

**A STUDY TO ASSESS THE EFFECTIVENESS OF BREAST FEEDING ON
PAIN EXPERIENCE OF INFANTS DURING INTRAVENOUS THERAPY
IN A SELECTED HOSPITAL AT COIMBATORE**

**M.Sc (NURSING) DEGREE EXAMINATION
BRANCH II-CHILD HEALTH NURSING**

**R.V.S COLLEGE OF NURSING
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“A Study to Assess the Effectiveness of Breastfeeding on Pain Experience of Infants during Intravenous Therapy in a Selected Hospital at Coimbatore”

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ABSTRACT

“A study to assess the effectiveness of breastfeeding on pain experience of infants during intravenous therapy in a Children Hospital at Coimbatore”

The aim of the study was to determine whether breastfeeding made any significant difference in the degree of pain experienced by infants while undergoing intravenous therapy such as intravenous canula insertion, intravenous medication administration and intravenous fluid administration.

An evaluative and comparative approach was considered. A quasi experimental post test only control group design was used. A convenient sample of 30 hospitalized infants (1 to 6 months) were selected from a Children Hospital at Coimbatore. The first 15 samples were assigned to experimental group and next 20 samples were assigned to control group.

During intravenous therapy (intravenous canula insertion, intravenous medication and intravenous fluid administration) pain was assessed by using FLACC scale (Face, Legs, Activity, Cry, Consol ability scale) is standardized infant pain scale. Five expert were validated the tool.

For the experimental group the intensity of pain was observed while mother was feeding the baby. Only once during intravenous canula insertion and thrice during intravenous medication administration and intravenous fluids administration procedure. From the control group the data was collected in the same manner without breastfeeding. The data was analyzed by using descriptive and inferential statistics.

The major findings were during intravenous canula insertion 20 babies did not experience pain, 66.67% had mild and 13.33 had moderate pain in experimental group. Where as in control group 6.67% infants had moderate pain and 93.33% had severe pain. During intravenous medication and intravenous fluid administration procedure 73.33% infants had no pain, 26.67% had mild pain in experimental group. Where as in control group 6.67% infants had moderate pain and 93.33% had severe pain. In the overall intravenous therapy 53.33% infants had no pain and 46.67% had mild pain in experimental group. All the 15 infants (100%) had severe pain in control group.

The mean pain score on the pain scale was 1.8 for the experimental group during intravenous canula insertion an against mean score was 9.4 for the control group with a statistical significant differences ($t = 15.80$, $df = 28$, $P < 0.01$).The mean pain score on the pain scale was 0.8 for the experimental group during intravenous medication administration an against mean score was 8.61 for the control group with a statistical significant differences ($t = 30$, $df = 28$, $P < 0.01$).The mean pain score on the pain scale was 0.77 for the experimental group during intravenous fluid administration an against mean score was 8.73 for the control group with a statistical significant differences ($t = 31.84$, $df = 28$, $P < 0.01$).

The mean pain score on the pain scale was 1.13 for the experimental group during overall intravenous therapy an against mean score was 8.92 for the control group with a statistical significant differences ($t = 48.69$, $df = 28$, $P < 0.01$).

The mean duration of crying was 2.07min for the experimental group during intravenous canula insertion an against mean score was 25.33 min for the control group with a statistical significant differences ($t = 15.30$, $df = 28$, $P < 0.01$). The mean duration of crying was 0.38 min for the experimental group during intravenous medication administration an against mean score was 13.11 min for the control group with a statistical significant differences ($t = 12.12$, $df = 28$, $P < 0.01$). The mean duration of crying was 0.38 min for the experimental group during intravenous medication administration an against mean score was 8.42 min for the control group with a statistical significant differences ($t = 03.64$, $df = 28$, $P < 0.01$).

The mean duration of crying was 3.29 min for the experimental group during overall intravenous therapy an against mean score was 47.27 min for the control group with a statistical significant differences ($t = 03.58$, $df = 28$, $P < 0.01$).

The study concluded that breastfeeding was effective in reducing pain perception of infants while carryout the intravenous therapy. Also breastfeeding has an influence in reducing the crying time during the intravenous therapy.

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INTRODUCTION

CHAPTER – I

INTRODUCTION

**“Kids are the blessings for today and
Promises for the day to come”**

BACKGROUND OF THE STUDY

The infant's body is the most super sensitive, delicate and susceptible form which can be easily harmed if not taken care of. The infant's health comprises of physical, mental and social well being. For keeping children healthy, apart from offering a healthy diet, sleep and exercise, regular checkups by some health care professionals are essential. This checkup is vital for the infant's development.

The triad problems, poverty, population explosion and environmental stress are great threat towards child's health in developing countries. Better nutrition, education, and family planning are the essential aspects to improve child's health. Educated parents who are associated with more knowledge on health, health practices and aware of health needs of children can give better health to their children.

Maternal health is a major determinant of child health. The healthy mother brings forth a healthy baby with better chance of survival. Child health depends on mother's age, parity, pre-pregnant health, antenatal care and spacing between two children.

Prenatal testing can provide valuable information about health of fetus. Blood tests and imaging studies are routine in most hospitals for pregnant mothers. Simple screen test and ultrasound testing does not pose any threat to the mother or to the unborn child. Prenatal diagnostic testing can be done through fetal ultrasound amniocentesis and chronic villous sampling. Pregnancy period is very important and defines development of the unborn child right from the initial embryo stage to the final birth. Diet, exercise, prenatal checkups are extremely important during

pregnancy. Necessary immunization and prenatal testing are undertaken in this period to ensure that both mother and child are in good health.

To prevent infant mortality and secure good health of the new born, neonatal health care becomes very important. The government's commitment to this goal is reflected in the constitution and the tenth five year plan as well as its rectification of the convention on the rights of the child. Transforming this commitment into action will ensure that each and every child reaches his or her full potential. UNICEF has given its support to the Government's Reproductive and Child Health and National Rural Health Programs emphasis the launch of a new Child Health Package, known as the Integrated Management of Newborn and Childhood illness.

When the baby is in the womb, baby is continuously fed and didn't know hunger. After birth babies need to be fed frequently. During the first few weeks, baby must be breast feed round the clock. Baby wants to nurse every 30 to 60 min, and stay in the breast for longer periods. This increase in nursing and signals the body to produce more milk as their babies enters a growth spurt.

A mother is truly the one who moulds her child from the moments of birth. The goodness of breast milk must be clearly understood, as a foundation for all round health. The World Breast Feeding Week (August 1 - August 7, 2006) will endeavor to celebrate the inherent wholesomeness of breast milk for infants, by disseminating vital information of it's benefits which is indeed a significant stepping stone for children.

A wealth of research has substantiated that breast milk is ideal nourishment for infants during the first year, as it is endowed with protective ingredients that guard against infection. Delicate and vulnerable to infections after birth, babies need to be nourished appropriately, which gives them immunity against prevailing illnesses.

Breast milk contains all the nutrients that a baby needs in the first few months for optimum growth and development, protects from allergy, physiological adaptation, emotional and physical bond between the mother and the baby. Advantages of breastfeeding in mother are, it suppresses ovulation, effectively

protecting against next pregnancy, lowers the risk of ovarian and breast cancer. The cost of human milk is negligible as compared to animal milk. The other benefits as reported through research studies in that breastfed babies have a higher IQ, less chances of developing hypertension, obesity, coronary artery disease and diabetes in their adult hood, and babies are protected against allergies. Breastfeeding shows the seeds for a life long bond between the mother and the child and all round health for the infant in the years to come.

Pain is one of the most common adverse stimuli experienced by children occurring as a result of injury, illness and necessary medical procedures. It is associated with increased anxiety, avoidance, somatic symptoms and increased parent distress. Despite the magnitude of effects that acute pain can have on a child, it is often inadequately assessed and treated. Numerous myths, insufficient knowledge among care givers and inadequate application of knowledge contribute to the lack of effective management for taking care of children with pain. Pain is an inherently subjective multi-factorial experience and should be assessed and treated as such. To accomplish this, health workers need to expand their knowledge, use appropriate assessment tools and techniques, anticipate painful experiences and intervene accordingly, use a multimodal approach to pain management, use a multidisciplinary approach when possible, involve families and advocate for the use of effective pain management in children.

Barriers to the treatment of pain in infants and children include the following, the myths that children, especially infants, do not feel the way adult do, or if they do there is no untoward consequence. Lack of assessment and reassessment for the presence of pain, misunderstanding of how to conceptualize and quantify a subjective experience, lack of knowledge of pain treatment, fears of adverse effects of analgesic medications including respiratory depression and addiction, the notion that addressing pain in children takes too much time and effort. Personal values and beliefs of health care professionals about the meaning and value of pain in the development of the child and about treatment of pain.

Health care professionals should anticipate predictable painful experiences and monitor the condition of patients accordingly. To treat pain adequately, ongoing

assessment of the presence and severity of pain and the child's response to treatment is essential, reliable, valid and clinically sensitive assessment tools are available for neonates through adolescents. When communication is difficult, personal assumption by health care professionals on the meaning of the behavior should be examined carefully. Pain expression reflects the physical and emotional state, coping style, family and cultural expectations can be misinterpreted by the health care professional.

Comprehensive pediatric care considers all aspects of distress and also should address the aspects in a compassionate, effective, timely, and multidimensional manner. Anxiety that are experienced by children and other symptoms that contribute to suffering need to be considered in the treatment plan for pain. Effective pain management thus generally involves an interdisciplinary therapeutic approach with a combination of pharmacological, cognitive, behavioural, psychological and physical treatment measures.

Non-Pharmacologic strategies are a key component in an overall effort to reduce the anxiety and pain associated with minor pediatric medical procedures such as venepuncture and immunization. Behavioural interventions typically involve teaching coping skills, including relaxation, or providing distraction. In general, behavioural approaches to children's pain management are grouped into those that occur prior to the medical procedure and those that are implemental at the time of the event. There are several potential mechanisms by which breast milk or breast feeding might provide an analgesic effect. Components of breast feeding that may be analgesic include presence of a comforting person (mother), physical sensation (skin to skin contact with comforting person), diversion of attention and sweetness of breast milk (preference of lactose or other ingredients present in the breast milk) and hind milk with increase fat content produce sedative effect.

Heine (1999) and Barrett (2000) proved that breast milk contains a higher concentration of tryptophan, a precursor of melatonin. Melatonin is shown to increase the concentration of beta endorphins and could possibly be one of the mechanisms for the nociceptive effects of breast milk. Among the analgesics studied for neonatal or infant's pain, breast feeding / breast milk is a natural, easily available, easy to use and

potentially risk free intervention. Only limited studies were conducted to see effectiveness of breast feeding for procedural pain.

Ricardo Carbajal (2003) conducted a study to investigate whether breast feeding is effective for pain relief during venepuncture in term neonate and compare any effect with that of oral glucose combined with a pacifier. The study concluded that breast feeding effectively reduces response to pain during minor invasive procedure in term neonates.

Osinaike (2007) conducted a study to determine the analgesic effects of breast feeding during venepuncture. The study concluded that breast feeding is analgesic effect in neonates during venepuncture and previous venepuncture and site of venepuncture do not seem to affect pain scores. Breastfeeding should be the first choice analgesic during painful procedures in neonates.

Allowing the child to be in a comfortable position during a procedure is an important component of an overall plan to decrease pain and distress. Children may be held by the parent, ideally in the parent's lap and facing the parent if possible. Children as young as 3 – 5 months who have some head and trunk control can be held in this manner.

Distraction has been shown to minimize children's fear, anxiety, and pain associated with acute painful medical procedures. Distraction is likely at least as effective as topical anesthesia in decreasing pain of immunization and venous access. Distraction stimuli vary and include movies, interactive toys, virtual reality goggles, music, bubble blowing and short stories. Distraction for pediatric pain management was equally effective across gender and ethnic groups and is most effective for children less than 7 years of age. It is important to select distraction stimuli that stimulate multiple senses (vision, hearing, touch) are age appropriate stimuli, and to involve the parents.

For infants, other interventions such as non-nutritive sucking, sucrose, pacifier, expressed breast milk, maternal holding and skin to skin contact have been shown to decrease the pain of minor procedure. Allowing breast feeding and skin to

skin contact during the procedure when possible is also effective for infants. Breast milk contains higher concentration of Tryptophan and lactose for the analgesic effects of breast milk. It is an intervention that could be easily adopted from the perspectives of health care providers and parents. No adverse effects of breastfeeding apart from rare transmission of micro organisms have been reported.

Raylene M. Phillips (2005) conducted a study to compare analgesic effects of breastfeeding Vs pacifier use in newborn infants undergoing blood collection via heel stick. Second to compare analgesic effects of pacifier use with maternal holding Vs non maternal holding. The study concluded that breastfeeding is more analgesic than non maternal holding with pacifier use, suggesting that maternal holding itself has as analgesic effect. Breastfeeding and maternal holding should be considered as pain control measures for the neonate during heel stick procedures.

Need for the study

The neonates and infants will have the immature immune system. Over crowding, poor socio economic status, poor feeding, family history of frequent illness, poor environmental sanitation may cause infection to the infants, and it leads to hospitalization.

If we see the hospital setting the invasive procedures such as intravenous insertion, intravenous medication and intravenous fluids administration, blood sampling etc. are carried out more commonly and causes pain during the insertion time. The infants can express their pain experience only through facial expression like crying, tightening of facial muscles etc.

Intravenous therapy is very common among infant's during hospitalization. In India the incidence shows that 3,870 of infants between 1 – 6 months who is undergoing intravenous insertion (0.32 sec), 2,540 infants getting intravenous medication (0.42 sec) and 2,270 infants getting intravenous fluids (0.47 sec) during hospitalization.

In Tamilnadu incidence shows that 478 infants between 1 – 6 months undergoing intravenous insertion (0.34 sec), 732 infants is getting intravenous medication (0.35 sec), 664 infants is getting intravenous fluids (0.4 sec) during hospitalization.

