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Isolated intestinal transit bipartition: a new strategy for staged surgery in superobesity.

Bipartição de trânsito intestinal isolada: uma nova estratégia para cirurgia em estágios em superobesos.

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ABSTRACT

Objective: biliopancreatic diversion with duodenal switch is a complex, malabsorptive procedure, associated with improved weight loss and metabolic control. Staged surgery with sleeve gastrectomy as the first stage is an option for reducing complications in superobese patients. However, some problems persist: large livers can hamper the surgical approach and complications such as leaks can be severe. Intestinal transit bipartition is a modified and simplified model of biliopancreatic diversion that complements sleeve gastrectomy. It is similar to the duodenal switch, but with less complexity and fewer nutritional consequences. This study assessed the feasibility and safety of isolated transit bipartition as the initial procedure in a two-step surgery to treat superobesity. **Methods:** this prospective study included 41 superobese patients, with mean BMI 54.5±3.5kg/m^2. We performed a laparoscopic isolated transit bipartition as the first procedure in a new staged approach. We analyzed weight loss and complications during one year of follow-up. **Results:** we completed all the procedures by laparoscopy. After six months, the mean percent excess weight loss was 28%, remaining stable until the end of the study. There were no intraoperative difficulties. Half of the patients experienced early diarrhea, and three had marginal ulcers. There were no major surgical complications or deaths. **Conclusion:** isolated laparoscopic transit bipartition is a new option for a staged approach in superobesity, which can provide a safer second procedure after effective weight loss over six months. It may be useful particularly in the management of patients with severe obesity.

Keywords: Biliopancreatic Diversion. Gastrectomy. Bariatric Surgery. Gastrointestinal Hormones. Obesity, Morbid.

INTRODUCTION

Due to intraoperative difficulties, to early surgical complications and to the often insufficient long-term weight loss, surgical treatment of patients with superobesity (SO) remains a challenge[1,2]. Roux-en-Y gastric bypass and sleeve gastrectomy (SG) have been the most widely used techniques. Nonetheless, the best results have been reported with the so-called malabsorptive operations[3,4]. Although the biliopancreatic diversion with duodenal switch (BPD-DS) promotes better weight loss and glycemic control than other techniques[5], its greater technical complexity, as well as the resulting gastrointestinal symptoms and long-term nutritional risks have limited its use[6].

To reduce perioperative risk, a two-step approach has been advocated: SG, followed by a biliopancreatic diversion (BPD) after the patient has lost a substantial amount of weight[7]. Despite providing better results, some surgical problems remain, such as approaching the esophagogastric junction region, which may be hampered by an enlarged steatotic liver. In addition, the approach carries potentially serious risks and complications, such as bleeding and SG fistulas.

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A better understanding of gastrointestinal physiology and in its relation to the metabolic pathways challenges the classic restriction and/or malabsorption mechanisms[8]. The effects of techniques such as BPD-DS can be explained by neurohormonal modulation and alterations of the microbiota and bile salt metabolism resulting from early and intense distal intestinal stimulation, malabsorption being an unnecessary and avoidable side effect[9]. This understanding allowed surgical models to be modified in order to develop the so-called pure metabolic surgery[10].

Santoro *et al.*[11] proposed a variant of BPD, the intestinal transit bipartition (ITB), in which a gastroileal anastomosis is performed in the pre-pyloric region, without exclusion of intestinal segments. The principle of this new surgical model is to promote only partial exclusion of the proximal bowel and to provide intense and early distal intestinal stimulation. Its efficacy seems to be similar to the classic BPD-DS[12]. In addition, the preservation of some duodenal food flow affords nutritional protection, ensuring full access to the digestive tract, maintaining proximal protective mechanisms against hypoglycemia and micronutrient absorption capacity.

The objective of this study was to evaluate the feasibility and safety of isolated ITB as a simple alternative to BPD, as the initial procedure in a two-stage approach to treat superobesity.

