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Original Research Article

Evaluation of the Efficacy of Postoperative Intravenous Patient-Controlled Analgesia Using Nalbuphine, Fentanyl, and Dexmedetomidine in Off-Pump Coronary Artery Bypass Surgery Patients: A Prospective Observational Study

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Conflict of interest: Nil

Abstract:

Objective: To compare the analgesic efficacy, haemodynamic effects, and safety of dexmedetomidine, fentanyl, and nalbuphine administered by intravenous patient-controlled analgesia (PCA) with a background infusion after off-pump coronary artery bypass grafting (OPCAB).

Design: Single-centre, hospital-based, prospective observational study.

Setting: Department of Cardiac Anaesthesiology, Max Super Speciality Hospital, Saket, New Delhi, India.

Participants: 150 adults aged 20-70 years, ASA physical status II-III, with ejection fraction >40%, scheduled for elective OPCAB, were included in three treatment groups according to the PCA regimen selected by the treating clinical team; 50 patients per group.

Exposure: On arrival in the ICU, patients commenced intravenous PCA with a background infusion of dexmedetomidine 0.5 mcg/kg/h (10-mcg bolus, Group D), fentanyl 0.5 mcg/kg/h (10-mcg bolus, Group F), or nalbuphine 50 mcg/kg/h (1-mg bolus, Group N), with a 15-minute lockout, until 48 hours after extubation.

Measurements and Results: Pain was assessed on a visual analogue scale (VAS) at rest, on coughing, and on movement; PCA demands and boluses, need for rescue analgesia, heart rate, blood pressure, Ramsay sedation score, and adverse effects were recorded at 0, 1, 6, 12, 24, and 48 h. From 6-48 h, VAS scores at rest, coughing, and movement were significantly lower with dexmedetomidine ($p<0.001$ for most comparisons). PCA demands and delivered boluses were lowest with dexmedetomidine (5.94±2.13 and 4.16±1.35), followed by fentanyl (12.42±3.31 and 8.84±1.71) and nalbuphine (19.82±6.09 and 11.52±1.78; $p<0.001$ for both comparisons). Rescue analgesia was required in 8%, 18%, and 36% of patients in Group D, F, N, respectively ($p=0.002$). Heart rate and blood pressure were significantly lower with dexmedetomidine throughout ($p<0.001$), without clinically significant hypotension or bradycardia. Sedation scores were higher with dexmedetomidine.

Conclusions: As a sole IV-PCA agent with a background infusion after OPCAB, dexmedetomidine provided lower pain scores, particularly during coughing and movement and reduced rescue-analgesia requirement compared with fentanyl and nalbuphine, with a stable haemodynamic profile and no serious adverse effects, suggesting that this regimen merits further comparative evaluation after cardiac surgery.

Keywords: Dexmedetomidine; Nalbuphine; Fentanyl; Patient-Controlled Analgesia; OPCAB; Postoperative Analgesia.

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Introduction

Inadequate postoperative analgesia after cardiac surgery remains a common problem associated with suboptimal outcomes. Poorly controlled pain triggers sympathetic activation and catecholamine release, which may contribute to myocardial ischaemia, arrhythmias, hypercoagulability, pulmonary complications, delirium, and wound infection. [1] Intravenous patient-controlled

analgesia (IV-PCA), first described in 1968, has become a standard method of postoperative pain control and provides better analgesia than conventional nurse-administered regimens after coronary artery bypass grafting (CABG). [2,3] Intravenous opioids remain the analgesics most commonly used for this purpose. [4]

Nalbuphine, a mixed agonist-antagonist opioid, produces analgesia through kappa-receptor agonism while attenuating mu-receptor-related adverse effects; its potency is comparable to morphine on a milligram basis, with a more favourable cardiovascular profile even at high doses. [5,6] Dexmedetomidine, a highly selective α2-adrenergic agonist, reduces central sympathetic outflow in a dose-dependent manner and produces opioid-sparing analgesia together with organ-protective effects against ischaemic and hypoxic injury. [7,8] Despite this favourable profile, data on dexmedetomidine used as a sole agent in an IV-PCA regimen remain scarce. Fentanyl, substantially more potent than morphine, is well suited to PCA because of its rapid onset and lack of active metabolites, and is frequently combined with a background infusion to improve analgesia while limiting adverse effects. [9]

