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HOW I DO IT

Longer Immediate Recovery Time After Anesthesia Increases Risk of Respiratory Complications After Laparotomy for Bariatric Surgery: a Randomized Clinical Trial and a Cohort Study

Eliana C. M. Sudré[1] · **Priscila R. de Batista**[2] · **Yara M. M. Castiglia**[3]

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Abstract
Background We compared the effects of two anesthesia protocols in both immediate recovery time (IRT) and postoperative respiratory complications (PRCs) after laparotomy for bariatric surgery, and we determined the association between the longer IRT and the increase of PRC incidence.
Methods We conducted the study in two stages: (i) in a randomized controlled trial (RCT), patients received either intervention (sevoflurane-remifentanil-rocuronium-ropivacaine) or control protocol (isoflurane-sufentanil-atracurium-levobupivacaine). All patients received general anesthesia plus continuous epidural anesthesia and analgesia. Treatment was masked for all, except the provider anesthesiologist. We defined IRT as time since anesthetics discontinuation until tracheal extubation. Primary outcomes were IRT and PRCs incidence within 15 days after surgery. We also analyzed post-anesthesia care unit (PACU) and hospital length of stays; (ii) after the end of the RCT, we used the available data in an extension cohort study to investigate IRT>20 min as exposure factor for PRCs.
Results Control protocol (n=152) resulted in longer IRT (30.4±7.9 vs 18.2±9.6 min; p<0.0001), higher incidence of PRCs (6.58 vs 2.5 %; p=0.048), and longer PACU and hospital stays than intervention protocol (n=200); PRC relative risk (RR)=2.6. Patients with IRT>20 min (n=190) presented higher incidence of PRCs (7.37 vs 0.62 %; p<0.0001); RR=12.06.
Conclusions Intervention protocol, with short-acting anesthetics, was more beneficial and safe compared to control protocol, with long-acting drugs, regarding the reduction of IRT, PRCs, and PACU and hospital stays for laparotomy in bariatric patients. We identified a 4.5-fold increase in the relative risk of PRCs when morbid obese patients are exposed to an IRT>20 min.

Keywords Obesity · Bariatric surgery · Anesthesia · Postoperative complications

The study was performed at Vila Velha City, Espírito Santo State, Brazil.

✉ Eliana C. M. Sudré
elianasudre@gmail.com

Priscila R. de Batista
pri.ftp@gmail.com

Yara M. M. Castiglia
yarac@fmb.unesp.br

[1] Department of Anesthesiology, VVH Medical Center, Vila Velha, ES, Brazil

[2] Department of Physiotherapy, VVH Medical Center, Universidade Federal do Espírito Santo, Vitória, ES, Brazil

[3] Department of Anesthesiology, UNESP—Universidade Estadual Paulista, Botucatu, SP, Brazil

Introduction/Purpose

Anesthetics with shorter duration of action reduce the IRT after anesthesia and improve lung function, oxygenation, and ventilation of obese patients at post-anesthesia care unit (PACU) [1–4], but the clinical significance of these effects has not yet been well established due to the lack of monitoring after PACU discharge. Because of the respiratory abnormalities [5] caused by obesity and by general anesthesia, we hypothesized that longer IRTs would increase the PRC risk in bariatric patients. Therefore, we compared the effects of two anesthesia protocols in both immediate recovery time (IRT) and postoperative respiratory complications (PRCs) after laparotomy for bariatric surgery as well as we compared two different IRTs (>20 vs ≤20 min) after these anesthesia

protocols to assess the IRT's effect on PRCs during the hospital stay and within 15 days after surgery.

Materials/Methods

Study Design and Participants We conducted a randomized controlled trial (RCT) at VVH Medical Center, Vila Velha, ES, Brazil, during 2012. After the termination of the clinical trial, we divided the 352 available patients according to the duration of their IRTs to conduct an extension cohort study: we compared IRT ≤20 vs >20 min to evaluate the association between the longer IRT and the increase in PRCs rate.

Inclusion Criteria Inclusion criteria include laparotomy for restrictive gastroplasty with Roux-Y gastric bypass and unconstrained written informed consent, regardless of age and sex.