During the invasive procedure the infants are separated from the parents for various investigations and further it increases the pain. In some private hospitals, children are handled by untrained and unskilled health professionals who also increase the pain for the baby.

Parents should be included in the preparation of the procedure and during the procedure for their children. Parents often have high anxiety that deserves attention, and parent's anxiety is strongly predictive of child procedural anxiety. Parent's behavior during children's procedures accounts for a fair amount of children's coping and distress. Parents should be trained to avoid criticism or reassurance (i.e. "It's okay. It's only going to hurt for a second") as this might increase the child's distress.

The health worker should have adequate knowledge and skills to carryout the procedure. Intravenous therapy is very common among hospitalized infants. The health professional should have adequate training and skills in inserting intravenous canula, administration of intravenous medication and intravenous fluids. They should handle the child gently while carrying out the procedure. Pharmacological interventions are rarely used during routine procedures like intravenous insertion, intravenous medication and intravenous fluids administration, blood sampling etc.

Relief of pain is a basic need and right of all children. Reducing discomfort of routine procedure, such as venepuncture or an intravenous canula insertion, intravenous medication administration etc can contribute the perceived satisfaction. A countless number of infants experience painful procedure such as venupuncture. intravenous medication, intravenous fluids are routine fact of primary care or diagnostic procedure.

For infants the interventions such as sucrose, non- nutritive sucking, and skin – to – skin contact has been shown to decrease the pain of minor procedure. Breast milk and breast feeding has also shown to be analgesic.

In foreign setups many researches are conducted and they proved that breast feeding effectively reduces response to pain during minor invasive procedure in infants. In our setup lack of studies related to this topic and also there is a lack of awareness among health professionals regarding effects of breast feeding in pain reduction.

Based on the investigator's experience, observation and interest, intravenous canula insertion, is a very common procedure, immediately after hospitalization of the child. But during insertion of intravenous canula the parents and children undergo stress because of pain. To overcome this stress the investigator is interested to do study on the effects of breast feeding in pain reduction during intravenous therapy procedures.

STATEMENT OF THE PROBLEM

A Study to assess the Effectiveness of Breast Feeding on Pain Experience of Infants during Intravenous Therapy in a Selected Hospital at Coimbatore.

AIM OF THE STUDY

The main aim of the study is to determine whether breast feeding makes any significant difference in the degree of pain experienced by infants while undergoing intravenous therapy such as intravenous canula insertion, intravenous medication administration and intravenous fluid administration.

OBJECTIVES OF THE STUDY

- To assess and compare the degree of pain in the experimental and control group during intravenous therapy (intravenous canula insertion, intravenous medication administration and intravenous fluid administration)
- To assess and compare the duration of crying in the experimental and control group during intravenous therapy.

HYPOTHESIS

H₁ : There will be a significant difference between the degree of pain in experimental and control group during various aspects of intravenous procedure.

H₂ : There will be a significant difference between the degree of pain in experimental and control group during overall intravenous therapy.

H₃ : There will be a significant difference between the mean pain score in experimental and control group during various aspects of intravenous procedure.

H₄ : There will be a significant difference between the mean pain score in experimental and control group during intravenous therapy.

H₅ : There will be a significant difference between the mean duration of crying in experimental and control group during various aspects of intravenous procedure.

H₆ : There will be a significant difference between the mean duration of crying in experimental and control group during overall intravenous therapy.

OPERATIONAL DEFINITION

Effectiveness

The changes expected to occur in the pain experience of infants during intravenous therapy as a result of breast feeding intervention.

Breast Feeding

It is the method of feeding the baby with milk directly from the mother's breast.

Pain

Pain is an uncomfortable sensation experienced by the infants during intravenous therapy while inserting canula, giving medication and fluids. The pain is measured by using Face, Legs, Activity, Cry, Consol ability scale (FLACC) which is mainly used for infants.

Intravenous therapy

Intravenous therapy refers to a procedure carried out into the vein which includes insertion of canula into the vein, administration of medication and fluids directly into the vein.

ASSUMPTION

- The pain responses of infants are observable, recordable and reportable.
- The infants are able to perceive pain sensation
- The pain responses of infants will vary from one infant to the other
- Breast feeding reduces pain perception.

DELIMITATION

The study is delimited to

- Infants aged 1 – 6 months.
- Infants who are hospitalized at least for one day with intravenous therapy
- Infants who are on breast feeding
- One selected hospital.

LIMITATION

- If the sample size is small result can not be generalized.
- Observation of pain response is limited to 3 observations during intravenous therapy (intravenous canula insertion, intravenous medication and intravenous fluids administration).

SCOPE OF THE STUDY

Evaluation of pain in neonates and infants is difficult due to the subjective nature of pain and the inability of infants to verbally express pain. The measures used to describe pain in neonates include motor responses, facial expression, cry and changes in physiological parameters.

Breast feeding is one of the effective non pharmacological pain management for infants. Breastfeeding is very common and easy to introduce without much time for preparation.

Finding of this study will determine that the breastfeeding will reduce the pain experienced by infants while undergoing intravenous therapy. Hence the health professional can apply breastfeeding technique during various invasive procedures in order to reduce the pain experience and promote comfort among infants.

CONCEPTUAL FRAME WORK

The conceptual frame work provides a certain frame reference for clinical, education, and research, it gives direction to research for relevant question, phenomenon and points out solution to practical problem.

Conceptual framework refers to interrelated concepts or abstractions that are assembled together in some rational scheme by virtue of their relevance to a common theme (**Polit and Hunger – 1999**)

Theoretical model for this study was derived from Callista Roy's adaptation model (1991). According to Roy's adaptation model, the goal of nursing is to facilitate adaptation between the person and the environment through the management of stimuli. The unique focus of the model is the input of the focal, contextual and residual stimuli acting through the regulator and cognator coping mechanism to produce behavioural responses in the four interrelated adaptive modes – self concept, role function, inter dependence and physiological purposes for the present study, the structure of the model is modified and the study tool is fitted as an input to stimulate, child's response to stimuli and breast feeding is the intervention to experimental group, without the manipulation of control group. Expected outcome is measured,

only within the experimental group during intravenous therapy including intravenous canula insertion, intravenous medication and fluids administration.

In this study the intravenous therapy is considered as focal stimuli because the infant's pain is related responses were tested as a result of intravenous therapy. The influencing factors such as hospital environment, nurse uniform, previous experience of intravenous therapy and hospitalization and residual stimuli are age and gender.

As a response to focal, contextual and residual stimuli the responses exhibited out in physical and psychological aspects. The physical responses to pain are aggressive behavior, anger, crying, and shouting, severe facial grimace, tensed muscle and stiff joints. The psychological responses to pain are fear, frustration, depression, withdrawal and non cooperative attitude.

As a nursing support system breast feeding is given to decrease the perceptual effect of the intravenous therapy. The desirable behaviors, pain experience measured by physical and psychological aspects.

In the experimental group the infants have a relaxed facial expression, absence of cry, relaxed posture, sociable, cooperative, more sensory threshold to pain and comfortable. The response for a painful stimulus remains same in control group.

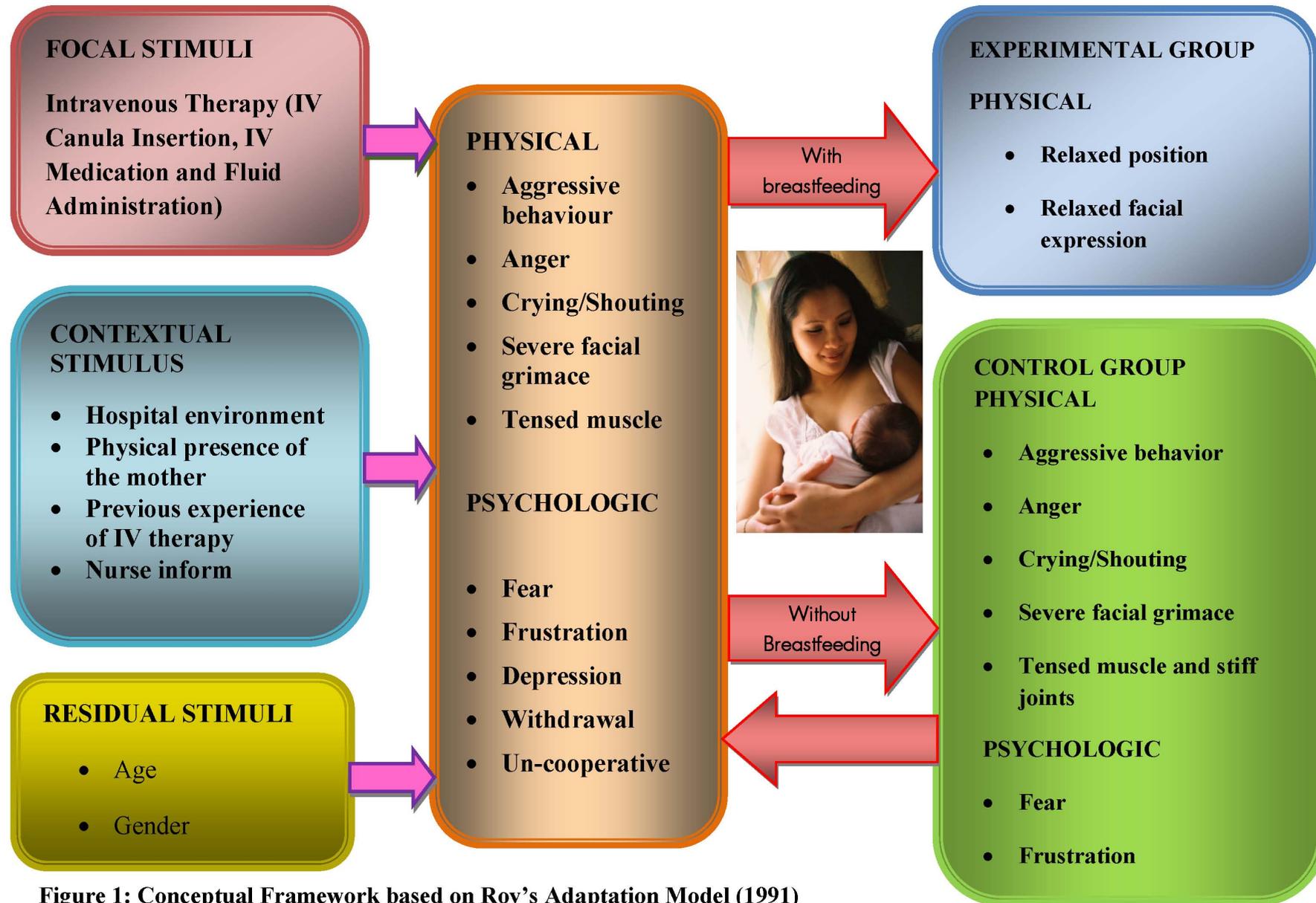


Figure 1: Conceptual Framework based on Roy's Adaptation Model (1991)

REVIEW OF LITERATURE

CHAPTER - II

REVIEW OF LITERATURE

A review of literature is an eventual aspect of scientific study. It involves the systematic identification, location, scrutiny and summary of the written materials that contain information on a research problem. It broadens the view of the investigator regarding the problem under investigation, helps in focusing on the issues especially concerning the study.

This chapter deals with the information collected in relation to the present study through published and unpublished materials which provided the foundation to carryout this study.

The literatures have been organized as follows:

1. Literature related to pain assessment during minor invasive procedure
2. Literature related to non-pharmacological pain relief intervention
3. Literature related to effect of breastfeeding on pain reduction

1. Literature related to pain assessment during minor invasive procedure

Harrison, Denise, Loughnan, Peter (2006) conducted a postal survey on pain assessment and procedural pain management practices in neonatal units. The objective of the study was to identify current pain assessment and procedural pain management practices in neonatal units. The survey comprised questions relating to pain assessment scores, pain reduction strategies for minor painful procedures and the use of articulated policies relating to procedural pain management. Participants were the nurse unit managers or their nominees of neonatal intensive care units. The result showed that surveys were sent to 181 eligible organizations, and 105 of these were returned (58%) six units (6%) used pain assessment scores on a regular basis, and 16 units (15%) had an articulated policy directing pain management practices during painful procedures. Non-nutritive sucking and various nursing comfort measures were

the pain reduction strategies most frequently used during minor painful procedures. 24 units (23%) used sucrose or other sweet – tasting solutions during procedures. Breast feeding during venupuncture, heel lance and intramuscular or subcutaneous injection was infrequently practiced and topical anesthetic agents were rarely used. They concluded that the majority of neonatal units have no articulated policy to guide pain management during painful procedures and do not regularly undertake pain assessments. Current evidence based strategies to reduce procedural pain in hospitalized infants are used infrequently.

Sinno H.P. Simons et al. (2003) conducted a prospective study of procedural pain and analgesia in neonates. The objective of the study was to assess the frequency of use of analgesics in invasive procedures in neonates and the associated pain. 151 neonates were selected and recorded all painful procedures including the number of attempts required, and analgesic therapy used during the first 14 days of NICU admission. The result showed that the highest exposure to painful procedures occurred during the first day of admission, many procedures were estimated to be painful. The primitive analgesic therapy was provided to fewer than 35% of neonates per study day, while 39.7% of the neonates did not receive any analgesic therapy in the NICU. The study concluded that the NICU procedures are painful, but only third of the neonates received appropriate analgesic therapy. Despite the accumulating evidence that neonatal procedural pain is harmful analgesic treatment for painful procedures is limited. Systematic approaches are required to reduce the occurrence of pain and to improve the analgesic treatment of repetitive pain in neonates.

