

Duodenal Exclusion Associated with Truncal Vagotomy as a treatment for Type II Diabetes Mellitus in patients with BMI between 26 and 38 kg/m²: Preliminary Results

Exclusão Duodenal Associada à Vagotomia Troncular como Tratamento para o Diabetes Melito Tipo 2 em Doentes com IMC entre 26 e 38 Kg/m²: Resultados Preliminares

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ABSTRACT

Type II Diabetes Mellitus (DM2) affects a great part of the obese population, but can also be diagnosed in those who are non-obese or even thin. Bariatric surgery stands out among the mechanisms that are proposed as cures for diabetes. In the surgery community, duodenal exclusion has been the focus of large studies, and has shown satisfactory results both in obese patients and in thin patients. The objective of the present study was to evaluate the efficacy of this technique associated with truncal vagotomy, aiming in this way of offering both a solution for DM2 and a reduction in body weight and improvement of the complications caused by both. This procedure was carried out 10 patients of both sexes with DM2, with ages between 40 and 65, and a BMI < 39 kg/m². The preliminary results through 3 months post-surgery were the reduction of serum glucose, reduction in body weight, and improvement in blood pressure and the lipid profile. It is believed that the critical component for the reduction of serum glucose was the duodenal exclusion of the passage of nutrients. As occurs with vagal blockade, weight loss is also expected with truncal vagotomy. The patients developed early satiety and reduction in the quantity of caloric intake. Based on the preliminary results we concluded that duodenal exclusion associated with truncal vagotomy is an effective technique for the treatment of DM2, and that the C-peptide levels predict its success, because the patients with the highest levels responded better to the treatment. Nevertheless, we must await the end of the present study for any definitive conclusions.

Key words: Type 2 diabetes mellitus. Duodenal exclusion. Truncal vagotomy.

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INTRODUCTION

Type II diabetes mellitus (DM2) – representing about 90% to 95% of all cases of diabetes mellitus – is a disease comprised of disturbances in the metabolism of carbohydrates, fats, and proteins, caused by alterations in the secretion of insulin in target tissues, characterized by a state of chronic hyperglycemia.¹

Its pathogenesis involves genetic factors and environmental factors, which encompasses lifestyles,

including physical inactivity, a diet that is not balanced associated with excess weight and, consequently, a body mass index higher than that considered healthy.^{2,3}

As mentioned above, excess weight (obesity) is considered an important risk factor for the development of DM2. This is due to its association with metabolic syndrome, which is also responsible for various other complications including hypertension and dyslipidemia.^{4,5}

Of the total percentage of the population with diabetes, it is estimated that 35% to 50% of individuals

do not know they have the disease, a fact which contributes to the early development of micro- and macrovascular complications, setting the stage for conditions such as chronic renal insufficiency, cerebrovascular accident, coronary artery disease, cardiomyopathy, among other complications responsible for the mortality and morbidity of these diseases.⁶

Diabetes mellitus becomes more complex the closer we get to normal indices of weight. The diabetic that is morbidly obese has clear resistance to insulin caused by the adipose that is accumulated in the body. In the thin diabetic, the factors which bring about the disease clearly are not related to an excess of fat, but the reason that insulin resistance is established in these patients has not been elucidated.⁷

Because of the extensive number of complications that can arise from DM2, this disease – when inadequately controlled – represents a considerable economic burden for the patient and for society. It has shown that such complications can be reduced when the hyperglycemia, hypertension, and dyslipidemia than are generally associated with DM2 are controlled.^{4, 8}

Various approaches to achieve this objective have been proposed, among them one that has received considerable attention is bariatric surgery in morbidly obese patients, which can prevent or cure DM2.⁹

Operations for obesity are classified as:

i. disabsorptive techniques, which interfere with food absorption and are effective in reducing body weight and in improving insulin sensitivity; ii. restrictive techniques, which limit stomach capacity; these have been largely abandoned due to the tendency of patients to regain the weight and less consistent metabolic results; iii. mixed techniques, which combine restrictive and disabsorptive techniques.^{10, 11}

Interestingly, all bariatric surgeries demonstrate notable impact on DM2, although with different degrees of efficacy. Two techniques stand out as the most effective: the Roux-en-Y gastric bypass, which is considered a mixed technique, and the Biliopancreatic Diversion, a disabsorptive technique which promotes normal concentrations of glucose, insulin, and glycosylated hemoglobin in 80% to 100% of morbidly obese patients operated in this fashion.¹²

Although the weight loss is directly related with changes in the sensitivity to insulin and to the level of glucose in the blood, it has been observed that

after the operation, glycemic control is frequently attained within days after the procedure, well before there has been significant weight loss. Based on this fact, it has been suggested that the laboratory improvement in DM2 could be a direct effect of anatomic and functional alterations provoked by the surgery and not solely by weight loss. To explain this effect, HICKEY and cols.¹⁵ propose two hypotheses. The first is that the reduction in food intake immediately after the surgery could be responsible for this improvement. The second hypothesis is that the exclusion of part of the gastrointestinal tract, which possesses an important endocrine activity, would be the mechanism responsible for rapid glycemic control.^{13, 14, 15}

Based on these data, it is believed that similar results should occur in patients with DM2 who are not morbidly obese.

