Classification System

Complications of vaginal supportive implants for prolapse surgery. New complications, new symptomatology, prevention and treatment

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Abstract: We describe a simple description of complications related to synthetic implants used in the treatment of stress incontinence or prolapse by the vaginal route. We describe their symptoms and propose a strategy for prevention and treatment of these complications. We will describe successively: *Type 1: defect of vaginal healing* - 1A: exposure of vaginal implant. 1B: abnormal healing: polyps, synechiae. *Type 2: infection of the implant* - 2A: persistent vaginal exposure with apparent local infection; 2B: infection along the implant; 2C: skin erosion near issue of the prosthesis, contiguous infection and fistulae along the supportive implant; 2D: contact abscess; 2E: distant abscess; 2F: fistulae; 2G: acute infection: pelvic cellulitis. *Type 3: contraction of implant* - Grade 1: palpation of supportive implant is painless, retraction moderate and asymptomatic, arm or body of the prosthesis is palpable but not thickened. Grade 2: retraction is moderate (less than about 30%) and\or without many symptoms, palpation may be sensitive, prosthesis globally moderately thickened without nodulae. Grade 3: important contraction (more than 50%) and\or painful palpation with localized thickening of the implant. 3A - important contraction, moderate symptomatology. 3B - important and symptomatic contraction. Grade 4: simple contact of implant is painful ++ even if contraction is not always palpable. *Type 4: erosions due to implant* a) erosions of vaginal fornix; b) uretral erosion; c) bladder erosion; d) rectal erosions; e) other distant erosions. This classification can only be temporary but distinguishes different types of complications too often mixed up in publications.

INTRODUCTION

Vaginal placement of synthetic meshes has become more and more popular for the treatment of genital prolapse. Recently many companies have commercialized some specific devices for this particular route. The term of meshes is probably inadequate as many devices are actually biological or both synthetic and biological. We will use here the term of vaginal supportive implants to address these material in their specific use for prolapse and incontinence surgery by thee vaginal route.

These meshes have been originally designed to be used in hernia abdominal surgery, and recently the success and good tolerance of sub urethral slings have encouraged their use by the vaginal route. Recently two companies have commercialized some specific devices for this particular route including for example The Prolift© (Ethicon Womens device as well as Apogee© and Perigee©). This specific vaginal implantation is responsible of specific complications that are not well described.

We will try here to summarize and classify these complications for future use in scientific complications.

After briefly reminding the materials and their classification we will describe complications after use of meshes, their symptoms, prevention and treatment.

We will not describe complications due to the technique itself such as dysuria or bladder instability after excessive tension of sub-urethral slings, or per operative complications as bladder perforation or major bleedings. These complications are not specific of the implant itself and should be described independently for each surgical technique.

I: CLASSIFICATION OF COMPLICATIONS due to supportive vaginal implants

Type 1: defect of vaginal healing (probably of vascular origin without infection).

1A: exposure of vaginal implant. This term should be preferred to vaginal granuloma or vaginal erosion both suggestive of infection for many surgeons.

1B: abnormal healing: polyps, synechiae.

– fortuitous, after lateral unnoticed perforation

– linked to defect of healing, median, under an incision.

Close to these, post surgical synechia or scar polyps are innocuous complications usually treated during consultation.

Type 2: infection of the implant

2A: persistent vaginal exposition with apparent local infection;

2B: infection along the implant;

2C: skin erosion near issue of the prosthesis, contiguous infection and fistulae along the supportive implant;

2D: contact abscess;

2E: distant abscess;

2F: fistulae;

2G: acute infection: pelvic cellulitis.

Type 3: contraction of implant

Grade 1: palpation of supportive implant is painless, retraction moderate and asymptomatic, arm or body of the prosthesis is palpable but not thickened.

Grade 2: retraction is moderate (less than about 30%) and\or without many symptoms, palpation may be sensitive, prosthesis globally moderately thickened without nodulae.

Grade 3: important contraction (more than 50%) and\or painful palpation with localized thickening of the implant.

3A - important contraction, moderate symptomatology.

3B - important and symptomatic contraction

Grade 4: simple contact of implant is painful ++ even if contraction is not always palpable.

