

# Modeling the effects of laparoscopic, Roux-en-Y, and non-surgical treatment on weight loss

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## ABSTRACT

- Forms of treatment for severe obesity fall into two categories: non-surgical treatment (i.e. behavioral therapy) and surgical treatment—the most common being laparoscopic gastric banding and Roux-en-Y gastric bypass.
- A RCT was conducted to test the hypothesis that surgical treatment promotes greater weight loss overtime compared to non-surgical treatment.
- Over a 24 month follow-up period, participants randomized to receive surgical treatment experienced significant decreases in BMI compared to those in the non-surgical arm.
- No difference was observed in BMI decrease between laparoscopic and Roux-en-Y treatment groups.

## OBJECTIVE

To assess and compare the effectiveness of surgical weight loss treatments (laparoscopic and Roux-en-Y) to a non-surgical control treatment over a 24 month period.

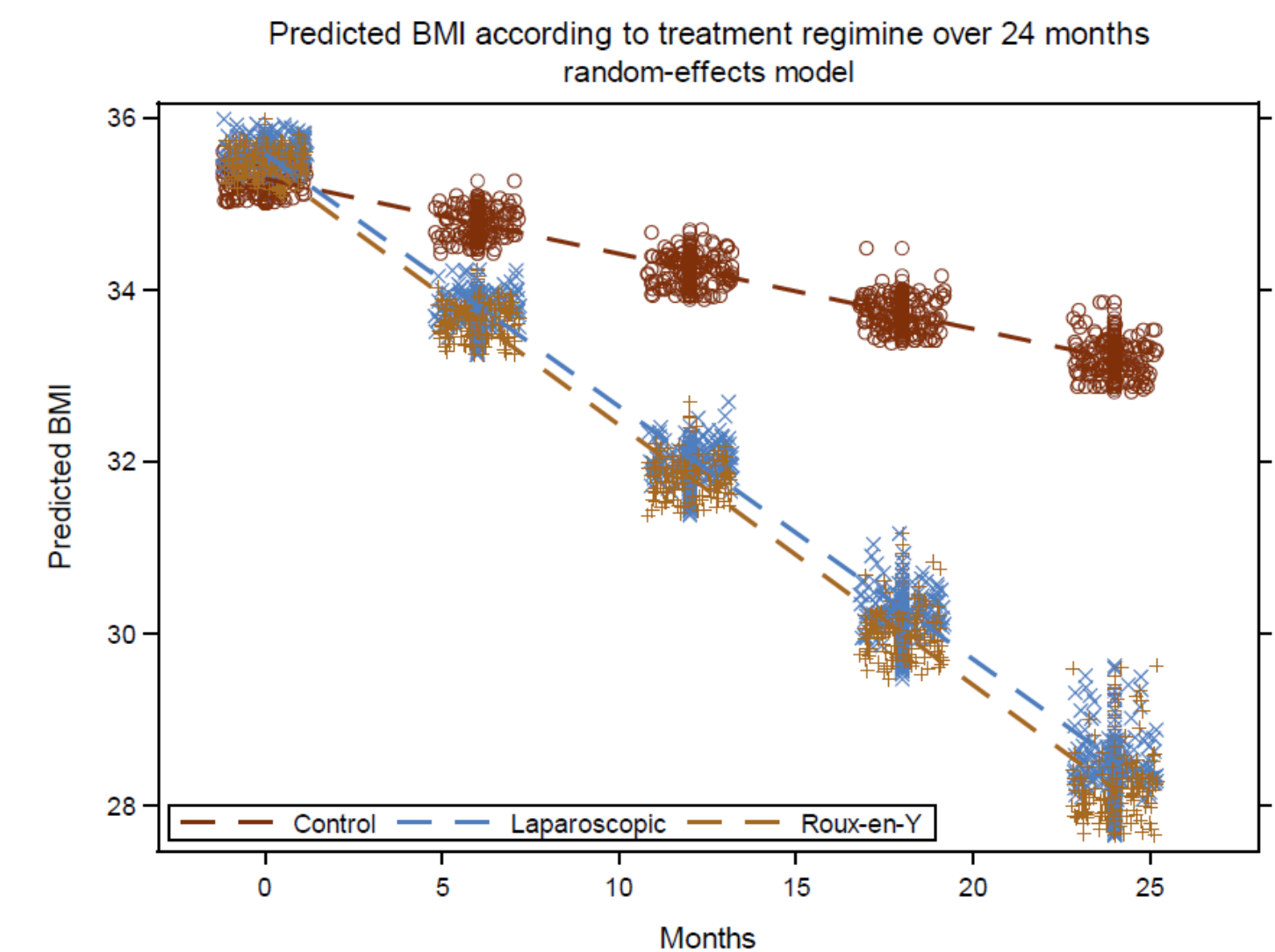
## METHOD

- 450 patients were randomized to receive a non-surgical treatment (control), laparoscopic adjustable gastric banding, or Roux-en-Y gastric bypass.
- Height and weight were measured at baseline, 6, 12, 18, and 24 months after randomization and were then converted into BMI. The number of alcoholic drinks consumed per week was also collected and diabetes and hypertension status was ascertained at baseline.
- Paired t-tests were used to assess overall change among each treatment.
- Two regression models were built: 1). Only analyzing the difference in BMI among treatments at the 24 month follow-up period 2). A mixed-effects regression model with a random intercept that accounted for all 5 follow-up periods.
- An interaction between treatment and follow-up month was included in the mixed effects model.
- Full models were first fitted that adjusted for diabetic status, hypertension status, number of drinks per week, and gender. If effects were not significant and were concluded to not confound the relationship between treatment and BMI, they were removed from the model.
- Assumptions for linear regression were assessed for both models
- Post-hoc analysis using Tukey-Kramer adjustment were conducted to assess differences among treatment groups when the main effect was significant.

## RESULTS

Type III analysis for effects in models

Model	Effect	F-value	Pr > F