METHODS

This study was approved by the National Research Ethics Commission (CAAE: 30301214.1.0000.5292). We obtained written informed consent from all patients. The study included patients with SO, with a BMI ranging from 50 to 60 kg/m^2, and aged from 20 to 60 years, who underwent the isolated ITB procedure and whom we prospectively followed for one year. Exclusion criteria included a history of previous gastrointestinal surgery or chronic disease that could interfere with outcome analysis and no having minimum psychosocial conditions to participate in the study, according to the assessment of a multidisciplinary team. We performed the surgical procedures between March and November 2015.

Before surgery, patients underwent upper digestive endoscopy with testing for *Helicobacter pylori,* which, if positive, was eradicated. We performed all procedures by laparoscopy. We positioned the access ports as shown in figure 1.

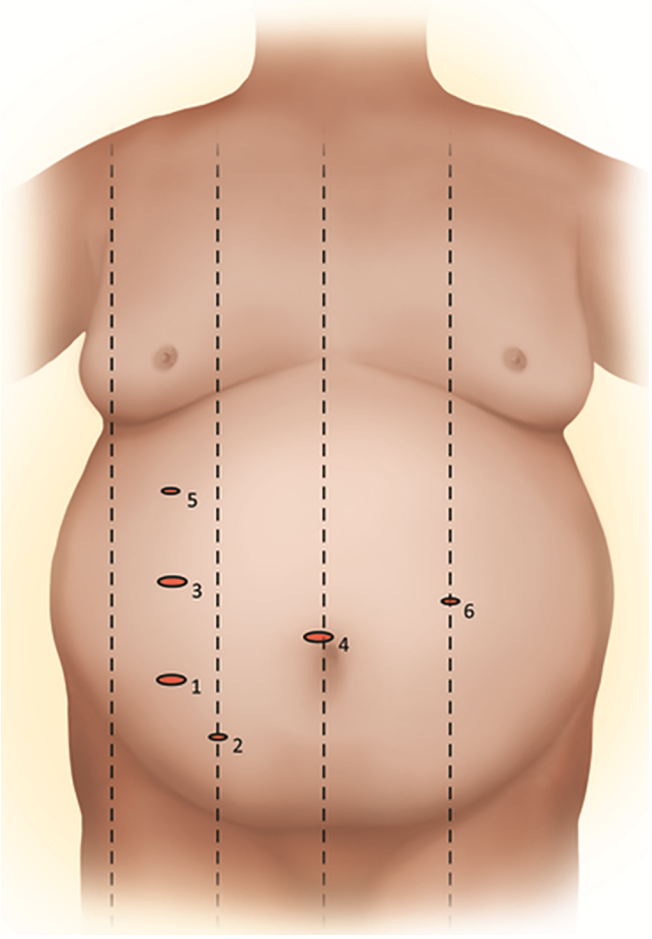

Figure 1. *Positioning of portals in the isolated bipartition.*

After laparoscopic exploration, we placed the patient in the Trendelenburg position, with the left lateral position of about 20º. We identified the ileocecal junction and sectioned the intestine 250cm proximal to the ileocecal valve.

We constructed a Roux-en-Y, lateral anastomosis measuring approximately 5cm in the pre-pyloric region of the great gastric curvature, with an termino-lateral enteroanastomosis to maintain an 80cm common canal (Figure 2). We then closed the mesenteric defect. All sutures were continuous, manual and in a single plane. We reintroduced a regular, consistency-free oral diet according to tolerance the next morning. We prescribed a proton pump inhibitor (40mg pantoprazole, daily) throughout the postoperative follow-up period.

