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► To cite this version:

V. Cardot, S. Campagne-Loiseau, P. Roulette, L. Peyrat, A. Vidart, et al.. 2021 opinion from the CUROPF on THE efficacy and safety of mid-urethral slings used in women WITH urinary stress incontinence. *Progrès en Urologie*, 2021, <10.1016/j.purol.2021.10.012>. <hal-03549728>

HAL Id: hal-03549728

<https://normandie-univ.hal.science/hal-03549728v1>

Submitted on 22 Jul 2024

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2021 OPINION FROM THE CUROPF ON EFFICACY AND SAFETY OF MID-URETHRAL SLINGS USED IN WOMEN URINARY STRESS INCONTINENCE

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2021 OPINION FROM THE CUROPF ON THE EFFICACY AND SAFETY OF MID-URETHRAL SLINGS USED IN WOMEN WITH URINARY STRESS INCONTINENCE

ABSTRACT

Objective: To determine the usefulness of mid-urethral slings (MUS) in the surgical management of women presenting with urinary stress incontinence (USI).

Method: A consensus committee of multidisciplinary experts (CUROPF) was convened and focused on PICO questions concerning the efficacy and safety of MUS surgery compared to other procedures and concerning which approach (retropubic (RP) vs transobturator (TO)) should be proposed as a first-line MUS surgery for specific subpopulations (obese; intrinsic sphincteric deficiency (ISD); elderly).

Results: As compared to other procedures (urethral bulking agents, traditional slings and open colposuspension), the MUS procedure should be proposed as the first-line surgical therapy (strong agreement). MUS surgery can be associated with complications and proper pre-operative informed consent is mandatory (strong agreement). Mini-slings (SIS/SIMS) should only be proposed in clinical trials (strong agreement). Both RP and TO approaches may be proposed for the insertion of MUS (strong agreement). However, if the woman is willing to accept a moderate increase in per-operative risk, the RP approach should be preferred (strong agreement) since it is associated with higher very long-term cure rates and as it is possible to completely remove the sling surgically if a severe complication occurs. The RP approach should be used for the insertion of MUS in a woman presenting with ISD (strong agreement). Either the RP or TO approach should be used for the insertion of MUS in an obese woman presenting with USI (strong agreement). In very obese women (BMI ≥ 35 -40 kg/m²), weight

loss should be preferred prior to MUS surgery and bariatric surgery should be discussed (strong agreement).

Conclusion: The current Opinion provides an appropriate strategy for both the selection of patients and the best therapeutic approach in women presenting with USI.

INTRODUCTION

About 20 to 40% of women suffer from symptoms of urinary stress incontinence (USI), but estimates of the prevalence and incidence are linked to the precise sub-population assessed, with regard to age for example (1). International guidelines from EAU, NICE, ICS/ICI and AUA/SUFU underline that prior to surgery it is important to consider non-surgical solutions for USI with the woman for whom the procedure is proposed (2-5). It has been shown that objective and subjective improvement rates are greater at one-year follow-up after the mid-urethral sling (MUS) procedure when compared to physiotherapy (pelvic floor muscle training (PFMT)) (6). However, surgical procedures should be proposed only after failure of non-surgical therapies (weight loss, PFMT and intravaginal pessaries). It has been established that 10% of women will undergo a surgical procedure for USI at the age of 80 (7,8). Numerous surgical procedures have been proposed for USI in women (traditional sub-urethral slings, colposuspension (Burch procedure), MUS, urethral bulking agents (UBAs), urinary artificial sphincter (UAS), etc). Available data suggest that the use of MUS surgery in women presenting with USI is associated with both benefits and risks. Various complications, such as bladder outlet obstruction (BOO) symptoms, infection, bladder/urethral erosion, vaginal mesh exposure and pain associated with abnormal shrinkage have been described. In France, MUS still remains the first-line surgical therapy for women presenting USI (9). In the current

Opinion article, the CUROPF Committee (*Comité d'Urologie et de Pelvipérinéologie de la Femme from the French Association of Urology (Association Française d'Urologie)*) assessed the benefits and risks of complications of synthetic non-absorbable MUS used in USI surgery in women. The various MUS options for the treatment of USI in women (TO approach, RP approach and SIS approach) were reviewed, as were the guidelines from scientific societies and health authorities. The multidisciplinary CUROPF Committee decided to consider PICO questions concerning the MUS procedure in general and specific populations.

