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## Residual gastric volume in morbidly obese diabetics after an overnight fasting or 3 hours of a carbohydrate-enriched supplement: a randomized crossover pilot study.

Gunther Peres Pimenta, Ozgur Dandin, Cervantes Caporossi, José Eduardo Aguilar Nascimento

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Gunther Peres **PIMENTA**

<https://orcid.org/0000-0002-1404-9193>

Ozgur **DANDIN**

<https://orcid.org/0000-0002-7386-6871>

Cervantes **CAPAROSSO**

<https://orcid.org/0000-0001-5819-3325>

José Eduardo **AGUILAR NASCIMENTO**

<https://orcid.org/0000-0002-3583-6612>

**Residual gastric volume in morbidly obese diabetics after an overnight fasting or 3 hours of a carbohydrate-enriched supplement: a randomized crossover pilot study.**

Volume gástrico residual em diabéticos obesos mórbidos após jejum noturno ou 3 horas de suplemento enriquecido com carboidratos: um estudo piloto cruzado randomizado.

Gunther Peres **PIMENTA**<sup>1</sup>, Ozgur **DANDIN**<sup>2</sup>, Cervantes **Caporossi**<sup>1</sup>,  
José Eduardo **AGUILAR NASCIMENTO**<sup>1</sup>

From <sup>1</sup>Universidade de Varzea Grande (UNIVAG), Department of Surgery, - Varzea Grande (MT), Brazil ; <sup>2</sup> University of Miami, Surgery – Miami (FL), USA

Autor Correspondente:

**Contribuição dos autores:**

Gunther Peres PIMENTA - realização da pesquisa, redação do artigo

Ozgur DANDIN - orientação e redação do artigo

Cervantes Caporossi - orientação e redação do artigo

José Eduardo AGUILAR NASCIMENTO - orientação da pesquisa, redação do artigo

**Short title:** Residual gastric volume in morbidly obese diabetics and carbohydrate-enriched supplement

Volume gástrico residual em diabéticos obesos mórbidos and suplemento enriquecido com carboidratos

## RESUMO

**RACIONAL:** Para reduzir o risco de regurgitação durante a anestesia para procedimentos eletivos, os volumes gástricos residuais (VRG) têm sido tradicionalmente minimizados com jejum noturno. O jejum pré-operatório prolongado tem algumas consequências adversas e tem sido abandonado para a maioria dos procedimentos cirúrgicos, com exceção de pacientes obesos e/ou diabéticos.

**OBJETIVOS:** O objetivo deste estudo foi avaliar o VRG em pacientes diabéticos obesos mórbidos após jejum tradicional ou abreviado.

**MÉTODOS** Este estudo foi aprovado pelo Comitê de Ética em Pesquisa em Seres Humanos da Universidade Federal de Mato Grosso, sob o número 179.017/2012. Este é um projeto prospectivo, randomizado e cruzado em 8 pacientes diabéticos tipo II com obesidade mórbida. O VRG foi medido endoscopicamente após jejum noturno tradicional (pelo menos 8 horas) ou após jejum abreviado (6 horas para sólidos e 3 horas para uma bebida contendo água mais 25 g (12,5%) de maltodextrina). Os dados são expressos como média e variação e as diferenças foram comparadas com testes t pareados em  $p < 0,05$ .

**RESULTADOS:** A população estudada tinha 41,5 (28-53) anos de idade, peso médio de 135 (113-196) kg, índice de massa corporal (IMC) de 48,2 (40-62,4) kg/m<sup>2</sup> e diabetes tipo II de 4,5 (1-10) anos. O VRG após o jejum abreviado foi de 21,5 (5-40) ml versus 26,3 (7-65) ml após o jejum tradicional. Essa diferença não foi significativa ( $p=0,82$ ).

**CONCLUSÕES:** O esvaziamento gástrico em pacientes diabéticos obesos mórbidos é semelhante após jejum tradicional ou abreviado com uma bebida com carboidrato.

