Does use of the Standard Clamp® improve outcomes in patients undergoing laparoscopic sleeve gastrectomy?

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Introduction

- The Standard Clamp® (Standard Bariatrics, Inc.) is a surgical device that is designed to clamp the entire length of the stomach and serves as guide during Sleeve Gastrectomy (SG)
- The purpose of this device is to develop a standard, anatomy-based approach to make SG more consistent.

Hypothesis

- By reducing variability and following more ideal anatomic parameters, we hypothesize that use of the Standard Clamp® for laparoscopic sleeve gastrectomy will lead to better patient outcomes.
- Outcomes evaluated were post-operative weight loss, reflux symptoms, leak, and conversion to gastric bypass.

Methods

- Retrospective Chart Review evaluating a sample of patients who underwent SG at a single comprehensive weight loss center from January 2013 to February 2021
- Excluded patients whose procedure was aborted intraoperatively (N=2), less than age 18 or greater than age 89
- 118 Standard Clamp (SC) patients and 75 No Clamp (NC) patients were included in analysis
- Data Collected: Age, Gender, Preoperative weight and BMI, Presence of reflux symptoms pre and post-operatively, postoperative weight loss at 3, 6, 9, 12, 18, 24, and 36 months, anastomotic leak, conversion to gastric bypass

Characteristics	SC (N = 118)	NC (N = 75)	p value
Age, mean (SD), y	43.2 (12.6)	40.9 (13.1)	0.98
Female, No. (%)	96 (81.4)	66 (88.0)	0.22
Weight, mean (SD), lbs.	290.7 (63.1)	289.5 (72.4)	0.57
BMI, mean (SD)	47.4 (8.1)	48.0 (10.7)	0.98
Reflux, No. (%)	61 (51.7)	31 (41.3)	0.16

Table 1. Baseline characteristics

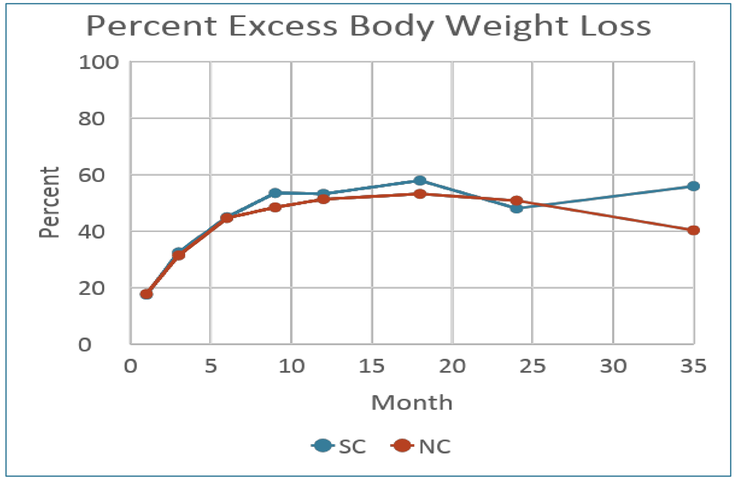


Figure 1. Percent excess body weight loss at 3, 6, 9, 12, 18, 24, and 36 months follow up. Differences between the two groups were not statistically significant except at 36 months (p = 0.04)



Figure 2. The Standard Clamp® surgical device (Standard Bariatrics, Inc)

Results

- Patients in the SC and control groups were similar with respect to age, sex, and preoperative BMI
- Presence of reflux of both pre and post-operatively was not statistically significant between the two groups
- Development of de novo reflux post-operatively was similar between the two groups.
- There was a trend to resolution of reflux post-operatively in the SC group compared to the NC group, though this was not statistically significant.
- No anastomotic leak was reported in either group.
- Two patients in the control group required revision to gastric bypass for post-operative reflux while none in the SC group did.
- There was no statistically significant difference in post-operative weight loss out to two years post-operatively.
- Difference of excess body weight loss at 36 months did show statistical significance in favor of the SC group, but this is limited by poor follow-up among our cohort.

Outcome	SC	NC	p value
Preoperative Reflux	61/118 (51.7%)	31/118 (41.3%)	0.16
Postoperative Reflux	42/118 (35.6%)	29/75 (38.7%)	0.76
De Novo Reflux	12/57 (21.1%)	10/44 (22.7%)	0.84
Reflux Resolved	31/61 (50.8%)	12/31 (38.7%)	0.27

Table 2. Comparison of reflux data between Standard Clamp® and No Clamp groups.

Conclusions

- Our study suggests that the use of the Standard Clamp® in laparoscopic sleeve gastrectomy results in similar outcomes and non-inferior when compared to the standard technique.
- There is a trend towards less de novo reflux and greater resolution of premorbid reflux in the SC group, although not statistically significant.
- A greater sample size will be necessary to draw definitive conclusions.

References

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