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Heterogeneity in reporting on urinary outcome and cure after surgical interventions for stress urinary incontinence in adult neuro-urological patients: A systematic review

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Aims: To describe all outcome parameters and definitions of cure used to report on outcome of surgical interventions for stress urinary incontinence (SUI) in neuro-urological (NU) patients.

Methods: This systematic review was performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The study protocol was registered and published (CRD42016033303; <http://www.crd.york.ac.uk/PROSPERO>). Medline, Embase, Cochrane controlled trials databases, and clinicaltrial.gov were systematically searched for relevant publications until February 2017.

Results: A total of 3168 abstracts were screened. Seventeen studies reporting on SUI surgeries in NU patients were included. Sixteen different outcome parameters and nine definitions of cure were used. Six studies reported on objective outcome parameters mainly derived from urodynamic investigations. All studies reported on one or more subjective outcome parameters. Patient-reported pad use (reported during interview) was the most commonly used outcome parameter. Only three of 17 studies used standardized questionnaires (two on impact of incontinence and one on quality of life). Overall, a high risk of bias was found.

Conclusions: We found a considerable heterogeneity in outcome parameters and definitions of cure used to report on outcome of surgical interventions for SUI in NU patients. The results of this systematic review may begin the dialogue to a future consensus on this topic. Standardization of outcome parameters and definitions of

Hashim Hashim led the peer-review process as the Associate Editor responsible for the paper.

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cure would enable researchers and clinicians to consistently compare outcomes of different studies and therapies.

KEYWORDS

neurogenic, outcome assessment, patient reported outcome measures, stress urinary incontinence, treatment outcome, urinary bladder, urinary incontinence

1 | INTRODUCTION

Patients with neurological disease may show various urological symptoms, depending on the type of disease and the neurological location of the lesion.^{1,2} Both storage and voiding problems can considerably reduce patients quality of life.³ An impaired neurological control of the external sphincter may be the cause of stress urinary incontinence (SUI), defined as urinary incontinence that occurs on exertion, effort, sneezing, or coughing.⁴ This bothersome condition affects many neuro-urological (NU) patients, typically those with a meningocele or a conus-cauda equina lesion.¹ Owing to the fact that SUI in NU patients often occurs together with other urological dysfunction such as detrusor overactivity and reduced bladder compliance,^{1,3} treatment of SUI in NU patients requires a specific approach. Moreover, NU patients may perceive bother from urinary incontinence differently compared to non-NU patients due to altered sensation and impaired mobility. Therefore, the outcome parameters and the definitions of success or cure used to report on outcome of surgical interventions for SUI in NU patients require specific attention.

To identify the most appropriate therapy, studies on the outcomes of the different therapies used to treat SUI in NU patients should ideally be reported in a standardized way. We performed a systematic review to describe all urinary parameters and definitions of success or cure used to report on outcome of surgical interventions for SUI in NU patients.

2 | MATERIALS AND METHODS

2.1 | Study registration

The study protocol was registered and published on PROSPERO (CRD42016033303) (<http://www.crd.york.ac.uk/PROSPERO>). This systematic review was performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement⁵ and Cochrane Handbook for Systematic Reviews of Interventions.⁶

2.2 | Literature search

The Medline, Embase, Cochrane controlled trials databases, and clinicaltrials.gov were systematically searched for all relevant publications until February 2017. The search strategy is available in Supplementary Material S1. Duplicates were removed. No date restrictions were applied. Non-English texts were excluded. Additionally, reference lists of relevant reviews were hand-searched for missed relevant articles.

2.3 | Study selection

Our aim was to include all publications of original studies that used a predefined urinary outcome parameter or a definition of success or cure to report on outcome of surgical interventions for SUI in adult NU patients. Conference abstracts, reviews, and case series with <10 NU patients were excluded. Reviews served only to check the references for eligible extra articles. Studies with both adult NU and non-NU patients or with both children and adult NU patients were included only if adult NU patients were separately reported on or if >90% of the study population were adult NU patients.

