



“A Study To Access The Effectiveness Of 24% Of Oralsucrose Administration In Reduction Of Pain Response Among Neonates During Iv Cannulation In Selected Hospital Bangalore”

MISS. URJITA MOHANTY¹

MRS. REMYA²

MISS SWAYAMPRAVA MISHRA³

1.P.G. SCHOLAR (DEPARTMENT OF MASTER OF SCIENCE IN PEDIATRIC NURSING), SARVODAYA COLLEGE OF NURSING, DASARAHALLI, BANGALORE.

2.HOD AND PROFESSOR (DEPARTMENT OF PEDIATRIC NURSING), SARVODAYA COLLEGE OF NURSING, DASARAHALLI, BANGALORE.

3.LECTURER (DEPARTMENT OF OBSTETRICS & GYNECOLOGICAL NURSING), SARVODAYA COLLEGE OF NURSING, DASARAHALLI, BANGALORE.

ABSTRACT

A study was conducted assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore.

The objectives of the study were,

1. To determine the extent of pain perceived by the control and experimental group of neonates during IV cannulation.
2. To determine the effectiveness of 24% oral sucrose solution upon pain perception of experimental group of neonates during IV cannulation.
3. To determine the association between selected demographic variables and pain perception of control and experimental group of neonates during IV cannulation

The hypothesis are :-

- H1: There will be significant difference in level of pain among neonates in experimental and control group after oral sucrose administration during IV cannulation at $P < 0.05$ level.
- H2: There will be significant association between the level of pain during IV cannulation among neonates in control group with their selected demographic variables at $p < 0.05$ level.

The research design was adopted for this study is a Quasi –experimental design. Post test only design with control group was chosen for this study. Purposive sampling technique was used for this study. Subjects were selected based upon the inclusion and exclusion criteria. 60 subjects were selected for the study. Purposively 30 Subjects were assigned to experimental group and 30 subjects were assigned to control group.

The investigator adopted CallistaRoy's adaptation theory (1999) as the conceptual framework for the study. Neonatal Infant Pain Scale (NIPS) developed by Lawrence 1993 was used for data collection. After data collection, data was organized, tabulated, summarized and analyzed. The study findings were discussed in this chapter with reference to the objectives of the study

Descriptive and inferential statistics were used to analyze the data. Analysis of demographic variables was done in terms of frequency and percentage distribution.

The frequency and percentage distribution of demographic variables in the experimental group majority (20)66.7% were age between birth -7 days, 60% in female, (23) 76.67% weight of the baby 2.501 -3.000kg, 19 (63.33%) babies are LSCS delivery, 26(86.67%) were no previous IV cannulation, 56

whereas in the control group, majority 21 (70%) were age between birth-7 days, 17(56.67%) in female, 20(66.67%) in the weight of the baby 2.251 – 2.500kg , 20 (66.67%) babies are LSCS delivery , 28(93.33%) were no previous experience of IV cannulation.

Comparison of post test level of pain between the experimental and the control groups was analysed by „t“ test .Which is an inferential statistical analysis. Association of post test level of pain in the control group with demographic variables was analysed by using chi-square test. The findings concluded that in the experimental group majority 16(53.67%) had mild pain and in control group majority 16(53.33%) had severe pain.

In the experimental group, the post test level of mean pain score was 2.3 with standard deviation 0.823 and in the control group the post test mean score was 4.43 with standard deviation 1.057. The mean difference score was ± 2.13 . The calculated „t“ value of 8.247 was statistically significant at $P < 0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

The study findings had revealed that in post test in the control group there was a no significant association with the level of pain and demographic variables .

Hence the 24% of oral sucrose administration was responded in reducing the IV cannulation pain

Key words: Effectiveness, NIPS module, IV

LIST OF ABBREVIATIONS USED

IV	INTRA VENOUS
NIPS	Neonatal Infant pain scale
FIG	Figure
SD	Standard Deviation
Df	Degree of freedom
NS	Not significant
χ^2	Chi-square

CHAPTER-I**INTRODUCTION**

Every neonate has his or her own perception of pain. A neurological response to tissue injury, pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.

Babies endure many minor but painful procedures during their stay in the NICU. These procedures are necessary for monitoring and managing the care needs of these babies. Newborns routinely experience pain from invasive procedures such as blood sampling and many diagnostic or therapeutic procedures. Neonates experience pain from the same intervention or clinical conditions as older children and adults. Available physiological studies suggest that newborn infants are more sensitive to pain in comparison to older children and adults.⁰¹

Verbalization of nociceptive sensation is the gold standard for assessment of pain. However, just because an individual cannot communicate verbally, it does not mean that he or she is not in pain, or is not in need of appropriate pain relieving interventions. Because neonates are incapable of verbally self-reporting pain others indicators such as physiologic, hormonal/biochemical, and behavioral response to painful stimuli can be used as forms of self-reporting to infer neonates are experiencing pain. Some of these physiologic indicators include increase in heart and respiratory rate and blood pressure and decrease in oxygen saturation.⁰²

The hormonal and biochemical indicators consist of increased stress hormones including catecholamine, corticosteroids, growth hormones, glucagon, epinephrine and non-epinephrine. Lastly, the behavioral indicators crying, body movement, and facial expressions, for examples, brow bulge, eye squeeze and nasolabial furrow.⁰³

Neonates, both term and preterm, experience pain and have the right to effective and safe pain relief. Compared with the adult, the neonates at birth, whether term or preterm, displays a hypersensitivity to sensory stimuli. Although there is mounting evidence that babies feel pain, it is often not managed adequately.⁰⁴

Inadequate pain management in neonates can lead to long term adverse consequences. Some of which include development of low threshold for pain and heightened response to painful stimuli.

The deleterious effects of pain in infants are fairly well described. They include physiologic and metabolic effects such as vital signs changes, alteration in cerebral blood flow and outpouring of stress hormones as well as behavioral changes, memory of the event and potentially negative long term effects on pain stimuli processing and response medical settings can be prevented or substantially reduced . Research has shown that failure to reduce pain in preterm infants may lead to permanent changes in brain processing and maladaptive behavior later.⁰⁵

Therefore, it is important that neonatal pain is managed adequately through either pharmacological or non pharmacological methods. Despite the advance in pain assessment and management, prevention

and treatment of unnecessary pain attributable to anticipated noxious stimuli remain limited. Various methods are used to reduce procedural pain in the newborn. One of the non pharmacological methods recommended is administering oral sucrose before and during the procedures .⁰⁶

The pain reducing effect of oral sugar solutions is believed to be mediated by two mechanisms: an oro-tactile stimulation by the intraoral fluid gives an initial effect and an oro-gustatory stimulation prolongs the effects through release of endogenous opioids. In a series of studies, oral sucrose of glucose has been used to alleviate pain reactions during blood sampling, by heel stick or venipuncture.⁰⁷

Other interventions such as non-nutritive sucking skin to skin contact and swaddling have also been proposed as means of reducing pain during blood sampling in newborns. Throughout history, feeding has been used to calm and comfort infants. Today, many care professionals encourage breast feeding before a painful procedure to keep the neonates satisfied and not showing so much pain.⁰⁸

Pain in newborn is very commonly overlooked, under recognized, and under treated. Health care providers must evaluate, recognize, prevent and manage pain in the newborn infants. Health care practitioners may not accurately interpret an infant's pain signals. Additionally, they may feel that, since opioid administration carries with it the risk of side effects such as respiratory depressions, the risk of pain alleviation are no warranted for short term, mildly painful procedures.⁰⁹

The above facts emphasize the need to identify effective pain intervention for infants that nurse can implement as independent practice decision. It is important to anticipate painful experience while child is hospitalized or receiving medical treatment. In recent years, nurses have placed increasing emphasis on developmentally sensitive care for neonates, recognizing the unique needs of these neonates who may have difficulty coping with extra uterine life. Oral sucrose has been studied extensively in neonates and shows promise as a development appropriate and effective means of relieving pain in neonates during procedures.

NEED FOR THE STUDY:

Adequate management of pain in infants and neonates has been handicapped by a number of factors. They were often treated as though they did not experience pain while undergoing invasive procedures. In 1986, paper on attitude towards pain in children revealed that 40% subjects who were pediatricians, surgeons and family practitioners suggested that infants do not experience pain in their first month of life. It was common before the 1990's for new born to undergo surgery with minimal anesthesia and did not receive essential post operative pain management. They were also subjected to painful procedures such as lumbar puncture, circumcision and ABG sampling without consideration of their discomfort or potential negative long term consequences.¹⁰

The thoughtful work of researchers who defined pain transmission in neonates and identified negative consequences due to inadequate treatment of pain manifested a dramatic impact on changing practices towards pain relief in new born period. More recently a researcher found that 99% of nurse who work with newborn believe that they do experience pain.¹¹

Approaches to preparing a child for a needle procedures obviously vary according to the age of the child. This involves primarily preparing the parents who had infants. Several pharmacological and physical approaches have been developed in an attempt to reduce pain at the skin prick site. Several pharmacological approaches also have been found to reduce pain associated with IV cannulation and other invasive procedure. Lidocaineprilocaine cream which was used one hour before needle insertion reduced pain during phlebotomy and cannulation. Amethocaine has been reported to have dramatic success in reducing pain of invasive procedures, but it is not universally available.¹²

Studies revealed that the use of simple freeze spray has reduced the pain of needle insertion. Pressure application by a cotton ball soaked in dichlorodifluoromethane and trichloro-monofluoromethane solution in pain reduction. Cognitive and behavioral techniques such as parental presence, skin to skin contact, skin tap technique reduce the anxiety associated with these procedures.¹³

In infants administration of 24%oral sucrose solutions placed in pacifier or on the tongue has dramatically reduced the pain while doing invasive procedures.¹⁴The study have shown that this effect

gradually decreases over time and is most potent in the first few months of life. Other investigations have shown that the effect of sucrose is not only one of the distracters but may be mediated through opioid pathways. The sucrose will block the pain fibers running down through the spinal cord which may occur during sucking which in turn have an analgesic effect. Pain has to be recognized by the health care providers and assessed appropriately. All invasive procedures which damage tissue and should be undertaken with appropriate pain relief.¹⁵

Encountering pain is one of the common pediatric practices. Procedural pain management of neonates remains a significant problem with the possibility of many factors hindering good management. A primary issue is that until the age of about five years a child is unable to communicate their feelings in the way an adult can self-report verbally; this includes pain.¹⁶

It has been documented that hospitalized neonates can face up to 400 painful procedures whilst they are being cared for in neonatal intensive care units. The most common painful procedures performed daily include heel lancing, venepuncture and collecting blood samples. Even with a considerable body of research evidence that has proven not only that neonates are able to feel pain, but also that prolonged exposure to pain can have potentially devastating consequences, including death, it appears that pain management is still far from optimal in nature. There should be recommendations for improvements in neonatal nursing practice, specifically regarding pain assessment and the use of non-pharmacological methods during painful procedures in the neonatal clinical settings.¹⁷

During the clinical experiences, the investigators came across many infants who were screaming due to pain during invasive procedures. This caused psychological impact for parents and difficulties in performing the procedures by the health workers. However, a review of the literature suggests that some nurses experience difficulties in recognizing pain indicators and its management.

In addition, some nurses do not always demonstrate an awareness of current pain research findings. The investigator also felt that there is a paucity of studies in this area in Indian setup. Considering the entire above facts, the researcher has felt the need to assess the effectiveness of administration

of 24% of sucrose solution on reducing IV cannulation pain in neonates. The investigator felt the need that the sucrose solution is cheap, easily available, without any additional training, and can be easily administered.

