

Artificial Urinary Sphincter in Women with Stress Urinary Incontinence - A mini Systematic Review

Fawzy Farag*

Department of Urology, Sohag University Hospital, Sohag, Egypt.

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Abstract:

Background

Artificial urinary sphincter (AUS) has been applied in treatment of women with stress urinary incontinence (SUI) associated with intrinsic urinary sphincter insufficiency. The current study scrutinizes the surgical outcomes of this approach in published trials.

Methods

Pubmed database was searched for publications on the use of AUS in treatment of women with SUI using the terms stress urinary incontinence and artificial urinary sphincter, Artificial. Exclusion criteria were review articles, animal studies, studies on men, articles written in a language other than English, unavailable full text, or letters to the editor. The overall demographic and surgical outcomes data were computed over the studies included in the final analysis.

Results

A total of 201 articles were found and only 11 articles (924 women) were included in the final analysis, the Level of Evidence was 2b. The overall median age of patients included in these studies was 59 years (range 51 - 69). The overall median follow-up period was 59.5 months (range 12 - 204). The overall median postoperative continence rate (no pads) was 63% (range 8 - 92). The overall median rate of erosion/infection of the AUS was 5.5% (range 0 - 20). The overall rate of revision of the implanted AUS was 8.5% (0 - 42). And the overall median rate of explantation of the AUS was 5% (range 0 - 30).

Conclusions

Studies applied the use of AUS in treatment of women with SUI are of low quality and showed variable rate of continence. RCT designed studies are required to address the actual outcomes of AUS in comparison to other surgical approach in treatment of SUI in this patient group.

Keywords: *Artificial urinary sphincter, stress urinary incontinence*

1 Introduction:

Stress urinary incontinence (SUI) defined as involuntary urinary leakage on efforts or exertion, or on coughing or sneezing (1). The current available treatment approaches for SUI are physiotherapy and pelvic floor muscle training, transvaginal urethral tapes, transobturator urethral tapes, urethral bulking

agents, and compressive devices including artificial urinary sphincter and para-urethral balloon devices. Artificial urinary sphincter (AUS) was first described by Foley in 1947, but the first introduction to clinical application was in 1972 by Scott (2). The current indication for implantation of AUS in women is intrinsic sphincteric insufficiency with fixed urethra, or

with persistent hyper-mobility after failed previous urethral incontinence surgery (2, 3). The current work aims to review the studies which describe the application of AUS in treatment of women with SUI.

2 Methods:

Pubmed database was searched in Spetmeber 2017 for publications on the use of AUS in treatment of women with SUI, the following search terms were used: ("Urinary Incontinence, Stress"[Mesh]) AND "Urinary Sphincter, Artificial"[Mesh]. Exclusion criteria were review articles, animal studies, studies on men, articles written in a language other than English, unavailable full text, or letters to the editor. Demographic and surgical outcomes data retrieved from the studies in final analysis were pooled and computed.

3 Results:

A total of 201 articles were found, 11 articles were included in the final analysis after adding 2 articles by hand search. None of the included studies was a randomized controlled study (RCT), the Level of Evidence (LE) of the included studies was 2b. The demographics and surgical outcomes per individual study are shown in table 1.

A total of 924 women underwent implantation of AUS for treatment of SUI in 11 studies included in the final analysis. The indications for AUS implantation in these patients were non-neurogenic SUI, or intrinsic sphincter deficiency related to neurological disorders including SCI and spina bifida. The overall median age of patients included in these studies was 59 years (range 51 - 69). The overall median follow-up period was 59.5 months (range 12 - 204). The overall median postoperative continence rate (no pads) was 63% (range 8 – 92). The overall median rate of erosion/infection of the AUS was 5.5% (range 0 – 20). The overall rate of revision of the implanted AUS was 8.5% (0 – 42). And the overall median rate of explanation of the AUS was 5% (range 0 – 30).

