

Synthetic mid-urethral sling for the treatment of stress urinary incontinence in women with neurogenic lower urinary tract dysfunction: results of a retrospective multicentric study

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THÈSE
POUR LE DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE
SPÉCIALITÉ : CHIRURGIE UROLOGIQUE

Par M. Clément SARRAZIN

[Données à caractère personnel]

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A Claire, enfin, j'ai une infinité de raison de te remercier mais je crains qu'elles n'intéressent que moyennement le jury. Merci pour ta patience et ton écoute. Merci pour les efforts que tu fais pour me soutenir au quotidien. J'ai beaucoup de chance.

Résumé

Bandelettes sous-urétrales synthétiques pour le traitement de l'incontinence urinaire à l'effort chez la femme présentant une dysfonction neurogène du bas-appareil urinaire : résultats d'une étude multicentrique rétrospective

Contexte : La bandelette sous-urétrale (BSU) synthétique est le traitement chirurgical de première intention pour le traitement de l'incontinence urinaire à l'effort (IUE) chez la femme. L'utilisation de BSU synthétique pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du bas-appareil urinaire (BAU) a été peu étudiée.

Objectif : Evaluer les résultats de la BSU synthétique pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du BAU.

Méthode : Une étude rétrospective multicentrique a été menée dans 3 centres français. Les femmes adultes pour lesquelles une BSU synthétique était implantée pour le traitement d'une IUE, qui présentaient une comorbidité neurologique diagnostiquée avant l'intervention, étaient incluses. Les patientes avec une durée de suivi inférieure à un an, une cure de prolapsus concomitante à l'implantation de BSU ou qui n'avaient pas eu de bilan urodynamique préopératoire étaient exclues. Le critère de jugement principal était la récidive de symptômes d'IUE à l'interrogatoire durant le suivi. Les critères de jugement secondaires étaient les réponses à des questions standardisées chez les patientes qui n'avaient pas été réopérées pour récidive de l'IUE durant le suivi : statut « sec » rapporté par la patiente, Patient Global Impression of Improvment (PGI-I) et score de gêne lié à l'incontinence urinaire évalué par la question 3 de l'International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF). La sécurité de l'intervention était évaluée par la survenue de complication durant le suivi, particulièrement l'hyperactivité vésicale (HAV) de novo, la rétention urinaire et l'exposition de bandelette. Les réopérations pour complication ou récidive de l'IUE étaient relevées.

Résultats : Cent quinze patientes ont été incluses. L'âge médian était de 53 ans (rang interquartile 46-64 ans). La durée médiane de suivi était de 53 mois (rang interquartile 46-64 mois). A la fin du suivi, 57 patientes (50 %) présentaient une récidive de l'IUE ou avaient été réopérées pour récidive de l'IUE. En analyse multivariée, l'âge inférieur à 50 ans, la positivité des manœuvres de soutènement urétral et la multiparité étaient des facteurs protecteurs indépendants de récidive de l'IUE (HR:0.3 IC95%(0.2-0.7) p<0.01; HR:0.5 IC95%(0.3-0.98) p=0.043 et HR:0.5 IC95%(0.2-0.98) p=0.043, respectivement). La voie d'implantation transobturatrice était un facteur de risque indépendant de récidive de l'IUE (HR:2.1 IC95%(1.1-4) p=0.029). Parmi les patientes qui avaient répondu aux questions standardisées, 53 % s'estimaient « sèches » et 77.4 % avaient un PGI-I inférieur ou égal à 2. La médiane du score de gêne lié à l'incontinence urinaire était 3 sur 10. Vingt-cinq des 52 patientes (48 %) qui avaient une IUE pure en préopératoire présentaient une HAV de novo. Neuf patientes (8 %) avaient présenté une exposition de bandelette. Seize des 69 patientes (23 %) en miction spontanée avaient présenté une rétention urinaire, parmi lesquelles 7 avaient été réopérées et 2 avaient définitivement recours aux sondages intermittents. Trente-six patientes (31.3 %) avaient eu une réopération ou plus durant le suivi.

Conclusion : La BSU synthétique est une option pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du BAU. Le taux de continence est acceptable et la satisfaction des patientes est élevée. Les patientes doivent être cependant informées du risque de complication et de réopération.

MOTS-CLÉS : INCONTINENCE URINAIRE À L'EFFORT; BANDELETTES SOUS-URÉTRALES; DYSFONCTION NEUROGÈNE DU BAS-APPAREIL URINAIRE

FILIÈRE : CHIRURGIE UROLOGIQUE

Abstract

Synthetic mid-urethral sling for the treatment of stress urinary incontinence in women with neurogenic lower urinary tract dysfunction: results of a multicentric retrospective study

Background: Synthetic mid-urethral slings (sMUS) are the first-line surgical treatment for stress urinary incontinence (SUI) in women. The use of sMUS for the treatment of SUI in women with neurogenic lower urinary tract dysfunction (NLUTD) has been poorly assessed. **Goals:** To assess the results of sMUS for the treatment of SUI in women with NLUTD. **Methods:** A retrospective multicenter study was carried out in 3 tertiary referral centers in France. Women aged 18 years old or older, who had a sMUS implantation to treat SUI, who had a relevant neurological disorder diagnosed before the intervention were included. Patients with a follow-up period of less than one year, a surgical cure of pelvic organ prolapse performed at the time of sMUS implantation or who did not have a preoperative urodynamic study were excluded. The primary outcome was recurrence of SUI during follow-up. Secondary outcomes were answers to standardised questionnaires among patients who did not have reintervention for recurrence of SUI during follow-up: patient reported "dry" status, Patient Global Impression of Improvment (PGI-I) and discomfort score related to urinary incontinence evaluated by question 3 of the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF). The safety of the intervention was assessed by the occurrence of complications during follow-up, particularly de novo overactive bladder (OAB), urinary retention and sMUS exposure. Reintervention for complications or recurrence of SUI were also noted.

Results: 115 patients were included. The median age was 53 years old (interquartile range 46-64 years old). The median follow-up duration was 53 months (interquartile range 46-64 months). At last follow-up, 57 patients (50%) presented with recurrence of SUI or had a reoperation for recurrence of SUI. In multivariate analysis, age below 50 years old, positive urethral support manoeuvres and multiparity were independent protective factors for SUI

recurrence (HR: 0.3 95% CI (0.2-0.7) p <0.01; HR : 0.5 95% CI (0.3-0.98) p = 0.043 and HR: 0.5 95% CI (0.2-0.98) p = 0.043, respectively). The transobturator tape route was an independent risk factor for SUI recurrence (HR: 2.1 95% CI (1.1-4) p = 0.029). Among the patients who answered the standardised questionnaires, 53% considered themselves "dry" and 77.4% had a PGI-I less than or equal to 2. The median discomfort score related to urinary incontinence was 3 out of 10. Twenty-five of the 52 patients (48%) who had pure SUI preoperatively presented de novo HAV. Nine patients (8%) had a sMUS exposure. Sixteen of the 69 patients (23%) who were on spontaneous voiding presented with urinary retention, of which 7 had reintervention and 2 required definitive intermittent catheterisation. Thirty-six patients (31.3%) had one or more reoperation during follow-up.

Conclusion: sMUS is an option for the treatment of SUI in women with NLUTD. The continence rate is acceptable and patient satisfaction is high. However, patients should be informed of the risk of complications and reoperation.

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Systematic review

Synthetic mid-urethral slings for the treatment of stress urinary incontinence in women with neurogenic lower urinary tract dysfunction: a systematic review

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Abstract

Aims: The aim of our study was to evaluate the efficiency and safety of Synthetic Mid-Urethral Slings (sMUS) for the treatment of stress urinary incontinence (SUI) in women with neurogenic lower urinary tract dysfunction (NLUTD).

Methods: Systematic review performed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Medline, Embase, Cochrane controlled trials databases were systematically searched from January 1995 to April 2021. Studies including adult women with NLUTD who had a sMUS for SUI were considered for inclusion. Primary outcome was success of the surgery according to studies criteria. Secondary outcomes were complications especially de novo urgency, urinary retention, tape exposure and revision for complications.

Results: 752 abstracts were screened and 9 studies were included representing 298 patients. Mean age was 52 years old and median follow-up was 41.3 months. sMUS insertion was successful in 237 patients (79.5%). Median rate of de novo urgency was 15.7% (range 8.3-30%). In patients with spontaneous voiding, the median rate of retention was 19.3% (range 0-46.7%) and 21 out of 26 patients required intermittent self-catherisation. Four cases of tape exposure were reported, and 8 patients underwent a revision for complications.

Conclusions: This review suggests that sMUS offer interesting success rates and acceptable morbidity and could be considered for the treatment of SUI in women with NLUTD. Further studies are required to define which patients would more likely benefit from this intervention, as well as its place among the other surgical treatments for SUI.

Introduction

Neurological diseases may lead to various patterns of lower urinary tract dysfunction, depending on the site and type of the lesion (1). The International Continence Society define the Adult Neurogenic Lower Urinary Tract Dysfunction (ANLUTD) as follows: "ANLUTD refers to abnormal or difficult function of the bladder or urethra in mature individuals in the context of clinically confirmed relevant neurologic disorder" (2). Among these dysfunctions, stress urinary incontinence (SUI) is defined as a "complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing" (2). SUI can be the consequence of a sphincter or pelvic floor muscle weakness caused by the neurological disease itself, especially in case of sacral spinal cord or infrasacral (cauda equina and peripheral nerves) lesions, leading to intrinsic sphincter deficiency (2) and is referred as neurogenic SUI (nSUI). SUI can also be due to sphincter injury as the result of prolonged urethral indwelling catheterisation or previous interventions. It can also arise from non-neurogenic causes such as urethral hypermobility, or a combination of those aetiologies (3). Due to the diverse spectrum of clinical conditions applying to women with NLUTD, prevalence of SUI in this population is not known. A prevalence of 49% of any kind of urinary incontinence has been reported in a population of women with spinal cord injury and was associated with decreased quality of life (4).

Although synthetic mid-urethral sling (sMUS) insertion is the most frequently performed anti-incontinence surgery in non-neurological women, owing to its good results and low morbidity (5), its use to treat SUI in women with NLUTD is currently not recommended. However, the European Association of Urology (EAU) and The International Consultation on Continence (ICI) consider sMUS as an option (3, 6).

No systematic review has yet focused on the results of sMUS in women with neurological diseases. The aim of our study was to evaluate the efficiency and safety of sMUS for the treatment of SUI in women with NLUTD.

Methods

Protocol and registration

The study protocol was registered (CRD42019134339) and published on PROSPERO (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) statement (7).

Information sources and search

A systematic review was conducted on MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials and Controlled Database of Systematic Records (CENTRAL) from January, 1995 (date of first description of sMUS implantation by U. Ulmstem) to March, 2021. Articles in English or French were considered. Duplicates were removed.

Eligibility criteria and study selection

Titles and abstracts were screened, and all relevant studies were reviewed in full text to identify those that met the inclusion criteria. Inclusion criteria were placebo-controlled randomised trials, meta-analysis, systematic reviews, cohort studies, case series, and retrospective studies evaluating sMUS implantation to treat SUI. The success of sMUS implantation had to be the primary outcome. Subjects were women with NLUTD. Studies including women with and without NLUTD were included only if results for women with NLUTD were reported separately. Studies including male and female patients, or female adult and children patients were included only if results for adult women with NLUTD were reported separately. Screening of articles was performed by 2 reviewers (CS and MB). Corresponding authors of the screened articles were contacted if precisions were needed regarding outcomes of interest. Discrepancy between the two authors was resolved by discussion or by consulting a third reviewer (GF or MAPV).

Data collection process

CS extracted data from the included publications using a standardized data extraction form. The primary outcome was the success rate of sMUS according to the definition used by each study. Secondary outcomes were complications after sMUS implantation. De novo urgency symptoms were defined as the description of urgency in women who had never experienced urgency before surgery. Urinary retention was the description of the inability to properly empty the bladder (2). Instauration of catheterisation due to urinary retention was also noted. Tape exposure was the description of any unusual tape display (8). Pelvic organ perforation was the description of any abnormal opening into hollow organ or viscus (8). Revision for complication was the necessity to perform a new intervention due to a complication. Description of any other complication with non-standardized term was extracted.

Intervention was detailed in terms of sling route (retropubic, transobturator or single-incision) and tension applicated on the string, when available. The population included in each study was described with their mean age, neurological disease, urodynamic observation, and pre-operative voiding mode. The types of neurogenic lesions were defined as Suprapontine Lesion (SPL), Suprasacral spinal cord/pontine lesion (SSL), Sacral spinal cord lesion, cauda equina and peripheral nerves lesion (SSCL/CEPNL) according to ICS standardized adult NLUTD clinical diagnoses (2). Length of follow-up in each study was defined as short-term, medium-term and long-term follow-up if median follow-up was below one year, from one to five years and above five years, respectively (5).

