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European Journal of Medical Research (2025) 30:320
https://doi.org/10.1186/s40001-025-02565-9

European Journal
of Medical Research

RESEARCH Open Access

Opioid-free anesthesia in bariatric surgery: a prospective randomized controlled trial

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Abstract

Background Bariatric surgeries are increasingly used to manage obesity, presenting significant perioperative challenges, especially with opioid use. Opioid-Free Anesthesia (OFA) is a multimodal technique to address these issues. This study aims to compare the effects of OFA and traditional Opioid-Based Anesthesia (OBA) on postoperative morphine consumption, hemodynamics, pain, postoperative nausea and vomiting (PONV), sedation, and patient satisfaction in bariatric surgery.

Methods A prospective controlled study was conducted in the operating room of a tertiary university hospital. It included patients aged between 18 and 65 years undergoing bariatric surgery. 58 obese patients were divided into two groups: 32 received OBA and 26 received OFA. The OFA regimen included lidocaine, ketamine, magnesium sulfate, dexmedetomidine, and dexamethasone. Main outcome measures included postoperative morphine consumption in the Post-Anesthesia Care Unit (PACU), 24 and 48 h after surgery. Secondary outcomes included hemodynamic parameters, sedation score, pain score, presence of nausea and/or vomiting, and overall patient satisfaction evaluated at 48 h postoperatively or before hospital discharge were recorded.

Results OFA significantly reduced postoperative morphine consumption (median dose of 8 mg vs.19 mg, $p = 0.000$). Visual analogue scale (VAS) scores for pain at rest, during movement, and during coughing were significantly lower in the OFA group. Both groups were hemodynamically stable perioperatively. There was no significant difference in PONV incidence or sedation levels between the groups in the PACU, 24 and 48 h after surgery. Patient satisfaction was higher in the OFA group, with 65% reporting a satisfaction score of ≥ 8/10 compared to 28% in the OBA group.

Conclusions OFA reduces postoperative morphine consumption and improves pain management without compromising hemodynamic stability or increasing sedation. Furthermore, the incidence of PONV was not significantly different and overall patient satisfaction was higher with OFA. These findings support the use of OFA in bariatric surgery, despite the need for further studies with larger sample sizes.

Keywords Bariatric surgery, Morphine, Nausea, Opioid-free anesthesia, Pain, Vomiting

Introduction

Obesity is recognized as a global epidemic and an independent disease [1], with over 890 million obese adults worldwide [2]. It is classified according to the body mass index (BMI) and becomes morbid with a BMI over 40 kg/m^2 [3]. Bariatric surgery, performed on approximately 600,000 patients annually [4], is a key intervention, though 75% of cases report moderate to severe postoperative pain [5].

Opioids are the most powerful class of pharmacological agents used to relieve pain and manage nociception during general anesthesia. It is estimated that they are administered postoperatively to approximately 99% of patients in the USA [6, 7].

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Among all medications used in anesthesia, opioids are the most controversial when used in obese patients, due to changes in their metabolism, pharmacokinetics and pharmacodynamics, as well as their side effects, particularly respiratory ones, which are exacerbated in obese patients.

Numerous protocols have been developed to limit or even eliminate the use of opioids in bariatric surgery, including Opioid-Free Anesthesia (OFA). OFA is a multimodal anesthesia technique that combines different medications without the use of morphine agents, regardless of the route of administration (intravenous, intrathecal, etc.). For OFA, opioids are replaced by anesthetic adjuncts, such as ketamine, lidocaine, dexmedetomidine, and magnesium [8].

This anesthesia technique is increasingly used, especially in bariatric surgery, to avoid opioids' side effects: respiratory depression, pharyngeal muscle weakness, negative inotropism, postoperative nausea and vomiting (PONV), pruritus, immunomodulation, potential neurotoxicity, and most importantly, hyperalgesia, which can paradoxically cause acute and chronic pain [9].

Lidocaine provides analgesic, anti-inflammatory, and anti-hyperalgesic effects, reducing postoperative opioid use [10]. Ketamine, an NMDA receptor antagonist, improves immediate postoperative pain and reduces PONV. Magnesium sulfate enhances analgesia and decreases opioid consumption, especially when combined with ketamine. Dexmedetomidine, an alpha-2 agonist, offers analgesia, anxiolysis, and anesthetic-sparing effects. Dexamethasone, a glucocorticoid, provides anti-inflammatory effects, reduces pain scores, and prevents PONV, with its efficacy potentially enhanced by magnesium in OFA protocols [5, 11].

