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Postoperative Analgesia in Gastroplasty under Total versus General Balanced Venous Anesthesia. A Double-Blind Randomized Clinical Trial

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Abstract

Introduction: *Bariatric surgery anesthesia must consider the patient's multisystem assessment with the aim of ensuring there is little or no impact on the postoperative period. Pain management is very important to sucess of the procedure. Methods: Double-blind randomized clinical trial to evaluate postoperative pain according to anesthetic technique, balanced general anestesia (BGA) or total intravenous anestesia (TIVA), in bariatric bypass surgery. Pain assessment was based on the visual analogue scale in the PACU and in the ward. Objective: Evaluate pain in patients undergoing BGA and TIVA for bariatric bypass surgery via laparoscopy, in the PACU and on the 1st postoperative day. Results: 144 patients were randomized with the help of a table generated by a statistician. Divided into two groups, one of which was applied AGB (n = 72) and the other, TIVA (n = 72). Patients were managed by the same surgery and anesthesiology team, had similar physical and clinical characteristics. In the PACU, the TIVA group had 49 patients (69.1%) who did not complain of pain, compared to 50 (69.4%) in the BGA group (p = 0.65); pain (VAS greater than 4) was reported in 15 (20.8%) patients in TIVA and 12 (16.7%) in BGA. In the ward, on the 1st POD, reports of pain decreased in both groups, with 10 patients (13.9%) in the TIVA group and 16 (22.2%) in the BGA group (p=0.64). There was no record of vomiting. One patient in the TIVA group complained of nausea. Conclusion: No significant difference in pain perception in patients undergoing TIVA or BGA.*

Keywords: *Bariatric Surgery; General Anesthesia; Pain; Postoperative; Postoperativa Nausea and Vomiting.*

1. Introduction

Obesity is a highly prevalent chronic disease that has acquired great importance in the global health context. It has a clinical diagnosis, routinely based on the Body Mass Index (BMI) and/or measurement of abdominal circumference. Overweight is defined as an increase in BMI from 25 to 29.9 kg/m², obesity as a BMI greater than or equal to 30 kg/m².[1]

According to data from the Brazilian Ministry of Health (2020), there was a 72% increase in the incidence of obesity between 2006 and 2019, which went from 11.8% to 20.3%, while the highest percentage is among women (21%).[2]

The classification of obesity involves its etiology and is divided into two stages. The first is the presence of peripheral insulin resistance, through fasting insulinemia and the calculation of homeostasis model assessment (HOMA-IR). The second stage is based on identifying the presence or absence of risk factors that favor weight gain. Such risks are separated into: syndromic; epigenetic, endocrinological, neurological and sleep disorders, use of drugs, psychosocial problems and/or somatic obesity. Different mechanisms may coexist, and the main objective of this classification is to broaden the view regarding the causal mechanisms of obesity and, thus, make therapeutic approaches more specific and efficient.[3]

Long-term consequences include coronary artery disease, hypertension, dyslipidemia, *diabetes mellitus*, gallbladder disease, joint degeneration,

obstructive sleep apnea, socioeconomic factors, and psychosocial impairment.[4]

Pain management is particularly relevant in the obese population due to their greater susceptibility to perioperative complications of cardiovascular, thromboembolic, or pulmonary origin. Surgical treatment, which is currently widespread, emphasizes the importance of understanding the analgesic requirements of these patients.[5]

Anesthetic planning for bariatric surgery should consider the multisystemic assessment of the patient, including clinical and surgical variables. Criteria such as sex, age, BMI, smoking, alcohol consumption, diabetes mellitus (DM), systemic arterial hypertension (SAH), chronic pain, chronic use of medications, previous surgeries, occurrence of previous acute postoperative pain and emotional changes, such as nervousness, apprehension, worry and sadness, should be identified.[6]

