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RESEARCH ARTICLE

ASTUDYTOASSESSTHEEFFECTOF CRYOTHERAPYONPAINAND SELECTEDBIOPHYSIOLOGICALPARAMETERS DURINGAVFISTULACANNULATIONAMONGPATIENTSONHEMODIALYSIS AT KMCH,COIMBATORE

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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 score during 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 sleepwithout 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 kidneysinourlives.

The kidneys excrete a number of end products of metabolism in urine. The kidneyseliminate these substances from the body at a rate that matches their production. In addition tothemetabolicwastes, the kidneysalsoexcreteforeign substances from the body such asdrugs, pesticides and other chemicals ingested in the food. Regulation of water and inorganicion 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 is a complete kidney failure and treatmentisnot given, death is inevitable.

End-stage renal disease (ESRD) or Chronic RenalFailure (CRF) is a worldwidepublic health problem. It is a mammoth medical, social and financial crisis for both patients and their families. Among India stotal 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 or azotemia (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 highmorbidity and mortality among patients with ESRD. Dialysis or kidney transplantation becomes necessary for patient survival.

A patientwith 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 sociated symptoms is a sociated symptoms."

majorconcernfornursesandhealthprofessionalsattemptingtoprovidethesepatientswithcomprehensivecare. Methodsofther apyfor CRF included i alysis 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 thekidneyscannotdoso. Theneedforthedialysis may be acute or chronic. Chronicormaintenance dialysis is indicated in CKDw henthere are uremic signs and symptoms affecting all body systems, hyperkalemia, fluid overloading not responsive to diuretics and fluid restriction and general lack of well being. Dialysis can be either hemodialysis or peritone addialysis.

Hemodialysis is the most commonly used method of dialysis and it is used for patientswho are acutely ill and require short term dialysis (days to weeks) and for patients with ESRDwho require long term or permanent therapy. In hemodialysis, the blood laden with toxins andnitrogenous 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 permeablemembrane, 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 undergosuccessful kidney transplantation. Patients receive chronic or maintenance dialysis is usually done three times aweek for at least 3-4 hours pertreatment.

ObtainingvascularaccessisoneofthemostdifficultproblemsassociatedwithHemodialysis.Access to the patient's vascular system must be established to allow blood tobe 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 permanent permanent catheters, subcutaneous and semi forthecannulationtostarthemodialysis. Hemodialysisisthemostfrequently used Renal Replacement Therapy with the AVF being the gold standard for vascular access which issurgically created by anastomizing an artery to a vein, either side to side or end to side. Thearterial segment of the fistula is usedfor arterial flow and the venous segmentfor 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 accommodate two large-bore (14-16 gauge) needles used in hemodialysis. The patient is also encouraged toperformexercisetoincreasethesize ofthesevessels (i.e., squeezinga rubberballforforearm fistulas). Once mature, native fistulas have excellentlong term patency rates andrarelybecome infected. Palder et al (1985) have reported that primary AV fistulas provide adequatevascular access for even 20 years. On an average, a patient on maintenance Hemodialysisundergoes 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 unpleasantsensory andemotionalexperienceassociated with actual or potential tissued amage, or described in terms of such damage. Epidemiologic data of pain in patients with ESRD are extremely limited; however, recent studies have shown that severe iscommoninESRD. Theliteratures suggest that 37% to 50% of hemodialy sispatients 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 anesthesiainto the standard of care for patients during AV fistula cannulation. Intradermal Lidocaine is avasoconstrictor, so it may cause the vein to become smaller and sometimes make it a littledeeper. 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 havecomplained pain during AV fistula cannulation but, majority of the patients with renal failureon Hemodialysis reported that pain during injection of local anesthesia as more terrible than the painfrom the cannulation itself.

"It would be good for us to remember that one of the greatest gifts we can share with others inpain,despair,orconfusionisaclearsenseofourpeaceandknowledgethatweareloved"

Robert J. Wicks

Now a days, health professionals increasingly focus on the management of pain toimprove 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 consideredasthesignificantpatientoutcomewhenevaluatingtheeffectivenessofnursingcare(Padilla et al., 1990; Ferrell et al., 1991; Barnason et al., 1998). However, a substantial body ofresearch indicated that pain continues to be a problemfor 45-75% of hospitalized patientswho 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 programsaimedatimprovingnurses "painmanagement.Pain control amongESRDpatientsisachallenge to the health care providers due to the relationship between medication clearanceand renal function. This leads to under treatment of pain or over sedation and untoward sideeffects/complications when using certain types of medications (Rehm, 2003). Here comes theneedforalternative therapiesinmanagingpaininpatients withCRF.

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 studieshave shown that alternative therapy techniques have a dramatic impact on the overall healthand 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 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 inwhich coldis 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, having been 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. Inaddition, vasoconstriction is induced, which reduces pain, bleeding and edema in damaged tissues. Today the use of Cryotherapy is widespread in the medical

arena. Studies have proven that it is an established method used in treating acute soft tissue injuries and as part of the treatment protocol for chronic injuries. Cryotherapy has also been proved to reduce pain effectively and reduce the recovery period in 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 to move a C-fiberpathway. Once the slow pain message reaches the brain, it takes a pathway to the hypothalamus and limbic system where the hypothalamus is responsible for the release of certain stress hormones in the body, while the limbic system is responsible for processing emotions. The brain sends signals down 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 indeveloping non-pharmacological treatments are based on the service are found to be an integral part of pain processing and new avenues for pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpathway. Once the slow pain tends to move a C-fiberpa

In addition to that, there are two types of nerve fibers that carry the majority of painsignals to the spinal cord: small diameter unmyelinated (A-delta) fibers and large diametermyelinated (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-beta fiber, the physical stimulation signal will reach the brain first because they movemore quickly than the pain signal. This supports the concept of cutaneous stimulation in painmanagement.

NeedForTheStudy

Over 1 million people with CRF worldwide are alive on dialysis with a functioninggraft. Incidence of CKD has doubled in the last15 years. In India, reports reveal that there is nincrease 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 CKDpatientinevery2000population.

Everyone would have definitely experienced some degree of pain and discomfortinthe lifetime. Pain is the most common reason for why people seek healthcare. Despite beingone of the most commonly occurring symptoms in the medical world, pain is the one of theleastunderstood. The context of comfort is the underwhich pain and pain management options are viewed. Pain management is considered as an important part of health care that the American Pain Society coined the phrase-"Pain; The Fifth Vital Sign" (Campbell 1995) to emphasize its significance and importance of effective pain management. Every member of the health care team should possess knowledge about the assessment of pain and its management both pharmacologically and non-pharmacologically.

The nurses, who are spending most of their working hours in interaction with thepatient unlike other members of thehealth care team have a central role in pain assessmentand management. The extent of nurse's involvement depends on the unique factors associated with the patient, the setting and the cause of the pain. Strategies include both pharmacologicsuch as opioids, NSAIDs etc and non pharmacologic making use of alternative therapies in order to control the pain these are widely in the clinical practice. The nurses assess the effectiveness of those interventions, monitoring for adverse side effects and serve as an an advocate for the patient when prescribed interventions are in effective in relieving pain. Procedural pain is one of the primary types of pain which the health care team encounter in their daily practice.

Effective procedural pain control is an essential component of the care of a patient. Apart from being inhumane, inadequate pain control, may result in increased morbidity ordecreased compliance to the treatment. Patients with endstagerenalfailure(ESRF)arerepeatedly exposed to stress and pain from approximately 300 punctures per year in their Arteriovenous fistula when they are on maintenance Hemodialysis. Repeated punctures at the AV fistula site lead to a considerable degree of pain, due to the caliber and length of the bevelof fistula needles. Pain being a sensitive, emotional, subjective and multi factorial feeling of the patient, lack of education, fear of complications associated with analgesic drugs, poor painassessment, and inadequate staffing are the causes for insufficient pain control. After hundreds of advances, the mainstay procedural pain therapy the of localanesthesia. When used properly, localanesthetics are safe and are effective inreducing

procedural pain, but they also carry with them undesirable side effects such as pain whileinjecting, allergic reactions, pruritus, and burning sensation. In high doses, local anestheticsmay produce toxic effects caused by being absorbed through the bloodstream into the rest ofthe body (systemic toxicity). This may significantly affect patient "sbreathing, heartbeat, bloodpressure, and other body functions (Webmed, 2010).

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 withcaution, because of the fine line between pain relief and toxicity, and consideration of thepatient sconcomitant health problems that influence the type of an algesia given. The alternative Medicine is an area of health care 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).

Touch is the language spoken through hands and understood by heart. Cutaneousstimulation will promote comfort by reducing the pain. Together, intention and touches set thetone and provide the basis for healing. The cutaneous stimulation is an independent nursing intervention which is used in various painful conditions, and is explained by Gate ControlTheory. Cutaneous stimulation modalities are clubbed with Acupressure to increase its effectiveness in pain management. The large intestine meridian is an acupressure point which is located on the back side of the hand between the thumb and the first finger. Its dominantuses are torelieve painin the shoulder and arm, rigidity of the neck, scapula, and eyediseases, and to treat constipation or other bowel disorders. Studies have also been conducted on the fact that Cryotherapy is equally effective in alleviating pain as a cutaneous stimulation technique safely and cost-effectively (Waters, 2003).

