DISSERTATION ON

"A STUDY TO ASSESS THE EFFECTIVENESS OF USING COLD NEEDLE FOR GIVING INTRAMUSCULAR INJECTION TO REDUCE PAIN PERCEPTION AMONG ADULTS ADMITTED IN MEDICAL WARDS AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL CHENNAI-03"

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CERTIFICATE

This is to certify that this Dissertation titled "A Study to Assess The Effectiveness of Using Cold Needle for Giving Intramuscular Injection to Reduce Pain Perception among Adults Admitted in Medical Wards at Rajiv Gandhi Government General Hospital Chennai-03" is a bonafide work done by Ms.Revathy.R, College of Nursing, Madras Medical College, Chennai – 600003 submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai-32 in partial fulfillment of the requirements for the award of Degree of Master of Science in Nursing, Branch-I, Medical Surgical Nursing, under our guidance and supervision during the academic period from 2012–2014.

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ABBREVIATIONS

IM	:	Intramuscular injection
WHO	:	Word Heath Organisation
IASP	:	International Association for the Study of Pain
χ2	:	Chi-square
Р	:	Probability level
Т	:	Test of significance
DF	:	Degrees of freedom
Н	:	Hypothesis
SD	:	Standard Deviation

ABSTRACT

An interventional study was carried out to find the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception. Simple random sampling technique was used, 60 male and female subjects who are receiving intramuscular injection admitted in Medical wards at Rajiv Gandhi Government General Hospital were selected. 30 subjects for each experimental and control group.True experimental design was used to conduct the study. Using cold needle technique intramuscular injection was given for experimental group. For Control group routine technique was given. Post assessment was done after interventions for both groups by using Wong Baker's Faces Pain Scale. Data was analysed with both descriptive and inferential statistical methods. Independent T test was used to compare the effectiveness between experimental and control group and Karl Pearson's co efficient of correlation was used to find out the relationship between demographic variable. After cold needle technique the mean pain score in experimental group was 0.67 and in control group was 6.73 after routine technique (Independent t test t=24.23, P=0.001). This shows that using cold needle technique is more effective in reducing pain perception among subjects received intramuscular injection.

The investigator thereby concludes that using cold needle technique has reduced the level of pain perception on subjects received intramuscular injection. Thus it encompasses commitment by nurse who can practice Cold needle technique to reduce the level of pain perception.

CHAPTER-I INTRODUCTION

"To do what else will do, a way that nobody else can do, inspite of all, we go through, is to be a Nurse."

- Rawsi Williams

The injection is an unpleasant experience for the patients. Extra caution is required when administering injection to all patients. Patient with health alteration, restore or maintain their health using a variety of strategies and medications are most frequently used to manage disease. Management of pain is an important part of a health professional's role. The challenge for clinicians is to balance pain control with concern for patient safety and side effects of pain treatments. A universal fear of pain seems to be present in common, to all injections. In some individuals, this fear of injection pain is severe enough to prevent them from receiving an injection. In others, this injection fear has reached phobia level. Over the years, clinicians have explored different ways to reduce injection pain.

Pain derived from Latin word '*Poena*' means '*Punishment*'. The relief of pain has been one of the primary reasons for the development of health care, yet often it is difficult to understand the meaning of the complaint of pain or how effectively they can assist the patient to regain control over his or her life. Pain has been introduced as the fifth vital sign by Joint Commission Of Health Care Organization (JCAHO) and they have published the standards for pain management in the hospital setting in 2001. Pain is omnipresent, an intolerable sensation and makes the patient vulnerable. There is a saying that there is no gain without pain.

Pain is one of the most common causes of human suffering. Procedures, many of which produce pain are common occurrences in health care today as a means of providing diagnostic information, treatment, or palliation. Any procedure causing actual or potential tissue damage has the potential to cause pain. Regardless of the procedure or setting, if pain is not anticipated and prevented or treated appropriately, patient may experience numerous harmful effects and pain levels may be higher with subsequent procedures (*Ducharme, 2000; Weisman, Bernstein, Schechter, 1998*).

Chever (1999), emphasizes the need to prevent pain rather than treat it. Many procedures which cause pain are performed by or assisted by nurses who may be in a position to help the individual. Pain management is now considered an important patient outcome when evaluating the effectiveness of nursing care (*Padilla et al, 1990, Ferrel et al, 1991*).

Injections are currently the gold standard for administering various medications parentrally. The World health organization (2006) estimated that 16 billion injections are administered per year. The most significant side effect related to IM injection is the accompanying pain. Patients are often afraid of receiving injections because they perceive that it will be painful. Pain during an IM injection is generally to be expected, intramuscular injections are one of the commonest causes of iatrogenic pain (1992).

Pain occurs in all clinical settings and among many different groups of patients. Nurses have a central role in pain assessment and management .Pain is one of the most common widely under-treated health problems. As a basic scientific definition, pain is a sensation caused by some type of noxious stimulus. From the behavioural aspect, pain is a pattern of responses that function to protect an individual from harm.

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant, subjective sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". Untreated and inadequately treated pain causes suffering. The intramuscular injection of medication is a procedure commonly performed by nurses and are associated with discomfort, pain and trauma to the injected tissue.

Medications have been administered by intramuscular injections for more than a century. This route of administration is most used and preferred, particularly when the medications are administered in small amount like codeine, morphine, gentamicin, prednisone, diclofeac sodium, paracetamol etc. Among others, intramuscular (IM) injection is a common procedure that nurses frequently carry out, which causes pain and distress to the recipient.

Pain originating from intramuscular (IM) injection should not be underestimated, because a painful injection might incite severe fear of injection, which may lead a patient to delay seeking medical help (Ozdemir & Bengu, 2009). There are four process of normal pain and they are transduction, transmission, perception and modulation [(Mc caffery & Pasero, 1994), (as cited by potter & Perry, 2012)]. A client in pain cannot discriminate among the processes. However, understanding each process helps the nurse to recognize factors that cause pain, symptoms that accompany pain and to find the rationale and action to select therapies.

Pain management strategy must be identified to promote optional pain relief ways to manage the clients pain may be pharmacologic and non pharmacologic including physical and behavioural measures such as touch, massage, application of heat and cold, acupuncture, relaxation, hypnosis and distraction etc. Proved effective in reducing pain. Cold

therapy is found effective in relieving IM injections pain in the previous studies [Denkler (2001), and Thomas (2008)].

1.1. NEED FOR THE STUDY

Intramuscular injections (IM) are a common, yet complex, technique used to deliver medication deep into the large muscle of the body. The goal of IM injection is to maximize the therapeutic effect of the medication, eliminate or minimize the complication and discomfort from IM injection. Giving injection is the routine nursing activity and good injection technique can make the experience for the patient relatively painless.

Schechter et al. (2007), stated that women consistently report pain more than men, and the underlying medical condition and the patient's previous experiences may also affect their perception of pain with IM injection. Application of cold for the reduction of pain during various invasive procedures including intramuscular injections is also widely tested and accepted. Using the body's own nervous system ,the gate control theory invokes the concept that the final common pathway for sharp pain to the brain can be blocked by the nerves that transmit cold.

One of the most effective method, the use of cold needles to reduce pain during intramuscular injections has been proved effective in different settings. A study conducted in the US to compare the pain associated with injection using frozen vs room temperature needles showed that frozen needles were less painful in 76.6% of patients. Another study which was conducted in India to assess the effect of temperature of needle on perception of pain during Intramuscular injection showed a significant reduction in pain with the use of cold needle.

Nurses are obligated to mitigate every kind of pain, even the minor procedural pain. Esmailzadeh and *Farhadi (2011)* state that IM

injection is an invasive and painful method of medication and local cold has the ability to decrease pain via decreasing transmission and perception. Studies have shown non pharmacologic interventions used alone or in conjunction with pharmacologic interventions have the potential to reduce the perception of pain associated with procedures. (*Friesner, curry and Moddeman 2006; Biermeier.W., Dale.S. Eshelman and Guzzetta. 2007*).

Using pre frozen needle is a simple and inexpensive way to reduce pain during intramuscular injections. No adverse effect of using cold needles was noted in the previous studies. The evidences of cold needle as an analgesic combined with the investigator's personal experience in different inpatient and outpatient treatment units, with patients suffering from procedural pain, the investigator wishes to conduct a study on the effect of cold needle on pain.

Pain is universal human experience and it is significant fear of most of the patients, the fear of pain is ranked only second to the fear of death. For some it is a minor inconvenience, for others it is a major problem that causes suffering and reduces quality of life. Pain is the commonest reason for seeking help from health care professionals. Nurses play a greater role in minimising the pain and discomfort during any invasive procedure.

A publication in year 2000 has highlighted poor patient satisfaction with the frequent use of intramuscular injections. Where researcher looked at the drug prescription charts of all patients on 10 surgical wards on two separate occasions found that out of 422 patients, 135 were prescribed intramuscular analgesic or anti-emetic drugs. Of these, 54 patients had received a total of 74 intramuscular injections. In summary, 40% of the total number of intramuscular injections was reported as painful by patients. A separate questionnaire revealed that

intramuscular injections are painful; the intramuscular route is frequently the preferred method of prescribing postoperative drugs.

