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Original Research Article

COMPARATIVE EVALUATION OF FENTANYL AND DEXMEDETOMIDINE IN PATIENT-CONTROLLED ANALGESIA FOR POSTOPERATIVE PAIN FOLLOWING MAJOR LAPAROSCOPIC ABDOMINAL PROCEDURES

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ABSTRACT

Background: Effective postoperative pain management remains a major challenge in anesthetic practice, directly influencing recovery, morbidity, and patient satisfaction. Patient-controlled analgesia (PCA) has emerged as a reliable modality that allows individualized analgesic delivery. While opioid-based PCA, particularly with fentanyl, is widely used, interest in non-opioid alternatives such as dexmedetomidine has increased due to their potential for improved analgesia and reduced adverse effects. Aim of the present work is to compare the analgesic efficacy, hemodynamic effects, and side-effect profile of dexmedetomidine versus fentanyl when administered via PCA for postoperative pain relief following major laparoscopic abdominal surgeries. **Materials and Methods:** In this prospective comparative study, 100 patients (ASA I–II) undergoing major laparoscopic abdominal surgeries were randomized into two groups (n=50 each). Group D received dexmedetomidine PCA and Group F received fentanyl PCA, both at a background infusion of 0.25 µg/kg/h with a bolus dose of 0.125 µg/kg and a lockout interval of 15 minutes. Pain scores (VAS), hemodynamic parameters, and respiratory variables were recorded up to 24 hours postoperatively. Analgesic consumption and adverse effects were also assessed. **Results:** Dexmedetomidine group demonstrated significantly lower VAS scores, reduced bolus demand, and decreased requirement for rescue analgesia, particularly in the early postoperative period. Hemodynamic parameters were more stable in Group D, with lower heart rate and blood pressure values. Fentanyl group exhibited a greater incidence of nausea, vomiting, and pruritus, whereas deep sedation was more common with dexmedetomidine. No clinically significant respiratory depression was observed in either group. **Conclusion:** Dexmedetomidine-based PCA provides superior analgesia with improved hemodynamic stability and a favorable side-effect profile compared to fentanyl, making it an effective alternative for postoperative pain management in laparoscopic surgeries.

INTRODUCTION

Postoperative pain remains one of the most common yet inadequately managed complications following surgery, significantly affecting patient recovery and overall outcomes.[1,2] Poorly controlled pain not only diminishes quality of life but is also associated with adverse physiological and psychological consequences, including increased morbidity, delayed recovery, prolonged hospital stay, and higher healthcare costs.[3,4] In addition, unrelieved pain can impair respiratory function by reducing alveolar ventilation and vital capacity, predisposing patients to atelectasis and pulmonary complications.[5-7] It may also contribute to thromboembolic events, myocardial ischemia, impaired wound healing, sleep disturbances, and the development of chronic pain syndromes.[5-7] Effective postoperative pain management is therefore a cornerstone of enhanced recovery protocols. Increasing awareness of the multidimensional nature of pain has led to the development of standardized assessment strategies, including its recognition as the "fifth vital sign".[6] Among the available tools, the Visual Analog Scale

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(VAS) and Numerical Rating Scale (NRS) are widely used due to their simplicity and applicability across diverse patient populations. Despite advancements in analgesic techniques, achieving optimal pain control remains challenging. Epidural analgesia and intravenous infusions provide effective analgesia but are associated with limitations such as invasiveness, risk of complications, and difficulty in titration.[8] In this context, patient-controlled analgesia (PCA) has emerged as a reliable and patient-centered modality. PCA systems allow patients to self-administer predetermined doses of analgesics, maintaining stable plasma drug levels while minimizing peaks and troughs associated with intermittent dosing.[9,10] This approach improves patient satisfaction, individualizes analgesic delivery, and reduces healthcare provider workload.[9-11]

