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Duodenal Exclusion in the Regulation of Glycemia in Type 2 Diabetic Patients Submitted to Gastrectomy with Roux-en-Y by Gastric Cancer: Cohort Study

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Abbreviations

Roux-en-Y gastric bypass surgery (RYGB)

Type 2 Diabetes Mellitus (T2DM)

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Disclosures

None of the authors have a conflict of interest

Transcript Profiling[2] [3]

This study did not have microarray data.

Writing Assistance

This paper did not have any writing assistance.

Author Contributions

CRediT authorship contribution statement

Maurice Franciss: design of the study, data Curation, analisis and interpretation, Writing - Review & Editing

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Marcus Ramos: data curation and collection, writing - Review & Editing

Bruno Zilberstein: conception, design of the study, Project administration, Validation, Writing - Review & Editing

All the authors approved the final version of the manuscript

Data Sharing

Research data (full-text protocol, database, informed consent, and statistical analysis plan) will be available with as few restrictions as possible. Requests should be sent to the corresponding author.

Duodenal Exclusion in the Regulation of Glycemia in Type 2 Diabetic Patients Submitted to Gastrectomy with Roux-en-Y by Gastric Cancer: Cohort Study

Abstract

Background: The effect of the duodenal exclusion in glycemic regulation has yet to be defined. Individuals with type 2 Diabetes Mellitus (T2DM) operated for other reasons than obesity, represent an adequate model to analyze clinical outcomes of duodenal exclusion.

Objective: To analyze the changes in glycemia and pharmacotherapy for T2DM in patients undergoing gastrectomy with Roux-in-Y derivation for gastric cancer.

Methods: An observational study was conducted in 2018 on patients who were submitted to surgery from 2001 to 2016. Medical records of 129 patients' cohort operated in two public hospitals were analyzed retrospectively before the surgery (T0) and one year after (T1). The research protocol was approved by the ethics committee. The final sample was mainly represented by women (50.5%) with a mean age of 65.5 years, and a mean body mass index of 26.5 kg/m^2 SD 4.30.

Results: One year later, mean glucose levels of the entire sample decreased (p=0.046), but 70% of patients with glycemia> 100 at T0, remained with the same value in T1. Glycated hemoglobin had no significant change (p=0.988). Regarding the pharmacotherapy for T2DM, 60.7% of the sample had no change. However, 6.7% had discontinuation of the medication with the improvement of T2DM. The multivariate model by classification and decision tree method (CART) found as predictors of change in DM2 medication, age (<62.5 years) and a body mass index (> 30.2 kg/m^2) with a predictive value of 71.4%.

Conclusion: There was no improvement of glycemia and pharmacotherapy in patients with T2DM who underwent gastrectomy with Roux-en-Y reconstruction, with a body mass index below 30 kg/m^2

Key Words: blood glucose; diabetes mellitus; stomach neoplasms; bariatric surgery; gastrectomy; Roux-en-Y anastomosis.

Introduction

Obesity is an endemic of the 21st century and Type 2 Diabetes Mellitus (T2DM) is one of its most serious and costly consequences (ref. 1) However, the world consensus in standardization of bariatric metabolic procedures stated in 2019 that those procedures are a viable long-term treatment option for T2DM. Techniques as Roux-en-Y Gastrectomy have been shown to be effective in the treatment of T2DM, suggesting that mechanisms in addition to weight loss are involved (ref. 2,3,4). Several studies have attributed the improvement of glycemic regulation to the secretion of incretins in the distal intestine, due to the stimulation of the earlier passage of food by this region (ref. 5,6). Another hypothesis confers the result to the exclusion of the proximal intestine (ref. 7). A meta-analysis done in 2017 concluded that patients with T2D treated by surgery compared to non-surgical treatment had a better remission rate and a lower risk of microvascular and macrovascular disease and mortality (ref. 8). Individuals with T2DM operated for reasons other than obesity, represent an adequate model to analyze the (ref. 9) clinical outcomes of duodenal exclusion (ref. 10). Therefore, the objective of this study was to analyze the glycemia changes in diabetic patients submitted to total or subtotal gastrectomy with Roux-in-Y derivation for gastric cancer.