However as outlined, with any injection, this is an invasive procedure with regards to breaking the body's natural barriers, there is always a risk of soreness and discomfort.

Pain management is one of the main facets of nursing care, where nurses need to be competent. Nurses are obligated to mitigate every kind of pain, even the "minor" procedural pain. Undoubtedly, procedural pain is an important source of discomfort for hospitalised patients from which, all instinctively try to escape. 10% of adults in the United States have needle phobia.

Lehman J F (1982) describes the effects of therapeutic cold in the treatment. A direct effect on the conduction of pain receptor and neurons, reducing the velocity and number of impulses is one way of alleviating the pain. It is evident that latter effect would only occur in the skin if the temperature were reduced.

In a systemic review of measures for reducing injection pain during adult immunization involves six studies representing 853 participants. One study evaluating pharmacological interventions (lidocaine-prilocaine) found them to be effective in reducing pain from immunization. Similarly, two studies evaluating physical pain relieving techniques, either skin cooling interventions (Fluori-Methane) or tactile stimulation (manual pressure at the site of injection) found them to reduce pain.

Studies involving pain associated with injections revealed significant positive findings with adults' nonpharmacologic intervention for pain management. More than 12 billion IM injections are administered annually throughout the world. The annual ratio of

injections per person ranged from 1.7 to 11.3. The investigator has worked in medical and surgical ward and has viewed pain of the client with various intramuscular injections.

Inspite of wide use of medical and nursing interventions in the health care measures, pain and fear associated with IM injection remains an unresolved problem of the contemporary medicine. So the researcher has undertaken this study to evaluate the effectiveness of cold needle in reducing the pain associated with IM injections.

1.2. STATEMENT OF THE PROBLEM

"A study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards at Rajiv Gandhi Government General Hospital Chennai-03".

1.3. OBJECTIVES

- To assess the level of pain perception among adult patients during intramuscular injection in control group with routine technique.
- To assess the level of pain perception among adult patients during intramuscular injection in experimental group with cold needle technique.
- To compare the level of pain perception among adult patients during intramuscular injection in both control and experimental group.
- To determine the level of pain perception among adult patients during intramuscular injection in both control and experimental group with selected demographic variables.

1.4. OPERATIONAL DEFINITIONS

Assess

It is the way of measuring the level of pain while giving intra muscular injection to adult subjects.

Effectiveness

In this study, it refers to the outcome of the cold needle technique on pain perception during intramuscular injection among adult subjects, as scored by a Wong Baker's Faces pain scale.

Pain

In this study, pain refers to the unpleasant experience at the injection site resulting from the administration of intramuscular injections as rated by the subjects on Wong Baker's Faces pain scale.

Intramuscular injection

In this study, it refers to the introduction of needle into the gluteal region for administering the medication.

Cold needle

In this study, it refers to the 23 gauge sterile disposable needle used for giving intramuscular injection which is cooled at the range of 0-2 degree celsius in the chiller chamber of refrigerator for 1-2 hours and stored in an ice box in which the temperature is maintained and measured with the help of a laboratory thermometer. Then it is attached to the syringe with loaded medicine just before the administration.

Adult patients

In this study, it refers to the subjects who are between 21 years to 60 years of age and admitted in medical wards in Rajiv Gandhi Government General hospital, and fulfills the inclusion criteria.

1.5. HYPOTHESIS

- H1 There will be a significant difference between cold needle IM injection and pain perception.
- H2 There will be a significant association between cold needle IM injection pain perception and selected demographic variables.

1.6. ASSUMPTION

There will be significant pain reduction among adults receiving intramuscular injection using cold needle technique.

CHAPTER-II REVIEW OF LITERATURE

"Pain is such an uncomfortable feeling that even a tiny amount of it is enough to ruin every enjoyment."

- Will Rogers

Review of literature is an important step in the development of a research project. It involves the systematic identification location, scrutiny and summary of written materials that contain information on research problem.

"The literature is reviewed to summarize knowledge for use in practice or to provide a basis for conducting study" (*Nancy Burns 2002*).

This chapter attempts to preset a broad review of the studies conducted, the methodology adopted and conclusion drawn by earlier investigation, it helps to study the problem in depth. The literature reviewed for the present had been presented under the following heading.

2.1. REVIEW OF RELATED LITERATURE

- Part-I : Studies related to Intramuscular injection and Pain.
- Part-II : Studies related to cold therapy in reduction of Intramuscular injection pain .
- Part-III : Studies related to effectiveness Cold needle on Intramuscular injection pain.

Part-I: Studies related to Intramuscular injection and pain

Nahm, S, Lee.J. et al. (2012) conducted a study to evaluate the influences of patient characteristics on pain perception due to intra muscular vaccine injection in healthy adult volunteers. The injection of

Hepatitis B vaccine using a 24 G needle was performed as uniform stimulus and the intensity of injection pain was measured immediately after the injection using a 100 mm Visual Analogue Scale (VAS). One hundred and sixty volunteers (65 males, 95 females) enrolled in this study and the average VAS score was 20.8 ± 17.1 (range 0 to 67) in males and 34.4 ± 19.7 (range 2 to 76) in females p <0.001. The study report concluded that gender appears to be the only factor that influences thepain of IM injection and pain reducing method will be needed when performing injection procedures particularly inwomen.

Kusumadevi et al. (2011), conducted a study at Victoria Hospital, Bangalore to estimate the pain sensitivity using Visual Analogue pain Scale after IM injections amoung adult men and women. The study sample was (140 men, 160 women) and its statistical result revealed a significant higher pain score was obsvered in women (1.94 + 1.10) as compared to men (1074 + 1.24) p=0.060). Also Epidemiological data have consistently demonstrated gender differences with women reporting a high frequency of several types of pain.

Cherwenka, I. D., Engstrom, L. J., et.al. (2010), a study to find out the procedures that nurses used to prepare and administer IM injections of fertility medications. A sample of 645 nurses was involved and descriptive survey design was adopted for the study. The study results declared wide variation in the procedures used by nurses to prepare and administer IM injectioof fertility medications and many nurses did not use procedures that can reduce the pain and tissue trauma associated with IM injections.

Akyol, A. (2010), conducted a study aimed at determining the impact of two different IM methyl prednisolone injections speed on pain intensity and pain duration. A one group quasi experimental design was used to study 10 seconds versus 30 seconds injection duration and a

sample of 25 patients were involved in the study. Data were collected using patient characteristics form and with Visual Analogue Scale (VAS). The mean difference in pain levels according to the VAS in the post injection period was significantly higher with administration of IM methyl prednisolone in 10 seconds compared with 30 seconds administration (VAS 1.9 vsl.3: p<.05). The study concluded that slow IM injection of steroid improves pain management.

National patient safety agency, (2007). Pain is a perceptual process that is usually initiated by the stimulation of peripheral nociceptors and transmitted to the sensory cortex by specialized pain fiber system. Once the patient experienced pain after IM injection, they become scared of getting the injection via IM route in future. Pain originating from IM injection should not be underestimated, because a painful injection may incite severe fear of injection. Malkin (2008) states that the technique for delivering IM injection remains rooted custom and practice. Poor practices of IM injection may create adverse risks patients and healthcare workers The administration of IM injection is an important part of medication management and a common nursing intervention in clinical practice. A skilled injection technique can make the patients experience less painful and avoid unnecessary complication. Pain perception is characterized by tremendous individual differences and is influenced by multiple biopsychosocial variables.

Cuppit, (2004), A publication in the year 2000 has highlighted poor patient satisfaction with the frequent use of IM injections. In this study the researcher looked at the drug prescription charts of all patients on 10 surgical wards on two separate occasions the researcher found that out of 422 patients, 135 were prescribed IM analgesic. Of these, 54 patients had received a total of 74 IM injections. In summary, 40% of the total number of IM injection was reported painful by the patients.

Part - II :Studies related to cold therapy in reduction of Intramuscular injection pain .

Sheikh, I.(2011), department of Medical Surgical Nursing, SEA College of Nursing, Bangalore, conducted a study to assess the effectiveness of ice cube application on reducing pain, before giving IM injection amoung adult patients. Pre experimental design (one group pre test poet test) was adopted for the study and a sample of 60 patients were involved through purposive sampling technique. The study concluded that, samples received ice application before IM injection has considerably less pain when compared to the samples received IM injection without ice application using ice at the injection site prior to the administration will helps to reduce the pain associated with IM injection

Emine Kol (2010), Conducted a study to evaluate the outcomes of Ice application for the control of pain associated with chest tube irritation. The randomizes and single blinded study consisted of 40 patients (20 in the control and 20 in the study group) who underwent Thoracotomy with chest tube placement. Standard post operative analgesic methods were applied to all patients. Additionally, ice (in flexible and bendable cold gel packs wrapped in fine cloth sheaths) was applied to the chest tube insertion site at the 24^{th} , 28^{th} , 36^{th} , and 40^{th} , postoperative hours for 20 minutes. Average pain severity scores during the mobilization activities, including coughing and walking, were compared and found to be significantly lower in the study group patients who received cold therapy than in the control group patients (p<0.05). The application of ice to the chest tube insertion site reduced pain associated with irritation along with the need for analgesics.