The aim of the study was to compare OFA and traditional Opioid-Based Anesthesia (OBA) in relation to the postoperative morphine consumption as well as their effects on hemodynamics, pain score, PONV, sedation, and patient satisfaction when using a combination of lidocaine, ketamine, magnesium sulfate, dexmedetomidine and dexamethasone for bariatric surgery. To our knowledge, no study has yet been conducted to specifically compare the combination of these 5 products with OBA in obese patients.

Materiel and methods

Ethics

Ethical approval for this study (CEHDF 1915) was provided by the Ethical Committee of Hôtel Dieu de France hospital, Beirut, Lebanon (Chairperson Prof Sami Richa) on November 2, 2021.

Written informed consent was obtained from all study participants. We conducted a controlled prospective study comparing impact of traditional OBA and OFA on the postoperative morphine requirements and other related side effects.

Recruitment and data collection

Between November 4, 2021, and November 2, 2022, obese patients, aged between 18 and 65 years and scheduled for bariatric surgery (gastric bypass or sleeve gastrectomy) at Hôtel Dieu de France Hospital, were selected. Patients willing to be included in the study were divided into two groups. Were excluded from the study patients who had: second or third-degree atrioventricular block, chronic treatment with beta-blockers with a preoperative heart rate < 50 bpm, heart failure with an ejection fraction < 40%, poorly controlled hypotension, epilepsy, liver failure, renal failure with a glomerular filtration rate < 30 ml/min, biochemical or clinical hyperthyroidism, known psychiatric disorders, drug addiction, or long-term opioid treatment.

The type of anesthesia technique was randomly chosen in advance using a generated randomization list. Randomization was conducted using a computer-generated random number, which was concealed within sealed opaque envelopes. The random sequence was created with R (package: randomizeR) by an independent statistician who was not involved in participant recruitment or data collection. Based on the randomization sequence, patients were assigned to one of the two groups. To reduce selection bias, the envelopes were sequentially numbered and opened only after participant enrollment, ensuring allocation concealment.

$$n = \frac{2\left(Z_{\beta} + Z_{\alpha/2}\right)^2 \cdot \sigma^2}{\Delta^2}$$

We reviewed data from patients who underwent bariatric surgery over a one-month period and found that the mean postoperative morphine consumption at our institution was approximately 15 mg. To detect a 50% reduction in mean morphine consumption, the required sample size was 28 patients per group based on the formula:

Where:

· $Z\alpha/2 = 1.96$ for $\alpha = 0.05$ (two-tailed test).

· $Z\beta = 0.84$ for $\beta = 0.20$ (for 80% power).

· $\sigma 2 = 100$ (estimated variance of morphine consumption).

· $\Delta = 15^{*}0.5 = 7.5$

→ n = 28 patients per group.

Pulse oximetry, electrocardiography, non-invasive blood pressure, and expiratory end-tidal carbon dioxide, were monitored in all patients.

In both groups, a rapid sequence induction was performed with Propofol and Succinylcholine, while maintenance of anesthesia was obtained using Sevoflurane and muscle relaxation by boluses of Rocuronium. At the end of the surgery, muscle relaxation was reversed with Sugammadex. All patients received PONV prophylaxis with Ondansetron 4 mg before the end of surgery.

In the OFA group, the following drugs were administered after intubation:

- Lidocaine, a bolus of 1.5 mg/kg followed by a continuous infusion of 1.5 mg/kg/h
- Ketamine, a bolus of 0.2 mg/kg followed by an infusion of 0.15 mg/kg/h
- Magnesium sulfate, 50 mg/kg over 30 min, followed by 8 mg/kg/h
- Dexmedetomidine, 0.2–0.5 mcg/kg/h adjusted according to blood pressure and heart rate
- Dexamethasone, a single dose of 8 mg

All medications, except Succinylcholine, were administered based on ideal body weight. The infusions of Ketamine, Lidocaine, Magnesium, and Dexmedetomidine were stopped after surgical hemostasis, almost 20 min before skin closure.

In OBA group, the doses of fentanyl administered during the surgery were based on the patient's clinical needs, including hemodynamic responses. All patients received an initial loading dose of fentanyl at induction, administered at 1 mcg/kg based on ideal weight. This dose was increased to 3–4 mcg/kg at the time of incision to ensure adequate analgesia. Additional intermittent boluses of 0.5–1 mcg/kg were given as needed throughout the procedure to maintain stable vital sign.

