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ORIGINAL ARTICLE

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Remifentanil versus placebo for analgesia during external cephalic version: a randomised clinical trial

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ABSTRACT

Background: Breech presentation occurs in up to 3% of pregnancies at term and may be an indication for caesarean delivery. External cephalic version can be effective in repositioning the fetus in a cephalic presentation, but may be painful for the mother. Our aim was to assess the efficacy of remifentanil versus placebo for pain relief during external cephalic version.

Methods: A randomized, double-blind, controlled trial that included women at 36–41 weeks of gestation with non-cephalic presentations was performed. Women were randomized to receive either a remifentanil infusion at 0.1 μg/kg/min and demand boluses of 0.1 μg/kg, or saline placebo. The primary outcome was the numerical rating pain score (0–10) after external cephalic version.

Results: Sixty women were recruited, 29 in the control group and 31 in the remifentanil group. There were significant differences in pain scores at the end of the procedure (control 6.5 ± 2.4 vs. remifentanil 4.7 ± 2.5, $P = 0.005$) but not 10 min later ($P = 0.054$). The overall success rate for external cephalic version was 49% with no significant differences between groups (remifentanil group 54.8% vs. control group 41.3%, $P = 0.358$). In the remifentanil group, there was one case of nausea and vomiting, one of drowsiness and three cases of fetal bradycardia. In the control group, there were three cases of nausea and vomiting, one of dizziness and nine cases of fetal bradycardia.

Conclusion: Intravenous remifentanil with bolus doses on demand during external cephalic version achieved a reduction in pain and increased maternal satisfaction. There were no additional adverse effects, and no difference in the success rate of external cephalic version or the incidence of fetal bradycardia.
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Keywords: Analgesia; External cephalic version; Remifentanil

Introduction

Breech presentation occurs in 3% of pregnancies,[1,2] and in many countries, 90% of these women undergo caesarean delivery.[3] Cephalic presentation and subsequent vaginal delivery are associated with reduced maternal and fetal morbidity.[4,5] and so the American College of Obstetricians and Gynecologists (ACOG) has proposed the use of external cephalic version (ECV) to turn the fetus to a cephalic presentation in an attempt to avoid caesarean delivery.[6] ECV is successful in 50–74% of studies,[7,8] and reduces the incidence of breech presentation and caesarean delivery by 9–16%.[9,10] Therapeutic manoeuvres that improve ECV success may further decrease caesarean deliveries, reduce the surgical risks for mother and baby and improve cost-effectiveness.[11,12]

ECV is painful for many pregnant women; studies using visual analogue pain scales have reported mean scores of 4.6–8.5 out of 10.[13] Some authors have used neuraxial analgesia for ECV, and this has been associated with improved pain scores and increased success of ECV.[14–16] However, neuraxial blocks may be associated with maternal hypotension, sedation, an increased hospital stay for a procedure that can be performed on an outpatient basis.[17,18] The optimum approach to pain control for ECV remains unclear.[19]

Remifentanil, an ultra-short acting synthetic opioid, is rapidly metabolised by non-specific esterases in blood and other tissues, and has a half-life of only 3 min. Consequently, it does not accumulate at the effect site, regardless of the dose administered.[20] A previous open, non-randomised study by our team showed promising results using remifentanil for ECV.[21] Although new for ECV, its use in labour is well established, and no

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harmful effects have been observed in the baby.[22–26] The primary objective of this clinical trial was to assess the analgesic efficacy of remifentanil for ECV. Secondary objectives were to assess safety and whether it was associated with an increase in the success rate of ECV compared to placebo.

Methods

A randomised, double-blind, placebo-controlled trial was carried out in a tertiary hospital that managed 3101 deliveries over the 12-month study period (April 2010–March 2011). The study was approved by the Clinical Research Ethics Committee of the Txagorritxu Hospital (ref: 2009-045; 17/11/2009), the Spanish Agency for Medicines and Health Products (AEMPS) and was registered with Clinicaltrials.gov (NCT01048398).