Risk of bias and quality assessment

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) 22-item checklist was used to assess the quality of observational and non-randomized studies (9). As we included only single-group before-after studies, we could not use the Cochrane risk of bias assessment tools. A list of the main confounders for surgical interventions for SUI in adult neuro-urological patients was developed previously and included age, mixed versus stress

urinary incontinence, underlying neuro-urological disease, perineal sensation, previous treatment for SUI and previous pelvic surgery (10). For each study, we considered whether each confounder was considered and whether, if necessary, the confounder was controlled for in the analysis. The risk of bias was high if the confounder had not been considered and was imbalanced between patients or not corrected during analysis (11). The risk of bias summary and graph were computed in Review Manager 5.2 (Informatics and Knowledge Management Department, Cochrane, London, UK). Quality and risk of bias assessments were performed independently by 2 reviewers (CS and MB) and discrepancy between the two authors was resolved by discussion or by consulting a third reviewer (GF or MAPV).

Statistical Analysis

Percentages were calculated for each study by dividing the number of patients eligible for each outcome measure by the number of patients who completed the last follow-up assessment. Results for comparable variables (age, length of follow-up, standardized complications) were reported using mean or median rates and ranges. Results on success were reported narratively as we anticipated the definition of success to be different in most studies.

Results

Study selection

The literature search was carried out in October, 2020 and actualised until April 2021. The search strategy and flow diagram are presented in **Figure 1**. Overall, 1047 citations were identified, 752 titles and abstracts were considered for inclusion, 189 full texts were read and 9 studies (12-20) were included.

Study characteristics, quality of studies and risk of bias assessment (**Table 1, Figure 2**). The characteristics of the studies included are presented in **Table 1**. There were 8 observational before-after studies (12, 13, 15-20) and 1 non-randomized pilot trial (14), for which only one of the two groups of patients were considered. Overall, the studies were of medium quality according to the STROBE checklist. Two studies satisfied the majority of items on the checklist and were considered to be of high quality (14, 15). One study satisfied the lowest number of checklist items and was deemed to be of lower quality than the other studies (17). Risk of bias assessment revealed moderate or high risk of bias (**Figure 2**).

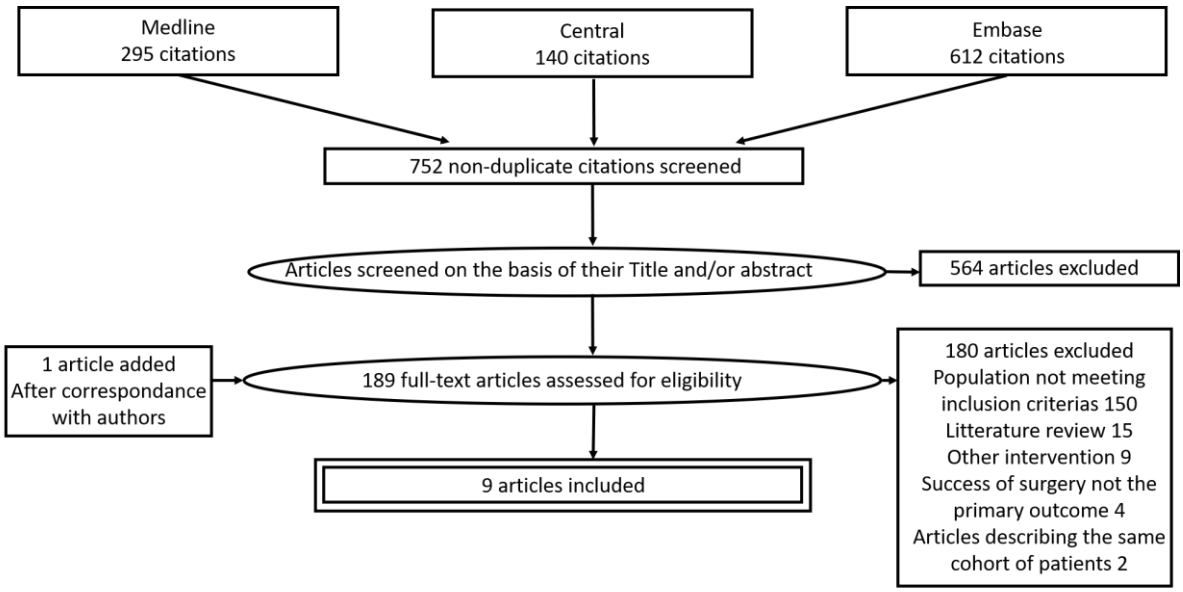


Figure 1: PRISMA flow diagram of identified, excluded, and included studies.

Authors (reference)	Study design	Level of evidence	Median follow-up duration (months)	Number of patients	Sling route	Age, mean (years)	Neurologic disease, n	Level of injury n	Urodyamic observation, n	Treatment for NDO, n	Pre-operative voiding mode, n
ABDUL-RAHMAN 2009 (12)	Before-after	4	111	12	Retropubic 12	53	Disc surgery 6 SCI 3 Spinal stenosis 3	SSCL/ CEPNL 9 SSL 3	NDU 11 NDO 1	Anticholinergics 1	ISC 9 No catheterisation 3
CHEN 2019 (13)	Before-after	4	All patients were followed up to 12 months	34	Retropubic and Transobturator,	NR Mean age of the whole cohort (NU and non-NU patients) 65	Radical pelvic surgery +/- pelvic radiotherapy 20 Pelvic RT alone 5 SCI 9	SSCL/ CEPNL 25 NR 9	NDU 34	NA	No catheterisation 34
EL-AZAB 2014 (14)	Non-randomised uncontrolled trial	2b	36	20	Retropubic 20	34	SCI 16 MMC 3 Spinal tumour 1	SSCL/ CEPNL 20	NDO 13	Anticholinergics 13	ISC 5 No catheterisation 15
HOLDØ 2019 (15)	Before-After	4	52.8	54	Retropubic 54	57	Intracranial 28 Intraspinal 20 Peripheral nerves 6	SPL 28 SSCL/ CEPNL 6 NR 20	NDU 13	NA	No catheterisation 54
LOSCO 2015 (16)	Before-after	4	67.2	27	Transobturator 27	56	SCI 27	SSL 16 SSCL/ CEPNL 11	NDO 6 LOC 4	Detrusor injection of botulinum toxin 6	ISC 11 IC 11 No catheterisation 5
PANNEK 2012 (17)	Before-after	4	6.8	9	Transobturator 9	45	SCI 9	SSL 8 SSCL/ CEPNL 1	NDO 7 NDU 2	Detrusor injection of botulinum toxin 3 Augmentation cystoplasty 3 Sacral deafferentation 1	ISC 7 IC 1 No catheterisation 1
PATKI 2009 (18)	Before-after	4	20	9	Retropubic 3 Transobturator 6	54	SCI 9	SSL 9	NDO 9 LOC 1	Detrusor injection of botulinum toxin 9	ISC 8 IC 1

SAKALIS 2018 (19)	Before-after	4	44.5	38	Retropubic 21 Transobturator 11 Single-incision 5	56	SCI 38	SSL 38	NDO 21 LOC 6	Detrusor injection of botulinum toxin 21	ISC 12 IC 22 No catheterisation 4
SHIN 2020 (20)	Before-after	4	NR Median follow-up of the whole cohort (NLUTD and non-NLUTD patients) 49.8	95	Transobturator 95	63	Cerebrovascular accident 38 Intervertebral Hernia 18 Spinal Stenosis 13 Parkinson's disease 10 Brain tumor 5 Other 2 NR 9	SPL 53 SSCL/ CEPNL 33 NR 9	NDO 56	NR 28	No catheterisation 95

Table 1: Characteristics of the included studies. *IC: Indwelling Catheterisation ; ISC: Intermittent Self-Catheterisation ; LOC: Loss of Compliance ; MMC : Meningomyelocele ; NDO: Neurogenic Detrusor Overactivity; NDU: Neurogenic Detrusor Underactivity ; NLUTD : Neurogenic Lower Urinary Tract Dysfunction ; NR : Not Reported ; RT : Radiotherapy ; SCI: Spinal Cord Injury; SPL: Supra-pontine Lesion; SSL: Pontine/Suprasacral spinal cord lesion; SSCL/CEPNL: Sacral spinal cord lesion or Cauda Equina and Peripheral Nerves Lesion.*

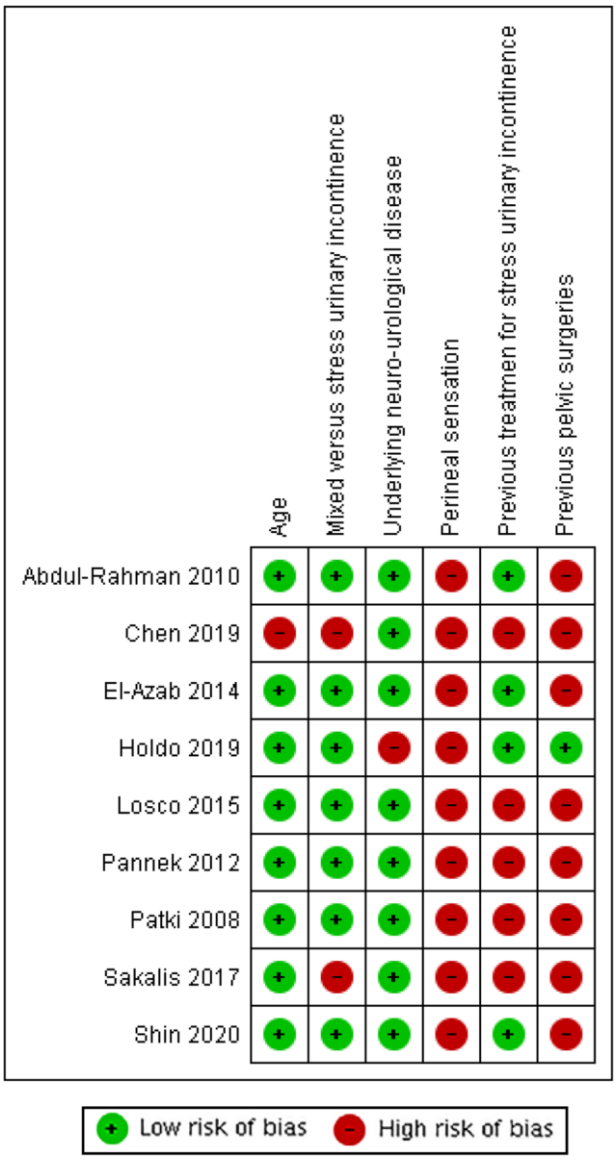


Figure 2: Risk of bias summary: review authors' judgements about each risk of bias item for each study included

Participants

The 9 studies reviewed included 298 patients. Mean age was 52 years old (range 18-88 years old). Neurological disease was available for 235 patients (78.9%). The most common neurological disease was spinal cord injury in 111 (47.2%) cases, followed by cerebrovascular accidents and intervertebral disc hernia in 38 (16.2%) and 24 (10.2%) patients, respectively. The type of neurological lesion could reliably be defined for 260 patients (87.2%). It was SPL for 81 (35.2%), SSL for 74 (23.1%) and SSPL/CEPNL in 105 (41.7%). Preoperative neurogenic detrusor overactivity (NDO) was reported in 113 patients (39%), for which at least 85 (75%) patients received specific treatment. It was a detrusor injection of botulinum toxin and anticholinergics in 39 (45.9%) and 14 (16.5%) patients, respectively. NDO medication was not reported for 28 patients (32.9%). 4 (4.7%) patients had surgical treatment for NDO, 3 (3.5%) augmentation cystoplasty and 1 (1.2%) sacral deafferentation. Other urodynamic observations were neurogenic detrusor underactivity (NDU) in 60 (13%) and low compliance in 11 patients (3.7%). Before sMUS insertion, 211 (70.8%) voided without bladder catheterisation (spontaneous voiding), 52 (17.4%) required intermittent self-catheterisation (ISC) and 35 (11.7%) had indwelling catheters. Voiding mode according to level of injury could

be assessed for 251 patients. 81 (100%) patients with SPL voided spontaneously. Among SSL patients, 5 (7.5%) voided spontaneously, 28 (42.5%) voided with ISC and 33 (50%) had indwelling catheter. For patients with SSPL/CEPNL, 86 (82.7%) voided spontaneously, 17 (16.3%) with ISC and 1 (1%) had indwelling catheter (**Annexe 1**).

The median follow-up length was 41.3 months (range 6.8-111). Most of the studies (14, 15, 16, 19, 20) had a medium-term follow-up. One study had a short-term follow-up (18) and two studies had long-term follow-up (13, 17).

Intervention

The sling route could reliably be extracted for 254 patients (88%): it was retropubic for 110 (43.3%) and transobturator for 139 (54.7%). A single incision sMUS was implanted in 5 (2%) patients. Five studies (12, 13, 14, 16, 19) reported an increased tightening of the tape during the implantation compared to the standard surgical technique in non-NLUTD patients.

