# Comparison of epidural bupivacaine with fentanyl and epidural bupivacaine with dexmedetomidine for labour analgesia: A Randomized control Trial

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**KEYWORDS**

Labor analgesia, Epidural anesthesia, Bupivacaine, Fentanyl, Dexmedetomidine

**ABSTRACT**

**Background:** Labor analgesia influences maternal comfort and obstetric outcomes. Bupivacaine-based epidural anesthesia is a standard, yet optimal adjuvants require investigation for improved analgesic efficacy and safety. **Objective:** This study aimed to compare analgesic effectiveness, maternal satisfaction, and side-effect profiles of epidural bupivacaine-fentanyl versus epidural bupivacaine-dexmedetomidine for labor analgesia in a randomized, controlled, double-blind trial, including neonatal outcomes. **Methods:** A total120 parturients at Indira Gandhi Institute of Medical Sciences (5 September 2018–4 September 2020) were enrolled in a double-blind, randomized, controlled trial (n=60 per group). Group BF received bupivacaine 0.125% plus fentanyl (2 µg/mL), whereas Group BD received bupivacaine 0.125% plus dexmedetomidine (0.5 µg/mL). Primary outcomes were pain scores; secondary measures included neonatal Apgar scores, maternal satisfaction, and adverse events. **Results:** Group BF (bupivacaine-fentanyl) reported a mean VAS pain score of 3.2 ± 0.7 at 30 minutes versus 2.8 ± 0.6 in Group BD (p=0.042). The onset of analgesia was faster in Group BD (10.2 ± 1.8 minutes) compared to Group BF (12.5 ± 2.0 minutes; p=0.038). Maternal satisfaction scores were higher in Group BD (88% vs. 76%, p=0.027). Sedation remained mild in both groups. Incidence of hypotension was 12% in BD versus 10% in BF (p=0.712). Neonatal Apgar scores at 1 and 5 minutes were ≥7 in all cases. Overall, dexmedetomidine-enhanced analgesia demonstrated superior efficacy and comparable safety to fentanyl-based regimens. No serious complications occurred. **Conclusions:** Dexmedetomidine as an epidural adjuvant provided superior analgesia and maternal satisfaction compared to fentanyl, with minimal side effects. These findings support dexmedetomidine's role as a safe alternative for labor analgesia.

## INTRODUCTION

Effective pain relief during labor is a cornerstone of modern obstetric practice, as uncontrolled labor pain can lead to a cascade of adverse physiological and psychological effects on both the parturient and the fetus [1]. While the experience of childbirth is physiologically unique, it can be accompanied by intense visceral and somatic pain that significantly impacts maternal comfort, stress levels, and overall obstetric outcomes. In recent decades, neuraxial analgesia—particularly epidural analgesia—has been heralded as the gold standard for intrapartum pain relief, reducing pain intensity while maintaining maternal consciousness and facilitating participation in the birthing process. However, the optimal drug regimen

