Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/18649
DOI URL: http://dx.doi.org/10.21474/IJAR01/18649

RESEARCH ARTICLE

A STUDY TO ASSESS THE EFFECT OF CRYOTHERAPY ON PAIN AND SELECTED BIOPHYSIOLOGICAL PARAMETERS DURING AV FISTULA CANNULATION AMONG PATIENTS ON HEMODIALYSIS AT KMCH, COIMBATORE

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Manuscript Info

Manuscript History
Received: 29 February 2024
Final Accepted: 31 March 2024
Published: April 2024

Abstract

The current study entitled 'a study to assess the effect of Cryotherapy on pain and selected Biophysiological parameters during arteriovenous fistula cannulation among patients on maintenance Hemodialysis' at KMCH, Coimbatore was undertaken, during the year 2010 - 2011 in partial fulfillment of the requirement for the degree of Master of Science in Nursing at KMCH College of Nursing, Coimbatore which is affiliated to Dr. M.G.R. Medical University, Chennai.

Objectives: To assess the pain intensity during Xylocaine infiltration. To determine the effect of Cryotherapy on pain and Biophysiological parameters during AV fistula cannulation. To associate the level of pain with selected demographic variables.

Design: Repeated Measures design.

Setting: Hemodialysis unit of Kovai Medical Center and Hospital, Coimbatore.

Sample: Sample size was 50.

Conceptual framework: Modified Orlando's Nursing process model.

Outcome measures: The demographic data was collected from the subjects. The pain intensity was measured during cannulation with Xylocaine and with Cryotherapy using Numerical Pain Rating Scale. The investigator recorded the Biophysiological parameters during the procedure.

Intervention: Cold application was done prior and during cannulation over on the web between the thumb and index finger of the hand which does not have the AV fistula.

Results: The mean pain score with Xylocaine infiltration at arterial site was 4.81 and at the venous site was 4.86. There was a significant reduction in the pain score during cannulation with the application of Cryotherapy. The mean pain scoreduring cannulation after Xylocaine at the arterial site was 1.59 and at the venous site was 1.51 whereas the mean pain score during cannulation after Cryotherapy was 0.96 and 0.92 correspondingly. But there was no statistically significant difference between the values of Biophysiological parameters such as BP, PR and RR during cannulation done with Xylocaine and with Cryotherapy. There was no significant association between pain score and age and gender of the subjects but there was significant association between pain and duration of illness and duration of treatment

Conclusion: Cryotherapy is an effective nonpharmacological measure in reducing pain during AV fistula cannulation among Hemodialysis patients.

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Introduction: -

"Bones can break, muscles can atrophy, glands can loaf, even the brain can go to sleep without immediate danger to survival. But should the kidneys fail . . . neither bone, muscles, gland nor brain could carry on" (Smith, 1953). This statement underlines the value of kidneys in our lives.

The kidneys excrete a number of end products of metabolism in urine. The kidneys eliminate these substances from the body at a rate that matches their production. In addition, to the metabolic wastes, the kidneys also excrete foreign substances from the body such as drugs, pesticides and other chemicals ingested in the food. Regulation of water and inorganic ion balance and regulation of acid-base balance are also the functions of kidneys. So, the proper functioning of the kidneys is highly essential for the normal bodily homeostasis. If there isa complete kidney failure and treatment is not given, death is inevitable.

End-stage renal disease (ESRD) or Chronic RenalFailure (CRF) is a worldwide public health problem. It is a mammoth medical, social and financial crisis for both patientsand their families. Among India's total population, around 7.85 million are suffering from CRF. This condition is a progressive, irreversible deterioration in renal function in which the body fails to maintain metabolic and fluid and electrolyte balance and results in uremia orazotemia (retention of urea and other nitrogenous wastes in the blood) The incidence of ESRD has increased by almost 8% per year in the past 5 years, with more than 3, 00,000 patients being treated in the United States (USRDS, 2001). Comorbid conditions contribute to the high morbidity and mortality among patients with ESRD. Dialysis or kidney transplantation becomes necessary for patients' survival.

A patient with chronic kidney disease (CKD) requires astute nursing care to avoid the complications and to manage stress and anxiety of dealing with a life-threatening illness. The increasing prevalence of CKD and its associated symptoms is a major concern for nurses and health professionals attempting to provide these patients with comprehensive care. Methods of therapy for CRF include dialysis and kidney transplantation.

Dialysis is an effective means of correcting metabolic toxicities at any age (Wood etal., 2001). It is used to remove fluid and uremic waste products from the body when the kidneys cannot do so. The need for the dialysis may be acute or chronic. Chronic or maintenance dialysis is indicated in CKD when there are uremic signs and symptoms affecting all body systems, hyperkalemia, fluid overloading not responsive to diuretics andfluidrestriction and general lack of wellbeing. Dialysis can be either hemodialysis or peritoneal dialysis.

Hemodialysis is the most commonly used method of dialysis and it is used for patients who are acutely ill and require short term dialysis (days to weeks) and for patients with ESRD who require long term or permanent therapy. In hemodialysis, the blood laden with toxins and nitrogenous wastes is diverted from the patient to the dialysis machine, in which the blood iscleansed and then returned to the patient. A Dialyzer serves as a synthetic semi permeable membrane, replacing the renal glomeruli and tubules as the filter for the impaired kidneys. For patients with ESRD, hemodialysis prevents death, but it neither cures renal disease, nordoes it compensate for the loss of endocrine or metabolic activities of the kidneys. Patients receiving hemodialysis must undergo treatment for the rest of their life or until they undergo successful kidney transplantation. Patients receive chronic or maintenance dialysis is usually done three times a week for atleast 3-4 hours per treatment.

Obtaining vascular access is one of the most difficult problems associated with Hemodialysis. Access to the patient's vascular system must be established to allow blood to be removed, cleansed and returned to the patient's vascular system at rates between 200- 800ml/min. Several types of access are available include arteriovenous fistulas (AVFs) andgrafts (AVGs), permanent and semi permanent catheters, subcutaneous ports and shunts for the cannulation to start hemodialysis. Hemodialys is the most frequently used Renal Replacement Therapy with the AVF being the gold standard for vascular access which is surgically created by anastomizing an artery to a vein, either side to side or end to side. The arterial segment of the fistula is used for arterial flow and the venous segment for reinfusion of the dialyzed blood. The fistula takes 4-6 weeks for maturation before it is ready for use. This gives time for healing and for the venous segment of the fistula to dilate to accommodatetwo large-bore (14-16 gauge) needles used in hemodialysis. The patient is also encouraged toperformexercisetoincreasethesize ofthesevessels (i.e., squeezing a rubber ball for forearm fistulas). Once mature, native fistulas have excellent long term patency rates and rarely become infected. Palder et al (1985) have reported that primary AV fistulas provide adequate vascular access for even 20 years. On an average, a patient on maintenance Hemodialysis undergoes 12 AV fistula punctures a week and would continue to do so throughout their lifetime or until a successful renal transplantation.

International Association for Study of Pain, (1979) defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Epidemiologic data of pain in patients with ESRD are extremely limited; however, recent studies have shown that moderate to severe chronic pain is common in ESRD.The literatures suggest that 37% to 50% of hemodialysis patients experience chronic pain and that for 82% of these patients' pain is moderate to severe inintensity (Davidson, 2003). Moreover, pain during arteriovenous fistula cannulation remains acommon problem in Hemodialysis patients. Most of the patients complain of moderate painduring AV fistula cannulation. Many healthcare institutions have integrated local anesthesia into the standard of care for patients during AV fistula cannulation. Intradermal Lidocaine is a vasoconstrictor, so it may cause the vein to become smaller and sometimes make it a little deeper. It causes a bee sting-type burning sensation that can be minimized by injecting the Lidocaine more slowly. There are no studies citing scarring from Lidocaine use. However, certain ethnic groups form keloid scars that can make cannulation through them very difficult (Ball, 2003). In the researcher's clinical experience, many patients on Hemodialysis have complained pain during AV fistula cannulation but, majority of the patients with renal failure on Hemodialysis reported that pain during injection of local anesthesia as more terrible than the pain from the cannulation itself.

"It would be good for us to remember that one of the greatest gifts we can share with others inpain, despair, or confusion is a clear sense of our peace and knowledge that we are loved"
RobertJ. Wicks

Now a days, health professionals increasingly focus on the management of pain to improve the quality of life for many patients living with chronic and terminal pain (Ferrell,1996; McCaffery & Ferrell, 1997; Howell, et al., 2000). Pain management is now considered as the significant patient outcome when evaluating the effectiveness of nursing care (Padilla et al., 1990; Ferrell et al., 1991; Barnason et al.,1998). However, a substantial body of research indicated that pain continues to be a problem for 45-75% of hospitalized patients who report experiencing moderate to severe levels of pain (Nash et al., 1994; Carr & Thomas,1997; Breitbart, Rosenfeld, &Passik, 1998; Yates et al., 1998) despite educational programs aimed at improving nurses' pain management. Pain control among ESRD patients is a challenge to the health care providers due to the relationship between medication clearance and renal function. This leads to under treatment of pain or over sedation and untoward side effects/complications when using certain types of medications (Rehm, 2003). Here comes the need for alternative therapies in managing pain in patients with CRF.

Non-pharmacologic pain management strategies can reduce the dose of an analgesic required to relieve pain and thereby minimize the side effects of drug therapy. Many studies have shown that alternative therapy techniques have a dramatic impact on the overall health and performance of persons with even high levels of chronic pain. Those interventions are suitable for procedures such as IV insertion that cause acute, transitory pain (Jacobson, 2006) by increasing patient's sense of personal control about managing their pain and bolster their coping skills. Benefits include possibly no side effects, a more positive patient experience, enhanced comfort, and an improved perception towards the procedure.

Cryotherapy is a convenient and simple alternative pain management technique in which cold is used for the treatment of injury or disease that can help the person to reduce pain quickly and cost effectively. The application of Cryotherapy has a long history, havingbeen used in the ancient Greek and Roman civilizations. Its primary objective is to lower the temperature of a tissue and thereby achieve a therapeutic benefit by suppressing the metabolic rate of the tissues thus preventing the tissue damage that can be caused by hypoxia. In addition, vasoconstriction is induced, which reduces pain, bleeding and edema in damaged tissues. Today the use of Cryotherapy is widespread in the medical arena. Studies haveproven that it is an established method used in treating acute soft tissue injuries and as part ofthe treatment protocol for chronic injuries. Cryotherapy has also been proved to reduce pain effectively and reduce the recovery periodin the postoperative time after reconstructive surgery of the joints.

The Gate Control Theory of Pain emphasizes on the modulation of inputs in the spinaldorsal horns and the dynamic role of the brain in pain processes. Psychological factors are found to be an integral part of pain processing and new avenues for pain control were opened. Based on the gate control theory, chronic pain tends tomovea C-fiber pathway. Once the slow pain message reaches the brain, it takes a pathway to the hypothalamus and limbics ystem where the hypothalamus is responsible for the release of certain stress hormones in thebody, while the limbic system is responsible for processing emotions. The brain sends signalsdown the spinal cord to open and close the nerve gates. If the person is in anxiety or in stress, descending messages from the brain amplify the pain signal at the nerve gate as it moves upthe spinal cord. Alternatively, impulses from the brain "close" the nerve gate, preventing the pain signal from reaching the brain and being experienced as pain. Most of the techniques in developing non-pharmacological treatments are based on these principles.

In addition to that, there are two types of nerve fibers that carry the majority of pain signals to the spinal cord: small diameter un myelinated (A-delta) fibers and large diameter myelinated (A-beta) fibers. Physical stimulation such as rubbing, massage, and vibration cause excitation in the A-beta nerve fibers, which conduct the signal more quickly than the A-delta fibers, where pain due to tissue injury is transmitted. If a pain signal is traveling to the brain via the A-delta fibers and a simultaneous physical stimulation signal is sent via A-betafiber, the physical stimulation signal will reach the brain first because they move more quickly than the pain signal. This supports the concept of cutaneous stimulation in pain management.

Need For The Study

Over 1 million people with CRF worldwide are alive on dialysis with a functioning graft. Incidence of CKD has doubled in the last 15 years. In India, reports reveal that there is an increase in the prevalence of CKD by 53% as compared to the statistics a decade ago. It is one of the most common illnesses in the country as it is estimated that there is one CKD patient in every 2000 population.