Exclusion Criteria Exclusion criteria include dyspnea at rest and previous bariatric surgery.

Withdrawal Criteria Withdrawal criteria include more than 5 % missing data, ineffective epidural anesthesia, surgical intercurrences, or non-respiratory complications.

Epidural Efficacy Definition Epidural efficacy is the absence of upper abdominal pain after awakening from general anesthesia; opioids and inhaled anesthetic consumption within the standardized values (Fig. 2).

Randomization Before surgery, each patient who met inclusion criteria was randomly allocated (ratio 1:1) to one of two study groups. An anesthesiologist not involved in the project tossed a coin every time a new patient was admitted to the surgical center: head stood for intervention and tail for the control protocol.

Masking Patients, surgeons, anesthesiologists who evaluated the outcomes and the statistician were masked about the allocation groups, but not the anesthesia provider.

Data Collection At the pre-anesthetic evaluation office, the researcher registered the demographic features (age, body mass index (BMI), sex, and physical status), the preoperative respiratory clinical history (obstructive sleep apnea (OSA), dyspnea on efforts, smoking, and asthma), and the results of spirometry and blood gases analyses. Other data were collected at surgical center, at PACU, at the ward, and during 15 days after surgery. The primary outcomes were IRT and PRC's incidence. The secondary outcomes were PACU stay and hospital stay.

Procedures All patients received similar care provided by the same anesthetic-surgical-physical therapy team. Except for the tested protocols, the standard of treatment was similar for all: premedication, prophylactic antibiotics, thromboprophylaxis, and monitoring resources (basal monitoring, bispectral index of the electroencephalogram (EEG-BIS), neuromuscular function monitor (train of four (TOF)-Watch), end-tidal (Et) CO_2, and anesthetic concentration). The anesthetic agent administration was adjusted according to clinical parameters and to EEG-BIS values (maintained between 40 and 60). The competitive neuromuscular blocker (NMB) administration aimed to keep the TOF count ≤1. The criteria to the tracheal extubation, to the transference from PACU to the ward (Fig. 1), and to the hospital discharge were similar for all patients. The surgeon standardized the criteria for discharge considering the walking ability, the respiratory comfort, the acceptance of the proposed diet, and the presence of intestinal function.

Anesthetic Techniques Patients designated to intervention protocol received a group of standard anesthetic agents (sevoflurane, remifentanil, rocuronium, and ropivacaine) which we considered potentially able to allow a faster IRT. Patients allocated to control protocol received classic agents (isoflurane, sufentanil, atracurium, and levobupivacaine). Figure 2 shows the dosage schemes for the drugs used in both protocols. All patients received an epidural catheter, approximately inserted between T12 and L1 for epidural anesthesia and for subsequent analgesia during the next 48 h. A test dose with local anesthetic (lidocaine 2 %, 60 mg with epinephrine 1:200.000) was applied

Tracheal extubation

Spontaneous ventilation;
$EtCO_2$ < 50mmHg;
$SatO_2$ > 90% without additional O_2;
TOF ratio ≥ 0.9;
BIS value > 90.

Transfer from PACU to the ward

Score 10 on Aldrette-Kroulik scale;
Score 2 on Ramsay sedation scale;
Score < 4 on pain VAS.

Fig. 1 Pre-defined and standardized criteria for tracheal extubation and transfer from the PACU to the ward. *EtCO2* end-tidal CO_2, *SatO2* arterial oxygen saturation, *TOF* train of four, *BIS* bispectral index of the electroencephalogram, *PACU* post-anesthesia care unit, *VAS* visual analogue scale