Type 4: erosions due to implant

"true" erosions are distinct from "vaginal erosions" due to vaginal exposition of the implant. They occur after healing due to local friction or compression by thee implant. Erosions are exceptionally vaginal though prosthesis may be exposed or vaginal fornix wounded during intervention. Close organs can show erosions mostly due to excessive tension, sometimes with contractions. This is exceptional in our experience. But it sometimes happened years or decades after cure of herniae or promonto-fixation

a) erosions of vaginal fornix;

b) uretral erosion:

c) bladder erosion;

d) rectal erosions;

e) other distant erosions.

This classification can only be temporary but distinguishes different types of complications too often mixed up in reviews.

It will grow richer with new headings. It already helps us giving new indications of genital prolepses cure by vaginal route.

II : SYMPTOMATOLOGY OF COMPLICATIONS

Type 1A and\or 1B

can be asymptomatic, or give vaginal discharges, leucorrhoea with sometimes slight spontaneous bleeding. But in our experience, an asymptomatic vaginal erosion has a major risk of becoming symptomatic.

Type 2

Complications usually give very important leucorrhoea, yellow or brownish, with spontaneous or provoked metrorrhagias seldom painful at early stages. Fistula will always be detected between prosthesis and vagina or skin with an aperture allowing emission of pus or at least dirty looking leucorrhoea. Sometimes difficult to find (it can be millimetric), always found by careful examination eventually under anesthesia. Infected prosthesis is often encapsulated in inflammatory tissue and a painful induration may often be found during vaginal exam.

Type 3

Contractions usually asymptomatic (grade 1) may give spontaneous or stress incontinence, or even pelvic pains and, above all dyspareunias (grade 3 or 4). Prosthetic retraction may be asymptomatic but local palpation is often a little painful Palpation feels the prosthesis, hardened and crumpled under vaginal wall. At the utmost, retracted tissue around the prosthesis will feel like endometriosis nodula with contraction of vagina and near organs (grade 3b)...

Type 4

Implants can be painful at palpation even if contraction is not prominent but can still be palpable. Retropubic tracts may generate pain all along their way, often triggered by palpation of the prosthesis. Some trans obturator tracts are not really retracted but painful with dyspareunia and stress pains. Should this symptomatology go on after medical treatment, and last for more than a few months, when pain is felt touching the prosthesis at bone contact, secondary resection may become necessary.

Type 5

Symptoms are directly dependent of the affected organ Isolated vaginal erosions often but not always give vaginal discharges and metrorragia.

Urethral erosions will often give bladder urgencies, mictional sensation of burning, urethrorragia, repeated urinary infections. Urethroscopy and\or cystoscopy should be systematic.

Bladder erosions have more or less the same signs.

Rectal erosions will give rectorragia, violent colics, tenesmus. Diagnosis can be made by rectal palpation or rectoscopy.

In all these cases, complications and infection may appear if diagnosis is late. Pelvic sonography will show better than IRM or scanner the retracted implant, will measure the retraction, show the prosthetic recesses, the situation of close organs to overlook eventual per-or post -surgery complications. On the whole, any long lasting symptoms after implant of prosthesis, especially with bleeding or infection at distance of surgery must conjure up all these diagnoses and call for complete exploration under general anaesthesia if needed.

III: PREVENTION OF COMPLICATIONS DUE TO SUPPORTIVE VAGINAL IMPLANTS

Prevention of complications type 1

They did not seem to us directly infectious but linked to problem in early cicatrisation of the vaginal scar. We must try at the utmost to have neat and clean scars, respect vascularisation with a dissection not too near vaginal mucosa and a neat resection of wound banks before vaginal suture.

– Vaginal prosthesis especially synthetic one should not stay in contact with vaginal scar. The vaginal fascia can be interposed or the prosthesis buried as far away as possible from vaginal scar.

– Last, it is important not to have pointless large scars, intersecting scars, T incisions giving a high number of vaginal scars.

– vascularisation of vaginal scars may also be altered by hysterectomy with ligation of cervico-vaginal vessels.