Marzieh Hasanpour, et al (2009), Purpose of this study was to assess the effect of local cold therapy and distraction in pain relief using penicillin intramuscular injection in children. In this work, 90 children

with ages from 5 to 12 who had penicillin injection intramuscularly in a health centre were studied the data was collected through interview and questionnaire. Oucher scale was used to measure pain intensity. Average pain intensity in local cold therapy, distraction, and control groups was 26.3, 34.3, and 83.3, respectively. The findings indicate that pain intensity was significantly higher in the control group than the experimental groups.

Chou SY, Liu HE (2008) conducted a study on comparison of effectiveness adopting a quasi experimental design in which moist and dry cryotherapy in reducing discomfort after orthognathic surgery. The purpose of this study was to compare the effectiveness between ice towel (Moist Cryotherapy) and ice pack (Dry Cryotherapy) in postoperative care. Orthognathic surgery is often performed to modify the facial appearance of individuals. Both the dry and moist cryotherapy reduced postoperative discomfort effectively.

Sabitha P.B.et al (2008) reported study to assess the effectiveness of cryotherapy on Arterio Venous fistula puncture related pain in Hemodialysis patients. Aconvenience sample of 60 patients (30 each in experimental and control group) by using randomized control trial objective and subjective pain scoring was done for two consecutive days with cryotherapy for the experimental and without cryotherapy for the control group. The objective Arterio Venous fistula puncture pain score on days 1 and 2 of hemodialysis patients on experimental group was found to be significantly reduced (p=0.001) so they concluded that cryotherapy is effective in reducing AV fistula puncture pain of Hemadialysis patients.

Amin A Algafly, Keith P George (2007) conducted a study on the effect of cryoytherapy on nerve conduction velocity, pain threshold and pain tolerance. A convenience sample of adult male sports players was

included in the study. In the control ankle, Nerve conduction velocity, pain threshold and pain tolerance did not alter when reassessed. In the ankle receiving cryotherapy, Nerve conduction velocity was significantly and progressively reduced (p<0.05).

East C.E, Begg L (2007) conducted a study on local cooling for relieving pain after perineal surgery in which seven studies including 159 women were compared cooling treatment such as ice, cold gel pads, or cold bath with no treatment. One study found that women reported less pain 24 to 72 hours after giving birth when they used the ice packs, rather than when they had no treatment. There is only a small amount of evidence of how safe and effective cooling treatments are used to relieve perineal pain.

Ali Fakhr Movahedi, et al (2006) The purpose of the studywas to determine the effect of local refrigeration prior to venipuncture on pain related responses in school age children a quasi experimental study. The samples were 80 children 6 to 12 years of age selected by purposive sampling. In the test group the injection site was refrigerated for three minutes using an ice bag. In the control group, the procedure was performed according to usual routine. The results of this study suggest that the use of local refrigeration prior to venipuncture can be considered an easy and effective intervention of reducing venipuncture related pain.

Finan et al (2006) conducted a study to assess the effectiveness of cryotherapy on post operative pain in gyneologic patients undergoing laparotomy (n=20) experimental group consists of 13 patients. All patients underwent exploratory laparotomy and received postoperative pain relief with intravenously administered analgesics. Data were analysed by descriptive and inferential statistics (p<0.05). The results

shows that the cryotherapy reduces the post operative pain in gynaecological patients undergoing laparotomy.

Laureauo, filho et al (2005) reported the effectiveness of cryotherapy on reduction of pain, swelling and trimus after third molar extraction n=14 with the group of 20 to 28 years. The sample consists of 11 women and 3 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 when he or she was awake. The patient did not receive cryotherapy on the other side. The authors performed clinical examinations to measure trimus and swelling before surgery, immediately after surgery. Overall they found significant differences between the control and treated (p<0.05). Cryotherapy was effective in reducing post operative swelling and pain.

Department of Dermatology, at Jordon University of Science and technology conducted a study to reveal whether cold air can reduce needle pain during injection. Patient undergoing skin injections (n=40) were included and the pain level after injection in each sample was assessed with Visual Scale (VAS). Injections were given with cold air and without cold air in the sample and the pain score was obtained. As per analysis, 33 patients had lower VAS score with cold air, 5 patients had worst VAS score and 2 patients did not have any change their pain score. The study concluded that cold air seems to be useful in reducing needle injection pain in majority of patients.

Part-III: Studies related to effectiveness of cold needle on IM injection pain

Mariya.B (2010), of St. Johns College of Nursing, Bangalore, conducted a study to determine effect of cold needle on perception of pain during IM injection. Crossover design was used in the study and a

sample of 60 patients who received inj. Tramadol was involved. The samples were randomly allocated to group 1 and group 2 and injections with routine technique and cold needle technique were given to each sample. The pain score was assessed using Numerical Pain Scale and the study report concluded that the samples received IM injection with cold needle had significant lower pain score than the sample received IM injection with routine technique.

Thomas.N (2008), department oMedical Surgical Nursing, AIIMS, New Delhi, conducted a study to assess the effect of temperature of needle on perception of pain during administration of intramuscular injection of Benzathine penicillin amoung RHD patients. The study report concluded their is significant reduction in the perception of pain with the use of cold needle among samples and using cold needle is a simple and inexpensive way to reduce pain during intramuscular injections.

Bartell (2008), An experimental study to assess the effect of needle temperature on pain ratings after injection was done in US. 80 participants received an injection of influenza vaccine in one arm and a saline injection in the other using a cold or room temperature needle in a double blinded fashion. In this study, no statistically significant change was observed between two techniques. The mean pain score for influenza vaccine with two injections was for cold needle 32.2 mm \pm 3.2 and room temperature needle 36.0 \pm 3.8. For saline injections it was 25.2 mm \pm 2.95 and 23.7 \pm 3.19 for cold needle and room temperature needle respectively. The study concluded that the use of cold needle may not be worth pursuing for injections with mild pain but may be worth while to explore using more painful injection.

The University of Wisconsin Madison, (2005), conducted a study to determine the effect of needle temperature on pain ratings following IM injection. A double blind controlled study design was adopted for the study and the sample involved were received with two injections (one contain 0.5 ml of season influenza vaccine and other contain .05 ml of normal saline). The pain score was assessed with Numerical Pain Scale. The study result revealed that the sample who received frozen needle IM injection had significantly less pain, when compare the samples who received with room temperature needle.

Denker, K, (2001), conducted a study to determine the pain associated with injection using frozen vs. Room temperature needles. A study of 77 patients who were received bilateral injections of botulinum toxins (12.5 units per injection) symmetrically into the right and left corrugators muscles using a 23 G needle was involved in the study. Each patient received one of the injections with a room temperature needle and the other with a needle that has been frozen overnight at -7 degree celcius. Using Numerical pain scale, the pain score was identified. The results of the study were analyzed using Paired "t" test and it revealed that the frozen needles were less painful in (76.6%) patients, more painful in 14 (18.2 %) patients and mild pain difference in 4 (5.2 %) patients. Mean pain score for the frozen needles resulted in significantly less pain (MD 1.2: SD±1.7<0.01).

2.1.CONCEPTUAL FRAMEWORK

The conceptual framework for this study is developed by the investigator based on Modified Donabedian's's Model. The focus of this theory is the adaptation of the individual to stimuli from the environment from within. Each component has a direct influence on the next, as represented by the arrows in the following schematic representation.



Structure refers to the attributes of the settings in which providers deliver health care, including material resources (electronic health records), human resources and organizational structure.

In this study, the structure includes the human resource demographic variables.

Process of care denotes what is actually done to the patient in the giving and receiving of care. Building on the example above, the provider could review whether an eligible patient has been placed on an Angiotensin converting enzyme inhibitor to help prevent future heart attacks.

In this study, process includes, using cold needle technique for giving intramuscular injection in experimental group. In this process, experimental group receives cold needle injection whereas control group receives routine technique.

Health outcomes are the direct result of a patient's health status as a consequence of contact with the health care system. In the above example, the patient receiving the preventive medications mentioned above could decrease the chance of dying from a heart attack.

The output is reduction in pain, among adult subjects receiving intramuscular injection in experimental group, and there is no significant change in pain perception among control group.



Fig-1: CONCEPTUAL FRAMEWORK MODIFIED DONABEDIAN'S MODEL (1980)

CHAPTER-III METHODOLOGY

"Historical methodology, as I see it is a product of common sense applied to circumstances"

- Samuel.E.Morison

Research Methodology provides a brief description of the method adopted by the investigator in the study. The methodology of research refers to the principles and ideas on which the researchers base their procedures and strategies. It includes the research approach , design, population, sampling technique, development and description of the tools and intervention, pilot study report, procedure for data collection and data analysis.

The study is aimed at assessing the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception The nature of the research problem and availability of the samples guided the selection of research approach.

3.1. RESEARCH APPROACH

A Quantitative Approach was adopted in this study as the investigation is aimed at evaluating the effectiveness of using cold needle technique for giving intramuscular injection among adult subjects.

