

Female Urology, urodynamics, incontinence and Pelvic floor

Management of Complications of Prosthetic Mid-urethral Tape Surgery for Stress Urinary Incontinence in Women

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OBJECTIVE	To propose guidelines for the management of complications of prosthetic mid-urethral tape surgery for stress urinary incontinence in women.
METHODS	These guidelines are based on an exhaustive literature review on retropubic and trans-obturator mid-urethral tape complications. The expert panel rated the level of evidence of each study, summarized literature for the treatment of each complication, and proposed guidelines.
RESULTS	Management of these complications is complex and the first treatment is crucial to offer the best functional result to the patient. We propose a standardized approach and guidelines for the management of complications to help physicians to early identify a surgical complication, offer adequate treatment for each complication and provide clear and appropriate information to patients. We detailed management of intraoperative complications as follows: bladder, urethral, vaginal, visceral, and vascular injury; short-term post-operative complications are the following: bleeding/hematoma, voiding dysfunction, pain, infection; and long-term post-operative complications are the following: chronic voiding dysfunction, de novo overactive bladder syndrome, chronic pain, dyspareunia, vaginal, bladder, and urethral tape erosion.
CONCLUSION	These guidelines may help physicians to improve management of prosthetic mid-urethral sling complications that may occur following stress urinary incontinence surgery. UROLOGY xx: xxx-xxx, xxxx. © 2024 Published by Elsevier Inc.

Stress urinary incontinence (SUI) is a common disease in women. It can lead to a significant deterioration of quality of life and may require surgical treatment including the use of prosthetic mid-urethral tape (MUT). The lifetime cumulative risk of any SUI surgery for women is 13.6%.¹ Prosthetic surgery has demonstrated its efficacy but sometimes lead to severe complications like tape erosion, pain, infection, voiding dysfunction with reintervention rate of 2.2%.² In

October 2020 Ministry of Health and Prevention published a decree to regulate MUT surgery for SUI in women. Management of the complications is complex and there are currently no national guidelines available in France. At the request of the Ministry of Health and Prevention, The French National Authority for Health, in collaboration with the French-speaking scientific societies as follows: AFU (French Society of Urology), SIFUD-PP (French-speaking Interdisciplinary Society of Urodynamics and Pelvi-Perineology), CNGOF (National College of Gynecologists and Obstetricians), SCGP (Society of Gynecologic and Pelvic Surgery), issued guidelines to support daily practice.

These recommendations are limited to the management of surgical complications of SUI surgery in women involving a prosthetic reinforcement element as follows: retropubic and trans-obturator MUT, excluding medical complication.

METHODS

These guidelines are based on an exhaustive literature review using PubMed, Embase and Cochrane database to

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identify relevant meta-analyses, randomized and non-randomized controlled trials and large uncontrolled studies, published through February 2023. Only French and English articles were included. Search strategy was based on key words and MeSH terms. The expert panel summarized literature for each question, rated the level of evidence (LE) of each study (LE1: Very powerful randomized comparative trials, meta-analysis of randomized comparative trials; LE2: Not very powerful randomized trials, well-run non-randomized comparative studies, cohort studies; LE3: case-control studies; LE4: non-randomized comparative studies with large biases, retrospective studies, transversal studies, series of cases), and proposed recommendations according to grading (grade A: scientifically established evidence; grade B: scientific presumption; grade C: low level of evidence. In the absence of any conclusive scientific evidence, practices have nevertheless been recommended based on agreement between all members of the working group (Expert Agreement: EA). Guidelines were established by a “working group” of 18 experts included physicians, healthcare professionals and patients (nurses, physical therapists, methodologists, members of patient’s associations, experts in medical and surgical fields). Guidelines were then proposed to a “reading group” for review. Members of the working and reading groups were experts chosen by HAS. When the reading group was undecided or disagreed with the initial recommendation (< 90% of responses from the reading group within range [5-9]), the working group discussed the relevance of the comments and, if applicable, modified the guidelines.

