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Synchronous Ipsilateral High Submuscular Placement of Prosthetic Balloons and Reservoirs

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ABSTRACT

Introduction: Synchronous ipsilateral high submuscular placement of artificial urinary sphincter (AUS) pressure-regulating balloons (PRBs) and inflatable penile prosthesis (IPP) reservoirs in a single submuscular tunnel is a novel strategy that could be advantageous for patients who have had major pelvic surgery.

Aim: To report our initial experience with synchronous ipsilateral vs bilateral placement of AUS PRBs and IPP reservoirs in men undergoing implant surgery.

Methods: We retrospectively reviewed all patients undergoing synchronous AUS and IPP placement from 2007 through 2015 by a single surgeon at our tertiary center. Patients were stratified according to ipsilateral vs bilateral placement of the AUS PRB and IPP reservoir.

Main Outcome Measures: Reoperation rates because of infectious or erosive complications and mechanical failure were assessed.

Results: Of the 968 implant surgeries during the study period, 47 men had synchronous device placement, of whom 17 (36%) underwent ipsilateral placement of the PRB and reservoir. During a median follow-up of 19 months (range = 1−84 months), reoperations were necessary in 12 of 47 (26%) and were similar between groups (ipsilateral, 5 of 17, 29%; bilateral, 7 of 30, 23%; $P = .73$). Most reoperations were due to AUS-related complications (10 of 12, 83%) and nearly all patients with reoperation (10 of 12, 83%) had compromised urethras (ie, prior urethral surgery, radiation, or prior AUS implantation). The most common indication for reintervention was cuff erosion (4 of 47, 9%), with no difference between groups (ipsilateral, 3 of 17, 18%; bilateral, 1 of 30, 3%; $P = .13$).

Conclusion: Synchronous ipsilateral high submuscular placement of urologic prosthetic balloons could safely facilitate prosthetic surgery in patients with a history of major pelvic and inguinal surgery. **Kavoussi NL, Hofer MD, Viers BR, et al. Synchronous Ipsilateral High Submuscular Placement of Prosthetic Balloons and Reservoirs. J Sex Med 2017;XX:X−X.**

Key Words: Penile Prosthesis; Artificial Urinary Sphincter; High Submuscular

INTRODUCTION

After prostatectomy, erectile dysfunction and urinary incontinence commonly coexist and negatively affect quality of life.[1−3] Concomitant treatment with synchronous implantation of an artificial urinary sphincter (AUS) and an inflatable penile prosthesis (IPP) is safe and leads to good functional outcomes and high patient satisfaction.[4,5] Simultaneous implantation has been shown to be cost effective, with savings of approximately $7,000 compared with individual asynchronous implantations.[6]

Traditional techniques for dual implantation have centered on the reservoir and/or pressure-regulating balloon (PRB) being placed in the space of Retzius.[5,7−11] However, patients with a history of major pelvic or groin surgery, including colorectal and hernia procedures, often pose unique challenges for reservoir and PRB placement. For example, patients after prostatectomy have an almost fourfold increase in inguinal hernia repair.[12] Similarly, men with prior device placement can present with limited options for creating a new, or separate, submuscular tunnel. During the past 5 years, we have shifted toward placing reservoirs and PRBs in a high submuscular (HSM) location to avoid retropubic dissection, an approach that has demonstrated high patient satisfaction[13]

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without adverse effects on device function.[14] To avoid the time and risk associated with reservoir and PRB placement in a reoperative field, we developed the novel technique of synchronous ipsilateral HSM (SIHSM) placement of PRBs and reservoirs.

AIMS

The purpose of this study was to assess whether the colocation of these prosthetic devices within a single submuscular tunnel would be associated with a higher rate of mechanical failure or complications. Therefore, we compared our experience with ipsilateral vs traditional bilateral placement of the AUS PRBs and IPP reservoirs in men having synchronous implant surgery. Our hypothesis was that SIHSM placement would be safe and well tolerated compared with traditional implantation techniques.

METHODS

From 2007 through 2015, 968 AUS and IPP surgeries were performed at our institution. All surgeries were performed by a single surgeon at our tertiary center. During the first 4 years of the study period, our preference for PRB and reservoir placement was the traditional approach of the space of Retzius. Since 2011, our preferred technique has been the SIHSM approach.