3.2. RESEARCH DESIGN

A research design chosen for this study was true experimental post test only control group design. This design is most suitable design for the present study because it helps the researcher to experiment the effectiveness of using cold needle in reducing pain perception during intramuscular injection among adult subjects admitted in medical wards.

Group	Intervention (IM Injection Using Cold Needle Technique)	Post Assessment Pain Level
Expermitnal Group	Х	01
Control Group	—	02

X - IM Injection using cold needle technique

01 - Post assessment pain score in Experimental group

02 - Post assessment pain score in Control Group

3.3. VARIABLES

Independent variable

Administering IM injection using cold needle technique.

Dependent variable

Pain perception.

Demographic Variables

Age, sex, religion, educational status, occupation, family income, marital status, Previous history of intramuscular injection.

3.4. SETTINGS OF THE STUDY

The setting for the study was conducted in Medical Ward at Rajiv Gandhi Government Hospital, Chennai- 03.

3.5. STUDY POPULATION

Population is the entire universe of individuals, objects and events potentially available for the research study. The study population consist of patient receiving intramuscular injection in medical wards at Rajiv Gandhi Government Hospital, Chennai-03.

3.6. SAMPLE

All the subjects receiving intramuscular injection with the age between 21 to 60 years.

3.7. SAMPLE SIZE

The sample size for this study is composed of 60 adult subjects, 30 for each experimental and control group.

3.8. SAMPLING TECHNIQUE

Probability Sampling Technique – Simple random sampling – lottery method used. Samples were randomly assigned to Experimental and control group.

3.9. CRITERIA FOR SAMPLE SELECTION

Inclusion criteria

Adult subjects who are

- Between the age group of 21 to 60 years, both male and female receiving intramuscular injections.
- Capable of giving adequate response to pain.
- ✤ Available during the study period
- Willing to participate in the study

Exclusion Criteria

Subjects who are

• Unconscious or critically ill.

- Receiving oily injections.
- Getting any other type of oral or IV analgesia
- Received sedatives less than two hours before the procedure.
- Unable to assume side lying position with flexed knees.
- Suffering from bleeding disorders.

3.10. DEVEPLOPMENT AND DESCRIPTION OF THE TOOL

After an extensive review of literature and discussion with the experts the following tools were prepared to collect data.

- Section-A : Demographic variable (Age, Sex, Education, Occupation, Family income, Religion, Previous history of IM injection).
- Section-B : Wong Baker's Faces Pain Scale

Interpretation of the pain score:

The scoring system is divided into following categories

0	-	No Pain

- 2 Mild Pain
- 4 `- Uncomfortable pain
- 6 Distressing pain
- 8 Horrible pain
- 10 Worst pain

3.11. ETHICAL CONSIDERATIONS:

The study was conducted after the approval of the Institutional Ethics Committee and Head of the Department, Institute of Internal Medicine, Madras Medical College and Rajiv Gandhi Government
General Hospital, Chennai -03. Informed consent was obtained from each study participant after giving full information about the study. Anonymity was assured to each participant and maintained by the researcher.

3.12. CONTENT VALIDITY

The content validity of the tool was established on the basis of opinion from the experts, Medical expert and Nursing expert and the tool was finalized.

3.13. PILOT STUDY

With formal permission from the Head of the department and content validity from the experts, the study was conducted in medical wards for 5 days at Rajiv Gandhi Government General Hospital, Chenai-03. By simple random sampling technique, 10 samples with intramuscular injection were selected. For the experimental group,cold needle technique was used for giving intramuscular injection and for control group hospital routine technique was followed. Post assessment was done using Wong Baker's Faces pain Scale. The study showed the feasibility to conduct the proposed study as planned.

3.14. REALIABILITY

After pilot study reliability of the tool was assessed by using test inter rater method and its correlation coefficient r –value is 0.88. This correlation coefficient is very high and it is good tool for assessing the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards at Rajiv Gandhi Government General Hospital, Chennai-03.

3.15. DATA COLLECTION PROCEDURE

The study was conducted with the permission of the Head of the Department and the Institutional Ethical committee. Inclusion criteria

was followed for sample selection .Information about the study was given to the subjects and informed consent was obtained in the prescribed form. The investigator assured the confidentiality. Subjects selected for pilot study were excluded. 60 Subjects were selected by Simple random sampling technique- lottery method was used to select the subjects from the sample frame and assigned to two groups -30 for each experimental and control group. Data was collected from the subjects. 23 gauge sterile disposable needle used for giving intramuscular injection which is cooled at the range of 0-2 degree celsius in the chiller chamber of refrigerator for 1-2 hours and stored in an ice box in which the temperature is maintained and measured with the help of a laboratory thermometer. Then it is attached to the syringe with loaded medicine just before the administration. Post assessment was carried out for both experimental and control group using Wong Baker's Faces Pain Scale to evaluate the effectiveness of intervention.

3.16. PLAN FOR DATA ANALYSIS

The data were planned to be analyzed in terms of objectives of the study using descriptive and inferential statistics.

Descriptive Statistics

- Frequency and percentage distribution to analyze the demographic data.
- Mean and standard deviation to assess the scores.

Inferential statistics

- Independent 't' test for comparison of experimental and control groups.
- Chi square to find the association between experimental and control groups and selected demographic variables.

The data analysis and interpretations of the results are given in the following chapter.

3.17. PROJECTED OUTCOME

The study findings will helpful for the health professional to elicit,

- the level of pain perception will be less while giving IM injection
- the level of comfort will be more while giving IM injection.
- the practice will make the painful IM injection procedure to the least possible extent.

FIG: 2 SCHEMATIC REPRESENTATION OF THE RESEARCH METHODOLOGY



CHAPTER-IV DATA ANALYSIS AND INTERPRETATION

"All great truths are simple in final analysis and easily understood, if they are not, they are not great truths"

- Napolean Hill

Data analysis is the method of organizing data in such a way that the research question can be answered. Interpretation is the process of making sense of results and of examining the implications of the findings within a border context.

The data collected from the samples to evaluate the effectiveness of using cold needle for giving IM injection to reduce pain perception at Rajiv Gandhi Government General Hospital were organized, analyzed, tabulated, and interpreted.

The data has been organized and presented in five section

The data collected was edited, tabulated, interpreted and findings obtained were presented in the form of tables and diagrams represent the following headings.

- Section-A : Assessment of Demographic profile
- Section-B : Assessment of the level of pain perception among adult subjects during intramuscular injection in control group with routine technique.
- Section-C : Assessment the level of pain perception among adult subjects during intramuscular injection in experimental group with cold needle technique.
- Section-D : Comparison of the level of pain perception among adult subjects during intramuscular injection in both control and experimental group.

Section-E : Determination of the level of pain perception among adult subjects during intramuscular injection in both control and experimental group with selected demographic variables.

SECTION-A: ASSESSMENT OF DEMOGRAPHIC PROFILE

Table-1: Frequency and percentage distribution of demographic variables

	Group						
Demographic v	Experi	iment	Cont	trol			
	No. of adults	%	No. of adults	%			
Age	21 -30 yrs	9	30.0%	7	23.3%		
	31 -40 yrs	6	20.0%	6	20.0%		
	41 -50 yrs	9	30.0%	9	30.0%		
	51 -60 yrs	6	20.0%	8	26.7%		
Sex	Male	18	60.0%	17	56.7%		
	Female	12	40.0%	13	43.3%		
Religion	Hindu	19	63.3%	18	60.0%		
	Christian	6	20.0%	8	26.7%		
	Muslim	5	16.7%	4	13.3%		
Educational Status	Illiterate	10	33.4%	9	30.0%		
	Primary	6	20.0%	7	23.3%		
	Secondary	7	23.3%	9	30.0%		
	Diploma	7	23.3%	5	16.7%		
Occupation	Unemployed	5	16.7%	12	40.0%		
	Government	1	3.3%	1	3.3%		
	Private	14	46.7%	12	40.0%		
	Business	9	30.0%	4	13.4%		
	Pensioner	1	3.3%	1	3.3%		
Monthly income	< Rs.1000	11	36.6%	8	26.6%		
	Rs.1000 - 3999	8	26.7%	12	40.0%		
	Rs.4000 - 6999	8	26.7%	8	26.7%		
	Rs.7000 – 9999	3	10.0%	2	6.7%		

	Group							
Demographic v	Experi	iment	Control					
Demographic variables		No. of adults	%	No. of adults	%			
Marital status	Unmarried	6	23.4%	5	16.7%			
	Married	18	60.0%	18	60.0%			
	Separated	1	3.3%	2	6.7%			
	Divorced	2	3.3%	1	3.3%			
	Widower	3	10.0%	4	13.3%			
Previous history of	Yes	29	96.7%	29	96.7%			
Intramuscular injection	No	1	3.3%	1	3.3%			

The above tables shows that majority of the samples were between the age group of 21-30 years in the experimental group (30.0%)& 41-50 years in the experimental group (30.0%) and the age group of 41-50 years in the control group (30.0%). Majority (60.0%) of the samples were male in the experimental group and (56.7%) were male in the control group.

