# A STUDY TO ASSESS THE EFFECTIVENESS OF CRYOTHERAPY ON PAIN AFTER THE INTRAVENOUS ADMINISTRATION OF CHEMOTHERAPEUTIC AGENTS AMONG PATIENTS WITH CANCER IN SELECTED HOSPITAL, CHERTHALA, ALAPPUZHA.

## BY 30093601

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

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#### CHAPTER - I

#### INTRODUCTION

#### **BACKGROUND OF THE STUDY**

Cancer is the second leading cause of death in our country. The term cancer is used to refer to malignant neoplasms. Cancer is a disease of the cell in which the normal mechanisms of the control of growth and proliferation have been altered. The experience of cancer is changing for our clients and families. The National Cancer Institute [NCI] estimates that 8.9 millions Americans alive today have a history of cancer.

Treatment options offered to cancer patients should be based on realistic and achievable goals for each specific type of cancer. The possible treatment goals may include complete eradication of malignant diseases [cure], prolonged survival and containment of cancer cell growth [control], or relief of symptoms associated with the disease [palliation]. Multiple treatment modalities including chemotherapy, radiation therapy, surgery, and biologic response modifier therapy may be used at various times.

The goals of chemotherapy [cure, control, palliation] chemotherapeutic agents may be administered in the hospital, clinic, or home settings by topical, oral, intravenous, intramuscular, subcutaneous, arterial, intracavitary, and intrathecal routes. The administration route depends on the type of agent, dose, and the type,location, and extent of tumour being treated. Special care must be taken whenever the chemotherapeutic agents are administered. Chemotherapeutic agents have a range of side effects that depend on the type of medications used. Common side effects include; fatigue, headace, severe pain, allergic reactions, loss of appetite, nausea, vomiting, black pigmentation, sepsis etc.

According to the [International association for the study of pain]"pain is an unpleasant sensory and emotional experience in association with actual or potential tissue damage." Approximately 30% to 50% with cancer experience pain while undergoing the side effects of cancer treatment such as chemotherapy, radiation therapy, and tumor excerting pressure on nerve., pain arises from any number of situations. Injury is a major cause, but pain may also arise from illness.

The word intravenous simply "within a vein". Therapies administered intravenously are often called speciality pharmaceuticals. If the cannula is not inserted correctly, or the vein is particularly fragile and ruptures, blood may leak into the surrounding tissue, this situation is known as a "tissuing" or a "blowing vein" especially the chemotherapeutic agents It may cause extravasation of the drug which can lead to edema, pain, and tissue damage, and even necrosis depending on the medications.

According to Dr John Diamond [2009] Up to 80% of cancer patients are reported to have died from complications from, treatment and side effects or related symptoms. The injection site reactions are local skin reactions. Mainly [extravasation]. One of the most important nurses responsibility to assess the pain and give supportive complimentary therapy. There are many ways to relieve pain. Treatments vary from individual to individuals depending upon the type and severity of pain.

The ultimate responsibility of the nurse is to provide comfort and relieve distress. One of the method that can be used to relieve the pain is cryotherapy. The cryotherapy is applied to the skin the initial response is vasoconstriction of the blood vessels. The mechanism of destruction in cryotherapy is necrosis, which results from the freezing and thawing of cells. Treated areas reepithelialize. Adverse effects of cryotherapy are usually minor. The

mechanism of action in cryotherapy can be divided into 3 phases: heat transfer, cell injury, and inflammation.

Cryotherapy as been used to relieve the pain for many years. The mechanisms of action is the stimulation of cold receptors which send back impulses which have to pass into the spinal cord via the posterior routes. The cold stimulation itself could be considered noxious and as such cause stimulation of areas in the mid brain which may in turn release beta endorphins into the posterior horn ,with a consequent reduction of pain. This will reduce the pain temporarily.

#### **NEED FOR THE STUDY**

The world wide burden of cancer is a major health problem with 8 millions new cases and 5 millions death per year. The burden from cancer may be described in terms of incidence. According to WHO The number of new cases per 100,000 each year. Prevalence is the number of people at a given point of time with a cancer diagnosis. Cancer incidence, prevalence, and mortality are higher in industrialized countries. WHO has proposed a global goal of reducing such chronic diseases death rate by 2% per annum form 2006to 2015.

Cancer prevalence in India is estimated to be around 2.5 million, with over 8,00,000 new cases and 5,50,000 deaths occurring each year due to this disease. More than 70% of the cases report for diagnostic and treatment services in the advanced stages of the disease, which has lead to a poor survival and high mortality rate

According to National cancer control programme[NCCP] estimated 7.6 millions mortalities were attributed to cancers in 2005 across the globe. The prevalence rate for all reported cancers is at 25 millions projected to ascend to 30 millions around the year of 2020.

Lisa schalmeister. [2008] reported a study to monitor the incidence, management, and relieving pain, after the intravenous administration of chemotherapeutic agents. Two clinical

trials were performed. Extravasation was the most common problem of this drugs. The incidence rate was 0.01% to 6%.

According to WHO The incidence of chemotherapeutic extravasation injuries including pain ranges from 0.5% to 0.6%. People die from chemotherapy because it is extremely toxic and ineffective. Most people die from chemotherapy rather than the cancer itself. The mortality rate is the number of death caused by cancer in the specified population in a given year. American cancer society [ACS] show changes in the mortality rates for cancer in both males and females.

Espinosa E et al.,[1996] conducted a study to assess the toxicities of the cisplatin and leucoverin combination with advanced non small cell carcinoma. Finally the study findings reveals that this regimen cannot be recommend for the patients. Due to its low response rate. And it was highly toxic.

During administration of chemotherapeutic agents The nurses responsibility is very important. The intravenous cannula is not inserted correctly it will cause severe pain, extravasation, and pigmentation. Injury is a major cause of pain. Chemotherapeutic drugs itself it will cause pain.

According to American nurses association [ANA] Pain is a feeling of distress, suffering of agony. Pain may also arises from an illness. One of most important nurses responsibility is to assess the pain and give supportive therapy. Cryotherapy is a complimentary therapy that has the potential for use by nurse in a multidisciplinary pain management programme. Pain assessment is an important part of any medical evaluation, and pain management is an important part of care. Left untreated, pain can suppress the immune system, It will leads to depression.

One of the best method that can be used to relieve the pain is cryotherapy. Cryotherapy involves the application of cold to relieve the symptoms. It numbs pain, reduces joint swelling, constricts blood vessels, and block nerve impulses to the affected area.cold can

be applied by using cold compresses, crushed ice, in a plastic bag wrapped in a towel, frozen gel packs.

Sabitha.P. B et al [2008] reported a study to assess the effectiveness of cryotherapy on arteriovenous fistula related pain in haemodialysis patients. On experimental group were found to be very effective. [p=0.001] so cryotherapy is effective in reducing puncture pain in haemodialysis patients.

Cryotherapy is the local or general use of low temperatures in medical therapy or the removal of heat from a body part. The term "crotherapy "comes from a greek word cryo means "cold" Therapy means "cure" The ultimate goal of cryotherapy is to decrease the cellular metabolism, increase the cellular survival, decrease the inflammation, decrease the pain and spasm and promote vasoconstriction. Cryotherapy is an application of ice pack applied over an injured area of the body. The immediate effect of cryotherapy is to produce immediate vasconstriction and reflexive vasodilatation.

#### STATEMENT OF THE PROBLEM

A study to assess the effectiveness of cryotherapy on pain after the intravenous administration of chemotherapeutic agents among patients with cancer in selected hospital, Cherthala, Alappuzha.

#### **OBJECTIVES**

 To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group.

To compare the mean difference on pain among the cancer patients between the experimental and control group. 3. To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

#### **HYPOTHESIS**

 $H_1$ : There will be a significant difference in pain before and after cryotherapy

among patients with cancer in experimental group.

H<sub>2</sub> : There will be a significant difference in the mean difference of pain among

cancer patients between the experimental and control group.

H<sub>3</sub> : There will be a significant association between mean difference in pain and

selected factors among patients with cancer in experimental group.

#### **OPERATIONAL DEFINITIONS**

- 1. Pain: Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."
- 2. Cryotherapy: Cryotherapy is an application of ice pack applied over an injured area of the body. It numbs pain,reduces joint swelling, constricts blood vessels, and block nerve impulses to the affected area.cold can be applied by using cold compresses, crushed ice, in a plastic bag wrapped in a towel, frozen gel packs.
- **3. Cancer Patients:** Cancer patients refers to those patients who were diagnosed to have malignancy by the oncologists.
- 4. Chemotherapy: Chemotherapy is the systemic treatment of cancer with chemicals . In chemotherapy, antineoplastic agents are used in an attempt to destroy tumour cells by interfering with cellular functions and reproduction.

- **5. Selected Factors**: Refers to those factors that can influence the pain reduction after the intravenous administration of chemotheropeutic agents among cancer patients
- 6. Intravenous Injection: Intravenous therapy, is the giving substances directly into a <u>vein</u>. The word intravenous simply means "within a <u>vein</u>".

#### **ASSUMPTION**

- 1. The patients would co operate and willing to participate in the study.
- The items included in the tool will be adequate and represent the measure of pain of cancer patients.
- 3. The response to numerical rating scale would be the true measure of the pain
- 4. Experienced by the intravenous administration of chemotherapeutic agents.
- 5. Every client is unique and responds in a unique manner to pain.

#### **DELIMITATION**

- 1. Patients in a selected hospital only.
- 2. Participants selected by non random method.
- 3. Pain was measured by numerical rating scale.

#### **CONCEPTUAL FRAMEWORK**

The present study was aimed at to evaluate the effect of cryotherapy on pain after the intravenous administration of chemotherapeutic agents among cancer patients. The conceptual framework of this study derived from gate control theory of pain.

Gate control theory of pain: The gate control theory was initially proposed in 1965 by Melzack and wall. Gating mechanism can be found in substantia gelatinosa cells

Within dorsal horn of the spinal cord, thalamus, and limbic system. This theory states that pain is a function of the balance between information travel into the spinal cord through large nerve fibers and information travel travelling into the spinal cord through small nerve fibers.

