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Treatment of Post-Prostatic Surgery Stress Urinary Incontinence

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1. Introduction

There are few long-term medical conditions and non-fatal injuries that are so inconvenient as the urinary incontinence in its various degrees. This situation effect the social life and there are consequences for the economic impact of this clinical condition in patients and health services.

The direct costs associated with urinary incontinence is related to aspects such as diagnostic tests, doctor visits, surgery, use of diapers, and others. Among the indirect costs can include the time available for patients and friends to care of incontinent patients, and the loss of productivity for the individual hours away at work. The worsening quality of life of the patient is considered an intangible cost, difficult to measure in monetary terms, but which constitutes an integral aspect of urinary incontinence.

Among the various causes of urinary incontinence, sphincter incompetence is one of the most common (Mundy, 1991). Fortunately, most patients with sphincter incompetence have simple stress incontinence, which usually responds well to one of several procedures for suspension of the bladder neck or urethra. However, surgery does not work without implants as favorably for the treatment of severe urinary sphincter, where the loss of urethral support is irrelevant (Mundy, 1991). In these circumstances, the best form of treatment is still the deployment of devices performing a specific function that compensates constrictor malfunction of the urethral sphincter (Hussain et al. 2005; Mundy, 1991; Schiavini et al. 2007; Vilar et al. , 2004).

The initial treatment of urinary incontinence with urethral devices date from 1947, when Foley described the first artificial sphincter (Foley, 1947). According to its proposal, the penile urethra was exteriorized, involved with the foreskin and, after healing, the device was placed around the urethra. This device consisted of a tube connected to a syringe, the patient carried in his pocket, and when wanted to maintain continence, insert some fluid that would exert pressure through the syringe. Foley's method fell into disuse due to the high incidence of urethral injuries.

In 1973, Scott and colleagues, based on the idea of Foley, have created a toilet model totally implantable device, the AMS 721, which was modified and optimized by Rosen, 1976 (Rosen, 1976, Scott et al., 1973). This device allowed compression of the bulbar urethra by inflating the device. Due to poor results, the device also fell into disuse.

Changes were made in the initial design and the most important was the use of a balloon to regulate the pressure valve in place.

Later models also incorporated an entirely new body of silicon, rather than a body of Dacron®. A decrease in the number of components and connections resulted in the current AMS 800 (Fig. 01a), a device consisting of 3 parts (Hussain et al., 2005).

The AMS 800 is a body-shaped strap that is placed around the bladder neck or bulbar urethra. This body is connected to a balloon pressure regulator via a control pump, located in the scrotum of the patient. The whole system is filled with saline, hydraulic operation. The pressure in the system and therefore the strength of the occlusive balloon body is determined by the throttle, being maintained in the system except when the pump is activated voluntarily by patients who do not account for intermittent catheterization. This activation provides the rapid emptying of saline in the body, which fluid is directed to the balloon pressure regulator, momentarily removing the occlusive force of the body and allowing urination by the patient (Fig. 01b). The body is kept empty for long enough (2-3 min) so that urination is complete before returning to gain momentum due to the return of occlusive saline (Hussain et al. 2005; Mundy, 1991).

Urinary incontinence after prostate surgery represents a social problem and public health, patient and burdening the state with direct and indirect costs and affect the quality of life of patients. The AMS 800 is the best treatment for the patients with severe sphincter incontinence, but preliminary data from the Constrictor Inflatable Periurethral are encouraging (Kuznetsov et al., 2000, Montague et al. 2001; Schiavini et al., 2007).

Treatments such as collagen injections and the periurethral sling men do not appear as effective alternatives for long-term treatment of severe forms of this type of incontinence. Despite the long history of use, collagen injections are associated with success rates that generally do not exceed 40% cure rate. Due to the metabolism of collagen in the body, there is a gradual decrease in cure rates associated with the technique. This transient effectiveness usually takes the need for applying multiple injections on each patient, increasing the treatment without increasing the rates of long-term success (Carson, 2002, Cespedes et al., 1999, Kuznetsov et al., 2000).

The male sling appeared as a possible treatment for patients with sphincter incontinence after prostate surgery. However, the results were effective only in patients with mild to moderate incontinence (Castle et al., 2005). Sahaja & Terris, 2006, also pointed out that the male sling would not be as effective as a device with more physiological action, such as the artificial sphincter. For the structural similarity between the body of the AMS 800 and the Constrictor, this reasoning could be extended to the Constrictor.

Another aspect to be considered is that, despite their recognized efficacy, the greater structural complexity of the AMS 800 has a direct impact on their high cost (Mundy, 1991). This is one of the reasons that explain the low access to this device for patients with urinary

sphincter in Latin America. Meanwhile, the Constrictor has provided preliminary efficacy results similar to the AMS 800, on a smaller device cost about 16 times.