Last Follow-up	Treatment	252.82	<.0001
	Gender	0.81	0.3676
	Diabetes	1.47	0.2258
	Hypertension	0.83	0.3632
	Number of drinks	0.45	0.5025
Mixed Effects	Treatment	0.59	0.5539
	Gender	2.84	0.0919
	Diabetes	0.10	0.7523
	Hypertension	0.94	0.3312
	Number of drinks	6.43	0.0113
	Month of follow-up	1317.24	<.0001
	Month, treatment interaction	136.81	<.0001



### Descriptive analysis:

- Each treatment arm had a total of 150 patients
- The sample consisted of 220 females and 230 males
- 314 patients had diabetes and 173 patients had a hypertension at baseline
- At baseline, among the control group the average BMI was 37.70, among the Roux-en-Y group the average BMI was 37.33, among the Laparoscopic group the average BMI was 37.58.
- Investigation of missing values showed that observations for BMI and # number of drinks were always missing together; the most missing values occur at the 6 month follow-up period and decreased over time.

### Overall change:

- Each treatment group experienced a significant decrease in BMI over 24 months
- Control:  $t = 14.58$ ,  $df = 136$ ,  $p < 0.0001$
- Laparoscopic:  $t = 35.74$ ,  $df = 135$ ,  $p < 0.0001$
- Roux-en-Y:  $t = 39.38$ ,  $df = 137$ ,  $p < 0.0001$

### Model (1):

- Examining BMI at 24 months revealed a significant main effect of treatment group after adjustment for all possible covariates,  $F = 252.82$ ,  $p < 0.0001$ .
  - Post-hoc analysis in a treatment only model revealed significant differences between the control group and laparoscopic group ( $p < 0.0001$ ) and between the control group and the Roux-en-Y group ( $p < 0.0001$ ); no difference was observed between the laparoscopic and Roux-en-Y groups ( $p = 0.15$ ).

### Model (2):

- Examining the change in BMI over 24 months revealed a significant interaction between time after randomization and treatment ( $F = 136.81$ ,  $p < 0.0001$ ) and a significant main effect of drink consumption ( $F = 6.43$ ,  $p = 0.01$ ).
  - Post-hoc analysis using the reduced model revealed significant differences between the Control group and the surgery groups at 6, 12, 18, and 24 months (all  $p < 0.0001$ ). No difference was observed between the laparoscopic and Roux-en-Y group at any month (see graph).
  - Among individuals with similar characteristics, on average, for every drink increase in the weekly number of alcoholic drinks consumed in a week BMI increased by 0.03.