The success of sMUS implantation is shown in **Table 2**.

Using the definition of success defined by each study (see details in **Table 2**), sMUS insertion was successful in 237 patients (79.5%). Five studies reported a success rate of at least 80% (range 33-100%). The success rate ranged from 52.4 to 100% and from 33 to 100% in patients who had their sMUS implanted using retropubic and transobturator route, respectively. Success rates seemed comparable between transobturator and retropubic route (**Annexe 2**) and irrespective of the type of lesion (**Annexe 3**).

Complications

Median de novo urgency rate was 15.7%, (range 8.3-30%). Anticholinergic medications or detrusor injection of botulinum toxin resolved urgencies in all cases.

Out of 211 patients who were in spontaneous voiding before surgery, 26 (12.3%) presented with postoperative urinary retention. Median urinary retention rate was 19.3% (range

0-46.7%). Urinary retention was managed with introduction of ISC in 21 patients (81%). 19 (90.4%) had SSCL/CEPNL, 1 (1.8%) had SPL and level of injury could not be defined for the other 1 patient. Five patients required secondary surgery to release the tension of the tape which solved urinary retention in all cases. Two of those patients had SPL, the level of injury could not reliably be assessed for the other 3 patients (**Annexe 4**)

Among the 52 patients who already performed ISC before the intervention, no de novo difficulty to perform ISC after sMUS implantation was reported.

Tape exposure was reported in 4 cases (range 0-11%). Two were vaginal exposure, 1 was urethral and for the last site of exposure was not reported. Management of tape exposure consisted of complete tape removal for vaginal erosion in 1, urinary diversion for urethral erosion and vesico-vaginal fistula in another and was not reported in the other 2 cases.

Three cases of pelvic organ perforation were reported, (range 0-9.1%). In all cases it was a bladder perforation following RP-sMUS insertion. Three cases of transient thigh pain were reported after TO-sMUS, 2 resolved at three days and 1 at six months.

Eight patients had tape revision for complications (range 0-11.1%), 5 had tape release for urinary retention, 1 had tape removal for erosion, 1 had urinary diversion for erosion, and 1 had tape removal for frequent autonomic dysreflexia episodes.

Complication rate did not seem to differ with sling route nor type of neurological lesion (**Annexe 3 and 4**).

Reference	Definition of success	Success rate
Study evaluating retropubic route only		
Abdul-Rahman 2009 (12)	Completely dry, no pads	9/12 (75 %)
El-Azab 2014 (14)	Negative cough stress test and no leakage during physical examination	16/20 (80 %)
Holdø 2019 (15)	No recurrence of UI during follow-up. Recurrence of UI defined as the presence of any bothersome symptoms of SUI reported by the patient and/or by a stress urinary incontinence index score > 0 indicative of bothersome symptoms of SUI on a validated questionnaire and/or a positive standardized stress test at follow up.	46/54 (85.2 %)
Study evaluating transobturator route only		
Losco 2015 (16)	No pads at last follow-up	22/27 (81.5 %)
Pannek 2012 (17)	No use of any pads (continent), pad use reduced by 50% (improved).	3/9 (33 %)
Shin 2020 (20)	No patient-reported SUI and no pad usage due to SUI	86/95 (93.7 %)
Study evaluating both route		
Chen 2019 (13)	Improved incontinence, indicating patients who became dry or had marked improvement of SUI based on the reported changes of the urine leakage severity from baseline to the postoperative condition at 12 months. Urine leakage severity was classified according to patients' subjective grading as mild, moderate and severe	Overall 26/34 (76.4 %)
Patki 2009 (18)	Patient satisfied with the procedure and no demonstrable incontinence associated with either NDO or stress on the VUDS during follow-up	Overall 9/9 (100 %) RP 3/3 (100 %) TO 6/6 (100 %)
Sakalis 2018 (19)	Use of none or a single safety pad per 24 hours at 1 year	Overall 20/37 (52.6 %) RP 11/21 (54.5 %) TO 6/12 (50 %) SI 3/5 (60 %)
Total		**237/298 (79.5 %)**

Table 2: Results on success of sMUS implantation *NDO: Neurogenic Detrusor Overactivity ; NR: Not Reported ; UI: Urinary Incontinence ; SUI: Stress Urinary Incontinence ; VUDS : Video-Urodynamics Studies ; NR: Not Reported*

.	de novo Urgency	Urinary retention among patients who voided without catheterization	Pelvic organ perforation	Tape Exposure	Other	Sling revision for complication
Study evaluating retropubic route only						
Abdul-Rahman 2009 (12)	1/11 (9.1 %) 1 treated with anticholinergics	0/3	1/12 (9.1 %) Bladder perforation	0	0	0
El-Azab 2014 (14)	6/20 (30 %) 6 treated with anticholinergics	7/15 (46.7 %) 7 (100 %) requiring definitive ISC	0	1/20 (5 %)	0	0
Holdø 2019 (15)	7/31 (22.6 %) Treatment not reported	5/54 (9.3 %) 2 (40 %) requiring definitive ISC	2/54 (3.7 %) Bladder perforation	0	Hematoma 2/54 (3.7 %)	3/54 (5.6 %) 3 tape releases for urinary retention
Study evaluating transobturator route only						
Losco 2015 (16)	2/24 (8.3 %) 2 treated with detrusor injection of botulinum toxin	2/5 (40 %) 2 (100 %) requiring definitive ISC	0	0	Tigh pain 3/27 (11.1 %) 2 resolved at 3 days 1 resolved at 6 months	0
Pannek 2012 (17)	NR	0/1 (0 %)	0	1/9 (11.1 %)	0	1/9 (11.1 %) urinary diversion for erosion
Shin 2020 (20)	4/22 (18.2 %) Medical treatment not reported	2/95 (2.3 %) 0 requiring definitive ISC	0	1/95 (1.1 %)	0	2/95 (2.3 %) 2 tape release for urinary retention
Study evaluating both route						
Chen 2019 (13)	NR	10/34 (29.4 %) 10 (100 %) requiring definitive ISC	NR	NR	NR	NR
Patki 2009 (18)	NA (all patients had urgencies before intervention)	NA (all patients were on ISC or IC)	0	0	0	0
Sakalis 2018 (19)	5/38 (13.2 %) 3/21 (14.3 %) after RP-sMUS 2/12 (18.1 %) after TO-sMUS 3 treated with anticholinergics 2 treated with detrusor injection of botulinum toxin	0/4 (0 %)	0	1/38 (2.7 %) After TO-sMUS	1/38 (2.7 %) pelvic hematoma after TVT + SPC 2/38 (5.4 %) vaginal bleeding 1/38 (2.7 %) frequent autonomic dysreflexia episodes after TVT 1/38 (2.7 %) leakage around SPC after TVT	2/38 (7.9 %) 1 tape removal for erosion 1 tape removal for autonomic dysreflexia
Median rate	**15.7 %**	**19.3 %**				

Table 3: Complications after sMUS insertion *NA : Not applicable ; NR : Not Reported ; IC : Indwelling catheter ; ISC : intermittent self-catheterisation; RP Retropubic; TO Transobturator ; sMUS : synthetic Mid-Urethral Sling*

Discussion

This systematic review is, to our knowledge, the first to look at the efficiency and safety of sMUS for the treatment of SUI in women with neurogenic lower urinary tract dysfunction. Five studies reported a success rate of at least 80%, with success rates in individual studies ranging from 33 to 100%.

About half of the patients included in this review had sacral spinal cord or infrasacral lesions leading to lower motor neuron lesion. These lesions classically generate nSUI related to intrinsic sphincter deficiency. Other patients had lesions above sacral spinal cord (upper lower motor lesion). As those patients usually have a preserved innervation of the striated sphincter, SUI is most likely to be due to a "non-neurogenic cause" (i.e. hypermobility) (1).

Finally, in case of extended grey matter lesion of the spinal cord (e.g ischemia), involving the sympathetic thoraco-lumbar centre and the sacral centres, the intrinsic sphincter deficiency can also be associated to bladder neck incompetence.

Although no direct comparison can be made between the different mechanism involved, the good results reported irrespective of the type of neurological lesion suggest that sMUS could be used for treating SUI whatever the level of the lesion, and whatever the theorical presence of intrinsic sphincter deficiency. Success rates did not seem to differ significantly between retropubic or transobturator route either.

Pre-operative evaluation is the key to ensure high success rate and avoid complication. Except for the study by Holdø et al (15), urodynamic studies were always performed and any co-existing finding, such as NDO, was treated to ensure low bladder pressure before surgery. This management is mandatory to ensure post-operative results, by preventing subsequent leakage due to urgency urinary incontinence, and to prevent upper urinary tract deterioration (3, 6).

Urinary retention was a frequently reported complication of sMUS implantation in this population. The rate of voiding dysfunction reached 46.7% with a median rate of 19.3%, higher than the mean incidence of 7.3% in non-neurogenic population (21). After sMUS implantation, even tension-free, obstruction can occur due to an increased bladder outlet resistance related to the tension directly applied against the urethra, as well as a kinking effect on the vaginal wall and proximal urethra cephalad to its placement (22). This increase in bladder outlet resistance, may alter bladder emptying, especially in patient with detrusor underactivity, and trigger the need for bladder catheterisation. In the present review, women with SSPL/CEPNL were more likely to require de novo intermittent self-catheterisation (**Annexe 4**). Therefore, female with NLUTD should always be assessed for their ability to perform ISC before a surgical treatment for SUI, in case of preoperative voiding dysfunction (poor bladder emptying, high post voiding residual, detrusor underactivity). If ISC is not possible, they should be informed of the possibility of temporary indwelling catheterisation or intermittent catheterisation by caregiver and the risk of surgical revision after sMUS insertion.

Another frequent complication was de novo urgency. The median rate was 15.7% (range 8.3-31%) which again seems higher than for non-NLUTD women for whom the mean range is around 10.2% (21). This higher rate could be explained by preoperative NDO or poor bladder compliance, and the evolution of the neurological disease. This could also be due to changes induced by increased bladder outlet resistance. Dave et al showed that NDO or poor compliance could happen after isolated bladder outlet procedures for neurogenic incontinence in children and young adults (23). In this review, de novo urgency was treated conservatively with antimuscarinic agents or detrusor injections of botulinum toxin. This advocates for a prolonged clinical and urodynamic follow-up in NLUTD patients, to treat any new symptom and to detect changes in bladder pressure during filling, in order to protect the upper urinary tract long term.

A concern frequently raised when discussing sMUS implantation in NLUTD patients is the theoretical increased risk of tape erosion. In this review, only 4 cases of tape erosion were reported (range 0-11%). This rate does not seem significantly higher than in non-neurogenic population (21) where the mean incidence is 2.5% (range 0-26%). Pelvic organ perforation was also a rare event, and its frequency did not seem to be increased compared to non-NLUTD patients.

The European Association of Urology and the International Consultation on Continence guidelines both recommends the use of autologous slings or artificial urinary sphincter to treat stress incontinence in women with NLUTD (3, 6).

Autologous slings increase bladder outlet resistance by directly compressing the proximal urethra and bladder neck. This technique has good success rate at mid-term for treating neurogenic incontinence in adult women with a success rate ranging from 72 to 84% (14, 24, 25, 26). Augmentation cystoplasty was frequently performed before or at the time of autologous sling implantation in those series. Catheterisation was almost always necessary after this surgery. De novo urgency was also reported after this procedure with rates ranging from 10 to 13.3% (14, 26).

Artificial urinary sphincter remains the gold standard in case of SUI with intrinsic sphincter deficiency, with good long-term success rates. Costa et al reported 49 out of 54 (90.7%) fully continent women with NLUTD after AUS and a mean follow-up of 9.6 years (27). Phé et al reported a continence rate of 57.7% in 26 neurological females after a mean follow-up of 7.5 years. Fourteen (53.8%) had had at least one previous anti-incontinence surgery, including retropubic sMUS (28). However, these good success rates must be put in balance with the high revision rates. Costa et al reported that presence of neurogenic bladder increased the risk of sphincter revision and explantation (27). Phé et al reported a survival rate of AUS without revision of 51% at 20 years (28).

The success and complication rates of sMUS reported in this review compare favourably with these two treatments, suggesting that sMUS insertion could be an interesting alternative treatment option to treat SUI in selected neurological women with NLUTD. Reducing the need for ISC compared to autologous slings, and representing a mini-invasive first-line treatment before considering artificial urinary sphincter placement. However, no conclusion can be drawn in the absence of randomized controlled trial comparing those surgical treatment.

We must acknowledge limitations of the present review. Studies included were of medium quality and presented with a moderate to high risk of bias. The analysis and conclusions of this review are therefore limited by the quality of included studies.