CHAPTER-II

OBJECTIVES

This chapter deals with the statement of the problem, objectives of the study, operational definition, hypothesis to meet the objectives of study, delimitation and conceptual framework of the study which provides a frame of reference. The statement of the problem selected for the study is as follows:

STATEMENT OF PROBLEM:-

“A study to assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore”

OBJECTIVES OF THE STUDY:-

1. To determine the extent of pain perceived by the control and experimental group of neonates during IV cannulation.
2. To determine the effectiveness of 24% oral sucrose solution upon pain perception of experimental group of neonates during IV cannulation.
3. To determine the association between selected demographic variables and pain perception of control and experimental group of neonates during IV cannulation.

OPERATIONAL DEFINITIONS

Effectiveness

In this study, it refers to the expected and desired change in the level of pain perceived by infants on administration of oral sucrose solution. It is measured using NIPS (Neonatal Infant Pain Scale).

Oral Sucrose Solution

In this study, it refers to the administration of 15 drops of 24% sucrose solution to neonates orally 2 minutes before IV cannulation prepared by researcher.

Pain Perception

In this study, it refers to the pain experienced by infants during IV cannulation measured using NIPS (Neonatal Infant Pain Scale). Riley infant pain scale is a rating scale to assess the pain in infants. Using NIPS (Neonatal Infant Pain Scale), The Neonatal Infant Pain Scale consisted of six groups of pain related parameters for which different scoring was given. At the end of pain assessment, pain level was graded based on the following scores; 0 - No pain, 1 - 2 - Mild discomfort, 3 - 4 - Moderate pain, 5 - 7 - Severe pain. Parameters used to evaluate are facial expression, Cry, Breathing Difficulty, Arms, Legs, State Of Arousal.

Neonate

In this study, it refers to children aged between from birth to 1 month admitted in KCG Hospital Malleswaram, Bangalore.

IV Cannulation

In this study, it refers to the insertion of a venous cannula into a vein, primarily for the administration of intravenous fluid & medication, blood collection, blood product administration. This invasive procedure is a common source of pain in infants.

HYPOTHESIS:-

- **H1:** There will be significant difference in level of pain among neonates in experimental and control group after oral sucrose administration during IV cannulation at $P < 0.05$ level.
- **H2:** There will be significant association between the level of pain during IV cannulation among neonates in control group with their selected demographic variables at $p < 0.05$ level.

ASSUMPTIONS:-

The study assumes that

- IV cannulation evokes pain response in neonates.
- Various strategies can be used to reduce the pain perceptions.
- Sucrose feeding is one of the strategies that can be used for pain reduction.

DELIMITATIONS:-

The study is delimited to;

- The study is limited to those neonates who had undergone IV cannulation admitted in hospital.
- The study is limited to new born up to 28days of age.
- The study is limited to the neonates those who were hemodynamically stable.

CONCEPTUAL FRAMEWORK

Conceptualization refers to the process of defining abstract ideas which are formulated by generalizing particular manifestation of certain behaviors. “A conceptual framework serves as a guide or map to systematically identify a logical precisely relationship between variable.” (Wood and Haber, 1994).

Polit and Hungler (2013) state that “the conceptual frame work is inter related concepts or abstractions that are assembled together in some rationale scheme by virtue relevance to a common thing”. This is the device that helps to stimulate research knowledge.

Conceptual Framework

The researcher adopts CallistaRoy’s adaptation model (1999). 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 activity through the regulator and cognator coping mechanism to produce behavioural responses in the four interrelated adaptation models, self concepts, role function, inter dependence and physiological purposes.

Systems:

Are a set of organized components related to form a whole body, Roy considers the recipient of care to be an open adaptive system.

Input:

In Roy's system input is identified as stimuli which can come from the environment or within the person. A focal stimuli was starting IV cannulation. Input stimulates child's response to stimuli. A contextual stimuli was the weight of the baby, Type of delivery, Previous experience of IV cannulation. A residual stimuli are age, sex.

Throughput:

Throughput refers to makes use of persons processes and effectors. Processes refers to level of pain in neonates during IV cannulation. Effectors refers to giving oral sucrose administration to reduce IV cannulation pain.

Output:

Output is the outcome of the system. In Roy's adaptation system output is categorized as adaptive responses that promote a neonates integrity or ineffective responses. These responses provides feedback to the system. So in this study the samples who were in experimental group had a reduction in the level of pain in neonates.

Paradigms:**Human Being:**

She emphasized human are individuals possesses unique potential and strives towards self direction and needy stimulation whatever the individual does ,it represents his or her best judgment at the movement .self awareness and self acceptance are essential to individuals. Sense of integrity and self worth these circumstances require respect from the nurse.

Health:

She does not define health, she supports the World health organization's definition of health.

Environment:

Roy's incorporates the environment within the realities in her framework which is a complex of extraneous factors and circumstances that are present in every nursing situation .Framework includes objects such as policies , setting, atmosphere, humans and happenings.

Nursing:

Nursing is a clinical discipline, is a practice discipline designed to procedure explicit desired results. The art of nursing is goal oriented activity requiring the application of knowledge and skills towards meeting a need for help experienced by a patient .Nursing is a helping process that extends to restore the patient's ability to cope with demands implicit in the situation.

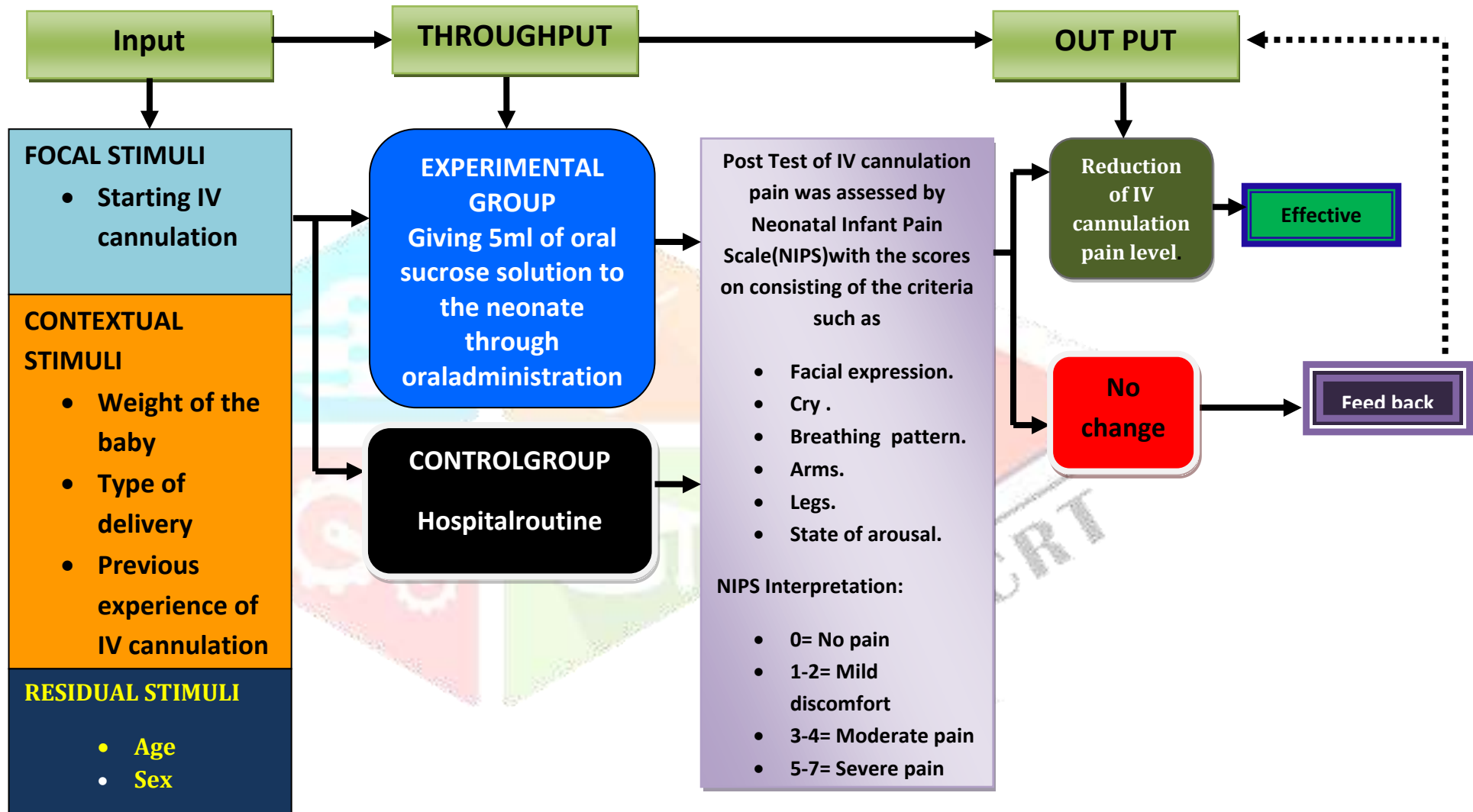


Fig.1.1- Callista Roy's Adaptation Model(1999)

CHAPTER-III

REVIEW OF LITERATURE

“Know safety, no injury. No safety, know injury”

Review of literature helps in supporting the studies to have in depth information in this area; researcher has reviewed various literatures from periodicals, journals and through web search.

Review of literature provides basis for future investigation, as insight into the problem and relates findings of the study to another. The extensive review of literature has been done and it is organized according to the following headings.

- A. Studies related to painful procedure in NICU.**
- B. Studies related to strategies to reduce pain during invasive procedures.**
- C. Studies related to effect of oral analgesia to reduce pain among neonates.**

A.STUDIES RELATED TO PAINFUL PROCEDURE IN NICU

A study was conducted on routine painful procedures can be harmful among 64 newborn in University of Siena, Italy. No differences were detected between advanced oxidation protein products and total hydro peroxide concentrations at the beginning and at the end of heel prick sampling, considering the whole cohort of babies. When babies' pain was high (ABC score 4), mean AOPP and TH blood levels increased significantly; in this case, mean AOPP value increased from, with a significant p value. These data show that even common routine procedures can be potentially harmful for the new born if they provoke a high level of pain.¹⁸

A study was conducted on painful procedures undergone in NICU among new borns in Hospital dentnants Armand Trousseau, Paris. During the study period, neonates experienced 60,969 first attempt procedures, with 42,413 (69.6 percent) painful and 18,556 (30.4 percent) stressful procedures. The average number of all procedures per neonate was 141 and the average number of procedures per day of hospitalization was 16. Each neonate experienced a Medan (midpoint) of 115 procedures during the study period and 16 procedures per day of hospitalization. The study concludes that each neonate experienced a median of 75 painful procedures and 10 painful procedures per day of hospitalization.¹⁹

A study was conducted on new born in intensive care often exposed to pain in Children's Hospital Armand Trousseau in Paris, of the 42,413 painful procedures included in this study on 2 percent of babies received pain medications and just 18.2 percent received non pharmacological pain therapy. That means about four out of five babies received no interventions to lessen their pain, according to the study". The study concludes that babies are exposed to a lot of painful and stressful procedures, mostly not treated with pain relieving interventions.²⁰

A study was conducted on comparison of three neonatal pain scales among 80 neonates during minor painful procedures. A sample of the study was evaluated by two observers according to the Neonatal Infant Pain scales, the Neonatal Facial Coding System and DAN. The highest correlation between the crying time and each different neonatal pain scales was found for NIPS. The study concludes that all three scales have comparable results, with slight different favoring NIPS ²¹.