Pain management of patients with chronic renal failure is an important aspect of care. Pharmacological pain management in renal failure is complex and is to be conducted with caution, because of the fine line between pain relief and toxicity, and consideration of the patient's concomitant health problems that influence the type of analgesia given. The alternative Medicine is an area of healthcare that has been rapidly evolving over the past few years. Some of the practices have been around for centuries, while others have become popular within the last few decades. Recent researches support non-pharmacological pain control measures such as distraction, especially humor, relaxation using the patient's own memory of peaceful events, and cutaneous stimulation, especially use of cold. Cutaneous stimulation can be effectively used at sites other than the site of pain (**McCaffery,2000).**

Moreover, during ten years of clinical experience, the researcher could recognize the need for alleviating pain with some non-pharmacological method for patients who are suffering from pain throughout their life time. Hence, the researcher identified the need for implementing some alternative therapies in managing procedural pain during AV fistula cannulation among Hemodialysis patients because she felt that the patients with CRF who are on dialysis suffer a lot with chronic as well as procedural pain. In addition to, the researcher was interested to find out the effect of Cryotherapy in pain so that it can be effectively used in managing pain in various conditions. This study was therefore undertaken to find out the effectiveness of the Cryotherapy on pain during AV Fistula puncture in HD patients so that it can be implemented in such population as evidence-based practice.

Statement Of The Problem

Effect of Cryotherapy on pain and selected Biophysiological parameters during arteriovenous fistula cannulation among patients on Hemodialysis at KMCH, Coimbatore.

Objectives Of The Study Were To:

1. Assess the pain intensity during Xylocaine infiltration
2. Determine the effect of Cryotherapy on pain and Biophysiological parameters during AVfistula cannulation.
3. Associate the level of pain with selected demographic variables

Operational Definitions

Effect – in terms of reduction of pain and change in Biophysiological parameters which is brought about by Cryotherapy

Cryotherapy – is the application of cold by using ice cubes over twelve minutes at LI4 meridian which corresponds to the web space between thumb and the index finger of the hand

Pain – an unpleasant sensory and emotional experience as measured by Numerical Pain Rating Scale (NPRS) during AVfistula cannulation

Hemodialysis - is a procedure by which toxin laden blood is diverted from the patient into a dialyzer and then returning clean blood to the patient

AV Fistula cannulation – is the venipuncture of the surgically created connection between a vein and an artery to use as a vascular access for Hemodialysis

Biophysiological parameters – refers to blood pressure, pulse rate and respiratory rate of the patient

Patients – are those who are diagnosed to have chronic renal failure and are on maintenance hemodialysis

Hypotheses

1. There will be significant difference between patients who receive Cryotherapy and those who receive Xylocaine in pain during AVFistula cannulation.
2. There will be significant difference between patients who receive Cryotherapy and those who receive Xylocaine in Biophysiological parameters during AVFistula cannulation.

Assumptions

1. Patients who undergo hemodialys experience pain during AV fistula cannulation
2. Pain will have an effect on Biophysiological parameters
3. Level of pain varies from person to person

Conceptual Framework

"Nursing is a distinct profession providing direct assistance to individuals in whatever they are found for the purpose of avoiding, relieving, diminishing or curing the individuals sense of helplessness"(Orlando,1972)

According to Orlando, the role of the nurse is to find out and meet the patient's immediate need for help. Therefore, nurses need to use their perception, thoughts about the perception or the feeling engendered from their thoughts to explore with patients of their behavior. This process helps nurse to find out the nature of the distress and what help the patient needs. Orlando's conceptualization of the deliberative nursing process fulfills the criteria of a theory. Incorporating validation into the nursing process discipline allows for maximal participation by the patient in his or her care. The nursing process discipline allows nurses to view the patient from a nursing perspective rather than from a medical disease orientation.

Nurses' action is to solve the patient's problem by applying cryotherapy which is a non-pharmacological measure for pain relief. This action helps in pain reduction and improves the patient's comfort. Moreover, nurse-patient interaction enhances the psychological well-being of the patients.

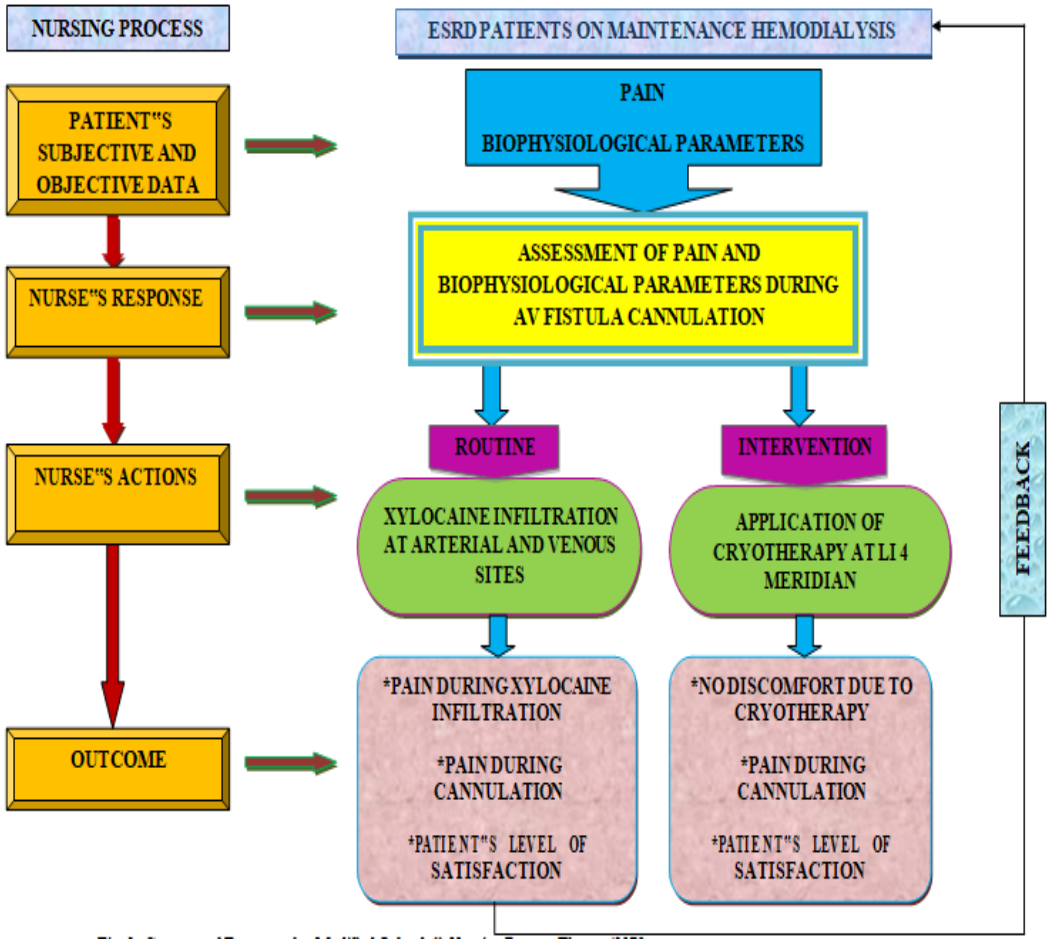

Fig.1: -ConceptualFramework–Modified Orlandos Nursing ProcessTheory (1972).

Review Of Literature: -

Literature Related to Hemodialysis and AVfistula

ESRD is a worldwide publichealth problem and concern with increasing incidence and prevalence, poor patient out comes and high cost. In 2002, Chalmers defined Chronic Renal Failure as a gradual and progressive loss of the ability of the kidneys to excrete wastes, concentrate urine, secrete hormones and conserve electrolytes. End stage kidney failure is the deterioration in renal function to the stage where renal dialysis or transplantation is required for survival (Terrill2002).

In 2002, Antolin and his colleagues have performed a retrospective analysis with a follow-up time of seven years among 3106 hemodialysis patients and 542 peritoneal dialysis patients and they studied on the significance of co morbidity factors such as age >70 years,cardiovascular disease, liver disease, diabetes mellitus and dyslipidaemia. They observed that the global survival as the same in both groups upto 32 months of treatment and they identified that those with comorbidity had a better survival on hemodialysis.

Kevan et al has conducted a study in 2001 on epidemiology of vascular access in theAustralian Hemodialysis population. The findings of the study revealed that despite a high overall prevalence of AVF use in Australia, a significant number of patients had AVG and catheter with age, gender and late referral were found to be reasons.Their study concluded that the provision of adequate pre-ESRD care for all patients with renal failure is required tofurther enhance the utilization of AVF and to reduce catheter rates in patients commencing hemodialysis as renal replacement therapy to minimize the detrimental effects of other vascular accesses.

Chhetri et al (2009) carried out a study on vascular access in Nepal among 82 patients attending HD unit over a period of one year. The analysis of the observed data revealed to the investigators that initial vascular access used was temporary ones such as sub clavian and internal jugular vein catheters. Only 47 patients were analyzed for the

second vascular accessand was found to be associated with feverin 7 (14.9%) and limb swelling in 1 (2.1%). Complications with the vascular accesses were found negligible by the investigators.

Deiham (2010) has investigated on determinants of hemodialysis on access survival. The investigator retrospectively analyzed the vascular access procedures performed over a two-year period and clinical data and concomitant medication were retrieved from files. Outcome parameters observed were primary (PP) and secondary patency (SP) and also freedom from repeated revascularization. The investigator's minimal follow-up with functioning access was 679 days. During the observation period, 244 patients underwent vascular access procedures. PP and SP were 35.6 % and 45.6 %, respectively, at 540 days. Presence of diabetes mellitus was associated with decreased PP and SP, whereas femalegender was associated with lower SP and freedom from repeated revascularization rates. Incontrast, presence of hyperparathyroidism was observed by the investigator as associated with higher SP and freedom from repeated revascularization rates.

Literature Related to effect of Cryotherapy and Gate Control Theory

Among the physical treatments to reduce pain, ice has had its place for many years. Cryotherapy is the simplest and most commonly used method in the treatment of acute musculoskeletal injury to reduce pain and inflammation. It is used to reduce tissue temperature and has various physiological effects i.e. vasoconstriction of blood vessels, decreased localmetabolism, decreased blood histamine release during inflammation and reduced nerve excitability (Schafer,1990). This makes Cryotherapy first in line for management of acute injuries concerning swelling, bleeding and pain relief (MacAuley,2001). Among chiropractic practitioners it is the most often utilized (94.5%) passive adjunctive therapy.

In the early 1960s, Melzack and Wall had described Gate Control Theory of pain dindetail as follows: stimulation of the skin creates nerve impulses to the spinal-cord and it either gets inhibited nerve impulses or enhanced at the level of the spinal cord. Nerve impulses traveling toward the brain in smaller nerve fibers of the spinal cord proceed at a steady rate. Continuous discharge keeps the pain gate open and enhances the transmission of pain. Burst-type impulses are mainly inhibitory and have the effect of keeping the pain gate partially closed resulting in diminishing the perception of pain intensity. When the large fiber impulses get artificially stimulated by vibration, scratching, or ice massage, the gate further closesresulting in a decrease in the sensation of pain. That was the reason for ice being successfully used in the treatment of musculoskeletal pain over the years. Melzack studied the use of ice massage of the web of skin between the thumb and forefinger for the reduction of acute dental pain. His work showed a 50 percent reduction in acute dental pain.

Melzack and Wall did not explain in their study that how they decided on the selected anatomical area to use ice massage. However, the two Physicians did studies comparing acupuncture to transcutaneous electrical nerve stimulation for pain relief. They have located within the anatomical area on the hand, as acupressure meridian point described in Acupuncture literature as Hoku or Large Intestine 4 (LI4). Large Intestine 4 has a pathway which travels from the tip of the forefinger up to the face and circles the teeth; it bifurcates at the shoulder to move downward wrapping around the entire colon. According to them, theskin between the thumb and forefinger is part of the thick, hard, and horny texture of the palm which can withstand the intermittent friction and cold temperatures used in this technique.

In 1994, Park, studied to identify the effect of cutaneous stimulation on reduction of AVF puncture pain. One group repeated measure post test research was designed and carried out among 45 hemodialysis patients. The researcher measured AVF puncture pain of control period first, and then the pain of experimental period (with cutaneous stimulation). He observed that the subjective pain scorein experimental period was slightly lower than in control period but the objective pain behavior score of arteriovenous fistula pain in experimental period was observed as higher.