Fran Lang Porter, Cynthia M. Wolf et al. (1996) conducted a survey regarding pain and pain management in newborn infants. The purpose of the study was to examine the beliefs and self – described behaviour of physicians and nurses regarding the management of procedural pain in newborn infants. A survey was distributed to 467 clinicians (nurses and physicians) working in eleven level II and four level III nurseries in a large metropolitan area. Respondents were asked to rate the painfulness of 12 common bedside nursery procedures and how often pharmacologic and non pharmacologic measures are currently used and should be used for those procedures. The results indicated that surveys were completed by 374 clinicians (80% response rate) physicians and nurses believe infants feel as much pain

as adults and that of the 12 listed procedures are moderately very painful. Neither pharmacologic nor comfort measures are believed to be used frequently, even for the most painful procedures. Physicians and nurses believe both pharmacologic and comfort measures should be used more frequently, but nurses believe comfort measures should be used more frequently than do physicians. The study concluded in despite their beliefs that infants experience significant procedure – related pain, clinicians believe pain management for infants remains below optimal levels. Barriers to more consistent and effective pain management need to be identified.

2. Literature related to non-pharmacological pain relief intervention

Castral F, Warnock F et al. (2009) conducted a study to evaluate the effects of skin-to-skin contact during heel prick in premature infants. Fifty nine stable preterm infants (born at least 30 weeks gestational age) who were undergoing routine heel lance were randomly assigned, 31 in experimental group and 28 in control group. In experimental group the infants were kept 15min of skin-to-skin contact before, during and following heel prick, and in control group infants underwent regular care. Throughout the heel lance procedure, all infants were assessed for change in facial action (NFCS), behavioral state, crying, and heart rate by using Neonatal Facial Activity Coding System (NFCS). The results showed that statistically significant differences were noted between the treatment and control groups during the puncture, heel squeeze and the post phases of heel prick. Infants who received skin-to-skin contact were more likely to show lower NFCS scores throughout the procedure. Both groups of infants cried and showed increased heart rate during puncture and heel squeeze although changes in these measures were less for the treated infants. They concluded that Skin-to-skin contact promoted reduction in behavioral measures and less physiological increase during procedure. It is recommended that skin-to-skin contact be used as a non-pharmacologic intervention to relieve acute pain in stable premature infants born 30 weeks gestational age or older.

Evelyn Cohen Reis, Erika Kraus Roth et al. (2003) conducted a study to assess the effectiveness, feasibility and parental acceptance of a simple combination pain reduction intervention for infants receiving multiple immunization injections. The infants receiving their second month immunizations, consisting of 4 injections

were selected as a sample. There were 116 infants participated. Subjects were randomly assigned to the intervention or control group for administration of 4 injections. The intervention group received sucrose and oral tactile stimulation and were held by their parents during immunization. The control group did not receive these interventions. The median first cry duration was 19.0 seconds for the intervention group compared with 57.5 seconds for the control group. Nurse rated ease of vaccine administration was equivalent for both treatment groups. They concluded that combining surge, oral tactile stimulation, and parental holding was associated with significantly reduced crying in infants receiving multiple immunization injections.

Larry Gray, Lisa watt and Elliott M. Blass (1999) conducted a prospective study on skin to skin contact is analgesic effect in healthy newborns. The objective of the study is to determine whether skin to skin contact between mothers and their newborns will reduce the pain experienced by the infants during heel lance. A total of 30 newborn infants were studied. The infants were assigned randomly to either being held by their mothers in whole body, skin to skin contact or to no intervention during a standard heel lance procedure. The result showed that crying and grimacing were reduced by 82% and 65%, respectively, during heel lance procedure among newborns in experimental group. Heart rate also was reduced substantially by contact. They concluded that skin to skin contact is remarkably potent intervention against the pain experienced during heel stick in newborns.

Upadhyah. A, Aggarwal. R, et al. (1998) conducted a study to assess the effectiveness of expressed breast milk (EBM) in reducing pain due to venupuncture in term neonates, as measured by behavioural and physiological observations. Eighty one full term neonates participated in the study. Two minutes before the venupuncture 40 babies received 5 ml of EBM, while 41 babies in control group received 5 ml of distilled water. The results showed that there was no difference in the baseline characteristics of the neonates in the two groups. The duration of crying was significantly shorter (95%) in babies fed EBM than in those fed distilled water. The modified Neonatal facial coding scores (NFCS) at 0, 1 and 3 was significantly lower in the EBM than in the distilled water group. The change in heart rate and oxygen saturation was significantly lower in the EBM group and returned to baseline values

sooner than in the Distilled water group. They concluded that feeding 5 ml of EBM before venupuncture is effective in reducing symptoms due to pain in term neonates.

3. Literature related to effect of breast feeding on pain reduction

D.Dilli, I.Kucuk, Y. Dallar (2009) conducted a study to investigate interventions that affect pain reduction during vaccination in infants and children attending a well-child unit. A consecutive sample of 243 children between age 0 and 48 months receiving their routine vaccinations was randomly assigned to one of the study groups. A total of 158 infants under age 6 months were randomly assigned to breastfeeding or no breastfeeding during immunization, and 85 children age 6 to 48 months were randomly assigned to receive 12% sucrose solution, Lidocaine- Prilocaine cream, or no intervention. All children were evaluated for crying time and pain score by a pediatrician using the Neonatal Infant Pain Scale (NIPS) for those under age 12 months and the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) for those over age 12 months. The results showed that breastfeeding in infants under age 6 months and use of sucrose or Lidocaine- Prilocaine in children age 6 to 48 months significantly reduced crying time and pain scores compared with control group. No difference in outcome was seen between the sucrose and Lidocaine- Prilocaine treatment groups. They concluded that breastfeeding may have an analgesic effect up to the age 6 months and that in older children, both sucrose and lidocaine-prilocaine reduce vaccination pain.

Aida Abdel Razek and Nagwa AZ El-Dein (2009) conducted a study to examine the effects of breastfeeding on pain relief during neonatal immunization injections. By using quasi-experimental design, this study was conducted in two maternal and child health centres in Jordan. Based on inclusion criteria were first year of age, breastfed and no concurrent illness, infants were divided into two groups. There were 60 infants in experimental group and 60 infants in control group. In the intervention group mothers were taken to a private room, seated and reclined on a comfortable chair with their infants awake in their arms, without cloth and with clean diapers. The mothers cradled their infants during breastfeeding to maintain full body skin-to-skin contact during immunization injections. In the control group infants were observed during routine immunization. Pain responses of infants during and after

immunization were assessed by using Facial Pain Rating Scale and Neonatal/Infant Pain Scale (NIPS), before, during and after the procedure. Infant's heart rates and duration of crying for both groups were calculated. Findings revealed that the crying time was shorter in intervention (breastfed) group than in the control group with a statistically significant difference in the duration of crying during and after immunization. They concluded that, breastfeeding and skin-to-skin contact significantly reduced crying in infants receiving immunization.

Leite, Adriana Moraes et.al (2009) conducted a study to investigate the effectiveness of breastfeeding in reducing pain in newborns undergoing blood collection for newborn screening. The study consisted of 60 full term newborns, 31 in the experimental group and 29 in the control group. The experimental group was breastfed 5 minutes before, during, and for 5 minutes after the blood collection procedure. Neonates in the control group were held in mothers' arms but not fed or given a soother. Heart rate was considered as an index of arousal. Sucking frequency was only evaluated in the experimental group. Compared with the control group, the experimental group had significantly lower, Neonatal Facial Activity Coding System and sleep-wake state scores and heart rates changes. In the experimental group sucking frequency was highest during the first 5 minutes of breastfeeding before the procedure. The different phases of the procedure were evaluated separately; the breastfeeding intervention covered the period from 5 minutes before the blood collection until the end of recovery; sleep-wake state was fully assessed and the sucking frequency in the experimental group was assessed during the procedure. The study concluded that breastfeeding was effective in reducing pain caused by blood collection for newborn screening.

Phillips R, Chantry C, Gallagher M, (2009) Analgesic effects of breastfeeding or pacifier use with maternal holding in term infants. The objective of the study was to compare analgesic effects of breastfeeding versus pacifier use in newborn infants undergoing blood collection via heel sticks, and to compare analgesic effects of pacifier use with maternal holding versus non maternal holding. A prospective, randomized, controlled trial design was used. There were 96 full term breastfeeding infants were selected. Infants randomized to 3 groups for analgesia breastfeeding, pacifier use while held by mothers, pacifier use while held by research

assistants (non mothers). Breastfeeding infants cried than infants using a pacifier while held by non mothers both during the procedure (69% Vs 100%, $P < .01$) and after the procedure (28% Vs 60%, $P = .03$). Those infants crying during the procedure cried for less time if held by their mothers either breastfeeding (33%, $P < .01$) or using a pacifier (45%, $P = .03$) than those using a pacifier while being held by non mothers (66%). They Concluded that Breastfeeding is more analgesic than pacifier use with non maternal holding. Maternal holding with either breastfeeding or pacifier use is more analgesic than non maternal holding with pacifier use, suggesting that maternal holding itself has an analgesic effect. Breastfeeding and maternal holding should be considered as pain control measures for the neonate during heel stick procedures.

Leite AM, Clin J Pain et al. (2009) conducted a study to investigate the effectiveness of breastfeeding in reducing pain in newborns undergoing blood collection for newborn screening. The sample of this randomized clinical trial study consisted of 60 full term newborns. 31 in the experimental group and 29 in the control group. The experimental group was breastfed 5 minutes before, during, and for 5 minutes after the blood collection procedure. Neonates in the control group were held in mothers arm but not fed or given a soother. The results showed that compared with the control group, the experimental group had significantly lower, neonatal facial activity coding system and sleep wake state scores and heart rates changes. In the experimental group sucking frequency was highest during the first 5 minutes of breastfeeding before the procedures. The different phases of the procedure were evaluated separately; the breastfeeding intervention covered the period from 5min before the blood collection until the end of recovery. Sleep wake state was fully assessed during the procedure. The conclusion of the study was that breastfeeding was effective in reducing pain caused by blood collection for newborn screening.

Elena Uga, Manuela Candriella (2008) conducted a study to evaluate the analgesic effect of breastfeeding during heel puncture in full term healthy newborn. They studied 200 healthy full term newborns ,100 in experimental group and 100 in control group. Pain assessment was evaluated by DAN scale (Douleur Aigue Nouveau ne scale). The findings revealed that the difference in score of pain according to the DAN scale was significant in the two groups of patients ($p = 0.000$); the medium score was 5.15 for controls and 2.65 for experimental group (newborns

sampled during breastfeeding). They concluded that breastfeeding is a potent analgesic intervention in newborn during heel puncture.

E. Efe, Z. Ozer (2007) conducted a study to examine the pain relieving effect of breastfeeding during immunization injections in healthy neonates. Sixty-six healthy infants returning to a clinic for their second, third, or fourth month immunization with intramuscular diphtheria, tetanus, and pertusis were randomized to be breastfed before, during, and after the injection or to be given the injection according to routine clinic procedure (no breastfeeding). To assess the pain responses of the neonates during and after immunization, they noted their heart rates, oxygen saturation levels, and length of crying. The crying time was shorter in the experimental (breastfeeding) group ($M \pm SD$ duration, 35.85 ± 40.11 seconds) than in the control group ($M \pm SD$ duration, 76.24 ± 49.61 seconds; $p = .001$). The heart rate and oxygen saturation levels were almost the same in both groups. They concluded that breastfeeding, maternal holding, and skin-to-skin contact significantly reduced crying in infants receiving an immunization injection or diphtheria, tetanus, and pertusis.

Modares Maryam, Vasegh Rahim Parvar S.F, et al. (2007) conducted a study to investigate the effect of breast feeding on pain control in newborns. A clinical trial design was used to evaluate analgesic effect of breast-feeding during injection of hepatitis B vaccine. 130 newborns had been referred for hepatitis B vaccination, were selected from Mirza Kochak Khan Hospital, Tehran, Iran. After describing the procedure testimonial was took from parents. Samples were divided randomly in tow groups. In experimental group, feeding was begun two minutes before injection and continued for 45 seconds. In the control group injection was made without breast feeding. Pain assessment was performed with Douler Aigue Nouveaune (DAN) scale. The results showed that in the experimental group 35.4% of newborns got 4 points and no one got more than 7 points according to DAN scale. In contrast the control group 32.4% got 8 points or more and no one got less than 3 points. The mean of pain severity in case group was 3.5 and in control group was 6.7 and it show significant difference according to Mann-Whitney U test ($p < 0.0001$). They concluded that breastfeeding can significantly reduce pain in newborns. Therefore they suggest this simple method generally for all painful procedure to prevent the development of possible permanent psychological effects in newborns.

Osinaike B.B, Oyedeji A.O. et al. (2007) conducted a study on effect of breast feeding during venupuncture in neonates. There were 38 neonates participated in the study. The study was cross over design where each neonate served as his/her own control. Median pain scores during venupuncture when neonates were being breastfed (BF) were compared with those when neonates were not being breastfed (NBF). The site of venupuncture and numbers of previous venupuncture were noted. Pain was assessed using Neonatal infant pain scale (NIPS). The results showed that the median pain score of the neonates when breastfed was 1.5 and 4 when not breastfed. The Kruskal Wallis H-Test did not show statistically significant differences between the breastfeeding and non breastfeeding groups when the number of previous punctures and site of venupuncture were considered. The study concluded that breastfeeding is analgesic in neonates during venupuncture and previous venupuncture and site of venupuncture do not seem to affect pain scores. Breastfeeding should be the first choice analgesic during painful procedures in neonates.

Shah PS, Aliwalas L, et al. (2007) conducted a study on breastfeeding or breast milk to alternative procedural pain in neonates. The objective of the study was to compare breastfeeding with control (Placebo, no treatment, sucrose, glucose, pacifiers or positioning) and compare breast milk with control for procedural pain in neonates. Systematic review and Meta analyses of randomized and quasi randomized trial of breast feeding or supplemental breast milk for procedural pain in neonates was carried out for the studies. The results showed that the breastfeeding group has significantly less increase in the heart rate, reduced proportion of crying time and reduced duration of crying compared to the swaddled or pacifier group. Premature infant pain profile scores were lower in the breastfeeding group when compared to the placebo and the groups positioned in mother's arms, but were not different compared to the no treatment and the glucose groups. Neonates in the supplemental breast milk group had a significantly less increase in the heart rate and Neonatal Facial Coding Score but no significant difference in the duration of crying time and oxygen saturation change compared to the placebo. They concluded that breast feeding or breast milk should be used to alleviate pain in neonates undergoing painful procedure compared to placebo, positioning, or no intervention. Administration of glucose sucrose had a similar effectiveness as breastfeeding for reducing pain.

