APPENDIX

In obese women, does weight loss/bariatric surgery improve FSUI?

Epidemiological studies have established that being overweight or obese is an important modifiable risk factor for urinary incontinence. SUI is positively correlated with body mass index (BMI), as each five unit increase in BMI above normal weight is associated with a 20–70% increase risk of urinary incontinence, and a 30–60% increased risk of incident incontinence over 5–10 years.[1] Central obesity (per 10 cm larger waist) and general obesity (per five unit increase in BMI) are both key metabolic factors associated with development of SUI in women.[2] Central adiposity is associated with an increase in intra-abdominal pressure, which increases intravesical pressure and urethral mobility, exacerbating SUI.[3] Weight reduction is shown to increase Valsalva leak point, and reduce intravesical bladder pressure, urethral mobility, incontinence episodes, and the need for absorptive pads.[4-6] Weight reduction may be achieved via dietary changes and behavioural interventions ("behavioral weight loss") or bariatric surgery ("surgical weight loss").

Observational studies and RCTs demonstrate that behavioral weight loss decreases SUI episodes among overweight and obese women. In a well-conducted RCT involving 338 overweight and obese women, those who had a mean weight loss of 8% (7.8 kg) experienced a 47% decrease in mean weekly number of incontinence episodes, compared to 28% in the control group who lost a mean 2% (1.5 kg).[7]

Among severely obese populations (BMI >40) planning weight reduction surgery, the prevalence of pure SUI is 28–33% and mixed incontinence 32–46%.[1] Numerous observational studies have reported substantial improvements in SUI following the first year of bariatric surgery.[4,8-10] Patients with an average weight loss of 49 kg experienced a significant improvement in SUI, frequency and leakage of any degree, and overall quality of life subsequent to surgery.[11] Complete resolution of SUI has been reported in up to 60% of patients who experienced a mean 70% weight loss and a mean decrease in BMI to 31.6.[12] Durability of improvements following bariatric surgery has been established up to three years, with greater weight loss independently associated with both improvement and remission of SUI.[13]

- **RECOMMENDATION 6:** Overweight or obese women with bothersome stress incontinence **should** be counselled that weight loss may improve their degree of incontinence *(Strength recommendation, High quality of evidence).*

- **RECOMMENDATION 7:** Surgical interventions for stress incontinence **should** be delayed in women considering bariatric surgery *(Strong recommendation, Moderate quality of evidence).*

References

1. Whitcomb EL, Subak LL, Effect of weight loss on urinary incontinence in women. *Open Access J Urol* 2011;3:123-32.
2. Lai HH, Helmuth ME, Smith AR, et al., Relationship between central obesity, general obesity, overactive bladder syndrome and urinary incontinence among male and female patients seeking care for their lower urinary tract symptoms. *Urology* 2019;123:34-43.
3. Swenson CW, Kolenic GE, Trowbridge ER, et al., Obesity and stress urinary incontinence in women: Compromised continence mechanism or excess bladder pressure during cough? *Int Urogynecol J* 2017;28:1377-85.
4. Bump RC, Sugerman HJ, Fantl JA, et al. Obesity and lower urinary tract function in women: Effect of surgically induced weight loss. *Am J Obstet Gynecol* 1992;167:392-7; discussion 7-9.
5. Subak LL, Whitcomb E, Shen H, et al. Weight loss: A novel and effective treatment for urinary incontinence. *J Urol* 2005;174:190-5.
6. Sugerman H, Windsor A, Bessos M, et al. Effects of surgically induced weight loss on urinary bladder pressure, sagittal abdominal diameter and obesity comorbidity. *Int J Obes Relat Metab Disord* 1998;22:230-5.
7. Subak LL, Wing R, West DS, et al. Weight loss to treat urinary incontinence in overweight and obese women. *N Engl J Med* 2009;360:481-90.
8. Burgio KL, Richter HE, Clements RH, et al. Changes in urinary and fecal incontinence symptoms with weight loss surgery in morbidly obese women. *Obstet Gynecol* 2007;110:1034-40.
9. Kuruba R, Almahmeed T, Martinez F, et al., Bariatric surgery improves urinary incontinence in morbidly obese individuals. *Surg Obes Relat Dis* 2007;3:586-90; discussion 90-1.
10. Laungani RG, Seleno N, Carlin AM. Effect of laparoscopic gastric bypass surgery on urinary incontinence in morbidly obese women. *Surg Obes Relat Dis* 2009;5:334-8.
11. Vella VL, Jaffe W, Lidicker J, et al. Prevalence of urinary symptoms in morbidly obese women and changes after bariatric surgery. *J Reprod Med* 2009;54:597-602.
12. Bulbuller N, Habibi M, Yuksel M, et al. Effects of bariatric surgery on urinary incontinence. *Ther Clin Risk Manag* 2017;13:95-100.
13. Subak LL, King WC, Belle SH, et al. Urinary incontinence before and after bariatric surgery. *JAMA Intern Med* 2015;175:1378-87.

