

**A COMPARISON OF THE INTRAMUSCULAR AND INTRAVENOUS
ROUTES FOR ADMINISTRATION OF MEPERIDINE
TO NULLIPAROUS AND MULTIPAROUS
LABOURING WOMEN**

BY

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**A Thesis
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**A Thesis/Practicum submitted to the Faculty of Graduate Studies of The University
of Manitoba in partial fulfillment of the requirements of the degree
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Abstract

The use of Meperidine is an accepted method of pain relief for labouring women. The intramuscular and intravenous routes are the most common routes used by a local tertiary care centre. The criteria for choosing the route to give the drug is not well established. Reliable and valid methods of evaluating pain relief are reported in the literature. This particular tertiary care setting mainly utilizes patients' general verbal reports and behavioural observations as evidence of effectiveness of pain relief. The experience of labour pain by nulliparas (women who have not delivered a viable infant) and multiparas (women who have delivered more than one viable infant) is varied, depending on a variety of coexisting factors, including the beliefs of caregivers. This research was based on theories proposed by McCaffery and Melzack and Wall that described a belief in what the patient says their pain experience is and which provided a distinct physiological explanation. Utilizing a mechanical visual analogue scale, 169 nulliparous and multiparous labouring women were asked to identify their perception of pain intensity after a random assignment to one of two treatment protocols. One of the protocols was for the drug administration and one was for placebo administration. Neither the patient nor researcher knew the actual route of drug administration. The four hypotheses were tested using repeated measures analysis of variance (ANOVA). Parametric *t* - tests for independent samples were done to test for differences between the nulliparous and multiparous groups. Chi-square tests were carried out on categorical data.

The results indicated that there was no difference in overall mean pain scores between women who received Meperidine by the intramuscular or intravenous routes. The intention of this study was to provide nurses with evidence-based information on which to choose the appropriate route for administration of pain relief.

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CHAPTER I

Introduction

Statement of the Problem

The ability to provide adequate pain relief to women during the labour and delivery process without causing iatrogenically-induced risk to the mother or her fetus is a primary goal of care-providers. Numerous pain-relieving methods are used to assist the mother to cope with her level of perceived pain. Some of these methods include prenatal childbirth education, back rubs, hydrotherapy, music, decreased environmental stimuli, and constant presence of a support person. Another method of pain relief is with the use of pharmacological options such as parenterally administered narcotics, epidural analgesia/anaesthesia and inhalation therapy (nitrous-oxide gas).

Data from a local tertiary-care centre indicate that more than 60% of the women who delivered from January 01 to December 31 of 1997 received some form of pain medication (LADIS, Women's Hospital, Health Sciences Centre). At least one-quarter of the pain medication is provided in the form of narcotic analgesia. To identify the actual numbers of nulliparous and multiparous women who receive a narcotic analgesic, a retrospective chart audit would have been necessary, as a certain percentage of these women also receive a combination of parenterally-administered narcotics and a subsequent epidural while in labour. Meperidine, also known as Demerol, is the most common parenterally administered narcotic.

The decision to administer Meperidine in labour is a collaborative one, involving

the physician, nurse and patient. Administration of a narcotic is based upon assessment of the patient's coping skills, progress in labour, and maternal and fetal well being. The physician's order usually states that Meperidine can be administered via the intramuscular (I. M.) or the intravenous (I. V.) route. Although a structured survey was not undertaken, informal discussions with nursing staff indicated that the choice of parenteral routes depended on a variety of factors. Some nurses discussed the choice of routes with their patient and some did not. Some nurses always gave the drug I. M., even if an I. V. for other needs such as hydration had been established. The usual method of giving the drug I. V. was by a buretrol (closed chamber) system. I. V. direct or "push" was rarely used.

Generally, this process seemed to provide effective pain relief for the labouring patients. However, other than an evaluation of analgesia effect through verbal inquiry or observations, no particular assessment system is documented. While pain scales have been reliably utilized for the labouring population (McGuire, 1984; Price, Harkins & Baker, 1987), such methods of pain level assessment have not been clinically implemented at the tertiary care centre.

In order for nurses and labouring women to make the best choice about the route of narcotic administration, knowledge regarding pharmacology of medications and methods for assessment of action and effect is required. The purpose of this study was to compare the self-reported pain levels of nulliparous and multiparous women who receive Meperidine via the intramuscular or intravenous routes.

Conceptual Framework

The conceptual framework for this study includes the work of McCaffery (1972), McCaffery and Beebe (1989) and Melzack and Wall (1965). These researchers proposed landmark theories in the understanding and management of pain. As a generic definition, McCaffery's statement that pain is whatever the person who is experiencing it says it is and existing whenever they say it does, can be applied to labour pain with some specific modifications. Despite the fact that birth pain is expected, it is none the less an acute and severe pain experience. In fact it ranks among the most intense pain recorded with the McGill Pain Questionnaire (Melzack, 1984). Pain in labour is as individual as the labouring woman and a core belief to this study is that the nurse accepts the validity and reality of that pain without question. Pain is an accepted reality to the labouring process; in some ways it is considered a "means to an end". However, this belief does not discount the reality that labour pain can and should be treated in whatever manner is requested by the patient and through whatever method is available to the caregiver. McCaffery and Beebe (1989) identify certain beliefs regarding pain control and patient's rights. These are:

that pain control:

1. is a legitimate therapeutic goal.
2. contributes significantly to the patient's physical and emotional well-being.
3. must rank high in the list of priorities in patient care.
4. is patient controlled.

...that the patient has a right:

1. to decide the duration and intensity of pain he is willing to endure or tolerate.
2. to be informed of all possible methods of pain relief along with the favorable and unfavorable consequences, as well as the controversial aspects.
3. to choose which pain control method(s) he wishes to try.
4. to choose to live with or without pain. (p.4)

Each of the above beliefs is fully supported in this paper and serves as a fundamental basis behind the concept of providing relief for labour pain. The beliefs are applicable to all types of pain, including labour pain. A commitment to these beliefs is a stepping stone towards understanding the interactive role of labouring women and their caregivers.

The basis for the gate control theory is that the transmission of potentially painful or noxious impulses to the level of conscious awareness may be affected by a gating (or input modulation) mechanism which may be located at the spinal cord level. It was felt that neural mechanisms in the dorsal horns of the spinal cord act like a gate which can increase or decrease the flow of nerve impulses from peripheral fibers to the spinal cord cells that project to the brain. Somatic input is therefore subjected to the modulating influence of the gate before it evokes pain perception and response. The theory suggests that large-fiber inputs tend to close the gate while small-fiber inputs generally open it, and that descending activities from the brain also profoundly influences the gate. It further suggests that sensory input is modulated at successive synapses throughout its projection from the spinal cord to the brain areas responsible for pain experience and response. Pain occurs when the number of nerve impulses that arrive at these areas exceeds a critical level

(Melzack, 1982; Jeans and Melzack, 1992). Melzack and Wall (1965) suggested that control of pain may be achieved by selectively influencing the large, rapidly conducting fibres. The gate may be closed by decreasing the small-fibre input and also by enhancing the large-fibre input.

Melzack and Casey extended the gate-control theory to include descriptions of three categories of activity, which interact with each other. The sensory-discriminative dimension is influenced by fast conducting spinal systems and is thought to give information about time, location and intensity of pain. Motivational-affective drive is influenced by slow conducting spinal systems and assesses the need for escape or attack from a noxious stimulus. The higher central nervous system processes provide a cognitive method of analyzing pain. This cognition is based on past experience, which is used to consider the probability of a certain outcome and the meaning of the pain (Jeans & Melzack, 1992).

But understanding and even applying a set of beliefs is one thing. Understanding and applying the scientific foundation of these beliefs is another. In the Wilson method of concept development as described by Rodgers and Knafl (1993), the first step is to isolate questions of fact from value. McCaffery and Beebe (1989) identify source of psychosocial values to consider and Melzack and Wall's classic gate control theory provide the source of physical foundations. The integration of the two theories to labour pain provides the conceptual model for this research. The uniqueness of labour pain is in its normality. It is not the result of a disease entity and is not usually associated with adverse psychological outcomes (Moore, 1997). For the purposes of this study the working definition of labour

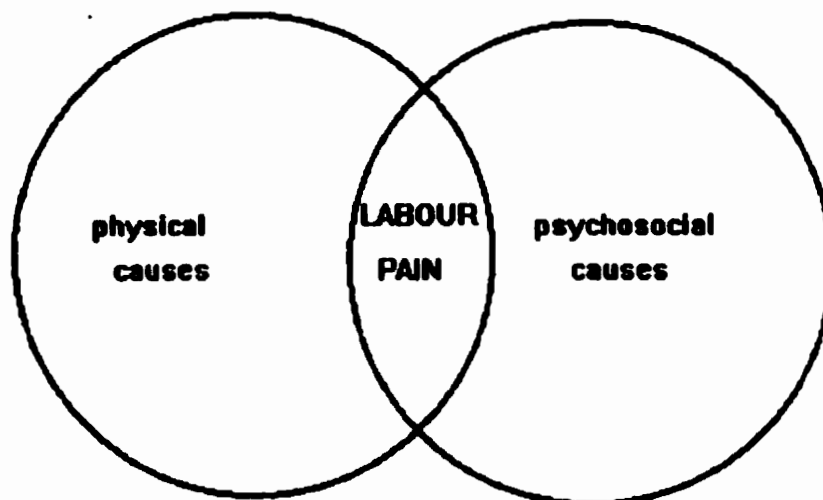


Figure 1

The perception of labour pain is influenced by the interaction of causes from both the physical and psychosocial spheres.

pain is: the acute physiological and psychological responses to the processes that occur during the events of childbirth. A successful approach to pain control in labour assesses and treats both the physical and psychosocial causes. Figure one graphically demonstrates the concept of the interplay between the physical and psychosocial causes of labour pain perception. The woman encountering labour pain does so with a varied history of pain experiences. The nurse who understands how the physiological sources and psychological influences are interactive throughout the labour process will be able to provide the optimum method of pain control.

CHAPTER II

Review of the Literature

The review of the literature will address the topics of general pain physiology and analgesic therapy to provide a basis of information on which to develop the understanding of labour pain. In particular, its physiological properties, assessment and pharmaceutical management will be discussed.

Of all the unique events that human beings experience, pain is one of the most individual. Many definitions have been applied to pain but it still remains an elusive and difficult phenomenon that defies objective explanations. The International Association for the Study of Pain (1979) defined pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage...” (p. 250). In order for the sensation of pain to occur, some type of cellular or tissue damage must have or will take place.

Whipple (1990) and Jacques (1994) discriminated between three types of pain - chronic, acute and cancer. Acute pain has a predictable end, which is usually associated with healing. It may occur for minutes or up to six months. Acute pain is usually sharp in nature and most often is caused by a sudden injury or disease process. Various autonomic nervous system- related signs are seen concomitantly with acute pain. These may include tachycardia, diaphoresis, hypertension, tachypnea, restlessness and anxiety. Chronic pain usually lasts longer than six months and is poorly localized. Chronic pain sufferers describe it as dull, aching, constant and nagging. They may exhibit exhaustion, listlessness, weight changes, insomnia and depression. Cancer pain is defined separately because it can be

acute or chronic. From 1990 to 1994, the prevalence of cancer has increased nearly 20% in the United States, partly attributable to improved diagnostic testing. However, as the number of cancer patients is increasing, so is the number of cancer patients with pain increasing. Epidemiological data demonstrated that a majority of patients experience cancer pain regardless of disease stage. Nearly 75% of patients with advanced disease experience pain, implying that the rate of adequate pain control is about 25% for the cancer group. (Roxane Pain Institute Slide Show, 1996).

The quality of life is obviously impaired when pain is unrelieved. This is applicable to those who experience pain that is acute, chronic or due to cancer. An achievable goal for pain management is to relieve pain in order to allow a reasonable ability to function in one's daily activities or to a level that is tolerable to the individual.

Cleland and Gebhart (1997) classified pain according to the source or site of pain origin, which can then be either somatic or visceral. Somatic pain, which is easily localized, may come from a superficial source, the skin, while a deep pain originates in muscles, joints or connective tissue. Visceral pain arises from internal organs, is diffuse and poorly localized. Angina and labour (birthing) pain are examples of visceral pain.

Physiological descriptions of pain include the concepts of nociception and noxious stimuli. Noxious stimuli cause tissue damage and begin the process of the pain experience. (Cleland & Gebhart, 1997; International Association for the Study of Pain, 1979).

Thermal (burns), electrical, mechanical and chemical sources are identified as noxious stimuli which then activate peripheral sensory receptors known as nociceptors.

“Nociceptors and the axons of neurons with which they are associated convey nociceptive

information to the spinal cord where autonomic and nociceptive reflexes are activated ...” (Cleland & Gebhart, 1997, p. 1). At the same time this data is sent to the brain via a supraspinal route. Although the International Association for the Study of Pain (1979) recommended the avoidance of using the term pain receptor or pain pathway when referring to nociceptor, the literature treats these terms as synonymous. Jacques (1994) stated that pain receptors respond to noxious stimuli and are termed nociceptors while Whipple (1990) claimed that sensory responses to pain-producing stimuli are transmitted from receptors in the skin and viscera.

Cleland and Gebhart (1997) subscribed to the International Association for the Study of Pain’s recommendation by identifying a difference between nociception and the actual experience of pain. Cleland and Gebhart are adamant that these are not different words for the same concept. Whereas nociception describes neural occurrences and reflex responses that are produced by a noxious stimulus, pain refers to the actual experience associated with the injury. Nociception can happen without the perception of pain and pain can be felt in the absence of nociception. In particular, there are many pain syndromes, which display no obvious pathophysiology, and yet the pain identified with them can be quite debilitating. Pain is always a psychological state (International Association for the Study of Pain, 1979) but there is no denying the fact that pain is usually described in connection to a physical origin.

An essential requirement in the process of pain sensation is the role of nerves, which are connected to the receptor. Three orders of neurons have been identified in the transmission of pain. These include:

1. "A beta" fibres that are a large diameter and covered with a myelin sheath.
2. "A delta" fibres that are myelinated, small in diameter and conduct impulses rapidly. They are associated with the sharp, pricking type of pain.
3. "C" fibres that are usually unmyelinated, small in diameter and have a slow conduction rate. C fibres are associated with the dull, aching pain sensations. The nerve endings or nociceptors of C fibres are activated by sources of a mechanical, chemical or thermal nature. Large diameter nerves conduct impulses faster than smaller diameters and the myelin sheath increases the speed of impulse conduction (Clancy & McVicar, 1992; Jacques, 1994; Melzack & Wall, 1965; Phillips & Cousins, 1986; Whipple, 1990).

In order to feel pain, cellular damage would likely have occurred. Substances such as histamines, bradykinins, potassium and prostaglandins are released. The combining action of these substances with the receptor sites on nociceptors begins the pain transmission process. The ongoing and relative balance of activity of the nociceptors will reach a threshold level or the least amount of stimulus intensity which is required to cause a nerve impulse or the level at which pain is perceived (International Association for the Study of Pain, 1979). When a primary afferent or first-order neuron receives noxious stimuli (chemical, thermal, or mechanical), the membrane of a nociceptor becomes permeable to sodium ions. The result is the development of depolarization, which triggers an action potential that travels the nerve cell axon to the dorsal horn of the spinal cord. Cleland and Gebhart (1997) identified this as the first or **transduction** stage of nociception. Afferent pathways are sensory and connect body receptors with integrating mechanisms of the central nervous system. This integration enables a person to be

conscious of their environment.

“A delta” and “C” nerve fibres enter the spinal cord through the dorsal horn, which contains several types of neurons. The nociceptive stimuli that activate the neurons in the dorsal horn are transmitted to the brain along one of three pathways. The spinothalamic (neospinothalamic), spinoreticular (paleospinothalamic) and spinobulbar pathways are ascending tracts that participate in the transmission of pain information through various mechanisms. Cleland and Gebhart (1997) described the next step in nociception as **central processing and abstraction** where the processing of neural signals by the central nervous system occurs in order to extract necessary information. In the abstraction stage, the nociceptive data travels to particular laminae in the gray matter of the dorsal horn activating cell layers in the laminae. The brain is processing and extracting the relevant features of information in the abstraction stage.

Cleland and Gebhart (1997) described the third stage as **modulation**. They claim that this stage is synonymous with control. “Typically, modulation implies inhibition or relief of pain, for example, through the use of drugs, but modulation can also include enhancement or facilitation of pain. That is, pain can be made worse or non-nociceptive inputs can be altered to be perceived as painful.” (p. 20.) The pain modulation stage includes both inhibition and facilitation. Despite the fact that different spinal tracts and neurotransmitters are used in inhibition and facilitation, both arise in the brainstem. Neural activity at the periaqueductal gray area of the midbrain mediates the inhibitions exhibited by exogenously administered medications such as opioid analgesics and by endogenous inhibitors. Several endogenous substances that exhibit analgesic properties include beta

endorphins, enkephalin and dynorphin (Roxane Pain Institute, 1996).

Cleland and Gebhart (1997) described the fourth and final neural stage of nociception as **development and plasticity**. Their belief is based on the premise that human perception of sensory stimuli constantly changes in order to respond to development, environmental experience, disease and injury. Cleland and Gebhart described these changes as plasticity, which can last for minutes or forever. The nervous system's response to nociceptive stimuli is a demonstration of plasticity. Dickenson (1996) identified plasticity as "alterations in transmission in nociceptive systems but also equivalent alterations in transmission in the ability to modulate the pain, (which) can be produced over short time courses due to alteration in pharmacological systems" (p. 113).

There is now very little doubt that even though newborns and children do not have the same experiences as adults in responding to noxious stimuli, nociceptors, nociceptive and autonomic reflexes are intact from birth and supraspinal integration of the nociceptive data is exactly as it is in adults. However, the development of emotional experience and learned features of responses to noxious stimuli is yet to be understood or explained.

Three main theories regarding the pain mechanism have been described and refined over approximately the last thirty-five years. Melzack and Wall first postulated the gate control theory in 1965. Their research involved new information, at the time, to refute the Specificity and Pattern theories. The **Specificity Theory** proposed that a mosaic of specific pain receptors existed within body tissue, which projected to a pain centre in the brain. It was identified that free nerve endings are the pain receptors and generated pain impulses that are carried by the A delta and C fibres and by the spinothalamic tract to

a pain centre in the thalamus. This theory claimed that pain is a specific sensation and that the intensity of pain is proportional to the extent of tissue damage. It was implied that the nervous system was a fixed direct-line communication system from the skin to the brain, which indicated a direct, invariant relationship between stimulus and sensation. However, because pain, pressure and temperature sensations all travel along the same fibres, the direct invariant relationship is disclaimed. The theory has been disputed because pain is not only a function of the amount of damage the body sustains but is also influenced by anxiety, prior conditioning and other psychological factors (Melzack, 1982; Melzack & Wall, 1965; Whipple, 1990).

The **Pattern Theory** maintained that the nerve impulse pattern or code for pain is produced by intense stimulation of non-specific receptors since there are no specific fibres and no specific endings. The theory explained that pain receptors and pathways are shared with other sensory experiences such as touch (Moore, 1997). Revisions to this theory described the concept of central summation utilizing a reverberating circuit mechanism where intense, pathological stimulation of the body sets up the circuit in spinal interneurons. Melzack and Wall (1965) felt that the Pattern Theory ignored the facts of physiological specialization whose “properties of each receptor-fiber unit - such as response ranges, adaptation rates, and thresholds to different stimulus intensities - play an important role in determining the characteristics of the temporal patterns...” (p.973).

The **Gate Control Theory** of pain claimed that stimulation of the skin causes nervous impulses to transmit to three spinal cord systems. These systems and their roles are the:

(1) small densely packed cells known as the substantia gelatinosa in two layers of the laminae of the dorsal horn. The substantia gelatinosa acts as a gate control system by modulating afferent patterns or sensory pathways.

(2) dorsal-column fibres which project toward the brain - the afferent patterns partially act as a central control trigger and initiates particular brain activities in the modulation stage.

(3) first central transmission (T) cells in the dorsal horn - these T cells activate the neural action mechanisms, particularly response and perception.

There are several gating mechanisms within the body besides the substantia gelatinosa, including areas within the brain such as the thalamus, reticular formation and the limbic system. The gate control theory was based upon the belief that pain information arrives at the gate (i.e. the substantia gelatinosa) and can only pass through when the gate is open, not when it is closed. If the gate mechanism is open, impulses stimulate cells in the dorsal horn. These impulses can then ascend the spinal cord to the brain and pain is perceived. The theory suggests that large-diameter A fibre input produces impulses that close the gate to activity. If the activity of small-diameter C fibres is predominant, the pain message can be transmitted. The release of excitatory neurotransmitters and subsequent excitation of postsynaptic neuron membranes in the ascending pain fibre tracts aid the opening of the gate. Substance P is inhibited during gate closure. Substance P is synthesized by spinal ganglia cells and is located at the peripheral terminal of unmyelinated primary afferent fibres. As a neurotransmitter, Substance P may participate in the development of visceral nociceptive pain from the gastrointestinal tract and ureters. (Roxane Pain Institute, 1996). The whole gating or input modulation process is dependent

upon:

1. The balance of activity of afferent A delta and C neurons and A beta neurons.
2. Descending control fibres from the brain's higher centres such as the raphe, trigeminal, and vestibular nuclei, hypothalamus and cerebral cortex. Even if the pain fibre input is the dominant one, the higher centres will modify the gating mechanism using the descending control dorsolateral neural pathways. Endogenous opiates (enkephalins and endorphins), functioning as neuromodulators, close the gate (Clancy & McVicar, 1992; Jacques, 1994; Whipple, 1990; Melzack, 1982; Melzack & Wall, 1965).

The four neural stages of nociception described by Cleland and Gebhart (1997) incorporate and redefine some aspects of the Gate Control theory as developed by Melzack and Wall (1965). The Gate Control premise has been modified with the inclusion of influences descending from the brainstem that modulate the gate. Other components such as sensory-discriminative, motivational-affective and cognitive are considered as important contributors to the integration and interpretation by the central nervous system to noxious information (Cleland and Gebhart, 1997).

Ultimately, it was agreed that "there are many chemical mediators and transmitters involved in pain, both at the site of the injury in the periphery and within the central nervous system. The final sensation of pain will depend on interactions between these transmitters" (Dickenson, p. 113).

