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Opioid-free versus opioid-based anesthesia in laparoscopic sleeve gastrectomy: a single-center, randomized, controlled trial

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Abstract

Background Opioids are commonly used in general anesthesia for pain management. However, they are linked to significant side effects. Patients undergoing laparoscopic sleeve gastrectomy, particularly those with obesity, are at higher risk of experiencing adverse effects associated with opioids. Therefore, there is a need to explore alternative anesthesia options that do not rely on opioids. This study aims to investigate the efficacy of opioid-free anesthesia (OFA) compared to traditional opioid-based anesthesia (OBA) in patients undergoing laparoscopic sleeve gastrectomy.

Methods This single-center randomized controlled trial included eighty-three patients undergoing laparoscopic sleeve gastrectomy in a tertiary hospital. Patients were randomly assigned to dexmedetomidine and lidocaine infusion (OFA) or remifentanil (OBA). All patients received intra-operative propofol, sevoflurane, a neuromuscular blocking agent, and ketamine. The primary outcome included opioid consumption during the post-anesthesia care unit (PACU). Secondary measures included intraoperative hemodynamic stability, time to extubation, PACU stay duration, opioid consumption during the first 48 h, and anti-emetic requirements. Independent samples t-test or Mann–Whitney *U* test was used to assess for differences across the two groups.

Results PACU morphine consumption, total postoperative morphine consumption, anti-emetic requirements up to 48 h after surgery, and pain levels after surgery were not statistically significantly different between OFA and OBA groups. Other variables were not statistically different between the two groups, except for intraoperative anti-hypertensives where more patients in the OFA groups required it.

Conclusions Opioid-free anesthesia hasn't shown an opioid-sparing effect in patients with obesity undergoing laparoscopic sleeve gastrectomy. Larger multi-center studies are required to fully establish its effectiveness.

Trial registration ClinicalTrials.gov (NCT03507634); first trial registration date: 12/04/2018; first posted date: 25/04/2018.

Keywords Bariatric surgery, Sleeve gastrectomy, Opioid-free anesthesia, Postoperative pain, Opioid

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Background

Following the introduction of modern anesthesia in 1846, perioperative pain control has remained a paramount concern for anesthesiologists and patients (Robinson and Toledo 2012). Opioids stand as the benchmark class of analgesic medications, possessing evident clinical significance in managing moderate to severe acute pain (Casely and Laycock 2022). Opioids are commonly employed in the field of anesthesiology; however, they are associated with numerous side effects. These include respiratory depression, upper airway obstruction, postoperative nausea and vomiting, ileus and constipation, central muscle rigidity, hypersomnolence, urinary retention (Kaiko 1997), and opioid-induced hyperalgesia (OIH) (Brush 2012). With the growing use of opioids, tolerance, defined as the need for higher opioid doses to achieve analgesia, can lead to inadequate pain control and dose escalation (Colvin et al. 2019). The Enhanced Recovery After Surgery programs have emphasized reducing in-hospital opioid use and prescribing opioids after discharge to help alleviate the side effects associated with their use, mainly as it's a routine perioperative practice (Maurer et al. 2023).

Obesity is linked to heightened pain sensitivity and a lowered pain threshold through various mechanisms, such as increased pro-inflammatory cytokines and a higher risk of sleep disturbances (Chin et al. 2020). Given these factors, opioids may exacerbate this mechanism in patients with obesity, as opioids are known to induce hyperalgesia, which is a characteristic phenomenon that acts paradoxically in patients receiving them (Lee et al. n.d.).