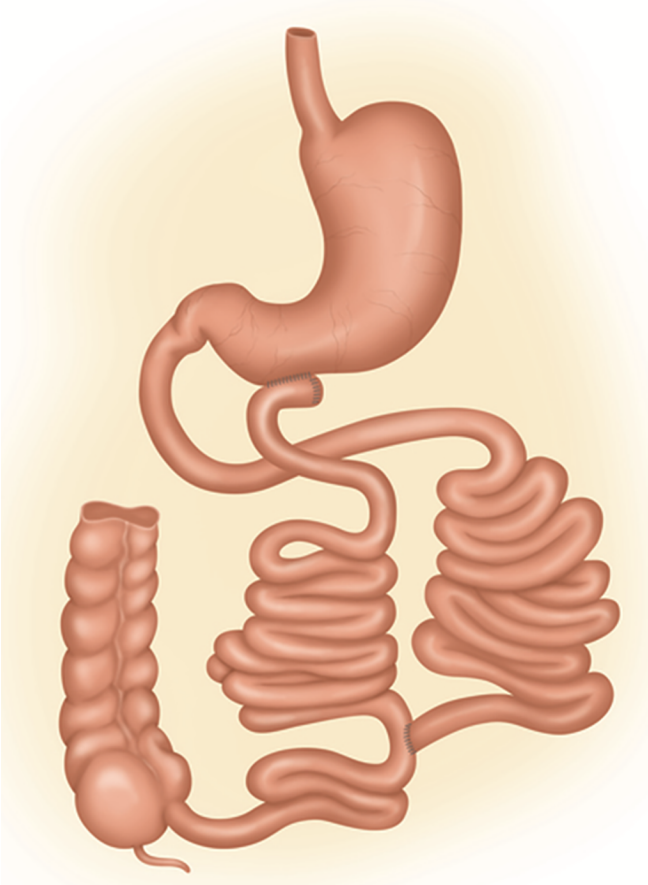

Figure 2. *Isolated bipartition.*

We reevaluated patients after one week and at one, three, six and 12 months postoperatively, including conducting a laboratory panel and an endoscopic examination at six and 12 months. We used a structured form for the evaluations. We obtained data on intraoperative difficulties from the surgical description, and systematically recorded anthropometric measurements, gastrointestinal symptoms and any complications. We classified Complications according to the American Society of Bariatric and Metabolic Surgery standardization[13], as early or late, and major or minor. If present, we recorded episodes of severe hypoglycemia, characterized by neuroglycopenic symptoms, such as unconsciousness or seizures that could not be controlled with dietary adjustments and drug therapy.

We planned sleeve gastrectomy for surgical completion, as the second stage, after one year. The description of these results, however, is not the purpose of the present study.

We expressed data as mean ± standard deviation (SD) or frequencies, according to the nature of the variable. We assessed weight loss by the percentage of excess weight loss (%EWL), the percentage of total weight loss (%TWL) and the percentage of excess BMI loss (%EBMIL). We assessed the control of metabolic comorbidities according to the glycated hemoglobin and blood pressure levels proposed by the American Diabetes Association (ADA)[14].

We performed statistical analyzes with the SPSS 25.0 (IBM, NY, USA) software. We used the Shapiro-Wilk test to test the distributions for normality, and the Friedman test and the analysis of variance (ANOVA), as appropriate, to evaluate changes in measures during the monitoring period. We set the significance level at $P<0.05$, and we applied the Bonferroni correction for multiple *post hoc* comparisons. For repeated measurements, due to the nature of the data, we selected the Friedman's nonparametric hypothesis test.

Before executing ANOVA, we verified all assumptions. We performed an intention-to-treat analysis to compare and validate the results obtained with the raw data, applying the last observation method to impute missing values.

RESULTS

In total, 41 patients met the inclusion criteria and underwent surgery. However, we excluded three of these patients from the statistical analysis: two due to loss of follow-up and one due to pregnancy after surgery. The average age of the patients (33 women and 5 men) was 42±10 years, mean weight was 135.24±17.05kg and the mean BMI was 54.65±3.55kg/m^2. In 28 patients (74%) and 37 (97%), hypertension and dyslipidemia were present, respectively. Initially, 15 of the patients (39%) had type-2 diabetes *mellitus.* At 12 months of follow-up, the mean total weight and BMI were 114.94±16.96kg and 46.4±5.3kg/m^2, respectively, and the mean %EWL was 28%±14% (Table 1).