The postoperative analgesia protocol was standardized in both groups, including 1 g Paracetamol and 50 mg of Ketoprofen given to all patients at skin closure as well as Morphine titration (2 mg every 5 min) to achieve a visual analogue scale (VAS) score less than 4 in the PACU (Post-Anesthesia Care Unit). On the surgical ward, all patients received for 48 h Paracetamol 1 g IV every 6 h regularly, Ondansetron 4 mg IV every 8 h and postoperative pain was treated with Morphine Sulphate 0.1 mg/kg subcutaneous every 6 h to achieve a VAS score less than 4.

Throughout the procedure, data collected included patient's gender, real and ideal weight, height, BMI, as well as the APFEL score and STOP-BANG score (appendix 1), along with the total dose of each anesthetic, vasopressor, and antihypertensive drug received, and Systolic Arterial Pressure (SAP), Mean Arterial Pressure (MAP) and heart rate variation. Hemodynamic instability was defined as 20% variability from baseline pre-induction values for either SAP, MAP or heart rate.

Postoperatively, hemodynamic parameters (heart rate and blood pressure), respiratory rate, sedation score using the Richmond Agitation-Sedation Scale (RASS) (appendix 2), pain score using VAS at rest, during movement, and coughing, presence of nausea and/or vomiting, morphine requirements, and overall patient satisfaction evaluated at 48 h postoperatively or before hospital discharge were recorded.

Nurses collected all these data hourly in the PACU, and every 6 h by anesthesia residents on the ward, who were unaware of the perioperative management details, thus blinded for the study. Hence, the study was not conducted in a double-blind manner, however research personnel (nurses and residents), who were unaware of the study groups, carried out data collection. Additionally, statistical analysis was performed by a statistician who was also blinded to the group assignments.

Statistical analysis

The distribution of continuous and ordinal variables was studied using the Shapiro–Wilk test, complemented by visual inspection of quantile–quantile (QQ) plots. Qualitative data were expressed as count, percentage, and its 95% confidence interval, and compared between the 2 groups using the Chi-square test, adjusted, if necessary, by Fisher's exact test.

Ordinal data and continuous data not following a normal distribution were expressed as median with interquartile range and compared between the 2 groups using the non-parametric Mann–Whitney test. Continuous data following a normal distribution were expressed as mean with standard deviation and compared between the 2 groups using the Student's t-test.

Two families of general linear models were constructed. For variables normally distributed (MAP, heart rate, and respiratory rate), the native variable was used by implementing its values directly into the model at H1, H2, H3, H6, H12, H18, H24, H36, and H48, for the 2 treatment groups. For variables not following a normal distribution (Urapidil dose, VAS at rest, VAS during movement, VAS during coughing, RASS), an inverse normal transformation (INT) was applied using Van Der Waerden (VW) ranks. The VW-transformed native variables were then entered into the general linear model following the same method described previously. In all general linear models, a repeated measures ANOVA was conducted using a type 3 sum of squares, with interaction

between time factor and studied factor, and verification of variance homogeneity.

Calculations were performed using SPSS software version 26 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

Results

Sixty patients were included in this study: 32 patients received traditional OBA, and 28 patients received OFA. Data concerning 2 patients in OFA group were not completed by investigators, so both patients were excluded from analysis. A consort flow diagram detailing the screening, recruitment, and analysis of the participants is shown in Fig. 1.

Patient characteristics (age, sex, BMI, ideal weight, APFEL score, and STOP-BANG score), as well as the duration of anesthesia were homogeneous between the two groups (Table 1).

Morphine consumption was significantly reduced in the OFA group, with a median dose of 8 mg compared to 19 mg in the group that received traditional OBA, with a p-value of 0.000 according to the Mann–Whitney test (Fig. 2).

It is also noteworthy that in the OFA group, patients did not consume any more morphine beyond the 24th postoperative hour.