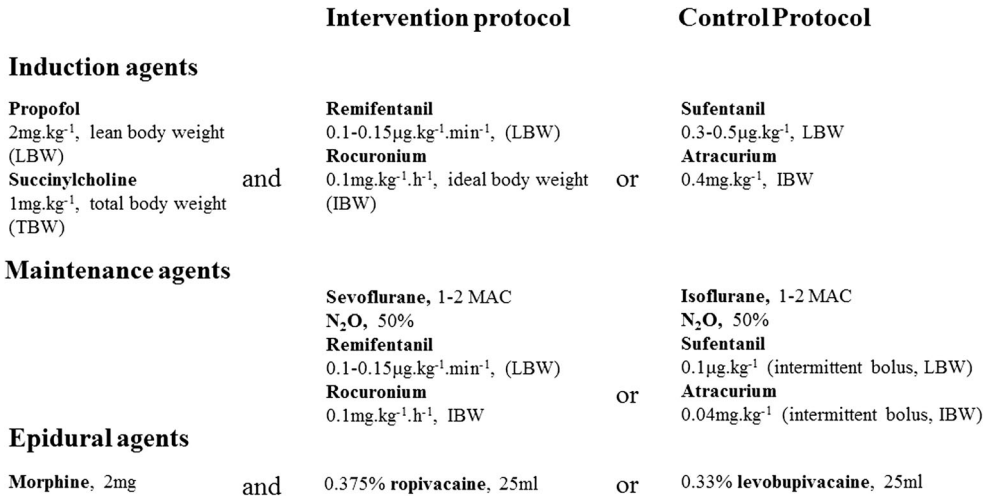

Fig. 2 Drugs used in intervention and control protocols. *LBW* lean body weight, *TBW* total body weight, *IBW* ideal body weight, *MAC* minimum alveolar concentration

through the needle and also through the catheter. Shortly after that, general anesthesia was induced and the patient was intubated. After correct positioning of orotracheal tube and hemodynamic stabilization, similar mechanical ventilation parameters were set for both groups (Fig. 3). Only after that, a single dose of morphine and local anesthetic (ropivacaine or levobupivacaine, according to the anesthetic protocol) was administered via the epidural catheter, which prevented us from checking the epidural anesthesia level before incision. Patients in whom epidural anesthesia was unsuccessful received analgesia with opioids intravenously and were excluded from analysis. For postoperative analgesia, we daily administered a bolus of 10 ml of 0.2 % ropivacaine plus morphine 2 mg, via epidural catheter, during 48 h after surgery.

Follow-up Patients received two post-anesthesia visits per day for epidural analgesia and data collection until hospital discharge. The patients, physical therapist, and surgeon were instructed to report immediately to the researcher, any suspected or confirmed PRC case, which had been defined previously (Fig. 4). On the seventh and on the 15th day after surgery, the researcher contacted the patients by telephone asking them about their respiratory conditions.

Outcomes The primary outcomes were the IRT after anesthesia and the PRC incidence during 15 days. Secondary outcomes were length of PACU and hospital stays.

Statistical Analysis We based the sample size calculation on the IRT after anesthesia. We established a 30 % decrease in the IRT for the intervention protocol as a significant value, and we calculated (α=0.05, β=95 %, and a one-tail hypothesis test) that it would be required to recruit a minimum of 127 patients per study protocol. We estimated that 20 % of the eligible patients might not complete the follow-up, so we enrolled 153 further patients to be randomized. We expressed the data as mean (standard deviations (SD)), median (limits), or percentage. We calculated the relative risk (RR) for the PRCs with a 95 % confidence interval (CI). We compared the protocols with independent samples *t* test, Mann-Whitney *U* test, logistic regression analysis, and ANOVA when appropriated.

Results

Randomized Clinical Trial

We randomly distributed 407 of 437 patients eligible for inclusion into two groups: intervention (n=223) and control (n=184)

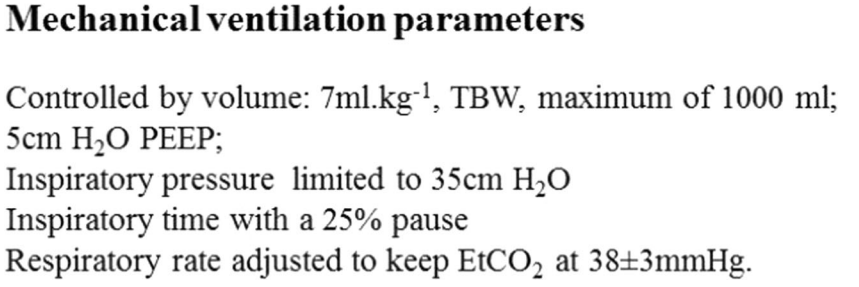

Fig. 3 Pre-defined and standardized criteria for mechanical ventilation. *TBW* total body weight, *PEEP* positive end expiratory pressure, *EtCO$_2$* end-tidal CO_2