Preoperative anxiety is closely linked to greater difficulty in venous access, mandibular stiffness during laryngoscopy, autonomic and hemodynamic fluctuations, need for higher doses of anesthetics and other drugs, in addition to a higher incidence of postoperative nausea and vomiting (PONV).[7]

The main objective of this study was to evaluate the prevalence and pain scores in the post-anesthesia care unit (PACU) in patients undergoing bariatric surgery using the balanced general anesthesia (BGA) technique versus the total intravenous general anesthesia (TIVA) technique. As secondary objectives, our study interest was to identify the prevalence of nausea and vomiting in the immediate postoperative period, also in the beds of the post-anesthesia recovery center, as well as the assessment of pain on the 1st postoperative day (1st POD) in these patients and the use of opioids in the ward beds.

2. METHODOLOGY

A double-blind, randomized clinical trial was conducted to assess the prevalence of postoperative pain and nausea or vomiting in patients undergoing BGA or TIVA for videolaparoscopic bariatric surgery. This trial was performed according to the CONSORT guidelines. This study was registered in the Brazilian Registry of Clinical Trials (ReBEC) under number RBR-4m5pdbf:

Patients referred to the Hospital do Coração de Goiás (HCOR) for bariatric surgery and who agreed to participate in the study by signing the informed consent form (ICF) were included. Sample size calculation was performed to ensure adequate statistical power for detecting clinically significant differences between anesthetic techniques. Based on a 95% confidence level (α=0.05) and a margin of error of 5%, a total sample size of 144 patients was determined. This calculation was based on the anticipated variability of the primary outcome measure, specifically postoperative pain scores, and aimed to provide sufficient power to detect a clinically meaningful difference between the anesthetic groups. The final sample size was adjusted to account for potential patient dropout, ensuring that the minimum required sample of 144 individuals would be achieved.

Patients with cognitive deficits who were unable to understand the researchers' instructions and patients who refused to participate in the study by not signing the ICF were excluded. In addition, patients with a previous history of major upper abdominal surgery and those involved in other interventional perioperative studies were excluded.

These patients were previously randomized to the balanced and total intravenous techniques. There was no interference by the research team in the indication for bariatric surgery or in its performance technique, nor in the anesthetic technique to be performed. The patient and the person responsible for the postoperative evaluation were blinded, and the anesthetic technique used was previously known only to the anesthesiologist in the operating room, as programmed in the randomization list.

The study asked about the presence of postoperative pain and its intensity using the Visual Analogue Scale (VAS), if any.

The tabulation and statistical analysis were performed in Microsoft Excel®, version 2010. Quantitative variables were presented as means, standard deviations, minimums and maximums. The distribution of these variables was analyzed by the Kolmogorov Smirnov test, when necessary, to calculate normality. Qualitative variables were presented in absolute numbers and proportions. Parametric variables were evaluated by the Student's t-test. For nonparametric data, the Mann-Whitney test was used. A 5% significance level was assumed ($p \leq 0.05$). The SAS® University Edition software was used for these calculations. All patients underwent pre-anesthetic evaluation less than one week before surgery. Upon arrival at the surgical center, patients were evaluated by the nursing team and

again by the anesthesiology service, in addition to checking the pre-anesthetic evaluation using the TASY® system.