Endnote (EndNote X7, Thomson Reuters, 1500 Spring Garden Street, Fourth Floor, Philadelphia, PA 19130) was used to store identified abstracts and to sort the abstracts for inclusion and exclusion. Each title and abstract was reviewed for eligibility by two out of four reviewing authors (BB, JG, JS, SR) independently. Articles of which the abstract met the eligibility criteria were reviewed in full text. Full text selection was performed by two authors independently (JG, SR) using a standardized screening form. Discrepancy between the two authors was resolved by discussion or by consulting a third reviewer (BB). We reported on the literature search and study selection in a PRISMA flow diagram.⁵

2.4 | Outcomes

All urinary outcome parameters and definitions of cure or success used to report on outcome of surgical interventions

for SUI in adult NU patients were summarized. Outcome parameters containing information from questionnaires and patient interviews were considered subjective outcome parameters. Outcome parameters were considered objective when derived from bladder diaries, pad tests, cough stress-tests, or urodynamic investigations.

2.5 | Data extraction and risk of bias assessment

Data on general study characteristics were retrieved by the first author and checked by JG. Two authors (SR and JG) independently extracted predefined data from the included publications using a standardized data extraction form. A risk of bias analysis for included non-randomized comparative studies was performed by using the Cochrane Risk of bias Assessment Tool⁷ in combination with an assessment of the main confounders following the recommendations of the Cochrane handbook for non-randomized comparative studies.⁶ A list of the main confounders was developed and a priori agreed on with clinical content experts (EAU Neuro-Urology guidelines panel). Identified confounders were age, gender, mixed versus stress incontinence, underlying NU pathology, perineal sensation, previous treatments for SUI, and previous pelvic surgeries. Confounders were determined for the studies during data extraction. The confounding bias was classified as “high” if the confounder was not considered or described, was imbalanced between the groups or was unadjusted during analysis. The risk of bias in non-comparative studies was determined by assessing the attrition bias (incomplete outcome data), the reporting bias (selective outcome reporting), and availability of an a priori protocol. External validity of these studies was reported by assessing whether participants were selected consecutively. This is a pragmatic approach based on methodological literature.^{8,9} In addition, the main confounders were assessed for these studies. The risk of bias figure was computed in Review Manager (RevMan) version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

2.6 | Subgroup analyses

Subgroup analyses were intended to be performed if there would be sufficient data. Predefined subgroups were men versus women, SUI versus mixed UI, underlying NU pathology, and no versus one/more former surgeries with potential effect on continence.

3 | RESULTS

3.1 | Search results

Figure 1 shows the PRISMA flow diagram of the literature search and study selection. After screening of 3168 abstracts,

182 full texts were reviewed. Finally, 17 studies were included in this systematic review.^{10–26}

3.2 | Characteristics of included studies

The included studies were published between 1995 and 2017 and report the results of various SUI surgeries. Table 1 shows the descriptives of the included studies. Most studies had a retrospective single-arm study design. With one exception, all studies were single-center studies. Twelve studies reported on NU patients only. A total of 452 NU patients were included in the studies. Most studies included mixed patient populations regarding underlying NU pathology, detrusor overactivity, mixed urinary incontinence and pure SUI, and patients with and without previous SUI, and other pelvic surgeries.

3.3 | Results on outcome parameters

Table 2 shows the outcome parameters used per study. In total, 16 different outcome parameters were used in the 17 included studies. Furthermore categorization of the outcomes differed (eg, patient-reported leakage/continence). Eleven studies had applied two or more outcome parameters. Six of the 17 studies reported on both an objective and a subjective outcome parameter.

