Comparative Study Between Intravenous Paracetamol And Tramadol As Intrapartum Analgesia In Primigravida A Randomized Controlled Trial

Thesis

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فى أمراض النساء والولادة

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List of Abbreviations

Abbreviation	Meaning
BMI .....:	Body mass index
CNS.....:	Central nervous System
DDI.....:	Dose- delivery interval
CS .....:	Cesarean section
CSE .....:	Combined Spinal-Epidural
IM .....:	Intramuscular
IQR.....:	Inter-quartile range
L_1.....:	Lumbar 1 vertebra
NSAID .....:	Non-Sterioidal Anti-Inflammatory Drug
NVD.....:	Normal vaginal delivery
S_2.....:	Sacral 2 vertebra
PTSD.....:	Post-Traumatic Stress Disorder
SD .....:	Standard Deviation
SPSS.....:	Statistical Package of Social Science
T1/2 .....:	Half life
T_{10}.....:	Thoracic 10 vertebra
TENS.....:	Transcutaneous Electrical Nerve Stimulation
UK.....:	United Kingdom
USA.....:	United States of America
VAS.....:	Visual Analog Scale
WHO .....:	World Health Organization

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Introduction

Pain during childbirth is one of the most *excruciating* pain experiences that women encountered in their lives ***(Eeriksson et al., 2006).*** Stretch of the cervix during dilatation, ischemia of the muscle wall of uterus with buildup of lactate, and stretch of the vagina and the perineum during the second stage of labour are probable causes of labour pain ***(Rouholamin and Hekmat, 2012).*** Fear of childbirth has been associated with longer first and second stage of labour and dissatisfaction with the childbirth experience ***(Saisto et al., 2001).*** Fear of childbirth has also been implicated in women's requests for caesarean sections and a resultant increased rate of caesarean sections ***(Eriksson et al., 2006).***

Adequate analgesia during labour has a positive influence on the course of labour. Most women who deliver in modern obstetric units request some form of pharmacological and non-pharmacological pain relief. The ideal obstetric analgesic should provide potent analgesic efficacy with minimal maternal and neonatal adverse effects. Epidural analgesia offers the best pain relief for many women in labour. But when it is contraindicated or woman does not wish to have an epidural analgesia, administration of

injectable opioids such as pethidine or Tramadol hydrochloride or injection of non-opioids as acetaminophen is a simple and less invasive alternative ***(Khooshideh and Shahriari, 2009).***

Tramadol hydrochloride is a synthetic analogue of codeine and has analgesic efficacy similar to opioid, acting by modifying transmission of pain impulse by altering mono amine reuptake mechanisms ***(Khooshideh and Shahriari, 2009).***

Tramadol can be administrated orally, rectally, intra-venous or intramuscular, and it is principally metabolized in the liver and 90% of it is excreted in urine (**Lee et al., 1993**). Transdermal delivery is a new modality of administration of tramadol offering a dual additional opportunity over all its well-known advantages ***(Hussein et al., 2009).***

Paracetamol (N-acetyl-P-aminophenol)is one of the most commonly prescribed analgesic for the treatment of acute pain and the efficacy of single-dose paracetamol as an intrapartum analgesic has been confirmed by various studies ***(Pandya, 2015).***

It provides onset of pain relief within 5 to 10 minutes after start of administration. The peak analgesic effect is

obtained in 1 hour and the duration of this effect is usually 4 to 6 hours ***(Sachs, 2005).***

Acetaminophen has no known indigenous binding sites and doesn't inhibit peripheral cyclooxygenase (COX) activity significantly ***(Kilicaslan, 2010).*** There is increasing evidence of a central anti-nociceptive effect, and the potential mechanisms for this include inhibition of central nervous system COX-2, inhibition of alleged central COX-3 that is selectively susceptible to acetaminophen and modulation of inhibitory descending serotonergic pathways ***(Koppert et al., 2004).***

Paracetamol provides effective analgesia in laboring patients in the absence of any side effects. In addition, the drug may be associated with reduced duration of labor. Thus, intravenous paracetamol may serve as an alternative to opioids for providing effective analgesia in laboring women ***(Elbohoty, 2012).***

In the last two decades, the visual analogue scale (VAS) has become one of the most popular methods for measurement of pain intensity. The VAS consists of a 10 cm line anchored by two extremes of pain, usually "no pain" and "unbearable pain" (or a similar verbal descriptor representing the upper pole). The patient is asked to make a

vertical mark through the line corresponding to the intensity of pain. The scale is scored by measuring the distance in mm from (no pain) to the patient's mark simple and reproducible ***(Rawer and Alvin, 1998).***

The visual analogue scale (VAS) is easy to use, provides reproducible results and is applicable to a variety of practice settings. It is also sensitive to treatment effects and the data derived can be analyzed using parametric statistical techniques ***(Todd, 1996).***

Aim of the Work

Primary outcomes:

The aim of this study is to compare the efficacy of intravenous infusion of paracetamol with IM tramadol as intrapartum analgesia, as demonstrated by the degree of pain relief.

Secondary outcomes:

1. To document safety and evaluate adverse events recorded during the study either maternal or neonatal.
2. Subsequent need of additional analgesia.

Research hypothesis:

primigravida in labour, Paracetamol may be effective as tramadol in relieving of labour pain with fewer side effects.

Research question:

In primigravida in labour does paracetamol effective as tramadol in relieving of this pain?

Primary outcomes:

This study aims to compare between the efficacy of intravenous infusion of paracetamol with IM tramadol as intrapartum analgesia in primigravida ,as demonstrated by the degree of pain relief.

Secondary outcomes:

1. To document safety and evaluate adverse events recorded during the study either maternal or neonatal.
2. Subsequent need of additional analgesia.