Rayiene M. Phillips, Caroline J. Chantry, et al. (2005) conducted a study on analgesic effects of breast feeding or pacifier use with maternal holding in term infants. The objective of the study is to compare analgesic effects of breast feeding versus pacifier use in newborn infants undergoing blood collection via heel sticks. Second, to compare analgesic effects of pacifier use with maternal holding versus non maternal holding. There were 96 full term breast feeding infants scheduled for routine newborn screening blood test via heel stick (n=96) selected. The result showed that fewer breast feeding infants cried than infants using a pacifier while held by non mothers both during the procedure (69% Vs 100%) and after the procedure (28% Vs 60%). Those infants crying during the procedure cried for less time if held by their mothers either breast feeding (33%) or using a pacifier (45%) than those using a pacifier while being held by no mothers (66%). They concluded that breastfeeding is more analgesic than pacifier use with non maternal holding. Maternal holding with either breastfeeding or pacifier use is more analgesic than, non maternal holding with pacifier use, suggesting that maternal holding itself has an analgesic effect. Breast feeding and maternal holding should be considered as pain control measures for the neonate during heel stick procedures.

Grandin.M, Finnstrom O, Schollin J (2003) conducted a study to compare the pain reducing effect of oral glucose with that of being breastfed shortly before venupuncture in newborns, and also the pain score and crying time with parents assessment. There were 120 full term newborns undergoing venupuncture which were randomly assigned to one of four groups. Breastfed and 1 ml placebo, breastfed and 1 ml 30% glucose, fasting and 1 ml placebo, fasting and 1 ml 30% glucose. Pain during venupuncture was measured with the premature infant pain profile (PIPP). The result showed that the PIPP score was significantly lower in the infants receiving glucose than in those not given glucose. There was a similar difference between newborn received breastfed and 1 ml 30% glucose and breastfed and 1 ml placebo. The median crying time during the first 3 minutes in groups I, II, III and IV were 63, 18, 142 and 93, respectively they concluded that breastfeeding shortly before venupuncture has major impact on the pain score and crying time. The combination of oral glucose and breastfeeding showed lowest pain score and significantly shorter duration of crying.

Gray L, Miller LW, Phillipp BL, Blass EM (2002) conducted a study to determine whether breastfeeding is analgesic in newborn infants undergoing lance a routine, painful, hospital procedure. A random sample of 30 full term breastfed infants was selected. Infants in the intervention group were held and breastfed by their mothers during heel lance and blood collection procedures. Infants in the control group experienced the same blood test while receiving the standard hospital care of being swaddled in their bassinets. Results showed that crying and grimacing were reduced by 91% and 84% respectively, during the blood collection in experimental group. They concluded that breastfeeding is a potent analgesic intervention in newborns during a standard blood collection.

CONCLUSION

The review of literature enlightened the investigator to develop an insight into the breastfeeding and its effects and response of the infants to feeding during minor, invasive procedure. This review helped the investigator gained in depth knowledge of the research problem and guided her in designing the study. This review enabled the researcher to carryout the study in the effective manner.

METHODOLOGY

CHAPTER – III

METHODOLOGY

The methodology of research indicates the general pattern of organizing the procedure of gathering valid and reliable data for the problem under investigation **Kothari (1996)**.

This chapter explains the methodology adopted by the researcher to assess the effect of breastfeeding on the pain perception during intravenous line insertion, intravenous medication administration, intravenous fluid administration and overall intravenous therapy. It deals with the research design, variables under the study, setting of the study, population, sample size, sampling technique and criteria for selection of the sample, development of tool, pilot study, data collection procedure and statistical analysis.

RESEARCH APPROACH

The present study aimed at evaluating the effect of the breastfeeding during intravenous line insertion, intravenous medication administration, intravenous fluid administration and overall intravenous therapy among hospitalized infants. Hence an evaluative and comparative approach was considered to be most appropriate to accomplish the objectives of the study.

RESEARCH DESIGN

A research design selected for this study was quasi – experimental post test only design (Experimental and control group).

Intravenous therapy	Intravenous canula Insertion	Intravenous medication administration	Intravenous fluid administration
Experimental group	X – O ₁	X-O ₂ –X-O ₂ -X-O ₂	X-O ₃ -X-O ₃ -X-O ₃
Control group	O ₄	O ₅ -O ₅ -O ₅	O ₆ -O ₆ -O ₆

- O₁ → Pain assessment of the experimental group during intravenous canula insertion with breastfeeding.
- O₂ → Pain assessment of the experimental group during intravenous medication administration with breastfeeding.
- O₃ → Pain assessment of the experimental group during intravenous fluid administration with breastfeeding.
- O₄ → Pain assessment of the control group during intravenous canula insertion without breastfeeding.
- O₅ → Pain assessment of the control group during intravenous medication administration without breastfeeding.
- O₆ → Pain assessment of the control group during intravenous fluids administration without breastfeeding.
- X → Breast feeding.

For the experimental and control group pain experience was assessed on numerical pain scale during intravenous therapy. For the experimental group pain experience of infants during intravenous therapy with breastfeeding was observed and recorded on the observational check list by using FLACC scale. For the control group pain experience was observed and recorded during intravenous therapy without breastfeeding. Only one observation done during intravenous canula insertion and three observations done during intravenous medication administration and intravenous fluid administration in both experimental and control group.

VARIABLES

Independent Variable:

Breast feeding

Dependent Variable:

- Degree of pain during intravenous therapy
- Duration of crying during intravenous therapy

SETTING OF THE STUDY

The physical location and conditions in which data collection takes place in a study is known as setting.

The setting for this study is the general medical ward of the selected Children Hospital, at Coimbatore. It is a 110 bedded private hospital which is headed by a Chairman and Director. This hospital provides services for diseases, prevention and immunization of child health. It has very good facilities and referral services in Coimbatore. The inpatient beds are distributed in 3 floors. Intensive care unit, diarrhea ward situated in ground floor with a bed strength of 15-20 in each. The first floor has neonatal ward, general medical ward and sepsis ward with bed strength of 10-30 beds in each. The second and their floor has semi private and private rooms with bed strength of 10 to 20 in each. This floor has general surgery, medical and isolation cases.

The staff and patient ratio is 3:1. The play room is situated in the ground floor near outpatient department and second floor which have adequate space and play materials to engage the hospitalized children.

POPULATION

The population comprised of all the infants in the age group of one to six months who were hospitalized in the general ward of the selected Children hospital at Coimbatore at the time of the study.

Sample Size

The sample consisted of 30 infants, 15 infants in experimental group and 15 infants in control group.

Sampling Technique

Non probability convenient sampling technique was adopted for the selection of the samples. Those who fulfilled the including criteria were included in the sample. First 15 samples were assigned to experimental group and next 15 samples were assigned to control group.

Criteria for sample selection

The following were the criteria for selection of samples for the study.

Inclusion criteria

1. Infants with 1-6 months of age.
2. Infants who were stay in the hospital.
3. Infants who were getting intravenous therapy minimum of 2 days (intravenous line insertion, intravenous medication intravenous fluids).
4. Infants who were breastfed.
5. Infants having mother as a bystander.

Exclusion Criteria

1. Very sick infants
2. Infants who were receiving analgesics, sedative medication.

DESCRIPTION OF THE TOOL

The tool used for this study was a FLACC (Face, Legs, Activity, Cry, Consol ability) scale cum observation check list with 2 parts.

Part I: It consisted of demographic data which included age, sex and educational status of mother. (Appendix - VI, Page no: 64)

Part II: It comprised of an observation check list to record the pain experience of infants. The tool used for this study was a FLACC (Face, Legs, Activity, Cry, Consol ability) standardized scale cum observation check list. The tool consist of 5 categories namely Face, Legs, Activity, Cry, Consol Ability. Under each category 3 items are there. Three columns were given with the heading intravenous canula insertion, intravenous medication administration and intravenous fluid administration. Under each of these heading 3 columns were provided to record the child pain response during each procedure. The response of pain was observed during various aspects of intravenous procedure namely intravenous canula insertion, intravenous medication

administration and intravenous fluid administration. These pain responses of the infants were observed by investigators. (Appendix - VI, page no: 66)

Scoring

The minimum obtainable score for each category of pain response was zero and maximum score 2. The total of maximum pain score was 10.

Score Interpretation

Based on the score the pain response is graded as follows:

Score	Categories
0	No pain
1 – 3	Mild pain
4 – 6	Moderate pain
7 - 10	Severe pain

DEVELOPMENT OF THE TOOL

The tool was developed based on the objectives of the study, review of literature and discussion with experts.

Several pain intensity scale are available. In this study FLACC scale (Face, Legs, Activity, Cry, Consol ability scale) was used. It is a standardized infant pain scale (Appendix - VI, page no: 66).

Breastfeeding technique

Apart from developing the tool for data collection it was also necessary to plan a definite technique of administering the breastfeeding to maintain uniformity.

Steps of breastfeeding

- Explain the procedure to the mother

- Position: Make the mother sitting straight with back supported
- Keep the baby in mother's lap
- The body part (hand/leg) which is going to use for intravenous therapy should be away from the mother.
- Support the body part during the procedure.

VALIDITY OF THE TOOL

The content validity refers to the degree to which an instrument measures what it is intended to measure (**Polit and Hungler – 1999**).

In order to establish the content validity, the tool was given to 3 nursing experts and two medical experts. Both the nursing experts were masters in nursing with Child Health Nursing Specialization and with 5 – 6 years of experience, one working as the Head of the Child Health Nursing department and the other as Associate Professors in different Colleges of Nursing, Coimbatore. One of the medical experts was a consultant Pediatrician with 15 years of experience and holding charge of a private Children Hospital and the other one was Consultant Pediatrician of a Private Multi Specialty Hospital in Coimbatore.

The tool was accepted by the experts. In demographic data birth order was removed by their suggestion. The modifications and suggestions of the observation check list were incorporated in the final preparation by the investigator.

RELIABILITY

Reliability is the ability of an instrument to measure consistently and its aims to measure, the extent to which random variations influence consistency, stability and dependability of results.

Reliability of the observational check list was established by inter rater method. Six infants who fulfilled the sample selection criteria were selected. Three children were assigned to control group and other three were assigned to experimental group, the tool was given to another researcher and the observations were done by two investigators at the same time. The reliability was calculated by Karl Pearson's

coefficient correlation. The obtained value was 0.98. The tool appeared to have a high reliability.

PILOT STUDY

A pilot study generally involves a small sample of subjects drawn from the same population as those from which the study sample will be drawn. During the pilot study the instrument goes through pretest.

A formal permission was sought to conduct the pilot study. A pilot study was conducted in the selected Children Hospital at Coimbatore. Six infants who fulfilled the sample selection criteria were selected by convenient sampling method from the pediatric ward. Three children were assigned to control and the other three were assigned to experimental group.

After self introduction, the investigator explained the purpose of the study to the mothers individually and collected demographic data.

By using FLACC scale the pain experience of the infants during intravenous therapy (such as intravenous canula insertion, intravenous medication and intravenous fluid administration) was observed. Only one observation done during intravenous canula insertion and three observations done during intravenous medication and intravenous fluid administration. The pain experience during various aspects of intravenous therapy were observed and recorded simultaneously in the observation check list.

For the experimental group, child was breastfed during intravenous therapy. The intensity of pain was observed and recorded simultaneously.

The period of pilot study extended for 10 days. The tool was found adequate. During the pilot study the investigator found that the nurses found it difficult to carry out the procedure during breastfeeding. Considering the difficulty, the investigator decided to provide comfortable position for both mother and nurse to carry out the procedure. This was more convenient for the nurses and the mother.

DATA COLLECTION

The main study was conducted at the selected Children Hospital at Coimbatore from 01-07-2009 to 02-08-2009. A written permission and formal consent were obtained from the selected Children Hospital Chairman and Director for the data collection. The investigator approached and explained about the study to the Chief Medical Officer, Nursing Superintendent, staff and Public Relation Officer and obtained co-operation from them.

Samples those who fulfilled the inclusion criteria were selected by convenient sampling method from the general medical ward. First 15 samples were assigned to experimental group and next 15 samples were assigned to control group. After selecting the infant, the investigator gave a self introduction and explained the purpose of the study and obtained mother's willingness. Then the demographic data were collected from the mother and simultaneously recorded. By using FLACC scale the pain experience of the infants were observed during various aspects of intravenous therapy such as intravenous canula insertion, intravenous medication and intravenous fluid administration procedure. In experimental group child was asked to give breastfeeding during intravenous therapy. The intensity of pain was observed and recorded. For the control group the breastfeeding was not given to the infants during intravenous therapy. Only one child was observed at a time.

For each child only one observation done during Intravenous canula insertion and three observations done during Intravenous medication administration and intravenous fluid administration procedure.

The level of pain was assessed with numerical pain scale and recorded simultaneously in the observation check list. Data was collected from all the infants of the experimental and control group. Duration of crying also was noted during each procedure.

Total period of data collection was 30 days. The investigator was able to get 2 or 3 samples per day.

PLAN FOR DATA ANALYSIS

The data obtained would be analyzed in terms of the objectives of the study using descriptive and inferential statistics.

Descriptive Statistics

- Frequency and percentage distribution were used to analyze demographic variables, to assess the degree of pain during intravenous line insertion, intravenous medication administration, intravenous fluid administration and overall intravenous therapy.
- Mean and standard deviation were used to determine the difference in degree of pain during intravenous therapy.

Inferential statistics

- 't' test was used to determine the significance of the difference in degree of pain and duration of crying during intravenous therapy in experimental group and control group.