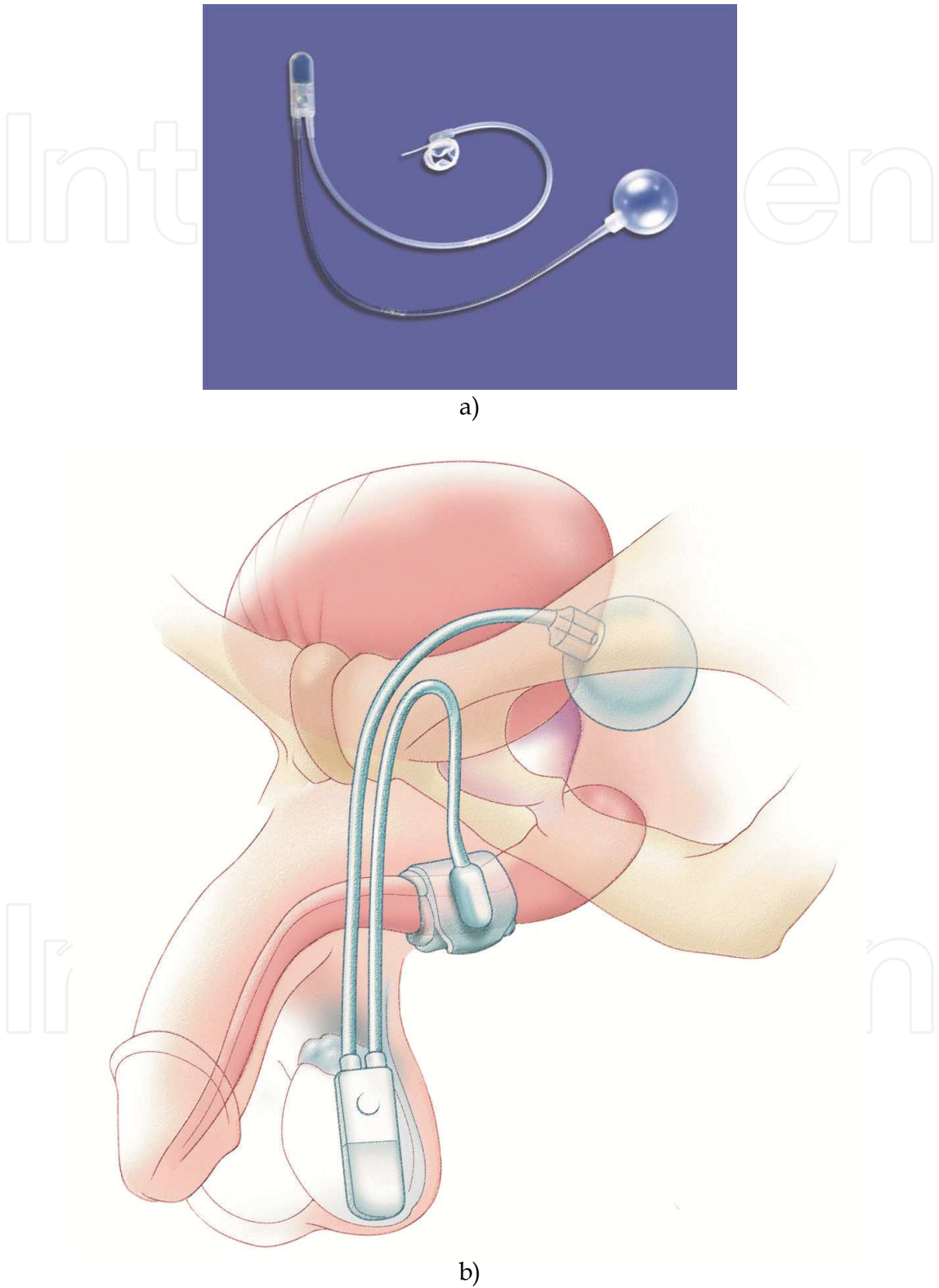


Fig. 1. a) AMS 800, a device of 3 parts - body, balloon and pump. b) Operating mode of the AMS 800 (Permission by American Medical Systems®)

2. Alternatives to the AMS 800 in the treatment of urinary incontinence

Currently, the only device on the market, indicating the use and operational mode that resembles the AMS 800 in strengthening occluding the urethra is developed by Constrictor Inflatable Periurethral SILIMED (Rio de Janeiro – Brazil), a device consisting essentially of 2 parts - body and valve constriction (Fig 2).