RESULTS

Intraoperative Complications

Bladder Injury. Suspect bladder injury in case of leakage of irrigation fluid through the penetration points or along the plastic sheaths protecting the tape and/or in case of hematuria (grade C).

For retropubic MUT, systematically perform intraoperative urethroscopy with a 70° lens or use a flexible cystoscope (EA).

In case of intra-operative isolated bladder perforation or intramural MUT position, the MUT has to be immediately repositioned, followed by urethroscopy to verify its good final position (grade C).

Urethral Injury. In case of intraoperative urethral injury, the MUT has to not be inserted during the surgical procedure (EA).

Vaginal Injury. When using a trans-obturator approach (TOA) out-in, sufficient vaginal dissection has to be performed beyond lateral vaginal fornix to guide the awl and avoid vaginal injury (EA).

In case of difficulty in dissecting the lateral fornix for TOT placement, a retropubic approach (RPA) must be considered (EA).

In case of vaginal injury, suture vagina (incision or wound) with slow-resorption thread (EA).

After each MUT surgery, check the quality of vaginal suture and absence of vaginal intrusion, especially in vaginal fornix in case of TOT placement (EA).

To avoid the risk of vaginal suture disunion, we recommend advising patient to avoid vaginal intercourse for at least 1 month after MUT surgery (EA).

Visceral Injury. Digestive symptoms such as abdominal pain, defense, occlusion, peritonitis, occurring at short-, mid- or long-term after RP tape placement leads to the suspicion of digestive complication. In this case, perform an abdominopelvic CT scan (EA).

In the event of a digestive injury, initiate rapid and specific management, including removal of the prosthetic material, if necessary and possible, with digestive surgeon collaboration (EA).

Vascular Injury. In order to limit this risk in the case of RPA, we recommend (EA) the following:

- limited flexion of patient’s thighs on the abdomen
- perfect immobility of the patient during tape positioning
- medial orientation of the awl (about 15°)
- preliminary skin mark of the outlet holes

In case of heavy vaginal bleeding, perform immediate vaginal compression and associated bladder filling, if necessary, to control the bleeding (EA).

In case of a major vessel injury discovered in immediate intra- or post-operative period, it is necessary to take advice from a vascular surgeon (EA).

Short Term Postoperative Complications

Hematoma, Postoperative Bleeding. In case of postoperative hematoma, we recommend a conservative treatment to control the expansion of hematoma (manual suprapubic compression and/or placement of intra-vaginal wicks and/or bladder filling) (EA).

If active bleeding is suspected, imaging prior to embolization may be suggested (EA).

In case of active bleeding, management by embolization or revision surgery will be discussed (EA).

In the event of unstable hemodynamics, urgent surgical revision is required, if possible, with the collaboration of a vascular surgeon (EA).

In the event of compressive hematoma, surgical or percutaneous drainage is recommended (EA).

Postoperative acute voiding dysfunction (VD). In case of post-operative acute urinary retention (AUR), perform pelvic examination to eliminate a local etiology (hematoma, forgotten pad, fecaloma, etc.) (EA).

After MUT surgery, assess micturition recovery with interrogation and evaluation of post-voiding residue (PVR), preferably using an ultrasound technique (EA).

To assess micturition recovery, it is necessary to obtain a micturition of sufficient volume (200 mL) (EA).

No drug is recommended for acute urinary retention (AUR) (EA).

Dilatation of the urethra or tape lowering by urethral maneuver is not recommended in the case of AUR due to the associated risks (erosion, injury, urethral incision) (EA).

In case of AUR, we recommend to surgically relax the tape (opening the incision and pulling down on the sling to give it more space from urethra) less than 7 days after surgery and do it by direct approach, except for patients with preoperative detrusor hypocontractility for whom the use of self-catheterization may be proposed (EA).

In the event of significant PVR, the choice between tape release and self-catheterization is made on a case-by-case discussion, with re-evaluation of micturition during post-operative follow-up. A perineal ultrasound can be performed to assess the position and tension of the MUT (EA).

