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Lucas Freton, Lauranne Tondut, Isabelle Enderle, Juliette Hascoet, Andrea Manunta, Benoit Peyronnet

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Lucas FRETON [1]; Lauranne TONDUT [1]; Isabelle ENDERLE [1]; Juliette HASCOET [1, 2]; Andrea MANUNTA [1]; Benoit PEYRONNET [1,2]

1: Service d'Urologie, CHU Rennes, 35000 Rennes, FRANCE

2: Equipe thématique INPHY CIC 1414 et INSERM UMR 991, Université Rennes 1, 35000 Rennes, France

Corresponding Author:

Lucas Freton

Service d'urologie

Hopital Pontchaillou

2 rue Henri Le Guilloux

35000 Rennes, France

mail: lucas.freton@gmail.com

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L. FRETON: Data collection, Manuscript writing

L. TONDUT: Data collection

I. ENDERLE: Data collection

J. HASCOET: Project development

A. MANUNTA: Project development

B. PEYRONNET: Project development, Manuscript editing

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Abstract

Objective: To compare the outcomes of the ACT® device to the ones of the artificial urinary sphincter (AUS) AMS 800 in the treatment of stress urinary incontinence due to sphincter deficiency in women

Methods: All the women who underwent a surgical treatment for stress urinary incontinence due to intrinsic sphincter deficiency from 2007 to 2017 were included in a single-center retrospective study. The primary endpoint was the functional outcome. Perioperative functional parameters were compared between the two groups.

Results:

25 patients underwent an ACT® implantation and 36 an AUS implantation. Patients in the AUS group were younger (62.9 vs. 70.4 years; p=0.03) with less comorbidity (ASA Score=3 in 12.1% vs. 33.3%; p=0.005). Operative time and hospital stay were shorter in the ACT® group (respectively 45.7 vs. 206.1 min; p<0.001; 1.7 vs. 7 days; p<0.001). There was a higher rate of intraoperative complications in the AUS group (47% vs. 8%; p<0.001) but the rates of post-operative complications were similar between both groups. The ACT® was associated with an increased risk of urinary retention (20% vs. 2.8%; p=0.04). Results were in favor of AUS for: decrease in USP stress incontinence subscore (-7.6 vs. -3.2; p<0.001), number of pads per 24h (- 4.6 vs. -2.3; p=0.002), PGII scale (PGII=1: 61.1% vs. 12%; p<0.001) and cure rate (71.4% vs. 21.7%; p<0.001).

Conclusion: In the present series, keeping in mind significantly different baseline characteristics, AUS implantation was associated with better functional outcomes than the ACT® in female patients with stress urinary incontinence due to intrinsic sphincter deficiency but with higher intraoperative complications rate, longer operative time and length of stay.

Keywords (MeSH): artificial urinary sphincter; urinary incontinence; sphincter deficiency; surgery

Brief summary: Artificial Urinary Sphincter and periurethral balloons are two options for female patients with intrinsic sphincter deficiency according to their health status.

Introduction

Stress urinary incontinence due to intrinsic sphincter deficiency is usually defined as the combination of a low urethral closure pressure, loss of urethral mobility, and a negative Marshall/Bonney test (urine leakage on straining or coughing not corrected by urethral support) [1; 2]. In daily practice, this condition is usually seen in two different populations: female patients who failed previous anti-incontinence surgical procedures (recurrent or persistent urinary incontinence after midurethral sling, Burch colposuspension,….) [3] or patients with neurogenic stress urinary incontinence (usually due to spinal cord injury or spina bifida) [4]. The management of these women remains highly controversial, fascial slings and bulking agents being the most commonly used treatment option in North America [5], while in several European countries, notably in France, external compression device, such as the Adjustable Continence Therapy (ACT®, Uromedia Inc., MN, USA) or the artificial urinary sphincter (AUS) AMS 800 (American Medical Systems, Minnetonka, MN, USA), are usually favoured. While several series have assessed the outcomes of various surgical treatment of intrinsic sphincter deficiency [1], studies comparing two treatment options are lacking. The aim of this study was to compare the outcomes of the ACT® device to the one of the artificial urinary sphincter AMS 800 in the treatment of stress urinary incontinence due to intrinsic sphincter deficiency in women.