This theory suggested that the existence of gate that could facilitates or inhibits the pain transmission is possible as the gate is controlled by the dynamic function of the certain cells in the spinal cords dorsal horn.pain messages send along the spinothalamic and spnoreticular tracts can be inhibited by activity in large diameter alpha and beta fibers and chemical substance like endorphin secretions. Endorphins blocks pain signals.

**Pain perception:** Is the point at which a person experience pain. In this study pain was measured in terms of pain scores by numerical rating scale.

**Intervention:** In this study the intervention is cryotherapy. Cryotherapy is administered to the experimental group. cryotherapy stimulates cold receptors which send back impulses into the spinal cord via the posterior root and effectively Block out the pain pathways. Control group received conventional methods of nursing care without cryotherapy.

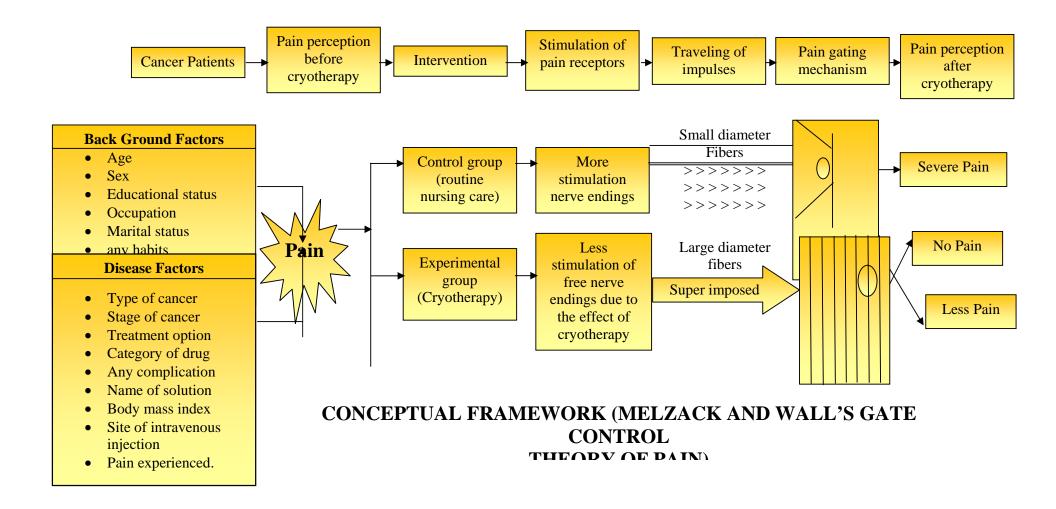
Stimulation of pain receptors: Pain is transmitted through the body the nervous system when nerve endings detect damage to apart of the body. The nerves transmit the warning through defined nerve pathways to the brain., where the signals are interpreted as pain. In control group more stimulation of free nerve endings. In experimental group less stimulation of free nerve endings due to relaxation caused by cryotherapy.

Traveling of pain impulses: Normally pain impulses are traveling through small short conducting fibers .Impulses from stimulation such as cold quickly transmitted by large fibers In

control group pain impulses will be will be conducted straight away by smll nerve fibers.which reach the gate of pain and open the gate, In experimental group where the patients receive cryotherapy.

Pain gating mechanism: Refers to the means of reducing pain. It either regulates or blocks the pain impulses along ihe central nervous syetem. When gates are open pain impulses flow easily through pain path ways.when gates are closed the pain pathways blocked and pain impulses become reduced.

Pain perception after cryotherapy was measured as mean reduction in pain It was hypothesized that the cryotherapy will make a significant difference in the pain after the intravenous administration of chemotherapeutic agents among cancer patients.



#### CHAPTER - II

#### **REVIEW OF LITERATURE**

According to cooper, "... a literature review uses as its database reports of primary or original scholarship, and does not report new primary scholarship itself. The primary reports used in the literature may be verbal, but in the vast majority of cases reports are written documents. The types of scholarship may be empirical, theoretical, critical/analytic, or methodological in nature. Second a literature review seeks to describe, summarise, evaluate, clarify and/or integrate the content of primary reports

The main purpose of reviewing relevant literatures to annotate and/or critique the literature in a subject area .Its ultimate goal is to bring the reader up to date with current literature on a topic and forms the basis for another goal, such as future research that may be needed in the area.

Review of literature were organized under the following heading.

- 1. Studies related to pain after the intravenous administration of chemotherapeutic agent.
- 2. Studies related to pain assessment.
- 3. Studies related to cryotherapy in general.

## I. STUDIES RELATED TO PAIN AFTER THE INTRAVENOUS ADMINISTRATION OF CHEMOTHERAPEUTIC AGENTS.

**Bristol [2011]** conducted a randomized study to monitor the adverse effect of chemotherapy alone. Study was conducted in America. [n=442] the adverse effect of

chemotherapy alone the groups were anemia[19% and 13%]. Skin reactions including pain[11%] and six patients experienced injection related reactions.

Lullmann.B.et al.[2010] conducted a study to report the pain level of children undergoing chemotherapy.cross over study was performed. The children received two punctures during their chemotherapy protocol.pain scores was measuring by using visual analogue scale. On the VAS pain scale, the mean pain was 2.3 (minimum 0, maximum 9.2) after 40 min and 1.9 (minimum 0, maximum 9.4) after 60 min according to the observations of the nurse and very similarly according to the parents' observations. The children expressed more pain after 40 min of EMLA[topical anesthetic cream] [ application time (mean pain, 3.5) and a significant pain reduction after 60 min application time (mean pain 1.7). In this study children experienced less pain after 60 min application time.

Lisa schalmeister.[2008] reported a survey to determine the incidence ,management, and relieving pain after the intravenous administration of chemotherapeutic agents. Two clinical trials were performed. Extravasation including pain was the most common problem of chemotherapeutic patients. Published incidence rates of chemotherapy extravasation range from 0.01% to6%.

Kane .R. C., et. al.,[2007] conducted a study to report the adverse effect of anthracycline extravasation .They were found to be it was very problematic and most reports are anecdotal .The study was conducted in US.For the treatment of extravasation resulting from intravenous anthracycline chemotherapy they wanted to administer dexrazoxane hydrochloride injection.They found that dexrazoxane dose was effective to reduce the extravasation. [n=57 patients]were experience extravasation from peripheral vein or central venous access with local swelling, severe pain, or redness

Espinosa E .et al [1996] conducted a study to assess the efficacy and toxicity of the cisplatin and leucoverin combination with advanced non small cell carcinoma. The dose consists of cisplatin 90mg/m and leucoverin on day 1 ,followed by oral LV 15mg/12 hrs on days 2 through 14. The courses were repeated every 28 days for a minimum of three per patients. The study findings reveals that the main side effects were skin toxicities, hematological, and gastrointestinal. The skin toxicities including pain was in 18% of the courses. Nausea and vomiting in 27% and diarrhea and epigastralgia in 13% each. The study findings reveals that this regimen cannot be recommend for the treatment for advanced non small cell carcinoma due to its low response rate and its high toxicity.

#### II. STUDIES RELATED TO PAIN ASSESSMENT

Roscetti A et al.,[2010] reported a study to examine the time to achieve pain relief in patients experienced periodic pain breakouts despite baseline therapy with analgesics. This study pain intensity and wellbeing were assessed by a numerical rating scale and karnofsky performance scale, respectively. Adverse events and sleep pattern were recorded. [n=85 patients] 14 experienced pain from non cancer diseases, and 71 had cancer related pain. Following stabilization of background pain, the intensity of daily pain improved; NRS decreased from baseline to day 14 for cancer (from 5.63 to 1.98) and non-cancer (from 8.00 to 1.00) groups (both p < 0.0001). Stabilization of background cancer-related or non-cancer pain with around-the-clock immediate release of morphine therapy resulted in fewer intense episodic pain breakouts, which were more quickly managed with rescue-dose IR morphine

Lisz w et al [2010] reported a prospective and descriptive study to determine the difference in pain intensity following surgery as self reported by patients and assessed by nurses. The study was based on purposive sampling method. Conducted between April 1 and July 31,2008 in the surgical wards of aregional teaching hospital in central Taiwan.Pain scores assessed by using numerical rating scale of 0 to 10. Two major findings included: (1) Pain

intensity scores self-assessed by patients ranged from 0 to 10. Scores assigned by nurses ranged between 0 and 6. Thus, patient scores were significantly higher than those assigned by nurses (p < .01). There was a discord in scoring between the two groups, with the gap ranging from 1 to 8. About 53.7% of nurses underestimated patient pain, while 31.5% overestimated it; and (2) The factor of nurse communication about pain with the patients had a negligible impact upon results. The study findings reveals that the nurses preferred using the numerical rating scale as the accurate pain score measurement.

Piva . S R et.al[2005] conducted a study to assess the responsiveness of numerical rating scale in patients with low back pain using a variety of methods. Cohort study was conducted among the patients in USA. Studies have assessed the reliability and validity of the numerical rating scale. Any change on the numerical rating scale during 1 and 4 weeks was examined by calculating the mean change, standardized effect size, responsiveness index. The majority of the patients had clinically meaningful after both 1 and 4 weeks of rehabilitation. The standard error of measure was equal to 1.02, corresponding to a minimum detectable change of 2 points. The area under the curve at the 1 and 4 weeks follow up was 0.72[0.62,0.81] and 0.92[0.86,0.97] respectively. The minimum clinically important difference at the 1 and 4 weeks follow up corresponded to a change of 2.2 and 1.5 points respectively. The study findings reveals that a 2- point changeon the numerical rating scale clinically meaningful change that exceeds the bounds of measurement error.

Aubrun et.al.[2003] conducted an observational study to assess the use of VAS and other pain scales by nurses in the postanaesthesia care unit at universite pierreet Mary curie, paris. Among 600 patients included in the study. Nurses used the VAS in 53%, the numerical rating scale in 30%. The verbal rating scale in12% and the behavioural scale in 5%. In 43% of the assessment, nursed did not use the VAS. The most frequently cited reason was related to their preference for other methods. In 54% of the assessment, the reason for not using the VAS was related to the patients, mainly when they were in too much pain to use it[22%] when the

patients was toomuch pain, the numerical rating scale was chosen in [54%] and the behavioural scalein [27%]. There was no difference between young Patients and elderly patients. The study findings reveals that although the VAS is the standard method to assess pain the nurse preferred using the numerical rating scle.