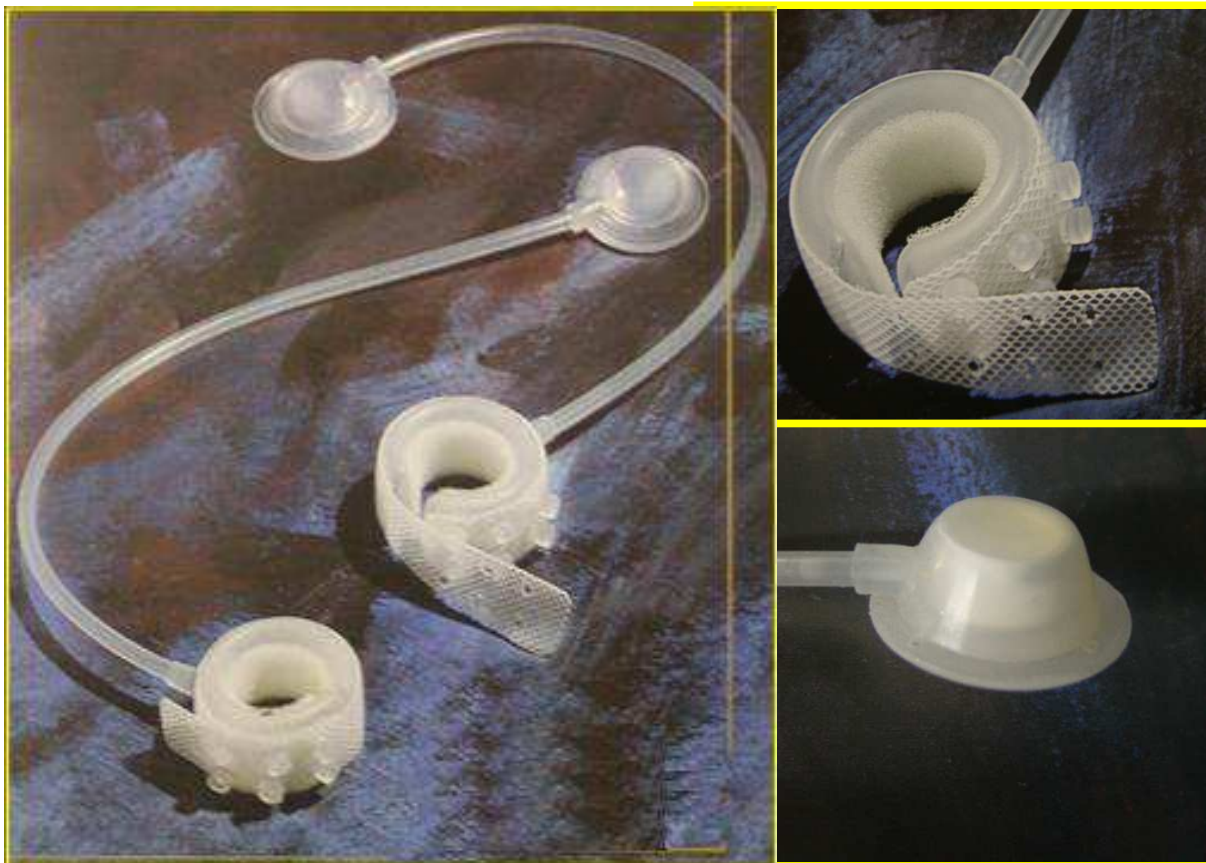


Fig. 2. Periurethral constrictor SILIMED, a two-part device (constrictor cuff and self-sealing valve with tube) (Permission by SILIMED®).

The main functional difference between the two devices is that the force of the occlusive body Constrictor Inflatable Periurethral remains constant throughout the duration of use of the device. If necessary, the patient's physician can make periodic adjustments of pressure in order to increase or decrease the force of the occlusive body, through the injection or removal of saline through the valve device in an outpatient setting. Meanwhile, the literature indicates a technical difficulty related to the change in pressure in the system of the AMS 800, possible only after revision surgery for the exchange of the balloon pressure regulator (Mundy, 1991).

The medical and scientific literature presents both AMS 800 and the Constrictor Inflatable Periurethral (preliminary data) as trusted devices and with good durability. Any problems would be reversed, in most cases, for simple or surgical outpatient review, which would ensure good continence rates, according to the criteria of effectiveness adopted by different authors (Hussain et al. 2005; Mundy, 1991; Schiavini et al. , 2007; Vilar et al. 2004; Webster & Sherman, 2005).

The relative simplicity of the Constrictor apparently does not interfere with its effectiveness. Studies of the groups of Dr. Salvador Vilar and Dr. João Schiavini Constrictor present with continence rates of around 85% during treatment, as mentioned ahead. Moreover, the Constrictor was also able to provide some patients voiding spontaneously, especially in adults with urinary incontinence after prostate surgery sphincter. Even in cases where intermittent catheterization was used, the rate of patient satisfaction were generally high (Vilar et al. 2004; Schiavini et al., 2007). The main results are described ahead.

2.1 Constrictor treatment in patients with neurogenic urinary incontinence

In 2000, Lima and colleagues from the Hospital Infantil Manoel Almeida, Federal University of Pernambuco - Recife, presented results on the use of inflatable Periurethral Constrictor for the treatment of urinary incontinence secondary to myelomeningocele. The 24 patients (14 men and 10 women) were in the age group 5 to 42 years, and were followed for an average of 4.2 years (1-84 months). Concomitant with the deployment of the device, 21 of these patients underwent cystoplasty to increase with the use of De-epithelialize colon. Twenty-one patients had a good result with the device in addition to being functional continents, giving a success rate of 87.5%. In 3 (12.5%) cases, the device was removed due to the occurrence of erosion and infection. At the end of the study, the authors stated that the use of inflatable Periurethral Constrictor would be a safe and effective in the treatment of long-term causes of neurogenic urinary incontinence (Lima et al., 2000).

In 2004, Vilar and colleagues presented a second study group related to the use of Constrictor Inflatable Periurethral the surgical treatment of urinary incontinence in 42 children (29 boys and 13 girls) with a mean age of 10.2 years (3 to 17 years). The group consisted of 29 neurogenic patients, 12 with bladder exstrophy and 1 with megalouretra. Concomitant with the deployment of the device, augmentation cystoplasty was performed in 34 patients. Patients were followed for an average of 5.2 years (4 to 104 months). In 25 patients in the neurogenic group the device was functional and provided continence, which represented a rate of continent patients during treatment of 86%. In 4 (14%) patients, the device was removed due to erosion (3) and infection (1). The patient was continent and megalouretra urinated spontaneously. In the exstrophy group, 10 patients had their devices explanted due to erosion and incontinence. Only two kept the device and performed intermittent catheterization. The authors concluded that the Constrictor Periurethral would be a long-term alternative, safe and effective for the surgical treatment of urinary incontinence cause neurogenic sphincter in children. Like previously reported for other implants, the authors emphasized that the device should be used with caution in patients with bladder exstrophy (Vilar et al., 2004).