Women were recruited consecutively during antenatal appointments. All non-labouring pregnant women at 36–41 weeks of gestation with a non-cephalic presentation confirmed by ultrasound scan were invited to participate. Exclusion criteria were: fetal abnormalities, intrauterine fetal death, suspicion of fetal growth restriction, fetal weight above 3800 g, maternal cardiovascular disease, American Society of Anesthesiologists class >2, severe hypertension, allergy to any trial medications, amniotic fluid index <4 cm, Doppler cerebroplacental ratio >5th percentile, abnormal cardiotocographic recordings, contraindications to vaginal delivery, uterine abnormalities, coagulation disorders, Rhesus incompatibility, multiple gestation, rupture of membranes and/or placental abruption.

After written informed consent, women were randomly assigned to the control or remifentanil groups using a computer-generated random sequence. Anaesthesiologists, midwives and obstetricians were blinded to allocation group. The hospital pharmacy prepared 100 mL infusion bags that contained either remifentanil (1 mg) or saline, which were labelled with the patient code and sent to the operative room.

Before ECV, all women were asked to arrive with an empty bladder, and a cardiotocogram (CTG) and amniotic fluid index were recorded (Appendix A). Mother and fetus were monitored for at least 30 min before attempting ECV. An intravenous infusion of ritodrine 200 μg/min was given for tocolysis. The procedure was performed by one of two experienced obstetricians. Fetal heart rate was measured throughout the procedure.

According to local institutional protocol, all patients received intravenous paracetamol 1 g in 100 mL saline 5 min before ECV. Subsequently, they received the study solution, delivered by a patient-controlled analgesia infusion pump (B Braun Medical, Melsungen, Germany) at 0.1 μg/kg/min, with rescue boluses on demand of 0.1 μg/kg/min and a lockout period of 4 min.

ECV was considered successful when a cephalic presentation, confirmed by ultrasound scan, was achieved. The procedure was stopped if the woman reported severe pain, if version could not be achieved readily, or if prolonged fetal bradycardia, uterine bleeding or placental abruption occurred. CTG was monitored for 45 min after attempted ECV. Data on maternal sedation and respiratory rate were collected by the anaesthesiologist using the modified Observer's Assessment of Alertness/Sedation Scale. Maternal oxygen saturation was measured continuously using pulse oximetry. Blood pressure was measured every 5 min; hypotension was defined as a fall in blood pressure of >20% from baseline and was treated with an intravenous bolus of ephedrine 5 mg.

The primary outcome, pain associated with ECV, was assessed using a numerical rating scale (0 = no pain, 10 = worst pain imaginable) immediately after finishing the procedure and again 10 min later. At both times, patients were asked about procedural pain. In addition, the women's level of satisfaction with the procedure was assessed using another numerical rating scale (0 = completely dissatisfied, 10 = completely satisfied) 10 min after the end of attempted ECV.

Nausea and vomiting were recorded as adverse effects, regardless of when they occurred, and were treated with intravenous ondansetron 4 mg. Other maternal side effects including drowsiness and dizziness were also documented.

Statistical analyses

Based on a previous pilot study, to detect a difference of $\geqslant 2$ points on the pain numerical rating scale, with population standard deviation of 3 points, with an α risk of 0.05 and power of 90%, 30 participants were required in each arm of the study. Given the nature of the study, participant loss to follow-up was not anticipated. Statistical analysis was carried out using IBM SPSS Statistics version 19. Continuous data were summarised as mean and standard deviation (SD), and qualitative data as frequency and percentage. Demographic data were analysed with chi-squared tests for the categorical variables (parity, presentation, ethnic group, location of the placenta and amniotic fluid index), and with Student's t tests for the continuous variables (maternal age, body mass index and estimated fetal weight).

For the primary end point, pain scores were compared using the Student's t test. Potential confounding variables, such as the duration and success of ECV, were assessed using multivariate linear regression analysis. For the secondary end points, ECV success, and the numbers of vaginal and caesarean deliveries were compared using chi-squared or Fisher's exact tests as appropriate. 95% confidence intervals (CI) are reported.

Results

In the study period (April 2010–March 2011) there were 66 non-cephalic presentations, representing 2.1% of all

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