The physiological processes of pain perception are extremely complex to describe. However, it is widely accepted that psychosocial factors affect the physical actions of opening or closing the gate. Pain perception is psychologically influenced by: anxiety,

cultural differences, the meaning of the situation, fear, perceived control of events, coping style, attention/distraction, observational learning or modelling, personality traits, age, marital adjustment, family size, gender, education, amount and type of medical/surgical procedure, and socioeconomic status (Albers, 1998; Clancy & McVicar, 1992; Jacques, 1994; Phillips & Cousins, 1986; Peck, 1986; Walding, 1991).

Each of the above psychological factors contributes to and supports the subjective aspects of the individual perception of pain. The nurse must understand how these factors are involved in pain interpretation in order to participate in the process of reducing or assisting the patient to cope with pain.

Anxiety may be considered as a positive or negative experience. It may be related to learning ability and stress where it becomes either a motivating or dissuasive factor. It is accepted that increased anxiety is related to increased pain. The gate control theory explained this phenomenon through the decreased levels of endogenous opiates due to descending control or to an increase in substance P levels. Walding (1991) also describes the body's reaction to anxiety through activation of the sympathetic nervous system, which is assisted by adrenalin and noradrenalin from the adrenal medulla and stimulated by the hypothalamus.

“The cultural background of an individual, learned through the process of primary socialization, also influences expression of pain” (Walding, p. 391). Studies have shown that cultural differences affect the amount and tolerance of pain that an individual will accept before verbalizing difficulty (Clancy & McVicar, 1992; Peck, 1986). The expression of pain through a language other than English may be restrained. The nurse

must appreciate the necessity of other methods of communicating such as non-verbal, if there is a language barrier.

The meaning of a medical or surgical procedure or the situation that is associated with pain may also affect the individual's response. If the connotation of the pain experience is linked to a life-threatening possibility, the individual will likely perceive the pain at a higher level than usual. Research has shown that if one does not believe that they can control an aversive event, the event is perceived as more aversive or painful. Even a perception of personal control may result in an internally oriented state, which may lead to a decreased powerlessness. Learned helplessness is developed if control is not sensed, particularly in situations in the health care system where patients and their families believe that their basic rights may not be considered when decisions are made regarding treatment (Peck, 1986).

The way in which a person copes with actual or anticipated pain must be discerned by caregivers. Coping style has been described as whether a person actively avoids information about an aversive event or actively seeks information about it. Assessment regarding previous experiences with pain and how the individual handled them will provide the nurse with information on which to develop the pain management plan (Peck, 1986).

Much of the research in pre-natal birth education regarding preparing for labour and delivery involved the concept of attention/distraction. This also may be applied to other pain situations. "Distraction from a painful stimulus can decrease the perception of pain and attention to the same stimulus can increase pain perception. When an individual

attends to something, he or she focuses his or her perceptual process on it to the exclusion of other internal or external stimuli.” (Peck, 1986, p. 256). However, the research also identified that attention-diversion strategies for a variety of pain sources can affect response and tolerance to the pain (Clancy & McVicar; Melzack, 1982; Peck, 1986; Phillips & Cousins, 1986; Walding, 1991).

Labour Pain Physiology

The sources of labour pain have been identified according to the stages and phases of labour. During stage one, the pain is largely visceral in origin. As the patient progresses through transition and into second stage, the pain becomes more somatic in nature. The main causes of pain in stages one and two are:

- dilatation of the cervix,
- contraction and distention of the uterine body,
- stretching, dilatation and distension of the outlet and perineum, and
- pressure and stretching of adjacent organs such as the parietal perineum, bladder, urethra, rectum, lumbosacral plexus, and lower ribs.

This belief is supported by the following facts: stretching of smooth muscle is considered a reasonable stimulus for visceral pain. There are correlations between the degree of dilatation of the cervix and the intensity of perceived pain, and between the onset of uterine contractions and the onset of pain (Bonica, 1979; Bonica & McDonald, 1990; Brownridge, 1995; Eggers, 1995). Eggers (1995) identified that as a physical source of pain, the reduced oxygen supply to the uterus during contractions causes an increased

level of lactic acid. However, both Bonica (1979) and Brownridge (1995) stated that, in fact, the uterine myometrium receives greater perfusion during, rather than between, intense sustained contractions. Their belief is that uterine ischaemia or inflammation is not a primary cause of pain. Visceral pain is caused by distension of smooth muscles of the hollow viscus and/or the intense contractions against obstruction of the outlet such as during descent of the presenting part. Other explanations for the occurrence of labour pain include stretching of adnexa and ligaments and pressure from pelvic bones and joints (Corli, Grossi, Roma & Battagliarin, 1986; Faure, 1991). Tissue damage and injury do occur during labour and delivery. The nociceptors (those receptors that respond to injury) transmit information to the brain along various pathways (Jacques, 1994). As contractions build in duration, frequency and intensity throughout the latent and active phases of stage one, a repeated stimulation of high threshold nociceptors occurs. These nociceptors require an intense stimulus in order to be activated but with this continuous and repetitive stimulation, the activation threshold diminishes. Subsequent stimuli do not need to be to the same extent in order to stimulate pain transmission (Bonica, 1979; Faure, 1991). The lower uterine segment and cervix produce a fairly weak contractile force during the early phases of labour and become even weaker at the completion of the first stage. Therefore, when labour pain is most severe, the cervix contracts the least.

The pain of stage one is transmitted to the spinal cord via the large diameter, myelinated A delta and small diameter, unmyelinated C fibres that originate in the lateral wall and fornices of the uterus. This pain is referred to the dermatomes, which are supplied by the same spinal cord segments that receive input from the uterus and cervix.

Dermatomes “are regions of skin innervated by axons from a single dorsal root of the spinal cord.” (Cleland & Gebhart, p. 16). This is an example of somatotopy, which is an organization of sensory input in the central nervous system. Afferent pathways are sensory and connect the body’s receptors with the integrating mechanisms of the central nervous system (Faut-Callahan & Paice, 1990). Pain fibres in the uterus, cervix, and vulva enter the dorsal horn at the thoracic (T)10-12 and lumbar (L)1 levels of the spinal column. Pain fibres that transmit information from the perineum enter the spinal cord at the sacral (S) 2-4 level. Visceral sensory fibres enter the dorsal horn at Lissauer’s tract and end mainly in laminae I and II, the substantia gelatinosa. It is here that primary afferent fibres synapse with second order neurons (Faut-Callahan & Paice, 1990). In the latent phase of stage one, the pain is perceived as an uncomfortable ache and is limited to the T11 and T12 dermatomes. As labour progresses into the active phase and uterine contractions become more intense, the pain becomes sharp and cramping and spreads to the T10 and L1 dermatomes (Bonica & McDonald, 1990). Even though the pain of labour is primarily visceral in origin, it is also considered to have elements of referred pain. This is “when the pain is perceived at a site of the body that is distant from the actual site of disease or injury...”(Whipple, 1990, p. 24). Labour pain is also considered to be referred because the cutaneous branch of T11 and T12 supply the skin covering the spinous processes of L3, L4, L5 and S1 and the cutaneous branch of L1 nerve, supplies the skin covering the middle part of the sacrum. (Faure, 1991). When the visceral pain fibres are stimulated, pain signals from the viscera, in particular, the uterus, cervix and perineum, are then sent through some of the same neurons that conduct pain data from the skin. (Whipple, 1990).

The transmission of contraction pain is slow. The pain is poorly localized, frequently referred to the abdomen, lower back and rectum, related to intrauterine pressure, variable in intensity and initiates a generalized autonomic response. Almost every body system responds in some manner to this stress reaction. The labouring woman who is experiencing pain may display:

1. respiratory effects such as hyperventilation, which can lead to hypocarbia and respiratory alkalosis, if prolonged. An increase in oxygen consumption is associated with painful contractions.
2. an effect on the release of such endogenous hormones as beta-endorphins and epinephrine which are important for the patient's inherent pain-coping abilities.
3. an increase in cardiac output, peripheral resistance and blood pressure.
4. excessive sympathetic uterine activity that may aggravate incoordinate contractility.
5. delayed gastric emptying due to effects of the autonomic nervous system. This is of concern as stomach contents are not only likely to be a higher volume but are also more acidic than in non-pregnant women, increasing the risk of potential aspiration if an anaesthetic is given (Brownridge, 1995).

The achievement of ten centimetres dilatation is the end of Stage One and the beginning of Stage Two of labour. The actual process of "pushing" usually begins at this point and may last anywhere from several minutes to several hours. Once the cervix is fully dilated, the amount of nociceptive stimulation arising from the cervix decreases. However, the contractions emanating from the uterine body and lower segment distension are as painful as those perceived in Stage One. An additional source of pain is due to the

progressively greater pressure of the presenting part on pelvic structures that are particularly pain-sensitive. Distension of the outlet and perineum are now new origins of pain. As the distension progresses due to descent of the presenting part, intense stretching and tearing of the fascia, subcutaneous tissues, and pressure on the perineal skeletal muscles occurs. Pain signals are transmitted by the pudendal nerves through the sacral plexus to the posterior root ganglia at the three sacral segments (S2, 3, and 4). The pain of the perineum has been described as sharp and can be localized to the regions supplied by the pudendal nerves. (Bonica, 1979; Bonica & McDonald, 1990; Faure, 1991; Lowe, 1996).

The fetus is not immune from the effects of labour pain. During a contraction the intermittent reduction of intervillous blood flow will negatively affect placental gas exchange. In particular the following effects can be seen:

- a shift to the left in the maternal oxygen dissociation curve diminishes the transfer of oxygen from mother to fetus
- maternal transfer of oxygen is diverted from the mother to the fetus,
- umbilical vasoconstriction causes a decrease in umbilical blood flow, and
- a reduction in uterine blood flow is provoked by an increase in norepinephrine and cortisol release.

The healthy fetus can tolerate this interruption because sufficient oxygen is stored in the fetal circulation to maintain its cardiac status. However, if excessive uterine activity were to be combined with unrelieved pain and a complicated pregnancy, the fetus is at risk for the development of hypoxia, hypercapnia and acidosis. Any co-existing medical or

obstetrical maternal or fetal complications may further complicate concomitant pain-induced reductions of oxygen and carbon dioxide transfer, which may result in perinatal morbidity (Bonica & McDonald, 1990; Brownridge, 1995).

Therefore, from this review of the literature, it is established that the pain of labour, though recognized as a necessity and a means to an end, may also adversely affect maternal and fetal well being. Many factors are involved in the perception of and coping with labour pain, some of which will be subsequently addressed. It is vital to accept the mother's report of the pain she feels and to base the best method to relieve the pain upon collaborative decision-making.

Physiological and Psychological Influences on Labour Pain

While physical pain in labour is explainable, intermittent and productive, it is not the only source of labour pain. Psychological and iatrogenic factors also have been implicated as both causes and influences on labour pain. Anxiety levels, adequacy of support systems, understanding the labour process, confidence in using pain-management techniques, cultural expectations of pain and childbirth, medical interventions and involvement in the decision-making process have been identified as influencing factors. (Eggers, 1995; Faure, 1991; Fridh, Kopare, Gaston-Johansson & Norvell, 1988; Lowe, 1989). It is vital that nursing staff involved in the care of labouring women understands the origins of labour pain from all aspects. Based upon a sound foundation of knowledge, the nurse can provide the necessary care.

The following have been identified as physical influences on labour pain perception:

Age of the woman- Faure (1991) identified that the older primipara may experience a more painful labour than the younger while Fridh et al. (1988) stated that women who are older with more children may have less sensory and affective pain during labour, in particular when the cervix is dilated at less than four centimetres. Previous experience with labour and the woman's feelings of control may be an explanatory reason. Sheiner, Sheiner & Shoham-Vardi (1998) also found that pain levels decreased significantly with maternal age. They found that the mean visual analogue scale rating of pain in labour for 55 women less than 20 years of age was 9.4 out of 10 while the mean score for 59 women who were greater than or equal to 35 years of age was 7.6 (p. 288).

Parity - lack of knowledge regarding what is to occur or what to experience may contribute to this factor. Lowe (1987) performed a non-experimental descriptive study to provide some clarity to the relationship of parity and pain. She used the McGill Pain Questionnaire with 17 primiparous and 33 multiparous women during each phase of Stage One and after Stage Two. Her results indicated that "although no significant effect for parity was identified across the phases of labour, primiparas reported more severe pain than multiparas during early labour, but less severe pain during second stage" (p. 343). Brown, Campbell & Kurtz (1989) utilized three self-report measures, the Visual Analogue Scale, Present Pain Intensity and the McGill Pain Questionnaire to 20 primigravidas and 58 multigravidas. They also found that parity correlated to reported pain during Stage One. Primigravidas had a significantly higher pain score on each measure than

multigravidas and also chose more pain descriptors per category than multigravidas. In another reported research study Lowe (1989) investigated the relationships between the perception of pain during active labour and nine predictor variables, of which one was parity. (The others were: age, childbirth preparation, state anxiety, confidence in ability to handle labour, concern regarding the outcome of labour, fear of pain, cervical dilatation, and frequency of contractions.) The Pain Rating Index of the McGill Pain Questionnaire was administered to 52 primiparous and 82 multiparous women during active labour. In evaluating the effect of parity on pain perception in labour, Lowe found that “parity did not contribute significantly to the variance in the pain in active labour” (p. 244). This supported her belief that once active labour is established and until the beginning of transition, the perception of pain is similar in primiparous and multiparous women. However, it is generally reported that multiparous women report less pain during early labour and an increased pain level during second stage which may be attributed to the speed and intensity of fetal descent (Lowe, 1996). Sheiner et al. (1998), using a linear regression analysis in their study, found that parity was correlated with levels of pain. They stated that “as parity increases, the levels of pain significantly decrease” (p.287).

Physical status of the parturient -Melzack et al. (1984) studied the influence of physical and psychologic variables on women’s perceptions of labour pain. “The only variable that significantly contributed to the pain scores of primiparous women was the ratio of their usual weight before pregnancy to their height - that is, the greater the woman’s usual weight per unit of height, the higher the pain scores.” (p. 583).

Multiparous women who weighed more and who had larger infants had higher pain scores.

Degree and speed of dilatation of the cervix- efficiency of latent labour or the rate of cervical dilatation have been shown to be inversely related to self-reports of pain during that phase. However, a higher level of pain and discomfort measured during the same phase was inversely related to the efficiency of active and second-stage labour (Wuitchik, Bakal & Lipshitz, 1989).

Relationship of the size of the fetus to the size of the birth canal- in the presence of dystocia due to a contracted pelvis or a large baby, labour pain is experienced more intensely (Bonica & McDonald, 1990; Melzack, 1984).

Intensity and duration of uterine contractions (whether natural or medically induced)- Brown, Campbell & Kurtz (1989) identified in their study, that women who received oxytocin induction had higher McGill Pain Questionnaire scores than those who did not. It is known that oxytocin administration increases intrauterine pressure causing an increase in pain intensity and a decrease in pain tolerance (Faure, 1991).

History of menstrual difficulties - strong evidence exists to support the fact that women who have dysmenorrhoea produce large amounts of prostaglandins, which are augmentors of contractions. Pharmaceuticals that inhibit prostaglandin synthesis also reduce menstrual pain. Due to a positive correlation between menstrual and labour pain, it is possible that women who experience severe labour pain may also produce excessive prostaglandins during labour (Melzack, 1984; Melzack, Kinch, Dobkin, Lebrun & Taenzer, 1984).

The following psychological factors have been implicated as influencing the

perception of labour pain (Bonica & McDonald, 1990; Eggers, 1995):

Mental status or personality factors - the only personality factors which have shown a consistent relationship with acute pain are neuroticism and extroversion.

Inconclusive results suggest that those patients who display behaviour consistent with neuroticism and extroversion may exhibit increased amounts of pain behaviour. (Peck, 1986).

Fear, anxiety and apprehension - a frequent cause of fear and anxiety is ignorance of and improper information relating to the labour process. The primipara may harbour fears of the unknown, death, suffering, or of complications to herself or her fetus (Bonica & McDonald, 1990). Green (1993) reported that there was a strong overall relationship between being worried about labour pain and worry about pain in every day life when a prospective study was done with 700 women who gave birth. However, when Lowe (1989) performed stepwise regression analysis on state anxiety (a transitory reaction that occurs in response to a specific situation, Walding, 1991), no data could support that state anxiety was a significant contributor. In the 1989 study, Lowe used the Self-Evaluation in Labor Questionnaire which “provides measures of state anxiety (anxiety), confidence in ability to handle labor (confidence), concern regarding the outcome of labor for self and baby (concern), and fear of pain (fear). Higher scores on this scale are associated with increased stress and represent increased state anxiety, decreased confidence in ability to handle labor, increased concern regarding the outcome of labor, and increased fear of pain” (p.244). Lowe’s results for state anxiety may be “statistically the result of the high correlation between anxiety and confidence and of the higher alpha coefficient for the

confidence subscale...” (p.244). Anxiety may be increased if the actions of caregivers are not explained, or if such environmental factors as noise-levels or strange surroundings, such as hospitals, are not explained. While some anxiety is usually expected, an unusual amount may magnify the perception of nociceptive input at the cortical level. Higher anxiety levels increase catecholamine production and secretion; and subsequently increase pain stimuli from the pelvis due to a decrease in blood flow and more muscle tension. The sympathetic nervous system is also activated, assisted by hypothalamus-stimulated adrenalin and noradrenalin. The body responds with an increase in heart rate and blood pressure, decreased gastric motility and blood flow to the viscera and skin, dilated pupils and sweating (Lowe, 1996; Walding, 1991).

Adequacy of a support system - Fridh et al. (1988) found that the way in which the husband of a labouring woman had experienced the pregnancy significantly correlated with labour pain. His positive attitude toward the event indicated a less painful birth experience. Melzack (1984) found that pain scores were higher when the husband was in the case-room than when he was absent. Melzack postulated that “this may reflect genuinely higher affective pain scores or may be due to a deliberate choice of descriptors in the attempt to impress the husband or express anger at him” (p. 327). However it has also been found that the presence of husbands in the labour room can be helpful by providing both physical and emotional support. (Moore, 1997).

Level of understanding of the labour process - much research has centred on the value of formal childbirth preparation and education. Lowe (1989) found that of nine predictor variables, childbirth education was one of three that contributed significantly to

the explanation of a variance for the total pain and affective scores of the McGill Pain Questionnaire's Pain Rating Index. However, "since preparation was not significantly related to anxiety or confidence, the traditional theoretical scheme of preparation for childbirth leading to decreased anxiety and increased coping skills, thereby mediating the perception of pain, does not appear to be supported by the study data. Rather, a more complex model may be indicated in which attitudinal changes toward the labour experience or increased social support prompted by childbirth education affect the perception of pain" (p. 244). In another study that was intended to explore differences in primiparous and multiparous women's descriptions of the quality and intensity of labour pain, Gaston-Johansson, Fridh and Turner-Norvell (1988) found a different effect of childbirth education. Eighty-eight percent of the primiparas and twenty percent of the multiparas who participated in their study attended childbirth education classes. Significantly higher in-labour scores were reported during Stage One and Stage Three from the class attendees compared to those who did not attend education sessions. Also, as a whole, subjects who participated in childbirth education consumed more pethidine. The purposes of childbirth education include reductions of fear, anxiety and tension, which in theory, should reduce pain when it is experienced. Whether prepared childbirth education diminishes pain through relaxation and distraction or primarily diminishes the emotional reactions to pain, lessens anxiety and instills confidence and self-esteem is under debate (King, 1995; Melzack, 1984). Melzack (1984) found that primiparas who received childbirth training had significantly lower pain scores than those who had did not attend formal programs. He believed that prepared childbirth courses should prepare expectant

parents for the possibility of deviations from the normal and for the need for alternate methods of pain relief. He did express the opinion that education can diminish pain but not to the point of claiming childbirth to be painless.

Confidence in own ability to use learned pain coping techniques - In answer to the controversy regarding prepared childbirth education, Lowe (1996) claims that it is more beneficial to study the relationship between pain during labour and a woman's confidence in her ability to handle the labour. This confidence could be considered an outcome of childbirth education and if effectively developed, it has been demonstrated to assist in decreasing pain perception and the use of analgesics. Lowe (1996) relates the development of confidence to a self-efficacy theory, which is most effectively demonstrated by multiparous women. They utilize past labour experiences to develop their interpretations of painful labour stimuli and are able to enhance self-confidence in managing pain.

Cultural responses - "culture is a well known influence in the expression and perception of pain and a mediator in the inference of pain in others" (Weber, 1996, p. 68). Even though women in all races and cultures experience pain in labour and childbirth, the interpretation, perception and response is quite different and varied. Weber (1996) urges that a cultural assessment should be made for all labouring women. She advocates that an emergent assessment can be done that includes a discernment of nationality, language, religion, and expectations about care. The purpose of this data-gathering tool is to promote effective communication and assist the woman to make appropriate choices. It is important to discuss the labour and delivery care with women, in particular those who may

not be familiar with western ways of health care. Despite the differences in environment, technology or coping styles, “in no known culture in the world is the pivotal life event of childbearing treated with indifference or neglect” (Callister, 1995, p.327). Regardless of the fact that women of a diverse cultural background are giving birth in western hospitals, they do have specific attitudes toward childbearing and its meaning and may suggest specific practices associated with the process (Bonica & McDonald, 1990; Callister, 1995; Eggers, 1995; Lowe, 1996).

Expectations -the realism of labour pain expectations can affect the ability to effectively cope with the pain. Green (1993) argues that if women go into labour expecting it not to be very painful they will actually suffer a higher level of pain. It is important that the woman and her supports do not view pain as wrong and to develop a plan to cope with the pain. Fridh et al. (1988) found that expectations of labour did not differ between primiparous and multiparous women. However, primiparas , more so than multiparas, reported that they expected labour pain to be more intense than menstrual pain. Green (1993) prospectively evaluated the expectations of 700 women regarding pain in labour, pain and education, anxiety and labour pain, use of labour-pain relieving methods such as analgesics or breathing and relaxation exercises. Green’s results indicated a strong relationship between expectations and experiences.

Women who did not expect a lot of pain were no more likely to find labor more painful than expected than those with more pessimistic expectations. Women who preferred to avoid drugs were more likely to do so. Women who expected to find breathing and relaxation exercises useful were more likely to find them so (Green, p. 71).