Waters and Raisler conducted a study on ice massage for the reduction of labor pain in 2003. They have investigated the use of ice massage over the acupressure energy meridian point large intestine 4 (LI4) to reduce labor pain during contractions. A one-group, pretest-posttest design was chosen by the investigators in which they used Visual Analog Scales (VAS) and the McGill Pain Questionnaire (MPQ) ranked numerically and verbally to measurepain levels. They used pretest as the control group. The investigators noted a pain reduction mean on the VAS of 28.22 mm on the left hand and 11.93 mm on the right hand. The post delivery rank was reported as MPQ

dropped from number 3 (distressing) to number 2 (discomforting). The study results supported that ice massage is a safe, non invasive, non-pharmacological method of reducing labor pain.

Klein **(**2009) studied that Cryotherapy has the primary effect of cooling tissue. The researcher identified basic physiologic effects such as decreased local metabolism, vasoconstriction, reactive hyperemia, reduced swelling/edema, decreased hemorrhage, reduced muscle efficiency, analgesia secondary to impaired neuro muscular transmission, pain reduction associated with the application of cold, reduction in muscle spasm and minimal upper motor neuron spasticity based on method of application and duration of the therapy.

Sabitha et al (2010) has undertaken a study to assess the effect of Cryotherapy on paindue to AVF puncture in hemodialysis patients. A convenient sample of 60 patients (30 inexperimental and 30 in control groups) who were undergoing hemodialysis by using AVF were assessed in a Randomized Control Trial by the group. The objective and subjective AV pain scores on days1and 2 of HD within the experimental group were found to be significantly reduced from an average of 3.8 on day 1 of HD (when the patient received routine care) to 0.7. Pain scores on days 1 and 2 of HD within the control group were found to be similar on two consecutive days of HD. They have concluded that cryotherapy is effective in reducing AVfistula puncture pain of hemodialysis patients.

Literature related to pain measurement and pain management in CRF

Patients with renal failure often experience pain. Moreover, they suffer from the pain during AV fistula cannulation every other day which is unavoidable as dialysis is their life-saving treatment option. But local anesthesia is not often used due to concerns of vasoconstriction, burning sensation, scarring, and infection in most of the dialysis centers. Optimal pain assessment and management are key clinical activities yet inadequate pain control among renal patients by health professionals persists.

Cohen et al (2000) conducted a prospective observational study among 131 renalpatients who have withdrawn themselves from the dialysis treatment demonstrated that 42% of patients experienced pain in their last 24 hours and due to pain during AVfistula cannulation.

A Research into Pain Perception with Arteriovenous Fistula Cannulation conducted by Figueiredo etal (2008) recorded that patients with end-stage renal failure undergoing haemodialysis are repeatedly exposed to stress and pain from frequent punctures to their arteriovenous fistula. The objective of the study was to measure pain associated with AVF needling and they used an analogue visual scale. Patients' perceptions were measured in three different HD sessions. Pain was considered mild during AVF needling. The button hole technique caused a mean degree of pain of 2.4 (±1.7), compared to 3.1 (±2.3) using the conventional rope ladder technique. They could analyze reduction in pain from the collected data associated with the buttonhole technique.

Literature related to factors affecting Pain and Biophysiological parameters

A study conducted by Tanaka et al (2001) investigated to compare the effect of two types of superficial Acupuncture stimulation using various physiological parameters and pain index. The subjects were10 chronic tension type headache sufferers and 2 types of Acupuncture procedures were administered. At the beginning and end of the experiment session, the investigators asked the subjects to rate the headache intensity with a VAS. Following the stimulations, the static EMG, heart rate and pulse height were continuously monitored for 30 min. Thirty minutes after the first stimulation, an averaged 59.1% pain scorereduction was obtained whereas the second stimulation produced only an averaged 21.9 %pain scorereduction. They found no statistically significant difference in the EMG, heart rate, and pulse height.

Bossart et al (2004) performed a prospective, observational study to determine the correlation between change in heart rate (HR) and change in pain among 975 Emergency Department (ED) patients. They included a convenience sample of patients presenting to an academic ED with pain. Heart rate and pain intensity were determined at the time of triage, 30min post pain treatment, and at discharge. They have finished the study stating that there was a poor correlation between change in pain intensity and change in heart rate among ED patients with acute pain. To sum up, pain is not just physiological response, but the psychological variables like behavioral and emotional responses influence the perception of pain. Each person is reacting to pain in a different way. Rarely studies have been conducted on the measures to reduce the pain experienced during procedures. Considering this aspect the

researcher was interested to conduct the study to reduce the pain perception during AV fistula cannulation with the application of Cryotherapy. The purpose of which was to aid cost effective nursing care if found effective.

Methodology:-

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Research Design

The design adopted for the study is Repeated Measures Experimental Design (Crossover Design).
Schematicrepresentationofthe design:

E X1 O1 X2 O2 X1 O3 X2 O4 X1 O5 X2 O6

X1 – With Xylocaine X2 - With Cryotherapy

O1 - Observation 1 with Xylocaine on day 1
O2 - Observation 2 with Cryotherapy on day 2
O3 - Observation 3 with Xylocaine on day 3
O4 – Observation 4with Cryotherapy on day 4
O5 – Observation 5with Xylocaine on day 5
O6 – Observation 6with Cryotherapy on day 6

The researcher used Repeated Measures Design to accomplish the study because Pain is as ubjective variable which changes time to time.

Variables Under Study

In this study, the independent variable was Cryotherapy and the dependent variables were Pain and Biophysiological parameters namely Blood Pressure, Pulse rate and Respiratory rate.

Setting Of The Study

The study was conducted at Kovai Medical Centre and Hospital, Coimbatore. It is an 800 bedded super specialty hospital. KMCH has got an exceptional Hemodialysis departmentrun for 24 hours a day. There are 2 dialysis units, one for infected patients and the other for non-infected patients. Totally, there are 15 hemodialysis machines, 5 for the infected cases and 10 for the non-infected cases. There are 5 technicians and 20 staff nurses for the unit and the unit performs approximately 60 Hemodialysis per day.

Population

Population for the study were the adult patients with Chronic Renal Failure who were undergoing Hemodialysis at KMCH Hemodialysis unit.

Sample Size

Sample size for the study was 50. The same subjects were exposed both to routine care and to the intervention on alternative days.

SamplingTechnique

Simple random sampling technique was adopted to select the sample from the population. Totally, 93 patients were there under the consultant Nephrologist. Out of them, 78 patients have met the inclusion criteria. Lottery method without replacement was adopted to select 50 samples by giving equal chance to each patient to be as a subject in the study.

Criteria For Sample Selction

Inclusion criteria

1. Patients who undergo maintenance Hemodialysis with AV fistula as the vascular access
2. Both male and female adult patients between the age group of 20-60 years
3. Patients who undergo atleast three Dialysis per week

Exclusion criteria

1. Patients with any Psychiatric illness

2. Patients who do not report any pain during the procedure.

Development Of The Tool

The tools used in this study consisted of 3 sections:

Section-1- Demographic and clinical profile

It included age, sex, maritalstatus, occupation, and educational status, duration of illness and duration of treatment.

Section -2- Biophysiological parameters

Measurement of blood pressure, pulserate, respiration rate during cannulation.

Section -3- Numerical pain rating scale (NPRS)

It was a 10-point subjective pain rating scale with 1cm= 1point in which 0 represents no pain and the pain intensity increases and the worst possible pain is represented by the point 10.

Description Of The Tool

Omron digital automatic monitor was calibrated for BP and pulse from the biomedical department. For the respiratory rate, inter rater reliability showed r=0.96.

Reliability and Validity of NPRS

The Numeric Pain Rating Scale has demonstrated good levels internal consistency with Cronbach‟s alpha co-efficient of 0.86 - 0.88 and test-retest reliability co-efficient ranged from 0.57-0.83 suggesting acceptable reliability of the measures. (Hadjistarropoulos etal2007). Herr and colleagues (2004) reported that a factor analysis showed that the Numeric Pain Rating Scale was valid. The validity of the NPRS has been well documented, and has demonstrated significant, positive relationship with other measures of pain intensity and sensitivity to changes due to treatment.

Description Of The Intervention

The primary purpose of the intervention (application of cryotherapy) was to reduce the pain intensity of the subjects during AV fistula cannulation. The required ice cubes for the application were kept ready in the freezer by the investigator. The prepared ice cubes were of 6-8 degree Celsius. Explanation regarding the procedure was given after making the subject lie comfortably on bed in the dialysis unit. Cold application was done on the web between the thumb and index finger of the hand which does not have the AV fistula (opposite arm). The procedure was started ten minutes before cannulation and was continued throughout the puncturing procedure and until two minutes after the procedure. Biophysiological parameters were recorded during cannulation and the pain was assessed with cannulation after Cryotherapy both at the arterial and venous sites of the AV fistula.

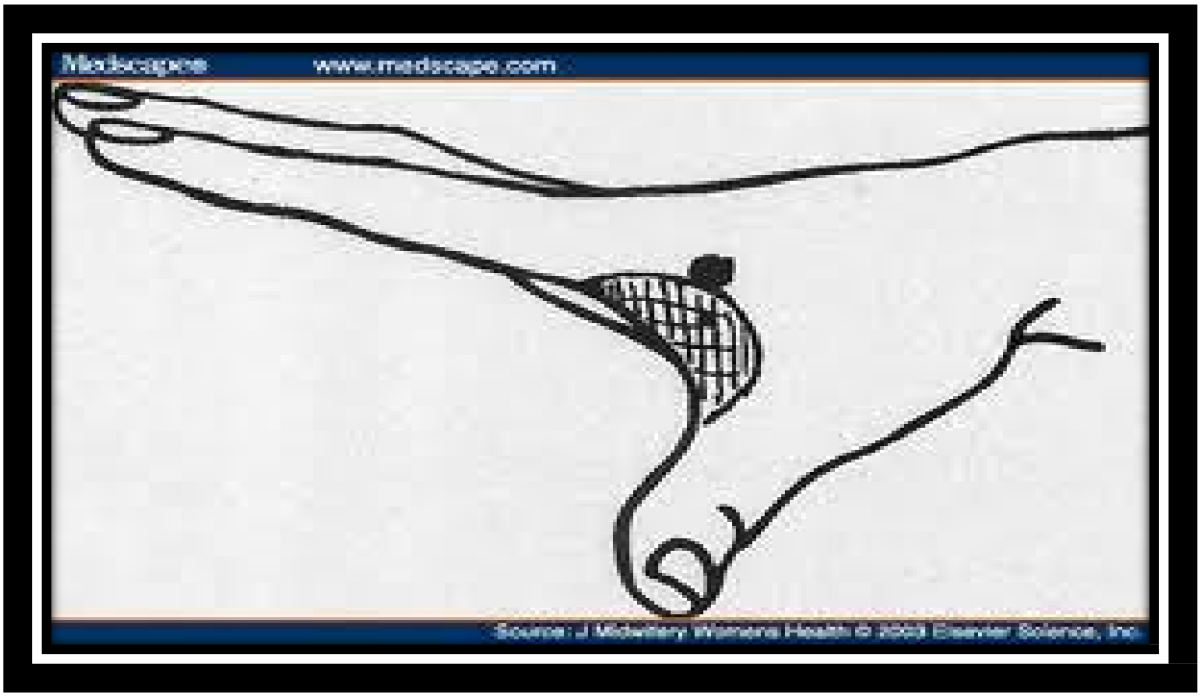

Fig. 2: - Anatomicallocation of LI4 Meridian/ Hoku point.

Pilot Study

Pilot study was conducted for a week among 5 patients to find out the feasibility of the study, the practicability of the intervention and to make sure the protection of the human subjects. The pilot study revealed the consistency of the application of Cryotherapy in reducing the pain during AV fistula cannulation. No changes were made in the methodology after the pilot study as the results were reasonable.

Procedure For Data Collection

Formal permission was obtained from the Chairman of the hospital and the consultant Nephrologist, KMCH.The permitted time for the data collection was 6 weeks. Subjects were selected based on the inclusion criteria. The investigator explained the details and benefits of the intervention. An informed consent was obtained from the subjects, and explained abouttheir right to withdraw from the study at any time. The demographic data were collected from the subjects and the clinical data were retrieved from the file. Each subject was followed for six consecutive days of dialysis. The calibrated Omron digital automatic monitor was used measuring BP and pulse rate. The researcher counted the respiratory rate manually. On the first, third and fifth days of Dialysis, cannulation was done with Xylocaine infiltration. Biophysiological parameters were recorded during cannulation and the pain was assessed with Xylocaine infiltration and with cannulation both at the arterial and venous sites of the AVfistula using NPRS. On second, fourth and sixth days of dialysis, the data were collected when the subjects were given Cryotherapy.