Although fentanyl and morphine are traditionally used after cardiac surgery, nalbuphine's equianalgesic potency, lower incidence of nausea, vomiting, and respiratory depression, and minimal cardiovascular effects make it an attractive alternative that has not been routinely evaluated in this setting. In our institution, fentanyl is used for intraoperative analgesia while intravenous paracetamol is primarily used for postoperative analgesia and intravenous tramadol for breakthrough pain. We adopted intravenous PCA after off-pump CABG (OPCAB), since it provides uniform pain relief without the risks associated with regional anaesthesia techniques. Few studies have directly compared dexmedetomidine, fentanyl, and nalbuphine as sole agents delivered by IV-PCA with a background infusion in this population. We therefore undertook this prospective observational study to compare the analgesic efficacy, haemodynamic effects, and adverse-effect profile of dexmedetomidine, fentanyl, and nalbuphine administered by IV-PCA after OPCAB.

Materials and Methods

Study Design and Setting: This single-centre, hospital-based, prospective, observational study was conducted in the Department of Cardiac Anaesthesiology, Max Super Speciality Hospital, Saket, New Delhi, India, over a 15-month period, after approval by the institutional ethics committee and with written informed consent from all participants.

Study Population: One hundred fifty adult patients of either sex, aged 20-70 years, with American Society of Anesthesiologists (ASA) physical status II-III and left ventricular ejection fraction >40%, scheduled for elective OPCAB, were enrolled. Patients were excluded if they were aged >70 years; were ASA IV-V; had abnormal hepatic or renal function (serum creatinine >1.5 mg/dL or bilirubin >1 mg/dL); required mechanical ventilation for >8 hours; had undergone previous CABG or valve surgery; had poor left ventricular function (ejection fraction <40%); underwent emergency surgery or re-exploration; developed haemodynamic instability; had postoperative mental confusion; or were unable to use a PCA device. Based on previously reported mean postoperative visual analogue scale (VAS) scores and PCA-demand data for fentanyl- and morphine-based regimens, a minimum sample size of 49 patients per group was calculated to provide 80% power at a 5% significance level; 50 patients were enrolled per group. Patients received dexmedetomidine (Group D), fentanyl (Group F), or nalbuphine (Group N) as selected by the treating operating team according to clinical judgement. All three regimens were available in routine practice. Treatment selection was made after enrolment and was not randomised. Each group comprised 50 patients.

Anaesthesia and PCA Protocol: General anaesthesia was induced with midazolam 1 mg, thiopental 4 mg/kg, and fentanyl 3-4 mcg/kg intravenously, with rocuronium 1 mg/kg for tracheal intubation, and maintained with 1% isoflurane in 40% oxygen, intermittent vecuronium boluses, propofol infusion (0.5-1.0 mg/kg/h), and intermittent fentanyl boluses (1-2 mcg/kg) as required. Intraoperative haemodynamic and fluid management were at the discretion of the attending anaesthesiologist. Surgery was performed through a median sternotomy using saphenous vein, radial artery, and internal thoracic artery grafts. Fentanyl boluses were stopped approximately 30 minutes before the anticipated end of surgery, and the propofol infusion was discontinued before transfer to the intensive care unit (ICU).

On arrival in the ICU, a continuous infusion of the selected analgesic was started via a peripheral vein using a PCA pump (CADD-Legacy® PCA Ambulatory Infusion Pump, Model 6300): Group D received dexmedetomidine 0.5 mcg/kg/h (10 mcg/mL) with a demand bolus of 10 mcg; Group F received fentanyl 0.5 mcg/kg/h (10 mcg/mL) with a demand bolus of 10 mcg; and Group N received nalbuphine 50 mcg/kg/h (1 mg/mL) with a demand bolus of 1 mg. In all groups, the demand bolus volume was 1 mL and the lockout interval was 15 minutes. Patients were weaned and extubated once standard criteria for haemodynamic stability, body temperature, chest-tube output, and respiratory

mechanics were met, and were re-instructed on VAS reporting and PCA use before postoperative assessments began. When the VAS score at rest exceeded 3, rescue analgesia (paracetamol 1 g intravenously) was administered. Study-drug infusions were continued for 48 hours after extubation.