Method

An observational, longitudinal, analytical cohort study with a retrospective approach following the STROBE guidelines (ref. 11) was developed in two large public health institutions with a high complexity level of attention after approval in the University of São Paulo Faculty of Medicine ethics committee No. 1.486.299.

Both institutions are units of a teaching complex of hospitals with approximately 2200 beds in São Paulo, Brazil. The first unit corresponded to a general hospital where the digestive system surgery team attended the population focus of this study; the second unit is an oncology-specialized hospital where the gastric oncology team treated patients with gastric cancer and diabetes. All patients were followed up by other specialties, such as Oncology, Endocrinology, Neurology, Nursing, and Physical Therapist, among others.

The inclusion criteria were being adult, having the diagnosis of T2DM by glycated hemoglobin and fasting glucose, and having been submitted to gastrectomy for gastric cancer treatment.

The physical and electronic charts concerning demographics (sex, age in years) and clinical variables (comorbidities, Body Mass Index in kg/m2, fasting glycemia in mg/dL, glycated hemoglobin in %, and medication use identifying the type and the doses) were checked before surgery (T0) and compared one year after (T1). The sample consisted of 129 patients over 18 years of age, diagnosed with T2DM and Gastric Adenocarcinoma, who underwent gastrectomy with Roux-en-Y Reconstruction. Data collection was performed in 2018.

The primary outcomes were changes in weight, BMI, fasting glycemia, glycated hemoglobin, and medications from T0 to T1.

Twenty-six patients were excluded due to lack of follow-up or death before one year of postoperative; the analysis sample (n=103) was represented by women 50.5% (n=52) and 49.5% men (n=51), with a mean age of 65.5 years (SD=9.57; 41-89 years). The distribution of the body mass index was 25 to 30 kg/m^{2}in 44.7% (n=46), below 25 kg/m^{2}in 38.8% (n=40), and greater than 30 kg/m^{2}in 16.5 % (n=17). Subtotal gastrectomy was performed in 79.6% (n=82) of the patients (Table 1), and total gastrectomy in 20,4% (n=21). Patients were submitted to surgery between 2001 and 2016, with 71% (n=73) being submitted to surgery after 2010.

Statistical analysis used central tendency measures, Student's t-test, and the Classification and Regression Tree model (CART) (ref. 12) to explore associated variables to the change in T2DM pharmacotherapy which considers the possible presence of confounding variables correlated to the primary outcome and the independent predictors, as an effort to control bias. Statistical results with $p<0.05$ were considered significant.

Results

After one year of the surgery, mean glucose levels decreased from 147.6 mg/dL (T0) to 134 mg/dL (T1) (p=0.046) (Figure 2), and 70% of patients with glycemia> 100 at T0, remained with the same value in T1. Glycated hemoglobin had no significant change (7.5% in T0 vs. 7.0% in T1, p=0.988). The mean body mass index decreased from 26.5 kg/m^2(T0) to 24.3 kg/m^2 (T1) ($p <0.001$) (Figure 1). After one year, 6.7% (n=6) had discontinuation of the medication with the improvement of T2DM, and 11.2% (n=10) decreased the hypoglycemic medication, while in 60.7% (n=54) had no change, and in 21.4% (n=19) it worsened (Figure 3). Patients with a body mass index between 30-35 kg/m^{2}had the best responses regarding the normalization of glycemic levels. The logistic regression model showed as predictors of change in medication the following

variables: age (<62.5 years) and body mass index (> 30.2 kg/m^2) with a predictive value of 71.4% (Figure 3).

Discussion

One of the least understood mechanisms that need to be better clarified is the action of foregut exclusion in bariatric and/or metabolic surgery in T2DM. The pathophysiology of the resolution of T2DM in these surgical interventions in patients with or without obesity is also unclear since, in all procedures for this purpose, there is an improvement in T2DM to a greater or lesser extent.