To address these issues and enhance postoperative recovery while ensuring patient comfort and adequate analgesia, researchers are currently investigating opioid-free anesthesia (OFA) as an alternative to opioid-based anesthesia (OBA) (Lavand'homme and Estebe 2018). OFA is an intra-operative approach that relies on a balanced and multimodal technique without the use of systemic, neuraxial, or intracavitary opioids (Beloeil 2019; Sultana et al. 2017). OFA represents a viable and safe choice for various types of surgical procedures, including bariatric surgery (Ahmed 2020; Malo-Manso et al. 2020; Mulier 2019; Sultana et al. 2017; Toleska and Dimitrovski 2019; Turan et al. 2015; Ziemann-Gimmel et al. 2014). Several agents can be utilized in OFA, including alpha-2 adrenergic receptor agonists, lidocaine, ketamine, dexamethasone, magnesium, nonsteroidal anti-inflammatory drugs, gabapentin, pregabalin, and acetaminophen (Ahmed 2020). To our knowledge, the literature lacks sufficient research studies to support adjudicating the use of OFA in patients undergoing laparoscopic sleeve gastrectomy. Therefore, this study aimed to assess the efficacy of OFA in bariatric surgery for patients with obesity by comparing it with routinely performed OBA. We hypothesize that OFA, compared to OBA, is associated with an opioid-sparing effect during the postoperative care unit stay.

Methods

Study design

This is a randomized single-center trial conducted at a tertiary medical center in Lebanon. This study obtained ethical approval from the Institutional Review Board at the Lebanese American University (LAUMCRH.HB2.28/Mar/2018) and complied with ethical considerations in human research. This study was registered with ClinicalTrials.gov (NCT03507634) on 12/04/2018 and was first posted on 25/04/2018. Written informed consent was obtained from all participants before initiating any study-related procedures.

Participants

All patients presenting to our center for elective laparoscopic sleeve gastrectomy were screened. Inclusion criteria were age between 18 and 65 years, with class II or III American Society of Anesthesiologists (ASA) classification, and eligibility for bariatric surgery [Obesity class 3 (BMI $\geq$ 40) without comorbidities, or Obesity class 2 ($35 \leq$ BMI ≤ 39.9) with comorbidities (type 2 diabetes mellitus T2DM, obstructive sleep apnea, hypertension, and hyperlipidemia) or Obesity class 1 ($30 \leq$ BMI ≤ 34.9) with treatment-resistant type 2 diabetes mellitus or metabolic syndrome] (Rubino et al. 2016). Exclusion criteria included renal, hepatic, or cardiac insufficiency, positive pregnancy test, alcohol or drug abuse, psychiatric disease, history of chronic pain, allergy or contraindication to any of the study drugs, and conversion to open surgery.

Randomization and blinding

A computerized random number generator created the allocation schedule. Patients remained blinded to their intervention groups. A registered nurse, uninvolved in the study, allocated the interventions using sealed envelopes. The nurse disclosed assignments to the anesthesiologist, resident, and operating room nurse, who were unblinded. However, they were not involved in the post-anesthesia care unit (PACU) or floor follow-up data collection procedures. Nurses in the PACU and on the floor remained blinded. The anesthesiologist and resident assessing patients on postoperative days 1 and 2 were also blinded to group assignments.

Anesthetic management

Patients included in the study received no premedication. Standard ASA monitoring devices were applied before

anesthesia induction, including a 5-lead electrocardiogram for continuous cardiac monitoring, including heart rate (HR), non-invasive blood pressure (BP) monitoring, and pulse oximeter for oxygen saturation monitoring. All patients underwent general anesthesia.

Patients in the OFA group received dexmedetomidine 0.5 mcg/kg and 1 mg/kg lidocaine over 10 min starting 10 min before induction. General anesthesia was intravenously induced using propofol (2 mg/kg), rocuronium (0.6 mg/kg), and ketamine (0.15 mg/kg). Anesthesia was maintained with sevoflurane (dial setting regulated to achieve a minimum alveolar concentration between 1 and 1.2 for the remaining duration of the surgery according to the mean age of the patients who all fall in the same age category) and a mixture of medical air and oxygen, intravenous infusion of 0.3 mcg/kg/h dexmedetomidine, 1.5 mg/kg/h lidocaine and 0.15 mg/kg/h ketamine.

