EFFECTIVENESS OF SWADDLING ON THE PAIN LEVEL DURING INVASIVE PROCEDURE AMONG NEWBORN BABIES

A DISSERTATION SUBMITTED TO THE TAMILNADU Dr.M.G.R MEDICAL UNIVERSITY, CHENNAI, IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

APRIL 2014

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CERTIFICATE

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"Oh, give thanks to the 'lord'; for He is good!

For His mercy endures forever"

- Pslams, 136:7

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ABSTRACT

In newborns the pain is unexplainable and unavoidable during the invasive procedures. The nurse should known the feelings and behaviours of newborns during the painful procedures, by using the pain minimizing methods to control the baby and their parents. Non-pharmacological technique is easier and cost effective method to reduce the pain in newborns. So the researcher conducted this study to assess the effectiveness of swaddling technique on pain level during invasive procedure among newborns admitted in selected hospitals at Madurai. The experimental approach and post test only non equivalent control group quasi experimental design was used and conceptual framework of the study was based on Ludwing Von Bertalantly's General System Theory. The population of the study was newborn the age of 1-14 days had undergone invasive procedures in Govt. Rajaji Hospital, Madurai. By using convenience sampling method and samples were assigned to experimental and control group, sample size 60 randomly. Data collection tool consist of demographic profile of the child and standardized pain assessment scale, NFCS- Neonatal Facial Coding System. The tool was given to five experts for validity. The reliability was tested ($r = 0.9$) using the interrator method. A pilot study was conducted to findout the feasibility of to conduct the study. Data collection procedure was conducted for six weeks. Data were analyzed by using descriptive and inferential statistics and the level of significance set was 0.05. The result shows that the mean post test pain score of the experimental group (4.06) significantly lower than the mean post test pain score of the control group (6.2) during the invasive procedures. The study concluded that swaddling technique was found to be very effective in reduction of pain level in newborn during invasive procedure.

CHAPTER – I

INTRODUCTION

"Heaven will hold you, before we do, and keep you safe until we come home to you"

Pain is the single most common reason for seeking acute medical care. Pain is a major source of distress for children and their families, as well as health care providers. Pain affects children of all ages, even preterm infants but they may lack that verbal capacity to describe their pain accurately. Many caregivers and health care providers have misconceptions about pain in children; it is difficult to assess the complex nature of the pain experience. The International Association for the Study of Pain (IASP) defines pain as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage". (Mersky and Bogduc,1994),

Marlow and Redding (2001) stated that pain is a subjective experience, infants and children respond to pain with behavioral reactions that depend upon their age and cognitive process. The young infant responds with total body movements associated with brief and loud crying. The toddlers respond with intense emotion and physical resistance to any actual or perceived painful experience, including clenched teeth, rocking, aggressive behaviour, and crying. Preschool children have limited ability to understand anything beyond the immediate event. They may see themselves as the cause of pain and fear mutilation, body invasion, and loss of recently gained control. School age children may try to be brave when experiencing pain. They are able to relate the pain to previous events and to use a variety of self initiating coping strategies. They include self distraction, relaxation and fantasizing (Broome, 1985).

Morton (1997) reported that, for paediatric patients presenting to the emergency department, medical procedures are often painful, unexpected, and heightened by pain situational stress and anxiety leading to an overall unpleasant experience. Perception of pain in paediatric is complex, and entails physiological, psychological, behavioral, and developmental factors. However, in spite of its frequency, pain in infants, children, and adolescent is often underestimated and under treated. It has also been shown that infants and children, who experience pain in early life, show long-term changes in terms of pain perception and related behaviours (Mc Grath and Frager, 1996).

Pawar and Garten, (2005), relief of pain is a basic need and right of all children. Management of pain in the child must be individualized. Age, sex, birth order, cultural background, parents, caregivers response and past experiences affect the child's response. Although the principles of pain evaluation and management apply across the human lifespan, infants and children present unique challenges that necessitate consideration of the child's age, developmental level, cognitive and communication skills, previous pain experiences, and associated beliefs.

Polkki, Vehvilainen-Julkunen & Pietila, (2001), non-pharmacological pain management is one approach to a comprehensive method of pain relief. They do not replace pharmacological methods of pain management and can be used in conjunction with pharmacological pain practices to enhance the patient's relief pain. Nonpharmacological pain management therapies can be classified into three categories. There are cognitive or behavioral strategies, which include distraction, relaxation, imagery, and breathing techniques. The second category is physical or cutaneous strategies, which include heat/cold, vibration, massage, position changes, and trans-

electrical nerve stimulation (TENS). Finally, there are environmental or emotional strategies such as touch, reassurance, or interior decorating of the room. Sometimes these therapies or treatment options will overlap with one category or another.

Hagan and Coleman (2001) reported that pain in infants and children can be difficult to assess which has led to the creation of numerous age-specific pain management. The newborn baby, the infants, and the toddler are unable to localize and describe the severity of pain. Health care workers need to be able to detect the symptoms and signs of pain in different age groups and determine whether these symptoms are caused by pain or other factors. It is difficult for health care professionals to foresee which measurement systems apply to accurately measure pain in the paediatric population. Health care professionals often prefer practical methods, which reliably tract the child's pain experience and pain control over time whereas researchers tend to focus on tools, which are meticulously proven for reliability with different observers. Thus a balance may be had to achieve. Barriers to pain management in children are numerous and include inaccuracies regarding pathophysiological mechanisms of pain with statements such as "children do not feel pain the way adults do", fears regarding the use of pharmacological agents and deficits in knowledge of methods of pain assessment. These myths and other factors such as personal values and beliefs, prevent adequate identification and alleviation of pain for all children (Foy, 2001).

Another study by Kankkunen, et al (2003) in Finland identified the use of non pharmacological pain therapies used by parents at home for their children. The most commonly used therapies included holding the child on their lap, comforting the child, and spending more time with the child. Parents usually used the methods that were most

familiar to them; however, if they were taught other methods before the children left the hospital they would use them to decrease the child's pain. The most thoroughly evaluated single component strategy is distraction. The theoretical explanation for the effectiveness of distraction lies in its ability to divert attention away from the painful stimulus.

Mc Caul and Malott (2004) hypothesized that the brain has a limited capacity to focus attention on stimuli. Therefore, using up attentional resources while engaging in a distracting task leaves little capacity for attending to painful stimuli.

Breman (2004), the role and responsibility of health care workers, particularly nurses are helping to the children during medical procedures. The nurse can help the child and parents to manage the stressful medical situation effectively. The goal of the nurse is to reduce the pain accompanying invasive procedures such as venipuncture and help to improve patient care and increase patient satisfaction.

Vassey and Carlon (1994) reported that a variety of distraction strategies have received empirical attention (e.g., party blowers, cartoon movies and music), and outcomes have been assessed in multiple dimensions (e.g., parent-report, self-report and observational distress). Despite the variability in strategies, the results of most studies demonstrate the efficacy of distraction as an intervention for paediatric pain and distress. Distraction is particularly appealing because it can be easily administered in a time- and cost-efficient manner.

Gonzales (1992) manipulated mothers verbalizations during preschoolers' routine immunizations to examine the relative effects of non procedural talk (distraction) and reassurance. Consistent with other studies, children whose mothers used non procedural talk as distraction displayed less distress than those who used reassurance.

Carla Morrow, et al., (2010), according to the study of reducing neonatal pain during routine heel lance procedures. Heel lancing is a routine procedure for collecting blood samples from newborn infants. In the study 42 newborns were randomly assigned to two groups. In one group, the procedure was performed the usual way, with the infant lying in a crib. In the other group, the infant was swaddled and held in an upright position during the procedure. Pain responses were assessed using a standard scale, based on observable behaviors (facial expressions crying, etc). Infants who were swaddled and held had significantly lower pain scores. On a 7-point scale, the average pain score was 1.3 for infants who were swaddled and held versus 2.7 for those who were not. Thus holding and swaddling reduced pain scores by about one half. The researchers thought that holding infants upright might also allow the blood sample to be collected more quickly and reduce the rate of inadequate blood samples. Although time to collect the samples was slightly shorter (by 30 seconds) for infants who were swaddled and held, the difference was not significant. Both techniques provided good blood samples for testing.

"It is important to evaluate and address pain issues experienced by neonates (newborns) during routine heel lancing, not only to increase the infants' comfort but also to decrease the negative consequences of excessive pain," Morrow and coauthors write. Especially in infants who require repeated blood sampling, an exaggerated pain response may develop. Studies have suggested longer-term developmental consequences as well.

NEED FOR THE STUDY:

Hester, (1993), pain may be described as a feeling of hurt or strong discomfort and is the body's way of sending a message to the brain that an injury has occurred.

Children consistently name the invasive procedures as the cause of the most painful experiences. The pain response is individual and is learned through social learning and experience. Early pain experience may play a particularly important role in shaping an individual pain response. Inadequate relief of pain and distress during childhood painful medical procedures may have long-term negative effects on future pain tolerance and pain responses.

Carlson et al., (2000) reported that a part of routine and specialized health care, children are subjected to a number of invasive medical procedures (e.g., immunizations and venipunctures). According to guidelines published by the United States Centers for Disease Control and Prevention in 2005, children are to receive roughly 29 intramuscular immunization injections by six years of age. These events are anxiety provoking and painful, especially for younger children, who exhibit higher distress than older children. In fact, Jacobsen reported that as many as 45% of four-to six-year-old children experience 'serious or severe distress' during immunization procedures. In many cases, procedure-related distress is so severe that it results in escape behaviour (e.g., kicking) and a need for child restraint.

Melzak & Wall, (1965). Pain is both a sensory and emotional personal experience, making assessment complex. Further, pain occurs across a spectrum of conditions including acute injuries and medical events, recurrent or chronic pain, and pain related to chronic disease. Acute pain is typically brief, ending around the time of the healing of an injury, or the termination of the stretching, contraction, or impingement of some part of the body (Cohen, Mac Laren, & Lim, 2007). Chronic pain, on the other hand, may or may not be symptomatic of underlying, ongoing tissue damage or chronic

disease. It can persist longer after an initial injury has healed or other event has occurred (typically longer than 3 months).

Blount, R.L, et al, (1996), the developing brain's neuronal architecture may be permanently altered by repeated noxious stimuli such as painful procedures. Pain is often associated with fears, anxiety and stress. In addition to the unnecessary short-term suffering, paediatric procedural distress can have long-term detrimental effects on the patient. For instance, Bijttebier and Vertommen found that children with a history of negative medical experiences showed higher levels of anxiety before a venipuncture procedure, and were more distressed and less cooperative during the procedure. Childhood medical distress has also been linked to adults' reports of pain and fear regarding medical events, and negative experiences with early medical procedures have been linked to the avoidance of future health care.

Woolf and Sulter, (1996), in addition, early painful procedures have been associated with increased behavioural sensitivity to later medical insults, a finding that is supported by recent physiological evidence indicating that activation of the non receptive system can alter neuropathways, resulting in increased sensitivity to later stimulation

Taddio et al, (1997), memory is an active process that influences subsequent experience. The way that children remember painful medical procedures affects their experience of pain and distress during subsequent procedures. Children who develop exaggerated negative memories of pain and anxiety tend to experience more pain and distress at subsequent procedures than children who accurately recall their experience (Chen, Zeltzer, Craske, & Katz, 2000). These memories can be formed very early in life, have the potential to persist into adulthood, and are predictive of fear and avoidance of

medical care later in life (Pate, Blount, Cohen, & Smith, 1996). It has been suggested that children's memories of early pain experiences may even initiate chronic pain syndromes and facilitate their persistence into adulthood (Sun-Ok & Carr, 1999).

Humphrey and Boon (2003) argued that venipuncture is not a benign stimulus for children, but an unpleasant sensory and emotional experience that threatens loss of control, so the child's response not a fear or phobia of needles but a normal anticipatory fear which involves the distress response. Roger reported that painful procedure like venipuncture is stressful situation for the children. Venipuncture in pediatrics situation is a more stressful event associated with medical encounters.

Pasero, (2004), research had shown that "severe, unrelieved pain can cause an over whelming stress response in both pre-term and full-term infants which can lead to serious complications and even death". In recent years, post-tramatic stress syndrome has been the subject of extensive research, both as to its cause and its treatment (Hamilton, 2008). Recent research suggests that unrelieved acute pain slows postoperative wound healing (Mc Guire, 2006). This evidence is not surprising, given our increasing knowledge of the effect of stress on the human body. Any factor that interrupts or interferes with normal pain transmission affects the awareness and response of clients to pain and places them at risk for injury. Analgesics, sedatives, and alcohol depress the functioning of the central nervous system. The relationship between pain and fear is convoluted and complex. Fear tends to increase the perception of pain, and pain increases feelings of fear and anxiety. This connection occurs in the brain because painful stimuli activate portions of the limbic system believed to control emotional reactions. People who are seriously injured or critically ill often experience both pain

and heightened levels of anxiety due to their feelings of helplessness and lack of control. Caregivers need to address both pain and anxiety and use all appropriate measures to relieve suffering.