Opioids have traditionally been the mainstay of postoperative pain management due to their potent analgesic effects. Fentanyl, a highly lipophilic μ-opioid receptor agonist, is commonly used in PCA owing to its rapid onset and favorable hemodynamic profile. However, opioid-based analgesia is associated with several adverse effects, including respiratory depression, nausea, vomiting, pruritus, constipation, and potential for dependence.[8] These limitations have driven the search for effective opioid-sparing alternatives. Dexmedetomidine, a highly selective α_2 -adrenoceptor agonist, has gained attention as a promising adjunct or alternative for postoperative analgesia. It exerts analgesic, sedative, and anxiolytic effects through central and spinal mechanisms, while also providing sympatholysis and hemodynamic stability.[12,13] Evidently, dexmedetomidine produces a unique form of sedation that allows easy arousal and minimal respiratory depression, making it particularly advantageous in the postoperative setting.[12,13] Furthermore, its opioid-sparing properties may reduce the incidence of opioid-related adverse effects. Laparoscopic abdominal surgeries, although associated with reduced tissue trauma compared to open procedures, can still result in significant postoperative pain, particularly within the first 24 hours. Factors such as pneumoperitoneum and residual carbon dioxide may contribute to visceral and referred shoulder pain.[14,15] Therefore, effective analgesic strategies are essential to optimize recovery in these patients. While fentanyl-based PCA is widely used, owing to its potent analgesic action mediated through μ-opioid receptor agonism in the central nervous system, evidence regarding the use of dexmedetomidine as a sole agent in PCA remains limited. In this context, the present study was designed to compare the analgesic efficacy, hemodynamic effects, and side-effect profile of dexmedetomidine and fentanyl when administered via PCA for postoperative pain relief following major laparoscopic abdominal surgeries.

MATERIALS AND METHODS

Study Design and Setting: This prospective comparative study was conducted in the Department of Anesthesiology at G. Kuppuswamy Naidu Memorial Hospital, Coimbatore, after obtaining approval from the Institutional Ethics Committee. The study was carried out over a period of 18 months.

Study Population and Eligibility Criteria

A total of 100 patients scheduled to undergo major laparoscopic abdominal surgeries were enrolled in this study. Eligible participants belonged to the American Society of Anesthesiologists (ASA) physical status I or II and were aged between 18 and 65 years. Patients with ASA physical status III or higher, known allergy to the study medications, body mass index greater than 30 kg/m², known cardiac illness, or those unwilling to provide consent were excluded. The purpose of the study was explained in detail to all participants, and written informed consent was obtained prior to inclusion.

Sample Size Calculation

The sample size was calculated using the formula $n_1 = \frac{(\sigma_1^2+\sigma_2^2/k)(Z_{1-\alpha/2}+Z_{1-\beta})^2}{d^2}$, assuming a type I error (α) of 0.05 and a power of 80% (β = 0.2). Based on this calculation, the required sample size was 44 patients in each group. To compensate for possible attrition, the sample size was increased to 50 patients per group, resulting in a total of 100 participants.

Randomization and Group Allocation

Participants were randomly allocated into two groups of equal size (n = 50 each) using computer-generated random numbers. Group D received dexmedetomidine, while Group F received fentanyl for patient-controlled analgesia.

Preoperative Preparation

All patients underwent a thorough pre-anesthetic evaluation prior to surgery. They were educated about the VAS for pain assessment and were instructed on the proper use of the PCA pump to ensure accurate postoperative pain reporting and effective use of the analgesic device.

Anesthetic Technique

Upon arrival in the operating room, baseline vital parameters including heart rate (HR), blood pressure (Bp), oxygen saturation (SPO_2), and respiratory rate (RR) were recorded. General anesthesia was induced using propofol 2 mg/kg, fentanyl 2 μg/kg, and vecuronium 0.1 mg/kg to facilitate endotracheal intubation. Patients were mechanically ventilated throughout the procedure. Anesthesia was maintained using isoflurane at approximately one minimum alveolar concentration (MAC), along with intermittent doses of vecuronium for muscle relaxation. Standard intraoperative monitoring, including electrocardiography, non-invasive BP, pulse oximetry, end-tidal carbon dioxide ($ETCO_2$), and temperature, was carried out continuously. All patients received intravenous paracetamol 1 g, lornoxicam 8 mg, and ondansetron 4 mg intraoperatively. No additional opioid boluses were

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administered during surgery. Hypotension (mean arterial pressure <60 mmHg) was treated with intravenous ephedrine 6 mg boluses, and bradycardia (heart rate <50 beats per minute) was managed with atropine 0.6 mg. Intravenous fluids (Ringer's lactate or normal saline) were administered based on maintenance requirements and intraoperative losses. At the end of surgery, neuromuscular blockade was reversed using neostigmine and glycopyrrolate, and patients were extubated after meeting standard extubation criteria. Postoperatively, supplemental oxygen at 4 L/min was administered via a Hudson mask for the first six hours for all patients.