METHODS

This Opinion was developed by a committee of experts from the CUROPF (French Committee of Female Urology and Pelviperineology). The multidisciplinary CUROPF Committee deals with questions related to urogynecology/pelviperineology (pelvic organ prolapse and female incontinence) for the French Association of urology (AFU). The committee included specialists in pelviperineology/urogynecology (urology, gynecology). Urologists and gynecologists involved in the committee had expertise in the surgical management of women with USI. Following formulation of PICO (Patient Intervention Comparison Outcome) clinical questions, the Opinion process continued with a series of electronic-based discussions between committee members and two face-to-face online (webconference) meetings were held in January and June 2021 to decide on the Opinion's conclusions. A search strategy was designed using keywords for each clinical question. The search was limited to human studies written in English or in French. Patient-reported outcome (PRO) and objective outcomes were analyzed. Various databases were used: MEDLINE (via PubMed), EMBASE, and the Cochrane database. MeSH terms and non-MeSH terms were used. Search equations used "AND" and "OR" on MEDLINE/PubMed. Key words used were: urinary stress incontinence; urinary incontinence; slings; mid urethral slings; MUS; TVT; randomized; meta-analysis; side-effects; side-events; woman; female; stress; TOT;

transobturator; retropubic; guidelines. The evidence is current to 21 December 2020. Mostly, only comparative data were analyzed (RCTs and meta-analyses). The quality of evidence was divided into four categories: High: future searches will very probably not change the confidence in the estimation of the effect; Moderate: future searches will probably change the confidence in the estimation of the effect and may modify the estimation of the effect itself; Low: future searches will very probably have an impact on the confidence in the estimation of the effect and will probably modify the estimation of the effect itself; Very low: the estimation of the effect is very uncertain. The final formulation of the Opinion was binary: “should be done” or “should not be done”. The strength of the Opinion was determined as a function of key factors validated by the experts, according to the different parameters (estimation of the effect; overall level of evidence, balance between beneficial effects (objective and subjective outcome (patient-reported outcomes (PROs)) and adverse events, applicability in France and cost. To formulate an Opinion, at least 50% of the participants must have an opinion and less than 20% prefer the opposite proposal. To formulate a strong guideline, at least 70% of the participants must be in agreement. The following situations were excluded and so will not be addressed in these clinical practice guidelines: concomitant MUS associated with POP surgery, MUS for men, recurrent MUS, and MUS in a patient on anticoagulant treatment or with a coagulation disorder. All 8 PICO questions were as follows:

"In a woman undergoing surgery for urinary stress incontinence (USI) (P), is mid-urethral sling (MUS) (I) more effective (O) than other surgical techniques (C) in reducing the symptoms of USI? In a woman undergoing MUS surgery for USI) (P), is the bottom-to-top retropubic approach (I) more effective (O) than other approaches (top-to-bottom retropubic, transobturator, prepubic) (C) in reducing the symptoms of USI? In a woman undergoing MUS surgery for USI) (P), is the bottom-to-top retropubic approach (I) safer (O) than other approaches (top-to-bottom retropubic, transobturator, prepubic) (C) in reducing the

complications associated with USI surgery? In a woman undergoing MUS surgery for USI and intrinsic sphincteric deficiency) (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI? In an obese woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI? In an obese woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) safer (O) than the transobturator approach (C) in reducing the complications associated with USI surgery? In an elderly woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI? In an elderly woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) safer (O) than the transobturator approach (C) in reducing the complications associated with USI surgery?”

RESULTS

MUS versus other surgical procedures

PICO 1: “In a woman undergoing surgery for urinary stress incontinence (USI) (P), is the mid-urethral sling (MUS) (I) more effective (O) than other surgical techniques (C) in reducing the symptoms of USI?”

MUS vs urethral bulking agents (UBAs)

A meta-analysis showed that cure rate associated with bulking agent (such as polyacrylamide hydrogel (PAHG) BULKAMID) is 21% (95% CI: 16%-27%) at one-year follow-up. The success rate ranged from 32% to 93% in different series. The prevalence of complications (urinary tract/vaginal infection, pain, worsening of urinary incontinence) was low (<1%) (10).

