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ARTICLE

Neurogenic stress urinary incontinence: is there a place for Adjustable Continence Therapy (ACT™ and ProACT™, Uromedica, Plymouth, MN, USA)? A retrospective multicenter study

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Abstract

Study design Retrospective cohort study.

Objectives To assess the effectiveness and complications of treatment for neurogenic stress urinary incontinence (nSUI) by Adjustable Continence Therapy (ACT™ and ProACT™).

Setting France.

Methods A retrospective multicentre study of consecutive patients with neurological pathologies treated for nSUI with ACT balloons.

Results From January 2001 to January 2013, 102 patients were implanted. Mean (SD) age at implantation was 48.4 (16.5) years. Patients were followed-up for a mean 2.7 (2.3) years. After implantation, 5.9% of patients were totally continent, 51.2% had an improvement in symptoms of at least 50% (including 14.6% with improvements of at least 90%), and 48.8% had improvements of < 50%, including 7.3% of treatment failures. Complications occurred in 70 patients (120 balloons): 21 balloon infections, 34 migrations, 18 device failures, 28 urethral erosions and 28 cutaneous erosions. The procedure was ineffective for 35 patients. Twenty patients underwent permanent explantation. The rate of migrations was lower in patients with upper motor neuron lesion than in those with lower motor neuron lesion ($p = 0.04$).

Conclusions ACT is a minimally invasive treatment for SUI related to sphincter deficiency. This is one of the first reports in a sample of patients with neurological disorders implanted by multiple surgeons. ACT could be a less invasive, appropriate alternative to artificial urinary sphincters. However, it is associated with frequent local complications which are easy to manage but that should be reduced in this challenging population.

Introduction

Neurogenic stress urinary incontinence (nSUI) occurs in neurogenic lower urinary tract dysfunction (NLUTD) due to lower motor neuron lesion (LMNL) involving sacral spinal cord centres (somatic sacral centre) or their efferent pathways (sacral roots or plexic lesions) leading to neurogenic intrinsic sphincter deficiency (nISD). The main aetiologies

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of LMNL leading to nISD are cauda equina lesions, conus medullaris lesions and spina bifida. In case of extended grey matter lesion of the spinal cord (e.g., ischaemia), involving the sympathetic thoraco-lumbar centre and the sacral centres, the nISD can be associated with bladder neck incompetence. NLUTD due to LMNL often leads to an association of nISD with detrusor acontractility. Less frequently, nISD may be associated with neurogenic detrusor overactivity (NDO), e.g. in some cases of conus medullaris lesions. The main method of bladder emptying in these neurological patients is intermittent catheterization (IC). According to the International Continence Society (ICS) criteria [1], nSUI is defined as a complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. Treatment for nSUI ranges from suburethral slings [2], to artificial urinary sphincters (AUS) considered as the gold standard [3]. The implantation of adjustable peri-urethral ACT™/ProACT™ balloons [4, 5] is a mini-invasive procedure. Its effectiveness in the treatment of urinary incontinence (UI) in men post-radical prostatectomy has been evaluated [6–8] and a prospective controlled study in women with non-nISD has been ongoing since 2016 [9]. A study of patients with nISD using intention-to-treat analysis found a 50% effectiveness rate [4]. SUI due to sphincter deficiency remains challenging to treat, particularly in patients with neurological pathologies because of the risk of failure: the intervention may be ineffective or complicated by infection.

The main objective of this study was to evaluate the efficacy and the rate of complications of the Adustable Continence Therapy in patients with nSUI. The secondary objective was to try to define the place for this technique in the treatment of nISD.

Methods

This was a retrospective, multicentre study of consecutive patients with nSUI who underwent implantation with adjustable periurethral balloons between January 2001 and January 2013 in four university hospitals. Exclusion criteria were no neurological cause of SUI or aged <18 years. The data were recorded in the patient files in paper and/or electronic format in accordance with the good practice guidelines of each institution. According to the French legislation, approval from an ethics committee was not needed to use data for this retrospective study.