PCA Protocol

The PCA infusion was initiated just prior to surgical incision and continued throughout the intraoperative period and for 24 hours postoperatively. In Group D, dexmedetomidine was administered at a background infusion rate of 0.25 µg/kg/hour, while in Group F, fentanyl was administered at the same rate. Both drugs were diluted with 0.9% normal saline to a total volume of 50 mL, such that 1 mL/hour delivered the required dose. After surgery, patients, if in pain, were given the option of delivering a bolus dose of 0.5 ml (equivalent to 0.125 µg/kg), by pressing the analgesic-demand button given to them. The delivery of one bolus dose of the drug was followed by a lockout interval of 15 minutes. Even if the patient pressed the analgesic demand button during the lockout interval, drug was not delivered.

Postoperative Management

Following surgery, patients were shifted to the postoperative care unit and were encouraged to use the PCA pump whenever they experienced pain, defined as a VAS score greater than 3. In cases where pain relief was inadequate despite PCA use, rescue analgesia with intravenous tramadol 50 mg was administered and could be repeated up to a maximum of 100 mg within 12 hours. Patients who did not achieve adequate pain relief even after rescue analgesia were excluded from the study and managed with intravenous morphine while continuing PCA. A total of two patients, one from each group, were excluded based on this criterion.

Outcome Measures

Pain intensity was assessed using the VAS immediately after surgery and at 1, 2, 4, 6, 12, and 24 hours postoperatively. Hemodynamic parameters, including HR, BP, SPO2, and RR, were recorded at the same time intervals. The total number of PCA bolus attempts, including unsuccessful attempts during the lockout period, as well as the number of successfully delivered boluses, were documented. The requirement for rescue analgesia was also recorded. Additionally, the incidence of adverse effects such as nausea, vomiting, pruritus, and deep sedation (defined as a Ramsay Sedation Score greater than 4) was noted.

Statistical Analysis

Data collected were entered and analyzed using Microsoft Excel. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Intergroup comparisons of continuous variables were performed using the independent Student's t-test, and categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value of less than 0.05 was considered statistically significant.

RESULTS

As shown in Table 1, the baseline demographic and clinical characteristics were comparable between the two study groups. There were no statistically significant differences in age or body mass index, indicating a similar distribution of patient characteristics across both groups. The distribution of ASA physical status was also comparable, with a greater proportion of patients in both groups belonging to ASA Grade II. This reflects a relatively uniform surgical risk profile among the study population. The absence of statistically significant differences in baseline variables suggests that the two groups were well matched, thereby minimizing potential confounding factors and allowing for a valid comparison of postoperative outcomes.

Table 1: Baseline Demographic and Clinical Characteristics of the Each Study Groups (n= 50)

Variable		Group D (n=50)	Group F (n=50)	P value
Mean Age (years)		53.96 ± 9.28	50.72 ± 9.48	0.087
Mean BMI (kg/m²)		25.61 ± 3.01	25.05 ± 3.13	0.361
ASA, N (%)	Grade I	18 (46.2%)	21 (53.8%)	0.539
	Grade II	32 (52.5%)	29 (47.5%)	

As presented in Table 2, baseline SBP, DBP, and MAP were comparable between the two groups, indicating similar preoperative hemodynamic status. At the end of surgery, a significant difference emerged between the groups, with patients in the dexmedetomidine group exhibiting lower SBP, DBP, and MAP compared to those receiving fentanyl. This difference reflects a better attenuation of the intraoperative stress response in the dexmedetomidine group. In the early postoperative period (1 hour), hemodynamic parameters were comparable between the groups, suggesting transient equilibration following surgery and anesthesia. However, from 2 hours onwards, a consistent and statistically significant trend was observed, wherein the dexmedetomidine group maintained lower SBP, DBP, and MAP compared to the fentanyl group. This trend persisted through 4, 6, 12, and 24 hours postoperatively. The sustained reduction in Bp parameters in the dexmedetomidine group may be

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attributed to its sympatholytic effects, resulting in improved control of perioperative hemodynamic responses. In contrast, the relatively higher values observed in the fentanyl group may reflect less effective modulation of sympathetic activity.