Patients in the OBA group were induced using propofol (2 mg/kg), fentanyl (2 mcg/kg), ketamine (0.15 mg/kg), and rocuronium (0.6 mg/kg). Remifentanil IV infusion was initiated with a dose range of 0.2–0.3 mcg/kg/min, depending on the patient's hemodynamic status. Anesthesia was maintained with sevoflurane/medical air/oxygen (as described above), remifentanil, and 0.15 mg/kg/h ketamine. The dosage calculation of the used drugs was based on the adjusted body weight (ABW).

Esmolol was used to keep the HR of less than 85 beats/min after other causes of tachycardia had been eliminated, such as hypovolemia or light depth of anesthesia. Atropine or glycopyrrolate was used to keep the HR above 40 beats/min. Phenylephrine or ephedrine and nicardipine were used to keep the mean arterial blood pressure within 20% of the baseline.

The infusion of each drug was stopped right after the removal of the trocars. Ketoprofen 50 mg and Paracetamol 1 g were administered intravenously 30 min before the end of surgery to all patients. Residual neuromuscular blockade was antagonized with intravenous neostigmine 0.04 mg/kg and glycopyrrolate 0.01 mg/kg. Sevoflurane was discontinued after the last skin suture. In a semi-sitting position, the patient was extubated and then transferred to the PACU.

Morphine titration was provided if the visual analog scale (VAS) score exceeded 4. A dose of 2–3 mg was given every five minutes until a VAS score of < 4 was achieved. Patients were discharged to the ward after they satisfied the PACU discharge criteria for the level of consciousness, respiratory stability, oxygen saturation status, hemodynamic stability, postoperative pain, and postoperative nausea and vomiting. In addition, nefopam 20 mg per dose was administered upon demand after surgery. After discharge from PACU, the pain was treated with paracetamol 1 g IV every 6 h, and breakthrough pain was treated by pethidine 1 mg/kg (50 mg S/S) subcutaneously as needed every 8 h as part of the postoperative pain control. Any side effects encountered during each visit were documented. Opioids, other than morphine including pethidine, used postoperatively were transformed to morphine equivalent doses in the analysis.

Variables collected

Demographic data were collected before the surgery, encompassing age, gender, weight, height, body mass index (BMI), and ABW. The primary outcome measure was postoperative morphine consumption in the PACU. Secondary endpoints included intraoperative vital signs, duration and medications used during surgery, PACU stay duration, VAS score at rest upon PACU discharge, opioid consumption during the first 48 h postoperatively, incidence of nausea and vomiting, anti-emetic use, and rescue pain medications. Additionally, the follow-up assessments up to 48 h postoperatively medication use consumption and postoperative opioid-related side effects, or side effects, i.e., such as pruritus, respiratory depression, and sedation.

Power and statistical analysis

Following Bakan et al.'s findings on OFA in laparoscopic cholecystectomy patients (2015) (Bakan et al. 2015) and based on 80% power and 5% level of significance, we converted fentanyl amounts to morphine-equivalent doses, and accordingly a total of 38 patients were required in each group. We aimed to recruit 43 patients each in the OFA and OBA groups to account for potential drop-outs. A pilot study for sample size calculation was not feasible.

Descriptive statistics were reported as means and standard deviations for continuous variables, while frequency and percentages were used to summarize categorical variables. The Shapiro–Wilk test was used to test for normality. The independent *t*-test or Mann–Whitney *U* test (if data was not normally distributed) was used to compare continuous outcomes between the two study groups. The chi-squared or Fisher exact test (if the expected outcome count is less than 5 per cell in the contingency table) was used to analyze categorical variables. A probability value (*p*-value) cutoff of 0.05 was used for statistical significance. Statistical analysis was performed using IBM SPSS version 28.0.