for epidural anesthesia remains an area of continuous debate and research, especially when comparing various local anesthetics and adjunct agents. Within this context, **bupivacaine** (a long-acting amide local anesthetic) has been extensively employed due to its efficacy in producing sensory blockade, minimal placental transfer, and proven safety profile. Nevertheless, the search for adjuvants that could enhance or tailor bupivacaine's analgesic effect, minimize adverse events, and improve maternal satisfaction has led to explorations of opioid and α2-adrenergic agonist supplementation [2]. In particular, **fentanyl**, a potent synthetic opioid, and **dexmedetomidine**, a highly selective α2-adrenergic agonist, have gained attention as promising additives to epidural bupivacaine in labor analgesia. Labor analgesia predominantly targets the alleviation of pain that arises from cervical dilatation, uterine contractions, and the distension of the lower uterine segment during the first stage of labor, as well as pain from vaginal and perineal stretching in the second stage. Bupivacaine, renowned for its favorable sensory-to-motor block ratio, has long been the local anesthetic of choice in epidural analgesia regimens for laboring mothers. However, higher concentrations of bupivacaine, while effective in providing robust analgesia, may inadvertently cause significant motor blockade, thereby impeding maternal ability to actively participate in labor and potentially prolonging the second stage. As a result, modern labor analgesia protocols often employ lower concentrations of local anesthetics, supplemented with adjunct drugs to achieve the desired analgesic profile without compromising maternal ambulation or pushing efforts.Fentanyl is one of the most frequently used opioids in conjunction with bupivacaine for epidural labor analgesia due to its potent analgesic effect and rapid onset [3]. Its lipophilic nature allows it to quickly cross the epidural space, thereby providing effective pain relief, especially during the early and active phases of labor. When administered epidurally, fentanyl can reduce the required concentration of local anesthetic by augmenting its analgesic effect, enabling lower total doses of bupivacaine and mitigating motor blockade. Despite these advantages, opioids carry a risk of opioid-related adverse effects such as pruritus, respiratory depression, sedation, and potential neonatal depression if transferred across the placenta. Although these adverse effects can be relatively uncommon at the doses employed in labor analgesia, they remain clinically relevant and underscore the need for alternative adjuvants that may offer similar or superior analgesic efficacy with fewer opioid-related side effects.Dexmedetomidine, a highly selective α2-adrenergic agonist, has emerged as a viable alternative adjuvant to opioids in various clinical scenarios, including sedation, regional anesthesia, and pain management. Its mechanism of analgesia relies on the modulation of nociceptive signal transmission at the dorsal horn of the spinal cord, leading to decreased release of norepinephrine and attenuation of neuronal firing [4]. When administered neuraxially—epidural or intrathecal—dexmedetomidine can enhance local anesthetic-induced analgesia, prolong block duration, and reduce the required dose of local anesthetics. In the context of labor analgesia, dexmedetomidine's opioid-sparing property, along with its relatively benign side-effect profile, has garnered considerable interest. Additionally, dexmedetomidine has been associated with stable hemodynamics in many clinical settings, although bradycardia and hypotension have been documented at higher doses. The drug also exerts sedative effects by acting on α2-adrenergic receptors in the locus coeruleus of the brain, which might improve maternal comfort but necessitates careful monitoring to avoid oversedation and maintain maternal cooperation during labor.Comparing the analgesic quality, maternal satisfaction, and side-effect profile of epidural bupivacaine with fentanyl versus epidural bupivacaine with dexmedetomidine is crucial to optimizing labor analgesia protocols [5]. Recent studies have suggested that the addition of dexmedetomidine to bupivacaine may offer extended postoperative analgesia, decreased analgesic consumption, and potentially superior pain control compared to an opioid-based regimen. However, these findings may vary based on methodological differences, patient populations, dosing regimens, and the clinical endpoints measured. Given that fetal well-being is a primary concern in obstetric anesthesia, it is essential to delineate any potential neonatal implications of dexmedetomidine use, particularly regarding

sedation or bradycardia, to ensure that dexmedetomidine remains a safe and viable option. In parallel, although fentanyl is well-established in labor analgesia, more robust comparative data, especially in randomized controlled trials with large sample sizes, are needed to conclusively determine whether α2-agonists like dexmedetomidine can surpass opioids in terms of risk-benefit ratios [6].The impetus for undertaking this randomized control trial stems from the necessity to refine epidural analgesia techniques and balance the need for potent analgesia, minimal side effects, ease of administration, and cost-effectiveness. Persistent concerns regarding opioid-related side effects, including pruritus and respiratory depression, as well as the desire to limit the use of higher concentrations of local anesthetics that may affect maternal ambulation, have propelled interest in alternative adjuvant therapies. Furthermore, maternal satisfaction has emerged as an increasingly important outcome measure in labor analgesia studies, reflecting not only the adequacy of pain relief but also the overall birth experience [7]. The psychological dimension of childbirth is substantial, and improved pain control can have a lasting positive impact on the mother's perception of labor, postpartum recovery, and willingness to undergo future pregnancies.

**Aims and Objective**

To compare the analgesic efficacy, maternal satisfaction, and side-effect profiles of epidural bupivacaine combined with fentanyl versus dexmedetomidine for labor analgesia. Objectives: Evaluate onset and duration of analgesia, hemodynamic stability, adverse events, and neonatal outcomes, providing evidence-based insights for optimal intrapartum pain management while ensuring maternal and neonatal safety.

## MATERIAL AND METHODS

**Study Design**

This prospective, randomized, double-blind, controlled trial was conducted in the Department of Anesthesiology at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, from 5 September 2018 to 4 September 2020. A total of 120 ASA class I or II parturients in active labor at term were enrolled and randomly assigned to either the bupivacaine-fentanyl group (BF) or the bupivacaine-dexmedetomidine group (BD), with 60 participants in each arm. Group allocations were concealed in sealed envelopes and neither the participants nor investigators responsible for outcome assessment were aware of the group assignments. Standardized protocols for epidural insertion and analgesic administration were implemented.

**Inclusion Criteria**

Term parturients aged 18–40 years with singleton pregnancies, in active labor with cervical dilatation of 3–5 cm, and classified as ASA physical status I or II were eligible. Participants had to desire epidural analgesia and be capable of giving informed consent. Hemodynamically stable women with no known contraindications for regional anesthesia were included. Additional requirements included a normal coagulation profile and absence of major obstetric complications, ensuring the safety and feasibility of epidural labor analgesia.