Sense of involvement in the decision-making process regarding labour pain

perception - Rajan (1993) analysed data from a national sample of 10,702 women regarding perceptions of pain and the effectiveness of pain relief methods. Her study speculated that midwives who have a more prolonged and intimate contact with labouring women are able to judge the amount of pain experienced more accurately and therefore to provide the most effective method of pain relief. In fact the findings indicated that the level of agreement between the perceptions of women and their caregivers about the effectiveness of various labour pain relief methods was quite low. The professional caregivers (midwives, obstetricians and anaesthetists) were more likely to agree with each other than they were with the labouring women. If discrepancies are evident between what the labouring woman desires for pain relief and what her care-givers think she should have, the woman may experience an increase in the physical pain and a sense of powerlessness (Lowe, 1996; Rajan, 1993). "In the case of pain, the care provider must realize that labor pain belongs to the woman experiencing it, and management of the pain also belongs to her" (Lowe, 1996, p.87). Henkelman (1994) discussed the issues of ethics in pain management and unequivocally states that first and foremost a person has the right to be involved in decisions regarding pain management interventions, so the onus is on the health care providers to assist the patient in informed decision-making. The goal is promote as much autonomy within the patient as is reasonable.

There are other influences on perception of labour pain including level of education, socio-economic status and previous non-labour pain experiences. In many

situations, it is virtually impossible for the nurse to completely assess potential pain responses. However, it is important to review the labouring woman's previous history and current facts in order to provide the most reasonable pain management options.

In light of the physiological basis for labour pain and the influencing factors on labour pain perception it is not surprising that there are numerous pain relief methods to offer. They include those of a medically based origin such as parenteral, inhalational and epidural medications. Non-medically based options include back rubs, hydrotherapy, music, decreased environmental stimuli and constant presence of a support person. The remainder of this literature review is dedicated to the assessment of labour pain and its relief, utilizing particular tools and to a discussion of the use of narcotic analgesics, particularly Meperidine to reduce labour pain.

Methods of Pain Assessment

Prior to the administration of any pharmacological agent, the nurse's role includes an assessment of the pain as it is experienced by the woman in labour. The argument is made for the distinguishing of pain assessment versus pain measurement. **Pain assessment** is the value-laden method used by caregivers to interpret pain. It is a process of identifying the actual occurrence, location, intensity and meaning of pain. The basis of pain assessment is that each time it happens, it is individual and that comparisons should be made from one time of assessment to the next within that particular person. The caregiver should not attempt to equate one person's pain with another's or to compare one

individual to a standard of intensity before pain relief is provided. The pain assessment, as part of the nursing process, culminates in interaction between the nurse and patient to develop goals and individual interventions. Lowe (1996) indicates that if pain assessment takes into consideration the sensory and affective concepts of labour pain; direct and indirect methods of evaluation should be used. Lowe (1996) also states that “assessment should include not only the intensity, the specific location(s), and pattern of the woman’s pain and discomfort, but also the degree of distress it is causing her.” (p. 87).

Pain measurement is the estimation or appraisal of pain by pre-set criterion. This is an attempt to quantify the unique experience of pain and to convert that experience into terms that can be compared for all patients. Measurement defines the commonality of the pain experience in terms of intensity, nature of the sensation, and effects of the pain. Measurement is needed to compare groups of patients when testing the overall effectiveness of health care interventions. A sense of control, consistency and normative values are related to measurement (Dick, 1995; Marvin, 1995).

Regardless of whether one employs assessment or measurement, the involvement of the individual patient is paramount to the process. Because pain is a subjective experience and should only be assessed from the patient’s perspective, self-report is the most useful method to determine treatment options. Although observations of patient behaviour and vital sign assessment are also appropriate, they must be considered as adjuncts to the patient’s actual statement of the when, where and how much pain is felt (Dick, 1995; McCaffery, 1997; McCaffery & Ferrell, 1991; McGuire, 1988; Scott, 1992).

While various methods can be implemented to achieve an accurate assessment of

labour pain, many care centres do not use a formal documentation system or questionnaire to objectively evaluate pain levels or effectiveness of pain relief methods. Until recently, there were no standards by which to judge the adequacy of pain treatment. The development of clinical guidelines by and for health care professionals and specialty interest groups assist in the process of accountability. “Although pain is one of the most treatable of symptoms, it is often cited as one of the failures of modern medicine” (Ferrell, Whedon & Rollins, 1995, p. 69). It behooves those who provide care for labouring women to specifically identify those areas where the assessment of pain can be accurate and credible as seen by both the caregiver and patient.

The choice of pain measuring devices depends upon the situation, the cognitive and physical abilities of the patient and purpose of use. Jensen, Karoly and Braver (1986) reviewed the following six scales:

- Visual Analogue Scale (VAS)
- 101-point Numerical Rating Scale
- 11-point Box Scale
- 6-point Behavioral Rating Scale
- 4-point Verbal Rating Scale
- 5-point Verbal Rating Scale.

Five criteria were used to evaluate the above scales. The criteria included the:

- (i) ease of administration and scoring
- (ii) rates of correct responding
- (iii) relative sensitivity as defined by the number of response categories they

provide

(iv) relative sensitivity as defined by their ability to detect treatment effects or their statistical power

(v) magnitude of the relationship between each scale and a “best possible” combined measure of subjective pain intensity.

Jensen, Karoly and Braver’s results indicated that the six pain intensity measures were more “similar than different in terms of the rates of incorrect responding and in terms of construct validity” (p. 124). They felt that the large correlation found between the measures used in their study were most likely due to the fact that the six measures were very similarly designed. They postulated that less association between scales may have resulted if more structurally different scales such as the McGill Pain Questionnaire were included. The authors indicated their preference for the 101-point Numerical Rating Scale as they were looking for the best scale to use to index chronic pain intensity levels. They cited its ease of administration, scoring, numerous (101) response categories and that it did not appear to be associated with age.

Clinical pain is defined by McGuire (1984) as “the perception of unpleasant stimuli arising from sensory alterations associated with a disease process and/or therapeutic and diagnostic procedures” (p. 152). The difficulty in measuring clinical pain is attributed to: the subjective nature of the experience, which is not readily or easily verified; a lack of quantifiable tools; and the reliability and validity of the instruments. Verbal rating, numerical and visual analogue scales (VAS) appear to be interchangeable in clinical settings. They all are highly correlated with the strongest relationship found between the

numerical and VAS ($r = .81$ to $.8$, $p = .01$ to $.001$). (McGuire, 1984).

Verbal Descriptor Scales (VDS) or verbal rating scales are made up of three to five numerically ranked choices or words such as None, Slight, Mild, Moderate, or Severe. The number corresponding to the word chosen is used to determine the intensity of the pain sensation on an ordinal level (McGuire, 1984). It is generally agreed that an individual's subjective rating of the pain intensity using word descriptors is a valid measurement. The application of the VDS to situations where measurement of pain intensity in relation to therapeutic interventions is accepted, however the scale may artificially categorize the intensity dimension of pain by forcing the patient to select a single word on a checklist. It is possible that the word may not actually reflect the patient's true sensation (McGuire, 1984).

A visual analogue scale is a line that represents the continuum of the symptom to be rated. It is normally ten centimetres long, marked at each end with labels that indicate the range being considered, for example in measuring pain, the phrases "pain as bad as it could be" and "no pain" or "no pain" and the "worst pain imaginable" are at either end. The patient is asked to put a mark through the line at the place that most accurately describes how much pain is felt at that time. If descriptive words such as "mild", "moderate" and "severe" are stated between "no pain" and "pain as bad as it could possibly be" the VAS is called a Graphic Rating Scale. Interval data is achieved on this scale by measuring from the "no pain" end to the point where the patient has made the mark. Scoring of the VAS may be done with a millimetre measurement from 0 to 100. The VAS is considered more sensitive to pain intensity measures than the VDS because of the

straight-line continuum as opposed to categorical responses. It has proven simplicity, reproducibility and universality and since it produces interval-level data, parametric statistics may be used in the analysis (Huskisson, 1983; Kremer, Atkinson & Ignelzi, 1981; Lee & Kieckhefer, 1989; McDowell & Newell, 1996; McGuire, 1988). Price, Bush, Long and Harkins (1994) claimed that the validation of a pain scale as a ratio scale is extremely important because only ratio scales provide accurate estimates of ratios of pain intensity and percent changes in pain. Their study examined and compared the extent to which two types of pain rating scales fulfilled the criteria for ideal pain measurement. They examined a simple numerical scale and a mechanical VAS with the response of orofacial pain patients to noxious thermal stimuli. The researchers asked:

Can mechanical VAS or simple numerical scales separately measure the sensory intensity and affective dimensions of pain? Are either or both types of pain scales consistent measures of both experimental and clinical pain? Does either or both types of pain scale provide measurements of perceived magnitude that at least approximate a ratio scale? (p. 218).

The results demonstrated that mechanical VAS and not simple numerical rating scales have ratio scale characteristics and therefore provide accurate estimates of ratios of pain sensation intensity and percent changes in pain intensity. Price et al. do concede that not all pain VAS are likely to be ratio scales and that the specific measurement points of the scale can be influenced by the particular words used to anchor the endpoints, by their length and by the instructions on use. Other potential sources of error in using the VAS include:

(1) the questionable accuracy in photocopying the scale, (2) the necessity of a very clear consistent explanation on how to use it, (3) the limitation imposed by the extremes at either end, (4) potential difficulties in grasping the concept of the scale, and (5) the requirement of manual dexterity to make the mark (Huskisson, 1983; McGuire, 1988; Price, Bush, Long & Harkins, 1994). Wewers and Lowe (1990) identify the fact that the VAS is usually presented in a “unidimensional” format which then makes it very difficult to identify which particular dimension is actually being evaluated by the subject. The subject who is asked to evaluate pain intensity may use the scale to reflect the emotional or psychosocial aspects of their pain experience. This supports Lowe and Robert’s (1988) premise that when evaluating pain in labour, it is next to impossible to isolate the pain experience from other influencing factors. There are varied opinions as to the positioning of the VAS for the patient to view. Some researchers prefer the horizontal position claiming the vertical may have a higher failure rate and give less normally distributed data (Huskisson, 1983; McDowell & Newell, 1996) However, on the whole there is not enough specific evidence to suggest that one position is preferred over the other (McGuire, 1988).

Revill, Robinson, Rosen and Hogg (1976) determined the reliability of the linear analogue scale prior to its use as a measure of pain in childbirth. They examined the memory of a pain experience distant in time by asking the study subject to recall a particular past pain situation, such as dysmenhorrea and to rate the pain by placing a vertical line between the two extremes. Using a 15-cm line length they were asked to repeat the procedure five minutes and twenty-four hours later. The researchers found no

significant differences between the mean differences and variance at five minutes and twenty-four hours. A highly significant correlation was discovered between each subject's initial score and that at five minutes or twenty-four hours.

Another group of subjects participated in determining the reliability of pain rating tests under the influence of 150 mg of Pethidine (Demerol). Of the twenty subjects, ten were in labour and ten were a control group. Results showed that there were no significant differences between the mean error or variance of the rating on one-fifth along the 15 cm line, regardless of whether pethidine was administered. The authors' conclusions were that "the linear analogue seems sufficiently sensitive and reproducible to study the opinions of patients having pethidine during labour..."(p. 1197).

Lowe and Roberts (1988) designed a non-experimental study to investigate the congruence between in-labour report and postpartum recall of labour pain as measured by the McGill Pain Questionnaire (MPQ). They identified that the two most common methods of labour pain measurements are retrospective self-reports and in-labour self-reports. The patient, through an interview or questionnaire usually completed several hours after the birth, provides the retrospective self-report. In some studies, however, the self-report is completed as long as three months after the delivery. Lowe and Roberts (1988) believe that the longer the length of time after the event, the more possibility there is for confounding elements to be introduced. The accuracy of memory may also affect the retrospective pain report. Norvell, Gaston-Johansson & Fridh (1987) asked whether women experiencing labour pain remember the intensity of that pain in the post-partum period. Utilizing a visual analogue scale (VAS), women were asked to assess their labour

intensity during early, active and transition labour and then again two days after the birth. Results showed that neither primiparas nor multiparas remembered their labour pain accurately and that the remembered ratings of pain in both groups were almost the same. Visual analogue scoring was used to assess discomfort as well as pain intensity. The researchers found that the "mean retrospective VAS rating for discomfort was almost ten points higher than the mean rating for pain for both groups" (p.84). Norvell et al. (1987) do not define how discomfort and pain are differentiated although, as previously indicated, mean values for each were measured. Niven (1988) found a different result for labour pain recall in a study of thirty-three women whose pain had been assessed at the time of birth three to four years previously. The MPQ and a VAS were re-administered to the same women. Niven found that all the subjects were able to complete the recall pain assessment scales and "that the average scores recorded on the three evaluative measures at the time of birth differed very little from those recorded three to four years later. (In fact), the correlation between these scores were all highly significant." (p. 84).

The nurse and patient must carefully consider pain assessment during labour if appropriate relief is to be administered. Retrospective studies are of value but Norvell et al. (1987) also discovered that their study subjects reported actual in-labour pain as more intense than that recalled in the post-delivery time. It is especially important to treat the pain when it occurs, to accept all reports of pain seriously, and to believe that the pain is whatever the person who is experiencing say it is (McCaffery, 1997; McCaffery & Beebe, 1989). Concern has been expressed that if the pain is not relieved, the patient may suffer such long-term consequences as acute anxiety, nightmares, and relationship adjustment

(Niven, 1988).

Use of Opioid Analgesia in Labour

The use of opioid analgesics to treat labour pain is a primary and longstanding method. One of the most common narcotic drugs administered through a parenteral route is Meperidine, whose trade name is Demerol. This drug was first synthesized in 1939, approved for use by midwives in 1950 (Crafter, 1989) and is the most frequently used drug in obstetric analgesia in North America, Great Britain, and Europe (Adams, 1995; Heyman, 1990; Elbourne & Wiseman, 1998).

Meperidine, as a pure narcotic agonist, occupies or binds tightly with a specific receptor site and produces an almost maximal activity at that particular receptor site (McCaffery & Beebe, 1989). Opioid receptors have been mapped in the spinal cord and the majority of the receptors are synthesized in the cell bodies of small afferent fibers in the dorsal root ganglion (Dickenson, 1988). The opioid receptor sites are located at the end of nerves in the brain and spinal levels. Narcotics interact with four distinct types of receptors, which are referred to as mu, delta, kappa and sigma. Meperidine action is mainly at the Mu and Delta sites. (Coalson & Glosten, 1991; Lowe, 1996; McCaffery & Beebe, 1989; Pedigo, 1989). Analgesia is promoted when opiates bind to these receptors and alter the perception of pain. Binding is a complex process involving the structural formula of the drug and certain forces which cause the drug's attraction and attachment to the site. The stronger the binding force, the more the drug is attached to the site. This reflects the drug's potency. A drug's efficacy or how well it acts in a controlled environment, results from the physical modification of the shape of the receptor-drug

relationship. A final process of the receptor site theory is the physiologic altering by the changed receptor-drug complex. Nerve impulses may be established or an enzyme system may be changed. Narcotic effect is based on all or some of the steps described above and complete or partial effect depends on the level of action within the process (Mather and Phillips, 1986).

Apart from the main purpose of reducing pain sensation, narcotic analgesics produce other results in the labouring woman. They include analgesia, respiratory depression, hypotension, mental clouding, decreased gastric motility and emptying. Pain relief with narcotics is dose-dependent, as are the adverse effects of hypotension, nausea and vomiting and the previously mentioned activities. A slow breathing pattern is a result of the brain's depressed response to carbon dioxide in the respiratory center (Pedigo, 1989). When the labouring woman is affected by narcotics that can lead to sedation; stressors such as position changes or soft-tissue respiratory obstruction can cause acidosis. This may be due to a decreased compensatory ventilatory effect and result in an increase in carbon dioxide tension. Orthostatic or peripheral hypotension is due to arterial and venous dilatation from the release of histamines or baroreflex interference (Ricciarelli, Gutsche & Smith, 1974; Heyman, 1990). To prevent the development of hypotension after administering opioids to the labouring woman, an avoidance of sudden position changes and adequate fluid volume are recommended.

Pregnancy causes an increased smooth muscle tone, decreased peristalsis, pyloric sphincter spasm and delayed gastric emptying. Such physical changes may contribute to the development of nausea and vomiting in labour. However, that same nausea and

vomiting may be caused by narcotic stimulation on the chemoreceptor trigger zones in the medulla oblongata and has been reported in approximately fifty per cent of labouring women (Coalson & Glostén, 1991; Shukla & Muir, 1993).

All narcotic agents cross the placenta and may cause loss of fetal heart beat-to-beat variability, decreased baseline fetal heart rate and neonatal respiratory depression at birth. Placental transfer, dose and route of drug administration and maternal uptake determine the amount of narcotic that reaches the fetus. The actual concentration of opioid in the maternal blood is determined by the amount and site of drug administration, how much of the drug reaches the tissues, maternal metabolism and the effects of renal excretion (Spielman, 1987). Factors controlling the amount of drug which reaches the fetus include: molecular drug weight, placental membrane structure, and how large of a placental area is affected by age and function ability. If the fetus is in an acidotic state or the mother is alkalotic, narcotics will become concentrated in the fetus due to the pharmacological structure of the drugs. Maternal disease states can affect placental circulation and contractions can decrease perfusion of intervillous space and uteroplacental blood flow thereby decreasing drug availability to the fetus. The result is the unpredictability of total drug transfer from mother to fetus and their subsequent effects (Spielman, 1987).

The consequences of opioids can affect the newborn for up to four days after delivery. The most immediate and serious problem is respiratory depression. Subsequent effects include shorter duration of wakefulness, less efficient breastfeeding, depressed visual and auditory attention, longer time to habituate to noise, and a decreased social responsiveness (Wiener, Hogg & Rosen, 1977). A fine line must be tread in order to

provide adequate analgesia while avoiding the maternal and fetal adverse effects (Heyman, 1990). "In general, the opioids produce maternal analgesia without loss of consciousness by raising the pain threshold and dampening pain perception (Lowe, 1996).

The timing and method of both the intravenous and intramuscular administration of narcotic drugs affect the course of labour. The onset of action is the period of time it takes after a drug is administered for it to produce a response. Intramuscular Meperidines's onset of action is ten to twenty minutes while the continuous I. V. route's action of the dose/diluent bolus administration, is 6-10 minutes (McCaffery & Beebe, 1989). Direct I. V. administration produces an onset of action in three to five minutes. The peak effect, or the time it takes for a drug to reach its highest effective concentration, of 25-50 mg I. V. Meperidine is five to ten minutes and forty to fifty minutes post 50-100 mg I. M. injection. The general duration of action is two to four hours for the I.M. and two to four hours post I.V. (Heyman, 1990; Lowe, 1996; Pedigo, 1989; Perry & Potter, 1994; Shannon, Wilson & Stang, 1992; Lehne, 1994).

If an opioid is given too early in labour, contraction augmentation may be necessary. Once the woman is in active labour, it appears that there is no lengthening of time in labour if the narcotic is given in therapeutic amounts. When an analgesic is administered, there is often a short period of decreased uterine activity. Some women may find themselves in more active labour after this delay due to decreased anxiety and serum concentrations of catecholamines (Berg & Rayburn, 1992; Spielman, 1987). "If pain relief is required early in labor because the patient's perceptions are of strong and painful contractions, it is reasonable to give medication. To wait until the cervix reaches a

predetermined dilation for drug administration may also further delay labor progress and cause unnecessary pain” (Mussell, 1998, p. 19-20).

Thomson and Hillier (1994) re-analyzed a convenience sample of thirty-two women who had been randomly allocated to directed or spontaneous pushing for receipt of analgesia. They found that the use of Pethidine for analgesia in the first stage of labour was connected to an increase in length of first and second stage of labour. This was a dose-related increase where the more medication the woman received, the longer both stages became.

The most appropriate method to administer the medication must be given serious consideration. The most frequent and convenient method is via the intramuscular (I. M.) route despite evidence that indicates it provides variable results in relation to time of onset, intensity and duration of analgesia (Benedetti, Chapman & Giron, 1990). An I. M. may be considered as the route of choice if the establishment of an intravenous (I. V.) is not part of routine labour care. It is also felt there may be less placental transfer of a narcotic to the fetus if the mother receives the drug I. M. (Lazebnik, Kuhnert, Carr, Brashear, Syracuse, & Mann, 1989). The I. M. route has certain disadvantages such as inability to maintain a constant blood concentration and a variable rate of absorption to each patient, site of injection and blood flow (McCaffery & Beebe, 1989, Spielman, 1987). The site of injection is an important consideration. Lazebnik et al. (1989) hypothesized that gluteus muscle absorption of Meperidine administered during labour would be impeded when compared with deltoid or I. V. administration. Their results supported their hypothesis as evidenced by plasma levels below effective ranges when the gluteal muscle

was injected while deltoid administration provided fast, therapeutic drug levels. Injections into such well-perfused muscles as the deltoid will result in faster and higher plasma level than into adipose tissue or muscles that may not be so well-perfused (Benedetti et al. 1990). No matter which muscle is used, post-injection site pain is a potential problem for the recipient. The ability to hold the infant may be impeded by deltoid muscle discomfort. For this reason many nurses chose the larger gluteal muscle as the injection site.

The I. V. method also has similar problems such as transient peak blood concentrations and intermittent pain control. However, there is still less variability in a peak plasma concentration and quicker onset of activity than compared to I. M. (Spielman, 1987). Dan, Rabinovici, Barkai, Modan, Etchin & Mashiach (1991) compared the effects of Nalbuphine (Nubain) to Pethidine (Meperidine) on labouring patients. In a randomized, double blind, prospective study either drug was administered to 137 women I.V. push. Degree of pain was evaluated on a numerical scale five minutes after the injection. Forty-three per cent of the patients rated their degree of pain at none or slight (0-1) and fifty per cent rated it as moderate (2-3). Nalbuphine was not found to be superior to Pethidine which contradicted other published reports that showed greater pain relief with Nalbuphine including a study by Frank, McAteer, Cattermole, Loughnan, Stafford and Hitchcock (1987) which found that PCA Nalbuphine produced better analgesia in primiparas than PCA Pethidine. Isenor and Penny-MacGillivray (1992) compared the effectiveness of Meperidine administered I. M. and I. V. plus intermittent bolus on 30 randomly assigned labouring women. The control group received 50-100 mg of Meperidine via the intramuscular route every two hours as needed. The experimental

group received a bolus of 25 mg when the continuous infusion (as patient- controlled analgesia) was initiated with a 60 mg/hour rate. Both groups were allowed a maximum of 200 mg. Pain was assessed with a VAS at the time of administration and every thirty minutes after until five hours post administration. The women who received I. V. Meperidine reported significantly lower levels of pain than women in the I. M. group. The women in the I. V. group also received significantly higher doses of the drug.