Results

Of the 103 patients assessed for eligibility, 83 patients were included in the analysis between March 2018 and December 2020 (40 patients in the OFA group and 43 patients in the OBA group). The flow chart is presented in Fig. 1. Patients' demographics and baseline characteristics are presented in Table 1.

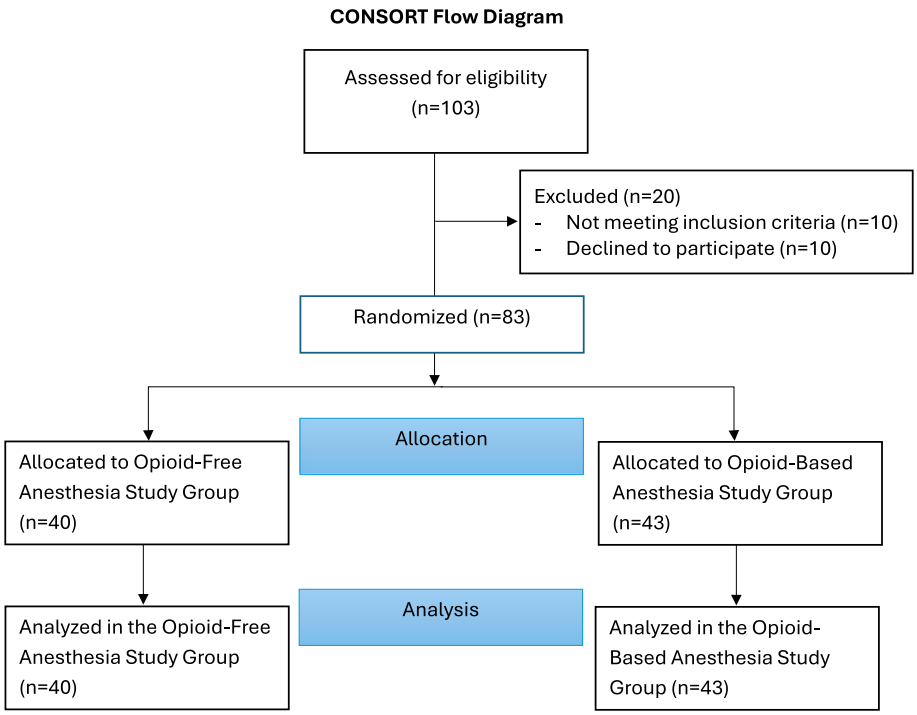

Fig. 1 Consort flowchart of the study included and excluded patients

Table 1 Subjects demographic data

Characteristics	OFA ($n=40$)	OBA ($n=43$)	*p* value
Age (years)	34.43 ± 10.97	34.7 ± 11.71	0.913
Gender (M/F)	20/20	16/27	0.24
ASA class			0.07
Class II	17 (42.5)	17 (39.5)	
Class III	23 (57.5)	26 (60.5)	
Weight (kg)	117.78 ± 21.43	121.23 ± 22.96	0.481
Height (cm)	169.83 ± 8.97	167.98 ± 10.02	0.38
BMI (kg/m^2)	40.75 ± 6.09	42.91 ± 6.74	0.128
ABW (kg)	85.24 ± 13.19	85.35 ± 13.88	0.969

OFA opioid-free anesthesia, *OBA* opioid-based anesthesia, *ABW* adjusted body weight

Intraoperative management

There were no statistically significant differences between the two groups in terms of intraoperative vital signs and medications used, except that more patients required anti-hypertensives in the OFA group compared to the OBA group (37.5% versus 13.95%, respectively; *p*-value = 0.014). The use of intraoperative vasopressors was not statistically significantly different between the two groups. There was no significant difference in surgery duration (124.58 ± 31.79 min in the OFA versus 128.35 ± 38.97 min in the OBA) and duration from end of surgery till extubation (11.83 ± 5.61 min in the OFA versus 11.88 ± 7.66 min in the OBA). Results pertaining to intraoperative management signs and drugs are presented in Table 2.

