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Functional outcomes of adjustable continence therapy (ACT) balloons in women : A multicentric retrospective study

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Introduction:

- Stress urinary incontinence (SUI) due to **intrinsic sphincter deficiency (ISD)** is often **associated with other mechanisms** of IU
- Various populations are concerned: **multi-operated women** and women with **neurogenic SUI**.
- The management of ISD is **complex and controversial** and various treatments are used.
- There is no clear guidelines about ACT™; it is generally used in female with **pure ISD** or after **failure of other therapies** in patients with SUI
- In complex situations and in frail patients, ACT™, which is a **mini-invasive, adaptable and reversible procedure**, appears to be a good option.

Objective:

The aim of this study is to assess efficacy and safety of the adjustable continence therapy device (ACT™) in the treatment of female pure stress (SUI) or mixed urinary incontinence (MUI).

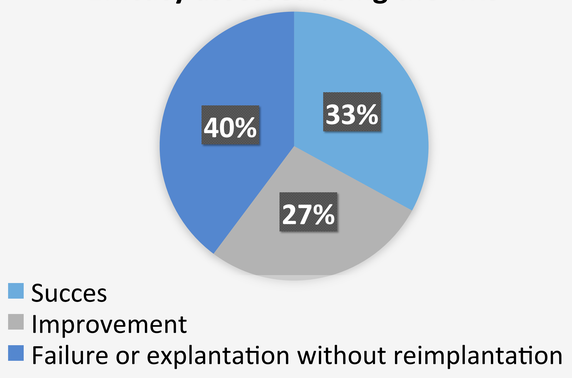
Patients and Methods:

- This is a **multicentric retrospective study**.
- All women undergoing ACT device placement between **2008 and 2016** to treat **SUI or MUI** were eligible.
- Regarding efficacy, the improvement was subjectively assessed using the **PGI-I** (Patient's Global Impression of Improvement) and a **numbered rating scale (NRS)** going from 0 to 10.
    - Success : NRS > 8
    - Improvement : NRS between 0 and 8
    - Failure : NRS = 0
- Regarding safety, **per- and post-operative complications** were retrieved. Early complications (<30 days) were reported according to the **Clavien-Dindo classification.**

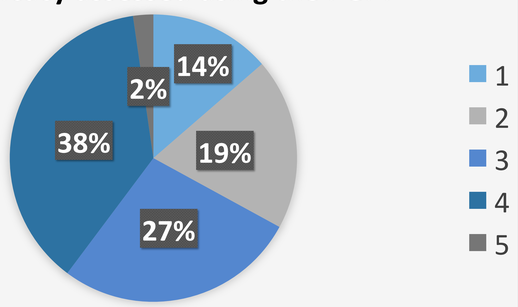
Results:

Population characteristics (n = 88)		
Mean age		68 yo (20-90)
Neurologic disease		25.0%
History of pelvic radiation therapy		10.2%
Previous surgery for UI		79.5%
Mean number of surgery for UI		1.5
Type of UI:	- Pure SUI	51.1%
	- MUI	48.9%

Efficacy assessed using the NRS



Effcacy assessed using the PGI-I



Mean follow-up period: 21 months (1-76)
Mean volume per balloon: 3.5mL

Per-operative complications	
Incidence: 6.8% (n = 6)	
Bladder injury	n = 5 (5.7%)
Vaginal injury	n = 1 (1.1%)

Early post-operative complications	
Incidence: 18.2% (n = 16) - Clavien-Dindo I or II	
Acute urinary retention	n = 9 (10.2%)
Hematoma	n = 3 (3.4%)
Infection	n = 1 (1.1%)
Due to comorbidities	n = 3 (3.4%)

Late post-operative complications	
Incidence: 18.2% (n = 16)	
Erosion	n = 7 (8.0%)
Infection	n = 1 (1.1%)
Migration	n = 8 (9.1%)
Urinary retention	n = 1 (1.1%)
Balloon dysfunction	n = 1 (1.1%)

Explantation: n = 29 (33%)

Conclusion:

- Limited efficacy in treating female SUI or MUI, with a **success or improvement rate of 60.2%.**
- Interesting safety profile, **with no severe complication** occurring throughout the follow-up period.
- High previous urinary incontinence surgery rate as well as the high neurogenic urinary incontinence among the studied population.