Two patients had %EWL>50%. Overall, patients experienced progressive weight loss, with significant differences between periods up to six months, but no significant difference between six months and one year (Figure 3).

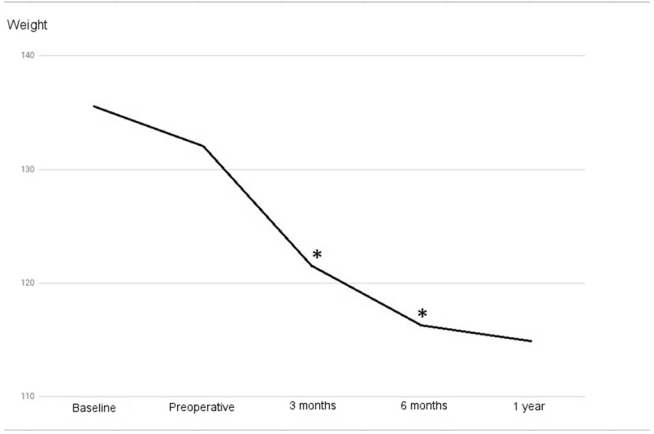

Figure 3. *Weight loss during follow-up.*

At 12 months of follow-up, the diabetes remission rate according to the ADA criteria was 33% (P<0.001). A subgroup analysis of diabetic patients showed a significant reduction in glycated hemoglobin (HbA1c) levels, with a mean decrease in HbA1c from 7.68%±2.5% preoperatively to 6.17%±1.80% in the 12-month follow-up (P<0.05). There was also a reduction in insulin use, with 3/15 (20%) diabetics taking preoperative insulin, but only 1/15 (6.6%) taking insulin therapy at 12 months. Nonetheless, this difference was not statistically significant. Initially, all 15 diabetic patients were treated with oral antidiabetic agents and, after 12 months, 8/15 (53.3%) continued using such drugs (P<0.05).

Table 1. *Initial characteristics (N=38).*

Characteristic	n	Mean±SD** or %
BMI* (kg/m^2)	38	54.5±3.5
Female	33	87%
Hypertension	28	74%
Diabetes	15	39%
Dyslipidemia	37	97%
HbA1c*** (%)	15	7.68±2.5
Blood glucose (mg/dl)	15	123.6±27.2
Insulin use	3/15	20%

** BMI: body mass index; ** SD: standard deviation; *** HbA1c: glycated hemoglobin.*

At baseline, 28 patients had hypertension, and at 12 months the remission rate was 39%, although this was not statistically significant (P=0.98) (Table 2). There were no reports of severe hypoglycemia during the study period.

We completed all operations by laparoscopy. The average hospital stay was 1.8±0.9 days, although one patient presented with persistent nausea and vomiting, leading to a longer postoperative hospital stay. There were no major complications or intraoperative difficulties and no deaths occurred in this series. Two patients had peroneal neuropathy and one required admission to the intensive care unit due to bronchospasm during anesthesia. Half of the patients (19/38) had early diarrhea, but this resolved completely after dietary and symptomatic measures, except for three patients requiring prolonged pharmacological and dietary treatment. We instructed patients to consume foods with low lipids, high protein and additional fibers. There were no cases of protein malnutrition. Five patients underwent emergency surgical treatment during follow-up, three for acute cholecystitis and two for acute appendicitis.

We performed endoscopic evaluations preoperatively and at six and 12 months postoperatively in 41, 27 and 34 patients, respectively. Preoperative endoscopic evaluations revealed 13 cases of Los Angeles grade A or B esophagitis. At six months, exams showed five cases of grade A or B esophagitis and three marginal ulcers, and at 12 months, there were four cases of Los Angeles grade A esophagitis and two cases of marginal ulcers. Marginal ulcers were not associated with *H. pylori* infection. There were no strictures or other complications related to the gastroileal anastomosis.