A study was conducted on experience influence in heel prick blood sampling among 340 neonates in NICUs of Europe. Babies were randomly allocated to be tested with either the Tenderfoot or Genie Lancet heel-prick device. Primary study outcomes include quality of the blood sample; time taken to collect the sample; number of heel pricks required to take the sample;

pain expressed by the baby. On all outcomes, the Tenderfoot device was more effective than the Genie Lancet. The study concludes that the Tenderfoot device saves significant time for midwifery staff, and reduces the need for more than one heel prick at each test, making it superior to the Genie Lancet device.²²

A study was conducted on the relationship between behavioral states and pain responses to various NICU among 60 neonates. Samples of 60 neonates were used for the study. A positive relationship was identified between ABSS (Anderson Behavioral State Scoring) ND CRIES. This study concludes that healthy newborn are in a state of active sleep and can adequately express pain – related responses to the NICU procedures that are appropriate with the nature of stimulation.²³

A survey was conducted on pain assessment and procedural pain among neonates in neonatal units in Australia. The survey comprised questions relating to pain assessment scores, pain reduction strategies for minor painful procedures. Surveys were sent to 181 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. The study concludes that Australian neonates units have no articulated policy to guide pain management during painful procedures.²⁴

A study was conducted on Validation of behavioral acute pain rating scale for term necessary among 42 newborns. Two observers evaluated independently each infant during a painful procedure. The finding reveals that the scale showed to be sensitive during painful procedures scores ranged from 1 to 10, with 95% of scores ≥ 3 . The study concludes that behavioral acute pain rating scale for newborns demonstrated a good specificity and sensitivity.²⁵

A study was conducted on pain assessment tool among ventilated 30 neonates in the neonatal intensive care unit. Assessment of ventilated infants, before during and after a known routine traumatic procedure using the Nepean neonatal intensive care unit pain Assessment Tool.

A sample of neonates was enrolled in the study over a one – half month. The study concludes that NNICUPAT show validity in the assessment of procedural pain in the ventilated neonate.²⁶

B. STUDIES RELATED TO STRATEGIES TO REDUCE PAIN DURING INVASIVE PROCEDURES.

A study was conducted on the efficacy of non – pharmacological interventions in the management of procedural pain among term neonates in Department of Obstetrics and Neonatology, Switzerland 13 randomized controlled studies and two Meta – analyses were taken for the study. The selected interventions were ‘non-nutritive sucking’, “music”, “Swaddling”. “Positioning”, olfactory and multisensory stimulations”. “Kangaroo care” and “Maternal Touch”. The study concludes that some of the non – pharmacological interventions have an evident favorable effect on pulse rate, respiration and oxygen saturation on the reduction of motor activity, and on the excitation states after invasive measures”.²⁷

A study was conducted on the effects of skin to skin contact during acute pain among 59 neonates in Boston Medical Centre, Boston, Massachusetts. A sample was randomly assigned to either 15 min of skin – skin contact before, during and following heel prick in treatment group and regular care in control group. Infants were assessed for change in facial action, behavioral states, crying and heart rate. 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. Skin to skin promoted reduction in behavioral measures and less physiological increase during procedure. The study concludes that skin to skin contact is used as a non-pharmacologic intervention to relieve acute pain in stable infants.²⁸

A comparative study was conducted among children less than 24 months to assess the efficacy of Eutectic mixture of local anesthetics with pre mixed 50% nitrous oxide / oxygen, used alone or

combined with eutectic mixture for pain alleviation during immunization with palivizunab injection in Synagi, Randomised double blind technique was used. Three different analgesic interventions were used.

- i. Eutectic mixture of local anesthetics application plus air inhalation.
- ii. Inhalation of 50:50 nitrous oxide and oxygen mixture plus application of placebo cream.
- iii. Nitrous oxide oxygen inhalation plus eutectic mixture of local anesthetic application.

The results revealed that the combined nitrous oxide oxygen plus eutectic mixture of local anesthetics was more effective than either local anesthetics or nitrous oxide or oxygen.²⁹

A study was conducted in an urban primary care pediatric practice in Toronto, Canada to compare acute pain response during immunization in infants using a slow standard technique versus a rapid pragmatic technique by randomized controlled trial. One hundred and thirteen infants participated. In standard group slow aspiration prior to injection, slow injections and slow withdrawal technique was used. Whereas in pragmatic group no aspiration, rapid injection and rapid withdrawal technique was used. Infant's pain was measured by modified behavior pain scale. The findings indicated that mean modified behavioral pain scores were higher in standard group i.e. 5.6 when compared to pragmatic group i.e., 3.3 and there were no observed difference in age, birth and prior analgesic use.⁽⁷⁷⁾ A comparative study was conducted to assess the effectiveness of kangaroo care and giving prone position on physiologic responses during IM injections in neonates delivered at Shariati hospital in Bandar Abbas City (Iran) and 100 neonates were randomly assigned to both intervention and control groups. In the intervention group, the neonate was held in kangaroo care for 10 minutes before injection until three minutes after injection and in the control group the neonate was in the prone position isolated without caregiver.

The primary outcomes were measured by heart rate and blood oxygen saturation rate before, during and three minutes after injections. The findings revealed that the heart rate during

the three minutes after injection for neonates of intervention group was significantly lower than the neonates in control group. However the heart rate and oxygen saturation were found to be normal for both groups.³⁰

A randomized controlled trial was conducted from a large tertiary hospital to measure the difference in pain scores for newborns who were held and swaddled while undergoing routine balance procedures compared to newborns that were lying on their backs and not swaddled during heel lance. Infants in the experimental group (n=22) were swaddled and held in an upright position during routine heel lance procedures while neonates in the control group (n=20) remained in a standard care position. Pain was measured with the Neonatal Inventory Pain Scale (NIPS) at two points in time for each group (just before the heel lance procedure and at the completion of the heel lance).³¹

C. STUDIES RELATED TO EFFECT OF ORAL ANALGESIA TO REDUCE PAIN AMONG NEONATES DURING INVASIVE PROCEDURE.

A prospective, double blind, randomized controlled trial was conducted in the postnatal ward of a tertiary care hospital in southern India to compare the effect of expressed breast milk, 25% dextrose and sterile water on procedural pain in neonates as assessed by the premature infant pain profile, changes in heart rate, oxygen saturation and duration of crying. 210 babies are required venipuncture for blood sampling. The face and crying of baby were video graphed and PIPP scale was used and the study concludes that EBM significantly reduces procedural pain in neonates though to a lesser extent as compared to 25% dextrose.³²

A double –blind clinical trial was conducted on the maternity and neonatal wards of the Heilig Hart Hospital in Mol. Belgium to investigate which concentration of glucose is most effective in reducing pain for venipuncture in the newborn. During the least 1 month, one of the four selected solutions was administered orally, 2 minutes before the venipuncture was performed. The pain from the skin puncture was scored using a validated pain scale (the Leuven Pain Scale). This study showed a significantly lower average pain score in the 30 percent glucose group when compared with the placebo group. The average pain scores in the 20 percent glucose group and the 10 percent glucose group were also significantly lower than those in the placebo group.³³

A quasi –experimental study was conducted to evaluate the effectiveness of breastfeeding oral sucrose and combination of oral sucrose and breastfeeding in infant's pain relief during the vaccination in ShahidanEbrahimin and Eram Health Centers of Tabriz. Infants under 3 month so of age entered the study and finally randomly have been put into four groups respectively; oral sucrose 25% breastfeeding, combined method and control groups. In case groups, cannulation was implemented two minutes after the mentioned interventions. NIPS (Neonatal Infant Pain Scale) was used in order to determine the pain score at 0.5 and 10 minutes after the vaccination. The findings of the present study indicated that the mean of the pain scale was the lowest immediately after the vaccination in breastfeeding group. But this difference was significant only in breastfeeding and control groups. The minimum crying time in breastfeeding group and the maximum time in control group.³⁴

A prospective, randomized, partially blinded, clinical trial was conducted to compare the efficacy of oral 25% dextrose treatment and / or skin – to – skin contact for analgesia in term of newborns during intramuscular injection of a hepatitis B vaccine. 640 term newborns were studied, who were placed in the room with their mothers in a third – level reference maternity hospital in Belem. Infants at 12 to 72 hours of life was assigned randomly to receive an intramuscularinjection of hepatitis B vaccine in the right thigh according to 4 analgesia groups,

that is , no analgesia (routine), oral 25% dextrose treatment, given 2 minutes before the injection; skin to skin contact, initiated 2 minutes before the injection and persisting throughout the procedure; and a combination of the oral dextrose treatment and skin to skin contact strategies. For all groups, Neonatal Facial Coding system and Neonatal Infant Pain Scale scores were evaluated before the procedure, during thigh cleansing, during the injection and 2 minutes after the injection. The use of oral 25% dextrose treatment reduced the duration of procedural pain in the studied population. Skin to skin contact decreased injection pain and duration. The combination of the 2 analgesic measures was more effective than either measure separately for term newborns.³⁵

CHAPTER-IV

RESEARCH METHODOLOGY

Methodology of research organizes all the components of study in a way that most likely will lead to valid answers for the problems that have been posted ²⁴.

This chapter deals with the methodology adopted for the study. It includes the research design, variables, setting, population, sample, and criteria for selection of the sample, sample size, sampling technique, development and description of the tool, content validity, pilot study, and reliability of the tool, data collection procedure and plan for data analysis.

RESEARCH APPROACH:

The investigator adopted a Quantitative research approach was adopted for the study, because the aim of the researcher was to assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore.

RESEARCH DESIGN

Polit & Beck (2008) defined research design as the overall plan for addressing a research

question, including specifications for enhancing the study's integrity. The research design adopted for this study is Quasi experimental, Post test only design with control group.

Group	Intervention	Post Assessment
Experimental	X	01
Control group		02

Key :

- 01-Post test in experimental group
- X- Intervention (oral sucrose solution)
- 02- Post test in control group

VARIABLES

Independent Variable

The variable that is believed to cause or influence the dependent variable is the independent variable (Polit& Beck, 2008). In this study, the independent variable is oral sucrose solution.

Dependent Variable

The variable hypothesized to depend on or be caused by another variable is the dependent variable (Polit& Beck, 2008). In this study, the dependent variable is the level of pain perception in neonates during IV cannulation.

Attribute variable

Variable that describes the study samples characteristics is termed as attribute variable (Polit& Beck, 2008). In this study, the attribute variables are the demographic variable proforma of the infant and the clinical variable proforma of the infants.

SAMPLING AND SAMPLING TECHNIQUES

Population:

Population is the entire set of individuals or object having some common characteristics (Polit & Beck 2008).

The target population in this study comprises of all infants, aged birth to one month who are undergoing IV cannulation. The accessible population in this study were infants birth to one month of age undergoing IV cannulation in KCG hospital, Malleswaram, Bangalore who met the inclusion criteria during the data collection period.

Sample:

Sample refers to a subject of a population that is selected to participate in a particular study. It is a portion of the population. Which represents the entire population. A sample size of 60 neonates who met the inclusion criteria were chosen for the study, in that 30 were taken for control group and 30 were taken for experimental group who satisfy the inclusion criteria.

Sample size

The sample comprises of sixty neonates (60) who met the inclusion criteria and studying in selected hospital, Bangalore .

Sample Techniques

It refers to, “The process of selecting a portion of the population to represent the entire population”. The investigator has selected the sample by Purposive Sampling technique for this study, as she has intentionally selected the neonates who were going to receive IV cannulation for the purpose of fluid infusion at the selected NICU.

CRITERIA FOR SAMPLE SELECTION

Inclusive Criteria

- Sample age group is from 1 to 28 days
- Neonates who have completed 28 weeks of gestation at the time of birth
- Neonates undergoing IV cannulation.

Exclusive criteria

- Neonates who are not haemodynamically stable
- Neonates who are on sedation or on ventilator
- Term neonates who are on NPO.

SETTINGS OF THE STUDY :

The physical location and conditions in which data collection take place in a study”. The study was conducted in KCG hospital, which is 7 km away from Sarvodaya College of Nursing, Bangalore . The total bed strength of the hospital is 500. This setting was selected because of the availability of participants and feasibility of conducting the study.