Oden A et al.,[2000] conducted a study to report the applicability of three different pain scales. Such as visual analogue scale, graphic rating scale, and the numerical rating scale. Data were collected in geriatric patients. At a university hospital. An interview was conducted with 167 patients. [age=80years]. Patients reported their experience of pain, ache or hurt[PAH] or other symptoms. The correlations were high and significant both between the ratings of the VAS, GRS and NRS (r = 0.78-0.92; p < 0.001) (alternative-forms reliability), and between the test and retesting (r = 0.75-r = 0.83; p < 0.001) (test-retest reliability). A logistic regression analysis showed that the probability to accomplish a rating on the pain scales decreased with advancing age of the patient. The study reveals that pain rating scales such as the VAS, GRS and NRS can be used to evaluate pain experience in geriatric patients.

#### III. STUDIES RELATED TO CRYOTHERAPY IN GENERAL

Sabitha.P.B.,etal [2008]reported a study to assess the effectiveness of cryotherapy on arteriovenous fistula puncture related pain in hemodialysis patients. A convenience sample of 60 patients [30 each in each experimental and control group] by using randomized control trial. Objective and subjective pain scoring was done on two consecutive days.with cryotherapy for the experimental and without cryotherapy for the control group.The objective arteriovenous fistula puncture pain score on days 1 and 2 of hemodialysis patients on experimental group were found to be significantly reduced [p=0.001].so they conclude that cryotherapy is effective in reducing arteriovenous fistula puncture pain of hemodialysis patients.

Richard.Eustice.et al., [2008] reported a study to assess the effectiveness of cryotherapy on relieving the symptoms of osteoarthritis. By using three randomized, controlled trials involving 179 patients with arthritis. The first of the three studies revealed that ice massage for 20 minutes ,a day ,5 days a week, for 2 weeks improved musle strength in the leg. The second study showed that patients using ice packs for 3 days had no significant improvement in pain . The third study indicated that cold packs applied to the knee for 20 minutes, 10 minutes, resulted in decreased swelling compared to the control group. To summarize, the ice massage were useful for reducing knee swelling.

Mcdonough.S.M.,et al.,[2006] reported a study to assess the efficacy of cryotherapy protocol in the management of acute angle sprains. Using randomized controlled trials. Two treatment groups were selected. Standard ice application n=46 intermittent ice application n=43.One,two three four, six weeks after the injury function, pain, swelling were recorded. Subjects treated with the intermittent protocol had significantly (p<0.05) less ankle pain on activity than those using a standard 20 minute protocol; however, one week after ankle injury, there were no significant differences between groups in terms of function, swelling, or pain at rest. Intermittent applications may enhance the therapeutic effect of ice in pain relief after acute soft tissue injury.

Laureano.Filho.,et al [2005] reported the effectiveness of cryotherapy on reduction of pain ,swelling, and trismus after third molar extraction.n= 14 were the age group of 20 to 28 years. The sample consists of 11 women and three men. The authors extracted two mandibular third molars at different times from each patient. Immediately after surgery, the patient underwent cryotherapy on one side for 30 minutes every one and one-half hours for 48 hours when he or she was awake. The patient did not receive cryotherapy on the other side. The authors performed clinical examinations to measure trismus and swelling before surgery, immediately after surgery and 24 and 48 hours after surgery overall they found significant

differences between the control and treated sides [p= < .05] cryotherapy was effective in reducing post operative swelling and pain.

Heriuchih.H.,et.al.,[2004] conducted a study on continous local pooling for pain relief follow total hip arthroplasty among 40 patients . subjects were randomnly assigned in two group.cryotherapy was given 1-4 days following surgery .after that pain score was assessed. By using numerical rating scale. The findings were revealed that cryotherapy group pain level is significantly lower than the control group.

Finan et.al.,[2002] conducted a study to assess the effectiveness of cryotherapy on post operative pain in gynecologic patients undergoing laprotomy. [n=20] .experimental group consists of 13 patients.and control group consists of 13 patients.All patients underwent exploratory laprotomy. And received post operative pain relief with intravenously administered analgesics. Data were analyzed by descriptive and inferential statistics. [P<0.05] The results shows that the cryotherapy reduces the postoperative pain in gynecologica patients undergoing laprotomy.

Allegaert.k.et. al .,[2003] reported a retrospective study to document the systemic evaluation of pain in neonates on prescription of intravenous analgesics.in a level -111 neonatal intensive care unit during a period before and after introduction of multidimensional pain scale. It was calculated in a group of infants. who all received cryotherapy for retinopathy of prematurity before and since introduction of pain evaluation. The number of prescribed vials increased from 3140+/-619[mean+/-SD] to 5915+/-675[p<0.05]. They conclude that systemic evaluation of pain increased awareness of treating and preventing pain in neonates even after correction of clinical co variables.

#### **CHAPTER - III**

#### **METODOLOGY**

This chapter deals with description of the different steps undertaken by the investigator for the study. It includes the research design, variables, setting, Population, sample size, sample technique, sample criteria, description of tool, content validity, pilot study, data collection procedure and plan for data collection procedure and plan for data analysis and ethical consideration.

#### RESEARCH DESIGN

The research approach in the study was quasi experimental design. To be specific, repeated measure time series with time series with control group design to evaluate the pain of intravenous administration of chemotherapeutic agents.

There were two groups, experimental and control group. The control group was similar to experimental group with regard to age and selected factors. The experimental group included those patients who were different from control group only with regard to receiving cryotherapy. Pretest and post test pain score was measured in both experimental and control group. Cryotherapy was administered to experimental group for 5-8 minutes at two intervals. For control Group pretest and post test pain score was measured at two intervals

#### RESEARCH DESIGN NOTATION

E : O1 X1 O2 O3 X1 O4

C : O5-O6 ----- O7 -----O8

E : Experimental group

C : Control group

X : Intervention the cryotherapy

- : No intervention

O1,O3 : Pre test in experimental group

O5,O7 : Pre test in control group

O2, O4 : Post test in experimental group

O6,O8 : Post test in control group.

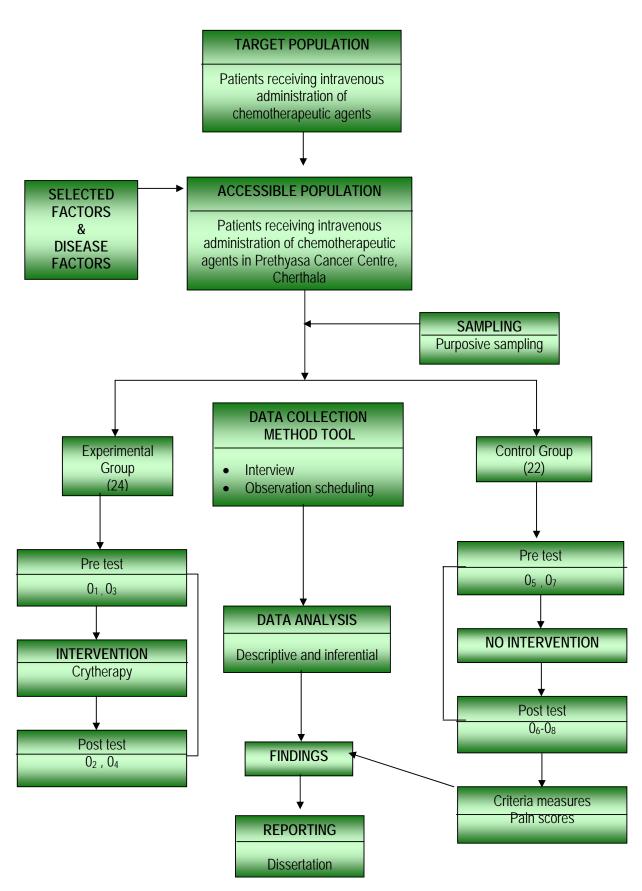


Fig. 2: DIAGRAMATIC REPRESENTATION OF RESEARCH DESIGN

#### **SETTING OF THE STUDY**

It is essential for the researcher to consider the setting in which the experiment is conducted. This study was conducted in the Prethyasa cancer institute and research centre at Green gardens hospital, Cherthala.

#### **VARIABLES**

The two categories of variables included were,

Independent variable : Cryotherapy

Dependent variable : Pain

#### **POPULATION**

Target population refers to the population that researcher wishes to make a Generalization. In this study the target population were the patients receiving Intravenous administration of chemotherapeutic agents.

The accessible population were patients those who receiving intravenous administration of chemotherapeutic agents admitted in Prethyasa institute of cancer and research centre, Green Gardens Hospital Cherthala.

#### **SAMPLING TECHNIQUE**

In this study the investigator selected the patients they were receiving Intravenous administration of chemotherapeutic agents by purposive sampling method.

#### **SAMPLING CRITERIA**

#### a. Inclusion Criteria:

Inclusion criteria are characteristics that each sample element must possess to be included in the sample. It specified the patients

- Diagnosed with cancer.
- Receiving chemotherapy.
- Of both sexes
- Who were above 20 years.
- Those who were willing to participate the study.
- Who were present at the time of data collection.
- Those who were able to understand Malayalam.

#### b. Exclusion Criteria

It specified the patients

- who were not oriented and conscious.
- who refused to participate in the study.
- who could not understand or speak Malayalam.

#### **SAMPLE SIZE**

Sample is subset of population that has been selected to represent the population of interest. The sample for the study was patients they were receiving intravenous administration of chemotherapeutic agents. The sample size for this study was arbitrarily decided to be 60. Finally a sample of 24 patients in experimental group and 22 patients in control group were included in the study. Other patients did not turn up for the second dose within the prescribed time.

**DEVELOPMENT OF TOOL** 

The investigator prepared and developed an interview schedule as a tool for

Present study after exploring all sources of information like extensive library Search, internet

sources and consultation with experts. Numerical pain rating scale was used to assess the

pain. Items regarding background factors and disease factors were developed by the

investigator.