All patients were received in the room, positioned in the supine position on the surgical table and monitored with pulse oximetry, CONOX®, cardioscopy and non-invasive blood pressure. Compression stockings and pneumatic boots were placed on all participants, and oxygen was provided via nasal catheter at 2 to 3 L/min. Venipunctures were performed in the upper limb using an antiseptic technique, using catheters 22G or 20G. As appropriate for the drug administered, the corrected ideal weight {(current weight - ideal weight) x 0.4 + ideal weight} was calculated for all patients for the correct dose. The infusion was started with ketamine 0.5mg/kg, dexmedetomidine 1 mcg/kg, lidocaine 1 mg/kg, parecoxib 40mg, dexamethasone 10 mg, scopolamine + dipyrone 16 mg + 2500 mg and the antibiotic cefoxitin, as recommended by the Hospital Infection Control Committee (CCIH) of the institution, at a dose of 4 g. These drugs were diluted in 250 ml saline solution and administered for 10 to 15 minutes. 100% oxygen was administered at a dose of 10 L/m via mask for denitrogenation for 5 minutes and then intravenous induction was started with sufentanil 0.2 to 0.3 mcg/kg, propofol 1 to 2 mg/kg, rocuronium 0.6 to 0.8 mg/kg. After induction, 10 mg of methadone was administered with an intramuscular injection. A target-controlled remifentanil pump was assembled at a dilution of 2000 mcg/20 ml and used in doses according to the hemodynamic and CONOX® response to surgical stimuli. Maintenance was performed according to the randomization that varied between total intravenous or balanced. If TIVA, another target-controlled propofol 10 mg/ml pump was equipped so that CONOX® varied between 40 and 60. If BGA was used, the proportion of sevoflurane delivered in percentage also varied according to CONOX® in the same scoring patterns. Positioning, joint cushions, eye care and chest, upper and lower limb restraints were checked in all patients. TAP block performed by the surgical team after pneumoperitoneum occurred in all patients. At the end of the surgery, the patients were decurarized with 200 mcg/kg of sugammadex, a second prophylaxis against nausea and vomiting was given with 4 mg of ondansetron, they were extubated in the operating room while awake and transferred to the anesthesia recovery room on a suitable stretcher, with the headboard elevated at 30º, where they received monitoring with pulse oximetry, cardioscopy and non-invasive blood pressure. There, they were evaluated for pain scores, nausea and postoperative vomiting as described above.

3. RESULTS

A total of 144 patients were randomized using a table generated by a statistician. They were divided into two groups, one of which received BGA (n = 72) and the other received TIVA (n = 72). The patients were managed by the same surgical and anesthesiology team. Both groups presented similar physical and clinical characteristics, as shown in Table 1.

Table 1. *Basic characteristics of the sample*

	Total Intravenous	Balanced	p
Weight (Kg)	117.2 ± 21.9	119.3 ± 22.1	0.59
Height (cm)	164.6 ± 9.4	167,9 ± 9,7	0.03
BMI (Kg/cm2)	43.0 ± 6.3	42.0 ± 6.6	0.39
AGE (years)	38.2 ± 9.5	38 ± 8.9	0.88
Lifestyle Habits			0.14
Sedentarism	30 (41.7%)	25 (34.7%)	
Etilism	0 (0%)	2 (2.8%)	
Smoking	1 (1.4%)	1 (1.4%)	
Sedentarism + etilism	6 (8.3%)	8 (11.1%)	
Sedentarism + smoking	0 (0%)	1 (1.4%)	
Etilism + smoking	1 (1.4%)	1 (14%)	
None	34 (47.2%)	34 (47.2%)	
Quantity of comorbities	0.8 ± 1.2	1,3 ± 1.4	0.14
Previous surgery	0.9 ± 0.7	0.8 ± 0.8	0.28
Quantity of previous surgeries			
0	14 (19.4%)	0 (36.1%)	
1	32 (44.4%)	31 (43.1%)	
2	17 (23.6%)	9 (12.5%)	
3	9 (12.5%)	5 (6.9%)	
4	0 (0%)	1 (1.4%)	
Legenda: Kg – kilogram; cm – centimeters; %- percent			

In the PACU, the TIVA group had 49 patients (69.1%) who did not complain of pain, compared to 50 (69.4%) in the AGB group (p = 0.65); severe pain (VAS greater than 4) was reported in 15 (20.8%) patients in the TIVA group and 12 (16.7%) in the AGB group. In the ward, on the 1st POD, the report of pain decreased in both groups, with 10 patients (13.9%) in the TIVA group and 16 (22.2%) in the BGA group (p = 0.64). Data are described in Table 2.

