

Intra-gastric Balloon Intolerance: A Retrospective Review of 100 Patients Treated with Two Different Devices

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²Disclosures: ReShape Medical, Inc (Consultant), Apollo Endosurgery, Inc (Consultant)

Background

The *ReShape*[®] Dual Balloon and *Orbera*[®] intra-gastric balloons (IGBs) are safe and effective nonsurgical treatments for obesity introduced in 2015 in the United States. Accommodative symptoms post-implantation may occur, reducing patient satisfaction and leading in some cases to early removal. We report on the tolerability of IGBs in 100 patients (the first 50 *Orbera* and the first 50 *ReShape*) from our bariatric practice.

Methods

- ❖ Single-center, retrospective data collection
- ❖ HIPAA compliant data collection form
- ❖ Trained research staff used practice EMR
- ❖ Variables included:
 - Baseline characteristics
 - Occurrence, severity and duration of symptoms
 - Early retrievals secondary to GI intolerance
 - Weight loss
- ❖ Treatment intervals:
 - *Orbera*: August 2015 to Feb 2016
 - *ReShape*: December 2015 to March 2016

Devices

Orbera

- Single balloon 400-700cc



ReShape

- Dual balloon 750-900cc
- Anti-migration design



Results

- ❖ **Baseline Characteristics**
 - 88% female with mean baseline age 48.9 (range 24-76), weight 231 lbs (range 155-329) and BMI 37.4 (range 28.8-56.2).
 - No significant difference in baseline characteristics between two IGB groups.

Baseline	Orbera n = 50	ReShape n = 50	p
Age	49.5 ± 12.1	48.4 ± 9.1	0.59
Hgt	65.6 ± 3.7	66.1 ± 3.1	0.52
BaseWgt	227.7 ± 42.1	234.7 ± 40.8	0.40
BMI	37.0 ± 4.9	37.8 ± 6.1	0.48
EW	74.2 ± 32.4	79.3 ± 36.4	0.46
% female	84%	88%	0.77

Table 1. Baseline Characteristics

*3 subjects had two sequential balloons and were analyzed according to the balloon in place at the time.