As recorded by Williams and Manias (2005) in their report on Pain Assessment and Management of Patients with Chronic renal failure. examined the although studies have renaleffectsofanalgesiaandhaveidentifiedthatpainispoorlymanagedinthepatientwithend stagerenalfailure, therewere no studies that examined pain assessment in renalfailure prior to reaching end stagerenal disease, or paincontrolinrenalfailurefromthenurses" perspective. Thereis only very littleinformation available toguidehealth professionals inpain management in patients with renal failure. Renal text books also do not directly addressthedifficultiessurroundingpainmanagementinrenalfailure(Daugirdasetal. 2001), althoughdrugdosinginrenalfailur eingeneralhasbeendescribedinpharmacologicalmonographs not readily available in the nurses" workplace (Aronoff et al. 1999, Bunn & Ashley, 2004). This literature has stimulated the investigator to stick on to the study. Theemergence of analgesic nephropathy 50 years ago remains a prominent untoward effect of analgesics that may significantly influence pain management practices; abuse of over-thecounteranalgesiccompoundsremainasignificantandcurrentcauseof kidneyfailure, McDonald&Russ (2003).

Moreover. during ten years of clinical experience, the researcher theneedforalleviatingpainwithsomenon-pharmacologicalmethodforpatientswhoaresuffering from pain throughout their Hence, researcher identified time. the the need forimplementingsomealternativetherapiesinmanagingproceduralpainduring AV fistulacannulation among Hemodialysis patients because she felt that the patients with CRF who areon dialysis suffer a lot with chronic as well as procedural pain. In addition to, the researcherwas interested to find out the effect of Cryotherapy in pain so that it can be effectively used inmanaging pain in various conditions. This study was therefore undertaken to find out theeffectiveness of the Cryotherapy on pain during AV Fistula puncture in HD patients so that itcanbeimplementedinsuchpopulationas evidence-basedpractice.

StatementOfTheProblem

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

ObjectivesOfTheStudyWereTo

- 1. assessthepainintensityduringXylocaine infiltration
- 2. determine the effect of Cryotherapy on pain and Biophysiological parameters during AV fistulacannulation.
- 3. associatethelevelofpainwithselecteddemographic variables

Operational Definitions

Effect – in terms of reduction of pain and change in Biophysiological parameters which isbroughtaboutbyCryotherapy

Cryotherapy – is the application of cold by using ice cubes over twelve minutes at LI 4meridian 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 ratingscale (NPRS)duringAVfistulacannulation

Hemodialysis - is a procedure by which toxin laden blood is diverted from the patient into adialyzerandthenreturningcleanbloodtothepatient

AV Fistula cannulation – is the venipuncture of the surgically created connection between aveinandanarterytouse as a vascularaccessforHemodialysis

Biophysiological parameters – refers to blood pressure, pulse rate and respiratory rate of thepatient **Patients** – are those who are diagnosed to have chronic renal failure and are on maintenancehemodialysis

Hypotheses

- 1. TherewillbesignificantdifferencebetweenpatientswhoreceiveCryotherapyandthosewhoreceive XylocaineinpainduringAVFistula cannulation.
- 2. There will besignificant difference between patients who receive Cryotherapy and those who receive Xylocaine in Biophysiological parameters during AVF is tula cannulation.

Assumptions

- 1. Patientswho undergohemodialysisexperience painduringAV fistulacannulation
- 2. PainwillhaveaneffectonBiophysiologicalparameters
- 3. Levelofpainvariesfrompersontoperson

ConceptualFramework

"Nursingisadistinctprofessionproviding 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)

Nursing is a complex field of study with a need for practical and hands-on training aswell as knowledge of theoretical andhistorical basis. Conceptual framework for this studywas formed on the basis of **Nursing Process theory**, created by Ida Jean Orlando who wasone among the early leaders in the field of nursing, developed her theory in 1961 as Dynamic Nurse- Patient Relationship; she furthered the development of her theory and published it as Nursing Process theory in 1972.

According to Orlando, the role of the nurse is to find out and meet the patient "simmediate 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 theirbehavior. This process helps nurse to find out the nature of the distress and what help the patient needs. The function is fulfilled when the nurse finds out and meets the patient s needfor help. Orlando s theory focuses on how to produce improvement in the patient condition. She asserts that the limitations on the patient s ability to meet his or her needs independently arises when the patient is receiving medical care or under medical supervision. Her theoryfollows the stepsin nursing process and meets the patient sneed. The major dimensions of the theory are:

- 1. The presenting behavior of the patient is expressed either interms of verbal or non-verbal language
- 2. Nurse"sresponsebyexploringthepatient"sbehavior
- 3. Nurse's action by delivering the needed care to solve the patient's problem
- 4. Outcomeintermsofpatientsatisfactionastheneedfor helpisresolved.

Orlando's conceptualization of the deliberative nursing process fulfills the criteria of atheory. 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 an ursing perspective rather than from a medical disease orientation.

PatientswithEnd-StageRenalDiseaseonmaintenancehemodialysisrequirehemodialysis3-4 times a week. This procedure requires arterial and venous access which is established by cannulation of AV fistula. Patients experience pain and discomfort during cannulation.

Nurse"s response to patient"s problem is by assessing the pain and biophysiologicalparameters.

Nurses" action is to solve the patient"s problem by applying cryotherapy which is anon-pharmacologicalmeasureforpainrelief. This action helps in pain reduction and improves the patient "scomfort. Moreover, nurse-patient interaction enhances the psychological well being of the patients.

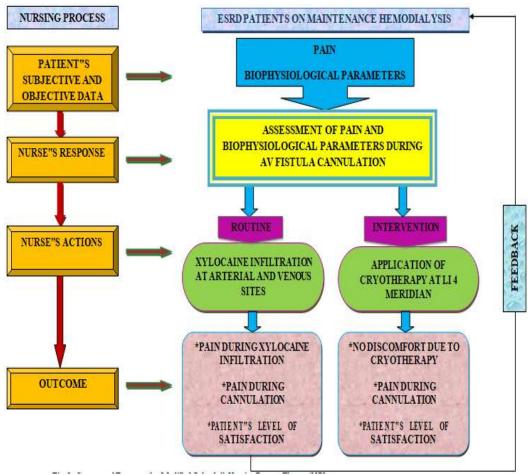


Fig.1:-ConceptualFramework-ModifiedOrlando"sNursingProcessTheory(1972).

Chapter-II

ReviewOfLiterature: -

Aliteraturereviewinvolvesscanningthepagesofanypublishedliteraturelikenewspaper,magazine,website,webpage,coll ection,books,paper,pamphletorevenunpublished manuscripts. Literature review is a part of the research where the researcher hasthe opportunity to strengthen the paper with the poured thoughts by the reliable authors on thetopic. This chapter deals with the facts gathered by the researcher which is relevant to thestudybyextensive reviewofavailableliterature inordertofortifythe presentstudy.

The collected information is analyzed and organized under the following headings:

- 1. Literaturerelatedto Hemodialysisand AV fistula
- 2. LiteraturerelatedtoCryotherapyandGate ControlTheory
- 3. Literaturerelatedtopainmeasurementand managementinpatientswithCRF
- 4. LiteraturerelatedtofactorsaffectingpainandBiophysiologicalparameters

LiteratureRelatedtoHemodialysisandAVfistula

ESRD is a worldwide publichealth problem and concern with increasing incidenceand prevalence, poor patient outcomes and high cost. In 2002, Chalmers defined ChronicRenal 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 (Terrill 2002).

In 2002, Antolin and his colleagues have performed a retrospective analysis with afollow-up time of seven years among 3106 hemodialysis patients and 542 peritoneal dialysispatients 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 thattheglobal survivalasthesameinboth groupsupto32monthsof treatmentandtheyidentified thatthose withcomorbidityhadabettersurvivalonhemodialysis.

As first described by Brescia et al in 1961, the primary arteriovenous fistula remainsthe best form of permanent vascular access. It ismore cost-effective and is associated withlessmortalitywhencomparedtoothervascularaccesses(USRDS,2009). Eventhenestablishing and maintaining a vascular access is one of the biggest problems among patients on Hemodialysis (Bonello, 2004); 20% of hospital admissions for clients on dialysis are forvascularaccess complications as statedby Saran, 2004.

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 highoverall 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 to further enhance the utilization of AVF and to reduce catheter rates in patients commencing hemodialysis as renal replacement the rapy to minimize the detrimental effects of other vascular accesses.

Chhetri et al (2009) carried out a study on vascular access in Nepal among 82 patientsattending HD unit over a period of one year. The analysis of the observed data revealed to theinvestigators that initial vascular access used was temporary ones such as subclavian 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.

In a prospective observational study, Lacson (2009) investigated onrelation between change in vascular access and mortality in maintenance hemodialysis patients. At baseline,79,545 patients had 43% fistulas, 29% catheters, and 27% grafts. The study data showed that compared with fistulas, deaths were higher for grafts and catheters. The analysis proved that catheters have the worst associated mortality risk. Change from a catheter to a fistula or graftwas noted by the investigators with significantly improved survival.

Ravanietal (2010)comparedoutcomesofarteriovenousgraftsandfistulasandstudied the variations in risk. Longitudinal data from 535 incident hemodialysis patients were collected and utilized by the investigators to study the relationship between access type and access survival. They reported that hazard for failure of fistulas and grafts declined over time, and became proportional after 3 months from surgery. The investigators considered the entire observation period and found out that grafts had slower hazard decline (P<0.001) with shorter median survival times than fistulas (8.4 versus 38.3 months).

