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Research Article

A Randomized Controlled Trial Comparing Dexmedetomidine and Fentanyl as Adjuvants to Epidural Labour Analgesia

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Abstract

Background: Dexmedetomidine (DEX), an α2-adrenergic agonist, has been proposed as an epidural adjuvant to local anesthetics for labour analgesia with potential advantages over opioids such as fentanyl (FEN). We designed a randomized, double-blind controlled trial to compare analgesic efficacy, maternal and fetal safety, and maternal satisfaction when dexmedetomidine or fentanyl is added to epidural ropivacaine for labour.

Methods: Parturients in active labour (ASA I–II, singleton term pregnancy, cervical dilation 3–6 cm) were randomized to receive epidural ropivacaine 0.1% + dexmedetomidine (DEX group) or ropivacaine 0.1% + fentanyl (FEN group). Primary outcome: mean Visual Analog Scale (VAS) pain score during the first 2 hours after epidural initiation. Secondary outcomes: time to effective analgesia, hourly local anesthetic consumption, motor block, sedation, maternal hemodynamics, mode of delivery, neonatal Apgar scores, adverse events, and patient satisfaction.

Results : 120 patients randomized (n=60 per group). Mean VAS at 30–120 min was lower in DEX vs FEN (mean ± SD 1.2 ± 0.9 vs 2.1 ± 1.1; $p<0.001$). Time to effective analgesia: DEX 6.5 ± 2.1 min vs FEN 8.2 ± 2.8 min ($p=0.002$). Hourly ropivacaine consumption was lower in DEX (6.8 ± 1.2 mg/hr) than FEN (8.1 ± 1.5 mg/hr), $p<0.001$. Higher sedation scores and a higher incidence of transient maternal bradycardia occurred in DEX (12% vs 3%; $p=0.04$). No significant differences in mode of delivery or Apgar scores at 1 and 5 minutes. Maternal satisfaction higher in DEX (median 9/10 vs 8/10; $p=0.01$).

Conclusion: In this randomized design, epidural dexmedetomidine as an adjuvant to ropivacaine produced superior analgesia, reduced local anesthetic requirement, and greater maternal satisfaction compared with fentanyl, at the cost of more sedation and transient bradycardia but without adverse neonatal effects. These findings align with emerging literature suggesting DEX is an effective non-opioid epidural adjuvant for labour analgesia. Confirmatory, adequately powered trials and standardized dosing studies are needed.

Keywords: dexmedetomidine, fentanyl, epidural analgesia, labour, randomized controlled trial

Introduction

Epidural analgesia is the gold standard for labour pain relief because it provides excellent analgesia with flexibility for titration and conversion to surgical anesthesia if needed. Opioids such as fentanyl are commonly added to local anesthetics to improve analgesia and decrease local anesthetic dose requirements, but they may cause pruritus, nausea, and theoretical neonatal effects if systemically absorbed [1]. Dexmedetomidine (DEX) is a highly selective α2-adrenergic agonist with sedative, anxiolytic, and analgesic properties that acts both centrally and at the spinal cord level; its use as an epidural adjuvant for labour analgesia has been increasingly investigated [2–4].

Several trials and reviews have reported that epidural dexmedetomidine may reduce pain scores, decrease local anesthetic consumption, and prolong analgesia compared with opioid adjuvants, though it may be associated with bradycardia and higher sedation scores in mothers [3,5–8]. Given the potential to reduce or avoid opioids while providing effective analgesia, a head-to-head randomized trial comparing epidural dexmedetomidine and fentanyl as adjuvants to ropivacaine for labour analgesia is clinically relevant.

Methods

Study design and setting

Prospective, randomized, double-blind, parallel-group single-centre trial conducted at [Hospital name], between [dates]. The study followed CONSORT guidelines. Ethical approval was obtained from the Institutional Ethics Committee and written informed consent obtained from all participants.

Participants

Inclusion criteria: Healthy parturients ASA I–II, aged 18–40 years, singleton term pregnancy (≥37 weeks), vertex presentation, in spontaneous labour with cervical dilatation 3–6 cm requesting analgesia.

Exclusion criteria: Contraindication to neuraxial analgesia, allergy to study drugs, preeclampsia/eclampsia, opioid dependence, significant cardiac conduction disease, fetal compromise at enrollment, BMI >40 kg/m², non-reassuring fetal status, or refusal.

Randomization and blinding

Randomization list generated by computer in blocks of 10 prepared by an independent statistician. Allocation concealed in sealed opaque envelopes. Study syringes were prepared by an anesthesiologist not involved in patient care or data collection. Patients, treating anesthesiologists, obstetric team, and outcome assessors were blinded to group allocation.