Postoperative assessments

– ***Primary outcome***

PACU morphine consumption was lower in patients undergoing OFA compared to OBA, however not statistically significantly different (5.55 ± 3.48 mg versus 6.38 ± 3.79 mg, respectively, *p*-value = 0.255). Results are presented in Table 3.

– ***Secondary outcomes***

The duration of stay was lower in the OFA group (94.85 ± 33.08 min) compared to the OBA group (104.19 ± 46.53 min), but it did not reach statistical significance (*p*-value = 0.302) (Table 3).

There was no statistical difference in morphine consumption up to 48 h after surgery between the two groups. Two time periods were considered, the PACU-24 h and 24–48 h, with morphine consumption of 5.79 ± 5.82 mg versus 7.28 ± 6.02 mg; *p*-value = 0.255 and 3.48 ± 4.42 versus 3.2 ± 4.8; *p*-value = 0.785; respectively (Table 4).

Table 2 Intra-operative data

	OFA ($n=40$)	OBA ($n=43$)	*p* value
Vital signs			
Mean SBP (mmHg)	106.26 ± 7.76	108.05 ± 8.54	0.322
Mean DBP (mmHg)	60.8 ± 5.61	62.21 ± 6.64	0.302
Mean HR (beats/min)	79.71 ± 8.28	79.50 ± 7.63	0.904
Duration			
Surgery (min)	124.58 ± 31.79	128.35 ± 38.97	0.632
Anesthesia (min)	165.35 ± 37.76	163.49 ± 44.43	0.838
End of surgery till extubation (min)	11.83 ± 5.61	11.88 ± 7.66	0.969
Medications			
Intra-operative anti-hypertensive (number of patients)	15 (37.5%)	6 (13.95%)	0.014*
Intra-operative vasopressors (number of patients)	15 (37.5%)	12 (27.91%)	0.351

OFA opioid-free anesthesia, *OBA* opioid-based anesthesia, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *HR* heart rate

* *p*-value < 0.05

Table 3 PACU stay

	OFA ($n=40$)	OBA ($n=43$)	*p* value
Morphine consumption (mg)	5.55 ± 3.48	6.38 ± 3.79	0.3
Duration of stay (min)	94.85 ± 33.08	104.19 ± 46.53	0.302
VAS upon discharge	0.58 ± 0.87	0.47 ± 0.8	0.551
Nausea medication (number of patients)	8 (20%)	12 (27.91%)	0.4
Rescue nefopam (number of patients)	10 (25%)	15 (34.89%)	0.327

OFA opioid-free anesthesia, *OBA* opioid-based anesthesia, *PACU* post-anesthesia care unit, *VAS* visual analog scale

Table 4 Post-PACU morphine and anti-emetic medications requirement

	OFA ($n=40$)	OBA ($n=43$)	*P* value
Morphine consumption (mg)			
PACU–24 h	5.79 ± 5.82	7.28 ± 6.02	0.255
24–48 h	3.48 ± 4.42	3.2 ± 4.8	0.785
Anti-emetic medications requirement			
0–24 h (dose)	29 (72.5%)	36 (83.72%)	0.215
24–48 h (dose)	16 (40%)	25 (58.14%)	0.099

OFA opioid-free anesthesia, *OBA* opioid-based anesthesia

There was no statistically significant difference between the two groups regarding VAS score on discharge from the PACU, need for anti-emetics, and need for rescue nefopam for pain (Table 3).

There was no statistical difference in anti-emetic consumption between the OFA and OBA groups (Table 4). Fewer patients in the OFA group required anti-emetic medications than the OBA group; the results did not reach statistical significance (p-value = 0.215 and 0.099, respectively).