Methods

Study design

All the 61 women who underwent a surgical treatment for stress urinary incontinence due to intrinsic sphincter deficiency from 2007 to 2017 were included in a single-center retrospective study. Intrinsic sphincter deficiency was defined as the combination of a low urethral closure pressure (<40 cm H2O), loss of urethral mobility, and a negative Marshall/Bonney test (urine leakage on straining or coughing not corrected by urethral support). The artificial urinary sphincter AMS 800 was considered as the standard treatment in these patients during the study period. The ACT® periurethral balloons became available in our center in 2011 and was used only in the following cases: moderate incontinence (subjectively defined as pad test < 200 g/24h), patients aged over 80 years and/or morbidly obese and/or lacking manual dexterity limiting the abilty to operate the sphincter pump,….) and/or with history of previous pelvic radiation therapy and/or patients who refused the implantation of an artificial urinary sphincter. From 2007 to 2011, all patients were offered AUS with no alternatives and from 2011 to 2017 patients with the aforementioned comorbidites and those with moderate incontinence were offered peri-urethral balloons and the other patients were offered an AUS (but some refused and preferred to receive peri-urethral balloons). In accordance with national guidelines [1], no other surgical treatment (e.g. fascial sling, bulking agents,…) was used to treat intrinsic sphincter deficiency during the study period. Hence, the inclusion criterion was: all female patients who underwent a surgical treatment for stress urinary incontinence due to intrinsic sphincter deficiency from 2007 to 2017.

The study was approved by the local ethics committee and was conducted following the principles of the Helsinki declaration. Consent from all study participants was obtained. The study was not supported by the industry. The primary endpoint was the functional outcome categorized as: cured (complete continence, i.e. no pads used), improved (decrease in number of pads per day or in urine leakage assessed through pad test) or failure (no decrease in number of pads per day or urine leakage assessed through pad test).

Adjustable Continence Therapy: device and surgical technique

All patients had a negative preoperative urine culture and received 2 g of Cephalosporin group 2 at the beginning of the procedure as antibiotic prophylaxis. Patients with a positive preoperative urine culture ($\geq 10^3$ CFU/mL) received antibiotic treatment according to the sensitivity of the bacteria isolated from their urine culture for a minimum period of two days before the implantation.

The ACT® kit contains two silicone elastomer balloons connected to a titanium port, a seringe and a ponction needle used to inflate the device through the titanium port. Balloons are available in 4 lengths from 6 to 9 cm, which will be determined using the trocar. This last tool is a part of dedicated tools with tipped stylet and a blunt-tipped stylet,.

The surgical procedure was performed as previously described by others [1, 6-8]. The balloons were placed at each side of the bladder neck using the trocar, which

was inserted using an incision in each labia majora, and the devices were pushed laterally to urethra to their correct position on each side of the bladder neck, slightly posterior (at 5 o'clock and 7 o'clock) which was controlled by fluoroscopy and flexible cystoscopy. The balloons were filled with 0.6 ml of an aqueous radiopaque solution through the titanium port, which was placed subcutaneously in the labia majora. The trocar was removed after inflation of the device, in order to avoid moving the device during the removal.

A urethral catheter was introduced for up to 12 hours and removed before the patient was discharged. The procedure was performed as outpatient surgery when deemed possible.

ACT implantations were performed by two surgeons with no previous experience of this surgery before the study period. Inflations of 0.6 ml were performed once a month from 1 month post-operatively in outpatient clinics without any anesthesia by injecting into the titanium ports, until a satisfactory improvement was observed and up to a maximum of 7 ml per balloon.