Fig. 4 Postoperative respiratory complications definition. *Confirmed by radiography and resulting in extension of hospitalization/re-hospitalization
#Due to respiratory reasons

- Tracheal extubation time > 2 hours;
- Respiratory failure;
- Severe bronchospasm;
- Aspiration of gastric contents;
- Atelectasis with clinical consequences*: cough, dyspnea, abnormal lung sounds;
- Pneumonia*: cough, dyspnea, abnormal lung sounds, purulent tracheobronchial secretion, body temperature > 38°C and / or leukocytosis (> 10,000/mm³);
- Intensive care unit admission#;
- Death#.

groups. At the end of the study, 352 patients (intervention, n= 200 and control, n=152) were evaluated in an available data analysis. The main reason for withdrawal was epidural failure (Fig. 5). We conducted the available data analysis without considering losses and withdrawals. The baseline characteristics were similar in both groups (Table 1) with no difference in the postoperative pain score, or in the requirement of analgesics during the postoperative period between the studied groups. However, the median IRT, the PRC incidence, the median PACU, and hospital stays were higher in control group compared to intervention group. During the hospitalization and up to 15 days after surgery, 15 patients (4.3 %) developed PRCs (Fig. 6), five in the intervention group and 10 in the control protocol (p<0.05; RR=2.6), (Table 2). Eleven patients (3.1 % of the total sample; 73.3 % of those with PCRs) were admitted into the ICU on an emergency basis, four in the intervention group and seven in the control group. There was no aspiration of gastric contents, and no postoperative death was primarily associated to PRCs. The OSA prevalence was the only preoperative characteristic with a positive correlation with PRCs (OR=6.8849, 95 % CI=2.36–20.05; p=0.0004).

Extension Cohort Study

There were 162 (46 %) patients in the faster IRT group (IRT≤ 20 min) and 190 (54 %) in the longer IRT group (IRT> 20 min). Only one patient (0.61 % of 162) with faster IRT has developed PRC versus 14 patients (7.36 % of 190) with longer IRT (Table 3; RR=12.06; 95 % CI=1.02–1.05; p<0.0001).

Discussion

The control group of anesthetic drugs (i.e., isoflurane, sufentanil, atracurium, and levobupivacaine) used on patients undergoing bariatric surgery by laparotomy resulted in longer IRT, higher incidence of PRCs, and longer PACU and hospital stays, when compared to an intervention protocol (sevoflurane, remifentanil, rocuronium, and ropivacaine) with the potential to accelerate the IRT. Both groups were similar and comparable regarding the demographic findings.