Hamilton, (2010), children manage pain and other stressors of life in different ways. Some see themselves as self-sufficient, internally controlled, and independent. As a result, they may deny the pain or be slow to admit they are suffering. Others see themselves as insufficient, externally controlled, and dependent on others to treat their pain. Self-sufficient, internally controlled children may do better with patient-controlled analgesia (PCA), whereas dependent, externally controlled individuals may prefer nurse administered analgesia. No matter what the coping style, it is the responsibility of caregivers to relieve pain. As children they learn what is and what not acceptable behaviour when experiencing pain is. In some cultures, any expression of pain is considered cowardly and shameful. Cultural beliefs and values affect the way children respond to pain. The meaning of pain itself may be markedly different in different cultures. Some ethnic groups see pain as a punishment for wrongdoing. Others see pain as a test of faith. And still others view pain as a challenge to be overcome. Recent immigrants to America are more likely to view pain from their cultural roots. Regardless of an individual's language, religion, or situation, nurses and therapists respect every person and strive to alleviate pain and suffering.

Hagan et al., (2001), the first step to adequate pain management is adequate assessment. Assessment instruments used must be practical, reliable, valid and appropriate for the Childs developmental stage. The unrelieved pain causes the body to release certain chemicals that may actually delay healing. Inadequate prevention

treatment of children's pain and distress responses to medical procedures may have long-term negative effects on their future pain responses.

Kozier (2008) reported that pharmacological management is an effective method to reduce pain in children. It involves the use to opioids (Narcotics), nonopioids/ nonsteroid anti-inflmmatory drugs and coanalgesic drugs. Health care personnels are using pharmacological techniques to relieve the pain perception of newborns. It is recommended that both pharmacological and non-pharmacological interventions, such as swaddling, be developed to minimize the discomfort of painful procedures.

Hockenberry, Wilson, Winkelstein, & Kline, (2003) a swaddling is a promising, cost effective, non-pharmacological technique in reducing pain and distress among newborns undergoing painful medical procedures and it is proved in different areas of different countries. Because of this the researcher selected this study to find out the effectiveness of the swaddling technique in selected hospitals in Madurai. The researcher in this study was, intended to use swaddling technique among newborns during invasive procedures.

STATEMENT OF THE PROBLEM:

A study to assess the effectiveness of swaddling on the pain level during the invasive procedures among newborn babies in a selected hospital at Madurai.

OBJECTIVES OF THE STUDY:

- To assess the pain level during invasive procedure among newborn babies in experimental group who got admitted in Neonatal Intensive Care.
- To assess the pain level during invasive procedure among newborn babies in control group who got admitted in Neonatal Intensive Care Unit.

- ❖ To evaluate the effectiveness of swaddling on the pain level during invasive procedure among newborn babies.
- ❖ To find association between the pain level of newborn babies in the experimental group and their selected demographic variables such as age, sex, weight, type of invasive procedure and duration of procedure.

HYPOTHESIS:

The following hypothesis will be tested at 0.05 level of significance.

H1:

The mean post test pain score of the new born babies in the experimental group who had swaddling will be significantly lesser than the mean post test pain score of the control group.

H2:

There will be a significant association between the mean post test pain score of babies in experimental group and their selected demographical variables such as age, sex, weight, type of invasive procedure and duration of procedure.

OPERATIONAL DEFINITION:

1. EFFECTIVENESS:

In this study it refers to the outcome of swaddling in reducing the pain in neonates who undergo invasive procedures. In this study it is the statistical measure of the differences in the mean post test pain score between the control and experimental group of new born babies who had swaddling during invasive procedures.

2. SWADDLING:

Swaddling is the art of snugly wrapping a baby in a blanket for warmth and security. It can keep your baby from being disturbed by her own startle reflex, and it can help her stay warm and toasty for the first few days of life until her internal thermostat kicks in. It may even help to calm your baby.

In this study, it is the practice of wrapping babies with 2 pieces of cloth with each 1 meter length & 1 meter width. One piece is used for covering the upper limb, chest and abdomen and the second piece was used to cover the lower limb, which ever area needed the prick, was left uncovered leaving it to access for procedures.

3. PAIN:

It is the unpleasant sensory and emotional experience that is caused by actual or potential tissue damage. In this study it refers to feeling of hurt experience or strong discomfort experienced by the new born babies during the invasive procedures by pain as measured by the Neonatal Facial Coding System (NFCS).

4. INVASIVE PROCEDURES:

An invasive procedure is medical procedure in which the body is "invaded" or entered by a needle, tube, device or scope. Invasive procedures can include anything from the simple needle prick for a blood test or shot, to inserting a tube, device or scope, to major surgeries.

In this study it refers to venipuncture for IV cannula insertion and venipuncture for blood sampling.

5. NEWBORN BABIES:

A newborn infant, or neonate, is a child under 28 days of age. During these first 28 days of life, the child is at highest risk of dying. It is thus crucial that appropriate feeding and care are provided during this period, both to improve the child's chances of survival and to lay the foundations for a healthy life.

ASSUMPTIONS:

- Every newborn is unique and responds in an unique manner in response to pain
- Nurse's have the responsibility in reducing of pain in newborn babies during hospitalizations.

DELIMITATIONS:

This study is delimited to,

1. The newborn babies who are admitted at Government Rajaji Hospital.
2. Six weeks of data collection period.

PROJECTED OUTCOMES:

- ❖ The study findings would help to determine the effectiveness of the swaddling technique in reducing the pain during invasive procedures.
- ❖ The study findings would help the nursing personnel to assess intensity of the procedural pain.
- ❖ The study findings would help the nursing personnel to select the appropriate instrument to assess the pain.
- ❖ It will help the health personnel to conduct further research studies in swaddling technique in reducing pain.

CONCEPTUAL FRAMEWORK

This study based on Von Bertalantly's General system theory according to this model, a system is a set of object together with relationship between the object and attributes. In general system theory the main concepts are input, throughput and output.

Input and output are processed by which a system is able to communicate and react with its environment.

Input can be defined as any form of energy that enter into system through it boundary. Through put is a process that occurs at some point between the input and output process. It enables the input to be transferred in such a way that it can be used readily by the system.

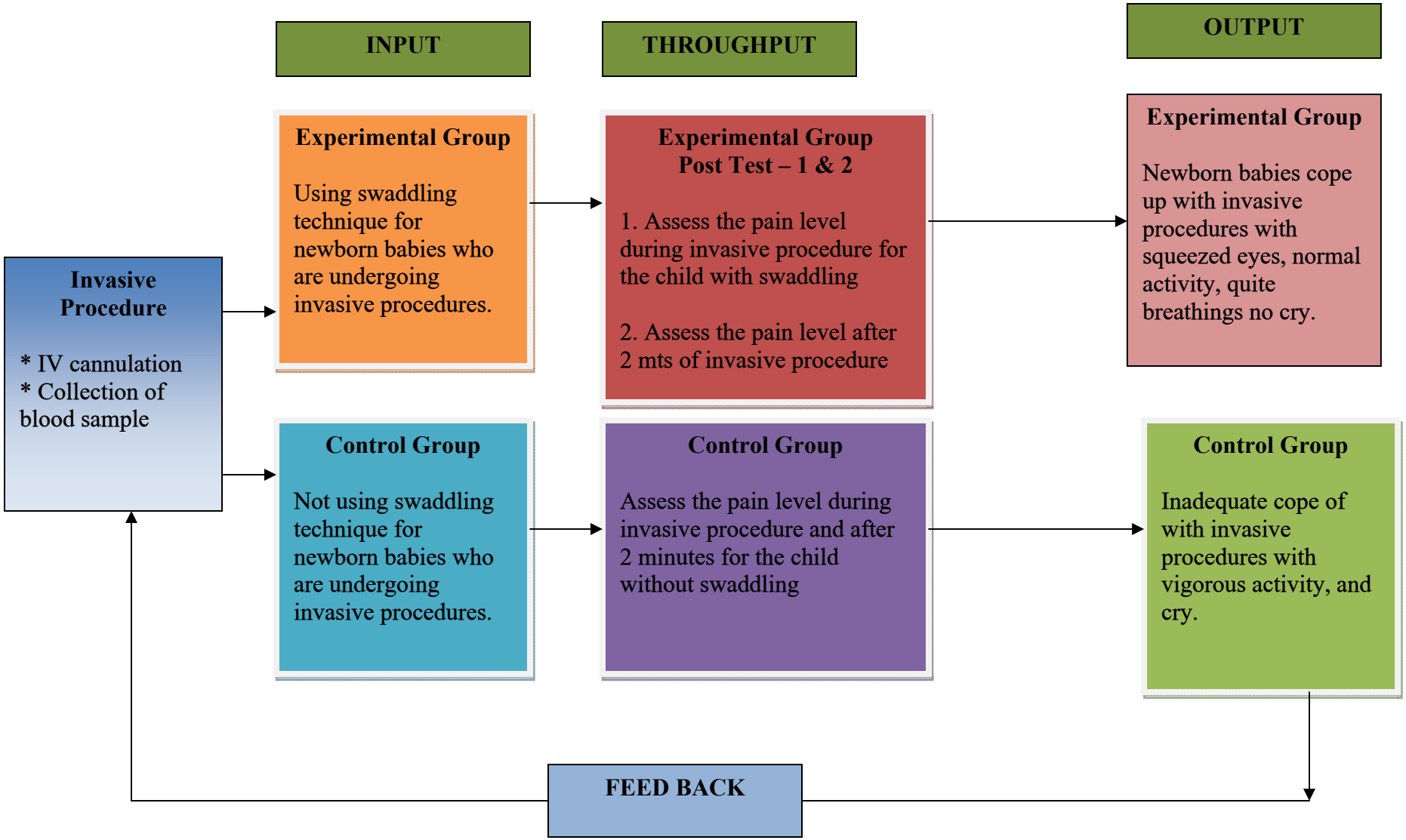
Output is an energy that is transferred to the environment.

Feedback refers to the environmental response to the systems, output used the system in adjustment, correction and accommodation to the interaction with the environment.

In this study input phase of the experimental group, swaddling done for newborn babies who are undergoing invasive procedure, but in control group did not do swaddling.

In the throughput phase, swaddling done to assess the pain level during invasive procedure. In the output phase, the experimental group able to cope up with invasive procedure as evidenced by squeezed eyes, quite breathing and no crying where as in control group not able to cope up with invasive procedure as evidenced by crying, vigorous movements.

CONCEPTUAL FRAMEWORK BASED ON LUDWIG VON BERTALANTLY'S GENERAL SYSTEM THEORY



CHAPTER – II

REVIEW OF LITERATURE

Review of literature is key step in the research process. The review of literature is defined as a broad, comprehensive in depth, systematic and critical review of scholarly publications, unpublished, scholarly print materials, audio-visual materials and personal communication.

This chapter deals with the literature review of available literature from published books, text books, research and non research article on the subjects related to the research study.

The available literature was organized under following headings.

I. Literature and studies related to pain

II. Literature and studies related to pain assessment

III. Literature and studies related to pain management

IV. Literature and studies related to swaddling technique.

I. LITERATURE AND STUDIES RELATED TO PAIN

DEFINITION:

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (American Pain Society, 2003; Gordon 2002).

TYPES OF THE PAIN:

Kozier (2008) stated that pain may be described in the terms of location, duration, intensity, and etiology.

Location:

Kozier (2008), Classification of pain based on where it is in the body (e.g. headache, backache, chest pain) may be useful in determining the client's underline problems or needs.

- Referred pain: Appear to arise in the different areas.
- Visceral pain: Pain arising from organs or hollow viscera

Duration:

Kozier (2008), When pain lasts only through the expected recovery period, it is described as

- Acute pain: It is a sudden or slow onset and regardless of the intensity.
- Chronic pain: It is prolonged, usually recurring or persisting over 6 months or longer and interferes with functioning.

1. Physiological Pain: It is experienced when an intact, properly functioning nervous system send signals that tissues are damaged, requiring attention and proper care.

Sub categories of physical pain include:

- Somatic pain: Pain originates in the skin, muscles, bone, or connective tissue.
- Visceral pain: Activation of pain receptors in the organs or / and hollow viscera.

2. Neuropathic pain: Pain experienced by people who have damaged or malfunctioning nerves. The nerve may be abnormal due to the illness, injury, or undetermined reasons.

Subtypes of neuropathic pain are being developed based on the part of the nervous system believed to be damaged (Pasero, 2004).

- Peripheral neuropathic pain: Follows the damage and / or sensitization of peripheral nerves.

- Central neuropathic pain: Results from the malfunctioning nerves in the central nervous system.
- Sympathetic maintained pain: Occurs occasionally when abnormal connections between pain fibers and the sympathetic nervous system perpetuate problems with both the pain and sympathetically controlled function.