Artificial Urinary Sphincter: device and surgical technique

The antibiotic policy used was similar to the one of ACT implantations (see above). The device used was the AMS 800 in all cases. The surgical techniques used were those previously described and followed the same principles regardless of the approach [9]. Briefly, the Retzius space was dissected until the bladder neck and the endopelvic fascia was opened on both sides of the urethra. The bladder neck was then dissected from the vagina below the periurethral fascia just below the level of

the catheter balloon. The surgeon introduced two fingers of his left hand into the vagina to help the dissection. At the end of the dissection the bladder was filled with saline stained with methylene blue to verify the integrity of the bladder neck. The bladder neck circumference was measured using a measuring tape. The cuff was then positioned around the bladder neck. The pump was implanted in one of the labia majora and the balloon in the prevesical space. An open approach was used from 2007 to 2012 with a few laparoscopic cases over this period. From 2012 to 2017, all implantations were performed through a robot-assisted approach. A single surgeon (AM) highly experienced in functional urology performed all open and laparoscopic cases. He was then involved as the assistant surgeon on the surgical field for the robotic implantations while two consecutive surgeons were performing the dissection at the console: a first surgeon highly-experienced in robotic surgery (SV; > 600 robot-assisted radical prostatectomy at the beginning of the present study) performed the first ten cases and a second surgeon, (BP, a young fellow who had performed only 20 robotic procedures before his first robotic AUS implantation) performed the subsequent cases.

The AUS were deactivated at the time of implantation and the urethral catheter was removed 2 days after surgery, bladder ultrasound was carried out to confirm adequate bladder voiding after catheter removal. Patients returned 6 weeks later for activating and learning to use the sphincter.

Pre and post-operative assessments

All patients underwent a complete work-up before surgery including: urodynamics, urethrocystoscopy, 3 days bladder diary, and pad test. The preoperative assessment also comprised a clinical interview, an urogynaecological examination and the Urinary Symptoms Profile (USP) [10] and the Internation Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) questionnaires [11] (from 2011 to 2017). Neurogenic stress urinary incontinence was defined as stress urinary incontinence in a patients with spinal cord injury or spina bifida.

Follow-up involved an outpatient visit at 3 months, 6 months and 1 year post-operatively and then annually with a clinical examination, a 3 days bladder diary and an uroflowmetry with ultrasound measurement of post-void residual urine volume. An urodynamic testing was performed 3 months after AUS implantation to measure post-operative urethral closure pressure but was not performed routinely after ACT® implantation (only in case of persistent urinary incontinence after inflation of up to 5 ml per balloon).

Postoperative complications were graded using the Clavien-Dindo classification [12] and were reported according to the EAU guidelines [13]. Failure was defined as explantation of the AUS device and divided into two categories: mechanical failure (perforation of any parts of the AUS or pump malfunction) and nonmechanical failure (cuff erosion, infection, pain, insufficient pressure). Hence, failure and continence status were analyzed separately and failure defined only the impossibility of maintaining the device in situ. Acute urinary retention was defined as a post-void residual volume > 150 ml postoperatively spontaneously resolving within the first 3 months after surgery. Chronic urinary retention was defined as the persistence of a post-void residual volume > 150 ml greater than three months after the implantation.

All urinary retentions were managed by clean-intermittent self-catheterizations (4 to 6 per day).

Statistical analysis

Perioperative and functional parameters were compared between the two groups. Means and standard deviations were reported for continuous variables, and proportions for nominal variables. Comparisons between groups were performed using the χ^2 test or Fisher's exact test for discrete variables, and Mann-Whitney test for continuous variables. Change of continuous variables over time was assessed using the McNemar test. Time to failure were estimated using the Kaplan-Meier method and compared between both groups using the log-rank test. Statistical analyses were performed using JMP v.12.0 software (SAS Institute Inc., Cary, NC, USA). All tests were two-sided with a level of p <0.05 considered statistically significant.

