Single centre experience and long-term outcomes of implantable devices ACT™ and Pro-ACT™ (Uromedica, Irvin, CA, USA) - Adjustable continence Therapy for treatment of stress urinary incontinence.

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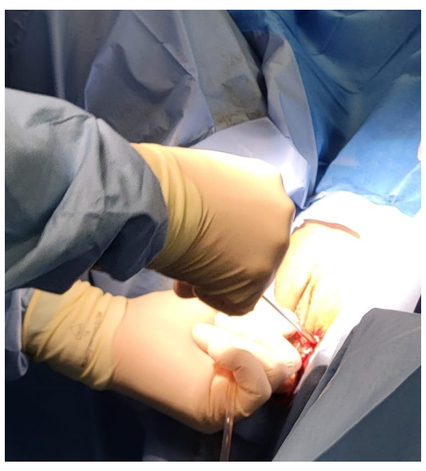
INTRODUCTION

- Adjustable peri-urethral balloons is an optional treatment in the management of intrinsic sphincter deficiency stress urinary incontinence
- This device has been evaluated since it was first implanted and is considered both safe and efficient in male and female patients
- However, placing this device in an expert center is recommended as it is associated with the risk of failure and complication.
- This study aimed to evaluate the long-term PUB durability and safety in both males and females with neurogenic or non-neurogenic SUI.



PATIENTS AND METHODS

Study design

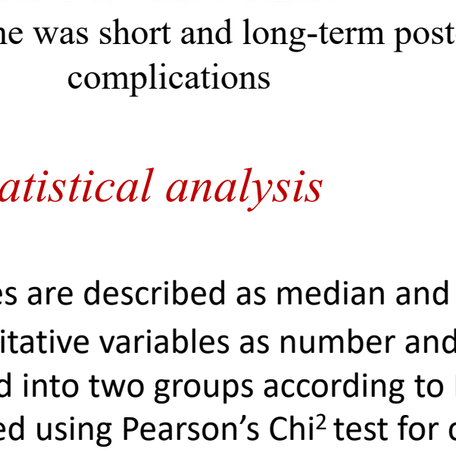
- Between January 2002 and December 2008, each patient who had balloon implantation was included in this study
- The inclusion criteria were patients with intrinsic sphincter deficiency refractory to perineal rehabilitation
- The surgery was performed by two experienced surgeons under general or spinal anesthesia

Outcomes

- Primary study outcomes were balloon global survival rate and survival without failure
- Secondary outcome was short and long-term post-operative complications

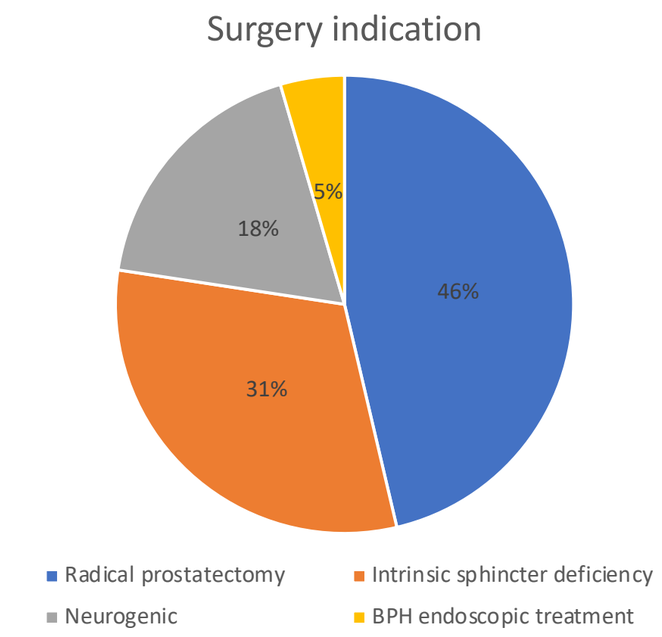
Statistical analysis

- Quantitative variables are described as median and interquartile range [IQR] and qualitative variables as number and percentage.
- Patients were divided into two groups according to PUB removal and were compared using Pearson's Chi² test for categorical variables and Mann-Whitney U test for continuous variables
- Removal-free survival rate was defined as the percentage of patients who did not have any PUB removal.
- Failure-free survival rate represented the patients who did not have any PUB failure
- Global survival rate corresponded to patients who still had their initial PUB at the end of the study