PATHOPHYSIOLOGY OF PAIN:

Paice, (2002), the pathophysiology of pain is usually divided into four distinct stages: 1) Transduction, 2) transmission, 3) Pain modulation, and 4) Perception. The brain can inhibit or facilitate the intensity and propagation of pain stimuli via specific neural pathways. This modulation function of the brain accounts for the variations in pain perception of different individuals who sustain identical injuries and receive the same drug therapies. Transduction occurs at the sensory level, when a stimulus is converted into a nerve signal. Transmission is the primary function of nerves that act as conduits transferring pain information from the peripheral nerves to the central nervous system. Pain modulation refers to the function or neural cells to inhibit, reduce, or dampen the intrinsic modulatory activity of the central nervous system, thus reducing the painful stimuli. Perception is the result of the three previous components of transduction, transmission and pain modulation is the conscious awareness, usually localized in certain areas of the body

THE EXPERIENCE OF PAIN:

Melzack and Casey (1968) stated that three systems interact usually to produce pain:

1. Sensory – discriminative system: Processes information about the strength, intensity, quality and temporal and spatial aspects of pain.
2. Motivational – affective system: Determines the individual's approach – avoidance behaviours.
3. Cognitive – evaluative system: Overlies the individuals learned behaviour concerning the experience of pain. It may block, modulate, or enhance the perception of pain.

FACTORS THAT INFLUENCE PAIN:

Hamilton (2010) stated that the perception of pain is influenced by physiologic, psychological, and cultural factors.

PHYSIOLOGICAL FACTORS:

Age:

Hamilton (2010) stated that the age affects the way people respond to pain. It influences both the development and decline of the nervous system. Aging affects the whole body, causing many painful degenerative disorders (such as osteoarthritis), secondary injuries (such as skin abrasions and fractures), and a host of common surgical procedures (such as cataract and hip replacement). Age also affects the way families and caregivers respond to complaints of pain.

Fatigue:

Hamilton (2010) stated that the fatigue decreases coping abilities and heightens the perception of pain. When people are exhausted from physical activity, stress, and lack of sleep, their perception of pain may be heightened and their coping skills

diminished. Thus, sleep and rest from physical, emotional, and social demands are important measures to managed pain more effectively.

Genetic Makeup:

Ruda et al., (2000), recent research suggests that sensitivity to and tolerance for pain may a genetically linked trait. This findings does not negate the need to managed pain adequately, regardless of inherited traits.

Memory:

Ruda et al., (2000), Memory of painful experiences, especially experiences that occurred as a very young child, may increase sensitivity and decrease tolerance to pain. For example, even young children remember the pain of an immunization at the doctor's office and hence forth may be afraid to visit the doctor again.

Stress Response:

Pasero, (2004). Research has shown that "severe, unrelieved pain can cause an over whelming stress response in both pre-term and full-term infants which can lead to serious complications and even death". In recent years, post traumatic stress syndrome has been the subject of extensive research, both as to its cause and its treatment (Hamilton, 2008).

Healing:

Mc Guire, (2006) recent research suggests that unrelieved acute pain slows post operative wound healing. This evidence is not surprising, given our increasing knowledge of the effect of stress on the human body.

PSYCHOLOGICAL FACTORS:

Fear and Anxiety:

Kozier, (2008), The relationship between pain and fear is convoluted and complex. Fear tends to increase the perception of pain, and pain increases feelings of fear and anxiety. This connection occurs in the brain because painful stimuli activate portions of the limbic system believed to control emotional reactions. People who are seriously injured or critically ill often experience both pain and heightened levels of anxiety due to their feelings of helplessness and lack of control. Caregivers need to address both pain and anxiety and use all appropriate measures to relieve suffering.

Coping:

Kozier, (2008), People manage pain and other stressors of life in different ways. Some see themselves as self-sufficient, internally controlled, and independent. As a result, they may deny the pain or be slow to admit they are suffering. Others see themselves as insufficient, externally controlled, and dependent on others to treat their pain. Self-sufficient, internally controlled people may do better with patient controlled analgesia (PCA), whereas dependent, externally controlled individuals may prefer nurse-administered analgesia. No matter what the coping style, it is the responsibility of caregivers to relieve pain.

Cultural Factors:

Kozier, (2008), Cultural beliefs and values affect the way people respond to pain. As children they learn what is an what not acceptable behaviour when experiencing pain is. In some cultures, any expression of pain is considered cowardly and shameful. In others, noisy demonstrations of pain are expected and acceptable. The meaning of pain

itself may be markedly different in different cultures. Some ethnic groups see pain as a punishment for wrong doing. Others see pain as a test of faith. And still others view pain as a challenge to be overcome. Recent immigrants to America are more likely to view pain from their cultural roots. Regardless of an individual's language, religion, or situation, nurses and therapists respect every person and strive to alleviate pain and suffering.

THEORIES OF PAIN:

Specificity Theory:

Von Frey (1895) argued that the body has a separate sensory system for perceiving pain-just as it does for hearing and vision-and this system contains its own special receptors for detecting pain stimuli, its own peripheral nerves and pathway to the brain, and its own area of the brain for processing pain signals. But this structure is not correct.

Pattern Theory:

Goldschneider (1920) proposed that there is no separate system for perceiving pain, and the receptors for pain are shared with other senses, such as of touch. According to this view, people feel pain when certain patterns of neural activity occur, such as when appropriate types of activity reach excessively high levels in the brain. These patterns occur only with intense stimulation. Because strong and mild stimuli of the same sense modality produce different patterns of neural activity, being hit hard feels painful, but being caressed does not.

Gate Control Theory:

Melzack and Wall's (1965) had proposed a theory of pain that has stimulated considerable interest and debate and has certainly been a vasy improvement on the early theories of pain. According to his theory, pain stimulation is carried by small, slow fibers that enter the dorsal horn of the spinal cord; then other cells transmit the impulses from the spinal cord up to the brain. These fibers are called T-cells. The T-cells can be located in a specific area of the spinal cord, known as the substantial gelatinosa. These fibers can have an impact on the smaller fibers that carry the pain stimulation. In some cases they can inhibit the communication of stimulation, while in other cases they can allow stimulation to be communicated into the central nervous system. For example, large fibers can prohibit the impulses from the small fibers from ever communicating with the brain. In this way, the large fibers create a hypothetical "gate" that can open or close the system to pain stimulation. According to the theory, the gate can sometimes be overwhelmed by a large number of small activated fibers. In other words, the greater the level of pain stimulation, the less adequate the gate in blocking the communication of this information.

Bresolin and Puccini (2003) performed a bibliographic review of recurrent pain in children and adolescents, focusing on differential diagnosis and management. The researchers collected the data from Medline and Lilacs databases, covering the last four and ten years, respectively. Classical studies and texts related to the matter were also included. Studies carried out in different parts of the world demonstrate that the most frequent kinds of recurrent pain in children and adolescents are abdominal pain, headache, and limb pain. The occurrence of organic aetiology is low, observed in 5% to

10% of the cases. Among the well defined organic aetiology, no predominance is observed. The main advances regarding the pathophysiology of recurrent pain in its main localizations were analyzed. Guidelines for the diagnostic and therapeutic approach of the most common infantile diseases related to recurrent pain are presented. The study concluded that recurrent pain in children and adolescents is very common and determines significant demand for healthcare services. Defined aetiology is only presented by 5% to 10% of patients. Anamnesis, physical examination and follow-up are extremely important instruments for dealing with such patients.

II. LITERATURE AND STUDIES RELATED TO PAIN ASSESSMENT:

Hamilton, (2010), The assessment of pain in children should include gathering all the same details as with adults, namely the location, intensity, quality, chronology, pattern, precipitating events, alleviating actions, and accompanying symptoms. Information about these factors is gained by means of a pain history, physical examination, observations, and various pain assessment scales. In today's information age, healthcare providers have ready access to earlier medical and surgical events in the life of infants and children. However, details about their pain, effective pain-relieving measures, and the family's customary approach to pain may not be included in the record. This information may be gathered in a pain history.

Pasero, (2002), Infants and children are dependent on the adults in their lives and in many ways moulded by them, observation of interactions between children and family members informs nurses and therapists about how they respond to pain. Children who have been punished or shamed for crying may not report pain and may suffer in silence.

Others who had been neglected or ignored may have found the only way to get attention was to cry; thus, they way need affection more than pain medicine.

Pain Assessment Scales:

Hamilton (2010) stated that children are in a state of constant change physically, mentally, and emotionally. For this reason, pain assessment strategies are more effective it they are adapted to chronological age, developmental level, functional status, cognitive ability, and emotional status. Although a complete pain assessment includes many variables, the most common one in hospitalized children is intensity. Thus, mot assessment scales focus on that issue. The table below lists some well-known assessment scales according to the age and development level of children.

TABLE 1:

PAIN ASSESSMENT SCALES FOR INFANTS AND CHILDREN

Age Group	Name of Scale	Description of Scale
Preterm: 28 to 36 weeks gestation	Premature Infant Pain Profile (PIPP)	Assessor observes for 5 to 30 seconds on various pain indicators, including physiologic signs; gestational age affects scoring (Pasero, 2002).
Preterm to 6 weeks	Neonatal Infant Pain Scale (NIPS)	Assessor scores infant on 7 criteria: cry, facial expression, breathing pattern, arm movement, leg movement, state of arousal (Lawrence et al., 1993)
Preterm to 6 weeks	Neonatal facial responses	Illustration of a neonate in pain
Birth to 6 weeks	CRIES Neonatal Post-Op	Assessor scores infant's crying,

	Pain Scale	requiring oxygen, increased vital signs, expression, sleeplessness as 0 to 10; severe pain = 10 (Pasero, 2002)
Birth to 3 years	Netherlands Comfort Scale	Assessor scores 0 to 5: child's alertness, agitation, respirations, crying, physical movement, muscle tone, facial tension; severe pain = 35 (Van Dijk, 2005)
Two months to 7 years	FLACC Behavioral Pain Assessment Scale	Assessor observes child for 1 to 5 minutes, then scores face, legs, activity, cry, consolability as 0 to 10; severe pain = 10 (Pasero, 2002).
3 to 6 years	Finger Span Scale	Assessor uses span of index finger and thumb to indicate degree of pain. Asks, "How big is your pain?" (Merkel S, 2002)
3 to 7 years	Oucher Scale (Photographs)	Photos of 3 children of different skin colours in 6 levels of pain, from no pain to severe pain (Ball & Binder, 1999)
3 to 7 years	Poker Chips	Assessor uses piles of poker chip, from 1 to 5; asks "How much is your pain?" (Ball & Binder, 1999)
4 to 16 years	FACES Pain Scale	Illustration of 6 round faces, smiling to crying.

4 to 16 years	FACES Pain Scale – Revised (FPS-R)	Illustration of 6 egg-shaped faces, "no pain" to "very much pain".
9 to 18 years	Number Scale	Assessor asks child "On a scale of 0 to 10, with 10 the most, how much is your pain?".

Leberon et al, (2012) conducted a study to assess acute pain and anxiety in children and adolescents by self-reports, observer reports, and a behaviour checklist. The study compared responses on a checklist of distress behaviours to ratings of medical-procedure-related pain and anxiety by 29 male and 21 female 6-17 yr old cancer patients and 1 adult observer. Results show that children showed greater behavioural distress than adolescents only during the actual medical procedure; however, additional behaviours were observed that suggested that the checklist was age-biased and that the 2 age groups experienced an equal amount of stress. This assumption was supported by a measure of intensity, observed reports, and patient self-reports, which showed no differences between the 2 age groups. None of the measures showed any significant differences for sex or ethnic origin. Data shows that children had less physical control and more emotional outbursts than adolescents during a stressful procedure. It is concluded that clinical research on pain and anxiety should incorporate both self-report and observer data.

Lenora et al., (2004) conducted a study to examine the issues of pain assessment in infants by acquiring all available published pain assessment tools and evaluating their reported reliability, validity, clinical utility and feasibility. A systematic integrative

review of the literature was conducted using the MEDLINE and CINHAL (trough February 2004), and Health and Psychosocial Instruments and Cochrane Systematic reviews (through 2003). Thirty-five neonatal pain assessment tools were found and evaluated using predetermined criteria. The critique consisted of a structured comparison of the classification and dimensions measured. Further, the population tested and reports of reliability, validity, clinical utility and feasibility were reviewed. Results show that out of 35 measures reviewed, 18 were unidimensional and 17 were multidimensional. Six of the multi dimensional measures were published as abstracts only, were not published at all, or the original work could not be obtained. None of the existing instruments fulfilled all criteria for an ideal measures; may requires further psychometric testing. The study concluded that when choosing a pain assessment tool, one must also consider the infant population and testing and the type of pain experienced. The decision should be made after careful considering the existing published options. Confidence that the instrument will assess pain in reproducible way is essential and must be demonstrated with validity and reliability testing. Using an untested instrument is not recommended and should only occur with in a research protocol, with appropriate ethics and parental approval. Because pain is a multidimensional phenomenon, well tested multidimensional instruments may be preferable. It is important that nurses do their best to reduce pain for neonates experiencing heel lancing. Because the evidence for nonpharmacologic pain relief during heel lancing has been varied. Evaluating alternative methods of nonpharmacologic neonatal pain control supports the identification of practical and accessible techniques that nurses can incorporate into their practice. Although a number of studies have described promising nonpharmacologic acute pain control in neonates, we do not know

whether every technique works for every neonate. In addition, it is essential that nurses study interventions that are easy to implement and that do not require much from the institution in terms of financial charges or additional physician orders. Comparatively little research has been done about the effectiveness of swaddling term neonates who are undergoing painful procedures, and thus this method was chosen as the subject of our nursing research.