The adjustable sphincter prostheses used were ACT™ for females and ProACT™ for males (Adjustable Continence Therapy, Uromedica, Inc., Plymouth, MN, USA). The only difference in the two prostheses is the length of the tube. The ACT™/ProACT™ prosthesis is comprised of an implantable silicone device that is adaptable, consisting of 2 balloons, a syringe and port puncturing needle to adjust the volume of the balloon.

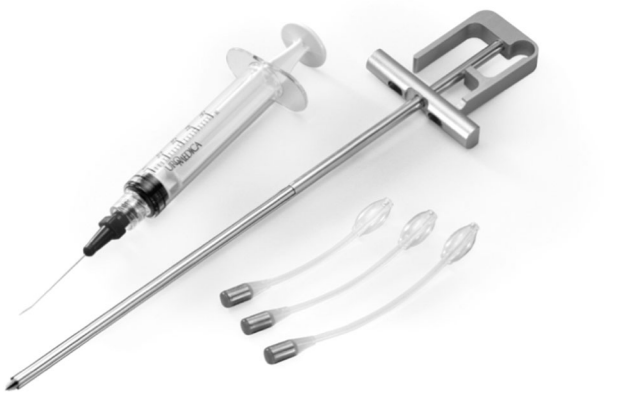

Fig. 1 Complete kit with from left to right: the inflation syringe with the port puncture needle, the trocart and cannulated sheath to slide the balloon into position. Devices of three different lengths are shown

The reusable instrument set for implantation (Fig. 1) includes:

A sharp trocart;
A blunt trocart;
A tissue expanding device (TED).

The system always includes two adjustable balloons, implanted on each side of the urethra, below the bladder neck (females) and at the level of the membranous urethra (males). Different guidance techniques and aids are used to facilitate implantation [8, 10]. The aim is to position the balloons in opposition to each other, at 3 and 9 o'clock relative to the urethra. The implantation is carried out under local (generally for females) or general anaesthesia. Implantation is carried out under radioscopic and endoscopic guidance (sometimes endorectal ultrasound guidance in males [11]), then the balloons are filled to 0.6 mL with a radio-opaque isotonic solution ensuring the initial filling of the balloons. The injection chambers are buried subcutaneously under the labia majora (females) and under the skin of the scrotum (males). In the case of tissue rigidity, the tissues surrounding the balloon are dilated using the TED. Patients on IC are able to perform their catheterizations just after the procedure. Balloon adjustments began 6 weeks after balloon placement, then once a fortnight until a steady-state was achieved (first maximum improvement without complication).

The following data were recorded: gender, age at the time of implantation, aetiology of the neurological pathology, neurological level and AIS (American Spinal Injury Association [ASIA] Impairment Scale) grade based on the International Standards for neurological classification of Spinal cord injury (SCI) for patients with SCI or cauda equina lesions [12]. The mode of bladder emptying, subjective

improvement perceived by the patients, complications and their onset were also recorded as well as associated treatment for NDO (anticholinergic drugs, intra-detrusor botulinum toxin A (BoNT-A) injections and surgeries).

Improvements in continence were evaluated using a numeric scale from 0 (no change) to 100 (complete dryness) rated by patients during a telephone interview carried out by one physical medicine and rehabilitation doctor.

If patients underwent further treatment for SUI after implantation, this was considered as a failure. Patients were considered to be improved if they rated the improvement in continence above 50%. Intention-to-treat analyses were carried out.

The urodynamic data collected were: presence/absence of involuntary detrusor contractions during the filling phase (NDO), detrusor compliance and maximal urethral closure pressure (MUCP). The definitions and units were in accordance with the ICS recommendations.

The type of anaesthesia used for the surgical procedure and the number of subsequent interventions were noted.

