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PERSPECTIVES/PROSPECTS

Adjustable Periurethral Balloons (ACT®) for the Treatment of Female Incontinence

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[bilingual abstract]

Introduction

There are many surgical techniques for treating female stress urinary incontinence, but they currently focus on implantation of suburethral slings, given the minimal invasiveness and simplicity of the procedure. Short and medium-term results are comparable to older reference techniques, particularly Burch colposuspension [1, 2], which has a success rate of 80 to 90% according to the series [3]. The failures and functional complications of the technique can be grouped into the following situations [4]:

- *de novo* or worsened bladder hyperactivity in cases of mixed incontinence;
- dysuria, or even chronic urinary retention, especially if the bladder was previously hyperactive;
- recurrence of stress urinary incontinence due either to insufficient correction or related to sphincter insufficiency.

The suitability of implanting a suburethral sling must be thoroughly considered, trying to evaluate the risk of failure, and especially identifying any risky situation. These situations can be summed up as follows:

- mixed urinary incontinence with a risk of increased bladder hyperactivity due to the procedure;
- dysuria or bladder hypotonia detected in the preoperative phase; polyphasic voiding by abdominal straining during flow measurement, and bladder filling pressure measurement. The risk is of chronic postoperative retention requiring self-catheterization;
- recurrence of urinary incontinence due to sphincter insufficiency. Sphincter insufficiency is diagnosed using a leak-point pressure test (VLPP) or especially low maximum urethral closure pressure on the urethral profilometric study, and persistence of stress leaks during the clinical exam in the absence of mobility of the urethral neck. This situation calls for implantation of an artificial sphincter with a success rate of 90% when the sphincter is in place [5]. However, it involves a more major surgery, which is more difficult for the patient to accept, and that can be hard to propose in patients who are very old or in poor general health;

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- difficult complex situations with numerous surgical failures, urethral damage making implantation of a suburethral sling or artificial sphincter hazardous.

For all of these clinical situations, a minimally invasive, easily reversible, and effective surgical solution would be a great benefit. The implantation of adjustable ACT® prostheses can be an answer in these situations.

Description of the Prosthesis and Its Presumed Mode of Action

The prosthesis consists of a silicone balloon that can contain up to 8 mL of isotonic fluid, connected to a thin tube emptying into a titanium covered injection port. In this tube, there is a second conduit in which a mandrel is inserted to keep the prosthesis rigid in order to facilitate its insertion (Fig 1).

Two prostheses are placed on either side of the urethra at the bladder neck, in a plane located below the pelvic aponeurosis (Fig. 2). They compress the urethra, as a periurethral injection could do, but the originality of the technique lies in the possibility of the volume of the prosthesis up or down, by means of a simple transcutaneous injection.

Fig. 1. Diagram of the Prosthesis

Injection Port Balloon

Conduit for the guide Metallic end

Fig. 2. Schematic representation of the position of the prostheses. The balloons are placed on either side of the urethra below the bladder neck between the vaginal wall and the pelvic aponeurosis.

[labels in diagram]
bladder pelvic aponeurosis

Vagina

Fig. 3. Operative principal. The guide is inserted under digital control using an imaging intensifier.

Unlike Urovive® balloons [6], the prosthesis is not positioned submucosally but periurethrally. Finally, the technique is easily reversible since the prostheses can be easily removed under local anesthesia.

Insertion Technique (Fig. 3)

The procedure may be done under general or local anesthesia, depending on the patient's wishes, and any anesthetic contraindications. The patient must be prepped in exactly the same way as for the insertion of an artificial sphincter: verifying the absence of urinary tract infection, thorough cutaneous preparation, shaving of the labia majora.

The patient is positioned in the dorsal decubitus position with legs spread a part and thighs flexed at a 45° angle. Insertion is monitored using an imaging intensifier and digital palpation of the vagina.

A preliminary endoscopy must be done to verify the absence of urethral or bladder lesions.

A 16 F Foley's catheter is inserted with opacification of the balloon using a contrast medium. The bladder may also be opacified with a diluted contrast solution.