Each study used a different definition of success, which is consistent with the review of Reuvers et al. The authors found considerable heterogeneity in outcome parameters and definitions of cure used to report outcomes of surgical interventions for SUI in neurological patients (10). It was not possible to pool the primary outcome in unified systematic meta-analysis.

As we did not have access to most individual patient data, we were not able to describe predictive factors of success or failure for sMUS insertion in this population. Efficiency of mid-urethral slings in patients without neurologic disease is mainly associated with the presence of urethral hypermobility (29, 30). As the presence of urethral hypermobility was rarely mentioned in the studies included, we were not able to verify this hypothesis in this review as well. Moreover, maximum urethral pressure closure (MUCP) was not known, and it would have been interesting to know its impact on success rate. Underlying mechanisms of SUI were not reported and it was therefore not possible to assess if outcomes differed between SUI related to urethral hypermobility or intrinsic sphincter deficiency. We also lacked sufficient data to conclude on adequate tape tension.

Success rate was a short or medium-term outcome measure in most studies. We know from studies including non-neurogenic patients that longer-term subjective success rates (at 5 years follow-up) can be inferior to short- and medium-term rates (5). The nature of studies included in this review, with inconstant reporting of co-interventions and confounding factors, could also lead to an overestimation of the efficiency of synthetic mid-urethral slings. Similarly, the definition of complications was frequently missing. As stated by Blaivas et al., under-reporting of adverse events in studies assessing the efficiency and safety of mid-urethral slings was frequent (21). It is therefore not unlikely for the complication rates reported here to be underestimated.

Conclusion

The insertion of sMUS results in interesting short to medium-term success rates for the treatment of SUI in women with neurogenic lower urinary tract dysfunction. Although more frequent than among women without NLUTD, complications were infrequent and could be managed conservatively most of the time. We outline the importance of detecting and monitoring high bladder pressures and informing the patient of a higher risk of post-operative catheterisation. Further work is needed to define predictive factors of success and the need for ISC, improve patient selection and refine the place of sMUS among other surgical options. Future studies should focus on using more standardised outcome measures and an improved reporting of potential confounding factors.

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Original article

Synthetic mid-urethral sling for the treatment of stress urinary incontinence in women with neurogenic lower urinary tract dysfunction: results of a multicentric retrospective study

Introduction

Neurological diseases may lead to various patterns of lower urinary tract dysfunction, depending on the site and type of the lesion (1). The international Continence Society defined the Adult Neurogenic Lower Urinary Tract Dysfunction (ANLUTD) as follows: "ANLUTD refers to abnormal or difficult function of the bladder or urethra in mature individuals in the context of clinically confirmed relevant neurologic disorder" (2). Among these dysfunctions, stress urinary incontinence (SUI) is defined as a "complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing" (2). In women with NLUTD, SUI can be the consequence of intrinsic sphincter deficiency caused by the neurological disease itself. SUI can also be due to direct sphincter injury as the result of prolonged urethral indwelling catheterisation or previous interventions. It can also arise from "non-neurogenic" causes such as urethral hypermobility, or a combination of those aetiologies (3). Given to the diverse spectrum of clinical conditions applying to women with NLUTD, prevalence of SUI in this population is not known. A prevalence of 49% of any kind of urinary incontinence has been reported in a population of women with spinal cord injury and was associated with decreased quality of life (4). In a population of spina bifida patients mostly constituted of women, urinary incontinence was reported in 75% of cases and health related quality of life was lower with increased amounts of urinary incontinence (5). Although synthetic mid-urethral sling (sMUS) insertion is the most frequently performed anti-incontinence surgery in non-neurological women owing to its good results and low morbidity (6), its use to treat SUI in women with NLUTD is currently not recommended. Autologous fascial slings or artificial

urinary sphincter are preferred. However, the European Association of Urology (EAU) and The International Consultation on Continence (ICI) consider sMUS as an option (3, 7).

We recently published a systematic review of the literature on the results of sMUS for the treatment of SUI in women with NLUTD. Insertion of sMUS resulted in interesting short to medium-term success rates and complications were infrequent and could be managed conservatively most of the time (8). However, we could not define which patients would more likely benefit from this intervention.

The aim of the current study was to assess the efficacy and safety of sMUS for the treatment of SUI in a large cohort of women with NLUTD and to identify predictive factors for success, failure, and complications.

Methods

The STROBE checklist was used in designing and reporting this study (9). This study was an uncontrolled retrospective cohort study conducted in three tertiary referral centres in France. We screened medical records of all patients who had an implantation of sMUS for SUI in these 3 high-volume French centres (Grenoble University Hospital from 01/2007 to 07/2020, Nantes University Hospital from 01/2004 to 07/2020 and Lyon-Sud Hospital from 01/2009 to 07/2020).

Inclusion criteria were women aged 18 years old or older, who had a clinically confirmed relevant neurologic disorder diagnosed before the intervention. Exclusion criteria were previous implantation of sMUS before the study period or before the neurologic disorder diagnosis; concomitant prolapse surgery; follow-up of less than 1 year or no baseline urodynamic assessment.

The types of lesions were defined as suprapontine lesion (SPL), suprasacral spinal cord/pontine lesion (SSL), sacral spinal cord lesion, cauda equina or peripheral nerve lesion (SSCL/CEPNL) according to ICS standardised adult NLUTD clinical diagnoses (2). Patterns

of NLUTD associated with each type of lesion is summarised in **Annexe 5**. All patients had a preoperative evaluation which included medical history and physical examination in lithotomy position. Urethral support manoeuvres were considered negative if they did not prevent urine leakage during a cough stress test or if they were not described. All women had urodynamic studies (UDS) including uroflowmetry, urethral pressure profile, filling cystometry using a standardised protocol in accordance with the good urodynamic practice guidelines of the International Continence Society (10). Low compliance was defined as bladder compliance ≤25 cmH2O (11); low maximal urethral closure pressure (MUCP) was defined as MUCP ≤30 cmH_2O (12). Patients with spontaneous voiding and presenting post-void residual >100 mL were taught intermittent catheterisation (IC) before the intervention. Any patient presenting with neurogenic detrusor overactivity (NDO) was treated with antimuscarinics or detrusor injections of botulinum toxin or with augmentation cystoplasty, prior to surgery. Surgery to insert the sMUS was carried out under general or spinal anaesthesia in accordance with the anaesthesiologic requirements and/or the patient's preference. The sMUS was a TVT (Tensionfree Vaginal Tape) (GYNECARE TVT™ Retropubic System Tension-Free) or a TOT (Transobturator Tape) (Monarch™) based on surgeon's preference. All sMUS were implanted in accordance with the standard technique (13, 14) and positioned tension-free beneath the urethra. Follow-up was carried out based on each institution protocol. Clinical and follow-up data were abstracted from patients' medical records and/or collected by telephone calls, in agreement with the institution's routine, if datas were missing.

Primary outcome was the failure of sMUS, defined by recurrence of SUI during follow-up. Recurrence of SUI was defined as the report of involuntary loss of urine on effort or physical exertion by the patient during follow-up. Secondary outcomes to assess sMUS efficacy were standardised questionnaire among patients who did not have reoperation for SUI during follow-up.

We recorded complete continence, defined as the reported “dry” status by the patient. Satisfaction was assessed using the patient global impression of improvement (PGI-I) (15), the patient was considered satisfied when she had PGI-I score ≤2. Subjects' quality of life after surgery was assessed using the question 3 of ICIQ-SF (“overall, how much does leaking urine interfere with your everyday life?”) with a discomfort score related to urinary incontinence rated from 0 (not at all) to 10 (a great deal) (16).

Secondary outcomes also included complications after sMUS implantation occurring during follow-up, in order to assess sMUS safety. De novo overactive bladder (OAB) syndrome was defined as the description of urgency/frequency and/or urgency urinary incontinence in women who had never experienced these symptoms before surgery. Urodynamic changes after sMUS implantation were assessed for patients who had at least one UDS after sMUS implantation. De novo NDO or de novo low compliance was the appearance of NDO or low compliance on a postoperative UDS for patients who did not have such observations on their preoperative UDS. Change in cystometric capacity, bladder compliance or MUCP was assessed by comparing preoperative values with values on last UDS available for each patient. Urinary retention was the description of the inability to properly empty the bladder (2). The International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery was used to standardise the documentation of each complication (17). This category–time–site (CTS) system describes a complication according to its anatomical site and severity (category), the timing of clinical diagnosis (time), and current sites affected (site). **Annexe 6** explains how the classification summarises any of a large range of possible clinical scenarios into a code. sMUS exposure was the description of any unusual sMUS display. Pelvic organ perforation was the description of any abnormal opening into hollow organs or viscus. Revision for complication was the necessity to perform a new operation because of a complication.

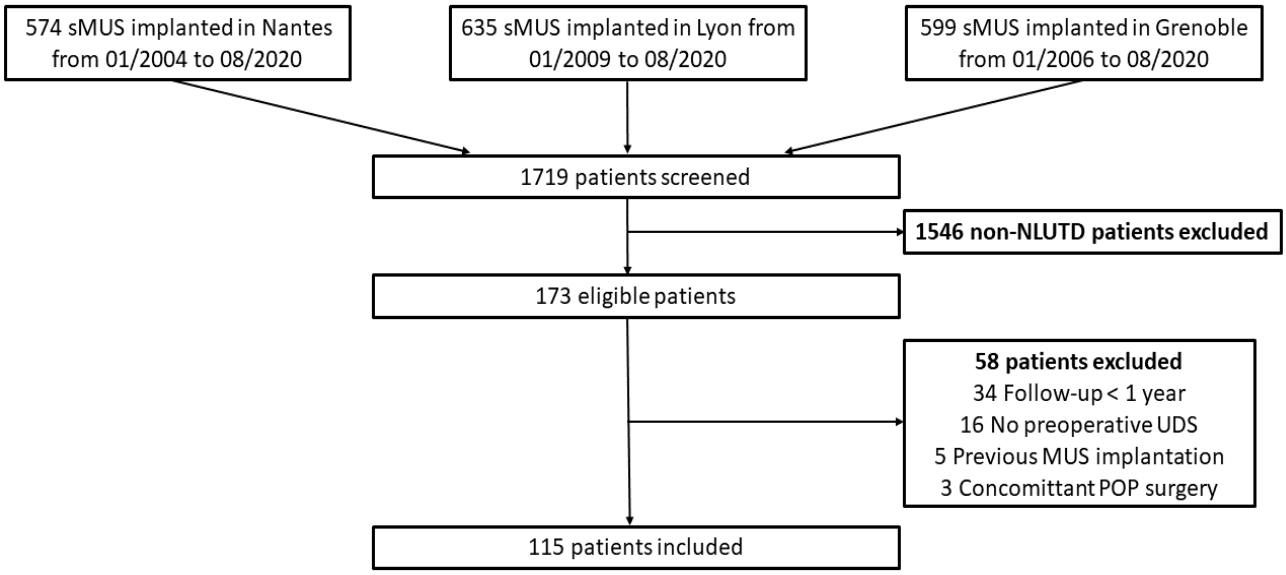
Statistical analysis

The analyses were carried out on the website https://www.pvalue.io. Percentages were calculated by dividing the number of patients eligible for each outcome measure by the number of patients who completed the last follow-up assessment. Continuous variables were reported as median and interquartile range (IQR). Kaplan-Meier survival curves were used to calculate risk factors for recurrence. To minimise the risk of bias, patients with gap of more than 2 years in their follow-up were excluded from the survival analysis. A list of the main confounders for surgical interventions for SUI in adult neuro-urological patients, including age, mixed urinary incontinence versus SUI, underlying neuro-urological disease, perineal sensation, previous treatment for SUI and previous pelvic surgery was developed previously and included in the analysis (18). The Cox proportional hazards model was used for univariate analysis to evaluate factors potentially affecting the risk of recurrence. All the covariates presenting significant correlation or a tendency towards association ($p<0.20$) in univariable analysis with the outcomes of interest (SUI recurrence) were entered into the multivariate analysis using the Cox proportional hazard model to select independent predictors. The log-rank test was used to compare survival curves of covariates associated with SUI recurrence in univariable analysis. Finally, univariate and multivariate analyses were performed to investigate factors affecting the risk of de novo OAB development. All the covariates presenting significant correlation or a tendency towards association ($p<0.10$) in univariable analysis were entered into the multivariate model using a logistic regression to select independent predictors. Continuous urodynamic variables were summarised as means and standard deviation. Differences between preoperative and postoperative values were assessed using paired student t test. Statistical significance was considered achieved when $p<0.05$.

Results

1719 patients were implanted with a mid-urethral sling during the study period, among whom 173 had neurogenic lower urinary tract dysfunction and were considered for inclusion. 58 were excluded and 115 patients were included for the analysis. **Figure 1** displays the study's flowchart.

Figure 1: Study's flowchart



Baseline clinical characteristics of the study participants are summarised in **Table 1**. Baseline urodynamic observations are shown in **Table 2.**

The most common neurological background was spine surgery in 37 (32.2%) cases, followed by spinal cord injury and cerebrovascular accidents in 23 (20%) and 12 (10.4%) patients, respectively. Details on neurological disease or background are available in **Annexe 7**.