2.2 Post-prostate surgery urinary incontinence.

In 2007, Schiavini & Resende Jr and colleagues, University Hospital Pedro Ernesto, Rio de Janeiro, showed their initial experience with the use of inflatable Periurethral Constrictor.

In this study, eighteen patients had urinary incontinence after radical retropubic prostatectomy, and five were previously submitted to procedures for the treatment of

bladder neck strictures. In all patients, the body of the device was placed around the bulbar urethra, with activation of the device after 8 weeks. Patients were followed from 6 to 36 months. For the authors, successful treatment was predefined as the need to use a diaper until the day - social continence, together with patient satisfaction.

2.2.1 Preoperative evaluation

The complete urologic evaluation was performed, including urine analysis, ultrasonography, cystography and urodynamic studies before to submit the patients to the surgery, respecting the inclusion and exclusion criteria previously established, as described below.

2.2.2 Inclusion criteria

- Men;
- 18 years or more;
- Diagnosis of sphincter incontinence after prostate surgery;
- Be in good general health prior to participation in the study, no significant clinical abnormalities determined by: clinical history, physical examination, blood chemistry, blood count, urinalysis (the results of biochemical tests or hematology or urinalysis laboratory do not contain references, the patient may be included only if the researcher finds that the changes are not clinically significant);
- Informed Consent in writing and signed by the patient.

2.2.3 Exclusion criteria

- Detrusor overactivity unresponsive to clinical treatment.
- Low compliance bladder;
- Use of drugs that interfere with bladder function;
- Severe urethral stenosis,
- History of significant disease (ex. cardiovascular, pulmonary, gastrointestinal, hematological, neurological, degenerative, hormonal, autoimmune or cancer).
- History of psychological instability;
- Presence of active infection;
- Any situation that increases the possibility of infection / erosion after body contact device with the bulbar urethra (ex. sequelae of prior radiotherapy);
- History of allergenicity to foreign bodies or silicone;
- History of drug abuse in the last two years;
- Risk that prevents surgical surgery / anesthesia;
- Any condition, which in the opinion of the investigator, may interfere with the patient participation in the study (ex. difficulty of meeting the requirements of the study, attend appointments, or any other situation that may affect the response of the questionnaire on quality of life by the patient);
- Patient expected to undergo surgery during the study period, which may affect the outcome;
- Patient undergone previous surgical treatment for the treatment of sphincter incontinence.