A short incision of one centimeter is made on the lateral cutaneous edge of the posterior part of each labium, allowing the guide to be inserted (Fig. 4). The guide must come into contact with the ischiopubic branch to avoid vaginal perforation, then cross the anterior vaginal cul-de-sac toward the bladder neck under digital control and imaging intensification. It is necessary to assess the mobility of the anterior vaginal wall, which could give the impression that the guide has been positioned correctly while the vaginal wall and the guide are moving forward together, causing the prosthesis to be inserted too far toward the distal end. Care must also be taken not to cross the pelvic aponeurosis or penetrate the bladder. It can be difficult to position the guide properly, and it is highly recommended that one be trained in the technique. The end must be in contact with the lateral wall of the urethra at the bladder neck. The inner part of the guide is withdrawn and the prosthesis can be inserted.

Fig. 4. Appearance of the prostheses, the guide, and the syringe equipped with its special needle.

The length of the prosthesis is chosen based on the depth at which the guide is to be inserted, but it is better to insert a long prosthesis that protrudes from the skin by at least three centimeters. In practice, the nine-centimeter prostheses are usually the best suited. The prosthesis is purged with an isotonic radio-opaque fluid (the same as the one used for artificial sphincters, for example, a mixture of 47% water and 53% Telebrix12®). It is this fluid that will be used to inflate the prosthesis. The needle equipped with the device must be the only one to be used in order not to wear out the injection port. The prosthesis must be complete emptied so as to obtain a balloon in the shape of a three-point star. After being coated with Xylocaine® gel, the prosthesis is inserted in the guide under imaging intensification. Its end is radio-opaque, so that it can be verified that it has actually reached the end of the guide. The guide is gently withdrawn, keeping the prosthesis in place. The prosthesis is then inflated with 1.5 to 2 mL of isotonic contrast fluid. The same procedure is done on the other side. Inspection under imaging intensification should show the balloons to be symmetrical.

An endoscopy of the urethra and bladder is done to check for perforations. A urethral or bladder perforation can lead to the implant being repositioned in a different path or abandonment of the technique, depending on the seriousness of the lesions.

A subcutaneous chamber, made toward the front of the labia majora with fine scissors, allows the injection ports to be positioned. The skin must be closed in two layers in order to keep the tubing away fro the incision. Usually, a Foley's catheter is left in place until the day after the procedure.

Postoperative Care

The bladder catheter is removed the next day. Before the patient is discharged, it is necessary to make sure there is no significant post-voiding residue. If there is dysuria or retention, the volume of the balloons must not be reduced, because of inflammation and the small possibility of a postoperative hematoma that could be the cause of this transitory retention. It is better to teach the patient to self-catheterize or, if necessary, have someone else perform the catheterizations if the patient is unable, rather than leaving an indwelling catheter. The surgical wounds must be kept clean and dry. The patient will be seen again six weeks later, the time that it takes for the prosthesis to be encapsulated and for the labia majora to be complete healed, for a possible adjustment.

Follow-up and Adjustments

The first adjustment may take place six weeks later if healing is complete and the labia majora are not painful. Of course, it is not useful unless incontinence persists and there is no dysuria. A clinical exam must be performed to check that the prosthesis have remained in the correct position. In there is any doubt, a radiographic follow-up may be performed and compared with the perioperative images. The adjustment is done with special needles that do not damage the injection port (23 G microlance® needles, ref. 300700 are validated by the manufacturer) using the same isotonic mixture as for the insertion. It is injected holding the port immobile at the labia majora so that the needle is inserted in the center of it. The adjustment volume must not exceed 1 mL on each side (as a general rule, 0.5 to 1 mL). The absence of post-voiding residue must be checked once the adjustment has been made. The timing of other adjustments will be based on the degree of residual incontinence, but it is preferable to wait at least one month between adjustments, the time it takes for the periprosthetic shell to reform, if needed. The volume of the balloons may reach 8 mL. Once continence is achieved, a follow-up at least once a year is advisable.

Complications and their Management

Absence of Improvement

If no improvement is observed in spite of several adjustments, it is advisable to check the position of the balloons, clinically and radiologically. An endoscopy (fiber optic scope allowing the urethra to be better visualized) must also be performed to check for erosion of the urethra or bladder. If it is necessary to change a balloon, it is best to deflate it completely a few weeks before the procedure so that the space housing the balloon closes up completely, which will avoid having the new balloon reoccupy the same place. Implantation of an artificial sphincter is possible after balloon insertion because they will be used as markers for the pericervical dissection and will be removed at the same time as the sphincter is inserted. Of course, it must be verified that the continued incontinence is not due to bladder instability, which requires identifying any obstruction and may possibly lead to deflating the balloons at the time of the treatment for hyperactive bladder.