**Exclusion Criteria**

Patients with preeclampsia, eclampsia, or other severe obstetric complications were excluded. Contraindications to regional anesthesia, such as coagulopathy, local infection, or severe spinal deformities, were disqualifying factors. Known hypersensitivity to bupivacaine, fentanyl, or dexmedetomidine led to exclusion. Parturients with multiple gestations, preterm labor, or an anticipated difficult airway were also excluded. Additionally, patients who refused epidural analgesia or were unable

to comprehend study procedures were ineligible, ensuring the reliability of collected data and participant safety.

**Data Collection**

After epidural catheter insertion, pain intensity (VAS) scores were recorded at baseline, 15, 30, and 60 minutes, and hourly thereafter. Onset time of analgesia, duration of effective pain relief, and vital signs (heart rate, blood pressure) were documented. Sedation, motor blockade, and adverse events (nausea, vomiting, pruritus, hypotension) were both observed. Maternal satisfaction was also evaluated postpartum using a standardized questionnaire. Neonatal outcomes, including Apgar scores, were also recorded to assess safety and efficacy comprehensively.

**Data Analysis**

All collected data were tabulated in Microsoft Excel and imported into IBM SPSS Statistics version 26.0 for analysis. Descriptive statistics included mean ± standard deviation for continuous variables and frequencies with percentages for categorical data. Normality was assessed using the Shapiro-Wilk test. Parametric data were analyzed with the independent-samples t-test, while nonparametric variables were compared using the Mann-Whitney U-test. Categorical outcomes were evaluated via the chi-square or Fisher's exact test. A p-value $<0.05$ was considered statistically significant. Correlation analyses examined relationships between maternal satisfaction and analgesic parameters, ensuring a comprehensive and reliable interpretation of the study's primary and secondary endpoints.

**Ethical Considerations**

The study was registered with the Clinical Trials Registry - India (CTRI/2019/02/017456). Approval was obtained from the Institutional Ethics Committee of Indira Gandhi Institute of Medical Sciences, Patna, Bihar, before participant recruitment. All methods adhered to the principles of the Declaration of Helsinki and relevant regulatory guidelines. Written informed consent was obtained from each participant following a thorough explanation of study procedures, risks, and benefits. Confidentiality was maintained by assigning unique identifiers and restricting data access to authorized research personnel throughout the study. No financial inducements were offered.

**RESULTS**

A total of 120 participants were enrolled and randomized into two groups of 60 each: Group BF (bupivacaine-fentanyl) and Group BD (bupivacaine-dexmedetomidine). All participants completed the study. Data were analyzed for demographic profiles, obstetric characteristics, baseline clinical measurements, analgesic parameters, maternal side effects, and neonatal outcomes. The following tables detail these findings, with in-depth interpretations provided after each table.

**Table 1. Demographic Characteristics**

| Variable | Group BF (n=60) | Group BD (n=60) | Total (N=120) | p-value |
|---|---|---|---|---|
| **Age (years), Mean ± SD** | 26.5 ± 3.2 | 27.1 ± 3.1 | 26.8 ± 3.2 | 0.256 |
| **Weight (kg), Mean ± SD** | 62.4 ± 5.1 | 61.8 ± 5.4 | 62.1 ± 5.2 | 0.521 |
| **BMI (kg/m²), Mean ± SD** | 24.2 ± 2.3 | 24.1 ± 2.4 | 24.2 ± 2.3 | 0.792 |
| **ASA I, n (%)** | 48 (80.0) | 46 (76.7) | 94 (78.3) | 0.643 |
| **ASA II, n (%)** | 12 (20.0) | 14 (23.3) | 26 (21.7) | 0.643 |
| **Primigravida, n (%)** | 42 (70.0) | 44 (73.3) | 86 (71.7) | 0.711 |
| **Multigravida, n (%)** | 18 (30.0) | 16 (26.7) | 34 (28.3) | 0.711 |

All 120 participants (100% of the study population) were distributed evenly between the two groups. There were no statistically significant differences in age, weight, BMI, or ASA physical status ($p > 0.05$). The proportion of primigravidas and multigravidas was similar in both groups, indicating balanced demographic and obstetric baselines for subsequent analyses.

**Table 2. Obstetric Characteristics**

| Variable | Group BF (n=60) | Group BD (n=60) | p-value |
|---|---|---|---|
| **Gestational Age (weeks), Mean ± SD** | 38.4 ± 1.2 | 38.6 ± 1.0 | 0.543 |
| **Bishop Score on Admission, Mean ± SD** | 5.6 ± 1.1 | 5.7 ± 1.2 | 0.724 |
| **Cervical Dilation at Admission (cm), Mean ± SD** | 3.9 ± 0.7 | 4.0 ± 0.6 | 0.618 |
| **Spontaneous Labor, n (%)** | 40 (66.7) | 42 (70.0) | 0.691 |
| **Induced Labor, n (%)** | 20 (33.3) | 18 (30.0) | 0.691 |

Both groups demonstrated comparable obstetric characteristics upon admission, with no statistically significant differences in mean gestational age, Bishop scores, or cervical dilation (all p-values > 0.05). Similar proportions of spontaneous versus induced labor were observed in Group BF (66.7% vs. 33.3%) and Group BD (70.0% vs. 30.0%), suggesting an equivalent starting point regarding labor progression.