**DESCRIPTION OF TOOL** 

The study tool consisted of three sections;

Section I : Back ground factors.

Section II : Disease related factors.

Section III : Numerical rating scale on pain.

Section I: This section consisted items regarding background factors like age, sex,

educational status, marital status, occupational status, any bad habits ,dietary habits, and any

family history of cancer.

Section II: This section consisted items regarding disease related factors such as

diagnosis, stage of cancer, treatment option, purpose of treatment, category of

chemotherapeutic agents, developing complication after the administration, drugs received at

present, name of the solution, Body mass index, site of intravenous injection, pain experienced

because of the disease, pain controlled through medication, other associated illness, sleep

pattern at night, and observation of the site before treatment.

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**Section III:** This section consisted of a scale ranging from 0-10 to assess the pain of intravenous administration of chemotherapeutic agents. The response ranged from "no pain" at all-0 to "severe pain-10.for the purpose of the study the average of two pretest and average of two post test were considered as pretest and post test respectively.

#### VALIDITY OF THE TOOL

The tool developed by the investigator was sent along with the request for validation to five experts including two oncologists and three nursing experts. The experts were requested to check for the relevance, sequence, adequacy of language of the tool. The tool was modified according to expert's opinion. The items with 100% agreement were in the tool. A few were modified and retained in the tool.

#### **PILOT STUDY**

Feasibility of the study was done among ten patients they were receiving intravenous administration of chemotherapeutic agents after obtaining permission from the authority. The setting was Prethyasa institute of cancer and research centre. Cherthala. It helped the researcher to ascertain the feasibility of the designed methodology.

#### RELIABILITY

The reliability of the instrument was established by inter rater reliability. The instrument was administered to 10 individuals simultaneously by one nursing personnel and the investigator. The tool was found to be reliable for the study. The obtained reliability co-efficient r=0.86, was high.

#### **CRYOTHERAPY INTERVENTION**

The investigator prepared a cryotherapy pack ,as specified ,A cryotherapy intervention guide was prepared after extensive search of books, journals, research and non research publications and websites on the internet. The steps for cryotherapy consists of preparatory phase ,action phase, and Post cryotherapy phase.as specified in appendix v "A cryotherapy intervention guide"

This therapy will be administered by the investigator immediately after the intravenous administration of chemotherapeutic agents with adequate explanations. This procedure takes 5 to 8 minutes.

#### **VALIDITY OF CRYOTHERAPY**

The steps involved in the cryotherapy was demonstrated by the investigator before four nursing experts. Due corrections were incorporated. Thus validity of the intervention was established.

#### DATA COLLECTION

The data were collected for 4 weeks from 7<sup>th</sup> October 2010 to 31 October 2010. Permission was sought and obtained from authorities of Prethyasa institute of cancer and research centre, Cherthala. Based on sample selection criteria using purposive sampling method samples were selected. The study purpose and method were explained to individual participants and informed consent was obtained.

The information regarding background factors and disease related factors were collected from 46 samples by interviewing them and observing health records. Pain was

measured using numerical rating scale from both the experimental and control group.with an interval of 10 minutes. The intervention cryotherapy was for experimental group. The evidence of intervention and pain were marked in a grid. Intervention was done at the bedside. The experiment was repeated twice during two consecutive doses.

#### PLAN FOR DATA ANALYSIS

The data were edited, coded and entered in Excel sheet. The data were analyzed using SPSS version 10. A probability of less than 0.05 was considered to be significant.

The data were analyzed as follows;

- Background factors of patient and disease related factors in experimental and control group were analyzed using descriptive statistics and chi-square.
- Data on effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group were analyzed using paired t test.
- Data to compare the mean difference on pain among cancer patients between the experimental and control group were analyzed using independent sample t test.
- Data on association between the mean difference on pain and selected factors among the cancer patients in experimental group were analyzed using linear regression.

#### ETHICAL CONSIDERATION

The study objective, intervention and data collection were approved by the research and ethical committee of the institution. Main study was conducted after obtaining permission from the Medical superintendent of green gardens hospital. Informed consent was obtained from the cancer patients. No routine care was altered or withheld.

# **CHAPTER - IV**

#### DATA ANALYSIS AND INTERPRETATION

The analysis and interpretation of data of this study is based on the data collected from the cancer patients. The data collected were edited, tabulated, and analyzed Using SPSS version 17. A probability value of less than 0.05 was considered to be significant. Findings were presented in the form of tables and diagrams.

The objectives of study were;

- To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group.
- To compare the mean difference on pain among the cancer patients between the experimental and control group.
- To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

The data analyzed were presented as follows;

Section – I : Data on background factors and disease factors of cancer patients in

the experimental and control group.

Section – II : Data on pain among the cancer patients in experimental group.

Section – III : Data on mean difference on pain between the experimental and

control group.

Section – IV : Data on association between the mean difference on pain and

selected factors among the cancer patients in experimental group.

# SECTION – I: DATA ON BACKGROUND FACTORS AND DISEASE FACTORS OF CANCER PATIENTS IN THE EXPERIMENTAL AND CONTROL GROUP.

TABLE – 1
Frequency and percentage distribution of cancer patients in the experimental and control group regarding their background factors.

(n = 46)

	Exper	imental	Control		Chi-square	
Background Factors	Group	(n = 24)	Group (ı	n = 22)	Test	
	No	%	No	%	1630	
Age						
31-40yrs	4	17	4	18	1.004	
41-50yrs	9	37	11	50	[p=.605]	
50-above	11	46	7	32	[NS]	
Educational status						
Primary school	11	46	12	54	2.628	
Secondary school	10	42	6	25	[.453]	
Higher secondary school	2	8	4	28	[NS]	
Graduate	1	4	0	0		
Employment status						
Employed	19	79	20	91	1.227	
Unemployed	5	21	2	9	[p=.418]	
					[NS]	
Marital status						
Married	24	100	22	100	Constant	
Unmarried	0	0	0	0		

Background Factors	Experimental  Group (n = 24)		Control Group (n = 22)		Chi-square Test
	No	%	No	%	
Family history of cancer					
Yes	11	46	13	59	1.511
No	13	54	9	41	[p=.470]
					[NS]

**Table -1** reveals the frequency and percentage distribution of cancer patients in the experimental and control group regarding their back ground factors.

It was inferred that majority of cancer patients in experimental group were 50 above age group 11[46%],had primary school education 11[46%],were employed 19[79%],were married 24[100%],had no family history 13[54%].

Also in control group majority of cancer patients were 41-50 years age group 11[50%],had primary school education 12[50%],were employed 20[91%],were married 22 [100%],had a family history13[59%].

Figure 3 reveals the frequency and percentage distribution of sex of cancer patients.

Both the sexes of cancer patients were equal distribution in experimental group 12 (50%). Majority of cancer patients were female 13 (59%) in control group.

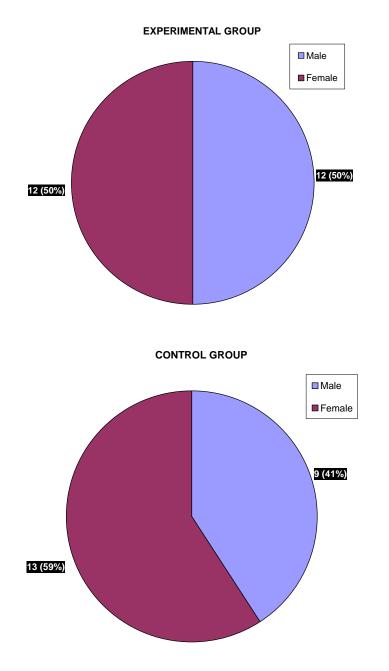


Fig. 3: FREQUENCY AND PERCENTAGE DISTRIBUTION OF SEX OF CANCER PATIENTS

**Figure 4** reveals the frequency and percentage distribution of habits of cancer patients.

Majority of cancer patients were not having any habits 12 (50%) in experimental group. Majority of cancer patients were both smoking and alcoholism 8 (36%) in control group.

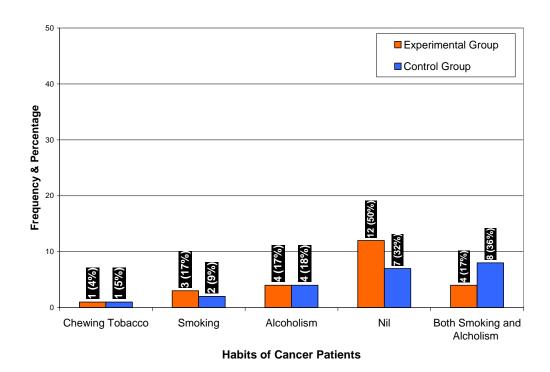


Fig. 4: FREQUENCY AND PERCENTAGE DISTRIBUTION OF HABITS OF CANCER PATIENTS.

Figure 5 reveals the frequency and percentage distribution of dietary habits of cancer patients.

Majority of cancer patients were non-vegetarian 23 (96%) in experimental group and 2 (26%) in control group.

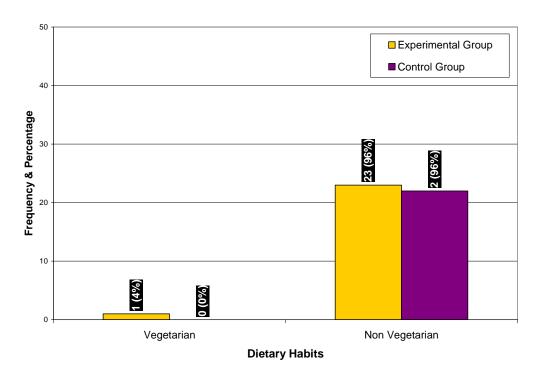


Fig. 5: FREQUENCY AND PERCENTAGE DISTRIBUTION OF DIETARY HABITS OF CANCER PATIENTS.

TABLE – 2
Frequency and percentage distribution of cancer patients in the experimental and control group regarding their disease related factors.

