

Original Research Article

Comparison of opioid based and opioid free anaesthesia in short obstetrics and gynecological day care procedures: a prospective, randomized, and comparative study

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Received: 30 June 2025

Revised: 04 August 2025

Accepted: 18 August 2025

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ABSTRACT

Background: There is scarce of data in resource-limited settings on comparing the feasibility, safety and efficacy of opioid based and opioid free anaesthesia in obstetrics and gynecological day care procedures.

Methods: This is a prospective, randomized, comparative study consisting total of 100 patients. Patients were randomly allocated in to two groups viz. group CGA (control) received standard fentanyl-based general anaesthesia i.e., fentanyl 1 µg/kg IV bolus and propofol 2-2.5 mg/kg IV for induction and group OFA (intervention) received multimodal opioid-free anaesthesia (OFA) i.e., lidocaine 1 mg/kg IV over 5 min, ketamine 0.5 mg/kg IV bolus, paracetamol 1g IV (or 15 mg/kg if <50 kg), and propofol 2-2.5 mg/kg IV for induction.

Results: Majority of the study subjects i.e., 28% were belonged to age group of 31-40 years in both group CGA and group OFA. BMI was majorly (70%) in the range of 18.5-24.9 kg/m². The incidences of PONV were significantly ($p=0.019$) higher in control group (44%) as compared OFA group (22%). The composite hemodynamic stability score ($p=0.005$), time to first analgesic requirement ($p<0.001$), overall patient satisfaction mean score ($p<0.001$), recovery time ($p<0.001$), were significantly better in group OFA as compared to group CGA. The total complication rate observed was comparatively lower in in group OFA (2%) as compared to group CGA (12%). Overall incidences of side-effects were lower in group OFA (2%) as compared to group CGA (12%).

Conclusions: Opioid-free anaesthesia regimen for a low-resource setting like our study setting has a promising success rate with reduced incidence of side-effects.

Keywords: Opioid-free anesthesia, PONV, Efficacy, Safety, Day care procedure

INTRODUCTION

The therapeutic use of opioids traces back to the 17th century. As medical science advanced, opioids especially potent ones became the cornerstone for managing both acute and chronic pain due to their strong analgesic properties.¹ Yet these agents act as a “double-edged sword,” delivering relief while also causing side-effects such as respiratory depression, nausea, vomiting, opioid-induced hyperalgesia, immunosuppression, pruritus, and myoclonus. Retrospective data reveal that perioperative opioid-related complications correlate with slower

recovery, extended hospital stays, higher readmission rates, and greater healthcare costs, all of which diminish patient satisfaction.² Emerging evidence further links perioperative opioids to increased postoperative morbidity, mortality, and in oncology higher rates of tumor recurrence or metastasis.³

Driven by the principles of “comfort medicine,” clinicians now seek analgesic approaches that minimize these drawbacks. Opioid-free anesthesia (OFA) embodies a multimodal strategy that combines various non-opioid medications and techniques to achieve high-quality

anesthesia without opioids.⁴ Published OFA regimens consistently reduce postoperative opioid requirements through extensive use of adjunct agents. Intravenous Lidocaine, for instance, blocks sodium channels, dampens N-methyl-D-aspartate receptors, provides analgesia and hypnosis, and blunts autonomic responses to surgical stress. Ketamine adds analgesic and hypnotic effects while preventing postoperative hyperalgesia. Agents such as clonidine and dexmedetomidine engage central α_2 -adrenergic receptors to yield sedation, hypnosis, anxiolysis, sympatholytic, and analgesia making them valuable OFA adjuvants. NSAIDs can halve morphine consumption, and both NSAIDs and dexamethasone furnish additional analgesia. Regional blocks, acupuncture, and local anesthetic infiltration further enhance pain control.⁵ OFA aligns seamlessly with enhanced-recovery after surgery, improving patient outcomes, lowering postoperative complications, and expediting recovery.⁶

The application of opioid-free anesthesia in short obstetrics and gynecological procedures offers several advantages that align with the priorities of modern healthcare. Faster recovery times, reduced incidence of postoperative nausea and vomiting (PONV), and lower risk of opioid-related side effects contribute to improved patient satisfaction and operational efficiency. These benefits are particularly relevant in day care settings, where patients are expected to resume normal activities shortly after discharge. Additionally, the avoidance of opioids aligns with the broader public health objective of curbing opioid misuse and dependency.⁷⁻¹⁰

