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ARTIFICIAL URINARY SPHINCTER MALFUNCTION: IS IT NECESSARY TO SUBSTITUTE THE WHOLE PROSTHESIS?

Hypothesis / aims of study

Artificial urinary sphincter is still the gold standard procedure to treat severe stress urinary incontinence. Nevertheless, revisions of the prosthesis still happen in 17% of cases in selected referring centres (1) but up to 80% in the literature (2).

When incontinence reappears (in absence of infection or erosion) mechanical failure, urethral atrophy or bladder overactivity might be the causes.

When a mechanical failure is found, all components of the prosthesis are usually changed.

Since 1998 we tried to find any leakage or malfunction of a single component of the prosthesis by refilling the system with contrast medium, in order to avoid the substitution of all components.

Study design, materials and methods

From 1998 to 2012 15 patients underwent 16 “refillings” of the artificial urinary sphincter AMS 800 to detect the cause of its mechanical malfunction. They represent 11 % of the whole number of prosthesis we implanted in the same period.

14 were male patients of whom 12 complaining of severe stress urinary incontinence after prostatic surgery and 2 after orthotopic bladder substitution. 1 was a woman with stress urinary incontinence due to urethral and pelvic bone fractures.

Before performing refilling, prosthesis infection was ruled out by symptoms and inspection and urethral erosion was excluded by urethroscopy.

The procedure was performed under local anaesthesia through an inguinal incision in order to isolate and cut the tube connections of the prosthesis. The balloon was deflated and the volume yearned measured to understand if there has been a leakage in the system. In any case, refilling of the balloon was performed with 22.5 ml of contrast medium checking any resistance to the inflow and/or measuring again the volume yearned in order to find any leakage or malfunction of the balloon. Then we checked proper functioning of the pump dipping both tubes in the contrast medium removing bubbles of air. At the end, the cuff was filled and emptied with 2.5 ml of contrast to check any leakage.

If no leakage was found and the pump was normally functioning, the system was refilled and reconnected and immediately activated.

If a leakage or malfunction was found in a single component, substitution of that component was planned.

Results

We divided the 16 refillings into 2 groups in order to better assess our results:

- 5 early refilling, which occurs soon after the implant;
- 11 late refilling, which occurs from 9 to 180 months after the implant.

The indication for performing refilling was, in the first group, persistence of incontinence in 4 patients and malfunction of the prosthesis in 1 at the time of activation; for the second group the problem was a recurrence of incontinence after a mean period of dryness of 7 years and 9 months.

In the first group, during refilling no leakage was found in any component of the prosthesis and continence was reached in all cases after simple connection of the system. Erosion of the cuff happened after 7 months in one case and malfunction of the prosthesis recurred after a virtual colonscopy one year later in another case.

In the second group, during the refilling, we found:

- malfunction of the balloon in 3 cases and of the pump in other 2. Therefore, these 5 patients underwent a substitution of a single component and afterwards 3 were all right for more than 1 year and the other 2 had still complications like erosion of the cuff after 3 months in one case and persistence of incontinence the other.
- In other 4 patients, only refilling was done and no leakage or malfunction of prosthesis components were found: two of them were all right for one year; the other two were all right only for two weeks one and 2 months the other; both underwent subsequent substitution of the whole prosthesis.
- In the last 2 patients we found a malfunction of the entire prosthesis and the patients underwent substitution of the whole prosthesis.

Interpretation of results

Refilling of an artificial urinary sphincter is the proposed procedure to check malfunction of the prosthesis. We introduced refilling to check if this procedure was enough to produce normal function of the prosthesis in some cases or to detect malfunction of a single component in others, in order to avoid the substitution of the whole prosthesis which is usually performed in these cases. Up to now, we have performed 16 procedures in 15 cases, 5 soon after the implant and 11 after a period of dryness. Refilling as the only procedure was able to produce normal prosthesis function in 7 occasions (44%) and the best results (100%) were obtained when malfunction occurred early after activation of the implant. In other 5 occasions (31%) refilling showed us malfunction of only one component and allowed us to substitute only that component, obtaining good results in 3 cases and in the other 2 only for 3 months.

Concluding message

We used refilling of the artificial urinary sphincter as a procedure to detect malfunctions of the prosthesis when infection and erosion are ruled out. In this way we were able to produce normal function of the prosthesis in 44% of cases and to substitute only one component of the AUS with good results in other 3 (19%). When refilling is performed for malfunction of the prosthesis

early after its activation, the results are even much better (100%) and avoid to submit patients to unnecessary, expensive and uncomfortable substitution of the whole prosthesis.

References

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Disclosures

Funding: NO **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** this study is retrospective: we used the technique in the past and we analysed the cases a long time later **Helsinki:** Yes **Informed Consent:** Yes