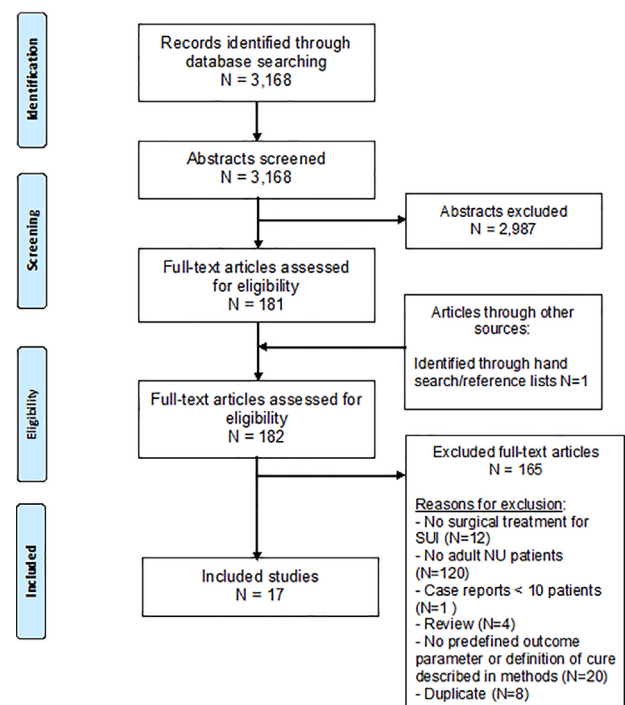


FIGURE 1 PRISMA flow diagram of identified, excluded, and included studies. NU, neuro-urological; SUI, stress urinary incontinence

TABLE 1 Characteristics of the included studies

Study	Study design	Evaluated intervention	NU patients/ total study population, no.	Type of NU patients	Age of NU patients, yr	Male/ female of NU patients,	NU patients with mixed urinary incontinence preoperatively, no.	NU patients with DO preoperatively, no.	NU patients with previous SUI surgeries, no.	NU patients with previous pelvic surgeries with potential effect on continence, no.	NU patients with normal perineal sensation, no.
Pannek et al. ¹⁰	Retrospective comparative	Transobuturator tape vs retropubic adjustable system	16/16 (100%)	43.8% thoracic SCI 25.0% lumbar SCI 12.5% cervical SCI 18.7% unknown	Mean 53.5	16/0	NR	0/16 (0%)—DO as an exclusion criterion	NR	5/16	NR
Phé et al. ¹¹	Retrospective single-arm	Artificial urinary sphincter	26/26 (100%)	12% spina bifida 23% thoracic SCI 65% lumbar SCI	Median 49.2	0/26	NR	16/26 (60.5%)	14/26	11/26	NR
Losco et al. ¹²	Retrospective single-arm	Transobuturator tape	27/27 (100%)	SCI	Mean 56	0/27	NR	6/27—all patients were successfully treated with Botox	NR	NR	NR
El-Azab et al. ¹³	Prospective non-randomized pilot study	Tension-free vaginal tape vs pubovaginal sling	40/40 (100%)	Sacral spinal pathology	Median 34	0/40	26/40 (65%)	NR	0/40	NR	NR
Costa et al. ¹⁴	Prospective single-arm	Artificial urinary sphincter	54/344 (15.7%)	53.7% spina bifida 33.3% acquired 9.3% posttraumatic 3.7% other congenital	NR (entire study population: mean 57.2)	0/54	NR (entire study population 65/344 mixed incontinence)	NR	NR (entire study population 66% had previous SUI surgeries)	NR	NR
Mehnen et al. ¹⁵	Retrospective single-arm	Adjustable continence therapy (ACT/ProACT)	37/37 (100%)	51.4% paraplegia Furthermore: lumbar stenosis, posttraumatic, MS, infectious disease	Mean 46.2	13/24	NR	21/37 (57%)	14/37	NR	NR
Groen et al. ¹⁶	Prospective single-arm pilot study	AdVance male sling	20/20 (100%)	60% MMC 40% lower SCI	Mean 23	2/00	NR	4/20 (20%)	2/20	1/20	10/20
Athanasopoulos et al. ¹⁷	Retrospective single-arm	Autologous fascia rectus sling	33/33 (100%)	63.6% MMC 36.4% SCI	Mean 37	0/33	NR	22/33 (66.7%)	NR	NR	NR
Charrier Kasler et al. ¹⁸	Retrospective single-arm	Artificial urinary sphincter	51/51 (100%)	69% SCI 31% MMC	Mean 35	51/0	NR	20/51 (39%)	NR (11 previous SUI surgeries in this patient group)	NR	NR
Abdul-Rahman et al. ¹⁹	Retrospective single-arm	Artificial urinary sphincter	12/12 (100%)	50% lumbar disc surgery 25% spinal stenosis	Mean 53	0/12	NR	1/12	4/12	NR	NR
Barsch et al. ²⁰	Retrospective single-arm	Artificial urinary sphincter	51/51 (100%)	49.0% thoracic SCI 43.2% lumbar SCI 7.8% cervical SCI	Mean 38.7	37/14	NR	NR (only included if DO was sufficiently suppressed)	NR	NR	NR
Ramsay et al. ²¹	Retrospective single-arm	Artificial urinary sphincter	11/39 (28%)	54.5% spina bifida 18.2% SCI Furthermore: sacral agenesis, postmeningitis, scoliosis	NR (entire study population: mean 57)	NR (entire study population: 38/1)	NR	NR	11/11	NR (in entire study population 25/39)	NR