DEVELOPMENT AND DESCRIPTION OF TOOL

The tool was developed after an extensive review of literature, internet search and experts opinion. It helped the investigator to select most suitable Neonatal Infant Pain Scale (NIPS). This study tool consisted of 2 sections, section A and section B

SECTION : A

This dealt with demographic data of the neonates. It included items such as age, sex, weight of the baby, previous experience of IV Cannulation.

SECTION : B

This dealt with measurement of pain experienced by the neonate with the help of NIPS (Neonatal Infant Pain Scale) developed by LAWRENCE in 1993. The Neonatal Infant Pain Scale consisted of six groups of pain related parameters for which different scoring was given.

The six parameters are mainly,

- Facial Expression
- Cry
- Breathing Difficulty
- Arms
- Legs

- State Of Arousal

At the end of pain assessment, pain level was graded based on the following scores;

- 0 - No pain.
- 1 - 2 - Mild discomfort.
- 3 - 4 - Moderate pain.
- 5 – 7 - Severe pain.

A copy of the NIPS is annexed in the appendix I.

TESTING OF THE TOOL

Reliability:

Prior permission was obtained from the hospital authorities. The tool was administered to 12 neonates during IV cannulation to establish reliability .One trained personnel and investigator recorded the observation items during IV cannulation. It was checked for reliability by inter -rater reliability method by using Karl pearson quotient (r), $r = \frac{\sum dxdy}{\sqrt{\sum dx^2 \times \sum dy^2}}$ was found to be 0.78 which indicated that the tool was reliable. Hence it was found feasible to conduct the study.

Validity:

Validity is the degree to which an instrument measures what is intended to measure. In this study validity of the tool was not required because the investigator has used a standardized Neonatal Infant Pain Scale developed by Lawrence in 1993 in order to assess the pain experienced by neonates. The suggestions and advices given by experts were considered and corrected.

PILOT STUDY

According to Dennise F. Polit (2011) Polit study is defined as “A small –scale version or trail run, done in preparation of a major study”

A Pilot study was conducted in Neonatal Intensive Care Unit(NICU) of KCG hospital from 07-01-2020 to 12-01-2020 after obtaining formal administrative and ethical approval and consent from parents of neonates. By using purposive sampling technique 12 neonates were selected as sample. Out of 12 ,6 samples were allotted to the experimental group and 6 were allotted to the control group . Pain was assessed during the IV cannulation . In experimental group pain was assessed with oral sucrose administration. In control group the pain was assessed without any intervention. The pain score was assessed with NIPS (Neonatal Infant Pain Scale). The pilot study did not show any major problems and the timing and intervention plan were found to be feasible.

Data collection method

After having obtained a formal written permission from to administrative officer of KCG hospital, the final study was conducted from 05-2-2020 to 04- 3-2020 on 60 neonates from NICU of KCG hospital. Neonates were identified as per the inclusion criteria .Subjects were selected using purposive sampling method and assigned to the experimental and control groups. The investigator selects the neonates receiving IV cannulation in NICU. The details of the study was explained to parents and a verbal consent was obtained. The information are collected as per the demographic proforma. The pain was assessed by NIPS during IV cannulation if it was only for fluid infusion. In experimental group oral sucrose administration was given before the procedure and pain assessment was done .In the control group observation of pain was made for 30 neonates where no intervention was given..

Data Analysis Plan

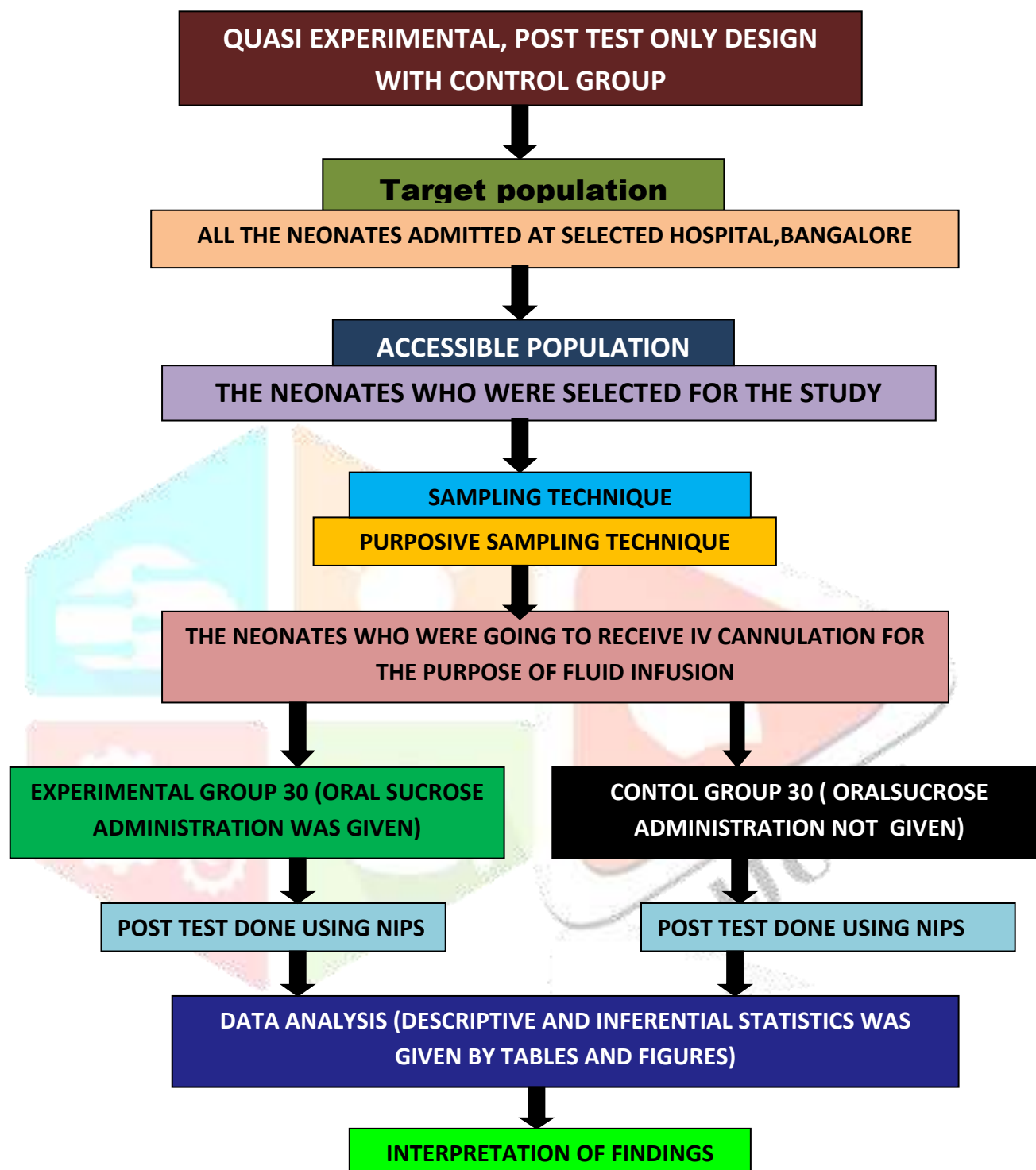
Descriptive and inferential statistics were used to analyze the data. Analysis of demographic variables was done in terms of frequency and percentage distribution of the post test level of pain in the experimental and control group.

Comparison of post test level of pain between the experimental and control group was done using central tendency such as mean, standard deviation and t-test techniques. Association of post test level of pain in the control group with their demographic variables was done by using chi-square test..

PROTECTION FOR HUMAN RIGHTS

The study was conducted after the approval of Ethical committee at Sarvodaya college of nursing. Formal written permission was obtained from the concern authorities of KCG Hospital. An informed verbal consent was obtained individually from parents of neonates who participated in the study. Confidentiality was assured to parents throughout the study. Parents were informed that their neonates participation were voluntary based and had the freedom to drop out from the study as when they liked to do so.

Fig 2: The schematic representation of the study design adopted for the research is given below:-



SAMPLE SIZE OF ESTIMATION

The sample size was calculated based on comparison of means with standard deviation (1.5 + 1.6 = 3.0) of the pilot study findings assuming 90% power, at 0.05 level of significance and 2. differences.

$$n = 2 \left\{ \frac{Z_{1-\alpha/2} + Z_{1-\beta}) S}{d} \right\}^2$$

Where,

$Z_{1-\alpha/2}$: value taking from standard normal distribution at a specified confidence level (For $\alpha = 0.05$, $Z_{1-\alpha/2} = 0.49$)

$Z_{1-\beta}$: value at specified power ($Z_{0.7} = 0.74$; $Z_{0.9} = 0.64$)

S: Standard Deviation

d: Clinically significant difference in means.

$$n = 2 \left\{ \frac{(0.49 + 0.64) 3}{2.4} \right\}^2$$

$$n = 2 \left\{ \frac{14.125}{2.4} \right\}^2$$

$$= 2 \times 14.125$$

$$= 28.$$

Though the estimated sample size was 28 as per the expert's suggestion the researcher has opted to take a level figure, i.e. 30 samples.in each control and experimental group

CHAPTER-V

RESULTS

All meanings, we know depend on the key of interpretation.

-George Eliot

The process of evaluating data using analytical and logical reasoning to examine each component of the data provided. This form of analysis is just one of the many steps that must be completed when conducting a research experiment. Data from various sources is gathered, reviewed, and then analysis method, some of which include data mining, text analytics, business intelligence and data visualizations.

Analysis is a process of organizing and synthesizing data so as to answer research questions and test hypothesis. (Poilt and Beck, 2010)

This chapter describes analysis and interpretation of data collected from 60 neonates (30 Experimental and 30 control group) on reducing pain to assess the effectiveness of 24% of oralsucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore. The collected data was organized, analyzed and tabulated by using descriptive and inferential statistics.

The analysis and interpretation of data were based on data collection and the results were computed by using descriptive (mean ,frequency ,percentage distribution and standard deviation) and inferential (,t"-test and chi-square test) statistics and the results were interpreted in tables, figures and diagrams

These data's were represented as follows.

1. **Section -I:** Frequency Percentage distribution of demographic variables in the experimental group and control group.

Data on demographic variables

Table-1:Frequency Percentage distribution of demographic variables in the experimental group and control group.

DEMOGRAPHIC VARIABLES	EXPRIMENTAL GROUP		CONTROLGROUP	
	NO	%	NO	%
Age in days				
Birth -7days	20	66.7	21	70
8-14 days	8	26.6	4	13.33
15-21days	2	6.66	5	16.67
>22days	0	0	0	0
Sex				
Male	12	40	13	43.33
Female	18	60	17	56.67
Weight of the baby				
<2.00kg	0	0	0	0
2.01-2.250kg	0	0	0	0
2.251-2.500kg	5	16.66	20	66.67
2.501-3.000kg	23	76.67	5	16.67
>3.000kg	2	6.67	5	16.66
Type of delivery				
Normal	11	36.67	10	33.33
LSCS	19	63.33	20	66.67
Forceps	0	0	0	0
Vacuum	0	0	0	0
Previous experience of IV cannulation				
Yes	4	13.33	2	6.67
No	26	86.67	28	93.33

The above table depicts that regarding Age among 30 neonates in the experimental group majority of 66.7% were aged between birth -7days, 26.7% are aged between 8-14 days, 6.66% are aged between 15-21 days and among 30 neonates in the control group 70% were aged between 0-7 days, 13.33% are aged between 8-14days, 16.67% are aged between 15-21 days.

In regards of sex among 30 neonates 60% females and 40% males were in the experimental group and among 30 neonates 56.67% were females and 43.33% were males in the control group.

