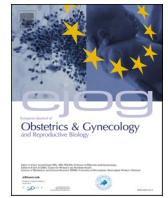


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Full Length Article



Diagnosis and management of complications following pelvic organ prolapse surgery using a synthetic mesh: French national guidelines for clinical practice

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ABSTRACT

Complications associated with pelvic organ prolapse (POP) surgery using a synthetic non-absorbable mesh are uncommon (<5%) but may be severe and may hugely diminish the quality of life of some women. In drawing up these multidisciplinary clinical practice recommendations, the French National Authority for Health (*Haute Autorité de santé*, HAS) conducted an exhaustive review of the literature concerning the diagnosis, prevention, and management of complications associated with POP surgery using a synthetic mesh. Each recommendation for practice was allocated a grade (A,B or C; or expert opinion (EO)), which depends on the level of evidence (clinical practice guidelines).

Preoperative patients' information: Each patient must be informed concerning the risks associated with POP surgery (EO).

Hemorrhage, hematoma: Vaginal infiltration using a vasoconstrictive solution is not recommended during POP surgery by the vaginal route (grade C). The placement of vaginal packing is not recommended following POP surgery by the vaginal route (grade C). During laparoscopic sacral colpopexy, when the promontory seems highly dangerous or when severe adhesions prevent access to the anterior vertebral ligament, alternative surgical techniques should be discussed per operatively, including colpopexy by lateral mesh laparoscopic suspension, uterosacral ligament suspension, open abdominal mesh surgery, or surgery by the vaginal route (EO).

Bladder injury: When a bladder injury is diagnosed, bladder repair by suturing is recommended, using a slow resorption suture thread, plus monitoring of the permeability of the ureters (before and after bladder repair) when the injury is located at the level of the trigone (EO). When a bladder injury is diagnosed, after bladder repair, a prosthetic mesh (polypropylene or polyester material) can be placed between the repaired bladder and the vagina, if the quality of the suturing is good. The recommended duration of bladder catheterization following bladder repair in this context of POP mesh surgery is from 5 to 10 days (EO).

Ureter injury: After ureteral repair, it is possible to continue sacral colpopexy and place the mesh if it is located away from the ureteral repair (EO).

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Rectal injury: Regardless of the approach, when a rectal injury occurs, a posterior mesh should not be placed between the rectum and the vagina wall (EO). Concerning the anterior mesh, it is recommended to use a macroporous monofilament polypropylene mesh (EO). A polyester mesh is not recommended in this situation (EO).

Vaginal wall injury: After vaginal wall repair, an anterior or a posterior microporous polypropylene mesh can be placed, if the quality of the repair is found to be satisfactory (EO). A polyester mesh should not be used after vaginal wall repair (EO).

Mesh infection (abscess, cellulitis, spondylodiscitis): Regardless of the surgical approach, intravenous antibiotic prophylaxis is recommended (aminopenicillin + beta-lactamase inhibitor: 30 min before skin incision +/- repeated after 2 h if surgery lasts longer) (EO).

When spondylodiscitis is diagnosed following sacral colpopexy, treatment should be discussed by a multidisciplinary group, including especially spine specialists (rheumatologists, orthopedists, neurosurgeons) and infectious disease specialists (EO).

When a pelvic abscess occurs following synthetic mesh sacral colpopexy, it is recommended to carry out complete mesh removal as soon as possible, combined with collection of intraoperative bacteriological samples, drainage of the collection and targeted antibiotic therapy (EO). Non-surgical conservative management with antibiotic therapy may be an option (EO) in certain conditions (absence of signs of sepsis, macroporous monofilament polypropylene type 1 mesh, prior microbiological documentation and multidisciplinary consultation for the choice of type and duration of antibiotic therapy), associated with close monitoring of the patient.

Bowel occlusion related to non-closure of the peritoneum: Peritoneal closure is recommended after placement of a synthetic mesh by the abdominal approach (EO).

Urinary retention: Preoperative urodynamics is recommended in women presenting with urinary symptoms (bladder outlet obstruction symptoms, overactive bladder syndrome or incontinence) (EO). It is recommended to remove the bladder catheter at the end of the procedure or within 48 h after POP surgery (grade B). Bladder emptying and post-void residual should be checked following POP surgery, before discharge (EO). When postoperative urine retention occurs after POP surgery, it is recommended to carry out indwelling catheterization and to prefer intermittent self-catheterization (EO).

Postoperative pain: Before POP surgery, the patient should be asked about risk factors for prolonged and chronic postoperative pain (pain sensitization, allodynia, chronic pelvic or non-pelvic pain) (EO).

Concerning the prevention of postoperative pain, it is recommended to carry out a pre-, per- and postoperative multimodal pain treatment (grade B). The use of ketamine intraoperatively is recommended for the prevention of chronic postoperative pelvic pain, especially for patients with risk factors (preoperative painful sensitization, allodynia, chronic pelvic or non-pelvic pain) (EO). Postoperative prescription of opioids should be limited in quantity and duration (grade C).

When acute neuropathic pain (sciatalgia or pudendal neuralgia) resistant to level I and II analgesics occurs following sacrospinous fixation, a reintervention is recommended for suspension suture removal (EO).

When chronic postoperative pain occurs after POP surgery, it is recommended to systematically seek arguments in favor of neuropathic pain with the DN4 questionnaire (EO).

When chronic postoperative pelvic pain occurs after POP surgery, central sensitization should be identified since it requires a consultation in a chronic pain department (EO).