Considering the religion, most of the adults 19 (63.3%) were Hindus in Experimental group and majority of adults 18 (60.0%) were Hindu in Control group. As for the educational status, majority of adults 10 (33.4%) are in the illiterate in Experimental group and most of the adults 9 (30.0%) were in the illiterate in Control group.

Considering the history of previous IM injection majority of adults 29 (96.7%) were experienced before in Experimental group and most of the adults 29 (96.7%) were experienced before in Control group.



Fig-3 : Distribution of age in Experimental and Control Group

Above figure shows the age distribution of experimental and control group were majority of the subjects belong to the age group of 41-50 years..



Fig-4 : Distribution of sex in Experimental and Control Group

Above figure represents the gender distribution were male subjects are more than the female subjects.



Fig-5 : Distribution of religion in Experimental and Control Group

Above figure represents that majority are Hindu from both experimental group (63.3%) and control group (60.0%).



Fig-6: Distribution of Education in Experimental and Control Group

Above figure represents that most of the subjects are illiterate (33.4% and 30.0% in experimental and control group respectively).



Fig-7: Distribution of Occupation in Experimental and Control Group

Majority of the subjects in experimental group is private (46.7%) and control group is (40.0%)



Fig 8 : Distribution of Monthly Income in Experimental and Control Group

Above figure shows that majority of the experimental group income is (36.6%) Rs.<1000 and majority of the control group's income is (40.0%) Rs.1000-3999.



Fig-9: Distribution of Marital Status in Experimental and Control Group

Above figure shows majority that are married (60.0% in experimental group and 60.0% in control group).



Fig-10: Distribution of History of IM Injection in Experimental and Control Group

Above figure shows that majority of subjects are hospitalized (96.7% in both experimental and control group)

Lovel of pain	Control group				
Level of parti	No. of adults	%			
No pain	0	0.0%			
Mild pain	0	0.0%			
Uncomfortable pain	0	0.0%			
Distressing pain	19	63.3%			
Horrible pain	11	36.7%			
Worst pain	0	0.0%			
Total	30	100.0%			

Table 2: Post Assessment of Level of Pain Among Control Group

Table 2 shows post assessment of level of pain among control group. In which control group, 63.3% of the adults are having Distressing pain, 36.7% are having Horrible pain.

Lovel of poin	Experimental group				
Level of pain	No. of adults	%			
No pain	0	0.0%			
Mild pain	20	66.7%			
Uncomfortable pain	10	33.3%			
Distressing pain	0	0.0%			
Horrible pain	0	0.0%			
Worst pain	0	0.0%			
Total	30	100.0%			

Table-3: Post Assessment of Level of Pain Among Experimental Group

Table 3 shows post assessment of level of pain among experimental group. In experimental group, 66.7% of the adults are having mild pain, 33.3% are having uncomfortable pain.

	Level of pain	Exp	erimental	С	ontrol	Chi square
		n	%	n	%	test
Post	No pain	0	0.0%	0	0.0%	χ2=60.00
assessment	Mild pain	20	66.7%	0	0.0%	P=0.001*** DF=3
	Uncomfortable pain	10	33.3%	0	0.0%	significant
	Distressing pain	0	0.0%	19	63.3%	
	Horrible pain	0	0.0%	11	36.7%	
	Worst pain	0	0.0%	0	0.0%	
	Total	30	100.0%	30	100.0%	

Table-4: Comparison of Level of Pain Between Experimental andControl Group

* significant at P \leq 0.05 ** highly significant at P \leq 0.01 *** very high significant at P \leq 0.001

Table 4 comparison of level of pain between experimental and control group. In experimental group, 66.7% of the adults are having mild pain, 33.3% are having uncomfortable pain. In control group, 63.3% of the adults are having Distressing pain, 36.7% are having Horrible pain

This difference is large and it is statistically significant difference. Statistical significance was calculated using **chi square test.**



Fig-11: Comparison of Level of Pain Between Experimental Group and Control Group

Above figure shows the effectiveness of using cold needle technique among experimental group who had mild pain (66.7%) during intramuscular injection where as control group who received routine needle technique had distressing pain (63.3%).

Group	No. of adults	Post '	Test	Student's			
Group	into: of adults	Mean	SD	independent t-test			
Experiment	30	0.67	0.96	+			
Control	30	6.73	0.98	t-24.231-0.001			

Table-5: Comparison of Pain Score Between Experimental andControl Group

* significant at P \leq 0.05 ** highly significant at P \leq 0.01 *** very high significant at P \leq 0.001

Table 5 shows comparison of pain score experimental and control group. Experimental group adults are having 0.67pain score and control group are having 6.73 pain score. So the difference is 6.07 pain score. This difference is large and it is statistically significant. It was calculated using student independent t-test.



Fig 12: Comparision of Mean Pain Score Between Experimental Group and Control Group

In experimental group, post test pain score is 0.67 where as in control group it is 6.73. so the difference is 6.06. This difference is statistically significant. It was calculated using student independent t- test.

Table-6: Effectiveness of Using Cold Needle for Giving IntramuscularInjection to Reduce Pain Perception among Experimental and ControlGroup

	Max score	Mean score	Mean difference with 95% Confidence interval	Percentage difference with 95% Confidence interval	
Experimental	10	0.67	6.07	60.7%	
Control	10	6.73	(5.56-6.56)	(55.6%-65.6%)	

Table 6 shows effectiveness of cold needle for giving intramuscular injection to reduce pain perception among experimental and control group. On an average, experiment group are having 0.67 pain score whereas in control group are having 6.73 pain score, so the difference is 60.7%. Post assessment score was analysed using proportion with 95% CI and mean difference with 95% CI is 60.7%. This difference shows the effectiveness of cold needle.

Demographic variables			Level o	f Pai			
		Mild pain		Unc	omfortable pain	Total	Chi square test
		N	%	Ν	%		
	20 -30 yrs	8	88.9%	1	11.1%	9	
A (70)	31 -40 yrs	5	83.3%	1	16.7%	6	χ2=9.50
Age	41 -50 yrs	6	66.7%	3	33.3%	9	p=0.03*
	51 -60 yrs	1	16.7%	5	83.3%	6	
Say	Male	15	83.3%	3	16.7%	18	χ2=5.63
Sex	Female	5	41.6%	7	58.4%	12	p=0.02*
	Hindu	14	73.7%	5	26.3%	19	χ2=1.27 p=0.53
Religion	Christian	3	50.0%	3	50.0%	6	
	Muslim	3	60.0%	2	40.0%	5	
	Illiterate	3	30.0%	7	70.0%	10	
Educational	Primary	4	66.7%	2	33.3%	6	χ2=10.69
Status	Secondary	6	85.7%	1	14.3%	7	p=0.01**
	Diploma	7	100.0%	0	0.0%	7	
Occupation	Unemployed	4	80.0%	1	20.0%	5	
	Government	1	100.0%	0	0.0%	1	χ2=1.94 p=0.74
	Private	8	57.1%	6	42.9%	14	
	Business	6	66.7%	3	33.3%	9	
	Pensioner	1	100.0%	0	0.0%	1	

Table7: Association between level of post assessment of levelof painand their demographic variables(Experimental group)

Demographic variables			Level of	f Pai			
		Mild pain		Uncomfortable pain		Total	Chi square test
		N	%	Ν	%		
	< Rs.1000	6	54.5%	5	45.5%	11	
Monthly	Rs.1000 – 3999	6	75.0%	2	25.0%	8	
income	Rs.4000 – 6999	5	62.5%	3	37.5%	8	χ2=2.54 p=0.46
	Rs.7000 – 9999	3	100.0%	0	0.0%	3	
	Unmarried	5	71.4%	2	28.6%	7	_
	Married	12	66.7%	6	33.3%	18	
Marital status	Separated	0	0.0%	1	100.0%	1	$\chi 2=2.57$ p=0.64
	Divorced	1	100.0%	0	0.0%	1	_
	Widower	2	66.7%	1	33.3%	3	
Previous history of Intramuscular injection	Yes	19	65.5%	10	34.5%	29	
	No	1	100.0%	0	0.0%	1	χ2=0.51 p=0.47

*significant at P \leq 0.05** highly significant at P \leq 0.01*** very high significant at P \leq 0.001

Table no 9 shows the association between level of pain reduction and their demographic variables. Younger, Males, more educated benefitted more. Statistical significance was calculated using chi square test.

