Adjustable Male Sling

Our Experiences with Placement of Adjustable Male Sling, Including a Case of Exstrophy-Epispadias

Initial Report

Abbas Basiri, Hossein Kilani

Urology and Nephrology Research Center, Shahid Labbafinejad Medical Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Corresponding Author:

Abbas Basiri, MD
Urology and Nephrology Research Center, No.103, 9th Boustan St., Pasdaran Ave., Tehran, Iran

Tel: +98 21 2256 7222
Fax: +98 21 2256 7282

E-mail: Basiri@unrc.ir

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Purpose: To present our experience of using an adjustable male sling, Argus® (Promedone SA; Cordoba, Argentina), in patients with stress urinary incontinence (SUI), and report its success, extension of indications, and management of complications.

Materials and Methods: We retrospectively evaluated Argus implantation results in 17 patients, including 15 post prostatectomy incontinence, one exstrophy-epispadias, and one neurogenic bladder patient. Of 17 patients, 12 had severe (more than 5 pads daily) and 5 had moderate SUI (2 to 5 pads daily). Seven patients had history of previous surgeries. Patients were evaluated pre-operatively with urodynamic study and cystoscopy.

Results: After median follow-up of 11.8 months (range, 3 to 22 months), 9 patients were continent, 7 had mild SUI (1 pad daily), and one had the device removed due to perineal and bladder symptoms. Argus adjustment was done in 10 out of 17 patients; 8 tightening and 2 loosening. In a totally incontinent exstrophy-epispadias patient with a history of multiple bladder surgeries, continence was achieved after device readjustment. In a patient with neurogenic bladder with a history of cystoplasty, severe SUI changed into a moderate sporadic SUI. In 2 patients, prosthesis infection occurred, which was managed with antibiotics without the need for Argus explantation.

Conclusion: Argus is a simple and good device to control incontinence in men. It may also be used in exstrophy-epispadias patient who is not a candidate for urinary sphincter implantation. Infection complication may be managed conservatively. To the best of our knowledge, this is the first report of successful Argus implantation in exstrophy-epispadias patient.

Keywords: urinary stress incontinence, suburethral slings, treatment outcome

INTRODUCTION

Male stress urinary incontinence (SUI) is mostly due to iatrogenic causes, particularly prostate surgeries.[1,2] Artificial urinary sphincter implantation has long been accepted as the gold standard for the treatment of male patients suffering from stress incontinence.[3,4] In recent years, several adjustable and non-adjustable devices have been introduced to treat male incontinence, from which Argus®, (Promedon SA; Cordoba, Argentina), as an adjustable device, has been used in several centers, and its efficacy and complication rates have been evaluated.[5,6]

Besides reporting our experience for applications and complications of Argus device, we also provide further indications and the possibility of medical treatment of prosthesis infection.

MATERIALS AND METHODS

We retrospectively assessed data of 17 patients who had undergone Argus implantation surgery from January 2010 to January 2012 in Labbafinejad Medical Center in Tehran, Iran. These patients were suffering from SUI after retropubic radical prostatectomy, adenomectomy, transurethral resection of the prostate, neurogenic bladder secondary to myelomeningocele, or exstrophy-epispadias.

Pre-operative evaluations included history taking, physical examination, urodynamic study, and urethrocystoscopy. Thereafter, those patients affected by SUI due to sphincteric incompetence were candidate for Argus implantation.

Argus device is actually a synthetic silicone sling for males comprising a silicone pad, which is placed over the bulbar urethra. There are two silicone columns on both sides of the pad, which traverse either sides of the bulbar urethra over the bulbospongiosus muscle and exit the rectus fascia in the abdomen, and are adjustable via washers lying over the columns (Figure 1).

By changing the washer positions over the columns, the pressure is exerted by the silicone pad over the urethra, which is indirectly measured via reverse leak point pressure (RLPP). Reverse leak point pressure is measured by the height of normal saline column, in which the retrograde flow of normal saline through the urethra is begun.

Of 17 patients, in 10 subjects with mean pre-operative RLPP of 31.75 cmH_2O, Argus was adjusted for a postoperative RLPP of 40 cmH_2O, regardless of pre-operative RLPP. In other 3 and 2 patients, post-operative RLPP of 50 cmH_2O and 35 cmH_2O were reached, respectively. In these latter 5 patients, postoperative RLPP differed from other 10 patients, mainly because RLPP changed disproportionately during Argus implantation with regard to the amount of tightening, ie, very slow or very rapid rise in RLPP with Argus tightening. In 2 patients with non-post prostatectomy incontinence, RLPP was adjusted at 58 cmH_2O and 20 cmH_2O in myelomeningocele and exstrophy-epispadias patients, respectively.