Olofsson, Ekblom, Ekman-Ordeberg, Hjelm, & Irestedt (1996) designed a study to compare the analgesic effect of Pethidine on labour pain with that of Morphine using a double blind, dose-response methodology. They assessed pain intensity, sedation, degree of tension, calmness, discomfort and exhilaration with separate horizontal linear visual analogue scales. The results indicated: (1) no significant change in pain over time, (2) that following treatment with opioids, fifteen out of twenty parturients requested epidural analgesia, (3) that significantly more pethidine patients reported nausea than those receiving morphine, (4) those receiving pethidine were calmer and more exhilarated, (5) significant sedation was seen with increasing doses over time but with no significant difference between the two drugs, (6) no significant difference in median time between the end of opioid administration and delivery between infants born to those receiving morphine and those receiving pethidine, and (7) no correlation was found between opioid dose and Apgar scores.

Olofsson et al. concluded that drugs that induce greater tolerance to pain by sedation may not allow the mother to enjoy and properly remember the event. They also stated that “systemic opioids may not provide significant analgesia in labour pain because

the assumption is that nociceptive spinal transmission during labour does not include opioid control mechanisms. Since it is generally assumed that systemically administered opioids exert their predominant direct effect on supraspinal structures, the activation of opioid receptors here seems to be insufficient for the control of labour pain” (p.971). Needless to say this publication sparked some controversy in the British medical journals. Kingdom & Woods (1997) responded by flatly denying that narcotic analgesia is unsafe and that they do have a role in modern labour pain management. Twycross (1997) also felt that systemic opioids should not be rejected when other pharmaceutical alternatives such as epidurals are costly and require specialized training.

The study by Dan et al. (1991) used the I. V. push or bolus method, which, while it provides the most rapid onset of analgesia, has a much shorter duration than I. M. injections. Patient-controlled analgesia is a form of continuous infusion however, another I. V. method in the form of buretrol administration is somewhat unique. There is little research available to provide an actual demonstration of its effectiveness although McCaffery and Beebe (1989) recommended calculation of drug concentration to fluid when using such a method.

The usual practice of the caregivers of the clinical setting where this study is intended to occur is to administer Promazine (Sparine) with Meperidine. If the Meperidine is given I. M., the Sparine is also drawn into the syringe. If the Meperidine is given I. V. buretrol, the Sparine is given after the Meperidine has infused or may not be given at all. Unit specific experience has shown that Sparine mixed with Meperidine in the buretrol increases the risk of maternal respiratory depression.

Sparine is a phenothiazine derivative and is classified as a central nervous system agent, psychotherapeutic, tranquilizer and anti-emetic (Freeman, Queener & Karb, 1995; Shannon & Wilson, 1992). "The incidence of postural hypotension and drowsiness is particularly high after parenteral administration" of Sparine (Shannon & Wilson, 1992). The role of Sparine is intended to be that of potentiator of the narcotic analgesic, in this case Meperidine. The purpose of the potentiator is to increase the analgesia of the narcotic. However, there are very few potentiators as most act more as additives than enhancers. This means they "add whatever primary effect they have to the action of the narcotic" (McCaffery & Beebe 1989, p.117; Britt & Pasero, 1998). An additional function of Sparine is as an anti-emetic in the study Labour and Delivery setting. It is, however, difficult to identify whether the nausea and vomiting experienced by the labouring woman is due to the labour process or the narcotic drug. McCaffery and Beebe (1989) question the true effectiveness of Sparine as an anti-emetic.

This literature review has included research and theory regarding the physiology of pain, the physiology of labour pain, the physical and psychological factors influencing labour pain, assessment and measurement techniques, and opioid analgesia effects on labour pain. The utilization of quantitative pain measuring tools is not in dispute. Yet the clinical application on a day-to-day basis in a busy tertiary care unit is limited. Nursing judgements regarding the method of analgesia medication may or may not include discussion with the patient and though usually based on experience and behavioural observation, the assessment is often subjective. Nurses need to be convinced that a recommended change in practise will be useful and not inconvenient or futile. Research

must address the effectiveness of Meperidine when administered via I. V. buretrol (closed-container) or I. M. and possibly provide evidence to caregivers that one method is more effective than the other. Caregivers must see the results of objective pain measurement methods in order to adopt them into their practise.

CHAPTER III

Methodology

Design

An experimental, prospective study has been designed to test the following hypotheses:

- 1) There will be no significant difference in overall Visual Analogue Scale mean scores between women who receive Meperidine in labour by the I. V. or I. M. route.
- 2) There will be no significant difference in pain scores at an earlier period of time between women who receive Meperidine in labour by the I. V. route and women who receive the drug via the I. M. route.
- 3) There will be no significant difference in pain scores for a longer period of time between women who receive Meperidine in labour by the I. M. route and women who receive the drug via the I. V. route.
- 4) There will be no significant difference in visual analgoue pain scores for multiparous versus nulliparous women.

For the purpose of this study, the buretrol administration consisted of the physician's prescribed dose (100 mg) of Meperidine diluted in 100 ml. of diluent (Normal Saline). The I. V. medication was administered through a volume infusion pump with 25 ml. infused over ten minutes at a rate of 150 ml/hour and the remainder was infused over 50 minutes at a rate of 90 ml/hour. The I. M. injection consisted of medication administration into a gluteal muscle.

Sample

A power analysis conducted with the Manitoba Nursing Research Institute (MNRI) statistical consultant identified that in order to achieve a .95 probability of d (effect size) = .8 at $\alpha = .05$, 42 subjects per cell were required for a total of 168 subjects. A post-data power analysis conducted by the MNRI statistical consultant concluded that the probability that the null hypothesis will be rejected when it should be rejected is 0.95.

Participants included a voluntary sample of 84 nulliparous and 84 multiparous women with anticipated uncomplicated vaginal deliveries. Forty-two nulliparous women were randomly assigned to Protocol A (See procedure description) and 42 were randomly assigned to Protocol B. Forty-two multiparous women were randomized to Protocol A and 42 were randomized to Protocol B.

One hundred and sixty-eight subjects are adequate to diminish the probability of getting a biased sample and provide ability to counterbalance atypical values (Polit & Hungler, 1995). In fact, ultimately 169 women were enrolled in the study. This included 85 nulliparas and 84 multiparas. Women with such complications as pregnancy-induced hypertension, insulin-dependent diabetes, antepartum hemorrhage, twin gestation or any conditions which could have adversely affect the mother or fetus were excluded from the study.

The study participant had to be able to understand English in order to comply with the use of the VAS and to be able to display some manual dexterity to handle the

mechanical VAS. The participant also had to be in established labour, early enough to be able to listen to and comprehend the study information, but not in such active labour that she would feel “pressured” to participate in order to receive an analgesic.

Setting

The research occurred in the Labour and Delivery Unit of a tertiary care teaching hospital in Winnipeg, Manitoba, Canada. Approximately 4000 deliveries occur annually at this institution.

Procedure

When the woman was admitted to the Labour and Delivery unit, the Labour and Delivery nurse approached the patient to obtain her permission to allow the nurse-research assistant to come into the room to describe the study. If the woman agreed, the research assistant was contacted to discuss the study with the woman. The Labour and Delivery nurse assigned to the care of the patient did not participate in providing information regarding the study. Upon such permission from the patient, the research assistant verbally described the study and gave the patient an Invitation to Participate (Appendix B) to read. Once this was completed, any questions that she had regarding the study were answered by the assistant. After obtaining informed consent (Appendix C), each participant was randomly assigned to one of the following protocols:

Protocol A: (to be applied to nulliparas and multiparas)

- (i) Demerol as ordered was diluted in 100 ml. of diluent (usually normal saline) in an I. V. buretrol system. Using a volumetric infusion control pump, twenty-five ml. was infused over 10 minutes at a rate of 150 ml/hour and
- (ii) the remaining 75 ml was infused over 50 minutes at a rate of 90 ml/hour.

AND

- (ii) A placebo was administered I. M. in a gluteal muscle at the same time as the I. V. infusion.

Protocol B: (to be applied to nulliparas and multiparas)

- (i) Demerol as ordered was administered in a gluteal muscle.

AND

- (ii) A placebo was administered in 100 ml. of diluent (usually normal saline) in an I.V. buretrol system. Using a volume infusion control pump twenty-five ml. was infused over 10 minutes at a rate of 150 ml/hour and the remaining 75 ml. was infused over 50 minutes at a rate of 90 ml/hour.

The patient was assured prior to the study that she would definitely receive the medication through one of the two routes. Co-operation with the hospital's Pharmacy Department was elicited. They were asked to prepare the medications for the above protocols, label them in order to blind the identity from the patient and the medication administrator, and to assign randomization. In other words, neither the medication administrator nor the patient knew which route was actually providing the drug.

As previously stated, randomization or random assigning of the study subjects occurred. This was to give every subject an equal chance of being assigned to any group (Polit & Hungler, 1995, p. 159). Random assignment utilized small manila-type envelopes with the treatment stated inside the envelope. As each subject was recruited, the next envelope in the file was opened and the stated treatment applied. This meant that Protocol A (i) occurred several times in a row or Protocol B (ii) occurred before Protocol A (ii).

Demographic and previous childbirth history data (Appendix E) was collected in order to describe the sample. Age, marital status, income, education, gravidity, and parity, race, childbirth preparation and personal assessment of menstrual pain in particular, was ascertained (Appendix E). This data was collected immediately after informed consent was obtained. Although either the patient or the researcher could have completed Appendix E, the subject independently provided the information the vast majority of instances.

Labour data, medication information, pain intensity and various other information (Appendix F) was obtained from the study participant and her chart from the time of drug administration until delivery. The pain scale was administered only by the assistant and only at the stated times. This was to maintain consistency in scale use.

Sparine was administered after administration of the Meperidine (Demerol) if the patient demonstrated nausea and vomiting. The current practice is to administer Sparine with Meperidine if the parenteral route is I. M. However, if the I. V . route was to be used; the Sparine would not be mixed in the buretrol chamber with the Meperidine. For the purposes of this study, if the Sparine was to be given at all, it was administered after the Meperidine has infused.

The study was submitted for ethical approval to the University of Manitoba Faculty of Nursing Ethical Review Committee and the tertiary care review committees. Informed consent was obtained from all subjects after being provided with a written explanation of the study. Participants were reassured that they will remain anonymous and were informed that they could withdraw from the study at any time. As previously stated, the patient was assured that pain medication would not be withheld regardless of participation. A letter was sent to all attending physicians to secure medical approval for patient participation (Appendix D).

Instruments

As described earlier, Jensen, Karoly and Braver (1986) identified certain criteria in the consideration of pain scales. These included the ease of administration and scoring, rates of correct response, the relative sensitivity of the scales as defined by the number of response categories provided and their ability to detect treatment effects and finally, the magnitude of the relationship between each scale and a 'best possible' combined measure of subjective pain intensity. Variations of a VAS are demonstrated in the literature. (Fridh et al. 1988; Isenor & Penny-MacGillivray, 1993; Lowe & Roberts, 1988; Melzack, Kinch, Dobkin, Lebrun & Taenzer, 1984; Price, Harkins & Baker, 1987). These researchers found the scales easy to administer and score. As women in labour have little time to spend on answering complicated questions or provide thought-provoking responses, a VAS can be quite appropriate. Even though Bonnel and Boureau (1985) and Isenor and Penny-

MacGillivray (1993) appreciated the intrinsic value of an instrument such as the McGill Pain Questionnaire, they questioned its applicability to labouring women. The average implementation time of the MPQ is thirty minutes, which, due to the acute quickly rising nature of labour pain, is somewhat impractical. Visual Analogue Scales are simple to administer and to score. They avoid artificial categorization and produce more sensitive measurements. Because the VAS produces interval level data, parametric statistics may be used in analysis. It is interesting to note that McGuire (1984, 1988) believed that the use of the VAS should be restricted to intensity only, while McDowell and Newell (1996) felt that "there is no reason why a VAS could not be applied in measuring other dimensions, such as levels of anxiety or the emotional responses associated with pain." (p.341). There are some differences of opinion regarding the horizontal versus vertical VAS. McDowell and Newell (1996) believe the horizontal scale is preferred because the failure rate may be higher in the vertical due to visual distortion when it lies flat on a table. The vertical scale may also give less normally distributed data. However, Huskisson (1983) and McGuire (1988) indicate that either way of using the scale is acceptable.

A mechanical visual analogue scale was used to determine pain intensity ratings. (Appendix A). It was shown to the study participant in a vertical position. The patient's side of the scale was a 100 mm red line with word anchors at either end. The bottom end stated "no pain" and the top end stated "worst possible pain." The other side was marked in millimetres. The patient was asked to move a sliding marker on the red line that best described how much pain was experienced at that particular time. The actual number (in mm) where the marker was placed was recorded. Documentation occurred on the

participant's data collection sheet (Appendix F). Pain ratings were requested immediately prior to protocol implementation, and then 10, 20, 30, 45, 60 minutes and every 30 minutes thereafter until 4 hours post-administration, dispensing of more analgesia i.e. a second dose of narcotic or epidural insertion, or birth of the infant, whichever came first.

Data Analysis

Parametric *t*-tests for independent samples were used to test for differences between the nulliparous and multiparous groups for demographic and labour data. Chi-squares were carried out on categories. This was considered a 'between patient' study because each subject received one treatment as opposed to a crossover technique or 'within patient' study where each subject receives all treatments (Dundee & Loan, 1981). Researchers are cautioned that "within-in subjects comparisons are more sensitive than between-subject and borderline areas do exist where the choice of test, parametric versus nonparametric, may make a difference in the conclusions drawn" (Wewers & Lowe, 1990, p.233). Because more than three measures of the dependent variable, VAS score, were taken repeated measures ANOVA (analysis of variance) was used. The ANOVA was applied because the nulliparous group consisted of those subjects who received Protocol A and B and the multiparous group consisted of those subjects who received Protocol A and B. Consultation with the Manitoba Nursing Research Institute statistician regarding appropriate data analysis occurred.

CHAPTER IV

Results

This study was done for several reasons. The first was to identify if the route used to administer analgesia to labouring women made a difference in self-assessed pain perception. The second reason was to determine if there were differences in pain scores as reported by nulliparous and multiparous women.

Demographic Data

A description of the sample is presented. The sample data was coded, entered and results of the treatment protocols were analyzed using the Statistical Package for the Social Sciences (SPSS) version 9 for Windows'98. Some data were analyzed using descriptive statistics to produce means, medians, ranges, and standard deviations. Other data were cross-tabulated with descriptive statistics to provide comparative data for the nulliparous and multiparous groups. The data were further analyzed utilizing a repeated measures analysis of variance (ANOVA).

Sample Characteristics

A total of 169 women voluntarily enrolled in the study from June 02, 1999 until December 22, 1999. The women were inpatients of a tertiary care Labour and Delivery unit at an inner city hospital. Although exact numbers were not kept, many women declined participating in the study after reading the Invitation to Participate. Some reasons included not wanting to receive two injections (establishing the I.V. and giving the I.M.

injection) and others did not want to have to look at the pain scale when they were in active labour.

The following results are based on the information received from the subject once consent was obtained and prior to administration of the medication. Each subject, as part of the consent process, independently completed the Demographic and Childbirth History Information form (Appendix A). The 169 subjects included 85 women who had never delivered a viable infant and were identified as nulliparas and 84 women who were described as multiparas because they had delivered at least one viable infant.

The 169 subjects ranged in age from 14 to 40 years with a mean of 25.70 and a standard deviation (SD) of 6.02. The subjects had experienced a range of one to nine pregnancies with a mean of 2.56 and a SD of 1.76. As the group included nulliparas and multiparas, the range of babies born alive was 0 to 6 with a mean of one and a SD of 1.35. Income of the subjects ranged from \$10,000 to \$80,000 per year with the mean occurring in the \$35,000 - \$49,999 bracket. However, 26 of the 169 (15.4%) subjects did not answer this question.

The 169 subjects attended school for a minimum of five to a maximum of 22 years. The mean was 11.97 years with a SD of 2.98. The educational institution ranged from grade school to university with the mean of the group completing some portion of high school.

The majority (68.6%) of the 169 subjects indicated that they were married or living with a partner. The participants' racial background was mainly divided between Caucasians (45.0%) and Aboriginal/Metis (43.2%). The majority (52.7%) of the 169

subjects indicated that the current pregnancy was not planned. Fifty-three per cent of the 169 subjects never attended childbirth education classes while a combined total of 46.8% attended classes in the current pregnancy or in a previous pregnancy.

The reported menstrual pain from 167 of the subjects (scores were not obtained from 2 of the subjects) ranged from 0 to 100 on a 100 - point scale. The mean was 33.19 with a SD of 25.06.

The nulliparas and multiparas are described according to the following variables: total number of pregnancies (gravida), number of babies that were born alive (para), age, income, highest level of education achieved, total years in school, whether an education degree was obtained, marital status, race, whether this pregnancy was planned, attendance at childbirth education classes, and self-assessment of menstrual pain. The population will be described in the order of the questions asked on the form. The following information represents a description of the sample population including personal demographic and obstetrical data.

Table 1

Total number of pregnancies (counting the present pregnancy)

	Number of Pregnancies									Total
	1	2	3	4	5	6	7	8	9	
Nullipara Count	63 74.1%	13 15.3%	6 7.1%	2 2.4%	1 1.2%					85 100%
Multipara Count		26 31.0%	21 25.0%	11 13.1%	12 14.3%	9 10.7%	2 2.4%	2 2.4%	1 1.2%	84 100%
Total Count	63 37.3%	39 23.1%	27 16.0%	13 7.7%	13 7.7%	9 5.3%	2 1.2%	1 1.2%	1 .6%	169 100%

The mean number of pregnancies experienced by the nulliparas was 1.41 with a SD of .82. The multiparas had a mean of 3.71 pregnancies with a SD of 1.7. Information regarding spontaneous or therapeutic abortions was not collected.

Because the Levene's Test for Equality of Variances revealed an $F = 47.449$ and a $p\text{-value} = .000$, the t-test for equality of means with equal variances not assumed was used. The t-test resulted in this: $t = -11.167$, $df = 119.211$, $p < 0.0005$.

Table 2

Total Number of Babies Born Alive

	Number of Babies born Alive							Total
	0	1	2	3	4	5	6	
Nullipara Count	85 100%							85 100%
Multipara Count		40 47.6%	19 22.6%	11 13.1%	11 13.1%	2 2.4%	1 1.2%	84 100%
Total Count	85 100%	40 23.7%	19 11.2%	11 6.5%	11 6.5%	2 1.2%	1 1.2%	169 100%

As per their definition, the mean numbers of babies born alive to nulliparas was 0. The mean for the multiparas was 2.04 with a SD of 1.25. The independent samples t-test (equal variances not assumed) result was: $t = -14.972$, $df = 83$, $p < 0.0005$.

Age (years)

The mean age of the 85 nulliparas was 23.6 years; the median was 22 years with a range from 14 to 38 years. The standard deviation was 5.8 years. The mean age of the 84 multiparas was 27.8 years; the median was 27.5 years with a range from 17 to 40 years.

The standard deviation was 5.5 years. An independent samples t-test for age resulted in: $t = -4.88$, d.f. 167, $p < 0.0005$. This indicated a significant difference in age between the nulliparas and multiparas.

Table 3

Total Combined Family Income (Before Taxes) Last Year

	10,000-19,999	20,000-34,999	35,000-49,999	50,000-80,000+	Unknown	Total
Nullipara Count	29 34.1%	11 12.9%	8 9.4%	22 25.9%	15 17.6%	85 100.0%
Multipara Count	32 38.1%	13 15.5%	9 10.7%	19 22.6%	11 13.1%	84 100.0%
Total Count	61 36.1%	24 14.2%	17 10.1%	41 24.3%	26 15.4%	169 100.0%

A parametric Pearson Chi-square test done on income gave the following result: $\chi^2(4, N = 169) = 1.202$, $p = .878$. This p -value indicated that there was no significant association between income level within the nulliparas and multiparas. Please note that significance levels reported for all Chi square results were identified by SPSS 9.0 as asymptotic significance.

Education

The mean of the nulliparas' total years spent in school was 12.2 with a range of 5 to 21 years. The median was 12 years. The mean of multiparas' total years in school was 11.7 years with a range of 6 to 22 years. The median was, as with the nulliparous group, also 12 years. See Table 4 for a breakdown of completion at each educational level. Table 5 provides the results of those who obtained an educational degree.

Table 4

Highest Education Level Achieved

	Grade school	High School	Community	University	Total
Nullipara Count	6 7.1%	48 56.5%	12 14.1%	19 22.4%	85 100.0%
Multipara Count	8 9.5%	51 60.7%	13 15.5%	12 15.5%	84 100.0%
Total Count	14 8.3%	99 58.6%	25 14.8%	31 18.3%	169 100.0%

$$\chi^2 (3, N = 169) = 1.991, p = .574$$

Table 5

Educational Degree

	Earned a degree		Total
	Yes	No	
Nullipara Count	13 15.3%	72 84.7%	85 100%
Multipara Count	9 10.7%	75 89.3%	84 100.0%
Total Count	22 13.0%	147 87.0%	169 100.0%

$$\chi^2 (1, N = 169) = .376, p = .376$$

Table 6

Marital status

	Marital Status			Total
	Single	Married/Living with Partner	Separated	
Nullipara Count	36 42.4%	49 57.6%	0 0.0%	85 100.0%
Multipara Count	15 17.9%	67 79.8%	2 2.4%	84 100.0%
Total Count	51 30.2%	116 68.6%	2 1.2%	169 100.0%

$$\chi^2 (2, N = 169) = 13.435, p = .001$$

Table 7

Racial Background

	White	Aboriginal/ Metis	Other	Total
	Nullipara Count	43 50.6%	29 34.1%	13 15.3%
Multipara Count	33 39.3%	44 52.4%	7 8.3%	84 100.0%
Total Count	76 45.0%	73 43.2%	20 11.8%	169 100.0%

$$\chi^2 (2, N = 169) = 6.192, p = .045$$

Table 8

Planned Pregnancy

	Planned Pregnancy		Total
	Yes	No	
Nullipara Count	37 43.5%	48 56.5%	85 100.0%
Multipara Count	43 51.2%	41 48.8%	84 100.0%
Total Count	80 47.3%	89 52.7%	169 100.0%

$$\chi^2 (1, N = 169) = .995, p = .319$$

Table 9

Attendance at childbirth education classes

	Attendance at Childbirth Education Class			Total
	Yes, during this pregnancy	Yes, during a previous pregnancy	No	
Nullipara Count	42 49.4%	0 0.0%	43 50.6%	85 100.0%
Multipara Count	12 14.3%	25 29.8%	47 56.0%	84 100.0%
Total Count	54 32.0%	25 14.8%	90 53.3%	169 100.0%

$$\chi^2(2, N = 169) = 41.840, p < 0.0005$$

Of note is the fact that of the total 85 nulliparas, 22 (26%) had experienced a previous pregnancy. However, none of the nulliparas had indicated that they had attended childbirth education in a previous pregnancy. The self-completed survey did not ask the participant to indicate at what gestation previous pregnancies had ended.