Does smoking cessation improve female stress urinary incontinence?

Although there are no direct trials investigating the effects of cigarette cessation on SUI, there is evidence supporting a relationship between smoking and worsening SUI. Bump et al identified an odds ratio of 2.20 of genuine SUI for former smokers and 2.48 for current smokers in comparison to non-smokers.[1] Higher daily cigarette consumption and cumulative lifetime consumption was also associated with increased risk of SUI. Furthermore, tobacco use is associated with higher failure rates of initial incontinence procedures, and subsequent increased risk of re-operation.[2]

Smoking is a contributing factor to development of chronic respiratory disease and excessive coughing which provide an increase in intra-abdominal pressure and possible stress incontinence.[3] Further, it is the most important risk factor for bladder cancer with relative risk versus never smokers of 3.47.[4] Smoking cessation is a general health measure that should be recommended to all patients with SUI with referral to community smoking cessation services.

- **RECOMMENDATION 8:** Smoking cessation **should be** recommended for all patients as a general public health measure and may reduce chronic cough and stress incontinence *(Clinical principle).*

References

1. Bump RC and McClish DK, Cigarette smoking and urinary incontinence in women. *Am J Obstet Gynecol* 1992;167:1213-8.
2. Sheyn D, James RL, Taylor AK, et al. Tobacco use as a risk factor for reoperation in patients with stress urinary incontinence: A multi-institutional electronic medical record database analysis. *Int Urogynecol J* 2015;26:1379-84.
3. Imamura M, Williams K, Wells M, et al. Lifestyle interventions for the treatment of urinary incontinence in adults. *Cochrane Database Syst Rev* 2015(12):CD003505.
4. Cumberbatch MGK, Jubber I, Black PC, et al. Epidemiology of bladder cancer: A systematic review and contemporary update of risk factors in 2018. *Eur Urol* 2018;74:784-95.

What is the evidence for use of pelvic floor muscle physiotherapy to treat urinary incontinence? Should particular methods be recommended?

Most of the literature regarding conservative management for stress urinary incontinence (SUI) relates to pelvic floor muscle training (PFMT).[1] PFMT aims to improve pelvic floor muscle (PFM) strength, endurance, power, relaxation, or a combination of these parameters.[2] Mechanisms of action for PFMT include: 1) The use of a conscious PFM pre-contraction, prior to and during effort or exertion, which clamps the urethra and increases urethral pressure, preventing urine leakage (the "Knack"); and 2) bladder neck support from strong, toned PFMs (resistant to stretching), which limits its downward movement during effort and exertion, thus preventing urine leakage.[2,3]

The most current update of the Cochrane Collaboration's review and recommendations from the International Consultation on Incontinence recommends PFMT as the first-line conservative management strategy for women with SUI.[1,3] The 31 randomized controlled trials (RCTs) in the Cochrane review represent a wide-ranging population of older and younger women from 14 countries, as well as the use of a range of patient-centered and clinical outcomes, which increase generalizability of study findings. Women with SUI in the PFMT group were eight times more likely to report *cure* [56% vs. 6%; risk ratio (RR) 8.38, 95% confidence interval (CI) 3.68–19.07, 165 women; high-quality evidence] when compared to no treatment/placebo or usual care. Women with SUI in the PFMT group were six times more likely to report *cure or improvement* (74% vs. 11%; RR 6.33, 95% CI 3.88–10.33; 242 women; moderate-quality evidence) when compared to no treatment/placebo or usual care.[3] Furthermore, women with SUI in the PFMT group were more likely to report a significant improvement in UI symptoms questionnaires (376 women; moderate-quality evidence) and in UI-specific quality of life (QoL) questionnaires (348 women; low-quality evidence). PFMT reduced 24-hour leakage episodes in women with SUI (mean difference (MD) 1.23 lower, 95% CI 1.78 lower to 0.68 lower; 432 women; moderate-quality evidence). Women in the PFMT group are also more satisfied with their treatment as well as their sexual outcomes. Adverse events were rare and minor.