Table 2: Comparison of Hemodynamic Parameters (SBP, DBP, and MAP) Between Study Groups at Different Time Points

Time (hrs)	Mean SBP			Mean DBP			Mean MAP		
	Group D	Group F	P value	Group D	Group F	P value	Group D	Group F	P value
B	139.2±23.0	136.0±22.5	0.484	80.7±13.9	81.5±14.2	0.766	100.2±15.9	99.7±16.0	0.874
EOS	124.9±17.3	158.7±22.5	<0.001*	76.9±10.3	93.9±9.3	<0.001*	92.9±11.8	115± 12.1	<0.001*
1	120.3±17.9	118.1±18.0	0.535	75.0±10.9	73.9±10.5	0.623	90.1±12.3	88.6±12.1	0.555
2	117.3±14.2	142.9±17.6	<0.001*	71.9± 9.6	88.0±7.8	<0.001*	87.0±10.5	106±8.3	<0.001*
4	110.9±5.5	131.1±16.6	<0.001*	68.9± 9.0	81.8±11.3	<0.001*	82.9±6.8	98.2±12.1	<0.001*
6	117.6±10.9	131.3±17.3	<0.001*	72.18±5.8	78.26±8.6	<0.001*	87.3±6.3	95.9±10.0	<0.001*
12	121.7±11.9	134.6±18.2	<0.001*	73.80±10	81.24±8.2	<0.001*	89.7±9.6	99.0±10.2	<0.001*
24	115.66±16.2	130.0±18.8	<0.001*	70.62±8.9	79.96± 10	<0.001*	85.6±10.4	96.6±12.1	<0.001*

Footnote: *SBP = Systolic Blood Pressure (mmHg); DBP = Diastolic Blood Pressure (mmHg); MAP = Mean Arterial Pressure (mmHg); Group D = Dexmedetomidine group; Group F = Fentanyl group. Data are expressed as mean ± standard deviation (SD). A p value < 0.05 was considered statistically significant;*

As shown in Table 3, baseline HR and RR were comparable between the two groups, while a small but statistically significant difference in baseline SpO_2 was observed, which was not clinically relevant. At the end of surgery and throughout the postoperative period, the dexmedetomidine group consistently demonstrated significantly lower HR compared to the fentanyl group, indicating better attenuation of sympathetic responses. A similar trend was observed for RR, with higher and more preserved respiratory rates in the dexmedetomidine group, whereas patients in the fentanyl group showed comparatively lower RR across most postoperative time points. SpO_2 remained within normal limits in both groups at all time points, with only occasional statistically significant differences that were not clinically meaningful. Pain assessment using the VAS revealed significantly lower pain scores in the dexmedetomidine group at the end of surgery and during the early postoperative period up to 6 hours. However, at later time points (12 and 24 hours), pain scores were comparable between the two groups, indicating convergence of analgesic effects over time.

Table 3: Comparison of Heart Rate, Respiratory Rate, SpO_2 , and VAS Scores between Study Groups at Different Time Points