Statistical Analysis

The data collected were analyzed by descriptive statistics by means of Mean, Standard Deviation, and Percentage to describe the demographic characteristics of the subjects and to describe the pain intensity of the subjects during Xylocaine infiltration and during AV fistula cannulation. Inferential statistics namely, paired and independent 't' test were used to compare the pain intensities and biophysiological parameters measured during various observationsduring cannulation done with Xylocaine infiltration and with Cryotherapy. One-way ANOVAwas performed to associate the pain intensity and selected variables.

Data Analysis and Interpretation

The science of collection, analysis, interpretation or explanation, and presentation of data is statistics. In fact, all the data collection and interpretation techniques used in Researchare part of statistics. It makes use of descriptive statistics for collection of data and inferential statistics for drawing inferences from the set of data. This chapter deals with the analysis and interpretation of the data collected to assess the effect of Cryotherapy on Pain and Biophysiological variables during AVfistula cannulation among patients on Hemodialysis.

The analyses and interpretation are organized as follows:
SECTION A: Description of Subjects according to their Demographic and Clinical profile
SECTION B: Description about the Mean Pain score of the Subjects
SECTION C: Description about the Biophysiological parameters during Cannulation
SECTION D: Comparison of the Mean Pain score on various Observations
SECTION E: Comparison of Biophysiological parameters on various Observations
SECTION F: Comparison of Pain score during AV fistula cannulation done with Xylocaine and done with Cryotherapy.
SECTION G: Comparison of Biophysiological parameters during AV fistula cannulation done with Xylocaine and done with Cryotherapy.
SECTION H: Association of Pain scores with selected Demographic and Clinical variables

SECTION A
Description of Subjects according to their Demographic and Clinical profile:
Table 1:- Description of Subjects according to their Demographic profile.

S. No	Demographic variables	f (N=50)	Percentage (%)
1.	Ageinyears		
	a) 21-30	10	20
	b) 31-40	8	16

	c) 41-50 d) 51-60	18 14	36 28
2.	Sex a) Male b) Female	 41 9	 82 18
3.	Marital status a) Single b) Married	 5 45	 10 90
4.	Educational status a) Primary b) Secondary c) Highersecondary d) Graduate e) Postgraduate	 9 20 10 6 5	 18 40 20 12 10
5.	Occupational status a) Employed b) Unemployed	 38 12	 76 24

Table 1 represents distribution of subjects according to their demographic characteristics. Out of 50 subjects; maximum subjects (18) were in the age group of 41-50. Regarding gender, 41 (82 percent) were males. According to their marital status, majority of them 45 (90 per cent) were married. 40 per cent of the subjects had secondary education and 10 had higher secondary education.38among50(76percent) subjects were employed.

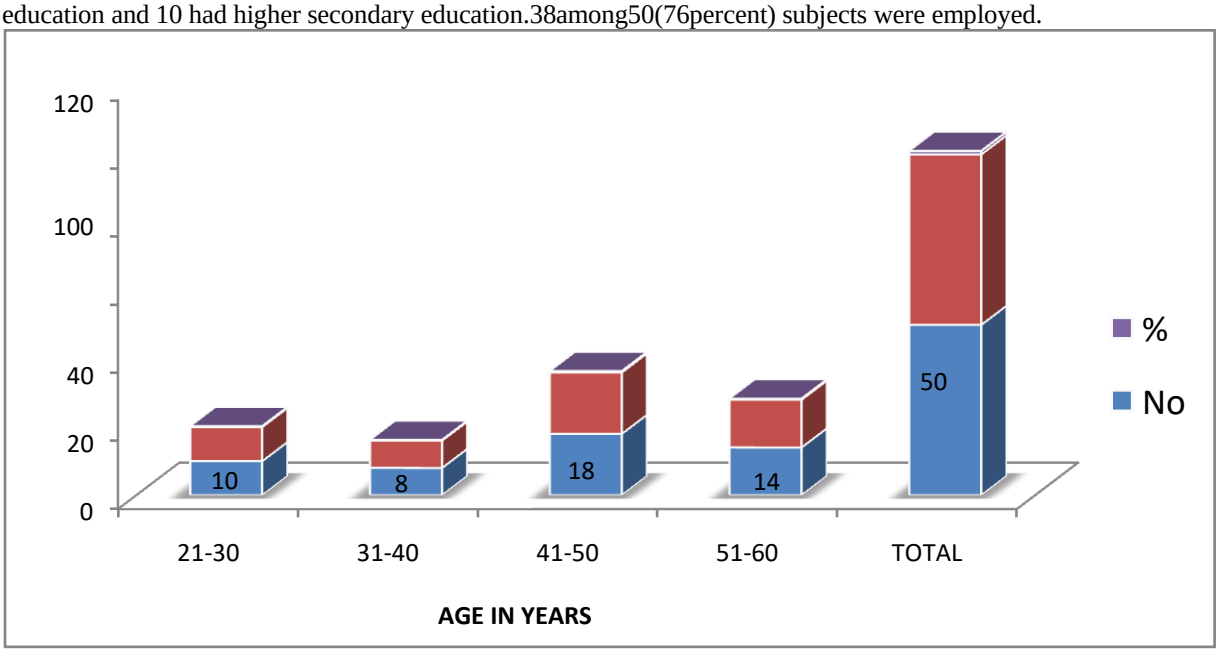

Fig.3:- Age wise distribution of the subjects.

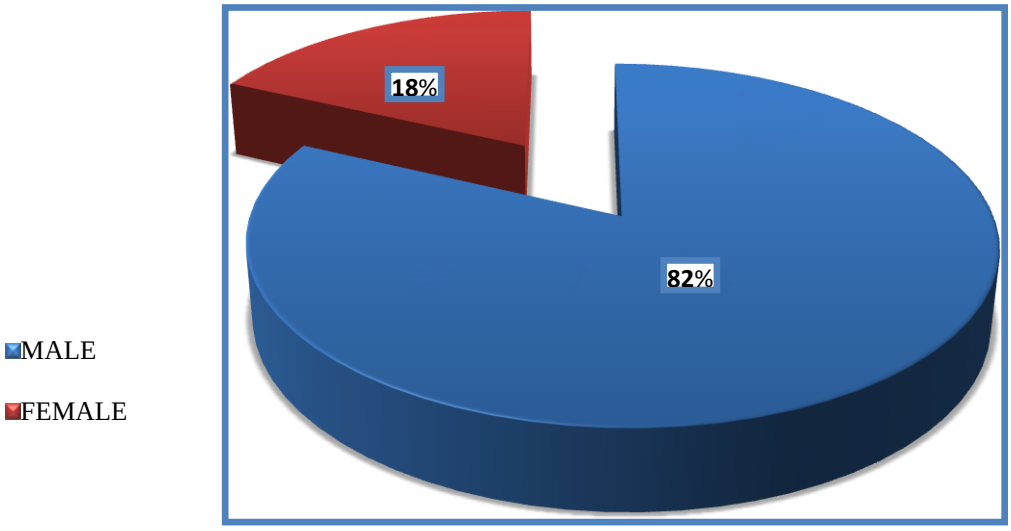

Fig.4:- Gender wise distribution of the subjects.

Table2: - Description of the Subjects according to their Clinical profile.

S. No	Characteristics	f (N=50)	Percentage (%)
1.	Duration of illness in years		
	a)1-3	12	24
	b)3-5	23	46
	c)5-7	15	30
2.	Duration of Hemodialysis in years		
	a)1-3	31	62
	b)3-5	9	18
	c)5-7	10	20

Table2 shows that 23(46 percent) subjects were suffering from renal failure for the past 3-5years and 31(62 percent) were undergoing Hemodialysis for a period of 1-3years

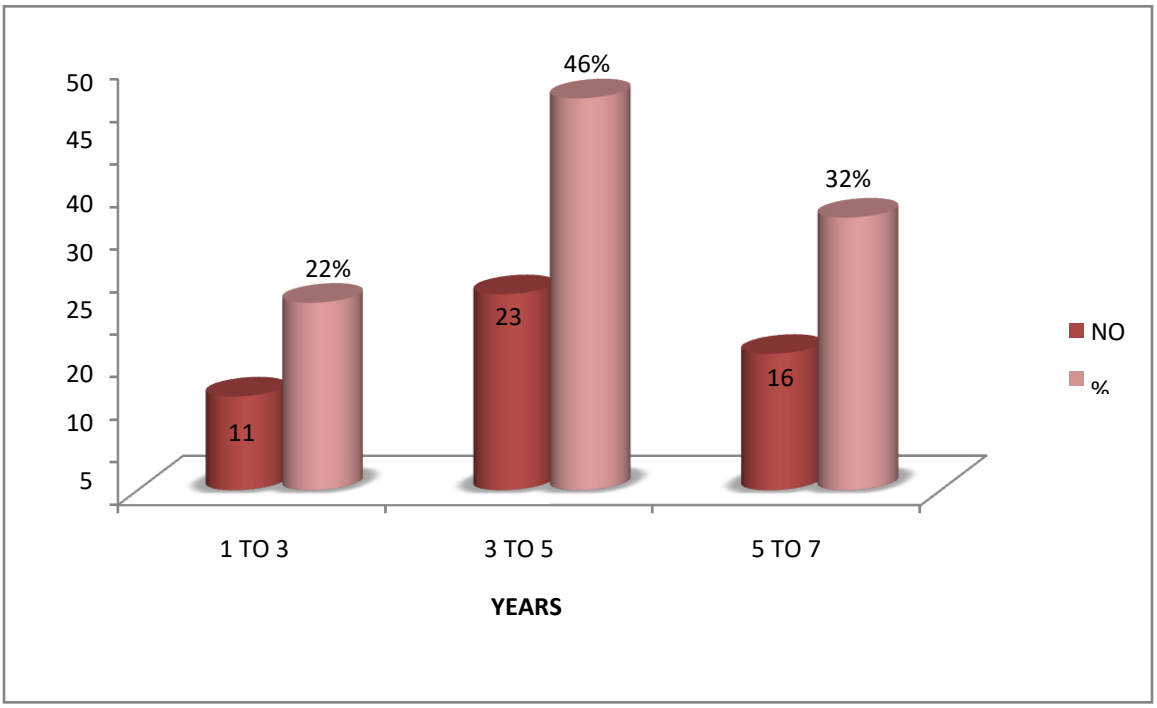

Fig.5:- Distribution of Subjects according to their Duration of Illness in years.

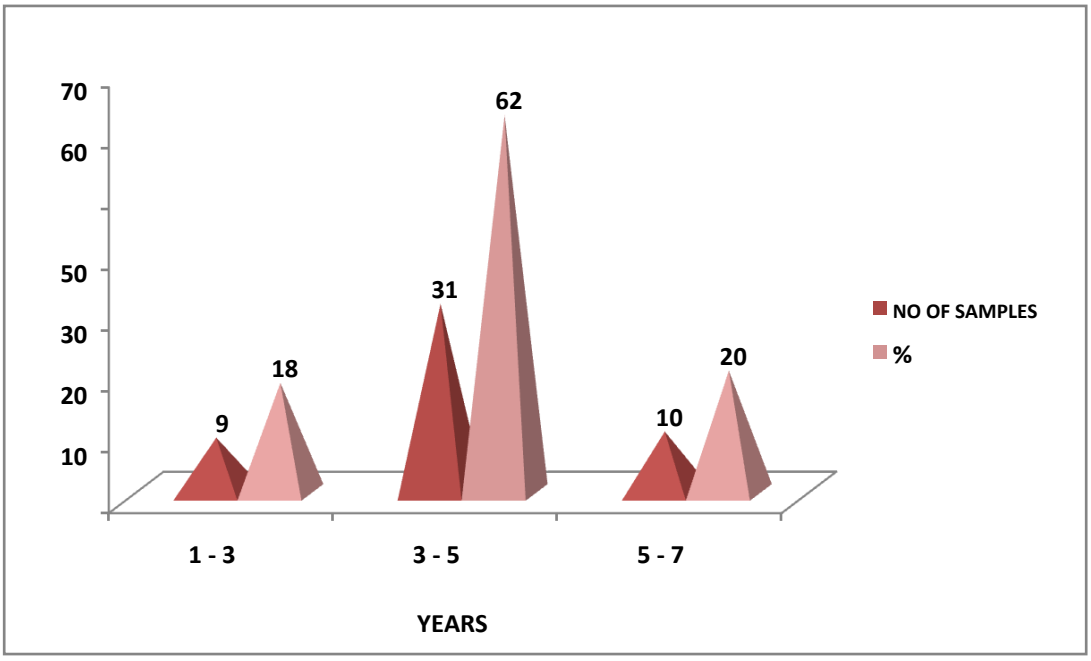

Fig.6: - Distribution of Subjects according to their Duration on Hemodialysis in years.