Overall, a three-month individualized or group-based supervised progressive and intensive PFMT, taught by a health professional after initial PFM evaluation, should be recommended over self-directed generic PFMT, usual care or watchful waiting according to the International Consultation on Incontinence recommendations.[1] Further research related to longer-term efficacy and cost-effectiveness is needed.

Finally, although current published studies have limitations, there does not appear to be any clear added benefit of using PFMT adjunctive therapies (biofeedback, electrical stimulation, or vaginal cones) in all women with SUI.[1] Adjunctive PFM therapies should be used on a case-by-case basis as they may be more appropriate for sub-groups of women (i.e., those showing significant weakness, atrophy and proprioception could benefit from electrical stimulation and biofeedback).[1] Further studies are needed in these patient subgroups.

- **RECOMMENDATION 11:** For the index patient, providers **should** recommend a three-month individualized or group-based supervised progressive and intensive PFMT program, taught by a health professional as first line treatment for FSUI *(Strong recommendation, High quality of evidence).*

References

1. Dumoulin CAT, Booth J, Bradley C, et al. Adult conservative management, in Incontinence: 6th International Consultation on Incontinence, C.L. Abrams P, Wagg A, Wein A, Editor. 2017, International Continence Society: Bristol. p. 1443-628.
2. Bo K, Frawley HC, Haylen BT, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and non-pharmacologic management of female pelvic floor dysfunction. *Int Urogynecol J* 2017;28:191-213.
3. Dumoulin C, Cacciari LP, Hay-Smith EJC, Pelvic floor muscle training vs. no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev* 2018;10:CD005654.

What are the key elements to include in obtaining informed consent for FSUI surgery?

A patient's ability to make good decisions in managing a condition are grounded in the relationship between her and her physician (in turn grounded in openness, trust, and good communication) and the effectiveness of the knowledge transfer between the two.[1]

FSUI is not a life-threatening condition, and treatment for it is aimed at improving a patient's quality of life. As such, physicians must take increased care in consenting patients for surgery, and the courts may hold a physician at a higher standard of disclosure in such cases. The need to emphasize careful informed consent is highlighted by public concern about pelvic mesh implantation fueled by media reports of litigation and health agency advisories. In a study of medical malpractice claims related to FSUI surgery between January 1, 1990, and January 1, 2020, Lynch et al reported that nearly half of claims in favour of the plaintiff related to negligence in preoperative care, and lack of informed consent was the most common underlying complaint (42.6%, n=26/61).[2]

Properly informing patients about FSUI surgery is challenging and takes a commitment of time and energy by the surgeon. Studies of patients undergoing MUS implantation indicate that recall of important potential risks was low, misconceptions about pelvic mesh are evident, and forgetting elements of the consent discussion translated to greater decisional regret.[3]

The consent process

The essential requirements of a valid consent process are that (a) it is voluntary; (b) the patient has adequate capacity to participate in the process; and (c) the patient is properly informed through the process. The latter requires that a certain standard is met when information is disclosed to the patient, and that the patient comprehends the information. Per the CMPA: "The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision."

The consent process begins by ensuring that the patient understands their diagnosis and any uncertainties about it are discussed. Key elements that should be disclosed in the consent discussion for FSUI surgery are listed in Supplementary Tables 1 and 2.

