Efficacy of Subcutaneous Sterile Water Injection In Pre-Sacral Region Versus Intra Muscular Diclofenac Sodium For Pain Relief After Caesarean Section

Thesis

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By

Marwa Hammad Yousef Gad
M.B.B.Ch Cairo University 2004
Resident of Obstetrics and Gynecology
EL Fayoum General Hospital

Under supervision of

Prof. Ahmed Mohamed Nour Eldin Hashaad
Professor of Obstetrics and Gynecology
Faculty of Medicine
Ain Shams University

Prof. Magdy Hassan Ahmed Kolaib
Professor of Obstetrics and Gynecology
Faculty of Medicine
Ain Shams University

Dr. Ahmed Elsayed Hassan Elbohoty
Lecturer in Obstetrics and Gynecology
Faculty of Medicine
Ain Shams University

Ain Shams University
Faculty of Medicine
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تحت إشراف

الأستاذ الدكتور/أحمد محمد نور الدين حشاد

أستاذ أمراض النساء والتوليد

كلية الطب- جامعه عين شمس

الأستاذ الدكتور/ مجدى حسن أحمد كليب

أستاذ أمراض النساء والتوليد

كلية الطب-جامعه عين شمس

الدكتور/أحمد السيد حسن البهوتى

مدرس أمراض النساء والتوليد

كليه الطب-جامعه عين شمس

كليـة الطب

جامعه عين شمس

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List of abbreviations

ACOG	American College of Obstetricians and Gynecologists.
BMI	Body mass index
C(Max)	Maximum plasma concentration
CNS	Central nervous system
Cox	Cyclooxygenase
CRF	Case record form
DNICS	Diffuse noxious inhibitory controls
GA	Gestational Age
HPBCD	Hydroxy Propyl B-Cyclodextrin Complexed Diclofenac
IASP	International association for study of pain
LAS	Lower Abdominal surgery
MPQ	McGill pain questionnaire
NRS	Numerical rating scale
NSAIDS	Non steroidal anti-inflammatory drugs
PAC	Patient controlled analgesia
PFC	Pain face scale
PG-BA	Propylene Glycol and Benzyle Alcohol
PGE2	Prostaglandin E2
PSIS	Posterior superior iliac spine
S*	Significant

List of abbreviations (Cont.)

SD	Standard deviation
SPSS	Statistical package for the social science
TAP	Transversus abdominus plain
TENS	Transcutenous electrical nerve stimulation
VAS	Visual analogue scale
VRS	Verbal rating scale
WHO	World Health Organization

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Introduction

Over the last two decades the number of caesarean sections being performed has increased dramatically ***(Villar et al., 2006).***

Childbirth is an important experience in a woman life**,** so high quality postoperative analgesia is important because the new mother has to recover from major intra-abdominal surgery , also caring for her newborn baby (***Goodman et al., 2004 ;WHO, 2006).***

The American College of Obstetricians and Gynecologists (ACOG) and American Society of Anesthesiologist issued a joint statement indicating that a women's request for pain relief is sufficient medical indication for pain relief ***(ACOG. 2002).***

Analgesic medication either pharmacological or non pharmacological methods, pharmacological methods commonly used for postoperative pain relief after caesarean section either opioids or non opioids and non pharmacological methods include many techniques that reduce painful stimuli, as used for management of low back pain in labor (***Pellegrini, 1998 ;Simkin and Hara, 2002).***

Centrally acting opioid drugs such as, morphine or its derivatives are usually used to achieve postoperative pain relief, but it associated with side effects such as, itching, nausea, vomiting, sedation and respiratory depression ***(Raffaeli et al., 2006).***

Diclofenac sodium, a potent prostaglandin synthesis inhibitor, it is one of Non Steroidal Anti-Inflammatory analgesics that is particularly effective against the visceral pain that arises from uterine incision following caesarean section

(Dahl et al., 2004). They have a well-documented opioid-sparing effect, but it associated with adverse effects, such as peptic ulceration, gastritis, renal impairment and in addition, these drugs are excreted in mother milk "small amount" **(*Olofsson et al., 2000; Hale et al., 2004)***.

An idea post-caesarean analgesic regiment would be one that was cost-effective, simple, have high quality pain relief but have low incidence of side effects and complications, also it would not interfere with the maternal care of newborn or with the establishment of breast feeding and would be minimal drug transfer into breast milk ***(Yost et al., 2004;Lavand' home, 2006).***

Sterile water injection is a simple and inexpensive way to provide a medication – free option to women who want to either avoid or delay use of opioid or non opioid analgesia ***(Martenssom et al., 1995).***

Subcutaneous injection technique in presacral region is less painful than intracutaneoas technique and is shown to be more tolerable for patients ***(Martensson el al., 2000).***

Cutaneous sterile water injection was showed to be effective in reducing low back pain in laboring women without side effects on fetus or mother ***(Bahasadri et al., 2006).***

Injection of sterile water stimulates nociceptors and has action resembles acupuncture ***(Ader et al., 1990).***

Counterirritation, the phenomenon of one painful stimulus reducing pain caused by a second noxious stimulus, may explain the pain reducing effect of sterile water injection and a cupuncture ***(Melzack, 1975)***. Diffuse noxious inhibitory controls (DNICS) is the inhibition of multireceptive neurons in dorsal horn of spinal cord, so pain is reduced in body regions

remote from those at which stimuli are presented ***(Le Bars, 1979***).