(Continues)

TABLE 1 (Continued)

Study	Study design	Evaluated intervention	NU patients/ total study population, no.	Type of NU patients	Age of NU patients, yr	Male/ female of NU patients, no.	NU patients with mixed urinary incontinence preoperatively, no.	NU patients with DO preoperatively, no.	NU patients with previous SUI surgeries, no.	NU patients with previous SUI surgeries, no.	NU patients with previous pelvic surgeries with potential effect on continence, no.	NU patients with normal perineal sensation, no.
Lai et al. ²² 2007	Retrospective single-arm	Artificial urinary sphincter	11/218 (5%)	Including SCI, spina bifida, tethered cord and pelvic fracture	Mean 46.3	11/0	NR	NR	NR (entire study population 25% previous SUI surgery)	NR (in entire study population 176/218)	NR	
Hamid et al. ²³	Retrospective single-arm	Polydimethylsiloxane submucoosal injections	14/14 (100%)	50% thoracic traumatic SCI 43% lumbar traumatic SCI 7% SCI after surgery	Mean 41	14/0	0/14 (0%)—urge urinary incontinence as an exclusion criterion	NR	NR	NR	NR	
Costa et al. ²⁴	Retrospective single-arm	Artificial urinary sphincter	27/206 (13%)	37.0% spina bifida 18.5% traumatic cauda equina lesion 33.3% SCI 11.1% other	Mean 35.6	0/27	NR	NR	13/27 previous surgery for incontinence (unclear if this was specifically for SUI)	NR	NR	
Bennett et al. ²⁵	Prospective single-arm	Periurethral collagen injection	11/11 (100%)	45% MMC 45% SCI 9% spinal cord tumor	Mean 30.2	9/2	NR	NR	NR	NR	NR	
Nataluk et al. ²⁶	Retrospective single-arm	Periurethral collagen injection	11/45 (24.4%)	NR	NR (entire study population: mean 60)	11/0	NR	NR	NR	NR	NR	

DO, detrusor overactivity; MMC, meningomyelocele; MS, multiple sclerosis; NR, not reported; NU, neuro-urological; SCI, spinal cord injury; SUI, stress urinary incontinence.

TABLE 2 Used outcome parameters to report on urinary outcome of surgical interventions for SUI in adult NU patients

Study	Objective outcome parameters				Subjective outcome parameters			
	Bladder diary	Pad test	Cough stress-test	Urodynamics	Patient-reported pad use	Patient-reported urinary leakage	Standardized questionnaires	Patient satisfaction
Pannek et al ¹⁰	NR	NR	NR	Reported: Bladder capacity Compliance Maximum detrusor pressure	Reported: Number of pads per day	NR	NR	NR
Phé et al ¹¹	NR	NR	NR	NR	Reported: Number of pads per day	NR	NR	NR
Losco et al ¹²	NR	NR	NR	NR	NR	Reported: Dry Improved Remaining wet	NR	Reported: Satisfied Not satisfied
El-Azab et al ¹³	NR	NR	Reported: Leakage at cough/Valsalva at 250ml	Reported: Postvoid residual volume	NR	NR	Reported: UDL-6 and IIQ-7	NR
Costa et al ¹⁴	NR	NR	NR	NR	NR	Reported: No leakage Some drops, no pad Use of pads	NR	NR
Mehnert et al ¹⁵	Reported: Urinary incontinence episodes (number/day)	NR	NR	NR	Reported: Pad use (number/day)	Reported: Complete continence ≥50% improvement <50% improvement/failure	NR	NR
Groen et al ¹⁶	NR	NR	NR	NR	Reported: Number of pads per day	NR	Reported: Visual analog scale for continence and ICIQ male short form	NR
Athanasopoulos et al ¹⁷	NR	NR	NR	NR	Reported: Mean number of pads per day	NR	NR	Reported: Global assessment question: "Are you satisfied with the outcome of the performed operation?" Yes/no
Charrier Kastler et al ¹⁸	NR	NR	NR	NR	NR	Reported: Dryness at least 4 h between 2 catheterizations/micturitions Only nocturnal leakage or need to wear pads or stress leakage Uncontrollable leakage causing discomfort	NR	NR1
Abdul-Rahman et al ¹⁹	NR	NR	NR	NR	Reported: Number of pads per day	NR	Reported: Assessment of health related quality of life	NR