Rating of menstrual pain

The last question on the Demographic and Childbirth History Information form asked the subjects to rate their menstrual period pain at the worst time of their period. The researcher showed the subject the Visual Analogue Pain Scale (See appendix A), asked her to recall her menstrual period pain and indicate its level using the scale.

Eighty-four nulliparas rated their menstrual period pain at a mean of 34.8 (out of 100). The median was 30.5 with a minimum of 0 and a maximum of 100.0. This made the

range 100 points. The standard deviation was 25.8.

The 83 multiparas mean rating was 31.9 out of 100 with a median of 32. The minimum score was, as with the nulliparas, 0. The maximum was 96. Therefore the range was 96. The standard deviation was 24.2. An independent t-test (equal variances assumed) resulted as follows: $t = .823$, $df = 165$, $p = .412$, indicating that the difference in menstrual pain assessment between the nulliparas and multiparas was not significant.

For a variety of reasons there were a number of women who completed the Demographic and Childbirth History Information form (Appendix D) and who did not continue in the study. None of the women received the study treatments and none of the data from the forms was included in the results. Some of the reasons cited by the women included a change of mind about continued participation, change of mind about using Meperidine (Demerol), requesting the use of a different type of pain relief such as an epidural, or not requiring any form of analgesia for labour pain. Exact numbers of women who fell into the above stated categories were not tabulated.

Once the subject requested Meperidine for pain relief, the Labour Data, Medication Record and Pain Intensity Ratings form (see Appendix F) was completed. As for the demographic data, the data obtained from Appendix F will be summarized for the groups as a whole and then described for the nulliparas and multiparas.

The group N for the following information was 169 except for contraction duration where the N was 168. When the Meperidine was administered, the frequency of the contractions ranged from a minimum of 1 minute to a maximum of 6. The mean was 2.92 minutes with a standard deviation of .90. The duration of the contractions ranged

from 30 to 90 seconds with a mean of 55.77 and a SD of 9.52. The intensity of the contractions was assessed as being mild (coded as a 1), moderate (coded as 2) or strong (coded as 3). The mean was 1.98, which could be interpreted as moderately-strong.

The cervical dilatation ranged from 0 to 8.5 cm when the drug was given. The group mean was 3.92 cm with a SD of 1.58. The consistency of the cervix was described as thick or less than 50% effaced and coded as 1, greater than 50% effaced and coded as 2 and if the consistency was not recorded, a code of 3 was given. The mean cervical consistency was 1.92 with a SD of .43. The station of the presenting part ranged from -3 to +1. The coded mean of 3.72 reflected a station of -1.

The pain scores are specifically described in Table 13a-1. The study began with 169 subjects with a pre-administration mean pain scale score of 69.62. The numbers sometimes gradually and sometimes quickly decreased from that point to the four hour time period where 16 subjects remained in the study. Their mean pain score was 72.94. An interesting observation was that from pre-administration until 2 hours after, the group minimum was 0 and the maximum was 100.

A companion was present for 156 of the 169 subjects. Twenty-one (12.4%) of the 169 subjects vomited while they were in the study; 27 (16.0%) complained of nausea; none of the subjects demonstrated hypotension or respiratory depression; and 2 (1.2%) demonstrated mental clouding. The two subjects who demonstrated mental clouding remained in the study as they were deemed capable of indicating pain scores. Seven (4.1%) of the 169 subjects received Promazine (Sparine) for demonstrated nausea and/or vomiting.

If the subject requested another form of pain control with medication, pain scoring was no longer collected from her. However, data was recorded regarding the various types of medication that was then used. Eighteen (10.7%) received a second dose of Meperidine and two (1.2%) went on to later receive a third dose of the drug. Twelve (7.1%) received Promazine, usually with the Meperidine. One subject was given a spinal anaesthetic while 70 (41.4%) of the total group of 169 received an epidural after Demerol. Forty-six (27.2%) used nitrous oxide. Many of these secondary sources of labour pain relief were used in combination. For example, some women received the second Demerol dose and used nitrous oxide during the transition phase of stage one.

The mean length of stage one was 9.62 hours with a minimum of 1 hour and a maximum of 31 hours. The SD was 6.35. The mean length of stage two was 42.06 minutes with a minimum of 0 and a maximum of 600 minutes (10 hours). One hundred and forty-seven (87.0%) of the subjects delivered their infants spontaneously. Five (3%) required forceps assistance, 5 (3%) required vacuum extraction and 12 (7.1%) delivered their infants by Caesarean Section.

The mean weight of the 169 infants was 3623.92 grams with a minimum of 1693 grams and a maximum of 4938 grams. The infants' one minute Apgar scores ranged from 2 to 9 with a mean of 7.6. The five-minute Apgar scores ranged from 7 to 10 with a mean of 8.8. Twenty (11.8%) of the 169 infants required positive pressure ventilation (PPV) at birth and 10 (5.9%) required Naloxone administration. The tertiary care centre's policy is that positive pressure ventilation must be given prior to administration of Naloxone. If this policy were adhered to, 10 of the infants who received PPV at birth did not require the

antagonist action of Naloxone.

The results of the two groups, the nulliparas and multiparas are now presented.

Contraction Data

Frequency

At the time of analgesia administration to the 85 nulliparas, the mean frequency, or length of time from the start of one contraction to the start of the next, was 2.8 minutes. The median was 2.5 minutes. The minimum time was 1.0 and the maximum was 5.50 minutes apart. The range was 4.5. The standard deviation was 0.90.

At the time of analgesia administration to the 84 multiparas, the mean frequency of contractions was 3.0 minutes and also with a median of 3.0 minutes. The minimum frequency was 1.0 minutes with a maximum of 5.0. The standard deviation was 0.90.

A t-test for independent samples (equal variances assumed) was done on contraction frequency. The result was: $t = -1.536$, $df = 167$, $p = .126$.

Duration

The nulliparas' mean duration, or length of time from the beginning until the end of a contraction, was 55.8 seconds with a median of 55.0. The minimum was 30.0 and the maximum was 75.0 seconds. The range was 45.0. The standard deviation was 7.86.

The mean duration of contractions experienced by the multipara group was 56.16 seconds with a median of 55 seconds. The minimum duration was 35.0 seconds and the maximum length of contractions at the time of the Meperidine administration was 90.00 seconds. The standard deviation was 10.8. The t-test result for independent samples

(equal variances not assumed) was: $t = -.254$, $df = 150.18$, $p = .80$.

Intensity

Intensity, or strength of a contraction, was described as mild, moderate or strong according to abdominal palpation assessed by the nurse in attendance or the researcher.

Table 10

Intensity of Contractions

	Intensity of Contractions					Total
	Mild	Mild-Mod.	Moderate	Mod.-Strong	Strong	
Nullipara Count	5 5.9%	12 14.1%	60 70.6%	8 9.4%	0 0.0%	85 100.0%
Multipara Count	1 1.2%	10 11.9%	57 67.9%	12 14.3%	4 4.8%	84 100.0%
Total Count	6 3.6%	22 13.0%	117 69.2%	20 11.8%	4 2.4%	169 100.0%

$$\chi^2 (4, N = 169) = 7.720, p = .102$$

Cervical DataDilatation

The examination of the cervix was not always done immediately prior to analgesic administration. Decisions whether or not to perform a vaginal examination prior to giving the Meperidine were usually made by the nurse or physician.

The nulliparas' mean dilatation of the cervix was 3.6 centimetres with a median of 3.5. The minimum of 0.0 and the maximum was 8.5 cm. The range was 8.5. The standard deviation was 1.6.

At the time of analgesia administration the mean dilatation of the cervix of the 84 multiparas was 4.2 centimetres with a 4.0 median. The minimum was 1.0 cm and the maximum was 7.5. The range was 6.50. The standard deviation was 1.5.

An independent t-test (equal variances assumed) resulted in: $t = -2.56$, $df = 167$, $p = .011$. The result of this test indicated a significant difference between the nulliparas

and multiparas in cervical dilatation when the Meperidine was administered.

Cervical Consistency

Cervical consistency is described as the degree of thinning as identified during the internal vaginal examination. The data is stated in Table 11.

Table 11

Cervical Consistency

	Consistency of Cervix			Total
	Thick (<50%)	Thin (>50%)	Unknown	
Nullipara Count	12 14.1%	70 82.4%	3 3.5%	85 100.0%
Multipara Count	11 13.1%	67 79.8%	6 7.1%	84 100.0%
Total Count	23 13.6%	137 81.1%	9 5.3%	169 100.0%

$$\chi^2 (2, N = 169) = 1.103, p .576$$

Presentation

Eighty-three of the 85 fetuses delivered to the nullipara group presented as cephalic. The other two were in the breech presentation. All of the 84 fetuses delivered in the multipara group presented as cephalic.

Station

The station or relationship to the maternal ischial spines of the presenting part is described in Table 12. If the presenting part is considered to be at zero (0) station it is said

to be engaged. If it is assessed at a minus one, two or three (-1, -2, -3), it is above the ischial spines. If it is below the spines it is at a plus (+1 or +2) station.

Table 12

Station of Presenting Part

	Station of Presenting Part							Total
	-3	-2.5	-2	-1	0	+1	Unknown	
Nullipara Count	6 7.1%	0 0.0%	28 32.9%	35 41.2%	13 15.3%	1 1.2%	2 2.4%	85 100.0%
Multipara Count	2 2.4%	3 3.6%	36 42.9%	30 35.7%	13 15.5%	0 0.0%	0 0.0%	84 100.0%
Total Count	8 4.7%	3 1.8%	64 37.9%	65 38.5%	26 15.4%	1 0.6%	2 1.2%	169 100.0%

$$\chi^2 (6, N = 169) = 9.379, p = .153$$

The unknown portion of the above multipara data is due to the absence of documentation on the patient's chart regarding that assessment. If the examination had occurred an hour or more prior to the analgesia administration, the examiner may not have been accessible to verbally confirm the results.

After administration of the analgesia.

Once the Meperidine was administered observations were begun regarding the patient's self-determined pain rating score, the presence of a companion during labour, the occurrence of drug adverse effects, the use of Promazine for nausea and/or vomiting, and the use of other medications for labour pain.

The study's design included the subject's use of a 100-point pain rating scale. The

scale consisted of a red line drawn on one side with the words “no pain” at one end and “worst pain” at the other end. The reverse side was scored from 0 to 100. This Visual Analogue Scale was held in a vertical position in front of the subject with the red line facing her. She was required to slide a plastic indicator to the spot where she perceived her pain to be at that particular moment. The researcher would read the pain rating as the number on the numbered side where the indicator was set. (Appendix A).

The subjects were asked to provide pain ratings immediately pre-analgesic administration, and at designated times after the medication was given. These times were at 10, 20, 30 and 45 minutes, 1 hour, 1 hour and 30 minutes, 2 hours, 2 hours and 30 minutes, 3 hours, 3 hours and 30 minutes and 4 hours. The mean scores are presented in the following tables for the nullipara and multipara groups for each time of pain assessment. These scores are generalized and therefore are non-specific to the intramuscular or intravenous routes.

Table 13a

Mean Pain Scores at Pre-Drug Administration (N = 169)

Pre-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	85 100.0%	69.21	70.00	22.00	100.00
Multiparas	84 100.0%	70.02	70.50	21.41	100.00

Equal variances assumed: $t = -.243$, $df = 167$, $p = .81$

Table 13b

Mean Pain Scores at 10 Minutes (N = 167)

10 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	85 100.0%	67.02	71.00	24.07	100.00
Multiparas	82 97.6%	70.02	69.00	21.74	91.00

Equal variances assumed: $t = -.333$, $df = 165$, $p = .739$

Table 13c

Mean Pain Scores at 20 Minutes (N = 166)

20 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	84 98.8%	59.94	61.00	24.65	100.00
Multiparas	82 97.6%	66.55	69.00	25.79	100.00

Equal variances assumed: $t = -1.688$, $df = 164$, $p = .093$

Table 13d

Mean Pain Scores at 30 Minutes (N = 155)

30 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	82 96.5%	57.32	59.5	28.47	100.00
Multiparas	73 86.9%	69.66	71.00	20.58	77.00

Equal variances not assumed: $t = -3.116$, $df = 147$, $p = .002$

Table 13e

Mean Pain Scores at 45 Minutes (N = 140)

45 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	82 96.5%	58.27	59.00	26.52	96.00
Multiparas	58 69.0%	65.17	69.00	27.01	100.00

Equal variances assumed: $t = -1.506$, $df = 138$, $p = .13$

Table 13f

Mean Pain Scores at 60 Minutes (N = 126)

60 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	73 85.9%	56.51	58.00	25.36	100.00
Multiparas	53 63.1%	69.79	74.00	26.51	100.00

Equal variances assumed: $t = -2.848$, $df = 138$, $p = .005$

Table 13g

Mean Pain Scores at 90 Minutes (N = 98)

90 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	63 74.1%	57.57	55.00	26.19	91.00
Multiparas	35 41.7%	67.94	69.00	24.90	100.00

Equal variances assumed: $t = -1.911$, $df = 96$, $p = .06$

Table 13h

Mean Pain Scores at 120 Minutes (N = 69)

120 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	48 56.5%	56.88	62.50	30.05	100.00
Multiparas	21 25.0%	68.81	74.00	25.54	98.00

Equal variances assumed: $t = -1.585$, $df = 67$, $p = .118$

Table 13i

Mean Pain Scores at 150 Minutes (N = 45)

150 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	34 40.0%	69.71	72.50	25.04	76.00
Multiparas	11 13.1%	70.46	83.00	35.05	92.00

Equal variances assumed: $t = -.078$, $df = 43$, $p = .938$

Table 13j

Mean Pain Scores at 180 Minutes (N = 29)

180 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	23 27.1%	70.87	75.00	20.89	72.00
Multiparas	6 7.1%	77.17	87.50	31.61	84.00

Equal variances assumed: $t = -.591$, $df = 27$, $p = .56$

Table 13k

Mean Pain Scores at 210 Minutes (N = 18)

210 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	15 17.6%	75.27	80.00	19.76	70.00
Multiparas	3 3.6%	66.33	89.00	49.10	90.00

Equal variances not assumed: $t = .310$, $df = 2.13$, $p = .784$

Table 13l

Mean Pain Scores at 240 Minutes (N = 16)

240 Minutes Post-Administration	Valid Subject Numbers	Mean Pain Score	Median	Standard Deviation	Range
Nulliparas	14 16.5%	75.00	81.50	22.06	70.00
Multiparas	2 2.4%	58.50	58.50	58.69	83.00

Equal variances not assumed: $t = .394$, $df = 1.04$, $p = .76$

As can be seen from Tables 13a-l, the pre-administration sample size began with 169 subjects and began reducing in numbers from then until the final assessment time at four hours post-drug administration. These scores do not separate the I. M. from the I. V. routes of drug administration but simply reflect the combined mean pain levels of the subjects. Also, the results of the independent samples t-tests indicated a significant difference in pain scores at 30 and 60 minutes between the nulliparas and multiparas.

Presence of a Companion during Labour

The researcher recorded the presence of a companion during labour. The length of time spent with the labouring woman, the quality of support provided, nor the total number of support persons was not noted. The recording of the presence of the companion did not include the attendance of the labour and delivery nurse.

Eighty-two (96.5%) of the 85 nulliparas had a companion present during labour. Three nulliparas (3.5%) did not have a support person present. Companions supported seventy-four (88.1%) multiparas during labour while ten (11.9%) had no companion present. In total, 92.3% of the subjects had a companion with them during their labour. $\chi^2(1, N = 169) = 4.174, p = .041$. This indicated a significant difference between the nulliparas and multiparas regarding the presence of a companion during labour.

After the Meperidine was administered and during the time the patient was on the study, data was collected regarding the presence of the potential drug side effects of nausea, vomiting, respiratory depression of a rate of <12 breaths per minute and mental clouding. The following tables will again describe the nullipara and multipara groups with the occurrence of each of the above stated effects.

Table 14

Occurrence of Nausea after Meperidine

	Nausea after Demerol		Total
	Yes	No	
Nullipara			
Count	18	67	85
% of nulliparas	21.2%	78.8%	100.0%
% within nausea	66.7%	47.2%	50.3%
Multipara			
Count	9	75	84
% of multiparas	10.7%	89.3%	100.0%
% within nausea	33.3%	52.2%	49.7%
Total			
Count	27	142	169
% of all	16.0%	84.0%	100.0%
% within nausea	100.0%	100.0%	100.0%

$$\chi^2(1, N = 169) = 3.445, p .063$$

Table 15

Occurrence of Vomiting after Meperidine

	Vomiting after Demerol		Total
	Yes	No	
Nullipara			
Count	16	69	85
% of nulliparas	18.8%	81.2%	100.0%
% of vomiting	76.2%	46.6%	50.3%
Multipara			
Count	5	79	84
% of multiparas	6.0%	94.0%	100.0%
% of vomiting	23.8%	53.4%	49.7%
Total			
Count	21	148	169
% of all	12.4%	87.6%	100.0%
% of vomiting	100.0%	100.0%	100.0%

$$\chi^2(1, N = 169) = 6.432, p = .011$$

Table 16

Occurrence of Mental Clouding after Meperidine

	Mental Clouding after Demerol		Total
	Yes	No	
Nullipara			
Count	1	84	85
% of nulliparas	1.2%	98.8%	100.0%
% of mental clouding	50.0%	50.3%	50.3%
Multipara			
Count	1	83	84
% of multiparas	1.2%	98.8%	100.0%
% of mental clouding	50.0%	49.7%	49.7%
Total			
Count	2	167	169
% of all	1.2%	98.8%	100.0%
% ment.clouding	100.0%	100.0%	100.0%

$$\chi^2 (1, N = 169) = .000, p = .993$$

None of the 85 nulliparas experienced respiratory depression or hypotension after the administration of the Meperidine. None of the 84 multiparas experienced respiratory depression after the administration of the Meperidine.

Sparine Administration

For the purposes of this study promazine hydrochloride (sparine) was not administered to the subject unless nausea and/or vomiting occurred more than once and could not be controlled with non-pharmacologic means. Table 17 identifies those subjects who required Sparine for nausea and vomiting. It is not within the goal of this paper to decide whether the nausea and/or vomiting could be attributed to the Demerol administration or to the gastrointestinal effects of labour.

Table 17

Sparine Administration for Nausea and/or Vomiting

	Sparine Administration		Total
	Yes	No	
Nullipara			
Count	6	79	85
% of nulliparas	7.1%	92.9%	100.0%
% of sparine for n &/or v	85.7%	48.8%	50.3%
Multipara			
Count	1	83	84
% of multiparas	1.2%	98.8%	100.0%
% of sparine for n &/or v	14.3%	51.2%	49.7%
Total			
Count	7	162	169
% of all	4.1%	95.9%	100.0%
% of sparine for n &/or v	100.0%	100.0%	100.0%

$$\chi^2(1, N = 169) = 3.664, p .056$$

Other Analgesia Used After the Initial Dose of Demerol

Pain ratings were collected from the woman until one of three events occurred. If she delivered the infant; if she reached four hours of time after the Demerol was administered; or if she requested another type of analgesia for the labour pain her participation in the study was discontinued. Pain ratings were collected from 16 of the 169 subjects for the full four hour time period. In total, 149 (including 15 of the previously mentioned 16 women) of the 169 subjects utilized another form of pharmacological analgesia. The following tables (18, 19, 20, 21, 22 and 23) provide the specific numbers of each group and other type of medication used.

Table 18

Sparine for Labour Pain

	Sparine for Labour Pain		Total
	Yes	No	
Nullipara Count	10 11.8%	75 88.2%	85 100.0%
Multipara Count	2 2.4%	82 97.6%	84 100.0%
Total	12 7.1%	157 92.9%	169 100.0%

$$\chi^2 (1, N = 169) = 5.640, p = .018$$

The Sparine was administered concomitantly with Demerol in eleven of the above twelve cases.

Table 19

Second Dose of Demerol for Labour Pain

	2 nd Demerol for Labour Pain		Total
	Yes	No	
Nullipara Count	13 15.3%	72 84.7%	85 100.0%
Multipara Count	5 6.0%	79 94.0%	84 100.0%
Total	18 10.7%	151 89.3%	169 100.0%

$$\chi^2 (1, N = 169) = 3.874, p = .049$$

Seven of the above 18 subjects received Demerol only. In other words it was not combined with Sparine. The results provided in Tables 18 and 19 indicate a significant difference in the use of a second dose of Demerol and Sparine between the nulliparas and multiparas.

Table 20

Third Dose of Demerol for Labour Pain

	3 rd Demerol for Labour Pain		Total
	Yes	No	
Nullipara Count	1 1.2%	84 98.8%	85 100.0%
Multipara Count	1 1.2%	84 98.8%	84 100.0%
Total	2 1.2%	167 98.8%	169 100.0%

$$\chi^2(1, N = 169) = .000, p .993$$

Table 21

Epidural for Labour Pain

	Epidural for Labour Pain		Total
	Yes	No	
Nullipara Count	51 60.0%	34 40.0%	85 100.0%
Multipara Count	19 22.6%	65 77.4%	84 100.0%
Total	70 41.4%	99 58.6%	169 100.0%

$$\chi^2(1, N = 169) = 24.331, p = <.0005$$

Table 22

Spinal Anaesthetic for Labour Pain

	Spinal Anaesthetic for Labour Pain		Total
	Yes	No	
Nullipara Count	0 0.0%	85 100.0%	85 100.0%
Multipara Count	1 1.2%	83 98.8%	84 100.0%
Total	1 0.6%	168 99.4%	169 100.0%

$$\chi^2(1, N = 169) = 1.018, p = .313$$

Table 23

Nitrous Oxide for Labour Pain

	Nitrous Oxide for Labour Pain		Total
	Yes	No	
Nullipara Count	17 20.0%	68 80.0%	85 100.0%
Multipara Count	29 34.5%	55 65.5%	84 100.0%
Total	46 27.2%	123 72.8%	169 100.0%

$$\chi^2(1, N = 169) = 4.499, p = .034$$

The Chi-square results from Tables 21 and 23 identified a significant difference in the use of epidurals and nitrous oxide after the study protocol between the nulliparas and multiparas.