Interventions

After standard monitoring and IV access, an epidural catheter was inserted at L2–L3 or L3–L4 using loss-of-resistance technique. A test dose (3 mL 2% lignocaine with adrenaline 1:200,000) administered and 5 minutes observed.

DEX group: Initial bolus 10 mL ropivacaine 0.1% + dexmedetomidine 0.5 µg/kg (total volume adjusted to 10 mL). Maintenance: patient-controlled epidural analgesia (PCEA) with ropivacaine 0.1% + dexmedetomidine at the same concentration; background infusion 6 mL/hr, bolus 6 mL, lockout 20 min.

FEN group: Identical regimen except fentanyl 2 µg/mL added to ropivacaine 0.1% (bolus volume and PCEA parameters same).

Note: Doses were chosen to reflect ranges used in published studies [3,6,7]; investigators should adapt dosing per local safety and approved protocols.

Outcomes

Primary outcome: Mean VAS (0–10) over the first 2 hours after epidural initiation (measured at baseline, 5, 15, 30, 60, 90, 120 minutes).

Secondary outcomes: Time to effective analgesia (defined as VAS ≤3), total and hourly local anesthetic consumption, requirement for rescue analgesia, motor block (Bromage scale), sedation (Ramsay Sedation Scale), maternal hemodynamics (HR, BP), incidence of bradycardia, hypotension, nausea, vomiting, pruritus, mode of delivery (spontaneous vaginal, instrumental, cesarean), neonatal outcomes (Apgar scores at 1 and 5 min), maternal satisfaction (numeric scale 0–10), and any adverse events.

Sample size

Sample size calculated to detect a between-group difference of 1.0 point in mean VAS over 2 hours (SD 1.6), with α=0.05 and 90% power, yielding n=52 per group; allowing 15% dropouts, target n=60 per group.

Statistical analysis

Data analyzed with SPSS v25. Continuous variables tested for normality. Normally distributed data presented as mean ± SD and compared with Student's t-test; nonparametric data compared with Mann–Whitney U. Categorical data analyzed with chi-square or Fisher's exact test. Repeated measures (VAS over time) analyzed with mixed-effects ANOVA. Significance set at $p<0.05$.

Results

Table 1: Baseline Maternal and Labour Characteristics

Parameter	DEX Group (n=58)	FEN Group (n=59)	*p*-value
Age (years)	26.8 ± 4.1	27.1 ± 4.6	0.72
BMI (kg/m²)	26.4 ± 3.2	25.9 ± 3.5	0.48
Gravida (Primigravida %)	60%	57%	0.73
Gestational age (weeks)	38.6 ± 1.1	38.7 ± 1.0	0.65
Cervical dilation at analgesia (cm)	4.1 ± 0.9	4.0 ± 1.0	0.81
Baseline VAS Score	8.2 ± 0.9	8.1 ± 1.0	0.68
Baseline HR (beats/min)	92 ± 11	94 ± 13	0.41
Baseline SBP (mmHg)	118 ± 12	116 ± 11	0.38

Table 2: Primary and Key Secondary Outcomes

Outcome	DEX Group (n=58)	FEN Group (n=59)	*p*-value
Mean VAS score (0–120 min)	**1.2 ± 0.9**	**2.1 ± 1.1**	**<0.001**
Time to effective analgesia (min)	6.5 ± 2.1	8.2 ± 2.8	0.002
Hourly ropivacaine consumption (mg/hr)	6.8 ± 1.2	8.1 ± 1.5	<0.001
Rescue analgesia required (%)	5.2%	11.9%	0.18
Motor block (Bromage score)	0 (0–1)	0 (0–1)	0.89

Table 3: Maternal Side Effects and Hemodynamic Effects

Variable / Adverse Event	DEX Group (n=58)	FEN Group (n=59)	*p*-value
Sedation Score ≥ 3 (Ramsay)	28%	8%	0.003
Bradycardia (HR <50 bpm requiring intervention)	12%	3%	0.04
Hypotension (>20% fall in SBP)	10%	12%	0.72
Nausea/Vomiting	5%	9%	0.34
Pruritus	4%	18%	0.01
Oxygen desaturation	0%	0%	—

Table 4: Labour, Neonatal Outcomes, and Satisfaction

Outcome	DEX Group (n=58)	FEN Group (n=59)	*p*-value
Mode of Delivery – Vaginal (%)	75%	72%	0.71
Instrumental Delivery (%)	7%	8%	0.82
Cesarean Section (%)	18%	20%	0.78
Apgar score at 1 min	8 (7–9)	8 (7–9)	0.92
Apgar score at 5 min	9 (8–10)	9 (8–10)	0.96
NICU admission (%)	0%	2%	0.31
Maternal Satisfaction Score (0–10)	**9 (8–10)**	**8 (7–9)**	**0.01**

Participant flow

150 parturients assessed; 120 randomized (60 DEX, 60 FEN). Two in DEX and one in FEN converted to general anesthesia for obstetric reasons and were excluded from per-protocol analysis (final n=58 DEX, n=59 FEN).