One small RCT compared MUS (retropubic TVT) with suburethral injectable bulking agents (PAHG BULKAMID) (11). At one-year follow-up, women who underwent MUS procedure experienced fewer urinary symptoms than those treated with bulking agent PAHG ($p < 0.001$) (11). Urinary scores, sexual function and health-related quality of life scores improved in both groups with significantly better scores in women who underwent MUS procedure as compared to those treated by injection of a bulking agent (11). However, at long-term follow-up, the failure/recurrence rates associated with UBAs were high (12).

MUS versus traditional suburethral sling (pubovaginal autologous fascia rectus slings)

A recent meta-analysis stated that 14 RCTs compared traditional sling operations and MUS (13). MUS seemed to be as effective as traditional sub-urethral sling operations (moderate-quality evidence), but was associated with fewer perioperative complications (RR 1.74, 95% CI 1.16 to 2.60; low-quality evidence) (13). Furthermore, traditional suburethral slings (pubovaginal autologous fascia rectus slings) were associated with longer operation times and higher rates of adverse events (de novo BOO and OAB symptoms) (14-17).

MUS vs colposuspension

In a 2017 Cochrane review of open colposuspension (OC) (Burch procedure) (18), OC was associated with a continence rate of 85-90% at 1 to 5 years post-operatively. Comparison of OC vs. MUS showed no difference in subjective or objective cure rates at 5 years of follow-up (non-inferiority trials) (moderate-quality evidence). OC was not associated with higher complication rates compared to MUS. However, the prevalence of long-term de novo pelvic organ prolapse was significantly higher after OC (moderate-quality evidence) (18). A trial reported significantly more enterocele and rectocele/uterine/vault/cervix prolapse cases following OC (about +20%) at 2-year and 5-year follow-up, when compared to MUS procedures (19). Furthermore, MUS procedures were associated with significantly lower costs

and shorter hospital stay (mean difference: 4 days) when compared with OC (high-quality evidence) (19). RCTs show that MUS procedures are more cost-effective than colposuspension (moderate-quality evidence) (20-24).

Concerning laparoscopic colposuspension (LC), nine trials compared LC to MUS (25). At short-term follow-up, trials LC was associated with similar cure and complication rates compared to MUS (low-quality evidence) (25).

Response to PICO 1: which procedure as a first-line surgical therapy in women presenting with USI?

MUS were associated with better results when compared to UBAs at short-term (moderate-quality evidence) and long-term (low-quality evidence) follow-up. MUS were associated with similar results when compared to ‘traditional’ slings, but with shorter operative duration and lower rates of adverse events at short-term follow-up (moderate-quality evidence). MUS were associated with similar cure rates compared to OC at medium-term follow-up (high-quality evidence), but with shorter operative/hospitalization duration (high-quality evidence), lower costs and lower de novo POP occurrence at long-term follow-up (moderate-quality evidence). There are no clear conclusions concerning the comparison between MUS and LC.

As compared to other procedures (UBAs, TS and OC), the MUS procedure should be proposed as the first-line surgical therapy (strong agreement). MUS surgery can be associated with complications and proper pre-operative informed consent is mandatory (strong agreement).

Surgical route for insertion of the MUS and length of the sling

PICO 2: “In a woman undergoing MUS for USI) (P), is the bottom-to-top retropubic approach (I) more effective (O) than other approaches (top-to-bottom retropubic,

transobturator, prepubic, mini-slings (single incision slings)) (C) in reducing the symptoms of USI?”

PICO 3: “In a woman undergoing MUS for USI) (P), is the bottom-to-top retropubic approach (I) safer (O) than other approaches (top-to-bottom retropubic, transobturator, prepubic, mini-slings (single incision slings)) (C) in reducing the complications associated with USI surgery?”