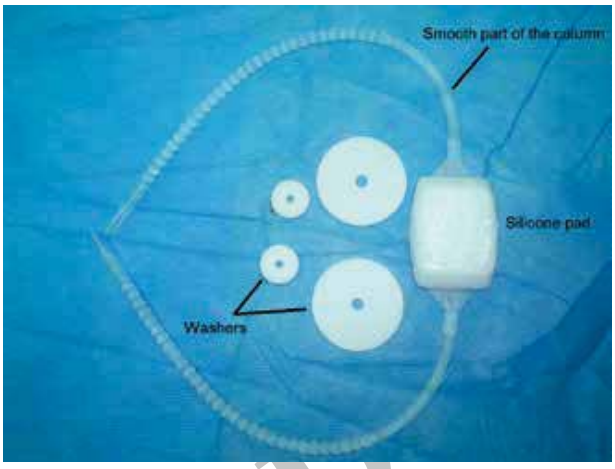

Figure 1. Argus device containing silicon pad, silicone columns, and washers.

Foley catheter was removed 48 hours postoperatively. Post-op follow-up included assessment of incontinence severity symptoms, irritative symptoms, and complications, such as prosthesis infection, perineal pain, and device erosion.

RESULTS

Mean age of the patients was 64 years (range, 17 to 80 years). Incontinence etiologies are demonstrated in Table 1. Of 17 patients, 12 were suffering from severe (using >5 pads daily) and 5 from moderate (using 2 to 5 pads daily) SUI. Fifteen patients were incontinent due to prostatectomy and 2 due to non-prostatectomy surgeries (one patient had neurogenic bladder and the other one had exstrophy-epispadias). The urodynamic study findings of 16 patients are shown in Tables 2 and 3. Urodynamic study could not be implemented in one

Table 1. Incontinence etiologies.

Etiology	Number
Radical prostatectomy	6
Adenomectomy	5
Transurethral resection of the prostate	4
Neurogenic bladder	1
Exstrophy-epispadiasis	1
Total	17

Table 2. Urodynamic findings of post prostatectomy incontinent patients.

Parameter	n
Filling phase	
Capacity	
Low	1
Normal	13
Compliance	
Low	1
Normal	13
Voiding phase	
Contractility	
Hypocontractile	3
Stable normocontractile	11

patient due to urethral pathology.

Follow-up duration was 11.8 months (range, 3 to 22 months). During follow-up period, Argus readjustment was done in 10 patients, including 8 tightening and 2 loosening procedures. Both loosening procedures were done in patients with post-operative RLPP of 50 cmH_2O.

Of 15 post prostatectomy incontinent patients, after Argus implantation, 8 were dry (including one patient requiring clean intermittent catheterization), 6 had mild urinary incontinence (at most 1 pad daily), and one had the device removed because of irritative urinary symptoms and perineal pain.

In a subgroup of post prostatectomy incontinent patients who had total urinary incontinence pre-operatively (10 patients), after Argus implantation, 6 became dry (including one patient requiring clean intermittent catheterization) and 4 had mild urinary incontinence.

Of 2 patients with non-post prostatectomy incontinence, one patient was a known case of repaired myelomeningocele with a history of ileocystoplasty and fascial sling, who was totally incontinent before Argus implantation. Although this patient underwent a tightening procedure during follow-up, he had still moderate urinary incontinence (2 to 5 pads daily). However, the severity of incontinence improved and he experienced subjective increased quality of life.

The other patient had exstrophy-epispadias, who had already undergone ileocystoplasty, bladder neck reconstruction, and fascial sling. This patient had continuous incontinence before Argus placement, but regained complete daily urinary continence with nocturnal incontinence. Seven months after the surgery, he underwent Argus readjustment due to reappearance of incontinence. At the second procedure, the device was completely loose, and tightening was impossible due to placement of washers on the smooth portion of silicone column. Therefore, we crossed the columns and used hem-o-lok at the point of the crossing to keep the columns crossed (Figure 2). This patient is currently completely dry using clean intermittent catheterization three months after the procedure.

Except the exstrophy-epispadias patient whose RLPP could not be raised by Argus tightening, in other 9 patients who underwent Argus readjustment, RLPP was measured before and after Argus adjustment. Of 7 patients who needed Argus tightening, in 6, RLPP had decreased from 44 cmH_2O to 38.5 cmH_2O postoperatively. In one patient, RLPP had actually increased from 35 cmH_2O to 42 cmH_2O in spite of reappearance of incontinence symptoms.

In 2 patients who underwent Argus loosening due to obstructive urinary symptoms, mean RLPP had increased from 45 cmH_2O to 59 cmH_2O, and in both patients RLPP had increased since the implantation. In exstrophy-epispadias patient, RLPP could not be raised, no matter how much Argus was tightened intra-operatively. We think it was due to anterior position of the urethra in this patient, which prevented the silicone pad from exerting enough pressure on the urethra to raise RLPP.

Of a total of 17 patients, 2 had suprapubic wound infection without erosion. One of them was the patient with neurogenic bladder with a history of augmentation ileocystoplasty. Both patients were admitted to the hospital and received appropriate intravenous antibiotic. Debridement was necessary in one

Table 3. Urodynamic findings of non-post prostatectomy incontinent patients.