(Continues)

TABLE 2 (Continued)

Study	Objective outcome parameters				Subjective outcome parameters			
	Bladder diary	Pad test	Cough stress-test	Urodynamics	Patient-reported pad use	Patient-reported urinary leakage	Standardized questionnaires	Patient satisfaction
Berssch et al ²⁰	NR	NR	NR	Reported: Leakage during VCMG Bladder capacity Compliance	Reported: Number of pads per day	NR	NR	NR
Ramsay et al ²¹	NR	NR	NR	NR	Reported: Number of pads per day	NR	NR	NR
Lai et al ²²	NR	NR	NR	NR	Reported: Patient-reported post-AUS pad use/day	NR	NR	NR
Hamid et al ²³	NR	NR	NR	Reported: Leakage during VCMG	Reported: Number of pads per day	NR	NR	NR
Costa et al ²⁴	NR	NR	NR	NR	Reported: daily pad use (yes/no)	Reported: No leakage Few drops but no pad use Use of pads	NR	NR
Bennett et al ²⁵	NR	NR	NR	Reported: valsalva leak point pressure	NR	Reported: No leakage Leakage with brisk exercise/lifting heavy Leakage with minimal exertion Incontinence in absence of physical exertion, including sleep	NR	NR
Nataluk et al ²⁶	NR	NR	NR	NR	NR	Reported: Totally dry Improved Unchanged Worse	NR	NR

NR, not reported; NU, neuro-urological; SU, stress urinary incontinence; VCMG, videocystometrogram.

TABLE 3 Used definitions of cure or continence to report on success of surgical interventions for SUI in adult NU patients

Study	Cure/continence	Definition used
Pannek et al ¹⁰	Cure	No pads or continence aids used
Phé et al ¹¹	Continence	No pad use
Losco et al ¹²	Continent status = dry	If patient reported complete correction of SUI + no pads usage
El-Azab et al ¹³	Cure	Negative cough stress test + no leakage during physical examination
Costa et al ¹⁴	Fully continent	Patient-reported “fully continent”
Mehnert et al ¹⁵	NR	NR
Groen et al ¹⁶	Cure	Score of 10 on VAS (indicating no incontinence) or using no pads
Athanasopoulos et al ¹⁷	Cure	No leakage per urethra, 0 pads per day.
Chartier Kastler et al ¹⁸	Perfect continence	Dryness at least 4 h between two catheterizations/micturitions
Abdul-Rahman et al ¹⁹	Cure	Completely dry, no pads
Bersch et al ²⁰	Cure	Subjective cure (no pads or continence aids) + objective cure (continence confirmed during urodynamic investigation)
Ramsay et al ²¹	Socially continent	0 or 1 pads/day
Lai et al ²²	NR	NR
Hamid et al ²³	Cure	Cessation of using pads and dry on VCMG
Costa et al ²⁴	Continence	Patient reporting no leakage and no use of pads
Bennett et al ²⁵	Cure	Patient reporting no leakage
Nataluk et al ²⁶	Continent or total continence	Totally dry on postoperative interview

NR, not reported; NU, neuro-urological; SUI, stress urinary incontinence; VCMG, videocystometrogram.

3.3.1 | Objective outcome parameters

Six of 17 (35.3%) included studies reported on objective outcome parameters. Pad tests were not reported on. In one study, patients used a bladder diary to report the number of urinary incontinence episodes per day. One study reported the results of a cough stress-test. Urodynamics was the most used investigation to measure an objective outcome parameter; that is, in five studies. Bladder capacity, compliance, maximum detrusor pressure, postvoid residual volume, leakage during videocystometrogram, and Valsalva leak point pressure were the objective outcome parameters that were derived from urodynamic investigations.