Results

Patients' characteristics

Over the study period, 61 patients were screened and all met the inclusion criterion: 25 underwent an ACT® implantation and 36 an AUS implantation. The study flow-chart is shown in figure 1. The patients' characteristics are summarized in table 1. Patients in the AUS group were younger (62.9 vs. 70.4 years; p=0.03) with less comorbidity (ASA Score=3 in 12.1% vs. 33.3%; p=0.005) and none had a history of previous pelvic radiation therapy conversely to those in the ACT® group (0% vs. 20%; p=0.009). More patients undergoing an AUS implantation had failed previous midurethral sling (66.7% vs. 40%; p=0.04) but the rate of neurogenic stress urinary incontinence was comparable between both groups (13.9% vs. 4%; p= 0.39) and the maximum urethral closure pressure did not differ significantly between the AUS and ACT® groups (27.3 vs. 28.8 cmH2O; p=0.61). The proportion of patients who had undergone a second midurethral sling was also similar in both groups (27.8% vs. 13.6%; p=0.21). The reasons for ACT® implantations were as follows: moderate incontinence in five patients (20%), comorbidites in 10 patients (40%) and 10 patients were offered an AUS but refused and then underwent implantation of ACT® (40%). Eight and five patients in the ACT and AUS group respectively had not undergone any anti-incontinence surgical procedure (32% vs. 13.9%; p=0.12).

Perioperative outcomes

Operative time was shorter in the ACT® group (45.7 vs. 206.1 min; p<0.001) and so was the length of hospital stay (1.7 vs. 7 days; p<0.001). There was a higher rate of

intraoperative complications in the AUS group (47% vs. 8%; p<0.001). The two intraoperative complications in the ACT® group were 1 bladder neck injury and 1 vaginal injury. The 17 intraoperative complications in the AUS group were 10 bladder neck injuries and 7 vaginal injuries. The rates of post-operative complications (40% vs. 47.2%; p=0.57) and of major post-operative complications (8% vs. 19.4%; p=0.28) did not differ significantly between both groups. There were two Clavien 3a complications in the ACT® group which were early vaginal erosions associated with a device infection which required explantation under local anesthesia in both cases. In the AUS group, seven clavien 3b complications occurred; 5 device infections and two large erosions which required all an explantation of the AUS under general anesthesia. The last major complication in the AUS group was a device infection, which occurred after a change of a first sphincter that got infected and treated conservatively. It was almost always associated with a bladder neck injury during the procedure. No Clavien 4 or 5 complications occurred in both groups. After a mean follow-up of 44.3 months in the AUS group (vs 22.3 months in the ACT® group; p=0.02) the explantation rate were similar in both groups (19.4% vs. 20%; p=0.99). All five explantations in the ACT® group were due to non-mechanical failure: It was due to device infection two cases, to symptoms worsening in two cases and in one case, ACT® were explanted before implantation of an AUS. Explantations in the AUS group were due to non-mechanical failure: Five were due to device infections; one to large vaginal erosion and one was explanted because of a bladder neck erosion. When a mechanical failure occurred, we managed the situation with a surgical revision and it has always been done successfully. Time-to-failure is shown in figure 2 (12-months cumulative failure rate: 14% in the AUS group vs 22% in the ACT® group; p=0.42).

Functional outcomes

The mean number of inflations in the ACT® group was 2.9 per balloon and the mean final volume of each balloon was 3.4 ml. In the AUS group a 61-70 cm H2O pressure balloon was used in all except one case (71-80 cm H2O) and the median cuff size was 70 mm. The decrease in USP stress incontinence subscore was significantly greater in the AUS group (-7.6 vs. -3.2; p<0.001; supplementary figure 1) and so was the decrease in mean number of pads per 24h (- 4.6 vs. -2.3; p=0.002; see table 3). The Patient-Global Impression of Improvement (PGII) [14] was better in the AUS group (PGII=1: 61.1% vs. 12%; p<0.001) as was the rate of patients cured (71.4% vs. 21.7%; p<0.001). Five patients in the ACT® group required the use of clean-intermittent self-catheterization postoperatively, at least for some time, compared to only one in the AUS group (20% vs. 2.8%; p=0.04). Two of the five patients who experienced urinary retention in the ACT® group complained from this condition so their balloons were partly deflated and they recovered spontaneous voiding in both case.