Table 1 – Baseline clinical characteristics

Characteristics	n = 115
Age, median (IQR)	53 (46-64)
Site of lesion	
SPL	23 (20)
SSL	30 (26.1)
SSPL/CEPNL	62 (53.9)
BMI, median (IQR)	26 (22.6-30.1)
BMI ≥30 kg/m²	30 (26.1)
Smoking habits	23 (20)
Vaginal delivery, median (IQR)	2 (0-2)
Vaginal delivery ≥2	63 (54.8)
Charlson score, median (IQR)	2 (1-3)
Wheelchair-bound	19 (16.5)
Previous surgery for SUI	7 (6.1)
Previous pelvic surgery	38 (33)
Pre-operative voiding mode	
Spontaneous voiding	69 (60)
Intermittent catheterisation	46 (40)
Urological medications	
Antimuscarinics	47 (40.9)
Detrusor injection of botulinum toxin	16 (13.4)
Pure Stress Urinary Incontinence (SUI)	52 (45.2)
Mixed Urinary Incontinence (MUI)	63 (54.8)
Positive urethral support manoeuvres	87 (75.6)
Altered perineal sensation	42 (36.5)
Sling route	
Retropubic	72 (62.6)
Transobturator	43 (37.4)

BMI = body-mass index; SPL = supra-pontine lesion; SSL = supra-sacral spinal cord lesion; SSPL/CEPNL = sacral spinal cord lesion or cauda equina or peripheral nerves lesion; IQR = interquartile range

Table 2 – Baseline urodynamics observations

Urodynamic observation	n=115
Cystometric capacity, mL, mean ±SD	413 ±127
MUCP, mean ±SD	48 ±22
MUCP ≤30 cmH_2O, n (%)	29 (25.2)
Compliance, mL/cmH_2O, mean ±SD	92 ±91
Low compliance ≤25 mL/cmH_2O, n (%)	9 (7.8)
Neurogenic detrusor overactivity, n (%)	31 (27)

SD= standard deviation; MUCP= maximal urethral closure pressure

Results on primary outcome (**Table 3**)

Median follow-up was 56 months (IQR 34-104 months). Fifty-eight patients (50%) had a recurrence of SUI or had a reoperation for SUI during follow-up. Thirty-two patients were lost to follow-up more than 2 years, 83 patients were included in survival analysis.

Table 3 reports univariable and multivariable analyses of all factors potentially involved in the risk of SUI recurrence during the follow-up. age <50 years, Vaginal delivery ≥2, positive urethral support manoeuvres, history of NDO, transobturator (TO) route, were associated with recurrent SUI in univariable analyses ($p < 0.2$ for all). Survival curves of covariates associates with SUI recurrence in univariable analyses are available in **Annexe 8**.

On multivariable analysis, age <50 years, Vaginal delivery ≥2, positive urethral support manoeuvres were independent protective factors against SUI recurrence (HR: 0.3 $p<0.01$; HR: 0.5 $p=0.043$ and HR: 0.5 $p=0.043$, respectively). TO route was an independent risk factor for SUI recurrence (HR: 2.1 $p=0.029$).

Results on secondary outcomes

Ninety-two patients did not have a reoperation for SUI recurrence and were eligible for efficacy analysis. Answers to the questionnaires were available for seventy-two patients (78.2%) (**Table 4**). Among them, 28 patients (38.9%) had SUI recurrence. Complete continence was achieved for 35 patients (48.6%). Fifty-five patients (76.4%) felt improved or very much improved compared to the situation before the intervention and were considered satisfied. Median discomfort score related to urinary incontinence (ICIQ-SF question 3) was 3/10, with 47 patients (65.3%) grading their bother below 5. For patients who had SUI recurrence, 13 (46.4%) were satisfied, median discomfort score was 5. Results of questionnaire are available in **Table 4**.

Table 3 - Uni- and multivariable analyses of variables potentially involved in the risk of failure of sMUS

	Univariable analysis[a]		Multivariable analysis[b]	
Variable	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value
Age <50 yr	**0.4 (0.2-0.9)**	**0.019**	**0.3 (0.2-0.7)**	**<0.01**
Type of neurogenic lesion, all classes combined		0.3	-	
SSL VS SPL	0.6 (0.2-1.3)	0.2		
SSPL/CEPNL VS SPL	0.5 (0.2-1.2)	0.12		
BMI ≥30 kg/m²	0.8 (0.4-1.7)	0.61	-	
Vaginal delivery ≥2	0.6 (0.3-1.2)	0.14	**0.5 (0.3-0.98)**	**0.043**
Wheelchair	0.6 (0.3-1.3)	0.2	-	
IC	0.7 (0.4-1.4)	0.4	-	
Previous pelvic surgery	1.1 (0.6-2.3)	0.68	-	
MUI	1.1 (0.6-2.1)	0.76	-	
Positive urethral support manoeuvres	0.6 (0.3-1.1)	0.083	**0.5 (0.2-0.98)**	**0.043**
Preserved perineal sensation	1.3 (0.7-2.6)	0.36	-	
MUCP ≤30 cmH_2O	1.4 (0.7-2.8)	0.26	-	
Compliance ≤25 cmH_2O	0.5 (0.2-1.7)	0.3	-	
History of NDO	0.5 (0.2-1.02)	0.056	0.6 (0.3-1.3)	0.21
TO route	**1.9 (1.01-3.7)**	**0.047**	**2.1 (1.1-4)**	**0.029**

CI = confidence interval; SPL = supra-pontine lesion; SSL = supra-sacral spinal cord lesion; SSPL/CEPNL = sacral spinal cord lesion or cauda equina or peripheral nerves lesion; BMI = body mass index; IC = intermittent catheterisation; NDO = neurogenic detrusor overactivity; MUI = mixed urinary incontinence; MUCP = maximal urethral closure pressure; TO = trans-obturator
***a**: Univariate Cox proportional hazard model **b:** Cox proportional hazard model*

Table 4 – Answers to standardised questionnaires

Score	n = 72
Reported "dry" status – n (%)	35 (48.6%)
Patient Global Impression of Improvement – n (%)	
1 or 2 (satisfied)	55 (76.4)
≥3	17 (23.6)
ICIQ-SF Question 3, median (IQR)	3 (0-5.25)
Score	Patients with SUI recurrence (n=28)
Patient Global Impression of Improvement – n (%)	
1 or 2 (satisfied)	13 (46.4)
≥3	15 (53.6)
ICIQ-SF Question 3, median (IQR)	5 (3-7.25)

ICIQ-SF = International consultation on incontinence questionnaire-short form; IQR = interquartile range

Results on complications (Table 5)

Twenty-five of the 52 patients (48%) who had pure SUI preoperatively presented de novo OAB. Obesity and TO route showed a trend toward association with de novo OAB symptoms on univariable analysis ($p<0.1$ for each). On multivariable analysis, no risk factor of de novo OAB symptoms were found (**Table 5**). De novo OAB symptoms were managed conservatively in all cases with antimuscarinic drugs alone (5 patients), tibial nerve stimulation alone (1 patient), antimuscarinic and detrusor injection of botulinum toxin (1 patient), antimuscarinic and tibial nerve stimulation (1 patient) or no treatment (17 patients).

Table 5 - Uni- and multivariable analyses of variables potentially involved in the risk of onset of de novo overactive bladder symptoms

	Univariable analysis[a]		Multivariable analysis[b]	
Variable	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value
Age <50 yr	1.1 (0.4-3.5)	0.83	-	
Type of neurogenic lesion, all classes combined		0.34	-	
SSL VS SPL	1.7 (0.3-11.4)	0.58		
SSPL/CEPNL VS SPL	0.6 (0.1-2.3)	0.43		
BMI ≥30 kg/m²	1.4 (0.4-4.9)	0.063	1.3 (0.3-4.8)	0.72
Vaginal delivery ≥2	0.5 (0.2-1.6)	0.28	-	
Wheelchair	-		-	
IC	0.8 (0.2-2.5)	0.7	-	
Previous pelvic surgery	1.6 (0.5-5.4)	0.43	-	
Smoking habits	1.6 (0.5-5.9)	0.43	-	
Positive urethral support manoeuvres	1.3 (0.4-4.8)	0.65	-	
Preserved perineal sensation	2.5 (0.8-8.8)	0.13	-	
MUCP ≤30 cmH_2O	0.6 (0.1-2.1)	0.43	-	
Reintervention for complication	0.5 (0.1-2.1)	0.38	-	
TO sling route	3.2 (0.9-13.7)	0.086	3.2 (0.9-13.5)	0.091

CI = confidence interval; SPL = supra-pontine lesion; SSL = supra-sacral spinal cord lesion ; SSPL/CEPNL = sacral spinal cord lesion or cauda equina or peripheral nerves lesion ; BMI = body mass index; IC = intermittent catheterisation; MUCP = maximal urethral closure pressure ; TO = trans-obturator
***a:** simple logistic regression*
***b:** logistic regression*

Fifty-eight patients had at least one postoperative UDS and were included for urodynamic change analysis. Median time between sMUS implantation and last UDS study was 28 months (IQR 13-63 months). No statistical significance between preoperative and postoperative cystometric capacity, bladder compliance or MUCP was found. Five patients developed de novo NDO and 6 patients had de novo low bladder compliance representing a rate of 15.1% and 11.8%, respectively. Two patients who had de novo NDO had de novo OAB symptoms after sMUS implantation, the others already had mixed urinary incontinence before the intervention. All were managed conservatively with antimuscarinics or detrusor injections of botulinum toxin. Three out of 6 patients who had new onset of low compliance were asymptomatic. One had de novo OAB symptoms and 2 had recurrence of MUI. Three were managed conservatively with botulinum toxin and/or antimuscarinics, 2 did not require treatment and 1 had augmentation cystoplasty and artificial urinary sphincter for intractable mixed urinary incontinence. **Table 6** shows pre- and postoperative urodynamic observations.

Table 6 – Urodynamic outcomes after sMUS implantation

Urodynamic observation	n=58 patients		p value
	Preoperative	Last UDS	
Cystometric capacity (mL), mean ±SD	431 ±139	417 ±114	0.55
MUCP (cmH_2O), mean ±SD	46.5 ±22	42.7 ±21	0.34
Compliance, (cmH_2O), mean ±SD	80 ±87	91 ±107	0.58
Low compliance <25cmH_2O, n (%)	7 (12.1)	13 (22.4)	NA
NDO, n (%)	25 (43.1)	30 (51.7)	NA
De novo urodynamic observation	Patient no./total no. (%)		
De novo NDO	5/33 (15.1%)		
De novo low compliance	6/51 (11.8%)		

UDS= urodynamic study; SD= standard deviation; MUCP = maximal urethral closure pressure; NDO= neurogenic detrusor overactivity; NA= not applicable

Table 7 shows the occurrence of complications other than de novo OAB symptoms and their management for each patient. Exposure occurred in 11 patients (9.6%) and required reoperation in 10 cases, with partial or complete sMUS excision. Eleven pelvic organ perforations occurred, all after retropubic sMUS. It was a bladder perforation during retropubic sMUS implantation in 10 cases, managed with needle withdrawal and immediate sMUS repositioning.

Sixteen out of 69 patients (23.2%) who voided spontaneously presented with urinary retention. Seven (43.7%) required sMUS release and 8 begun IC. At last follow-up, 2 patients required definitive IC. One patient had post void residual >100 mL and was satisfied with this situation, without any complication related to this residual.