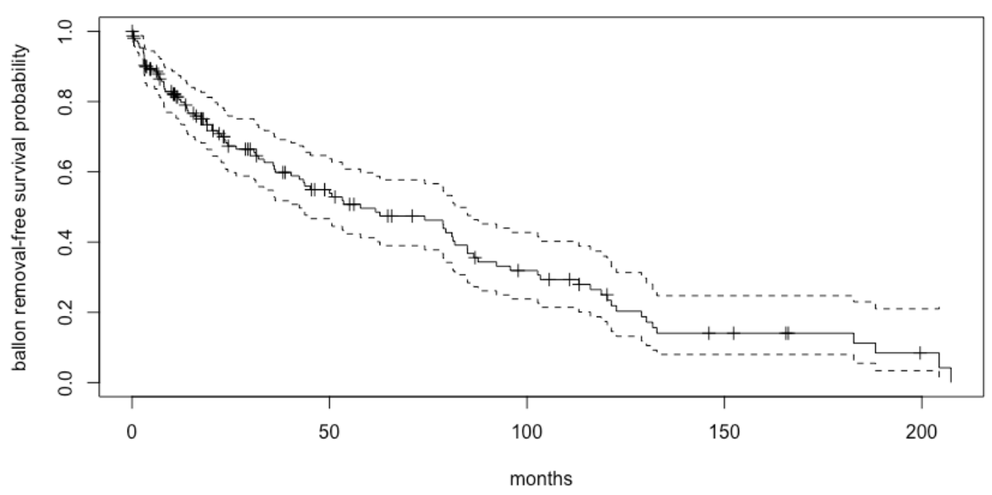


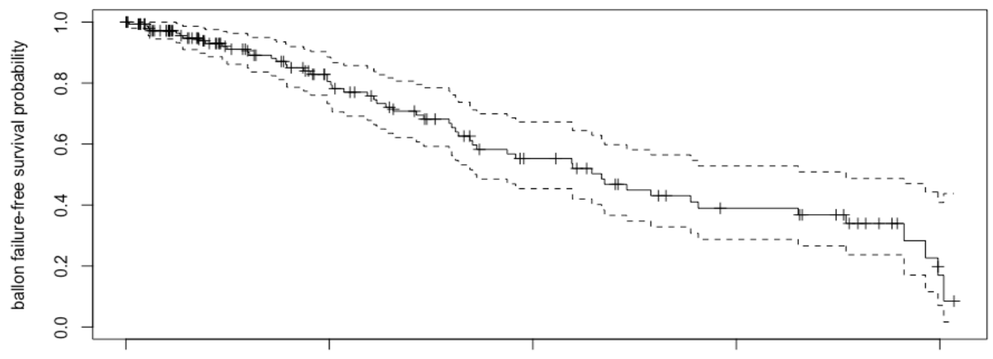
RESULTS

- A total of 177 consecutive patients from 2002 to 2008 were included in the study with a 70.5 median age.
- The 3 main causes of SUI were radical prostatectomy, idiopathic intrinsic sphincter deficiency and neurogenic sphincter deficiency
- Overall, 7 patients had post-operative acute urinary retention and only 3 patients had a Clavien≥3 post-operative complication
- During the follow-up, almost 20% of the patient had balloon or port erosion



- Overall, 93 balloon were removed after initial surgery, including 40 for complications and 53 for PUB failure.
- Global survival rate was 47.5% with a 58 months median survival
- Survival without failure rate was 68.4% accounting for a median survival duration of 116.9 months





- Additionally, when the cause of SUI was previous BPH treatment, Cox univariate analysis evidenced that it was a balloon removal risk factor

Variable	HR [95%CI]	p-value
Male gender	0.9 [0.6-1.4]	0.7
Age in years[1]	1 [0.9-1.1]	0.9
Diabetes	2.2 [1-4.8]	0.07
Anticoagulation	1.9 [0.8-4.8]	0.2
Antiplatelet agent	1.1 [0.6-2.1]	0.7
Incontinence cause		
Intrinsic sphincter deficiency	1 [Reference]	-
Radical prostatectomy	0.9 [0.5-1.4]	0.6
Neurogenic	0.9 [0.5-1.6]	0.6
BPH endoscopic treatment	3.8 [1.1-12.9]	0.04
History of radiotherapy	1.4 [0.8-2.5]	0.2
Left balloon volume maximal filling in mL[1]	0.9 [0.9-1.1]	0.09
Right balloon volume maximal filling in mL[1]	0.9 [0.8-1.1]	0.1

CONCLUSION

- In this study, we evidenced acceptable long-term efficiency and survival of PUB in the management of SUI in both neurogenic and non-neurogenic populations.
- The procedure was safe with a low number of intraoperative adverse events.
- However, we evidenced 25% long-term postoperative complications mostly due to balloon erosion