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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 SUI 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 PGf-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:

<table>
<thead>
<tr>
<th>Population characteristics (n = 88)</th>
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<tbody>
<tr>
<td>Mean age</td>
</tr>
<tr>
<td>68 yo (20-90)</td>
</tr>
<tr>
<td>Neurologic disease</td>
</tr>
<tr>
<td>25.0%</td>
</tr>
<tr>
<td>History of pelvic radiation therapy</td>
</tr>
<tr>
<td>10.2%</td>
</tr>
<tr>
<td>Previous surgery for IU</td>
</tr>
<tr>
<td>79.5%</td>
</tr>
<tr>
<td>Mean number of surgery for IU</td>
</tr>
<tr>
<td>1.5</td>
</tr>
<tr>
<td>Type of UI:</td>
</tr>
<tr>
<td>- Pure SUI</td>
</tr>
<tr>
<td>51.1%</td>
</tr>
<tr>
<td>- MUI</td>
</tr>
<tr>
<td>48.9%</td>
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</tbody>
</table>

Efficacy assessed using the NRS
- Success: 40%
- Improvement: 33%
- Failure or explantation without reimplantation: 27%

Efficacy assessed using the PGf-I
- Grade 1: 2%
- Grade 2: 14%
- Grade 3: 38%
- Grade 4: 19%
- Grade 5: 27%

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

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.