Grunau et al (2009) looked at the relationship between multiple painful procedures among term and preterm infants comparing later cognitive, behaviour and motor abilities. 211 newborns (137 pre terms and 74 full terms) for evaluation at 8 and 18 months. Results established that both preterm and term infants who experienced higher number of skin breaking procedures, during the neonatal period also exhibited lower levels of cognitive and motor development as toddlers.

Taddio, et al (2009), who demonstrated that infants who were exposed to repeated (more than 5) painful needle punctures on the first day of life showed a greater pain response during later needle punctures when compared with neonates who had been exposed to a fewer number of needle punctures. It also appears that altered pain perception has long-term consequences in some vulnerable neonates, which may include cognitive and behavioral deficiencies.

Klein, et al (2009), who examined whether pain and stress experienced by premature infants predicted temperament in later toddlerhood. They prospectively recruited 56 infants from the neonatal intensive care unit (NICU); 26 were followed up as toddlers. Researchers carefully documented both behavioural and physiologic pain responses for each infant while in the NICU, and temperament at toddlerhood was

assessed using the mother's responses to the Early Childhood Behavior Questionnaire (ECBQ). Infants who experienced greater reactivity to pain during their NICU admission also scored higher on the ECBQ. The researchers concluded that toddlers exposed to repeated painful stimuli as premature newborns had behavioral responses indicating more stressful reactions to early childhood experiences.

III. LITERATURE AND STUDIES RELATED TO PAIN MANAGEMENT:

Kozier (2008), the goals of management are to relieve pain both physically and emotionally, reduce complications, and facilitate a return of function. Management include:

1. Pharmacological Management:

Kozier (2008), Pharmacologic interventions include nonopiodis, opioids, and adjuvant drugs.

Non-opioid Medicines:

Kozier (2008), Non-opioid medicines are used to treat mild to moderate pain. Some examples of non-opioid medicines include:

- Acetaminophen (Tylenol) – 10-15 mg/kg/dose
    - Acetaminophen is an analgesic and antipyretic agent.
- Paracetomol – 10mg/kg four divided doses
    - Paracetamol is an analgesic and antipyretic drug. It reduces the synthesis of prostaglandins which are responsible for the mediation of pain and fever.

- Ibuprofen – 5-10mg/kg/dose; max 40mg/kg/day
    - It is a non steroidal anti-inflammatory drug used in the treatment of pain, fever, dysmenorrhoea, osteoarthritis, rheumatoid, and other rheumatic and non rheumatic inflammatory disorders, and vascular headaches.

Opioid Medicines:

Kozier (2008), Opioid medicines are used to treat moderate to severe pain. It includes,

- Morphine - 0.2-0.4mg/kg q 3-4 hr orally
  0.1-0.2 mg/kg IM q 3-4 hr

  It is a potent opiate analgesic drug that is used to relieve severe pain.
- Codeine - 1mg/kg q 3-4 hr orally

  Codeine is a weak opioid analgesic used in the treatment of moderate pain.
- Oxycodone - 2mg/kg q 3-4 hr orally

  It is a strong narcotic pain reliever. This medication is used to treat moderate to severe pain that is expected to last for a long period of time.

2. Non Pharmacological Management:

Hamilton, (2010), pain is a subjective experience, influenced by the emotions, stress, sleep, activity, and even nutrition, it can be controlled by a variety of interventions. Fortunately, children respond well to non pharmacologic pain reduction measures, especially when they are used in conjunction with appropriate pharmacologic interventions.

Number of non pharmacological interventions (e.g. Distraction, prayer, relaxation, guided imagery, music and biofeedback etc) are available that lessen the pain.

Non pharmacological interventions include cognitive behavioral and physical approaches. The goals of cognitive-behavioral interventions are to change client's perceptions of pain, to alter pain behavior, and to provide clients with a greater sense of control (Gruner and Lande, 2006; Mc Caffery and Pasero, 1999).

According to Hamilton (2010) some of the non pharmacological interventions are:

- **Comforting** is one of the most important non drug measures to relieve pain. The enfolding arms of a parent or caregiver around a frightened, hurting child provide far more than physical warmth. They give the child basic needs important to survival, such as safety, security, acceptance, and recognition. In fact, studies show that infants who do not receive adequate amounts of touch fail to thrive, even when they are fed and otherwise cared for (Polan, 1999). As a consequence, nurses encourage parents to participate in the care of children in pain. If parents are not available, surrogates may be found to provide this valuable intervention.
- A swaddled infant is securely wrapped in a blanket to prevent excessive movement. Facilitated tucking is a hand-swaddling technique that holds the infant's extremities flexed.
- **Relaxation, hypnosis, and imager**, when used in conjunction with analgesics, are especially effective pain relieving measures for children. Because children have an active imagination, unhampered by learned responses, they are able to disassociate from present reality to imaginary scenes and situations. These measures are especially useful when children must undergo repeated procedures that cause fear and pain.

- **Applications of hot and cold** have been used for centuries to dull the pain of an acute injury and treat painful muscle spasms. Young athletes are well acquainted with the use of cold to contract blood vessels, reduce inflammation, and numb peripheral nerves, and with heat to decrease muscle spasms and increases blood flow. People of every age find warm baths and soaks comforting and pain relieving.
- **Massage and touch** stimulate the skin and comfort individuals of every age, even tiny pre-term infants. These measures give both children and adults the non possessive warmth and unconditional positive regard so needed when people are suffering and frightened.
- **Transcutaneous electrical nerve stimulation (TENS)** delivers small amounts of electrical stimulation to the skin by electrodes. This stimulation may interfere with the transmission of pain from the peripheral nerves to the spinal cord. TENS is used for both acute and chronic pain in children of school age and older.

Kline et al., (2009) had conducted a comparative study to find out the effectiveness of teaching mental imagery (MI) for pain management versus conducting a detailed inquiry (DI) about pain-related experiences with acutely injured PICU patients. The participants included 44 hospitalized children and adolescents assigned to one of two intervention groups, mental imagery or detailed inquiry. The pain was assessed pre and post-intervention using the Wong-Baker Faces Pain Rating Scale and a 0-10 Likert pain rating scale, and the Paediatric Trauma Score was utilized to assess the severity of each child's injury. Result shows that's Boys in the mental imagery condition exhibited a significant decrease in average pain ratings. Girls on the metal imagery condition

exhibited a non-significant decrease in average pain ratings. The researchers concluded that teaching children the use of mental imagery for pain management in an intensive-care setting was supported; the use of detailed inquiry with boys was not supported.

Shela Mathai et al (2006) conducted a randomized study to compare non pharmacological method to decrease the pain heal pricks in 104 stable term neonates. Non nutritive sucking (NNS), rocking, sucrose, distilled water, and expressed breast milk were used as pain decreasing agents. Duration of cry and Douleur Aigue du Nouveau-ne (DAN) score were used to assess pain. Physiological parameters were also recorded before and after the stimulus. At 30 seconds after the stimulus, the pain sores were lowest in the sucrose group but this was not sustained at 1,2 and 4 minutes. At 2 and 4 minutes pain scores were lower in the NNS and rocking groups as compared to sucrose, distilled water, expressed breast milk and massage. The total duration of crying was also lower in the NNS and rocking groups. In conclusion the study suggested that rocking or giving a baby a pacifier are more effective non pharmacological analgesics than expressed breast milk, distilled water, sucrose or massage for the pain of heel pricks in neonates.

Non-nutritive Sucking and Pain Relief:

Carbajal, et al., (1999) studied 150 term neonates experiencing venipuncture. Each infant was randomly assigned to one of six groups; no treatment (n=25), placebo (n=25), pacifier (n=25), 2 mL 3 glucose (n=25), 2mL 30% sucrose (n=25), and 2 mL sucrose combined with sucking on a pacifier (n=25). Infnats the NNS alone group had significant reduction in pain ($p<0.001$).

Oral Sucrose and Pain Relief:

Mathai et al., (2006) studied 104 term neonates at 24 hours of life who were undergoing routine heel lance procedures and random assigned them to receive one of six interventions: expressed breast milk (n=18), sucrose (n=17), distilled water (n=15), NNS (n=18), massaging (n=17), and rocking (n=17). Again infants receiving oral sucrose and NNS experience significantly reduced pain ($p<0.001$).

Breastfeeding and Pain Relief:

Carbajal, el al., (2003) studied 180 full-term neonates during a routine venipuncture procedure. Infants were randomly assigned one of four groups: breastfeeding (n=44), held by their mother (n=45), mL of sterile water orally (n=45), or 30% sucrose followed by NNS (n=45). Both breastfeeding and oral sucrose combined followed by NNS proved to significantly reduce infant pain responses ($P<0.0001$).

IV. LITERATURE AND STUDIES RELATED TO SWADDLING TECHNIQUE:

There was sufficient evidence to support the use of swaddling/tucking as an efficacious intervention for reducing pain-related distress reactivity and immediate pain-related regulation in pre-term infants. Two studies that were not included in the analysis due to use of an active control group, suggested that swaddling was as efficacious as containment but not as efficacious as kangaroo care.

Yamada et al., (2008), swaddling combined with positioning the neonates in upright during routine heel lance procedures offers nurses a nonpharmacologic method of neonatal pain reduction for heel sticks. This technique can be easily implemented on any unit independent of facility protocols. Further more, the technique is not associated with may cost or policy development, making it more likely that nurses can use it in practice.

The effect of clinical nursing practice guideline for swaddling on pain relief from heestic in neonates. Sinpru et al (2007) Thailand, selected 60 samples, gestational age 34 – 42 weeks, body weight 2.5-4kg. Heart rate and oxygen saturation were measured using pulse oximeter. Pain score was evaluated by Neonatal Facial Coding System. The results suggest that neonatal swaddling is an effective tool to reduce pain during a heel stick blood sampling.

Researcher's from the Chinese University of Hongkong, (China), (2012). Investigated the effect of swaddling in premature newborns. They randomly assigned 27 premature infants to be swaddled and 27 to no intervention. They report that the mean post test and pre test score were lower in the intervention than the control group during, immediately after, and 2, 4, and 6 minutes after a heel stick (P=0.001). The mean heart rate and oxygen saturation were also lower in the intervention group than in the control group at all these time points (P<0.001). They speculate that swaddling provides stimulation across the proprioceptive thermal and tactile sensory systems that may reduce pain through gate control mechanisms. Huang et al (2004) and Johnson et al (2008), suggested that swaddling is a effective in pain reducing method in preterm infants.

Gray, et al (2002) examined 30 infants comparing breastfeeding (n=15) versus swaddling (n=15) during a routine heel lance procedure. Infants assigned to the breastfeeding group experienced significantly decreased crying and grimacing (p=.001) and 11 of the 15 breastfeed infants did not cry at all during the procedure.

Yamada et al., (2008), swaddling alone has also been shown to decrease pain perception in preterm neonates; however, there are few studies evaluating swaddling in term neonates. Huang, Tung, Kuo and Ying-Ju (2004) studied 32 preterm infants in

which each subject was randomly assigned to receive either swaddling as an intervention to pain from a routine heel lance procedure. Infant heart rates recovered significantly sooner following the heel lance procedure in the swaddling group ($p<.05$). Prasopkittikun et al (2003) included four studies comprising 108 infants for a meta-analysis of swaddling. Swaddling both term and preterm infants was found to be moderate to highly effective at reducing pain infants experienced from heel lance procedures.

Using the swaddling technique, nurses can implement the procedures in this study independent of either facility protocols or maternal feeding preferences. Because this technique can be easily implemented on any unit without associated cost or policy development, nurses may be more likely to put it into practice.

Cignacco et al (34), 2007, n=15, swaddling have positive effects on behavioural and/or physiological indicators of pain

Prasopkittikun et al, 2003, n=4, Nonpharmacological interventions for heel lance, swaddling (MES = 0.79, 95% CI 0.53 to 1.05) reduced pain scores compared with control in full-term infants; swaddling (MES = 0.53, 95% CI 0.27 to 0.80) reported adverse effects of the non-pharmacological interventions reviewed.

Among the 78 articles reviewed, they identified 9 RCTs that met the criteria of the Cochrane Central Register of Controlled Trials of all articles reviewed, 9 were articles on swaddling in relation to sleep state and arousal, 8 articles described the effect of swaddling on temperature control, 6 articles discussed the effect of swaddling on motor development. 4 articles set out the effects of swaddling on pain control, and the effect on crying behavior was discussed in 4 articles.

CHAPTER – III

RESEARCH METHODOLOGY

Research methodology provides a brief description of the method adopted by the investigator in this study. Research methodology includes research approaches, research design, setting, population, sample, sample size, sampling technique, criteria for sample selection, description of the tool, validity, reliability, pilot study, data gathering process, plan for data analysis and the protection of human subjects.

RESEARCH APPROACH:

The research approach used for this study is Quantitative approach. According to Polit, 2001, Quantitative approach is study to explore the dimension of a phenomenon or to develop hypothesis and about the relationship between the phenomenon. This study aims at evaluating the effectiveness of swaddling on pain among the neonates during the invasive procedures and 2 minutes after the procedure.