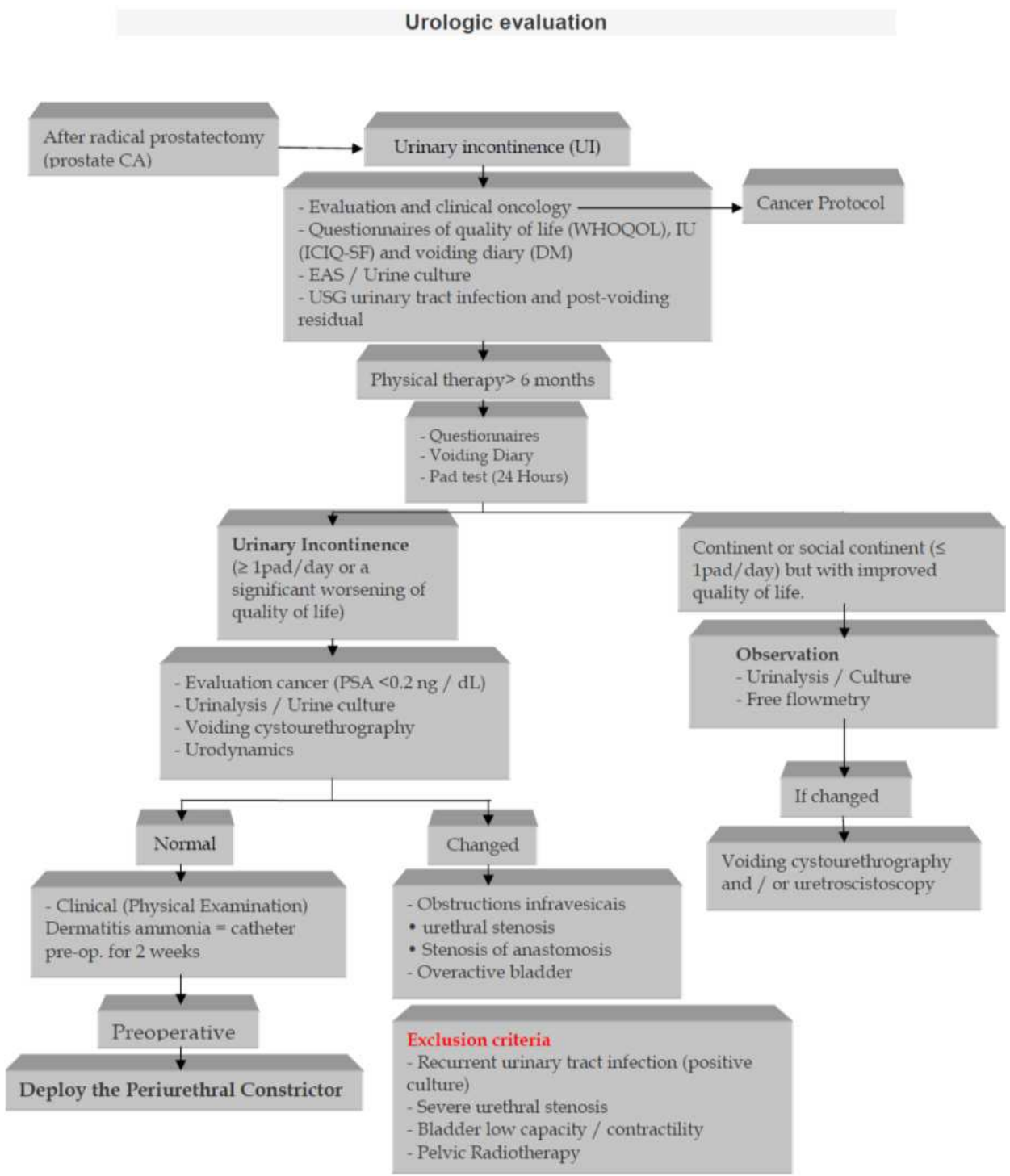


Fig. 3. Urologic Evaluation

2.3 Surgical approach and intra-operative procedures

The patient is subjected to anesthesia in the operating room after evaluation by the anesthesiologist. Prophylaxis with intravenous antibiotics (3rd generation cephalosporin) will be held 30 minutes before starting surgery. Will be held genital shaving and antiseptis genital at least 5 minutes and drapes are placed.

Ureteroscopy with internal urethrotomy was performed when it was not possible to place a bladder catheter preoperatively.

To implement the Constrictor Inflatable Periurethral around the bulbar urethra, the surgical access of up to 10cm in the perineal raphe, with the developer in the lithotomy position. The muscle fibers bulb-cavernous must be separated in the longitudinal direction, and the bulbar urethra dissected easily visible and later by creating the space for placing the constriction around her body (Fig-4).

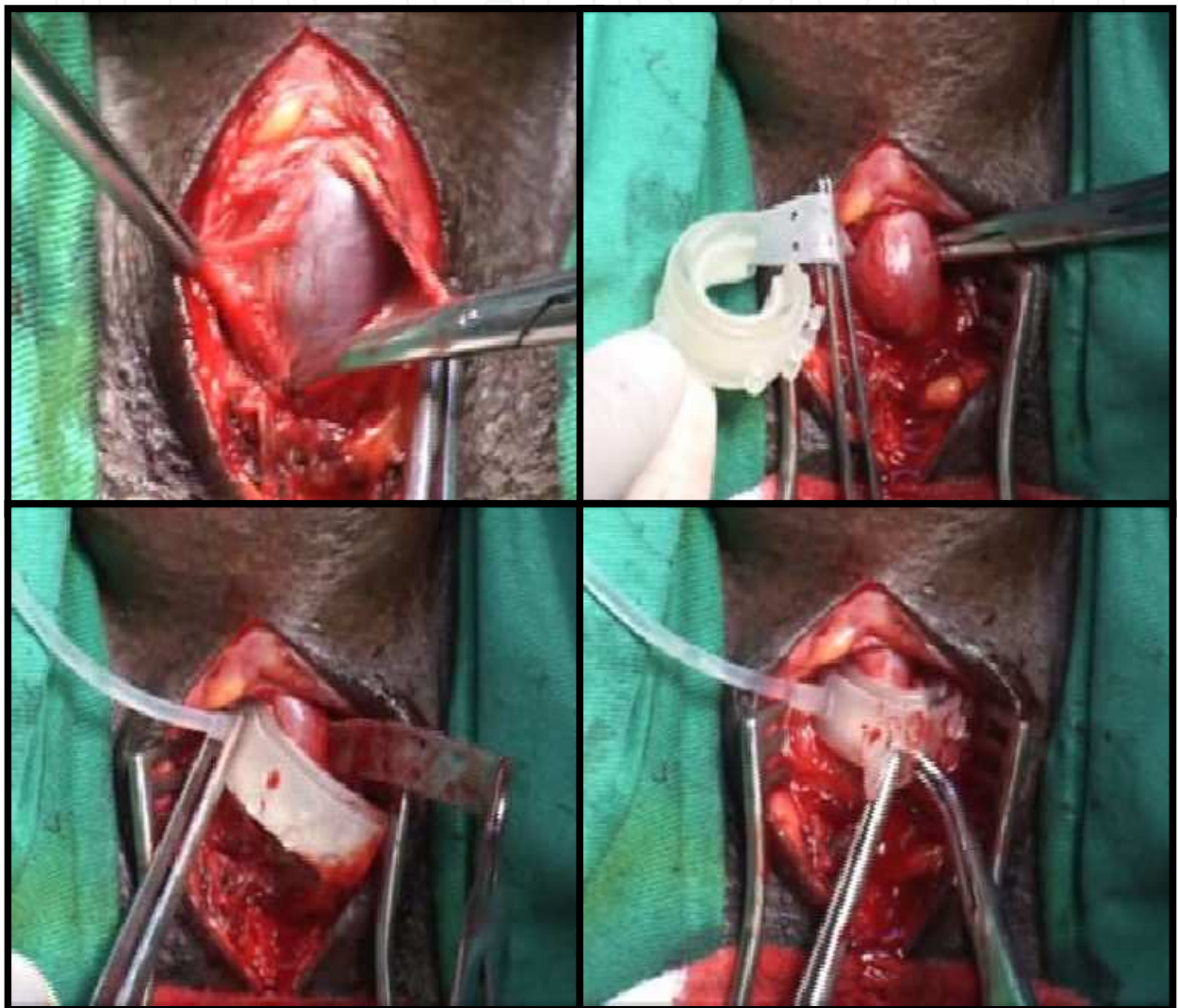


Fig. 4. Details of the constrictor cuff implantation around the bulbar urethra, after the dissection and separation of the bulbospongiosus muscle fibers.