Post-Delivery Data

Stage One

Eighty-one of the 85 nulliparas completed stage one or reached 10 cm dilatation. The mean length of stage 1 was 11.67 hours. The minimum was 2.01 hours; the maximum was 31.00 hours with a range of 29.00. The standard deviation was 6.96.

Eighty-three of the 84 multiparas completed first stage. One did not because a Caesarean Section was performed before the end of this stage was reached. The mean length of first stage for the multiparas was 7.61 hours. The minimum was 1.00 hours and the maximum was 21.00 with a range of 20.00. The standard deviation was 4.97. An independent samples t-test for the length of stage 1 with equal variances not assumed resulted in: $t = 4.281$, $df = 144.52$, $p < 0.0005$. This indicated a significant difference in the length of first stage between the nulliparas and multiparas with the multiparas' first stage lasting a shorter length of time, which is to be expected.

Stage Two

Due to the minimal length of time for second stage that was experienced by many multiparas, the length will be reported in total minutes.

For 79 of the 85 nulliparas, the mean length of second stage was 80.78 minutes (1.35 hours). The minimum was .05 minutes and the maximum was 600.39 (10.00 hours). The range was 600 minutes (10.00 hours) with a standard deviation of 108.18 minutes (1.8 hours).

For 83 of the 84 multiparas, the mean length of second stage was 5.21 minutes with a minimum of 0 minutes and a maximum of 60.31 minutes (1.00 hours). The standard

deviation was 16 minutes.

The independent samples test for second stage (equal variances not assumed) resulted in: $t = 6.139$, $df = 81.57$, $p < 0.0005$. This result indicated a significant difference in the length of second stage between the nulliparas and multiparas.

Table 24 identifies the various methods through which the 169 subjects delivered.

Table 24

Type of Delivery

	Type of Delivery				Total
	Spontaneous Vaginal	Forceps	Vacuum Extractor	Caesarean Section	
Nullipara Count	65 76.5%	4 4.7%	5 5.9%	11 12.9%	85 100.0%
Multipara Count	82 97.6%	1 1.2%	0 0.0%	1 1.2%	84 100.0%
Total	147 87.0%	5 3.0%	5 3.0%	12 7.1%	169 100.0%

$\chi^2(3, N = 169) = 17.094$, $p = .001$

Infant Data

The mean weight (grams) of the infants born to the nulliparas was 3561.31 with a minimum weight of 1693.00 and a maximum of 4938.00 grams. The range was 3245.00 and the standard deviation was 550.26.

The mean weight of the infants delivered of the multiparas was 3687.27 grams with a minimum of 2495.00 and maximum of 4747.00 grams. The range was 2254.00 and the standard deviation was 469.75.

Information regarding the administration of positive pressure ventilation and

naloxone (narcan) was obtained through a chart review if the researcher was not present at the time of delivery. The following tables (25 and 26) provide the data regarding these treatments to the infant.

Table 25

Administration of Positive Pressure Ventilation after Delivery

	Administration of Positive Pressure Ventilation		Total
	Yes	No	
Nullipara Count	12 14.1%	73 85.9%	85 100.0%
Multipara Count	8 9.5%	76 90.5%	84 100.0%
Total	20 11.8%	149 88.2%	169 100.0%

$$\chi^2(1, N = 169) = .855, p = .355$$

Table 26

Administration of Naloxone (Narcan) after Delivery

	Administration of Naloxone (Narcan)		Total
	Yes	No	
Nullipara Count	4 4.7%	81 95.3%	85 100.0%
Multipara Count	6 7.1%	78 92.9%	84 100.0%
Total	10 5.9%	159 94.1%	169 100.0%

$$\chi^2(1, N = 169) = .451, p = .502$$

Apgar Score

The Apgar scoring occurs at one and five minutes of age. The immediate resuscitation of the infant, which may include the administration of positive pressure ventilation or naloxone does not wait for the one minute Apgar score to be assessed. The Apgar scores are generally determined by the Labour and Delivery nurse, but if the hospital's Neonatal Resuscitation Team is present for any particular reason, the Apgar score will be set by a member of the team.

The mean Apgar score at one minute of age for the infants born to the nullipara group was 7.47 (out of a maximum of 10). The minimum was 2.00 and the maximum was 9.00 with a range of 7.00. The standard deviation was 1.84. The nulliparas' mean five minute score was 8.11 with a minimum of 7.00 and a maximum of 10.00 giving a 3.00 range. The standard deviation was 0.55.

The mean Apgar score at one minute in the multipara group was 7.74. The minimum was 2.00 and the maximum was 9.00, with a range of 7.00 and a standard deviation of 1.70. Independent samples t-test (equal variances assumed) resulted in: $t = -.980$, $df = 167$, $p = .328$. The multiparas' mean five minute Apgar score was 8.80. The minimum was 7.00 and the maximum was 9.00 with a range of 2.00. The standard deviation was 0.51. Independent samples t-test with equal variances assumed was: $t = .174$, $df = 167$, $p = .862$.

In summary, significant results were obtained when chi-square was used to test for differences between the nulliparas and multiparas for the following variables: marital status ($p = .001$), racial background ($p = .045$), attendance at childbirth education classes ($p <$

.005), the presence of a companion during labour ($p = .041$), vomiting after the administration of Meperidine ($p = .011$), the use of a second dose of Meperidine ($p = .049$), Sparine ($p = .018$), epidurals ($p < .0005$), and nitrous oxide for labour pain ($p .034$), and the type of delivery ($p = .001$).

As previously stated, the significance value for marital status was $p = .001$. However, 2 cells (33.3%) had expected counts less than 5 with a minimum expected count of .99. As there were only 3 categories (single, married/living with partner, and separated), the decision was made to accept this significance value without recoding the variable. The majority of the subjects were single (nullipara $n = 36$, multipara $n = 15$) or married/living with a partner (nullipara $n = 49$, multipara $n = 67$). A total of 2 women were separated and none indicated that they were divorced or widowed. The p -value of .001 is very significant and identifies a difference between the nulliparas and multiparas for the single and married/living with a partner, categories.

The racial background variable also showed that 5 cells (50%) had expected counts of less than 5 with a minimum expected count of .99. However, the categories in the racial background variable were recoded. This was done as there were five categories with three of the five having sparse counts. The Asian, Black and Other numbers were recoded to become the Other category. The chi-square result gave a moderately significant p -value of .045, indicating that there was some difference but not a large one, between the nulliparas and multiparas for racial background.

When independent samples t -tests were used to test for differences between nulliparas and multiparas, the following variables were identified as having significant p -

values: age ($p < .0005$), cervical dilatation at the time of Meperidine administration ($p = .011$), pain score 30 minutes after analgesic ($p = .002$), pain score 60 minutes after analgesic ($p = .005$), length of stage one ($p < .0005$), length of stage two ($p < .0005$). The significant result for the lengths of stage one and two with multiparas having shorter lengths are expected. Although the significant values were obtained for the total number of pregnancies and total number of babies born alive, this is expected given the definition of the nulliparous and multiparous groups.

Results of Hypotheses Testing

To test the first hypothesis, “there will be no difference in overall Visual Analogue Scale mean pain scores between women who receive Meperidine in labour by the intravenous (I. V.) or intramuscular (I. M.) route”, a general linear model repeated measures analysis of variance (ANOVA) was used. Since repeated measurements are not independent, the one-way analysis of variance (ANOVA) cannot be used to test this hypothesis; a repeated-measures analysis of variance is more appropriate to test this hypothesis.

A repeated measures ANOVA was conducted using **within subject** factor (pain scores measured over time) and one **between subject** factor (route of administration). The **between subject** factor (intramuscular or intravenous) was used to classify observations into two different groups. Table 27 summarizes the results of **within subject** and **between subject** mean pain scores from pre-administration until 60 minutes after administration.

Table 27

Group Statistics

Pain Score Time Level	Route of Administration	N	Mean	Standard Deviation	Standard Error Mean
Pre-Analgesic	I.M.	84	67.6071	23.4521	2.5588
	I.V.	85	71.6000	19.6537	2.1317
10 minutes post	I.M.	83	64.5301	23.4637	2.5755
	I.V.	84	70.6429	22.0419	2.4050
20 minutes post	I.M.	83	61.5301	25.2448	2.7710
	I.V.	83	64.8795	25.5192	2.8011
30 minutes post	I.M.	77	58.7662	25.3937	2.8939
	I.V.	78	67.4359	25.5076	2.8882
45 minutes post	I.M.	68	60.3088	23.3201	2.8280
	I.V.	72	61.9028	29.9432	3.5288
60 minutes post	I.M.	63	64.2063	25.7351	3.2423
	I.V.	63	59.9841	27.4229	3.4550

Repeated measures were used in this study for several reasons. Firstly, repeated measures offer the possibility of an increase in precision. Secondly, as the responses of different subjects to the same treatment can be quite dissimilar, using repeated measurements allows the researcher to separate out the variability attributable to differences among subjects. This may reduce the error variability, resulting in more precise estimates of factor effects. (Shott, 1990.)

Repeated measures ANOVA or within-subjects ANOVA “is used when there are three or more measures of the same dependent variable for each subject” and when “multiple measures of the same dependent variable are collected longitudinally at several points in time.” (Polit and Hungler, p. 418.) In this study, the pain score is the dependent variable and, is measured by the subject and recorded on at least six different points in

time.

In order to test the null hypothesis with respect to **within subject** factors, a univariate, multivariate or adjusted univariate approach may be used. To determine whether the univariate approach should be used, a statistical test called Mauchly's test of sphericity was carried out. "This is a test of the hypothesis that the variance-covariance assumptions needed for the univariate approach are met... If the p-value for Mauchly's test is greater than or equal to the significance level α selected by the researcher, the univariate approach can be used. If the p – value is less than α , the multivariate approach or an adjusted univariate approach should be used." (Shott, p. 169.) In other words, a nonsignificant p-value for Mauchly's test indicates that the univariate approach should be used. A significant p-value for Mauchly's test indicates that the univariate approach cannot be used and that the multivariate approach or an adjusted univariate approach must be used.

Based on Mauchly's test of sphericity with a p value = .000, sphericity cannot be assumed in this case (See Table 28). Therefore, multivariate tests were used for testing the following **within subject** factors:

- (A) Factor 1 or the first 6 times of pain ratings (pre-analgesia administration, 10, 20, 30, 45, and 60 minutes post-administration) and
- (B) the interaction of Factor 1 with the route of administration (I.M. or I.V.)

Table 28

Mauchly's Test of Sphericity

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Greenhouse-Geisser	Huynh-Feldt	Lower-Bound
FACTOR1	.499	84.296	14	.000	.800	.837	.200

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

The multivariate approach is a general method in which linear combinations of the differences between observations for different factor levels (in this case the first six times of pain ratings) are analyzed. "Multivariate statistics, such as Pillai's trace, Hotelling's trace, Wilks' lambda, and Roy's largest root, are used instead of F statistics to test the hypothesis ..." (Shott, p. 174.) Multivariate testing is therefore used for **within subject** factors which are Factor1 (i.e. pain scores over time) and the interaction of Factor1 (i.e. pain scores over time) with route of drug administration (**between subjects**) which is also considered a within subject testing method. The total number of subjects available for this test was 125.

Table 29

Multivariate Tests^b

Effect	Value	F	Hypothesis df	Error df	p - value
FACTOR1 (Pain score from pre to 60" post) Wilks' Lambda	.822	5.153 ^a	5.000	119.000	.000
FACTOR1*ROUTE (I.M. or I.V.) Wilks' Lambda	.918	2.137 ^a	5.000	119.000	.066

a. Exact statistic

The Wilks' Lambda multivariate test shown in Table 29 indicates a significant p-value of less than .001 for the within subject effect of pain. Hence, these results indicate that the **within subject** pain levels changed significantly from pre-drug administration through to 60 minutes later.

To determine if route of administration affected pain scores, the Wilks' Lambda multivariate test is also applied to the interactions of FACTOR1 and route of administration (I. M. or I. V.). When alpha is again set at .05, the p-value of .066 did not indicate significance (see Table 29). In this case, the interpretation can be made that the changes in the subjects' self-assessed pain levels were not affected by which route the drug was administered.

In order to test the hypothesis, "there will be no difference in overall Visual Analogue Scale mean pain scores between women who receive Meperidine in labour by the I. M. or I. V. route", the between subjects effects test was conducted.

Table 30

Tests of Between Subjects Effects

Measure: MEASURE_1

Transformed Variable: Average

Source	Type III Sum Of Squares	df	Mean Square	F	p-value
ROUTE	4315.746	1	4315.746	1.886	.172
Error	281485.688	123	2288.502		

As indicated in Table 30, a p-value of .172 for the between subjects effects is greater than the significance level, which has been set at 0.05. Therefore, the null hypothesis stating that: there will be no difference in overall Visual Analogue Scale mean pain scores between women who receive Meperidine in labour by the I. V. or I. M. routes is supported. Hypotheses two and three are discussed together because both relate to the factor of pain scores over time. The hypotheses are as follows:

2. There will be no significant difference in pain scores at an earlier period of time between women who receive Meperidine in labour by the I. V. route and women who receive the drug via the I. M. route.
3. There will be no significant difference in pain scores for a longer period of time between women who receive Meperidine in labour by the I. M. route and women who receive the drug via the I. V. route.

A general linear model repeated measures contrasts test was carried out to test these hypotheses. Contrasts tests are used to look for differences among the levels of a factor. In

this study the contrasts test was used to determine where differences occurred among the first six time levels in FACTOR1. The difference contrast test was selected from the following types: deviation, simple, Helmert, repeated, and polynomial. The difference contrast test, also known as a reverse Helmert, compares the mean of each level (except the first) to the mean of previous levels or categories (Norušis, 1993, p. 138). Statistics obtained from the difference contrast test are presented in Table 31

Table 31

Tests of Within-Subjects Contrasts

Source	FACTOR1	Type III Sum Of Squares	df	Mean Square	F	Sig.
FACTOR1 (Pain scores from pre to 60" post)						
	Level 2 vs. Level 1	999.785	1	999.785	1.896	.171
	Level 3 vs. Previous	6732.591	1	6732.591	16.677	.000
	Level 4 vs. Previous	5079.583	1	5079.583	14.127	.000
	Level 5 vs. Previous	2794.578	1	2794.578	9.406	.003
	Level 6 vs. Previous	99.323	1	99.323	.245	.622
FACTOR1*ROUTE (I.M. and I.V.)						
	Level 2 vs. Level 1	34.665	1	34.665	.066	.798
	Level 3 vs. Previous	101.855	1	101.855	.252	.616
	Level 4 vs. Previous	433.197	1	433.197	1.205	.275
	Level 5 vs. Previous	602.858	1	602.858	2.029	.157
	Level 6 vs. Previous	3343.573	1	3343.573	8.246	.005
Error(FACTOR1)						
	Level 2 vs. Level 1	64865.463	123	527.361		
	Level 3 vs. Previous	49655.617	123	403.704		
	Level 4 vs. Previous	44226.269	123	359.563		
	Level 5 vs. Previous	36544.640	123	297.111		
	Level 6 vs. Previous	49871.223	123	405.457		

Statistics from the difference contrast test verified that significant differences in

self-assessed pain scores occurred at different times following administration of analgesic. At 20 minutes (level 3) there was a significant difference in pain perceptions as measured by a Visual Analogue Scale when compared to the average of the mean scores from levels two and one. [$F(1, 123) = 16.677, p = .000$].

Similarly, at 30 minutes post administration of analgesia there was a statistically significant difference in pain perception when compared to the average of the mean scores from Level 3 (20 minutes), Level 2 (10 minutes) and Level 1 (pre-administration). [$F(1, 123) = 14.127, p = .000$]. Also, at level 5 (45 minutes) post- administration of analgesia there was a statistically significant difference in pain perception when compared to level 4 (30 minutes), level 3 (20 minutes), level 2 (10 minutes) and level 1 (pre-administration). [$F(1, 123) = 9.406, p = .003$].

Using the same p-value of .05, the FACTOR1 by ROUTE contrasts are not, for the most part, significant. Therefore, the route of administration did not have an effect on the perception of pain scores over time.

Figure 2 provides a graphic summary of the mean pain scores from pre-analgesia to 60 minutes post-administration for the I. M. and I. V. routes. The vertical axis represents the mean scores on the pain scale from 0 to 100. The horizontal axis represents the time the scores were analyzed beginning at pre-analgesia until 60 minutes post-administration.

Figure 2. Mean Pain Scores Over Time for I. M. versus I. V. Administrations

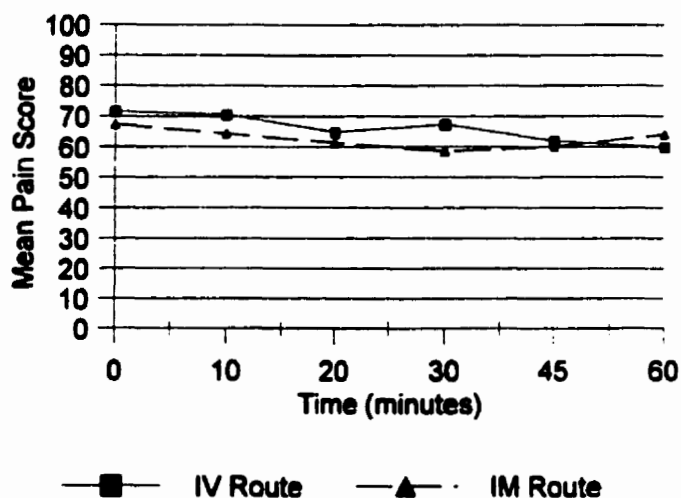


Figure 2 depicts less pain reported by the I. M. group from pre-administration until at least 20 minutes post-drug administration. The I. M. group steadily declines until 30 minutes where it begins to rise. At this point, the I. V. group appears to peak and then begins a decline. The two groups intersect at point just after 45 minutes.

The graph indicates that pain scores were not lower sooner after with the I. V. route. The graph also demonstrates that women who received the medication by the I. M. route, had lower pain scores at least until the 45 – 60 minute time. But the difference failed to reach statistical significance.

The null hypotheses for Hypotheses 2 and 3 are supported. Thus, women who received Meperidine by the I. V. route did not have lower pain scale scores sooner after administration than women who received the drug by the I. M. route. Similarly, women

who received Meperidine by the I. M. route did not have lower pain scale scores for longer periods of time than women who received the drug by the I. M. route.

Hypothesis number 4 states: "there will be no difference in Visual Analogue Scale pain scores for multiparous versus nulliparous women. The **within subject factor** is pain scores over time and the **between subject factor** for this hypothesis is parity. A total of 125 subjects (73 nulliparas and 52 multiparas) were included in the analysis of this hypothesis. Table 32 summarizes the **within subject** and **between subject** mean pain scores for time and parity.

Table 32

Group Statistics

Pain Score Time Level	Parity	N	Mean	Standard Deviation	Standard Error Mean
Pre-Analgesic	Nullipara	85	69.2118	22.0038	2.3867
	Multipara	84	70.0238	21.4172	2.3368
10 minutes post	Nullipara	85	67.0235	24.0743	2.6112
	Multipara	82	68.2073	21.7413	2.4009
20 minutes post	Nullipara	84	59.9405	24.6510	2.6896
	Multipara	82	66.5488	25.7903	2.8481
30 minutes post	Nullipara	82	57.3171	28.4670	3.1436
	Multipara	73	69.6575	20.5813	2.4089
45 minutes post	Nullipara	82	58.2683	26.5219	2.9288
	Multipara	58	65.1724	27.0115	3.5468
60 minutes post	Nullipara	73	56.5068	25.3553	2.9676
	Multipara	53	69.7925	26.5086	3.6412

Table 33

Multivariate Tests^b

Effect	Value	F	Hypothesis df	Error df	p - value
FACTOR1 Wilks' Lambda	.838	4.587 ^a	5.000	119.000	.001
FACTOR1*PARA Wilks' Lambda	.958	1.033 ^a	5.000	119.000	.402

a. Exact statistic

The Wilks' Lambda multivariate test from Table 33 indicates a significant p-value of .001 for the within subject effect of pain. This provides support to indicate that the pain levels changed significantly from pre-drug administration through to 60 minutes later.

The Wilks' Lambda multivariate test was applied to the interaction of FACTOR1 (pain scores over time) and parity (nullipara or multipara). With an alpha set at .05, the p-value of .402 obtained is not significant. Therefore, parity did not influence the subjects' self-assessed pain levels.

To test the fourth hypothesis, a between subjects effects test was conducted.

Table 34

Tests of Between Subjects Effects

Measure: MEASURE_1
Transformed Variable: Average

Source	Type III Sum of Squares	Df	Mean Square	F	p-value
PARA	1823.461	1	1823.461	4.896	.029
Error	45810.111	123	372.440		

As shown in Table 34, a significant p-value of .029 is obtained for the between-subjects effects. Therefore the evidence would support rejecting the null hypothesis that: there will be no difference in Visual Analogue Scale pain scores for multiparous versus nulliparous women. If this is the case, the alternative hypothesis could state that the mean scores between the multiparas and the nulliparas are different with the multiparas reporting higher mean pain scores.

A general linear model repeated measures test of within-subjects contrasts test was carried out (Refer to Table 35).

Table 35

Tests of Within-Subjects Contrasts

Source	FACTOR1	Type III Sum Of Squares	df	Mean Square	F	Sig.
FACTOR1						
	Level 2 vs. Level 1	905.567	1	905.567	1.717	.192
	Level 3 vs. Previous	6176.524	1	6176.524	15.322	.000
	Level 4 vs. Previous	4241.326	1	4241.326	11.915	.001
	Level 5 vs. Previous	2281.402	1	2281.402	7.706	.006
	Level 6 vs. Previous	20.612	1	20.612	.049	.826
FACTOR1*PARA						
	Level 2 vs. Level 1	37.727	1	37.727	.072	.790
	Level 3 vs. Previous	174.348	1	174.348	.433	.512
	Level 4 vs. Previous	875.474	1	875.474	2.459	.119
	Level 5 vs. Previous	731.478	1	731.478	2.471	.119
	Level 6 vs. Previous	1167.644	1	1167.644	2.759	.099
Error(FACTOR1)						
	Level 2 vs. Level 1	64862.401	123	527.361		
	Level 3 vs. Previous	49583.124	123	403.115		
	Level 4 vs. Previous	43783.993	123	355.967		
	Level 5 vs. Previous	36416.020	123	296.065		
	Level 6 vs. Previous	52047.152	123	423.148		

Statistics from the difference contrast test verified that significant differences in self-assessment pain scores occurred at different times following administration of analgesia. At 20 minutes (Level 3) there was a significant difference in pain perception as measured by the Visual Analogue Scale when compared to the average of the means for Level 2 (10 minutes) and Level 1 (pre-administration) [$F(1, 123)=15.322, p = .000$]. At 30 minutes (Level 4), there was a statistically significant difference in pain perception when compared to Levels 3, 2, and 1 [$F(1, 123)=11.915, p = .001$].