Supplementary Table 1. Key elements to disclose in consent discussion for FSUI

Element	Notes
Alternatives to surgery (inform patient and offer prior to surgery)	Include: Use of absorbent products, lifestyle modifications, pelvic floor muscle training, pessaries. Discuss the risks, if any, of leaving the condition untreated
Surgical options	Include: Periurethral bulking, mid-urethral slings, retropubic colposuspension, autologous fascial slings
Expected outcomes	Include: Short- and long-term outcomes, satisfaction vs. cure rates

Usual postoperative course and restrictions	Outline the expected perioperative experience
Potential risks	"Material" risks (those that might influence the choice to proceed by a reasonable person) must be disclosed (Table 2). Materiality is influenced by both frequency and seriousness of the risk. Advise patient of signs/symptoms to watch for that could require early or immediate treatment ("informed discharge").

Other elements to consider in the consent discussion include the FDA classification of mesh, surgeon's experience, potential off label usage of products if appropriate, and any conflicts of interest.

Supplementary Table 2. Key material risks associated with FSUI surgery	
Generic	**Procedure-specific**
Bleeding	Failure to resolve SUI
Infection	De novo or worsening OAB
Injury to adjacent structures/organs (where appropriate, advise patient that "blind" passage of trocars/instruments has inherent risks)	Transient or permanent voiding dysfunction that could require use of catheters or secondary intervention
Thromoboembolic complications	Chronic pain, dyspareunia
Risks of positioning (e.g., neurapraxia)	Mesh erosion
Anesthesia risks	Mesh extrusion

Patients should understand that some complications could require further intervention to resolve, and that some can have significant and permanent impact on urinary, bowel and/or sexual function and quality of life. Implantation of materials for FSUI is intended to be permanent. Products such as mesh can be removed but complete removal is not always possible and surgery to remove them can result in additional morbidity. With respect to mesh, current advisories and position statements should be discussed and made available.

Comprehension of material

The physician should take "reasonable steps" to ensure the patient has understood the information, including personally attending the patient visit, monitoring the patient's reaction to the information, and allowing the patient to ask questions.

Documentation and supplementary materials

The consent "form" does not replace the discussion between physician and patient, which is the important element of the consent process; rather, it is simply evidentiary written confirmation that the discussion and explanations took place and the patient agrees to proceed. Additional detailed notes in the chart contemporaneous with the discussion are beneficial if consent is ever called into question.

Handouts and supplementary materials should be seen only as an adjunct, albeit an important and valuable one, to consent discussions. They should be provided well in advance with an opportunity given to ask questions about the material prior to final consent. A notation about the material given should be made in the chart, and older versions of any material should be kept available in case they are called into question in the future. Consent "checklists" may also be considered, but their purpose should be to promote patient discussions and not as a defensive strategy against future litigation.[1]

References

1. Digesu GA, Swift S, Handley V. Informed consent checklists for midurethral slings: A common-sense approach. *Int Urogynecol J* 2017;28:1639-43.
2. Lynch NB, Xu L, Ambinder D, et al. Medical malpractice in stress urinary incontinence management: A 30-year legal database review. *Curr Urol* 2021;15:137-42.
3. McFadden BL, *et al.* Patient recall 6 weeks after surgical consent for midurethral sling using mesh. *Int Urogynecol J* 2013;24:2099-104.

How should a woman who demonstrates an abdominal voiding pattern be counselled about her treatment options or FSUI?

Valsalva voiding is an adaptive response to both bladder dysfunction (detrusor underactivity) and obstructed voiding (dysfunctional voiding, prolapse, etc.). Surgical interventions that serve to increase urethral resistance as the anti-incontinence mechanism (urethral bulking, pubovaginal sling, retropubic colposuspension) could increase the risk of further voiding dysfunction in these patients and result in urinary retention post-surgery; however, there is a paucity of studies assessing the effect of preoperative Valsalva voiding on surgical outcomes after FSUI surgery. It is also apparent that urodynamic parameters cannot reliably predict postoperative urinary retention.[1,2]

Tension-free midurethral slings should in theory impart minimal risk of postoperative voiding complications in these patients, and this has been confirmed in small, single-center studies.[3] Other small studies, however, have demonstrated an increased risk of urinary retention post-procedure, although the effect appears to be temporary and the risk of persistent urinary retention/voiding dysfunction beyond the first three weeks is similar between those that void with and without Valsalva voiding maneuvers. Therefore, Valsalva voiding may predict a delayed return to patient baseline voiding post-procedure.[4,5]