R© software was used for the statistical analysis. Results were expressed as numbers and percentages for qualitative variables and means and standard deviations for quantitative variables. If this test was significant, a test for multiple comparisons was performed with Bonferroni correction. In the majority of contingency tables constructed, the numbers were below 2.5, thus a Fisher's exact test was used. Significance was set to $p < 0.05$. The multivariate Cox's model test was performed.

Table 1 Distribution of aetiologies

Paraplegia: $n = 61$ (59.8%), ♂ = 37:
Traumatic: 47 (46.1%), ♂ = 31
Ischaemic causes: 4 (3.9%), ♂ = 1
Spinal cord angioma: 2 (2%), ♀ = 2
Myelitis: 2 (2%), ♀ = 2
Ependymoma: 2 (2%), ♂ = 2
Decompression sickness: 1 (1%), ♂ = 1
Post-arachnoiditis: 1 (1%), ♂ = 1
Gunshot wound: 1 (1%), ♂ = 1
Post-operative haematoma following spinal surgery: 1 (1%), ♀ = 1
Spina bifida: 12 (11.8%), ♂ = 7
Cauda equina lesions: 10 (9.8%), ♂ = 6
Tetraplegia: $n = 4$ (3.9%), ♂ = 3
Neuropathy of undetermined aetiology: 4 (3.9%), ♂ = 1
Multiple sclerosis: 2 (2%), ♀ = 2
Following pelvic fracture: 1 (1%), ♀ = 1
Radiculopathy following radiotherapy: 1 (1%), ♀ = 1
Lesion during pelvic-surgery: 1 (1%), ♀ = 1
Cerebral palsy: 1 (1%), ♀ = 1
Myasthenia gravis: 1 (1%), ♂ = 1
Poliomyelitis: 1 (1%), ♀ = 1
Cerebellar ataxia: 1 (1%), ♀ = 1
Missing data: 2 (2%), ♀ = 2

n number of patients, ♂ males, ♀ females

Results

Population

Sociodemographic data

A total of 102 patients (55 males, 47 females) were implanted with ACT™/ProACT™ balloons to treat nSUI during the study period. Mean (±SD) age at implantation was 48.4 (±16.5) years (range: 21.1–85.9 years). Mean (±SD) time between onset of the neurological lesion and implantation (excepted congenital lesions, $n = 12$) was 9.2 (±9.9) years, median 5.9 years (range: 1–55 years).

Aetiologies

The distribution of aetiologies and neurological status are presented in Tables 1 and 2.

Seventy-five patients (73.5%) had SCI or Cauda equina syndromes and 12 patients (11.8%) had Spina Bifida. Fifty-five patients had upper motor neuron lesions (UMNL) (53.9%) and 39 had LMNL (38.2%). Data were missing for eight patients (7.9%). Among the patients with UMNL, NDO was treated with oral anticholinergics alone in 39 patients, with BoNT-A injections in 15 patients, augmentation enterocystoplasty in 15 patients and one patient had previously been implanted with a sacral anterior root stimulator (SARS).

Table 2 SCI and cauda equina lesions: neurological status and gender

	AIS					
NLI	AIS A	AIS B	AIS C	AIS D	Missing data	Total
≥T9	$n = 13$ (♂ = 11)	2 (♂ = 1)	2 (♀ = 2)	–	3 (♂ = 2)	20 (♂ = 14)
T10-L2	19 (♂ = 13)	2 (♂ = 1)	4 (♂ = 2)	3 (♂ = 2)	5 (♂ = 1)	33 (♂ = 19)
L3-S1	6 (♂ = 4)	–	2 (♂ = 2)	–	3 (♀ = 3)	11 (♂ = 6)
S2-S5	9 (♂ = 4)	–	–	–	2 (♂ = 2)	11 (♂ = 6)
Total	47 (♂ = 32)	4 (♂ = 2)	8 (♂ = 4)	3 (♂ = 2)	13 (♂ = 5)	75 (♂ = 45)

♂ males, ♀ females, *n* number of subjects, *NLI* neurological level of injury

Method of bladder emptying

Prior to implantation, 90 patients (87.2%) performed clean intermittent self-catheterizations, 5 (4.9%) were able to void completely, spontaneously and voluntarily, two patients (2%) had indwelling catheters and one patient (1%) used reflex micturition. Data were unclear for four patients (3.9%) (mixed methods of micturition).