Subgroup of persistent/recurrent stress urinary incontinence after midurethral slings

In this subgroup, no patients in the ACT® group had undergone previous pelvic radiation therapy. Mean age was similar in both groups (71.7 vs. 66.4; p=0.23; see table 4) and the maximum urethral closure pressure of patients who underwent an AUS or an ACT® implantations were comparable (24.9 vs. 26.4 cm H2O; p=0.64). The proportion of patients who had undergone a second midurethral sling did not

differ significantly between both groups (37.5% vs. 10%; p=0.21). The rate of intra-operative complications remained higher in the AUS group (54.2% vs. 10%; p=0.02). The rate of post-operative complications tended to be higher in the AUS group (54.2% vs. 20%; p=0.13). The explantation rate did not differ significantly between the two groups (30% vs. 25%; p=0.99). AUS outperformed ACT® in terms of functional outcomes with a higher cure rate (66.7% vs. 30%; p=0.04) and a greater decrease in USP stress incontinence subscore (-8 vs. -5.3; p=0.003).

Discussion

According to the International Consultation on Urological Diseases (ICUD), stress urinary incontinence would affect from 5 to 15% and up to 30% in women over 70-year old [15].. Two decades ago, the works of Ulmsten and DeLancey has changed the understanding of stress urinary incontinence by outlining the distinct role of urethral support and function of urethral muscles [16; 17]. This gave birth to the concept of intrinsic sphincter deficiency meaning an impaired sphincter functioning due to loss of elasticity and coaptation [18]. While most of stress urinary incontinence in female patients is mainly due to urethral hypermobility, the exact proportion of these women who suffer from some degree of intrinsic sphincter deficiency remain unknown [1]. The optimal management of women with stress urinary incontinence due to intrinsic sphincter deficiency is still a matter of debate. While the American Urological Association (AUA) 2017 guidelines [19] do not mention the role of AUS or ACT® in their treatment algorithm; the European Association of Urology (EAU) 2017 guidelines consider that they might have a role but that secondary synthetic sling, colposuspension or autologous sling are first options for women with complicated stress urinary incontinence [20]. The French Association of Urology (AFU) recommends AUS as the gold-standard treatment for severe SUI due to intrinsic sphincter deficiency and ACT® as a possible alternative in these patients [21]. These heterogeneous recommendations may be explained by the paucity of data in the literature. To date, no study has compared fascial slings to AUS or ACT®. To our knowledge, the present series is one of the first to compare two different techniques of intrinsic sphincter deficiency management in female patients and the first to compare these two specific devices. In the present study, AUS implantation was associated with better functional outcomes than ACT® implantation in female

patients with stress urinary incontinence due to intrinsic sphincter deficiency but with higher intraoperative complications rate, longer operative time and prolonged length of stay.

The morbidity of AUS implantation was higher than the one of ACT®, despite comparable post-operative complications rate. The high morbidity of the AUS in female patients has often been assumed to be the key factor that has limited its widespread [4]. This high complication rate might be due to the technically challenging dissection of the bladder neck, located deep in the pelvis with an urethral-vaginal septum often difficult to open due to the amount of previous surgical procedures. In recent years, the use of a robotic approach has been proposed to facilitate AUS implantation in women [22]. In a preliminary report, robotic AUS implantation appeared to decrease post-operative complications rate, blood loss and length of stay with a trend towards lower intraoperative complications compared to the open approach. Hence, one may assume that the difference we observed in terms of morbidity between AUS and ACT® may be tempered with a purely robotic AUS cohort (our cohort included a mix of open, laparoscopic and robotic AUS implantation).