Section –B

Description about the Mean Pain scoreof the Subjects:

Table3:- Mean andSD of Pain scores during Xylocainein filtration on Day1,3and 5 **N=50**

Day	Puncture site	Mean	S.D
1	Arterial	4.88	1.15
	Venous	4.96	1.20

3	Arterial Venous	4.78 4.88	1.20 1.17
5	Arterial Venous	4.76 4.74	1.13 1.12

The table 3 shows the mean and the standard deviation of the pain scores of the subjects during Xylocaine infiltration at arterial site and venous site on three consecutive days of dialysis. Withregard to the arterial site, 4.88 were the maximum score and the minimum score was 4.76 whereas 4.96 was the maximum score at the venous site and 4.74 was the minimum pain score.

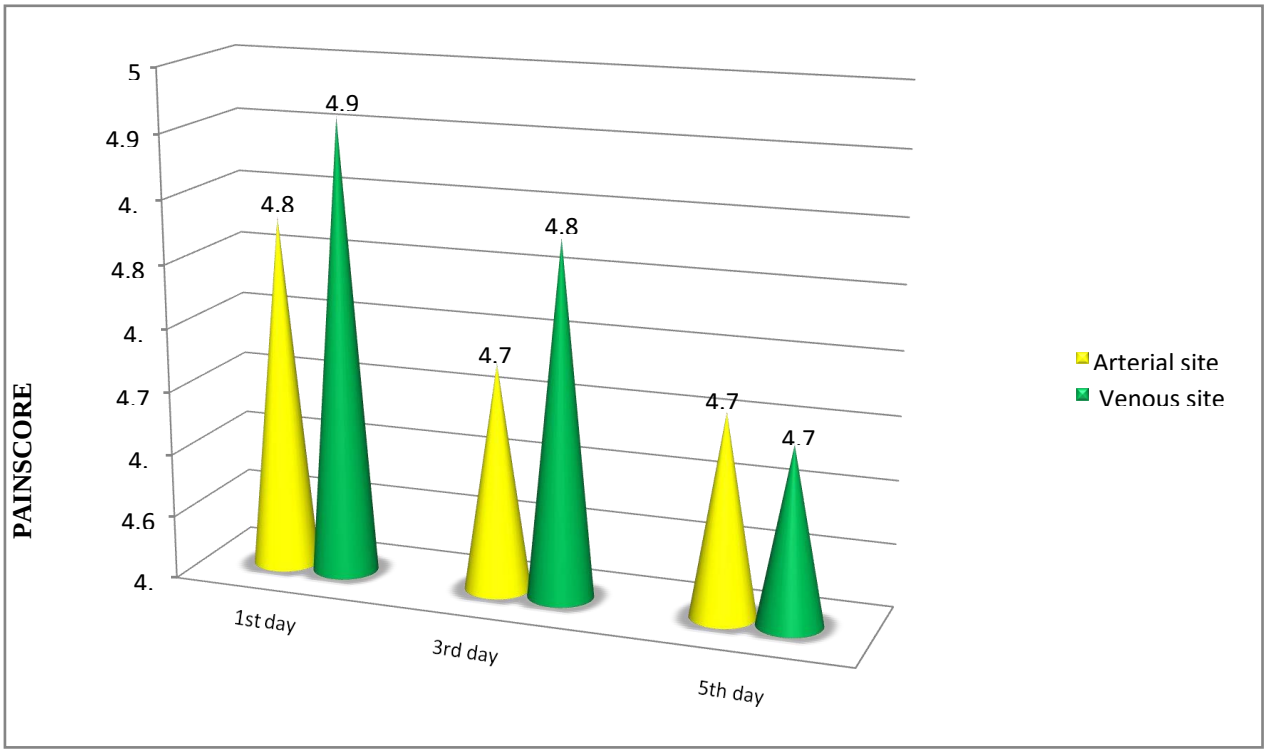

Fig. 7:- Painscores during Xylocaine in filtration on three alternative days of dialysis.

Table 4: - Mean and SD of the Pain scores during Cannulation after Xylocaine infiltration on Day1,3 and 5.

Day	**Puncture site**	**Mean**	**S.D.**
1	Arterial Venous	1.62 1.54	0.60 0.61
3	Arterial Venous	1.58 1.50	0.54 0.51
5	Arterial Venous	1.56 1.48	0.50 0.51

This table describes the mean and the SD of the pain scores of the subjects during AV fistula cannulation after Xylocaine infiltration at arterial site and venous site on day1, 3 and 5. With regard to the arterial site, 1.62 was the maximum and the minimum score was 1.56 where as 1.54was the maximum and 1.48 was the minimum painscore at the venous site.

Table 5:- Mean and SD of Pain scores during Cannulation after Cryotherapy on Day 2, 4 and 6.

Day	**Puncturesite**	**Mean**	**S.D.**
	Arterial	0.96	0.35

2	Venous	0.92	0.40
4	Arterial	0.98	0.25
	Venous	0.94	0.37
6	Arterial	0.94	0.31
	Venous	0.90	0.36

This table depicts the mean and SD of the painscores of the subjects during AV fistula cannulation at arterial site and venous site after Cryotherapy on day2, 4 and 6. In regard to painscore at the arterial site, 0.98 was the maximum and the minimum was 0.94 where as 0.94 was the maximum and 0.90 was the minimum painscore at the venous site.

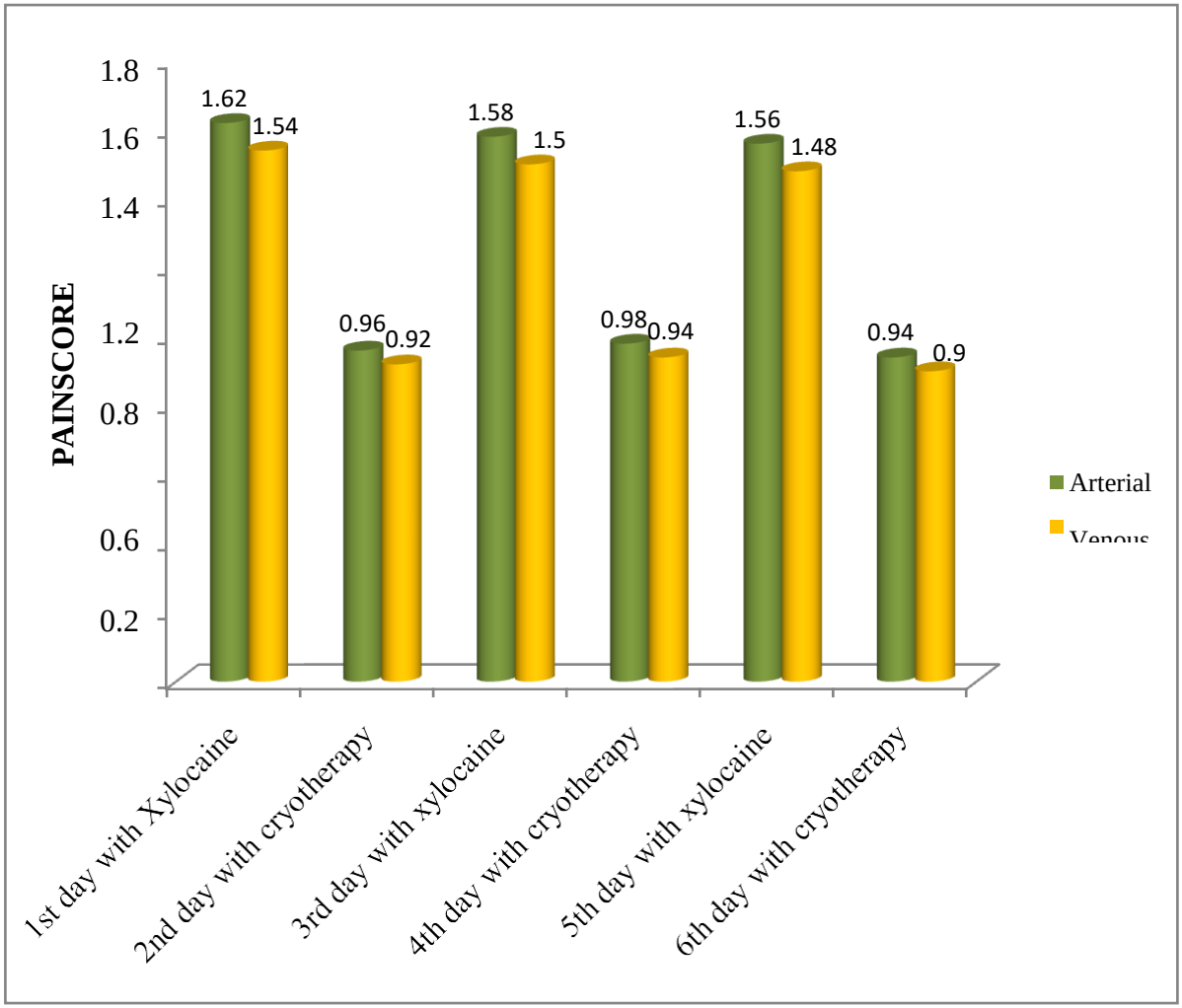

Fig. 8: - Painscores during Cannulation after Xylocaine infiltration after Cryotherapy on various Observations.

SectionC

Description about the Biophysiological parameters during cannulation:

Table6:- Mean andSD of Systolic and Diastolic Blood Pressure during Cannulation on various Observations.

SNo.	BloodPressure	WithXylocaine		WithCryotherapy	
		Mean	S.D	Mean	S.D
1	Systolic	148.7	20.62	148.8	20.63
	Diastolic	82.08	8.92	82.20	8.91
2	Systolic	148.82	20.50	148.84	20.50
	Diastolic	82.32	7.52	82.14	7.53

3	Systolic	148.88	20.66	148.82	20.66
	Diastolic	82.22	7.78	82.20	7.77

The above table displays the description of the mean and standard deviation of systolic and diastolic blood pressure readings on various observations during AV fistula cannulation done after Xylocaine infiltration and after Cryotherapy. The values show that there is no noticeable difference amongvarious observations.

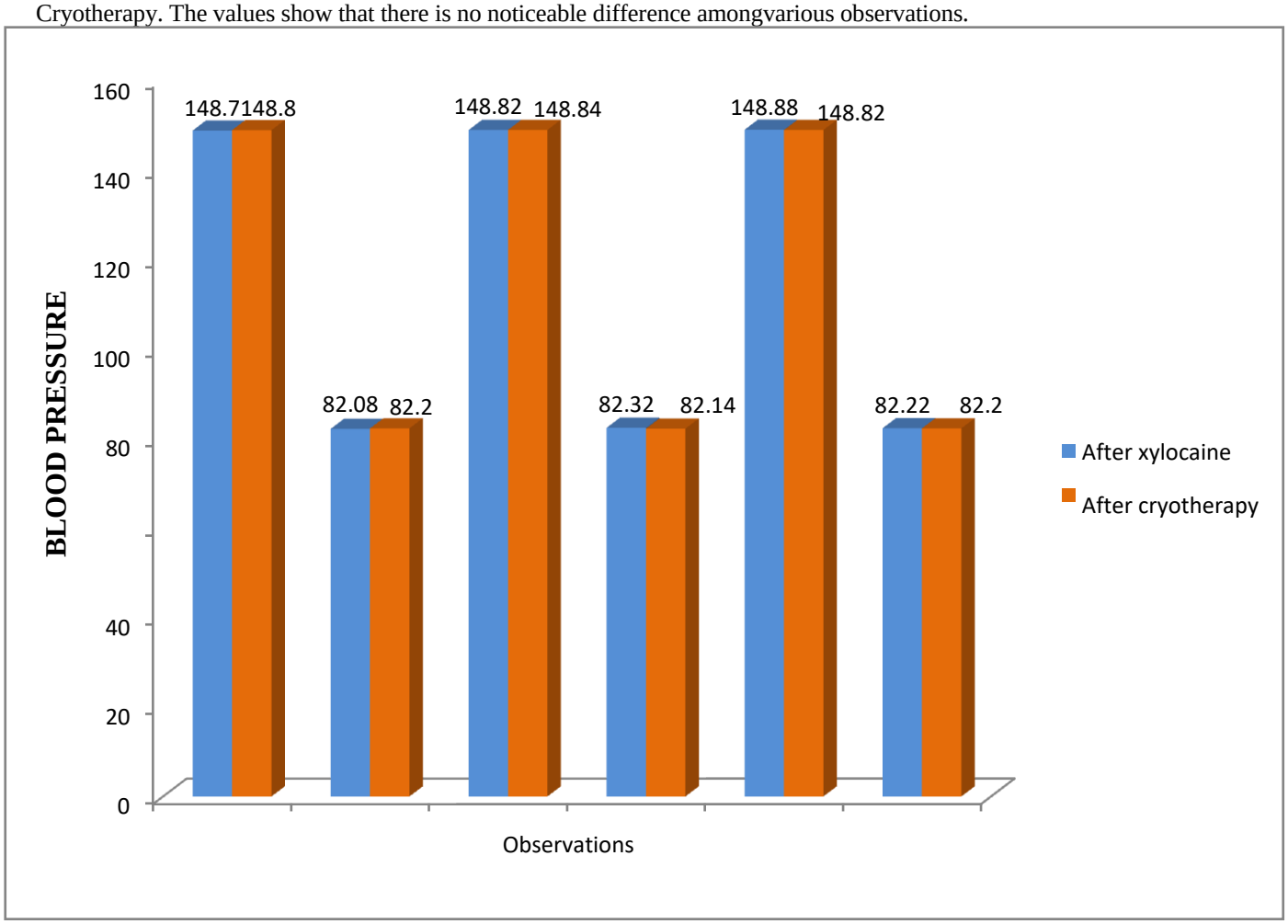

Fig.9:- Mean Systolic and Diastolic Blood Pressureduring Cannulation on various Observations.

