The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity

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Dual Ballon System + Diet + Exercise (DUO = 187 pts)

VS

Sham endoscopy + Diet + Exercise (DIET = 139 pts)

multicenter clinical study

SOARD 2015

Study objectives

Endpoints:

✓ Comparing %EWL between DUO and DIET groups at 24 weeks;
✓ Comparing the proportion of DUO pts achieving > 25% EWL at 24 weeks;
✓ Weight loss maintenance at 24-48 weeks follow-up;
✓ Impact on comorbidities and QoL;
✓ Safety profile's evaluation
✓ Accomodative symptoms assessment

Excess Weight Loss

Comparison of %EWL between DUO and DIET groups at 24 weeks

SOARD 2015

Complications

Early DBS retrieval: 15%*

*(7.7% after reduction of filling volume for short stature subjects)

Gastric Ulceration (discovered at retrieval procedure)

Before distal device tip modification

39% FREQUENCY (p<0.0001)

1.6 mm SIZE

After distal device tip modification (softer, smaller, smoother)

10% (p=0.0002)

0.8 mm SIZE

Adverse events

Insertion/retrieval procedure-related:

- Esophageal mucosal tear during retrieval = 1 (hemostatic suture)
- Cervical esophageal perforation during retrieval = 1 (antibiotic)
- Unsuccessful DBS insertion = 1

Non procedure-related:

- E-G junction bleeding ulcer = 1 (transfusion)
- Post-retrieval pneumonia = 1 (antibiotic)
- DBS deflation = 6% (2 early retrieval)
60 Patients
Mean initial BMI: 38.8 kg/m²
Mean implantation time: 12 min (range 8-25)
Mean treatment duration: 6.9 months

Complications
1 early removal for intolerance
1 early deflation without migration
1 gastric perforation
14 gastric ulcers (not clinically significant)

Weight loss outcomes

<table>
<thead>
<tr>
<th>Table 1: Weight changes after Dual balloon procedure (n=60)</th>
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<tbody>
<tr>
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<tr>
<td>Obesity grade</td>
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<tr>
<td>BMI 40-44 kg/m² (n=19)</td>
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<tr>
<td>BMI &gt; 44 kg/m² (n=21)</td>
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<tr>
<td>Gender</td>
</tr>
<tr>
<td>Male (n=49)</td>
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<tr>
<td>Female (n=11)</td>
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<tr>
<td>Age</td>
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<tr>
<td>&lt; 40 years (n=34)</td>
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<tr>
<td>&gt; 40 years (n=26)</td>
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