It is now widely accepted through the urogynecology community that rather than looking for an objective cure in every case, physicians should adapt their treatments to patient's expectation and profile [23]. Our results are of interest in that regard as AUS, by outperforming ACT® in terms of functional outcomes, might be an appropriate option for patients with intrinsic sphincter deficiency seeking for cure of their urinary incontinence. Conversely, with its fair safety profile despite older patients with more comorbidity and previous pelvic radiation therapy (20%), the ACT® could

be a reliable option for patients looking for improvement of their urinary incontinence.

Another point of interest of this study is that the ACT® was associated with an increased risk of urinary retention postoperatively. This finding emphasizes an important point of strength of the AUS, as it is the only therapy of stress urinary incontinence due to intrinsic sphincter deficiency increasing urethral pressure during storage while maintaining a low urethral resistance during voiding by opening the device cuff. Indeed, the mechanism of action of ACT® is similar to the one of other treatment options such as fascial slings or bulking agents, by creating a permanent (ie that cannot be relieved) external compression over the urethra to preserve continence [5]. Long-term data regarding the impact of this increase bladder outlet resistance on detrusor contractility are lacking [24] but by analogy to what is seen in men with long-lasting benign prostate obstruction, one could assume that this external compression treatment options (i.e. ACT®, bulking agent or fascial sling) may lead to detrusor underactivity in the long-term. The benefits of ACT over bulking agents or fascial slings in that regard is that the obstruction can be fully relieved, as outlined in our series, by deflating the balloons.

Our study had several limitations that should be emphasized. Firstly, its retrospective and nonrandomized design could have partly flawed our results, notably because of an obvious selection bias with patients' characteristics differing in both groups, which we aimed to balance by performing a subgroup analysis. Another limitation is the relatively small sample size of our series, which may lead to a lack of statistical power and which prevented to perform multivariate analyses. We reported the early experience of a medium volume center for the two techniques and our findings may

have differed if coming from a tertiary volume center with a larger experience in AUS and ACT® implantations. There is still no consensus regarding the definition of intrinsic sphincter deficiency and the one we used in this study could therefore be a matter of debate. The various approaches used in the AUS group (i.e. open, laparoscopic, robot-assisted) might have been a confounder when analysing perioperative outcomes. Despite these drawbacks, we believe that the comparative data we provide are of value while the optimal management of SUI due to intrinsic sphincter deficiency remains to be determined.

Conclusion

In the present series, the patients in the two groups differed significantly in age, ASA score, history of pelvic radiation therapy and history of previous midurethral sling, which might have biased our findings**.** AUS implantation was associated with better functional outcomes than the ACT® in female patients with stress urinary incontinence due to intrinsic sphincter deficiency but with higher intraoperative complications rate, longer operative time and length of stay. Post-operative complications and explantation rates were similar between both groups. Future prospective randomized trials are needed to better define treatment algorithms of female patients with stress urinary incontinence due to intrinsic sphincter deficiency.