Table 2. *Pain assessment – Visual Analogue Scale (VAS)*

	Total Intravenous	Balanced	p
RPA			**p = 0.65**
No pain	49 (68.1%)	50 (69.4%)	
1 to 4	8 (11.1%)	10 (13.9%)	
5 to 10	15 (20.8%)	12 (16.7%)	
Ward			**p = 0.64**
No pain	62 (86.1%)	56 (77.8%)	
1 to 4	6 (8.3%)	15 (20.8%)	
5 to 10	4 (5.6%)	1 (1.4%)	

There was no record of vomiting, and only one patient in the AVT group complained of nausea, as shown in Table 3.

Table 3. *PONV Assessment*

	Total intravenous	Balanced	p = 0.32
Nausea	1 (1.4%)	0	
Vomit	0	0	
None	71 (98.6%)	72 (100%)	

4. Discussion

Anesthetizing morbidly obese patients is a challenge, and therefore, several studies have been conducted to clarify techniques and procedures that can improve adverse effects, such as pain, nausea and vomiting, awakening and post-anesthetic recovery times, among others.

According to our study, there was no statistically significant difference in the assessment of pain between patients undergoing BGA and TIVA for bariatric surgery by videolaparoscopy. A clinical trial with a sample group of 183 patients, with methods similar to ours, but using desflurane in BGA, also concluded that there was no difference in pain quantification between the group undergoing the intravenous and inhalation techniques.[8]

A systematic review based on seven randomized studies, totaling 693 patients, showed that there was no difference in postoperative pain at 30 minutes, 1 hour, or 24 hours, nor in the demand for opioids after surgery, regardless of whether BGA or TIVA.[9] However, studies show that when comparing other parameters, the choice of technique interferes with the outcome. Intravenous anesthesia was preferable for reducing episodes of nausea and vomiting.[9] Sevoflurane, on the other hand, was shown to be superior for maintaining hemodynamic stability and rapid recovery from anesthesia in obese patients.[10]

Pain assessment is always a challenge. It is worth remembering that, for the same surgical technique, the same painful nociceptive stimulus may have different clinical representations, knowing that each patient reacts differently due to psychological, social, cultural and other issues. Therefore, pain inhibition may occur in various receptors where multimodal anesthesia acts, which may be adrenergic, serotonergic and opioids.[11] Patients who receive preemptive analgesia have fewer complaints of pain and less need for the administration of narcotic drugs in the postoperative period. [12,13] The patients in our study received preemptive analgesia, there was no contraindication due to allergy or any other reasons, so all patients were administered dipyrone, scopolamine, parecoxib, lidocaine without vasoconstrictor, ketamine and dexmedetomidine approximately 30 minutes before the surgical incision. Other measures that can be adopted to alleviate painful stimuli are regional blocks. In the anesthetic strategy, we chose not to perform them. However, the laparoscopically assisted transversus abdominis block was a specific stage of the surgical technique, which we did not intend to intervene in. All patients underwent the same blockade, with 0.5% ropivacaine solution, respecting the maximum dose. Studies have shown that this

blockade is advantageous compared to placebo[14] and equivalent to that performed with ultrasound (transversus abdominis plane block – TAP block)[14,15] and to paravertebral block.[16] In particular, a meta-analysis covering 12 studies up to 2023 indicated that TAP block was superior among peripheral regional block techniques.[17]

A question regarding the pain scores found in the study may suggest good analgesic coverage, but we lack comparative studies both in the option of postoperative administration of medications, as well as the continuous infusion of ketamine, lidocaine and dexmedetomidine throughout the intraoperative period. Another question that we can ask is in relation to the degree of postoperative sedation in this technique, since deeper degrees of sedation can mask greater degrees of pain in the immediate postoperative period, which would be a negative misleading factor in relation to the technique used. On the other hand, low pain scores in the late postoperative period can be a positive factor of this technique.