3.3.2 | Subjective outcome parameters

Patient-reported pad use (number of pads/24 h or yes/no daily pad use reported during an interview) was the most utilized outcome parameter; used in eleven studies. Three studies applied standardized questionnaires. In seven studies patients reported on their urinary leakage status in a post-intervention interview. Two studies reported on patient satisfaction.

3.4 | Results on definition of success or cure

Table 3 provides an overview of the different definitions for cure or continence used. Fifteen of 17 studies reported on

such a definition. In these 15 studies, nine different definitions were used. Only two of five studies that reported on cure and used an objective and a subjective outcome parameter, used a combination of both outcomes to define cure.

3.5 | Subgroup analyses

It was not contributive or possible to perform subgroup analyses. First, the number of included studies was small; second, because most studies identified included mixed populations (gender, underlying NU pathology, SUI, and mixed UI, former surgeries with potential effect on continence); and finally, subanalyses and information on predefined groups was often missing (Table 1).

3.6 | Risk of bias assessment

Most of the included studies were assessed as having high or unclear risk of bias (Figure 2). In most retrospective studies, it was unclear if an a priori protocol was available and if there was selective outcome reporting. In one third of these studies, it was unclear if there were incomplete outcome data. Most studies included study participants consecutively. The two comparative studies had a high risk of bias for most assessed factors of the Cochrane Risk of bias Assessment Tool and the confounding factors.