Outcome Measures: The primary outcomes were postoperative pain, assessed on a 0-10 cm VAS at rest, on coughing, and on movement at 0, 1, 6, 12, 24, and 48 hours after extubation; the total number of PCA demands and delivered boluses; and the requirement for rescue analgesia over the 48-hour period. Secondary outcomes were heart rate and systolic, diastolic, and mean arterial pressures at the same time points; sedation assessed using the 6-point Ramsay scale; and adverse events, including nausea, vomiting, pruritus, hypotension (systolic blood pressure fall >20% from baseline or <90 mmHg despite inotropic support), bradycardia (heart-rate reduction of >20% from baseline), and respiratory depression (apnoea, respiratory rate <10/min, or SpO_2 <93%).

Statistical Analysis: Data were analysed using IBM SPSS version 22 (IBM Corp., Armonk, NY, USA). Normality was assessed by the Shapiro-Wilk test and visual inspection of histograms and Q-Q plots. Normally distributed continuous variables were compared across groups using one-way ANOVA, with post-hoc Bonferroni or least significant difference (LSD) testing where appropriate. Non-normally distributed variables were expressed as medians (interquartile range) and compared using the Kruskal-Wallis test. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. A p value <0.05 was considered statistically significant.

Ethical Considerations: This study was approved by the Institutional Ethics Committee of Max Super Speciality Hospital, Saket, New Delhi (approval number: TS/MSSH/SKT-2/CAR_ANAES/IEC/18-49), and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants, and data were anonymised using participant identification numbers.

Results

Of 150 patients enrolled, all completed the study and were included in the final analysis (50 per group). Demographic and baseline clinical characteristics, including age, sex, ASA physical status, height, weight, and comorbidities, were comparable across groups (Table 1). Intraoperative fentanyl consumption and duration of mechanical ventilation were also similar between groups (Table 2).

Baseline haemodynamic parameters recorded on arrival in the ICU did not differ significantly between groups (heart rate, p=0.448; systolic blood pressure, p=0.915; diastolic blood pressure, p=0.566; mean arterial pressure [MAP], p=0.755). After extubation, heart rate and MAP were significantly lower in Group D than in Groups F and N at every time point from 0 to 48 hours (p<0.001; Table 3). Systolic and diastolic blood pressures followed a similar pattern, falling from 116.88±4.41/64.28±3.59 mmHg at 0 hours to 109.88±5.02/61.32±5.65 mmHg at 48 hours in Group D, compared with smaller reductions in Groups F and N (p<0.001 at all time points).

Median VAS scores at rest were comparable among groups in the first hour after extubation but were significantly lower in Group D from 6 to 48 hours (p<0.001). VAS scores on coughing differed significantly between groups from 6 to 48 hours (p≤0.019), and VAS scores on movement differed significantly between groups at every time point studied (p<0.001) (Table 4).

The total number of PCA demands and delivered boluses over 48 hours was lowest in Group D (5.94±2.13 demands, 4.16±1.35 boluses), intermediate in Group F (12.42±3.31 demands, 8.84±1.71 boluses), and highest in Group N (19.82±6.09 demands, 11.52±1.78 boluses; p<0.001 for both). Correspondingly, the requirement for rescue analgesia was lowest in Group D (8%), followed by Group F (18%) and Group N (36%; p=0.002) (Table 5).