RESEARCH DESIGN:

The study design selected for this study is post test only, non-equivalent control group quasi experimental design.

Group	**Intervention**	**Post Test – I (During Procedure)**	**Post Test – II (After 2 minutes)**
Experimental Group	X	O_1	O_2
Control Group	-	O_3	O_4

KEYS:

X	-	Intervention (swaddling)
O_1	-	Post test -I of experimental group (During the procedure)
O_2	-	Post test -II of experimental group (After 2 minutes)
O_3	-	Post test –I of control group (During the procedure)
O_4	-	Post test –II of control group (After 2 minutes)

Two groups were selected for the study, one group had an intervention (with swaddling) and the other group had no intervention. Post test was done for both the groups during the procedure and 2 minutes after procedures.

VARIABLES:

Dependent variable - Level of pain

Independent variable - swaddling

SETTING OF THE STUDY:

The study was conducted in Neonatal Intensive Care Unit of Government Rajaji Hospital, Madurai. It is 3 kms from Sacred Heart Nursing College. It is a 2418 bedded hospital. It has many specialty unit, it includes the pediatric medical and Surgical ward and Neonatal intensive care unit medical ward includes more than 150 beds and the surgical unit has 60 beds. The neonatal intensive care unit has 60 beds.

POPULATION:

A population is the entire aggression of case that meets designated criteria. In this study, neonates, who are undergoing invasive procedures. (IV cannula insertion and blood sampling) formed the population.

SAMPLE:

Sample is a subset of population, selected to participate in a study (Polit 2008). In this study, newborn babies, who were admitted in Government Rajaji hospital and who fulfilled the criteria were selected as the sample.

SAMPLE SIZE:

60 newborn babies who had any one invasive procedures.

30 newborn babies with swaddling and 30 newborn babies without swaddling.

SAMPLING TECHNIQUE:

The hospital was selected by using convenient sampling method. Samples were assigned to experimental and control group. Convenience sampling is a nonprobability sampling technique where subjects are selected because of their convenient accessibility and proximity to the researcher.

SAMPLING CRITERIA:

INCLUSION CRITERIA:

- Newborn babies who had an invasive procedure
- Both sexes were included.
- Only term new borns were included
- Newborns without pain medications administered prior to participating in the study.

EXCLUSION CRITERIA:

- Newborn babies who are critically ill.
- Newborn babies with neurological deficits.
- Newborn babies with birth defects.

RESEARCH TOOL:

It consists of two sections.

SECTION I:

It consists of demographic data of the babies, age, sex, weight, type of invasive procedures, and duration of procedure.

SECTION II: NEONATAL FACIAL CODING SYSTEM (NFCS)

THIS TOOL HAS 9 ITEMS FACIAL ACTIONS MONITORED INCLUDE:

(1) Brow lowering (lowering and drawing together of the brow can result in brow bulge)

(2) Eyes squeezed shut

(3) Deepening of the naso-labial furrow (fold)

(4) Open lips (any separation of the lips is an occurrence)

(5) Vertical mouth stretch

(6) Horizontal mouth stretch

(7) Taut tongue (cupping of the tongue)

(8) Chin quiver (high frequency vibration of the chin and lower jaw)

(9) Lip pursing (tightening the muscles around the lips to form an "oo")

ACTION POINTS

Did not occur - 0

Occurred - 1

INTERPRETATION:

- Minimum score: 0
- Maximum score for full term infants: 9

Mild - 0 – 3

Moderate - 4 – 6

Severe - 7 – 9

TESTING OF TOOL

VALIDITY:

- To evaluate the validity of the tool, it was submitted to experts in the field of pediatric nursing, medicine and with the dissertation committee of the college of nursing.

RELIABILITY:

Inter-rater method was used to find out the reliability of the instrument. The tool was administered to samples and assessed by investigator and was assessed by another observer for the same sample simultaneously. Three samples for the experimental group and the three samples for control group were selected and the instrument was applied in the same manner. The reliability of the inter-rater method in NFCS scales was r=0.09.

INTERVENTION:

- The researcher kept the things required for swaddling ready before the invasive procedure.
- All neonates in the study group were swaddled according to the clinical nursing practice guidelines using two pieces of cloth of both sizes which were 1 meter length x 1 meter width each.
- The neonate was laid on a piece of cloth, one side of the cloth brought over one arm, passed between the chest and the other arm, and then tucked under the baby.

- ❖ The swaddling was done in the procedure room where the invasive procedure was done.
- ❖ The limb used for the procedure was left exposed.

PILOT STUDY:

Pilot study was conducted to determine the feasibility of the study. It was conducted in Government Rajaji Hospital, Madurai with 6 newborn babies who were undergoing invasive procedures.

DATA COLLECTION PROCEDURE:

The data collection was done for 6 weeks. The permission was obtained from the authorities concerned from the Hospital before the pilot study and actual data collection begins. The nature of the study was explained to, parents and health personnel. Researcher maintained good rapport with parents.

Every week from Monday to Saturday the data were collected. The data were collected from 9 am to 2 pm. Every day two to three samples were selected by the investigator. First 3 weeks assessed the control group. Then the experimental group selected and swaddling technique applied.

Convenience sampling method was used to select the sample. Samples were assigned to experimental and control group. On the day of data collection the researcher introduced himself to the newborns mothers. The swaddling technique done to the neonates in the procedure room who had undergone invasive procedures. Before the procedure the researcher had arranged and kept ready the scoring tools. At the time of performing invasive procedure observed the changes of newborns activities and after 2 mts again observe the behavior changes. First week 10 samples, second week 12

samples, third week 9 samples, fourth week 14 samples and fifth week 15 samples were selected by the researcher.

In this study, the researcher applied swaddling technique for experimental group during the invasive procedure which was done by experienced doctors or nurses.

PLAN FOR DATA ANALYSIS:

After the data collection, the collected data were organized and tabulated. The data were analyzed according to objectives of the study, by using frequency and inferential statistics (chi-square).

PROTECTION OF HUMAN SUBJECTS:

The proposed study was conducted after the approval of the dissertation committee of the college. Permission was obtained from Dr. Bala Shankar, MD., Govt. Rajaji Hospital, Madurai. The oral consent of each subject's parent was obtained before starting the data collection. Assurance was given to them that the anonymity of each individual would be maintained.

CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of the data collected to determine the effect of the swaddling technique to assess the pain level during & after 2 mts of the invasive procedures. This analysis was done based on the objectives of the study. The data was collected and tabulated and also described as follows:

PRESENTATION OF THE FINDINGS OF THE STUDY:

SECTION I:

1. **Frequency and percentage distribution of demographic variables of experimental and control group.**
2. **Frequency and percentage distribution of participants according to the level of pain, in the experimental group, during and after 2 mts of the invasive procedures.**
3. **Frequency and percentage distribution of samples according to the level of pain in control group during and after 2 mts of the invasive procedures.**

SECTION II:

4. **Comparison of mean posttest-I and post test-II pain score of experimental group.**
5. **Comparison of mean posttest-I and post test-II pain score of control group.**

SECTION III.

6. **Comparison of mean posttest-I pain score of experimental and control group during the invasive procedure.**

7. **Comparison of mean posttest-II of pain score of experimental and control group after 2 minutes of the invasive procedure.**

SECTION IV:

8. **The association between pain score level and the selected demographic variables age, sex, weight, type of invasive procedure, and duration of procedure.**

SECTION – I

Table 1: Frequency and percentage distribution of demographic variables of experimental and control group.

Demographic variables	Experimental group (n = 30)		Control group (n = 30)		Total (n = 60)	
	f	%	f	%	f	%
Age:						
a. 1 – 7 days	25	83.33	23	76.66	48	80
b. 8 – 14 days	5	16.66	7	23.32	12	20
Sex:						
a. Male	20	66.66	13	43.33	33	55
b. Female	10	33.33	17	56.66	27	45
Weight:						
a. < 2 kg	0	0	1	3.3	1	1.66
b. 2 – 3 kg	23	76.6	20	66.66	43	71.66
c. > 3 kg	7	23.3	9	30	16	26.66
Type of invasive Procedure:						
a. I.V	6	20	4	13.33	10	16.66
b. Blood sampling	24	79.9	26	86.66	50	83.33
Duration of Procedure:						
a. < 5 min	24	79.9	8	26.66	32	53.33
b. 5 – 10 min	6	20.00	22	73.33	28	46.66

The age of the samples varied from 1-14 days majority of the samples in the experimental group, 25 (83.33%) were between 1-7 days, 5 (16.66%) were between 8-14 days and in the control group majority of the samples 1-7 days, 23 (76.6%) and in the 8-14 days, 7 (23.32%).

Regarding sex in experimental group, the majority of the samples were males 20 (66.66%), females 10 (33.33%) and in the control group majority of the samples were females 17 (56.66%), males 13 (43.33%).

Considering the weight 23 (76.6%) newborns were between 2-3 kg, 7 (23.3%) newborns were more than 3 kg in the experimental group. In the control group majority 20 (66.66%) newborns were between 2-3 kg, 9(30%) above 3 kg, and 1 (3.3%) weight less than 2 kg.

According to the type of invasive procedure, 24 (79.9%) newborns were in the experimental group underwent blood sampling and 6 (20%) underwent I.V. cannualation and 26 (86.66%) newborns were in the control group underwent blood sampling and 4 (13.33%) newborns were underwent I.V. cannulation.

In relation to the duration of the invasive procedure 24 (79.9%) newborns were in the experimental group having less than 5 minutes of duration and 6 (20%) newborns having 5-10 minutes duration.

In control group 8 (26.66%) newborns were underwent the procedure for <5min, and 22 (73.33%) newborns were underwent the procedure for 5-10 min duration.

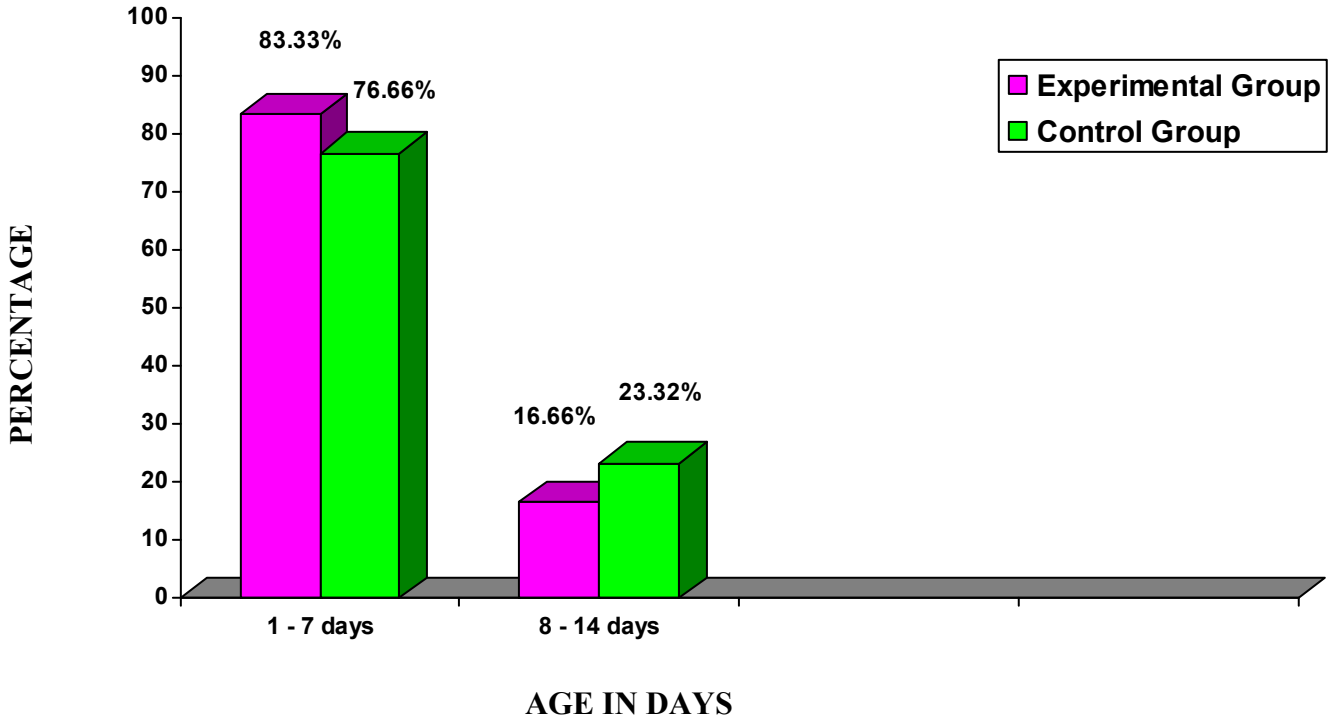


Fig 2: Distribution of Sample Interms of Age (in days)

