Midwifery 30 (2014) 36–42

Contents lists available at ScienceDirect

Midwifery

journal homepage: www.elsevier.com/midw

Subcutaneous administration of fentanyl in childbirth: An observational study on the clinical effectiveness of fentanyl for mother and neonate

Julie Fleet, BA App Sc (Dev Dis), Grad cert (Rehab), BMid (Hons), RM (PhD candidate)*, Meril Jones, RN, BSc (Hons) PhD (Senior Lecturer), Ingrid Belan, BSc, PhD (Senior Lecturer)

School of Nursing & Midwifery, Flinders University, GPO Box 2100, Adelaide, South Australia, Australia

ARTICLE INFO

Article history:
Received 21 February 2012
Received in revised form
19 January 2013
Accepted 22 January 2013

Keywords:
Fentanyl
Pain relief
Labour
Subcutaneous

ABSTRACT

Objective: to explore the maternal and neonatal effects of fentanyl administered subcutaneously to women during labour.
Design: two methods were used: (1) A retrospective audit of the birth register and maternal and neonatal records for the period from January 2000 to December 2007. (2) A pilot study was also conducted on a convenience sample of women between July 2008 and October 2008.
Setting: this study was conducted within a maternity unit at a rural South Australian hospital where approximately 350 babies are birthed each year.
Participants: audit participants included women who had uncomplicated pregnancies and birthed at term (37–42 weeks gestation). Women in the experimental group consisted of those who had utilised only subcutaneous fentanyl for pain relief ($n=75$), or nitrous oxide and oxygen prior to being administered subcutaneous fentanyl ($n=196$). Stratified random selection based on parity and age was used to determine the control group, which consisted of women who used no pharmacological pain relief ($n=196$).

The pilot study involved a convenience sample of women ($n=10$) assessed to have an uncomplicated pregnancy and labour occurring at term (≥ 37 weeks gestation).
Measurements: audit variables examined included the women's age, parity, labour duration, mode of birth (spontaneous or assisted), analgesia used, total dosage, time administered prior to birth, time of birth, neonatal Apgar scores, time to establish breathing, naloxone use, days spent in hospital post-birth and breast-feeding outcomes upon discharge.

The pilot study explored maternal effects assessed pre- and 30 minutes post-administration of subcutaneously administered fentanyl by observing pain scores, vital signs, sedation levels, nausea/vomiting scores and anti-emetic use. To assess possible adverse effects in the neonate Apgar scores, time to establish respiration, naloxone use, transfer to neonatal nursery and breast-feeding outcomes upon discharge were recorded.
Findings: women in the experimental groups were more likely to be induced, experienced a longer duration of labour and had an increased likelihood of an assisted vaginal birth. The average total dose of fentanyl administered was 250 μg. Neonatal outcomes were comparable between groups when examining Apgar scores <7 at 1 and 5 minutes and time to establish breathing. There was, however, a significant difference with naloxone administration between the groups. There was no significant difference between groups in hospital stay or breast-feeding on discharge.

The pilot study identified a clinically significant reduction in pain scores for 78% of women following the administration of subcutaneous fentanyl, with the average pain score decreasing from 8.4 (± 1.4) to 7.2 (± 1.1) (paired t-test, $p=0.017$). Vital signs were not affected, no anti-emetics were required and all women remained alert with no sedation noted.
Key conclusions: the audit identified fentanyl use was associated with a longer length of labour, but this may be explained by more women in the experimental groups requiring induction of labour than those in the control group. However, length of hospital stay, breast-feeding rates and neonatal outcomes were comparable amongst the three groups.

Results of the pilot study are consistent with those of the audit in relation to the effects on mother and neonate. In addition, the pilot study begins to provide evidence that fentanyl is efficacious in providing pain relief.

* Corresponding author
E-mail address: julie-anne.fleet@flinders.edu.au (J. Fleet).

http://dx.doi.org/10.1016/j.midw.2013.01.014

Implications for practice: results of this study are the first to explore the effects of fentanyl administered subcutaneously to women during labour. This method of analgesia offers women an additional choice of pain relief during childbirth and may be particularly beneficial in remote and rural settings where resources are often limited and access to specialist services difficult. Further research, however, is required to be able to generalise the outcomes and provide further data to support the clinical effectiveness of this route of administration of fentanyl.