Urodynamic data

Eighty patients had urodynamic results before implantation. Data were missing for twenty-two patients. Mean (± SD) MUCP was 33.2 (±18.7) cm H_20. Mean (± SD) amplitude of maximal detrusor contractions was 28.5 (±18.1) cm H_2O for patients with NDO ($n = 55$).

Previous urological treatments

Twenty-nine patients (28.4%) had undergone at least one treatment for UI prior to balloon implantation. Previous treatments included TVT/TOT (20 patients, one male), AUS (six patients), suburethral slings (five patients), Burch colposuspensions (two female patients), and Urovive® balloons (one patient).

Other non-sphincter related urological treatments included: supratrigonal cystectomy with augmentation cystoplasty (15 patients), Mitrofanoff/Monti continent cystostomy (seven patients), sacral colpopexy (five female patients), S3 sacral neuro-modulation (four patients), sphincterotomies (endoscopic ($n = 3$), with stent ($n = 1$)), SARS (one patient), and internal urethrotomy (one patient). One patient had undergone endoscopic resection of benign prostatic hypertrophy, and two radical prostatectomies for prostate adenocarcinoma.

Perioperative data of implantation of adjustable peri-urethral ACT™/ProACT™ balloons

A total of 148 procedures were performed (102 de novo implantations and 46 re-implantations). Seventy-one were under general anaesthesia (48%), 33 under local anaesthesia (22.3%), 34 without anaesthesia (23%), and 2 with spinal anaesthesia (1.4%). Data were missing for eight procedures (5.4%).

The mean (±SD) post-implantation follow-up was 2.7 (±2.3) years, median 2.1 years (range: 0–8.1 years) and the mean (±SD) time between implantation and phone call was 5.32 (±2.8) years (range: 0.2–11.35 years).

At phone call following implantation, 42 patients out of 82 patients (51.2%) who were contacted experienced improvements in symptoms of at least 50%, including four patients who were completely continent (4.9%) and 12 (14.6%) who were at least 90% improved. Forty patients (48.8%) were improved by <50%, including 6 (7.3%) who perceived no improvement. Seventeen patients were lost-to-follow-up. Three died of causes unrelated to the balloons. No significant relationship was found between effectiveness of the balloons and gender, neurological level of injury (NLI), AIS grade, presence of NDO, and the value of abdominal leak point or MUCP.

The rate of definitive explantation was 34.3%. Seventy patients out of 94 patients (74.5%) ($n = 120$ balloons) underwent temporary or definitive explantation because of complications. Most explantations were carried out during urological consultations under local anaesthesia. The follow-up is presented in Fig. 2. Seventeen patients (out of 70 complicated patients, 24.3%) experienced infections, 26 migrations, 18 ruptures, 23 urethral/bladder/vaginal erosions and 21 cutaneous erosions. The technique was ineffective for 36 patients. Twenty-four patients had no complications. Data was missing for eight patients. The complications occurred at a mean (±SD) of 1.68 (±1.77) years (median: 0.96, range: 0.03–8.11) from the time of surgery. Rate of migration was lower in patients with UMNL than LMNL (13 vs 8, $p = 0.04$). Urethral erosion was higher in females than males (14 vs 6, $p = 0.01$). There was a tendency for a higher risk of urethral erosion in patients with UMNL (13 vs 3, $p = 0.05$). No other correlations were found between neurological level and the occurrence of complications.

