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ORIGINAL ARTICLE

Programmed intermittent epidural bolus versus continuous epidural infusion for pain relief during termination of pregnancy: a prospective, double-blind, randomized trial

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ABSTRACT

Background: Pain is a major concern during medical abortion but no evidence-based recommendations for optimal analgesia during medical termination of pregnancy are available. We compared two methods of epidural analgesia during second trimester termination of pregnancy, with the primary aim of assessing the incidence of motor block.

Methods: Women were randomly assigned to receive continuous epidural infusion (CEI Group; n=52) or programmed intermittent epidural bolus (PIEB Group; n=52). Assessment of motor block was performed every hour. Patients with a modified Bromage score <6 were considered to have motor block.

Results: Motor block occurred more frequently in the CEI Group compared with the PIEB Group (46.2% vs. 5.8%, P<0.001). Pain scores were low and comparable between groups. Patients in the CEI Group experienced nausea more frequently than those in the PIEB Group (34.6% vs. 13.5%, P=0.022). The degree of satisfaction was higher in the PIEB Group compared with the CEI Group.

Conclusions: During second trimester termination of pregnancy in our patient groups, a programmed intermittent epidural bolus technique was associated with less motor block and greater patient satisfaction than continuous epidural infusion. Both techniques had similar analgesic efficacy.

Keywords: Analgesia; Epidural; Labor; Motor block; Termination of pregnancy

Introduction

Medical methods for second trimester voluntary termination of pregnancy (TOP), compared with surgical procedures, have the advantages of being operator-independent and providing an intact fetus for pathological examination. However, medical methods require longer hospitalization and surgical removal of retained productions of conception is sometimes required. Furthermore, medical procedures are associated with more pain than surgical techniques.[1] Pain is a characteristic feature of medical abortion and may be extremely severe.[2–5] Although pain is a major concern of the medical abortion process, few trials have investigated this topic[6–14] and there is no evidence-based recommendation for optimal analgesia during the procedure. Both the American Society of Anesthesiologists and the American College of Obstetricians and Gynecologists underline that among the different pharmacological methods used for analgesia during labor and delivery, neuraxial techniques are the most flexible, effective and least depressing to the central nervous system. Therefore, an effort should be made to maximize the availability of these methods for pain management during obstetric procedures.

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Maintaining epidural labor analgesia with a programmed intermittent epidural bolus (PIEB) technique reduces maternal motor block compared with continuous epidural infusions (CEI).[15] Therefore, we hypothesized that during second trimester TOP procedures, use of PIEB would result in a lower incidence of motor block than CEI with a similar level of analgesia. Medical TOP may be prolonged (often 15–24 h) and thus may be a stressful event for the patient. For these reasons, in our institution, this type of procedure is conducted in a dedicated single room where the patient can stay with her partner, move freely and eat and drink small amounts. Therefore, we consider that the preservation of motor function in women undergoing TOP is important.

The primary objective of this study was to compare the incidence of motor block during epidural analgesia using PIEB versus CEI in patients undergoing second trimester TOP. Secondary objectives were to assess analgesia, patient satisfaction, total anesthetic drug consumption, duration of labor and the incidence of adverse events.

Methods

This prospective, double-blind, randomized study included women who underwent voluntary second trimester TOP at the Obstetrics and Gynecology Unit, IRCCS San Martino Hospital and National Institute for Cancer Research, University of Genoa, Italy. Patients were recruited between October 2011 and June 2013. The trial protocol was approved by the Institutional Review Board (n.9/2011 [2011/09/23]) and registered at www.clinicaltrials.gov (NCT01860521). The trial was conducted according to the Declaration of Helsinki and all women included in the study gave written informed consent.

Patients undergoing second trimester TOP (<24 weeks of gestation) were invited to participate in the study. In our institution only medical treatment is offered for second trimester TOP and women requiring analgesia are offered an epidural infusion. Inclusion criteria were: age $\geqslant$18 years, patients undergoing medical TOP, comprehension of Italian language, request for analgesia with baseline pain score $\geqslant$30 mm on a 100-mm visual analog pain scale (VAPS). Exclusion criteria were: contraindication to epidural analgesia or narcotics, history of drug abuse, maternal disease (severe asthma, cardiac, liver or renal disease), inability to comprehend or comply with the analgesic procedures.

Patients were randomized to PIEB (PIEB Group) or CEI (CEI Group). Block randomization was used to ensure that the number of subjects assigned to each group was equally distributed. Block size varied randomly to reduce the likelihood of foreknowledge of intervention assignment. Allocation codes were sealed in consecutively numbered opaque envelopes. Immediately before starting the analgesic regimen, the envelope assigned to the patient was opened by an unblinded researcher (RS) who set up the epidural pump accordingly. Patients were blinded to group assignment and other study investigators, including those assessing study outcome measures, were blinded to group assignment and to study design. Infusion pumps were inserted into an opaque, portable bag.

On admission to hospital, gestational age was confirmed by ultrasonography. Patients received a 1 mg gemeprost pessary in the posterior fornix of the vagina every 3 h, up to five doses. If expulsion of the fetus did not occur, the therapeutic regimen was repeated 24 h after the initiation of treatment. Induction-to-abortion time was defined as the time between the first gemeprost pessary administration and fetal expulsion. Failure of induction of abortion was defined as women who did not deliver after two completed cycles, after which different methods of abortion were considered. In women with a uterine scar from a previous cesarean section, a single cycle of labor induction was performed; gemeprost was administered every 6 h up to five doses.[16] In these patients, failure of induction of abortion was defined as women who did not deliver after 48 h. If ultrasonography showed retained productions of conception, evacuation of the uterus was performed under epidural anesthesia.[17] Patients without complications (hemorrhage due to atony, placental retention, uterine perforation, fever) were discharged after at least 6 h from expulsion or uterine curettage.

After administration of the first gemeprost pessary, the epidural procedure began when the patient requested analgesia with baseline pain score $\geqslant$30 mm on a 100-mm VAPS labelled "no pain" (left limit) and "worst imaginable pain" (right limit). The procedure started with intravenous infusion of 500 mL lactated Ringer's solution. Epidural analgesia was performed in the sitting position at the L2–3 or L3–4 interspace. The epidural space was identified using the loss-of-resistance to saline technique (<2 mL) with an 18-gauge Tuohy needle. A multi-orifice epidural catheter was introduced 3–4 cm and tested with 3 mL of 1.5% lidocaine with epinephrine 5 μg/mL.[18]

All patients received an initial 20 mL epidural loading dose of 0.0625% levobupivacaine plus sufentanil 10 μg. Participants who had blood or cerebrospinal fluid aspirated from the catheter were excluded from the study. Patients who did not have a VAPS $\leqslant$10 mm within 30 min of the epidural injection were deemed to have a failed block and were excluded from the study. Patients were randomized to receive PIEB or CEI. The PIEB pump was programmed to deliver 0.0625% levobupivacaine with sufentanil 0.5 μg/mL with a 10 mL bolus every hour, starting 60 min after the initial loading dose. The CEI pump was programmed to