



## Nurse practitioner led pain management the day after caesarean section: A randomised controlled trial and follow-up study



Anthony Schoenwald<sup>a,b,c,\*</sup>, Carol Windsor<sup>b,c</sup>, Edward Gosden<sup>c</sup>, Clint Douglas<sup>b,c</sup>

<sup>a</sup> Department of Nursing & Midwifery, Ipswich Hospital, P.O. Box 73, Ipswich, QLD 4305, Australia

<sup>b</sup> Queensland University of Technology, School of Nursing, Victoria Park Road, Kelvin Grove, QLD 4059, Australia

<sup>c</sup> Institute of Health and Biomedical Innovation, Queensland University of Technology, 60 Musk Avenue, Kelvin Grove, QLD 4059, Australia

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### ABSTRACT

**Background:** Pain on the day after caesarean section is often treated with controlled-release oxycodone to supplement the decline in analgesia from intrathecal opioids. Evidence suggests that caesarean birth is a biopsychosocial experience where a comprehensive approach is needed that promotes control and participation in pain management.

**Objectives:** This study compared immediate-release oxycodone integrated with supportive educational strategies to controlled-release oxycodone. A follow-up phase aimed to explore pain over three months.

**Design:** This study was a two-group parallel randomised controlled trial.

**Setting:** A metropolitan hospital in Australia with a birthing suite, operating rooms, and a postnatal unit.

**Participants:** English-speaking women scheduled for elective caesarean section were mailed trial information. Exclusion criteria included contraindications to intrathecal analgesia, herpes simplex infection, a history of chronic pain, opioid tolerance, or substance abuse. A total of 131 participants were recruited and randomised out of 298 eligible participants.

**Methods:** Group allocation was undertaken using sequentially numbered opaque sealed envelopes. The nurse practitioner intervention commenced on the day after surgery with immediate-release oxycodone alongside supportive strategies. The control group received scheduled doses of controlled-release oxycodone. All participants could request additional oxycodone or tramadol. Primary outcomes were pain intensity and secondary outcomes included patient global impression of change, pain interference, opioid consumption, and maternal perception of control. A follow-up phase evaluated pain outcomes over three months.

**Results:** The final sample size was 122, with 61 participants in each group. Pain intensity scores were analysed by linear mixed regression models. There were no statistical differences over 24 h between the control and intervention groups at rest ( $p = 0.40$ , 95% CI – 4.8 mm, 11.9 mm) or on sitting or moving ( $p = 0.561$ , 95% CI –15.2 mm, 8.3 mm). Patient global impression of change was significant over three hours ( $p = 0.014$ , OR = 2.5, 95% CI 1.2, 5.3). The intervention group reported less pain interference while consuming less oxycodone ( $p < 0.05$ ). There was no difference between groups in terms of perceived control over pain management ( $p = 0.273$ , 95% CI –16.2 mm, 4.6 mm). The follow-up analysis graded 5.9% of participants as experiencing severe pain interference. Chronic pain following caesarean was associated with postnatal depression ( $p < 0.001$ ).

**Conclusions:** The research showed that a nurse practitioner intervention can improve pain management following caesarean section. The results underscore the influence of biological, psychological, and social factors on acute pain. Hence, this study reinforces the need for a biopsychosocial approach to acute pain management following caesarean delivery.

#### What is already known about the topic?

- Caesarean section is a painful experience for many women who find

it difficult to mobilise and care for their babies.

- The experience is complex and is influenced by biological, psychological and social factors.

\* Corresponding author at: Department of Nursing & Midwifery, Ipswich Hospital, P.O. Box 73, Ipswich, QLD 4305, Australia.

E-mail addresses: [Anthony.Schoenwald@health.qld.gov.au](mailto:Anthony.Schoenwald@health.qld.gov.au) (A. Schoenwald), [c.windsor@qut.edu.au](mailto:c.windsor@qut.edu.au) (C. Windsor), [edward.gosden@qut.edu.au](mailto:edward.gosden@qut.edu.au) (E. Gosden), [c2.douglas@qut.edu.au](mailto:c2.douglas@qut.edu.au) (C. Douglas).

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- Oral oxycodone is a common analgesic used to manage pain following caesarean section.

### What this paper adds

- Nurse practitioners are well positioned to provide effective individualised analgesia and supportive care that can reduce the impact of pain following caesarean section.
- Many factors influence pain outcomes following caesarean section that have implications for pain management including maternal control and participation, maternal catastrophising, and postnatal depression.
- This study's findings provide additional support for a biopsychosocial approach to the evaluation and management of caesarean pain.

## 1. Introduction

Pain following caesarean section is a complex problem that interferes with maternal recovery and function (Chin et al., 2014; Karlstrom et al., 2007; Schyns-van den Berg et al., 2015; Zanardo et al., 2010). On the day after surgery, caesarean pain is often worse than other major surgical procedures (Gerbershagen et al., 2013), including abdominal or vaginal hysterectomy (Marcus et al., 2015). The reasons are multifactorial and include the type of surgical incision, a previous negative experience, and catastrophising about pain (Dehghani et al., 2014; Ortner et al., 2013). Compared to vaginal delivery, women might also experience loss of control over decision-making (Fenwick et al., 2003; Fisher et al., 1997; McAra-Couper et al., 2010) and receive less pain relief due to an expectation that they mobilise and perform infant care regardless of pain (Marcus et al., 2015). Poor analgesia can also result from the diminished effect of intrathecal opioids at the time women are expected to mobilise (Karlstrom et al., 2010). Randomised controlled trials have not considered the transition phase from intrathecal opioid analgesia to oral opioids following caesarean section, or controlled for the influence of psychosocial factors on pain outcomes.