ANALYSIS AND INTERPRETATION

CHAPTER – IV

ANALYSIS AND INTERPRETATION OF DATA

“**James A Fain (2003)** defines data analysis as the systematic organization and synthesis of research data, and the testing of research hypotheses using those data”. Interpretation is the process of making sense of the results of a study and examining their implications.

This chapter deals with the analysis and interpretation of data collected from 30 infants, aged 1 month to 6 months admitted in hospital. The data have been analyzed and presented under the following headings.

1. Demographic characteristics of the experimental and control group

This analysis has been done to find out the frequency and percentage distribution of demographic variables such as age, sex and educational status of mothers in experimental and control group.

2. Assessment of pain in experimental and Control group during intravenous therapy

Pain has been analyzed in four degrees (No pain, mild pain, moderate pain, severe pain) for the experimental and control group during intravenous therapy in frequency and percentage. Comparison of degree of pain in experimental and control group has been done by mean score and its significance by statistical test during intravenous canula insertion, intravenous medication administration, intravenous fluids administration and overall intravenous therapy.

3. Association of mean duration of crying in experimental and control group during intravenous therapy

The analysis has been done to find out the association between the mean duration of crying during intravenous canula insertion, intravenous medication and intravenous fluids administration in experimental and control group, relationship between duration of crying in overall intravenous therapy and their level of significance.

1. DEMOGRAPHIC CHARACTERISTICS OF THE EXPERIMENTAL AND CONTROL GROUP

TABLE – I

FREQUENCY AND PERCENTAGE DISTRIBUTION OF EXPERIMENTAL AND CONTROL GROUP ACCORDING TO DEMOGRAPHIC VARIABLES

N = 30

S. No	Demographic Variables	Experimental group N=15		Control Group N= 15	
		Frequency	Percentage	Frequency	Percentage
1	Age in months				
	a 1-3	14	93.30	13	86.67
	b 4-6	1	06.70	2	13.33
2	Sex				
	a Male	9	60.00	6	40.00
	b Female	6	40.00	9	60.00
3	Educational Status of Mother				
	a Illiterate	0	00.00	1	06.67
	b Primary	3	20.00	1	06.67
	c Secondary	2	13.33	2	13.33
	d Higher Secondary	4	26.67	6	40.00
	e Graduate	6	40.00	5	33.33

Table I presents the demographic characteristics of the sample.

Age : Majority of the experimental (93.3%) and control (86.67%) were in the age group of 1-3 months .

Sex : Majority (60%) of the infants were male in experimental group and female in control group.

Educational Status: The level of education of mothers ranged from illiterate to graduation. six mothers (40%) in experimental group were graduates and 6 mothers in the control group (40%) had higher secondary education.

2. ASSESSMENT OF PAIN IN EXPERIMENTAL AND CONTROL GROUP DURING INTRAVENOUS THERAPY

TABLE – II

FREQUENCY AND PERCENTAGE DISTRIBUTION OF EXPERIMENTAL AND CONTROL GROUP IN FOUR DEGREES OF PAIN DURING INTRAVENOUS CANULA INSERTION

N = 30

S. No	Demographic Variables	Experimental group N=15		Control Group N= 15	
		Frequency	Percentage	Frequency	Percentage
1	No Pain (0)	3	20.00	-	-
2	Mild Pain (1-3)	10	66.67	-	-
3	Moderate Pain (4-6)	2	13.33	1	06.67
4	Severe Pain (7-10)	-	-	14	93.33

Table II presents the distribution of experimental and control group in four degrees of pain during intravenous canula insertion.

In experimental group 3 infants (20%) did not experience pain, 10 infants (66.67%) had mild pain and 2 infants (13.33%) had moderate pain during intravenous canula insertion. In the control group one infant (6.67%) had moderate pain and 14 infants (93.33%) had severe pain during the intravenous canula insertion procedure.

The table clearly indicates that when the infants are breastfed during intravenous canula insertion the degree of pain experienced is less than control group.

Figure 2 highlights the degree of pain in experimental and control group during intravenous canula insertion.

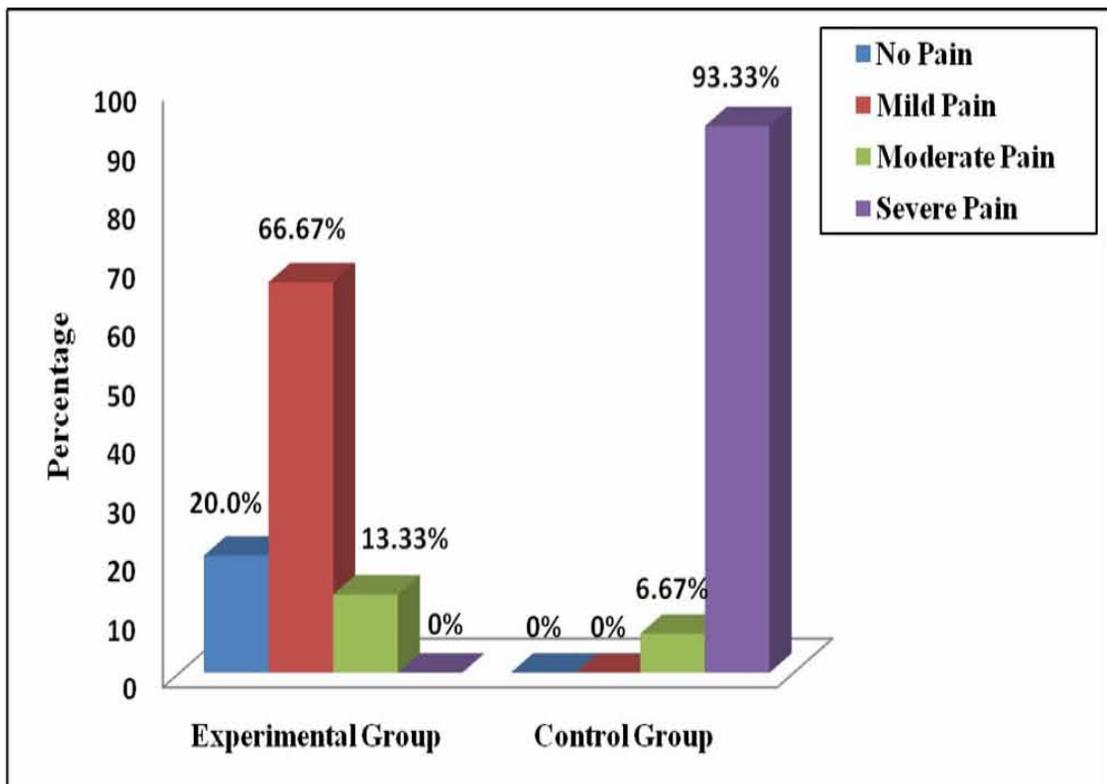


Fig 2: Degree of pain during intravenous canula insertion in experimental and control group in percentage

TABLE – III

**FREQUENCY AND PERCENTAGE DISTRIBUTION OF
EXPERIMENTAL AND CONTROL GROUP IN FOUR DEGREES OF
PAIN DURING INTRAVENOUS MEDICATION ADMINISTRATION**

N = 30

S. No	Degree of pain	Experimental group N=15		Control Group N= 15	
		Frequency	Percentage	Frequency	Percentage
1	No Pain (0)	11	73.33	-	-
2	Mild Pain (1-3)	4	26.67	-	-
3	Moderate Pain (4-6)	-	-	1	06.67
4	Severe Pain (7-10)	-	-	14	93.33

Table III presents the distribution of experimental and control group in four degrees of pain during intravenous medication administration.

In experimental group 11 infants (73.33%) did not experience pain, only 4 (26.67%) had mild pain while administrating intravenous medication.

In control group one infant (6.67%) had moderate pain and 14 infants (93.33%) experienced severe pain during the administration of medication.

It is quite evident that when infants are breastfed during intravenous medication administration, the degree of pain experienced is less.

Figure 3 highlights the degree of pain during administration of intravenous medication in experimental and control group.

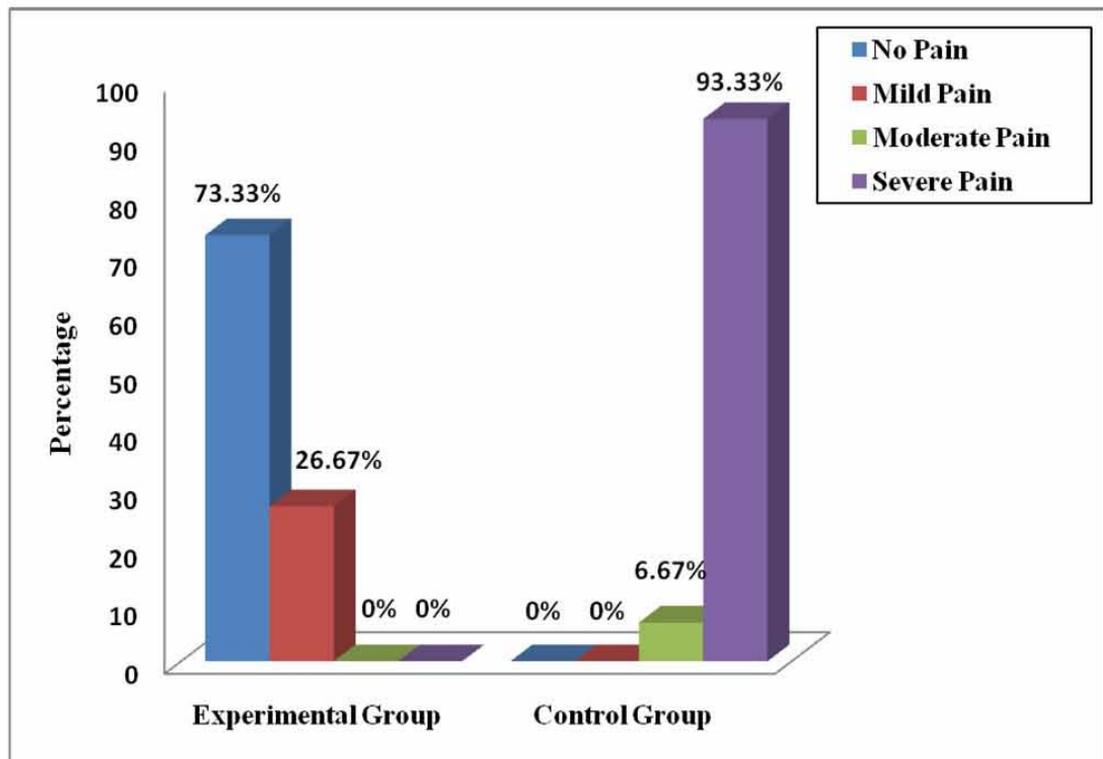


Fig 3: Degree of pain during administration of intravenous medication in the experimental and control group in percentage

TABLE – IV
FREQUENCY AND PERCENTAGE DISTRIBUTION OF
EXPERIMENTAL AND CONTROL GROUP IN FOUR DEGREES OF
PAIN WHILE STARTING INTRAVENOUS FLUIDS

N = 30

S. No	Degree of pain	Experimental group N=15		Control Group N= 15	
		Frequency	Percentage	Frequency	Percentage
1	No Pain (0)	11	73.33	-	-
2	Mild Pain (1-3)	4	26.67	-	-
3	Moderate Pain (4-6)	-	-	1	06.67
4	Severe Pain (7-10)	-	-	14	93.33

Table IV presents the distribution of experimental and control group in four degrees of pain while starting intravenous fluids.

In the experimental group 11 infants (73.33%) did not experience pain. Only 4 (26.67%) infants had mild pain while starting intravenous fluids.

In control group one infant (06.67%) had moderate pain and 14 infants (93.33%) experienced severe pain while starting intravenous fluids.

It is quiet evident that when infants are breastfed while starting intravenous fluids the degree of pain experienced is less.

Figure 4 highlights the degree of pain in the experimental and control group while starting intravenous fluids.

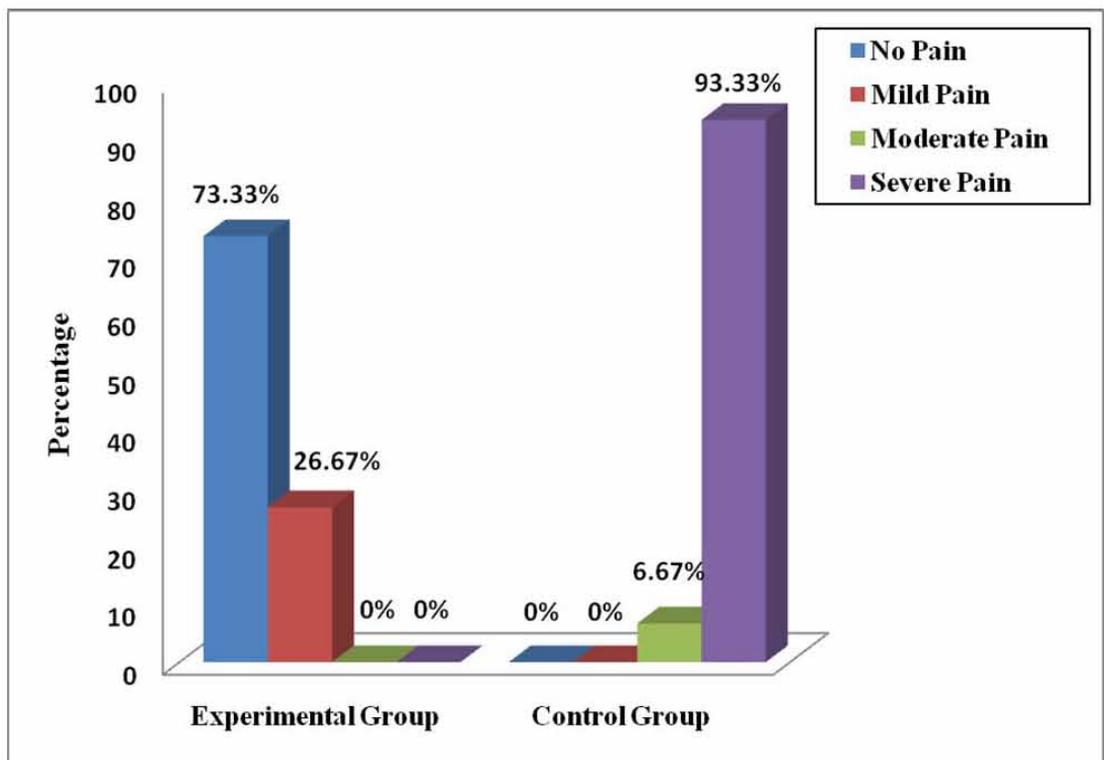


Fig 4: The degree of pain in the experimental and control group while starting intravenous fluids

TABLE – V
FREQUENCY AND PERCENTAGE DISTRIBUTION OF
EXPERIMENTAL AND CONTROL GROUP IN FOUR DEGREES OF
PAIN DURING OVERALL INTRAVENOUS THERAPY

N = 30

S. No	Degree of pain	Experimental group N=15		Control Group N= 15	
		Frequency	Percentage	Frequency	Percentage
1	No Pain (0)	8	53.33	-	-
2	Mild Pain (1-3)	7	46.67	-	-
3	Moderate Pain (4-6)	-	-	-	-
4	Severe Pain (7-10)	-	-	15	100.00

Table V presents the distribution of experimental and control group in four degrees of pain during overall intravenous therapy.