Postoperative Pain. In the event of severe acute pain in the immediate post-operative period following MUT insertion, not responding to medical treatment, we recommend discussing early tape removal with the patient (EA).

Postoperative Infection. It is not recommended to prescribe postoperative antibioprophyllaxis to reduce the risk of postoperative urinary tract infection (EA).

Prescribe antibioprophyllaxis intraoperatively and perform preoperative urine culture in accordance with antimicrobial prophylaxis guidelines (grade C).³

In case of MUT infection signs (cellulitis, contiguous abscess, etc.), prosthetic material must be removed as quickly as possible and as completely as possible (EA).

Long Term Complications

Late Chronic VD. Diagnosis of chronic VD must be considered in cases of emptying difficulties with a modified urinary stream, the need for postural adaptation associated with significant PVR, recurrent urinary tract infections, signs of overactive bladder (OAB) and leakage by overflow (EA).

Evaluation is necessary to search for (EA):

- PVR > 150 mL with ultrasound techniques (bladder scanner or ultrasonography)
- obstruction on urodynamic assessment ($Q_{max} < 12$ mL/s associated with maximum detrusor pressure (P_{detMax}) > 25 cmH₂O)⁴
- a protrusion hanging in the urethra when passing through during urethrovesical fibroscopy and/or

MUT erosion (particularly if associated with hematuria or per-micturition pain).⁵

In cases of symptomatic chronic obstruction, revision surgery is the first-line treatment (EA).

Intermittent self-catheterization should be limited to patients with pre-operative detrusor hypocontractility (EA).

At long term after MUT surgery, MUT relaxing is no longer possible and urethral maneuvers using urethral dilators are not recommended (EA).

Partial removal of the sub-urethral portion (or even the entire sub-urethral tape) is recommended when lateral section has failed to restore good urethral mobility, or when a first simple section of the sub-urethral tape has failed (EA).

As a second-line treatment, self-catheterization is recommended for patients who refuse repeat surgery or have too many comorbidities (EA).

Patients should be informed of the risk of SUI recurrence after MUT section/removal (EA).

De Novo Overactive Bladder Syndrome. Evaluation and treatment of OAB after MUT is summarized in [Figure 1](#).

Perform the following tests to identify OAB etiology: urine culture, flowmetry with PVR, bladder and/or perineal ultrasound and urethro-vesical fibroscopy and, if necessary, urodynamic assessment (EA).

OAB treatment after MUT is based on usual OAB treatments:

- Hygieno-dietetic measures and pelvic floor muscle training
- Medical treatments
- Posterior tibial neurostimulation
- In case of refractory OAB: surgical treatments (botulinum toxin, sacral neuromodulation, augmentation cystoplasty)

Chronic Pain. Inform patient of the risk of chronic pain in the event of pre-operative pain, pelvic sensibilization and/or myofascial pain (EA).

Use RPA for patients with chronic pre-operative pain, pelvic sensibilization or myofascial pain (EA).

Before confirmation of a Postoperative chronic pelvic pain (PCPP) diagnosis, it is recommended to search another organic etiology by clinical examination, cystoscopy and imaging (ultrasound or MRI) (EA).

In case of PCPP after MUT (EA):

- eliminate other pain etiology (organic etiologies)
- propose conservative non-surgical treatments (local estrogen therapy, analgesics, rehabilitation, physiotherapy, neurostimulation, etc.) as first-line treatment
- refer the patient to a pain specialist
- perform a local anesthetic infiltration as a pre-surgical diagnostic test