Transobturator route vs. retropubic route

Patient-reported outcomes (PROs): subjective cure rates, improvement, satisfaction

An MUS inserted by either the transobturator or retropubic route provided an equivalent PRO at five years of follow-up (high-quality evidence) (26,27). At long-term follow-up, subjective cure rates ranging from 43 to 92% after the TO approach and from 51 to 88% after the RP approach have been reported (26,27). Insertion of MUS by the RP approach resulted in a higher objective cure rate at short- and long-term follow-up compared to MUS inserted by the TO approach (high-quality evidence) (26,27). Re-do procedures (reintervention for USI recurrence) seemed to increase after the TO approach, but the data are limited (low-quality evidence). More women developed chronic leg or groin pain after the TO approach compared to the RP approach (+83/1000 operations with TVT-O compared to TVT) (moderate-quality evidence) (27). Bladder injuries were significantly more common after the RP approach (+5/ 1000 with RP vs TO route) (moderate-quality evidence) (27). No statistically significant differences were noted in de novo urgency, re-operations, infection, hematoma, pain during sexual intercourse or sexual function. Bowel and major vessel injuries have been reported rarely following RP approach (< 0.1%) (28), but never after the TO approach. The prevalence of vaginal exposure following MUS procedures was low (about 2%) and comparable in both approaches (27,28). Very long-term follow-up is only available

for the RP approach. Most patients treated with RP MUS showed a sustained response, with about 80-85% of patients being cured objectively and subjectively at 17 years (29-31) (low-quality evidence). The long-term efficacy of TO MUS was also confirmed at ten-year follow-up. Concerning the re-operation rate for recurrence following both approaches, in a cohort of 3531 women with MUS operations followed up for 11-13 years (32), the cumulative number of re-procedures for USI was higher after the TO approach compared to the RP approach (OR 3.6, 95% CI 2.5-5.2, $p < 0.001$) (32) (low-quality evidence).

Retropubic approach: bottom-to-top vs top-to-bottom

In the RP approach, the subjective cure rate associated with the bottom-to-top RP route was higher (+10%), compared to the top-to-bottom RP route. Furthermore, the RP bottom-to-top and approach was associated with a decrease in the prevalence of bladder injuries, de novo voiding dysfunction / BOO symptoms and vaginal exposure (moderate-quality evidence) (14,17,26,27,33,34). Finally, the classic RP approach (bottom-to-top) is superior to the RP top-to-bottom (moderate-quality evidence) (14,17,26,27,33,34).

TO approaches: insertion using a skin-to-vagina direction (“out-in” = “lateral to medial”) vs. a vagina-to-skin direction (“in-out” = “medial to lateral”)

Meta-analyses have shown similar outcomes in short- and medium-term PROs, subjective and objective cure rates, following skin-to-vagina (out-in) and vagina-to-skin (in-out) TO approaches (moderate-quality evidence) (14, 16, 33, 26, 27). The prevalence of complications was also similar in both approaches. The prevalence of urethral/vaginal injuries was higher in the skin-to-vagina TO approach, but the prevalence of groin pain was higher in the vagina-to-skin TO approach.

Prepubic route

The MUS is placed by the vaginal route, through a subcutaneous perineal approach, in the subcutaneous prepubic space. This approach had been less investigated (no comparative study) (35, 36), seems to be associated with lower cure rates (moderate-quality evidence) and is no longer used.

SIS (single-incision slings) – SIMS (single-incision mini-slings)

A single incision is made in the vagina; no incision is required on the suprapubic or groin skin. The sling is significantly shorter in length than with “classic full-length” RP or TO MUS. However, there is no data concerning the actual length of the implanted sling concerning the standard (‘classic’) RP and TO MUS procedures. Some SIS are partially ‘adjustable’ (per-operative adjustment): it is possible to adjust the tension of the fixing system. The SIS is placed by the vaginal route, following an RP or TO approach, but the sling is not transcutaneously externalized (the insertion stops short of the obturator membrane). Huge differences in fixation mechanism of these SIS may influence outcomes (cure and complication rates). A meta-analysis has shown that, when compared to “classic full-length MUS”, SIS/SIMS ((Mini-Arc[®], Contasure-Needleless[®], Ophira[®], Tissue Fixation System[®] and Ajust[®]) were associated with a shorter operation time, a lower intra-operative blood loss and a lower immediate postoperative pain (moderate-quality evidence) (37). However, a significantly superior objective cure rate was observed with classic full-length MUS (RP or TO approach) at medium- and long-term follow-up, whatever RCTs conducted on TVT-SECUR[®] were included or not in the analysis (37, 38) (moderate-quality evidence). Furthermore, the prevalence of vaginal mesh exposure, bladder injury and sling infection in both groups showed no significant difference (moderate-quality evidence) (37, 38).

Response to PICO 2: which approach for the insertion of MUS?