Demographic variables			Level of				
		Distressing pain		Hor	rible pain	Total	Chi square test
		Ν	%	Ν	%		
Age	20 -30 yrs	5	71.4%	2	28.6%	7	
	31 -40 yrs	5	83.3%	1	16.7%	6	χ2=2.61
	41 -50 yrs	4	44.4%	5	55.6%	9	p=0.45
	51 -60 yrs	5	62.5%	3	37.5%	8	
Sex	Male	11	64.7%	6	35.3%	17	χ2=0.03
	Female	8	61.5%	5	38.5%	13	p=0.85
Religion	Hindu	13	72.2%	5	27.8%	18	$\chi^{2=3.14}_{p=0.21}$
	Christian	5	62.5%	3	37.5%	8	
	Muslim	1	25.0%	3	75.0%	4	-
Educational	Illiterate	4	44.4%	5	55.6%	9	
Status	Primary	4	57.1%	3	42.9%	7	$\chi^{2=2.90}$
	Secondary	7	77.8%	2	22.2%	9	p=0.40
	Diploma	4	80.0%	1	20.0%	5	
Occupation	Unemployed	6	50.0%	6	50.0%	12	
	Government	1	100.0%	0	0.0%	1	
	Private	9	75.0%	3	25.0%	12	$\chi 2=4.16$ p=0.38
	Business	3	75.0%	1	25.0%	4	
	Pensioner	0	0.0%	1	100.0%	1	

Table-8: Association Between Post Assessment Level of Pain Scoreand Demographic Variables (Control)

			Level of				
Demographic variables		Distressing pain		Horrible pain		Total	Chi square test
		Ν	%	Ν	%		
	< Rs.1000	2	25.0%	6	75.0%	8	
Monthly income	Rs.1000 - 3999	10	83.3%	2	16.7%	12	
	Rs.4000 - 6999	5	62.5%	3	37.5%	8	χ2=2.54 p=0.44
	Rs.7000 - 9999	2	100.0%	0	0.0%	2	
Marital status	Unmarried	4	80.0%	1	20.0%	5	
iviantai statas	Married	10	55.6%	8	44.4%	18	
	Separated	2	100.0%	0	0.0%	2	χ2=4.18 p=0.38
	Divorced	0	0.0%	1	100.0%	1	
	Widower	3	75.0%	1	25.0%	4	
Previous	Yes	18	62.1%	11	37.9%	29	
Instory of Intramuscular injection	No	1	100.0%	0	0.0%	1	p=0.43

* significant at P ≤ 0.05 ** highly significant at P ≤ 0.01 *** very high significant at P ≤ 0.001

Table 8 shows the association between level of pain reduction and their demographic variables. None of the demographic variables are significantly associated with level pain score. Statistical significance was calculated using chi square test.



FIG 13: Association Between Post Assessment Level Of Pain And Age

Above figure shows the pain perception among 21-30 years mild pain (88.9%) and uncomfotable pain is (11.1%). It shows that pain perception is less in younger than elder age group.



FIG-14 : Association between Post Assessment Level of Pain and Gender

Above figure shows the pain perception among males having mild pain (83.3%) and uncomfortable pain is (11.1%). It shows that pain perception is less in younger than elder age group.



Fig-15 : Association Between Post assessment level of pain and Education

CHAPTER- V DISCUSSION

"New opinion often appears first as jokes and fancies, than as blasphemies andtreason, then as questions open to discussion and finally established truths"

- George Bernard Shaw

The study was conducted to evaluate the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adult subjects at Rajiv Gandhi Government General Hospital, Chennai-03. After the analysis and interpretation of the data obtained from the samples, the researcher found, there was a significant reduction in the pain perception with cold needle IM injection.

CHARACTERISTICS OF DEMOGRAPHIC VARIABLES

Table 4.1 showed the demographic variables of the 60 subjects who participated in the study. Equal number of subjects (30.0%) belonged to the age group of 21-30 yrs and 41-50 yrs in Experimental and (30.0%) were between 41-50 years in Control Group. Group Majority of the samples were male (53.3%) in Experimental group and (60%) were males in Control group. Majority (63.3%) of them belongs to Hindu in experimental group and (60.0%) in control group. Majority (33.4%) of the samples are illiterate in experimental group and (30.0%) in control group. Majority (46.7%) of them were employed in private in experimental group and (40.0%) were unemployed and (40.0%) were employed in private in control group. Majority (36.6%) of them had income at the range of <1000 in experimental group and (40.0%) of them had income at the range of Rs.1000-3999 in control group. Majority (60.0%) of them were married in experimental group and (60.0%) of them in control group. Majority (96.7%) of the sample had

previous history of intramuscular injection i experimental group and (96.7%) in control group.

The first objective was focused to assess the level of pain perception among adult subjects receiving IM injection in control group with routine technique.

The Wong Baker's Faces Pain Scale was used to assess the level of pain perception among 30 subjects in the control group. With subjective Wong Baker's Faces Pain Scale (63.3%) subjects had Distressing pain, and (36.7%) subjects had Horrible pain during assessment.

Nahm, S, Lee.J. et al. (2012) conducted a study to evaluate the influences of patient characteristics on pain perception due to intra muscular vaccine injection in healthy adult volunteers. One hundred and sixty volunteers (65 males, 95 females) enrolled in this study and the average VAS score was 20.8 ± 17.1 (range 0 to 67) in males and 34.4 ± 19.7 (range 2 to 76) in females p <0.001.

The second objective targeted to assess the level of pain perception among adult subjects during intramuscular injection in experimental group with cold needle technique.

The Wong Baker's Faces Pain Scale was used to assess the level of pain perception among 30 subjects in the control group. With Wong Baker's Faces Pain Scale (66.7%) subjects had mild pain, and (33.3%) subjects had uncomfortable pain during assessment.

Thomas.N (2008), department of Medical Surgical Nursing, AIIMS, New Delhi, conducted a study to assess the effect of temperature of needle on perception of pain during administration of intramuscular injection of Benzathine penicillin amoung RHD patients. The study report concluded their is significant reduction in the perception of pain with the use of cold needle among samples and using cold needle is a simple and inexpensive way to reduce pain during intramuscular injections.

Mariya.B (2010), of St. Johns College of Nursing, Bangalore, conducted a study to determine effect of cold needle on perception of pain during IM injection. The pain score was assessed using Numerical Pain Scale and the study report concluded that the samples received IM injection with cold needle had significant lower pain score than the sample received IM injection with routine technique.

The third objective aimed to compare the level of pain perception among adult subjects during intramuscular injection in both control and experimental group

Mean score for the experimental group was 0.67, whereas for control group the mean score was 6.73, revealing difference of 6.07 pain score. This difference is large and it is statistically very highly significant at $P \le 0.001$ level.

This results was supported by **Denker.K.** (2001), study conducted to determine the pain associated with injection using frozen vs. room temperature needles. The study results elicited that the frozen needles were less painful, with the mean pain score of 1.7 vs. 2.9 for the room temperature needle (p=0.001). Also, use of frozen needles resulted in significantly less pain(MD. 1.2;, 1.7; P<0.01).

The fourth objective concentrated to determine the level of pain perception among adult subjects during intramuscular injection in both control and experimental group with selected demographic variables.

Age $(X^2=9.50, p=0.03)$, Sex $(X^2=5.63, p=0.02)$, Educational status $(X^2=10.69 p=0.01)$, are significantly associated with their level of pain in Experimental group. Samples in the age group of 21-30 years 8 (88.9%) of them had mild pain and 1 (11.1%) of them had uncomfortable pain. Subjects in the age group of 41-50 years only 6

(66.7%) of them had mild pain and 3 (33.3%) had uncomfortable pain. The above pain score shows that younger age group has more pain tolerance.

Comparing the sex majority of male samples 15 (83.3%) were havingmild pain and 3 (16.7%) were in uncomfortable pain. In female samples majority 7 (58.4%) were in uncomfortable pain and remaining (41.6%) of them were having mild pain, which shows male subjects are more benefited than female subjects.

The result of the study thus concluded that, association exists between the samples demographic variables like age, sex, education and occupation with their level of pain.

CHAPTER-VI SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

"Be yourself and think for yourself, and while your conclusions may not be infallible, they will be nearer right than the conclusions forced upon you"

- Elbert Hubbard Quotes

A study is said to be incomplete, if it results are not communicated effectively to its users and consumers. This chapter outlines the present study approaches, major findings with inferences drawn from it, implication for nursing profession, limitations, conclusions and recommendations.

6.1. SUMMARY

The crucial focus of the study was to evaluate the effectiveness of using cold needle on IM injection to reduce pain perception among adult patients at Rajiv Gandhi Government General Hospital, Chennai-03.

The design adopted for the study was true experimental post test only control in nature and the conceptual framework was based on Donabedian's Model. The study tol contains the demographic variables and scales of Standardized Wong Baker's Faces Pain Scale which had the maximum score of 10.

The main study was conducted at Rajiv Gandhi Government General Hospital, Chennai-03, and a sample of 60 subjects were selected based on the inclusion criteria, in which 30 subjects were allotted to the experimental group and the remaining were in the control group. The sampling technique used was Probability sampling technique and the data were collected after getting consent from the subjects. Analysis was done using descriptive and inferential statistics, the obtained results were presented using tables and figures.

OBJECTIVES OF THE STUDY

- To assess the level of pain perception among adult patients during intramuscular injection in control group with routine technique.
- To assess the level of pain perception among adult patients during intramuscular injection in experimental group with cold needle technique.
- To compare the level of pain perception among adult patients during intramuscular injection in both control and experimental group.
- 4) To determine the level of pain perception among adult patients during intramuscular injection in both control and experimental group with selected demographic variables.

Hypothesis formulated were

- H1 : There will be a significant difference between cold needle IM injection and pain perception.
- H2 : There will be a significant association between cold needle IM injection pain perception and selected demographic variables.