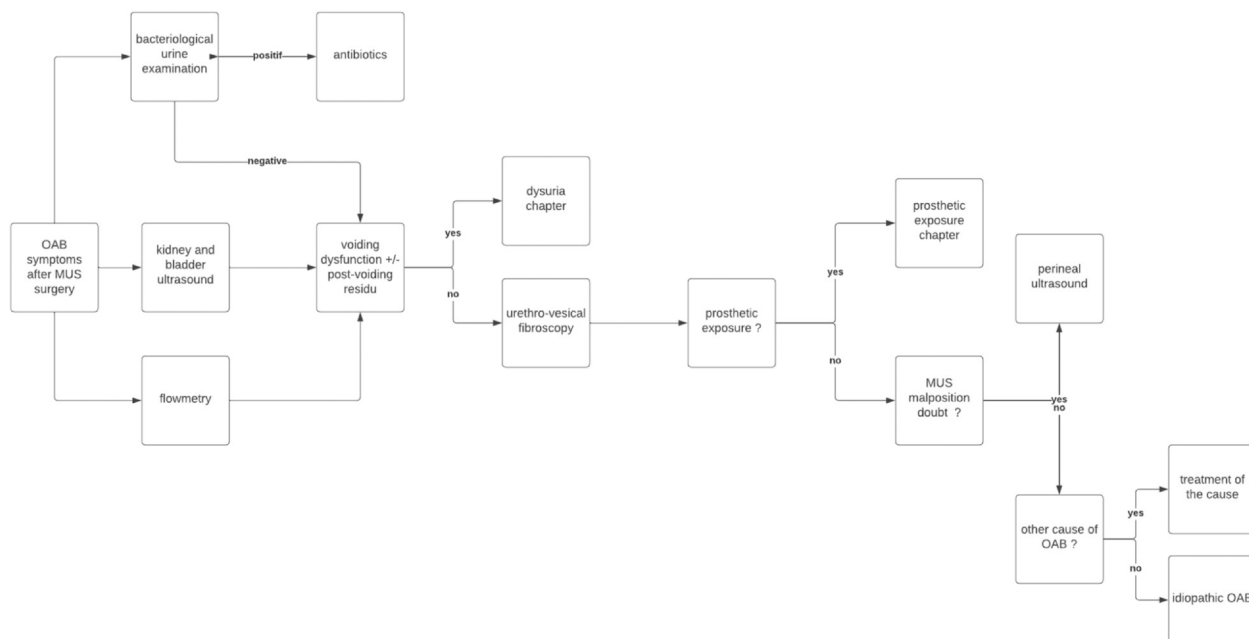


Figure 1. Evaluation and treatment of overactive bladder after mid-urethral tape surgery for stress urinary incontinence in women. Perform the following tests to identify OAB etiology: urine culture, flowmetry with PVR, bladder and/or perineal ultrasound and urethro-vesical fibroscopy and, if necessary, urodynamic assessment.

- propose MUT removal which leads to an improvement in pain in around 2/3 of cases ⁶
- MUT removal must be performed by a trained surgical team
- the choice of partial or complete MUT removal will be based on multidisciplinary discussion (literature data is insufficient to recommend one technique or the other).

Do not insert a new synthetic prosthesis at the same time as MUT removal (EA).

Dyspareunia. Pre-operative and post-operative dyspareunia must be evaluated, if necessary, using validated questionnaires, PISQ 12 for example ⁷ (EA).

If dyspareunia (or hispareunia) occurs or worsens postoperatively after MUT surgery:

- perform a vaginal examination seeking for MUT erosion or a trigger zone on the tape path (EA).
- We recommend looking for associated secondary vaginismus (EA).

No additional exam is recommended unless abscess or periprosthetic collection is suspected (EA). In this case, gynecological and perineal ultrasound and/or pelvic-perineal MRI are recommended to confirm diagnosis (EA).

Perineal physiotherapy, psycho-sexology or local treatment can be proposed first but must not delay invasive treatment if needed (infiltration or MUT removal) (EA).

In case of erosion, removal of all or exposed portion of the MUT is recommended (EA).

When no erosion is associated, infiltration test of the painful area with local anesthetics can be discussed as therapeutic test, before considering MUT removal (EA).

If the MUT is removed, the trigger zone must be removed, but not systematically the entire MUT (EA).

If a new MUT is planned after a primary TOT, the new MUT must be inserted via a different approach (RPA) (EA).

Vaginal Erosion. Vaginal erosion must be searched by clinical examination in the event of bleeding, vaginal discharge, dyspareunia, hispareunia, pelvic pain, sensation of intravaginal foreign body (EA).