Solesky et al (2010) have done a prospective survey and maintained vascular accessdata based on a comprehensive, patient-centered analysis of arteriovenous access placementand interventions, central venous catheter use, and associated complications. 39 patients withAVF, 8 prosthetic grafts and 52 catheters were followed longitudinally for an average of 4.1yrstodeterminethetimeofinitialcannulation,needforrevision,andthetimeofabandonment for each angio access. The collected data showed that an AVF prevalence ratewas 66%,meetingthe 65% goalsetbytheinvestigators.

Deiham (2010) have investigated on determinants of hemodialysis on access survival. The investigator retrospectively analyzed the vascular access procedures performed over atwo-yearperiod 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 revascul arization. The investigator "sminimal follow-up with functioning access was 679 days. During the observation period, 244 patients under went 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 musculoskeletalinjury to reduce pain and inflammation. It is used to reduce tissue temperature and has various physiolo

gical effects i.e. vaso constriction of blood vessels, decreased local metabolism, decreased blood his taminer eleased uring inflammation and reduced nerve excitability (Schafer, 1990). This makes Cryotherapy first in line formanagement of a cutein juries concernings welling, bleeding and pain relief (Mac Auley, 2001). Among chiropractic practitioners it is the most often utilized (94.5%) passive adjunctive the rapy.

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 eithergets inhibited nerve impulses or enhanced at the level of the spinal cord. Nerve impulsestraveling 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 closes resulting 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 icemassage of the web of skin between the thumb and forefinger for the reduction of acute dentalpain. His workshowed a 50 percent reduction inacute dentalpain.

Melzack and Wall did not explain in their study that how they decided on the selectedanatomical area to use ice massage. However, the two Physicians did studies comparingacupuncture to transcutaneous electrical nerve stimulation for pain relief. They have located within the anatomical area on the hand, as a cupressure 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, the skin between the thumb and forefinger is part of the thick, hard, and horny texture of the palmwhich can with stand the intermittent friction and cold temperatures used in this technique.

A research paper was presented at the University of Southern Queensland, Australia inJune, 1992 on Ice Massage for the Reduction of Labor Pain, and at a Midwifery EducationSeminar, Florida, 1993. A second, larger study was also carried out by a group of researchersin1999-2002. The results on Ice Massage for the Reduction of Labor Pain, was published in the Journal of Midwifery and Women s Health, November 2003. Medscape (WebMD Health Professional Network) had chosen the protocol as best in maternal health journals for the week and printed on the internet in its entirety. In 2010 it was included in Midwifery Best Practice, Vol5.

A study conducted by Nicholson and his colleagues in 1994 with the purposetoidentify and validate the effectiveness of selected cutaneous stimulation pain managementinterventions including heat and cold application, massage and Transcutaneous ElectricalNerve Stimulation (TENS). The authors concluded that cutaneous stimulation interventions are very effective means to manage pain.

In 1994, Park, studied to identify the effect of cutaneous stimulation on reduction of AVF puncture pain. One group repeated measurepost test research was designed and carriedout among 45 hemodialysis patients. The researcher measured **AVF** puncture pain controlperiodfirst, and then the pain of experimental period (with cutaneous stimulation). He observed that the subjective in experimental period was slightly lower than incontrolperiodbuttheobjectivepainbehaviorscoreofarteriovenousfistulapaininexperimentalperiodwas observedashigher.

Barber etal (1998) conducted research toevaluate the effects of cold therapy forpost operative pain in outpatientArthroscopic Anterior Cruciate Ligament Reconstructions.51 patients received cold therapy for 7 days. 49 patients had no cold therapy. Evaluation ofpain was done by the investigators at 1, 2 and 8 hours after surgery and then daily. Pain wasassessed using Visual Analogue Scale and Likert scales. The study reported that cold therapyloweredpain,reducedanalgesicusage,increasedkneeflexionandcontinuouspassivemovementamongexperimen talgroupthanthecontrolgroup.

Morsi (2002) conducted research on cold therapy after Total Knee Arthroplasty(TKA). Thirty patients who had undergone bilateral TKA were selected randomly. For everypatient, one limb was connected with cooling device applied over the surgical dressing postoperatively and the other limb with TKA with no cooling device attached. The limb connected to the cooling device was observed by the investigator with increased range of motion anddecreasedpain.

Edzard et al (2004) performed a study on Ice freezes pain? A review of the clinicaleffectiveness of analgesic cold therapy by the researchers revealed that ice has a strong short-term analgesic effect in many painful conditions. They have suggested that serial applicationsmay also be helpful because mechanisms by which cryotherapy elevates pain threshold werefoundtobe duetoanantinociceptiveeffectonthe gatecontrolsystem.

Studieshaveshownthatcoldapplications reduce themetabolic rate of at issue, decrease pain and swelling, and reduce muscle spasm. Most health care practitioners use icetherapy for treatment of bruises, strains, sprains, and muscle tears. Cryotherapy is familiar with the RICE (rest, ice, compression, and elevation) principle following acute soft tissue injury (Daniel, 2008).

Hubbard in 2004 stated that one of the primary reasons that clinicians use Cryotherapyin the management of acute injuries is due to its analgesic effect. Cold can increase painthreshold anddecrease the sensation of painty reducing nerve conduction velocity.

Bleakley et al (2004) had assessed on the use of ice in the treatment of acute softtissueinjurybymeansofasystematicreviewofrandomizedcontrolledtrialsstronglysuggested that based on the available evidence. cryotherapy was seemed effective indecreasingpain. Their study had concluded that ice and compression seemed to be significantly more effective than ice alone in terms of decreasing pain. In the majority of thestudies, they could find out that difference in the effectiveness of ice and compression compared with compressional one.

Kuzhanthaivel(2004)performedaprojectontheeffectofCryotherapyonpostoperative pain among 30 patients with fracture and reported that Cryotherapy can be included in nursing care among patients with fracture and surgical interventions as a modality to relieve pain.

Rodrigues et al in 2005 analyzed the side effects, such as pain, trismus and swelling, after the removal of third molars, by comparing the use or absence of Cryotherapy in the reduction of these effects 24 and 48 hours after surgery. It was an intra-individual, self-controlled, singleblind study. Cryotherapy was found to be effective in reducing swelling and pain in the study sample, and they recommended using it to reduce postoperatives welling and pain and pain in the study sample, and they recommended using it to reduce postoperatives welling and pain in the study sample, and they recommended using it to reduce postoperatives welling and pain in the study sample.

Seiki (2002) had reported that pain relief with cold application could be due to manymechanisms including altered Nerve Conduction Velocity (NCV), inhibition of nociceptors, are duction inmuscle spasms and/orareductioninmetabolic enzyme activitylevels.

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 meridianpoint 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 reductionmean on the VAS 28.22 mm on the left hand and 11.93 mm on the right hand. postdeliveryrankwasreportedasMPQdroppedfromnumber3(distressing)tonumber2(discomforting). The studyresultss upportedthaticemassageisasafe,noninvasive,nonpharmacologicalmethodofreducinglaborpain.

Kuoetal(2004)carriedoutastudyonthesorenessandnumbnesseffectofacupuncture on skinblood flowwith the purpose toinvestigate the effectof the De-Qisensationsofacupuncture(sourness-distensionanddistension-numbness)stimulation.42healthy medical student volunteers were given acupuncture by the investigators at the Hoku(LI-4) acupoint when they were resting. During a test that lasted 30 minutes, the respondents"skin blood flow was measured at the Quchi (LI-11) acupoint and their palm temperature wasmeasured by the investigators. In conclusion, when the test persons felt the sore and numbDe-Qi sensation, the investigators could identifyan increase of blood flow at the acupuncturepoints. Theirstudy results suggested thatincreasedflow canbe one of the mechanismsaccountingformeridiansystemresponses duringacupuncture andacupressure.

Haywardetal (2006) found in their randomized clinical trial that 16 of the 20 participants reported that the soreness caused by two lignocaine injections into the hallux was significantly reduced with a six-minute application of iceprior to injection.

Algafly, (2006) investigated the effect of Cryotherapyon Nerve Conduction Velocity (NCV), Pain Threshold (PTH) and Pain Tolerance (PTO) and described that Cryotherapy can increase paint olerance and pain the part of the

thresholdattheankleandthatwasassociated with a significant decrease in Nerve Conduction Velocity. In the control ankle, there was no alteration in NCV, PTH and PTO when they reassessed. In the ankle receiving Cryotherapy, it was found that NCV was significantly and progressively reduced as ankle skintemperature was reduced to 10°C.

Ownby (2006) conducted apilotstudy using randomized control trialson the effectsof ice massage on neuropathic pain in persons with AIDS to determine the feasibility of alarger study. Two treatments were used by the investigator consisted of ice massage and dry-towel massage among 33 persons with AIDS who had neuropathic pain. The obtained datashowed that there was a decrease in pain intensity over time with both the ice massage andtowelmassageand theresearcherconcluded that their trevention had some clinical benefit.

Bastian et al (2007) investigated prospectively among 107 patients who requiredextraction of two wisdom teeth, one on the left and one on the right side of the lower jaw todetermine the effect of cryotherapy during the surgical removal of wisdom teeth in reducingthe intensity of pain and general discomfort. They have carried out Cryotherapy on one sideonly. They have recorded intensity of pain by employing a Visual Analogue Scale. They haveconcluded that cryotherapy is effective in reducing pain, swelling and general discomfortfollowingextractionofawisdomtoothinthelowerjawwithoutcreatingirreversiblesequelae.

