A STUDY TO EVALUATE THE EFFICACY OF USING COLD NEEDLE FOR GIVING INTRAMUSCULAR INJECTION TO MINIMISE THE PAIN INTENSITY AMONG PATIENTS ADMITTED AT SELECTED TERTIARY CARE HOSPITAL BELGAUM

[1]MRS.SHEELA.NIRWANI, [2]MS.JENESIS.FERNANDES
[1]Lecturer
[1] KAHER, Institute of nursing science,Demeed University

ABSTRACT

PROBLEM STATEMENT

"A study to evaluate the efficacy of using cold needle for giving intramuscularinjection to minimise the pain intensity among patients admitted at selected tertiary care hospital Belgaum"

BACKGROUND

Needle procedures are rampant over a lifetime, especially in juvenescence and can cause pain and fear. The diminution of pain has been a key aspect in the role of healthcare workers. The fear of needles can cause anxiety and can be an obstruction while receiving vaccines. Injection fear and an unpleasant prior experience can invoke trepidation and shock and can cause fainting in a few, it's common among a cluster of patients. Administering an Intramuscular injection by the routine technique is a common procedure carried out to deliver a medication. However, this can cause pain and fear in patients so the study focuses on administering an intramuscular injection by using a Cold Needle technique.

METHOD

A True Experimental post-test-only control research design was used to determine the effectivity of using a Cold Needle technique. 60 participants were selected and divided equally into Experimental and Control Group by random sampling. The test was performed and intervention was given to the Experimental group. The levels of pain were measured using a 10-point Numerical pain scale.

RESULTS

The difference between the Experimental and Control group was ruled out, the Mean pain score after intervention in Case group is 1.73 ± 1.08 and the Mean pain score without intervention in Control Group is 7.17 ± 1.05. The post-test mean values of pain among the experimental and control group were obtained at $p<0.001$. which proposes that reduced levels of pain in experimental group at the time of IM inoculation was because of using cold needle as an intervention and not accidental or by luck. A significantly high difference was detected.

CONCLUSION

The study concludes that using the cold needle technique was successful in lowering pain.

KEYWORDS: Cold Needle technique, Intramuscular injection, Pain

CHAPTER I INTRODUCTION

Fear interferes with the implementation and success of traditional pain management strategies. Needle procedures are rampant over a lifetime, especially in juvenescence and can cause pain and fear. The diminution of pain has been a key aspect in the role of healthcare workers. Patients adopt various coping plans to obliterate pain and supervise their health conditions. The fear of needles can cause anxiety and can be an obstruction while receiving vaccines. Injection fear and an unpleasant prior experience can invoke trepidation and shock and can cause fainting in a few, it's common among a cluster of patients.

Various procedures have been dispensed for easing pain, which has been an essential duty of a nurse. Every kind of drug dispensation has to be done meticulously and with the uttermost adeptness in order to come to the desired locus. The intramuscular passage permits the quick absorption of the medication into the circulatory system. Making use of the right system of injecting and choosing the accurate area can decrease the possibility of any hindrance, which in order can give rise to issues if not undertaken with caution.

The worry can be steered clear if the site for injecting is precisely recognized and a proficient established approach is implemented. The usual spot for intramuscular injections involves the deltoid muscle of the arm and the gluteal muscle of the buttock. In juveniles, the vastus lateralis muscle of the thigh is preferred. Injections are one of the most routinely utilized medical procedures with an approximate 20 billion administrations done annually. Most are done for vaccinations and the rest are carried out for analeptic purposes. In India, private physicians administered antibiotics, vitamins and analgesics with a striking figure of 96 %. Per person yearly, the number of injections vary from 0.9 to 8.5 with an average of 1.5 injections on an annual footing.

The process of injections should be done with utmost care so that there is no pain or stress caused to the patient. Nurses should abide by required protocols and welfare procedures. a figure close to 502,000 demises were recorded by the W.H.O solely because of unreliable and faulty applications which could have put a stop by implementing proper safety protocols. Pain linked due to anxiety also during any excruciating procedures can be brought under control when conventional and proper techniques are used by nurses. The expertise and approach used during the introduction of any drug by applying pressure can change the perceptiveness of the pain of the patient. Since the formative and prior years, healthcare personnel know of the fact that IM injections that are simple to administer can avoid issues.

The process of inoculation (IM) by administration of penicillin was carried out initially by doctors and later by Nurses and then has been the most viable and habitual process also being the most effective methods of injecting medicine instantaneously which is moped up in the muscle.

In order for quick taking in of the medicine, the process of intramuscular administration has proven to be a very important and functional approach. The medicine is put precisely into the muscle which paves the way for the medicine to acquire effortless entry into the muscle and speedily begins with its curative action.

The procedure of inoculating into a patient via intramuscular injections are meant to be the best fitting and secure.

Undoubtedly, all human beings undergo different levels of pain, it being a thorough individual response that every single person goes through, thereby seeking help to alleviate it through healthcare facilities.