Considering patients with a body mass index <25 kg/m^{2}and T2DM, it is desirable to maintain transit of the proximal intestine because it is where the absorption of nutrients occurs. Its preservation would lead to a better quality of life and a reduction in long-term nutritional complications since they do not require more significant weight loss, but only glycemic control and weight maintenance are required; for this reason, the analysis of the real importance of the exclusion of the proximal intestine in metabolic surgery as a treatment of T2DM in this type of patients is relevant.

Bariatric surgery, which, in all its versions, causes a decrease in the gastric chamber, always induces a lower food intake, which causes significant weight loss and improves comorbidities, especially DM2, in people with obesity (ref. 13). This assertion was partially evidenced in this study because, although the 8% decrease in the mean body mass index in the total sample was significant, with a greater effect of the total vs. subtotal gastrectomy, this significance was not maintained when the change in body mass index was analyzed among groups of patients with a body mass index below or above 30 kg/m^2 at baseline. This phenomenon

can be explained by the treatment focus that receives cancer, diabetes mellitus and obesity in patients with the three diseases (ref. 14), compatible with the profile of patients considered in this study. In this case, the treatment aims to improve the general state of the patient before the cancer treatment (chemotherapy and radiotherapy), which includes maintenance of the weight and the ingestion of a hyperproteic diet.

Distal Intestine Theory has a strong foundation in the literature and is known to be one of the fundamental mechanisms for the stimulation of pancreatic β cells. Already the theory of exclusion of the proximal intestine is still much discussed. In view of these facts, in this study, we sought to analyze patients who had undergone a duodenal exclusion technique and who had T2DM, thus seeking to contribute to the understanding of the Proximal Intestine Theory.

Recently, Huh et al. (2018) have shown, in an experimental study with insulin-resistant Sprague-Dawley rats submitted to three types of Gastrojejunal Derivation in Roux-en-Y, conventional (5% gastric new camera, 15 mm food loop and 40 mm biliopancreatic loop), (5%, 8 mm and 4 mm) and a greater gastric background (30%, 8 cm, 4 cm), which only conventional surgery with exclusion of 15 cm of the proximal intestine favored a glycemic improvement with a decrease in GIP53 (ref. 15).

In the present study, it was not possible to directly analyze the role of GIP, but it is assumed as a present variable, since all patients were submitted to duodenal exclusion and, in some cases, total gastrectomy with gastric fundus ablation, responsible for the secretion of ghrelin, the hunger hormone.

Analyzing the results of this study, it was verified that there is no significant improvement in the glycemic levels of the patients submitted to total or subtotal gastrectomy with the Roux-

in-Y shunt. This suggests that the Proximal Intestine Theory may not be the single and predominant factor for the improvement of diabetes. It is known that weight loss as an isolated factor improves glycemic levels due to decreased peripheral resistance to insulin since patients with low body mass index do not achieve an improvement in glycemic levels.

Thus, body mass index reduced 2.14 units, with the greatest decrease in patients submitted to total gastrectomy. Blood glucose decreased by 13.62 units, with only 30% of patients below 100 at T0, Hb1Ac did not significantly reduce. Most patients remained unchanged with hypoglycemic pharmacological treatment, 21.35% presented worsening, 6.74% discontinued treatment and 11.24% had a decrease or a positive change. Individuals with a body mass index between 30 and 35 kg/m^2 represented the highest proportion of patients whose pharmacological treatment improved.

A systematic review compared the clinical effectiveness between Roux-in-Y gastric bypass surgery (RYGB) and Sleeve Vertical Gastrectomy was published by Yip et al., who defined remission of T2DM by normalization of Hb1Ac, and the postoperative follow-up was performed in > 50% of the sample. The authors showed that, at the three postoperative months, 67% of patients submitted to Gastrojejunal Derivation in Roux-en-Y and 56% to GV had remission of DM2 (Hb1Ac <6.5%); 76% of the patients submitted to Gastrojejunal Derivation in Roux-en-Y and 68% to GV at 12 months and 81% of those who underwent Gastrojejunal Derivation in Roux-en-Y and 80%, ESR at 36 months, with no statistical difference. Meta-analysis did not favor any of the surgeries. Perhaps these data are further evidence of duodenal exclusion, and therefore the Proximal Intestine Theory does not have the role assigned to it.