Concerning myofascial pain syndrome (clinical pain condition associated with increased muscle tension caused by myofascial trigger points), when chronic postoperative pain occurs after POP surgery, it is recommended to examine the levator ani, piriformis and obturator internus muscles, so as to identify trigger points on the pathway of the synthetic mesh (EO).

Pelvic floor muscle training with muscle relaxation is recommended when myofascial pain syndrome is associated with chronic postoperative pain following POP surgery (EO). After failure of pelvic floor muscle training (3 months), it is recommended to discuss surgical removal of the synthetic mesh, during a multidisciplinary discussion group meeting (EO). Partial removal of synthetic mesh is indicated when a trigger point is located on the pathway of the mesh (EO). Total removal of synthetic mesh should be discussed during a multidisciplinary discussion group meeting when diffuse (no trigger point) chronic postoperative pain occurs following POP surgery, with or without central sensitization or neuropathic pain syndromes (EO).

Postoperative dyspareunia: When de novo postoperative dyspareunia occurs after POP surgery, surgical removal of the mesh should be discussed (EO).

Vaginal mesh exposure: To reduce the risk of vaginal mesh exposure, when hysterectomy is required during sacral colpopexy, subtotal hysterectomy is recommended (grade C).

When asymptomatic vaginal macroporous monofilament polypropylene mesh exposure occurs, systematic imaging is not recommended. When vaginal polyester mesh exposure occurs, pelvic +/- lumbar MRI (EO) should be used to look for an abscess or spondylodiscitis, given the greater risk of infection associated with this type of material.

When asymptomatic vaginal mesh exposure of less than 1 cm² occurs in a woman with no sexual intercourse, the patient should be offered observation (no treatment) or local estrogen therapy (EO). However, if the patient wishes, partial excision of the mesh can be offered.

When asymptomatic vaginal mesh exposure of more than 1 cm² occurs or if the woman has sexual intercourse, or if it is a polyester prosthesis, partial mesh excision, either immediately or after local estrogen therapy, should be offered (EO).

When symptomatic vaginal mesh exposure occurs, but without infectious complications, surgical removal of the exposed part of the mesh by the vaginal route is recommended (EO), and not systematic complete excision of the mesh.

Following sacral colpopexy, complete removal of the mesh (by laparoscopy or laparotomy) is only required in the presence of an abscess or spondylodiscitis (EO).

When vaginal mesh exposure recurs after a first reoperation, the patient should be treated by an experienced team specialized in this type of complication (EO).

Suture thread vaginal exposure: For women presenting with vaginal exposure to non-absorbable suture thread following POP surgery with mesh reinforcement, the suture thread should be removed by the vaginal route (EO). Removal of the surrounding mesh is only recommended when vaginal mesh exposure or associated abscess is diagnosed.

Bladder and ureteral mesh exposure: When bladder mesh exposure occurs, removal of the exposed part of the mesh is recommended (grade B).

Both alternatives (total or partial mesh removal) should be discussed with the patient and should be debated during a multidisciplinary discussion group meeting (EO).

Introduction

Complications associated with pelvic organ prolapse (POP) surgery using a synthetic non-absorbable mesh are uncommon (<5%), but may be severe and may hugely diminish the quality of life of some women [1–3]. In drawing up these clinical practice recommendations, the French National Authority for Health (*Haute Autorité de santé*, HAS) conducted an exhaustive review of the literature concerning the diagnosis, prevention, and management of complications associated with POP surgery using a synthetic mesh. The final objective is to reduce the prevalence (prevention) and enhance the quality of the diagnostic process and the management of these complications. These recommendations concern the management of surgical complications, including prevention, identification (diagnosis), assessment (evaluation) and treatment. These recommendations are limited to the management of complications from POP surgery using a prosthetic reinforcement element. Medical complications (stroke, thromboembolic event, etc.), recurrence of POP and the management of *de novo* stress urinary incontinence were excluded.

Methods

This study was based on an exhaustive review of the literature (*meta-analyses*, randomized and non-randomized controlled studies, and large uncontrolled studies) published on the subject up until February 2023. French- and English-language articles from Medline, PubMed, EMBASE, and the Cochrane Database were searched, using adapted key words (MeSH and no MeSH). The expert editors summarized the literature for each of the questions addressed, rated the level of evidence (LE) and proposed recommendations (according to grading).

Guideline proposals were established by a “working group” (20 experts), following which these recommendations were externally amended by a group of multidisciplinary expert proofreaders. The members of the working and reading groups were chosen by HAS following proposals by the parties concerned by the topic: national professional specialty councils, the board of general medicine (general practitioners), professional organizations, patient and user associations and French academic urogynecology/pelvipérinéologie societies (*Association française d’urologie (AFU)*, *Collège national des gynécologues et obstétriciens français (CNGOF)*, *Société interdisciplinaire d’urodynamique et de pelvipérinéologie (SIFUD-PP)*, *Société nationale française de coloproctologie (SFCP)*, and *Société de chirurgie gynécologique et pelvienne (SCGP)*). The experts asked to join the working group reported their declaration of interests. These conflict of interest declarations were analyzed based on the topic by an ethics board dedicated to the management of conflicts of interest. The existence of major interests, as defined in the “*Guide on the declaration of interests and management of conflicts of interest*” justified the exclusion of some proposed experts. The declarations of interests of the experts of the working group were published on the government website <https://dpi.sante.gouv.fr>. The members of the working group updated their conflict of interest declaration during the creation of the guidelines.

The members of the working group included physicians and non-

physician healthcare professionals (nurses, physical therapists, methodologists, members of associations of patients or users of the healthcare system, experts in medical and surgical fields, HAS representatives). Representatives of the government administration, health insurance sector, and healthcare industry did not participate in the working group.