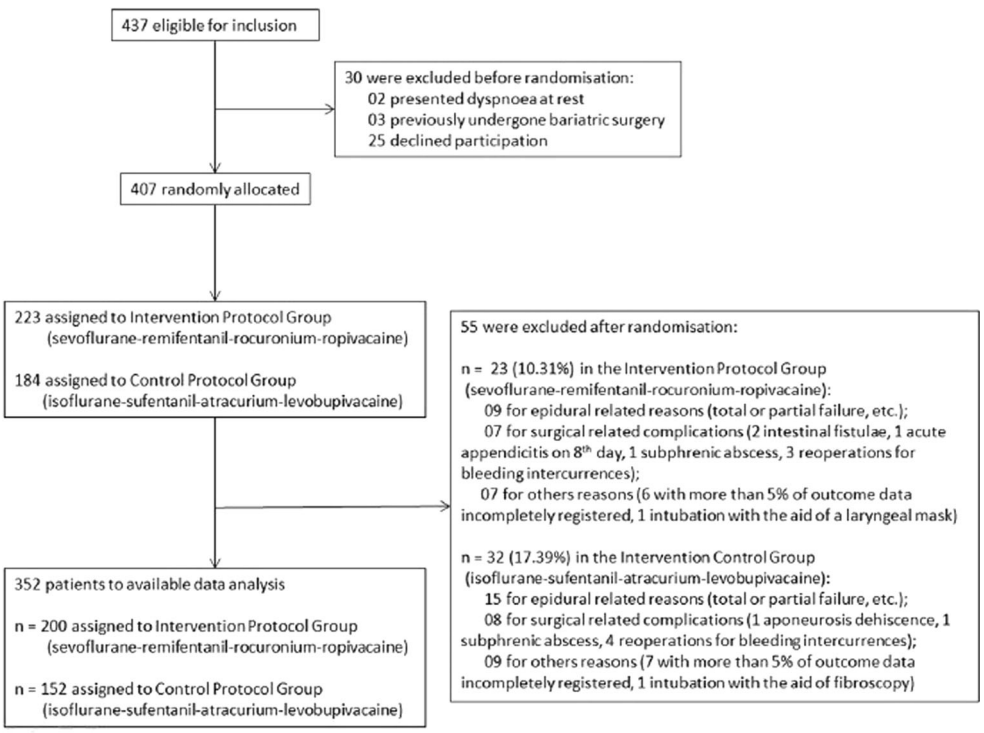

Fig. 5 The trial profile

Table 1 Baseline demographic, clinical characteristics, and other outcomes

	Intervention (n=200)	Control (n=152)
Age (years)[a]	37.0 (11.3)	36.6 (11.1)
BMI (kg/m^2)[a]	46.2 (6.4)	44.7 (5.9)
Sex[a]		
Female	151 (75.5 %)	116 (76.3 %)
Male	49 (24.5 %)	36 (23.7 %)
Physical status (ASA classification)		
2	114 (57 %)	88 (57.8 %)
3	86 (43 %)	64 (42.1 %)
Operative time (min)[b]	180.1 (48)	176.2 (55)
Pain (VAS score)[c]	2 (0–4)	2 (0–4)
OSA confirmed[a]	89 (44.5 %)	79 (51.9 %)
Obstructive spirometry[b]	11 (5.5 %)	8 (5.3 %)
Restrictive spirometry[b]	15 (7.5 %)	10 (6.57 %)
Hypoxia (blood gases analysis)[b]	4 (2 %)	3 (2 %)
Hypercapnia (blood gases analysis)[b]	33 (16.5 %)	24 (15.7 %)
Asthma[b]	46 (23 %)	31 (20.4 %)
Dyspnea on effort[b]	159 (79.5 %)	122 (80.3 %)
Smoking[b]	47 (23.5 %)	38 (25 %)

Intervention sevoflurane-remifentanil-rocuronium-ropivacaine, *control* isoflurane-sufentanil-atracurium-levobupivacaine, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *VAS* visual analog scale, *OSA* obstructive sleep apnea

Data are *n* (%), median (range), or mean (SD, 95 % CI). $p>0.05$

[a] Normal distribution: *t* test applied

[b] Skewed distribution: Mann-Whitney test applied

[c] Measurements made repeatedly in the same subject, ANOVA applied

Figure 6 shows a brief description of all PRCs, but the significant difference in PRCs incidence between the two protocols is best highlighted in Table 2. The collected data allowed us to an interpretation of the risk of PRCs in the sample. The control protocol, which determined significantly higher IRT values than the intervention protocol, also resulted in higher incidence (absolute risk) of PRCs as well as in a positive correlation with PRCs. With the cohort study, we have identified a 4.5-fold increase in relative risk of PRCs when comparing IRT>20 min vs IRT≤20 min, regardless of the anesthetic protocol. The longer IRT from anesthesia, which can be explained by the pharmacological characteristics of the group of drugs used in the control protocol, showed a cause-effect type relationship with the higher incidence of PRCs and probably also contributed to the greater length of stay in the recovery room and hospital. The higher incidence of PRCs in the control protocol, however, is not the reason of the difference observed in the length of hospital stay. In fact, we used the median of the data (and not its mean) as a measure of its central tendency, so we could avoid any effect of discrepant data. The absence of a standardized PRC definition in literature has led to a large variability on PRCs incidence over the time. We investigated atelectasis, pneumonia, and respiratory failure because these are the most important PRCs [6]. Different criteria for patient's selection also impair the risk factors determination. Factors affecting PRCs are related to patient's health status and to anesthesia/surgical effects [7]. No current evidence provides strong support for recommending one anesthetic technique over another to reduce the PRC risk. Although fair evidence suggests that short-acting NMB agents might reduce PRC risk [8], other factors also may affect IRT. The action of remifentanil and sevoflurane ends faster than that of sufentanil and isoflurane [9–11]. Accumulation of volatile anesthetics in adipose tissue may delay the recovery from anesthesia, and it might be exaggerated in morbidly obese patients. Lower IRTs than those of our patients have been reported after minor or more superficial surgeries, or in non-obese patients, or after surgeries with other anesthetics (e.g., desflurane) [1, 3, 4]. Desflurane has been suggested as a good option to obese patients because of its faster and consistent recovery profile [12], but it was not available to this study. Even in seemingly awake patients, small inspired fractions of anesthetics can blunt the hypoxic ventilatory response and also can impair protective functions during early recovery increasing the PRC risk [13]. Rocuronium and atracurium are both