A longitudinal prospective study in a public hospital in the city of São Paulo with 11 morbidly patients with obesity with a mean body mass index of 44.06 ± 6.59 kg / m2 and previously diagnosed with T2DM showed a decrease in glycemia and in peripheral insulin resistance after five days on average, of postoperative gastroplasty with Roux-in-Y bowel bypass. In this study, the patients were fed a standard balanced diet, through a gastrostomy catheter in the gastric remnant (1-3 days) and later orally (4-7 days). On the first seven postoperative days, a significant increase in GLP-1 was observed, strengthening the Distal Intestine Theory. There was additionally reduction of the gastric inhibitory polypeptide and no change in ghrelin, and these results were not associated with the mechanism of action of T2DM remission. The improvement in glycemic and insulin control was independent of the passage of food through the duodenum, offering evidence against the Proximal Intestine Theory (ref. 16).

It should be emphasized, therefore, that, in relation to theories that seek to explain the genesis of diabetes improvement after bariatric and metabolic surgery, there is apparently no support for the Proximal Intestine Theory. On the other hand, this study opens perspectives for the analysis of the role of bariatric/metabolic surgery in low weight patients.

In the present study, the sample consisted mainly of patients with a body mass index lower than 30 kg/m^2, in whom gastrectomy was not motivated by overweight or DM2, which makes them a good group of analysis on the effects of the operation on people with low BMI. However, because they are individuals with cancer, there is a possibility that the treatment for cancer itself may have influenced and hindered glycemic control (as previously commented), being a confounding factor when analyzing the association between the predictors and the outcomes (ref. 17).

On the other hand, according to a review, there is a tendency among patients with T2DM and cancer to adhere more to cancer care rather than T2DM treatment, increasing the risk of worse clinical outcomes and the occurrence of complications. This may explain the negative clinical results of improvement of T2DM in the present study sample, although none of the patients underwent any complementary treatment other than the surgical one.

The limitations of the present study are mainly defined by the retrospective methodology, whose data source were electronic and physical records, there is a limitation of the information recorded. Additionally, the difficulty of determining the duration of preoperative T2DM limited the analysis of the influence of this variable on the postoperative glycemic control outcome.

As a perspective, it is understood that controlled and prospective studies comparing the effects of proximal bowel exclusion on lean adults with T2DM, enterohormone dosage, long-term follow-up and analysis of surgical procedures that do not have the duodenal exclusion, but that stimulated entero-hormonal secretion, such as intestinal bipartition (Santoro technique) (ref. 18) or the technique of vertical gastrectomy associated with jejunoileal deviation (ref. 19).

Conclusion

The study demonstrated that there was no improvement of glycemia in patients with DM2 who underwent total or subtotal gastrectomy with Roux-en-Y reconstruction, with a body mass index below 30 kg/m^2. No evidence was found corroborating the theory of the proximal intestine. There are indications that surgery may influence glycemic control when BMI> 30 kg/m^2 and age less than 62.5 years.

COI Statements

MYF, BZ, LC, MB MFKPR and BZ do not have conflict of interest to declare.

CVSG has received a doctorate scholarship from Coordination for the Improvement of Higher Education Personnel CAPES and personal fees for consulting for Essity®, Bbraun®, and 3M ® not related to the present study.