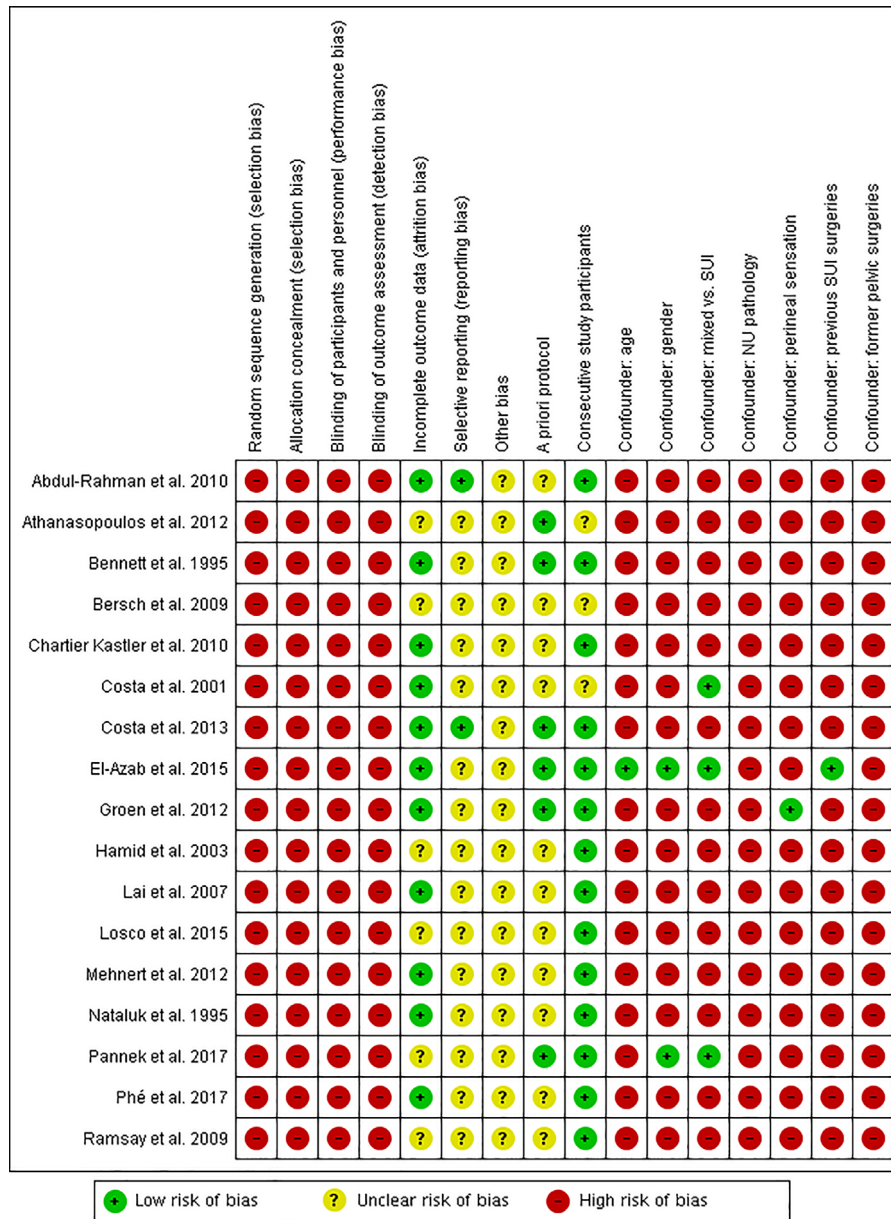


FIGURE 2 Risk of bias summary. NU, neuro-urological; SUI, stress urinary incontinence

4 | DISCUSSION

4.1 | Principal findings

In this systematic review, we have presented all parameters and definitions of cure to report on the outcome of surgical interventions for SUI in adult NU patients. Sixteen different outcome parameters and nine different definitions of cure or continence were used. Most outcomes and definitions of cure were based on non-standardized patient self-assessments (of pad use per day or leakage/continence). A minority of studies made use of objective outcome parameters or validated questionnaires. To the best of our knowledge, this is the first systematic review on this topic in this specific

patient group. It is evident that there is a considerable heterogeneity in the urinary outcome parameters and definitions of cure used to report on outcome of surgical interventions for SUI in adult NU patients.

4.2 | Findings in the context of the existing evidence

The heterogeneity of outcome reporting makes it more difficult to interpret and compare different studies and therapies. The Core Outcome Measures in Effectiveness Trials (COMET) initiative supports the development of standardized sets of outcomes in all fields of health research.²⁷ In the field of urology such core outcome sets are available for prostate cancer and male sexual dysfunction, but not for UI. The

International Continence Society (ICS) and the International Consultation on Incontinence (ICI) recommend using both objective and subjective outcome parameters in UI research.^{28,29} Despite this, these organizations do not provide a definition of cure or make recommendations for the specific outcome parameters to be used.

Specifically, in the field of NU patients undergoing SUI surgery there is no consensus on outcome parameters. The ICS does not provide a recommendation on this topic for research in NU patients. The ICI recommends using changes in detrusor leak point pressure for research purposes in NU patients if appropriate.²⁸ Nevertheless, this parameter was not used in any of the included studies in our systematic review. The EAU guidelines mention prevention of deterioration of the upper urinary tract and optimization of the quality of life as the most important urological treatment goals for NU patients.³⁰ Therefore, we would expect urodynamic investigations and quality of life measures to be used more often in this patient group. NU patients may have altered sensation and impaired mobility and consequently perceive (UI) complaints different than to non-NU patients. Thus, measuring patients' perception of UI complaints and their health-related quality of life (rather than quantifying symptoms) is important, especially in this patient group. Phé et al³¹ and Castillo et al³² reported in their reviews on the commonly used outcome parameters and definitions of cure or treatment success used after SUI surgery (not specifically on NU patients). Phé et al³¹ reviewed publications on all SUI surgeries from 1995 to 2014 and Castillo et al³² focused on publications on female SUI from 2005 and 2006. In our systematic review, we found that five out of 17 (29.4%) included studies used outcome parameters derived from urodynamic investigations. Phé et al³¹ and Castillo et al³² found that urodynamic investigations were performed in 12 of 54 studies (22.2%) and in 37 of 92 studies (40.2%), respectively. Only two of the 17 (11.8%) studies in our review applied questionnaires on the impact of UI and only one study used quality-of-life assessments. The questionnaires administered were the UDI-6, IIQ-7, visual analog scale for continence, and ICIQ male short form. These are validated questionnaires, but not specifically for NU patients. Although validated (disease-specific) quality of life questionnaires such as the (SF-)Qualiveen^{33,34} have been introduced in the recent past, they have not always been available. In the review by Phé et al³¹ validated questionnaires (including quality of life measures) were used in 55.6% and in the review by Castillo et al³² validated questionnaires were used in 40.2% and quality of life measures were used in 60.9% of the studies. So contrary to our expectations, urodynamic investigations and quality of life measures were not used more often in our systematic review in NU patients. For retrospective studies, only available measures from clinical practice can be used. The high number of retrospective studies

in our systematic review compared to Phé et al³¹ and Castillo et al³² could explain the different findings. On the other hand, one would expect quality of life measures and urodynamic investigations as standard of care in NU patients.