Regarding pain score (VAS), the difference at the first postoperative hour for VAS at rest, during movement, and during coughing was not significant between the two groups, with p-values of 0.905, 0.805, and 0.72, respectively. However, VAS decreased over time in both groups, and overall, the VAS scores at rest, during movement, and during coughing were significantly lower in the OFA group compared to OBA group, with

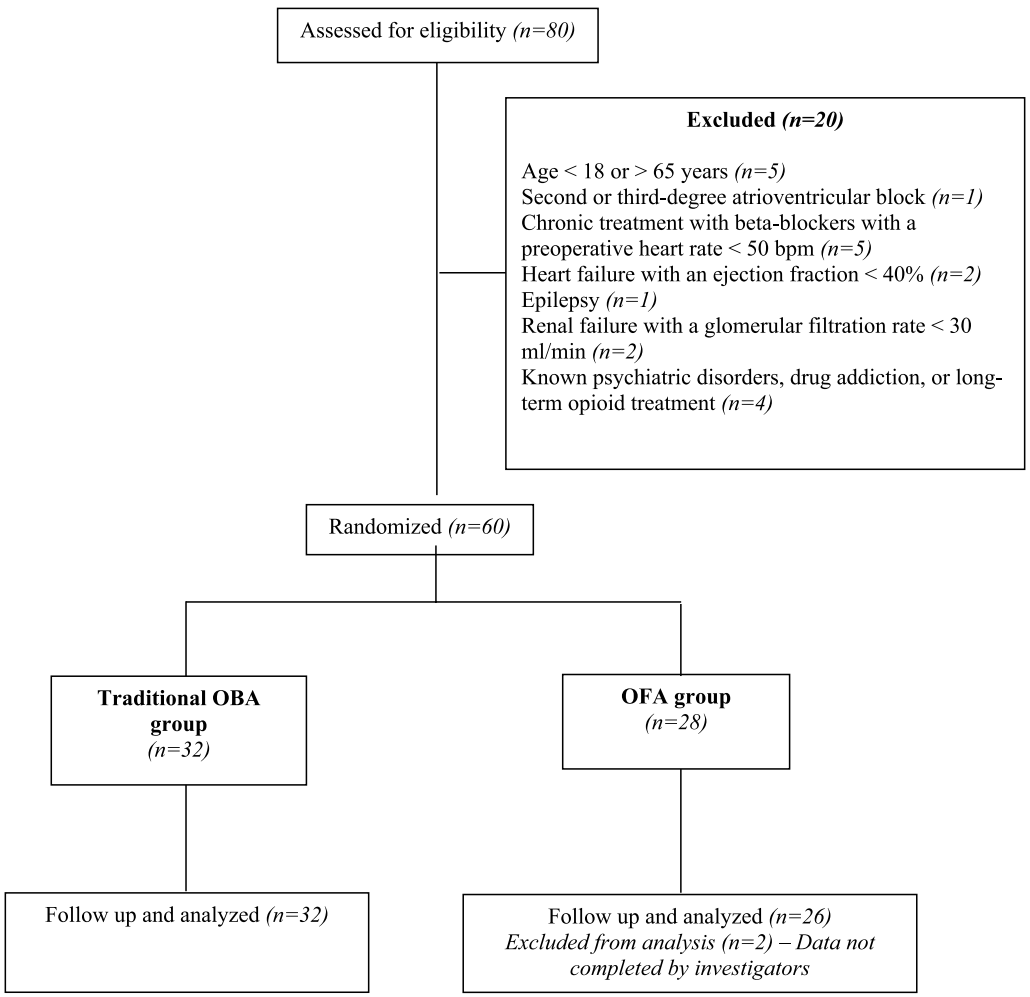

Fig. 1 CONSORT Flow Diagram showing in detail the recruitment, exclusion, and inclusion of patients. 32 OBA patients and 26 OFA patients were included in the final data analysis

Table 1 Demographic characteristics of patients in both groups showing no statistically significant difference between studied groups

	OBA	OFA	*P*
Age (years) mean ± SD	39 ± 11	37 ± 11	*0.362*
Weight (kg) mean ± SD	115 ± 21	119 ± 21	*0.549*
Height (cm) mean ± SD	167 ± 10	168 ± 9	*0.705*
BMI (kg/m^2) mean ± SD	40.7 ± 7.8	41.7 ± 5.9	*0.613*
Ideal weight (kg) mean ± SD	61.5 ± 7.5	61.8 ± 6.7	*0.892*
Sex ratio (Male/Female)	10/22	9/17	*0.786*
STOP-BANG ≥ 5 n(%)	3(9.4)	4(15.3)	*0.432*
APFEL Score ≥ 2 n(%)	8(25)	11(42.3)	*0.535*
History of abdominal surgery n(%)	15(46.9)	16(61.5)	*0.301*
Duration of anesthesia (h)	2.25 [2–2.5]	2.5 [2–2.75]	*0.710*
Duration of surgery (h)	1.58 [1.33–1.83]	1.83 [1.33–2]	*0.266*
Type of surgery (Gastric bypass/ Sleeve gastrectomy)	4 / 28	3 / 23	*1.000*

cm = centimeter, h = hour, Kg = kilogram, OBA = Opioid-Based Anesthesia, OFA = Opioid-Free Anesthesia, SD = standard deviation

respective p-values of 0.021, 0.001, and 0.000 ($p < 0.001$) (Fig. 3).