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Tables

Table 1. Sample Characterization

Sex	**Female 52 (50.5%)** / Male 51 (49.5%)
Mean Age	65,5 ± 9,57 years (min. 41 e max. 89 years)
Comorbidities	66% with Arterial Hypertension
Gastrectomy Type	Subtotal: 79,6% (n=82) Total: 20,4% (n=21)
BMC Distribution	<25 kg/m2 38,8% (n=40) 25 a 30 kg/m2: 44,7% (n=46) >30 kg/m^2: 16,5% (n=17)
Gastric Adenocarcinoma TNM 2010	IA (36,9%, n=38) / IB (10,7%, n=11) IIA (14,6% n=15) / IIB (7,8%, n=8) IIIA (10,7% n=11) / IIIB (8,7% n=9) IIIC (7,8% n=8) / IV (2,9% n=3)
Clavien-Dindo Classification (Moreira, 2016)	Grau I: 1,9% (n=2) Grau II: 8,7% (n=9) Grau IIIb: 13,6% (n=14) Grau IVa: 2,9% (n=3) Grau IVb: 1% (n=1)

Figures

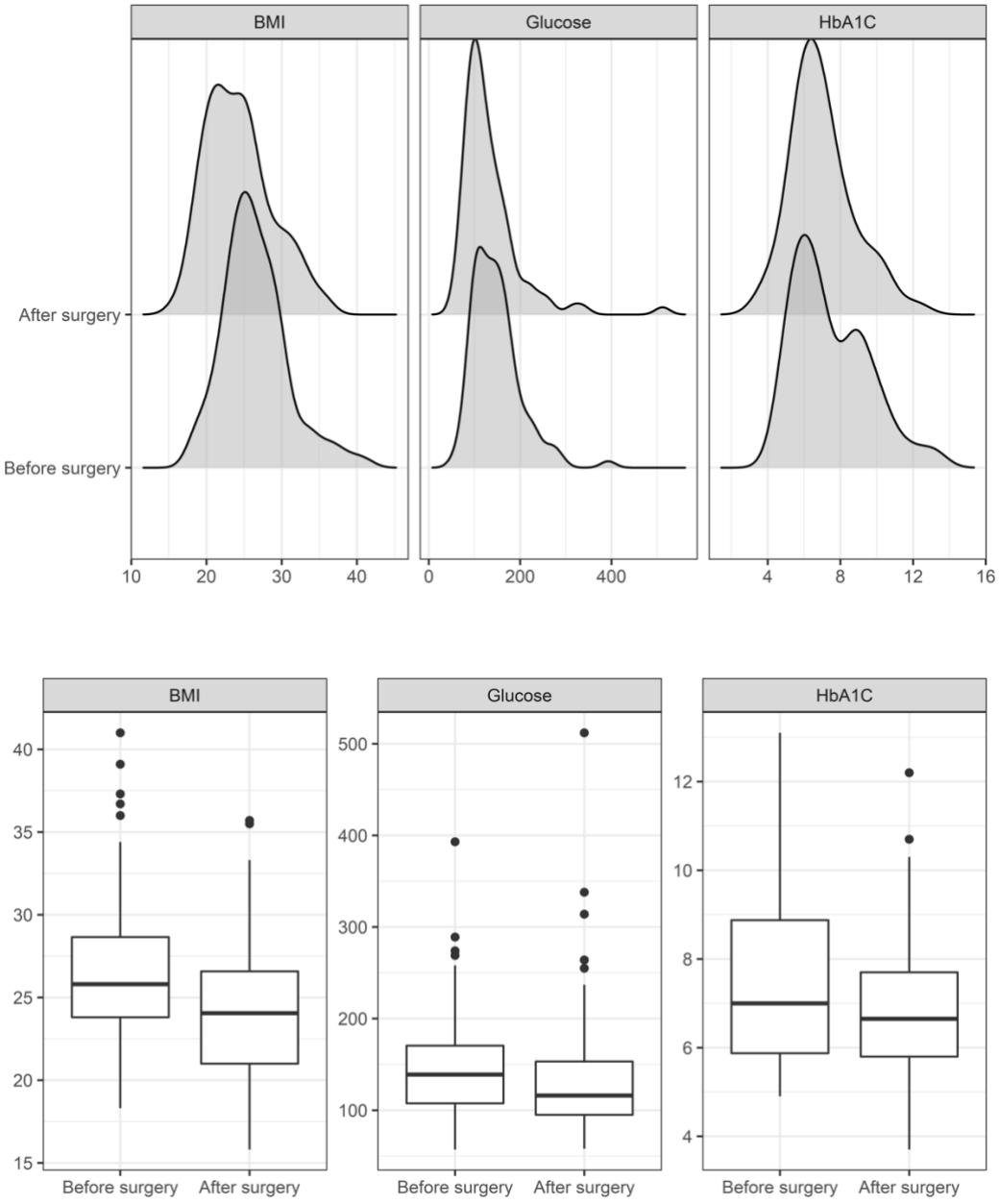

Figure 1. Changes in clinical variables after one year of gastrectomy with Roux-in-Y in diabetic patients with Gastric cancer. Data indicates the distribution of clinical variables in T0 and T; Boxplot express median, mean and quartiles. The lower graphs illustrate

the overlap of the data at both points of analysis. Comparisons between T0 and T1 were performed by paired T-Test; significance level at 5%.

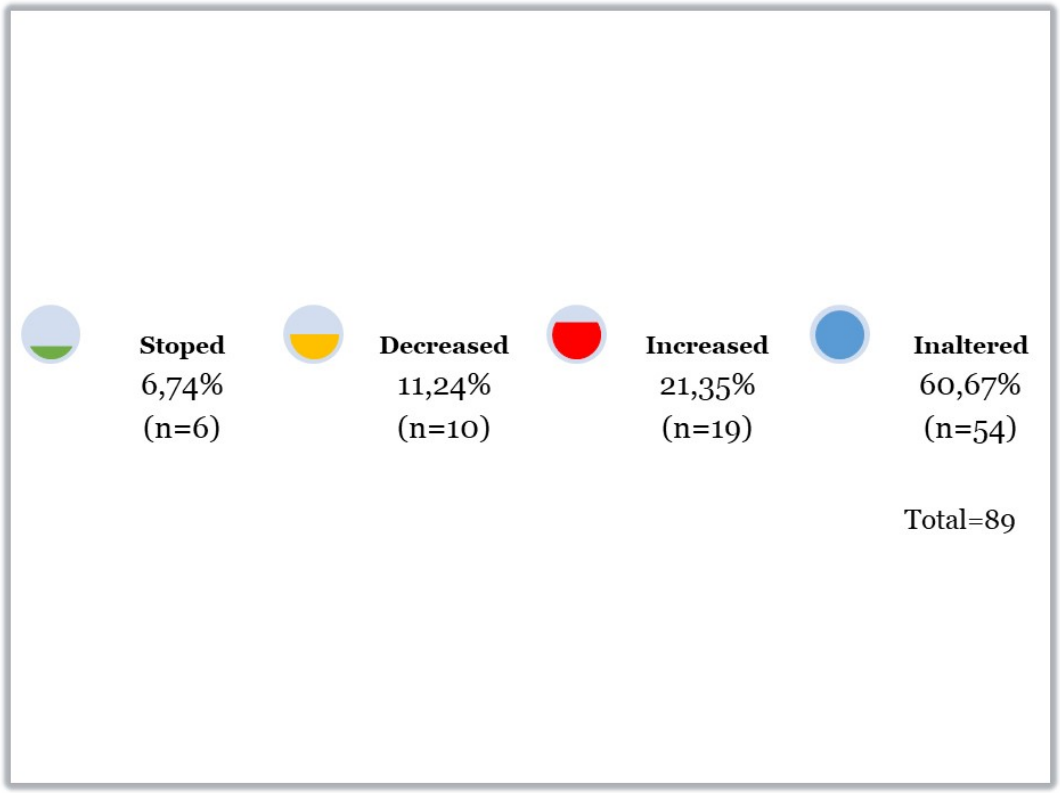

Figure 2. Changes in the hypoglycemic agents' treatment after 1-year of gastrectomy. Data is showed in terms of sample proportions (n=89).