Mean HR		Mean RR		Mean SpO_2		Mean VAS	
Group D	Group F	Group D	Group F	Group D	Group F	Group D	Group F
89.5±15.3	92.7±16.0^{NS}	19.4±2.8	19.2±2.7^{NS}	99.5±0.83	99.9±0.36**	—	—
67.6±11.3	87.3±9.2***	21.3±3.2	19.1±2.0***	99.3±0.24	99.5±1.07^{NS}	1.60±1.57	2.62±1.06***
59.6±5.8	82.6±12.9***	20.4±1.8	16.7±2.1***	99.4±1.37	98.7±2.17^{NS}	0.98±1.07	2.32±1.09***
63.4±6.9	89.0±9.7***	20.0±2.6	14.2±3.0***	99.7±0.70	99.2±1.48*	1.06±0.84	1.66±0.96***
62.0±6.1	85.9±9.0***	20.3±2.6	13.1±2.0***	99.7±0.69	99.5±1.01^{NS}	0.84±0.73	1.94±1.53***
66.0±6.4	86.5±9.4***	20.2±3.1	13.2±2.5***	99.6±0.79	99.5±0.97^{NS}	0.68±0.84	1.18±1.06*
63.8±7.9	82.0±10.8***	20.1±3.0	16.2±2.4***	99.7±0.59	99.2±1.59*	0.38±0.69	0.62±0.63^{NS}
73.1±10.0	78.1±9.6*	21.1±3.0	18.4±4.3***	99.6±0.56	99.5±1.09^{NS}	0.74±0.52	0.58±0.49^{NS}

Footnote: *B = Baseline; EOS = End of Surgery; HR = Heart Rate (beats per minute); RR = Respiratory Rate (breaths per minute); SpO_2 = Peripheral Oxygen Saturation (%); VAS = Visual Analog Scale; Group D = Dexmedetomidine group; Group F = Fentanyl group; NS = Not statistically significant (p ≥ 0.05). Statistical significance was defined as follows: p < 0.05 (*), p < 0.01 (**), and p < 0.001 (***).*

Dexmedetomidine demonstrated superior analgesic efficacy compared to fentanyl, as reflected by a significantly lower number of bolus demands (Table 5). Despite this, the number of bolus doses actually delivered was comparable between the groups, likely due to the effect of PCA lockout intervals. Furthermore, patients in the dexmedetomidine group required significantly fewer episodes of breakthrough analgesia, reinforcing its effectiveness in postoperative pain control. In terms of adverse effects, a lower incidence of nausea and vomiting was observed in the dexmedetomidine group, although this did not reach statistical significance. Pruritus was noted only in the fentanyl group, whereas deep sedation was observed exclusively in the dexmedetomidine group, with both findings being statistically significant. The incidence of hypotension was low and comparable between the two groups. Evidently, dexmedetomidine was associated with reduced analgesic requirements and an opioid-sparing effect, albeit with a higher incidence of sedation, while fentanyl was associated with typical opioid-related adverse effects.

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Table 4: Comparison of Analgesic Requirements and Adverse Effects between Study Groups

Parameter	Group D (n=50)	Group F (n=50)	P value
Number of bolus demands	17.20 ± 4.67	20.38 ± 6.49	0.006*
Number of bolus doses delivered	11.38 ± 4.23	12.18 ± 3.13	0.285
Number of breakthrough analgesia doses	1.12 ± 0.85	1.96 ± 1.07	<0.001*
Nausea/Vomiting	3 (6.0%)	9 (18.0%)	0.065
Pruritus	0 (0.0%)	4 (8.0%)	0.041*
Deep Sedation	4 (8.0%)	0 (0.0%)	0.041*
Hypotension	1 (2.0%)	0 (0.0%)	0.317

DISCUSSION

Effective postoperative pain management remains a critical component of perioperative care, particularly in patients undergoing laparoscopic abdominal surgeries. Despite advancements in analgesic techniques, achieving optimal pain control while minimizing adverse effects continues to be challenging. PCA offers an individualized approach to pain management; however, the choice of agent significantly influences both efficacy and safety outcomes.