Number of observations across treatment, diabetic status, and hypertensive status at baseline

	Female						Male						Total					
	Diabetes			Hypertension			Diabetes			Hypertension			Diabetes			Hypertension		
	Yes	No	Total	Yes	No	Total	Yes	No	Total	Yes	No	Total	Yes	No	Total	Yes	No	Total
Control	53	18	71	30	41	71	60	19	79	38	41	79	113	37	150	68	82	150
Roux-en-Y	56	24	80	27	53	80	47	23	70	22	48	70	103	47	150	49	101	150
Laparoscopic	43	26	69	31	38	69	55	26	81	25	56	81	98	52	150	56	94	150
Total	152	68	220	88	132	220	162	68	230	85	145	230	314	136	450	173	277	450

## CONCLUSION

**Patients in all 3 treatments experienced significant decreases in BMI. Surgical treatment, however, promotes greater weight loss over 24 months compared to non-surgical treatment.**

- On average, among randomized to receive laparoscopic treatment had a BMI of 29.93 at 24 months (compared to 37.58 at baseline) and patients randomized to receive Roux-en-Y surgery had a BMI of 29.53 at 24 months (compared to 37.33 at baseline)
- No significant difference in BMI was observed between patients randomized to laparoscopic and Roux-en-Y treatment but both surgery groups had a significantly lower BMI at 24 months compared to the control group.
- Among those with a similar propensity, patients randomized to receive laparoscopic treatment experienced, on average, a 0.2094 greater decrease in BMI per month compared to the control group, adjusting for the number of drinks consumed per week, while patients randomized to receive Roux-en-Y treatment experienced, on average, a 0.2225 greater decrease in BMI per month compared to the control group, adjusting for the number of drinks consumed per week.
- The effect of alcohol, as shown in the mixed-effects model indicates drug misuse/dependency might offset positive health outcomes associated with weight loss treatment.
- Future research should focus on weight loss past the 24 month follow-up period and examine if there is a rebound in weight gain.
- Based on these analysis, surgical treatment should be considered the ideal for medically urgent weight loss.

Mean and standard deviation of BMI across treatment, diabetic status, and hypertensive status at monthly follow-up

		Diabetes				Hypertension				Total	
		Yes		No		Yes		No		Total	
		Mean	Std	Mean	Std	Mean	Std	Mean	Std	Mean	Std
Control	0	37.55	2.16	38.16	2.20	37.46	2.20	37.90	2.15	37.70	2.18
	6	31.36	1.80	31.98	1.72	31.39	1.73	31.65	1.86	31.53	1.80
	12	32.76	2.11	33.07	2.03	32.96	2.13	32.72	2.05	32.83	2.08
	18	33.57	2.29	33.78	1.77	33.48	2.34	33.73	2.03	33.62	2.17
	24	34.66	2.32	34.54	1.59	34.45	2.30	34.78	2.02	34.63	2.15
Roux-en-Y	0	37.21	2.16	37.59	1.95	37.21	1.90	37.39	2.20	37.33	2.10
	6	31.51	2.17	31.68	1.88	31.31	1.95	31.68	2.13	31.56	2.08
	12	30.65	1.79	30.51	1.82	30.37	1.62	30.72	1.87	30.61	1.79
	18	29.52	1.95	29.60	2.21	29.34	1.96	29.66	2.05	29.55	2.02
	24	29.63	2.03	29.32	1.92	29.36	1.95	29.61	2.02	29.53	1.99
Laparoscopic	0	37.78	2.08	37.20	2.05	37.76	2.15	37.47	2.04	37.58	2.08
	6	31.82	2.03	31.13	2.26	31.85	2.19	31.41	2.10	31.58	2.13
	12	30.93	1.91	30.27	1.99	30.87	2.06	30.58	1.90	30.69	1.96
	18	29.78	1.70	29.86	1.95	29.76	1.49	29.84	1.96	29.81	1.79
	24	30.04	1.76	29.73	2.19	29.97	2.07	29.91	1.84	29.93	1.92