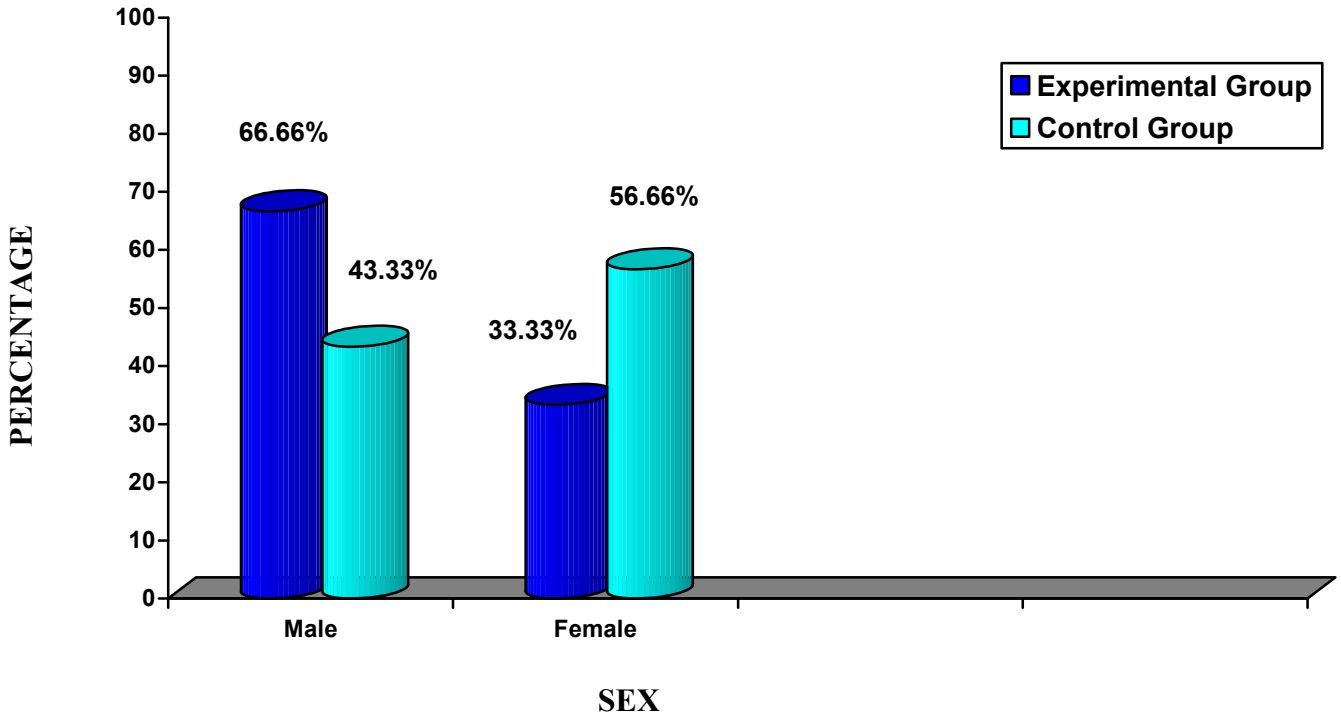


Fig 3: Distribution of Sample Interms of Sex

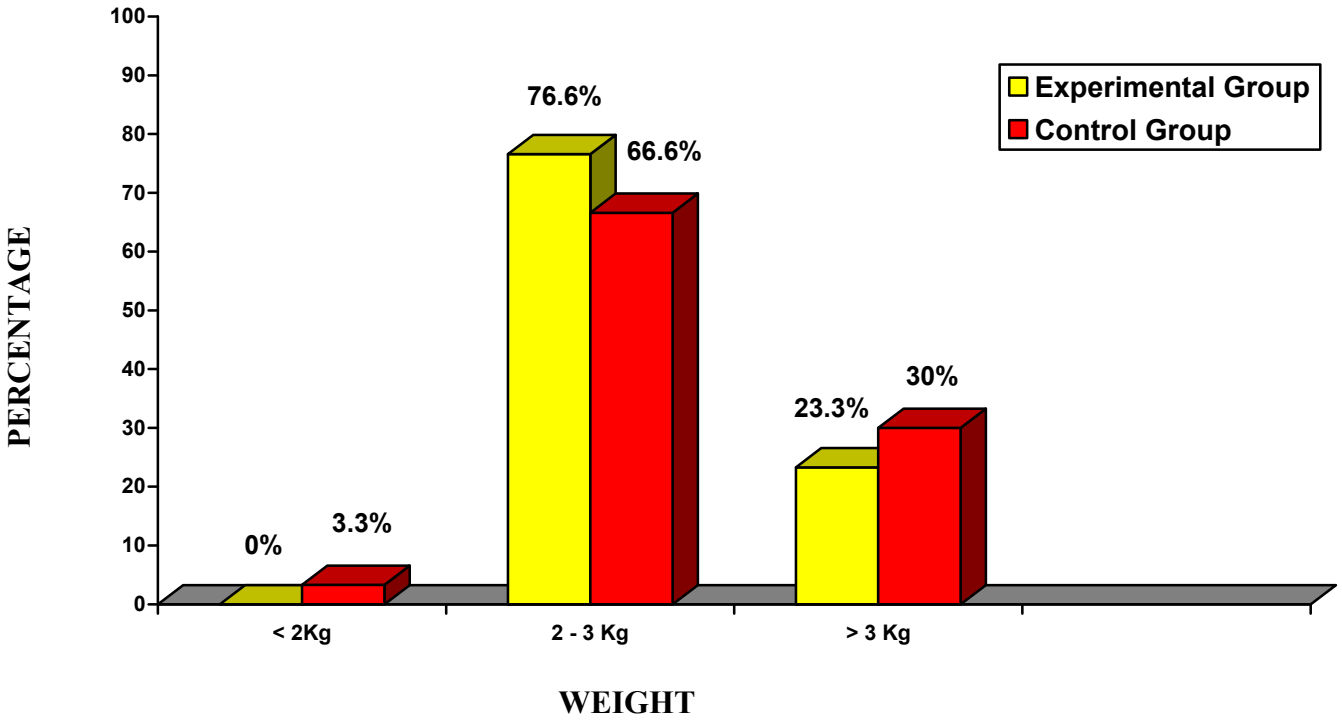


Fig 3: Distribution of Sample Interms of Weight

Table 2: Frequency and percentage distribution of sample according to the level of pain, in the experimental group, during and after 2 mts of the invasive procedures.

N = 30

Level of Pain	Experimental Group (n = 30)			
	Post test – I		Post test – II	
	f	%	f	%
Mild pain (1-3)	7	23.33	29	96.67
Moderate pain (4-6)	23	76.67	1	3.33
Severe pain (7-9)	-	-	-	-

Based on the pain level, the subjects were classified under into 3 groups.

Mild pain (1-3), moderate pain (4-6), severe pain (7-9) based on the neonatal facial coding system-scale for pain assessment.

Post test-I mild pain 7 (23.33%) moderate pain 23 (76.67%).

In post test-II, mild pain 29 (96.67%), moderate pain 1 (3.33%) in the experimental group.

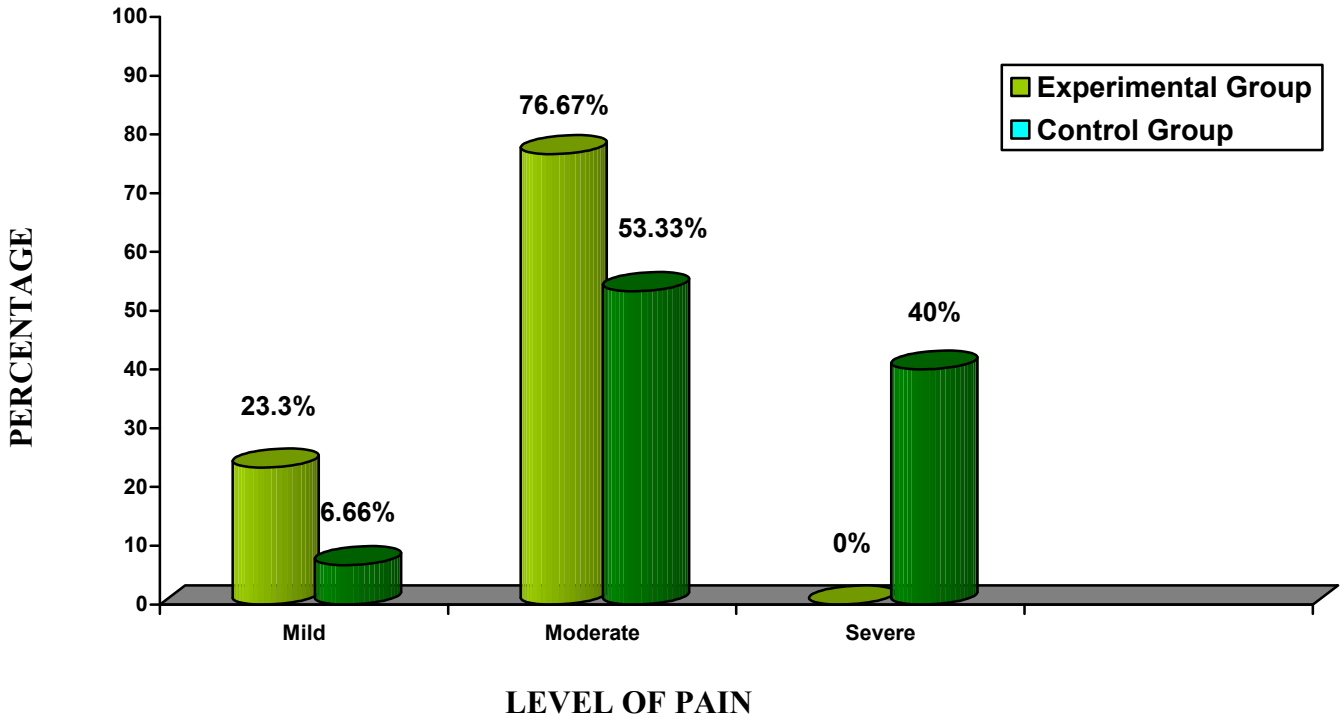


Fig 4: Distribution samples according to the level of pain in the experimental group and control group during the invasive procedures

Table 3: Frequency and percentage distribution of samples according to the level of pain in control group during and after 2 mts of the invasive procedures.

Level of Pain	Control Group (n = 30)			
	Post test – I		Post test – II	
	f	%	f	%
Mild pain (1-3)	2	6.66	27	90
Moderate pain (4-6)	16	53.33	3	10
Severe pain (7-9)	12	40	-	-

Based on the pain level scores obtained the subjects were classified into 3 groups, mild pain (1-3), moderate pain (4-6), severe pain (7-9) based on neonatal facial coding system (NFCS).

Table 3 shows, that post test - I 2 had mild pain (6.6%), moderate pain 16 (53.33%), severe pain, 12 (40%), and post test-II mild pain 27 (90%), moderate pain 03 (10%) in the control group.

SECTION II

Table 4: Comparison of mean posttest-I and post test-II pain score of experimental group.

N = 30

Experimental Group	N	Mean	S.D	't' value
Post test-I	30	4.06	0.85	16.66*
Post test-II	30	0.66	1.01	

Significant at 0.05 level.

To find out if there was any difference between the mean pain scores posttest-I & posttest-II and after the swaddling technique, the null hypothesis was stated as follows.

Table 4 shows that mean posttest I pain score (4.06) was higher than the mean posttest-II pain score (0.66). The obtained 't' value 16.66 at df. 29 was significant at 0.05 level.

Table 5: Comparison of mean posttest-I and post test-II pain score of control group.

N = 30

Control Group	N	Mean	S.D	't' value
Post test-I	30	6.2	1.42	6.15*
Post test-II	30	1.73	1.24	

Significant at 0.05 level.

To find out if there was any difference between the mean pain scores posttest-I & post test-II and after the swaddling technique, the null hypothesis was stated as follows.

Table 5 shows that mean posttest I pain score (6.2) was higher than the mean post test-II pain score (1.73). The obtained't' value 6.15 at df. 29 was significant at 0.05 level. At the time of procedure the pain level is higher and after two minuets the pain level is lesser.

SECTION III

Table 6: Comparison of mean posttest-I pain score of experimental and control group during the invasive procedure.

N = 60

Group	N	Mean	S.D	't' value
Experimental Group	30	4.06	0.85	7.37*
Control Group	30	6.2	1.42	

Significant at 0.05 level.

To find out if there is any difference between the men post test pain score based on clinical criteria of experimental and control group after the swaddling technique during the invasive procedures, the null hypothesis is stated as follows.

In the present study there will be no significant difference between the mean post test I pain score of experimental and control group.

Table 6 shows that the mean post test pain score of the experimental group 4.06 after the swaddling techniques is lower than the mean post test pain score of control group 6.2. The obtained 't' value is 7.37 which is significant at 0.05 level.

This indicates that the difference between the mean is 2.1 is a true difference and has not occurred by chance. The difference between the two means could be due to the effect of swaddling technique. So the above finding supports the research hypothesis and the investigation rejects the null hypothesis.