In the present study, dexmedetomidine demonstrated superior analgesic efficacy compared to fentanyl when used as the sole agent in PCA, particularly during the early postoperative period. This finding is consistent with previous studies that have highlighted the analgesic and opioid-sparing properties of dexmedetomidine. For instance, Wang et al., 2016 reported that dexmedetomidine infusion via PCA provided effective postoperative analgesia following gynecological laparoscopic procedures, with reduced analgesic requirements and improved patient comfort.[16] Similarly, Chen et al. 2017 demonstrated enhanced pain control with dexmedetomidine following laparoscopic cholecystectomy, supporting its role as an effective alternative to opioids.[17]

The improved analgesic profile of dexmedetomidine can be attributed to its central and spinal α2-adrenoceptor agonist action, which modulates nociceptive transmission and reduces sympathetic outflow. This mechanism not only enhances analgesia but also contributes to improved hemodynamic stability. In the present study, patients receiving dexmedetomidine exhibited better attenuation of perioperative hemodynamic responses, which aligns with findings reported by Martina Rekatsina et al., who observed that dexmedetomidine provides stable perioperative hemodynamics, albeit with an increased tendency toward hypotension in some patients.[18]

Another notable finding of this study was the preservation of respiratory function in the dexmedetomidine group. Unlike opioids, which are known to cause dose-dependent respiratory depression, dexmedetomidine maintains respiratory drive even at higher doses. This observation is supported by previous literature, which consistently reports minimal respiratory compromise with dexmedetomidine-based sedation and analgesia.[19-21] In contrast, the relatively lower respiratory rates observed in the fentanyl group in our study are in keeping with the known respiratory depressant effects of opioids.

With regard to analgesic consumption, dexmedetomidine was associated with reduced demand for bolus doses and a lower requirement for rescue analgesia, reflecting its sustained analgesic effect. These findings further reinforce the opioid-sparing potential of dexmedetomidine, which has been emphasized in multiple clinical studies evaluating multimodal analgesic strategies.[22,23]

The side-effect profile observed in this study was consistent with the pharmacological properties of the study drugs. Opioid-related adverse effects, such as pruritus and a higher incidence of nausea and vomiting, were more commonly associated with fentanyl. Similar observations have been reported by Kim et al., 2008 who highlighted nausea as a frequent complication of opioid-based PCA.[24] Additionally, a meta-analysis by Schnabel et al., 2013 demonstrated a reduced incidence of postoperative nausea and vomiting with dexmedetomidine compared to opioid-based regimens.[25]

Conversely, dexmedetomidine was associated with a higher incidence of sedation, which is a well-recognized pharmacodynamic effect due to its action on the locus coeruleus.[26] However, this sedation is often described as cooperative or arousable sedation and may be beneficial in the postoperative setting by promoting patient comfort and reducing anxiety. Importantly, although hypotension was observed in a small proportion of patients receiving dexmedetomidine, the overall incidence was low and did not differ significantly between the groups.

Taken together, the findings of the present study suggest that dexmedetomidine is an effective and safe alternative to opioids for use in PCA, particularly in the context of laparoscopic surgeries where enhanced recovery and early mobilization are desired. Its ability to provide effective analgesia, maintain hemodynamic stability, preserve respiratory function, and reduce opioid-related adverse effects makes it a valuable component of postoperative pain management strategies.

Despite its strengths, the present study has certain limitations that should be considered while interpreting the findings. Blinding was limited to patients, as observer blinding was not feasible due to logistical constraints, which may introduce potential observer bias. Additionally, the two study drugs differ in their pharmacokinetic and pharmacodynamic profiles; although comparable infusion rates were selected based on prior literature, this may limit direct equivalence. The inclusion of

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patients on beta-blockers could have influenced heart rate assessment. Furthermore, postoperative monitoring was restricted to the first 24 hours, limiting the evaluation of longer-term outcomes. The exclusion of patients with higher ASA grades, extremes of age, and BMI >30 kg/m² also restricts the generalizability of the results to a wider patient population.

CONCLUSION

The findings of the present study indicate that dexmedetomidine-based patient-controlled analgesia provides superior postoperative pain relief compared to fentanyl, particularly in the immediate postoperative period, with reduced analgesic requirements. In addition, dexmedetomidine offers better hemodynamic stability while maintaining adequate respiratory function. Furthermore, its opioid-sparing effect is reflected in a lower incidence of opioid-related adverse effects such as nausea, vomiting, and pruritus, although it is associated with a higher incidence of sedation, which remains clinically manageable. Evidently, dexmedetomidine represents a safe and effective alternative to opioids for postoperative pain management in patients undergoing major laparoscopic abdominal surgeries.

Conflict of Interest: Authors declare no Conflict of Interest.

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