The pipe must be routed through the subcutaneous space and the valve implanted in the suprapubic region or subdartic within the scrotum, where it can be punctured (Fig-5).

The Constrictor Inflatable Periurethral should have your air completely removed before being introduced into 2 ml of pyrogen-free saline. Meticulous haemostasis is essential to reduce risk of haematoma formation.

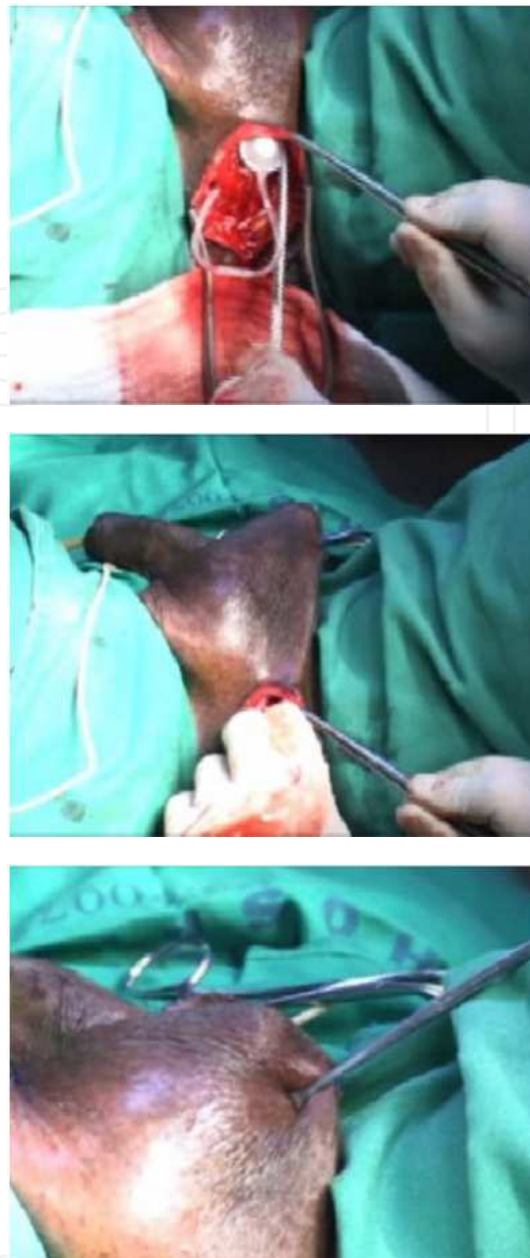


Fig. 5. Details of the valve implantation at the subdartic space of the scrotum.

2.4 Post operative care

The urethral catheter can be withdrawn on the 1st postoperative day. Activation of Inflatable Periurethral Constrictor should be held approximately 8 weeks (at least 6 and at most 12 weeks) after implantation, when a urodynamic study should be performed in conjunction with the measurement of pressure inside the device.

To enable Inflatable Periurethral Constrictor, you should use a butterfly type intravenous scalp, 25G to 27G, previously filled with sterile saline, and pyrogen, to puncture the valve. The puncture should be done in the center of the constrictor valve in 90-degree angle, avoiding the edges of this valve, where the silicon is thinner, not to damage it. Must be injected sterile saline and pyrogen in an amount sufficient to produce continence, even

during sudden increase in abdominal pressure, such as episodes of coughing, but allows good urinary flow, without causing urinary retention.

During the activation step, the clinician must be careful that the needle is inserted into the valve without excessive force, which could cause bending at the end of the needle and damage to the silicone septum during their re-treatment, thus undermining the proper functioning valve device.

In addition, the use of large-caliber needles can destroy the valve.



Fig. 6. Periurethral constrictor's activation by injection of saline solution through the self-sealing valve located at the scrotum. After activation, the patient had a good urine flow and achieved urinary continence.

2.5 Efficacy variables

The subjective and objective efficacy of the intervention was determined monthly in the first year and quarterly by the end of the third year (final visit) based on clinical results obtained in the patient Pad Test and questionnaires.

The questionnaires validated quality of life WHOQOL (World Health Organization - Quality of Life) and ICIQ-SF (International Consultation on Incontinence Questionnaire - Short Form) were used as an instrument of measurement.

2.6 Observations and measurements postoperative

The recommendations for postoperative monitoring are in the figure below (Fig-7).

