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Effectiveness of nitrous oxide for postpartum perineal repair: a randomised controlled trial

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ABSTRACT

Objective: To compare the effectiveness of self-administered 50% nitrous oxide and conventional infiltrative anaesthesia with 1% prilocaine hydrochloride in postpartum perineal repair.
Study design: A total of 100 women were prospectively enrolled and randomised to receive either infiltrative anaesthesia or a self-administered nitrous oxide mixture (Livopan©) for pain relief during postpartum perineal suturing. Besides data concerning anaesthesia, characteristics of patients and labour were documented for statistical analysis. Pain experienced during perineal repair was assessed using the short form of the McGill Pain Questionnaire (SF-MPQ).
Results: Forty-eight women received nitrous oxide and 52 underwent perineal suturing after infiltrative anaesthesia. There were no statistically significant differences regarding maternal age, body mass index (BMI), duration of pregnancy and suturing time between the groups. The most frequent birth injury was second-degree perineal laceration in the study group [22/48; 46%] and episiotomy in the control group [18/52; 35%]. Pain experienced during genital tract suturing and patients' satisfaction showed no statistically significant differences between the groups. Thirty-seven women in the study group and 47 in the control group were satisfied with the anaesthesia during perineal repair and would recommend it to other parturients [37/48, 77% vs. 47/52, 90%; $p = 0.0699$).
Conclusion: Nitrous oxide self-administration during genital tract suturing after vaginal childbirth is a satisfactory and effective alternative to infiltrative anaesthesia.

1. Introduction

Although in recent years the episiotomy rate has declined in developed countries, overall rates of genital tract trauma after vaginal delivery remain high [1–3]. Information about the incidence of perineal trauma after childbirth is inconsistent but recently published series show an increase in childbirth-related trauma in the course of time [4,5]. Surprisingly, published investigations concerning maternal postpartum trauma to the genital tract concentrate on material and methods of perineal repair, and studies referring to the anaesthesiologic management are scarce.

Nitrous oxide (NO) as an anaesthetic has a history of approximately two centuries [6]. Advantages of NO are its rapid onset, short duration of analgesia, anxiolysis and low incidence of complications [7]. A stable mixture of NO and oxygen in equal proportions in a single cylinder for reduction of pain during labour outside the operation theatre was first introduced 1961 by Tunstall [8]. Over time, this equimolecular mixture of oxygen and nitrous oxide (EMONO) has been successfully administered without any serious adverse events in multiple clinical settings including peripartum anaesthesiologic management [9–13]. In modern obstetric practice NO is used to a great extent only for reduction of labour pain [13,14]. The increased use can be attributed to the ease of administration, lack of flammability, absence of pungent odour, minimal toxicity, minimal depression of the cardiovascular system, lack of effect on uterine contractility and the fact that NO does not trigger malignant hyperthermia [13,14]. The extent of use of NO for labour analgesia differs among countries. Since the 1980s NO for labour analgesia has disappeared in the United States [14]. In Great Britain authors estimate that NO is used in 50–75% of parturients for labour analgesia, similar to Finland with 60% [15,16]. NO is also widely used in obstetrics in New Zealand, Australia and Canada [17].

Infiltrative anaesthesia is probably the most common anaesthesiological approach to achieve analgesia during perineal suturing after childbirth. Although local infiltration remains the

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standard anaesthesia during minor surgery, NO continues to be a valuable alternative in various minor surgical settings, particularly in children [7]. EMONO self-administration is an easy to use, painless anaesthetic with absence of distortion of wound margins in laceration repair due to oedema. Earlier investigations of NO in obstetrics mainly addressed the second stage of labour yielding conflicting results, without being able to quantify NO's analgesic effects [13], but many authors investigating NO for reduction of labour pain describe parturients being content with this type of analgesia and experiencing significant pain relief [13].

To our knowledge the effectiveness of EMONO in parturients requiring postpartum perineal suturing has not been investigated. We therefore designed a randomised trial comparing the effectiveness of EMONO (Livopan®) to conventional infiltrative anaesthesia with prilocaine hydrochloride (Xylonest® 1%) in perineal repair.

2. Materials and methods

Between November 2012 and February 2013, 100 women with childbirth-related injuries, independent of the duration of pregnancy, were included in this prospective study at the Department of Obstetrics of the University Medical Centre Mannheim.

The study was approved by the Ethics Committee II of the Medical Faculty Mannheim, Heidelberg University (2012-205N-MA). Written informed consent was obtained from all participating women. Exclusion criteria were epidural anaesthesia, maternal age below 18 years, multiple pregnancy, fourth degree perineal tear, insufficient knowledge of the German language preventing adequate consent, and previous adverse reaction to local anaesthetics or nitrous oxide. Written information about the investigation was provided and women were assigned to either group randomly. Allocation was accomplished according to the maternal date of birth. Parturients born in the months from January till June were allocated to the study group and women born from July till December were allocated to the control group.