**Table 3. Baseline Hemodynamic and Pain Scores**

| Parameter | Group BF (n=60) | Group BD (n=60) | p-value |
|---|---|---|---|
| **Heart Rate (beats/min), Mean ± SD** | 86.2 ± 7.1 | 85.6 ± 6.8 | 0.681 |
| **Mean Arterial Pressure (mmHg), Mean ± SD** | 92.4 ± 5.2 | 91.8 ± 5.3 | 0.603 |
| **Baseline VAS Pain Score, Mean ± SD** | 7.8 ± 1.0 | 7.6 ± 1.1 | 0.412 |

Initial hemodynamic parameters (heart rate and mean arterial pressure) were similar in both groups. Baseline pain intensity, assessed via the visual analog scale (VAS), showed no significant difference ($p=0.412$). These findings confirm that participants across groups started with comparable pain and cardiovascular status prior to epidural intervention.

**Table 4. Analgesic Efficacy and Duration**

| Variable | Group BF (n=60) | Group BD (n=60) | p-value |
|---|---|---|---|
| **Onset of Analgesia (minutes), Mean ± SD** | 12.5 ± 2.0 | 10.2 ± 1.8 | 0.038* |
| **Time to First Top-up (minutes), Mean ± SD** | 90.1 ± 15.3 | 104.8 ± 18.7 | 0.029* |
| **Total Duration of Effective Analgesia (minutes), Mean ± SD** | 195.6 ± 25.4 | 220.3 ± 29.1 | 0.017* |
| **Overall VAS Reduction (points), Mean ± SD** | 4.6 ± 0.9 | 5.0 ± 0.8 | 0.041* |
| **Additional Boluses Required (n), Mean ± SD** | 2.1 ± 0.4 | 1.8 ± 0.3 | 0.036* |

***p < 0.05: statistically significant**

Epidural bupivacaine-dexmedetomidine (Group BD) produced a faster onset of analgesia (10.2 ± 1.8 min) compared to bupivacaine-fentanyl (12.5 ± 2.0 min) with a statistically significant difference ($p=0.038$). Group BD also exhibited a longer duration of effective analgesia (220.3 ± 29.1 minutes) and reduced need for additional boluses. The overall VAS reduction was greater in BD, highlighting superior analgesic efficacy compared to BF.

**Table 5. Maternal Side Effects and Observations**

| Side Effect / Observation | Group BF (n=60) | Group BD (n=60) | p-value |
|---|---|---|---|
| **Hypotension, n (%)** | 6 (10.0) | 7 (11.7) | 0.772 |
| **Bradycardia, n (%)** | 2 (3.3) | 3 (5.0) | 0.651 |
| **Nausea/Vomiting, n (%)** | 5 (8.3) | 3 (5.0) | 0.461 |
| **Pruritus, n (%)** | 8 (13.3) | 2 (3.3) | 0.048* |
| **Sedation Score≥2, n (%)** | 3 (5.0) | 4 (6.7) | 0.701 |
| **Shivering, n (%)** | 10 (16.7) | 8 (13.3) | 0.612 |

***p < 0.05: statistically significant**

Maternal side effects were generally mild and not significantly different between the two groups, except for pruritus, which occurred more frequently in the fentanyl group (13.3% vs. 3.3%, p=0.048). Hypotension and bradycardia incidences were low and comparable. Sedation scores remained within acceptable limits, showing no significant intergroup variation.

**Table 6. Neonatal Outcomes**

| Outcome | Group BF (n=60) | Group BD (n=60) | p-value |
|---|---|---|---|
| **Apgar Score at 1 min, Mean ± SD** | 7.8 ± 0.4 | 7.9 ± 0.3 | 0.453 |
| **Apgar Score at 5 min, Mean ± SD** | 9.0 ± 0.2 | 9.1 ± 0.3 | 0.261 |
| **NICU Admission, n (%)** | 1 (1.7) | 1 (1.7) | 1.000 |

No statistically significant differences were noted in neonatal outcomes between groups. All neonates demonstrated satisfactory Apgar scores at 1 minute and 5 minutes. Only 2 infants in the entire cohort (1.7% per group) required short-term NICU observation; neither demonstrated any complications related to maternal analgesia. both regimens provided effective pain relief, but bupivacaine-dexmedetomidine (BD) achieved a faster onset of analgesia, a longer duration of pain relief, and reduced rescue analgesic requirements compared to bupivacaine-fentanyl (BF). Pruritus was significantly more common in the BF group, though other adverse effects were rare and comparable. Neonatal outcomes were uniformly reassuring, reinforcing the safety of both analgesic approaches. These results suggest dexmedetomidine is a valuable epidural adjuvant that may enhance maternal analgesic quality and satisfaction without compromising hemodynamic stability or neonatal wellbeing.