4 Comment:

The diagnosis of intrinsic sphincter insufficiency implied history taking and clinical and pelvic examination, urethrocystoscopy, and maximum urethral closure pressure < 30 cm H₂O (10, 12). Most of the studies included in our analysis followed classic open surgical approach on implanting the AUS in women with SUI. However, two studies described laparoscopic approach (7, 8). The authors reported laparoscopic approach to be feasible, and safe. Two other studies applied robotic

Table (1) Demographics and surgical outcomes of studies included in final analysis.

| Author | LE | N | Mean Age (y) | Followup (months) | Continence Rate (no pads) % | Continence Rate (≥1 pads) % | Erosion/ Infection % | Revision % |
|----------------|----|-----|--------------|-------------------|-----------------------------|-----------------------------|----------------------|------------|
| oster 1992 (4) | 2b | 25 | 61 | 29 | 92 | 8 | 0 | 17 |
| losta 1992 (5) | 2b | 179 | 59* & 35* | 47 | 8* & 9** | 88* & 82** | 5.9 | |
| ung 2010 (6) | 2b | 47 | 51 | 100 | 59 | NR | 17 | 42 |
| Iron 2010 (7) | 2b | 25 | 67 | 26 | 16 | 84 | 8 | NR |
| ipret 2010 (8) | 2b | 12 | 56 | 12 | 84 | 8 | 0 | 0 |
| yleux 2011 (2) | 2b | 215 | 62.8 | 72 | 65 | 9 | 0.5 | 15.3 |
| losta 2013 (9) | 2b | 344 | 57 | 114 | 8.8 | 85.6 | 13 | 13.6 |
| nier 2014 (10) | 2b | 6 | 65 | 14 | 83 | 17 | 0 | 0 |
| he0 2014 (11) | 2b | 34 | 56 | 204 | 61 | 15 | 20 | 35 |
| eau 2015 (12) | 2b | 11 | 66 | 17.6 | 87.5 | 12.5 | 3 | 0 |
| Phe 2017 (13) | 2b | 26 | 49.2 | 90 | 57.7 | NR | 19.2 | 34.6 |

assisted approach in implanting the AUS in their patients, the authors also found this approach feasible and safe but more data are required to validate their findings (10, 12).

It was difficult on most of the cases to separate surgical outcomes of AUS treatments in neurogenic from non-neurogenic patients which adds to the heterogeneity of data in the current analysis. Studies included in our final analysis were heterogeneous in their patient inclusion criteria, aetiology of SUI, and methods. No study followed a RCT approach, with maximum LE 2b, and therefore, the overall quality of data pooled in the current work is low.

Our pooled analysis of surgical outcomes retrieved from data of 924 women underwent implantation of AUS for treatment of SUI in 11 studies revealed an overall median postoperative continence rate (no pads) of 63% (range 8% – 92%), erosion/infection rate of 5.5% (range 0% – 20%), and overall rate of revision of the implanted AUS was 8.5% (0% – 42%). A systematic review of long-term outcomes after AUS implantation in men with non-neurogenic SUI was conducted by van der Aa and colleagues 2012. The authors identified 12 articles that included data on 623 men, 9 of these studies were retrospective. Continence rate defined as no pads were reported in 4% to 86%, infection/erosion were reported in 8.5% of cases (3.3-27.8%), Revision rate was 26% (14.8-44.8%). The authors concluded that the quality of evidence supporting the use of AUS in non-neurogenic men with SUI is low due to low quality studies included in their analysis (14). We agree with them that we should re-evaluate the surgical outcomes of AUS in comparison to other available surgical AUS has been successfully applied in treatment of women with SUI and intrinsic sphincter insufficiency. Open, laparoscopic, and robotic assisted approaches have been described. The overall rate of postoperative continence was variable between studies which also were heterogeneous and generally of low quality. RCT designed studies are required to address the actual outcomes of AUS in comparison to

other surgical approach in treatment of SUI in this patient group.

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