Assumptions of the study were

There will be significant pain reduction among adults receiving intramuscular injection using cold needle technique.

Review of Literature was

Done to understand the and to know the effectiveness of using cold needle for giving intramuscular injection

Methodology of the study was

Quantitative approach, true experimental design was selected with 60, 30 for each Experimental and 30 control group, by simple random sampling technique - lottery method from the sample frame within the inclusion criteria. The study was carried out at Medical wards, Rajiv Gandhi Government General Hospital, Chennai-03 with the permission of Head of the Department and Ethics Committee approval. Informed consent obtained from the subjects and information about the study was given to them. Subjects selected for pilot study were excluded. Demographic data was collected from the subjects. Using cold needle technique intramuscular injection was given for experimental group. For Control group routine technique was given. Post assessment was done after interventions for both groups by using Wong Baker's Faces Pain Scale.

6.2 MAJOR FINDINGS

The major findings are summarised as follows

According to the age of the adults in years, equal number of subjects (30.0%) belonged to the age group of 21-30 yrs and 41-50 yrs in Experimental Group and (30.0%) were between 41-50 years in Control Group.

In considering the gender, majority of adults 16(53.3%) were males in Experimental group and majority of adults 18 (60%) were males in Control group.

Majority (63.3%) of them belongs to Hindu in experimental group and (60.0%) in control griup.
Majority (33.4%) of the samples are illiterate in experimental group and (30.0%) in control group.

Majority (46.7%) of them were employed in private in experimental group and (40.0%) were unemployed and (40.0%) were employed in private in control group.

Majority (36.6%) of them had income at the range of <1000 in experimental group and (40.0%) of them had income at the range of Rs.1000-3999 in control group.

Majority (60.0%) of them were married in experimental group and (60.0%) of them in control group.

Majority (96.7%) of the sample had previous history of intramuscular injection in experimental group and (96.7%) in control group.

Mean score for the experimental group was 0.67, whereas for control group the mean score was 6.73, revealing difference of 6.07 pain score. This difference is large and it is statistically very highly significant at $P \le 0.001$ level.

Significant difference was found in the post assessment mean values of level of pain among Experimental and Control group. The mean values of post assessment of level of pain among Experimental group (0.67)was lower than control group (6.73) revealing that using cold needle technique was more effective in reducing pain during intramuscular injection among adults.

The association between subject's age in demographic variable showed significant association with pain score in both experimental and control group Statistical significance was analyzed using Pearson Chi square and Yates corrected Chi square test.

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6.3. NURSING IMPLICATION

The investigator had drawn the following implications for the study, which are necessary in the field of Nursing practice, Nursing Education, Nursing Administration and Nursing Research.

NURSING PRACTICE

- 1) These findings will help the nurses in clinical and public health sector to implement the use of cold needle during IM injection.
- The method of using cold needle during IM injection will helpful to reduce the fear of injection pain in subjects.
- This method of administering intramuscular injection will enhance comfort to the patient.
- This method will improve the health seeking behaviour of subjects in future.
- 5) It helps to improve the standard of providing nursing care by implementing evidence based practice.

NURSING EDUCATION

- This study findings will be helpful in reforming the traditional way of teaching IM injection procedure to the student nurses.
- 2) It provides an opportunity for the student nurses to learn about the collaboration of alternative therapies in nursing practice.

NURSING ADMINISTRATION

 The study finding helps the nurse administrators in formulating revised protocols and policies on IM injections. It provides opportunity for the nurse administrators to conduct inservice education regarding the evidence based nursing practice on administering IM injection.

NURSING RESEARCH

- As intramuscular injection is the common nursing procedure carried out by all nurses worldwide, more studies regarding the practice should be encouraged.
- 2) The study findings can be published in journals to disseminate the use of cold needle on IM injection.

The findings of the study served as a basis for the nursing professionals and students to conduct further studies in injection technique.

6.4. RECOMMENDATIONS

This study recommended the following suggestions,

- A similar study needs to be conducted in varies settings in order to draw generalization of the findings.
- 2) A similar study may be done with larger sample for the generalization of results.
- 3) A longer period of intervention can be studied for more reliability and effectiveness.
- 4) A comparative study may be done to evaluate the effectiveness of cold needle between intramuscular and intra dermal injections.
- 5) A comparative study may be done to evaluate the effectiveness of cold needle IM injection between physical built and pain perception in adults.

6.5. CONCLUSION

Intramuscular injections may be unpleasant experience for the subjects which are commonly carried out by the nurses. The present study aimed to evaluate the effectiveness of cold needle on IM injection pain perception among adult subjects. There is a significant a difference between the age group of 41-50 years of age and were males. There is a significant a difference between the level of pain perception and cold needle IM injection among adult subjects. Also there is a significant association exist between demographic variables such as age, sex and occupation with the level of pain perception. So in clinical practice, the use of cold needle can be implemented as a routine procedural way of administering IM injections to ensure optimal level of comfort by minimizing the procedural pain.

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NET RESOURCE

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- 2) http://www.ampainsoc.org/whatnew/toc-road.htm.
- 3) http://www.pain.ac.in/upload/05.n002-20778.doc
- 4) http://www.ncbi.n/m.nib.gov/pubmed.
- 5) http://www.slidesshare.net/kamalesh/im injection.
- 6) http://www.best nursing practices.org/pain relief.
- 7) http://www.ispub.com/ostia/index.php.
- 8) http://www.pain management nursing.org/articles/51524-9042.
- 9) http://www.rgub.ac.in/edc/online/uploads.
- 10) http://tnaionline.org/owg-10/6
- 11) htpp://www.rguhs.ac.in
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APPENDIX I

SECTION A

SOCIO DEMOGRAPHIC DATA

Sample No:

1. Age in years			
a) 21 -30		b) 31-40	
c) 41- 50		d) 51-60	
2. Sex			
a) Male		b) Female	
3. Religion			
a) Hindu		b) Christian	
c) Muslim		d) others	
4. Educational Statu	IS		
a) Illetrate		b) Primary	c) secondary
d) Diploma		e) Degree	
5. Occupation			
a) Unemploye	ed 🗌	b) Government	c) private
d) Bussiness		e) Pensioner	
6. Income			
a)Rs. < 1,000		b)Rs.1000 – 3,999	c) Rs. 4,000 – 6,999
d) Rs. 7,000 – 9,	999	e)Rs. > 10,000	

7. Marital status

a) Unmarried		b)married			c) separated	
d) divorced		e) widow/widowe	er			
8. Previous Experience of Intramuscular injection						
a) Yes		b) No]		

WONG BAKER'S FACES PAIN RATING SCALE:

PURPOSE: This scale is used to assess the level of pain perceived by the adults.



SCORING KEY:

0-No pain

2-Mild pain

4-Uncomfortable pain

6-Distressing pain

8-Horrible Pain

10-Worst Pain

PROCEDURE

COLD NEEDLE:

Cold needle refers to usage of 23 gauze sterile disposable needle used for giving intramuscular injection which is cooled at the range of 0 to -2^{0} Celsius in the chiller champer of refrigerator for 1-2 hours and stored in an ice box and attached to the syringe with loaded medicine just before the administration at the bed side.

STORAGE OF NEEDLE

- > In the chiller tray of the refrigerator, at the range of $0-2^{\circ}$ Celsius.
- ➤ Transporting to the cold needle to the bedside : Ice box.

ARTICLES REQUIRED

A). A sterile injection tray

- Disposable syringe with appropriate size needle (23 gauze needle)
- Antiseptic solution
- Sterile cotton balls
- \triangleright 23 gauze sterile needle to withdraw the medicine.
- B). Small K basin.
- C). Ice pack in box.
- D). Needle destroyer.
- E). Medicine card.

STEPS IN PROCEDURE:

- \clubsuit Provide privacy and explain the procedure to the patient .
- Load the medication from ampoule into 2 ml syringe using 23 gauze needle at room temperature .
- Position and expose appropriate site.
- ✤ Identify dorsogluteal site.
- ✤ Clean the skin with cotton ball moistened.
- ✤ Expel air from syringe.
- \clubsuit Remove the needle used for loading .
- ✤ Attach the cold needle to the syringe.
- Stretch the skin tightly and insert cold needle using 90 ° angle, and puncture the site.
- Check the patency by pulling back the piston.
- Withdraw the cold needle , and apply gentle pressure at the site with cotton swab.
- Position the patient comfortably.
- Record the date, time, and name of the drug, dosage, route, and signature of the nurse.