The project manager (CRD) sent the members of the reading group the evidence report, the initial version of the guidelines and a questionnaire that included a discrete numerical scale (agreement ranking from 1 to 9 and a free-text area for each recommendation made). Each member of the reading group judged the acceptability, applicability and readability of each recommendation. The reading group included 56 people concerned by the topic, experts in the subject or not. Like the working group, this reading group was multidisciplinary and multi-professional. The project manager, in collaboration with the chair of the working group, was responsible for the analysis of the responses and their synthesis.

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 recommendation.

Each recommendation for practice was allocated a grade (see Table 1), which not only depended on the level of evidence (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), but also on feasibility and ethical factors. Grade A represents the scientifically established evidence; grade B represents a scientific presumption; grade C is based on a low level of evidence, generally founded on LE3 or LE4. In the absence of any conclusive scientific evidence, some practices have nevertheless been recommended on the basis of agreement between all the members of the working group (“expert opinion, EO”).

Results

Per-operative complications

The prevalence of per-operative complications associated with POP mesh surgery is less than 5 % (LE1). The level of evidence concerning patient subgroups associated with a higher risk of complications following POP surgery is very low. Therefore, each patient must be informed concerning the risks associated with POP surgery (EO).

Hemorrhage and blood transfusion

Randomized and comparative trials showed an increase in the prevalence of hemorrhage and blood transfusion following vaginal mesh surgery when compared to autologous vaginal surgery or laparoscopic mesh surgery (sacral colpopexy) (LE1) [1–3]. The prevalence of hemorrhage is lower in laparoscopic vs. open abdominal mesh surgery. Concomitant hysterectomy is associated with an increase in the prevalence of hemorrhage regardless of the abdominal or vaginal surgical approach (LE2).

Concerning the “prophylactic” placement of vaginal packing following surgery by the vaginal route, a randomized clinical trial (RCT) and comparative series showed no decrease in the amount of post-operative bleeding or in the prevalence of postoperative pelvic hematoma in packing groups (LE2); furthermore, the amount of bleeding was low in all groups. The placement of vaginal packing is not recommended following POP surgery by the vaginal route (grade C). Concerning the infiltration of the vaginal wall by a vasoconstrictive solution at the beginning of vaginal surgery, an RCT showed a lower amount of per-operative bleeding in the intervention group (ornipressin) vs. the control group (saline), but the amount of bleeding was very low in both groups [4] (LE2). Vaginal infiltration using a vasoconstrictive solution is not recommended during POP surgery by the vaginal route (grade C).

During laparoscopic sacral colpopexy, when the promontory seems highly dangerous (vein bifurcation covering the anterior vertebral ligament or difficult dissection) or when severe adhesions prevent access to the anterior vertebral ligament, alternative surgical techniques should be discussed per operatively, including colpopexy by lateral mesh laparoscopic suspension, uterosacral ligament suspension, open abdominal mesh surgery, or surgery by the vaginal route (EO).

Postoperative hemorrhage should be suspected when asthenia, fever or tachycardia occurs or when the patient suffers from abdominal/pelvic pain, urinary retention, urinary frequency and urgency, or obstructed defecation syndrome (EO). A clinical exam including a pelvic and vaginal exam, and a blood test (hemoglobin level) are mandatory when postoperative hemorrhage is suspected; a radiological exploration is also required (ultrasonography or CT scan) (EO).

Concerning the diagnosis of postoperative hemorrhage following laparoscopic sacral colpopexy, a large retrospective series showed no advantage associated with systematic postoperative hemoglobin test [5] (LE3). Prescription of a systematic postoperative hemoglobin test is not recommended following laparoscopic sacral colpopexy (grade C).

Concerning the treatment of postoperative hemorrhage following POP surgery (reintervention, uterine artery embolization, etc), no guideline was addressed since the literature showed no relevant study.

Bladder injury

The risk of bladder injury is significantly higher (4-fold) following POP mesh surgery by the vaginal route compared to autologous vaginal POP surgery (LE1), with no identified risk factor (LE3) [6]. The risk of bladder injury is not higher following POP mesh surgery by the vaginal route compared to the abdominal route (LE1) [7]. A history of total hysterectomy is a risk factor for bladder injury in POP mesh surgery by the abdominal route (LE3). Per-operatively, A systematical search for signs of bladder injury is recommended (macroscopic hematuria, presence of air in the urine collector) (EO). If there is any doubt about a bladder injury, bladder leak test (distension of the bladder using methylene-blue dye solution) is recommended (EO). When a bladder injury is diagnosed, bladder repair by suturing is recommended, using a

slow resorption suture thread, plus monitoring of the permeability of the ureters (before and after bladder repair) when the injury is located at the level of the trigone (EO). When a bladder injury is diagnosed, after bladder repair, a prosthetic mesh (polypropylene or polyester material) can be placed between the repaired bladder and the vagina, if the quality of the suturing is good. The risk of bladder mesh exposure seems not to be increased if the quality of the repair is satisfactory. After systematic per-operative prophylactic antibiotic therapy, no prolongation of this antibiotic therapy is systematically required. The recommended duration of bladder catheterization following bladder repair in this context of POP mesh surgery is from 5 to 10 days (EO). Post-operative cystography is not systematically recommended.

Ureter injury

The prevalence of ureter injury following POP surgery ranges from 0.3 % (sacral colpopexy) to 5 % (uterosacral suspension). There are no data to recommend routine cystoscopy for evaluation of ureteral permeability during sacral colpopexy. Ureteral repair is performed using ureteral stenting and suturing and/or ureteral resection anastomosis, or ureterovesical reimplantation. After ureteral repair, it is possible to continue sacral colpopexy and place the mesh if it is located away from the ureteral repair (EO).