Median Ramsay sedation scores were significantly higher in Group D than in Groups F and N at all time points (p<0.05), most notably immediately after extubation (Table 6). Oxygen saturation was comparable across groups for the first 12 hours; small but statistically significant differences emerged at 24 and 48 hours (p=0.038 and p=0.049, respectively) without clinical relevance. Nausea, vomiting, and pruritus were more frequent in Group F (30%, 22%, and 18%, respectively) than in Groups D (12%, 0%, 0%) and N (16%, 4%, 8%); the difference did not reach statistical significance for nausea (p=0.057), and p-values for vomiting and pruritus were not reported in the original analysis (Table 7). No episodes of respiratory depression or clinically significant hypotension or bradycardia requiring intervention were observed in any group.

Discussion

Effective analgesia after cardiac surgery reduces sympathetically mediated complications and supports earlier mobilization, yet pain control in this setting remains challenging. [10] Severe pain at rest, on coughing, and on movement has been reported in a substantial proportion of patients after CABG, with a median duration of several days, [11] while inadequate analgesia is linked to impaired respiratory mechanics, hypoxaemia, myocardial

ischaemia, and delayed recovery. [10] Multimodal strategies, including thoracic epidural analgesia, have been used to mitigate these risks, but the risk of epidural haematoma and other complications in anticoagulated cardiac surgical patients limits their routine use. [10] PCA allows opioid dosing titrated to pain intensity while limiting adverse effects, [12] and adding a background infusion to a PCA regimen has been reported to improve analgesia and reduce supplemental demands. [12,13]

In this prospective observational study of 150 patients undergoing OPCAB, dexmedetomidine used as a sole agent for intravenous PCA with a background infusion was associated with lower postoperative pain scores, fewer PCA demands and boluses, and a markedly reduced need for rescue analgesia compared with fentanyl and nalbuphine. These findings were accompanied by lower heart rate and blood pressure and a greater depth of sedation, neither of which required clinical intervention, and were not offset by an increase in nausea, vomiting, pruritus, or respiratory depression.

The marked and sustained reduction in heart rate and mean arterial pressure observed with dexmedetomidine reflects its action as a highly selective, centrally acting α2-adrenergic agonist that reduces central sympathetic outflow in a dose-dependent manner. [7,8] Our findings parallel those of Ickeringill et al. [14] who reported a fall in heart rate from a mean of 85±17 to a nadir of 78±13 beats/min within four hours of starting a dexmedetomidine infusion without a loading dose ($p<0.0001$), corresponding to reductions of approximately 8% in heart rate and 10% in systolic blood pressure from baseline; as in our study, these changes were statistically significant but did not necessitate hae-modynamic intervention. In contrast, Abd Aziz et al [25] observed an early rise in MAP during the first hour of dexmedetomidine infusion, followed by a subsequent decline, and reported a lower heart rate with dexmedetomidine than with morphine (86±2.7 vs 92±1.5 beats/min, $p=0.028$). Because the heart rate and blood pressure reductions in our study evolved gradually over the 48-hour infusion period and no patient required vasopressor or chronotropic support for bradycardia or hypotension, we interpret these changes as a predictable pharmacological effect, which could, in principle, be advantageous by reducing myocardial oxygen demand, although this was not directly assessed in our study.

The lower VAS scores at rest, on coughing, and on movement observed with dexmedetomidine are consistent with reports of its opioid-sparing analgesic action in other surgical populations. Wang et al. [16] similarly found that dexmedetomidine alone (0.25 mcg/kg/h) produced better postoperative analgesia than fentanyl (0.2 mcg/kg/h) after gynaecological laparoscopic surgery. Priye et al. reported significantly lower VAS scores with dexmedetomidine added to PCA fentanyl after cardiac surgery at 0, 6, 12, 18, and 24 hours (all $p<0.001$), together with lower 24-hour fentanyl consumption in the dexmedetomidine group than in the placebo group (128.13±35.78 vs 201.56±36.99 mcg, $p<0.001$), consistent with an opioid-sparing effect in that randomised study, although sedation may also affect pain reporting. [24]