In asymptomatic patients simple follow-up can be proposed (EA).

In symptomatic, non-sexually active patients with small vaginal erosion (< 1 cm), intravaginal application of local estrogen, in the absence of contraindication may be proposed (EA).

In other cases, as a simple vaginal suture may expose to erosion recurrence, we recommend removing the exposed prosthetic segment before vaginal suture (EA).

Late Bladder Erosion. This complication must be investigated in case of micturition pain or vaginal pain, OAB symptoms, recurrent urinary tract infections or hematuria (EA).

If bladder erosion is suspected, urethrovesical rigid (with 70° lens) or flexible cystoscopy is recommended for the diagnosis (EA).

We recommend removing the intravesical fragment of the tape (EA).

Patient must be informed of the risk of persistent OAB, persistent pain, recurrence of incontinence after MUT removal and the risk of tape erosion recurrence (EA).

Choose excision of the exposed tape rather than endoscopic destructive treatment (mechanical or laser) (AE).

In patients with severe co-morbidities, cystoscopic approach is the first treatment option to choose with information upon the risk of secondary erosion of residual material (EA).

Urethral Erosion. Urethral erosion should be suspected in case of urethral or vaginal pain, VD, OAB symptoms, recurrent urinary tract infections, hematuria or urethrorrhagia (EA).

If urethral erosion is suspected urethrocystoscopy must be performed to confirm the diagnosis (EA).

Removal of the exposed MUT fragment from the urethra is recommended (EA) as the following:

- surgery should be performed by a trained surgeon
- there is no consensus on the procedure for exposed MUT removal

Surgical MUT removal should be preferred to endoscopic or laser treatment (EA).

Patients should be informed of the risk of recurrence of incontinence and urethral fistula after tape removal (EA).

DISCUSSION

There are no national French guidelines for management of complications after prosthetic surgery for SUI. These complications are rare but lead to severe functional consequences. The first treatment of the complication is crucial to offer the best functional results to the patient. That is why standardized approach is needed.

Intraoperative Complications

Bladder Injury. Rates of bladder perforation are low but significantly higher in case of RPA ($\leq 5\%$) versus TOA ($< 1\%$).⁸⁻¹⁰

Risk factors identified were: BMI < 25 , history of surgery for SUI or prolapse, concomitant prolapse surgery, beginning of surgeon's learning curve (higher rate for the first 5 cases decreasing with the cumulative number of cases performed).¹¹⁻¹⁴

Bladder perforation usually seems to have no long-term consequences if observed intraoperatively and if the tape is correctly repositioned directly but some studies have had conflicting results.¹⁵

Urethrocystoscopy is ideally done with a 70° lens or a flexible cystoscope to give a clear view of the anterior and lateral bladder wall and the bladder neck.¹⁶

For TOA, the working group was unable to reach a consensus on whether urethrocystoscopy should be performed systematically or only in specific situations (early experience, suspected bladder injury).

There is insufficient data to prove the need for systematic postoperative catheterization and a minimum duration of it or justify hospitalization instead of ambulatory after intraoperative bladder injury.

There is no reliable data to support the need for additional postoperative antibiotic to the standard intraoperative antibiophylaxis.

Urethral injury. Urethral injury is rare (1%). Retropubic approach and history of urethral surgery were identified as risk factors in Imamura systematic review.¹⁷

If intraoperative injury to the urethra is suspected, urethroscopy is indicated¹⁸ before the urethra is sutured, regardless of the type of MUT. Rigid (with optic 0° or 12° lens) or flexible cystoscopy confirm diagnosis. The urethra is repaired with separate sutures made of absorbable suture.¹⁹ To avoid secondary urethral erosion, MUT should not be inserted at the same time.²⁰

Vaginal Injury. Vaginal injury is mainly described with trans-obturator tape. Ford et al, in a Cochrane review published in 2015, considered 3 studies including 541 patients, showed a lower risk of vaginal perforation with the in-out technique (RR of 0.25, 95% CI 0.12 to 0.53).²¹

Visceral Injury. Prevalence of digestive injury is low (0.04% in case of TVT).²¹

Published data reported more frequently in patients with low BMI (< 25).

