Comparing Weight Loss Outcomes of Bariatric Surgery and Non-Surgical Therapy for Obesity: A Randomized Clinical Trial

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ABSTRACT

Obesity is a significant public health concern that affects millions of people worldwide, so effective weight loss treatments are necessary. The two main treatments for obesity are non-surgical therapy and bariatric surgery. The study intended to assess the effectiveness of the two most commonly used bariatric surgeries, Laparoscopic adjustable gastric banding (LAGB) and Roux-en-Y gastric bypass (RYGB), in comparison to non-surgical therapy in treating obesity.

This study randomized 450 participants to receive non-surgical therapy, LAGB, or RYGB, and measured their BMI at different time points over a 24-month period. The analysis showed that both LAGB and RYGB were effective in reducing BMI, with RYGB being potentially more effective than LAGB. The GEE approach indicates that treatment type, the time elapsed since treatment and low alcohol consumption were associated with lower BMI. Overall, the study supports the effectiveness of bariatric surgery in treating obesity.

OBJECTIVE

Obesity is associated with a range of health problems, including type 2 diabetes, hypertension, cardiovascular disease, and mortality. Two main treatments for obesity are non-surgical therapy and bariatric surgery. This study aimed to assess the effectiveness of the most commonly used bariatric surgery, Laparoscopic adjustable gastric banding (LAGB) and Roux-en-Y gastric bypass (RYGB), compared to non-surgical therapy in achieving weight loss among eligible patients.

METHODS

Randomized Clinical Trial: A randomized clinical trial was conducted with 450 eligible patients randomly allocated to receive non-surgical therapy (TRT Control), LAGB (TRT LAGB), or RYGB (TRT RYGB). The patients' height and weight were measured at baseline and 6, 12, 18, and 24 months after randomization and converted into BMI, while other factors such as the Compulsive Behaviors Questionnaire (CBQ) and alcohol consumption were also recorded at each visit.

Cross-sectional regression model using the last measurements: First, consider the analysis of the association between BMI measured in the 24th month and different types of treatments, adjusted for gender, Diabetes status at baseline, Hypertension status at baseline, and the number of alcoholic drinks consumed per week in the 24th month. Then a stepwise model selection procedure was conducted to choose the most fitted model. Corrected BIC is used as an optimization value for stepwise selection.

Generalized estimating equation (GEE) approach: A GEE approach was used to investigate the association over time. The final model was selected by comparing QIC values (the model fits better when QIC is smaller).

RESULTS

Descriptive analysis

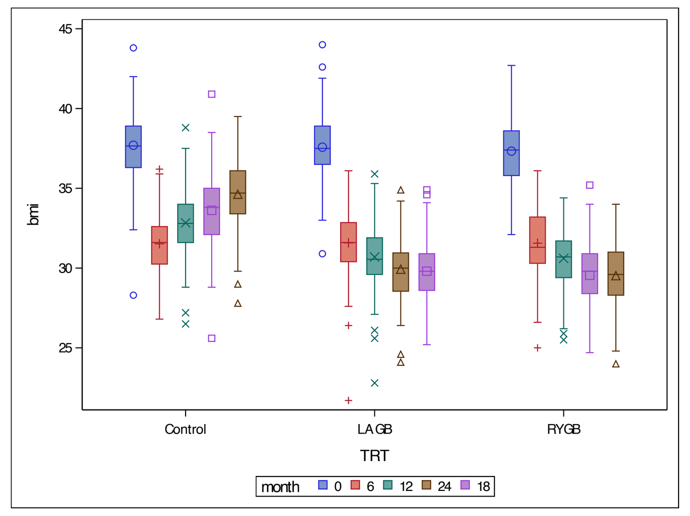

Fig. 1 Changes of BMI over time by treatment

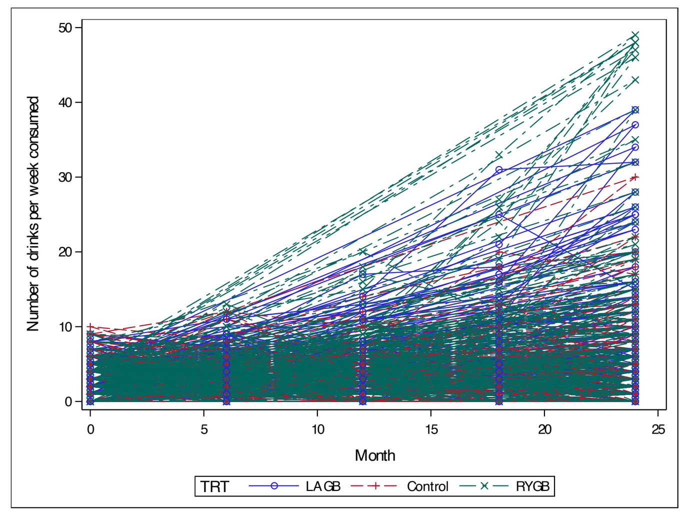

Fig. 2 Spaghetti plot for drinks by treatment

In the cohort of 450 participants, 230 were males and 220 were females. At baseline, 69.78% of the entire cohort had Diabetes and 38.44% had Hypertension. Among male participants, 70.43% had Diabetes and 36.96% had Hypertension at baseline, while among female participants, 69.09% had Diabetes and 40.00% had Hypertension at baseline.