Rectal injury

The prevalence of rectal jury following POP surgery is less than 0.4 %, regardless of the surgical route and the type of surgery (mesh reinforcement or autologous technique) [2]. There no published comparative data concerning the diagnosis or prevention of rectal injury following POP surgery. The rectal injury should be repaired using a slow absorbing suture thread without tension and without narrowing the rectum. Systematic gastrointestinal stoma is not recommended. Regardless of the approach, when a rectal injury occurs, a posterior mesh should not be placed between the rectum and the vagina wall (EO). Concerning the anterior mesh, it is recommended to use a macroporous monofilament polypropylene mesh (EO). A polyester mesh is not recommended in this situation (EO).

Bowel injury

Bowel injury is a very rare complication of POP surgery. There are no comparative data. After bowel repair, it is possible to continue POP surgery as planned, including mesh interposition (EO).

Vaginal wall injury

The prevalence of vaginal wall injury is about 1 % during laparoscopic sacral colpopexy. There are no data concerning the prevention of this complication. After vaginal wall repair, an anterior or a posterior microporous polypropylene mesh can be placed, if the quality of the repair is found to be satisfactory (EO). A polyester mesh should not be used after vaginal wall repair (EO). There are no data concerning the

Table 1
Grading system for rating level of evidence and guidelines.

1a. Level of evidence (LE) grades.				
Quality/level of evidence (LE)				
1 (high)	We are very confident that the true effect lies close to that of the estimate of the effect			
2 (moderate)	We are moderately confident in the effect estimate			
3 (low)	Our confidence in the effect estimate is limited			
4 (very low)	We have very little confidence in the effect estimate			
1b. Definition of the strength of the recommendations.				
	GRADE A strong recommendation (we recommend)	GRADE B weak recommendation based on scientific presumption (we suggest strongly)	GRADE C weak recommendation based on a low level of evidence (we suggest)	EXPERT OPINION (we suggest but there is no evidence)
Positive	“It is recommended to do...”	“It is recommended to do...”	“It is recommended to do...”	“It is recommended to do...”
Negative	“It is recommended <u>not</u> to perform ...”	“It is recommended <u>not</u> to perform ...”	“It is recommended <u>not</u> to perform ...”	“It is recommended <u>not</u> to perform ...”

usefulness of prolonged antibiotic prophylaxis in this situation.

Postoperative complications

Infection

Regardless of the surgical approach, intravenous antibiotic prophylaxis is recommended (aminopenicillin + beta-lactamase inhibitor: 30 min before skin incision +/- repeated after 2 h if surgery lasts longer) (EO).

Bowel occlusion related to non-closure of the peritoneum

Peritoneal non-closure may increase the risk of bowel occlusion due to adhesion between the bowel and the mesh, but it is possible that bowel occlusion is linked to the abdominal approach itself. Peritoneal closure is recommended after placement of a synthetic mesh by the abdominal approach (EO).

Hematoma and postoperative anemia

Placement of vaginal packing following POP surgery by the vaginal route is associated with a decrease in the prevalence of hematoma without an increase in associated pelvic/vaginal pain [8], but the overall prevalence of required reintervention is low. Systematic placement of vaginal packing following POP surgery by the vaginal route is not recommended (EO).

The prevalence of hemorrhage is decreased following POP surgery by the abdominal approach. Routine blood sampling for hemoglobin assay after sacral colpopexy is not recommended (EO).

Urinary retention

The prevalence of urinary retention after POP surgery ranges from 7 to 30 %. Bladder emptying and post-void residual should be checked following POP surgery, before discharge (EO). Risk factors for urinary retention are high-grade cystocele and associated concomitant procedures (mid-urethral sling, hysterectomy, rectal prolapse repair). Prolonged postoperative urinary catheterization is unnecessary for most women and early catheter withdrawal reduces the risk of urinary tract infection and shortens the length of stay. It is recommended to remove the bladder catheter at the end of the procedure or within 48 h after POP surgery (grade B). Prophylactic use of tamsulosin appears to be effective in reducing the incidence of acute urinary retention and the mean post-void residual volume following POP surgery (LE2) [9], but it is an off-label use in France. Preoperative urodynamics is recommended in women presenting with urinary symptoms (bladder outlet obstruction symptoms, overactive bladder syndrome or incontinence) (EO).

When postoperative urine retention occurs after POP surgery, it is recommended to carry out indwelling catheterization and to prefer intermittent self-catheterization (EO).

Postoperative pain

The prevalence of prolonged chronic pain after POP surgery ranges between 2.5 % and 7.5 %, regardless of the surgical approach and the use or not of mesh reinforcement (LE2) [6,10,11].

When chronic postoperative pelvic pain occurs after POP surgery, central sensitization should be identified since it requires a consultation in a chronic pain department (EO). Central sensitization in chronic pelvic pain syndrome corresponds to impaired nociception and is defined by clinical criteria (Convergences PP criteria) [12]. It corresponds to a diffuse painful syndrome, disproportionate to the limited findings on physical examination and/or complementary investigations. It associates a reduction in pain perception thresholds (perineal and/or vulvar pain in response to normally non-painful stimulation) with a response to diffuse pain increased in intensity, in time and in space.

Patients should be informed of the risk of persistent postoperative pain, especially for those presenting high-risk factors (history of chronic pain, even other than pelvic or perineal pain, *levator ani* myalgia, allodynia and/or hypertonic disorders of the pelvic floor) (EO).