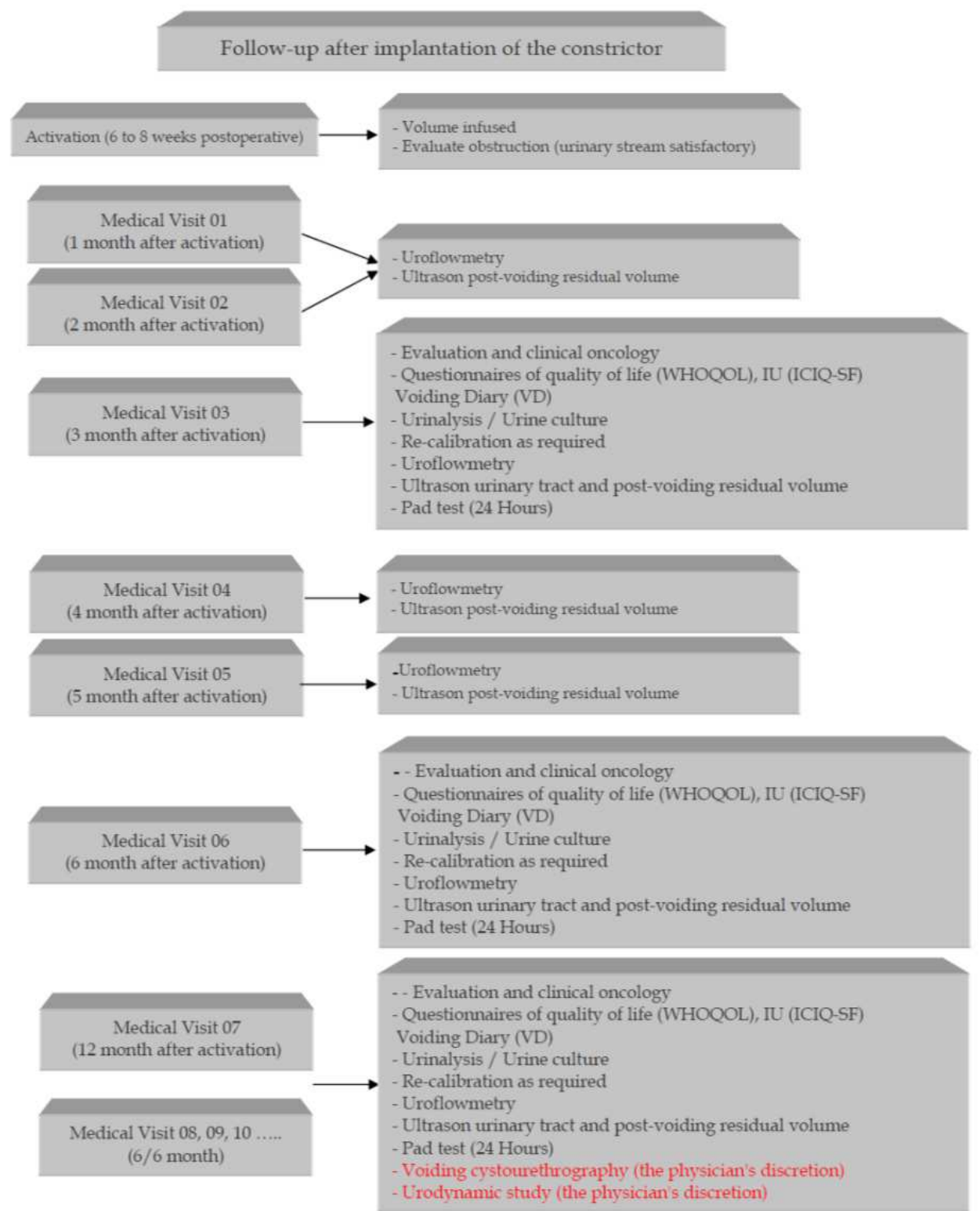


Fig. 7. Urologic Evaluation Postoperative.

2.7 Results – AMS 800®

Follow-up ranged from 27 to 132 months (mean 53.4 +- 21.4 months). There was a significant reduction in pad count from 4.0 +- 0.9 to 0.62 +- 1.07 diapers per day ($P<0.001$) leading to continence in 90%. Twenty patients (50%) were completely dry, and 16 (40%) required 1 pad per day. There was a significant reduction on the impact of incontinence decreasing from 5.0 +- 0.7 to 1.4 +- 0.93 ($P_{0.001}$) in a visual analogue scale (VAS). Surgical revision rate was 20%. Preoperative urodynamics was useful to identify sphincter deficiency. Except by a tendency of worse results in patients with reduced bladder compliance (RBC), other urodynamic parameters did not correlate with a worse surgical outcome. (Trigo Rocha F, et al. 2008).

Author	Number	Follow-up (yr)	Continence Rate (%)
Marks and Light	37	3.0	94.5
Light and Reynolds	126	2.3	96.7
Perez and Webster	49	3.7	85.0
Mottet <i>et al.</i>	103	1.0	86.0
Martins and Boyd	28	2.0	85.0
Fleshner and Herschorn 1996	30	3.0	87.0
Current series	40	2.5	90.0

AUS = artificial urinary sphincter; PRPUI = postradical prostatectomy urinary incontinence.

Fig. 8. Continence rates after AUS implantation in patients with PRPUI (Modified from Trigo Rocha F, et al. 2008)

The main complications related to the AMS 800 are: Revision rate of the device in 5 years (26%), malfunctioning device (8%), pain/discomfort (6,9%), slow healing of wounds (5,7%), bladder spasms (2,3%), activation difficult (2,3%), displacement of the device (3,5%), erosion tissue (2,3%), disabling difficult (1,1%), infection (2,3%), recurring incontinence (3,5%), fistula formation (1,1%), hematoma (1,1%), swelling (2,3%), hydrocele (1,1%), erosion tissue/infection (1,1%), patient dissatisfaction (1,1%), incontinence position (1,1%), wound infection (1,1%), urinary retention (1,1%) (Shellock F, et al. 1988; Litwiller SE, et al. 1996)

2.8 Results - Constrictor inflatable periurethral®

The results obtained in 2007, four patients had neurogenic functional implants. Were continents and performed intermittent catheterization. In the group of prostatectomy patients, 15 had functional implants, and 2 performed intermittent catheterization. In three patients, the valve implant some leakage of saline, after activating the device, which was easily solved by changing the valves. Only one implant fail to function properly and was removed. Other two implants were removed early due to erosion, probably caused by

iatrogenic complications that occurred during dissection of the bulbar urethra. Thus, 19 patients with functional implants represented a success rate of 86%, during an mean follow up of 28 months (6 to 50 months). (Schiavini et al, 2007).