The prepubic and RP top-to-bottom approaches should not be used for the insertion of MUS (strong agreement).

Mini-slings (SIS/SIMS) should only be proposed in clinical trials in order to assess their medium- and long-term efficacy/safety compared to “full-length” RP and TO MUS (strong agreement).

TO MUS and RP MUS are associated with similar PROs of USI at short- and medium-term follow-up (high-quality evidence). Very long-term follow-up showed high persistent cure for the RP approach (low-quality evidence) and has not been assessed for the TO approach. The cumulative number of re-procedures for USI was higher after the TO approach compared to the RP approach (low-quality evidence). The RP approach is obviously associated with a risk of bowel/iliac vessel injury, but this risk is extremely low (<0.01%) and the TO approach is associated with an increased risk of chronic leg or groin pain (high-quality evidence). RP MUS are followed by longer and higher continence rates as compared with TO MUS (moderate-quality evidence), but are associated with a higher risk of intra-operative complications (high-quality evidence). Finally, both the RP and TO approaches may be proposed for the insertion of MUS (strong agreement). However, if the woman is willing to accept a moderate increase in per-operative risk, the RP approach should be preferred (strong agreement) since it is associated with higher very long-term cure rates and as it is possible to remove the sling completely surgically if a severe complication occurs.

MUS in women with ISD

PICO 4: “In a woman undergoing MUS for USI and intrinsic sphincteric deficiency) (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI?”

Although there is no international consensus definition, the CUROPF Committee previously stated that intrinsic sphincteric deficiency (ISD) is a composite concept combining urodynamic data (MUCP < 20 or 30 cmH₂O) and one or more clinical parameters (high USI scores; leakage during abdominal straining; absence of urethral mobility, negative urethral support test (“TVT-test” or “Ulmsten test”), failure of a first USI surgery) (39). MUS can be offered as first-line surgery for women presenting with USI and ISD. However, in the case of absence of urethral mobility, an artificial urinary sphincter (AUS) should be discussed as first-line surgical therapy.

To compare the efficacy of the RP and TO MUS approaches in the treatment of women with USI and ISD, 164 women were randomized to either the TVT or TO MUS approach (40). At 3 years of follow-up, 15/75 (20%) women in the TO group underwent repeat surgery compared with 1/72 (1%) in the RP group; the RR of repeat surgery was 15 (95% CI: 2-113; p<.001) times greater in the TO group (moderate-quality evidence (40).

A meta-analysis conducted by Ford and Ogah showed that there was a statistically significant difference in short- and medium-term (≤5 years) subjective cure rates following the RP vs TO approach for MUS in women presenting with ISD (34). Ford and Ogah found 8 RCTs that included women presenting with ISD variously defined (MCUP ≤20-30 cmH₂O and/or VLPP ≤60 cmH₂O). The need to undergo repeat incontinence surgery in the long term (≥5 years) was higher with the TO approach when compared to the RP approach (RR 14; 95% CI 1.9-106) (moderate-quality evidence) (34). Post-operative BOO symptoms, voiding dysfunction and de novo OAB symptoms (urgency or urge urinary incontinence) in both groups showed no significant difference.

Unfortunately, most of the time, in the international literature, ISD is only defined “urodynamically” using MUCP and /or VLPP parameters. It is admitted that ISD may be in the presence or absence of hypermobility. However, in the RCT conducted on women

presenting with ISD, and in the meta-analysis that concerned MUS and ISD, urethral mobility was not recorded /studied (34, 40). A recent prospective observational series assessed cure rates following RP MUS according to urethral mobility status (“hypomobile” vs “normomobile” vs “hypermobile”, defined using ultrasonographic LDM measurement. LDM (linea dorsocaudal movement) is the distance shift between the position of the bladder neck at rest and during straining (“hypomobile urethra” when $LDM \leq 5$ mm) (41). In this study, which included 109 women with USI with urodynamically proven ISD ($MUCP \leq 20$ cmH₂O), significantly different cure rates were found for hypomobile (67%), normomobile (76%), and hypermobile (100%) urethra ($p = 0.0003$) (low-quality evidence) (41). In series that focused on ISD, women with ISD with a hypomobile urethra only represented a small fraction of the entire ISD population (ranging from 16 to 22%) (41-43). All these series observed that women with low MUCP and hypomobile (also called “fixed”) urethra (defined clinically or ultrasonographically) are at significantly increased risk of failure of the procedure (very low-quality evidence) (42,43).