In regards with Weight of the baby: among 30 neonates 76.67% in weight of the baby between 2.501-3.000kg, 16.66% were between 2.251-2.500kg, and 6.67% of baby are above 3.00 kg in experimental group and among 30 neonates 66.67% in weight of the baby between 2.251 – 2.500kg, 16.67% are in between 2.501-3.00 kg 16.66% are above 3.00kg, in the control group,

Regarding the Type of delivery among 30 neonates 63.33% babies are LSCS delivery, 36.67 are normal in the experimental group and among 30 neonates 66.67% babies are LSCS delivery and 33.33 are normal in the control group.

Regarding with Previous experience of IV cannulation among 30 neonates 86.67% were no previous experience of IV cannulation and 13.33% are having the exposure in experimental group and whereas in the control group among 30 neonates 93.33% were no previous experience of IV cannulation and 6.67 are having the exposure.

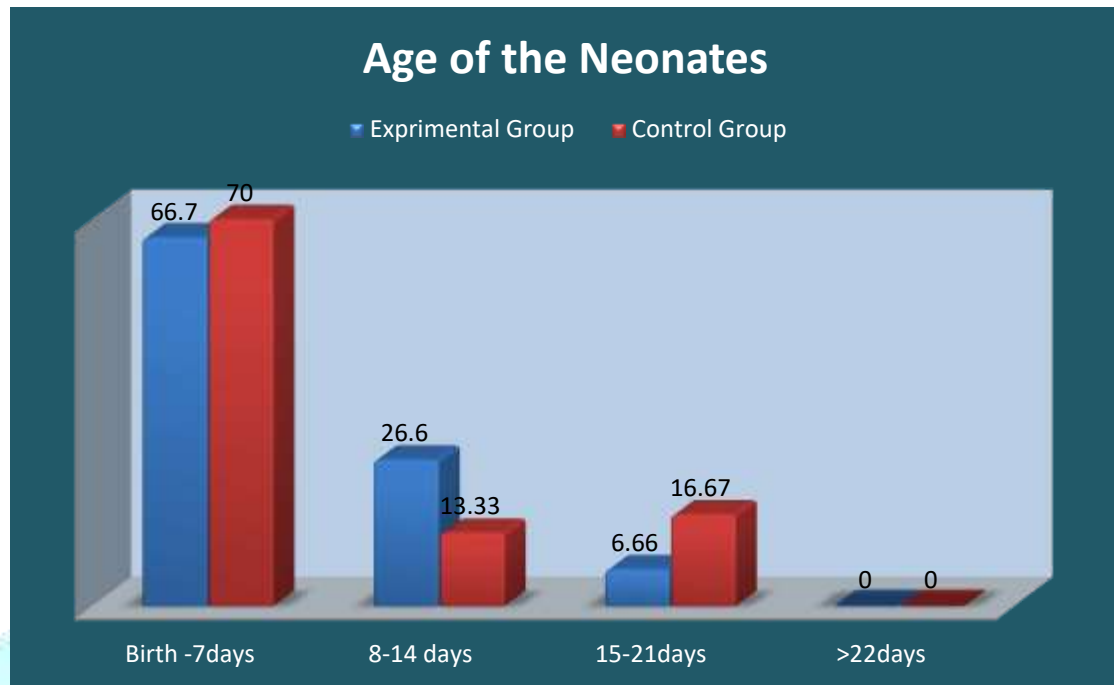


Figure 3: Distribution of neonates according to their age

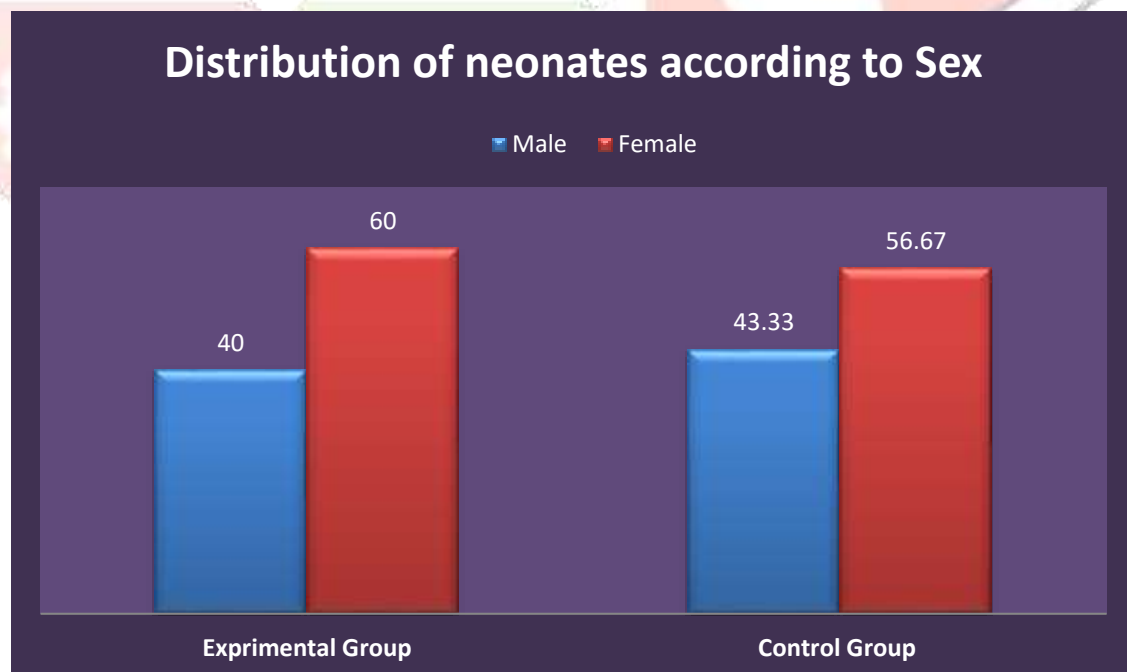


Figure 4: Distribution of neonates according to their age

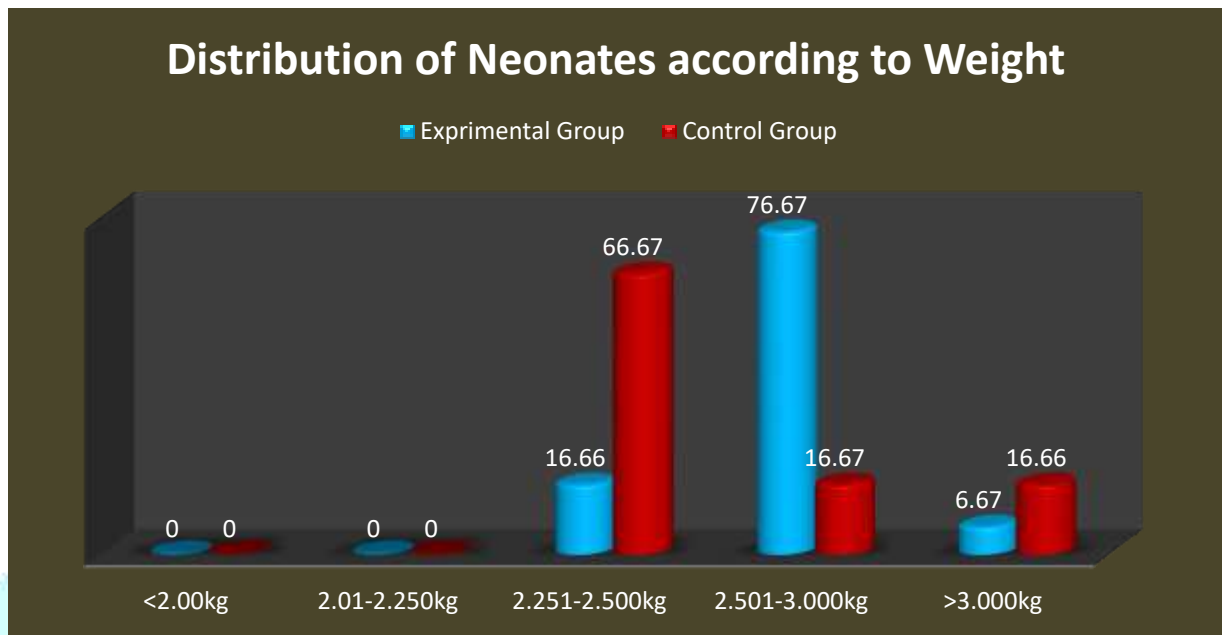


Figure 5: Distribution of Neonates according to weight.

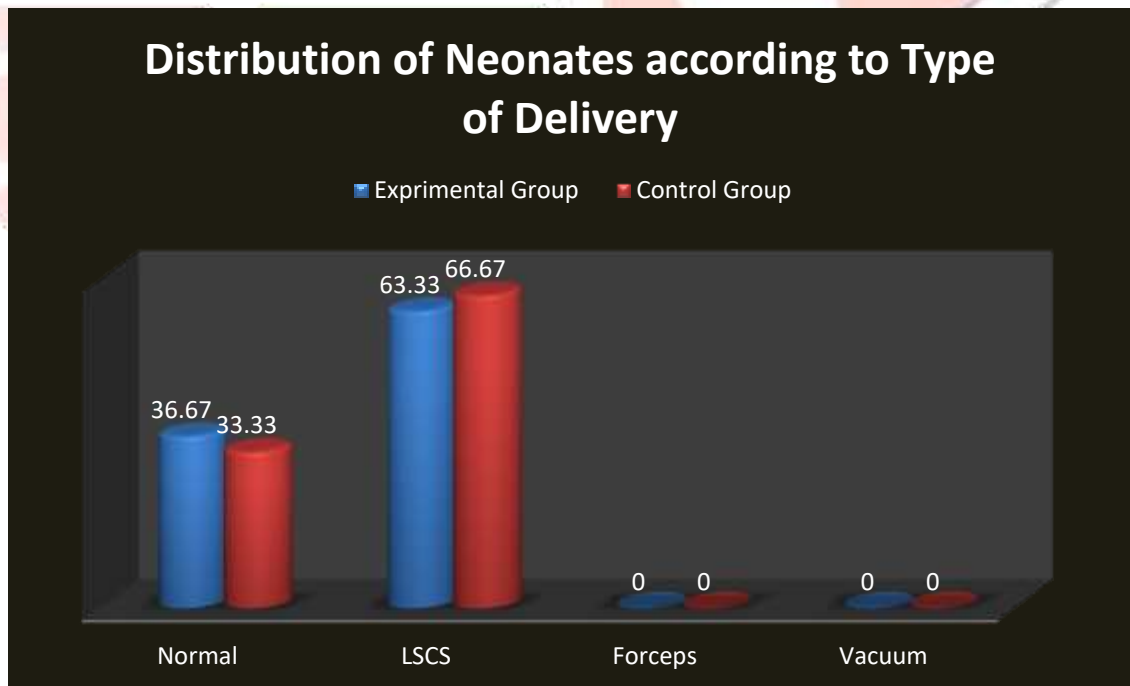


Figure 6: Distribution of Neonates according to Type of Delivery

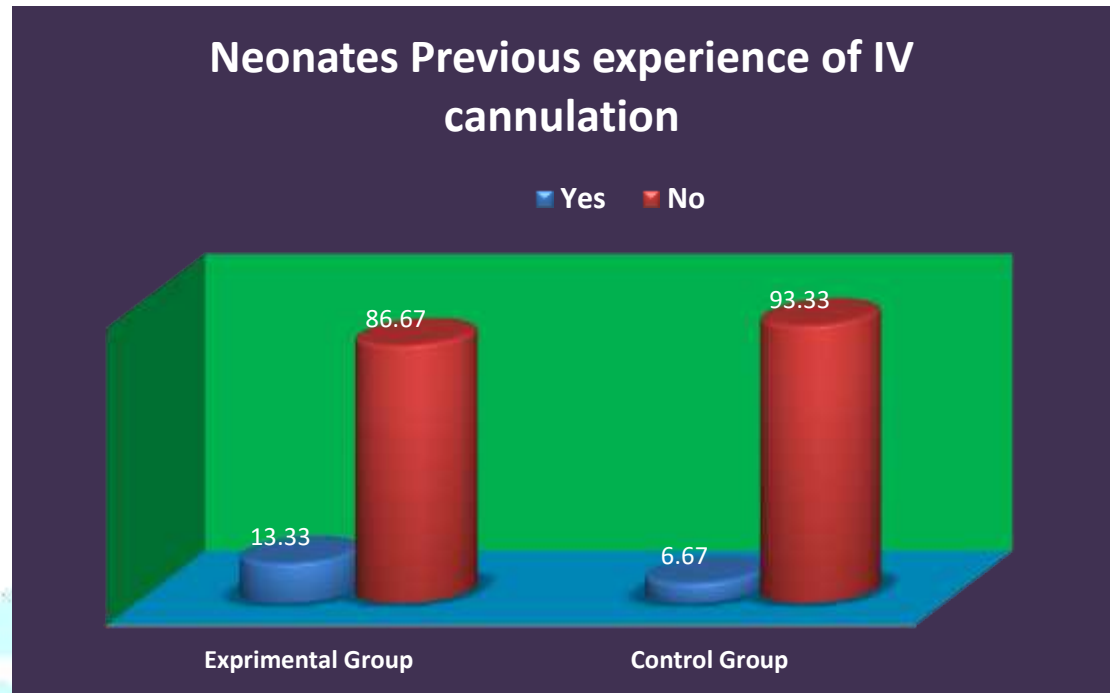


Figure 7: Distribution of Neonates according to Previous experience of IV cannulation.