Also, at Level 5 (45 minutes post-administration), a statistically significant difference in pain perception resulted when compared to the averages of the means of

Level 4 (30 minutes), Level 3 (20 minutes), Level 2 (10 minutes) and Level 1 (pre-administration) [$F(1, 123)=7.706, p=.006$].

PARA (nullipara or multipara) was then interacted with FACTOR1 (pain scores over time) in the test of within-subjects contrasts. Using an alpha of .05, the resultant statistics were not, for the most part, significant.

Figure 3. Mean Pain Scores of Nulliparas and Multiparas

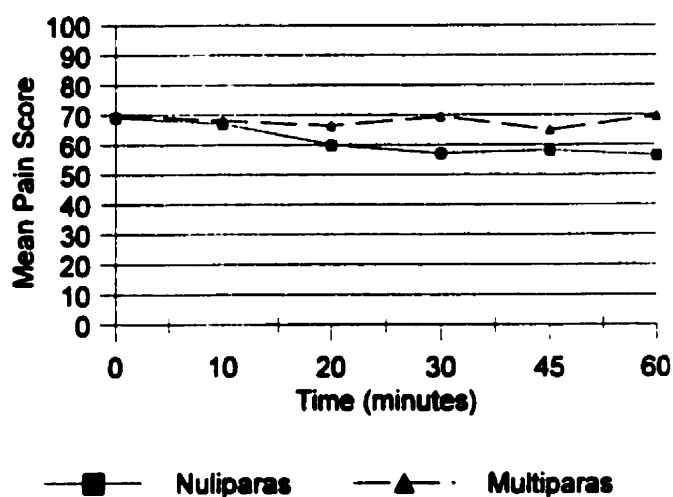


Figure 3 gives a graphic summary of the mean pain scores for the nulliparas and multiparas. As can be seen, nulliparous pain scores are consistently lower for the first 60 minutes but this difference failed to reach statistical significance.

Figure 4. Mean Pain Scores for I. M. and I. V. Routes in Nulliparas and Multiparas

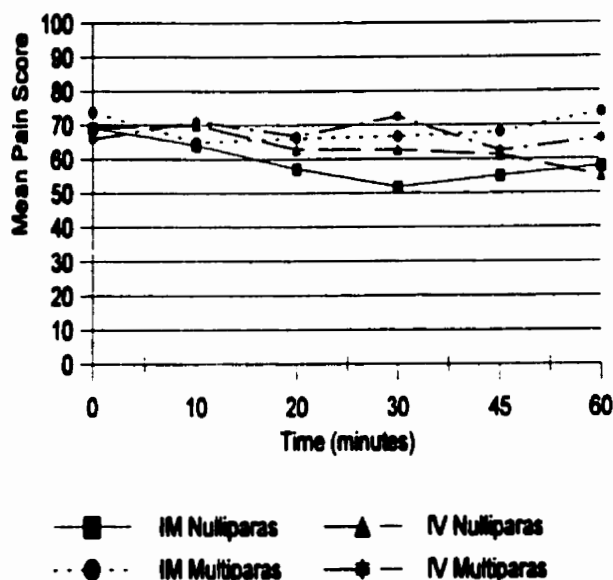


Figure 4 depicts the mean pain scores of the nulliparas and multiparas via the intramuscular and intravenous routes. The vertical axis is the pain score beginning at 0 and ending at 100. The horizontal axis is time beginning at pre-administration until 60 minutes after administration.

For the most part of Figure 4, the multiparas' pain scores are higher than the nulliparas. At the 10 minute time, the pain score actually increased for both groups who received the drug I. V. At 20 minutes the I. M. multiparas' mean pain score began to rise and did not decrease again. At 30 minutes, the lowest pain scores are recorded by the I. M. nulliparas. At 45 minutes, the I. V. multiparas reported their lowest mean scores and then began another increase; while the I. V. nulliparas began to show their lowest scores

since pre-administration. At 60 minutes, the mean pain scores for all groups except the I. V. nulliparas were ascending.

The results portion of this chapter summarized the data collected from 169 women. The data was obtained from subject-completed forms that requested demographic and childbirth history information. It included data regarding pregnancies, age, income, education, marital status, race, childbirth preparation and menstrual pain perception. Other data was obtained by the researcher-completed Labour Data, Medication Record and Pain Intensity Ratings form. It included information regarding the contractions, cervical assessment, Visual Analogue Scale pain scores, drug administration, and post-delivery data about the mother and her infant. The data was presented as a summary for the whole group and then presented for the nulliparous and multiparous groups. The independent samples t-test was done to test the differences between the group means for some variables. The Pearson chi-square test was used to compare the observed frequencies of categories for those variables that were considered categories.

The four hypotheses were then discussed with the tests that were used. Repeated measures analysis of variance for within subject factors and between subject factors occurred. The first hypothesis: there will be no difference in overall Visual Analogue Scale mean pain scores between women who receive Meperidine in labour by the I. V. or I. M. routes was supported.

The second hypothesis: there will be no significant difference in pain scores at an earlier period of time between women who receive Meperidine in labour by the I. V. route and women who receive the drug via the I. M. route was also supported.

The third hypothesis: there will be no significant difference in pain scores for a longer period of time between women who receive Meperidine in labour by the I. M. route and women who receive the drug via the I. V. route was supported.

The fourth hypothesis: there will be no difference in Visual Analogue Scale pain score for multiparous versus nulliparous women was rejected. The next chapter of this study will discuss the data set and results as it relates to the literature review and conceptual model. Limitations of the study, clinical relevance, and implications for future research will be provided.

CHAPTER V

Discussion

This research study was designed to identify if the route of Meperidine administration to women in labour made a difference to Visual Analogue Scale mean pain scores. The conceptual framework that guided this study was based on the original and subsequently updated work by McCaffery (1972) and Melzack & Wall (1965). The underlying belief is that pain is what the patient says it is and that pain in labour has a distinct and scientific basis. However, it is also acknowledged that the perception of pain in labour depends upon numerous factors. These can include previous experience, anxiety levels, childbirth preparation, marital status, length of labour and contraction frequency, duration and intensity.

The 169 subjects who voluntarily agreed to be in this study were randomized to one of two protocols. Pain scores were self-assessed using a 100-point mechanical Visual Analogue Scale at pre-determined time periods. Demographic and childbirth history data, which was provided by the participants, and labour data, medication and pain intensity ratings, were analyzed using independent samples t-tests and chi-square tests. The four hypotheses were tested using repeated measures analysis of variance (ANOVA). The hypothesis testing indicated that there was no difference in overall Visual Analogue Scale mean pain scores between women who received Meperidine in labour by the intravenous (I. V.) or intramuscular (I. M.) route. The testing also indicated that Meperidine given I. V. did not result in lower mean pain scores at an earlier period of time and that

Meperidine given I. M. did not result in lower mean pain scores for a longer period of time. Data testing indicated that there was a difference in Visual Analogue Scale pain scores for multiparous versus nulliparous women.

In this chapter, results of the study are discussed in relation to the conceptual framework, the literature review, the stated research hypotheses and the data set. Implications for nursing practice and future research will be discussed.

Study Findings in Relation to the Conceptual Framework

The conceptual framework upon which this study is based acknowledges the work of McCaffery (1972), McCaffery and Beebe (1989) and Melzack and Wall (1965). The study supports the framework's premise that pain is whatever the person who is experiencing it says it is and existing whenever they say it does. The labouring woman's self-assessment of her pain is taken as a true value. The women who participated in the study were intrigued by the use of a mechanical measurement of their pain. Occasionally, some women found it intrusive and exhibited a small amount of impatience when they were asked to adjust the scale at the point that best represented their current level of pain.

The labour pain experienced by the women in this study was always accepted as a reality and was treated as soon as requested. Once the woman was approached to participate in the study and once she agreed to become part of it, she was made aware of the fact that she was in control. The pain control and patient's rights developed by McCaffery and Beebe (1989) are an integral component to the study's philosophy. The

beliefs describe pain control as: (1) a legitimate therapeutic goal, (2) contributing significantly to the patient's physical and emotional well-being, (3) ranking high in the list of priorities in patient care, and (4) a patient controlled concept. The patient's rights included the right to: (1) decide the duration and intensity of pain that will be tolerated, (2) be informed of all possible methods of pain relief along with favourable and unfavourable consequences, (3) choose which method of pain control will be tried, and (4) choose to live with or without pain.

These beliefs and rights were in evidence throughout the study. The management of labour pain is considered one of the primary goals in labour and delivery care. The study's purpose is based on that goal. The remembrance of a positive childbirth experience that includes satisfactory pain control would be highly significant to her future well-being. The study identified one type of pain management that was described in the context of all other available options. Once the woman decided that the treatment protocol was not providing the type of pain control that she desired she was immediately offered other choices. Some women agreed to participate in the study yet clearly stated that their personal goal was to conduct their labour pain without medication. After signing the consent form, the patient was not approached by the research assistant until the patient requested the need for the study drug.

The conceptual framework of this study could be a basis for philosophy of care in most labour and delivery units. It embraces the concept of the woman and her labour pain at the centre of the intertwining circles. See Figure 1. The framework acknowledges the ownership of labour pain by the woman and understands that previous history, past

experience, cultural, social, and physical factors influence the perception of the pain. It also offers an opportunity for further development and expansion that would identify the role of companions and professional caregivers.

The response to the physiological aspect of the conceptual framework was reflected in the acceptance of labour pain as a normal experience using the explanation of the gate control theory. The interaction of sensory-discriminative dimensions, motivational-affective drive, and cognitive activity provide rationale for the process of pain perception. The combination of these theories assisted with the development of the working definition of labour pain for this study as: "the acute physiological and psychological responses to the processes that occur during the events of childbirth". Figure 1 graphically demonstrates the meshing of these responses and their influence on the perception of labour pain. The results of this study show that no one single factor causes a woman's response to her labour. The results demonstrate the importance of careful review of the labouring woman's demographic data, previous experience with childbirth and how she has prepared for the labour. The psychosocial and physical factors are numerous but if they are known, can provide valuable information to assist in helping the woman to cope with the pain of labour.

Hypotheses

The first null hypothesis in this study, which stated "there will be no difference in overall Visual Analogue mean pain scores between women who receive Meperidine in labour by the intravenous or intramuscular route," was supported. The first six

measurements of pain scores beginning at pre-administration and continuing at 10, 20, 30, 45 and ending at 60 minutes were utilized as there were sufficient subject numbers in the sample to this time. The group statistics, as seen in Table 27, identified the particular mean scores for the nulliparas and multiparas for each route of administration. Multivariate testing was used for testing the within subject factors of the pain scores over time and their interaction with the route of administration which is considered a between subjects factor.

The second hypothesis stated: "there will be no significant difference in pain scores at an earlier period of time between women who receive the drug I. V. than from women who receive it I. M." In other words, when Meperidine is given by the I. V. route, it is not expected that there will be significant differences in the mean pain scores earlier after administration than when it is given I. M. The third hypothesis stated: "there will be no significant difference in pain scores for a longer period of time from women who receive the drug I. M. than from women who receive it I. V." This null hypothesis is saying that when the drug is given I. M., it is not expected that there will be significant differences in the mean pain scores for a longer period of time than when it is given I. V.

To test hypotheses two and three a repeated measures contrasts test was used to look for differences among the levels of the pain scores from pre-administration until 60 minutes later. Results at three levels indicated that pain scores again changed significantly over time. The difference contrast test was used to compare the I. M. and I. V. routes to the pain scores. The results showed a lack of significance from pre-drug administration until 45 minutes. Therefore, the second and third null hypotheses were

supported. Thus, there were no differences in mean pain scores at an earlier period of time when women received the drug I. V. and there were no differences in mean pain scores for a longer period of time when women received the drug I. M.

The statistical testing process rejected the fourth hypothesis: "there will be no difference in Visual Analogue Scale pain scores for multiparous and nulliparous women". When a test of between-subjects effects was done, the resulting p-value was .029, which provided the evidence to reject the fourth hypothesis. Statistics from the difference contrasts test verified that significant differences in self-assessed pain scores occurred at different times following administration of analgesia.

Study Findings in Relation to the Literature Review

The questions that now require answering are: (1) why wasn't there a difference between the routes? (2) why wasn't there a difference in mean pain scores at an earlier time period when the drug was given I. V.? and (3) why wasn't there a difference in mean pain scores for a longer period of time when the drug was given I. M.?

The Labour and Delivery caregivers (nurses and physicians included) from this tertiary care centre have practised under the belief that route of medication administration makes a difference in the management of pain during labour. The research literature generally supports this understanding. In at least half of the labouring patients today, the primary route for parenteral administration of Meperidine is I. M. It is interesting to note that the use of this route is not endorsed in the United States. Britt and

Pasero (1998) believe that “the I. M. route of administration, which isn’t recommended for any type of pain management, is particularly inappropriate during labor because unreliable absorption makes it difficult to predict when peak effects will be achieved” (p. 10). However, a recent review was done of 16 trials published between 1969 and 1993 and occurring in Europe, Singapore, South Africa, and the United States (Elbourne & Wiseman, 2000). The objective of the review was to compare the use of Pethidine (also known as Meperidine or Demerol) in the I. M. form to other opioids also given intramuscularly. Even though the review did not examine the effectiveness of one route versus another, the total number of women in all 16 studies exceeded 3000. The reviewers concluded: “although there are considerable doubts about its effectiveness for maternal pain relief, and concerns about its potential maternal, fetal, and neonatal side-effects, there is as yet no convincing research evidence on which to base a decision to use any of the alternative opioids considered in this review” (Elbourne & Wiseman, 2000, p.7).

The intravenous protocol used in this study is rather unique but can be compared to studies using volumetric pumps that provide continuous infusion and to patient-controlled analgesia, which offers a combination of continuous and intermittent bolus infusions (Frank et al., 1987; Isenor & Penny- MacGillivray, 1992; Rayburn, Leuschen, Earl, Woods, Lorkovic, & Gaston-Johansson, 1989; Robinson et al, 1980). In the actual practice setting, due to a restricted number of available controlled-volume infusion pumps, one is rarely used to give the opioid. For this reason the medication (usually 100mg (1 ml) of drug is added to 100 ml of a diluent solution) is administered by gravity flow. The intention is to initially provide a bolus amount of drug, usually over ten

minutes and then to titrate the rate over a 50 minute time period according to the patient's perceived and demonstrated pain perception. In order to achieve a flow infusion that was constant, this study administered the Demerol via a volumetric pump (donated for the duration of the study by Baxter Corporation). One hundred mg of Meperidine was added to 100 ml of diluent (usually normal saline). The first 25 ml was given over a 10 minute period and the remainder, 75 ml, was administered over 50 minutes. To this extent the study protocol for I.V. administration resembles the use of continuous infusion systems.

This labour and delivery unit rarely administers Meperidine as a direct I.V. bolus or intermittent injection which may also result in transient peak blood concentrations and intermittent pain control (Mather & Phillips, 1986). The unit also infrequently uses any other type of narcotic opioid for parenteral administration other than the occasional use of Morphine or Fentanyl. Some studies utilized a dosage/kg of body weight protocol (Olofsson et al., 1996; Robinson et al., 1980). Although this is also a recommended method of administration made by McCaffery and Beebe (1989) and Mather and Phillips (1986), it is not a common practice protocol in many labour and delivery areas. The usual dose given is 100 mg and when the labouring woman is considered to be smaller in physical stature, 75 mg is administered. Eighteen subjects in this study received a second dose of Meperidine (nulliparas n = 13, multiparas n = 5) and one subject from each group went on to receive a third dose of the drug. This not an unusual analgesic dosage amount as labouring women could tolerate maximum dosages of 200 mg of Meperidine (Isenor & Penny – MacGillivray, 1993; Rayburn et al. 1989; Robinson et al. 1980). However, the concern is not so much with the woman as it is with cumulative effects of a narcotic on the

newborn which can include a shorter duration of wakefulness, less efficient sucking, depressed visual and auditory attention, longer time to habituate to noise and a decreased social responsiveness(Coalson & Glostén, 1991; Spielman, 1987; Wiener, Hogg, & Rosen, 1977).

There are numerous route and pharmacology issues in the administration of any drug. In considering the reasons why there was no difference in mean pain scores when Meperidine was given to women via the I. V. or I. M. routes, some review of drug infusion theory must be provided. To reiterate Britt and Pasero's (1998) concern regarding I. M. administration, variable pain control occurs because of the inability of a drug given intramuscularly to achieve and maintain an adequate drug concentration at the level of the opioid receptors (Mather & Phillips, 1986). It is also acknowledged that I. M. opioids are variable in their rate of absorption among individuals with alternating periods of pain, such as labour. These intervals may be complicated by decreased levels of consciousness, respiratory depression, vomiting, hypotension and dysphoria (displays of anguish, agitation or restlessness). The subjects in this study did not display decreased levels of consciousness, hypotension (defined as a systolic measurement of less than 100 mm Hg) or respiratory depression, which was defined as less than 12 breaths per minute, after receiving the Demerol. Twenty-one or (12.4%) of all the subjects vomited at least once after the drug administration.

"It has been known for many years that administration of small boluses of intravenous narcotics produced more rapid, more effective analgesia than the intramuscular route. Continuous infusion of opioids was found to be even more effective,

...” (Mather & Phillips, 1986, p. 88). To a certain extent this statement cannot be corroborated by the data to support the second and third null hypotheses. Figure two depicts the mean pain scores of all the nulliparas and multiparas who received the drug via the I. M. and I. V. routes. It can be seen from the graph that the I. M. route pain scores decreased during the first 30 minutes and then began a slow incline. It also shows the I. V. route taking at least ten minutes before a decrease in scores occurs, then peaks at 30 minutes with a decline to the 60- minute time. At 30 minutes the scores associated with the I. M. route are at their nadir mean of about 59 and the scores associated with the I. V. route appear to be at their post administration mean peak of about 68.

The principle behind the regimen used for the I. V. administration protocol in this study “is that at a steady state (the equilibrium between drug concentrations in blood and tissues), the ratio between drug input (infusion rate) and drug output (total body clearance) is constant (equal to steady-state blood concentration). Unless a loading dose is used, steady state will not occur until about four to six times the slow half-life has elapsed.” (Mather & Phillips, 1986, p. 90). The I. M. Meperidine basically provided an expected response reflected by an onset of action in the first ten to twenty minutes. The I. V. route also reflected the action of dose/diluent bolus administration, which is 6-10 minutes (McCaffery & Beebe, 1989). As a consideration of the action of direct intravenous injections, note that the I. V. equianalgesic dose of 100 mg (1 ml) I. M. of Meperidine is 25-50 mg (McCaffery, 1997). If this equianalgesic dose is diluted in 5 ml of normal saline and directly administered into a vein or through an intravenous port over a 2-3 minute time period, the onset of action would be 3-5 minutes. Therefore, it is

important to appreciate how the different parenteral injections work and when to expect their onset of action within the labouring woman.

Some explanation for the lack of difference in the mean pain scores and for the actions of the two routes can be related to the similarity in the infusion methods. Regardless of whether the current pregnancy is the first or the fifth for a woman, hemodynamics are essentially the same, if the pregnancy is uncomplicated. The blood volume of the pregnant woman increases by 50% in pregnancy as does renal plasma flow, which affect circulation and concentration of medications. "After intravenous administration, any opioid is redistributed in a sequence, from the perfusion-rich group, including brain, heart, kidneys, and liver, to the perfusion-mediocre group such as muscle and skin, to the perfusion-poor groups such as fat" (Mather & Phillips, 1986, p. 83). Although the uterus is not considered a primary organ of initial perfusion, Bonica (1979) and Brownridge (1995) claim that the uterine myometrium receives an increased perfusion during intense sustained contractions. It is surmised that plasma concentrations and pharmacokinetic information of Meperidine are different in pregnancy than when compared to non-pregnant values.

This again brings the discussion back to why the study results demonstrate a general lack of significant difference in mean pain scores in the first 60 minutes, after labouring women receive Meperidine via the I. M. or the I. V. route. The conclusion is that since the I. V. protocol was infused over a one - hour time, it provided a continuous infusion that was similar to the actions of an I. M. injection, albeit the drug circulation would be more direct since it was infusing into a vein. The evaluation of whole blood

concentrations of both routes of administration would give more accurate and definitive information support to this conclusion.

The following discussion describes why there might have been significant differences in mean pain scores between the multiparas and nulliparas. The suggestions are based on the tests used to identify differences between the nulliparas and multiparas and on the literature review.

Independent samples t-tests revealed that the pain scores immediately pre-analgesia administration were not significantly different for the two groups. However, the cervical dilatation of the two groups was significantly different prior to or just at, the pre-drug administration time period. At initiation of the medication protocols, the nulliparas' mean cervical dilatation was 3.6 cm and the multiparas' mean cervical dilatation was 4.2 cm. Researchers have identified that there are correlations between cervical dilatation and perceived pain (Bonica & McDonald, 1990; Brownridge, 1995).

Other cervical data such as consistency did not indicate a significant difference. Also, the application of the independent samples t-test to frequency and to duration of contractions; and the use of the chi-square test for intensity of contractions did not identify a significant difference between the nulliparas and multiparas. The lack of significance for these variables between the nulliparas and multiparas indicates the similarity of events that were occurring in both groups at the time of analgesia administration.

Figure four graphically displays the mean pain scores of the nulliparas and multiparas via the intramuscular and intravenous routes. It identifies that for the majority of the time between pre-administration until 60 minutes afterwards, the multiparas' mean

pain scores are higher than the nulliparas. The multiparas who received Meperidine intravenously experienced several peaks and valleys in their pain scores during the first 60 minutes.