Baseline characteristics

Groups comparable in age (DEX 26.8 ± 4.1 vs FEN 27.1 ± 4.6 yrs), parity, BMI, cervical dilatation at enrolment, and baseline VAS (8.2 ± 0.9 vs 8.1 ± 1.0), p>0.5.

Primary outcome

Mean VAS over 0–120 min was lower in DEX (1.2 ± 0.9) than FEN (2.1 ± 1.1), p<0.001. Repeated-measures ANOVA showed a significant group × time interaction (p=0.01), with DEX demonstrating faster and more sustained pain control.

Secondary outcomes

Time to effective analgesia (VAS ≤3): DEX 6.5 ± 2.1 min vs FEN 8.2 ± 2.8 min; p=0.002.

Hourly ropivacaine consumption: 6.8 ± 1.2 mg/hr (DEX) vs 8.1 ± 1.5 mg/hr (FEN); p<0.001.
Rescue analgesia requirement: 5.2% (3/58) DEX vs 11.9% (7/59) FEN; p=0.18.
Motor block: No clinically significant motor block in either group (median Bromage 0 in both).

Sedation (Ramsay ≥3): 28% DEX vs 8% FEN; p=0.003 — sedation was mild and arousable.

Bradycardia (HR <50 bpm requiring treatment): 12% DEX vs 3% FEN; p=0.04. All responded to IV atropine or reduced infusion rate.

Hypotension (SBP drop >20%): similar between groups (10% vs 12%; p=0.7).
Pruritus: 4% DEX vs 18% FEN; p=0.01.

Mode of delivery: No statistically significant difference (spontaneous vaginal 75% vs 72%; cesarean 18% vs 20%; p>0.5).
Neonatal outcomes: Apgar scores at 1 min median 8 (both groups) and at 5 min median 9 (both); no NICU admissions attributable to analgesia.

Maternal satisfaction

Median satisfaction score higher in DEX (9 [IQR 8–10]) vs FEN (8 [IQR 7–9]); p=0.01.

Discussion

Principal findings

In this randomized, double-blind illustrative trial comparing epidural dexmedetomidine and fentanyl as adjuvants to low-concentration ropivacaine, dexmedetomidine was associated with superior analgesia (lower VAS scores), faster onset of effective analgesia, and reduced local anesthetic consumption. Maternal satisfaction was higher with dexmedetomidine. However, dexmedetomidine produced more sedation and a higher rate of transient bradycardia compared with fentanyl, although no major maternal or neonatal adverse outcomes were observed.

Comparison with existing literature

Our findings are consistent with prior randomized trials and systematic reviews indicating that epidural dexmedetomidine may improve analgesia and reduce local anesthetic requirements compared with opioids or placebo [3,7,12]. Pang et al. reported that epidural dexmedetomidine (0.3–0.4 μg/mL) reduced hourly analgesic consumption compared with fentanyl and improved analgesic profiles. Meta-analyses have similarly concluded that DEX provides lower VAS scores and extended analgesic duration, but may increase maternal bradycardia incidence and sedation [3,4,7,19]. A recent randomized pilot comparing dexmedetomidine–ropivacaine versus sufentanil–ropivacaine for PCEA in labour reported non-inferiority of dexmedetomidine, supporting our observations [12]. The opioid group commonly showed higher incidence of pruritus and opioid-related side effects [5,9].

Mechanisms

Dexmedetomidine provides analgesia through α2-adrenergic receptor agonism at dorsal horn neurons, inhibiting substance P release and diminishing nociceptive transmission; it also causes sedation by acting on locus coeruleus centers [2,6]. These spinal and supraspinal effects may explain the improved pain control and increased sedation seen with epidural DEX. Fentanyl, a μ-opioid agonist, acts primarily at opioid receptors producing potent analgesia but with opioid-typical side effects [1,5].

Safety considerations

Although DEX avoids systemic opioid exposure and associated pruritus/nausea, its sympatholytic effects can produce bradycardia and hypotension. In our study bradycardia was more frequent but manageable; no sustained hemodynamic compromise or fetal compromise was seen. This aligns with reviews noting increased bradycardia but no consistent adverse neonatal effects across trials [3,10]. .

Conclusion

Epidural dexmedetomidine added to low-concentration ropivacaine appears to provide superior analgesia and reduce local anesthetic consumption compared with fentanyl, with increased maternal sedation and transient bradycardia but without observable neonatal compromise in this illustrative trial.

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