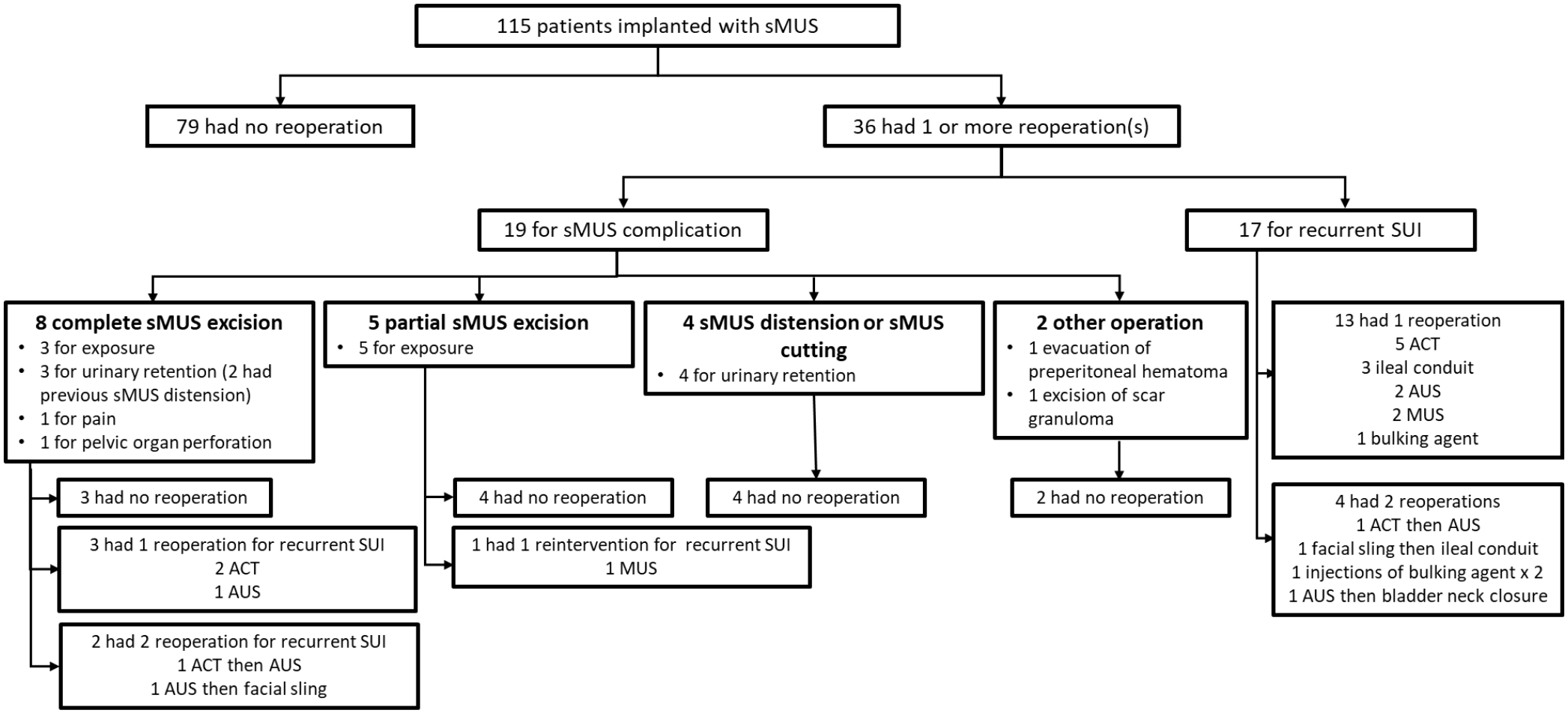
Overall, 36 patients (31.3%) had one or more reoperation for sMUS complication and/or SUI recurrence during follow-up. One or more reoperation(s) due to sMUS complication were necessary for 19 patients (16.5%). Twenty-three out of 58 patients (39.6%) who had a recurrence of SUI had one or more anti-incontinence procedure. **Figure 2** details causes, and types of operations performed.

Table 7: Complications other than de novo OAB symptoms according to IUGA/ICS terminology and classification. Each CTS code represents a patient who had a specific complication, with its management on the same row. If more than one patient had the same complication, their number is indicated between brackets, as well as the number of patients who had the same type of management.

Complication type	Rate	Description (n)	CTS code	Management (n)	sMUS route (n)
sMUS Exposure	9/115	Vaginal (6)	2AT3S1	non-operative management	RP
			3AT2S1	sMUS partial excision	RP
			3AT4S1 (2)	sMUS partial excision (2)	RP (2)
			3BT4S1	sMUS partial excision	TO
			3CT2S1	sMUS complete excision	RP
		Urethral (2)	4BT3S5	sMUS complete excision	RP
			4BT4S3	sMUS complete excision	RP
		Bladder (1)	4BT4S3	sMUS partial excision	RP
Pelvic organ perforation	11/115	Small intra-operative defect (10)	4AT1S3 (10)	intra-operative sMUS repositioning (10)	RP (10)
		Sigmoid colon (1)	5CT1S5	sMUS complete excision	RP
Urinary retention	16/69	Requiring surgery (7)	4BT1S1	sMUS distension	TO
			4BT2S1 (5)	sMUS distension then complete excision (2); sMUS complete excision (1); sMUS cutting (1); sMUS distension (1)	RP (3); TO (2)
			4BT3S1	sMUS distention	TO
		Requiring catheterisation (8)	-	transient 6 (2 after revision for urinary retention)	RP (5); TO (1)
			-	definitive 2	RP (1); TO (1)
Other	4/115	Pain >6 weeks (2)	6BT3S4	sMUS complete excision	RP
			6BT4S4	non-operative management	TO
		Scar granuloma (1)	6BT3S3	granuloma excision	RP
		Pelvic hematoma (2)	7AT2S3	non-operative management	RP
			7AT2S3	hematoma evacuation	RP
		Vaginal bleeding (1)	7AT2S1	non-operative management	RP

CTS = category-time-site; RP = retropubic; TO = transobturator.

Figure 2: Causes and type of reoperations after sMUS implantation



Discussion

To the best of our knowledge, this study is the largest series reporting the results of sMUS for the treatment of SUI in women with NLUTD. We found that success rate is acceptable with 1 out of 2 patients presenting no SUI recurrence at last follow-up. Patient satisfaction is high, but complication rate may also be significant.

SUI in NLUTD patient is a complex entity to manage because it can be due to various causes which are frequently associated. Lesions involving sacral centres of the spinal cord, the cauda equina or peripheral sacral nerves (lower motor neuron lesions) classically lead to neurogenic SUI related to intrinsic sphincter deficiency. Iatrogenic SUI may also occur in case of long-term indwelling catheter with direct injury of the striated sphincter and the bladder neck, leading also to intrinsic sphincter deficiency. Finally, female patients with NLUTD, as well as in the general population, may also experience pregnancy and vaginal delivery, leading to a decrease of the anatomic support and to SUI due to urethral hypermobility (3).

The success rate in our study seems to be lower than the average success rate found in our systematic review on sMUS in women with NLUTD (8). However, median follow-up in our study was 70 months while it was 41.3 month is in our systematic review. Success rate was a short or medium-term outcome measure in most studies included in our review. However, we know from studies including non-NLUTD women that there is a decrease in subjective success rate with time (long term >5 years compared to short and medium-term) (6) that could explain this difference. In addition, definition of recurrence was stringent in our study because described as any symptom of SUI reported by the patient during follow up. Thirty-five out of 58 patients (60.4%) who had SUI recurrence did not have another anti-incontinence procedure. Among them, half of the patients who answered PGI-I questionnaire felt “improved” or “very much improved” compared to their situation before the sMUS operation, despite their SUI recurrence. This underlines the difficulty to find appropriate outcome parameters and

definitions of success to report on outcome of surgical interventions for SUI in patients with NLUTD (14). Outcomes of anti-incontinence procedures could be considered positive even if some urinary leakage persists, especially in NLUTD patients who may be bothered from urinary incontinence differently compared to non-neurogenic patients due to altered sensation and impaired mobility.

In our study, multiparity and positive urethral support manoeuvres seemed to be protective factors for SUI recurrence. Multiparity is a known cause of urethral hypermobility (19). Urethral support manoeuvres are thought to mimic the effect of a surgical correction of SUI by reducing urethral hypermobility (20). In non-NLUTD patients, evidence exists about the fact that urethral hypermobility and/or positive urethral support manoeuvres may be predictive of good post-operative results of sMUS (21-23). However, tests for urethral mobility or competence are not recommended in international guidelines (24). Despite no standardised evaluation of urethral hypermobility with Q-tip test (25) was used in our study, our results suggest that a component of urethral hypermobility at clinical examination may predict sMUS success in NLUTD patients. Our results argue that urethral support manoeuvres should be systematically performed for initial evaluation of SUI in women with NLUTD, as a determinant in the selection of the therapy.

Age below 50 was also a protective factor for SUI recurrence. Laterza et al demonstrated that higher age at surgery had a detrimental influence on the objective cure rate and subjective outcomes at 5 years after sMUS. Ageing of pelvic floor tissue is due to decreased number of vascular plexuses and collagen type II/III content in the urethral submucosa and to changes in striated pelvic floor muscle. This is a risk factor for the deterioration of the continence mechanisms, and consequently, also for the efficacy of anti-incontinence surgery (26).

TO route was also an independent risk factor for SUI recurrence. Reports suggest that success of sMUS implanted using the TO route decline over time compared those using the retropubic route, with need for repeat incontinence surgery in the long term (6, 27). Moreover, retropubic route seems to be more effective than TO slings in the presence of intrinsic sphincter deficiency in non-NLUTD women (28). As mentioned earlier, a component of intrinsic sphincter deficiency is frequently present in SUI for women with NLUTD, thus explaining this difference in recurrence rate.

No pre-operative urodynamic parameter was significantly associated with SUI recurrence in our study. However, EAU and ICI recommend performing a urodynamic investigation before any surgical treatment of complicated urinary incontinence, and incontinence in NLUTD patient is considered complicated (7, 29). This management is mandatory to detect NDO and poor bladder compliance before surgery, which need to be controlled first, to ensure low pressure reservoir. In our study, rate of de novo NDO and de novo low compliance was 15.1% and 11.8%, respectively. This could be due to the evolution of the neurological disease, or to changes induced by increased bladder outlet resistance. Dave et al. showed that NDO or poor compliance could occur after isolated bladder outlet procedures for neurogenic incontinence in children and young adults (30). Even if those parameters were treated conservatively, this advocates for a regular follow-up after sMUS surgery in NLUTD patients. Any clinical change should trigger an urodynamic investigation to identify and treat factors that may lead to high pressure reservoir, in order to prevent upper urinary tract deterioration (7).

About half of the patient who had pure SUI before the intervention presented de novo OAB symptoms during follow-up. This rate is the highest described after sMUS surgery in a cohort of NLUTD patients (8). Those results must be nuanced. Follow-up of our cohort was among the longest among NLUTD patients and in the long run, a relevant percentage of women

may naturally develop age-related OAB symptoms, and this could play a confounding role. Half of the patients did not take specific medication for OAB at last follow-up and all the other were treated conservatively with antimuscarinics or detrusor injection of botulinum toxin. Nevertheless, this data is important for preoperative counselling because the presence of postoperative OAB symptoms has a relevant effect on patient satisfaction and health-related quality of life after sling surgery.

This study is the first to report on complications of sMUS surgery in NLUTD patients with the IUGA/ICS joint classification. sMUS exposure rate (9.6%) in our series was among the highest rates described in a cohort of NLUTD patient (range 0-11%) (8). Chughtai et al reported a 3.7% rate of exposure and a 6.7% rate of reoperation 7 years after synthetic MUS procedure for SUI in a large cohort of 36195 non-NLUTD patients (31). Reports have shown that use of various synthetic devices such as artificial urinary sphincter or adjustable continence therapy in NLUTD patient is associated with higher risks of complications and revision in the long term compared to no-NLUTD patient (32, 33). An explanation could be a decreased tissue quality in NLUTD patients, especially in neurogenic peripheral lesions (32).

Urinary retention remained a frequent complication with 23% requiring management. In our cohort, patients in spontaneous voiding preoperatively were taught ISC in case of significant post-void residual before the intervention, but most cases occurred for patient with no preoperative post-void residual. However, some of these patients probably had unsustained and/or low detrusor contractility but given voiding cystometry was not part of the pre-operative assessment, these data were not available. Revision resolved the urinary retention in all cases but one. Due to the small number of each type of complication, we could not perform statistical analysis to find specific risk factor. Complications were managed with sMUS partial or complete excision, with most patient not requiring subsequent intervention for SUI recurrence.

The EAU and ICI guidelines both recommend the use of autologous slings or an artificial urinary sphincter to treat SUI in women with NLUTD (3, 7).

Concerning autologous slings, only results for short to medium-term follow-up have been reported in NLUTD patients, with a success rate ranging from 72% to 84% (34-37). IC was almost always necessary after this surgery. De novo urgency was also reported after this procedure, with rates ranging from 10% to 13.3% (36, 37). However, augmentation cystoplasty was frequently performed before or at the time of autologous sling implantation in those series, making interpretation of de novo OAB rate difficult.

Artificial urinary sphincter remains the gold standard in the case of SUI due to neurogenic intrinsic sphincter deficiency, with a high proportion of fully continent patients after a long-term follow-up (32, 38). Major drawback of this intervention in NLUTD women is the need of a training period involving numerous patients (32) and the high revision rate. Costa et al. reported that the presence of neurogenic bladder increased the risk of sphincter revision and explant (32). Phé et al. reported a survival rate of AUS without revision of 51% at 20 years (38).