SECTION :B

TABLE: 2 Frequency percentage distribution of post test level of pain in the experimental group and control group

Group	No Pain		Mild Pain		Moderate Pain		Severe Pain	
	No	%	No	%	No	%	No	%
Experimental Group	0	0	16	53.67	14	46.33	0	0
Control Group	0	0	0	0	14	46.67	16	53.33

The above table shows that in the experimental group majority 16 (53.67%) had mild pain, 14 (46.33%) had moderate pain and in control group majority 16(53.33%)had severe pain, 14 (46.67%) had moderate pain.

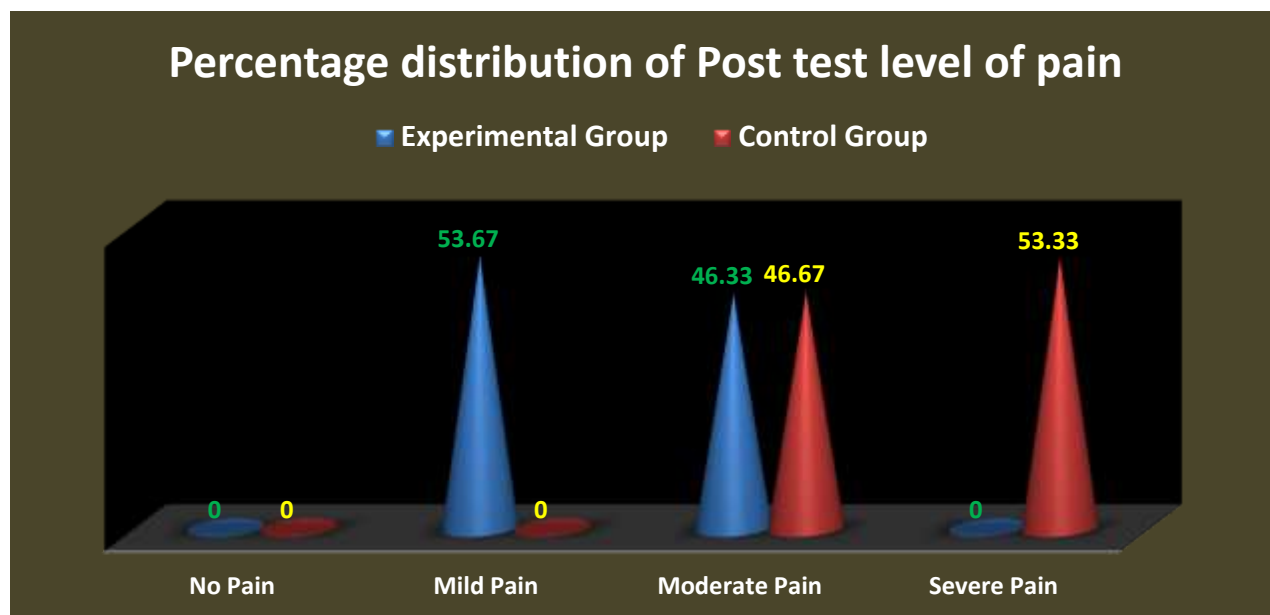


Figure 8: Frequency percentage distribution of post test level of pain in the experimental group and control group.

SECTION :C

Table:3 Comparison of post test level of pain between the experimental and control group

Post Test Level of pain	Mean score	S.D	Meandifference	t value
Experimentalgroup	2.3	0.823	2.13	8.247*(s)
Control group	4.43	1.055		

The above Table depicts that in the experimental group, the post test level of mean pain score was 2.3 with S.D 0.823 and in the control group the post test mean score was 4.43 with S.D 1.055. The mean difference score was ± 2.13 .

The calculated 't' value of 8.247 was statistically significant at $P < 0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

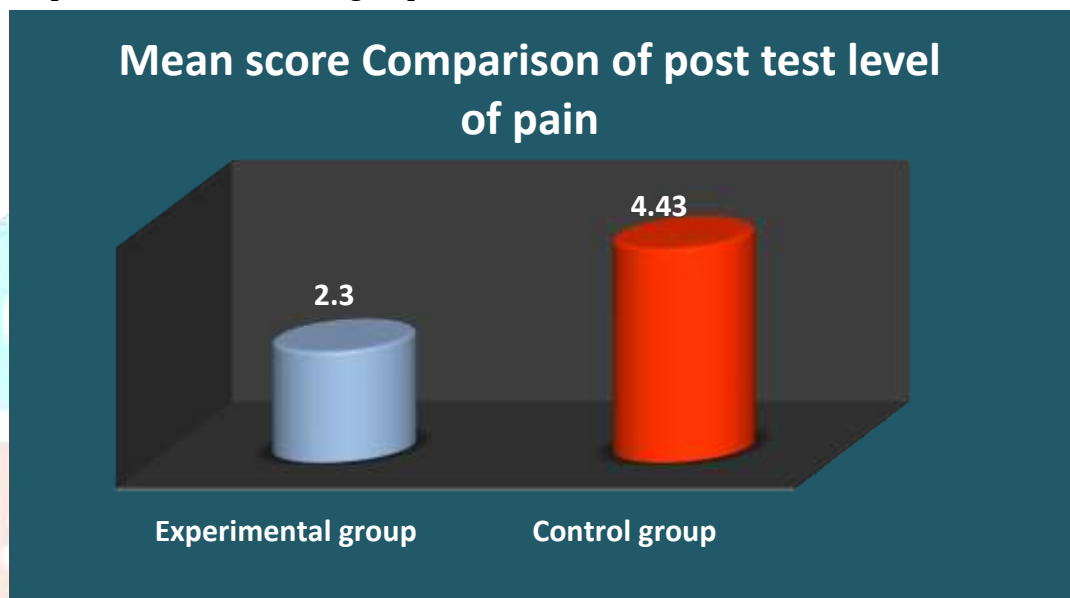


Figure 9: Mean score Comparison of post test level of pain in the experimental group and control group.

SECTION-D

Table:4 Association of post test level of pain in the control group, with the subjects demographic variables

n=30

Demographic variables	No Pain		Mild Pain		Moderate Pain		Severe Pain		Chi-square Value
	No	%	No	%	No	%	No	%	
Age in days									2.26 df=2 (NS)
Birth -7days	0	0.00		0.00	12	40	13	43.33	
8-14 days	0	0.00		0.00	2	6.67	1	3.33	
15-21days	0	0.00		0.00	0	0.00	2	6.67	
>22days	0	0.00		0.00	0	0.00	0	0.00	
Sex									0.088 df=1 (NS)
Male	0	0.00		0.00	6	20	6	20	
Female	0	0.00		0.00	8	26.67	10	33.33	
Weight of the baby									0.494 df=2(NS)
<2.00kg	0	0.00		0.00	0	0.00	0	0.00	
2.01-2.250kg	0	0.00		0.00	0	0.00	0	0.00	
2.251-2.500kg	0	0.00		0.00	3	10	2	6.67	
2.501-3.000kg	0	0.00		0.00	9	30	12	40	
>3.000kg	0	0.00		0.00	2	6.66	2	6.67	
Type of delivery									0.265 df= 1 (NS)
Normal	0	0.00		0.00	4	13.33	6	20	
LSCS	0	0.00		0.00	10	33.33	10	33.34	
Forceps	0	0.00		0.00	0	0.00	0	0.00	
Vacuum	0	0.00		0.00	0	0.00	0	0.00	
Previous experience of IV cannulation									0.904 df=1 (NS)
Yes	0	0.00		0.00	0	0.00	1	3.33	
No	0	0.00		0.00	14	46.67	15	50	

NS-Not significant

In the above Table shows that the demographic variables had not shown any statistically significant association with the level of pain in the control group. This could be due to smaller sample size.

CHAPTER - VI**DISCUSSION****DISCUSSION**

This chapter discusses in detail the finding of the analysis in relation to the objectives of the study. The following were the objectives of the study and further discussion will exemplify how these objectives were satisfied by the study was conducted to assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore.

The sampling technique is purposive sampling technique was used for this study . The total sample size was 60, among them 30 were in the control group and 30 were in the Experimental . Neonatal Infant Pain Scale (NIPS) developed by Lawrence 1993 was used for data collection. After data collection, data was organized, tabulated, summarized and analyzed. The study findings were discussed in this chapter with reference to the objectives of the study.

The objectives were,

1. To determine the extent of pain perceived by the control and experimental group of neonates during IV cannulation.
2. To determine the effectiveness of 24% oral sucrose solution upon pain perception of experimental group of neonates during IV cannulation.
3. To determine the association between selected demographic variables and pain perception of control and experimental group of neonates during IV cannulation

The frequency and percentage distribution of demographic variables in the experimental group majority (20)66.7% were age between birth -7 days, 60% in female, (23) 76.67% weight of the baby 2.501 -3.000kg, 19 (63.33%) babies are LSCS delivery, 26(86.67%) were no previous IV cannulation, 56

whereas in the control group, majority 21 (70%) were age between birth-7 days, 17(56.67%) in female, 20(66.67%) in the weight of the baby 2.251 – 2.500kg , 20 (66.67%) babies are LSCS delivery , 28(93.33%) were no previous experience of IV cannulation.

1. The first objective was to determine the extent of pain perceived by the control and experimental

group of neonates during IV cannulation..

In the experimental group majority 16(53.67%) had mild pain and control group majority 16 (53.33%) had severe pain.

The study findings were consistent with the study conducted by oral administration 33% sucrose on pain level of neonates under IV cannulation also showed experimental group 53.67% had mild pain and control group 53.33% had severe pain.

2. The second objective was to determine the effectiveness of 24% oral sucrose solution upon pain perception of experimental group of neonates during IV cannulation.

In the experimental group , the post test level of mean pain score was 2.3 with S.D 0.823 and in the control group the post test mean score was 4.43 with S.D 1.055.

The calculated “t” value of 8.247 was statistically significant at $P < 0.001$ level indicating that there was significant difference in the post test level of pain between the experimental and control group.

Hence the null hypothesis H1 stated that There will be significant difference in level of pain among neonates in experimental and control group after oral sucrose administration during IV cannulation at $P < 0.05$ level.