Before surgery, all men underwent bladder outlet evaluation to ensure no obstruction. Those with evidence of luminal narrowing (<14 Fr) were treated endoscopically for obstruction and their prosthetic surgery was postponed until the urethral caliber (≥14 Fr) was known to be stable. On the day of surgery, standard perioperative antibiotics were administered and included cefazolin (vancomycin, if allergic) and gentamicin. Before incision, a plugged urethral catheter was placed to prevent urine spillage.

AUS cuff placement was performed through a perineal incision. Then, the legs were lowered and the IPP cylinders were placed through a separate penoscrotal incision. A submuscular tunnel was developed through the external inguinal ring for PRB and reservoir placement as previously described.[15] The AUS cuff tubing was passed from the perineum to the penoscrotal incision for connection. The IPP reservoir and PRB were placed through the penoscrotal incision into the same long HSM tunnel. The decision to place the two devices in an ipsilateral vs bilateral tunnel depended on a history of inguinal surgery or prior prosthetic device placement and the ease of HSM tunnel development. Occasionally, a counter incision was used to assist with component placement and tunnel development in patients with complex bilateral inguinal or major pelvic surgery. In all synchronous ipsilateral cases, PRBs were placed cephalad to the relatively larger IPP reservoir to prevent balloon herniation.

All patients were discharged within 24 hours of the operation after catheter removal. Patients underwent AUS device activation and penile prosthesis education 6 weeks after surgery. Subsequent follow-up visits were scheduled at 3 months and then annually or as needed based on patient request or the discretion of the surgeon. High-risk patients, defined as having a compromised urethra, included those with prior urethral surgery, radiation, or AUS implantation.[16]

Data Collection and Analysis

After institutional review board approval, we performed a retrospective review of all patients undergoing urologic prosthesis surgery by the senior author during the study period. Patients were grouped according to whether they had synchronous ipsilateral vs bilateral placement of the AUS PRB and IPP reservoir. Outcomes assessed included need for reoperation because of infection (diagnosed clinically by fever, increased white blood cell count, and/or scrotal erythema), device erosion or extrusion, mechanical failure, and AUS-related urethral atrophy.

The primary outcome was all-cause reoperation. Subgroup analyses evaluated features associated with device erosion and/or infection, mechanical failure, and AUS-related urethral atrophy. Continuous variables were assessed with the Student t-test and categorical variables were assessed with the Fisher exact test. Statistical significance was defined as a P value less than .05. All analyses were conducted in SPSS 22 (IBM Corp, Armonk, NY, USA).

RESULTS

Of the 968 implantations performed during the study period, 95 patients (10%) underwent IPP and AUS implantation. Of these patients, we identified 47 with synchronous device placement including 17 (36%) with ipsilateral placement and 30 (64%) with bilateral placement of the PRB and IPP reservoir. Patient groups proved to be similar based on age; history of coronary artery disease, diabetes mellitus, smoking, and radical prostatectomy; and usage of a 3.5-cm cuff at time of implantation (Table 1). Of patients undergoing ipsilateral placement, 10 (59%) had American Medical Systems (Minnetonka, MN, USA) and seven (41%) had Coloplast (Minneapolis, MN, USA) penile implants. Ipsilateral placement was associated with a notably higher incidence of high-risk patients including those with a compromised urethra (88% vs 33%; $P = .02$) and prior pelvic radiation (59% vs 27%; $P = .06$).

Median follow-up was 19 months (interquartile range = 5−36), during which time 12 of 47 patients (26%) required device reoperation (synchronous ipsilateral, 5 of 17, 29%; bilateral, 7 of 30, 23%; $P = .73$; Table 2). Overall, there was no difference in the 20-month all-cause reoperation-free survival between cohorts (88% vs 83%; $P = .73$; Figure 1). The most common indication for reintervention was cuff erosion (4 of 47, 9%), with no difference between synchronous ipsilateral (3 of 17, 18%) and bilateral (1 of 30, 3%; $P = .13$) groups. In the SIHSM group, there was a single mechanical failure from a PRB leak occurring in a patient with a Coloplast IPP reservoir and an AUS PRB; however, no patient developed herniation of the IPP reservoir or PRB. In the synchronous bilateral group, AUS events included urethral atrophy (n = 2), leak of the IPP reservoir (n = 1), and herniation (n = 1). In total,