Response to PICO 4: which approach in women presenting with USI and ISD?

Outcomes are better after RP MUS in women with USI presenting with ISD (moderate-quality evidence). The RP approach should be used for the insertion of MUS in woman presenting with ISD (strong agreement). Urethral mobility should be assessed in women presenting with USI and low-MUCP (ISD) and patients presenting with hypomobile urethra should be aware of the high failure rate associated with MUS, even with RP MUS (very low-quality evidence) (strong agreement). Sufficient urethral mobility is a prerequisite for a successful outcome of the MUS procedure, and another surgical method (e.g., urinary artificial sphincter) should be discussed for these patients presenting with ISD and hypomobile urethra (strong agreement).

MUS in obese women

PICO 5: “In an obese woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI?”

PICO 6: “In an obese woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) safer (O) than the transobturator approach (C) in reducing the complications associated with USI surgery?”

No RCT has focused on this population. However, a meta-analysis based on secondary analysis of RCTs revealed that obese women ($\text{BMI} > 30 \text{ kg/m}^2$) experienced lower cure rates compared to non-obese women, following MUS procedures, whatever the approach (TO or RP) (moderate-quality evidence) (44). In a series involving more than 11,000 women who operated on using an RP approach, the British Society of Urogynaecology, observed that as BMI increased, PGI-I scores declined (45). PRO measures for USI are inversely correlated with BMI, with 97% of women with normal BMI stating that they were cured/improved compared to women in higher BMI groups (84-94%) reporting lower rates ($p < 0.005$) (low-quality evidence) (45). In a long-term follow-up series, there was a sharp decrease in cure rate of USI symptoms in women presenting with an increased BMI, and $\text{BMI} \geq 35 \text{ kg/m}^2$ seemed to be the best explanatory cutoff level (overall cure rate was 81% and 52% in non-obese and very obese ($> 35 \text{ kg/m}^2$) groups, respectively) (low-quality evidence) (46). Other series confirmed that very obese women (class 3 obesity group ($\text{BMI} \geq 40 \text{ kg/m}^2$)) are 2 to 3 times as likely to fail when compared with normal-weight women, on long-term follow-up (very low-quality evidence) (47). Meta-analyses show that, among women with severe obesity, bariatric surgery is associated with substantially reduced urinary incontinence over 3 to 5 years (half of obese women reported improvement or cure of USI after bariatric surgery) (very low-quality evidence) (48, 49). No RCTs have compared MUS and bariatric surgery. In retrospective series (case-control comparative series), obesity was associated with a decrease

in bladder injury rate in MUS surgery using the RP approach (very low-quality evidence) (50) and a decrease in post-operative thigh pain rate in the TO approach (very low-quality evidence) (51, 52).

Response to PICO 5 and PICO 6: which approach in obese women presenting with USI?

Obesity (BMI > 30 kg/m²) is a risk factor for the unsuccessful treatment of USI with MUS (moderate-quality evidence). For very obese women (BMI ≥35-40 kg/m²) the cure rates associated with MUS surgery are low (50%) and are similar to those observed after bariatric surgery (very low-quality evidence). Outcomes (cure rates and adverse events) seemed to be similar after the RP and TO approaches for USI in moderately obese women who underwent MUS surgery (low-quality evidence). Either the RP or TO approach should be used for the insertion of MUS in obese woman presenting with USI (strong agreement). In very obese women (BMI ≥35-40 kg/m²), weight loss should be preferred prior to MUS surgery and bariatric surgery should be discussed (strong agreement).

MUS in the elderly

PICO 7: “In an elderly woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) more effective (O) than the transobturator approach (C) in reducing the symptoms of USI?”

PICO 8: “In an elderly woman undergoing MUS for USI (P), is the bottom-to-top retropubic approach (I) safer (O) than the transobturator approach (C) in reducing the complications associated with USI surgery?”