The study findings were consistent with the study conducted by Giuseppe De Bernardo (2019) the effect of Oral 24% sucrose associated with nonnutritive sucking for pain control in healthy term newborns receiving venipuncture beyond the first week of life. The SD score (interquartile range) of the neonates when Oral 24% sucrose fed was 1.50(1-2) and 4.00(2-6) when not breast feed ($p=0.0001$)³⁶

3. The third objective was to determine the association between selected demographic variables and pain perception of control and experimental group of neonates during IV cannulation

The association table that the demographic variables had not shown any statistically significant association with the level of pain in the control group.

The conceptual framework of this study was based on CallistaRoy’s adaptation model (1999). This model describes the goal of nursing is to facilitate adaptation between person and the environment through the management of stimuli. The focal stimuli is considered as IV cannulation because the neonates pain is

related responses were tested as a result of intravenous therapy. The contextual stimulus such as weight of the baby, type of delivery, previous experience of IV cannulation and residual stimuli are age and sex as a response to focal, contextual and residual stimuli the responses exhibited out in physical and psychological aspects. The physical responses to pain are facial expression, crying, breathing pattern, arms restrained, leg restrained, state of arousal and psychological response.

The investigator given 33% oral sucrose administration to neonates and assess the pain level through (NIPS) by evaluation of post assessment level of pain.

The findings concluded that the neonate in the experimental group had reduction in the level of pain when compared with control group .Hence the 33% oral sucrose was responded to reduce the IV cannulation pain among neonates.

CHAPTER - VII

SUMMARY

This chapter presents with summary, conclusion, limitations and recommendations for further studies. Further it includes implications of findings of this study in Nursing Practice, Nursing Education, Nursing Administration and Nursing Research.

SUMMARY

This chapter presents a brief summary of the research study. The primary aim of the study was to assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore.

OBJECTIVES:

1. To determine the extent of pain perceived by the control and experimental group of neonates during IV cannulation.
2. To determine the effectiveness of 24% oral sucrose solution upon pain perception of experimental group of neonates during IV cannulation.

3. To determine the association between selected demographic variables and pain perception of control and experimental group of neonates during IV cannulation

The target population is comprised of all neonates admitted at KCG hospital, Malleswaram.

Accessible population refers to the aggregate of cases which confirm to the designated criteria and which to accessible the researchers as a pool of subjects for the study. In this study is comprised of neonates those who are in pediatric unit. The physical location and conditions in which data collection take place in a study. The study will be conducted in KCG hospital malleswaram . It is 6km away from Sarvodaya College Of Nursing, Bangalore. The total bed strength of the hospital is 479. This setting was selected because of the availability of participants and feasibility of conducting the study.

The research design was adopted for this study is a Quasi –experimental design. Post test only design with control group was chosen for this study. Purposive sampling technique was used for this study. Subjects were selected based upon the inclusion and exclusion criteria. 60 subjects were selected for the study. Purposively 30 Subjects were assigned to experimental group and 30 subjects were assigned to control group.

The tool used to collect the data consisted of two parts,

Section A: consisted of the demographic Variables with age, sex, weight of the baby, type of delivery, H/o previous experience of IV cannulation.

Section B 60 consisted of NIPS (Neonatal Infant Pain Scale) developed by Lawrence in 1993. NIPS interpretation:

0 - No pain.

1 - 2 - Mild discomfort.

3 - 4 - Moderate pain.

5 – 7 - Severe pain

validity of the tool was not obtained because the investigator selected a standardized Neonatal Infant Pain Scale developed by Lawrence in 1993. Reliability of the tool was tested by using test-retest method the formula was, $r = \frac{\sum dx dy}{\sqrt{\sum dx^2 \times \sum dy^2}}$ ($r = 0.78$) Data collection was done for 4 weeks. Sample subjects were selected based on the inclusion and exclusion criteria. Demographic variables were collected. Post test was done by using Neonatal Infant Pain Scale. Intervention was done with 33% oral sucrose administration of 2 ml to the selected neonates by using dropper just before introducing a sterile IV cannula into vein of the neonates .

After that collected data were analyzed by both descriptive statistics (inclusive of mean, standard deviation , frequency and percentage) and inferential statistics (inclusive of dependent and paired „t“ test ,chi-square) and results were interpreted in the forms of tables ,figures and diagrams.

Major Findings of the Study:

With regard to the level of IV cannulation pain among neonates, most of them were found to have severe and moderate pain in the control group , as measured by NIPS and experimental Group exhibited only moderate and mild . It revealed that the pain during cannulation which denotes that the reduction of pain was due to 33% sucrose oral administration.

regarding Age among 30 neonates in the experimental group majority of 66.7% were aged between birth -7days, 26.7% are aged between 8-14 days, 6.66% are aged between 15-21 days and among 30 neonates in the control group 70% were aged between 0-7 days, 13.33% are aged between 8-14days , 16.67% are aged between 15-21 days .

In regards of sex among 30 neonates 60% females and 40% males were in the experimental group and among 30 neonates 56.67% were females and 43.33% were males in the control group.

In regards with Weight of the baby: among 30 neonates 76.67% in weight of the baby between 2.501-3.000kg, 16.66% were between 2.251-2.500kg, and 6.67% of baby are above 3.00 kg in experimental group and among 30 neonates 66.67% in weight of the baby between 2.251 – 2.500kg, 16.67% are in between 2.501-3.00 kg 16.66% are above 3.00kg, in the control group,

Regarding the Type of delivery among 30 neonates 63.33% babies are LSCS delivery, 36.67 are normal in the experimental group and among 30 neonates 66.67% babies are LSCS delivery and 33.33 are normal in the control group.

Regarding with Previous experience of IV cannulation among 30 neonates 86.67% were no previous experience of IV cannulation and 13.33% are having the exposure in experimental group and whereas in the control group among 30 neonates 93.33% were no previous experience of IV cannulation and 6.67 are having the exposure.

The pain mean score of group A was 2.3 with standard deviation 0.822 and group B mean score was 4.43 with standard deviation 1.054. The mean difference was 2.13. The obtained „t“ value was 8.247, where as the table value was 3.46. It was significant at $p < 0.001$ level. It was inferred that 33% oral sucrose administration was highly effective in reducing IV cannulation pain among neonates receiving IV cannulation. With regard to the association between the level of IV cannulation pain and selected demographic variables in control group . The study findings had revealed that in post test in the control group there was a no significant association with the level of pain and demographic variables .

CONCLUSION:

The study finally concluded that administration of 2ml 24%oral sucrose administration just before starting IV cannulation for neonates on Iv infusion ,has a positive effect on reducing pain for the neonates. This conclusion was made based on the „t“test value which was found to be highly significant.

CHAPTER - VIII

CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

Newborn infants experience pain just as older children and adolescents experience pain; however, clinicians' ability and approach to assessing and managing neonates is inadequate and controversial. Newborn infants experience acute measurable physiologic, behavioral, metabolic, and hormonal responses to pain. This is because the experience of pain occurs during a critical time of neurologic maturation. In

fact, preterm infants have demonstrated an exaggerated acute response to pain and worse behavioral and sensory long-term outcomes when compared to term neonates

Neonatal pain is best managed using a multi-directional approach which can be conceptualized in a tiered manner and includes non-pharmacologic and pharmacologic modalities.

In a systematic review, Stevens et al. established that in the neonatal population, sucrose significantly reduces pain associated with procedures. While the reported outcomes varied among the studies included in this meta-analysis, patients receiving sucrose were found to have significant reductions in behavioral and physiologic indicators of pain, as well as improvements on several different validated pain scores. Specifically, measures of physiologic response, such as changes in heart rate, oxygen saturation, and vagal tone, were dampened when compared to placebo. The use of sucrose in neonates, when compared to breast milk or pacifier use, has also been associated with a reduction in behavioral indicators of pain, such as crying and grimacing during painful procedures

The present study was designed to assess the effectiveness of 24% of oral sucrose administration in reduction of pain response among neonates during IV cannulation in selected hospital Bangalore was undertaken by Miss. Urita Mohanty in Partial fulfillment of the requirement for the degree of Master of Science in Pediatric Nursing under Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore.

This chapter presents the conclusion drawn, implication, limitation, suggestion and recommendations.

From the finding of the pretest study it was concluded that administration of 2ml 33% oral sucrose administration just before starting IV cannulation for neonates on IV infusion, has a positive effect on reducing pain for the neonates. This conclusion was made based on the „t“ test value which was found to be highly significant. Therefore the awareness of the oral sucrose administration can be further be improved by an ongoing teaching and in service education.

IMPLICATION OF THE STUDY

The findings of the study have several implications in following field. It can be discussed in four areas namely, Nursing practice, Nursing administration, Nursing education and Nursing research..

Nursing Practice

- oral sucrose administration for IV cannulation pain management can be included as nursing procedure to while providing care for neonates during IV cannulation.
- The mothers of neonates undergoing IV cannulation can be encouraged to carry out this method if nurses are occupied by IV cannulation procedure.
- oral sucrose administration alleviates the anxiety and discomfort with in the mother who may feel very much comfortable and happy due to pain reduction in the baby and the baby is calm.
- The oral sucrose administration can be effectively instituted in the pediatric ward and NICU. as the neonates are temporarily separated from mother.

Nursing Education

- Administration of oral sucrose administration during IV cannulation for neonates can be included in the curriculum for 3rd year Bsc nursing course ,along with neonatal care in the pediatric ward and NICU..
- Nursing students should be supervised by instructors while administering oral sucrose administration during IV cannulation so that it can become a routine in NICU.
- Adequate inservice training can be given to the nursing staff and students regarding oral sucrose administration in reducing IV cannulation pain.
- Health education can be given to mothers of newborns in pediatric ward and NICU.

Nursing Administration

- The Nurse administrators can initiate oral sucrose administration to reduce the IV cannulation pain through developmental programme like in-service education and continuing nursing education programme.

- Nurse administrator can prepare written policies and protocols regarding administration of oral sucrose administration during IV cannulation for all neonates in pediatric ward and NICU.

Nursing research

- The nurse researcher can conduct many more studies in different areas of neonatal units to bring about newer perspective in nursing care.
- The study finding will motivate the initial researchers to conduct the same study on large scale and study will be the reference for the extensive and intensive nursing care.

LIMITATIONS

- No limitation was encountered by the investigator during or after the study.

RECOMMENDATIONS

- A similar study can be replicated on a large sample size.
- A similar study can be conducted in different settings such as newborn care units or infant care units.
- A similar study can be done with other intervention to reduce IV cannulation pain such as oral glucose administration, breast feeding to neonates during IV cannulation or various non pharmacological interventions. .

CONCLUSION:

This chapter dealt with the nursing implications, suggestions and recommendation of the study. The overall experience of conducting this study was a satisfying one. This study opens a new area for further research on neonatal pain management.

ACKNOWLEDGEMENT

“Thanks to God for his indescribable gift”

I am grateful to almighty for this grace & blessing throughout my study without which nothing would have been possible. I convey my thanks to all those associated with this research project.

I owe my sincere gratitude to **Patron, Managing Director, Principal of Sarvodaya College Of Nursing** for their expert guidance, valuable suggestions, support and timely help needed for the study.

I wish to acknowledge my sincere gratitude to my **Guide Prof.Mrs.Remya** for her support, valuable suggestions and timely help rendered to me throughout the study.

My sincere thanks to **All the Faculty Members** of Sarvodaya College Of Nursing , Bangalore for sparing their time willingly whenever I approached them. I am grateful to **All Research Tool Validators** who spent their valuable time in validating the tool and helped me with their valuable suggestions and expert advice.