By comparison, Gurbet et al. [17] reported broadly similar mean VAS scores across morphine, fentanyl, and remifentanil PCA groups after OPCAB (2.9, 2.4, and 2.0, respectively, 30 minutes after extubation, converging to 0.5, 0.7, and 0.8, respectively by 24 hours), without significant between-group differences. This suggests that when fentanyl is compared with other full mu-agonist opioids rather than with dexmedetomidine, differences in analgesic efficacy may be less apparent. This contrasts with the clear separation we observed between fentanyl and dexmedetomidine throughout the study intervals. For nalbuphine, our finding of higher VAS scores relative to both dexmedetomidine and fentanyl broadly agrees with Lejus et al., who reported higher VAS scores at rest with nalbuphine than with fentanyl 18, 21, and 24 hours after starting analgesia, and higher evoked pain scores with nalbuphine during physiotherapy from 30 to 48 hours. [20] This contrasts with Shokri and Ali who reported significantly lower VAS scores with nalbuphine than with morphine at 6, 16, and 24 hours after cardiac surgery ($p<0.001$). [22] The discrepancy may reflect the different drugs used for comparison (morphine, rather than dexmedetomidine or fentanyl) as well as differences in nalbuphine dosing, since reported PCA regimens for this drug vary considerably, from a basal infusion of 0.02 mg/kg/h with 0.02-mg/kg bolus doses described in a paediatric review [21] to substantially higher continuous-infusion rates used in adult studies. [19] It is possible that the 50-mcg/kg/h basal infusion selected for our study, although chosen to provide equianalgesic dosing relative to fentanyl and dexmedetomidine, was relatively conservative for the intensity of post-sternotomy pain, particularly during coughing and movement, and that a fixed, non-titrated infusion rate disadvantaged this group more than the other two.

The number of PCA demands and delivered boluses provides an objective, patient-driven measure of analgesic adequacy that complements VAS scoring. The substantially lower demand and bolus counts in Group D are consistent with better reported analgesia, and mirror the pattern described by Gurbet et al, [17] in whose study total PCA demands and boluses were highest with remifentanil (37.4±9.45 and 29.2±7.97) and lower with morphine

(22.5±6.9 and 17.3±5.66) and fentanyl (23.4±7.23 and 18.5±5.84) over 24 hours, again highlighting that the magnitude of separation between agents depends heavily on which drugs are being compared and at what relative doses.

The requirement for rescue analgesia followed the same trend as pain scores and PCA demands, being lowest with dexmedetomidine (8%), intermediate with fentanyl (18%), and highest with nalbuphine (36%). Ickeringill et al. [14] reported that 48% of patients receiving a dexmedetomidine infusion without a loading dose required no additional analgesia or sedation at all, and that only 14% of those requiring rescue therapy needed a clinically significant additional dose, broadly supporting the adequacy of dexmedetomidine as a primary analgesic agent after major surgery.

The higher Ramsay sedation scores observed with dexmedetomidine, particularly in the immediate post-extubation period, reflect its intrinsic sedative-hypnotic action and did not correspond to any adverse clinical consequence such as delayed extubation or reintubation in our cohort. The higher incidence of nausea, vomiting, and pruritus in the fentanyl group is consistent with the mu-opioid-receptor-mediated adverse-effect profile of pure agonists and has been similarly reported by Gurbet et al. [17] who found a significantly higher incidence of pruritus with fentanyl-based PCA than with morphine or remifentanil, without significant between-group differences in Ramsay sedation scores or respiratory depression. A statistically significant but clinically unimportant degree of sedation with dexmedetomidine at 6 and 12 hours has also been reported by Priye et al [24] ($p<0.001$ and $p=0.046$, respectively), consistent with our observation that sedation differences, although statistically robust, were not associated with adverse outcomes in our study.