N°	Group Protocol	PRC before PACU discharge	OSA confirmed	Description	Evolution
1	Intervention	No	No	Atelectasis, 3th day	3 days extension of hospital stay
2	Intervention	Yes	No	Bronchospasm	24 hours in ICU
3	Intervention	Yes	Yes	IRT > 2 hours	24 hours in ICU
4	Intervention	Yes	Yes	Respiratory failure	24 hours in ICU
*5	Intervention	Yes	Yes	Respiratory failure	24 hours in ICU
6	Control	Yes	Yes	Respiratory failure	24 hours in ICU
7	Control	Yes	Yes	Respiratory failure	24 hours in ICU
8	Control	No	Yes	Atelectasis, 8th day pleural effusion, respiratory failure	80 days in ICU + 10 extra days extension of hospital stay
9	Control	Yes	Yes	Acute pulmonary edema due to negative inspiratory pressure	24 hours in ICU; 7 days extension of hospital stay
10	Control	Yes	Yes	Respiratory failure	24 hours in ICU
11	Control	No	Yes	Atelectasis, 3th day	24 hours in ICU; 6 days extension of hospital stay
12	Control	No	Yes	Atelectasis, 3th day; pleural effusion; respiratory failure	30 days in ICU
13	Control	No	No	Atelectasis, 3th day	7 days extension of hospital stay
14	Control	No	No	Atelectasis, 3th day	7 days extension of hospital stay
15	Control	No	Yes	Atelectasis, 3th day	5 days extension of hospital stay

Fig. 6 Brief description of the postoperative respiratory complications. *PRC*postoperative respiratory complication, *ICU*intensive care unit. *Number 5 corresponds to the only PRC occurred in a patient with tracheal extubation time < 20 min

intermediate-acting NMB agents. However, they were employed in different ways, as a continuous infusion or *in bolus*, respectively. After repetitive administration of NMB agents, even with TOF ratio ≥0.9, muscle weakness from impaired neuromuscular transmission can occur [14] and may be associated with inhibition of the hypoxic ventilatory response and upper airway or pharyngeal dysfunction [15]. Even small degrees of postoperative residual curarization increase critical respiratory event incidence in PACU [14] and delay PACU discharge [16]. The PRCs we registered might be explained by anatomical, physiological, and pharmacological changes associated with obesity, but the PRC rate of 4.26 % in our entire sample was much lower than the 17–88 % previously published. [17]. Pain relief is a basic requirement of accelerated postoperative recovery programs because pain intensity affects inspiratory force and predisposes to hypoventilation and atelectasis after thoracic/upper abdominal open surgeries [18, 19]. Epidural morphine administration provided excellent analgesia in both groups, and the low dose utilized of this opioid is beneficial and safe

Table 2 Primary and secondary outcomes

	Intervention (*n*=200)	Control (*n*=152)	*p* value
Primary outcomes			
IRT time (min)	18.2 (2–170)	30.4 (9–165)	<0.0001
PRCs incidence	RR=2.6; 5 (2.5 %)	10 (6.58 %)	0.048
Secondary outcomes			
PACU stay (min)	164.9 (124–360)	193.1 (120–1440)	<0.0001
Hospital stay (h)	48 (40–132)	60 (48–960)	<0.0001

Intervention sevoflurane-remifentanil-rocuronium-ropivacaine, *control* isoflurane-sufentanil-atracurium-levobupivacaine, *IRT* immediate recovery time, *PRCs* postoperative respiratory complications, *RR* relative risk, *PACU* post-anesthetic care unit

Data are *n* (%) or median (limits). Skewed distribution, Mann-Whitney test applied.