(n = 46)

	Exper	imental	Control		Chi-
Background Factors	Group	(n = 24)	Group (	n = 22)	square
	No	%	No	%	Test
Stage of cancer ?					
Cancer in situ	1	4	1	5	6.473
Tumor limited to the tissue of origin	7	29	6	27	[p=.167]
Limited local spread	11	46	6	27	[Ns]
Extensive local and regional spread.	3	13	9	40	
Metastasis	2	8	0	0	
Treatment option ?					.000
Radiation + surgery	12	50	11	50	[p=1.000]
+ chemotherapy.					[NS]
Radiation chemotherapy.	12	50	11	50	[د۱۱]
Purpose of treatment.					2.185
Curative	19	79	13	59	[p=.202]
Palliative	5	21	9	40	[Ns]
Category of chemotherapeutic					
drug.					
Cell cyclic specific	8	33	10	45	.862
Cell cycle non specific	13	54	10	45	[p=.835]
Miscellaneous	2	8	1	5	[NS]
Both cell cyclic specific and non	1	4	1	5	
specific.					

	Exper	imental	Cont	trol Chi-	
Background Factors	Group	(n = 24)	Group (	n = 22)	square
	No	%	No	%	Test
How long you are receiving					
chemotherapy?					1.115
<1 year	24	100	21	95	[p=.478]
1-2 year	0	0	1	5	[NS]
Any complications after					
chemotherapy?					
Extravasation	0	0	1	5	2.740
Vomiting	9	38	6	25	[p=.602]
Headache	8	33	10	45	[NS]
Any other	4	17	4	18	
Nil	3	13	1	5	
Specify the name of the solution?					.700
Normal saline	18	75	14	63	[p=.525]
Dextrose.	6	25	8	36	[NS]
Body mass index?					
Malnourished	5	21	3	13	2.366
Normal	11	46	15	68	[p=306]
Obese.	8	33	4	18	[Ns]
Size of the needle					
18 gauge	24	100	20	90	2 201
20 gauge	0	0	1	4	2.281
22 gauge	0	0	1	4	[p=.320]
24 gauge	0	0	0	0	[Ns]

	Experimental		Control		Chi-
Background Factors	Group	(n = 24)	Group (	n = 22)	square
	No	%	No	%	Test
Site of intravenous injection					
Radial	7	29	8	36	2.965
Ulnar	11	46	2	9	[p=.397]
Brachial	0	0	7	32	[Ns]
Metacarpal.	6	25	5	22	
Pain experienced because of the					
disease?					722
Mild	7	29	5	22	.733
Moderate	8	33	6	25	[p=.693]
Sever	9	38	11	50	[NS]
Pain controlled through					
medication?					1.158
Fully controlled	0	0	1	5	[p=.560]
Partially controlled	20	83	17	77	[NS]
Un controlled	4	17	4	18	
Other associated illness?					
Hypertension	7	29	7	31	
Diabetes mellitus	6	25	11	50	5.193
Nil	6	25	3	13	[p=.268]
Both diabetes and hypertension	5	20	1	5	[NS]
Sleep pattern at night?					
Disturbed	11	46	7	31	1.498
Adequate	11	46	14	63	[p=.473]
Can't sleep at night.	2	8	1	4	[NS]

	Exper	imental	Control		Chi-
Background Factors	Group (n = 24)		Group (n = 22)		square
	No %		No	%	Test
Observation of the site before					
treatment?					
Erythema	4	17	3	13	10.917
Swelling	8	33	17	77	[p=.028]
Induration	1	4	0	0	[NS]
Black discolouration	8	33	2	9	
Nil	3	13	0	0	

**Table 2** reveals the frequency and percentage distribution of cancer patients in the experimental and control group regarding their disease factors.

It was inferred that majority of cancer patients in experimental group were tumor limited local spread 11 [46%],had received both,radiation+surgery+chemotherapy and radiation+chemotherapy12[50%],were taking curative treatment19[79%],were receiving cell cycle non specific 13[54%],were receiving chemotherapy <1 year 24[100%],had developed complication after chemotherapy vomiting 9[38%],had received normal saline 18[75%],were normal body mass index 11 [46%], had a needle size of gauge 18 24[100%],had received the injection site of ulnar 11[46%],had experienced pain because of the disease as severe 9[38%],had pain controlled through medication as partially controlled 20[83%]. Had associated illness of hypertension 7[29%],had both disturbed and adequate sleep pattern 11[46%],had developed both swelling and black discolouration 8[33%].

Also in control group majority of cancer patients were extensive local and regional spread 9[40%]had received both radiation+surgery+chemotherapy and radiation+chemotherapy11[50%],were taking curative treatment 13[59%],were receiving both cell cycle

specific and cell cycle nonspecific 10[45%], were receiving chemotherapy <1year 21[95%], had developed complication after chemotherapy as headache 10[45%], had received normal saline 14[63%] were normal body mass index 15[68%] had a needle size of 18 gauge 20[90%] had received the injection site of radial 8[36%],had experienced pain because of the disease as severe 11[50%],had pain controlled through medication as partially controlled 17[77%],had associated illness of diabetic mellitus 11[50%],had adequate sleep pattern 14[63%],had developed swelling17[77%]before the treatment.

Figure 6 reveals the frequency and percentage distribution of type of cancer.

Majority of cancer patients were Ca Breast 6 (25%) in experimental group and Ca Ovary and Ca Liver 3 (14%) in control group.

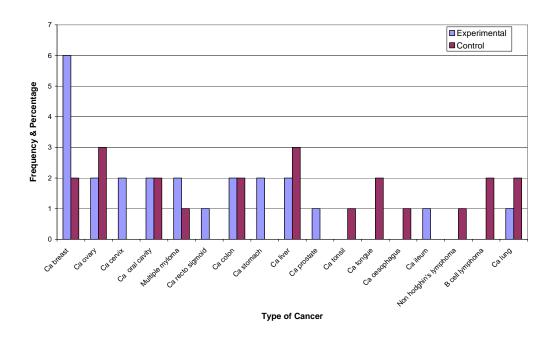


Fig.6: FREQUENCY AND PERCENTAGE DISTRIBUTION OF TYPE OF CANCER.

**Figure 7** reveals the frequency and percentage distribution of number of drugs received at present of cancer patients.

Majority of cancer patients received two drug 23 (96%) in experimental group and 17 (77%) in control group.

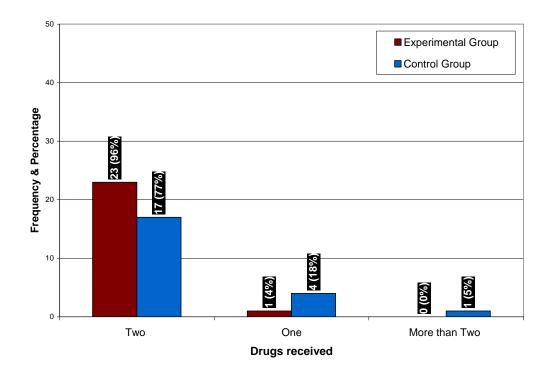


Fig. 7: FREQUENCY AND PERCENTAGE DISTRIBUTION OF NUMBER OF DRUGS RECEIVED OF CANCER PATIENTS.

**Figure 8** reveals the frequency and percentage distribution of number of times Intravenous injection administered per day of cancer patients.

Majority of cancer patients were administered Intravenous injection once 24 (100%) in experimental group and 20 (90%) in control group.

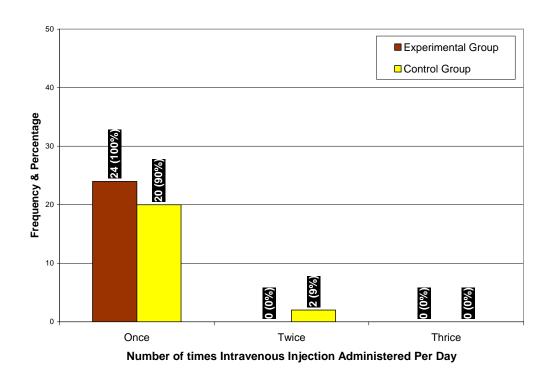


Fig. 8: FREQUENCY AND PERCENTAGE DISTRIBUTION OF NUMBER OF TIMES INTRAVENOUS INJECTION ADMINISTERED PER DAY OF CANCER PATIENTS.

**Figure 9** reveals the frequency and percentage distribution of fluids supplementation of cancer patients.

Majority of cancer patients were received fluids 24 (100%) in experimental group and 21 (95%) in control group.

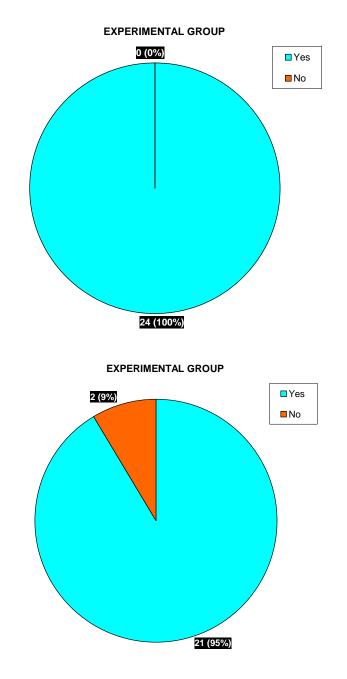


Fig. 9: FREQUENCY AND PERCENTAGE DISTRIBUTION OF FLUIDS SUPPLEMENTATION OF CANCER PATIENTS.

# SECTION – II: DATA ON PAIN AMONG THE CANCER PATIENTS IN EXPERIMENTAL GROUP.

For the purpose of the study the following null hypothesis was stated,

 $H_{01}$ : There will be no significant difference in pain before and after cryotherapy among patients with cancer in experimental group.

TABLE – 3

Mean, SD, mean difference and "t "value on pain before and after cryotherapy in experimental group between 1st and 2nd intervention

(n = 46)

Toot	Intervention	maan	CD	Mean	't 'value
Test	Intervention	mean	SD	difference	(p)
Pre Test		5.83	2.18		8.377
Post Test	<b>1</b> st			1.71	[P=.001]
FUSI TESI		4.13 2.01	2.01		(S)
Pre Test		6.25	1.51		9.405
D. J.T. J	2 <sup>nd</sup>	4.58	1.50	1.67	[p=.001]
Post Test					(S)

**Table 3** shows the mean, standard deviation, mean difference and "t" value of pain after cryotherapy in experimental group between the 1st and 2nd intervention.