- **RECOMMENDATION 26:** Patient with Valsalva voiding considering surgical interventions for FSUI **should** be counselled on a possible increased risk of urinary retention/worsening voiding dysfunction after surgery, and a possible delayed return to baseline voiding *(Clinical principle).*

- **RECOMMENDATION 27:** Physicians **should not** rely on preoperative urodynamic parameters to predict postoperative voiding dysfunction *(Weak recommendation, Low quality of evidence).*

References

1. Blanchard KA, Wilson WJ, Jr., Winters JC. Can urodynamic studies identify patients at risk for voiding difficulty after pubovaginal sling? The "voiding quality index". *Ochsner J Spring* 2007;7:20-3.
2. Lemack GE, Krauss S, Litman H, et al. Normal preoperative urodynamic testing does not predict voiding dysfunction after Burch colposuspension versus pubovaginal sling. *J Urol* 2008;180:2076-80.
3. Anderson BB, Pariser JJ, Pearce SM, et al. Safety and efficacy of retropubic mid-urethral sling placement in women who void with Valsalva. *Urology* 2016;91:52-7.
4. Gracely A, Major N, Zheng Y, et al. Do urodynamics predict urinary retention after sling placement in the complex patient: The value of reproducing symptoms on urodynamics. *Int Urogynecol J* 2021;32: 81-6.
5. Pham KN, Topp N, Guralnick ML, et al. Preoperative Valsalva voiding increases the risk of urinary retention after midurethral sling placement. *Int Urogynecol J* 2010;21:1243-6.

How should a woman with a urethral diverticulum and a history of SUI be counselled about treatment options for SUI?

It is estimated that 29% of women with urethral diverticula (UD) have SUI and that 36–45% of these women have persistent SUI after diverticulectomy.[1,2] Furthermore, 13–49% of women undergoing urethral diverticulectomy develop de novo SUI after surgery, although most often the SUI is mild.[2,3]

If an UD is identified during the workup of FSUI, it is recommended to excise it surgically vaginal before surgically addressing the FSUI component.[4] A staged approach allows a trial of conservative management before considering further surgery. Options for anti-incontinence procedures during or after urethral diverticulectomy include Burch colposuspension or pubovaginal sling.[5] It is not recommended to use synthetic material (such as MUS) in this patient population; the location of the polypropylene mesh and plane distortion following diverticulectomy significantly increase the risk of urethral erosion.[6]

In three retrospective studies (Supplementary Table 3), the addition of a pubovaginal sling to the urethral diverticulectomy led to more women having improved or resolved SUI symptoms as compared to no anti-incontinence procedure;[7-9] however, there may be a higher rate of UTI and urinary retention with the pubovaginal sling. If a woman has significant preoperative SUI (not postvoid dribbling), an urethral diverticulectomy and incontinence procedure may be considered; however, there is a limited role for an anti-incontinence surgery to prevent de novo SUI, as approximately 60% of patients will have resolution of de novo SUI over time.[1]

Supplementary Table 3. Summary of retrospective studies

Reference	Study description	Outcome	Comments
7	485 urethral diverticulectomies with 96 concomitant PVS	Addition of PVS improved odds of SUI resolution (adjusted OR 2.27, 95% CI 1.02–5.03, p=0.043). It was not significantly protective against de novo SUI (adjusted OR 0.86, 95% CI 0.25–2.92; p=0.807)	Higher risk of urinary retention and recurrent UTIs with the PVS
8	38 urethral diverticulectomies with concomitant PVS	90% reported complete resolution of SUI symptoms.	2 patients had urethral diverticula recurrence and 2 had SUI recurrence
9	61 urethral diverticulectomies with 24 concomitant PVS	Resolution of SUI in 83% who underwent a simultaneous PVS compared 53% in the urethral diverticulectomy alone group	

- **RECOMMENDATION 28:** If a physician identifies an UD during the workup of FSUI, it **should** be excised trans-vaginally before surgically addressing the FSUI component *(Clinical principle)*.

- **RECOMMENDATION 29:** If a woman has significant preoperative SUI (not postvoid dribbling), the physician **may** offer simultaneous urethral diverticulectomy and non-mesh incontinence procedure; however, there is a limited role for an anti-incontinence surgery to prevent de novo SUI as approximately 60% of patients will have resolution of de novo SUI over time *(Clinical principle)*.