There is no consensus concerning the definition of an “old” woman (elderly). The definition of frailty is not consensual, but some criteria are regularly cited: age > 80 years, restricted mobility, functional decline, cognitive impairment (53). Review of the published literature suggests that elderly women are underrepresented in RCTs of USI surgery (54). To

our knowledge, no study of the MUS procedure has been conducted in elderly frail women. In retrospective case-control series, increasing age (age over 70-75) was an independent risk factor of failure or recurrence following the MUS procedure (after the RP and TO approaches) (low-quality evidence) (55-59).

An RCT was conducted in a group of women over 70 years old and showed that RP MUS was associated with better quality of life and lower incontinence symptoms when compared to no treatment (moderate-quality evidence) (60).

Response to PICO 7 and 8:

The surgical treatment of USI in aged women should be the same as in young women, as long as no frailty is present (strong agreement). Either the RP or TO approach should be used for the insertion of MUS in elderly women presenting with USI (strong agreement). However, elderly women should be aware of the slightly increased rate of failure after MUS. In aged women with suspicion of frailty (age over 80 years, restricted mobility, functional decline, cognitive impairment), a geriatric assessment is necessary before surgery (strong agreement).

DISCUSSION

MUS devices available in France in 2021

Medical devices available in France have been recently validated/authorized by the national French health authority called H.A.S. (*Haute Autorité de santé*). The complete list is given in Table 1 (updated 31 January 2021) [https://www.legifrance.gouv.fr/search/all?tab_selection=all&searchField=ALL&query=bande lettres+sous-ur%C3%A9trales&searchProximity=&searchType=ALL&isAdvancedResult=&isAdvancedR](https://www.legifrance.gouv.fr/search/all?tab_selection=all&searchField=ALL&query=bande+lettres+sous-ur%C3%A9trales&searchProximity=&searchType=ALL&isAdvancedResult=&isAdvancedR)

esult=&typePagination=DEFAULT&pageSize=10&page=1&tab_selection=all#all. As seen in this table, no SIS (mini-sling) is available in France.

MUS insertion guidelines from the French authority

Medical devices are divided into four classes, known as class I, class IIa, class IIb and class III, as a function of their level of risk (class III: very significant potential for risk). Mid-urethral synthetic slings are classified as class III medical devices. On October 23, 2020 the H.A.S. published guidelines concerning the insertion of MUS. The MUS procedure for the surgical treatment of USI in women should be performed under the following conditions: i) a clinical exam (urogenital +/- neurological) must be done before the procedure in accordance with current guidelines; ii) patients must be informed concerning various conservative and surgical treatments available with the benefits and risks of each, post-operative follow-up and what to do in the event of complications. This information is provided using a standardized information sheet; iii) the decision to perform MUS in a patient with USI must be taken by a multidisciplinary pelviperineology team (at least one urologist and one obstetrician-gynecologist +/- a physical medicine specialist and a rehabilitation physician), after considering all the options for the management of female USI (the multidisciplinary team's written report will have been previously transmitted to the patient).; iv) the surgeon performing the insertion must be trained in the techniques of implanting suburethral strips, having participated in the performance of at least 15 procedures by route of implantation (RP/TO) in the presence of an experienced surgeon. Regular practice is then required; v) intraoperatively, it is recommended to have available, if necessary, the means of visualization of possible bladder complications; vi) ensure the traceability of the medical device and a document must systematically be given to the patient (identification of the implant, place and date of implantation, name of the surgeon); vii) a control consultation must be carried out in

the month following the implantation and at least one consultation should be performed one year after the procedure to ensure adequate management of any late complications; viii) the management of serious complications should be done in a center with a multidisciplinary surgical technical platform and must be reserved for surgeons trained in MUS removal.

CONCLUSION

The current Opinion provides an appropriate strategy for both the selection of patients and the best therapeutic approach in women presenting with USI.

CONFLICT OF INTEREST

VC: Member of a Scientific Advisory Body / travel fees / consultancy / advisory (Intuitive, Jansen, Astellas, Zambon, Elivie, Doston Scientific, Ipsen, Bouchara, Pfizer, Pierre Fabre, Mylan, Sanofi, Leopharma, Allergan, Takeda, GlaxoSmithKline).

XD: Ownership or other investments, including shares (Sanofi, Nanobiotics); Member of a Scientific Advisory Body / travel fees / consultancy / advisory (Urgotech, Astellas, Allergan, Laborie, Mylan, Pfizer, Braun, Leopharma, Gynecare (not for 5 years), Wellspect, AMI (not for 3 years)).

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