Before POP surgery, the patient should be asked about risk factors for prolonged and chronic postoperative pain (pain sensitization, allodynia, chronic pelvic or non-pelvic pain) (EO). Preoperative pain is not a typical symptom of POP. In the presence of pain, it is recommended to look for a cause other than POP.

No data were found concerning the impact of the use of retractors intraoperatively or mesh tension on the postoperative pain level.

Concerning the prevention of postoperative pain, it is recommended to carry out a pre-, per- and postoperative multimodal pain treatment (grade B). The use of ketamine intraoperatively is recommended for the prevention of chronic postoperative pelvic pain, especially for patients with risk factors (preoperative painful sensitization, allodynia, chronic pelvic or non-pelvic pain) (EO). Postoperative prescription of opioids should be limited in quantity and duration (grade C).

When acute neuropathic pain (sciatalgia or pudendal neuralgia) resistant to level I and II analgesics occurs following sacrospinous fixation, a reintervention is recommended for suspension suture removal (EO).

When chronic postoperative pain occurs after POP surgery, it is recommended to systematically seek arguments in favor of neuropathic pain with the DN4 questionnaire (EO). Sacral colpopexy seems to be more frequently associated with pelvic pain as a vegetative symptom and neuralgia of thoraco-lumbar origin, while vaginal surgery seems to be associated with pudendal and/or obturator neuralgia.

Concerning myofascial pain syndrome (clinical pain condition associated with increased muscle tension caused by myofascial trigger points), when chronic postoperative pain occurs after POP surgery, it is recommended to examine the *levator ani*, *piriformis* and *obturator internus* muscles, so as to identify trigger points on the pathway of the synthetic mesh (EO).

Pelvic floor muscle training with muscle relaxation is recommended when myofascial pain syndrome is associated with chronic postoperative pain following POP surgery (EO). Published data concerning steroids or anesthetic or lipofilling infiltrations are rare. After failure of pelvic floor muscle training (3 months), it is recommended to discuss surgical removal of the synthetic mesh, during a multidisciplinary discussion group meeting (EO). Removal of synthetic mesh is associated with a decrease in pain in patients presenting with chronic postoperative pain, especially when the pain is associated with vaginal mesh exposure (LE2). Partial removal of synthetic mesh is indicated when a trigger point is located on the pathway of the mesh (EO). Total removal of synthetic mesh should be discussed during a multidisciplinary discussion group meeting when diffuse (no trigger point) chronic postoperative pain occurs following POP surgery, with or without central sensitization or neuropathic pain syndromes (EO).

Postoperative dyspareunia

The prevalence of *de novo* postoperative dyspareunia ranges from 0 to 9 %, regardless of the surgical route and technique or a synthetic mesh interposition. Dyspareunia may be the consequence of mesh shrinkage, vaginal mesh exposure or pelvic or perineal nerve injury. When *de novo* postoperative dyspareunia occurs after POP surgery, surgical removal of the mesh should be discussed (EO).

Vaginal mesh exposure

Vaginal mesh exposure is defined as a permanent suture/mesh visualized through separated vaginal epithelium [13,14]. Given the average time to onset of vaginal mesh exposure, it is recommended to carry out a vaginal examination one month and one year postoperatively (EO). However, vaginal mesh exposure can also occur many years after surgery. Signs and symptoms suggestive of vaginal mesh exposure are as follows: vaginal bleeding, dyspareunia, hispareunia, vaginal discharge, vaginal pain. Signs of associated infection are as follows: fever, collection, abdominal or lumbar pain, purulent vaginal discharge, cellulitis or abscess.

A meta-analysis of non-randomized series showed that uterine

conservation was associated with a decrease in the prevalence of vaginal mesh exposure after POP surgery using synthetic mesh insertion, compared to concomitant associated total hysterectomy (OR = 0.16; 95 %CI: 0.03–0.97) (LE3) [15]. To reduce the risk of vaginal mesh exposure, when hysterectomy is required during sacral colpopexy, subtotal hysterectomy is recommended (grade C).

When asymptomatic vaginal macroporous monofilament polypropylene mesh exposure occurs, systematic imaging is not recommended. When vaginal polyester mesh exposure occurs, pelvic +/- lumbar MRI (EO) should be used to look for an abscess or spondylodiscitis, given the greater risk of infection associated with this type of material. When symptomatic vaginal mesh exposure occurs, the following complementary exams should be discussed: urethrocytoscropy, bacteriological vaginal sampling, pelvic/perineal ultrasound, pelvic MRI, abdominal and pelvic CT scan, blood sampling (leukocytes, CRP, procalcitonin, etc), rectosigmoidoscopy, etc. The prescription of these additional examinations should be adapted according to the symptoms and the results of the clinical examination. In the case of suspected infectious complication associated with vaginal prosthetic exposure (abscess, cellulitis, spondylodiscitis), pelvic MRI is recommended, combined, if necessary, with a CT scan. If a fistula is suspected, associated with vaginal mesh exposure, the appropriate examinations should be carried out.

No treatment (observation) and local estrogen therapy are associated with a low prevalence of vaginal wound healing, (0–25 % and 20 %, respectively) (LE4) [16].

When asymptomatic vaginal mesh exposure of less than 1 cm² occurs in a woman with no sexual intercourse, the patient should be offered observation (no treatment) or local estrogen therapy (EO). However, if the patient wishes, partial excision of the mesh can be offered.