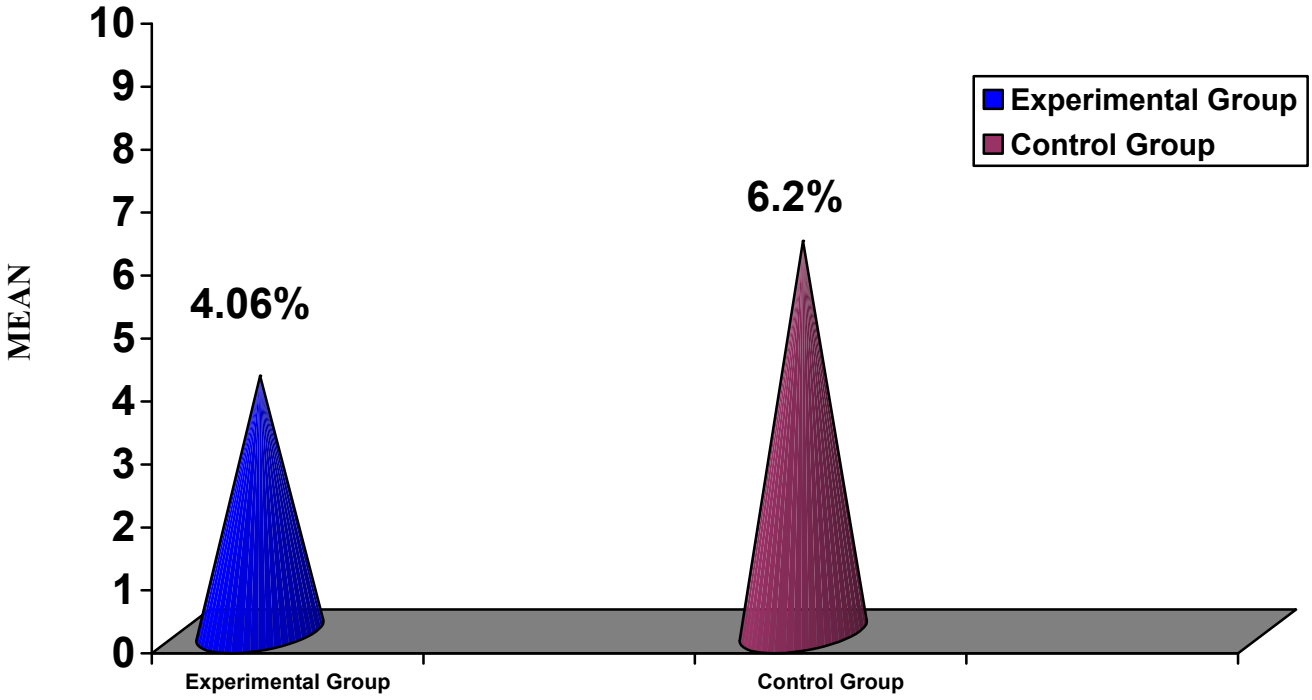


Fig 5: Comparison of mean post test-I level of pain score in experimental and control group during the invasive procedures

Table 7: Comparison of mean posttest-II of pain score of experimental and control group after 2 minutes of the invasive procedure.

N = 60

Group	N	Mean	S.D	't' value
Experimental Group	30	0.66	1.01	3.68*
Control Group	30	1.73	1.24	

Significant at 0.05 level.

To find out if there is any difference between the men post test pain score based on clinical criteria of experimental and control group after the swaddling technique during the invasive procedures, the null hypothesis is stated as follows.

In the present study there will be no significant difference between the mean post test I pain score of experimental and control group.

Table 7 shows that the mean post test pain score of the experimental group 0.66 after the swaddling techniques is lower than the mean post test pain score of control group 1.73. The obtained 't' value is 3.68 which is significant at 0.05 level.

This indicates that the difference between the mean is 2.1 is a true difference and has not occurred by chance. The difference between the two means could be due to the effect of swaddling technique. So the above finding supports the research hypothesis and the investigation rejects the null hypothesis.

SECTION IV

Table 8: The association between pain score level and the selected demographic variables age, sex, weight, type of invasive procedure, and duration of procedure.

Demographic Variables	N	Pain Score		$\chi 2$
	n = 60	Above mean	Below mean	Value
Age:				
a. 1 – 7 days	48	27	21	0.80 #
b. 8 – 14 days	12	5	7	(df=1)
Sex:				
a. Male	33	19	14	4.91 *
b. Female	27	13	14	(df=1)
Weight:				
a. < 2 kg	1	1	0	3.53 #
b. 2 – 3 kg	43	23	20	(df=2)
c. > 3 kg	16	8	8	
Type of invasive Procedure:				
a. I.V	10	4	6	0.858 #
b. Blood sampling	50	28	22	(df=1)
Duration of Procedure:				
a. < 5 min	32	28	4	30.02 *
b. 5 – 10 min	28	4	24	(df=1)

* - Significant at 0.05 level # - Not significant at 0.05 level

Hypothesis:

Table 7 shows that there was association between pain score and sex, obtained chi-square value 4.91 at df (1) was significant at 0.05 level.

Regarding the pain score level and weight, the calculated chi-square value was 3.53 at df (2) was not significant at 0.05 level.

This table is to find out where there is any association between the pain score of the experimental group and the demographic variables such as age, sex, weight, type of invasive procedure and duration of the procedure.

The null hypothesis stated as follows:

There is no significant association between pain score and selected demographic variables (age, weight, and type of invasive procedures).

In order to find out the association between the pain score and age of new born baby in days the chi-square was computed and obtained $\chi 2$ value is 0.80 at df (1) which was not significant at 0.05 level. This shows that there was no significant association between the pain score and age.

In order to find out the association between the pain score and sex the chi-square was computed. The obtained $\chi 2$ value is 4.91 at df (1) which was significant at 0.05 level. This shows that there was association between the pain score and sex.

In order to find out the association between the pain score and weight, the chi-square was computed. The obtained $\chi 2$ value is 3.53 at df (2) which was not significant at 0.05 level. This shows that there was no significant association between the pain score and weight.

In order to find out the association between to pain score and type of invasive procedure, the chi-square was computed. The obtained $\chi 2$ value is at df () which was not significant at 0.05 level. This shows that there was no significant association between the pain score and type of invasive procedures.

In order to find out the association between the pain score and duration of the procedure, chi-square was computed. The obtained $\chi 2$ value is 0.12 at df (1) which was significant at 0.05 level. This shows that there was association between the pain score and duration of the procedure.

Hence there is no association between pain score and age, weight, type of invasive procedure. The research accepts the null hypothesis and rejects the research hypothesis.

There is an association between pain score and sex and duration of the procedure. So with regard to sex and duration of the procedure the researcher rejects the null hypothesis and accepts the research hypothesis.

CHAPTER – V

DISCUSSION

The aim of the study was to evaluate the effectiveness of the swaddling technique in reducing pain during invasive procedures among newborns. The subjects were selected as per inclusion criteria. Then the data were selected as per the inclusion criteria. Then the data were collected by using NFCS (Neonatal Facial Coding System) scale for both experimental and control groups.

The findings of the study were discussed in this chapter with the reference of the objectives of the study.

THE DEMOGRAPHICAL CHARACTERISTICS OF THE SAMPLE:

The study findings show that 80% of newborns were 1-7 days, and 20% of newborns were 8-14 days.

- With regard to sex 55% were male and 45% were female.
- Regarding the weight of newborns, 1.66% were less than 2 kg, and 71.66% were 2-3 kg and 26.66% were more than 3kg of body weight.
- Regarding the type of invasive procedure 16.66% of newborns had undergone vaccination and 83.33% of newborns had undergone blood sampling collection.
- With regard the duration of invasive procedures 53.33% undergone the procedure for less than 5 minutes and 46.66% had undergone the procedure. 5 to 10 minutes and 26.66% had undergone the procedure more then 10 minutes.

THE FIRST OBJECTIVE OF THE STUDY WAS TO ASSESS THE PAIN LEVEL DURING & 2 MINUTES AFTER THE INVASIVE PROCEDURES AMONG THE EXPERIMENTAL GROUP OF NEWBORNS

The data presented in the table 2 shows that 96.67% newborns had mild pain and 3.33% newborns had moderate pain and 0% newborns had severe pain during the time of the procedure in the experimental group.

According to the gate control theory the dorsal born of the spinal cord is an extremely important site for pain modulation (Mezack % Wall 1965). The theory hypothesizes that in the dorsal born of the spinal cord, a balance exists between large diameter non pain fibers and small diameter pain fibers that synapse on central transmission cells. Simulation of small diameter pain fibers allow the pain transmission (i.e. the gate is open) where as stimulation of large diameter non pain fibers inhibits the transmission of cell activity and closes the gate.

THE SECOND OBJECTIVE OF THE STUDY WAS TO ASSESS THE POST TEST PAIN LEVEL DURING & 2 MINUTES AFTER THE INVASIVE PROCEDURES AMONG THE NEWBORNS IN THE CONTROL GROUP.

The data presented in table 2 shows that 6.6% newborns had mild pain and moderate pain53.33 % and severe pain 40% newborns had severe pain in the control group.

According to Coghill (2003) people who reported higher levels of pain showed increased activation in areas of the brain important in pain; the primary somatosensory cortex, which contributes to the perception of pain where a painful stimulus is located on the body and the anterior cingulated cortex, which is involved in transmitting pain signals

from the spinal cord to higher brain regions. This difference between cortical and thalamic patterns of activation may help explain pain differences between individuals. The incoming painful information is processed by the spinal cord in a generally similar manner. But once the brain gets involved, the experience becomes very different from one individual to the next.

Carla Morrow, (2010), Measured the difference in pain scores for newborns who were held and swaddled while undergoing routine heel lance procedures. A total of 42 neonates recruited from a large tertiary hospital were enrolled in a randomized controlled trial. Infants in the experimental group (n = 22) were swaddled and held in an upright position during routine heel lance procedure while neonates in the control group (n = 20) remained in a standard care position. Pain was measured with the Neonatal Inventory Pain Scale (NIPS) at two points in time for each group (just before the heel land procedure and at the completion of the heel lance). Total collection time was measured using a stopwatch accurate to $1/100^{th}$ of a second. Specimen quality was measured based on the number of rejected specimens for each group. Descriptive statistics and 't' tests were used to analyze the data. The results that swaddling combined with positioning neonates during routine heel lance procedure reduces the pain level.

THE THIRD OBJECTIVE OF THE STUDY WAS TO EVALUATE THE EFFECTIVENESS OF THE SWADDLING TECHNIQUE ON PAIN LEVEL DURING INVASIVE PROCEDURES AMONG NEWBORNS.

a) Comparison of mean post test pain score of experimental and control group during the invasive procedures.

Table 4 shows that mean post test pain scores of the experimental group which is lesser than the mean post test pain score of control group during the invasive procedure. The obtained 't' value is 11.73 which is significant at 0.05 level. The difference between the two means could be due to the effect of swaddling technique.

The study finding of Nitaya et al (2009) supported the above findings. The study was conducted with approval from the faculty of graduate studies, Mahidol University and Vajira Hospital. He selected two groups. One group as control group and another is study group (experimental). Swaddling done prior to the heel stick procedure and after that the neonate was unswaddled. The video recording continued for 5 minutes after the heelstick. He used to record a video records, to record a close-up view of the neonates face and the procedures showing a clock and pulse oximeter at all times. It results, swaddling according to a clinical nursing practice guidelines can help relieve pain during neonatal heelsticks.

b) Comparison of mean post test pain score of experimental and control group based on clinical criteria during the invasive procedures.

Table 5 shows that mean face score of the experimental group (7.95%) after give applying swaddling technique during the procedure is lower than mean face score of

control group. The obtained value is (4.6%) which is significant at 0.05 level. The difference between the two means due to the effect of swaddling technique.

The study conducted by researchers from the Chinese University of Honkong in China, investigated the effect of swaddling in premature newborns. They randomly assigned 27 premature infants to be swaddled and 27 to no intervention. They report that the mean PIPP scores were lower in the intervention than the control group during, immediately after 1 and 2, 4 and 6 minutes after a heel stick (P=0.01). Both heart rate and oxygen saturation in the swaddled babies returned to the baseline level at 2 minutes, but it took 6 to 8 minutes for these rates to return to baseline in the control group. Speculates that swaddling provides stimulation, across the proprioceptive, thermal, and tactile sensory systems that may reduce pain through gate control mechanisms.

THE FOURTH OBJECTIVE OF THE STUDY WAS TO FIND OUT THE ASSOCIATION BETWEEN PAIN LEVEL OF NEWBORN IN THE EXPERIMENTAL GROUP & CONTROL GROUP WITH THEIR SELECTED DEMOGRAPHIC VARIABLES SUCH AS AGE, SEX, WEIGHT, TYPE OF INVASIVE PROCEDURE AND DURATION OF THE PROCEDURE.

Sinpru, (2007), selected 60 samples, gestational age 34-42 weeks, body weight 2.5-4 kg. Heart rate and oxygen saturation were measured using pulse oximeter. Pain score was evaluated by Neonatal Facial Coding System. The results suggest that neonatal swaddling is an effective tool to reduce pain during a heel stick blood sampling.

In order to find out the association between the pain score and selected demographic variables, chi-square test was computed. There is no association between demographic variables like age, weight, type of invasive procedure.