Participants in different treatment groups have similar proportions of gender (p=.4001), Diabetes status (p=.1582), and Hypertension status (p=. .0742), indicating the effectiveness of randomization.

In the 24th month, there were 411 observations on BMI and the number of alcoholic drinks consumed, with 39 missing values. The BMI was right-skewed with a range of 24 to 39.5 and a mean of 31.36 and a standard deviation of 3.07. The number of alcoholic drinks consumed per week in the 24th month was also right-skewed, ranging from 0 to 49, with a mean of 6.77 and a standard deviation of 8.76.

According to Fig 1, the mean BMI decreased in all three groups during the first 6 months but started to increase from the 7th month to the 24th month in the control group, while it continued to decrease in the LAGB and RYGB groups. The mean BMI of the RYGB group from the 6th month to the 24th month was lower than the corresponding mean BMI in the LAGB group, suggesting that RYGB may be more effective than LAGB for those patients. According to Fig 2, the variation of alcoholic drinks consumed increases greatly over time.

Cross-sectional regression model using the last measurements

The corrected Bayesian Information Criterion (BIC) was used to optimize the stepwise selection procedure. Based on Table 1, the model suggested that bmi4 is predicted by trt. This model is statistically significant compared to the null model (p<.0001). 56.9% of the variation in BMI measured in the 24th month is explained by the difference in treatment groups. On average, individuals who received LAGB or RYGB treatment had a lower BMI in the 24th month compared to the control group. Furthermore, individuals who received RYGB treatment had a lower BMI compared to those who received LAGB treatment.

Table. 1 Estimated cross-sectional regression model

Parameter		Estimate	Standard Error	t Value	Pr > |t|	95% Confidence Limits	
Intercept		34.62627737	0.17290600	200.26	<.0001	34.28637957	34.96617518
TRT	LAGB	-4.69686561	0.24497509	-19.17	<.0001	-5.17843650	-4.21529471
TRT	RYGB	-5.10019042	0.24408262	-20.90	<.0001	-5.58000690	-4.62037393
TRT	Control	0.00000000	.	.	.	.	.

Table. 2 Analysis Of GEE Parameter Estimates

Parameter		Estimate	Standard Error	95% Confidence Limits		Z	Pr > |Z|
Intercept		38.6851	0.2501	38.1948	39.1753	154.66	<.0001
TRT	LAGB	-4.0300	0.3576	-4.7309	-3.3291	-11.27	<.0001
TRT	RYGB	-4.3048	0.4051	-5.0989	-3.5108	-10.63	<.0001
TRT	Control	0.0000	0.0000	0.0000	0.0000	.	.
drink		0.0341	0.0139	0.0068	0.0613	2.45	0.0143
month		-0.3369	0.0077	-0.3521	-0.3218	-43.59	<.0001

Generalized estimating equation (GEE) approach

After conducting model selection using QIC as the optimization criterion, the suggested model is BMI ~ TRT + DRINK + MONTH (Table 2). This model has a smaller QIC value (2005.7) compared to the full model (2026.0), indicating a better fit. The regression estimates show that people who received LAGB or RYGB treatment had, on average, a lower BMI than those in the control group, after adjusting for measured time (in months) and the number of alcoholic drinks per week consumed at that time.

Overall, the suggested model provides a more comprehensive understanding of the factors associated with BMI in this study population. The results suggested that BMI was lower for individuals who received LAGB or RYGB treatment, had later measured time in months, and had a low number of alcoholic drinks per week consumed. However, further research is needed to investigate the potential effects that were not captured by this model.

DISCUSSION

The results indicate that the cohort of 450 participants was well randomized, with similar proportions of gender, diabetes status, and hypertension status in different treatment groups. The results from descriptive analysis and the cross-sectional regression model supported the effectiveness of both treatments in reducing BMI. Furthermore, RYGB may be more effective than LAGB in reducing BMI in this population. The GEE approach provided a more comprehensive understanding of factors associated with BMI, suggesting that LAGB or RYGB treatment, later measured time in months, and low alcohol consumption were associated with lower BMI. These findings reinforce the effectiveness of LAGB and RYGB treatments.

Included a relatively large sample size of 450 participants, the statistical power and reliability of the findings of this study should be enhanced. The study employed a randomized controlled trial design, which is considered the gold standard for evaluating the effectiveness of medical interventions. This ensures that the treatment groups were comparable at baseline and minimizes the potential for confounding factors to influence the results. Also, the study followed up the participants for 24 months, which allowed for the evaluation of the long-term effects of the treatment interventions. Employed a range of statistical techniques, including descriptive statistics, cross-sectional regression, and generalized estimating equations, the study can provide a comprehensive analysis of the data.

However, there are still several limitations to this study. For example, the missing data for BMI and the number of alcoholic drinks consumed per week records at some time may limit the validity of the statistical analysis and introduce bias into the results. Additionally, some of the self-reported data, such as the number of alcoholic drinks consumed per week, may be subject to reporting bias. Participants may underreport or overreport their alcohol consumption, which could affect the results. Furthermore, there may be unmeasured confounding variables that could affect the results. For example, factors such as socioeconomic status, dietary habits, and physical activity levels could influence BMI and may differ between the treatment groups.

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