There was a significant difference in pain after cryotherapy in 1st and 2nd doses.t=8.377 [p<0.05], t=9.405 [p<0.05] respectively. Therefore null hypothesis was rejected.

It was inferred that cancer patients in experimental group had significant reduction in pain after cryotherapy. And it was found to be effective.

# SEDTION III: DATA ON MEAN DIFFERENCE ON PAIN BETWEEN THE EXPERIMENTAL AND CONTROL GROUP

For the purpose of the study the following null hypothesis was stated,

 $H_{02}\,$ : There will be no significant difference in the mean difference of pain among cancer patients between the experimental and control group

TABLE – 4

Mean difference, SD, difference in mean difference and " t value on pain between the experimental and control group.

Group	Intervention	Mean difference	SD	Difference in mean difference	't'value
Experimental	<b>1</b> st	1.71	1.00		4.920
group				1.21	[p=.001]
Control group	1 <sup>st</sup>	0.50	0.60		(S)
Experimental	2 <sup>nd</sup>	1.67	0.87		5.025
group				1.30	[p=.001]
Control group	2 <sup>nd</sup>	0.36	0.49		(S)

**Table 4** shows the mean difference, SD, difference in mean difference ,and "t" value of pain among cancer patients between experimental and control group.

The mean difference on pain during 1<sup>st</sup> and 2<sup>nd</sup> intervention among cancer patients in experimental and control group was significant. t=4.920[p<0.05],t=5.025 [p<0.05] respectively.

There was a significant reduction in pain after cryotherapy in  $1^{st}$  and  $2^{nd}$  intervention. Therefore the null hypothesis was rejected.

SECTION – IV: DATA ON ASSOCIATION BETWEEN THE MEAN DIFFERENCE ON PAIN AND SELECTED FACTORS AMONG CANCER PATIENTS IN EXPERIMENTAL GROUP.

TABLE – 5
Linear regression regarding association between mean difference in pain and background factors among cancer patients in experimental group.

Variables	Variables Beta "t" p		n	CI	95%
variables	Deta		P	Lower	Upper
Age	093	667	.625[NS]	-1.754	1.579
Sex	.270	.408	.753[NS]	-11.209	11.952
Educational Status	442	-1.217	.438[NS]	-4.421	3.648
Employment status	.051	.123	.922[NS]	-8.876	9.050
Any bad habits	637	-2.741	.233[NS]	-2.397	1.546
Dietary habits	228	-1.090	.473[NS]	-9.965	8.390
Family history of any cancer	.922	5.545	.114[NS]	-1.437	3.662

**Table – 6** shows that beta value, "t" value, 95% confidence interval regarding pain and background factors among cancer patients in experimental group based on linear regression.

The background variables such as age, sex, educational status, employment status , any bad habits, dietary habits, any family history of cancer, were not significantly associated with pain among cancer patients[p>0.05]

TABLE – 6
Linear regression regarding association between mean difference in pain and disease factors among cancer patients in experimental group.

Variables	Beta	"†"	Р	95% CI	
variables	Value		•	Lower	Upper
Type of cancer	.010	.014	.991[NS]	-1.467	1.471
Stage of cancer	.918	1.559	.363[NS]	-4.747	6.074
Treatment option	.585	2.244	.267[NS]	-3.757	5.369
Purpose of treatment	928	-1.438	.387[NS]	-15.507	12.354
Category of chemotherapeutic agent	.132	.377	.770[NS]	-3.984	4.228
Any complication	.162	.784	.577[NS]	-1.327	1.501
How many drugs are you received	.324	.526	.692[NS]	-25.832	28.065
Specify the name of the solution	1.096	2.171	.275[NS]	-8.464	11.953s
Body mass index	.251	1.087	.474[NS]	-2.547	3.023
Site of intravenous injection	.044	.107	.932[NS]	-3.141	3.194
Pain experienced because of the disease	.164	.606	.653[NS]	-2.778	3.057
Pain controlled through medication	429	-1.676	.343[NS]	-6.803	5.217
Other associated illness	734	-2.092	.284[NS]	-1.692	1.214
Sleep pattern at night	.323	.581	.665[NS]	-7.344	8.048
Observation of the site before treatment?	.112	.278	.827[NS]	-2.555	2.670

**Table – 7** shows that beta value, "t" value, 95% confidence interval regarding pain and disease factors among cancer patients in experimental group based on linear regression.

The disease factors such as type of cancer, stage of cancer ,treatment option ,purpose of treatment, category of chemotherapeutic agent, any complication after chemotherapy, number of drugs received, specify the name of solution? body mass index ,,site of intravenous injection, pain experienced because of the disease, pain controlled through medication, other associated illness, sleep pattern at night, observation of the sight before treatment? respectively were not significantly associated with pain among cancer patients[p>0.05]

Therefore it was inferred that background and disease factors are not influenzed in the reduction of pain among cancer patients in experimental group.

# CHAPTER - V

# SUMMARY, FINDINGS, DISCUSSION, IMPLICATIONS, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

The essence of research project is based on study findings, limitations, interpretations of the result and recommendations that incorporate the study implications. It also gives to the results obtained in this study.

#### **SUMMARY**

The prime aim of the study was to assess pain before and after cryotherapy among cancer patients.

The objectives of the study were,

- To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group.
- 2 To compare the mean difference on pain among the cancer patients between the experimental and control group.
- To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

The review of literature enabled the investigator to develop conceptual framework, tool and methodology for the study. Literature review was done as follows studies related to pain of intravenous administration of chemotherapeutic agents, studies related to pain assessment. studies related to cryotherapy in general.

The conceptual framework adopted for the present study was based on the gate control theory Melzack and Wall [1965]. This model helped the investigator to assess the effect of cryotherapy on pain among chemotherapeutic patients. Cryotherapy is used as pain relieving measures.

The present study was quasi experimental, Independent variable in this study was cryotherapy and dependent variable in this study was pain after intravenous administration of chemotherapeutic agents. Associate variable for this study were background factors and disease related factors.

The tool developed and used for the study was an interview schedule. Numercal rating scale was used to assess the pain. The content validity of the tool was established by 5 experts. The reliability of the tool was established by inter rater reliability computed reliability coefficient r=0.86 was high.

The main study was conducted in prethyasa institute of cancer and research centre cherthala. Prior permission from the authorities was sought and obtained. Individual informed consent was taken from study sample. The study sample were selected by purposive sampling method based on sample selection criteria.

A total of 46 patients [24 experimental group,22 control group] where selected. Data were collected from both the experimental and control group. The intervention cryotherapy was given 5-8 minutes for experimental group. Pretest and post test pain score was measured. Intervention was done at the bedside. All the patients received their routine care. The collected data were analyzed and interpreted based on objective using spss package[version17] at 0.05 level of significance.

#### CHARACTERISTICS OF STUDY SAMPLES

Majority of cancer patients in experimental group were 50 above years 11 [46%] were both the sexes equal ,had primary education 11 [46%] had employed 19 [79%] were married 24 [100%] had no other bad habits 12 [50%] were nonvegeterian 23 [96%] had no family history of cancer 13 [54%]

Also in control group majority of cancer patients were 41 to 50 years 11 [50%] were females 13 [59%] had primary education 12 [54%]had employed 20 [91%] were married 22 [100%] had bad habits of both smoking and alcoholism 8[36%]were nonvegetarian 22 [96%] had family history of cancer 13 [59%]

#### **FINDINGS**

The major findings of the study presented under following headings based on the objectives of the study.

Objective -1: To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group

There was a significant difference in pain after cryotherapy in 1st and 2nd doses.t=8.377
 [p<0.05], t=9.405 [p<0.05] respectively. Therefore null hypothesis was rejected</li>

Objective -2: To compare the mean difference on pain among the cancer patients between the experimental and control group.

• The mean difference on pain during 1<sup>st</sup> and 2<sup>nd</sup> intervention among cancer patients in experimental and control group was significant. t=4.920[p<0.05],t=5.025 [p<0.05] respectively. There was a significant reduction in pain after cryotherapy in 1<sup>st</sup> and 2<sup>nd</sup> intervention.

Objective -3: To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

• There was no significant association between the mean difference and the selected variables such as age ,sex ,educational status , Employment status ,any bad habits ,Dietary habits ,family history of cancer , type of cancer, stage of cancer , purpose of treatment,Category of chemotherapeutic agents ,any complication developed after the administration of drug ,how many drugs are you received at present , specify the name of the solution , Body mass index ,site of intravenous injection , pain experienced because of the disease ,pain controlled through medication , Other associated illness , sleep pattern at night ,observation of the sight before treatment ,among experimental group [p>0.05] were not significantly associated with pain among cancer patients.

#### **DISCUSSION**

The results of the study were discussed based on the finding of the study.

Finding 1: To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group.

There was a significant difference in pain after cryotherapy in 1<sup>st</sup> and 2<sup>nd</sup> doses.t=8.377
 [p<0.05], t=9.405 [p<0.05] respectively. Therefore null hypothesis was rejected</li>

This findings were supported by the related studies conducted by Sabitha P.B et.al., a study to assess the effectiveness of cryotherapy on arteriovenous fistula puncture related pain in hemodialysis patients .The objective pain score of hemodialysis patients on experimental group were found to be significantly reduced. [p=0.001].Laureano et.al., reported the effectiveness of cryotherapy on reduction of pain,swelling,and trismus after third molar extraction [p<.05] and it was found that cryotherapy was effective in reducing pain.

Finding 2: To compare the mean difference on pain among the cancer patients between the experimental and control group.

• The mean difference on pain during 1st and 2nd intervention among cancer patients in experimental and control group was significant. t=4.920[p<0.05],t=5.025 [p<0.05] respectively. There was a significant reduction in pain after cryotherapy in 1st and 2nd intervention.

The above findings of the study was supported by the related study conducted **Allegaert.k et.al.**, intravenous injection of pain in neonates on prescription of analgesics. The number of prescribed vials increased from 3140+/-619[mean+/-SD to 5915+/-675[p<0.05]children who received cryotherapy.

