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ORIGINAL ARTICLE

# Urethral pressure controlled balloon refilling or balloon change for artificial sphincter secondary procedure?

## *Repressurisation par remplissage du ballon sous contrôle de la pression urétrale ou changement de ballon du sphincter artificiel, dans la gestion de la perte secondaire d'efficacité de la prothèse sphinctérienne AMS800®*

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**KEYWORDS**
Urinary incontinence;
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AMS800®;
Revision;
Explantation

**Summary**
*Objectives.* — To report our experience of inflating or changing pressure balloon to treat recurrent urinary incontinence after AMS800® implantation instead of changing all the devices.
*Patients and methods.* — A retrospective study was conducted in a tertiary reference center between 2005 and 2015. All patients, treated by AMS800® implantation for post-prostatectomy urinary incontinence and whom balloon was subsequently changed or inflated, were included. Main clinical end point was the need for another surgery. Secondary end points were urethral erosion, infection, and efficacy on pad test and pad use.
*Results.* — Thirty-one patients were included. All had had a 61—70 cm $H_20$ balloon implanted, with a single cuff (13 with transcorporeal placement). Twenty-one patients had their balloon changed for a 71—80 cm $H_20$ type, while 10 patients had their balloon refilled (median 3 mL [range 2—7]). Median follow-up was 23 months (range 1—129). Overall rate of another subsequent surgery was 48.3% ($n = 15$). Erosion and atrophy occurred more frequently after balloon repressurizing than after balloon replacement (80% vs 33%, $P = 0.024$). At last follow-up, median pad use was higher in repressurizing group (2 vs 1, $P = 0.033$).

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*Conclusion.* — Balloon repressurizing is associated with a higher erosion and reoperation rate than changing pressure balloon. Continence results seem better when PRB is changed. It could be an alternative instead of changing all devices in patients with frail urethra.
*Level of evidence.* — 4.


**MOTS CLÉS**
Incontinence urinaire ;
Spincter urinaire artificiel ;
AMS800® ;
Révision ;
Explantation

**Résumé**
*Introduction.* — Le but de cette étude était d'évaluer les résultats du changement ou du remplissage du ballon réservoir de pression lors d'une perte secondaire d'efficacité d'un sphincter AMS800® chez l'homme.
*Méthodes.* — Une étude rétrospective de l'ensemble des patients ayant eu un changement de ballon ou un regonflage de ballon de sphincter artificiel AMS800®, entre 2005 et 2016, dans un centre universitaire de référence a été menée. Le critère de jugement principal était le taux de ré-opération après repressurisation. Les critères secondaires étaient la survenue d'érosion urétrale, d'infection, l'efficacité du traitement évaluée par le pad-test des 24 h et le port de garnitures.
*Résultats.* — Trente et un patients ont été inclus. Tous les patients ont été implantés avec un dispositif AMS800® avec ballonnet 61—70 cm $H_20$, avec placement initial de la manchette en péri-uréthral ($n = 18$) ou intracaverneux ($n = 13$). Une simple repressurisation (regonflage de 2 à 5 mL sous contrôle de pression uréthrale rétrograde) a été effectuée dans 10 cas et un changement de ballon (71—80 cm $H_20$) dans 21 cas. La médiane de suivi était de 23 mois (1—129). Au total, 48,3 % ($n = 15$) des patients ont nécessité une reprise chirurgicale. La repressurisation du ballon était associée à un risque accru d'érosion et d'atrophie urétrale (80 % vs 33 %, $p = 0,024$). Le taux subjectif de continence était également plus faible (nombre de protections par jour, 2 vs 1, $p = 0,033$).
*Conclusion.* — Le changement du ballon de régulation de pression (71—80 cm $H_2O$ à la place de 61—70 cm $H_2O$) entraîne moins de réintervention, de morbidité et une meilleure continence que la repressurisation seule.
**Niveau de preuve.—** 4.


## Introduction

The artificial urinary sphincter (AUS) has become the ''gold standard'' in the treatment of moderate to severe male urinary incontinence (UI) after radical prostatectomy [1]. Hydraulically controlled AMS800® device (Boston Scientific, Boston, MA, USA) is one of the most frequent sphincter implanted all over the world, with excellent long-term results [2,3]. AMS800® failure is defined by persistent or recurrent incontinence after device implantation. It is caused by mechanical or non-mechanical failure that can, sometimes, overlap [4]. Several techniques have been reported to treat AMS800® failure due to urethral atrophy and mechanical or non-mechanical failure without any consensus about whether to change all the device [5] or only one component of the device such as downsizing the cuff [6,7], adding a second cuff, implanting transcorporal cuff [8] or repositioning the cuff to a more proximal or distal location [9]. However, changing the cuff implies another urethral surgery with an increased risk of urethral injury and erosion [10]. It is also possible to increase pressure around the urethra by inflating or changing the pressure regulating balloon (PRB) with a higher rating (61—70 cm $H_20$ to 71—80 cm $H_20$) without touching the cuff which could theoretically avoid urethral injury. In this study, we report the largest series in the literature that compare inflation of PRB with PRB upsizing to treat AMS800® failure.

## Materials and methods

We retrospectively reviewed all patients implanted with AMS800®, who had their 61—70 cm $H_20$ PRB changed or inflated for persistent or recurrent incontinence, in our academic center, between 2005 and 2016. Clinical factors such as incontinence cause, radiation history, prior urethral surgery, incontinence surgery, number of pad use and pad test volume, and surgical details such as cuff size, PRB pressure and placement technique were computerized and analyzed. All devices were initially placed through a perineal incision. When AMS800® failure occurred, patients were evaluated with urinary analysis, fibroscopy to eliminate urethral erosion and to objective coaptation failure of the cuff and urodynamic study to analyze RCOP. Plain X-ray

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