Title:
Spinal sufentanil for relief of labor pain in primi- and multiparous parturients
NCT ID not yet assigned
Document Date: 05/29/2019

1 INTRODUCTION
Any parturient should be offered safe and effective analgesia at short notice during labor, and therapeutic options are pharmacological (nitrous oxide, non-opioid and opioid analgesics, regional and neuraxial nerve blocks) and non-pharmacological (hypnosis, biofeedback, intra- or subcutaneous sterile water injection, immersion in water, aromatherapy, relaxation techniques, acupuncture or acupressure, massage, transcutaneous electrical nerve stimulation) interventions. \(^1\) Neuraxial (epidural and/or spinal) nerve block is the most effective method of intrapartum pain relief in contemporary clinical practice. \(^2\) Intrathecal administration of local anaesthetic and/or opioid provides effective, although transient, pain relief during spontaneous vaginal delivery. However, although spinal opioid is being used more for obstetric analgesia, effects and adverse effects of intrathecal sufentanil alone for relief of labor pain have not been compared between primi- and multiparous parturients.
This descriptive study was designed to evaluate effects and potential adverse effects of spinal sufentanil for obstetrical pain relief in primi- and multiparous parturients.

2 MATERIAL AND METHODS

2.1 Ethical approval
The study design was approved by the regional Human Research Ethics Review Board, Lund, Sweden (Dnr 2015/687).

2.2 Study design and setting
This descriptive study is based on retrospective data on obstetrical management of patients at the maternity ward of the Central Hospital in Kristianstad, Sweden, between 7\(^{\text{th}}\) January 2013 and 29\(^{\text{th}}\) July 2016.
2.3 Patients
We included 164 (82 primi- and 82 multiparous) obstetrical patients given intrathecal sufentanil for labor pain. Demographic, obstetrical, and neonatal information in patients admitted to the maternity ward was obtained from the local obstetrical hospital database (Obstetrixtm, Cerner Sverige AB, Stockholm, Sweden).

2.4 Spinal analgesia
Spinal analgesia (SA) was provided by a resident or specialist anaesthesiologist with the patient in a sitting or a recumbent position. A pencil-point needle, primarily 27 G (0.4 mm), otherwise 25 G (0.5 mm), was used for transdermal intrathecal administration of 2.0 ml of sufentanil 5 µg/ml (Sufenta®, Janssen-Cilag AB, Solna, Sweden) at low-lumbar level. Blood pressure was recorded before, immediately after, and at five-minute intervals for 20 minutes after the block. Any decrease in blood pressure by more than 30 % from the baseline level despite infusion of crystalloid was defined to indicate maternal hypotension.

2.5 Study data
Maternal demographics (age, height, weight, body mass index), obstetrical (medical history, gestational age, cervical dilation, progress of labor, indication and time for SA, hypotension, use of oxytocin, fetal bradycardia or late deceleration during the first hour after SA, supplementary analgesia, instrumental delivery, intrapartum Cesarean section (CS), third- or fourth-degree perineal tear, maternal satisfaction with pain relief, postdural puncture headache, use of epidural blood patch), and neonatal (time of birth, fetal heart rate (FHR), Apgar score, weight at birth, use of neonatal intensive care, feeding) data was obtained as reported above.

2.6 Statistical analysis
A total sample size of 150 parturients had been calculated to enable differences of at least 20 % versus 5.0 % in proportions of obstetrical and neonatal problems between (equal numbers of) primi- and multiparous mothers to be statistically confirmed with 80 % power and 95 % probability.
Descriptive parametric data is reported as mean ± standard deviation (SD), and proportions in percent with 95% confidence interval (CI).

Parametric data was compared with two-tailed unpaired student’s t-test, and proportions analyzed with Fisher’s exact test.

Probability ($P$) values < 0.05 were considered statistically significant.