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Original Contribution

Intravenous dexamethasone as an adjunct to improve labor analgesia: A randomized, double-blinded, placebo controlled clinical trial☆

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ABSTRACT

Objective: To study the role of intravenous (i.v.) dexamethasone as an analgesic adjunct in labor analgesia.
Design: Double-blinded randomized controlled trial.
Setting: Labor analgesia in a tertiary-care teaching hospital.
Patients: Eighty consenting ASA I-II parturients, age > 18 year, nulliparous, single gestation, cephalic presentation at ≥36 wk. of gestation, in early spontaneous labor (cervical dilatation ≤ 5 cm) requesting epidural analgesia.
Interventions: The patients were randomized to two groups. The Dexa group received 8 mg of dexamethasone i.v. in 50 ml normal saline approximately 45 min before the procedure. Placebo group patients received 50 ml normal saline only. All patients underwent epidural labor analgesia per hospital protocol. After an initial bolus, they received continuous background infusion of 5 ml/h of 0.1% of levobupivacaine with 2 μg/ml of fentanyl, with the provision of patient controlled boluses of 5 ml of the same drug combination with a lockout interval of 12 min if needed.
Measurements: Primary outcome measure: hourly average consumption of neuraxially administered levobupivacaine-fentanyl combination. Secondary outcomes and observations: pain score, maternal satisfaction, sensory and motor block characteristics, hemodynamic parameters of mother, fetal heart rate, duration of second stage of labor, mode of delivery, Apgar scores at 1 and 5 min, and adverse effects.
Main results: Average hourly drug consumption was significantly lower in Dexa group as compared to Placebo group (10.34 ± 1.79 ml/h vs. 11.34 ± 1.83 ml/h; mean difference 1.007, 95% CI 0.199–1.815; P = 0.015). The median number of bolus doses was 4 (interquartile-range [IQR] 3–5.75) and 5 (IQR 3–6) in the Dexa and Placebo groups, respectively (P = 0.162). There was no significant difference between groups with regard to pain scores, maternal satisfaction and hemodynamics, mode of delivery, and adverse effects.
Conclusions: I.v. dexamethasone significantly decreased hourly average drug consumption of levobupivacaine-fentanyl combination through the epidural route, demonstrating the epidural drug dose sparing effect during labor analgesia.

1. Introduction

Labor pain is usually the most severe pain a woman will ever experience [1]. The American College of Obstetricians and Gynecologists and the American Society of Anesthesiologists (ASA) state, "There is no other circumstance where it is considered acceptable for an individual to experience untreated severe pain, amenable to safe intervention, while under a physician's care. In the absence of a medical contraindication, maternal request is a sufficient medical indication for pain relief during labor" [2]. Although severe pain in healthy parturients is not life-threatening, it can have numerous neuropsychological consequences. Postnatal depression may be more common when analgesia is not used [3].

It is now well recognized that the only consistently effective method of pain relief during labor is lumbar epidural analgesia using local anesthetic alone or along with an adjuvant [4,5]. Adjuvant or analgesic adjunct drugs help decrease the effective dose of local anesthetic used and also enhance the quality of analgesia [6], opioids being the most common [7]. Some newer adjuvants such as clonidine and neostigmine have been used for labor analgesia but are associated with side effects

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like hypotension, bradycardia and sedation [8]. Because of these adverse effects, adjuncts might be less suitable in pregnant women.

Dexamethasone, a well-known anti-inflammatory drug, has also been investigated for its analgesic efficacy as an adjunct. A recent metaanalysis concluded that patients treated with a single intravenous (i.v.) perioperative dose of dexamethasone experienced less postoperative pain and required less postoperative opioids [9]. It is also being investigated as an i.v. adjunct to central neuraxial blockade [10]. Although numerous studies have evaluated that dexamethasone is a safe, effective, and inexpensive choice to reduce postoperative pain when given shortly before surgery, there is a paucity of studies assessing its intrapartum use [11,12]. Thus, the current study aimed to evaluate the role of i.v. dexamethasone as adjuvant to neuraxial analgesia for labor pain. The hypothesis was that i.v. dexamethasone used as an adjunct would improve labor analgesia without compromising safety to the mother and the newborn.

2. Material and methods

This was a double blind, prospective, randomized, placebo controlled study, conducted at Government Medical College and Hospital, Chandigarh, India, which is a tertiary-care medical teaching institute in north India. Approval for the study was obtained from the Institutional Ethics Committee. The study was registered with the Clinical Trials Registry of India (the trial was registered in May 2014 with the trial Reference No. Ref/2014/03/006694, final CTRI Registration No. CTRI/2014/05/004596).