With a study carried out in rats, RUBINO¹⁶ proposed that the mechanism responsible for the improvement of DM2 would be the exclusion of the duodenum, because the exclusion of this region stimulates the intestine to secrete a substance which acts on the pancreas, improving its function and with this impacting positively on diabetes mellitus.

In 2007, COHEN and cols.⁹ conducted a study about the efficacy of this procedure that preserves the anatomy of the stomach in humans with DM2 and who had a body mass index between 22 and 34 Kg/m². These authors had a satisfactory result in terms of glycemic control by the fifth postoperative week.

In the present study truncal vagotomy associated with duodenal exclusion in a Roux-en-Y similar to that performed in the biliopancreatic diversion with duodenal switch procedure will be performed. Vagotomy consists of the sectioning of the vagal nerves in order to reduce peptic hydrochloric acid secretion of the stomach.¹⁷

The idea for this association arose from review of two studies. One of them¹⁸ evaluated the effect of vagal blockade on caloric intake, satiety during meals and satiety between meals; and in the other study¹⁹ the safety and effectiveness blockade on excess weight was assessed. The first study found an increase in satiety between meals, a decrease in the eating capacity during meals, and a lower level of calories ingested. In the second study, results were also satisfactory, and the vagal blockade was considered a safe and beneficial procedure for those who are overweight.^{18, 19}

Based on these data it is believed that with truncal vagotomy it will be possible to obtain results similar to those attained with vagal blockade.

Parameters considered important for indicating the surgery for control of DM2 include plasma level of C peptide used to assess the secretory capacity of the pancreas, and the plasma levels of anti-GAD (anti-glutamic acid decarboxylase), which should be within normal limits, or in other words, not have identified the presence of an autoimmune process in patients considered to have DM2.^{7, 20}

The present study seeks to evaluate the effects of duodenal exclusion associated with truncal vagotomy on DM2 and excess body weight, and also investigate if the levels of C peptide are important factors for performing the surgery.

METHODS

Patients

Ten patients of both sexes of the Hospital Cândido Rondon (HCR) in Ji-Paraná, RO with a diagnosis of type II diabetes mellitus, and with age ranging between 40 and 65 years, underwent duodenal exclusion and truncal vagotomy, all performed by the same surgeon.

For inclusion criteria, the patients were required to have a body mass index (BMI) below 40 kg/m², C peptide levels greater than 1 ng/mL, and anti-GAD levels less than 1 U/ml, and agreed to sign an informed consent document after having all the risks and benefits offered by the surgery explained.

The patients also underwent an individual psychological evaluation in order to evaluate the individual's state of awareness and if he or she was suitably prepared for the surgery. The patient also underwent a battery of gastrointestinal, cardiac and pulmonary function evaluations in order to rule out any contraindications to a surgical procedure involving anesthesia. Any patient with a malignant disease would have been excluded, and this did not occur in the present study.

A follow-up protocol was developed with clinical and laboratory parameters. At each outpatient follow-up visit arterial blood pressure was measured and the BMI determined. Laboratory examinations included glucose, glycosylated hemoglobin, hemoglobin, hematocrit, LDL, HDL and total cholesterol, calcium, iron, albumin, globulin, total protein, and vitamin B12 in order to detect possible

metabolic disorders and compare whatever changes appeared after the surgery.

The patients will be followed from the preoperative period until they complete one year postoperatively. In the postoperative period, the first outpatient visit occurred within one month after the surgery, the second visit after three months, and every 90 days thereafter until they had completed one year of follow-up. As the period of follow-up has not been completed, this report presents the preliminary results through 90 days post-surgery.

The surgical technique consisted of performing a truncal vagotomy with preservation of the stomach associated with complete section of the first portion of the duodenum with a linear stapler achieving the duodenal exclusion of the Roux-en-Y. The intestinal loop had a length of 2.5 meters starting from the cecum where it was sectioned with a second trigger of the linear stapler. Next, the intestinal course was reconstructed by pre-colic latero-lateral mechanical anastomosis between the jejunum and the greater curvature of the gastric antrum, next to pylorus. The segment that remains between where the first portion of the duodenum was sectioned up to where the jejunum was sectioned was manually anastomosed 80 cm from the ileo-cecal valve.