A study on the effects of Cryotherapy, Transcutaneous Electrical Nerve Stimulationand their combination on Femoral nerve electrical activity by Santuzzi et al (2008) clearlydepicted that Cryotherapy produces analgesia by two main local mechanisms, the neural andthevascularmechanisms. They explained that in the neural and the vascular mechanisms. They explained that in the neural and the vascular mechanisms of pain and with regard to the vascular effects of cryotherapy, the analgesia was associated with a decrease in blood flow, caused by cold-induced vaso constriction as well as reduced neural metabolism.

A project on the efficacy of Ethyl Chloride spray and ice cube as analgesic treatmentforantibioticskintestamong50healthyadultvolunteers.Eachsubjectwasgivenan intradermal skin test on both different arms after analgesic pre-treatment and the painanddiscomfortassessedusing Visual Analogue Scale. It was depicted by the investigators that ice cube application vapocoolant was more effective than the spray reducing pain ofantibioticskintestand90% of subjects preferred theice cube pre-treatment for the intradermals kintest. (Yoon&Chung, 2008).

Klein (2009) studied that Cryotherapy has the primary effect of cooling tissue. Theresearcheridentifiedbasicphysiologiceffectssuchasdecreasedlocalmetabolism, vasoconstriction, reactive hyperemi a, reduced swelling/edema, decreased hemorrhage, reduced muscle efficiency, analgesia secondary to impaired neuromuscular transmission, pain reduction associated with the application of cold, reduction in muscle spasm and minimal uppermotor neuronspasticity based on method of application and duration of the therapy

A Randomized Controlled Crossover Study conducted Lauraet al (2009)was by on Effects of Ice Massage on Pressure Pain Thresholds and Electromy og raphy Activity Postexer cise concluded massage after isokinetic exercise produced an immediateincrease of pressure pain thresholds over the Vastus Medialis (VM), Vastus Lateralis (VL), and Rectus Femoris (RF) muscles. They have recorded that EMG activity over the VL musclein recreational athletes, had suggested ice massage may result in a hypo analgesic effect andimprovements in EMG activity.

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 AVFwere assessed in a Randomized Control Trial by the group. The objective and subjective AVpainscoresondays1and2ofHDwithintheexperimentalgroupwerefoundtobesignificantly reduced from an average of 3.8 on day 1 of HD (when the patientreceivedroutine care) to 0.7. Pain scores on days 1 and 2 of HD within the control group were found tobe similar on two consecutive days of HD. They have concluded that cryotherapy is effective in reducing AV fistula puncture pain of hemodialy sispatients.

LiteraturerelatedtopainmeasurementandpainmanagementinCRF

Patients with renal failure often experience pain. Moreover, they suffer from the painduring AV fistula cannulation every other day which is unavoidable as dialysis is their life-savingtreatmentoption. Butlocalanesthesia is not often used due to concerns of vaso constriction, burning sensation,

scarring, and infection in most of the dialysis centers. Optimal pain assessmentand managementare key clinical activities yetinadequate paincontrolamongrenal patients by health professionals persists.

Bennett and Porter (1998) stated that as many questions about the exact etiology of an algesic nephropathy remain, there exists the need for more research to determine the exact prevalence of this disease and for pharmaceutical companies to conduct stringent tests on thesafetyof their an algesics.

Miller et al (2001) performed a prospective, randomized, quasi-experimental study byusing a convenient sample who were undergoing outpatient or same-day surgery to assesspatient'sperceptionofpainassociated with peripheral intravenous cannulation, using 3 methods of applying local anesthetics such as injection of 1% lidocaine, application of topical EMLA cream and treatment with "Numby Stuff". After the intended analgesic treatment was completed, 18-gauge IV catheters were inserted, and the investigators asked the patients torate the amount of pain experienced with it. They utilized visual analog scale as the tool of measurement for pain by the investigators. Results of the study showed that out of 3 methods tested by the researchers, the data indicated that the Numby Stuff system using ion to phoresis is the superior method for decreasing the pain associated with peripheral IV cannulation.

A study entitled"Pain MeasurementTools AndMethods In Clinical Research InPalliative Care" was conducted by an Expert Working Group of the European Association ofPalliative Care (2002) to review the status of the use of Pain Measurement Tools (PMTs) inpalliative care inamultilingual-multicentersetting. Theirstudyrecommendedthat standardized methods should be applied for the use of PMTs in palliative care researches. VAS, NPRS, Verbal Rating Scales, the McGill Pain Questionnaire and Brief Pain Inventorywere recommended by their vestigators in palliative care settings.

Kurella etal (2003) had reviewed the evidence on pharmacokinetics and side effects of the various analgesic drugs in renal failure. Most of the analgesics are excreted renally orby the liver, and so even the use of paracetamol (acetaminophen) was cautioned among renalfailure patients.

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

A Research into Pain Perception with Arteriovenous Fistula Cannulation conducted byFigueiredoetal(2008)recordedthatpatientswithend-stagerenalfailureundergoinghaemodialysis exposed to stress and pain from frequent punctures to their arteriovenous fistula. The objective of the study was to measure pain associated with AVFneedling and they used a analogue visual scale. Patients perceptions were measured in threedifferentHDsessions. PainwasconsideredmildduringAVFneedling. Thebuttonholetechnique 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 collecteddata associated with the button hole technique.

Literature related to factors affecting Pain and Biophysiological parameters

Carlsonetal(1997)conductedresearchtoidentifythepsychologicalandphysiological variables among 35 persons reporting Masticatory Muscle Pain (MMP) from 35Normal Controls (NC). They have evaluated subjects' emotional and physiological responses(Heart Rate, Blood Pressure, Respiration, Skin Temperature, and Muscle Activity). The havedrawnaconclusionthatpersonswithMMPreportedgreaterfatigue,disturbedsleep,depression, anxiety, menstrual symptoms, and less self-deception than matched controls. Atrest, MMPs were found tohavelower end tidal carbon dioxide levels andlower diastolicblood pressures than the NCs. Muscle pain patients reported lower pressure pain thresholdsthantheNCs atthe rightorleftMasseterandrightTemporalissites.

conducted by Tanaka et al (2001)investigated to compare effect of twotypesofsuperficialAcupuncturestimulationusingvariousphysiological parametersandpainindex. The subjects were 10 chronic tension type head a chesufferers and 2 types of Acupuncture procedures were administered. At the beginning and end of the experimentsession, theinvestigators asked the subjects to rate the headacheintensity with a VAS. Following the stimulations, the static EMG, heart rate and pulse height were continuouslymonitored 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 score reduction. 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 EmergencyDepartment (ED) patients. They included a convenience

sample of patients presenting to anacademic ED with pain. Heart rate and pain intensity were determined at the time of triage, 30minpostpaintreatment, 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 a cutepain.

To sum up, pain is not just physiological response, but the psychological variables likebehavioral 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 thepain experienced during procedures. Considering this aspect the researcher was interested toconductthestudy toreduce thepain perception during AV fistula cannulation with the application of Cryotherapy. The purpose of which was to aid cost effective nursing care if found effective.

Chapter III

Methodology:-

Research methodology is logical way solve a problem. It discipline a to is studyinghowstudyistobecarriedout.Inactualfact,theproceduresbywhichresearchersgoabouttheirwork of describing, explaining and predicting phenomena by which findings were obtained. It is essential for a researcher to design a methodology for the selected problem to have blue printof the study in advance. So, in this chapter the investigator portrays the methods adopted toaccomplish the research and it deals with the research design, variables under study, setting ofthe study, population, sample size, sampling technique, criteria for the selection of sample, description of the tool, testing of the tool, pilot study, procedure for data collection and statistics analysis.

ResearchDesign

The designad opted for the study is Repeated Measures Experimental Design (Crossover Design). Schematic representation of the design:

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

XI– WithXylocaine X2-WithCryotherapy

O1 —Observation1withXylocaine onday1O2— Observation2withCryotherapyonday2O3 — Observation3withXylocaine onday3O4— Observation4withCryotherapyonday4O5 —Observation5withXylocaine onday5O6—Observation6withCryotherapyonday6

The researcher used Repeated Measures Design to accomplish the study because Painis asubjectivevariable which changes time to time.

VariablesUnderStudy

In this study, the independent variable was Cryotherapy and the dependent variableswere Painand Biophysiological parameters namely Blood Pressure, Pulserate and Respiratory rate.

SettingOfTheStudy

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 departmentrum for 24 hours a day. There are 2 dialysis units, one for infected patients and the other fornon-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 unitperforms approximately 60 Hemodialysis perday.

Population

Population for the study were the adult patients with Chronic Renal Failure who wereundergoingHemodialysis atKMCH Hemodialysisunit.

SampleSize

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

SamplingTechnique

Simplerandomsamplingtechniquewasadoptedtoselectthesamplefromthepopulation. Totally, 93 patients were there under the consultant Nephrologist. Out of them, 78patients have met the inclusion criteria. Lottery method without replacement was adopted toselect50samplesbygivingequalchancetoeachpatienttobeasasubjectinthestudy.

CriteriaForSampleSelction

Inclusioncriteria

- 1. PatientswhoundergomaintenanceHemodialysiswithAVfistulaasthevascularaccess
- 2. Bothmaleandfemaleadultpatientsbetweentheagegroupof20-60years
- 3. PatientswhoundergoatleastthreeDialysisperweek

Exclusioncriteria

- 1. PatientswithanyPsychiatricillness
- 2. Patientswhodonotreport anypainduringtheprocedure.

DevelopmentOfTheTool

The toolsusedinthisstudyconsisted of 3 sections:

Section-1-Demographicandclinical profile

Itincludedage, sex, marital status, occupation, and educational status, duration of illness and duration of treatment.