Table 3 Extension cohort study results. Longer immediate recovery from anesthesia, respiratory complications, length of PACU, and hospital stays

Longer IRT (TE time>20 min) (n=190)		p value
PRCs	RR=12.06; OR=1.0309; 95 % CI=1.02–1.05	<0.0001
PACU stay	OR=1.0037; 95 % CI=1.00–1.01	0.0071
Hospital stay	OR=1.0419; 95 % CI=1.02–1.07	0.0007

IRT immediate recovery time, *TE* tracheal extubation, *PRCs* postoperative respiratory complications, *RR* relative risk, *OR* odds ratio, *PACU* post-anesthesia care unit

in OSA patients [20]. We selected ropivacaine for the potentially accelerated immediate recovery protocol because of its lesser motor blocking potency compared to levobupivacaine [21], but specific motor block evaluation was not an outcome of this study. Obesity is also strongly and directly related to OSA's severity [22]. Eleven (73 %) patients with PRC also had OSA; eight of which presented respiratory obstruction immediately after extubation, a complication typically described in adult obese patients with OSA [20]. OSA prevalence, with similar distribution in both groups, increased the PRC risk almost seven times (OR=6.8849). Seven patients (1.99 %) developed moderate, severe, or massive amount of symptomatic atelectasis after PACU discharge, which resulted in a variable extension of hospital stay. General anesthesia results in collapse of 10 % of lung tissue, but this value may exceed 25–40 % [23] in obese individuals [5, 24] who develop more extensive and long-lasting postoperative atelectasis [25] which may contribute to the development of pneumonia [26]. The total ICU admission rate in our study (3.1 %) was also lower than that previously reported [27]. Anesthetic agents may present an additive effect over other interventions (e.g., patient positioning, mechanical ventilation, surgical trauma) and diseases (e.g., obesity, OSA) with further impairment on respiratory muscles function and respiratory failure [28]. Most of our sample patients probably presented postoperative atelectasis [25], but, as postoperative care was similar for all, our findings suggest that patients who recovered earlier from the anesthetic depressant effects also returned faster to their pre-anesthetic conditions [28]. In the RCT study, any or all anesthetic drugs used in the control group might have contributed to the greater incidence of PRCs. In the cohort study, we observe that just one in 15 patients with PRCs had an IRT<20 min, implying that IRT>20 min may be a risk factor for these PRCs. Since PRCs contribute for risks related to anesthesia and surgery and are a source of postoperative morbidity, mortality, and longer hospital stays [29], obese patients would certainly benefit from anesthetic protocols which enable an enhanced immediate recovery from anesthesia.

This study may present some potential biases: all study subjects were from a private health service, and all perioperative care was provided by the same health professionals.

Conclusions

The intervention anesthesia, which consisted of short-term anesthetic agents, is more efficacious and safe compared to the long-term protocol anesthesia regarding the reduction of IRT, PCRs, and PACU and hospital stays for laparotomy in bariatric patients. Furthermore, we identified a 4.5-fold increase in the relative risk of PRCs when morbid obese patients are exposed to an IRT>20 min regardless the anesthetic protocols. These findings provide evidence for short-term benefits of faster IRT. More researches are needed to corroborate with our findings.

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Authors' Contributions Eliana Cristina Murari Sudre is an investigator anesthesiologist and responsible for the literature search, study design, data collection, data interpretation, writing and drafting of the work and revising it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Priscila Rossi de Batista is responsible for the data analysis, data interpretation, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Prof. Yara Marcondes Machado Castiglia is a consultant anesthesiologist and responsible for the data interpretation, drafting of the work and revising it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Compliance with Ethical Standards

Statement of Human Rights The study has been approved by the national research ethics committee (Brazil Platform), and all procedures performed were in accordance with its ethical standards and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individuals included in the study.

Conflict of Interest The authors declare that they have no competing interests.

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