Introduction

Although the majority of women in labour choose to use pharmacological pain relief there has been an ongoing debate about efficacy and the clinical effectiveness of each method (Jones et al., 2012). Although epidural analgesia is known to provide effective pain relief, epidurals are associated with adverse effects (Jones et al., 2012), maybe contraindicated or provide inadequate pain relief (Agaram et al., 2009). In addition, not all facilities have access to 24 hour anaesthetic services. In these situations women may be offered an opioid to manage the pain of labour. Recent statistics showed that 19.1% of South Australian (SA) women received a parenterally administered opioid in labour (Chan et al., 2011).

Pethidine remains the most widely used parenterally administered opioid for the relief of labour pain (Bricker and Lavender, 2002; McCool et al., 2004; Althaus and Wax, 2005; Sosa et al., 2006; Douma et al., 2010). However, when multiple doses are administered there are increased risks to the neonate (Kuhnert et al., 1985). This, in part, relates to the active metabolite norpethidine which is only partially antagonised by naloxone. These adverse effects are problematic in rural areas when access to anaesthetic and neonatal services is limited. One alternative to pethidine may be the use of fentanyl. In a study comparing intravenous (IV) fentanyl with IV pethidine for analgesia in labour, it was concluded that fentanyl was preferable, because it was associated with fewer maternal and immediate neonatal adverse effects (Rayburn et al., 1989b). Fentanyl metabolism does not result in the formation of an active metabolite and the terminal elimination half-life in the neonate is 5.3 hours (Koehntop et al., 1986), compared with pethidine's metabolite, norpethidine, which has a half-life of approximately 60 hours (Kuhnert et al., 1985).

Fentanyl administered via intermittent subcutaneous injection, in settings such as palliative, paediatric, and post-operative care, have been reported to provide effective pain relief with few adverse effects (Hunt, 1999; Dietrich and Tobias, 2003; Capper et al., 2010). Over the past 15 years, in an attempt to improve birth outcomes and reduce the number of resources required, several rural South Australian (SA) hospitals have been administering fentanyl via the subcutaneous route when women request pain relief during childbirth. The clinical effectiveness of this method of analgesia during labour, however, has not been examined (Fleet et al., 2011).

The aim of this study was to investigate the practice of administering fentanyl subcutaneously by conducting a retrospective audit of maternal and neonatal records. As data regarding the efficacy of subcutaneously administered fentanyl for pain relief during childbirth was not available in the medical records, a pilot study that examined efficacy and explored possible maternal and neonatal adverse effects was conducted.

Methods

There are two components to this study: a retrospective audit and a pilot study.

Design

1. *Audit*: A non-experimental retrospective audit of medical records conducted during the period from January 2000 to December 2007.
2. *Pilot study*: A non-experimental pilot study was conducted on a convenience sample of women between July 2008 and October 2008.

Setting

This study was conducted in a maternity unit within a SA rural hospital where approximately 350 babies are born each year. Maternity care was provided by four obstetrically trained general practitioners, an obstetric consultant, midwives and physiotherapists.

Ethics

Ethics approval was granted by the Flinders University Social and Behavioural Research Ethics Committee (SBREC) and by the SA rural hospital's Neonatal and Maternal Committee.

Participants

Audit

The participants for the experimental groups were selected from a total of 418 women who had been administered subcutaneous fentanyl for pain relief during childbirth from the dates January 2000 until December 2007. All women birthing in this rural hospital were considered low risk and birthed at term (37–42 week gestation). Women who used fentanyl, in addition to nitrous oxide and oxygen (N_2O+O_2) and/or epidural and/or spinal or pethidine ($n=147$), were excluded from analysis due to confounding factors. This included women who had been administered fentanyl subcutaneously due to ineffective epidural block or while awaiting preparation for theatre. The remaining 271 women were evaluated as follows: a fentanyl only group ($n=75$), who utilised only subcutaneously administered fentanyl for pain relief and a second group of women who utilised N_2O+O_2 prior to the subcutaneous administration of fentanyl ($n=196$). Data for the two subgroups were then compared to a control sample of 196 women who also birthed within this same rural SA hospital during this period, but had not used pharmacological pain relief during labour.

As 657 women met the criteria for the control group, a stratified random selection based on parity and age was used to determine these participants. As more women who birthed without using pharmacological pain relief were of multiparity, the control sample size ($n=196$) was used to match the larger experimental group and enabled the ratio between primiparity and multiparity to be similar between both experimental groups.

The sample size required for the study was estimated for an ANOVA design involving three groups (control and two subgroups) using the software programme G Power 3.1. A total