“More than my life” How could I forget to thank my beloved **family?** Finally their love, care, prayer, sacrifice and their every possible effort made me to complete the dissertation without which this course have remained a highly strenuous task.

I am greatly thankful to my **classmates and friends** who help me for encouraging and completing my dissertation timely.

I am greatly thankful to the participants of the study who gave me their valuable time and extended their co-operation during the research project without whom the task would ever be achieved.

I would like to thank the **administrative staff** for their valuable support and co-operation.

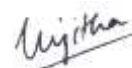
Owing to the slips in my memory, there might be the possibilities of having missed the mention of many individual, who directly and indirectly have stood up to me this far. To all of them, thank you for making my walk possible this far, thank you for putting me back on my feet every now and then when I stumbled.

Thank you for standing by me and thanks a lot for making me accomplish this milestone.

I gratefully acknowledge **Rajiv Gandhi University of Health Sciences, Bangalore**, for providing the opportunity to conduct this research study.

Place: BANGALORE

Signature of Candidate



Date:

MS. URJITA MOHANTY

REFERENCES

1. Linda A. Hatfield. Neonatal pain: What's age got to do with it. *SURGICAL NEUROLOGY INTERNATIONAL* 2014; 5(13): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4253046/> (accessed 15 March 2020).
2. Murkis S and Subramanian S. Sucrose for analgesia in newborn infants undergoing painful procedures. <https://extranet.who.int/rhl/fr/node/75733> (accessed 15th March 2020).
3. Kenneth M Prkachin,. Assessing pain by facial expression: Facial expression as nexus. *Pain ResearchManagement*2014;14(1): .<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2706565/> (accessed 15 March 2020).
4. Dr Anne King. Neonates do not feel pain': a critical review of the evidence. Oxford University Press 2014; 7(14): . <https://doi.org/10.1093/biohorizons/hzu006> (accessed 15 March 2020).
5. Morika D. Williams, B. Duncan X. Lascelles. Early Neonatal Pain—A Review of Clinical and Experimental Implications on Painful Conditions Later in Life. *Front Pediatrics* 2020; 8(30): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7020755/> (accessed 15 March 2020).
6. Royal children hospitals . Sucrose (oral) for procedural pain management in infants. https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Sucrose_oral_for_procedural_pain_management_in_infants/ (accessed 15th March 2020).
7. ZainabSuhrahi, Hamid Taghinejad, KobraValian, KouroshSayehmiri, SafouraTaheri. A Comparative Study on the Efficacy of Glucose and Sucrose on the Vaccination Pain: A Randomized Controlled Clinical Trial. *Journal Clinical Diagnosis Research* 2014; 8(10): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4253236/> (accessed 15 March 2020).
8. WHO. Infant and young child feeding. <https://www.who.int/nutrition/publications/infantfeeding/9789241597494.pdf> (accessed 15th March 2020).
9. Hooten M, Thorson D, Bianco J, Bonte B, Clavel Jr A, Hora J. Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management. Institute for Clinical Systems Improvement 2017; 1(3): . <https://www.icsi.org/wp-content/uploads/2019/01/Pain.pdf> (accessed 15 March 2020).
10. ManalKassab, Jann P Foster, MaralynFoureur, Cathrine Fowler. Sweet-tasting solutions for needle-related procedural pain in infants one month to one year of age. *Paediatric Child Health* 2014; 2012(12): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369933/> (accessed 15 March 2020).
11. ManalKassab, Jann P Foster, MaralynFoureur, Cathrine Fowler. Neonatal procedural pain: a survey of nursing staff. *Paediatric nursing* 2003; 15(5): . https://www.researchgate.net/publication/10686750_Neonatal_procedural_pain_a_survey_of_nursing_staff (accessed 15 March 2020).
12. María Dolores Cárcelos José MaríaAlonso , Martin García-Muñoz, María Dolores Nájera. Amethocaine-lidocaine cream, a new topical formulation for preventing venopuncture-induced pain in children. *Paediatric nursing* 2003; 27(3): . https://www.researchgate.net/publication/11354362_Amethocaine-lidocaine_cream_a_new_topical_formulation_for_preventing_venopuncture-induced_pain_in_children (accessed 16 March 2020).
13. Laura D. Seligman, Thomas H. Ollendick, . Cognitive Behavioral Therapy for children. *PubMed Central* 2003; 20(2): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3091167/> (accessed 16 March 2020).
14. Linda Lefrak, , Kelly Burch, RhetaCaravantes, Kim Knoerlein, Nancy DeNolf, Jill Duncan,. Sucrose Analgesia: Identifying Potentially Better Practices. *PEDIATRICS* Volume 118, Supplement 2, November 2006 2016; 18(2): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3091167/> (accessed 16 March 2020).
15. KhawlaNuseir, ManalKassab,Mohammed Al-Azzani. Sweet Solution Analgesia. *Clinical Nursing Research* 2016; 1(1): . <https://www.intechopen.com/books/pain-relief-from-analgesics-to-alternative-therapies/sweet-solution-analgesia> (accessed 16 March 2020).
16. GabijaPancekauskaitė, LinaJankauskaitė. Paediatric Pain Medicine: Pain Differences, Recognition and Coping Acute Procedural Pain in Paediatric Emergency Room. *Medicina* 2018; 54(6): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6306713/> (accessed 16 March 2020).
17. Manuela Filippa,PierrickPoisbeau, JérômeMairesse, Maria GraziaMonaci, Olivier Baud,PetraHüppi, et al . Pain, Parental Involvement, and Oxytocin in the Neonatal Intensive Care Unit. *Frontiers psychology* 2019; 10(2): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6454868/> (accessed 16 March 2020).

18. Bellieni, Carlo ,Iantorno, L , Perrone, Serafina , Rodriguez, Longini, Mariangela et al . Even routine painful procedures can be harmful for the newborn. PubMed 2011; 147(1-3): .https://www.researchgate.net/publication/26853268_Even_routine_painful_procedures_can_be_harmful_for_the_newborn (accessed 16 March 2020).
19. Ricardo Carbajal,AndreRousset, Claude Danan, Sarah Coquery, Paul Nolent, Sarah Ducrocq, etal. Newborns In ICUs Often Undergo Painful Procedures, Most Without Pain Medication. JAMA 2011; 300(1): . <https://www.sciencedaily.com/releases/2008/07/080701165057.htm> (accessed 19 March 2020).
20. Elaine M Wilson-Smith. Procedural Pain Management in Neonates, Infants and Children. Reviews in pain 2011; 5(3): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4590075/> (accessed 19 March 2020).
21. ZeynepSedaUyan, HülyaBilgen, AhmetTopuzoğlu, IpekAkman, ErenOzek. Comparison of three neonatal pain scales during minor painful procedure. Journal Maternal Fetal Neonatal Medicine 2011; 21(5): .doi:10.1080/14767050802034107 (accessed 19 March 2020).
22. Shepherd AJ, Glenesk A, Niven CA, Mackenzie J.. A Scottish study of heel-prick blood sampling in newborn babies. Midwifery. 2012; 22(2): . doi:10.1016/j.midw.2005.07.002 (accessed 21 June 2020).
23. LiisaHolsti, Ruth E Grunau, EilonShany. Assessing pain in preterm infants in the neonatal intensive care unit: moving to a 'brain-oriented' approach. Pain Management 2014; 1(2): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3161414/> (accessed 21 June 2020).
24. Denise Harrison , Peter Loughnan, Linda Johnston. Pain assessment and procedural pain management practices in neonatal units in Australia. Journal of Pediatric Child Health 2014; 42(1): . <https://pubmed.ncbi.nlm.nih.gov/16487381/> (accessed 21 June 2020).
25. Carbajal R, Paupe A, Hoenn E, Lenclen R, Olivier-Martin M. Evaluation behavioral scale of acute pain in newborn infants. Arch Pediatrics 2014; 4(7): . <https://pubmed.ncbi.nlm.nih.gov/9295899/> (accessed 21 June 2020).
26. Marceau J.. Pilot study of a pain assessment tool in the Neonatal Intensive Care Unit. Journal Paediatr Child Health 2014; 39(8): . <https://pubmed.ncbi.nlm.nih.gov/14629525/> (accessed 21 June 2020).
27. Eva Cignacco, Jan P H Hamers, LilianStoffel, Richard A van Lingen, Peter Gessler, Jane McDougall,etal. The efficacy of non-pharmacological interventions in the management of procedural pain in preterm and term neonates. A systematic literature review. European Journal of Pain 2016; 11(2): . <https://pubmed.ncbi.nlm.nih.gov/16580851/> (accessed 21 June 2020).
28. Gray L, Watt L, Blass EM.. Skin-to-skin contact is analgesic in healthy newborns.. Pediatrics 2011; 105(1): . <https://pubmed.ncbi.nlm.nih.gov/10617751/> (accessed 21 June 2020).
29. Ricardo, Biran, Valerie ,Lenclen, Ralph, Cimerman, . EMLA Cream and Nitrous Oxide to Alleviate Pain Induced by Palivizumab (Synagis) Intramuscular Injections in Infants and Young Children. Pediatrics 2008; 121(1591): . https://www.researchgate.net/publication/5395037_EMLA_Cream_and_Nitrous_Oxide_to_Alleviate_Pain_In_duced_by_Palivizumab_Synagis_Intramuscular_Injections_in_Infants_and_Young_Children/citation/download (accessed 21 June 2020).
30. Moshe Ipp, Anna Taddio, Jonathan Sam, Morton Goldbach, Patricia C Parkin. Vaccine-related pain: randomised controlled trial of two injection techniques. Arch Dis Child 2007; 92(12): . <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2066084/> (accessed 21 June 2020).
31. Ashraf Mohamadzadeh, Farhat A and Khazainejad S. The effect of kangaroo mother care on physiologic responses to pain of an intramuscular injection in preterm neonates. Journal of Nursing & Care 2013; 3(21): . <https://www.hilarispublisher.com/proceedings/the-effect-of-kangaroo-mother-care-on-physiologic-responses-to-pain-of-an-intramuscular-injection-in-preterm-neonates-15816.html> (accessed 21 June 2020).
32. Morrow C, Hidinger A, Wilkinson-Faulk D. Reducing neonatal pain during routine heel lance procedures.. MCN Am J Matern Child Nurs. 2010; 35(6): . doi:10.1097/NMC.0b013e3181f4fc53 (accessed 21 June 2020).
33. Jagdish Prasad Sahoo, SumanRao, SaudaminiNesargi, Thomas Ranjit, Ashok C, SwarnarekhaBhat. Expressed Breast Milk vs 25% Dextrose in Procedural Pain in Neonates: A Double Blind Randomized Controlled Trial. Journal of pediatrics 2013; 50(1): . <https://www.indianpediatrics.net/feb2013/feb-203-207.htm#:~:text=The%20median%20crying%20time%20was,%2C%20Procedural%20pain%2C%20PIPP%20score.> (accessed 21 June 2020).

34. Ben Dilen , Monique Elseviers . Oral Glucose Solution as Pain Relief in Newborns: Results of a Clinical Trial. Birth issues in perinatal care 2010; 37(2): . <https://doi.org/10.1111/j.1523-536X.2010.00389.x> (accessed 21 June 2020).
35. Chermont AG, Falcão LF, de Souza Silva EH, de Cássia Xavier Balda R, Guinsburg R. Skin-to-skin contact and/or oral 25% dextrose for procedural pain relief for term newborn infants.. Pediatrics. 2010; 124(6): . doi:10.1542/peds.2010-0993 (accessed 21 June 2020).
36. De Bernardo G, Riccitelli M, Sordino D, et al. Oral 24% sucrose associated with nonnutritive sucking for pain control in healthy term newborns receiving venipuncture beyond the first week of life. J Pain Res. 2019;12:299-305. Published 2019 Jan 8. doi:10.2147/JPR.S184504