Finding 3: To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

• There was no significant association between the mean difference and the selected variables such as age ,sex ,educational status , Employment status ,any bad habits, Dietary habits , family history of cancer , type of cancer, stage of cancer , purpose of treatment, Category of chemotherapeutic agents ,any complication developed after the administration of drug ,how many drugs are you received at present , specify the name

of the solution, Body mass index, site of intravenous injection, pain experienced because of the disease, pain controlled through medication, Other associated illness, sleep pattern at night, observation of the sight before treatment, among experimental group [p>0.05] were not significantly associated with pain among cancer patients.

#### **IMPLICATIONS**

The study had implications, guidelines and suggestions for nursing practice, nursing education, nursing administration and nursing research.

#### **Nursing Practice**

- Cryotherapy is an effective measure to block the pain pathway. Research
  evidence shows that cutaneous application is an independent nursing
  intervention to minimize the pain .Nurse should effectively use this measure to
  alleviate the intravenous administration of chemotherapeutic agents.
- Nurses plan the goal of nursing management and enhance the nurse patient relationship and sense of well being to the patient through the development of mutually agreed goals.
- Cryotherapy should be considered as an integral part of pain relief management in nursing. It numbs pain, reduces joint swelling, constricts blood vessels, and block nerve impulses to the affected area.

#### Nursing Education

- Nurse educators should encourage nursing students to utilize cryotherapy as measure for reducing the pain of intravenous administration of injections.
- In service education programme should be conducted for nursing personnel and help nurses to gain knowledge about cryotherapy.

#### **Nursing Administration**

- Nursing departments should have policy decision to use cryotherapy as an essential nursing activity to reduce the intravenous administration of chemotherapeutic agents.
- Administration must provide adequate cryotherapy packs and materials for effective nursing care.

#### **Nursing Research**

- The study will be a valuable reference material for future researchers.
- The findings of the study would help to expand the scientific body of professional knowledge upon which further researches can be conducted.
- Cryotherapy may be studied more scientifically and used as a specific nursing intervention.

#### **LIMITATIONS**

- Random selection was not done.
- Experience level of investigator.
- Study was done on limited sample.
- Procedure takes time, consuming the nursing hours.

### **RECOMMENDATIONS**

- Randomized controlled trial can be done.
- Similar study can be conducted for a larger group.
- Effect of cryotherapy for a prolonged period can be studied

# **CONCLUSION**

The following conclusion was drawn from the following study. The cancer patients in the experimental group had reduction in pain after the intravenous administration of chemotherapeutic agents by administering cryotherapy. The future of this field of nursing science promises to be one of the rapid significant growth. The results of which will directly influence patient care in the aspects of evidence based nursing care.

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# APPENDIX - I

#### LETTER SEEKING PERMISSION FOR CONTENT VALIDITY

From,

30093601

II year M.Sc (Nursing),

Annai J K K Sampoorani Ammal College of Nursing

Komarapalayam,

Namakkal district.

To,

Through

The Dean,

Annai J K K Sampoorani ammal College of Nursing,

Komarapalayam,

Namakkal District.

Respected Madam/sir

Sub: Letter requesting consent to validate the tool.

I am 30093601, II year M.Sc., Nursing student of Annai JKK Sampoorani Ammal College of Nursing Komarapalayam, under the Tamil Nadu Dr. M G R Medical University, Chennai.

As a partial fulfillment of M.Sc Nursing Programme, I am conducting "A study to assess the effectiveness of cryotherapy on pain after the intravenous administration of chemotherapeutic agents among patients with cancer in selected hospital, Cherthala, Alappuzha". Herewith I am sending the tool for content validity for your expert opinion. I humbly request yourself to spare a little of your valuable time for me which I remain ever grateful to you.

Thanking you

Place: Komarapalayam, Yours sincerely Date: (30093601)

# APPENDIX - II

#### **CONTENT VALIDITY CERTIFICATE**

I hereby certify that I have validated the tool of 30093601, II M.Sc (Nursing), student of Annai J.K.K.M Samporani Ammal College of nursing, Komarapalayam, who is undertaking the following study on "A study to assess the effectiveness of cryotherapy on pain after the intravenous administration of chemotherapeutic agents among patients with cancer in selected hospital, cherthala, Alappuzha"

Place: Komarapalayam	Signature of the expert
Date:	
	Designation

# APPENDIX - III

#### LIST OF EXPERTS

#### 1. Dr.SARAMMA P.P M.N Ph.D

Senior lecturer in nursing

Sree chithra Tirunal institute for medical sciences and technology

Trivandrum.

#### 2. Prof.JESSIE SUDARSANAM

H.O.D of medical surgical nursing
Annai JKK Sampoorani Ammal College of Nursing
Komarapalayam

#### 3. Mrs SHOBANA

Associate professor

Department of Medical surgical Nursing

Annai JKK Sampoorani Ammal College of Nursing

Komarapalayam

#### 4. Dr.SOMARAJAN MD

Senior consultant oncologists

Prethyasa institute of cancer and research centre

Cherthala, Alappuzha.

#### 5. **Dr MOHANAN MD**

Senior oncologist

Prethyasa institute of cancer and research centre

Cherthala, Alappuzha.

#### APPENDIX - IV

#### LETTER SEEKING PERMISSION TO CONDUCT RESEARCH STUDY

From,

Ms.Jissa K Joy

II year M.Sc (Nursing)

Annai J.K.K.M Sampoorani Ammal College of Nursing.

Komarapalayam – 638183.

Namakkal District.

To.

Dr.Sister.Michael Francis Bsc,MD,MRCP,

President in M.J.K.M

Cancer Research Centre

Green Gardens Hospital

Cherthala

Alappuzha District

Kerala

Through,

The Dean,

Annai J.K.K.M Sampoorani Ammal College of Nursing.

Komarapalayam - 638183.

Namakkal District.

Annai J. K. K. Sampoorand

Ammal College of Nursing.

Sub: Seeking permission to conduct the research study. Komarapalayam-638 183.

Respected sir,

I, Ms. Jissa K Joy (30093601), II year M.Sc nursing student of Annai J.K.K.M. Sampoorani Ammal College of nursing, under the Tamil Nadu Dr. M.G. R Medical University, Chennai.

As a partial fulfillment of university requirement for an award of Master of Science in Nursing Degree, I am conducting a research on the following "A study to assess the effectiveness of cryotherapy in pain reduction during intravenous injection of chemotherapeutic agents among cancer patients at selected areas."

I would like to conduct this research study in your esteemed institution. Hence I request you to kindly grant permission for the same.

Thanking you.

Place: Komarapalayam

Date

Yours faithfully Ms.Jissa K Joy (30093601)

Parisonal granted to Swa. K. Say.

Sa. Minchael Francis

Paraganit

MSKMCR. Grangandus, charles

# APPENDIX - V

# INFORMED CONSENT FORM

# APPENDIX - VI

# INTERVIEW/OBSERVATION SCHEDULE ON PAIN AMONG PATIENTS WITH INTRAVENOUS INJECTION OF CHEMOTHERAPEUTIC AGENTS

	Code. No	_
SECTION	N: A	
	*	
BACKGROUND V	VARIABLES	
INSTRUCTION: The interviewer is red	quested to ask question and read	i
response one by one and place a tick (	$\checkmark$ ) in the given box against the	2
responses given by the client		
1. State your age		
a. 21-30 yrs		
b. 31-40 yrs		
c. 41-50 yrs	. 🗆	
d. 50 above		
2. Sex of the client		
a. Male		
b. Female		
3. Educational status		
a. Illiterate		
b. Primary school		

c. Secondary school	
d. Higher secondary	
e. graduate	
4. Employment status	
a. Unemployed	
b. Employed	
5. State the marital status of the client	
a. Single	
b. Married	
c. Divorce	
d. Widow / Widower	
6. Do you have any of the following habits?	
a. chewing tobacco	
1 1.	
b. smoking	
c. alcoholism	
c. alcoholism	
c. alcoholism  7. State your dietary habits	
<ul><li>c. alcoholism</li><li>7. State your dietary habits</li><li>a. Vegetarian</li></ul>	
<ul><li>c. alcoholism</li><li>7. State your dietary habits</li><li>a. Vegetarian</li></ul>	
<ul> <li>c. alcoholism</li> <li>7. State your dietary habits <ul> <li>a. Vegetarian</li> <li>b. Non-Vegetarian</li> </ul> </li> <li>8. State the family history of Cancer</li> </ul>	
<ul><li>c. alcoholism</li><li>7. State your dietary habits</li><li>a. Vegetarian</li><li>b. Non-Vegetarian</li></ul>	
<ul> <li>c. alcoholism</li> <li>7. State your dietary habits <ul> <li>a. Vegetarian</li> <li>b. Non-Vegetarian</li> </ul> </li> <li>8. State the family history of Cancer</li> </ul>	

#### **SECTION-B**

#### DATA ON DISEASE

#### INSTRUCTION

This section seeks information regarding clinical variables such as diagnosis, duration and medication. The interviewer will check the records of the patient /ask the item and fill the details.