Prevention of complications type 2

We do not know well the mechanism of these infections, their exact origin, the bacteriological type of germs Bacteriological study of infected implants may find no germs or many but with no prevailing one. Antibiotherapy cannot be an efficient prevention. Real infections are scarce with monofilamentous knitted polypropylene. We only saw one early (TVM group) cellulitis at day 7, or pelvic abscesses after surinfection of a true haematoma. We will describe later its treatment. Infection of vagina, urinary infections must be treated before any surgery. Infection is more frequent with certain materials:

– polyesters;

– silicone coated prostheses;

– micro porous synthetic mesh as Goretex.

Risks being higher with vaginal route a priori contraindicates these materials by this route (without proof of good animal and human tolerance).

Vaginal insertion of material always needs:

– good asepsy;

– strict respect of hospital hygiene rules;

– pre surgical diagnosis of local or general infection will post pone intervention;

– manipulation of implants implies changing gloves;

– insertion of implant during surgery must be as late as possible so it has shortest possible contact with surgical field;

– implants must be taken out of its wrapping as late as possible;

– implants will not be placed if there is a per surgical rectal wound.

Prevention of complications type 3

Retraction of prosthesis has no sure physiopathology, so prevention remains empiric. Symptomatology is more important when suspension of prosthesis is tight, more frequent when prosthesis is exposed. So we try:

– not to fix a prosthesis with suture thread and

– to treat quickly any exposition of prosthesis large or resisting medical treatment

– pre surgical vaginal atrophy may be treated by local oestrogens to have more supple tissues during and after surgery.

In all cases, prosthesis should not be too superficial so as not to exacerbate signs when placing it, dissection must be deep so prosthesis is not directly under vaginal mucous membrane.

Prevention of complication type 4

– any compression of adjacent organs must be avoided with

– no fixation of prosthesis by stitches

– no prosthesis placed next urethral, bladder or rectal wound.

IV: TREATMENT OF COMPLICATIONS DUE TO IMPLANTS

Type 1A

– Medical treatment

Should first be tried especially with old patients cured of their prolepsis and asymptomatic. But, in our experience, we have a high risk of secondary signs except with monofilamentous polypropylene. These complications are not surely infectious so we try and propose a simple and local disinfection and hope to enhance cicatrisation.

Treatment varies with the importance of vaginal defect. <1 cm^2: medical treatment has large chances of success. >2 or 3 cm^2 they are minimal and surgical resection must often be chosen. When there is association of vaginal infection, local antibiotics may be tried, then antiseptics or antibiotics.

– If cicatrisation of a large area is difficult, surgical resection must usually be done in operating theatre with usual asepsis measures. Technical gestures are simple but must be very cautious to avoid recurrence of deficient cicatrisation and secondary complications such as wound or secondary fistula of close organs.

Technical description: partial resection of a supportive vaginal implant

Presurgery check up

When there is big defect of vaginal healing under bladder, or the smallest doubt about bladder integrity, cystoscopy must be done. When implant is prerectal, rectal palpation must confirm rectal integrity, or even rectoscopy.

These explorations will be repeated under anaesthesia, implants seized with clamp, put under traction. Vagina is dissected around the implant and freed on half a centimeter about around the cicatrisation defect. Implant thus exposed is resected with cold scissors and surgical lancet. After incision of half the circumference about, free border of resected piece is seized with clip, traction separates prosthesis from underlying organs. Bipolar scissors may then help to dissect and coagulate without changing tool. Dissection and resection of exposed prosthesis is progressive, underlying organs are once more explored with a methylene blue test of bladder or rectum. When the wall of bladder or rectum is thin or wounded, it is classically stitched up, imperviousness then controlled. Vagina is shut " tension free " without resection.

Type 1B

Vaginal synechiae, vaginal polyps if symptomatic, may be split up during consultation.

Treatment of infectious complication type II

– Emergency withdrawal when there is infection or defect of cicatrisation of an implant "at risk";

– Medical treatment: defect of vaginal cicatrisation with monofilamentous knitted polypropylene implant;

– Partial resection of implant when defect of vaginal cicatrisation resists medical treatment or first intention defect is > 4 cm^2

Technical description: withdrawal of infected implant

Withdrawal is always easier when implant is infected, infection important and spread to the whole implant.

Presurgical check up

– When sub vesical vaginal healing is largely faulty or rectracted or when there is any doubt about vesical integrity, cystoscopy must be done.