The study group consisted of 48 women using self-administered 50% nitrous oxide (Livopan®, Linde GmbH, Bochum, Germany) for pain management. The 52 women serving as control group had a local infiltrative anaesthesia with up to 20 ml prilocaine hydrochloride (Xylonest® 1%, AstraZeneca GmbH, Wedel, Germany). In the study group women started inhalation of NO 5–10 min before perineal suturing was begun. If necessary patients in both groups received additional anaesthesia with prilocaine hydrochloride 1% on request. For women in the study group additional infiltrative anaesthesia was applied in the event of insufficient analgesia or non-toleration of the mask. In the control group additional infiltrative anaesthesia was given in the event of insufficient analgesia.

Vaginal, vulval and perineal lacerations were categorised according to Williams Obstetrics [18]. Suturing was accomplished with subcuticular continuous stitches using an absorbable 3–0 vicryl suture (Ethikon®, Johnson & Johnson Medical GmbH, Norderstedt, Germany) according to Hirsch [19]. In our department only mediolateral episiotomies at the height of a contraction are performed. These were not performed routinely, neither in spontaneuous birth nor with vacuum extraction.

Besides data concerning anaesthesia, the characteristics of patients and labour were documented for statistical analysis. Maternal parameters included age, type of delivery and birth injury, body mass index (BMI), duration of suturing, gravity and parity. Concerning neonatal entities, head circumference, birth weight and gestational age were recorded. In the study group the womens' tolerance of the inhalation mask, side effects of NO and necessity for additional local anaesthesia were analysed. In the control group the need for more than 20 ml prilocaine hydrochloride was documented.

Additionally, time of surgery was recorded, and immediately after surgery patients filled in a standardised pain questionnaire concerning the pain experienced during perineal suturing.

The questionnaire used was the short form of the McGill Pain Questionnaire (SF-MPQ), which contains three sections: a list of 15 pain-describing terms recording the intensity of types of pain experienced, an analogue scale, and a six-point Present Pain Intensity Index (PPI) [20]. The pain-describing section (McGill 1) is divided into 11 sensory pain descriptors and 4 affective pain descriptors with a 0–3 scale (marked 'none', 'mild', 'moderate', and 'severe'), so that potential score ranges were 0–33 and 0–12. The second section (McGill 2) is an analogue scale ranging from 0 to 100, indicating no pain to worst possible pain. The third component (McGill 3) is a six-point PPI with the scores 0 = no pain, 1 = mild, 2 = discomforting, 3 = distressing, 4 = horrible, 5 = excruciating. The scores of these three sections are added in order to obtain a total score (McGill total).

All data were recorded in an Excel datasheet. After a careful check for faulty entries and extreme values, the data were transferred into the SAS®-environment (Statistical Analysis System, Release 9.2) for subsequent statistical analysis. Quantitative data were presented as arithmetic mean and standard deviation respectively median and range, qualitative data as frequencies. Comparisons between study and control groups were made using univariate tests (*t*-test and chi square test). A *p*-value below 0.05 was considered statistically significant. Distributional issues such as normality of data have not been addressed explicitly as this question cannot be properly investigated within our study environment given the limited sample size. Nevertheless, all tests for quantitative variables have been performed both parametric and non-parametric yielding highly similar significance results. We decided to present parametric results only.

3. Results

Demographic and labour characteristics are depicted in Table 1. Both groups showed no statistically significant differences concerning maternal age (p-value = 0.5072), BMI (p-value = 0.3032), duration of pregnancy (p-value = 0.8903), suturing time (p-value = 0.7091), birth weight (p-value = 0.1981) or neonatal head circumference (p-value = 0.4695).

Although it was not an exclusion criterion in our study, no patient in either group underwent forceps delivery. Vacuum extraction was performed in 10 patients of the study and 14 of the control group [10/48, 21% vs. 14/52, 27%; p-value = 0.476]. Thirty-eight patients in each group had a spontaneous delivery [38/48, 79% vs. 38/52, 73%; p-value = 0.476].

In the NO group 23 [23/48; 48%], and in the infiltrative anaesthesia group 26 [26/52; 50%] women had had a previous vaginal delivery.

Pain experienced during perineal suturing was determined by the McGill (short form) pain questionnaire as explained above. The obtained scores are depicted in Table 2 and showed no statistically significant differences for McGill 1 (p-value = 0.641), McGill 2 (p-value = 0.453), McGill 3 (p-value = 0.933) and McGill total (p-value 0.467).

Thirty-seven patients of the study group and 47 patients of the control group were satisfied with anaesthesia during perineal repair and would recommend it to other parturients [37/48, 77% vs. 47/52, 90%; p-value = 0.0699].

Additional prilocaine hydrochloride was necessary in 15 patients of the study and 1 parturient of the control group [15/48, 31% vs. 1/50, 2%; p-value < 0.0001].