Section -2- Biophysiological parameters

Measurementofbloodpressure, pulserate, respiration rateduring cannulation.

Section -3-Numerical pain ratingscale (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.

DescriptionOfTheTool

Omron digital automatic monitor was calibrated for BP and pulse from the biomedicaldepartment. For the respiratory rate, interrate reliability showed r=0.96.

Reliability and Validity of NPRS

The Numeric Pain Rating Scale has demonstrated good levels internal consistencywith Cronbach's alpha coefficient of 0.86 - 0.88 and test-retest reliability co-efficient rangedfrom0.57-0.83 suggesting acceptable reliability of the measures. (Hadjist arropoulosetal 2007). Herrand 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 hasdemonstrated significant, positive relationship with other measures of painintensity and sensitivity to changes due to treatment.

DescriptionOfTheIntervention

The primary purpose of the intervention (application of cryotherapy) was to reduce thepain intensity of the subjects during AV fistula cannulation. The required ice cubes for theapplication were kept ready in the freezer by the investigator. The prepared ice cubes were of6-8 degree Celsius. Explanation regarding the procedure was given aftermaking thesubjectlic comfortably on bed in the dialysis unit. Cold application was done on the web between thethumb 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 painwas assessed with cannulation after Cryotherapy both at the arterial land venous sites of the AV fistula.

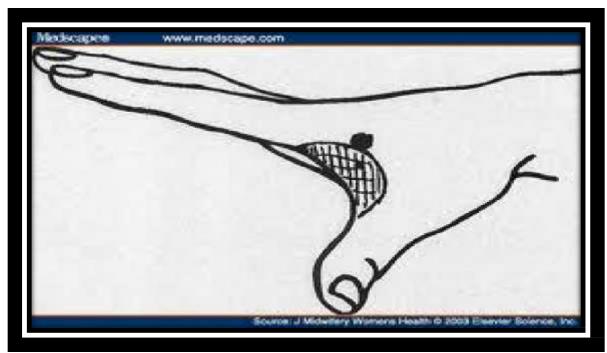


Fig. 2:- Anatomicallocation of LI4 Meridian/ Hoku point.

PilotStudy

Pilot study was conducted for a week among 5 patients to find out the feasibility of thestudy, the practicability of the intervention and to make sure the protection of the humansubjects. 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.

ProcedureForDataCollection

Formal permission was obtained from the Chairman of the hospital and the consultantNephrologist, 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 about their 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 in filtration. Biophysiological parameters were recorded during cannulation and the pain was assessed with Xylocaine in filtration and with cannulation both at the arterial and venous sites of the AV fistula using NPRS. On second, fourth and sixth days of dialysis, the data were collected when the subjects were given Cryotherapy.

StatisticalAnalysis

The data collected were analyzed by descriptive statistics by means of Mean, StandardDeviation, and Percentage to describe the demographic characteristics of the subjects and todescribe the pain intensity of the subjects during Xylocaine infiltration and during AV fistulacannulation.Inferentialstatisticsnamely,paired and and another the statement of the subjects and biophysiological parameters measured during various observations during cannulation done with Xylocaine infiltration and with Cryotherapy. One way ANOVAwas performed to associate the pain intensity and selected variables.

ChapterIV

DataAnalysisAndInterpretation

The science of collection, analysis, interpretation or explanation, and presentation ofdata 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 Cryotherapyon Pain and Biophysiological variables during AV fistula cannulation among patients on Hemodialysis

Theanalysesand interpretationareorganized as follows:

SECTION A:DescriptionofSubjectsaccording totheirDemographic and Clinicalprofile

SECTION B:Descriptionabout the MeanPainscoreoftheSubjects

SECTION C:Descriptionaboutthe Biophysiological parameters during Cannulation

SECTION D : Comparison of the Mean Painscore on various

ObservationsSECTIONE:ComparisonofBiophysiologicalparametersonvarious Observations

SECTION F :Comparison of Pain score during AV fistula cannulation done with Xylocaine and done with Cryotherapy.

 $SECTIONG: Comparison of \\ Biophysiological parameters during AV fistula cannulation done \\$

with Xylocaine and done with Cryotherapy.

SECTIONH: 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	l f	Percentage(%)
5.110	2 cmograpme variables	(N=50)	Tereentage(70)
1.	Ageinyears		
	a) 21-30	10	20
	b) 31-40	8	16
	c) 41-50	18	36
	d) 51-60	14	28
2.	Sex		
	a) Male	41	82
	b) Female	9	18
3.	Maritalstatus		
	a) Single	5	10
	b) Married	45	90
4.	Educationalstatus		
	a) Primary	9	18
	b) Secondary	20	40
	c) Highersecondary	10	20
	d) Graduate	6	12
	e) Postgraduate	5	10
5.	Occupationalstatus		
	a) Employed	38	76
	b) Unemployed	12	24

Table 1 represents distribution of subjects according to their demographic characteristics. Out of 50subjects; 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) weremarried. 40 per cent of the subjects had secondary education and 10 had higher secondaryeducation.38among50(76percent)subjects wereemployed.

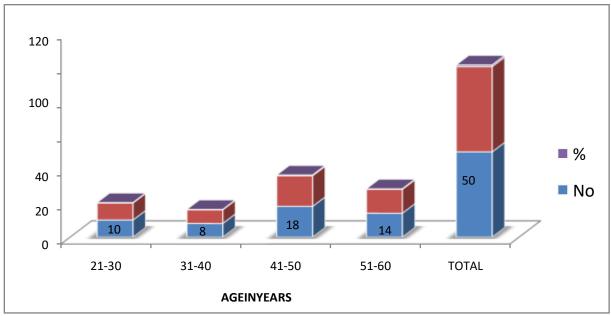


Fig.3:- Agewisedistribution of the subjects.

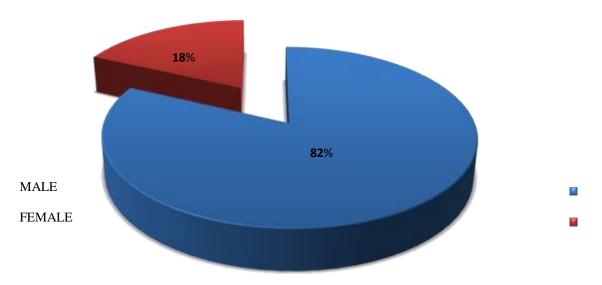


Fig.4:- Genderwise distribution of the subjects.

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

S.No	Characteristics	f	Percentage(%)
		(N= 50)	
1.	Durationofillness inyearsa)1-3		
	b)3-5	12	24
	c)5-7	23	46
		15	30
2.	DurationofHemodialysisinyearsa)1-3		
	b)3-5	31	62
	c)5-7	9	18
	·	10	20

Table2showsthat23(46percent)subjectsweresufferingfromrenalfailureforthepast3-5yearsand31(62percent)were undergoingHemodialysisfora periodof1-3years

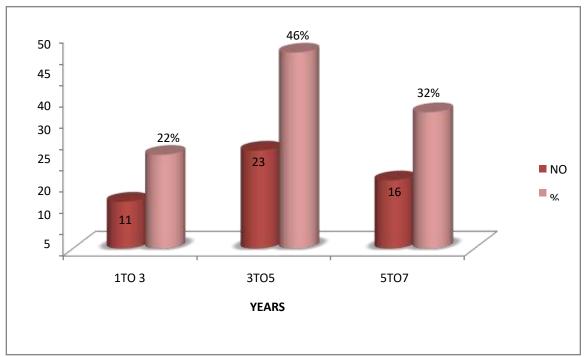
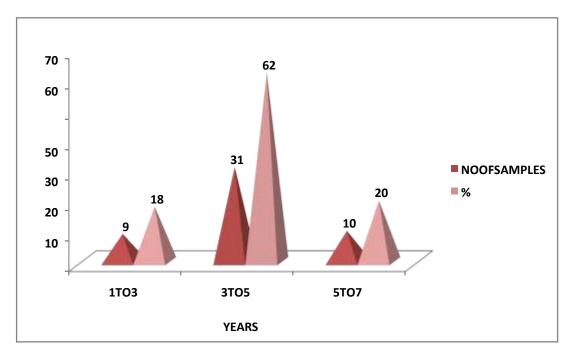


Fig.5:- Distribution of Subjects according to their Duration of Illness in years.



 $\textbf{Fig.6:-}\ Distribution of Subjects according\ to their Duration\ on Hemodialysis in\ years.$

Section –B **Descriptionaboutthe MeanPainscoreoftheSubjects:**

Table3:- Mean and SD of Pain scores during Xylocaine in filtration on Day 1,3 and 5 N=50

Day	Puncturesite	Mean	S.D
1	Arterial	4.88	1.15
	Venous	4.96	1.20
3	Arterial	4.78	1.20

	Venous	4.88	1.17
5	Arterial	4.76	1.13
	Venous	4.74	1.12

The table 3 shows the mean and the standard deviation of the pain scores of the subjects duringXylocaine infiltration at arterial site and venous site on three consecutive days of dialysis. Withregard to the arterial site, 4.88 were the maximum score andthe minimum score was 4.76whereas4.96 wasthemaximumscore at the venoussite and 4.74 wasthe minimum pain score.