DISCUSSION

With the development of knowledge about gastrointestinal physiology and its relationship with the metabolic pathways, other mechanisms of bariatric and metabolic operations that do not involve classical mechanical restriction and/or malabsorption have been better known[15].

Table 2. *Main metabolic results (data expressed as mean ± standard deviation).*

	Baseline (n=38)	Before surgery (n=38)	3 months (n=38)	6 months (n=36)	1 year (n=38)
BMI** (kg/m^2; mean±SD)	54.5±3.5	52.9±4.0	48.5±4.9*	47±4.6*	46.4±5.3*
%EBMIL*** (%; mean±SD)	-	5±9	21±12*	26±12*	28±14*
%TWL$^{\#}$ (%; mean±SD)	-	3±5	11±6*	14±15*	15±7*
%EWL$^{\#\#}$ (%; mean±SD)	-	5±9	21±12*	26±12*	28±14*
Patients with hypertension	(n=28)	(n=28)	(n=28)	(n=28)	(n=28)
Remission of hypertension	-	0	10 (36%)	11 (39%)	11 (39%)
Diabetic patients	(n=15)	(n=15)	(n=7)	(n=12)	(n=12)
Diabetes remission	-	0	1 (7%)	7 (33%)	7 (33%)
HbA1c$^{\#\#\#}$ (%; mean±SD)	-	7.68±2.5	5.92±0.38*	6.22±2.01*	6.17±1.80*
Blood glucose (mg/dl; mean±SD)	-	123.6±27.2	110.9±18.4	117.9±48.5	113.6±49.5
Use of medication	15 (100%)	15 (100%)	5 (33.3%)	7 (46.7%)	8 (53.3%)
Use of insulin	3 (20%)	3 (20%)	1 (6.6%)	1 (6.6%)	1 (6.6%)

** P<0.05 compared with baseline; ** BMI: body mass index; *** %EBMIL: percentage of excess body mass index loss; # %TWL: percentage of total weight loss; ## %EWL: percentage of excess weight loss; ### HbA1c: glycated hemoglobin.*

This has stimulated changes in established operations and the development of new surgical approaches[16-18]. The concept of ITB stems from the hypothesis that malabsorption may not be the main mechanism underlying duodenal switch BPD (BPD-DS), but an unnecessary and avoidable side effect. The modified BPD approach proposed by Santoro *et al*.[12], involving a pre-pyloric, gastroileal anastomosis and no duodeojejunal exclusion, provides for proximal intestinal deactivation (foregut hypothesis) and early and intense distal intestinal stimulation (hindgut hypothesis)[12]. This opens up a new perspective that may offer a useful alternative to more complex situations such as overweight. Therefore, in this study, we prospectively evaluated a different strategy for a two-stage surgery approach, which used laparoscopy isolated ITB as the initial procedure rather than the originally proposed SG.

The 12-month follow-up of 38 patients operated with this approach showed 28% mean EWL and significant metabolic benefits, without major complications. Cossu *et al*.[19] observed similar results, with metabolic improvement and mild weight loss in a study in which they performed a duodenal switch (DS) without gastric resection in 24 patients with mild obesity. However, they performed a long intestinal segment exclusion and a duodeno-ileostomy, while in our study there was no excluded segment with the isolated ITB.

In a randomized trial of BPD-DS *versus* Roux-en-Y gastric bypass in a SO group followed for five years, Risstad *et al*.[6] showed that patients undergoing BPD-DS had greater weight loss and improved low-density lipoprotein, triglyceride and glycemic levels, but with a higher occurrence of surgical complications, gastrointestinal adverse effects and nutritional complications. There was no difference between the two patient groups regarding improvement in quality of life[6].