The size (n) of the nullipara group decreased from 85 at the pre-analgesia administration to 73 by 60 minutes. This was a decrease of 12 (14%) subjects in the nulliparous group. The size (n) of the multipara group decreased from 84 at pre-analgesia administration to 53 at 60 minutes post-analgesia administration. This was a decrease of 31 (37%) subjects in the multiparous group. This change in nullipara and multipara subjects was attributed to the delivery of the infant or to the use of other types of analgesia. As per the study protocol, once a subject used any other type of analgesia /anaesthesia, her participation in the study was discontinued.

The mean age of the multiparas in this study was 27.8 years while the mean age of the nulliparas was 23.6 years. This was considered to be significant and suggests that older women may perceive more pain in labour. This differs from the study done by Fridh, Kopare, Gaston-Johansson and Norvell (1988). They identified that younger women experienced more pain than older women and concluded that “women who are older with more children have less sensory and affective pain during labor...” (p. 122).

The rejection of the fourth hypothesis, that “there will be no difference in Visual Analogue Scale pain scores for multiparous versus nulliparous women” suggests that the mean scores between the multiparas and the nulliparas are different. Figures 3 and 4 show that the multiparas have higher mean pain scores. This is in contrast to Lowe (1989) who found that “parity did not contribute significantly to the variance in the pain of active

labor” (p. 244) and to Fridh and Gaston-Johansson (1990) who found that multiparas had less pain than primiparas in the first two stages of labour.

Some explanation of the differences in this study’s results from those of Lowe and Fridh and Gaston-Johansson may be attributed to the causes of labour that subjects from this study were experiencing. Although data was not collected regarding how labour was established, many of the subjects were experiencing induced labours by oxytocin, prostaglandin applications and artificial rupture of membranes. Induction of labour may produce a different type of contraction and subsequently a different type of labour pain as compared to those labours that are established “naturally”. “When augmentation of uterine contraction by oxytocin increases intrauterine pressure, the intensity of pain increases and the woman’s tolerance of the painful experience decreases, especially when labor is prolonged” (Faure, p. 346).

Another significant difference between the nulliparas and multiparas was attendance at childbirth education classes. Fifty-six per cent of the 84 multiparas had never attended a childbirth class. This does not assume that self-teaching did not occur. Many women learn from reading, watching information programs or videos and talking to family and friends. The accuracy and value of the information must be taken into consideration by the woman and used to accommodate her education needs. It also cannot be assumed that because a woman has previously experienced labour, she will be prepared for the pain and cope more effectively. Each labour is different and perhaps the knowledge that could be obtained from trained educators would help with pain management. It is somewhat unusual for women to attend prenatal childbirth classes after their first delivery, although

12 multiparas of the 84 in this study did indicate that they had attended classes during the current pregnancy.

Racial background was significantly differently between nulliparas and multiparas. Forty-three (51%) of nulliparas were Caucasian and 29 (34%) were Aboriginal/Metis. Thirty-three (39%) of multiparas were Caucasian while 44 (52%) were Aboriginal/Metis. In total the 169 subjects were represented by 76 (45%) Caucasian and 73 (43%) Aboriginal/Metis and 12% of other racial background. This representation is not unusual as a report provided by an Aboriginal Services Review committee at the hospital where the study occurred, stated that the Aboriginal population ranges from 25 to 60% of all patients on a daily basis. However, the Profile of Manitoba's Aboriginal Population stated that the Aboriginal culture represents 10.6% of the total population of Manitoba (1995).

The presence of a support system is very valuable toward the ability to cope with labour pain. Family or friends supported or comforted 88% of the multiparas and 96.5% of the nulliparas. A moderate significant difference between nulliparas and multiparas was seen for the presence of a companion. Regardless of how many times labour is experienced, it can be frightening and lonely, even when a support person is present. If a woman is undergoing the situation without a familiar face next to her, it can increase her perception of her pain. However, please note that data was not collected regarding the actual length of time the nurses spent with the patients or what kind of care was provided by the nurses on this unit. Without question the assistance and encouragement given by professionals is absolutely vital to women but it was not the intention of this study to evaluate this dimension.

Several other significant differences that were observed when testing for differences among the nulliparas and multiparas. Currently, on the unit where the study occurred, Promazine (Sparine) is administered if Meperidine is given intramuscularly. Sparine is not given if Meperidine is given intravenously unless the labouring woman displays nausea and/or vomiting. The Sparine is then administered after the Meperidine has completed infusing. In total, 27 (16%) of all the subjects were nauseated with no significant difference between the nulliparas and multiparas. A total of 21 (12.4%) women displayed vomiting during their labour, which was considered significant between nulliparas and multiparas. Sixteen of the women who vomited were nulliparas and five were multiparas. However, only 7 (4.1%) of the 169 women were assessed to actually require the drug and thus received Sparine for nausea and vomiting. There are other ways of treating nausea and/or vomiting during labour. If a woman identifies that she is nauseated, sucking on ice chips and sipping small amounts of water are helpful. The addition of anti-emetic drugs may not be entirely necessary. It is questionable as to whether or not Sparine's role for labouring women is as a narcotic potentiator or anti-emetic. Its action with the I. M. injection may be more that of an additive and induces the relaxant effects of tranquilizers. If it was truly considered to be anti-emetic, it would be given after the I. V. infusion, however, in the majority of the I. V. situations, nursing staff never give Sparine. It is difficult to decide if giving Sparine is part of preventative medicine. It may be more appropriate to give it once the nausea and/or vomiting is actually evidenced. But the other argument can be presented that Sparine is classified as an anti-emetic and should be given to prevent emesis. For the most part, those subjects who

vomited, had only a single episode and once they appeared to have emptied their stomachs, there were minimal repeats.

Prior to the data collection period of this research the use of epidurals for labour pain was about 40% on the study unit. This percentage was corroborated in the study as 70 (41.4%) subjects received an epidural. There was also a significant difference between the nulliparas and multiparas with more nulliparas (51) than multiparas (19) having epidurals. The chi-square application to the use of nitrous oxide inhalation gas revealed a significant difference between the nulliparas and multiparas with 29 multiparas using the gas versus 17 nulliparas. The second administration of Meperidine also demonstrated moderate significance with more nulliparas (13) than multiparas (5) using the drug again.

In total, 138 (82%) subjects used some other form of analgesia after the study Meperidine was given. The use of additional analgesia requires a review of the information that is provided to women regarding pain control during labour. Meperidine given to nulliparas may be considered for different purposes than in multiparas. An opportunity exists for future discussion with nurses and physicians regarding their understanding and objectives for the use of Meperidine with nulliparous and multiparous women. The utilization of a variety of pain control methods that include pharmacological and comfort measures is expected in the management of labour pain. It is important that caregivers understand the interaction of the drug with the factors of route of administration and parity.

Limitations of the Study

Women who could not understand or read English were prevented from participating in the study and this may limit generalizability. The mechanical Visual Analogue Scale to score pain levels did not seem to be a physical or conceptual hindrance. In general, the women who agreed to participate seemed to understand what the scale represented and how to use it.

The application of these results is limited to those women with uncomplicated pregnancies and labours. The occurrence of pregnancy-induced hypertension, insulin-dependent diabetes, antepartum hemorrhage, twin gestations or any other conditions which may have adversely affected the mother or fetus were excluded from the study.

The results of the cervical dilatation may not be accurate to the time of medication administration. In some cases, the cervical examination did not occur immediately prior to establishing the study protocol. The examination may have, in fact, occurred up to one hour prior. Therefore, some subjects may have been even further dilated at the time of medication administration.

The results are only applicable to the assessment of pain levels felt immediately prior to analgesia administration and to the first 60 minutes after the protocol initiation. The results are also limited to the active and transition phases of the first stage of labour. Even though there is no denying the influence of the state of anxiety or discomfort levels over pain control in labour, these elements were not assessed in this study.

Implications for Practice

The intention of this study was to discover whether the route of administration of Meperidine would make a difference in the mean pain scores of labouring women. The results showed that the route did not make a difference in the first 60 minutes after the medication was administered. What does this mean for nurses who practice in labour and delivery areas? The primary recommendation from this study is that if an intravenous infusion has already been established for other purposes, this route should be used for administration of the Meperidine. If at all possible, a volumetric pump should be established to infuse the solution in a controlled method. Granted, this requires added time to obtain and set-up the equipment and there may be a lack of available pumps in some settings, but a pump does provide more reassurance of accuracy of infusion rates as compared to gravity flow. If an I. V. infusion is not in place, administer the medication via the I. M. route. This recommendation applies equally to nulliparas and multiparas.

The use of some type of pain assessment scale is recommended as a result of this study. The scale does not necessarily have to be the same type as used in the study. As a small piece of equipment, pain scales tend to become lost or misplaced. The use of numerical scales where the patient is asked to rate her pain from 0 to 10 with 0 being no pain and 10 being the worst possible pain is acceptable. The documentation of a pain assessment system that is used by all caregivers provides consistency in assessment of pain before and after analgesia administration. Analysis of pain rating scores and application to nulliparous and multiparous labouring women will assist the nurse to make knowledgeable

decisions regarding the provision of pain relief.

Another recommendation is to use Sparine only when needed. The drug should not be added to the syringes for I. M. Demerol injections. This may contradict the purpose of anti-emetics but if only small portions of labouring women actually experience vomiting, the generalized use of Sparine for the larger groups is unnecessary and not warranted.

Information obtained from this study regarding patients' perceptions of pain relief from separate routes of administration will improve the overall labour and delivery experience for women. If a philosophy that states pain is whatever the person who is experiencing it says it is and existing whenever they say it does, is truly endorsed by labour and delivery caregivers, the involvement and satisfaction of the woman will be greatly enhanced. Discussion between the nurse and labouring woman regarding her pain relief requirements must be ongoing. The true belief in the philosophy as earlier stated is key to the labouring woman's ownership and participation in management of her labour pain. The goals of the labour and delivery are collaboratively set but can be mutually agreed upon and achieved to everyone's satisfaction.

Recommendations for Future Research

The six-month duration of this research study on the tertiary care labour and delivery unit provided an opportunity for discussion with caregivers and women in labour. Through this discussion and review of the study, ideas for future research were developed.

Suggestions for future research also include a further look at the pain relieving

effects of intramuscular Meperidine with and without the use of Sparine. Subjects could be randomized to a control group of Meperidine only and to an experimental group of Meperidine and Sparine.

The state of anxiety or expectation of and actual pain levels could be additionally assessed to replicate research done by Fridh and Gaston-Johansson (1990) or Lowe (1989) in order to determine their effects on labour pain. This would add to the body of knowledge related to the experience of labour pain.

Although the use of pharmacological methods of pain control is an accepted method of pain management during labour, the collaboration of the specialities of nursing, obstetrics, and anaesthesia in future research involving the use of other medications would be of value. Keeping in mind the review of Elbourne and Wiseman (2000) and the fact that Meperidine has been the mainstay of pain management during labour and delivery for over forty years, it may still be feasible to introduce an alternate drug and compare it to Meperidine. This suggestion for further research is due to the identified concerns with Meperidine that include nausea and vomiting and neonatal effects that can occur immediately post-delivery and last for several days thereafter.

In conclusion, this chapter reviewed the four hypotheses and the influencing factors behind the results. The first hypothesis was supported and therefore it was found that: "there was no difference in overall Visual Analogue mean pain scores between women who receive Meperidine in labour by the intravenous or intramuscular route."

The results supported the second hypothesis that "there will be no difference in pain scores at an earlier period of time between women who receive Meperidine by the

I. V. route and women who receive the drug via the I. M. route”. Support was also obtained for the third hypothesis that “there will be no significant difference in pain scores for a longer period of time between women who receive Meperidine by the I. M. route and women who receive the drug via the I. V. route”. However, the fourth hypothesis, “there will be no difference in Visual Analogue Scale pain scores for multiparous versus nulliparous women” was rejected.

The variables where significance was demonstrated between nulliparas and multiparas were described. These included: marital status, attendance at childbirth classes, presence of a companion, vomiting after Meperidine administration, the use of a second dose of Meperidine, the use of epidurals and nitrous oxide, pain scores at 30 and 60 minutes post-medication, age and cervical dilatation.

The results indicate that route for Meperidine administration does not make a difference in pain self-assessment in the first 60 minutes. A difference in self- assessed pain scores was observed between nulliparas and multiparas with multiparas recording higher pain scores. Implications for nursing practice and future research were provided in light of these findings.

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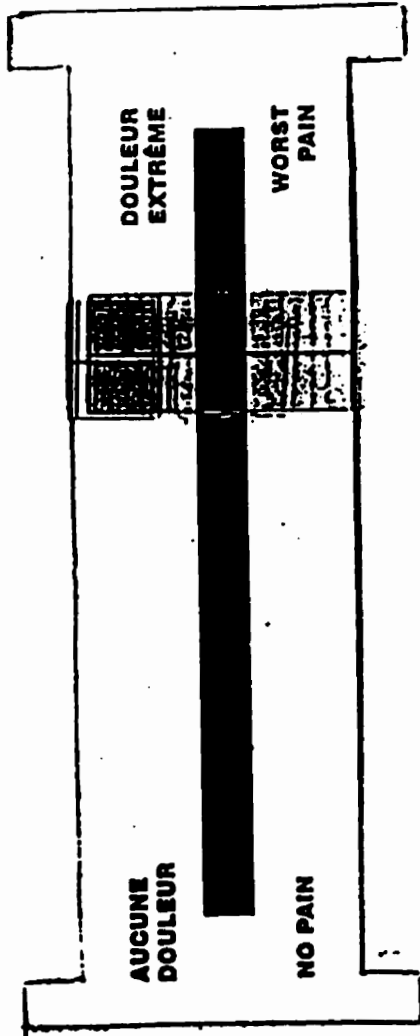
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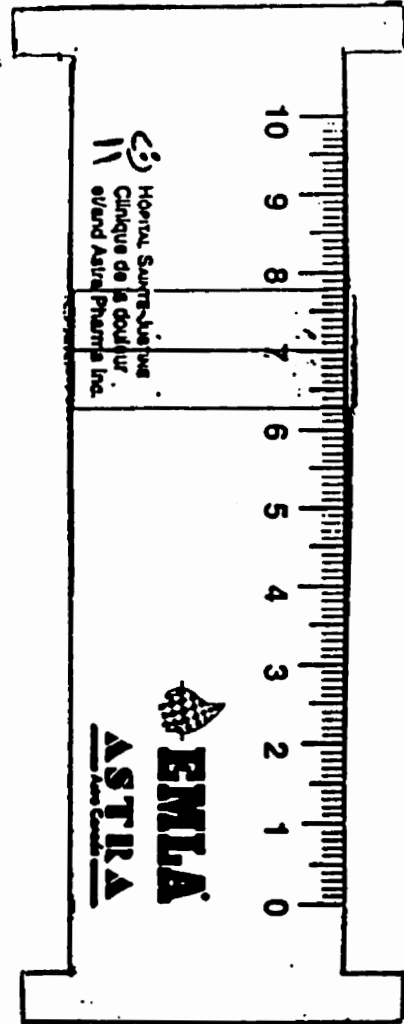
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Appendix A

Visual Analogue Scale



Patient's Side



Nurse's Side

Appendix B

Invitation to Participate

I am a Registered Nurse who is enrolled in the Master of Nursing Program at the University of Manitoba. I am doing a study to determine the best way to give pain control drugs to women in labour. I am asking you to take part in this study that will compare the intramuscular and intravenous methods of receiving the narcotic drug, Demerol, for your labour pain.

At the current time, in this hospital, most women who receive Demerol for their labour pain receive one injection, either by the intramuscular or intravenous route. Sometimes women who have an intravenous infusion in place may also receive the drug intramuscularly. The intention of this study is to determine which route works most effectively.

If your doctor orders Demerol and you agree to participate, an intravenous fluid system will be established prior to receiving the Demerol. When you, your nurse and doctor decide that it is time to receive the Demerol, you will also receive a needle into a muscle in your buttock. The drug will be given either by the needle in your muscle or through the intravenous. You will not know which way the drug has been given as the choice between these two options will be determined by chance. However, you will receive the Demerol for your labour pain.

Sometimes nausea and vomiting are experienced in labour. In this hospital, a drug (Sparine), may be given with the Demerol to prevent nausea. If you decide to participate in this study, you will not be given the Sparine unless you actually become nauseated or vomit. The medication will be given through the intravenous infusion.

Although you may not choose between the two alternatives, you may withdraw from the study at any time. If you choose not to participate, your care will not be affected.

Those participating in the study are asked to fill out a brief form about themselves, including questions about your age, education, and income. It will take approximately 5 minutes to fill out and if you wish, the research nurse can help you. After receiving the pain medication (in the way chosen by chance), you will be asked to rate your pain on a simple scale every 5 to 30 minutes. Additional information about your childbirth will be collected from your hospital chart.

You will remain anonymous. Your name will not be on any of the study questionnaires. A code number will be assigned to you and will appear on the questionnaires, so if it is necessary, your name can be matched to the questionnaire at a later date.

Thank you for considering this opportunity to gain more information about the management of labour pain. If you agree to participate, you will be asked to sign a consent. If you would like to have a summary of the study results, please fill out the information below. The results may be published in a journal, however, no names will be used and only the group results will be reported.

If you have any questions, or wish to discuss this further, you can contact me or
Dr. Annette Gupton phone 474-7135

Thank you, Susan Mussell RN BN phone 787-2619

Please send a copy of the study summary results to:

Name: _____

Address: _____

Appendix C

Consent to Participate

I have been invited to participate in a research project that compares the methods of giving the drug, Demerol, for pain in labour. The research is being conducted by Susan Mussell, a Master of Nursing student at the University of Manitoba. Participation in this project is entirely voluntary. I am under no obligation to do so. By signing below, I am consenting to be a part of the study. The study has been approved by the Ethical Review Committee of the Faculty of Nursing at the University of Manitoba.

I understand that my participation includes filling out a brief form and having the way this pain medication is given determined by chance. I understand that I will receive two injections, one by the intramuscular route and one by the intravenous route. I also understand that I will not receive a drug for nausea and vomiting unless I actually feel nauseated or vomit.

I understand that I will be rating my pain level using a scale and allowing a research nurse to read my chart for information. All information will be kept confidential. My name will not be linked with the results of the study.

I have had all my questions answered to my satisfaction and freely agree to participate in the study. I have been offered a copy of the summary of the project.

Date: _____

Participant: _____

Witness: _____

Appendix D**Letter to Attending Physicians****Date:****To: Dr. Savas Menticoglou
Clinical Chief, Department of Obstetrics
Women's Hospital, Health Sciences Centre****From: Susan Mussell RN BN
Nursing Inservice, Women's Hospital****Re: Demerol in Labour Nursing Research Project**

To enhance knowledge about the administration of Meperidine to women in labour, I will be conducting the following study: "Comparison of the Intramuscular and Intravenous Routes for Administration of Meperidine to Nulliparous and Multiparous Labouring Women". Women admitted to the Labour and Delivery Unit at Women's Hospital with uncomplicated pregnancies will be invited to participate. When Meperidine is ordered by the physician, women will be randomly assigned to receive it by the intravenous or intramuscular route.

This study has been approved by the University of Manitoba Faculty of Nursing Ethical Review Committee.

Please convey this information at the next Women's Hospital Obstetrics and Gynecology Departmental meeting. If the physicians require further information about the study or do not want their patients to participate in this study, I may be contacted at 787-2619.

APPENDIX E

Demographic and Childbirth History Information
 (To be completed by the participant and/or researcher at the time of consent)

1. How many times have you been pregnant (counting the present pregnancy)? _____

2. How many of your babies have been born alive? _____

3. What is your age (years)? _____

4. What was your total combined family income (before taxes) last year?

\$10,000-19,999 _____

\$20,000-34,999 _____

\$35,000-49,999 _____

\$50,000-64,999 _____

\$65,000-79,999 _____

Over \$80,000 _____

5. Please circle the highest education grade you have completed

Grade School

1 2 3 4 5 6 7 8

High School

9 10 11 12

Community College/Vocational School

1 2 3 4

University

1 2 3 4 5 6 7 8 9 10

Degrees earned _____

6. Please state your marital status

Single _____

Married/Living with a partner _____

Separated _____

Divorced _____

Widowed _____

7. What is your racial background?

White _____

Aboriginal/Metis _____

Asian _____

Black _____

Other _____

8. Was this a planned pregnancy?

Yes _____

No _____

9. Have you attended childbirth education classes?

Yes, during this pregnancy _____

Yes, during a previous pregnancy _____

No _____

10. How would you rate your menstrual period pain? (The researcher will show you a scale to use)

Pain rating _____ (mm)

APPENDIX F

Labour Data, Medication Record and Pain Intensity Ratings

1. Study Patient Number _____
2. Birth Number _____
3. Date Medication Administered: _____
4. Time Administered: _____
5. Time of onset of labour (contraction frequency 15 minutes or less): _____

At the time of analgesia administration:**6. Contraction Data:**

Frequency (minutes): _____ Duration (seconds): _____

Intensity (mild, moderate, strong): _____

7. Cervical Data:

Dilatation (cm): _____ Consistency of cervix (thin, thick): _____

8. Presentation (eg. vertex, breech) _____

9. Station of presenting part: _____

After administration of the analgesia

10. Patient's self-determined pain rating score (mm):

Immediately pre-analgesic (0 time) _____ 10 (minutes) _____ 20 _____

30 _____ 45 _____ 1 hr _____ 1 hr 30 min _____ 2 hrs _____

2 hrs 30 min _____ 3 hrs _____ 3 hrs 30 min _____ 4 hrs _____

11. A companion was present during labour

Yes _____

No _____

12. Side effects displayed by labouring woman after administration of Demerol (eg. Nausea and vomiting, respiratory depression, hypotension, mental clouding):

Describe _____

Sparine Administration

No _____ Yes _____ If Yes:

13. Amount: _____

14. Route: IM _____ IV _____

15. Time of Administration: _____

Other analgesia used after Demerol(eg. 2nd dose of Demerol, epidural, nitrous oxide):

No _____ Yes _____ If Yes:

16. Type: _____

17. Time administered: _____

Post-Delivery Data:

18. Length of Stage One(hours) _____

19. Length of Stage Two _____

20. Type of delivery (Spontaneous, forceps, C/S) _____

Infant Data

21. Weight of infant (grams) _____

22. Administration of Positive Pressure Ventilation: Yes _____ No _____

23. Administration of Naloxone (Narcan): Yes _____ No _____

24. Apgar Scores: 1 minute _____ 5 minutes _____

Comments: _____
Route of Meperidine Administration: IV _____ IM _____ (to be declared upon completion of study)