Still, these advantages remain under debate. In a large multicenter trial of 314 non-cardiac operations including 18 gynecologic cases, dexmedetomidine-based OFA led to delayed extubation, longer post-anesthesia care-unit (PACU) stays, postoperative hypoxemia, and severe bradycardia, prompting early termination.¹¹ Two other sizable trials from high-income settings comparing dexmedetomidine-centered OFA with conventional general anesthesia (CGA) in laparoscopic gynecologic surgery found similar postoperative pain, opioid consumption, PONV rates, and antiemetic use, yet reported greater sedation and extended PACU stays in the OFA cohorts.^{12,13} Conversely, studies from low- and middle-income nations also using dexmedetomidine in gynecologic surgery have demonstrated superior hemodynamic stability alongside the anticipated OFA benefits.^{10,14-16}

Moreover, to the best of our knowledge, there are no studies comparing the feasibility, safety and efficacy of opioid based and opioid free anaesthesia in obstetrics and gynecological day care procedures at our study setting. With this scenario, present study was conducted with the main purpose to compare effectiveness of opioid based and opioid free anaesthesia with regards to incidences of PONV, hemodynamic stability, and first post-operative analgesic requirement and safety with regards to side

effects were evaluated along with patient satisfaction undergone obstetrics and gynecological day care procedures.

METHODS

Study population

This is a prospective, randomized, comparative study conducted with total of 100 patients admitted for Obstetrics and Gynecological day care procedures at Department of Anesthesiology, Krishna Institute of Medical Sciences (KIMS), Karad, Maharashtra. The ethical committee approval and written informed consent were obtained before the conduct of study.

Inclusion criteria

Female patients aged 21–65 years, American Society of Anesthesiologists (ASA) physical status I or II, body mass index (BMI) $<30 \text{ kg/m}^2$, and scheduled for elective day-care obstetric or gynaecological procedures amenable to general anaesthesia and lasting $<60 \text{ min}$ (e.g., suction and evacuation, cervical cerclage, cervical or endometrial biopsy, dilatation and curettage) were included.

Exclusion criteria

Patients with known allergy or hypersensitivity to any study medication *viz.* fentanyl, ketamine, lidocaine, paracetamol, propofol or related agents, and history of psychiatric illness, chronic opioid use, or substance-use disorder were excluded.

Study design

100 patients were randomly allocated in to two groups *viz.* group CGA (control) and group OFA (intervention). Group CGA received standard fentanyl-based general anaesthesia *i.e.*, fentanyl $1 \mu\text{g/kg}$ IV bolus and propofol $2\text{--}2.5 \text{ mg/kg}$ IV for induction. Supplemental oxygen as required. Bolus of inj. propofol as and when required for maintenance. Group OFA received multimodal opioid-free anaesthesia *i.e.*, lidocaine 1 mg/kg IV over 5 min, ketamine 0.5 mg/kg IV bolus, paracetamol 1 g IV (or 15 mg/kg if $<50 \text{ kg}$), and propofol $2\text{--}2.5 \text{ mg/kg}$ IV for induction. Supplemental oxygen as required. Bolus of inj. propofol as and when required for maintenance.

Pre-anaesthetic evaluation

On the day prior to surgery, a detailed pre-anaesthetic evaluation was conducted for all patients, which included a general physical examination, systemic assessment and preoperative laboratory investigations *viz.* complete blood count (CBC), blood sugar, routine and microscopic urine examination, blood urea, serum creatinine, and electrocardiography (ECG). Patients were kept nil per oral (NPO) for six hours before surgery to ensure proper anaesthetic management.

Anesthesia protocol

On arrival in pre-operative room, intravenous line was secured with a 20-gauge cannula and IV fluid started. Baseline vitals such as heart rate (HR), non-invasive blood pressure (NIBP), and room air saturation were recorded. All patients received premedication as per the OT protocol for both the groups as follows: inj. ranitidine 0.5 mg/kg IV, inj. metoclopramide 0.15 mg/kg IV, inj. midazolam 0.05 mg/kg IV, and inj. ondansetron 0.15 mg/kg were given. After shifting the patient to the operation theatre, monitors such as an ECG, pulse oximetry (SpO₂), and NIBP were attached.