**Palavras-chaves:** Esvaziamento Gástrico. Carboidratos. Obesidade Mórbida. Diabetes Mellitus Tipo 2.

## ABSTRACT

**BACKGROUND:** To reduce the risk of regurgitation during anesthesia for elective procedures, residual gastric volumes (RGV) have traditionally been minimized with overnight fasting. Prolonged preoperative fasting have some adverse consequences and has been abandoned for most surgical procedures, with the exception of obese and/or diabetic patients.

**AIMS:** The aim of this study was to assess the RGV in morbidly obese diabetics patients after traditional or abbreviated fasting.

**METHODS:** This study was approved by the Committee of Ethics in Research in Human Beings from the Federal University of Mato Grosso, number 179.017/2012. This is a prospective, randomized, and cross-over design in 8 morbidly obese type II diabetic patients. RGV was measured endoscopically after either traditional overnight fasting (at least 8 hours) or after abbreviated fasting (6 h for solids and 3 hours for a drink containing water plus 25 g (12.5%) of maltodextrin). Data are expressed as mean and range and differences were compared with paired t tests at  $p < 0.05$ .

**RESULTS:** The study population was 41.5 (28-53) years old, with a mean weight of 135 (113-196) kg, body mass index (BMI) 48.2 (40-62.4) kg/m<sup>2</sup>, and having type II diabetes for 4.5 (1-10) years. The RGV after abbreviated fasting was 21.5 (5-40) ml vs 26.3 (7-65) ml after traditional fasting. This difference was not significant ( $p=0.82$ ).

**CONCLUSIONS:** Gastric emptying in morbidly obese diabetics patients is similar after either traditional or abbreviated fasting with a carbohydrate drink.

**Keywords:** Gastric emptying. Carbohydrates. Obesity, Morbid. Diabetes Mellitus, Type 2

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**Correpondence:** José Eduardo Aguilar Nascimento. Email: [aguilar@terra.com.br](mailto:aguilar@terra.com.br)

**Image**

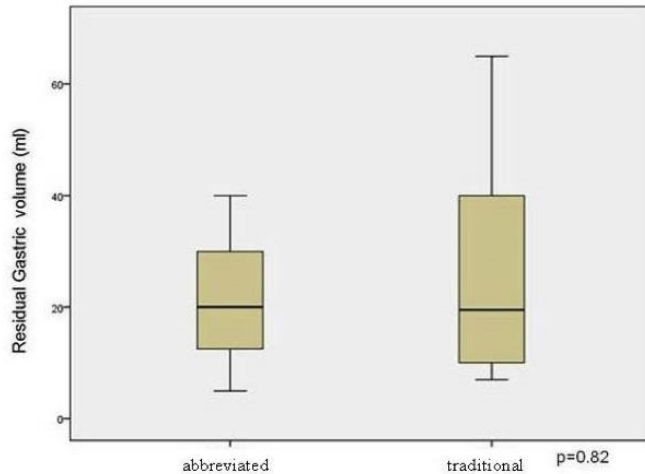


Figure 1. Residual gastric volume after abbreviated and traditional fasting.

### Central message

Preoperative overnight fasting for elective surgical patients ensures safe gastric emptying and is prescribed to avoid complications such as vomiting and aspiration of gastric contents, during the induction of anesthesia or light sedation. Morbidly obese patients have increased intra-abdominal pressure, and consequently, higher rates of gastroesophageal reflux. However, this study showed no difference in the time required for gastric emptying in obese individuals, compared with non-obese ones.

### Perspectives

Gastric emptying in morbidly obese diabetics patients is similar after either traditional or abbreviated fasting with a carbohydrate-rich drink. These findings support the idea of shortening the preoperative fasting period for sedation or general anesthesia in obese patients with type II diabetes.

## INTRODUCTION

Preoperative overnight fasting for elective surgical patients ensures safe gastric emptying and is prescribed to avoid complications such as vomiting and

aspiration of gastric contents, during the induction of anesthesia or light sedation<sup>29,26,42</sup>. However, this protocol was instituted in the middle of the last century when anesthetic techniques were rudimentary<sup>42</sup>.