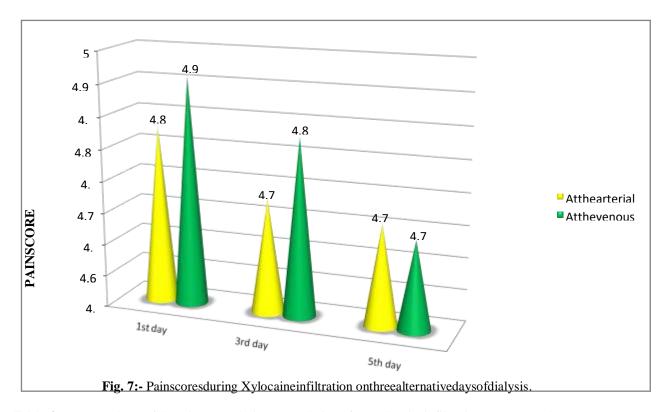


Table 4:- Mean and SD of the Painscores during Cannulation after Xylocainein filtration on Day 1,3 and 5.

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

This table describes the mean and the SD of the pain scores of the subjects during AVfistulacannulation after Xylocaine infiltration at arterial site and venous site on day1, 3 and 5. Withregard to the arterial site, 1.62 was the maximum and the minimum score was 1.56 whereas 1.54was themaximumand1.48was the minimumpainscoreatthevenous site.

Table 5:- Mean and SD of Pain scores during Cannulation after Cryotherapy on Day 2, 4and6.

Day	Puncturesite	Mean	S.D.
	Arterial	0.96	0.35
2			0.40

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

ThistabledepictsthemeanandSDofthepainscoresofthesubjectsduringAVfistulacannulation at arterial site and venous site after Cryotherapy on day2, 4 and 6. In regard to painscore at the arterial site, 0.98 was themaximum and theminimum was 0.94 whereas 0.94 wasthe maximumand0.90was the minimumpainscoreatthe venous site.

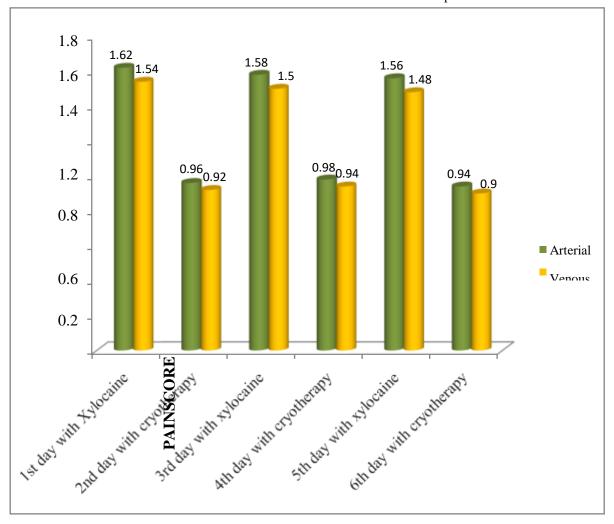


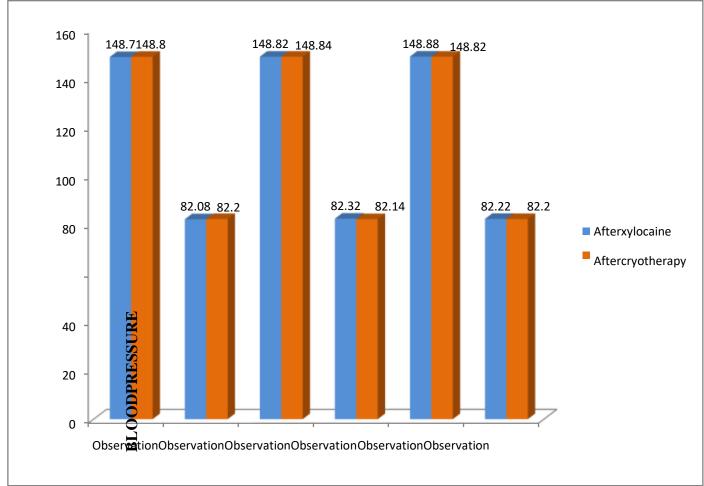
Fig. 8:- PainscoresduringCannulation afterXylocaineinfiltrationandafterCryotherapyonvariousObservations. SectionC

Description about the Biophysiological parameters during cannulation:

 $\textbf{Table 6:-} \ Mean and SD of Systolic and Diastolic Blood Pressure during Cannulation on various Observations.$

		WithXylocaine		WithCryotherapy	
SNo.	BloodPressure	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 doneafter Xylocaine infiltration and after Cryotherapy. The values show that there is no noticeable difference among various observations.



 $\textbf{Fig.9:-} \ Mean Systolic and Diastolic Blood Pressure during \ Cannulation \ on various Observations.$

Table7:- MeanandSDofPulserateduringCannulationonvariousObservations.

	Mean	S.D	Mean	S.D
Observation	WithXylocaine		WithCryotherapy	
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 AVfistula cannulation with Xylocaine and with Cryotherapy. The values show that there is nonoticeable differencebetweentwomodes of care.

Table 8:-MeanandSDofRespiratory rateduringCannulation variousObservations.

	Mean	S.D	Mean	S.D
Observation	WithXylocaine		WithCryotherapy	
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.

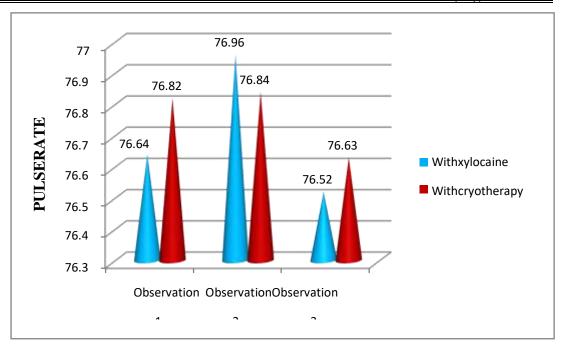


Fig. 10:- MeanPulserateduringCannulationonvariousObservations.

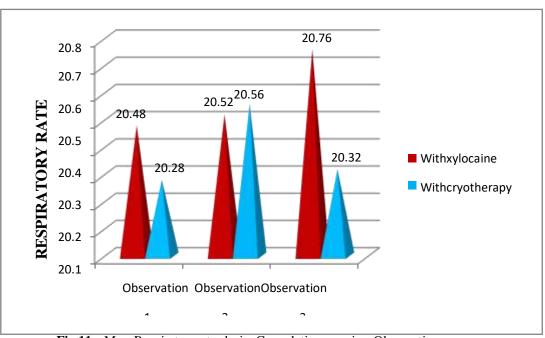


Fig.11:- MeanRespiratoryratesduringCannulationonvariousObservations.

SectionD

Comparison of the Mean Pains cores on various Observations:

Table 9:- Comparison of Mean Pains cores during Xy locaine in filtration at the Arterial and Venous sites N=50

Day	Mean	S.D.	"t"value			
At the	arterialsite					
Observ	ration1&3					
1	4.88	1.15	1.068(NS)			
3	4.78	1.20				
Observ	Observation1&5					
1	4.88	1.15	1.122(NS)			
5	4.76	1.13				

Observat	Observation3&5					
3	4.78	1.20	0.314(NS)			
5	4.76	1.13				
Attheve	nous site					
Observat	tion1&3					
1	4.96	1.19	0.912(NS)			
3	4.88	1.17				
Observat	tion1&5					
1	4.96	1.20	0.718(NS)			
5	4.90	1.12				
Observat	Observation3&5					
3	4.88	1.17	0.304(NS)			
5	4.90	1.12				

This table shows the comparison between the pain scores at arterial and venous sites among 3observations with Xylocaine. The computed"t" values show no significant difference in the painscores bothatthearterialandvenous site

 $\label{prop:comparison} Table 10: \textbf{-} Comparison of Mean Pains cores during Cannulation after Xylocaine in filtration at the Arterial and Venous sites \textbf{N}=\textbf{50}$

Day	Mean	S.D.	"t"value
At the	earterialsite		
Observ	vation1&3		
1	1.62	0.60	0.514(NS)
3	1.58	0.54	
Observ	vation1&5		
1	1.62	0.60	0.750(NS)
5	1.56	0.50	
Observ	vation3&5		
3	1.58	0.54	0.344(NS)
5	1.56	0.50	
Atthe	venous site		
Observ	vation1&3		
1	1.54	0.61	0.504(NS)
3	1.50	0.51	
Observ	vation1&5		
1	1.54	0.61	0.710(NS)
5	1.48	0.51	
Observ	vation3&5		
3	1.50	0.51	0.330(NS)
5	1.48	0.51	

This table shows the comparison between the pain scores at the arterial and venous sites duringAV fistula cannulation after Xylocaine infiltration on various observations. The computed"t" values shown ostatistically significant difference in the pain score among 3 different observations

 $\label{lem:comparison} \textbf{Table 11:-} Comparison of Mean Pains cores during Cannulation after Cryotherapy at the Arterial site and Venous sites \textbf{N=50}$

51C511-50								
Day	Mean	S.D.	"t"value					
At thea	At thearterialsite							
Observa	ation2&4							
2	0.96	0.35	0.324(NS)					
4	0.98	0.25						
Observa	ation2&6							
2	0.96	0.35	0.328(NS)					
6	0.94	0.31						
Observa	Observation4&6							
4	0.98	0.25	0.590(NS)					
6	0.94	0.31						

Attheve	Atthevenous site						
Observat	tion2&4						
2	0.92	0.39	0.344(NS)				
4	0.94	0.37					
Observat	tion2&6						
2	0.92	0.39	0.306(NS)				
6	0.90	0.36					
Observat	Observation4&6						
4	0.94	0.37	0.582(NS)				
6	0.90	0.36					

This table shows the comparison between the pain scores at the arterial and venous sites duringcannulation after Cryotherapy application on day2, day4 and day6 of dialysis. The computed"t" values shows no statistical significant difference in the pain score among various observations.