Erosion and Infection

Erosion of the prosthesis may occur at the labia majora, or in the vagina, bladder, or urethra. Clinically, the labium is inflamed, painful, and may exude a small amount of pus. The prosthesis may sometimes be pushed out by the urethra. Erosion or infection of a prosthesis requires its removal. It is removed in a simple procedure under local anesthesia by making an incision in the skin across from the injection port, then completely deflating the prosthesis, which can then be extracted. In the event of urethral or bladder erosion, it is best to leave a Foley's catheter in place for about a week. It usually heals fastest with local wound care to the labia majora. It is possible to reinsert the prosthesis, but not until at least three months have passed.

Migration of the Prosthesis

Even remotely, migration of the prosthesis can be observed, most often distal, with the balloon being palpable on the lateral surface of the lower part of the vagina. It is possible to change it to put it in the proper position. In this case, it must be completely deflated a few weeks before the repeat procedure.

Persistent Retention

This is a rare situation (I have never personally had to treat it). The balloons may be deflated, but it is better to wait six weeks before performing this procedure.

Outcomes

Studies on this type of prosthesis concern mainly men [2.7] and the French National Authority for Health (HAS) has recently issued a favorable opinion, finding it to be an important service needing a prospective follow-up for the treatment of male urinary incontinence. Few studies have been published on the evaluation of results in women because the procedure is recent and aimed at only a specific population of urinary incontinence patients. A French multicenter prospective study presented at the Congress of the French Urology Association in 2004 [8] will be published soon [9]. Sixty-eight patients with stress urinary incontinence with sphincter insufficiency (maximum urethral closing pressure = 23 ± 11 cm of water) have been treated using this device. Eighteen patients had the devices removed because of erosion, shifting, or infection, but 6 were later able to be reimplanted. At two years, 39 patients were assessable: 6 (21%) were dry and 19 (66%) were greatly improved.

The results of our series were presented at the Congress of the SIFUD-PP in June 2007 [10]. Between October 2001 and October 2005, we treated 40 female patients with an average age of 71 years, presenting with stress urinary incontinence with sphincter insufficiency. Forty-five percent of them had already undergone surgery for incontinence, and 15% had a neurological condition that affected their vesicosphincteral balance. Twenty-two and a half percent had mixed incontinence and 40% had bladder acontractility. The mean maximum urethral closing pressure was 24 cm of water. Seven patients had the devices removed because of a complication, and 6 had them reimplanted. Three patients had them removed at the same time an artificial sphincter was implanted because they were ineffective. The mean number of adjustments was 1.9 (± 1.1). With a mean follow-up of 15.3 months, 15% are dry, 30% have minimal leakage, 40% have moderate leakage and consider themselves improved, and 15% still have severe leakage. One patient has *de novo* bladder instability.

Discussion

These results can be considered clearly inferior to other therapies, but they concern a population in whom treatment proves to be difficult and generally fail to respond to standard treatments. The procedures is quite short (an average of 30 minutes), but the implantation of the balloons is not always easy and it is possible that part of the failures are due to improper positioning of the balloons. Using 3D imaging (such a scanning) could provide interesting data, but the population in whom it failed should then be compared with the population in who it succeeded. A lack of urethral compliance may also work against this population who had already had surgery (some of them several times), but this parameter is hard to evaluate.

The technique is still very recent and not very widely used. It must be the subject of further evaluations and longer-term follow-up, but it offers the advantage of filling a therapeutic void for urinary incontinence due to sphincter insufficiency when other therapies cannot be used. Moreover, its minimally invasive nature, the possibility of adjusting the volume of the balloons and easily removing the prosthesis if necessary make it an original therapy that may be highly beneficial in complex or risky situations of stress urinary incontinence. There are, in fact, few therapeutic alternatives: the artificial sphincter gives excellent results in incontinence due to sphincter insufficiency [5], but it involves more major surgery; periurethral injections give

unsatisfactory results in this population [11], Remeex® [12] type adjustable slings lack the advantage of reversibility offered by ACT® prostheses.

No patient has shown long-term pain or discomfort related to the prosthesis. The impact on sexual function was difficult to analyze in this elderly population.

Conclusion

Because of its minimally invasive, adjustable, and reversible nature, stress urinary incontinence treatment by implantation of ACT balloons seems to be a very promising technique in complex or risky situations. It supplements the therapeutic arsenal in this population for whom there are few alternatives.

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