Table7: - Mean and SD of Pulse rate during Cannulation on various Observations.

Observation	Mean With Xylocaine	S. D	Mean With Cryotherapy	S. D
1	76.64	5.01	76.82	4.44
2	76.96	5.00	76.84	4.85
3	76.52	4.57	76.63	4.60

Table 8 gives the description of the mean and standard deviation of pulse rates on six days of AV fistula cannulation with Xylocaine and with Cryotherapy. The values show that there is no noticeable difference between two modes of care.

Table 8:-Mean and SD of Respiratory rate during Cannulation various Observations.

Observation	Mean WithXylocaine	S. D	Mean WithCryotherapy	S. D
1	20.48	1.37	20.28	1.47
2	20.52	1.42	20.56	1.69
3	20.76	1.56	20.32	1.54

Table 8 illustrates the details of the mean and standard deviation on various observations of respiratory rates during AV fistula cannulation with Xylocaine and with Cryotherapy. The values illustrate that there is no noticeable variations between various observations.

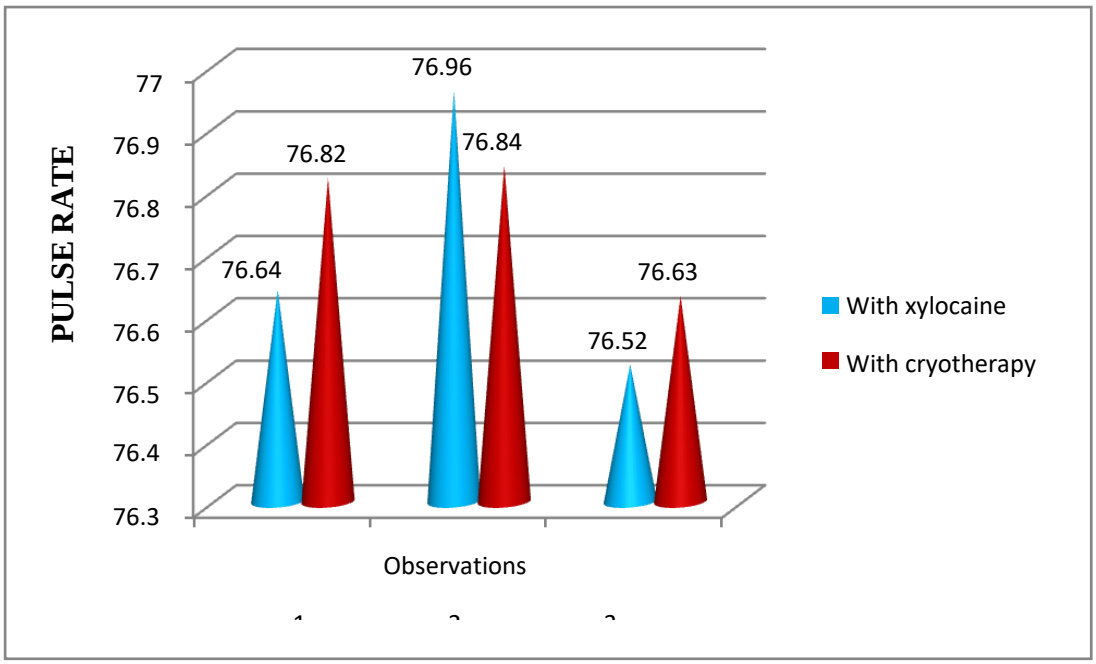

Fig. 10:- Mean Pulse rate during Cannulation on various Observations.

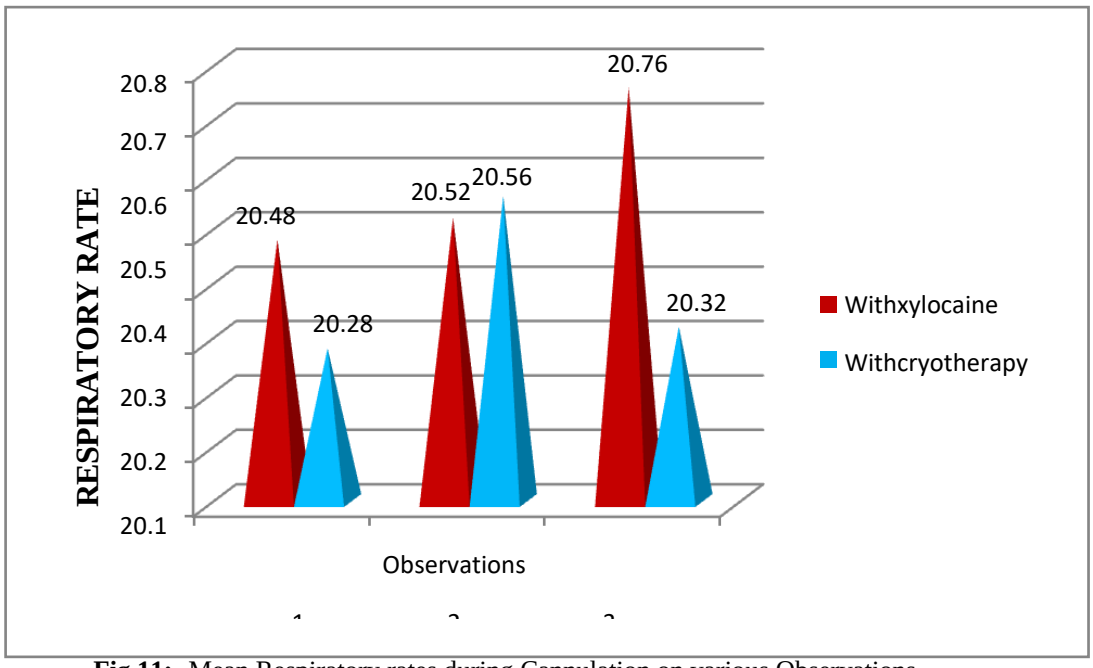

Fig.11:- Mean Respiratory rates during Cannulation on various Observations.

SectionD

Comparison of the Mean Pain scores on various Observations:

Table 9:- Comparison of Mean Pain scores during Xylocaine infiltration at the Arterial and Venous sites**N=50**

Day	**Mean**	**S.D.**	**'t'value**
At thearterialsite			
Observation1&3			
1 3	4.88 4.78	1.15 1.20	1.068(NS)
Observation1&5			

1 5	4.88 4.76	1.15 1.13	1.122(NS)
Observation3&5			
3 5	4.78 4.76	1.20 1.13	0.314(NS)
Atthevenous site			
Observation1&3			
1 3	4.96 4.88	1.19 1.17	0.912(NS)
Observation1&5			
1 5	4.96 4.90	1.20 1.12	0.718(NS)
Observation3&5			
3 5	4.88 4.90	1.17 1.12	0.304(NS)

This table shows the comparison between the pain scores at arterial and venous sites among 3 observations with Xylocaine. The computed 't' values show no significant difference in the painscores both at the arterial and venous site

Table 10:-Comparison of Mean Painscores during Cannulation after Xylocaine infiltration at the Arterial and Venous sites **N=50**

Day	**Mean**	**S.D.**	**'t' value**
At the arterial site			
Observation1&3			
1 3	1.62 1.58	0.60 0.54	0.514(NS)
Observation1&5			
1 5	1.62 1.56	0.60 0.50	0.750(NS)
Observation3&5			
3 5	1.58 1.56	0.54 0.50	0.344(NS)
At the venous site			
Observation1&3			
1 3	1.54 1.50	0.61 0.51	0.504(NS)
Observation1&5			
1 5	1.54 1.48	0.61 0.51	0.710(NS)
Observation3&5			
3 5	1.50 1.48	0.51 0.51	0.330(NS)

This table shows the comparison between the pain scores at the arterial and venous sites during AV fistula cannulation after Xylocaine infiltration on various observations. The computed 't' values shown o statistically significant difference in the painscore among 3 different observations

Table 11:-Comparison of Mean Painscores during Cannulation after Cryo therapy at the Arterial site and Venous sites **N=50**

Day	**Mean**	**S.D.**	**'t'value**
At the arterial site			
Observation 2&4			
2 4	0.96 0.98	0.35 0.25	0.324(NS)
Observation 2&6			
2 6	0.96 0.94	0.35 0.31	0.328(NS)
Observation 4&6			

4 6	0.98 0.94	0.25 0.31	0.590(NS)
At the venous site			
Observation 2&4			
2 4	0.92 0.94	0.39 0.37	0.344(NS)
Observation 2&6			
2 6	0.92 0.90	0.39 0.36	0.306(NS)
Observation 4&6			
4 6	0.94 0.90	0.37 0.36	0.582(NS)

This table shows the comparison between the pain scores at the arterial and venous sites during cannulation after Cryotherapy application on day2, day4 and day6 of dialysis. The computed't' values show no statistically significant difference in the painscore among various observations.

SectionE

Comparison of Biophysiological parameters on various observations:

Table 12:-Comparison of Mean Systolic Blood Pressure during Cannulation after Xylocaine infiltration and after Cryotherapy **N=50**

Day	**Mean**	**S.D.**	**'t' Value**
With Xylocaine			
Observation1&3			
1 3	148.70 148.82	20.62 20.50	0.862(NS)
Observation1&5			
1 5	148.70 148.88	20.62 20.66	0.974(NS)
Observation3&5			
3 5	148.82 148.88	20.50 20.66	0.516(NS)
WithCryotherapy			
Observation2&4			
2 4	148.80 148.84	20.63 20.49	0.294(NS)
Observation2&6			
2 6	148.80 148.82	20.63 20.66	0.297(NS)
Observation4&6			
4 6	148.84 148.82	20.49 20.66	0.291(NS)

This table shows the comparison between the blood pressure readings during cannulation after Xylocaine infiltration and after Cryotherapy on various observations. The computed 't' values show no statistically significant difference in the blood pressure readings among 3 days of both with Xylocaine and with Cryotherapy.

Table 13:-Comparison of Mean Diastolic Blood Pressure during Cannulation after Xylocaine infiltration and after Cryotherapy **N =50**

Day	**Mean**	**S.D.**	**'t' Value**
With Xylocaine			
Observation1&3			
1 3	82.08 82.32	8.92 7.52	0.892(NS)
Observation1&5			
1 5	82.08 82.22	8.92 7.78	0.703(NS)
Observation3&5			
3	82.32	7.52	0.671(NS)

5	82.22	7.78	
WithCryotherapy			
Observation2&4			
2 4	82.20 82.14	8.91 7.53	0.742 (NS)
Observation2&6			
2 6	82.20 82.26	8.91 7.77	0.443(NS)
Observation4&6			
4 6	82.14 82.26	7.53 7.77	0.604(NS)

This table shows the comparison between the Diastolic blood pressure readings during cannulation after Xylocaine infiltration on various observations. The computed 't' values shown no statistically significant difference in the blood pressure readings among various observations.