Results

❖ Accommodative Symptoms

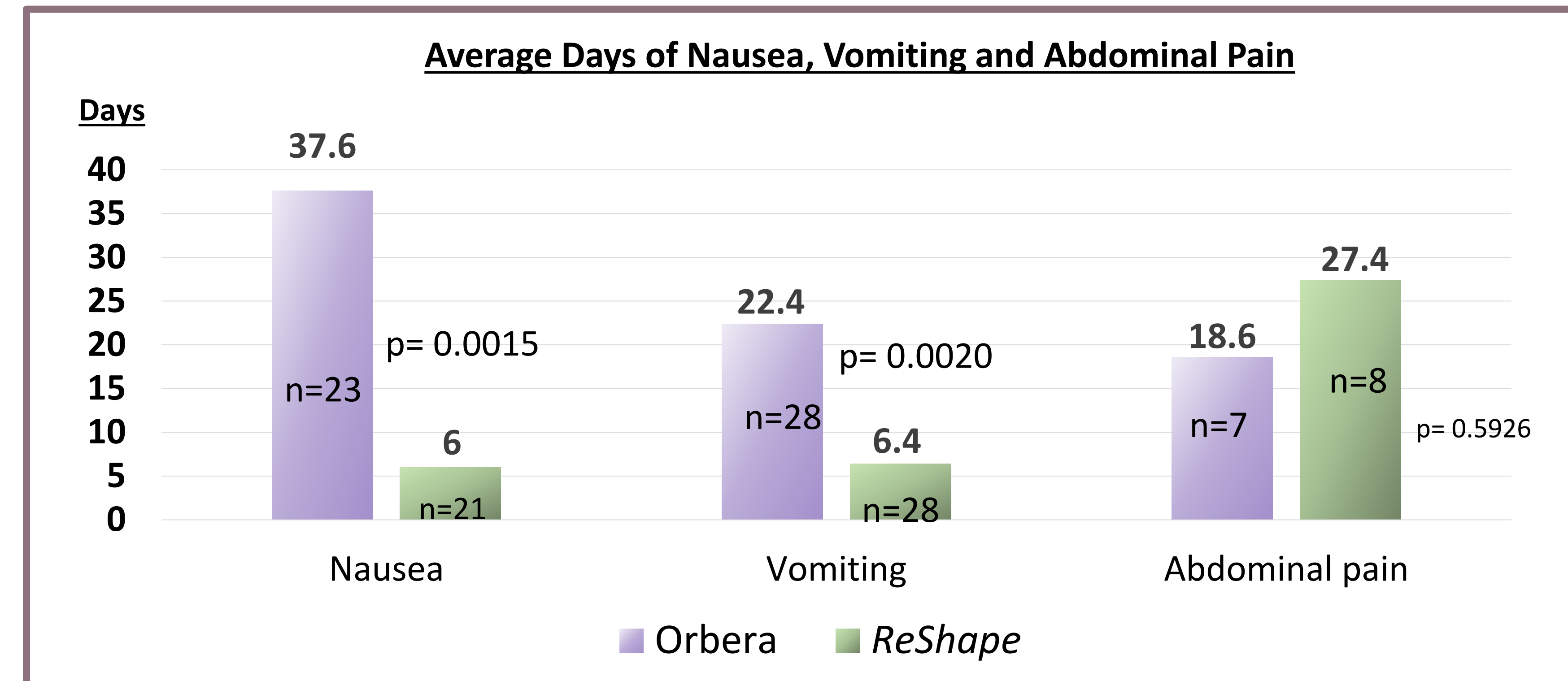
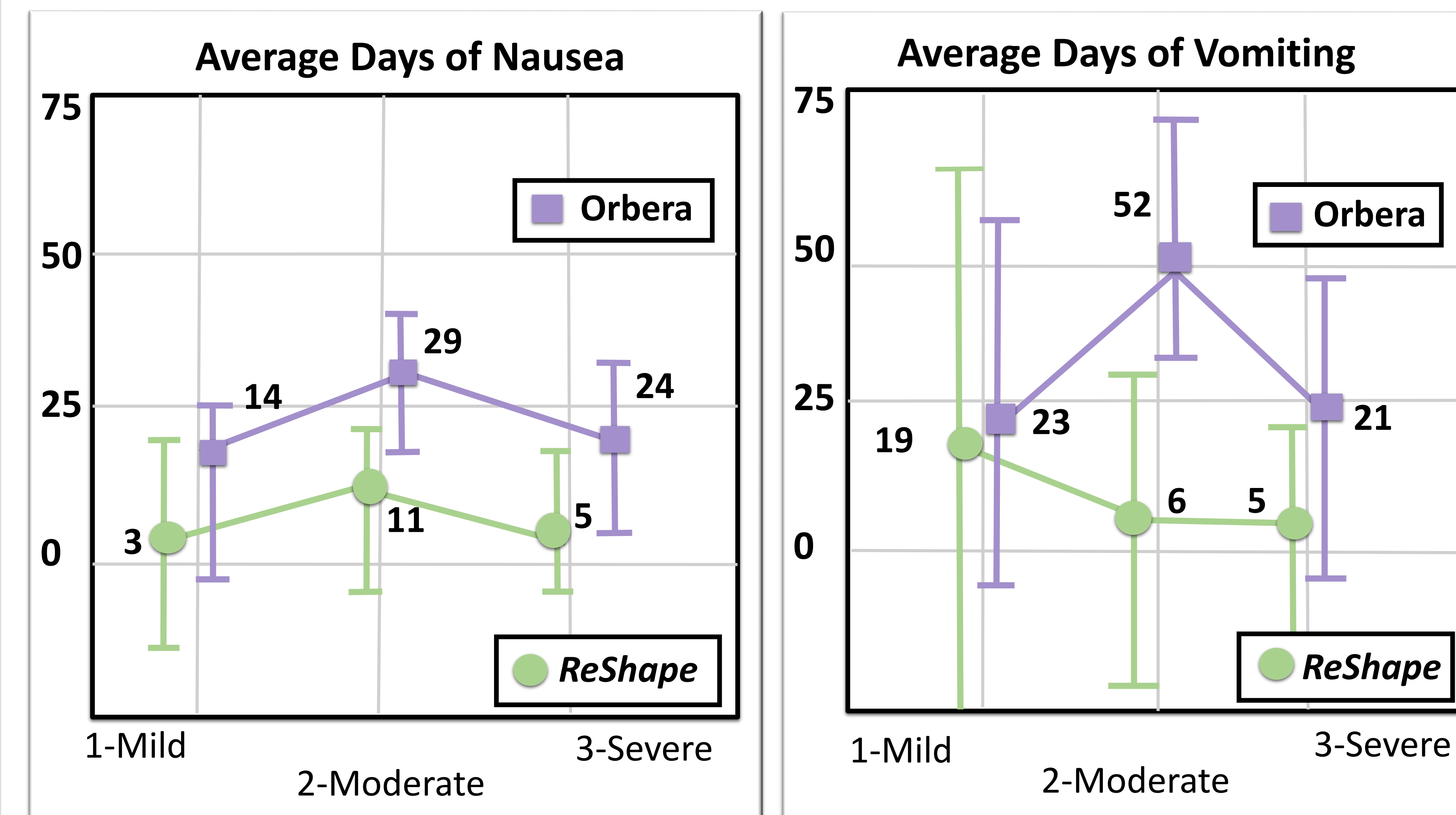