Vascular Injury. Vascular injury (of a major blood vessel: external iliac, femoral or epigastric vessels) is rare (0.07%)²² but it is a vital emergency. The risk is higher with RPA.²³

Short-term Postoperative Complications

Hematoma, Postoperative Bleeding. The rate of bleeding complications is higher in RPA than in TOA.²³ Prevalence of intraoperative bleeding complications (bleeding greater than 200 mL) is between 0.1% and 3.3%, regardless of the approach. Prevalence of symptomatic postoperative hematomas ranges from 0.5% to 4.1%.^{24,25} Conservative treatment is effective in 65 to 100% in case of hematoma.²⁶

Active bleeding with failing of conservative treatment is rare and only described in case reports.

Postoperative Acute VD. Prevalence of postoperative acute urinary retention (AUR) ranges from 1 to 14.9%.²⁴

Principal risk factor is a preoperative Qmax < 15 mL/s.²⁷

Most clinical trials reported PVR > 100 -150 mL as indicative of VD.^{28,29} A survey, published in 2021, reported the different definitions of PVR used in practice by urologist: > 100 mL for 16.5%, > 150 mL for 25.5%, > 200 mL for 20.2% and more than a third of the total bladder volume in 19.1% of cases.³⁰

The working group chose to define pathological PVR as a value greater than 150 mL, or a micturition volume less than 2/3 of the pre-micturition volume (urine volume + PVR).

In 2018, International Uro-Gynecological Association did not recommend dilatation of the urethra due to the absence control group studies, and a reported excess risk of urethral erosion in small case series.²⁹

A Norwegian registry study compared intermittent self-catheterization (>7 days), MUT mobilization (within 1 week after surgery) and MUT section following 585 AUR. Authors reported similar results between MUT mobilization and intermittent catheterization. However, patients who underwent intermittent catheterization were more likely to have MUT section afterwards (19% vs 10%, $P = .027$). Risk of SUI recurrence at 1 year was lower in case of MUT mobilization (7%) than intermittent catheterization (17%, $P = .023$) or MUT section (24.7%, $P = .001$).³¹

Postoperative Pain. Acute postoperative pain (<2 weeks) is frequent (15%), TOA compared to RPA is associated with lower rates of suprapubic pain (RR 0.29 [CI 95%: 0.11-0.78] $P = .01$) and higher rates of groin pain (RR 4.45 [CI 95%: 2.8-7.08] $P < .0001$).²³

A complete clinical examination is required to eliminate immediate complication such as hematoma or infection.

There is no literature data on early tape removal cases due to severe post-operative pain. However, in the event of severe acute pain in the immediate post-operative period following MUT insertion, not responding to medical treatment, we recommend discussing early tape removal with the patient.

Postoperative Infection. Published data does not show a significant risk reduction in case of preventive postoperative antibiotic treatment.³²

Long-term Complications

Late Chronic VD. Clinical diagnosis of chronic VD is difficult as it is often paucisymptomatic.

Risk factors for chronic VD are:

- Preoperative $Q_{max} < 15 \text{ mL/s}$ ³³
- Concomitant prolapsus surgery³⁴
- Pre-existing detrusor hypocontractility on pre-operative urodynamic evaluation

The risk of de novo VD after 3 months post- MUT is significantly lower in case of TOA.²³

There is no consensus on the choice of surgical technique which can be:

- lateral section of the MUT whatever the initial approach was
- or partial removal of the sub-urethral MUT portion.

Partial removal of the suburethral portion is associated with an increased risk of urethral injury and SUI recurrence, compared with simple MUT section.³⁵

De Novo Overactive Bladder Syndrome. OAB rates are heterogenous among studies. When the symptom evaluated was urge urinary incontinence, rates ranged from 8 to 33%.³⁶ When symptoms studied were pollakiuria and de novo urgency, rates ranged from 2% to 15%.²¹

BMI > 25, prior incontinence and/or prolapse surgery, seem to be associated with higher risk of de novo post-MUT OAB.^{37,38}

Only 2 studies identified more OAB after TVT than TOT, with low statistical evidence.