2.1. Study subjects and groups

Eighty healthy parturients belonging to ASA status I and II, age > 18 year, nulliparous, single gestation, cephalic presentation at ≥36 wk of gestation, in early spontaneous labor (cervical dilatation ≤ 5 cm) requesting epidural analgesia were enrolled in the study. Exclusion criteria were refusal by parturient, parturients who had received parenteral opioids in the last 4 h, systemic and local sepsis, abnormal coagulation profile, parturients having multiple pregnancies and premature labor, obstetric complications (e.g., premature rupture of amniotic membranes), noncephalic presentations, allergy to study drugs, i.e., levobupivacaine and fentanyl, history of peptic ulcer disease, known case of uncontrolled diabetes mellitus, and patient who had received dexamethasone in last 7 days for fetal lung maturity. Patients with pre-existing diabetes mellitus prior to pregnancy were included in the study if their sugar levels were controlled, i.e., Hb1C <6.5. Patients on insulin were excluded.

After obtaining written informed consent from the parturients, 80 participants were randomly assigned to two groups of 40 each (CONSORT flow diagram shown in Fig. 1) by computer generated random numbers. Cervical dilatation and patient characteristic data including age, weight, height and baseline investigations were recorded.

For the Dexa Group, the test drug was prepared by adding 8 mg of dexamethasone to 50 ml normal saline and this was given to the patient intravenously over 15 min. The Placebo Group received 50 ml of plain normal saline only. The saline infusion containing the study drug was prepared by an anesthesiologist not involved in the study. The group

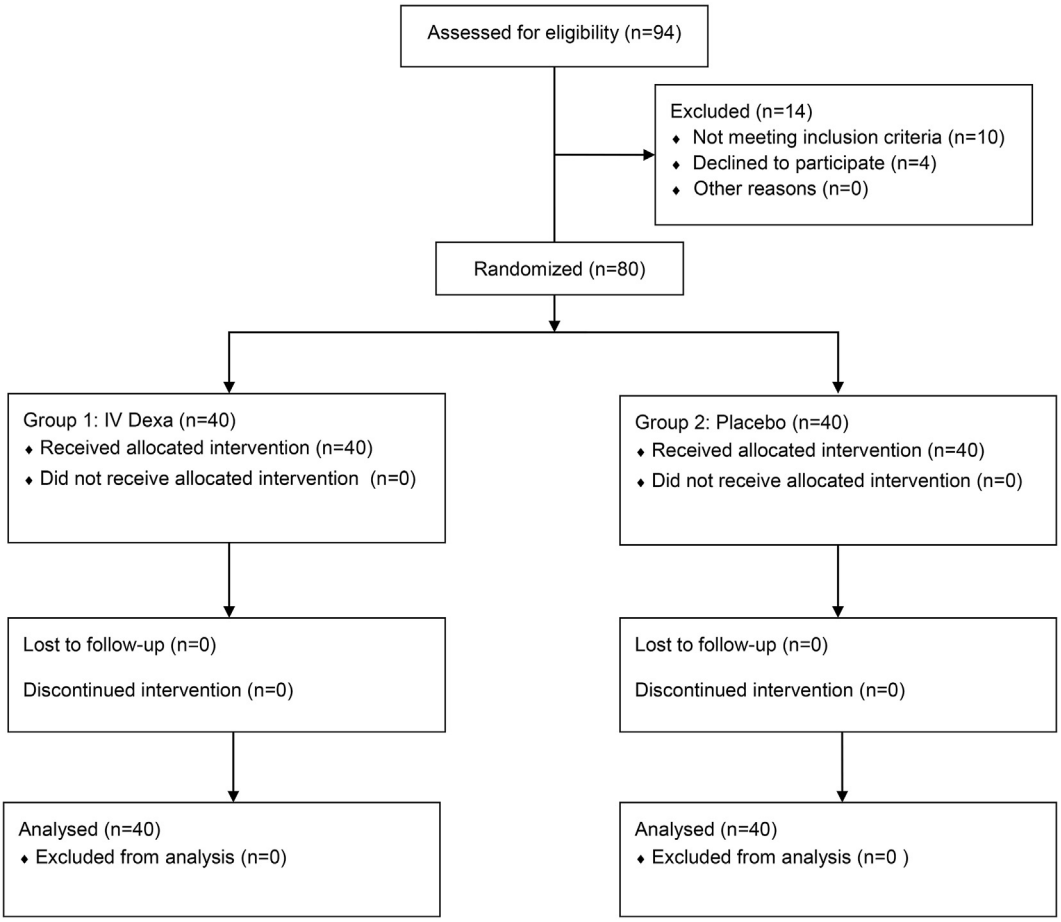

Fig. 1. CONSORT Flow Diagram.