When asymptomatic vaginal mesh exposure of more than 1 cm² occurs or if the woman has sexual intercourse, or if it is a polyester prosthesis, partial mesh excision, either immediately or after local estrogen therapy, should be offered (EO).

When symptomatic vaginal mesh exposure occurs, but without

infectious complications, surgical removal of the exposed part of the mesh by the vaginal route is recommended (EO), and not systematic complete excision of the mesh.

Following sacral colpopexy, complete removal of the mesh (by laparoscopy or laparotomy) is only required in the presence of an abscess or spondylodiscitis (EO).

When vaginal mesh exposure recurs after a first reoperation, the patient should be treated by an experienced team specialized in this type of complication (EO).

No comparative study has assessed the effectiveness of the different options (observation, local estrogen therapy, partial removal and total removal of the mesh). Our group proposes an algorithm (inspired by the AUGS/IUGA/FPMRS algorithm) [13] for the management of vaginal mesh exposure, according to the type of the material (see Fig. 1 and Fig. 2).

Suture thread vaginal exposure

For women presenting with vaginal exposure to non-absorbable suture thread following POP surgery with mesh reinforcement, the suture thread should be removed by the vaginal route (EO). Removal of the surrounding mesh is only recommended when vaginal mesh exposure or associated abscess is diagnosed.

Bladder and ureteral mesh exposure

Bladder and ureteral mesh exposure is very rare (<0.5 %) (LE2) and occurs mostly during the first year following surgery (LE1) [3,17,18]. Due to a very low prevalence of this of kind complication, the analysis of literature does not provide evidence concerning associated risk factors (concomitant hysterectomy or incontinence surgery, route of surgical placement of the mesh [abdominal or vaginal], mesh material type and weight (grammage), etc). Associated bladder injury is not associated with increased incidence of bladder mesh exposure if the injury is identified and repaired (LE2). The technique of bladder repair and the duration of bladder catheterization are not reported in most studies.

Bladder (or ureter) mesh exposure should be considered when de

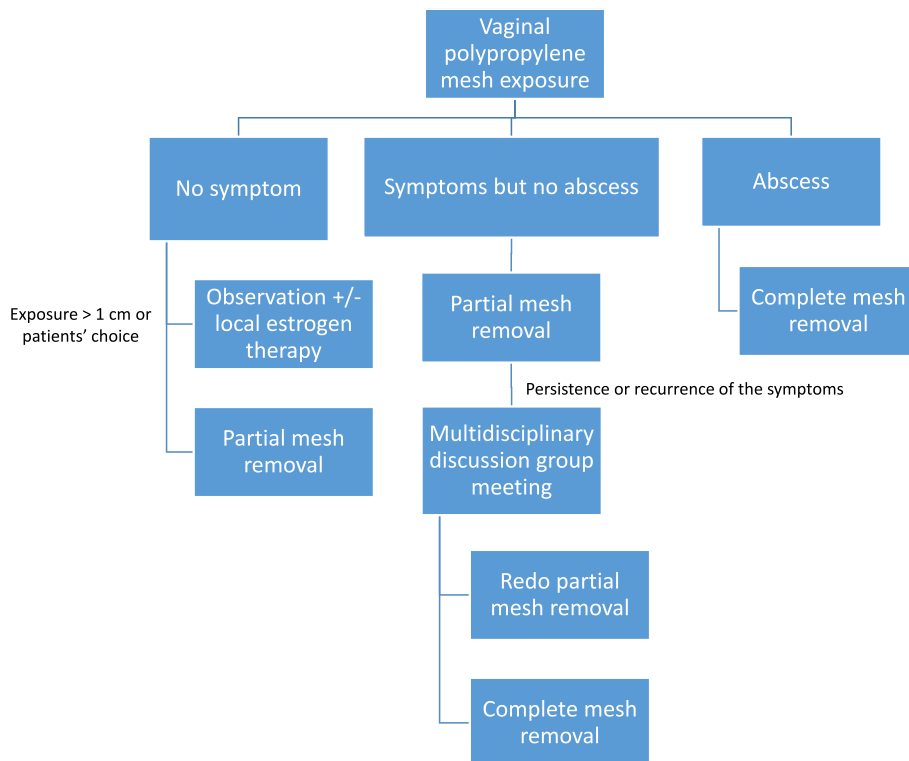


Fig. 1. Management of patients presenting with vaginal macroporous monofilament polypropylene mesh exposure, regardless of the route of the initial surgery.