When comparing PONV, OFA group patients had a lower incidence of PONV; however, this difference was statistically nonsignificant (Table 2).

During the intraoperative period, there was no significant difference between the two groups regarding the number of episodes of hypotension, the occurrence of bradycardia or the need for vasopressors (Table 3).

During the first postoperative period, systolic blood pressure (SBP) was lower in OFA group with a p-value of 0.021. However, there was no significant difference in SBP beyond the second hour. The MAP, heart rate, and respiratory rate were also comparable between the two groups.

No significant difference was observed in the sedation scale of patients between the two groups, whether in immediate postoperative recovery in the recovery room (P-value 0.592 at H + 1 according to Mann–Whitney test) or even later in the surgical ward.

Finally, at the end of their hospital stay or at 48 h after surgery, patients in OFA group were more satisfied than those in OBA group. Sixty-five per cent of subjects who received OFA reported a global satisfaction score of ≥ 8/10, compared to 28% of patients in OBA group. This difference was statistically significant with a P-value of 0.003 according to the Mann–Whitney test.

Discussion

This prospective randomized study demonstrated a reduction in postoperative morphine consumption as well as pain scores when using OFA for bariatric surgery without increasing any side effect like bradycardia, hypotension and sedation. Furthermore, there was no difference in PONV, and patients had a higher

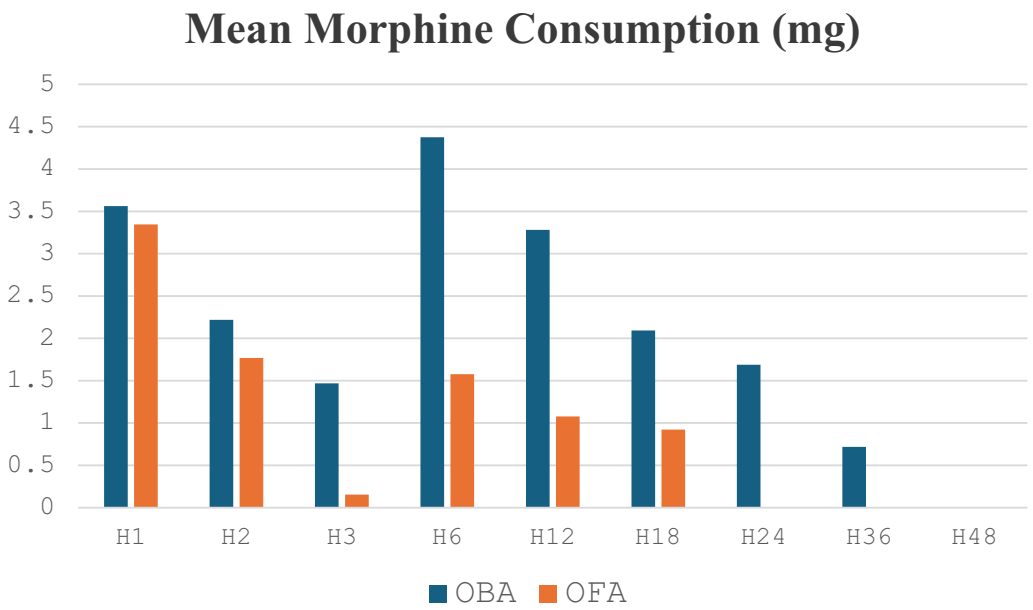

Fig. 2 Comparison of postoperative morphine consumption at different times between OBA group and OFA group showing statistically significant reduced consumption in the OFA group over time, $p < 0.001$ (OBA = Opioid-Based Anesthesia, OFA = Opioid-Free Anesthesia)