Discussion

OFA did not achieve a postoperative opioid-sparing effect compared to OBA in patients undergoing laparoscopic sleeve gastrectomy. This was evidenced by the non-statistically significant comparisons between the two groups in terms of morphine consumption in the PACU and up to 48 h postoperatively. This indicates that there is no preference between OFA and OBA modalities for postoperative opioid consumption in this study population. Hemodynamically, patients in the OFA group were more unstable as they required more anti-hypertensive drugs.

The researchers have been conducting studies with the aim of proving that OFA offers superior outcomes compared to OBA, particularly in light of the known drawbacks associated with opioid use. However, the results of different studies vary as well as their methods, surgery type, and population studied. In line with our results, a recently published study by Barakat et al. has not found a significant difference in morphine consumption during the PACU stay after major spine surgery in OFA patients compared to OBA patients (Barakat et al. 2024). That being said, a significant difference in cumulative morphine consumption was detected during the first 24 h

after surgery. This difference could be attributed to study power analysis or populations (Barakat et al. 2024). Torre et al. investigated the advantages of OFA in bariatric surgery and failed to find any significant difference in opioid use on the day of surgery or postoperative days 1, 2, and 3 (Torre et al. 2022). In the same vein, a meta-analysis provided evidence that OBA does not reduce opioid consumption in the postoperative period when compared with OFA (Frauenknecht et al. 2019; Salomé et al. 2021). More recently, a study by Mieszczański et al. also showed no differences in opioid consumption postoperatively between OFA and OBA in patients undergoing laparoscopic sleeve gastrectomy. However, in contrast to our result regarding the higher proportion of patients requiring anti-hypertensives in the OFA group, more patients in their OFA group required vasopressors than the OBA group (Mieszczański et al. 2023). This discrepancy could be attributed to the higher doses of dexmedetomidine that were used by Mieszczanski et al., which is associated with bradycardia and hypotension (Djalali Motlagh et al. 2021). On the contrary, a recent study published by Ulbing et al. concluded that OFA patients required fewer postoperative opioids in the first 24 h after surgery compared to OBA patients (Ulbing et al. 2023). Our study's results may be attributed to the administration of ketamine. This assertion finds support in the study by Hasanein et al., which demonstrated that patients receiving ketamine alongside remifentanil required less morphine in the PACU compared to those receiving only remifentanil (Hasanein et al. 2011). Research indicates that glutamate release and NMDA receptor activation are key mechanisms underlying OIH. A meta-analysis by Wu et al. demonstrated that NMDA receptor antagonists, such as ketamine, can reduce analgesic requirements and pain intensity associated with remifentanil, thereby improving postoperative patient satisfaction (Wu et al. 2015). Considering the well-established risk of remifentanil-induced hyperalgesia, relying solely on remifentanil for intraoperative and postoperative analgesia was considered suboptimal (Yi and Pryzbylkowski 2015). Therefore, the rationale for using ketamine in the OBA and not restricted to the OFA group is to counteract the hyperalgesia effects of remifentanil. Since all our patients received ketamine, this could explain why there was no significant difference in morphine consumption between both groups in the PACU and postoperatively. These results indicate that our approach is at least comparable to OBA in postoperative pain management while also preventing patient exposure to opioids during surgery.

That being said, the safety of OFA was challenged in a trial conducted by Beloeil et al., which was terminated due to serious incidents of hypoxemia and bradycardia (Beloeil et al. 2021). However, in selected surgical procedures, such as laparoscopic upper gastrointestinal surgery, the intra-operative use of OFA can significantly reduce postoperative adverse events without evidence of increased intra-operative complications (Olausson et al. 2022).