The computed chi-square values are 0.80 at (df=1), 3.53 at (df=2), 0.858 at (df=2), was not significant at 0.05 level.

In order to find out the association between the pain score and sex and duration of procedure, the chi-square was computed. There was a significant association between pain score and sex. The obtained chi-square value is 4.91 at (df=1), and significant association between the pain score and during of the procedure 30.02 at (df=2). Hence the researcher rejects the null hypothesis and accept the research hypothesis.

In conclusion the swaddling technique had the effect on reducing pain during invasive procedures, which can be used clinically in relieving pain among children. Through this study finding, the investigator has made an attempt to highlight the effect of swaddling technique in pain reduction.

CHAPTER – VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

This chapter deals with the summary, conclusions, implications and also recommendations for different areas with nursing practice, nursing education, nursing administration and nursing research.

SUMMARY:

Pain in newborn is complex, and often difficult to assess. The intended the researcher to study the effect of the swaddling technique on pain during invasive procedures among newborns admitted in Govt. Rajaji Hospital, Madurai.

The following objectives were set for the study;

1. To assess the pain level during & 2mts after the invasive procedures among the experimental group of newborns after the swaddling technique.
2. To assess the pain level during & 2mts after the invasive procedures among the newborns in the control group.
3. To evaluate the effectiveness of the swaddling technique on pain level during & after 2 mts of invasive procedures among newborns.
4. To find the association between pain level of newborn in the experimental group and control group with their selected demographic variables such as age, sex, weight, type of invasive procedure, and duration of the procedure.

The following hypothesis were set for the study and all the hypotheses were tested at 0.05 level of significance.

The mean post test pain score of the experimental group of newborns who had swaddling technique significantly lesser than mean post test pain score of control group.

There was significant association between pain scores of newborns in the experimental group with selected demographic variables such as sex, and duration of the procedure.

The purpose of undertaking this study was to evaluate the effectiveness of the swaddling technique in reducing pain during invasive procedures. An in depth review of literature was collected for the study. The conceptual framework adopted for this study was modified Von Bertalantly's General System Theory.

An experiment approach and post test only equivalent control group quasi experimental design was chosen for conducting the study. The population chosen for the study was 0 to 14 days of newborns who had undergone invasive procedures like IV cannulation and collection of blood sample. The study subjects were selected by using the convenience sampling technique.

The tool used for the study was NFCS scale.

A pilot study was conducted to assess the feasibility of the study. Main study was conducted with 60 samples (30 in experimental group and 30 as a control group) for the period of five weeks. The data collected were analyzed using both descriptive and inferential statistics.

The data regarding demographic variables as well as distribution of samples were presented in terms of frequency and percent age, inferential statistics for identifying the

significance of the swaddling technique (independent 't' test). The chi-square was computed to find out the significant association between pain score and selected demographic variables such as age, sex, weight, types of invasive procedure and duration of the procedure.

THE MAJOR FINDINGS OF THE STUDY:

Demographic Data of the Sample:

a. With regard to age, 80% of newborns were 0-7 days, 20% of newborns were 8-14 days.

b. Regarding sex 33% were male, and 45% were female.

c. Regarding weight 1.66% of newborns were less than 2kg, 71.66% were in 2-3 kg, and 26.66% were more than 3 kg.

d. Regarding the type of invasive procedure 16.66 % were undergone IV cannulation, and 83.33% were undergone collection of blood samples.

e. With regard to the duration of the procedure 53.33% had undergone the procedure for less than 5 minutes and 46.66% had undergone the procedure 5 to 10 minutes.

Effects of swaddling technique in during painful procedure

- The mean post test score of experimental group during the invasive procedures lower than the mean post test score of control group at the level of $P<0.05$ findings.
- The mean post test pain score of experimental group during the invasive procedures lower than the mean post test pain score of control group based on clinical criteria at the level of $P<0.05$ level (table 5)
- There was no significant association between age, weight, type of invasive procedure chi-square value were 0.80, 3.53, 0.85.

- There was a significant relationship between sex and duration of procedures chisquare value were 4.91 and 30.02.

CONCLUSIONS:

The following conclusions are drawn from the study.

- With regard to age 48 (80%) of newborns were 1-7 days, and 12 (20%) newborns were 8-14 days.
- Regarding sex 33 (55%) newborns were male, and 27 newborns (45%) were female.
- With regard to weight 1 (1.66%) newborn was less than 2kg, 43 newborns (71.66%) were in 2-3 kg, and 16 newborns (26.66%) were more than 3 kg.
- Regarding the type of invasive procedure 10 newborns (16.66%) were undergone I.V cannulation and 50 (83.33%) were undergone collection of blood sampling.
- With regard to the duration of the procedure 32 neonates (53.33%) were undergone the procedure for less than 5 minutes and 58 neonates (46.66%) were undergone the procedure 5 to 10 minutes.

The mean post test pain score of the experimental group significantly lower than the mean post test pain score of the control group during the invasive procedure.

There was no significant association between pain score and age, weight, type of invasive procedure.

There was a significant association between pain score and sex and duration of invasive procedure.

Thus the research study concludes that the newborn who received the swaddling technique during the procedure experienced less pain than the control group.

IMPLICATIONS:

Implications for nursing practice.

1. The nurse plays a major role in the management of pain relieving methods among the newborns.
2. In the clinical setting the finding of this study will help the nurses to manage the pain for newborn who undergo painful procedures by using swaddling technique in the hospital or ambulatory care setting.
3. The nurse can utilize this evidence based practice to improve the quality and standard of care given to the newborn. This study helps the nurse practitioners to use swaddling technique during the invasive procedure. It helps the nurse to aware and skillful in assessing pain among newborns.

Implications for Nursing Education:

1. Education plays a vital role in the modification of behaviour and practice among the nurses as well as the student nurses.
2. Non-pharmacological management of pain to the newborn should be included in the nursing curriculum and in formulating procedure in the manual of nursing practice. There by they can learn about the swaddling technique and its effectiveness during invasive procedures and they will apply in the clinical setting.

Implication for Nursing Administration:

1. Administration in nursing are challenged to undertake the health need of the most vulnerable group by effective organization. Newborn come under this group.

2. The nurse administrator can make a policy and protocol for using the swaddling technique as one of the pain relieving technique for the newborn.
3. Nurse administrators can conduct in-service education and workshop about various non pharmacological measures that to manage the pain among newborn with the help of medical experts in the field of paradiatrics. So the nurse administrators play a vital role in implementing the practice.

Implication for Nursing Research:

1. One of the aims of nursing research is to expand and broaden the scope of nursing; the findings of this study will provide the baseline data about the pain intensity and implication of swaddling technique. It can used for further studies in this area.
2. This study also brings more facts and more studies which is needed to be done and different setting and it is culturally acceptable.

LIMITATIONS

1. Because of small sample size, findings must be interpreted with caution
2. This study was limited to children with newborn admitted in Government Rajaji Hospital at Madurai
3. The study period was limited to six weeks for data collection

RECOMMENDATIONS:

- A similar kind of study can be conducted for a large group to strengthen the findings.
- Similar study can be conducted among different age groups of children.
- A study can be done to assess the knowledge, attitude and practice of non pharmacological management of pain among the staff nurses in the paediatric setting of the hospital.
- A similar kind of study can be conducted for children undergo other types of invasive procedures.
- A similar kind of study can be conducted for children who had post operative pain.

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APPENDIX – I

COPY OF LETTER SEEKING PERMISSION

TO CONDUCT THE STUDY IN SELECTED AREAS IN MADURAI DISTRICT.

Dr. NALINI JEYAVANTHYA SANTHA
Principal.

4/235, COLLEGE ROAD
THASILDAR NAGAR
MADURAI – 625 020
PHONE: 2534593

Ref. UT: SHNC: 2014

Date:

To

Respected Sir / Madam,

Sub: Sacred Heart Nursing College, Madurai – Project work of M. Sc (Nursing) student – permission requested – reg.

We wish to state that Mrs. Shunmuga Pritha.C, II year M. Sc (Nursing) student of our college has to conduct a Research project, which is to be submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of University requirements.

The topic of research project is "A study to assess the effectiveness of swaddling on the pain level during invasive procedure among newborn babies in selected hospitals at Madurai."

.

We therefore request you to kindly permit her to do the research work in your organization under your valuable guidance and suggestions.

Thanking you,

Yours faithfully,

Principal
SACRED HEART NURSING COLLEGE
ULTRA TRUST, MADURAI – 20.

APPENDIX – II

LETTER REQUESTING OPINONS AND SUGGESTIONS OF EXPERTS FOR ESTABLISHING CONTENT VALIDITY AND VALIDITY OF TOOL

From

C. Shunmuga Pritha,
IInd Year M.Sc (Nursing),
Sacred Heart College of Nursing,
Madurai – 20.

To,

Respected Sir / Madam,

SUB : Requesting opinions and suggestion of experts for the content validity and validity of tool.

I am a post graduate student (Pediatric Speciality) of Sacred Heart Nursing College. I have selected the below mentioned topic of the research project submitted to DR. M.G.R. Medical University, Chennai as a fulfillment of Master of Science in Nursing.

TITLE OF THE TOPIC:

"A study to assess the effectiveness of swaddling on the pain level during invasive procedure among newborn babies in selected hospitals at Madurai"

With regard to this may I kindly request you to validate my content and tool for its relevancy. I am enclosing the objectives of the study. I would be highly obliged and remain thankful if you could validate and send it as early as possible.

Thanking You.

Place:
Date:

Your's faithfully,

(Shunmuga Pritha. C)

APPENDIX - III

List of Experts Consulted for the content validity of research tools

1. Dr. Balasankar, MD., DCH.,
   PROFESSOR OF PEDIATRICS
   Govt. Rajaji Hospital,
   Madurai.
2. Mrs. Chandrakala, M.Sc (N)., Ph.D.,
   Vice Principal,
   HOD of Medical Surgical Nursing'
   Sacred Heart Nursing College,
   Madurai.
2. Mrs. Juliet Sylvia, M.Sc (N), Ph.D.,
   HOD of Community Dept.,
   Sacred Heart Nursing College,
   Madurai.
3. Mrs. Devakirubai, M. Sc (N), Ph. D.,
   Professor,
   College of Nursing
   Sacred Heart Nursing College,
   Madurai.

APPENDIX – IV

DEMOGRAPHIC DATA

1. Age - a. 1-7 days

b. 8-14 days

c. 15-21 days

d. 22-28 days

2. Sex - a. Male

b. Female

3. Weight - a. < 2kg

b. 2-3 kg

c. > 3kg

4. Type of Invasive Procedure _____

a. Intravenous cannula insertion

b. Blood sampling

5. Duration of procedure _____

a. < 5 minutes

b. 5 – 10 minutes

APPENDIX – V

TOOL

Neonatal Facial Coding System (NFCS) for Pain Evaluation in Newborn Infants

Facial actions monitored:

(1) Brow lowering (lowering and drawing together of the brow can result in brow bulge)

(2) Eyes squeezed shut

(3) Deepening of the naso-labial furrow (fold)

(4) Open lips (any separation of the lips is an occurrence)

(5) Vertical mouth stretch

(6) Horizontal mouth stretch

(7) Taut tongue (cupping of the tongue)

(8) Chin quiver (high frequency vibration of the chin and lower jaw)

(9) Lip pursing (tightening the muscles around the lips to form an "oo")

In addition a tenth activity was monitored in preterm infants:

(10) Tongue protrusion (this is a "no pain" response in full term infants)

Action Points

Did not occur - 0

Occurred - 1

Interpretation:

- Minimum score: 0
- Maximum score for premature infants: 10
- Maximum score for full term infants: 9

APPENDIX – VI

INTERVENTION

Swaddling Technique:

Swaddling techniques are developmentally used non-pharmacological techniques by the nurses or other health personnel in order to reduce pain in newborn babies. It helps them to manage the painful situations easily and effectively. It is easy to done and less cost effective.

Aim:

Assess the effectiveness of the swaddling technique during the invasive procedures.

Cotton clothes (1 meter width & 1 meter length) is used for swaddling technique.

Procedure:

1. Preparatory Stage:

- Establish a therapeutic relationship by building rapport and gain the confidence of the newborn babies parents
- Explain about the procedure and swaddling technique to the parents and nurses.
- Clear the doubts of the parents
- Get oral consent from the parents
- Arrange cotton clothes in the procedure room before the procedure start.
- The area for the invasive procedure, the limb is free, without the swaddling.

2. Intervention Stage:

- Place the newborn baby in a comfortable position on the swaddling cloth. 2 cotton clothes were used (each 1 meter length & 1 meter width) one cloth for

cover the upper limbs and chest and abdomen. Another one to cover the lower limbs.

- ❖ According to the limb and the procedure have to leave the involved limbs freely without swaddling.
- ❖ The researcher has to swaddle the baby and watch for the behavioural changes by using neonatal facial coding system.
- ❖ The duration of the pricking time and 2 minutes after the procedure has to observe the scores.

Termination Phase:

- ❖ Assess the newborn babies reaction
- ❖ Make the newborn's and parents comfort.