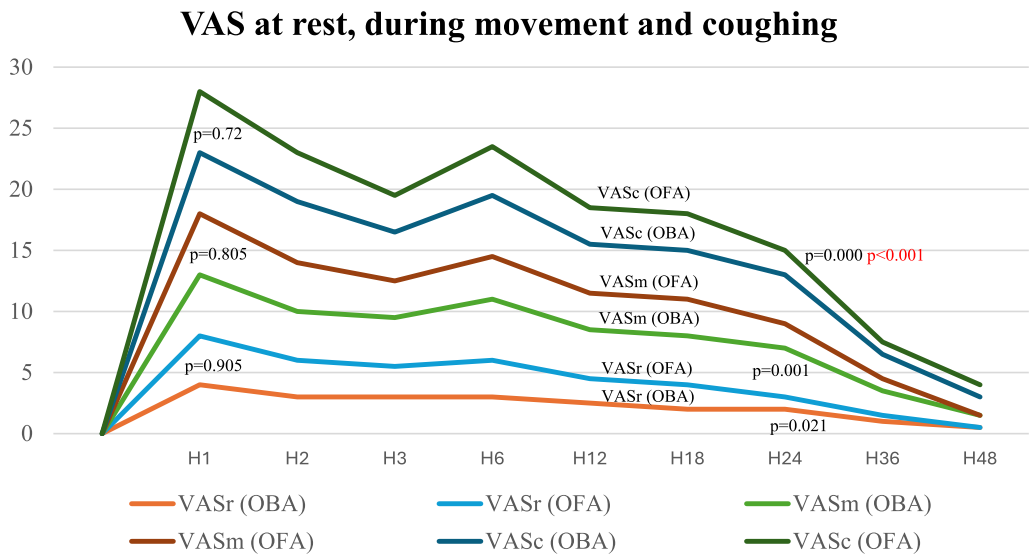

Fig. 3 Pain scores: visual analogue scale (VAS) during different postoperative times at rest (r), during movement (m) and during coughing (c) showing a comparable VAS score at 1 h. A statistically significant difference in VAS is shown afterwards. (OBA = Opioid-Based Anesthesia, OFA = Opioid-Free Anesthesia, p on the left is for the first postoperative hour between OFA and OBA, p on the right is for the hole 48 h between OFA and OBA)

Table 2 Incidence of Postoperative Nausea and Vomiting in both groups at 2 h and 24 h after surgery showing no significant difference between groups.

	OBA n (%)	OFA n (%)	*P*
PONV H2	4 (12.5)	4 (15.4)	*1.000*
PONV H24	8 (25)	3 (11.4)	*0.193*

OBA = Opioid-Based Anesthesia, OFA = Opioid-Free Anesthesia, PONV = Postoperative Nausea and Vomiting

satisfaction score when opioids were not administered during surgery.

What is new in our study is that patients in OFA group received a combination of five different drugs: lidocaine, ketamine, magnesium sulfate, dexmedetomidine and dexamethasone, during anesthesia to avoid the use of opioids. Several studies have used some of these products in the OFA and others are underway [12] but no study to our knowledge has combined all these 5 products together in comparison to opioids alone.

Intravenous lidocaine has analgesic, anti-inflammatory and anti-hyperalgesic properties [10]. Lidocaine blocks voltage-gated sodium channels, hyperpolarization-activated cyclic nucleotide channels, G protein-coupled receptors and potassium receptors, and increases intracellular calcium concentration [5]. A study comparing intravenous lidocaine (1.5 mg/kg 5 min before induction of anesthesia, followed by infusion 2 mg/kg/h until end of surgery) with placebo showed a reduction in morphine consumption after bariatric surgery [13].

Ketamine is a N-methyl-D-aspartate (NMDA) receptor antagonist which has analgesic and anti-hyperalgesic properties [5]. A meta-analysis demonstrated improvements in pain outcomes immediately after surgery through perioperative intravenous ketamine administration despite the absence of analgesic benefit in the late postoperative period and a positive impact on PONV in bariatric surgery [11].

Magnesium sulfate has also been reported as an adjuvant to analgesics in the perioperative period and reduces opioid consumption in obese patients undergoing sleeve gastrectomy [14]. Moreover, the association of magnesium and ketamine in bariatric surgery as well as and in scoliosis surgery decreases morphine requirements in the first 24 h compared with ketamine alone or placebo [15, 16].