Abbreviations

ACT : Adjustable Continence Therapy

AMS: American Medical System

ASA : American Society of Anesthesiologists

AUA : American Urological Association

AUS : Artificial Urinary Sphincter

EAU : European Association of Urology

ICIQ-SF: Internation Consultation on Incontinence Questionnaire Short Form

ICUD : International Consultation on Urological Diseases

PGII: Patient-Global Impression of Improvement

SUI : Stress Urinary Incontinence

USP : Urinary Symptoms Profile

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Fig. 1 Study flow-chart

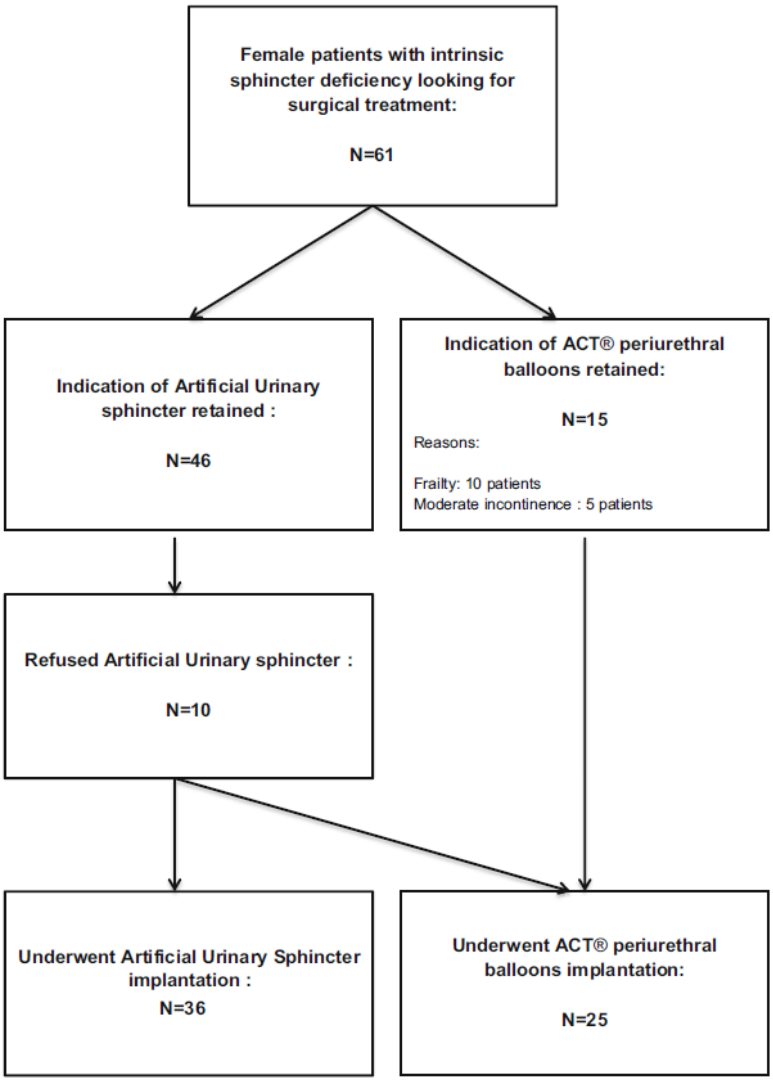
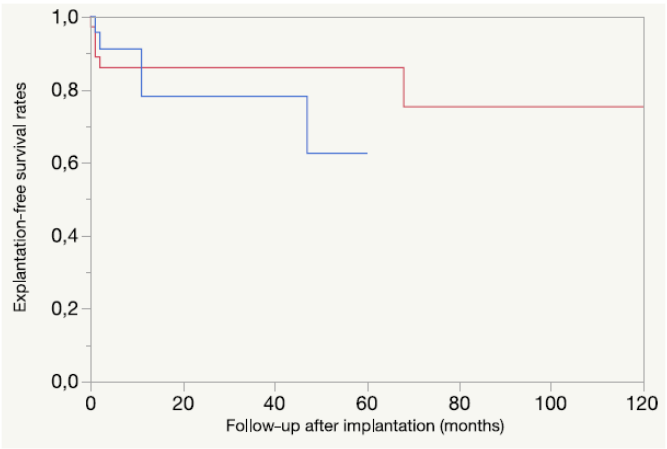


Fig. 2 Time to failure comparison



		20 months	40 months	60 months	80 months	100 months	120 months
ACT N= 25	Number at risk	11	6	3	0	0	0
	Number of failure	4	0	1	0	0	0
AUS N=36	Number at risk	24	17	11	6	3	3
	Number of failure*	5	0	0	1	0	0