Taken together, our findings suggest that dexmedetomidine, when used as a sole PCA agent with a modest background infusion, was associated with better analgesic outcomes and may warrant further evaluation as an opioid-sparing alternative to fentanyl and nalbuphine for postoperative analgesia after OPCAB, while also providing a degree of sedation that may be desirable in the early postoperative period. Given the well-documented adverse consequences of inadequately controlled postoperative pain after cardiac surgery, including impaired respiratory mechanics, myocardial ischaemia, and delayed mobilization, [1,10,11] an analgesic regimen associated with lower VAS scores with fewer supplemental opioid requirements has the potential to improve both patient comfort and postoperative recovery. Because thoracic epidural analgesia carries a recognized risk of epidural haematoma in anticoagulated cardiac surgical patients, a well-tolerated systemic option such as dexmedetomidine-based PCA may represent a useful alternative or adjunct within a multimodal analgesic strategy, particularly for patients in whom regional techniques are contraindicated. As treatment selection was based on clinical judgement rather than random allocation, confounding by indication and other unmeasured differences between groups cannot be excluded. The unadjusted group comparisons should therefore be interpreted as associations rather than causal treatment effects.

Conclusion

In patients undergoing off-pump coronary artery bypass grafting, dexmedetomidine administered as a sole agent by intravenous PCA with a background infusion was associated with lower pain scores, particularly during coughing and movement and a lower requirement for rescue analgesia compared with fentanyl and nalbuphine, and lower heart rate and blood pressure, without serious adverse events observed in this cohort. These findings support further evaluation of dexmedetomidine as a PCA analgesic after cardiac surgery, including dose-ranging studies in larger and more diverse surgical populations.

Conflict of Interest: The authors declare no conflict of interest.

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Table 1: Baseline demographic and clinical characteristics of the study groups (N=150)

Characteristic	Group D (n=50)	Group F (n=50)	Group N (n=50)	P value
Age (years), mean ± SD	60.16 ± 5.18	60.56 ± 4.05	59.78 ± 5.02	0.717
Male sex, n (%)	45 (90)	42 (84)	41 (82)	0.500
ASA physical status II, n (%)	33 (66)	33 (66)	35 (70)	0.886
ASA physical status III, n (%)	17 (34)	17 (34)	15 (30)	
Height (cm), mean ± SD	169.84 ± 7.62	168.10 ± 7.43	166.80 ± 4.12	0.072
Weight (kg), mean ± SD	76.22 ± 4.43	76.26 ± 4.66	74.52 ± 4.07	0.082
Diabetes mellitus, n (%)	21 (42)	19 (38)	19 (38)	0.894
Hypertension, n (%)	31 (62)	27 (54)	32 (64)	0.558
Current smoker, n (%)	18 (36)	13 (26)	14 (28)	0.513

ASA, American Society of Anaesthesiologists; SD, standard deviation.

Table 2: Intraoperative fentanyl consumption and duration of mechanical ventilation

Variable	Group D	Group F	Group N	P value
Intraoperative fentanyl consumption (mcg), mean ± SD	596 ± 67.64	598 ± 70.68	591 ± 64.44	0.868
Duration of mechanical ventilation (min), mean ± SD	355.1 ± 55.14	362.2 ± 45.57	349.4 ± 51.61	0.455

Table 3: Postoperative heart rate and mean arterial pressure at follow-up time points

Time point	Group D	Group F	Group N	P value
Heart rate (beats/min), mean ± SD				
0 hour	70.12 ± 4.46	83.18 ± 5.36	82.06 ± 4.77	<0.001
1 hour	68.10 ± 3.80	81.14 ± 6.10	80.43 ± 4.16	<0.001
6 hours	67.16 ± 4.51	78.84 ± 5.61	79.73 ± 5.97	<0.001
12 hours	65.64 ± 3.53	77.12 ± 5.04	80.67 ± 6.35	<0.001
24 hours	65.66 ± 3.61	75.54 ± 5.25	75.27 ± 5.30	<0.001
48 hours	64.86 ± 3.08	72.48 ± 5.02	71.84 ± 3.89	<0.001
Mean arterial pressure (mmHg), mean ± SD				
0 hour	81.66 ± 3.65	87.38 ± 5.31	90.56 ± 3.84	<0.001
1 hour	81.06 ± 3.64	88.40 ± 4.88	89.78 ± 3.36	<0.001
6 hours	78.92 ± 3.68	87.36 ± 6.72	89.16 ± 4.39	<0.001
12 hours	76.42 ± 2.76	85.59 ± 4.98	89.52 ± 5.22	<0.001
24 hours	76.92 ± 3.53	83.56 ± 4.70	86.00 ± 4.53	<0.001
48 hours	77.56 ± 5.09	80.78 ± 4.39	81.62 ± 2.55	<0.001