Correlations between gender and complications or efficacy are presented in Table 3a, b. The distribution shows patients without complications had a greater percentage improvement than patients with complications. There was a significant relationship between complications and improvement with a higher rate of improvement in patients without complications ($p = 0.0002$). The results showed patients with complete sensory and motor lesions experienced more complications than the other AIS grades ($p = 0.02$). There was a tendency towards less complications in males than females (25 vs 12, $p = 0.06$). The assessment of ACT™/ProACT™ balloons over time is presented in Fig. 3. The multivaried Cox's model shows less complications in patients with UMNL ($p = 0.032$) and in patients with an AIS C lesion ($p = 0.022$).

Twenty patients (21.3%) required another surgical treatment: AUS ($n = 13$ patients), non-continent diversion (Bricker procedure) ($n = 2$), closure of the bladder neck ($n = 2$), autologous suburethral sling ($n = 2$) and urethral ligature ($n = 1$). Sixteen patients (17%) in whom the balloon implants had failed were awaiting further treatment. Data were missing for four patients.

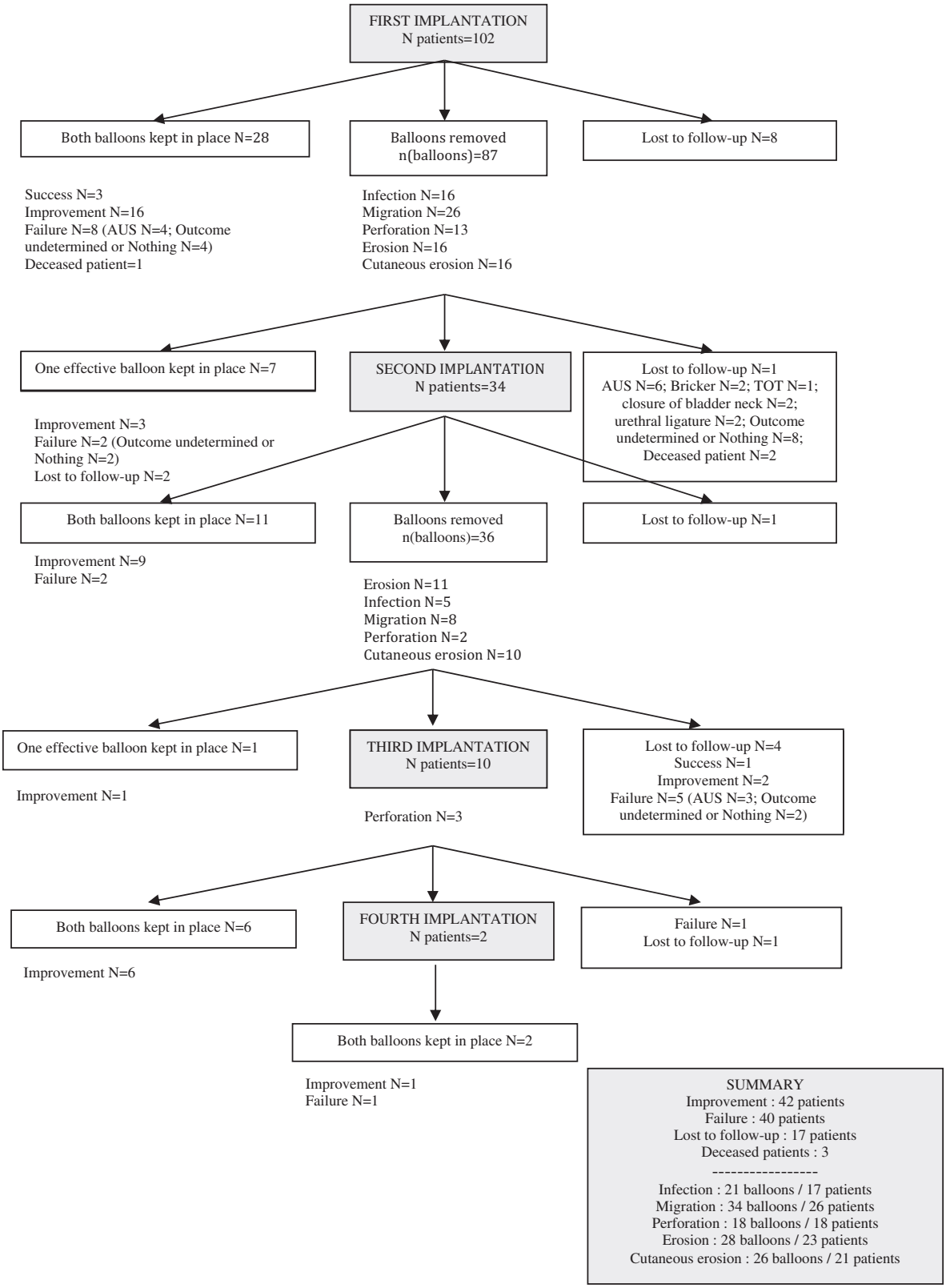

Fig. 2 Flow-chart and follow-up of ACT™/ProACT™ balloons

Table 3 Subjects repartition presenting complications (3a) and improvement ≥ 50% (3b) in our whole sample in grey font and related to gender

	No complications	Complications	Missing data	
Whole sample, *n* (%):	24 (%)	70	8	
- Females, *n*	5	36	6	Fisher exact test: $p = ns$
- Males, *n*	19	34	2	
	Improvement < 50%	Improvement ≥ 50%	Missing data	
Whole sample:	40	42	20	
- Females	25	13	9	Fisher exact test: $p = ns$
- Males	15	29	11	

There is no significant (ns) difference between females and males, Fischer exact test

Discussion

Our study has some weaknesses and limitations: the first one is that data were collected retrospectively from the files by one investigator. The multicentric design, which increased the number of included patients, could lead to a lack of homogeneity. Nevertheless, this study has been conducted in the framework of highly specialized teams in neuro-urology.