Dexmedetomidine side effects are mainly restricted to hemodynamic alterations, which include transient hypertension, bradycardia, and hypotension, owing to pre- and postsynaptic α2-receptor activation, resulting in vasoconstriction, vasodilatation, and reflex bradycardia (Weerink et al. 2017). Zhao et al. demonstrated that the incidence of bradycardia is significantly lower with a loading dexmedetomidine dose of 0.5 mcg/kg compared to loading doses of 1 or 0.75 mcg/kg (Zhao et al. 2016). In our study, a loading dose of 0.5 mcg/kg was administered slowly over 10 min, which could be associated with the safety profile we covered throughout the operation. Additionally, high-dose remifentanil regimens (1–5 mcg/kg/min) have been associated with hypotension and bradycardia (Steinlechner et al. 2007). Ketamine has been shown to mitigate the hemodynamic changes induced by remifentanil, providing more hemodynamic stability and a satisfactory recovery profile (Hasanein et al. 2011). In our study, all patients received an hourly dose of 0.15 mg/kg ketamine.

Consistent with our results, where more patients in the OFA group required intra-operative anti-hypertensives, 28% of patients receiving dexmedetomidine and lidocaine as part of the OFA regimen required nitroglycerine to treat intra-operative hypertension, particularly at the beginning of surgery in patients undergoing laparoscopic cholecystectomy (Bakan et al. 2015). This similarity in the results could be attributed to the constant maintenance dose of 0.3 mcg/kg/h of dexmedetomidine.

No significant differences were observed between the end of surgery to extubation and PACU duration stay. In contrast, Soudi et al. reported that OFA patients required more time to extubate and longer periods to achieve an Aldrete score of 9; this could be attributed to the higher dexmedetomidine dose administered in their study (Soudi et al. 2022).

There are several limitations to our study. First, our study population was limited to patients of two surgeons undergoing laparoscopic bariatric surgery at a single hospital center. This restriction may limit the generalizability of our study findings. Second, another limitation could be the constant infusion rate of dexmedetomidine compared to the variable infusion rate of remifentanil. This discrepancy might have contributed to the increased use of anti-hypertensive medications in the OFA group. Third, ketamine was used in the remifentanil group to mitigate the hyperalgesic effects of remifentanil, which could have influenced pain scores and morphine consumption in

the OBA group. If we had excluded ketamine from the OBA group, a statistically significant difference in the primary and secondary outcome effect measures might have been observed. Future research should explore the role of ketamine in similar comparative studies. Moreover, due to funding scarcity and reduced surgical activity in our country amid the economic crisis, conducting a pilot study or retrospective power analysis was not feasible. Future studies should consider this study to base their sample size calculation and consider a multicenter design.

Conclusion

Opioid-free anesthesia modality did not exert an opioid-sparing effect in patients with obesity undergoing laparoscopic sleeve gastrectomy. Concerns around the hemodynamic stability of OFA are still questionable. Therefore further investigation is needed to fully confirm its safety and effectiveness, in addition to reassessing its potential to minimize opioid consumption postoperatively in larger, multi-center trials and different modes of anesthetic management.

Abbreviations

OBA	Opioid-based anesthesia
OFA	Opioid-free anesthesia
ASA	American Society of Anesthesiologists
PACU	Post-anesthesia care unit
HR	Heart rate
ABW	Adjusted body weight
VAS	Visual analog scale
BMI	Body mass index
SBP	Systolic blood pressure
DPB	Diastolic blood pressure

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Not applicable.

Authors' contributions

HB analyzed and interpreted the data, designed and conducted the study, and reviewed the relevant literature. LG recruited patients, collected and analyzed data, and reviewed the relevant literature. JAN recruited patients, collected data, and reviewed the relevant literature. VYK reviewed and approved the final manuscript. OA was a major contributor in writing the manuscript. MEH analyzed the data. RAN recruited patients, collected data, and contributed to editing the manuscript. All authors read and approved the final manuscript.

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Data availability

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This study received ethical approval from the Lebanese American University ethical board, and an informed consent form to participate in the study was obtained from all the participants. Ethical approval number: LAUMCRH.HB2.28/Mar/2018.

Consent for publication

None.

Competing interests

The authors declare no competing interests.

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