In addition to its long-term associated nutritional problems, BPD-DS is a complex operation that carries a high risk for SO patients. Strategies aimed at reducing perioperative risks have been described. However, conservative preoperative weight loss attempts have shown limited impact[20]. A two-step approach has been proposed, with SG as the first procedure. Although the usefulness of staged surgery for SO patients is controversial[21], and not all SO patients present risks that justify this approach[22], patients with known risk of intraoperative difficulties may benefit[23].

Our proposal to use isolated ITB has some advantages that may characterize it as the best alternative initial procedure for a two-step approach. When this technique is used, it is not necessary to approach the region of the esophagogastric junction, limiting the steps of the upper abdomen to the pre-pyloric region of the great curvature, avoiding the need to manipulate a very frequently enlarged steatotic liver, with risk of lacerations and bleeding[24]. In addition, the risks of the intestinal stage are lower than those associated with SG, attested by the absence of major complications in our series, indicating a possible risk reduction.

Studies have shown that a %TWL of only 5% in the preoperative period is associated with a significant reduction in perioperative risks[25,26]. Although weight loss was generally higher in the series for which the SG is the initial procedure, the mean %TWL at six months of 15.7% observed in our patients attests to the efficacy of the use of ITB as an initial preparatory procedure for a second step.

However, there was no significant additional weight loss after six months, suggesting that this would be the appropriate time to complete the SG supplementing operation.

In addition to its effects on weight loss, ITB has metabolic benefits. Approximately 40% of our patients were diabetic and two thirds were hypertensive. At 12 months, we observed complete remission in 33% and 38% of these patients, respectively. Recently, Azevedo *et al*.[27] reported a randomized study with SG-ITB for severely diabetic patients, confirming the strong metabolic impact of the operation[27]. Although we are convinced that SG is essential to the full effects of this new surgical model, isolated ITB probably brings additional metabolic benefits to weight loss, potentially providing better preparation for the second operation.

Although a gastroileal anastomosis with an intact stomach presents a risk of marginal ulcers, this was not a big problem in our series. All patients were endoscopically evaluated for *H. pylori* preoperatively, which, when found, were eradicated. There were three cases of marginal ulcer (8%) and only one patient, who was not taking the proton pump inhibitor prescribed systematically throughout the study period, was symptomatic. All three patients responded promptly to the adjustment of drug therapy. Marginal ulcers were not described in the original proposal SG-ITB[12], probably due to the protective effect of resection of most gastric oxyntic cells and sustained reduction in ghrelin levels observed after SG. Despite the additional risk of ulcer without gastric resection, Cossu *et al*.[19] observed a higher incidence of anastomotic ulcer (29.1%) with BPD without gastric resection compared to the present study (8%), suggesting a different risk of ulcer due to different anastomotic site.

The postoperative bowel symptoms observed in some patients were probably due to the bowel loop configuration used in this series. We reproduced the original proposal of Santoro *et al*.[12], which retained the classic SG-DS loop configuration, with a common channel of only 80cm. Longer common channels with smaller or absent food loops may be the best settings for reducing unwanted bowel symptoms without compromising the effectiveness of the operation[28]. This is supported by evidence suggesting that the separation of food from biliopancreatic enzymes, aiming at malabsorption, is probably not the most logical strategy for obtaining the effects of neurohormonal modulation in procedures with purely metabolic goals[29]. Early enzyme action may play an important role because nutrients in the hydrolyzed form seem to promote more efficient intestinal stimulation[30]. This may explain the good results obtained with techniques that use a short food loop or none at all[31]. A 200cm common channel with a 50cm food loop is our current standard model. Other surgeons experienced in this type of surgery tend to use a similar model.