Dexmedetomidine is an alpha 2 adrenergic receptor agonist which has many benefits: analgesic, inhibiting the sympathetic outflow, anti-hyperalgesic, decreasing anesthetic requirement, anxiolysis and reduction of shivering threshold [5]. A recent study indicates that OFA based on dexmedetomidine is effective; however, prolonged extubation time and cardiovascular

Table 3 Hypotension and bradycardia, vasopressor and antihypertensive requirements during intraoperative period in both groups showing no difference between groups

	N		OBA n(%)		OFA n(%)		*P*
Number of hypotension episodes	0		20(62.5)		18(69.2)		*0.839*
	1		4(12.5)		2(7.7)		
	2		6(18.8)		2(7.7)		
	3		2(6.3)		1(3.8)		
	4		0(0.0)		3(11.5)		
Number of bradycardia episodes	0		31(96.9)		25(96.2)		*0.881*
	1		1(3.1)		1(3.8)		
Norepinephrine (mcg)	N	Median	10	125 [100–250]	11	250 [125–200]	*0.108*
Ephedrine (mg)	N	Median	9	12 [6–18]	8	18 [11–26]	*0.241*
Urapidil (mg)	N	Median	4	25 [25–38]	7	30 [25–50]	*0.611*

OBA = Opioid-Based Anesthesia, OFA = Opioid-Free Anesthesia

complications are few risks associated with dexmedetomidine [17].

Dexamethasone is a glucocorticoid which has anti-inflammatory properties, reducing pain scores and preventing PONV [5]. In a prospective, randomized study using OFA protocol with dexmedetomidine, ketamine, and lidocaine for bariatric surgery, Perez and al., did not find any reduction in 24-h postoperative opioid consumption when compared with fentanyl [17]. The positive results in our study may be due to the addition of Magnesium and Dexamethasone.

Berlier and al., in a retrospective study comparing OFA and OBA in bariatric surgery found that patients in OFA group needed less morphine during the first 24 h after surgery too [18]; however, in their protocol, Ketamine was used in OBA group and all patients had Dexamethasone, Magnesium sulfate and Lidocaine.

Furthermore, what is even more interesting is that the morphine consumption in patients who received OFA is nil after the 24th postoperative hour. This could possibly suggest fewer adverse effects of opioids and earlier discharge from the hospital, fitting within the framework of ERAS (Enhanced Recovery After Surgery). However, the length of hospital stay was not evaluated in our study.

Recently, Ulbing and al [8], found a reduction in both opioid need postoperatively and postoperative pain when comparing OFA to OBA, but they used much higher doses of dexmedetomidine and continuous infusion of dexmedetomidine, ketamine and lidocaine was continued as first-line analgesic in recovery room and without an evaluation of VAS scores during movement, and coughing as we did.

Concerning PONV, we did not find any significant difference between groups. This was not the case in other studies [12, 19, 20]. The most probable explanation is that incidence of PONV was not very high in our patients (11.4% and 25%), probably because all patients received 2 L of intravenous crystalloids for optimal hydration and Ondansetron systematically for PONV prevention [21]. A larger number of patients in each group should be included to prove a reduction in PONV.

Side effects of drugs used for OFA, specially dexmedetomidine, are hypotension, bradycardia and sedation after surgery [21]. We did not find any difference in hemodynamic variability, the number of episodes of hypotension, the occurrence of bradycardia nor the need for vasopressors. Sedation scores were comparable between both groups. This is because we used small doses of dexmedetomidine (0.2–0.5 mcg/kg/h) without a loading dose and because infusions of ketamine, lidocaine, magnesium, and dexmedetomidine were stopped almost 20 min before awakening.

Patients' satisfaction scores 48 h after surgery were higher after OFA, probably because they were less painful and had a better postoperative recovery. This result agrees with other studies comparing postoperative recovery between OFA and OBA patients using a 40 questions questionnaire 24, and 48 h after recovery [8, 19].

In terms of costs, OFA typically involves the use of different adjuncts which can be more expensive than

traditional opioids like Fentanyl. While the upfront cost of these medications might be higher, they could potentially reduce the need for postoperative opioid analgesics and reduce complications like PONV which could lead to shorter hospital stays and lower overall healthcare costs. OBA, while less expensive initially, could result in higher postoperative care costs and longer recovery times due to opioid-related side effects.

The clinical implications of our study extend beyond just the immediate postoperative period. Future research should focus on long-term outcomes, including the potential for reduced chronic pain and opioid dependency, as well as the feasibility of OFA in different types of surgeries and patient populations. Additional studies could explore the optimal dosing and combination of adjuncts, as well as any potential side effects or risks associated with prolonged use of these agents.

Limitations

This study has few limitations. First, it was conducted at a single center with a relatively small sample size, which may limit the generalizability of our findings, even if we did have significant results.