In this study, forty-two patients (51.2%) experienced improvements in symptoms of at least 50%, of which four patients were completely continent (4.9%) and 12 (14.6%) were at least 90% improved. The rate of definitive explantation was 34.3%.

The majority of patients studied used ISC in accordance with international recommendations. Patients with continuous drainage ($n = 2$) sustained traumatic tetraplegia. They had long-term indwelling catheters and leakages around the catheters. Methods of micturition had not been modified after the balloon implantations.

ACT™ was initially evaluated for the treatment of non-nSUI in females, and ProACT™ in males following radical prostatectomy [13–16]. The rate of totally continent patients was 52–80% [13–16] and the device is now FDA approved for men [17]. The difference between the results of the present study and those in the literature in patients without neurological pathology can be attributed to the complexity of the management of neurogenic patients. We expected the type of neurological lesion to influence results, however this was not significant, probably due to the heterogeneity of the sample in terms of neurological diseases, neurological levels, UMNL or LMNL, NDO.

This was an exhaustive, retrospective, multicentre study of ACT™/ProACT™ balloons implantation in specialized neuro-urological centres by multiple surgeons. Only two single-centre studies have evaluated this therapy for nSUI [4, 5]. The present study integrated these 37 patients previously studied [4] and extended the follow-up. Mehnert et al. [4] found complete continence in 21% of patients, improvements of more than 50% in 67.6% and 64.8% of patients at 1 and 2 years, respectively, with permanent explantation in 39.4% of patients. The duration of follow-up was 4 years. In the present study, more patients were included but the mean follow-up was less (mean: 2.7 years; median: 2.1 years; range: 0 to 8.1 years)—even though one patient has an 8 years follow-up. Ammarati et al. [5] treated 16 patients; 43.75% of patients were dry and 18.75% improved more than 50% with a follow-up of 37 months (range: 7 to 156). The difference between the success rates found in these two studies could be explained by many factors including the definitions of continence and the use of single-/multi-centre designs that affect interoperator variability.