Table 4: Median (interquartile range) VAS pain scores at rest, on coughing, and on movement

Time point	Group D	Group F	Group N	P value
VAS score at rest, median (IQR)				
0 hour	2 (2, 3)	2 (2, 2)	2 (2, 2)	0.737
1 hour	2 (2, 2)	2 (2, 2)	2 (2, 2)	0.103
6 hours	2 (1, 2)	2 (2, 2)	2 (2, 3)	<0.001
12 hours	1 (1, 2)	2 (1, 2)	2 (2, 2)	<0.001
24 hours	1 (1, 1)	1 (1, 2)	2 (2, 2)	<0.001
48 hours	1 (1, 2)	1 (1, 1)	2 (1, 2)	<0.001
VAS score on coughing, median (IQR)				
0 hour	3 (3, 3)	3 (3, 3)	3 (2, 3)	0.254
1 hour	3 (3, 3)	3 (3, 3)	3 (3, 3)	0.237
6 hours	3 (3, 3)	3 (3, 3)	3 (3, 3)	0.009
12 hours	2.5 (2, 3)	3 (2.75, 3)	3 (3, 5)	<0.001
24 hours	2 (2, 3)	2 (2, 3)	3 (2, 3)	0.019
48 hours	2 (2, 2)	2 (2, 2)	2 (2, 2)	0.015
VAS score on movement, median (IQR)				
0 hour	2 (2, 3)	3 (2, 3)	3 (2, 3)	<0.001
1 hour	2 (2, 3)	3 (2, 3)	3 (3, 3)	<0.001
6 hours	2 (2, 3)	2.5 (2, 3)	3 (3, 3)	<0.001
12 hours	2 (2, 2)	2 (2, 3)	3 (3, 4)	<0.001
24 hours	2 (1, 2)	2 (2, 2)	3 (2, 3)	<0.001
48 hours	1 (1, 2)	2 (1, 2)	2 (2, 2)	<0.001

IQR, interquartile range; VAS, visual analogue scale (0-10 cm).

Table 5: PCA demands, delivered boluses, and need for rescue analgesia over 48 hours

Variable	Group D (n=50)	Group F (n=50)	Group N (n=50)	P value
PCA demands, mean ± SD	5.94 ± 2.13	12.42 ± 3.31	19.82 ± 6.09	<0.001
PCA boluses delivered, mean ± SD	4.16 ± 1.35	8.84 ± 1.71	11.52 ± 1.78	<0.001
Need for rescue analgesia, n (%)	4 (8)	9 (18)	18 (36)	0.002

Table 6: Median (interquartile range) Ramsay sedation scores

Time point	Group D	Group F	Group N	P value
0 hour	3 (2, 3)	2 (2, 2)	1.5 (1, 2)	<0.001
1 hour	3 (2, 3)	2 (1, 2)	2 (1, 2)	<0.001
6 hours	2 (2, 2)	2 (1, 2)	2 (1, 2)	<0.001
12 hours	2 (2, 2)	2 (1, 2)	2 (1, 2)	<0.001
24 hours	2 (2, 2)	2 (1, 2)	2 (2, 2)	0.041
48 hours	2 (2, 2)	2 (1, 2)	2 (2, 2)	<0.001

Table 7: Adverse effects across the study groups

Adverse effect, n (%)	Group D (n=50)	Group F (n=50)	Group N (n=50)	P value
Nausea	6 (12)	15 (30)	8 (16)	0.057
Vomiting	0 (0)	11 (22)	2 (4)	NA*
Pruritus	0 (0)	9 (18)	4 (8)	NA*

*NA, p-values were not reported in the original analysis. Zero counts do not preclude Fisher's exact test.

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