In the update made in 2010, and Schiavini & Resende Jr and colleagues, 30 patients were evaluated and followed up for a mean of 42.1 months (range, 13-72). In 22 patients (73.3%), the implanted devices were functional, 16 patients (53.3%) were completely dry, and 06 (20%) required 1 pad per day; 20 voided spontaneously, and 2 performed intermittent catheterization. Among them, 7 patients were submitted for ambulatory review – within 2 weeks of the activation of the device – to increase the occlusive static pressure of the cuff (range of volume added, 0.4-1.7 mL); and 4 were submitted for surgical exchange of the valve because of leakage of saline solution. Despite these occurrences, all of these patients claimed they were very satisfied with the results.

The main complications were urethral cuff erosion in 4 patients (13.3%) and infection in 3 patients (10%), leading in these cases to early and complete removal of the devices. An eighth patient remained incontinent after the device reactivation because of detrusor hyperreflexia. In this series, there was no occurrence of any other major complications.

3. Comment and conclusion

In the last years, the urological community has been developing new procedures to treat postprostatic surgery urinary incontinence. Despite their long history of use, collagen injections are associated with low cure rates. Moreover, collagen is gradually reabsorbed by the organism, leading to additional applications of the product, along with no significant increase in long-term cure (Cespedes.1999; Kuznetsov et al. 2000).

The male sling appeared as another alternative treatment for these patients, but seems to be effective only in mild and moderate cases of postprostate surgery urinary incontinence (Castle et al. 2005; Montague et al. 2001).

Although the artificial urinary sphincter is considered as the standard treatment for moderate and severe cases of postprostate surgery urinary incontinence, it is a high-cost device. In the present study, the authors present results of a surgical alternative for the treatment of postprostate surgery urinary incontinence. For this, we used the periurethral constrictor, a two-part device with a constrictor cuff positioned around the bulbar urethra and hydraulically activated through a self-sealing valve with a tube. Previous studies had already presented the device as a safe and effective alternative for the treatment of neurogenic urinary incontinence (Lima SVC, et al. 2000; Vilar FO, et al. 2004).

This is particularly true if we consider that the erosion and infection cases were probably caused by bulbar urethral injuries that occurred during its dissection and cuff positioning in an early phase of the study during the learning curve of the technique. Along the series, there were no new cases of erosion and infection.

Our experience indicates that the periurethral constrictor is less susceptible to mechanical problems or improper functioning, which agrees with the studies of neurogenic patients. The eventual problems were easily managed by simple surgical reviews with local anesthesia in the case of the exchange of leaking valves, or ambulatory reviews to adjust the

occlusive pressure of the system—once the presence of a self-sealing valve permits suitable readjustments through simple transcutaneous injections at any time on an outpatient basis, which makes the overall procedure safer and less expensive by avoiding unnecessary surgical reviews. In the case of the valves, we verified that the leakages were inadvertently caused by needle perforations of the edge of the valve (where the silicone is thin) during the activation of the device. As a result of this, a project alteration of the valve that greatly diminished this risk was performed, and there was no occurrence of any other improper functioning of the device afterward.

The periurethral constrictor may also be an important option in the treatment of sphincteric urinary incontinence in elderly, parkinsonian, and hemiplegic patients who have suffered cerebral vascular accident or other conditions that contribute to the decrease of manual dexterity (which would prevent the manipulation of the artificial sphincter's mechanism). Another indication would be for incontinent patients who have sustained sphincter injury with bladder atony, which can benefit from the use of the device for staying dry and voiding by intermittent catheterization.

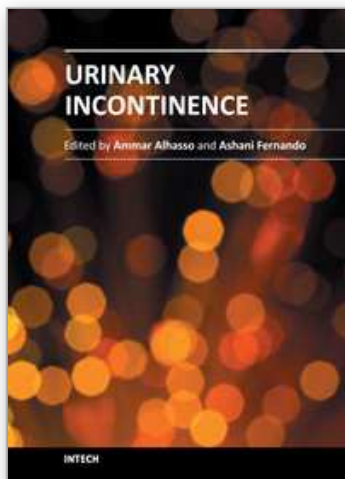
Moreover, the low cost of the periurethral constrictor is also an important characteristic in its favor when compared with the already established AMS 800. The rates of efficacy that are apparently similar between both devices and the constrictor's lower cost may encourage its use in all cases of postprostate surgery urinary incontinence where economic aspects are an important variable to be considered, including those where the artificial sphincter may also be indicated but its high cost prevents its use.

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Urinary Incontinence

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Management strategies are framed within a multidisciplinary team structure and as such a range of specialists ranging from psychologists, specialist nurses, gynaecologists and urologists author the chapters. There are some novel methods outlined by the authors with their clinical application and utility described in detail, along with exhaustive research on epidemiology, which is particularly relevant in planning for the future.

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