It is now recognized that prolonged fasting can amplify the organic response to the trauma of surgery by increasing insulin resistance, acute-phase response and also it may lead to an increased loss of lean body mass<sup>31,14</sup>. By the 1980s, it was already known that gastric emptying of water and other noncaloric fluids followed an extremely fast exponential curve<sup>15,12</sup>. A large body of evidence has consistently shown that oral intake of clear fluids up to 2 h before the induction of anesthesia does not increase gastric volume or acidity<sup>35,27,4,30</sup>. Furthermore, carbohydrate (CHO)-rich drinks given 2-3h prior to the induction of anesthesia may add beneficial effects for the patients. The intake of CHO-rich drinks not only is safe<sup>11,32</sup>, but may decrease postoperative insulin resistance<sup>15</sup> and also reduce nausea and vomiting<sup>20,13</sup>. Thus, it may enhance postoperative recovery. For these reasons, many services have abandoned antiquated policies of prolonged fasting in most conditions<sup>28,31,25,23</sup>, the exception of intestinal obstruction, obesity, and presumed slow gastric emptying conditions such as pregnancy, diabetes, and gastroparesis<sup>33,4,2,37</sup>. Various international societies of anesthesia recommend 6-8h fasting for solids but allow clear or CHO-drinks 2-3h before surgery<sup>26,23,21,43</sup>.

Morbidly obese patients have increased intra-abdominal pressure, and consequently, higher rates of gastroesophageal reflux<sup>41,24</sup>. However, some studies have shown however that there is no difference in the time required for gastric emptying in obese individuals, compared with non-obese ones<sup>36,28,44</sup>. Nonetheless, there are few studies that investigated how is the residual gastric volume (RGV) 2-3h after the intake of CHO-drink in obese diabetic patients. New data on this topic would be important to increase the debate on whether it is safe or not safe to abbreviate preoperative fasting in this subset of patients. Therefore, the aim of this study was to assess the residual gastric volume (RGV) in morbidly obese type II diabetic patients by examining gastroscopy after either traditional fasting or abbreviated fasting with CHO-rich drinks.

## METHODS

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This is a prospective, randomized, and cross-over trial design with a group of morbidly obese and type II diabetic patients. This study was approved by the Committee of Ethics in Research in Human Beings from the Federal University of Mato Grosso, number 179.017/2012 and is in accordance with the ethics principals set out in the Helsinki Declaration (2000), and meets Brazilian national legal specifications. All patients participating in this study signed an informed consent form. The study was registered in ClinicalTrials.gov under the number NCT02114008.

The population of this study was composed of 8 type II diabetic patients with morbidly obesity. These obese patients were all in the waiting list as candidates for bariatric procedures. We included patients who were between 18 and 55 years of age, of both sexes, with body index mass (BMI) equal or greater than 40 Kg/m<sup>2</sup>. They all were using either oral hypoglycemics or insulin to control the diabetes. Diabetes of all participants was under control (fasting glycemia less than 140 mg/dL) and a endocrinologist provide information that the amount of maltodextrine intake would not induce any harm for the patients. All subjects did not receive additional antidiabetic drugs before or after the intake of the CHO-rich drink. We excluded patients with gastroparesis, with prior abdominal operations, who did not follow the fasting protocol, and those who were using medications such as prokinetics and H<sup>+</sup> pump inhibitors for gastrointestinal symptoms.

The randomization was done at the admission through random numbers generated by a computer software available online at [www.graphpad.com](http://www.graphpad.com).

Patients underwent two endoscopic examinations within two weeks interval. The main endpoint was the RGV measured by a certified endoscopist after aspiration of gastric contents into a graduated cup.

We compared the RGV after either traditional fasting (at least 8 hours before the test) or abbreviated fasting (6 hours fasted for solids followed by the intake of 200ml of beverage containing water plus 25g (12.5%) maltodextrin 3 hours before the test.