In the experimental group 8 infants (53.33%) did not experience pain, 7 infants (46.67%) had mild pain during overall intravenous therapy.

In control group all 15 infants (100%) had severe pain during overall intravenous therapy.

From the table it can be concluded that when infants were breastfed during intravenous therapy it appeared that the pain experience of the infant was less. They experienced only mild pain. When the infants were not breastfed during intravenous therapy, it was noted that they experienced severe pain.

Figure 5 highlights the overall degree of pain in experimental and control group during intravenous therapy.

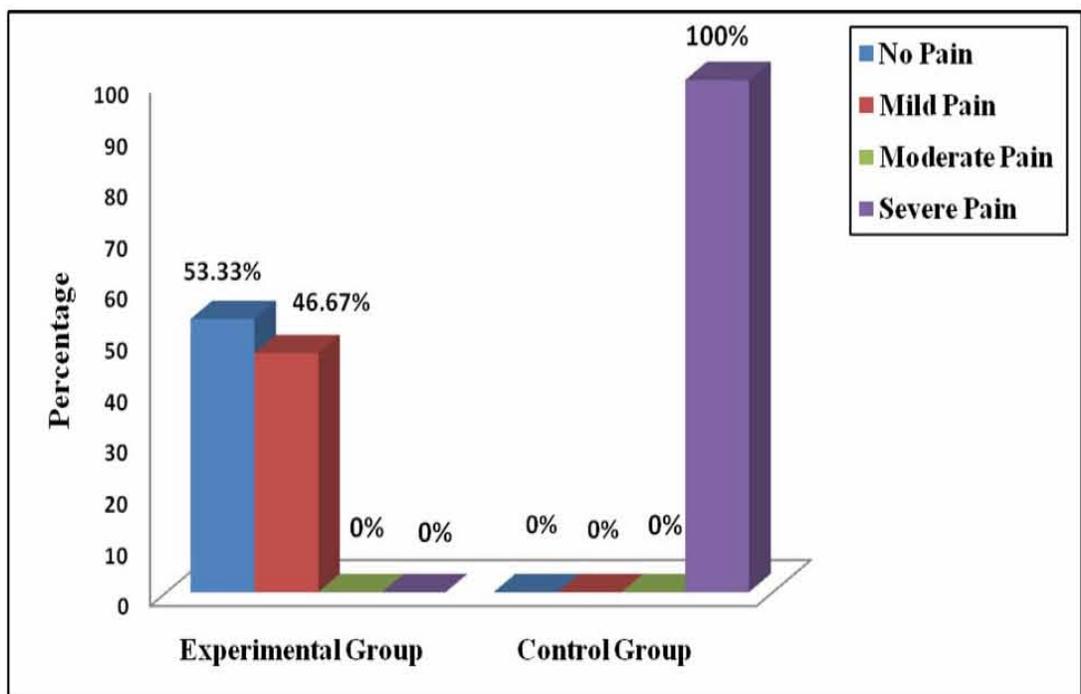


Fig 5: The overall degree of pain in experimental and control group during intravenous therapy

TABLE – VI

MEAN PAIN SCORE AND MEAN PAIN SCORE PERCENTAGE OF EXPERIMENTAL AND CONTROL GROUP DURING INTRAVENOUS PROCEDURE AND LEVEL OF SIGNIFICANCE

N = 30

S. No	Procedure	Max. Score	Experimental group N=15			Control Group N= 15			Mean Difference	Un Paired Value P < 0.01 df – 28
			Mean	SD	MS %	Mean	SD	MS%		
1	IV canula Insertion	10	1.8	1.56	18.00	9.40	1.08	94.00	7.60	15.80*
2	IV Medication	10	0.8	1.67	08.16	8.61	1.0	86.00	7.80	30.00*
3	IV Fluids	10	0.77	0.50	07.70	8.73	1.04	87.30	7.96	31.84*

*-Significant, **NS**-Not significant, **df** - degree of freedom, Table Value – 2.76

Table VI presents the mean pain score of experimental and control group during intravenous procedure

The mean pain score of experimental group while inserting canula, during intravenous medication and fluid administration is ranged from 0.77 to 1.8 on the numerical pain scale, which indicates a lesser degree of pain.

In the control group in all the three aspects of intravenous therapy the mean score ranged from 8.61 to 9.40 on the pain scale which indicates a severe degree of pain. Statistically there was a significant difference in all the three aspects of intravenous therapy. The experimental group experienced mild pain where as the control group experienced severe pain.

This table concludes that among the 3 procedures pain experienced during intravenous canula insertion is more than intravenous medication and intravenous fluid administration in both the group.

The H₁ stated that there will be a significant difference between the degree of pain in experimental and control group during various aspects of intravenous procedure. Statistically there is a significant difference between the mean score of experimental and control group in all the three aspects of intravenous procedures (intravenous canula insertion $t = 15.80$, $df = 28$, $P < 0.01$, intravenous medication administration $t = 30.00$, $df = 28$, $P < 0.01$ intravenous fluids administration $t = 31.84$, $df = 28$, $P < 0.01$). Therefore the hypothesis is accepted.

Figure 6 highlights the mean pain score in experimental and control group during various aspects of intravenous procedure.

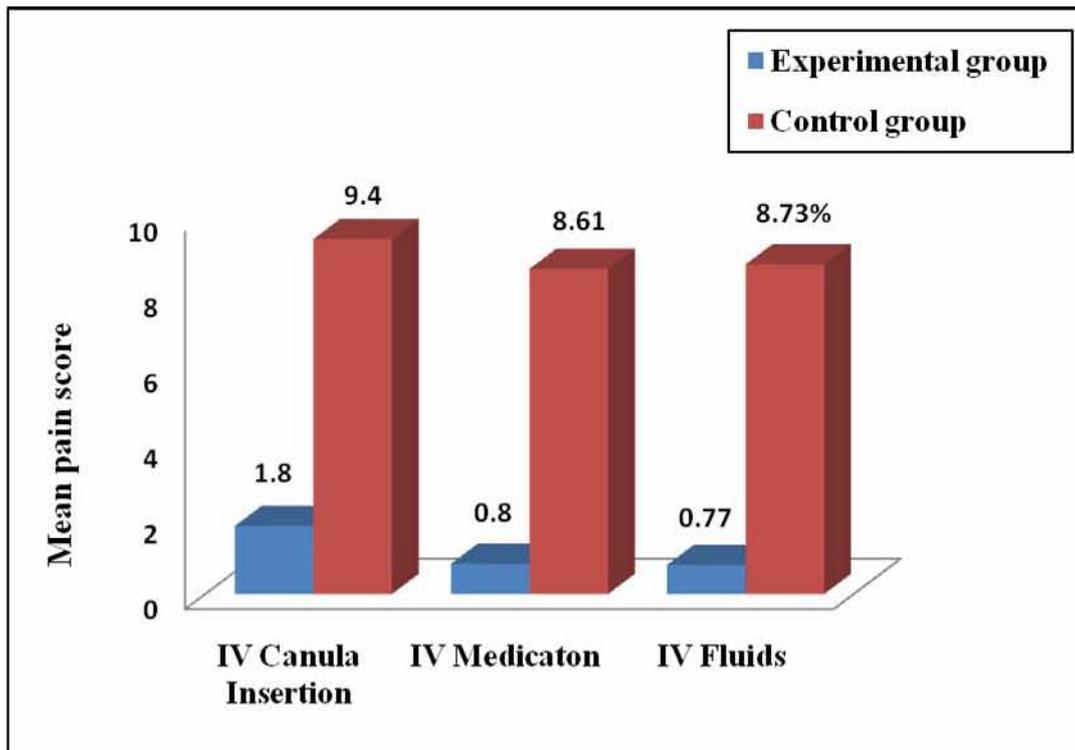


Fig 6: The mean pain score in experimental and control group during various aspects of intravenous procedure

TABLE – VII

MEAN PAIN SCORE AND MEAN PAIN SCORE PERCENTAGE OF EXPERIMENTAL AND CONTROL GROUP DURING OVERALL INTRAVENOUS THERAPY

N=30

S. No	PROCEDURE	Max Score	Experimental group N=15			Control Group N= 15			Mean Difference	Un paired Value P<0.01 df-28
			Mean	SD	MS%	Mean	SD	MS %		
1.	Over all IV therapy	10	1.13	0.69	11.30	8.92	0.3	89.20	7.79	48.69*

*-Significant, **NS**-Not significant, **df**- degree of freedom, Table Value – 2.76

Table VI presents the mean pain score of experimental and control group during overall intravenous therapy.

The mean pain score of experimental group during overall intravenous therapy was 1.13 on the numerical pain scale, which indicated a lesser degree of pain. In control group during overall intravenous therapy the mean pain score was 8.92 on the pain scale which indicated a severe degree of pain. Statistically there was a significant difference in overall intravenous therapy.

The table concludes that the experimental group experienced very mild pain where as control group experienced severe pain during overall intravenous therapy.

The H₂ stated that there will be a significant difference between the degree of pain in experimental and control group during overall intravenous therapy. Statistically there is a significant difference between the experimental and control group during intravenous therapy (over all intravenous therapy t test = 48.69, df - 8, p<0.01). Therefore the hypothesis is accepted.

Figure 7 highlights the mean pain score in experimental and control group during overall intravenous therapy.

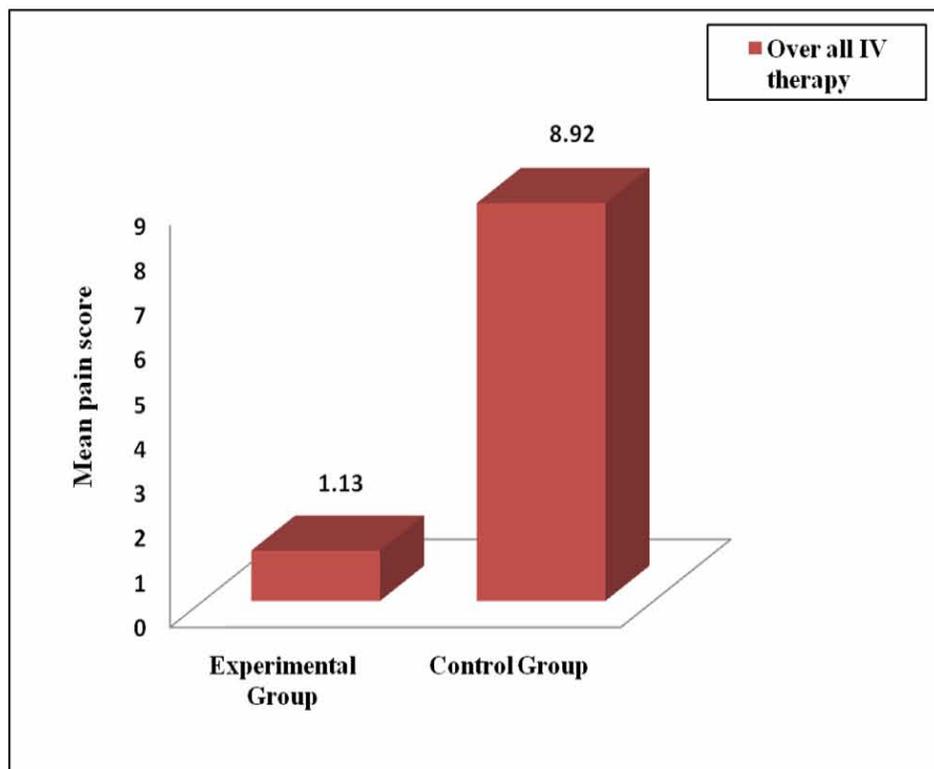


Fig 7: The mean pain score in experimental and control group during overall intravenous therapy

3. ASSOCIATION OF MEAN DURATION OF CRYING IN EXPERIMENTAL AND CONTROL GROUP DURING INTRAVENOUS THERAPY

TABLE – VIII

MEAN DURATION OF CRYING IN EXPERIMENTAL AND CONTROL GROUP IN DIFFERENT ASPECTS OF INTRAVENOUS PROCEDURE AND ITS LEVEL OF SIGNIFIGANCE

N=30

S. No	Procedure	Experimental group		Control Group		Unpaired 't' test P < 0.01 df - 28
		Mean Duration in min	SD	Mean duration in min	SD	
1	IV Canula insertion	2.07	2.32	25.33	05.33	15.30 *
2	IV Medication	0.38	0.41	13.11	04.00	12.12 *
3	IV fluids	0.38	0.50	8.42	02.90	03.64 *

Table VIII presents the mean duration of crying in experimental and control group in different aspects of intravenous therapy.