Second, the study was not conducted in a double-blind manner, however data collection was carried out by research personnel (nurses and residents) who were unaware of the study groups. Additionally, statistical analysis was performed by a statistician who was also blinded to the group assignments.

Third, we used anti-emetic regularly for all patients which may have been a limiting factor for PONV diagnostic, and we did not use any validated score to evaluate PONV.

Fourth, we did not evaluate awakening duration after the end of surgery, nor length of stay in PACU. These parameters could have been modified by analgesic drugs used even though anesthesia time and sedation scores were not statistically different between groups.

Fifth, the median BMI of 40 in our study cohort is on the lower end for bariatric surgery patients, which could cause selection bias and limit the generalizability of the findings to the broader bariatric surgery cohort. However, the study included patients across a range of BMI levels, and higher BMI individuals were not specifically excluded. Nevertheless, the population in this study primarily comprises individuals who, while not necessarily classified as severely obese, are motivated by aesthetic concerns rather than purely medical ones. In this context, many patients with BMI levels lower than the typical threshold for bariatric surgery candidates (BMI often ≥ 40) opt for surgery to improve their appearance or body shape. This is consistent with trends in certain demographics or regions where individuals with moderate obesity may still seek bariatric surgery due to factors related to personal health and appearance.

Conclusion

The use of OFA combining five different drugs (lidocaine, ketamine, magnesium sulfate, dexmedetomidine and dexamethasone) appears to be beneficial in reducing postoperative morphine consumption and pain scores when compared to conventional OBA for bariatric surgery. It gives a comparable hemodynamic stability, with higher satisfaction scores and patients do not need any morphine after the 24th postoperative hour thus OFA deserves to be performed in the absence of contraindications.

Appendix 1: STOP BANG Score

The STOP BANG score is used to detect obstructive sleep apnea (OSA) preoperatively. Each item scores 1 point. OSA is suspected with a score > 3, and the risk of severe OSA is high with a score ≥ 5 [22].

Item	Question
1. **S**noring	Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?
2. **T**ired	Do you often feel tired, fatigued or sleepy during the daytime?
3. **O**bserved	Has anyone observed you stop breathing during your sleep?
4. Blood **P**ressure	Are you being, or have been, treated for high blood pressure?
5. **B**ody mass index	Is your body mass index > 35 kg/m²?
6. **A**ge	Are you > 50 years old?
7. **N**eck circumference	Is your neck circumference > 40 cm?
8. **G**ender	Are you male?

Appendix 2: Richmond Agitation-Sedation Scale

Richmond Agitation-Sedation Scale [23].

Score	Term	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitation	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient–ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
−1	Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice
−2	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
−3	Moderate sedation	Any movement (but no eye contact) to voice
−4	Deep sedation	No response to voice, but any movement to physical stimulation
−5	Unarousable	No response to voice or physical stimulation

Procedure

1. Observe patient. Is patient alert and calm (score 0)?
   Does patient have behavior that is consistent with restlessness or agitation (score +1 to +4 using the criteria listed above, under DESCRIPTION)?
2. If patient is not alert, in a loud speaking voice state patient's name and direct patient to open eyes and look at speaker. Repeat once if necessary. Can prompt patient to continue looking at speaker.
   Patient has eye opening and eye contact, which is sustained for more than 10 seconds (score −1).
   Patient has eye opening and eye contact, but this is not sustained for 10 seconds (score −2).
   Patient has any movement in response to voice, excluding eye contact (score −3).
3. If patient does not respond to voice, physically stimulate patient by shaking shoulder and then rubbing sternum if there is no response to shaking shoulder.
   Patient has any movement to physical stimulation (score −4).
   Patient has no response to voice or physical stimulation (score −5).

Acknowledgements
Not applicable

Author contributions
C.D., R.M., M.A and H.J. have given substantial contributions to the conception or the design of the manuscript and have participated to writing the original draft; C.D., M.A., J.T. to acquisition, analysis and interpretation of the data; C.D., N.N., H.J. to reviewing and editing the final draft of the manuscript. All authors read and approved the final version of the manuscript.

Funding
The authors report no involvement in the research by the sponsor that could have influenced the outcome of this work.

Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Ethical approval for this study (CEHDF 1915) was provided by the Ethical Committee of Hôtel Dieu de France hospital, Beirut, Lebanon (Chairperson Prof Sami Richa) on November 2, 2021.
Written informed consent was obtained from all study participants.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Received: 14 January 2025 Accepted: 7 April 2025
Published online: 23 April 2025

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