presented limited the ability to make strong recommendations [1]. The need for more robustly designed randomized controlled trials with standardized objective and validated subjective outcomes was highlighted. Reporting both subjective and objective outcomes is extremely important because of the well-known discrepancies between clinical and objective measures recorded by physicians and the subjective perception of symptoms by patients [2]. The International Continence Society (ICS) and the 4th International Consultation on Incontinence (ICI) previously published a list of recommended outcome measures (OMs) for incontinence therapy, including a list of subjective and objective outcomes [3]. Grade A, "highly recommended" questionnaires were those with well-published data proving their validity, reliability, and responsiveness to change. The use of high-quality questionnaires was strongly recommended for assessing both a patient's perspective of symptoms and their impact on quality of life. Unfortunately, most recent studies have not followed these guidelines and significant inconsistency in OM reporting remains. Definitions of cure and improvement or failure are also extremely variable, with most relying on unvalidated questionnaires and patient self-assessment. This makes useful comparisons between published studies very difficult, if not impossible. Multiple reports have demonstrated the need for a consensus and standardization in the choice of OMs used for reporting of anti-incontinence and VD procedures [1,4,5].

The aim of this study was to review the use of OMs and definition of success in the literature on SUI and VD surgery in an attempt to provide much-needed recommendations and to gain some consensus for future publications.

2. Evidence acquisition

We conducted a literature search in September 2015 using the PubMed database. Filters were applied to capture only full-length articles published in English between January 2010 and September 2015. We limited our search to the past 5 yr in an effort to base our recommendations on the most recent data available. We included articles reporting on outcomes of surgery for SUI and for incomplete emptying, urinary retention, and VD.

The surgeries of interest for the treatment of SUI were sling procedures (midurethral sling, mini-sling and pubovaginal slings), Burch and Marshall-Marchetti-Krantz urethropexy, and needle suspensions. The following search was performed: "stress urinary incontinence" AND "surgery" AND "women". A filter term for clinical trials was also used.

Surgeries for the treatment of VD and incomplete emptying were sling excision or revision or incision, urethrolysis, and bladder neck incision. The following searches were performed: "women" AND "primary bladder neck obstruction"; "sling excision" AND "women"; "sling incision" AND "women"; "urinary retention" AND "surgery" AND "women"; "voiding dysfunction" AND "surgery" AND "women".

We excluded articles reporting outcomes for patients with pelvic organ prolapse (unless outcomes for SUI were well defined) or neurogenic bladder, and for incontinence in men, children and pregnant women. Outcomes of treatments for urgency urinary incontinence were excluded from this review as its management is mostly nonsurgical and the success criteria used for sacral nerve neuromodulation are already well established. Bulking agents were also excluded from this review to focus only on open and vaginal surgical treatments for SUI. Abstracts from key urologic and urogynecologic meetings were not included as most do not clearly describe the OMs and definition of success used. Editorials, commentaries, review articles, and meta-analyses were also excluded.

The resulting abstracts and full-text articles were read in depth, and articles meeting the inclusion and exclusion criteria were included in the review. Data collected from each publication included type of study, journal in which the study was published, country of origin, study aim, publication data, specific objective, subjective OMs, and specific objective and subjective definitions of success used. Data from the relevant papers were extracted and entered

Table 1 – Questionnaires and criteria used for subjective cure

Questionnaire and criteria	Times used (*n*)
ICS Grade A recommended questionnaire	
UDI/UDI-6	10
ICIQ-short form	6
Incontinence Impact Questionnaire-7	3
King's Health Questionnaire	3
ICIQ-FLUTS	1
ICIQ-urinary incontinence	1
Incontinence Severity Index	1
Urinary Incontinence Severity Score	1
Validated but not ICS recommended questionnaire	
PGI-I	12
Medical Epidemiologic and Social Aspects of Aging	5
Pelvic Floor Disorder Index-20	1
Quality of life	1
PGI-I-continence	1
PGI-I-severity	1
Not validated/other criteria	
Subjective home questionnaires	12
Number of pads/d	4
Absence of retreatment	4
3-d voiding diary	2
Visual analog scale	4
Other	3

ICS = International Continence Society; UDI = Urinary Distress Inventory; ICIQ = International Consultation on Incontinence Modular Questionnaire; FLUTS = female lower urinary tract symptoms; PGI-I = Patient Global Impression of Improvement.

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