ACT®

Artificial urinary sphincter

Log-rank test : p=0.42

* 1 failure occured at 126 months

Table 1 : Patients' characteristics

	ACT® N=25	**Artificial urinary sphincter N=36**	**p-value**
Mean age (years)	70.4 (± 3.1)	62.9 (± 2.5)	**0.03***
Body Mass Index (kg/m^2)	26.1 (± 1.4)	28.6 (± 3.1)	0.10
ASA score 1 2 3	 0 (0%) 16 (66.7%) 8 (33.3%)	 10 (30.3%) 19 (57.6%) 4 (12.1%)	**0.005***
History of pelvic radiation therapy	5 (20%)	0 (0%)	**0.009***
History of any previous pelvic surgery	19 (76%)	28 (77.8%)	0.87
History of previous midurethral sling	10 (40%)	24 (66.7%)	**0.04***
Neurogenic stress urinary incontinence	1 (4%)	5 (13.9%)	0.39
Maximum urethral closure pressure (cmH2O)	28.8 (± 2.7)	27.3 (± 2.3)	0.61

*** :statistically significant**

Table 2 : Perioperative outcomes

	ACT® N=25	**Artificial urinary sphincter N=36**	**p-value**
Operative time (min)	45.7 (± 7.7)	206.1 (± 7.7)	**<0.001***
Length of hospital stay (days)	1.7 (± 1)	7 (± 0.9)	**<0.001***
Intra-operative complications	2 (8%)	17 (47%)	**<0.001***
Post-operative complications	10 (40%)	17 (47.2%)	0.57
Major post-operative complications (Clavien ≥ 3)	2 (8%)	7 (19.4%)	0.28
Explantation	5 (20%)	7 (19.4%)	0.99

*** : statistically significant**

Table 3: Functional outcomes

	ACT® N=25	**Artificial urinary sphincter N=36**	**p-value**
Mean number of pads /24h Preoperatively At 6 months	 4.5 (± 0.3) 2.2 (± 0.3) [1]	 5.2 (± 0.3) 0.6 (± 0.2) [1]	 0.14 **0.002 ***
PGII (6 months) 1 : Very improved 2 : Improved 3 : Slightly improved 4 : Unchanged 5-7 : Woresened	 3 (12%) 6 (24%) 8 (32%) 6 (24%) 2 (8%)	 22 (61.1%) 5 (13.9%) 2 (5.6%) 6 (16.7%) 1 (2.8%)	**<0.001***
Complete continence at 6 months	5 (21.7%)	25 (71.4%)	**<0.001***
USP stress incontinence sub-score (/9) *Preoperatively* *At 6 months*	 7.8 (± 0.5) 4.8 (± 0.7) [1]	 8.4 (± 0.5) 0.3 (± 0.5) [1]	 0.22 **<0.001***
Median follow-up (months)	11 [4-42.5]	37.5 [12.8-65.8]	**0.02 ***

*** :statistically significant**
[1] : statistically significant change from baseline (p<0.05)

Table 4: Subgroup of recurrent/persistent incontinence after midurethral slings

	ACT® N=10	**Artificial urinary sphincter N=24**	**p-value**
Mean age (years)	71.7 (± 3.3)	66.4 (± 2.1)	0.23
Maximum urethral closure pressure (cmH2O)	24.9 (± 3.5)	26.4 (± 2.5)	0.64
Intra-operative complications	1 (10%)	13 (54.2%)	**0.02***
PGII (6 months) 1 : Very improved 2 : Improved 3 : Slightly improved 4 : Unchanged 5-7 : Woresened	 1 (10%) 3 (30%) 4 (40%) 1 (10%) 1 (10%)	 15 (62.5%) 5 (20.8%) 2 (8.3%) 4 (16.7%) 1 (4.2%)	**0.02***
Complete continence at 6 months	3 (33.3%)	16 (66.7%)	**0.04***
USP stress incontinence sub-score (/9) *Preoperatively* *At 6 months*	 7.8 (± 0.5) 3.5 (± 0.6) [1]	 8.4 (± 0.5) 0.4 (± 0.5) [1]	 0.22 **0.003***
Explantation	3 (30%)	6 (25%)	0.99

*** :statistically significant**
[1] : statistically significant change from baseline (p<0.05)