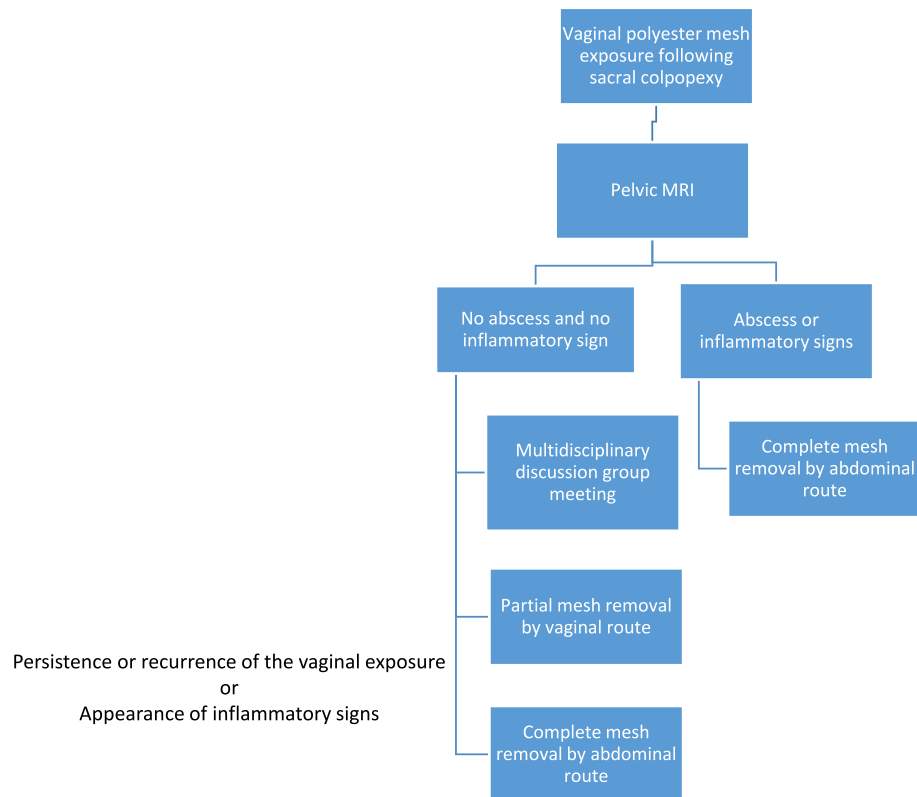


Fig. 2. Management of patients presenting with exposure of polyester mesh placed by the abdominal route.

novo urinary symptoms occur following mesh POP surgery (bladder/ureteral stone/lithiasis, hematuria, recurrent UTIs, bladder pain, OAB symptoms, etc), whatever the interval between mesh placement and symptom onset (grade C).

Prior to mesh removal surgery, the diagnosis of bladder mesh exposure should be made using cystoscopy; other exams may be appropriate according to the types of symptoms (pelvic/abdominal ultrasonography, MRI and/or CT scan (grade C).

When bladder mesh exposure occurs, removal of the exposed part of the mesh is recommended (grade B). When compared with total mesh removal (by the abdominal and/or vaginal route), partial mesh removal by cystoscopy is associated with a lower rate of operative complications, but is associated with an increased rate of exposure recurrence, an increased risk of persistent symptoms, and an increased reintervention rate (LE4) [12,18–22]. Both alternatives (total or partial mesh removal) should be discussed with the patient (NICE patients' decision aid might be appropriate) [23] and should be debated during a multidisciplinary discussion group meeting (EO).

Mesh infection (abscess, cellulitis, spondylodiscitis)

A surgical site infection (SSI) is defined by the Centers for Disease Control (CDC) as follows: an infection that occurs after surgery (<3 months) in the part of the body where the surgery took place. Infection of the implanted mesh may be the consequence of direct inoculation during the surgical procedure or by ascending infection (through the vaginal scar after concomitant total hysterectomy, through the cervical canal remaining after subtotal hysterectomy or through a vaginal mesh exposure or a digestive fistula) or by hematogenous spread. Risk factors for an SSI are linked to Altemeier's surgical wound contamination classification, operation duration and the patient's American Society of Anesthesiologists score. Infections that are infrequent complications following mesh POP surgery (<0.5 %) (LE: 1) [2], should be distinguished from bacterial colonization, which is very frequent following mesh vaginal surgery (up to 80 %) [24,25]. "Infection", "abscess",

"cellulitis" and "spondylodiscitis" are not defined precisely in the literature, but are listed in the ICS-IUGA terminology and classification of the complications related directly to the insertion of meshes in female pelvic floor surgery [26] (i.e. cellulitis is classified 6C; paravaginal abscess 1D; abscess associated with vaginal mesh exposure 2D [vaginal mesh exposure < 1 cm] or 3D [vaginal mesh exposure > 1 cm]; spondylodiscitis 6C).

Concerning the prevention of mesh infection following POP surgery, a prospective comparative series (involving patients operated on by the abdominal or vaginal route) showed that a single dose of antibiotic prophylaxis (added to preoperative vaginal disinfection using chlorhexidine or povidone iodine) was associated with a comparable rate of SSI, when compared to antibiotic treatment for several days (LE2) [27]. It is not possible to recommend a particular type of mesh or a particular type of fixation to the promontory, in order to limit the risk of spondylodiscitis after sacral colpopexy (EO).

Spondylodiscitis is defined as an infection of the intervertebral disc with concomitant vertebral osteomyelitis [28]. The etiologies of spondylodiscitis are rarely mesh-related complications; mostly, spondylodiscitis is caused by hematogenous spread. Therefore, when spondylodiscitis occurs several years after sacral colpopexy, the context should be analyzed before drawing conclusions about the etiology. The time lapse since mesh placement, associated vaginal mesh exposure, pelvic abscess, fistula, and the bacteriological results should be analyzed. About 40 cases of spondylodiscitis have been reported following POP mesh surgery or rectopexy [29]. Spondylodiscitis was diagnosed after a median delay of 76 days (IQR: 30–165) following mesh placement. Associated vaginal mesh exposure or fistula was diagnosed in about one-third of cases. The diagnosis was made because patients presented lumbar or dorsal pain (85 %), fever (49 %), and/or vaginal discharge (15 %), and/or neurological signs of radicular or spinal compression (such as pain, deficit or, exceptionally, paraparesis) (22 %) [29]. Diagnosis was made in most reported cases using CT and/or lumbosacral MRI. In a prospective series of 30 women who underwent a

non-complicated sacral colpopexy, no change in lumbosacral MRI was observed after surgery (LE4) [30]. Non-surgical treatment using antibiotic therapy was carried out in 29 % of cases. In 71 % of cases, reoperation was done with mesh and/or wire/tacker removal, in 40 % of cases, a neurosurgical procedure (laminectomy) was necessary, and in 11 patients (40 %) two further interventions were performed and antibiotic therapy (alone or combined with surgical treatment) lasting 1 to 3 months was carried out [29].