All the endoscopic procedures were scheduled to begin at 9 AM, and were performed by the same board-certified endoscopist. He performed the endoscopies blind to the study design. The endoscopies were conducted at Gastroclinica, Cuiaba, Brazil, between April to June, 2018. Sedation was performed by certified anesthesiologist who also was blind to this study. A intravenous bolus injection of 2 ml of lidocaine hydrochloride (Astra Zeneca, São Paulo, Brazil) followed by 100 to 150mg of propofol before endoscopy were done in all cases. Digital oximetry was carried out throughout the procedure. Patients were positioned in left lateral recumbent throughout the endoscopy. A flexible electronic video endoscope (EG2770K; Pentax Corporation, Tokyo, Japan) of 9 mm in outer diameter was used for conventional upper endoscopy, according to a standard protocol recommended by the fabricator. All gastric fluid was thoroughly suctioned through an endoscope side port. The RGV were measured and recorded. by the endoscopist after aspiration of gastric contents.

Comparison of RGV between the two groups were done by paired t tests. All statistical analysis were made by software Statistical Package for the Social Sciences (SPSS for Windows 11.0). The minimum accepted significance level was 5% ( $p < 0.05$ ).

## RESULTS

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All participants have followed the fasting protocol in the two periods of the study. There were no complications during the endoscopic procedures. The gastroscopist reported that in all cases, the aspiration of gastric contents was very easy and did not increase the duration of the procedure. All patients were found to have a mild gastritis.

All patients were receiving oral hypoglycemic drugs, and 2 of them were under different doses of subcutaneous insulin. All of them had fasting hyperglycemia less or equal 140 mg/dL at the moment of the test. The clinical and demographic characteristics for these patients can be seen in Table 1.

Gastric contents were found in all patients. The mean RGV in the abbreviated fasting group was 21.5ml (range 5 - 40ml) while in the traditional

fasting group was 26.3ml (range 7 - 65 ml). These findings can be seen in Figure 1.

The difference between groups was not significant ( $p=0.82$ ). The findings in each one of the patients can be seen in Table 2.

## DISCUSSION

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The main finding of the study was that CHO-rich drink given 3h before sedation for endoscopic procedure did not increase the RGV in this group of morbidly obese diabetics patients. Another important finding was that all exams were easily performed without anesthetic complication such as gastroesophageal reflux or broncho aspiration. These results suggest that the abbreviation of fast for upper endoscopy in morbidly obese patients is safe. Furthermore, these findings not only reinforce the prescription of CHO-rich drinks before procedures to abbreviate fasting, but they are also in accordance with previous data from the literature<sup>33,5,2</sup>.

Many traditional peri-procedural prescriptions, including pre-procedural overnight fasting, are based on dogma rather than scientific evidence<sup>29,19</sup>. Supported by the dogma of "nil per os" before surgery<sup>29</sup>, obese patients have been considered a high-risk population for bronchial aspiration during the induction of anesthesia due to a combination of increase gastric acid secretion low gastric pH<sup>40</sup>. However, it was shown that the intake of clear liquid or CHO-rich drinks 2-3 hours before gastroscopy did not elevated the gastric pH and did not increased the RGV<sup>38,3</sup>. Another study showed that gastric emptying in patients with type 2 diabetic is not delayed, suggesting that a carbohydrate-rich beverage may be safely administered before anesthesia<sup>18</sup>. Finally, studies have shown that fasting abbreviation in morbidly obese patients undergoing sleeve gastrectomy is safe<sup>22,34</sup>.

Modern procedures recommended by multimodal protocols<sup>37,43,17,1</sup> in elective surgical patients include the reduction of preoperative fasting times, which may result in reduced morbidity and shorter postoperative hospital stays<sup>34,9,39</sup>. Prolonged preoperative fasting induces insulin resistance, stimulates the glycogenolysis, proteolysis, lipolysis, and may increase glycemia<sup>7,10</sup>. Insulin

resistance induced by fasting is similar to the mechanism occurring in patients with type II diabetes. This is followed by a decrease in oxidative glucose disposal, particularly in muscle cells<sup>6</sup>. Prolonged preoperative fasting may also lead to an increase in the inflammatory markers of the acute-phase response after surgery. Conversely, CHO-rich oral supplements taken 2-3h before surgery may attenuate the metabolic response<sup>37,41,45</sup>. The meta-analyses conducted by Awad et al, including 21 controlled and randomized studies, concluded that the abbreviation of preoperative fasting in major elective abdominal surgeries may reduce the length of hospital stay and the postoperative insulin resistance<sup>8</sup>.