Adjustable continence therapy (ACT) has also been described as an option for treating SUI for NLUTD women (33,39). Success rate is moderate with around 50% of patients improved more than 50% of their urine loss after implantation (33). Complications can be easily managed and repeat balloon implantation/explant does not appear to alter the rate of continence for other surgical procedures, particularly the artificial urinary sphincter. Authors concluded that this surgery is a reasonable therapeutic option especially in NLUTD patients who are at high risk of complication in case of more invasive surgery. In our cohort, 9 patients had an ACT as a second line treatment for SUI recurrence.

sMUS could therefore have a place as a first line treatment for SUI in female with NLUTD, including those with urethral hypermobility corrected by positive urethral support manoeuvres. Retropubic route should probably be preferred in this population. In the absence

of urethral hypermobility, or negative manoeuvres, autologous slings or artificial urinary sphincter should probably be preferred and may be also proposed as a concomitant procedure for patients requiring augmentation cystoplasty and/or continent cystostomy. Adjustable continence therapy could represent a mini-invasive option as a first line treatment or as a supplementary treatment after unsatisfactory outcomes. Nevertheless, no definitive conclusion can be drawn in the absence of comparative studies.

Strengths of our study are (1) multicentre study, (2) long-term follow-up, (3) validated subjective questionnaire to assess quality of life and subjective outcomes, (4) validated terminology and classification to characterise complications.

We must acknowledge the limitations of the present study. Data were collected retrospectively from patients' note. Each center had their own follow-up protocol which were not strictly identical. Our study was retrospective, observational and lacked a control arm, therefore presenting with a risk of bias. We tried to control for confusion bias by systematically reporting known confounder for SUI in NLUTD women, but we could not include them all in multivariate analysis. Population was heterogeneous with various neurological conditions responsible for NLUTD, therefore comparing patients between each other was difficult. This reflects the heterogeneity of cases encountered in clinical practice, and we chose to pool patients with comparable type of neurological lesion, to allow comparisons. The criteria we used to define recurrence and assess the failure of sMUS implantation did not include an objective outcome measure as recommended by the EAU. Cough stress test was not systematically performed during follow-up as patient subjective impression was considered the most important outcome, but it is not unlikely that SUI recurrence rate could be overestimated as SUI and urgency urinary incontinence can sometime be difficult to discriminate, especially in patients with altered perineal sensations.

Conclusion

This study was the largest cohort evaluating the results of sMUS for the treatment of SUI in female with NLUTD. Success rate is acceptable and seems related to young age, positive urethral support manoeuvres and urethral hypermobility while failure is associated with TO route. Satisfaction with the procedure is high. Despite a rather simple management, patients should be informed of the risk of revision for complication. Comparative studies are needed to confirm the place of sMUS among the other anti-incontinence procedure for SUI in NLUTD women.

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Conclusions signées

THÈSE SOUTENUE PAR : Clément SARRAZIN

TITRE :

BANDELETTE SOUS-URETRALE SYNTHETIQUE POUR LE TRAITEMENT DE L'INCONTINENCE URINAIRE A L'EFFORT CHEZ LA FEMME PRESENTANT UNE DYSFONCTION NEUROGENE DU BAS-APPAREIL URINAIRE : RESULTATS D'UNE ETUDE RETROSPECTIVE MULTICENTRIQUE

CONCLUSION :

Contexte : La bandelette sous-urétrale (BSU) synthétique est le traitement chirurgical de première intention pour le traitement de l'incontinence urinaire à l'effort (IUE) chez la femme. L'utilisation de BSU synthétique pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du bas-appareil urinaire (BAU) a été peu étudiée.

Objectif : Evaluer les résultats de la BSU synthétique pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du BAU.

Méthode : Une étude rétrospective multicentrique a été menée dans 3 centres français. Les femmes adultes pour lesquelles une BSU synthétique était implantée pour le traitement d'une IUE, qui présentaient une comorbidité neurologique diagnostiquée avant l'intervention, étaient incluses. Les patientes avec une durée de suivi inférieure à un an, une cure de prolapsus concomitante à l'implantation de BSU ou qui n'avaient pas eu de bilan urodynamique préopératoire étaient exclues. Le critère de jugement principal était la récidive de symptômes d'IUE à l'interrogatoire durant le suivi. Les critères de jugement secondaires étaient les réponses à des questions standardisées chez les patients qui n'avaient pas été réopérées pour récidive de l'IUE durant le suivi : statut « sec » rapporté par la patiente, Patient Global Impression of Improvment (PGI-I) et score de gêne lié à l'incontinence urinaire évalué par la question 3 de l'International Consultation on Incontinence Questionnaire–Short Form (ICIQ-SF). La sécurité de l'intervention était évaluée par la survenue de complication durant le suivi, particulièrement l'hyperactivité vésicale (HAV) de novo, la rétention urinaire et l'exposition de bandelette. Les réopérations pour complication ou récidive de l'IUE étaient relevées.

Résultats : 115 patientes ont été incluses. L'âge médian était de 53 ans (rang interquartile 46-64 ans). La durée médiane de suivi était de 53 mois (rang interquartile 46-64 mois). A la fin du suivi, 57 patientes (50 %) présentaient une récidive de l'IUE ou avaient été réopérées pour récidive de l'IUE. En analyse multivariée, l'âge inférieur à 50 ans, la positivité des manœuvres de soutènement urétral et la multiparité étaient des facteurs protecteurs indépendants de

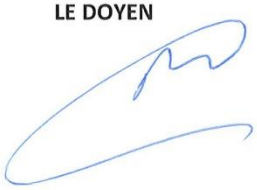
récidive de l'IUE (HR: 0.3 IC 95%(0.2-0.7) p<0.01 ; HR: 0.5 IC95%(0.3-0.98) p=0.043 et HR: 0.5 IC95%(0.2-0.98) p=0.043, respectivement). La voie d'implantation transobturatrice était un facteur de risque indépendant de récidive de l'IUE (HR : 2.1 IC95%(1.1-4) p=0.029). Parmi les patientes qui avaient répondu aux questions standardisées, 53% s'estimaient « sèches » et 77.4 % avaient un PGI-I inférieur ou égal à 2. La médiane du score de gêne lié à l'incontinence urinaire était 3 sur 10. Vingt-cinq des 52 patientes (48 %) qui avaient une IUE pure en préopératoire présentaient une HAV de novo. 9 patientes (8 %) avaient présenté une exposition de bandelette. Seize des 69 patientes (23 %) en miction spontanée avaient présenté une rétention urinaire, parmi lesquelles 7 avaient été réopérées et 2 avaient définitivement recours aux sondages intermittents. Trente-six patientes (31.3 %) avaient eu une réopération ou plus durant le suivi.

Conclusion : La BSU synthétique est une option pour le traitement de l'IUE chez la femme présentant une dysfonction neurogène du BAU. Le taux de continence est acceptable et la satisfaction des patientes est élevée. Les patientes doivent être cependant informées du risque de complication et de réopération.

VU ET PERMIS D'IMPRIMER

Grenoble, le 09/09/2021

LE DOYEN



Pr. Patrice MORAND

LE PRÉSIDENT DE LA THÈSE



Pr. Jean-Luc DESCOTES

Serment d'Hippocrate

Au moment d'être admis à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux. Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité. Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré et méprisé si j'y manque.

Annexes

Annexes for the systematic review

Annexe 1: Pre-operative voiding mode according to type of neurological lesion based on individual patient datas. Only studies for which voiding mode could reliably be assessed according to type of neurological lesion were included.

Spontaneous voiding 172/251 (68.5 %)					
SPL 81/81 (100 %)		SSL 5/66 (7.5 %)		SSPL/CEPNL 86/104 (82.7 %)	
Holdø 2019	28/28	Abdul-Rahman 2010	1/3	Abdul-Rahman 2010	2/9
Shin 2020	53/53	Sakalis 2018	4/38	Chen 2017	25/25
				El-Azab 2014	15/20
				Holdø 2019	6/6
				Losco 2015	5/11
				Shin 2020	33/33
Intermittent Self-Catheterisation 45/251 (18 %)					
SPL 0/81 (0 %)		SSL 28/66 (42.5 %)		SSPL/CEPNL 17/104 (16.3 %)	
		Abdul-Rahman 2010	2/3	Abdul-Rahman 2010	7/9
		Losco 2015	6/16	El-Azab 2014	5/20
		Patki 2009	8/9	Losco 2015	5/11
		Sakalis 2018	12/38		
Indwelling Catheter 34/251 (13.5 %)					
SPL 0/81 (0 %)		SSL 33/66 (50 %)		SSPL/CEPNL 1/104 (1 %)	
		Losco 2015	10/16	Losco 2015	1/11
		Patki 2009	1/9		
		Sakalis 2018	22/38		

SPL : Supra-Pontine Lesion ; SSL : Supra-Sacral Lesion ; SSPL/CEPNL : Sacral Spinal Cord or Cauda Equina and Peripheral Nerves Lesion

Annexe 2: Success rate, urinary retention rate and de novo urgency rate based on individual patient data according to sling route. Only studies for which outcomes could reliably be assessed according to sling route were included. Urinary retention rate was only assessed among patient who voided spontaneously before the intervention.

Success			
Retropubic route (n = 109)		Transobturator route (n = 149)	
Abdul-Rahman 2010	9/12 (75 %)	Losco 2015	22/27 (81.5 %)
El-Azab 2014	16/20 (80 %)	Pannek 2012	3/9 (33.3 %)
Holdø 2019	46/54 (85.2 %)	Patki 2008	6/6 (100 %)
Patki 2008	3/3 (100 %)	Sakalis 2017	6/12 (50 %)
Sakalis 2017	12/21 (54.5 %)	Shin 2020	86/95 (93.7 %)
***De novo* urgency**			
Retropubic route (n = 83)		Transobturator route (n = 70)	
Abdul-Rahman 2010	1/11 (9.1 %)	Losco 2015	2/27 (7.4 %)
El-Azab 2014	6/20 (30 %)	Pannek 2012	0/9 (0 %)
Holdø 2019	7/31 (22.6 %)	Sakalis 2017	2/12 (18.2 %)
Sakalis 2017	3/21 (14.3 %)	Shin 2020	4/22 (18.2 %)
Urinary retention			
Retropubic route (n = 72)		Transobturator route (n = 109)	
Abdul-Rahman 2010	0/3 (0 %)	Losco 2015	2/5 (40 %)
El-Azab 2014	7/15 (46.7 %)	Pannek 2012	0/1 (0 %)
Holdø 2019	5/54 (9.3 %)	Shin 2020	2/95 (2.3 %)

Annexe 3: Success rate, urinary retention rate and de novo urgency rate based on individual patient data according to type of neurological lesion. Only studies for which outcomes could reliably be assessed according to type of neurological lesion were included. Urinary retention rate was only assessed among patient who voided spontaneously before the intervention.

Success					
SPL (n = 28)		SSL (n = 63)		SSCL/CEPNL (n = 62)	
Holdø 2019	25/28 (89.3 %)	Losco 2015	14/16 (87.5 %)	Chen 2017	20/25 (80 %)
		Patki 2008	9/9 (100 %)	El-Azab 2014	16/20 (80 %)
		Sakalis 2017	20/38 (52.6 %)	Holdø 2019	5/6 (83.3 %)
				Losco 2015	8/11 (72.7 %)
***De novo* urgency**					
SPL (n = 20)		SSL (n = 51)		SSCL/CEPNL (n = 35)	
Holdø 2019	7/20 (35 %)	Losco 2015	1/13 (7.7 %)	El-Azab 2014	6/20 (30 %)
		Sakalis 2018	5/38 (13.2 %)	Holdø 2019	1/4 (25 %)
				Losco 2015	1/11 (9.1 %)
Urinary retention					
SPL (n = 28)		SSL (n = 4)		SSCL/CEPNL (n = 51)	
Holdø 2019	3/28 (10.7 %)	Sakalis 2018	0/4 (0 %)	Chen 2017	6/25 (24 %)
				El-Azab 2014	7/15 (46.7 %)
				Holdø 2019	0/6 (0 %)
				Losco 2015	2/5 (0 %)

SPL= suprapontine lesion ; SSL= suprasacral spinal cord lesion ; SSCL/CEPL: sacra spinal cord or cauda equina and peripheral nerves lesion.