Despite the ICS and ICI recommendations, in only six of 17 (35.3%) included studies in this systematic review both a subjective and an objective outcome parameter was used and only two of these studies used a combination of these parameters to define cure. Compared to the reviews of Phé et al³¹ and Castillo et al³² in non-neurological patients, where about half of the studies reported on both a subjective and an objective outcome, this number is low. The high number of retrospective studies could again be an explanation for this finding. Comparable to our results, in the reviews of Phé et al³¹ and Castillo et al³² a minority of studies used a combination of subjective and objective outcome parameters to define cure.

Pad use reported by the patient during an interview was the most used outcome parameter in the studies included in our systematic review. Phé et al³¹ reported on this outcome for some studies, but not structurally for all and Castillo et al.³² did not mention this outcome parameter in their review. In one included study¹⁷ of our review this outcome parameter was chosen because it would reflect the quality of life, referring to a publication by Stoffel et al³⁵ that found a correlation between patient-reported pad use and the impact of UI on quality of life. In other publications the reason for choosing this outcome parameter is not clear, but might be the ease of collecting this information (especially for retrospective series) for both patient and researcher; in addition it does not interfere in a patient's "normal daily voiding routine" (as a bladder diary might do). It is questionable if patient-reported pad use during an interview reflects the quantity of urine lost³⁶ specifically for NU patients with altered sensation in whom the use of incontinence pads is often discouraged to prevent skin problems. Furthermore, it is unknown if patient-reported pad use is comparable to bladder diary reported pad use. As using this outcome parameter may be advantageous, we suggest to further investigate this outcome parameter on psychometric properties, such as test-retest reliability, correlation with bladder diary reported pad use, quantity of urine lost, and quality of life.

4.3 | Implication for research and clinical practice

Farag et al³⁷ reported on the success rates of surgical treatments for SUI in both adult and pediatric NU patients in a systematic review. Farag et al³⁷ compared the combined success rates of the included studies on urethral bulking agents to urethral sling procedures and artificial urinary sphincters. These studies however used variable definitions of success. A consistent comparison of the outcomes of therapy can only be made after standardization of outcome parameters and definitions of cure or success. We therefore recommend developing a core

outcome set for use in UI research with NU patients. It is important that not only medical experts, but also patients and caregivers will be involved in the development of this outcome set, in order to include the various perspectives and also to increase the willingness to implement the outcome set. Until such a set has been developed, we recommend using an objective and a subjective outcome parameter and the combination of both to define cure. Because of the importance of the quality of life, specifically in NU patients, we recommend the use of a disease-specific quality of life questionnaire or a bother questionnaire validated for NU patients such as the (SF-)Qualiveen^{33,34} as a subjective outcome parameter. Implementing such questionnaires in both research and clinical practice places a focus on optimization of the quality of life for these patients and makes it possible to compare outcomes of different studies. A clear recommendation for the use of a specific objective parameter is not feasible because there is insufficient scientific evidence on the psychometric properties of the different objective measures (bladder diaries, urodynamics, and pad tests), specifically regarding NU patients.³⁸

4.4 | Strengths and limitations

Performing this systematic review, we followed the recommended Cochrane⁶ and PRISMA guidelines.⁵ Our study gives a clear overview of all used urinary parameters and definitions of success or cure to report on the outcome of surgical interventions for SUI in NU patients, and will hopefully begin the dialogue to a future consensus on this topic. Unfortunately, the included studies were primarily retrospective and of poor scientific quality. Furthermore, subgroup analyses were not possible due to the limited number of included studies.

5 | CONCLUSIONS

This is the first systematic review that has evaluated the various urinary parameters and definitions of cure to report on outcome after surgery for SUI in adult NU patients. We found a considerable heterogeneity in used outcome parameters and definitions of cure. As it is difficult to interpret and compare the outcomes of different therapies as investigators use different reporting systems of outcomes and definitions of cure, the results of this study will hopefully begin the dialogue to a future consensus on this topic.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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