According to the International Association for the Study of Pain, caesarean section is high risk surgery for the development of chronic postsurgical pain (IASP, 2011). Poor postoperative analgesia and pain interference with usual activities (Chin et al., 2014; Karlstrom et al., 2007; Zanardo et al., 2010) can lead to psychological problems such as postpartum depression that potentiate this risk (Eisenach et al., 2008; Hiltunen et al., 2004; Lou and Kong, 2012). Furthermore, caesarean surgery may contribute to the development of neuropathic pain due to nerve trauma (Landau et al., 2013; Loos et al., 2008; Ortner et al., 2013; Richez et al., 2015). These problems, either individually or combined, can result in chronic pain and disability (Niklasson et al., 2015; Liu et al., 2013; Nikolajsen et al., 2004). Thus, the design of this study conceptualised acute pain broadly and over time to address the complexities of the experience (Edoziem, 2015; Lowe, 2002; McNeil and Jomeen, 2010; Turk et al., 2010).

For postoperative pain management, a one-size-fits-all approach with scheduled analgesic doses may not address the complexity of the pain experience that is marked by individual variation in pain response and analgesic requirements (Turk et al., 2010). Pain interventions with multiple components, therefore, may be more effective as individual uniqueness is considered in terms of knowledge about analgesics and participation in postoperative pain management (Jensen et al., 2015; Moseley and Butler, 2015; Turk and Okifugi, 2002). It has also been proposed that improved postoperative outcomes can be achieved through greater patient control and participation in decision-making about the administration of analgesics (Kaptain et al., 2016; Zoega et al., 2014). In Australia, nurse practitioners use advanced health assessment skills to safely prescribe analgesics (Australian Health Practitioner Regulation Agency, 2016; Cashin et al., 2014; Schoenwald, 2011). Because acute pain management occurs within a social context (Keefe, 2009), nurse practitioners can also interact with women to

foster participation and control over analgesic therapy, and reduce the impact of acute pain (Hobson et al., 2006; Kitzingier, 2012; McNeil and Jomeen, 2010; Turk et al., 2010; Wiech et al., 2006).

Oxycodone is the most common opioid analgesic used after caesarean section and is standardised care in many settings after intrathecal morphine or other interventions have lost effect (Davis et al., 2006; Dieterich et al., 2012; McDonnell et al., 2010; Seaton and Reeves, 2009; Zhong et al., 2014). Unlike controlled-release oxycodone, the immediate-release formulation can assist women to plan times of mobilisation and other activities in line with the predicted shorter time to maximum concentration (Aspen, 2017; Mundipharma, 2017). Thus, knowledge of the pharmacology of oxycodone might reduce pain interference with mobilisation and the ability to care for a baby. It also has a shorter duration of action (Aspen, 2017). Women can request it intermittently every 3–4 h to hasten analgesia and reduce pain interference depending on the level of activity required.

Only two studies have compared immediate-release oxycodone to other therapies following caesarean section. Davis and others found that this formulation of oxycodone, as a combination tablet with paracetamol, was comparable to intravenous patient-controlled analgesia in terms of analgesia at 24 h (Davis et al., 2006). An Australian trial compared a schedule of immediate-release oxycodone (following 20 mg of controlled-release oxycodone) to intrathecal morphine and found that oral oxycodone could provide comparable analgesia when measured over 24 h (McDonnell et al., 2010). While these trials demonstrated the effectiveness of immediate-release oxycodone for caesarean pain, the conclusions were based on pain intensity scores alone. Furthermore, the influence of other factors that can affect pain perception following caesarean section were not controlled for in the statistical analyses.

For acute pain management, the evidence and clinical guidelines support the use of immediate-release oxycodone over other formulations (Analgesic Expert Group, 2012). No studies have integrated oral oxycodone with other strategies to improve outcomes following caesarean delivery and many interventions to reduce pain have centred around invasive procedures (Booth et al., 2016; Kainu et al., 2012; Larsen et al., 2015; Mishriky et al., 2012). Moreover, the days following have received little attention in terms of the effectiveness of oral pain interventions or the impact of pain over the months ahead.

### 1.1. Objectives

The aim of this randomised controlled trial was to compare a nurse practitioner intervention to a standard prescription of controlled-release oxycodone in the context of diminished opioid analgesia from intrathecal morphine. Participants were followed-up to explore the experience of pain and how pain impacts on maternal health over three months. Thus, two research questions formed the platform for this research:

1. Does a nurse practitioner intervention result in improved analgesia on the day after caesarean section when compared to standard management with controlled-release oxycodone?
2. What is the experience of postsurgical pain over three months following caesarean section?

## 2. Design and setting

The setting was a metropolitan public hospital in Australia. The hospital had a birthing suite and a postnatal unit with 34 beds. There were seven operating theatres and an intensive care unit. Postoperative pain management was governed by an acute pain service staffed by three nurses (including a nurse practitioner) with occasional medical support for five out of seven working days. The intervention was delivered by one nurse practitioner (first author) who was not involved with the care of participants in the control group.

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