RESULTS

In the present study six patients were women, four were men. With the preoperative BMI ranging between 26 and 38 kg/m², none of the subjects was morbidly obese. Thus, patients were classified as overweight or Class I or Class II obesity.

The preoperative glucose was over 100mg/dl in all patients, even those using medication. No patient had a C peptide less than 1 ng/ml; the highest level was 3.8 ng/ml in one of the patients. No patient had an anti-GAD level above 1 U/ml. The glycosylated hemoglobin of the patients was between 6.4% and 11.5% (Table 1).

The time since diagnosis of type II diabetes mellitus (DM2) vary between 4 and 14 years. The majority of patients had comorbid conditions (Table 2).

The preoperative laboratory studies included lipid profiles: total cholesterol ranged between 142mg% and 262mg%, triglycerides between 119mg% and 310mg%, HDL between 32mg% and 54mg%, and LDL between 88mg% and 196mg%.

Table 1 - Preoperative profile of the 10 patients: BMI, fasting glucose, C peptide, anti-GAD and glycosylated hemoglobin.

Patient	IMC	Fasting Glucose	C peptide	Anti-GAD	Glycosylated Hemoglobin
1	26	322	3.1	0.1	11.5
2	27	242	1.85	0.72	8.7
3	31	110	3.8	0.6	11
4	38	162	3.03	1.0	7.3
5	35	121	1	0.6	7.5
6	35	289	3.17	1.0	10.8
7	38	169	2.7	0.1	7.8
8	31	153	1.6	0.6	6.4
9	28	157	1.3	0.8	8.8
10	38	167	2.37	0.5	8.3

Table 2 - Morbidities associated with Type II Diabetes Mellitus in the patients who participated in this study.

Morbidity	Number of Patients
Arterial Hypertension	5
Esophagitis	1
Dyslipidemia	3
Steatosis	2
Gastritis	1
Cholecystopathy	2
None	1

There were no complications during the operative period. All patients remained hospitalized after the procedure. Several required close observation in an intensive care unit. There were no postoperative complications; all patients were discharged by the third postoperative day.

Routine laboratory studies were obtained one month postoperatively and again three months after the surgery. During this period serum glucose levels were reduced in 100% of the patients (Table 3), and consequently there was also a reduction in glycosylated hemoglobin levels.

The reduction in body mass index (BMI) was between 2 kg/m² and 5 kg/m² during the first postoperative month and between 3 kg/m² and 7 kg/m² by the third postoperative month.

The lipid profile of these patients also changed over this period: total cholesterol declined to between 140mg% and 229mg%, triglycerides to between

109mg% and 267mg%, HDL to between 22mg% and 54mg%, and LDL to between 61.4mg% and 167mg%.

In general, levels of calcium, iron, albumin globulin, total protein and vitamin B12 remain within reference ranges considered normal.

DISCUSSION

Diabetes mellitus is the most common metabolic diseases, affecting close to 7.6% of the adult population between 30 and 69 years; it is estimated that in 2030 some 366 million people will have diabetes around the world. It constitutes a disease that has been responsible for the increase in mortality from cardiovascular diseases and microvascular complications, and as was seen earlier, DM2 affects the largest percentage of this population.^{5,20,21}

This study had the objective of giving continuity to the previous descriptions about the efficacy of duodenal exclusion on DM2 in patients who are not morbidly obese; however, it is unprecedented when the proposal is the association of truncal vagotomy with duodenal exclusion. This study is part of a larger, master's thesis study, which is in development.

Bariatric surgeries definitively result in improvement or reversal of DM2, but it is noted in surgical practice that those techniques in which there is duodeno-jejunal exclusion, and those exclusively disabsorptive, are the most effective.²²

DM2 can be associated with other comorbidities, for example dyslipidemia and arterial

Table 3 - Comparison of the serum glucose profile of the 10 patients: preoperative, 30 days post-operative, and 90 days post-operative.

Patient	Preoperative Glucose	Glucose 30 days Post-Operative	Glucose 90 days Post-Operative
1	322	130	80
2	242	105	102
3	110	80	80
4	162	127	82
5	121	140	114
6	289	186	78
7	169	105	80
8	153	130	120
9	157	133	117
10	167	127	110

hypertension. These two comorbidities were the most common among the participants of this study.²³

In almost all of the subjects there was an important reduction in the serum glucose in the first postoperative month, and several became euglycemic. Only after the third postoperative month was glycemic control attained by all patients.

For COHEN⁷, C peptide levels indicate whether the surgery can really cure DM2. The level of this substance determines whether a diabetic is still able to synthesize insulin. In this study, besides this, it was observed that the subjects that had the highest C peptide levels were those that best responded to treatment, and most rapidly achieved glycemic control. Several of these patients attained glycemic control within one month postoperatively.