The differences in the rate of complications compared with data in the literature may be due to the specificity of patients with neurological disorders. Concomitant NDO that is untreated/insufficiently treated can increase UI. Data in the literature highlight the importance of gaining a balance between controlling NDO and ISD [4, 18]. However, NDO fluctuates depending on different parameters (urinary infection, compliance with anticholinergic treatment, time since last BoNT-A injections etc.). The results of the present study must therefore be interpreted cautiously, since 15 patients had undergone BoNT-A injections. The evaluation of the balloons was one-off and did not take this balance into account. The mean maximal values for the detrusor contractions evaluated were preoperative and one-off values. They may not therefore reflect intra-detrusor pressure at the time of evaluation.

Patients with UMNL seemed to have less risk of balloon migration. Muscle tone and bulk around the perineum likely helps to maintain the position of the balloons and reduces the risk of mal-positioning and/or migration. However, there was a tendency for greater urethral erosion in these patients with UMNL. The rate of definitive explantation in this study was similar to data in the literature, despite the fact that the global rate of complications was higher.

The indications for ACT™/ProACT™ for the treatment of nSUI have not been precisely defined. Quality of life was not evaluated in the present study, however a significant number of patients experienced considerable improvements, avoiding or delaying further major interventions. We

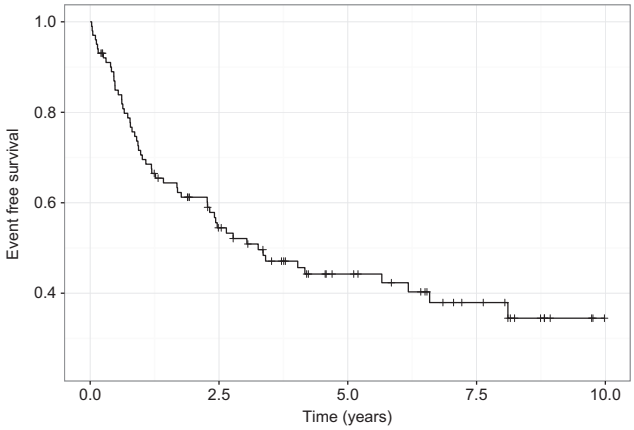

Fig. 3 Survival model (Cox's model) to assess ACT™/ProACT™ balloons over time

suggest balloons could be the first line of treatment insofar as the technique is mini-invasive and can be carried out without general anaesthesia. Moreover, complications are of minor severity and easy to manage. This technique should also be the first choice for patients with contra-indications to general anaesthesia and/or major surgery. In our practice, we use the same indications as for AUS: nSUI due to a LMNL or iatrogenically denervated perineum (Brindley procedure). The ICI report [19] published in 2013 did not include ACT, underlining the fact that use of this treatment for neurogenic patients is quite recent.

Despite our multicenter study and the learning curves for this surgery, we did not find a place for ACT™/ProACT™ in nSUI therapy. The small number of patients and their heterogeneity did not enable subgroup analyses. A prospective multicenter study could answer these questions.

Conclusion

Although the gold standard treatment in terms of continence remains the AUS, ACT™/ProACT™ balloons offer patients a new treatment for nSUI. Their advantages are: they are safe and require mini-invasive procedures allowing ambulatory treatment. Despite a high rate of complications, the balloons can be explanted as ambulatory surgery using local anaesthesia with the option of reimplantation at 3 months, and last but not least, implantation/explantation does not limit other continence devices at a later time. So ACT™/ProACT™ could be considered as a first line treatment option. In our mind, the ideal population is patients with LMNL performing IC and with SUI and detrusor acontractility. Further prospective studies with homogeneous population of LMNL are required in order to confirm this opinion.

Author contributions BPV conceptualized the study. All authors were involved in designed study. LLN, ECK, PD, XG and PG prepared data analyses. YR, BPV and ECK coordinated data analyses and interpretations. YR analysed the data. All authors assisted overall interpretation and contextualization. YR, BPV wrote the first draft of the manuscript. All authors critically reviewed and approved manuscript.

Compliance with ethical standards

Conflict of interest EC-K has served as consultant for Uromedica. Remaining authors declare that they have no conflict of interest.

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