– When supportive implant is prerectal, rectal exam must assess integrity of rectum.

Surgery begins by exploring exposition, repeating exams under anaesthesia, looking for aperture of vaginal fistula through which prosthesis might be palpable. More often, prosthesis is not palpable above all after sub urethral sling. A fine forceps will try to seize the prosthesis through aperture of fistula.

Implant is then gently and slowly tracted along its initial axis. It is easier when prosthesis is infected or encapsulated in an infectious shell. Implant will slowly and totally appear through the fistula if infection is diffuse all along its length, when there is a near abscess, a cutaneo vaginal fistula or cellullitis.

When infection is only partial with trans ligament, trans obturator or transperineal passage, infection often does not diffuse beyond the ligament. Retroligamental, transperineal or transobturator part of the implant remains firmly fixed. Progressive traction will break prosthetic arm near this zone. Ablation must be as complete as possible to avoid relapse. Dissection, as large as possible, tries to seize the implant next to obturator membrane or next to ligament of insertion. If prosthesis comes off at once exam must control its whole length is present. If not, dissection must go on until complete resection of the prosthesis sometimes changing route of access. If implant breaks and part of it is still palpable in dissection space it must be seized with the same forceps to realize total ablation of the material.

– Total resection: when intervention is finished, it is not necessary to close vagina, post surgical drainage will be better.

– Subtotal resection usually when implant is not totally infected. Resection of infected zone up to obturator membrane is usually enough for secondary cicatrisation. But the risk, at least theoretical, of distant relapse needing emergency consultation must be known by the patient.

– When supportive implant is synthetic, it is large and resection difficult. Intervention will use about the same technique as large resection for retraction we are going to describe.

Treatment of complications type III: retractions, pains

Prosthetic retractions need surgery when they are a discomfort for patients. They are often difficult to treat. There is no relapse of prolepsis, other organs are near. Partial ablation is usually enough, resection of lateral prosthetic arms hazardous by routine route . Large resection of median part of the prosthesis, as near the prosthetic arms as possible may reduce pain.

Technical description: complete resection of a supportive retracted implant

First surgical time is infiltration of retracted zone after palpation, deep between implant and nearest organ that is rectum. Rectal exam rules out rectal erosion of implant. Medial incision of vagina follows the first incision done when fixing the prosthesis. Between implant and vagina, dissection is easier after infiltration and usually easy at contact of implant seized with serrated dissecting forceps. Same is done between implant and rectum if there is ablation of anterior implant. After dissection, arms of the implant may be seen, only remaining suspension points which must be cut as far as possible.

Resection of sub urethral portion of a sub urethral implant

If it is done for pain, sling must be resected in the zone painful at palpation. Vaginal route may be complemented by laparotomy or laparoscopy to resect retro pubic portion of sling, or by trans obturator route if the sling goes through obturator. Resection may be done for a complication due to excessive tension; dysuria, bladder instability or such as dyspareunia. Resection technique is the same but, when tension is excessive, the sling stuck under urethra, access may be difficult and lateral approach better with less risk of urethral wound. Transverse incision will be done facing the implant. The implant is located by vaginal palpation or a transurethral sound giving a "striction" sign. Regular palpation of the sling guides dissection until contact. It is then seized by a forceps, tightened and dissected at vaginal contact, going towards urethra but cautiously not to injure it. Dissection then goes round the other side for complete resection of the sling. Before closing vagina, integrity of urethra is controlled by urethral sound or urethroscopy. Any injury needs strict suture in two plans of wounded vagina and its fascia for a lesser risk of secondary fistula.

Treatment of complications type IV: erosions of near organs

These complications remain exceptional if none of these organs has been wounded during surgery. Any pre surgical suspected lesion must be confirmed: Cystoscopy for bladder lesion, urethroscopy for urethral lesion, rectal palpation and rectoscopy for rectal lesion. Pelvic and perineal sonography may be very useful. Treatment is large resection of prosthesis as described above.

CONCLUSION

Supportive vaginal implants, for cure of urinary incontinence or genital prolapse, have specific complications that could be lessened by prevention. Any surgeon using these products should know early treatment and specific strategies.

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