Parameter	n
Filling phase	
Capacity	
Low	0
Normal	2
Compliance	
Low	0
Normal	2
Voiding phase	
Contractility	
Hypocontractile	0
Stable normocontractile	2

patient. After complete response to antibiotic and infection eradication, both patients were discharged from the hospital without the need for device explanation, and were followed up accordingly.

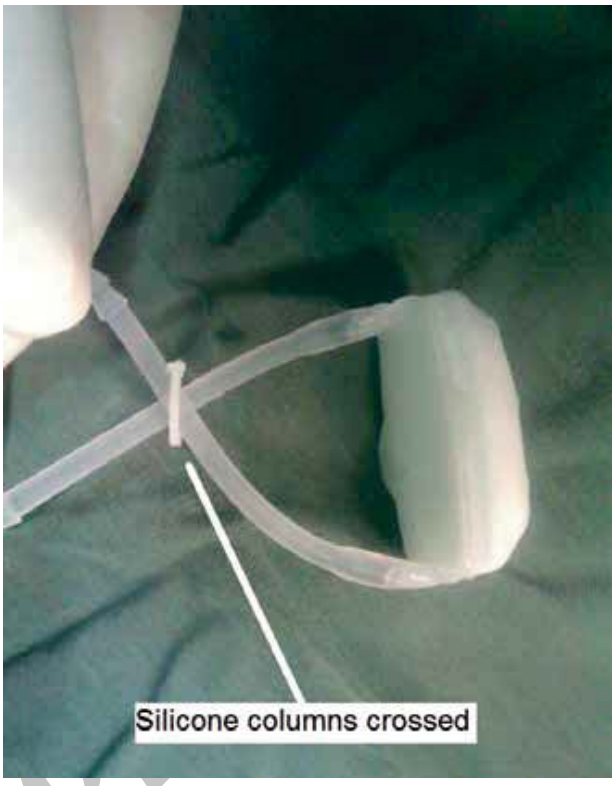

Figure 2. Silicone columns crossed using hem-o-lok.

DISCUSSION

At the moment, the artificial urinary sphincter is the standard procedure for male SUI with high success (70% to 90%) and patient satisfaction (90%) rates.[7] But high costs, complicated surgical procedure, and the need for patient manipulation for an acceptable void have prompted manufacturers to search for and evaluate newer devices. These newer devices are either adjustable or non-adjustable. Adjustable devices have the advantage of making surgeon able to change the pressure exerted on the urethra.

In most of the studies on Argus device, the improvement rate has been 79% to 83% (needing 0 to 1 pad daily),[6,8] except in one study, in which the improvement rate was 28% with complication rate of 35% leading to device explantation.[9] In our study, improvement rate in patients with post prostatectomy incontinent was 94% with 53% of patients being dry postoperatively, in comparison with the rates of 66% to 73% reported in other studies. Lower percentage of dry patients in our study might reflect high percentage of pre-operative severe SUI (80%) in comparison with other studies (about 40% in a couple of studies).[9,10]

Argus implantation success relies on finding an appropriate RLPP, in which patient voids completely. In the present study, we measured RLPP before and after every primary implantation and subsequent readjustment. Evaluation of these data showed that in patients with the same severity of incontinence, RLPP might differ considerably (17 to 54 cmH_2O). Therefore, the final postoperative RLPP should be individualized.

Reverse leak point pressure measurement before and after each session of readjustment showed that RLPP might increase or decrease in time. This change in RLPP might be the result of interaction between patient's pelvic and perineal tissues with the foreign body (Argus device) placed over the bulbar urethra. Assessment of the impact of the pelvic and perineal anatomy, obesity, body mass index, and other issues on RLPP requires further studies.

Studies on Argus device have shown its efficacy on post prostatectomy incontinence. Stress urinary incontinence in men might be due to other causes, such as neurogenic blad-

der and some congenital anomalies affecting the bladder and bladder neck, eg, exstrophy-epispadias. The efficacy of bulbourethral sling procedure on incontinent patients suffering from neurogenic bladder has been evaluated.[11,12] It has been shown that success rates in these patients are lower than that of patients with post prostatectomy incontinence. In our study, the patient with neurogenic bladder had moderate SUI (requiring 2 to 3 pads daily). In spite of improvement in his quality of life, this patient still relies on pads.

To the best of our knowledge, for the first time in this study, Argus was implanted in an incontinent exstrophy-epispadias patient even with a history of augmentation ileocystoplasty, bladder neck reconstruction, and fascial sling, which were successfully performed. In this patient, total continence was achieved after Argus readjustment in the second procedure.

Wound and prosthesis infection occurred in 2 patients in our study. Eradication of wound infection without the need for device explantation might suggest the possibility of retaining the device in this complication.

Short duration of follow-up can be mentioned as a drawback of this study; however, the patients enrolled in this study will be followed up. Another shortcoming might be the lack of standard evaluation of quality of life with proper questionnaires.

CONCLUSION

Using adjustable sling in men results in acceptable continence rates in spite of the need for readjustments. Our study also suggests that it is possible to retain the device while treating the infection with intravenous antibiotic and wound debridement.

CONFLICT OF INTEREST

None declared.

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