When spondylodiscitis is suspected, it is recommended (EO) to look for vaginal mesh exposure, to perform pelvic and lumbosacral MRI including spinal sequences, to perform blood cultures, to seek specialist advice (infectious disease specialist, neurosurgeon, rheumatologist, orthopedic surgeon, for example) and to discuss vertebral disk puncture biopsy when blood cultures are negative.

When spondylodiscitis is diagnosed following sacral colpopexy, treatment should be discussed by a multidisciplinary group, including especially spine specialists (rheumatologists, orthopedists, neurosurgeons) and infectious disease specialists (EO).

Microbiological documentation should be obtained, and mesh removal surgery (for bacterial documentation) discussed in order to initiate targeted antibiotic therapy (EO).

Concerning pelvic abscesses, in the majority of retrospective series, abscesses after prolapse surgery were treated by drainage surgery and removal of the mesh and wires/tackers, combined with antibiotic therapy [31–33].

Two retrospective series accumulating 5 cases of abscess following synthetic mesh sacral colpopexy (macroporous monofilament polypropylene mesh) described conservative management of these abscesses: drainage associated with antibiotic therapy, with two-year follow-up [34,35]. These abscesses were drained percutaneously (under CT guidance) and antibiotic therapy was carried out, without mesh removal [34,35]. The patients were followed up for 1 to 2 years, with no sign of recurrence of the abscess. However, the authors report that one case required reoperation for colorectal resection for “obstruction”. The authors of these few cases describe contraindications to this “conservative” treatment: absence of digestive wound/fistula, absence of immunosuppression, absence of sepsis, mesh type other than type 1 polypropylene.

When a pelvic abscess occurs following synthetic mesh sacral colpopexy, it is recommended to carry out complete mesh removal as soon as possible, combined with collection of intraoperative bacteriological samples, drainage of the collection and targeted antibiotic therapy (EO). Non-surgical conservative management with antibiotic therapy may be an option (EO) in certain conditions (absence of signs of sepsis, macroporous monofilament polypropylene type 1 mesh, prior microbiological documentation and multidisciplinary consultation for the choice of type and duration of antibiotic therapy), associated with close monitoring of the patient.

De novo overactive bladder (OAB) syndrome

The prevalence of *de novo* OAB symptoms following mesh POP surgery varies between 12 and 30 %, irrespective of the route and the type (mesh vs autologous) of surgery [6]. There are sufficient data to address the issue of the impact of the level of bladder dissection on the occurrence of *de novo* OAB symptoms.

When *de novo* OAB symptoms occur following mesh POP surgery, bladder mesh exposure should be considered (EO). Explorations (cystoscopy, CT, MRI, ultrasonography, urodynamics ...) will depend on the context and associated symptoms. Management involves medical therapies of idiopathic OAB symptoms [36]. OAB symptoms may resolve or not following mesh removal [31].

Ureteral kinking/stricture/obstruction and fistulae

The prevalence of ureteral stricture/obstruction and fistulae following mesh POP surgery is about 0.1 % (LE2) [3,18,37,38]. Utero-sacral apical suspension and anterior paravaginal and sacrospinous

fixation seems to be associated with an increased risk of ureteral kinking. Peroperatively, it is possible to check ureteral flow by intravenous indigo carmine blue injection and cystoscopy. However, the predictive value of this test is not established, and some cases have shown that a normal check may be associated with postoperative ureteral obstruction because postoperative inflammation may worsen the obstruction of the ureter [39]. Other techniques should be assessed, such as ureteral stenting or ureteral indocyanine green fluorescent visualization by retrograde ureteral intraoperative catheterization.

The diagnosis of ureteral kinking/stricture/obstruction and fistulae following mesh POP surgery involves ultrasonography, CT and MRI (EO). Renal failure should be considered.

Management of ureteral kinking/stricture/obstruction and fistulae following mesh POP surgery involves reintervention using ureteral stenting and/or reconstructive ureteral reimplantation (ureteroneocystostomy) and/or mesh removal (EO).

Rectal injury and rectal mesh exposure

The prevalence of rectal injury is below 1 % during mesh POP surgery, and the prevalence of rectal mesh exposure is very low, below 0.1 % (LE2) [3,40–42]. No specific risk factor for rectal injury or rectal mesh exposure was identified in the literature.

Non-absorbable synthetic mesh should not be placed in the rectovaginal septum when a rectal injury occurs (EO).

The diagnosis of rectal mesh exposure requires rectoscopy, colonoscopy, CT, MRI and ultrasonography imaging (EO).

When postoperative rectal mesh exposure is diagnosed, reintervention is mandatory (EO) and involves transrectal mesh removal and/or laparoscopic or open combined surgery for rectal resection/anastomosis and/or mesh removal. A stoma is not systematically created [40].

Obstructive defecation syndrome (ODS)

The prevalence of *de novo* ODS symptoms following mesh POP surgery is about 2 % (LE4) [40–42]. Data concerning the management of *de novo* ODS symptoms following mesh POP surgery are rare and inconclusive and do not permit any recommendation to be made.

Discussion

Clinical common sense must prevail to adapt these recommendations to each patient and to the setting of the clinical case.

Conclusion

Surgeons should implement established preventive recommendations that may reduce the risk of complications. The current guidelines may help physicians and patients in the improvement of management of mesh-related complications that may occur following POP surgery.

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