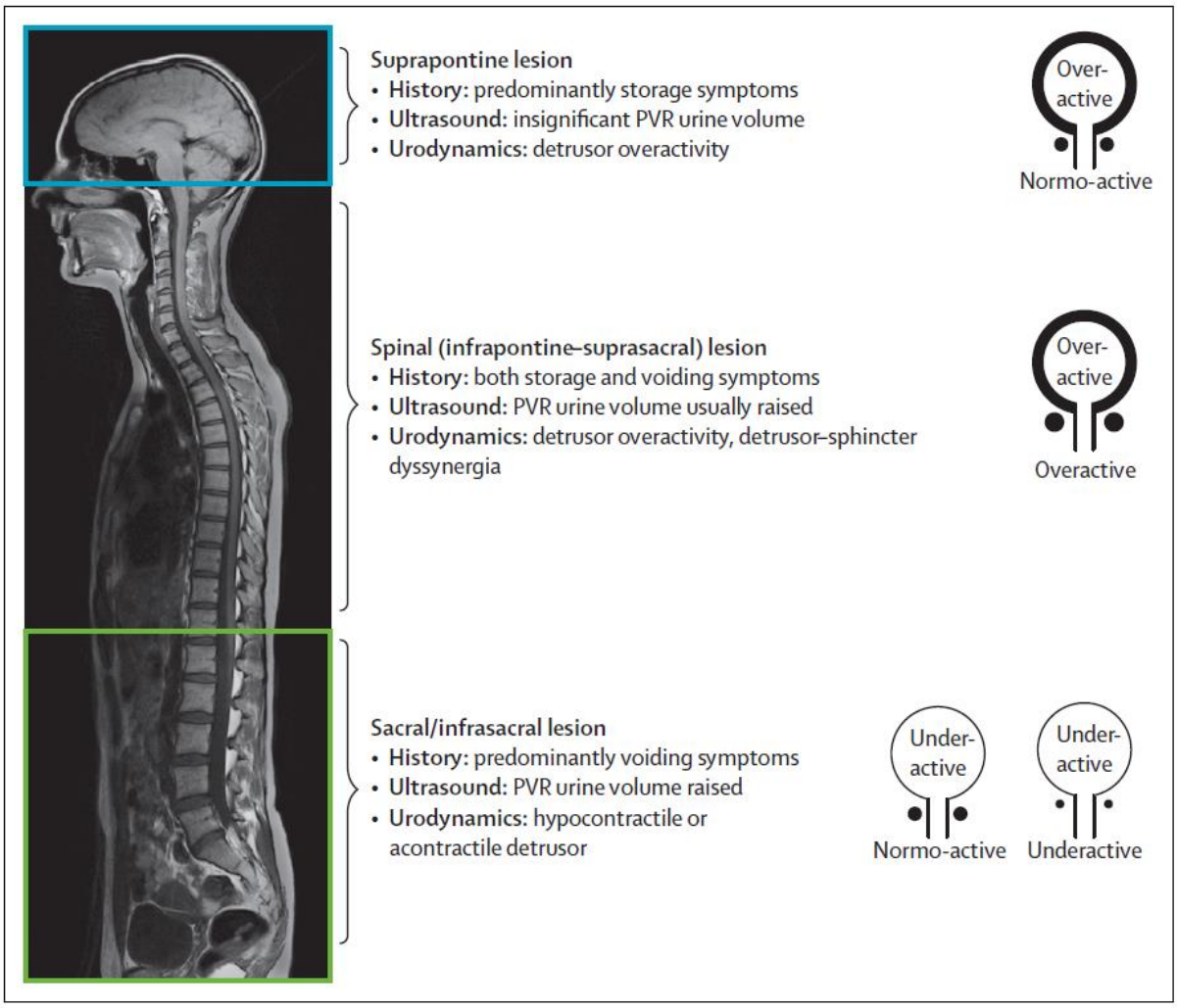
Annexe 4: Post-operative voiding mode based on individual patient data according to type of neurologic lesion. Only studies for which voiding mode could reliably be assessed according to type of neurologic lesion were included.

Spontaneous voiding 152/251 (60.6 %)					
SPL 80/81 (98.8 %)		SSL 5/66 (7.5 %)		SSPL/CEPNL 67/104 (64.4 %)	
Holdø 2019	27/28	Abdul-Rahman 2010	1/3	Abdul-Rahman 2010	2/9
Shin 2020	53/53	Sakalis 2018	4/38	Chen 2017	15/25
				El-Azab 2014	8/20
				Holdø 2019	6/6
				Losco 2015	3/11
				Shin 2020	33/33
Intermittent Self-Catheterisation 65/251 (25.9 %)					
SPL 1/81 (1.2 %)		SSL 28/66 (42.5 %)		SSPL/CEPNL 36/104 (34.6 %)	
Holdø 2019	1/28	Abdul-Rahman 2010	2/3	Abdul-Rahman 2010	7/9
		Losco 2015	6/16	Chen 2017	10/25
		Patki 2009	8/9	El-Azab 2014	12/20
		Sakalis 2018	12/38	Losco 2015	7/11
Indwelling Catheter 34/251 (13.5 %)					
SPL 0/81 (0 %)		SSL 33/66 (50 %)		SSPL/CEPNL 1/104 (1 %)	
		Losco 2015	10/16	Losco 2015	1/11
		Patki 2009	1/9		
		Sakalis 2018	22/38		

SPL= Supra-Pontine Lesion ; SSL= Supra-Sacral Lesion ; SSPL/CEPNL= Sacral Spinal Cord or Cauda Equina and Peripheral Nerves Lesion

Annexes for the original article

Annexe 5: Patterns of lower urinary tract dysfunction following neurological disease



The pattern of lower urinary tract dysfunction following neurological disease is determined by the site and nature of the lesion. Figures on the right show the expected dysfunctional states of the detrusor–sphincter system. PVR = post-void residual. *(From Panicker JN, Fowler CJ, Kessler TM. Lower urinary tract dysfunction in the neurological patient: clinical assessment and management. Lancet Neurol. 2015;14(7):720-32)*

Annexe 6: IUGA/ICS classification of complications *(From Haylen BT, Freeman RM, Swift SE, et al. An International Urogynecological Association (IUGA)/International Continence society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urodyn. 2011;30(1):2–12)*

CATEGORY

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal**: no epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	**1A**: Abnormal prosthesis or graft finding on clinical examination	**1B**: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	**1C**: Infection (suspected or actual)	**1D** = Abscess
2	**Vaginal**: smaller ≤ 1cm exposure	**2A**: Asymptomatic	**2B**: Symptomatic	**2C**: Infection	**2D** = Abscess
3	**Vaginal**: larger >1cm exposure, or any extrusion	**3A**: Asymptomatic 1-3A*a* if no prosthesis or graft related pain	**3B**: Symptomatic 1-3B (*b-e*) if prosthesis or graft related pain	**3C**: Infection 1-3C /1-3D (*b-e*) if prosthesis or graft related pain	**3D** = Abscess
4	**Urinary Tract**: compromise or perforation Including prosthesis (graft) perforation, fistula and calculus	**4A**: Small intraoperative defect e.g. bladder perforation	**4B**: Other lower urinary tract complication or urinary retention	**4C**: Ureteric or upper urinary tract complication	
5	**Rectal or Bowel**: compromise or perforation including prosthesis (graft) perforation and fistula	**5A**: Small intraoperative defect (rectal or bowel)	**5B**: Rectal injury or compromise	**5C**: Small or Large bowel injury or compromise	**5D** = Abscess
6	**Skin and / or musculoskeletal**: complications including discharge pain lump or sinus tract formation	**6A**: Asymptomatic, abnormal finding on clinical examination	**6B**: Symptomatic e.g. discharge, pain or lump	**6C**: Infection e.g. sinus tract formation	**6D** = Abscess
7	**Patient**: compromise including hematoma or systemic compromise	**7A**: Bleeding complication including haematoma	**7B**: Major degree of resuscitation or intensive care*	**7C**: Mortality * *(additional complication - no site applicable - **S 0**)	

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours | **T2**: 48 hours to 2 months | **T3**: 2 months to 12 months | **T4:** over 12 months

SITE

S1: Vaginal: area of suture line | **S2**: Vaginal: away from from area of suture line | **S3**: Trocar passage Exception: Intra-abdominal (**S5**) | **S4**: other skin or musculoskeletal site | **S5**: Intra-abdominal

N.B.
1. **Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.**
2. **The highest final category for any single complication should be used if there is a change over time. (patient 888)**
3. **Urinary tract infections and functional issues (apart from 4B) have not been included.**

IUGA ICS

CODE ☐☐☐ - T ☐ - S ☐

Annexe 7: Neurological disease or relevant neurological background of the participants

Neurologic disease or background	n = 115
Spine surgery, n (%)	37 (32.2)
Spinal cord injury, n (%)	23 (20)
Cerebrovascular accident, n (%)	12 (10.4)
Radical pelvic surgery, n (%)	9 (7.8)
Multiple sclerosis, n (%)	8 (7)
Meningomyelocele, n (%)	7 (6.1)
Cerebral tumour, n (%)	6 (5.2)
Other spinal cord disease, n (%)	6 (5.2)
Other neurological disease, n (%)	4 (3.5)
Parkinson's disease, n (%)	3 (2.6)

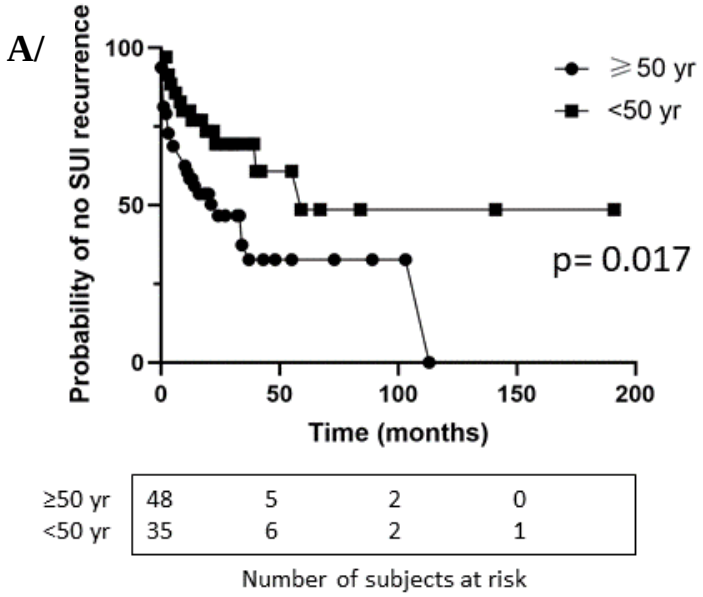
Annexe 8: Kaplan meier curves of covariates associated with SUI recurrence on univariate analyses. Log-rank test was used to compare survival curves.

A/ Age, <50 VS ≥50

B/ sMUS route, RP VS TO

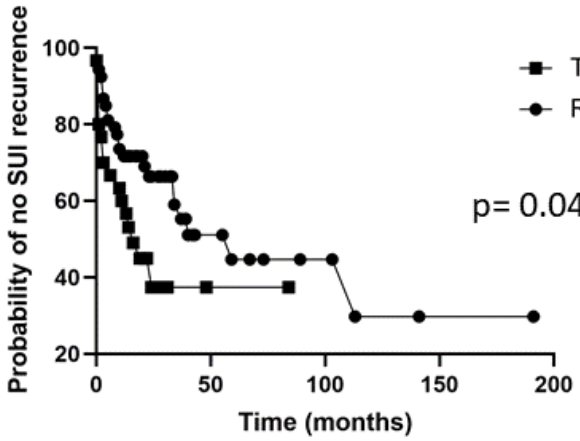
C/ Vaginal deliveries, <2 VS ≥2

D/ Urethral support manoeuvres, positive VS negative



Annexe 8 (continued)

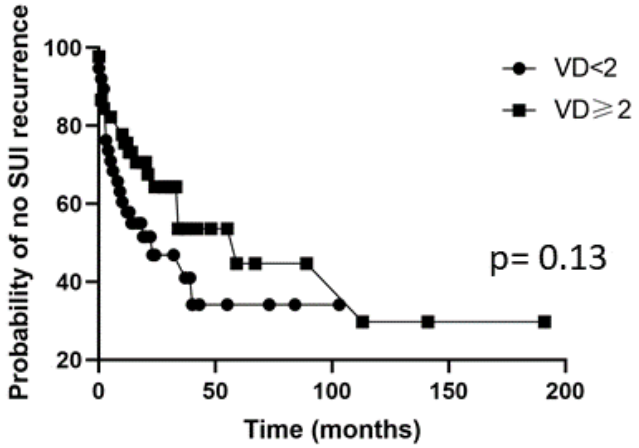
B/



RP	53	10	4	1
TO	30	1	0	0

Number of subjects at risk

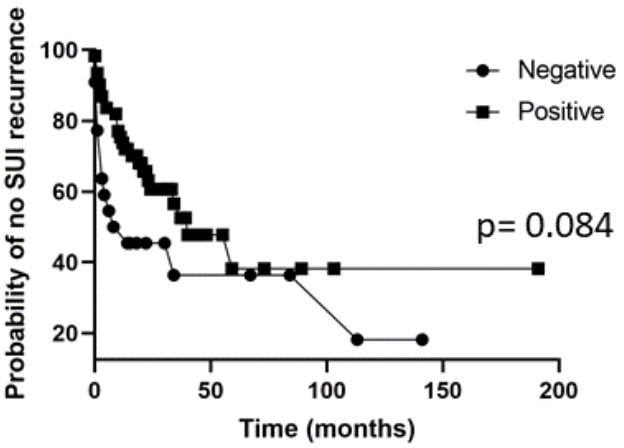
C/



VD <2	38	4	1	0
VD ≥2	45	7	3	1

Number of subjects at risk

D/



Negative	22	4	2	0
Positive	61	7	2	1

Number of subjects at risk