Many studies have concluded that injection of sterile water in presecral region was effective in relief of low back pain during labour ***(Hutton et al., 2009)***, so we did this study to show the analgesic effect of subcutaneous injection of sterile water on Egyptian women after caesarean section, one of important Obstetrics operations.

Aim of the work

Primary Objective

To compare the efficacy of subcutaneous sterile water injection in pre-sacral region with intramuscular diclofenac sodium injection during the early postoperative period after caesarean section as demonstrated by the degree of pain relief.

Secondary Objectives

1-Subsequent need of additional analgesia.

2-To document safety and evaluate adverse events recorded during the study.

Pathophysiology of Pain

According to the International Association for the Study of Pain (IASP), pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage ***(Merskey, 2005)***.

Types of pain:

There are two distinct types of pain, both occurring after each other in response to a single stimulus, these are fast and slow pain, fast pain is short, well localized, stabbing in character, matched in intensity of the stimulus, it begins and ends abruptly and slow pain is longer in duration, diffuse, throbbing, burning, or aching in character and it is seldom matched to the intensity of the stimulus ***(Stoelting, 1993)***.

Classification of Pain: (Merskey *and Bogduck, 1994)*.

Pain can be classified according to various criteria:

- According to pathogenesis; e.g. nociceptive and neuropathic pain
- According to duration; Acute and chronic pain
- According to the site of origin; e.g. abdominal, leg pain
- According to the cause; e.g. cancer, postoperative pain

Sources of pain:

1-Nociceptive pain: Results from damaged tissues, pain caused by activation of nociceptive afferent fibers ***(Hnorio and Benzon, 2005)***.

Nociceptors:

Nociceptors are naked nerve endings of primary afferents of Aδ and C fibers, these nerve endings are widely distributed in superficial layers of the skin, being more abundant in more sensitive areas ***(Marchand***, ***2008***). All types of nociceptors are characterized by having a high threshold for impulse initiation, they do not adapt as opposed to other sensory receptors, and this non-adaptability is protective in the sense that more tissue damage produces more pain signals as pain receptors do not stop sending impulses ***(Stoelting, 1993)***

Visceral pain* (*Gebhart, 2000)

Pain arising from viscera has a number of characteristic features:

- Poorly localized, associated with nausea and autonomic disturbance.
- May be colicky, often referred to another part of the body.
- Pain is elicited by distension, ischemia and inflammation.

Somatic pain: (Merskey and Bogduck, 1994)

Sharp, stabbing pain and usually well localized to the area of injury. It results from injury of skin, mucosa, muscles, bone, tendons, arteries, ligaments and joints.

2-Neuropathic pain: Results from nerve damage or disease ***(Macintyre and Schug, 2007)***

3-Inflammatory pain

Inflammatory pain is associated with the healing process following lesion, inflammation is natural protective reaction of the organism following an injury, and inflammatory substances are released into the periphery by cells in the area of damaged tissue but can also arise from hyperactivity of the nociceptive neurons in the CNS ***(Marchand, 2008)***

Pain Pathway:

Pain is conducted along three-neuron pathways that transmit noxious stimuli from the periphery to the cerebral cortex (**Fig.** 1)**,**the primary afferent neurons which are located in the dorsal root ganglia synapse with second-order neurons that cross the midline and ascend in the contralateral spinothalamic tract to reach the thalamus, the second-order neurons synapse with third-order neurons which send projections to the cerebral cortex Stimuli **(*Morgan et al., 2002).***

Modulation of Pain:

It is the process whereby nociceptive transmission is modified through a number of neuronal influences,pain modulating mechanisms operate at different levels in the pain pathway including peripheral sensitization of nociceptors, central sensitization at the level of the spinal cord, and the action of the dorsal horn cells as a gate for control of pain transmission. Lastly, these pain modulating mechanisms are controlled by the brain inhibitory (analgesia) system ***(Woolf and Chong, 1993)***.

Tissue injury stimulates:

- Synthesis of arachidonic acid metabolites from the adjacent membranes including prostaglandins (PGs),

Cyclooxygenase enzyme is two types (Cox-1 and Cox-2), both are inhibited by acetylsalicylic acid, indomethacin and most of the NSAIDs, and thus they can induce analgesia ***(Framer and Bruch, 1992)***.

- Release of neuropeptides such as substance P and calcitonin gene related peptide from C fibers. This "inflammatory soup" which also contains histamine, serotonin, potassium ions, and hydrogen ions which activate and sensitizes the peripheral nerve endings causing vasodilatation and plasma extravasation, these results in swelling, tenderness,pain**,** potassium are responsible for C fiber activation, prostaglandins (especially PGE_2 and $PGF_{2\alpha}$) mediate continued nociceptor sensitization and an associated diminution in pain threshold ***(Raja, 1988)***.

- Substance P together with serotonin greatly increases vascular permeability, which ensures further release of bradykinin (neurogenic inflammation). A vicious cycle is established whereby bradykinin and prostaglandins stimulate further release of substance P, which in turn sensitizes additional nociceptors immediately adjacent to the site of injury ***(Cousins et al., 1989)***.