One of the biggest current challenges is the implementation of a protocol with 2-3 hours of fasting period. This is because, in addition to the problem of dogma, it is easier to simply prescribe no oral intake after midnight. Therefore, it is difficult to educate patients and hospital staff to adhere to the new guidelines<sup>26</sup> and implement fasting abbreviation.

Despite the advantages and safety demonstrated by new studies<sup>33,5,2,37,43,44</sup>, as well as in this study, there is still a need for more scientific evidence. The findings in our pilot study warrant some criticism, as the sample size was very small and limited to only 8 individuals. Thus, extrapolation of these findings for clinical application should be done with caution. However, crossover studies are considered adequate and valid in the current literature to address this type of research question. Controlled randomized crossover studies hold significant importance in medical research. This design enables the subjects to be compared with themselves, guaranteeing optimal control groups. As a result, this significantly reduces biases and confounding variables compared to other randomized studies. Furthermore, we can conclude that crossover studies are statistically efficient, cost-effective, and require only a small number of individuals in their design<sup>25</sup>.

## **CONCLUSIONS**

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Gastric emptying in morbidly obese diabetics patients is similar after either traditional or abbreviated fasting with a carbohydrate-rich drink. These findings support the idea of shortening the preoperative fasting period for sedation or general anesthesia in obese patients with type II diabetes.

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Table 1. Demographic characteristics of the patients.

<b>Variable</b>	<b>N or Median</b>	<b>Range or %</b>
Age (y/o)	41	28-53
Male (N,%)	4	50
Weight (kg)	136	113-196
BMI (kg/m <sup>2</sup> )	48.2	40.1-62.1
Time having Diabetes (years)	4.5	3-10

BMI=body mass index

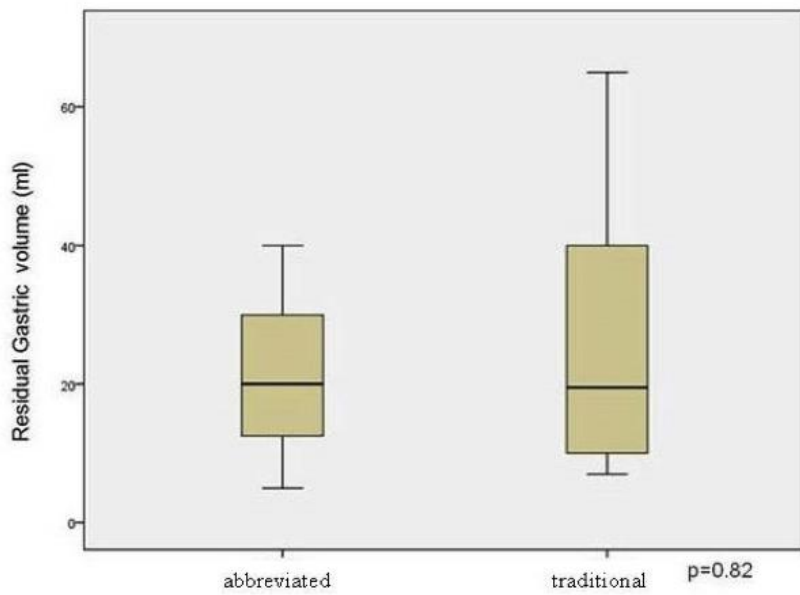


Figure 1. Residual gastric volume after abbreviated and traditional fasting.

Table 2. Residual gastric volume (mL) found in each individual after traditional or abbreviated fasting.

Patient number	Abbreviated Fasting (3h CHO-drink)	Traditional Fasting (8h)
1	5	65
2	10	14
3	20	10
4	20	7
5	40	40
6	20	25
7	40	40
8	15	10

P=0.82 (Paired T test) ; CHO= carbohydrate

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