SectionE

Comparison of Biophysiological parameters on various observations:

Table12:-

 $Comparison of Mean Systolic Blood Pressure during Cannulation after Xylocaine in filtration and after Cryotherapy {\bf N=50}$

Day	Mean	S.D.	"t" Value	
With X	ylocaine	•	•	
Observa	ation1&3			
1	148.70	20.62	0.862(NS)	
3	148.82	20.50		
Observa	ation1&5			
1	148.70	20.62	0.974(NS)	
5	148.88	20.66		
Observa	ation3&5			
3	148.82	20.50	0.516(NS)	
5	148.88	20.66		
WithC	ryotherapy			
Observa	ation2&4			
2	148.80	20.63	0.294(NS)	
4	148.84	20.49		
Observa	ation2&6			
2	148.80	20.63	0.297(NS)	
6	148.82	20.66		
Observa	ation4&6			
4	148.84	20.49	0.291(NS)	
6	148.82	20.66		

This table shows the comparison between the blood pressure readings during cannulation afterXylocaine 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 bothwithXylocaine and withCryotherapy.

Table13:-ComparisonofMeanDiastolicBloodPressureduringCannulationafterXylocaineinfiltrationandafterCryotherapyN = 50

Day	Mean	S.D.	"t" Value					
With 2	With Xylocaine							
Observ	ration1&3							
1	82.08	8.92	0.892(NS)					
3	82.32	7.52						
Observ	ration1&5							
1	82.08	8.92	0.703(NS)					
5	82.22	7.78						
Observ	Observation3&5							
3	82.32	7.52	0.671(NS)					
5	82.22	7.78						

WithCr	WithCryotherapy						
Observa	Observation2&4						
2	82.20	8.91	0.742				
4	82.14	7.53	(NS)				
Observa	tion2&6						
2	82.20	8.91	0.443(NS)				
6	82.26	7.77					
Observa	Observation4&6						
4	82.14	7.53	0.604(NS)				
6	82.26	7.77					

ThistableshowsthecomparisonbetweentheDiastolicbloodpressurereadingsduringcannulation after infiltration on various observations. The computed "t" values shownostatisticalsignificantdifferenceinthebloodpressurereadingsamongvarious observations.

Table 14:- Comparison of Mean Pulser at esduring Cannulation with Xylocaine in filtration and with Cryotherapy N=50

Day	Mean	S.D.	"t" Value
With	Xylocaine	•	·
Observ	ation1&3		
1	76.82	4.44	0.374(NS)
3	76.84	4.85	
Observ	ation1&5		
1	76.82	4.43	0.497(NS)
5	76.63	4.60	
Observ	ation3&5		
3	76.84	4.85	0.505(NS)
5	76.63	4.59	
WithC	Cryotherapy		
Observ	ation2&4		
2	76.64	5.01	0.783(NS)
4	76.96	5.00	
Observ	ation2&6		
2	76.64	5.01	0.397(NS)
6	76.52	4.57	
Observ	ation4&6		
4	76.96	5.00	0.812(NS)
6	76.52	4.57	

This table shows the comparison between the pulse rates during cannulation after Xylocaineinfiltration and with Cryotherapy on various observations. The computed "t" values shows no statistical significant difference in the pulse rates among various observations.

Table 15: - Comparison of mean Respiratory rates during Cannulation after Xylocaine in filtration and after Cryotherapy. The property of the property of

Day	Mean	S.D.	"t" Value
With	Xylocaine		·
Observ	vation1&3		
1	20.48	1.37	0.098(NS)
3	20.52	1.42	
Observ	vation1&5		
1	20.48	1.37	0.438(NS)
5	20.76	1.56	
Observ	vation3&5		
3	20.52	1.42	0.208(NS)
5	20.76	1.56	
WithC	Cryotherapy		
Observ	vation2&4		
2	20.28	1.47	0.431(NS)
4	20.56	1.69	
Observ	vation2&6	•	•

2	20.28	1.47	0.096(NS)
6	20.32	1.54	
Observa	tion4&6		
4	20.56	1.69	0.272(NS)
6	20.32	1.54	

This table shows the comparison between the respiratory rate during cannulation with Xylocaineinfiltration and with Cryotherapy on various observations. The computed "t" values show no statistically significant difference in the respiratory rates among various observations

Comparison of pains coreduring AV fistula cannulation after Xylocaine and after Cryotherapy: Table 16:-

Comparison of Mean Pains cores during AV fistula cannulation do newith Xylocaine in filtration and do new ith Cryotherap v.

S.No.	Painscore	Mean	S.D.	"t"value
1.	With XylocainewithCryotherapy	1.59	0.546	11.885**
		0.96	0.345	
Attheve	noussite: -			
2	With XylocainewithCryotherapy	1.51	0.540	11.273**
		0.92	0.338	

^{**}Significant at0.01level

The above table compares pain scores during cannulation after Xylocaine infiltration and afterCryotherapyapplication. The independent "t" computed and the values obtained were 11.885 and 11.273 for the arterial site pain scores and venous site correspondingly the values are more than the table value (2.390) at df48 which is statistically highly significant. The values infer that Cryotherapyhasane ffectine ducing pain during AV fistula cannulation among Hemodialy significants.

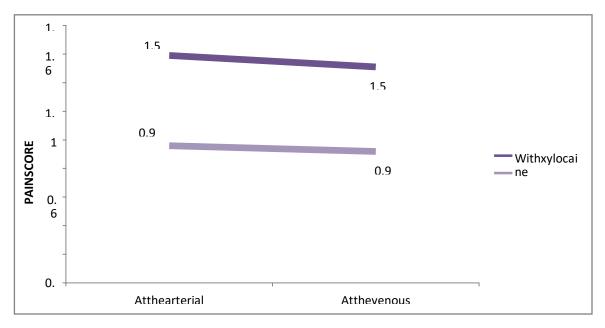


Fig. 12:- ComparisonofMeanPainscoresduringCannulationdonewithXylocaine infiltrationanddonewithCryotherapy.

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 X vlocaine and	vithCrvotherapy.
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S.No	Variables	Mean S.D.		"t"value		
		Xylocaine	Cryotherapy	Xylocaine	Cryotherapy	
	Systolic					
1.	BloodPressure	148.80	148.98	20.59	20.59	0.905(NS)
	DiastolicBlood					
2.	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 duringcannulation done with Xylocaine and done with Cryotherapy. The computed" t" values give aninference that there is no statistically significant difference among biophysiological parametersamong various observations during AV fistula cannulation done with Xylocaine infiltration andwith Cryotherapy which gives an inference that Cryotherapy has no effect on biophysiological parameters during AV fistula cannulation.

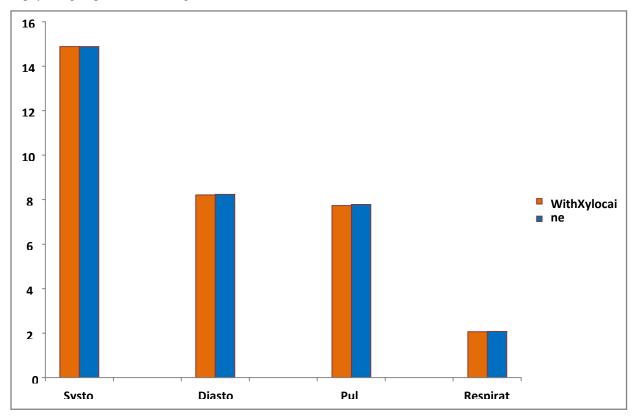


Fig. 13:-Comparison of Biophysiological parameters during Cannulation done with Xylocaine and done with Cryotherapy.

SectionH

Associationofpainscore withselectedvariables:

Table 18: - Association between pains core and demographic variables.

S.No.	Demographicvariables	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 score with age and gender of thestudy samples. F values show that there is no significant association existing between pain scoreandtheselecteddemographic variables

Table19:- Association between Painscore and 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

Theabovetabledisplaystheassociationbetweenthepainscoreandclinical variables. The computed F value to associate pain score and 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 pains core of the subjects and duration of their illness.

Table 20:- PostHoctestsofassociation with Pain score and Duration of Illness.

S.No.	ClinicalVariable	Mean	SD
1 Durationofillnessinyears			
	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 score of 3-5 years (mean-0.90, SD-0.33) and the pain score of 1-3 years (mean-1.10, SD-0.35) were significantly different from the pains cores of 5-7 years (mean-0.82,SD-0.27). However, there was no significant difference existed between the pains core of 1-3 years and 3-5 years.

Table21:- Association between Painscore and Duration of Hemodialysis in years.

S.No.	Clinicalvariable	N	Mean painscore	SD	F-value
1	Duration				
	onHemodialysisinyears				
	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 score and duration of hemodialysis inyears. 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:- PostHoctestsofassociation with Pain scoreand Duration of Hemodialysis.

S.No.	ClinicalVariable	Mean	SD
1 Duration			
	onHemodialysisinyears		
	a)1-3		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 score of 3-5 years onhemodialysis (mean-0.96, SD-0.33) and the pain score of 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 score of 1-3 years and 3-5 years.

Chapter V

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

The present study was designed to assess the effect of cryotherapy onpainandbiophysiological 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.