The anesthesia protocol was followed as per study design for group CGA and group OFA. The hemodynamic parameters were continuously monitored before induction (baseline), and 2 min, 3 min, and 5 min after induction, and till the end of procedure. The study procedure was standardized to all the patients. After the procedure patients were observed for 2 hours in post-operative period and were observed for PONV, time for first rescue analgesia, patients' satisfaction and other post-operative side effects along with early recovery of patient. Post operatively if patient complaints of PONV inj. dexamethasone 0.14 mg/kg was given.

Data collection and assessment parameters

Incidence of PONV within the first 24 hours were measured as primary endpoint. Magnitude of intra-operative composite hemodynamic variations, time to first postoperative analgesic requirement, PACU-visual-analogue pain score (VAS) of 0–10 (Figure 1) for 30 min, patient-reported satisfaction at 24 hours, measured on a five-point Likert scale (Figure 2), post-operative recovery of patients based on modified Aldrete score for discharge of patient from PACU (Figure 3) were evaluated as secondary endpoints.

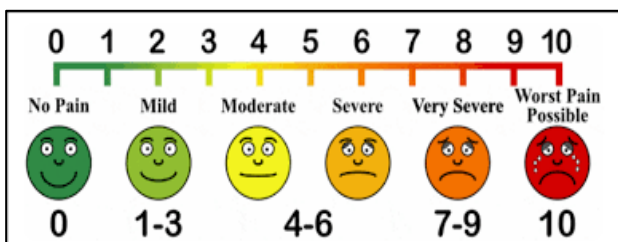


Figure 1: Visual analogue scale (VAS).

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

Figure 2: Five-point Likert scale.

Table 1: Modified Aldrete score.

Criteria	Characteristics	Points
Activity	Able to move 4 extremities	2
	Able to move 2 extremities	1
	Unable to move extremities	0
Respiration	Able to breathe deeply and cough freely	2
	Dyspnea or limited breathing	1
	Apneic	0
Circulation	BP \pm 20% of pre-anesthetic level	2
	BP \pm 20-49% of pre-anesthetic level	1
	BP \pm 50% of pre-anesthetic level	0
Consciousness	Fully awake	2
	Arousable on calling	1
	Not responding	0
Oxygen saturation	Able to maintain O ₂ saturation >92% on room air	2
	Needs oxygen to maintain O ₂ saturation >90%	1
	O ₂ saturation <90% even with supplemental oxygen	0

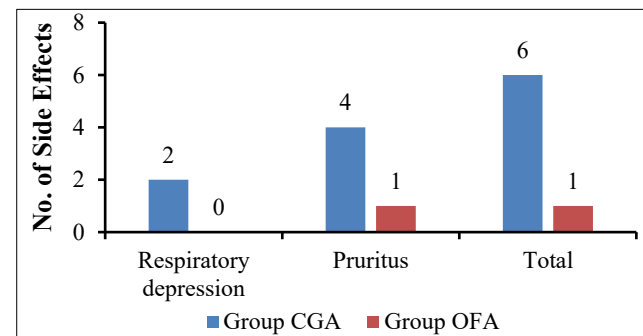


Figure 3: Incidence of intraoperative side effects.

Statistical analysis

Data was entered in Microsoft Excel 2021 and analysis was done using statistical software for social sciences (SPSS) version 21. Categorical variables were represented in the form of percentages, and frequencies. Continuous variables were presented as descriptive statistics (mean and standard deviation). Categorical variables were analysed using the Chi-square test. Comparison of continuous variables between the study groups was done using independent sample t-test. $P \leq 0.05$ was considered statistically significant.

RESULTS

Patient characteristics

Majority of the study subjects i.e., 28% were belonged to age group of 31-40 years in both group CGA and group

OFA. BMI was majorly (70%) in the range of 18.5-24.9 kg/m². However, distribution of study subjects based on age ($p=1.000$) and BMI ($p=0.890$) between Group CGA and group OFA was not statistically significant (Table 2).

Table 2: Patient characteristics.