## DISCUSSION

Our study revealed no statistically significant differences between Group BF and Group BD in terms of mean age, mean weight, body mass index (BMI), and American Society of Anesthesiologists (ASA) physical status classification. Moreover, the distribution of primigravida (first-time mothers) and multigravida (women with previous deliveries) was similar across both cohorts, thereby indicating an equitable baseline. This absence of demographic disparity is essential for internal validity, as it reduces the likelihood that confounding variables tied to weight, body habitus, parity, or baseline health status could account for differences in analgesic outcomes or side-effect profiles [8].The mean age of our participants was approximately 26–27 years, which aligns with the reproductive age group typically seeking obstetric care in a tertiary hospital setting. Comparatively, a study by Khosravi *et al*., investigating epidural labor analgesia in a similar population reported a mean participant age of around 25–26 years, mirroring the demographic profile in our study [9]. The balanced distribution of ASA I/II patients in both groups (≈78% ASA I; 22% ASA II overall) likewise mirrors patterns reported by Jain *et al*.,, where

parturients with mild systemic diseases were represented in a similar proportion [10]. Such parity reinforces the likelihood that any differences in outcomes reflect the effects of the pharmacologic interventions rather than disparities in maternal health status.Regarding parity, around 70% of our participants were primigravidas. This composition is consistent with many contemporary obstetric anesthesia trials. Primigravidas, in particular, may experience more intense labor pain due to untested cervices and vaginal canals, making them especially valuable for studies investigating analgesic interventions. Consequently, having an equivalent percentage of primigravidas in both groups underpins the comparability of analgesic experiences. Overall, our demographic findings suggest that the parturients in both arms shared homogeneous baseline characteristics, providing a robust platform to attribute observed differences predominantly to the analgesic technique.

In this investigation, obstetric variables—such as gestational age, Bishop scores, cervical dilation at admission, and mode of labor onset (spontaneous or induced)—did not differ significantly between the BF and BD groups (Table 2). This finding is crucial, as labor progression and cervical readiness can substantially influence epidural analgesic requirements and maternal perception of pain. In particular, the Bishop score is commonly used to estimate the success rate of labor induction. Having near-identical mean Bishop scores (5.6 vs. 5.7) and cervical dilations (3.9 cm vs. 4.0 cm) at the time of epidural placement ensures that any variations in analgesic response are less likely to stem from disparities in cervical effacement or dilatation.The proportion of spontaneously initiated labor (≈68.3% overall) and induced labor (≈31.7% overall) was also well-balanced in both groups. It is well-established that induction of labor may affect the intensity and duration of labor, potentially altering analgesic needs. A matched distribution in spontaneous versus induced labor across the two study arms reduces confounding factors, further validating that any discernible group differences can be attributed primarily to the epidural regimen. A similar distribution has been reported in comparable randomized controlled trials examining neuraxial analgesia adjuvants, indicating that our obstetric parameters are representative of a typical population of laboring women [11].Previous research has shown that maternal BMI can impact epidural catheter placement and spread of local anesthetic, particularly in obese parturients. However, our average BMI of approximately 24–25 kg/m² in both groups places these parturients within the normal to slightly overweight category, mitigating the confounding effects of extreme obesity on neuraxial drug distribution. Overall, the comparable obstetric characteristics and normal-range BMI distribution in our study population indicate that labor progression factors were evenly balanced, thus permitting a fair comparison of analgesic regimens.

Our baseline hemodynamic data—heart rate and mean arterial pressure—exhibited no significant intergroup differences, and both groups had comparable baseline VAS (visual analog scale) pain scores (7.6–7.8) at the outset (Table 3). These findings are consistent with the principle that randomization and blinding facilitate a balanced distribution of pre-intervention variables.Hemodynamic stability before epidural placement is a key consideration for safe conduction of neuraxial anesthesia [12]. Ensuring that participants had similar initial cardiovascular parameters helps to rule out any confounding influences associated with pre-existing hypotension or tachycardia, which can modify the impact of epidural drugs. High baseline VAS scores reflect the substantial pain typical of active labor, underscoring the clinical relevance of providing effective analgesia. Comparable baseline pain intensities mean that any subsequent differences in VAS scores at follow-up times can be more credibly attributed to the difference in epidural adjuvant (fentanyl vs. dexmedetomidine).Similar baseline findings have been reported by Ali *et al*., in parallel comparative trials. In both of those studies, parturients commenced labor analgesia with high VAS readings in the 7–8 range [13]. This uniformity across various settings reinforces the premise that labor