Themajor resultsofthe studyare discussed according to thebelow objectives:

Discussion:-

Thefirst objectivewastoassessthepainintensityduringxylocaineinfiltration

The hemodialysis unithas a routine to administer intradermal xylocaine injection toanesthetize the arterial and venous site prior to cannulation. Almost every patient complains ofpain 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 consecutivedays 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 moderatepainduringthexylocaineinfiltration.

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

To determine the effect of cryotherapy on pain and biophysiological parameters, theinvestigator assessed the level of pain of the subjects with cannulation after xylocaine and aftercryotherapy by using the same tool and both the values were compared. Blood pressure, pulserateandrespiratoryrate were recordedunderbothsituations andwerecompared.

Themean painscoreof thesubjects duringcannulation afterxylocaineinjection 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 duringcannulation even after xylocaine is administered as local anaesthetic. The mean pain score ofpatients with cannulation after cryotherapy at arterial site were 0.96, 0.98 and 0.94 and at venoussite were 0.92, 0.94 and 0.90 on the 2nd, 4th and 6th days of dialysis respectively. The findings ofthe study suggest that the patients suffer from mild pain during cannulation after cryotherapy butthe pain intensityislesserthanthe painduringcannulationafterxylocaineinfiltration.

The pain scores during cannulation with xylocaine and with cryotherapy were comparedusing independent"t"test. The"t"value of the comparison between the pain score at the arterialsite 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 comparisonbetween the pain perception at the venous site with cannulation after xylocaineinjection andwith cannulation after cryotherapy was 11.273 indicated that the pain intensity with cryotherapywas 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 inreducing pain during AV fistula cannulation and xylocaine infiltration needle pricks (i.e. 2 prickspereachdialysis)andassociatedpaincanbeavoided.

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 20.592 respectively. The calculated"t" value was 0.905 which gave an inference that there was no significant change in the systolic blood pressure between cannulation done with xylocaine and cryotherapy amongthesubjects. Themeans core 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 thediastolicblood pressure readings under both conditions.. Themean pulse rates with xylocaineandwithcryotherapywere77.32and77.80withstandarddeviationsof4.810and4.239respectively. The calculated"t"value was 0.917 which showed significantchangeinthepulseratesunderbothconditions. Themeanrespiratoryrateswithxylocaineandwithcryotherapywere2 0.67and20.70withstandarddeviationsof1.496and1.580correspondingly. The computed"t"value was 0.210 which indicated that there is no significantchange in the respiratory rates between AV fistula cannulation done with xylocaine and withcryotherapy. Theoverallinference is that cryotherapy has no effect on biophysiological parameters such as blood pressure, pulse rate and respiratory rate among the subjects. Thesefindings of the study portray that cryotherapy cutaneous stimulation among hemodialysispatients duringAVFcannulationhas noeffectonbiophysiologicalparameters.

The results of the present study are in contradictory to the findings of the study conducted Park (1994). In that study, Cardiopulmonary signs of arteriovenous fistula puncture pain inexperimental period was found to behigher than in control period (pulse paired t=-0.8, p=0.42; systolic BPpaired t=0.98, p=0.33; diastolic BP paired t=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 score with age of the subjects and genderdifferences. The results showed that pain was neither associated with age nor with gender of thesubjects. Therefore, it is concluded that baseline factors are independent of their pain score with regardtotheir demographic variables.

A study conducted by Kelly to determine the minimum clinically significant difference invisual analogue scale (VAS) pain scores for acute pain in the emergency department setting andto determine whether this difference varies with demographic profile and pain intensity. Resultsof 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 finding softher present study indicating that base line factors are independent of their pains core with regard to their demographic profile.

One way ANOVA was used to associate the pain score with duration of illness and duration of treatment. The obtained Fvalues were 6.063 and 6.013 which showed that there was significant association (at 0.05 level) between the pain score and 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 induration 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 whereasthere exists a significant association between association between the pain score and the selectedclinicalvariables such as duration of illness and duration on hemodialysis.

Summary

The study was conducted to assess the effect of cryotherapy onpainandbiophysiologicalparametersduring AV fistula cannulation among patients on he modialy sis at KMCH, Coimbatore.

The study testedandprovedthe hypothesis thatthere willbe 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.

Thetoolsused bytheinvestigator fordatacollectionconsisted of sections are follows: Section-1Demographic and clinical profile of the subjects

Section-2 Recordofblood pressure, pulse rateandrespiratory rate Section-3 Numerical Pain Rating Scale

The data were collected for a period of 6 weeks. Both xylocaine in filtration and cryother apy application were used in same subject sast he investigator adopted repeated measures design. Based on the objectives and hypotheses, data were analyzed using both descriptive and inferential statistics.

Majorfindingsofthe study:-

- 1. The mean pain score with xylocaine infiltration at arterial site was 4.81 and at the venoussite was 4.86.
- 2. Therewasasignificantreductioninthepainscoreduring cannulation aftertheapplication of cryotherapy when compared to the pain score during cannulation afterxylocaine infiltration. The mean pain score during cannulation after xylocaine infiltrationat the arterial site was 1.59 and at the venous site was 1.51 whereas the pain score aftercryotherapy was 0.96 and 0.92 respectively. The "t" values of the comparison between these scoreswere 11.885 and 11.273 which showed significance at 0.05 level
- 3. Therewasnostatisticallysignificant difference in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the values of biophysiological parameters among xylocaine and cryother apparence in the value in the value
- 4. There was no significant association between pain score and demographic variables such as age and gender.
- There was significant association between pain score and duration of illness and duration of treatment. The values showed that the patients had reduced pain intensity with increase induration of illness and duration of treatment.

Conclusion:-

Healthcareprofessionalshaveadutytoprovidecompassionatecaretoallpatients(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. Theinvestigatorwasverykeentofindanalternativepainmanagementstrategyamonghemodialysispatientstoaid theminreducing thepain intensityduring AV fistulacannulation.

The conclusion of the studywas drawn as follows:

The study findings revealed the effect of cryother a pyassuperior to the xylocaine in filtration in reducing pain intensity during AV fixed annulation.

This study also revealed there is no variation in blood pressure, pulse rate and respiratoryrate between cannulation done with xylocaine infiltration and with cryotherapy. These studyfindings agree withvarious otherstudies conductedinsamefiled.

Implications

Nurses can incorporate cryotherapy during painful procedures to reduce the patient's painintensity. Pain associated with cannulation is a common complaint in hospitals. Present studyfindings have several implications in nursing practice, nursing education, nursing research andnursing administration.

Nursingpractice

Nursing practice has a direct and significant impact on human health. Providing optimal patientcare is one of the vital functions of the nurse. The study reveals that cryotherapy application iseffective 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 hemodialysisunit to follow this technique before AV fistula cannulation rather than anesthetizing the area withxylocaine as it itself gives patients moderate pain due to infiltration. The study serves as an eyeopener among nurses and other health care professionals to recognize the benefits of alternative painmanagement techniques such as cryotherapy.

Nursing education

Nursing education is to prepare nurses with the potential for imparting nursing care mosteffectively. The nurse educator can include alternative pain management techniques such ascryotherapy inin-serviceeducation which can be adopted by 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 thereby 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 managements trategies. The nurse educator can create awareness about the use of alternative pain managements trategies among other health care professionals too.

Nursingresearch

Re-thinking and re-evaluation of the previous nursing artprocedures and knowledgeshouldbe done, to keep the knowledge up to date. The main goal of nursing research should betoimprove patient care ultimately. Since the health care system

todayisdrivenbycost, researchaboutoutcomes related to costise specially important. Today "shealth care environment continua llyplacesincreasingdemandsonnursestocommunicate, share and synthesize information and to implement patient care scientific evidence.Appropriate utilizationofresearchhelpsnursestomakedecisionsbasedonevidencesforpatientcare. The finding of the present study can be afoundation to conduct a study on large population to prove the effectof cryotherapy strongly on reducing the pain during AV fistula cannulation. The study can bereplicated in dialysis centers where no local anesthesia is used to find out the exact effect ofcryotherapytopromotethepatient"scomfortandcompliancetowardshemodialysis. The implication of the study can be used as a motivation for nurses to conduct research in future on alternative methods of pain The study conducted check ofcryotherapyamongvarious management. can be to the effect otherproceduralpaincontrols.

Nursingadministration

Prevention of pain provides more effective pain relief than treatment of established pain. Writtenguidelineshouldbeprovidedtostandardizeandimprovedocumentationrelatedtopainassessment, necessary modification in pain relief strategies and presence of any side effects. Painscores 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 forimparting healthcare services to the target population. Nursing administrator can formulate theprotocol topractice cryotherapy amonghemodialysis patients during cannulation. In-serviceeducation can be scheduled to disseminate the research findings among nursing staff and otherhealthcareprofessionals.

LimitationsOfTheStudy

- 1. Thestudysamplesizewassmall.
- 2. Thestudyincludedpatientswhowereonhemodialysisatleast3timesaweek

Recommendations:-

- 1. Asimilarstudycanbeconductedwithalargesamplesize
- 2. Thestudycan bereplicated byusing otherresearchdesigns
- 3. AstudycanbecarriedoutincenterswherethereisnoxylocaineinfiltrationpriortoAV fistulacannulation
- 4. Astudycanbeperformedwithcombinationofotheralternativepainmanagementstrategiesincontrollingproceduralpain
- Acomparativestudybetweencryotherapyandothernonpharmacologicalmethodsinreducingproceduralpaincanbecon ducted
- 6. Astudytoassesstheknowledgeandattitudeamongnursesoncomplementaryandalternative therapiesinmanagingproceduralpaincanbecarriedout.

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