செவிலியக் கல்லூரி சென்னை மருத்துவ கல்லூரி சென்னை –03

பகுதி – அ

சுயவிபர கேள்வி தாள்			
மாதிரி எண்:			
1. வயது			
அ) 21 வயது முதல் 30 வயது வரை			
ஆ) 31 வயது முதல் 40 வயது வரை			
இ) 41 வயது முதல் 50 வயது வரை			
ஈ) 51 வயது முதல் 60 வயது வரை			
2. பாலினம்			
அ) ஆண்			
ஆ) பெண்			
3. மதம்			
அ) இந்து			
ஆ) கிரிஸ்தவர்			
இ) இஸ்லாமியர்			
ஈ) மற்றவர்			
4. கல்வித்தகுதி			
அ) படிக்கதவர்			
ஆ) ஆரம்பகல்வி			
இ) மேல்நிலை			
ஈ) உயர் நிலை			
உ) பட்டபடிப்பு			

- 5. தொழில்
 - அ) வேலை இல்லாதவர்
 - ஆ) தனியர் வேலை
 - இ) அரசாங்க வேலை
 - ஈ) சுய தொழில்

6.மாதந்திர வருமானம் (ரூபாயில்)

- அ) 1,000 கீழ்
- ஆ) 1,000 4,000
- **(a)**) 4,001 7,000
- rF) 7,001 10,000
- உ) 10,000 மேல்
- 7. திருமண நிலை
 - அ) திருமணமாகாதவர்
 - ஆ) திருமணமானவர்
 - இ) தனித்து வாழ்பவர்
 - ஈ) விவாகரத்தானவர்
 - உ) கணவன்/மனைவியை இழந்தவர்

8. தசை ஊசி போட்டதற்கான முன் அனுபவம்

- அ) ஆம்
- ஆ) இல்லை



CERTIFICATE OF TOOL VALIDATION

This is to certify that the tool constructed by Ms. R. Revathy, M.Sc Nursing II year, College of Nursing, Madras Medical College Chennai-03 which is to be used in her study titled **"A study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards at Rajiv Gandhi Government General Hospital, Chennai 3."** has been validated by the undersigned. The suggestions and modifications given by me will be incorporated by the investigator in concern with their respective guide. Then she can proceed to do the research.

SIGNATURE WITH SEAL DIRECTOR AND PROFESSOR Institute of Internal Medicine Madras Medical College, Govt. General Nessaul, Madras-600 Cou

NAME : DESIGNATION : COLLEGE :

PLACE : DATE :

CERTIFICATE OF TOOL VALIDATION

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SIGNATURE WITH SEAL PRINCIPAL MADHA COLLEGE OF NURSING MADHANAGAR, KUNDRATHUR CHENNAL - 600 063 PHONE: 24780736

NAME : DESIGNATION : COLLEGE :

PLACE : DATE :

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

''தசை ஊசி போடும்போது ஏற்படும் வலியை, குளிர்வூட்டபட்ட ஊசியை பயன்படுத்தி போடுவதின்மூலம் வலி குணற்தலின் திறனை கண்டறிதல் பற்றிய ஆய்வு ''

பங்கு பெறுபவரின் பெயா்: வயது: தேதி: உள் நோயாளி எண்:

அதன் நோக்கங்களும் முறையாக அறிந்து கொண்டேன். எனது சந்தேகங்கள் அதன் நோக்கங்களும் முறையாக அறிந்து கொண்டேன். எனது சந்தேகங்கள் அனைத்திற்கும் தகுந்த விளக்கம் அளிக்கப்பட்டது. இந்த ஆய்வில் முழு சுதந்திரத்துடன் மற்றும் சுயநினைவுடன் பங்கு கொள்ள சம்மதிக்கிறேன்.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்துகொண்டு நான் எனது சம்மதத்தைத் தெரிவிக்கிறேன். இச்சுய ஒப்புதல் படிவத்தை பற்றி எனக்கு விளக்கப்பட்டது.

இந்த ஆய்வினை பற்றிய அனைத்து தகவல்களும் எனக்கு தெரிவிக்கப்பட்டது. இந்த ஆய்வில் எனது உரிமை மற்றும் பங்கினை பற்றி அறிந்து கொண்டேன்.

இந்த ஆய்வில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின்பேரில் தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்து கொண்டேன்.

இந்த ஆய்வில் கலந்து கொள்வதன்மூலம் என்னிடம் பெறப்படும் தகவலை ஆய்வாளர் இன்ஸ்டிட்யூசனல் எத்திக்ஸ் கமிட்டியினரிடமோ, அரசு நிறுவனத்திடமோ தேவைப்பட்டால் பகிர்ந்து கொள்ளலாம் என சம்மதிக்கிறேன்.

இந்த ஆய்வின் முடிவுகளை வெளியிடும்போது எனது பெயரோ, அடையாளமோ வெளியப்படாது என அறிந்து கொண்டேன். இந்த ஆய்வின் விவரங்களைக் கொண்ட தகவல்தாளைப் பெற்றுக் கொண்டேன்.

இந்த ஆய்வில் பங்கேற்கும்பொழுது ஏதேனும் சந்தேகம் ஏற்பட்டால், உடனே ஆய்வாளரை தொடாபு கொள்ள வேண்டும் என அறிந்து கொண்டேன்.

இச்சுய ஒப்புதல் படிவத்தில் கையெழுத்திடுவதன்மூலம் இதிலுள்ள அனைத்து விஷயங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது என்று தெரிவிக்கிறேன் என்று புரிந்து கொண்டேன். இசசுய ஒப்புதல் படிவத்தின் ஒரு நகல் எனக்கு கொடுக்கப்படும் என்று தெரிந்து கொண்டேன்.

ஆராய்ச்சியாளர் கையொப்பம் தேதி:

பங்கேற்பாளர் கையொப்பம் தேதி:

INSTITUTIONAL ETHICS COMMITTEE MADRAS MEDICAL COLLEGE, CHENNAI -3

EC RegNo.ECR/270/Inst./TN/2013

Telephone No : 044 25305301 Fax : 044 25363970 Date:22.07.2013

CERTIFICATE OF APPROVAL

To R.Revathy, M.Sc.,(N) II year, College of Nursing, Madras Medical College, Chennai-3.

Dear R.Revathy

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The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A Study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards at Rajiv Gandhi Government General Hospital, Ch.03" No.03072013.

The following members of Ethics Committee were present in the meeting held on 06.07.2013 conducted at Madras Medical College, Chennai -3.

1.	Dr.G.SivaKumar, MS FICS FAIS	Chairperson
2.	Prof. R. Nandhini MD	Member Secretary
	Director, Instt. of Pharmacology, I	MMC, Ch-3
3.	Prof. Shyamraj MD	Member
	Director i/c , Instt. of Biochemist	ry, MMC, Ch-3
4.	Prof. P. Karkuzhali. MD	Member
	Prof., Instt. of Pathology, MMC, C	h-3
5.	Prof. Kalai Selvi	Member
	Prof of Pharmacology, MMC, Ch-3	3
6.	Prof. Siva Subramanian,	Member
	Director, Instt. of Internal Medicir	ne, MMC, Ch-3
7.	Thiru. S. Govindsamy. BABL	Lawyer
8.	Tmt. Arnold Saulina MA MSW	Social Scientist
	We approve the proposal	to be conducted in its presented
for	m.	n en stenne – an eren standestandet – Sebte er Berek, S e an-Sourisbergeren (b

Sd/ Chairman & Other Members The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Na

Member Secretary, Ethics Committee

L3.NO. 282/CON) MME/ Chennen 3 dt 16.7.13.

From

Ms. R. Revathy,

8

M.Sc(Nursing) II year, College of Nursing, Madras Medical College, Chennai-3.

То

The Professor and HOD,

Institute of Internal Medicine, Rajiv Gandhi Government General Hospital, Chennai-03.

Through Proper Channel,

Respected Sir,

Sub: Requesting Permission to conduct a research study-reg

I, Ms.R.Revathy, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission for the study proposed to conduct on the topic "A study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards atRajiv Gandhi Government General Hospital,Chennai-03." to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Thanking you,

Date: LG. 07.13 Place: CHENNAL-03 Yours obediently,

R. Renty

(R. Revathy)

Lr. No. 282/CON) MMC/ Chermo 3 21-16-7-13

From

Ms. R. Revathy,

3

M.Sc(Nursing) II year, College of Nursing, Madras Medical College, Chennai-3.

To

The Dean,

Madras Medical College, Chennai-03.

Through Proper Channel,

Respected Sir,

Sub: Requesting Permission to conduct a research study-reg

I, Ms.R.Revathy, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission for the study proposed to conduct on the topic "A study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in medical wards atRajiv Gandhi Government General Hospital,Chennai-03." to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Thanking you,

Date: 16.07.13

Place: CHENNAL-03

Yours obediently,

R. Realty

(R. Revathy)

CERTIFICATE OF ENGLISH EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation topic "A study to assess the effectiveness of using cold needle for giving intramuscular injection to reduce pain perception among adults admitted in Medical wards at Rajiv Gandhi Government General Hospital, Chennai - 03" done by Ms. R. Revathy, M.Sc Nursing II year, College of Nursing, Madras Medical College, Chennai – 03, has been edited for English language appropriateness.

Date: 06.02.2014

Place: Chennai - 03.

M ybune

(M. Gokul Praveen Babu, M.A) Assistant Professor, Department of English, Tagore College of Arts and Science, Chrompet, Chennai – 44.

(M. Gokul Praveen Babu, M.A) Assistant Professor, Department of English, Tagore College of Arts and Science, Chrompet, Chennal - 44,