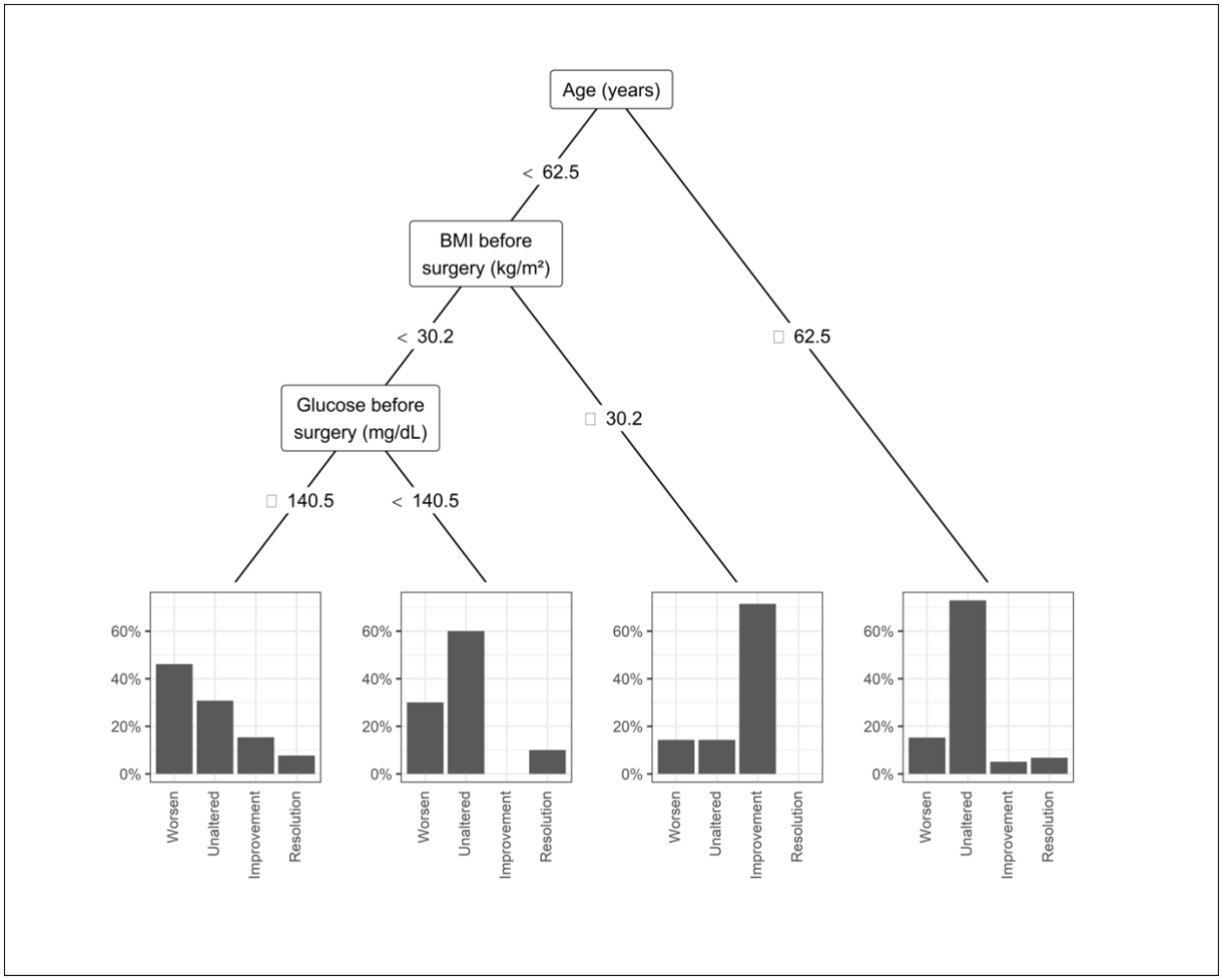

Figure 3. Predictors of pharmacotherapy changes in patients with T2DM and Gastric Cancer, after one year of gastrectomy with Roux-in-Y. Data analyzed by the Multivariate Logistic Regression Model Classification and Regression Tree.

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- The authors declare that the data, applications, and other content underlying the manuscript are referenced.
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