Variables	Group CGA (n=50)	Group OFA (n=50)	P value
Age (years)			
21–30	13 (26.0)	13 (26.0)	1.000
31–40	14 (28.0)	14 (28.0)	
41–50	7 (14.0)	7 (14.0)	
51–60	10 (20.0)	10 (20.0)	
61–65	6 (12.0)	6 (12.0)	
BMI (kg/m²)			
<18.50	4 (8.0)	4 (8.0)	0.890
18.50–24.90	35 (70.0)	35 (70.0)	
25.00–29.90	11 (22.0)	11 (22.0)	

Values are expressed as n (%)

Primary endpoint

The incidences of PONV observed in group CGA and group OFA was found to be 44% and 22% respectively with statistically significant ($p=0.019$) differences (Table 3).

Table 3: Incidence of postoperative nausea and vomiting (PONV).

PONV	Group CGA (n=50)	Group OFA (n=50)	P value
Yes	22 (44.0)	11 (22.0)	0.019
No	28 (56.0)	39 (78.0)	

Values are expressed as n (%)

Secondary endpoints

The results of secondary endpoints were represented in Table 4. Results depicted that the composite hemodynamic stability score ($p=0.005$), time to first analgesic requirement ($p<0.001$), overall patient satisfaction mean score ($p<0.001$), recovery time ($p<0.001$) were significantly better in group OFA as compared to group CGA. The total complication rate observed was comparatively lower in group OFA (2%) as compared to group CGA (12%).

Safety

Two cases of respiratory depression (4%) and four cases of pruritus (8%) were observed, in group CGA. Whereas, only one case of pruritus (2%) was observed in group OFA. Although the overall incidences of side-effects were lower in group OFA (2%) as compared to group CGA (12%), there was no statistically significant ($p=0.11$) differences was observed (Figure 3).

Table 4: Secondary endpoints.

Secondary endpoints	Group CGA (n=50)	Group OFA (n=50)	P value
Composite hemodynamic stability score	85.00±5.00	90.00±4.00	0.005
Time to first analgesic requirement (min)	36.50±10.20	46.78±12.24	<0.001
Overall patient satisfaction (mean score)	2.96±1.01	1.92±0.78	<0.001
Recovery time (min)	92.76±12.56	81.80±8.34	<0.001
Total complication rate (%)	12.00	2.00	0.110

Values are expressed as mean±SD unless otherwise stated

DISCUSSION

There is scarce of data in resource-limited settings on comparing the feasibility, safety and efficacy of opioid based and opioid-free anaesthesia in Obstetrics and Gynecological day care procedures. We aimed to assess whether a deliberately constructed multimodal OFA regimen *viz.* combining low-dose ketamine, intravenous lidocaine and paracetamol could equal or surpass the outcomes like PONV, hemodynamic stability, intra-operative adequacy and postoperative recovery profile of a standard fentanyl-based general anaesthetic (CGA) in patients undergone short obstetric and gynaecological day-care procedures.

Our study results on patient characteristics revealed that majority of the study subjects i.e., 28% were belonged to age group of 31-40 years in both control and OFA groups. BMI was majorly in the range of 18.5-24.9 kg/m². However, distribution of study subjects based on age ($p=1.000$) and BMI ($p=0.890$) between control and OFA groups was not statistically significant. These findings were in accordance with previous studies published in the literature by various other research investigators. In a study conducted by Hakimoglu et al, randomized 105 women yet reported a marginal age skew ($p=0.21$).¹⁷ Sultana et al reported that demographic imbalance is a recurrent weakness in OFA reports, citing obesity and obstructive-sleep-apnea cohorts whose body habitus differed by up to 4 kg/m² between study arms.³ Contrastingly, our strict exclusion of BMI <30 kg/m² mirrors the selection criteria of Lavand'homme and Estebe study which advocated initial OFA adoption in healthier ASA I–II patients to reduce confounding factors.¹⁸ In a large observational study carried out by Smith et al reported a significant BMI gap of 27.80±5.30 in OFA versus 29.40±4.80 in OBA ($p=0.04$) necessitating regression adjustment.¹⁹ These findings were in consistent with our study findings on BMI distribution. Our study demographic harmonization therefore strengthens internal

validity and permits a clearer head-to-head appraisal of opioid inclusion versus avoidance.