Figure 1. Duration of Accommodation



Figures 2a and 2b. Comparison of Accommodation Duration by Severity

The difference in duration across the measures of severity is also significant:

- *ReShape* balloons were associated with significantly shorter durations of nausea for all 3 severities (p=0.0077).
- *ReShape* balloons were associated with shorter durations of vomiting for all 3 severities that approached statistical significance (p=0.066).

Results

❖ Intolerance Retrievals

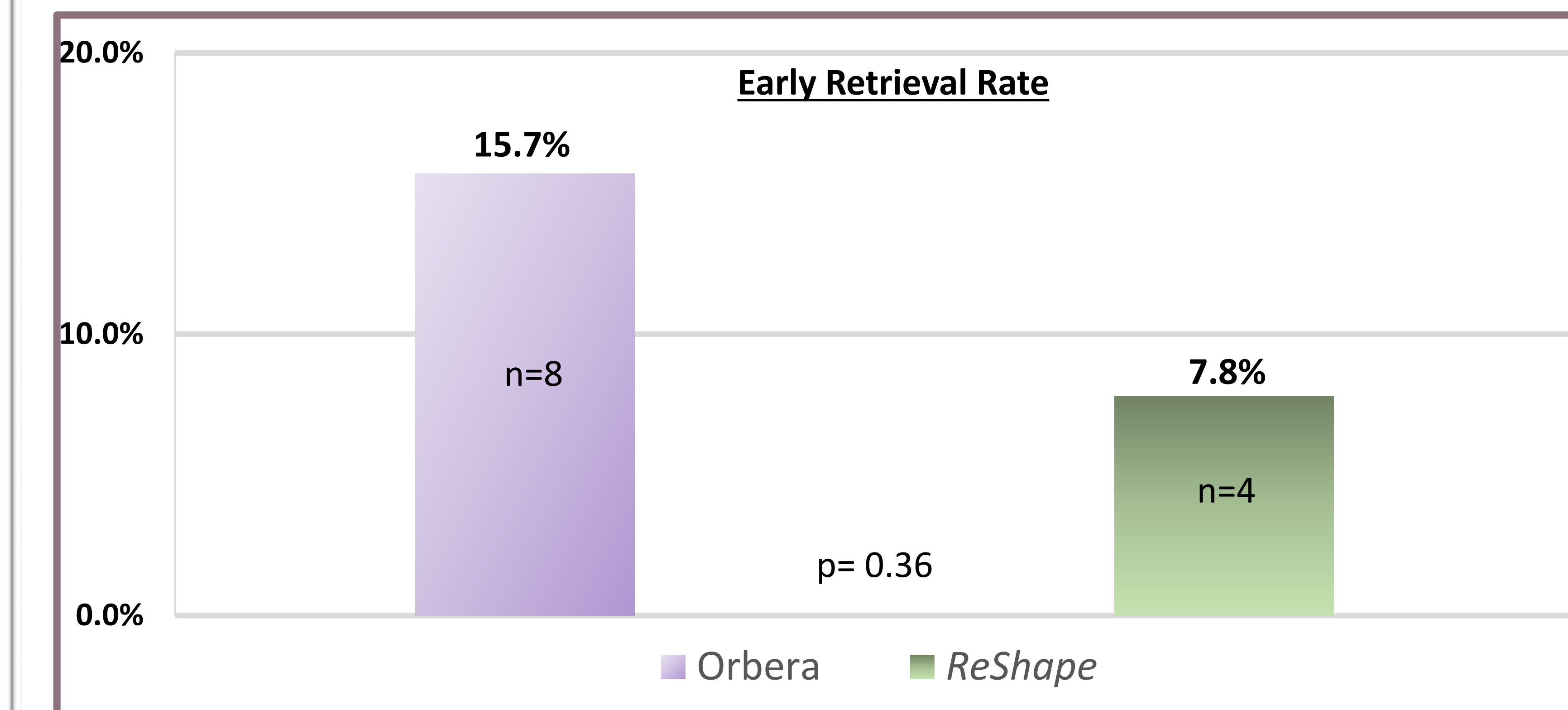


Figure 3. Early Retrievals for Intolerance