pain is intense, especially during the active phase, and that effective interventions are paramount for improving maternal comfort. Overall, the absence of baseline disparity in our trial sets the stage for a valid appraisal of differential drug effects on both analgesia and maternal hemodynamics during labor.One of the main objectives of this trial was to explore whether dexmedetomidine, an α2-adrenergic agonist, provides superior or comparable analgesic benefits relative to fentanyl when each is combined with bupivacaine for epidural labor analgesia. Our results demonstrated that Group BD achieved a significantly faster onset of pain relief (10.2 ± 1.8 minutes) than Group BF (12.5 ± 2.0 minutes, p=0.038). The time to first top-up and the total duration of effective analgesia were likewise longer in the BD group (Table 4). These findings align with previous reports suggesting that dexmedetomidine enhances local anesthetic spread and analgesic synergy via presynaptic inhibition of norepinephrine release and a decrease in sympathetic outflow.

**Faster Onset of Analgesia**

The mechanism by which dexmedetomidine accelerates the onset of epidural analgesia is multifactorial. Not only does dexmedetomidine cause significant analgesic effects through α2-adrenoceptor activation in the dorsal horn of the spinal cord, but it also potentiates local anesthetic blockade by promoting hyperpolarization of nerve fibers. Opioids, such as fentanyl, also facilitate analgesia by binding to μ-opioid receptors in the spinal cord, but fentanyl's primary site of action and the synergy with local anesthetics may not be as profound in accelerating onset compared to dexmedetomidine's mechanism.Studies by Emam *et al*.,corroborate the finding of a quicker onset of analgesia with dexmedetomidine-laced neuraxial blocks [14]. In their analysis, dexmedetomidine decreased the onset time by roughly 2–3 minutes relative to opioids. This modest yet clinically relevant benefit can have considerable impact on maternal comfort, especially during the active stage of labor when contractions intensify.

**Prolonged Analgesic Effect**

Our trial further noted that the mean total duration of effective analgesia was markedly higher in the BD group (220.3 ± 29.1 minutes) compared to the BF group (195.6 ± 25.4 minutes, p=0.017). This extended analgesic window was manifested in fewer additional boluses (1.8 ± 0.3 vs. 2.1 ± 0.4, p=0.036) and an overall greater reduction in VAS pain scores for BD participants. This phenomenon is in line with Callaha *et al*., who reported that dexmedetomidine effectively prolongs local anesthetic–induced sensory blockade, owing to its robust α2-adrenoceptor-mediated anti-nociceptive effects in both spinal and supraspinal centers [15].In contrast, fentanyl's primary advantage in epidural analgesia lies in its rapid onset and potent antinociceptive action at μ-opioid receptors. However, its effect can be somewhat shorter-lived compared to α2-agonists. The synergy between fentanyl and bupivacaine is well documented, but many investigators have concluded that dexmedetomidine can provide a more sustained analgesic effect with potentially fewer side effects, especially pruritus. This aligns closely with our findings, which showed reduced pruritus and a longer period of analgesia in the dexmedetomidine group.

**Clinical Implications for Labor Management**

Faster onset and prolonged duration mean fewer top-ups, decreased total drug requirements, and improved maternal satisfaction. In busy labor wards, reducing the frequency of epidural boluses can alleviate the workload on anesthesia providers and potentially lower the total drug exposure for both mother and fetus. Additionally, better quality analgesia over a sustained duration can reduce maternal stress, catecholamine release, and maternal fatigue, all contributing to a more positive labor experience. These factors collectively underscore why dexmedetomidine may serve as an excellent adjunct to local anesthetics in an obstetric population.However, it is essential to note that the analgesic benefits of dexmedetomidine

must be balanced against potential hemodynamic alterations such as bradycardia and hypotension, which can occur with α2-agonists [16]. As revealed in our data and corroborated by other studies, these side effects were clinically manageable and did not differ significantly from those in the fentanyl-based group, indicating that dexmedetomidine's theoretical drawbacks can be mitigated by careful dosing and vigilant monitoring.Maternal side effects represent a critical domain in evaluating the clinical value of any analgesic regimen for labor. Our findings showed that the incidence of hypotension was relatively low and similar in both groups (10.0% in BF vs. 11.7% in BD, p=0.772), and bradycardia occurred in only a handful of cases (3.3% in BF vs. 5.0% in BD, p=0.651). Notably, Group BF reported significantly more pruritus (13.3%) compared to Group BD (3.3%, p=0.048), while all other side effects—such as nausea, vomiting, sedation, and shivering—did not differ significantly (Table 5).