1. Ty	pe of cancer	(diagnosis)	
2. St	age of cancer	(Based on record)	
a.	Stage 0	: Cancer insitu	
b	Stage 1	: Tumor limited to the tissue of origin	
c.	Stage 2	: Limited local spread	
d	Stage 3	: Extensive local and regional spread	
e.	Stage 4	: Metastasis	
3. Tr	eatment option	on	
a.	Radiation +	Surgery+ Chemotherapy	
b.	Radiation +	Chemotherapy	
4. Pu	rpose of treat	ement	
a.	Curative		
b.	Palliative		
5. Sta	ate the catego	bry of chemotherapeutic drug taken	
	Cell Cycle s	Control (Control (Con	

b. Cell cycle nonspecific	
c. Miscellaneous	
6. How long you are receiving chemotherapy	
a. < 1 year	
b. 1-2 Year	
c. Above 2 years	
7. Whether the patient had developed any complication	after the
administration of chemotherapeutic agents?  a. Extravasation	
b. Vomiting	=
c. Headache	
d. Any other (Specify)	
8. How many chemotherapeutic agents are you received at prese	nt?
a. one	
b. two	
c. more than two	
9. Number of times the intravenous injection is administered per	day?
a. Once	
b. Twice	
c. Thrice	

10.	Ar	ny other fluids supplementation?	
	a.	Yes	
	b.	No	
11.	If	yes, specify the name of the solution	
	a.	Normal Saline	
	b.	Dextrose	
	c.	Ringer lactate	
	d.	Any other(specify)	
12	. Bo	ody mass index of the patient - HeightCms, Weight	Kg
	a.	Malnourished	
	b.	Normal	
	c.	Obese	
13	. Si	ze of the needle used for intravenous injection?	
	a.	18 gauge	
	b.	20 gauge	
	c.	22 gauge	
	d.	24 gauge	
14	. Si	ite of intravenous injection	
	a.	Radial	
	b.	Ulnar	
	c.	Brachial	
	d.	Metacarpal	

15	. Pa	ain experienced because of the disease	
	a.	Mild	
	b.	Moderate	
	c.	Severe	
16	. St	tate the pain controlled through medication?	
	a.	Fully controlled	
	b.	Partially controlled	
	c.	Uncontrolled pain	
17	. O	ther associated illness, if any	
	a.	Hypertension	
	b.	Diabetes mellitus	
	c.	Renal disease	
	d.	Other disease	
	e.	Nil	
18	. Sl	eep pattern at night	
	a.	Disturbed	
	b.	Adequate	
	c.	Can't sleep at night.	
19	. O	bservation of the site before the treatment	
		a. Erythema	
		b. swelling	
		c. induration	

#### SECTION - C

#### VISUAL ANALOGUE SCALE

#### INSTRUCTION:

The given scale measures the experience of pain ranging from '0' which means no pain, '10' refers to severe pain. The client is requested to choose a number from 0 to 10 indicating the pain experienced by the patient after receiving cryotherapy. The pain score may be entered in the given column.

No p	oain								Severe	pain
0	1	2	3	4	5	6	7	8	9	10

Day	1		2		
Site					
	Pre	Post	Pre	Post	
Measurement					
of Pain					

# SECTION - D

Experie	ence with cryotherapy	versus pain
a.	Reduced	
b.	Not reduced	
C	Cannot express	

# APPENDIX - VII

കീമോതെറാപ്പി മരുന്നുകൾ രക്തസിരകളിലൂടെ കുത്തിവയ്ക്കുമ്പോൾ ഉണ്ടാകുന്ന വേദന അറിയുവാനുള്ള ചോദ്യാവലിയും, നിരീക്ഷണവും.

			2
		ക്രമനമ്പര	à•
		(63/2/17/12/	
	വിഭാഗം	എ	
e	അടിസ്ഥാനവി		
	- 7		
നിർദ്ദേശം:	ഈ ഭാഗം അർബുദരോഗിക	ംളുടെ അടിസ്ഥാ	നവിവരങ്ങൾ അവശശപ
	ടുന്നു. അഭിമുഖക്കാരി ഓരേ		
100			
	ചോദിച്ച് അതിനുള്ള മറുപ	ടി തന്നിതിക്കുന്ന	കാളത്തിൽ ശരി എന്ന
	രേഖപ്പെടുത്തുക.		
1. വയസ്സ്	, a		
· ·	എ. 21–30 വയസ്സ്		
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	6121. 31-40 (ДФСС		
190	സി. 41–50 വയസ്സ്		
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ള. വിദ്യാഭ്യ <u>ാ</u>	സയോഗൃത		
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*			
	ബി. പ്രൈമറി		
	സി. സെക്കൻഡറി		
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L	ഡി. ഹയർസെക്കൻഡറി		
	ഇ. ബിരുദധാരി		

	4. ജോലിന	റിലവാരം		
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		ബി. വിവാഹിത		
		സി. വിവാഹമോചിതൻ		
		ഡി. വിധവ	- man placed	
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		ബി. പുകവലിക്കുക		
		സി. മദൃപിക്കുക		
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		ബി. മാംസഭോജി		
	8. കുടുംബര	ത്തിൽ ആർക്കെങ്കിലും പാരമ്പ	ര്യമായി അർബുദരോഗം ഉണേ	ഭാ? ഹന്ന്
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		എ. ഉണ്ട്		
		ബി. ഇല്ല		

# വിഭാഗം ബി രോഗസംബന്ധമായ ചരിത്രം

നിർദ്ദേശം: ഈ ഭാഗം അർബുദരോഗികളുടെ രോഗസംബന്ധമായ രോഗനി	ർണസം
കാലയളവ്, മരുന്നുകളെ സംബന്ധിച്ച ചരിത്രം ആവശൃദ്യെ	usimus,
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രേഖ പരിശോധിച്ച് ഈ ഭാഗം പൂരിപ്പിക്കുന്നു.	10230
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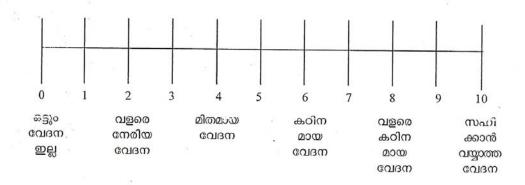
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ബി. ആവശ്യത്തിന്	
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ബി. നീര്	
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#### വിഭാഗം സി വിഷ്യൽ അനലോഗ്സ്കെയിൽ

നിർദ്ദേശം: താഴെ തന്നിരിക്കുന്ന സ്കെയിൽ അളക്കുന്നത് വേദന അനുഭവ പ്പെടുന്ന രീതിയാണ്. '0' എന്നത് അർത്ഥമാക്കുന്നത് വേദന ഒട്ടുമില്ല. '10' അർത്ഥമാക്കുന്നത് സഹിക്കാൻ വയ്യാത്ത വേദന ക്രൈയോ തെറാപ്പി സ്വീകരിച്ചതിനുശേഷം രോഗിക്ക് അനുഭവപ്പെടുന്ന വേദനയുടെ അളവ് പൂജ്യം മുതൽ പത്ത് വരെയുള്ള ഏതെങ്കിലും സംഖ്യ തിരഞ്ഞെടുത്ത് രേഖപ്പെടുത്താൻ രോഗിയോട് ആവശ്യപ്പെടുന്നു. ഈ വേദനയുടെ അളവ് താഴെ തന്നിരിക്കുന്ന ഗ്രിഡിൽ രേഖപ്പെടുത്തുക.



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#### APPENDIX - VIII

#### [Part-1]

#### **CRYOTHERAPY INTERVENTION GUIDE**

#### **DEFINITION**

Crtotherapy refers to the nursing interventions through continuous application of ice packs. It uses extreme cold to freeze and destroy the tissue it numbs pain, reduces swelling, constricts the blood vessels and block nerve impulses to the affected area.

#### I. PREPARATORY PHASE

A tray containing ice cubes in a plastic container wrapped with a cotton cloth.one mackintosh to place under the injection site.

One more towel to wipe of the area after the procedure. Pain scale to check the level of pain and recording articles.

#### II. PREPARATION OF CLIENT AND UNIT

- 1 Explain the procedure to the patient.
- 2 Place the mackintosh under the injection site.
- 3 Provide comfortable position to the patient.
- 4 Cryotherapy plastic container is placed and carried to the bed side of the patient.

#### **III. ACTION PHASE**

- 1 wash hands
- 2 Wipe the outside of the ice pack and cover it with a cotton cloth.
- 3 cryotherapy applying 3cm away from the injection site.
- 4 The ice pack is applied for 5-8 minutes.

# IV POST CRYOTHERAPY PHASE;

- 1 The area must be dried well with a towel.
- 2 Client must be made comfortable.
- 3 Observe the site for any complications.
- 4 Wash hands.
- 5 Document the patient's response.
- 6 Record the pain level.

### **ABSTRACT**

A quasi experimental study to assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among patients with cancer in selected hospital, Alappuza district ,Kerala.It was conducted as a partiall fulfillment of the requirement for the award of the degree of Master of science in nursing by 30093601 from Annai JKK Sampoorani Ammal college of Nursing, under The Tamilnadu Dr.MGR Medical University,Chennai, 2010 – 2011.

The objectives of the study were (1) To assess the effectiveness of cryotherapy on pain before and after the intravenous administration of chemotherapeutic agents among the cancer patients in experimental group. (2) To compare the mean difference on pain among the cancer patients between the experimental and control group. (3) To test the association between the mean difference on pain and selected factors among the cancer patients in experimental group.

The hypothesis formulated were (H<sub>1</sub>) There will be a significant difference in pain before and after cryotherapy among patients with cancer in experimental group. (H<sub>2</sub>) There will be a significant difference in the mean difference of pain among cancer patients between the experimental and control group. (H<sub>3</sub>) There will be a significant association between mean difference in pain and selected factors among patients with cancer in experimental group.

Literature review was done and organized under following headings; (1) Studies related to pain after the intravenous administration of chemotherapeutic agent. (2) Studies related to pain assessment. (3) Studies related to cryotherapy in general

The conceptual framework adopted for the present study was based on the gate control theory proposed in 1965 by Melack and Wall. The research design used was quasi experimental, repeated measure time series with control group design.

The tool developed and used for data was interview schedule. Numerical rating scale was used to assess the pain. The content validity of the tool was established by inter rater reliability, computed reliability coefficient r=0.86 was high. The pilot study was conducted

The main study was conducted in the Prethyasa cancer institute and research centre at Green gardens hospital, Cherthala. The information regarding background factors and disease related factors were collected from 46 samples by interviewing them and observing health records. Pain was measured using numerical rating scale from both the experimental and control group. with an interval of 10 minutes. The intervention cryotherapy was for experimental group. The evidence of intervention and pain were marked in a grid. Intervention was done at the bedside. The experiment was repeated twice during two consecutive doses.

The findings of the study were; There was a significant difference in pain after cryotherapy in 1st and 2nd doses. The mean difference on pain during 1st and 2nd intervention among cancer patients in experimental and control group was significant

Crotherapy was an effective intervention in reducing pain after the intravenous administration of chemotherapeutic agents among cancer patients. The implication limitation and recommendation were adequately spelt.