Table 14:-Comparison of Mean Pulse rates during Cannulation with Xylocainein filtration and with Cryotherapy **N =50**

Day	**Mean**	**S.D.**	**'t' Value**
With Xylocaine			
Observation1&3			
1 3	76.82 76.84	4.44 4.85	0.374(NS)
Observation1&5			
1 5	76.82 76.63	4.43 4.60	0.497(NS)
Observation3&5			
3 5	76.84 76.63	4.85 4.59	0.505(NS)
WithCryotherapy			
Observation2&4			
2 4	76.64 76.96	5.01 5.00	0.783(NS)
Observation2&6			
2 6	76.64 76.52	5.01 4.57	0.397(NS)
Observation4&6			
4 6	76.96 76.52	5.00 4.57	0.812(NS)

This table shows the comparison between the pulse rates during cannulation after Xylocaine infiltration and with Cryotherapy on various observations. The computed 't' values show no statistically significant difference in the pulse rates among various observations.

Table 15: -Comparison of mean Respiratory rates during Cannulation after Xylocaine infiltration and after Cryotherapy.

Day	**Mean**	**S.D.**	**'t' Value**
With Xylocaine			
Observation1&3			
1 3	20.48 20.52	1.37 1.42	0.098(NS)
Observation1&5			
1 5	20.48 20.76	1.37 1.56	0.438(NS)
Observation3&5			
3 5	20.52 20.76	1.42 1.56	0.208(NS)
WithCryotherapy			
Observation2&4			

2 4	20.28 20.56	1.47 1.69	0.431(NS)
Observation2&6			
2 6	20.28 20.32	1.47 1.54	0.096(NS)
Observation4&6			
4 6	20.56 20.32	1.69 1.54	0.272(NS)

This table shows the comparison between the respiratory rate during cannulation with Xylocaine infiltration and with Cryotherapy on various observations. The computed 't' values show no statistically significant difference in the respiratory rates among various observations

Comparison of painscore during AV fistula cannulation after Xylocaine and after Cryotherapy:

Table 16:-Comparison of Mean Painscores during AV fistula cannulation done with Xylocainein filtration and done with Cryotherapy.

Atthearterialsite: -				
S.No.	**Painscore**	**Mean**	**S.D.**	**'t'value**
1.	With XylocainewithCryotherapy	1.59 0.96	0.546 0.345	11.885**
Atthevenoussite: -				
2	With XylocainewithCryotherapy	1.51 0.92	0.540 0.338	11.273**

******Significant at 0.01level

The above table compares pain scores during cannulation after Xylocaine infiltration and after Cryotherapy application. The independent't' computed and the values obtained were11.885 and 11.273 for the arterial site pain scores and venous site correspondingly the values are more than the table value (2.390) at df 48 which is statistically highly significant. The values in for that Cryotherapy has an effect in reducing pain during AV fistula cannulation among Hemodialysis patients.

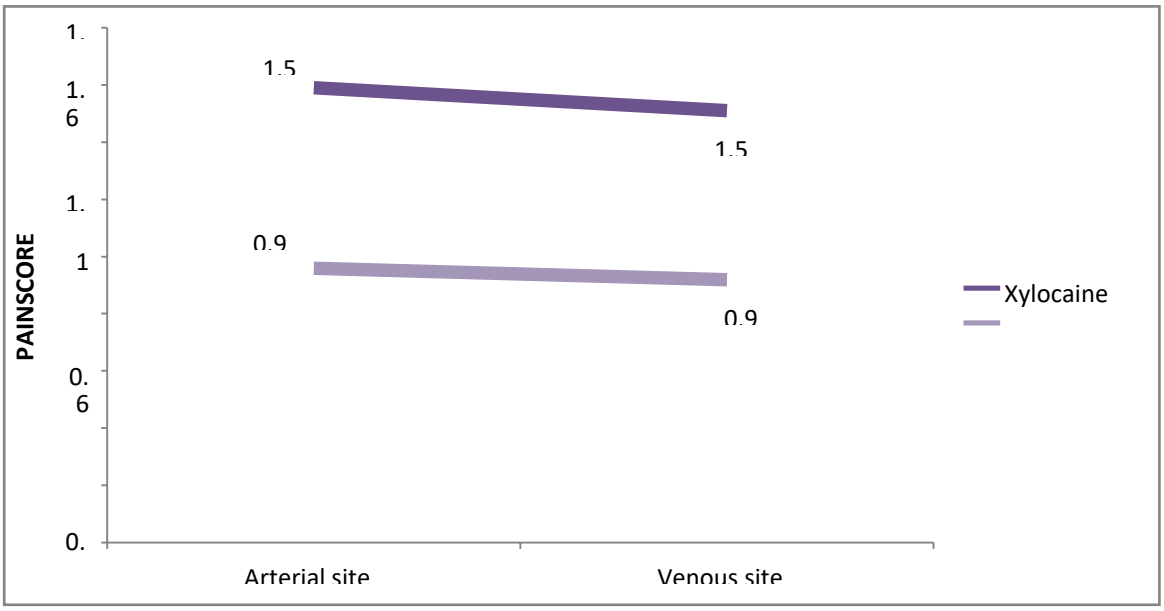

Fig. 12: - Comparison of Mean Painscores during Cannulation done with Xylocaine infiltration and done with Cryotherapy.

SectionG

Comparison of Biophysiological parameters during AV fistula cannulation done with Xylocaine and done with Cryotherapy:

Table 17:-Comparison of Biophysiological parameters during cannulation done with Xylocaine and done with Cryotherapy.

S. No	Variables	Mean		S.D.		't'value
		Xylocaine	Cryotherapy	Xylocaine	Cryotherapy	
1.	Systolic BloodPressure	148.80	148.98	20.59	20.59	0.905(NS)
2.	DiastolicBlood Pressure	82.21	82.47	8.07	8.16	0.987(NS)
3.	PulseRate	77.32	77.80	4.81	4.24	0.917(NS)
4.	RespiratoryRate	20.67	20.70	1.50	1.58	0.210(NS)

The given table explains the comparison between selected biophysiological parameters during cannulation done with Xylocaine and done with Cryotherapy. The computed 't' values give an inference that there is no statistically significant difference among biophysiological parameters among various observations during AV fistula cannulation done with Xylocaine infiltration and with Cryotherapy which gives an inference that Cryotherapy has no effect on biophysiological parameters during AV fistula cannulation.

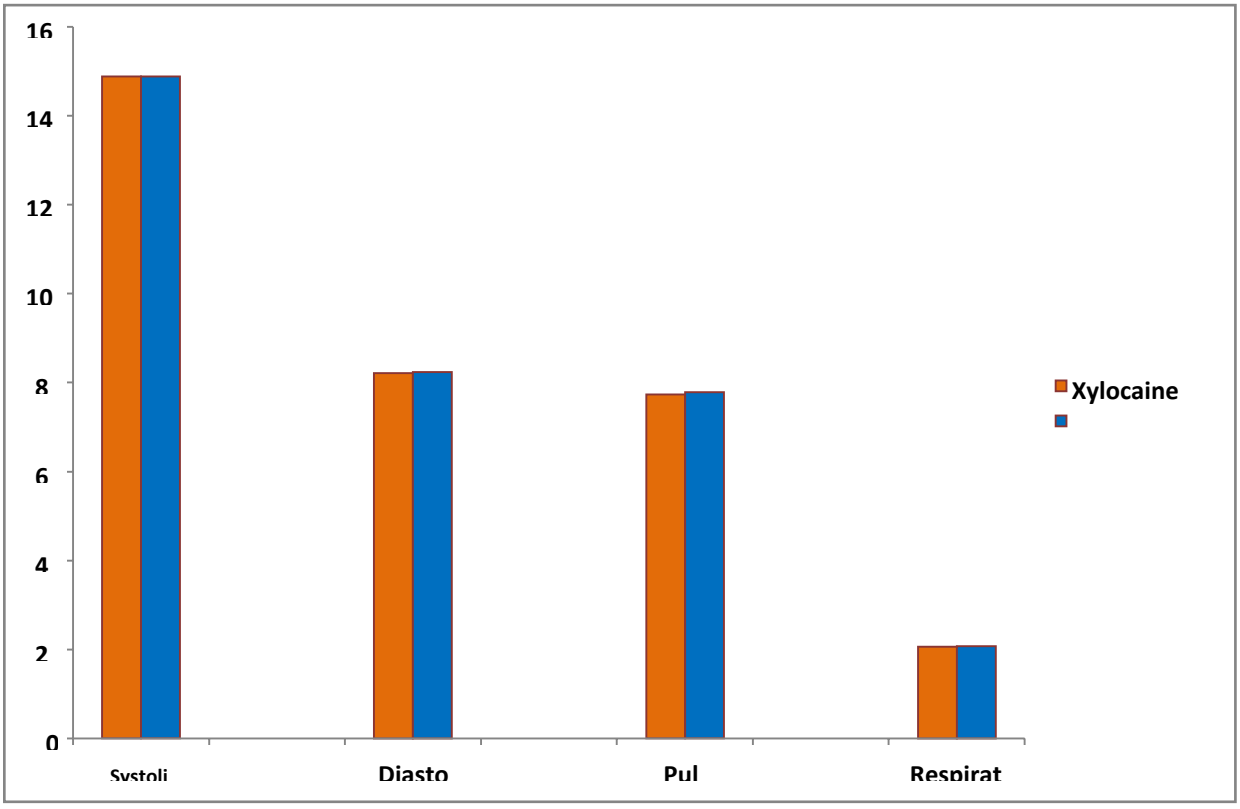

Fig. 13: -Comparison of Biophysiological parameters during Cannulation done with Xylocaine and done with Cryotherapy.

Section H

Association of pain scorewith selected variables:

Table 18:-Association between painscore and demographic variables.

S.No.	Demographic variables	N	Mean painscore	SD	F-value
1	Age(inyears)a)21-30				
	b)31-40	10	0.92	0.40	
	c)41-50	8	0.96	0.35	0.78
	d)51-60	18	0.94	0.37	
		14	0.94	0.31	
	Total				
		50	0.94	0.36	
2	Gender				
	a) Male	41	0.94	0.37	
	b) Female	9	0.95	0.35	0.12
	Total	50	0.95	0.36	

The above table displays that F values computed to associate pain scorewith age and gender of the study samples. F values show that there is no significant association existing between pain scoreand the selected demographic variables

Table 19:- Association between Pain scoreand Duration of Illness in Years.

S.No.	Clinicalvariable	N	Mean painscore	SD	F-value
1	Durationofillnessinyears				
	a)1-3				
	b)3-5	12	1.10	0.35	6.063*
	c)5-7	23	0.90	0.33	
		15	0.82	0.27	
	Total				
		50	0.94	0.36	

*Significantat 0.05level

The above table displays the association between the pain scoreand clinical variables. The computed F value to associate pain scoreand duration of illness was 6.063 (Table value is 4.46 for 2 and 8 degrees of freedom) which is significant at 0.05 level. It gives an inference that there is significant association between the pain scoreof the subjects and duration of their illness.

Table 20:- Post Hoctests of association with Pain scoreand Duration of Illness.

S.No.	Clinical Variable	Mean	SD
1	Duration of illness in years		
	a)1-3		
	b)3-5	1.10	0.35
	c)5-7	0.90	0.33
		0.82	0.27

Post Hoc comparisons using the Turkey HSD test indicated that the pain scoreof 3-5 years (mean-0.90, SD-0.33) and the pain scoreof 1-3 years (mean-1.10, SD-0.35) were significantly different from the pain Scores of 5-7 years (mean-0.82, SD-0.27). However, there was no significant difference existed between the pain scoreof 1-3 years and 3-5 years.

Table 21:- Association between Pain score and Duration of Hemodialysis in years.

S.No.	Clinicalvariable	N	Mean pain score	SD	F-value
1	Duration on Hemodialysis in years				
	a)1-3	9	1.06	0.34	6.013*
	b)3-5	31	0.96	0.33	

	c)5-7	10	0.80	0.31	
	Total	50	0.94	0.36	

*Significantat 0.05level

The above table displays the association between the pain scoreand duration of hemo dialysis in years. The computed F value to associate pain score and duration on Hemodialysis was 6.013 (Table value is 4.46 for 2 and 8 degrees of freedom) which is significant at 0.05 level. It indicates that there is significant association between the pain score of the subjects and their duration on Hemodialysis.

Table 22:- Post Hoc tests of association with Pain scoreand Duration of Hemodialysis.