The mean duration of crying in experimental group while inserting canula, during intravenous medication administration and intravenous fluids administration ranged from 0.38 min to 2.07 minutes which indicated a lesser duration of crying. In control group in all the 3 aspects of intravenous therapy the mean duration of crying ranged from 8.42 minutes to 25.33 minutes which indicates a severe degree of pain. Statistically there was a significant difference in the duration of crying time in all three aspects of intravenous therapy.

The table concludes that the experimental group showed very less duration of crying where as the control group showed higher duration of crying.

The H₃ predicts that statistically there is a significant difference between the mean duration of crying in experimental and control group in all the three aspects of intravenous procedure (intravenous canula insertion t = 15.30, df – 28, P < 0.01,

intravenous medication administration $t = 12.12$, $df = 28$, $P < 0.01$, intravenous fluids administration $t = 03.64$, $df = 28$, $P < 0.01$) Therefore the hypothesis is accepted.

Figure 8 highlights the mean duration of crying during intravenous procedures in experimental and control group.

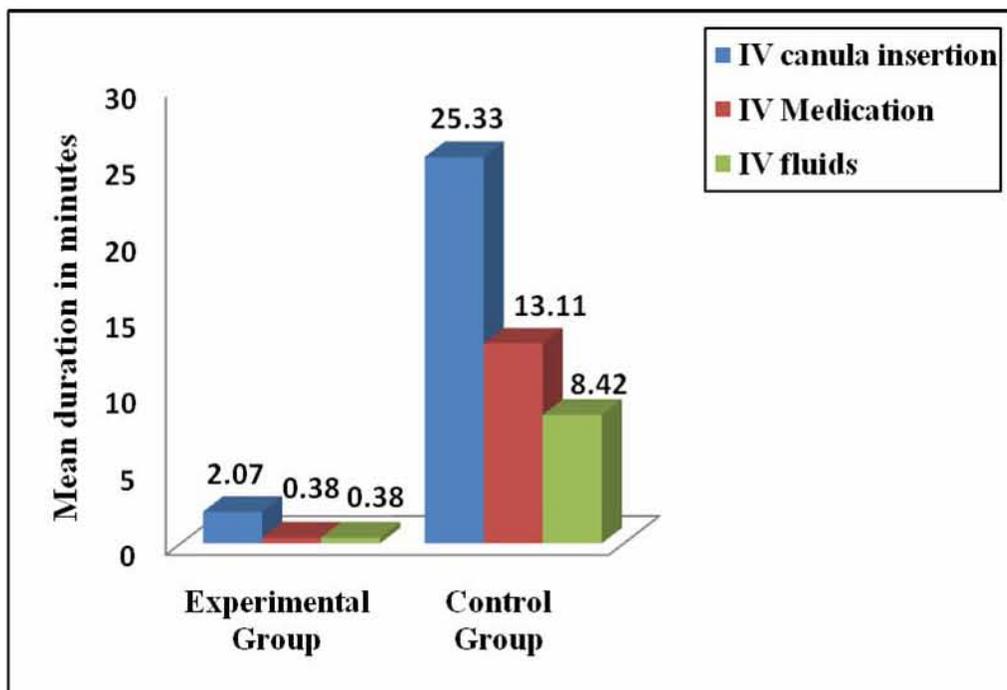


Fig 8: The mean duration of crying during various aspects of intravenous procedures in experimental and control group.

TABLE – IX

MEAN DURATION OF CRYING IN EXPERIMENTAL AND CONTROL GROUP IN OVERALL INTRAVENOUS THERAPY AND ITS LEVEL OF SIGNIFIGANCE

N=30

S. No	Procedure	Experimental group		Control Group		Unpaired 't' test P < 0.01 df - 28
		Mean Duration in min	SD	Mean Duration in min	SD	
1	Overall intravenous therapy	3.29	02.49	47.27	08.12	03.58*

Table IX presents the mean duration of crying in experimental and control group in overall intravenous therapy.

The mean duration of crying in experimental group during over all intravenous therapy is 3.29 minutes and in control group 47.27 minutes, which indicated the experimental group experienced very less duration of crying where as the control group experienced higher duration of crying. Statically there was a significant difference in the duration of crying time in overall intravenous therapy.

The table concluded that the experimental group showed a very less mean duration of crying where as the control group showed a high duration of crying during overall intravenous therapy.

The H₆ predicts that there will be a significant difference between the mean duration of crying in experimental group and control group during overall intravenous therapy. Statistically there is a significant difference between the experimental and

control group in overall intravenous therapy. (Intravenous therapy $t = 03.58$, $df = 28$, $p < 0.01$). Therefore the hypothesis is accepted.

Figure 9 highlights the mean duration of crying in experimental and control group during overall of intravenous therapy.

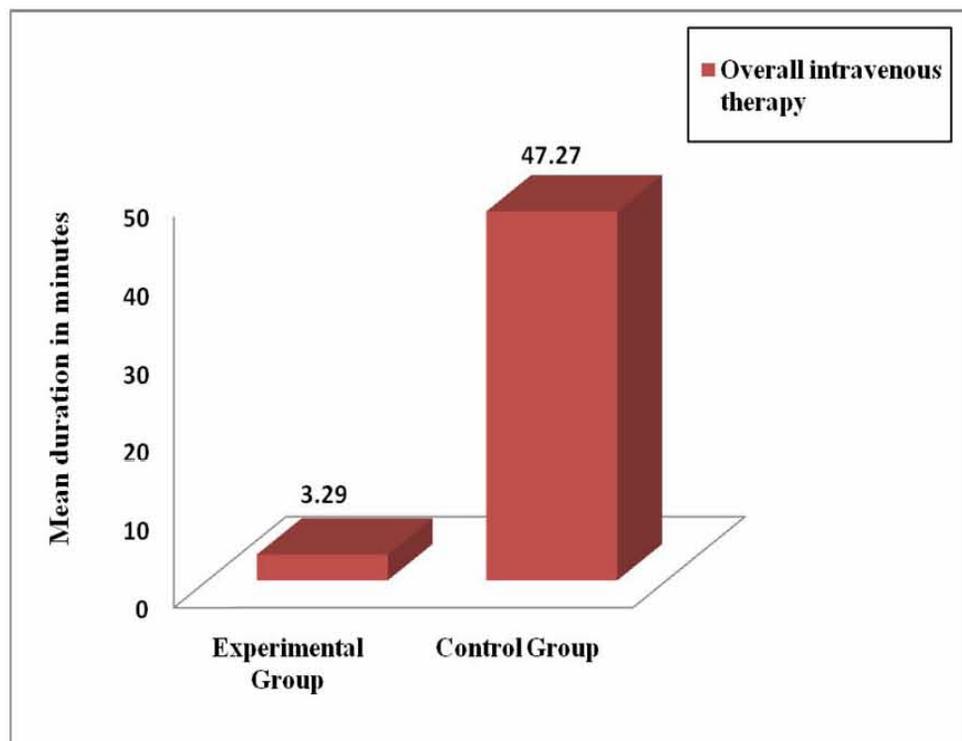


Fig 9: The mean duration of crying in experimental and control group during overall intravenous therapy

DISCUSSION

CHAPTER – V

DISCUSSION

The purpose of the present study was to evaluate the effectiveness of breastfeeding on pain experience of infants during intravenous therapy. This chapter presents the main finding and its discussion.

1. Demographic characteristics of the control and experimental group

Table I The sample in the control and experimental group equally proportionate to demographic variables. In both groups 86.67% and 93.30% of sample belonged to the age group of one to three months and others (6.70% and 13.33%) belonged to the age group of 4 to 6 months respectively. Sixty percentages of the infants were male and 40% were females in experimental group. Where as in control group 40% of infants were male and 60% were females. In the level of education of mothers 20%, 13.33%, 26.67% and 40% belonged to primary, secondary, higher secondary and graduate respectively in experimental group. Where as in control group 6.67% samples belonged to illiterate and primary education, and others (13.33%, 40% and 33.33%) belonged to secondary, higher secondary and graduate education respectively. There was no significant variation in the control and experimental group.

2. Assessment of pain in experimental and control group

Table II During intravenous canula insertion procedure in experimental group 20% of infants did not experience pain 66.67% infants had mild pain and 13.33% had moderate pain. In the control group 6.67% infants had moderate pain and 93.33% had severe pain.

The present study was supported by a study done by **Osinaike. B et al. (2007)** on effectiveness of breastfeeding during venepuncture in neonates, that concluded breastfeeding is analgesic in neonates during venepuncture and previous venepuncture

and site of venepuncture do not seem to affect pain score. Breastfeeding should be the first choice analgesic during painful procedures in neonates.

Table III and IV More than half of the infants (73.33%) did not experience pain, 26.67% had mild pain during intravenous medication and intravenous fluids administration in experimental group. In control group 6.67% had moderate pain and 93.33% infants had severe pain during intravenous medication and intravenous fluids administration procedure.

The present study was supported by a study done by **Raylene M. Phillips et al. (2005)** on effects of breastfeeding or pacifier with maternal holding in term infants during blood collection via heel sticks that concluded that maternal holding itself has an analgesic effect. Breastfeeding and maternal holding should be considered as pain control measures for the neonates during blood collection via heel stick procedure.

Table V The comparison of degree of pain experienced by the infants during over all intravenous therapy in the control and experimental group the findings revealed that 53.33% of infants did not experience pain and 46.67% had mild pain during overall intravenous therapy with breastfeeding in experimental group. Where as 100% of infants experienced severe pain without breastfeeding during intravenous therapy in control group.

The present study was supported by a study done by **Ricardi Carbajal, et al. (1996)** on analgesic effect of breastfeeding for pain relief during venepuncture in term neonates that concluded breastfeeding effectively reduces response to pain during minor invasive procedure in term neonates.

Table VI The comparison of mean pain score of experimental and control group during intravenous procedure such as intravenous canula insertion, intravenous medication and intravenous fluids administration. The findings revealed that all the three aspects of intravenous therapy the mean pain score ranged from 0.77 to 1.8 (mild pain) in experimental group and the mean pain score ranged from 8.61 to 9.40 (severe pain) in the control group. Statistically there was a significant difference

between the mean pain score of experimental and control group in all the three aspects of intravenous procedure (intravenous canula insertion $t = 15.80$, $df = 28$, $P < 0.01$, intravenous medication administration $t = 30$, $df = 28$, $P < 0.01$, intravenous fluid administration $t = 31.84$, $df = 28$, $P < 0.01$).

The present study was supported by a study done by **Gray L, Miller L. W (2002)** on analgesic effect of breastfeeding in new born infants undergoing blood collection procedure. That concluded breastfeeding is a potent analgesic intervention in newborns during a standard blood collection.

Table VII The comparison of mean pain score of experimental and control group during overall intravenous therapy finding revealed that the mean pain score of experimental group was 1.13 (mild pain) and 8.92 (severe pain) in control group during overall intravenous therapy. Statically there was a significant difference in mean pain score ($t = 48.69$, $df = 28$, $P < 0.01$) in experimental and control group during overall intravenous therapy.

The present study was supported by a study done by **Leite A.M, et al. (2009)** on effectiveness of breastfeeding for reducing pain in newborns undergoing blood collection that concluded, breastfeeding was effective in reducing pain caused by blood collection procedure for newborns.

3. Association of mean duration of crying in experimental and control group during intravenous therapy

Table VIII and IX The mean duration of crying in different aspects of intravenous therapy finding revealed that, the duration of crying in experimental group while inserting canula, intravenous medication and intravenous fluids administration ranged from 0.38 minutes to 2.07 minutes which indicated a lesser duration of crying. Where as in control group all three aspects of intravenous therapy the mean duration of crying ranged from 8.42 minutes to 25.33 minutes which indicated a severe degree of pain. In over all intravenous therapy the mean duration of crying was 3.29 minutes in experimental and 47.27 minutes in control group. Statistically there was a significant difference in mean duration of crying in

experimental and control group during various aspects of intravenous procedure and over all intravenous therapy (intravenous canula insertion $t = 15.30$, $df = 28$, $P < 0.01$, intravenous medication administration $t = 12.12$, $df = 28$, $P < 0.01$, intravenous fluid administration $t = 3.64$, $df = 28$, $P < 0.01$)

The present study was supported by a study done by **Grandin M. et al. (2003)** on breastfeeding and oral glucose additive effects on pain reduction and crying time in newborns that concluded, combination of oral glucose and breast feeding showed lowest pain score and significantly shorter duration of crying.

**SUMMARY,
FINDINGS,
CONCLUSION,
IMPLICATION AND
RECOMMENDATION**

CHAPTER – VI

SUMMARY OF THE FINDING, CONCLUSION, IMPLICATION AND RECOMMENDATION

INTRODUCTION

This chapter discuss about the summary of the study, findings, conclusion, implication, and recommendation.

SUMMARY OF THE STUDY

Pain is one of the most common adverse stimuli experienced by infants as a result of injury illness and necessary medical procedures

Intravenous therapy is a very common procedure during hospitalization. Breastfeeding helps in reduction of pain. The investigator conducted a study to assess the effectiveness of breastfeeding on pain experience of infants during intravenous therapy in a selected Hospital at Coimbatore.

The setting of the study was general medical ward of selected Children Hospital at Coimbatore. The sampling technique was non probability convenient sampling method with sample size of 30, out of which first 15 samples were assigned to experimental group and next 15 samples were assigned to control group. FLACC (Face, Legs, Activity, Cry, Consol ability scale) scale is a standardized tool used for assessment of pain. The research approach used in the study was a comparative approach and design was quasi experimental post test only control group design. A modified conceptual framework was formulated on Roy's adaptation model which provided a useful means in assessing the reduction of pain experience during intravenous therapy among hospitalized infants.