❖ Weight Loss

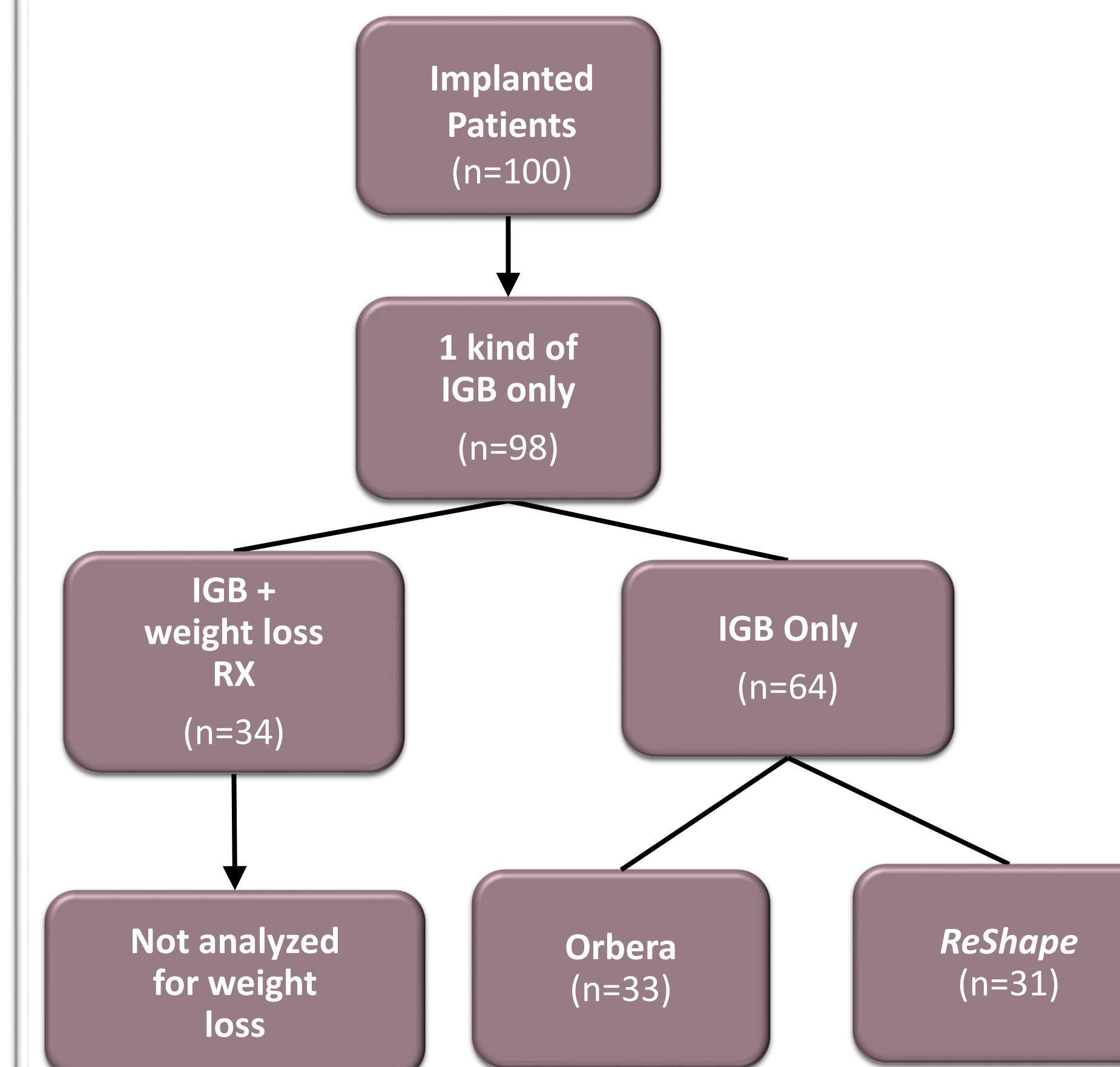


Figure 4. Weight Loss Analysis Consort Diagram

	Orbera n=33	ReShape n=31	p
Pounds	21.9 ± 13.7	23.4 ± 13.1	0.67
%TBWL	10.2 ± 6.6	10.0 ± 5.0	0.88
%EWL	39.4 ± 32.1	35.8 ± 21.8	0.60

Table 2. Weight Loss, IGB only Subjects

Conclusions

- ❖ Both IGBs are effective for weight loss in patients with obesity.
- ❖ *ReShape* patients had much shorter symptom durations for nausea and vomiting.
- ❖ Early retrievals due to intolerance were required twice as often in *Orbera* patients compared with *ReShape* patients.