Another point of discussion, thinking about multimodal anesthesia, would be the use of magnesium. Its use is already consolidated in the multimodal strategy because it acts both to reduce pain scores, hyperalgesia, consumption of analgesics, nausea and vomiting, among others[18]. In our techniques, magnesium was not used due to its undesirable effects, such as areflexia, prolonged neuromuscular blockade, delayed awakening and prolonged sedation[19]. Even so, we remain uncertain whether the use of magnesium could have influenced positively or indifferently the results presented.

In a study with 271 patients by Silva et al., where differences in analgesia were compared in the immediate postoperative period of bariatric surgery using three different techniques (group 1 with analgesia based on morphine, remifentanil and sufentanil; group 2 with morphine, sufentanil and dexmedetomidine; group 3 with target-controlled infusion of remifentanil, methadone, dexmedetomidine, magnesium sulfate and lidocaine), interesting data were found, in which analgesia in the third group was superior in relation to the others. In this study, however, the drugs for anesthetic maintenance were not compared, with it being described only that sevoflurane was used in proportions that maintained the anesthetic depth monitor (CONOX®) with a target between 40-60. Even so, it was evident that the multimodal strategy associated with methadone is superior to other venous strategies that do not involve joint peripheral blocks. This study also showed that methadone is safe, reduces postoperative opioid consumption, reduces postoperative pain scores and is superior to the technique based on the isolated use of sufentanil intraoperatively.[20]

From a quality perspective, all patients underwent pre-anesthetic consultation on an outpatient basis. It has already been established that prior medical care guarantees several advantages, such as reduced anxiety, reduced morbidity, reduced costs and improved anestesia.[20] Since many patients still have fears and mistrust about anesthesia, we believe that the pre-anesthetic evaluation may also have an influence on the pain results presented. Therefore, it is necessary to clarify all doubts and questions regarding the anesthetic procedure during the consultation. For the anesthesiologist, the consultation is also beneficial to anticipate possible intraoperative complications, airway management, as well as medication adjustment, guidance on fasting, and others.[20]

Regarding PONV, patients undergoing bariatric surgeries have at least two aggravating risk factors for this complication (general anesthesia and intraperitoneal surgery with manipulation of loops). Other variable factors are described in the simplified Apfel score: smoking, female gender, previous history of PONV and use of opioids in the postoperative period.[21] Studies report an incidence of 30% in the general surgical population and 80% in high-risk patients.[22]

Total intravenous general anesthesia with propofol would have lower PONV rates as an expected result, since it is also considered an antiemetic agent[22], however the data did not show a significant difference between the two techniques used. The measures that contributed to the low incidence of these complaints in the postoperative period can be attributed to the Enhanced Recovery after Surgery (ERAS) protocol in bariatric surgery, which recommends multimodal prophylaxis with at least two antiemetics, lower doses of opioids, videolaparoscopic surgery and monitoring with CONOX® for reduced use of hypnotic anesthetics[23].

Monitoring the depth of anesthesia with CONOX® is a resource that directs the use of smaller amounts of inhalational agent, which in turn can reduce the likelihood of PONV. However, we have as a limiting factor the lack of

a gas analyzer, since the hospital's anesthesia equipment did not have such a device.

The other points recommended in the ERAS protocol and that were duly followed in this study are special attention to handling of the difficult airway, protective mechanical ventilation, monitoring with CONOX®, deep neuromuscular blockade with complete reversal and the non-routine use of probes and drains[24]. As the main limitation, our work does not include monitoring of neuromuscular blockade due to the unavailability of Train of Four (TOF) in the hospital. We admit that the tool would add fundamental data for the detailed study of pain.

5. Conclusion

In this study, we observed that there was no significant difference in the perception of pain in patients undergoing bariatric surgery using the total intravenous general anesthesia technique or balanced general anesthesia. Regarding the scores of postoperative nausea and vomiting, there was also no difference between the groups.

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