The tool in this study was an interview schedule cum observation check list FLACC scale(Face, Legs, Activity, Cry, Consol ability) standardized tool used for

pain assessment during intravenous therapy. Five experts validated the tool and reliability of tool was confirmed.

By using FLACC scale the pain experience of infants were observed during various aspects of intravenous therapy (intravenous canula insertion, intravenous medication and intravenous fluids administration). For the experimental group the intensity of pain was observed while mother was feeding the baby. Only once during intravenous canula insertion and thrice during intravenous medication administration and intravenous fluids administration procedure. From the control group the data was collected in the same manner without breastfeeding. The data was analyzed by using descriptive and inferential statistics.

SUMMARY OF THE FINDINGS

Demographic characteristics of the control and experimental group

In both groups 86.67% and 93.30% of sample belonged to the age group of one to three months and others (6.70% and 13.33%) belonged to the age group of 4 to 6 months respectively. 60% of the infants were male and 40% were females in experimental group. Where as in control group 40% of infants were male and 60% were females. In the level of education of mothers 6.67 % to 20 % were belongs to illiterate, primary and secondary education and others (26.67% to 40.00%) belonged to higher secondary education and graduate in both groups.

Assessment of pain in experimental and control group during intravenous therapy

During Intravenous canula insertion procedure 3 infants (20%) did not experience pain,10 infants (66.66%) had mild pain and 2 infants (13.33%) had moderate pain in experimental group. In control group one (6.67%) infant had moderate pain and 14 infants (93.33%) had severe pain during intravenous canula insertion procedure.

During intravenous medication and intravenous fluids administration procedure 11 infants (73.33%) did not experience pain and 4 infants (26.67%) had mild pain in experimental group. Where as in control group one infant (6.67%) had moderate pain and 14 infants (93.33%) had severe pain during intravenous medication and intravenous fluids administration procedure.

During overall intravenous therapy 8 (53.33 %) infants did not experience pain and 7 infants (46.67%) had mild pain in experimental group. Where as in control group all 15 infants (100 %) were experienced severe pain.

In the experimental group infants showed marked step-down of pain experience after breastfeeding intervention as compared to control group. It indicated that breastfeeding intervention was effective on reducing the pain experience among infants in the experimental group.

SIGNIFICANT FINDINGS

The mean pain score was ranged from 0.77 to 1.8 (mild pain) in experimental group and ranged from 8.6 to 9.4 (score pain) in the control group during three aspects of intravenous procedure namely intravenous canula insertion, intravenous medication and intravenous fluids administration. While comparing both the group statistically there was a significant difference in the mean pain score of all three aspects of intravenous procedure with breastfeeding in experimental group (intravenous canula insertion t test = 15.80, df- 28, $P < 0.01$, intravenous medication administration $t = 30.00$, df – 28, $P < 0.01$, intravenous fluid administration $t = 31.84$, df – 28, $P < 0.01$). Mean pain score of experimental group was 1.13 (mild pain) and in control group 8.92 (severe pain) during overall intravenous therapy. Statistically there was a significant difference in the mean pain score during overall intravenous therapy with breastfeeding in experimental group [$t = 48.60$. df – 28, $P < 0.01$].

Association of mean duration of crying in experimental and control group during intravenous therapy

The mean duration of crying in experimental group during three aspects of intravenous procedure [intravenous canula insertion, intravenous medication and intravenous fluids administration] ranged from 0.38 minutes to 2.07 minutes which indicated a lesser duration of crying. Where as in control group the mean duration of crying during all three aspects of intravenous procedure ranged from 8.42 minutes to 25.33 minutes which indicated severe degree of pain. Statistically there was a significant difference in the mean duration of crying in experimental group with breastfeeding intervention (intravenous canula insertion $t=15.30$, $df - 28$, $P < 0.01$ intravenous medication administration $t= 12.12$, $df - 28$, $P < 0.01$ intravenous fluids administration $t = 03.64$, $df - 28$, $P < 0.01$).

The mean duration of crying in experimental group, during overall intravenous therapy is 3.29 minutes and in control group 47.27 minutes which indicated that the experimental group experienced very less duration of crying time than the control group. Statistically there was a significant difference in the duration of crying during overall intravenous therapy with breastfeeding in experimental group($t=3.58$, $df - 28$, $P<0.01$).

CONCLUSION

The results of the study showed that there was a significant difference found in degree of pain and the mean duration of crying during intravenous therapy in the experimental group as compared to control group. This changed could be due to effect of breastfeeding intervention during Intravenous therapy. Hence the investigator concluded that breast feeding was very effective in reducing the pain and duration of crying during intravenous therapy.

IMPLICATION

The findings of this study recommend the implication on nursing practice, nursing education, nursing administration and nursing research.

NURSING PRACTICE

Nurses are the majority in any health care setting. They should be able to take up the role of giving importance to pain management among hospitalized infants during minor invasive procedures. Breast feeding is one of the non pharmacological method used in pain management. Nurse need to have a through knowledge about the breast feeding techniques and its importance, so that it can be incorporated in their practice. Nurse also should take up a key role in educating and reinforcing the parents, family members and care takers about the importance of breast feeding in child health and pain management. Nurse must practice the breast feeding intervention during minor painful procedures for pain management.

NURSING EDUCATION

Before nurses can utilize their practice, they need to have strong foundations in terms of education. Nurse's educators not only have a role for the student but also newly appointed staff. The education in the clinical areas could be in the form of

- Orientation program for new staff to imbibe the importance of breast feeding
- To create awareness regarding breast feeding techniques
- To create awareness regarding effects of breastfeeding in pain management
- Updating the knowledge of the staff by proper and relevant in-service education programs to emphasize breastfeeding intervention during minor painful procedures
- Ward teaching and nursing rounds for both students and staff in the hospital with regard to incorporation of breastfeeding in the care of the infants during painful procedures
- The nurse educators should take initiative to assess the need for teaching importance of breastfeeding in pain management to those needs of it.

NURSING ADMINISTRATION

- ❖ The administrators should formulate policies regarding practice of breastfeeding intervention during minor painful procedure by the pediatric nurses working with children who are hospitalized.
- ❖ The nursing service administrators themselves should practice breast feeding intervention during minor painful procedures for pain management in care of children and also influence their staff to practice the same.

RECOMMENDATIONS

The study recommends the following for further research

- Studies can be conducted to assess the knowledge of health team members or other health workers regarding effectiveness of breastfeeding in pain management.
- Similar studies can be conducted focusing on other painful procedures in different settings. Research design can also be made different to highlight the effectiveness of breastfeeding in the pain reduction.
- Similar studies can be conducted to assess the effectiveness of breastfeeding during repeated painful procedures among newborns.
- Comparative studies can be done on effectiveness of breastfeeding and other non pharmacological methods for intravenous pain management in different settings.
- Comparative studies can be done on effectiveness of breastfeeding before and after the painful procedures.
- A study can be replicated with a large sample in different settings.

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APPENDICES

APPENDIX – I

LETTER REQUESTING PERMISSION TO CONDUCT THE STUDY

To

The Honorable secretary
Masonic Children Hospital,
Race corse,
Coimbatore.

Respected Sir/Madam,

Sub:Letter requesting permission for conducting the study

----- is a post graduate Nursing student of our institution. She has selected the below mentioned topic for her research project to be submitted to The Tamilnadu Dr. M.G.R Medical University of Health Science, as a partial fulfillment of Master Nursing Degree.

“A study to assess the effectiveness of breastfeeding on pain experience during intravenous therapy procedure among infants in selected hospitals at Coimbatore”.

Regarding this project, she is in need of your esteemed help and co-operation as she is interested in conducting a study of her project, in your institution. I request you to kindly permit her to conduct the proposed study and provide her the necessary facilities.

The student will furnish further details of the study if required personally. Please do the needful and oblige.

Thanking you,

Place:

Yours faithfully,

Date:

PRINCIPAL

APPENDIX – II

REQUISITION LETTER FOR CONTENT VALIDITY

From,

II Year M.Sc (N) Student,
RVS College of Nursing
Sulur, Coimbatore.

To,

Through the Principal,

Respected Madam/ Sir

Sub: - Letter requesting opinion and suggestion of experts for establishing content validity of the tool.

I am a M.Sc (N) student in RVS College of Nursing, Sulur, Coimbatore in the speciality of Pediatric nursing. As per requirement for the partial fulfillment of this nursing degree under Tamil Nadu Dr.MGR Medical University. I have selected the following topic for dissertation.

“A study to assess the effectiveness of breastfeeding on pain experience during intravenous therapy among infants in selected hospitals at Coimbatore”.

I kindly request you to go through the research tool and validate against criteria given in the sheet.

Thanking you

Yours faithfully,

Enclosure:-

1. Objectives of the study
2. Hypothesis
3. Description of the tool
4. Research Tool
5. Criteria rating for validation
6. Content validation certificate

APPENDIX – III

CERTIFICATE OF CONTENT VALIDITY

This is to certify that the tool developed by _____ M.Sc (N) II year student, RVS College of Nursing, RVS Educational Trust, Sulur, Coimbatore, to collect data on the problem.

“A study to assess the effectiveness of breastfeeding on pain experience during intravenous therapy among infants in a selected hospital at Coimbatore”

Is validated by the undersigned and she can proceed with this tool to conduct the main study.

Name :

Address :

Signature :

Seal :

Date :

LIST OF EXPERTS

Medical expert

1. Dr. Krishnaswami M.B.B.S., DCH

Chief Medical Officer, Pediatrician

Masonic children hospital,

Race course road,

Coimbatore.

2. Dr. Ramamoorthy M.B.B.S., DCH

Medical officer, pediatrician

RVS Multi Specialty Hospital,

Coimbatore.

Nursing Expert

1. Mrs. Emerensia M.Sc (N)

Associate professor,

Child Health Nursing,

RVS College of Nursing

Coimbatore.

2. Mrs. N. Vijaya lakshmi M.Sc (N)

Professor

Child Health Nursing,

K.G. College of Nursing,

Coimbatore.

3. Mrs. Beryl Juliet M.Sc (N)

Associate professor,

Child Health Nursing

SRIPMS, College of Nursing,

Coimbatore.

4. Mrs. Suganthi M.Sc (N)

Associate Professor,

Child Health Nursing,

SRIPMS, College of Nursing,

Coimbatore.

APPENDIX – IV

CRITERIA FOR VALIDATION

Criteria rating scale for validating the observation schedule which measuring the pain experience during intravenous therapy

Kindly go through this tool please give your views regarding clarity, relevance, adequacy and remarks.

Items	Clarity	Relevance	Adequacy	Remarks
PART- I Demographic profile				
1				
2				
3				
4				

PART – II PAIN ASSESSMENT BY FLACC SCALE				
Items	Clarity	Relevance	Adequacy	Remarks
During IV canula insertion				
During IV medication				
While starting IV fluids				

APPENDIX – V

REQUISITION LETTER FOR CO – GUIDE

From

M.Sc Nursing II year,
RVS College of Nursing,
RVS Institute of Health Sciences,
Sulur, Coimbatore.

To

Dr. Krishanaswamy, M.B.B.S, DCH
Chief Medical officer,
Masonic children Hospital,
Race Course Road,
Coimbatore.

Through the Principal,

SUB: Request for Co-Guide

I wish to state that I am II year M.Sc nursing Student of RVS College of Nursing have selected the below mentioned topic for dissertation as a partial fulfillment for the Master of Nursing degree to The Tamilnadu Dr. MGR Medical University.

“A study to assess the effectiveness of breastfeeding on pain experience of infants during Intravenous therapy in a selected Hospital at Coimbatore”

Regarding this I am in need of your valuable help and co-operation by providing services to be a co-Guide for my study.

I humbly request your highness to consider the same do the needful.

Thanking you

Yours Sincerely

APPENDIX – VI

RESEARCH TOOL

INTRODUCTION

Pain is one of the most common adverse stimuli experienced by children occurring as a result of injury, illness and necessary medical procedures. There are many non pharmacological methods available for reducing the pain. Breast feeding is most effective in step–down the pain experience among the infants during intravenous therapy.

PURPOSE

The purpose of this study is to find out the effectiveness of breastfeeding in reducing the pain experience during intravenous therapy among infants.

INSTRUCTION

- Kindly give the information which is asked
- Your response will be kept confidential

PART –I

DEMOGRAPHIC PROFILE

1. Age

a) 0 – 6 months

b) 7 – 12 months

2. Sex

a) Male

b) Female

3. Education of mother

a) Illiterate

b) Primary

c) Secondary

d) Higher secondary

e) Graduate

PART – II

FACE, LEGS, ACTIVITY, CRY, CONSOLABILITY SCALE (FLACC)

For younger children and older children who are developmentally preverbal communicators, an assessment of behavior in response to potentially painful procedures or stimuli is in order. The FLACC scale offers one technique.

Each value receiving a score of 0, 1, 2 based on the response or assessment.

SCORE

0-No pain, 10-High level pain

0 – No pain

1 – 3 Mild pain

4 – 6 Moderate pain

7 – 10 Severe pain

FLACC SCALE

OBSERVATION SCHEDULE

S. No	CATEGORY	During IV canula insertion			During IV medication			Starting IV fluids		
		Observation			Observation			Observation		
		1	2	3	1	2	3	1	2	3
Face										
0	No particular expression smile									
1	Grimace, disinterested, tight facial muscles, furrowed brow, chin, jaw									
2	Frequent to constant quivering chin, clenched jaw									
Legs										
0	Normal position /Relaxed									
1	Uneasy, restless, tense									
2	Kicking, or legs drawn up									
Activity										
0	Lying quietly, normal position, moves easily									
1	Squirming , shifting back and forth, tense									
2	Arched, rigid or jerking									
Cry										
0	No cry (awake/ sleep)									
1	Moans/ whimpers, occasional complaints									
2	Crying steadily, screams or sobs, frequent complaints									
Consol ability										
0	Content, relaxed									
1	Reassessed by occasional touching, hugging, distractible									
2	Difficult or comfort									
Duration of crying										
Total Score										