**Hemodynamic Stability**

Dexmedetomidine is known to reduce sympathetic tone and can cause bradycardia and hypotension by activating central α2-adrenergic receptors. Nevertheless, in our study, the difference in hypotension (p=0.772) and bradycardia (p=0.651) rates between the two groups was not statistically significant. Proper fluid preloading, meticulous titration of the epidural dosage, and close hemodynamic monitoring likely contributed to minimizing these side effects. This safety profile corroborates the results reported by Marolf *et al*., in which dexmedetomidine's cardiovascular effects were modest and clinically manageable when used at appropriate doses [17].Fentanyl, meanwhile, is less likely to induce bradycardia or hypotension in the doses commonly used for epidural labor analgesia, but it can cause mild sedation or respiratory depression if dosed excessively. We observed only a slight difference in sedation scores between BF (5.0% sedation score ≥2) and BD (6.7%), with no statistical significance (p=0.701). None of the participants in either group demonstrated clinically significant respiratory depression. This is consistent with other trials that have employed low-dose fentanyl in conjunction with local anesthetics.

**Pruritus**

One of the more distinct findings was the higher incidence of pruritus in Group BF (13.3% vs. 3.3% in BD). Pruritus is a well-recognized side effect of neuraxial opioid administration, attributed to the μ-opioid receptor-induced release of histamine and other mediators in the central nervous system. Although pruritus was mild and did not necessitate discontinuation of analgesia in most cases, it can nevertheless be bothersome and adversely affect maternal satisfaction [18].Dexmedetomidine, by contrast, has been associated with a relatively lower incidence of pruritus and nausea, as its mechanism of action is distinct from that of opioids. This advantage can significantly improve maternal comfort, particularly in prolonged labors requiring multiple epidural top-ups. While α2-agonists are not entirely devoid of side effects, their lack of histaminergic or opioid receptor-mediated pruritus represents a beneficial characteristic in labor analgesia protocols.

**Other Side Effects**

Nausea and vomiting occurred in a small subset (8.3% in BF vs. 5.0% in BD), mirroring the relatively low rates reported in analogous studies of neuraxial labor analgesia. Shivering was noted in 16.7% of BF participants and 13.3% of BD participants, without statistical significance. Obstetric shivering may arise from multiple factors, including hormonal fluctuations, analgesic-induced thermoregulatory changes, and parturient anxiety [19]. Overall, the lack of major or life-threatening complications underscores that both epidural bupivacaine-fentanyl and bupivacaine-dexmedetomidine can be administered safely, provided that meticulous monitoring and dose adjustments are in place.Ensuring fetal safety is paramount in obstetric anesthesia. Consequently, our study evaluated neonatal well-being via Apgar scores at 1 and 5

minutes and rates of NICU admission. The results showed no statistically significant differences between the two groups with mean Apgar scores at 1 minute around 7.8–7.9 and at 5 minutes around 9.0–9.1, while NICU admissions (1.7% in both groups) were minimal and not linked to the analgesic technique.

**Apgar Scores and Drug Transfer**

Apgar scoring is an indirect measure of neonatal adaptation, evaluating appearance (color), pulse (heart rate), grimace (reflex irritability), activity (muscle tone), and respiration. Scores ≥7 at 1 minute and ≥9 at 5 minutes are considered reassuring. Our observations are consistent with those of previous research on epidural labor analgesia regimens Li *et al*., indicating no clinically significant transplacental transfer of either fentanyl or dexmedetomidine in doses used for labor analgesia [20].While fentanyl can cross the placenta, leading to concerns about neonatal respiratory depression a similar study, the low doses typically employed in epidural infusions mitigate this risk. Dexmedetomidine also crosses the placenta, but current evidence suggests minimal adverse neonatal effects when used judiciously. Our data reinforce that, under prudent dosing and vigilant monitoring, neither adjuvant notably compromises neonatal well-being.

**Neonatal Intensive Care Unit Admission**

Two neonates (one in each group) briefly required NICU admission; the reasons involved mild transitional difficulties and not analgesic-induced depression. This 1.7% rate is within the normal range for full-term deliveries at tertiary care centers, often reflecting non-anesthesia-related circumstances such as mild respiratory distress or suspected neonatal infection. Thus, neither epidural regimen was implicated in any notable neonatal complications. These results are consistent with broader literature that has reported similar findings for both opioid- and α2-agonist–based neuraxial labor analgesia [21].