References

1. Barratt R, Malde S, Pakzad M, et al. The incidence and outcomes of urodynamic stress urinary incontinence in female patients with urethral diverticulum. *Neurourol Urodyn* 2019;38:1889-900.
2. Chavez JA, Fuentes JL, Christie AL, et al. Stress urinary incontinence after urethral diverticulum repair without concomitant anti-incontinence procedure. *Urology* 2021;154:103-8.
3. Lee UJ, Goldman H, Moore C, et al. Rate of de novo stress urinary incontinence after urethal diverticulum repair. *Urology* 2008;71:849-53.
4. Lee W, Uberoi P, Coy DL, et al. Erosion of mesh mid-urethral sling into a complex urethral diverticulum: Diagnosis, evaluation, and surgical management. *Urology* 2020;141:e1-2.
5. Kim HW, Lee JZ, Shin DG, Pathophysiology and management of long-term complications after transvaginal urethral diverticulectomy. *Int Neurourol J* 2021;25:202-9.
6. Pacer E, Duenas-Garcia OF, Hota L, et al. Urethral diverticulum following polypropylene mesh midurethral slings: A literature review. *Biomed Res Int* 2020;2020:6761581.
7. Bradley SE, Leach DA, Panza J, et al. A multicenter retrospective cohort study comparing urethral diverticulectomy with and without pubovaginal sling. *Am J Obstet Gynecol* 2020;223:273 e1- 9.
8. Enemchukwu E, Lai C, Reynolds WS, et al. Autologous pubovaginal sling for the treatment of concomitant female urethral diverticula and stress urinary incontinence. *Urology* 2015; 85:1300-3.
9. Greiman A, Rittenberg L, Freilich D, et al. Outcomes of treatment of stress urinary incontinence associated with female urethral diverticula: A selective approach. *Neurourol Urodyn* 2018; 37:478-84.

Does the use of mesh-based midurethral slings cause autoimmune diseases or cancer?

There have been concerns raised by patients, advocacy groups, and physicians[1] that transvaginal mesh implantation may lead to an increased risk of systemic disease. This hypothetical link was supported by initial microscopy studies showing breakdown of the polypropylene fibers in resected mesh specimens, however, subsequent work has shown that with the proper processing of the transvaginal mesh product after removal there is no evidence of degradation or oxidization.[2] Large studies using administrative data from New York state have not found any associated between transvaginal mesh and autoimmune diseases or cancer.[3,4] A systematic review that included all polypropylene mesh products found four relevant studies, and there was no link with autoimmune diseases.[5] Additional studies in Sweden and Ontario have not found any association between transvaginal mesh and cancer.[5,6]

- **RECOMMENDATION 33:** Physicians **should** counsel patients that there is no evidence mesh midurethral slings are associated with an increased risk of cancer or autoimmune disease *(Clinical principle).*

References

1. Tervaert JWC. Autoinflammatory/autoimmunity syndrome induced by adjuvants (Shoenfeld's syndrome) in patients after a polypropylene mesh implantation. *Best Pract Res Clin Rheumatology* 2019;32:511-20.
2. Thames SF, White JB, Ong KL. The myth: In vivo degradation of polypropylene-based meshes. *Int Urogynecol J* 2017;28:285-97.
3. Chughtai B, Sedrakyan A, Mao J, *et al.* Challenging the myth: Transvaginal mesh is not associated with carcinogenesis. *J Urol* 2017;198:884-9.
4. Chughtai B, Sedrakyan A, Mao J, et al. Is vaginal mesh a stimulus of autoimmune disease? *Am J Obstet Gynecol* 2017;216:495.e1-7.
5. Kowalik CR, Zwolsman SE, Malekzadeh A, et al. Are polypropylene mesh implants associated with systemic autoimmune inflammatory syndromes? A systematic review. *Hernia* 2022;1-10.
6. Vigil HR, Wallis CJD, Zhang B, et al. Stress incontinence surgery does not cause pelvic malignancy: A population-based cohort study. *J Urology* 2021;205:1725-32. doi:10.1097/ju.0000000000001631