S.No.	ClinicalVariable	Mean	SD
1	Duration on Hemodialysis in years		
	a)1-3	1.06	0.34
	b)3-5	0.96	0.33
	c)5-7	0.80	0.31

Post Hoc comparisons using the Turkey HSD test indicated that the pain scoreof 3-5 years on hemodialysis (mean-0.96, SD-0.33) and the pain scoreof 1-3 years (mean-1.06, SD-0.34) were significantly different from the pain scores of 5-7 years (mean-0.80, SD-0.31). However, there was no significant difference existed between the pain scoreof 1-3 years and 3-5 years.

Discussion, Summary, Conclusion, Implication, Limitation And Recommendations:-

The present study was designed to assess the effect of cryotherapy on pain and biophysiological parameters during AV fistula cannulation among patients on maintenance hemodialysis at KMCH, Coimbatore. To evaluate the effect of cryotherapy on pain and selected biophysiological variables, the researcher carried out the study on 50 patients and adopted Repeated Measures Design.

The major results of the study are discussed according to the below objectives:

Discussion:-

The first objective was to assess the pain intensity during xylocaine infiltration

The hemodialysis unit has a routine to administer intradermal xylocaine injection to anesthetize the arterial and venous site prior to cannulation. Almost every patient complains of pain with xylocaine infiltration. So, in this study, the investigator assessed the pain intensity of subjects with xylocaine infiltration by using Numerical Pain Rating Scale for three consecutive days of hemodialysis.

The mean pain scores of the subjects during xylocaine infiltration at arterial site andvenous site on three alternative days of dialysis were 4.88, 4.78, 4.76 and 4.96, 4.88, 4.74respectively. These findings of the study indicate that all the patients are suffering from moderate pain during the xylocaine infiltration.

The second objective was to determine the effect of cryotherapy on pain and biophysiological parameters during AV fistula cannulation

To determine the effect of cryotherapy on pain and biophysiological parameters, the investigator assessed the level of pain of the subjects with cannulation after xylocaine and after cryotherapy by using the same tool and both the values were compared. Blood pressure, pulserate and respiratory rate were recorded under both situations and were compared.

The mean pain scoreof the subjects during cannulation after xylocaine injection atarterial site and venous site on the 1st, 3rd and 5th days of dialysis were 1.62, 1.58, 1.56 and 1.54,1.50, 1.48 respectively. The findings indicate that the patients suffer from mild pain during cannulation even after xylocaine is administered as local anaesthetic. The mean pain score of patients with cannulation after cryotherapy at arterial site were 0.96, 0.98 and 0.94 and at venous site were 0.92, 0.94 and 0.90 on the 2nd, 4th and 6th days of dialysis respectively. The findings of the study suggest that the patients suffer from mild pain during cannulation after cryotherapy but the pain intensity is lesser than the pain during cannulation after xylocaine infiltration.

The pain scores during cannulation with xylocaine and with cryotherapy were compare dusing independent 't' test. The 't' value of the comparison between the pain score at the arterial site with cannulation after xylocaine injection and with cannulation after cryotherapy was 11.885indicated that the pain intensity with cryotherapy was very less. The 't' value of the comparison between the pain perception at the venous site with cannulation after xylocaine injection and with cannulation after cryotherapy was 11.273 indicated that the pain intensity with cryotherapy was less. The researcher therefore concluded that cryotherapy had an effect in reducing painduring AV fistula cannulation among the subjects. This proves that cryotherapy has an effect in reducing pain during AV fistula cannulation and xylocaine infiltration needle pricks (i.e. 2 pricks per each dialysis) and associated pain can be avoided.

The comparison between the selected biophysiological parameters with xylocaine and with cryotherapy was performed using independent 't' test. The mean systolic BP with xylocaineand with cryotherapy were 148.80 and 148.98 with standard deviations of 20.590 and 20.592respectively. The calculated 't' value was 0.905 which gave an inference that there was nosignificant change in the systolic blood pressure between cannulation done with xylocaine and cryotherapy among the subjects. The mean score of diastolic BP with xylocaine and with cryotherapy were 82.21 and 82.47 with a Standard Deviation of 8.070 and 8.155 respectively. The calculated 't' value was 0.987 which indicated that there was no significant change in the diastolic blood pressure readings under both conditions. The mean pulse rates with xylocaine and with cryotherapy were 77.32 and 77.80 with standard deviations of 4.810 and 4.239 respectively. The calculated 't' value was 0.917 which showed that there was no significant change in the pulse rates under both conditions. The mean respiratory rates with xylocaine and with cryotherapy were 20.67 and 20.70 with standard deviations of 1.496 and 1.580 correspondingly. The computed 't' value was 0.210 which indicated that there is no significant change in the respiratory rates between AV fistula cannulation done with xylocaine and with cryotherapy. The overall inference is that cryotherapy has no effect on biophysiological parameters such as blood pressure, pulse rate and respiratory rate among the subjects. These findings of the study portray that cryotherapy as a cutaneous stimulation among hemodialysis patients during AVF cannulation has no effect on biophysiological parameters.

The results of the present study are in contradictory to the findings of the study conducted by Park (1994). In that study, Cardiopulmonary signs of arteriovenous fistula puncture pain in experimental period was found to be higher than in control period (pulse paired t=-0.8, p =0.42; systolic BPpairedt=0.98, p= 0.33; diastolic BP pairedt= 0.43, p=0.66).

The third objective was to associate the level of pain with selected demographic variables

One way ANOVA was used to associate the pain scorewith age of the subjects and gender differences. The results showed that pain was neither associated with age nor with gender of the subjects. Therefore, it is concluded that baseline factors are independent of their pain scorewith regard to their demographic variables.

A study conducted by Kelly to determine the minimum clinically significant difference in visual analogue scale (VAS) pain scores for acute pain in the emergency department setting and to determine whether this difference varies with demographic profile and pain intensity. Results of their study showed that there was no statistically significant difference between the minimum clinically significant differences in VAS pains cores based on gender (p = 0.172), age (p =0.782), or cause of pain(p=0.84). The study supports the findings of the present study indicating that base line factors are independent of their pain score with regard to their demographic profile.

One way ANOVA was used to associate the pain scorewith duration of illness and duration of treatment. The obtained F values were 6.063 and 6.013 which showed that there was significant association (at 0.05 level) between the pain scoreand the clinical profile of the subjects such as duration of illness and duration of treatment. The pain was found to be reduced with the increase in duration of illness and treatment.

The findings of this study proves that there exists no significant association between the painscore and the selected demographic variables such as age and gender of the patients where as there exists a significant association between the pain scoreand the selected clinical variables such as duration of illness and duration on hemodialysis.

Summary

The study was conducted to assess the effect of cryotherapy on pain and biophysiological parameters during AV fistula cannulation among patients on hemodialysis at KMCH, Coimbatore.

The study tested and proved the hypothesis that there will be significant difference between subjects in the level of pain during AV Fistula cannulation who receive cryotherapy and those who are on xylocaine.

The study tested and rejected the hypothesis that there will be significant difference between subjects in biophysiological parameters during AV Fistula cannulation who receive cryotherapy and those who are on xylocaine.

The tools used by the investigator for data collection consisted of 3 sections are follows: Section-1 Demographic and clinical profile of the subjects

Section-2 Record of blood pressure, pulse rate and respiratory rate Section-3NumericalPainRatingScale

The data were collected for a period of 6weeks.Both xylocaine infiltration and cryotherapy application were used in same subjects as the investigator adopted repeated measures design. Based on the objectives and hypotheses, data were analyzed using both descriptive and inferential statistics.

Major findings of the study:-

1. The mean pain score with xylocaine infiltration at arterial site was 4.81 and at the venous site was 4.86.
2. There was a significant reduction in the pain score during cannulation after the application of cryotherapy when compared to the pain score during cannulation after xylocaine infiltration. The mean pain scoreduring cannulation after xylocaine infiltration at the arterial site was 1.59 and at the venous site was 1.51 whereas the pain score after cryotherapy was 0.96 and 0.92 respectively. The't' values of the comparison between these scores were 11.885 and 11.273which showed significance at 0.05 level
3. There was no statistically significant difference in the values of biophysiological parameters among xylocaine and cryotherapy application.
4. There was no significant association between pain scoreand demographic variables such as age and gender.
5. There was significant association between pain scoreand duration of illness and duration of treatment. The values showed that the patients had reduced pain intensity with increase in duration of illness and duration of treatment.

Conclusion:-

Health care professionals have a duty to provide compassionate care to all patients (Zempsky et al 2004). Effort should be made to assess and manage acute pain, as by doing so; nurses can reduce pain, increase patient comfort and satisfaction, and improve patient outcomes. The investigator was very keen to find an alternative pain management strategy among hemodialysis patients to aid the min reducing the pain intensity during AV fistula cannulation.

The conclusion of the study was drawn as follows:
The study findings revealed the effect of cryotherapy as superior to the xylocaine infiltration in reducing pain in tensity during AV fistula cannulation

This study also revealed there is no variation in blood pressure, pulse rate and respiratory rate between cannulation done with xylocaine infiltration and with cryotherapy. These study findings agree with various other studies conducted in same filed.

Implications
Nurses can incorporate cryotherapy during painful procedures to reduce the patient‟s pain intensity. Pain associated with cannulation is a common complaint in hospitals. Present study findings have several implications in nursing practice, nursing education, nursing research and nursing administration.

Nursing practice
Nursing practice has a direct and significant impact on human health. Providing optimal patient care is one of the vital functions of the nurse. The study reveals that cryotherapy application is effective in reducing pain intensity during AV fistula cannulation among hemodialysis patients. In order to promote the comfort of the patients, it is imperative that

the nurses in hemodialysis unit to follow this technique before AV fistula cannulation rather than anesthetizing the area with xylocaine as it itself gives patients moderate pain due to infiltration. The study serves as an eye opener among nurses and other health care professionals to recognize the benefits of alternative pain management techniques such as cryotherapy.

Nursing education

Nursing education is to prepare nurses with the potential for imparting nursing care most effectively. The nurse educator can include alternative pain management techniques such as cryotherapy inin-service education which can be adoptedby the students and the nursing personnel as an independent nursing intervention in their day-to-day clinical practice to promote the comfort of the patients and there by to avoid the ill effects of the pharmacological agents. By inculcating knowledge and by demonstrating how to deliver it through staff development activities, their knowledge can be updated on the importance of alternative pain management strategies. The nurse educator can create awareness about the use of alternative pain management strategies among other health care professionals too.

Nursing research

Re-thinking and re-evaluation of the previous nursing art procedures and knowledge should be done, to keep the knowledge up to date. The main goal of nursing research should be to improve patient care ultimately.Since the healthcare system today is driven by cost,research about outcomes related to cost is especially important.Today‟s health care environment continually places increasing demands on nurses to communicate, share and synthesize information and to implement patient care based on scientific evidence.Appropriate utilization of research helps nurses to make decisions based on evidences for patient care.The finding of the present study can be a foundation to conduct a study on large population to prove the effect of cryotherapy strongly on reducing the pain during AV fistula cannulation. The study can be replicated in dialysis centers where no local anesthesia is used to find out the exact effect of cryotherapy to promote the patient's comfort and compliance towards hemodialysis. The implication of the study can be used as a motivation for nurses to conduct research in future on alternative methods of pain management. The study can be conducted to check the effect of cryotherapy among various other procedural painc ontrols.

Nursing Administration

Prevention of pain provides more effective pain relief than treatment of established pain. Written guideline should be provided to standardize and improve documentation related to pain assessment, necessary modification in pain relief strategies and presence of any side effects. Pain scores should be documented in writing, just like vital signs, making them readily available to allmembers of the healthcare team. Nurse as an administrator has a role in planning the policies for imparting healthcare services to the target population. Nursing administrator can formulate the protocol to practice cryotherapy among hemodialysis patients during cannulation. In-service education can be scheduled to disseminate the research findings among nursing staff and other healthcare professionals.

Limitations Of The Study

1. The study sample size was small.
2. The study included patients who were on hemodialysis at least 3 times a week

Recommendations:-

1. A similar study can be conducted with a large sample size
2. The study can be replicated by using other research designs
3. A study can be carried out in centers where there is no xylocaine infiltration prior to AV fistula cannulation
4. A study can be performed with combination of other alternative pain management strategies in controlling procedural pain
5. A comparative study between cryotherapy and other non pharmacological methods in reducing procedural pain can be conducted
6. A study to assess the knowledge and attitude among nurses on complementary and alternative therapies in managing procedural pain can be carried out.

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