Despite the frequent occurrence of early diarrhea in the present study, there were no cases of protein malnutrition or episodes of severe hypoglycemia. This provides more evidence that the preservation of some flow into the duodenum has a protective effect on nutrition and results in better glycemic regulation[27]. The frequency of intestinal symptoms may have been influenced by the larger diameter of the gastroileal anastomosis than in the original proposal by Santoro *et al*.[12], which was thus performed due to concerns that the absence of SG could lead to anastomosis dysfunctionalization. In addition, the intact stomach may have caused a greater nutrient overload into an ileum that in some patients was still without hypertrophic adaptation.

Obesity has become a major public health problem in developing countries. An advantage of the alternative technique evaluated in this study is its simplicity, ability to promote preliminary weight loss and possible risk reduction. Advanced laparoscopy abilities allowed the safe execution of a manual anastomosis without the use of disposable, expensive materials, as mechanical devices and ultrasonic energy. Leaving the stomach intact allowed the rapid reintroduction of a regular oral diet, reducing the consumption of hospital supplies and promoting early discharge.

This study had some limitations. We studied the applicability of the new technique in superobese patients, but only in individuals with BMI<60kg/m^2. Patients with higher BMI are likely to derive greater benefit from a two-step operation. Our results were limited to the period prior to the second stage, the sleeve gastrectomy after one year. We are currently collecting data for the second stage. The impact of a staged approach is best evaluated when both procedures are executed and long-term results are available. However, our greatest interest here was to present ITB as the first possible step of a new surgical option for the management of SO, aiding in preliminary weight loss and possible risk reduction.

We conclude that laparoscopic isolated intestinal transit bipartition is a new option as the first step of a staged approach for patients with SO. Avoiding SG as a first step simplifies the procedure, preventing the manipulation of large livers and easing the access to the upper abdomen. This approach also seems to be safer, since it escapes potentially serious complications of SG, such as gastric leaks, during the first step. Effective weight loss observed after six months may allow for a second, safer, definitive procedure and may be particularly useful in treating patients with severe obesity. Prospective and randomized studies comparing more frequent options such as BPD or RYGB are needed to define more precisely the role of this proposed new strategy in the treatment of superobesity.

R E S U M O

Objetivo: *o duodenal switch é um procedimento disabsortivo complexo, associado aos melhores resultados de perda de peso e controle metabólico. A cirurgia em etapas, com gastrectomia vertical como primeiro passo, é uma opção para reduzir complicações em pacientes superobesos. No entanto, alguns problemas persistem, como fígados grandes, que dificultam a abordagem cirúrgica, e complicações, como fístulas graves. A bipartição do trânsito intestinal é um modelo modificado e simplificado de desvio biliopancreático que complementa a gastrectomia vertical. É semelhante ao duodenal switch com menores complexidade e consequências nutricionais. Este estudo avaliou a viabilidade e a segurança da bipartição de trânsito isolada como o procedimento inicial para tratar a superobesidade.* **Métodos:** *foram incluídos 41 pacientes superobesos, com IMC médio de 54,5±3,5kg/m^2. Uma bipartição de trânsito isolada laparoscópica foi realizada como o primeiro procedimento em uma nova abordagem em duas etapas. Perda de peso e complicações foram analisadas durante um ano de acompanhamento.* **Resultados:** *todos os procedimentos foram completados por laparoscopia. Após seis meses, a perda média de excesso de peso percentual foi de 28%, permanecendo estável até o final do estudo. Não houve dificuldades intraoperatórias. Metade dos pacientes apresentou diarreia precoce e três tiveram úlceras marginais. Não houve complicações cirúrgicas maiores ou mortes.* **Conclusão:** *a bipartição de trânsito isolada laparoscópica é uma nova opção para uma abordagem em estágios na superobesidade, que pode permitir um segundo procedimento mais seguro após a perda de peso ao longo de seis meses. Pode ser útil, particularmente, para pacientes com obesidade grave.*

Descritores: *Desvio Biliopancreático. Gastrectomia. Cirurgia Bariátrica. Hormônios Gastrointestinais. Obesidade Mórbida.*

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