**Comparison with Other Studies**

These findings correspond to numerous randomized trials worldwide. Mohammed *et al*. also identified a shorter onset and longer duration of analgesia when dexmedetomidine was included in epidural solutions for laboring women [22]. A similar study demonstrated that the addition of dexmedetomidine to local anesthetics not only extended the analgesic duration but also reduced postoperative analgesic requirements and improved maternal satisfaction. Another comparative study by Shrief *et al*., echoed these results in a population of low-risk parturients, reinforcing that dexmedetomidine may surpass fentanyl in providing stable and sustained labor analgesia [23]. Differences in study designs, sample sizes, drug concentrations, and ethnic or regional populations might yield minor variations in magnitude, but the overarching consensus tilts in dexmedetomidine's favor for a variety of analgesic endpoints.Regarding side effects, the lower incidence of pruritus in the dexmedetomidine group has been a recurring theme in multiple investigations. Hypotension and bradycardia, frequently considered limiting factors for α2-agonists, did not significantly differ from the fentanyl group in our trial nor in multiple prior studies. It is likely that adjusting the dexmedetomidine dosing range (commonly 0.5–1 μg/kg loading doses for epidural or intrathecal routes, followed by lower infusion rates) mitigates the magnitude of α2-mediated sympatholysis.As for neonatal outcomes, we found alignment with the existing literature, indicating no detrimental effects of epidural dexmedetomidine on Apgar scores or NICU admissions. The consensus is that if maternal hemodynamic parameters remain stable and drug doses are within safe limits, the fetus is usually well-protected from any adverse consequences of neuraxial analgesia.

**Limitations**

Despite these robust findings, some limitations warrant mention. First, our trial was confined to a single tertiary care center (Indira Gandhi Institute of Medical Sciences, Patna), possibly limiting generalizability

to different hospital settings or patient populations with distinct demographic or sociocultural profiles. Second, while we used standardized epidural techniques and drug concentrations, minor variations in the timing of top-ups, infusion rates, or adjustments based on clinical judgment may introduce a degree of variability. Third, we did not measure maternal stress hormone levels (like cortisol or catecholamines), which could provide a biochemical correlate to analgesic adequacy and neonatal well-being [24]. Additionally, our sample size, while adequate to detect differences in analgesic efficacy and major side effects, might be underpowered to detect very rare complications or to perform detailed subgroup analyses for high-risk pregnancies. Lastly, the follow-up period was largely confined to the immediate intrapartum and early postpartum phases, leaving open questions about longer-term maternal satisfaction, postpartum depression indices, and neonatal neurobehavioral outcomes.

**Future Directions**

Future research could address these limitations by expanding the study to multiple centers with varied patient demographics and by increasing sample sizes. Incorporating objective measures of maternal stress response, quality-of-life questionnaires for postpartum evaluation, and neonatal neurobehavioral assessments would yield a more holistic picture of the interventions. Investigators might also explore alternative doses or infusion regimens of dexmedetomidine to further optimize its analgesic benefits while minimizing potential hemodynamic compromise. Additionally, the cost-effectiveness of dexmedetomidine relative to opioids remains an important consideration, particularly in resource-limited settings, and should be investigated in future trials.A particularly interesting avenue for subsequent studies involves analyzing the combination of low-dose dexmedetomidine with low-dose opioids to harness a multimodal approach. Such a regimen might leverage the advantages of both drug classes while reducing each agent's side-effect profile [25]. Innovations in patient-controlled epidural analgesia pumps could also refine dosing schedules, offering personalized analgesic titration based on real-time pain assessments and sedation levels. In obstetric populations, ensuring that these technological and pharmacological refinements always align with maternal-fetal safety remains a paramount priority.

## CONCLUSION

This randomized controlled trial comparing bupivacaine-fentanyl and bupivacaine-dexmedetomidine epidural regimens in parturients at term demonstrates that dexmedetomidine provides several advantages over fentanyl. Notably, it offers a faster onset of analgesia, a longer duration of pain relief, and reduced pruritus, while maintaining maternal hemodynamic stability and high neonatal Apgar scores. Both groups displayed minimal incidence of clinically significant side effects, indicating that vigilant monitoring and judicious dosing preserve maternal-fetal safety. Improved analgesic quality and maternal satisfaction in the dexmedetomidine group underline the promise of α2-agonist adjuvants in obstetric anesthesia. Although confirmatory research with larger, multicenter trials is warranted, these findings align with an expanding body of evidence supporting dexmedetomidine's favorable risk-benefit profile as an epidural adjunct for labor analgesia.

**Recommendations**

Consider dexmedetomidine as a first-line epidural adjuvant for labor analgesia where clinically feasible.
Use careful dosage titration and continuous hemodynamic monitoring to mitigate potential bradycardia or hypotension.
Conduct larger multicenter studies to confirm these results and evaluate cost-effectiveness.

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