The rates of de novo OAB increase with post-operative delay (3.6% after 2 years, 10.8% after 5 years, and up to 15% at 10 years).³⁹

Pre-existing OAB prior to surgery may alter the results of MUT surgery. Based on current data, it is not possible to predict the post-operative evolution of this pre-existing OAB.

Chronic Pain. PCPP is pain at the surgical site or projected into the territory of a nerve located in the surgical site, persisting for more than 3 months after surgery and significantly affecting quality of life.⁴⁰ Frequency is higher after TOT (6 to 10%) than TVT (1%), especially with groin and up thigh pain.⁴¹

Chronic post-operative pain prevention is based on research for a painful background, with a risk of chronic pain in case of pelvic sensibilization and myofascial pain already existing pre-operatively, especially for the TOA which passes through muscular structures.

Risk of urinary incontinence recurrence is > 1/3 after tape revision surgery. A new surgery for SUI can be performed after with more than 75% satisfaction rate.⁴²

Dyspareunia. Pain felt by the patient during intercourse is called dyspareunia, while the pain felt by her partner is called hispareunia. The rate of de novo dyspareunia ranges from 0% to 14.5%.⁴³

De novo dyspareunia and hispareunia can be associated to a MUT complication especially vaginal erosion.⁴⁴ There is no sufficient data to choose one approach over another, however, RPA appears to be less likely to cause de novo or enhanced dyspareunia.

The rate of success in reducing pain after tape removal (improvement or disappearance) is between 74% and 96%.^{45,46} In literature, the risk of SUI recurrence ranges from 20% to 50% after MUT removal.^{47,48}

Vaginal Erosion. Vaginal erosion can occur long time after surgery and prevalence ranges from 2 to 5%.²¹

According to literature data persons with diabetes, smoking, immunodepression, history of pelvic surgery or radiotherapy, and advanced age are at higher risk of vaginal erosion.¹⁶

In case of small (<0.5 cm), asymptomatic vaginal erosion, conservative treatment with application of local trophic creams may be considered.¹⁶

The biggest study is retrospective involving 2823 patients between 1999 and 2017. Thirty-three patients (1.17%) had vaginal erosion and 31 underwent surgical management. Twenty patients had MUT removal and only 1 of them required further management at 6 months, whereas 11 patients had simple vaginal closure without MUT removal and 7 required a second procedure.⁴⁹

Late Bladder Erosion. Bladder erosion is rare (1%). It's usually revealed during months following surgery but can occur sometimes after several years. The presentation is usually non-specific.⁵⁰

Risk factors include concomitant prolapse surgery (particularly if concomitant hysterectomy is performed), submucosal path of the MUT, or unrecognized bladder wound during MUT insertion.⁵¹

Laser destruction of the tape may lead to incomplete excision and difficulties in surgical revision in case of erosion recurrence.⁵²

Urethral Erosion. Urethral erosion is rare (1%). It usually occurs during months following surgery but can sometimes occur after several years.⁵⁰ In recently published review on bladder and urethral erosion results for laser ablation were a complete disappearance of the MUT for 55%, 17%, and 5,6% after 1, 2, and 3 sessions respectively and 7% required open surgery. Complication rate was 24% (SUI 21%).⁵²

Endoscopic procedure leads to a less invasive shorter procedure but does not always allow complete MUT removal with a risk of more difficult and more morbid subsequent surgery.⁵⁰

The surgical procedure allows complete removal of the exposed fragment, but with a significant risk of post-operative SUI.⁵³

CONCLUSION

The current guidelines may help physicians and patients to improve management of prosthetic related complications that may occur following SUI surgery.

French Guidelines

French entire guidelines and references are published on the HAS website (Haute Autorité de Santé—Complications de la chirurgie avec prothèse de l'incontinence urinaire d'effort et du prolapsus génital de la femme (has-sante.fr).

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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