Opioids are potent emetics via their direct action on chemo-trigger zone receptors in the brainstem.²⁰ The result of this central stimulation during the perioperative period leads to PONV, more common in major gynecological surgery, where PONV occurs at incidences of 50-80%.²¹ In our study the incidences of PONV were significantly ($p=0.019$) higher in control group (44%) as compared to OFA group (22%). Hence, similar to previous studies on gynecology surgery,^{10,14,22-26} the frequency of incidences of PONV were significantly reduced in the OFA group in our study.

Literature reports evidenced that the synergistic analgesic effects of lidocaine, dexamethasone, magnesium sulphate, clonidine, and low-dose ketamine, have been shown to have an overall greater analgesic effect as well as an opioid-sparing property, an anti-inflammatory effect and an anti-hyperalgesic effect than opioids.²⁷⁻³¹ In concurrence with literature findings in our study time to first analgesic requirement was significantly longer with faster recover time in OFA group when compared with control group. Furthermore, our results concur with those of clinical studies on similar abdominal gynecological surgical procedures, laparoscopic gynecological surgery, where significantly less postoperative pain, a net reduction of postoperative opioid consumption and less rescue consumption of non-opioid analgesics like paracetamol, tramadol, pethidine and Ketorolac.^{10,15,25,32} Moreover, overall patient satisfactions were significantly better in OFA group as compared to control group in our study. In addition, overall incidences of side-effects were significantly lower for OFA regimen as compared to control regimen in our study.

It could be understood from literature about the mechanism of action of ketamine by which it exerts analgesic and anti-inflammatory effects is as follows; ketamine analgesia is obtained from its inhibitory central and peripheral action on N-methyl-D-aspartic acid (NMDA) receptors involved in the transmission and modulation of acute pain. Ketamine used at low doses in OFA has an anti-inflammatory effect and anti-hyperalgesic effects exerted still via NMDA receptor antagonism leading to good analgesia against both acute and chronic surgical pain.³³ Due to these aforementioned effects, it is quite clear now that opioids intraoperative use can be substituted by the intraoperative use of ketamine, even without dexmedetomidine as an adjunct.³⁴

Although dexmedetomidine is the reference OFA drug due to its α_2 -adrenergic analgesic-sedative-hypnotic-sympatholytic properties, its worldwide use is limited by its availability and relatively high financial cost. As such, adapted OFA regimens not containing dexmedetomidine such as ketamine + lidocaine + propofol + atracurium, or ketamine + propofol + magnesium sulfate + clonidine + rocuronium, or ketamine + lidocaine + propofol +

paracetamol like in our study have been used in gynecology surgery with stable composite hemodynamic profiles and no complications.^{10,25}

The significance of this study is multifaceted. Clinically, short gynecological procedures constitute a high-volume outpatient workload in which rapid turnover, minimal adverse events and high patient comfort are paramount; demonstrating superior or equivalent results without opioids directly challenges long-standing practice norms and offers an immediate pathway to safer, smoother recoveries. From a safety perspective, eliminating intra-operative opioids addresses well-recognized complications respiratory depression, urinary retention, pruritus, nausea, vomiting and opioid-induced hyperalgesia while simultaneously reducing the risk that peri-operative exposure seeds persistent postoperative opioid use, a contributor to the broader opioid epidemic. Operationally, even modest improvements in recovery-room discharge times and reductions in rescue interventions translate into meaningful efficiency gains for busy ambulatory theatres and resource-limited centers alike. Economically, the OFA cocktail relies on inexpensive, widely available drugs, enabling scalability without financial barrier. Thus, the study outcomes possess both immediate bedside applicability and broader public-health resonance.

Limitations

Our study has certain limitations. First, the sample size was smaller due to single-centre study, a larger sample size may be needed for this study. Second, there has been a lack of validated depth of anesthesia and nociception monitors during OFA. Finally, the follow-up period was restricted to for the first day after surgery only.

CONCLUSION

In conclusion, OFA is more effective in reducing the incidence of post-operative nausea and vomiting with stable hemodynamics, early patient recovery and reduced incidence of side-effects and when compared with opioid based anaesthesia in patients undergoing short obstetrics and gynecological day care procedures. Hence, adapted opioid-free anaesthesia regimen for a low-resource setting like our study setting has a promising success rate with reduced incidence of side-effects.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gejji J, Joshi VM. Comparison of opioid based and opioid free anaesthesia in short obstetrics and gynecological day care procedures: a prospective, randomized, and comparative study. *Int J Res Med Sci* 2025;13:3727-33.