It is postulated that diabetes control is a direct effect of duodenal exclusion.²⁴ In 2006, RUBINO²⁵ and cols. demonstrated in one of their studies that duodenal exclusion of the passage of nutrients is a critical component of the control of DM2.

As the group of patients that were part of this study were classified as overweight or Class I or Class II obesity, the truncal vagotomy was performed associated with duodenal exclusion in order to together promote the resolution of DM2, and also to promote weight loss in these patients.

Without exception, all the patients achieved significant weight reduction during this period. Just as occurs in vagal blockade, the weight loss was also

expected with truncal vagotomy. The patients experienced early satiety and a reduction in the quantity of caloric intake.

Historically, surgical vagotomy was used as a treatment for ulcers. Over time it was noted that this technique caused anorexia and weight loss by mechanisms that are not clear, and with this observation, vagal blockade began to be performed as a treatment for obesity.¹⁹

The impact on levels of triglycerides and LDL and total cholesterol were also observed over the course of follow-up. Almost 90% of the patients had reduction in all of these measures.

It is known that elevated lipids and type II diabetes are two possible triggers of cardiovascular diseases, which represent the greatest cause of mortality. Various randomized placebo-controlled studies have demonstrated that a reduction in total and LDL cholesterol is associated with a lower incidence of cardiovascular events. Three of our patients had dyslipidemia. In these patients a reversal of the lipid profile would constitute a lowering of the risk of a cardiovascular event. Even if it did not constitute a risk for the majority of the patients in this study, it nevertheless constituted a method of prophylaxis.²⁶

No patient developed nutritional disorders over the course of the study; however the risk of complications developing after the 90 day period of observation could not be excluded. Because with duodenal exclusion the stomach is preserved, the complications which are common with the Roux-em-

Y gastric bypass, such as anemia and vitamin B12 deficiency, are avoided.⁹

There was also improvement and reduction in blood pressure in our patients probably as a consequence of glycemic and lipid control, and the loss of body weight that occurred. The mechanisms responsible for this improvement are a reduction of hyperinsulinemia and of insulin resistance, a reduction of sympathetic activation as a result of the reduction in leptin levels, and reduction of intra-abdominal hypertension which frequently occurs in this class of patients.¹¹

CONCLUSION

Duodenal exclusion associated with truncal vagotomy produced satisfactory preliminary results, since it acted in a positive way not only on the DM2,

but also on excess body weight, on the lipid profile, and on blood pressure of the patients who participated in the study.

As these are only preliminary results, the data described in this study are not definitive, and may present changes in its efficacy over the course of time. This research will continue until the patients have completed one year of follow-up.

It has been shown, then, for now, that these surgical technique utilized in this study represents a safe mode of treatment of DM2 in patients who are not morbidly obese, but that present lesser degrees of obesity.

With the glycemic results obtained, one can also conclude that C peptide constitutes an important factor in the surgery in the fight against DM2. When this peptide is encountered in high levels, the patient has a greater chance of a better and more rapid response to the proposed treatment.

RESUMO

O diabetes melito tipo 2 (DM2) atinge grande parte da população obesa, podendo também ser diagnosticado em magros. Dentre os mecanismos que são propostos para a cura do diabetes destaca-se atualmente a cirurgia bariátrica. No meio cirúrgico, a exclusão duodenal tem sido foco de grandes estudos e tem demonstrado resultados satisfatórios tanto em doentes obesos quanto em magros. O objetivo do presente estudo foi avaliar a eficácia dessa técnica associada à vagotomia troncular, visando dessa forma ofertar junto à resolução do DM2 uma redução no peso corporal e melhora das complicações causadas por ambos. Essa técnica foi realizada em 10 doentes com DM2, de ambos os sexos, com idades entre 40 e 65 anos, e IMC menor de 39 kg/m². Os resultados preliminares de até três meses pós-cirurgia foram uma redução da glicemia, redução do peso corporal, melhora no perfil lipídico e da pressão arterial. Acredita-se que o componente crítico para redução da glicemia seja a exclusão duodenal da passagem de nutrientes. Assim como ocorre no bloqueio vagal, a perda de peso já era esperada também através da vagotomia troncular. Os doentes apresentaram saciedade precoce e redução no volume de ingestão calórica. Conclui-se com os resultados preliminares que a exclusão duodenal associada à vagotomia troncular demonstra ser uma técnica eficaz para tratamento de DM2, e que os níveis de peptídeo C determinam o seu sucesso, pois os doentes que apresentaram níveis mais elevados responderam melhor ao tratamento, no entanto se requer termino do presente estudo para uma conclusão definitiva.

Palavras-chave: *Diabete Melito tipo 2. Exclusão duodenal. Vagotomia troncular.*

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