Pain has been quoted by the IASP, that it's not merely a reaction to something or an indication but much more of a tedious constraint that should be focused more upon in order to manage patient care. With the help of John Hopkins School of Medicine, the IASP has rephrased the definition of pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage." One of the most notable elements in patients is procedural pain. Nurses adopt various methods that can help patients to control procedural pain. They play a vital role in evaluating and coping with pain related by such operations which can comfort patients facing difficulties and to ease pains. Mostly pain is correlated with damage in the tissue and it also has a physiological connotation to it, physiologically pain is evident when sensory nerve endings known as nociceptors (a.k.a pain receptors) remain in correspondence with an agonizing or pernicious stimulant, the following nerve signal progresses from the sensory nerve right till the spinal cord, where the signal is swiftly averted to the brain by means of nerve region in the area of the spinal cord and the brainstem region. There is an expeditious reaction that the brain develops to the pain sensation in an effort to stop the activity which brings about the pain.

The nurse has to take measures in an explicable fashion to successfully control the patient's pain and also should be well versed to attempt appropriate procedures that aid the process and relatively skilful in the pursuit of pain management. Patients which the nurses attend to may experience pain in various ways and unlikely extents,

pain management given in a right manner can influence a patients approach and can get rid of debilitating pains, making the patient feel comforted and content.

Nurses play an important role in pain management and directly impact hospitalized patients going through harrowing pains after various procedures. The nurses have to adopt viable effective procedures to aid a patient after post – operative pains. Non pharmacological interventions can be useful in the process of

alleviating different degrees of pain faced by the patients.

With the right intervention and with the right appropriate knowledge and skills required and the best techniques implemented through right decision-making strategies can change the perceptivity in the mindset of patients comforting them and thus providing the patient with the best superlatives.

NEED AND SIGNIFICANCE OF STUDY

Pain being the sign and prodrome for an ailment causes people to pursue medical intervention and healthcare, that being said palliative care is indispensable in mitigating pain. Nurses being the embodiment of health promotion play a very significant role in healthcare services. Despite the fact that there are many regimens involved in the mitigation of pain, nurses play a major role in evaluation, observation, elucidation and intervention of pain. Nevertheless, research studies report insufficient and inapt care of patients undergoing pain.

Pain perpetuates to be subjective and moral hurdle because of its intuitive and subjective nature, with the prospective to dehumanize the patient suffering from an illness, who are directly reliant on caregivers for effective care. Nurse to their best capacity have an important responsibility to tend to their patients making them feel less anxious or distressed thereby eliminating needless suffering.

The quality of care rendered by the nurse determines efficacious pain management. Pain should be tackled, this should be of paramount importance because of the complicated and individualistic nature of pain. Nurses need a more comprehensive approach that involves the multifaceted experience of pain. The role of the nurse is to not see pain as someone else's duty as deliverance from trauma and pain is key to each individual patient.

Intramuscular (IM) injection is a usual procedure in contemporary medical science. Mostly vaccines and drugs are administered intramuscularly through this method. Intramuscular injections are generally used in lieu of intravenous injections because some drugs cause irritation to the veins or in view of the fact that an appropriate vein cannot be located. The absorption rate is rapid in intramuscular injections than subcutaneous injections, the reason being that the muscle tissue has a substantial blood supply than tissue beneath the skin. The capacity of medication the muscle tissue can hold is greater to an extent than the subcutaneous tissue.

Using the right methods and techniques while injecting can be of preferred experience for the patient in terms of pain rather than an ordeal. Based on proof, women experience additional pain than men. Pain caused by injections can be gruesome and distressing. Among numerous non – pharmacological procedures, implementation of cold alleviates the capacity of pain fibres, to transfer pain signals and decrease or lessen the affliction related with numerous sorts of injections. The gate theory suggests in the case of the body's own nervous system, that the concluding common nerve pathway for pain to the brain is inhibited by the nerves that transmit the feeling of cold. The cold receptors can desensitize or extinguish pain.

This validates that the use of cold needle approach shows to be more effectual in hampering pain among volunteers and patients who received injections. By using the cold needle method, the investigator deduces that the level of pain perception had lessened, that was experimented on the subjects who received injections, hence it calls for investigators to carry out further works on the effect of cold needle on pain. Therefore, it incorporates dedication by nurses who can perform the cold needle technique to lower the perceptivity of pain.

Pain being a common dilemma, the physicians go through ample problems in sussing pain, in spite of years of research, thus making it in its entirety a subjective issue while having very few ways to compute it objectively. Depending on individuals it may be a small problem while for some it may be substantial that causes anxiety and stress thereby decreasing the standard of life, thus pain is the principal cause of calling out on healthcare personnel. Nurses being at the crux of the matter play a major and decisive role in pain management during an incursive procedure. A report published in the year 2004 showed that most patients who where usually giving the Intramuscular injection had a bad experience deeming Intramuscular injections to induce pain, also that the intramuscular route being the favoured procedure of prescribing post-surgical medication.

Moreover, with any sort of injections, it being a tedious process in relation to shattering the body's natural limits, there are possibilities of distress and malaise. The fear and escape are something that a patient with needle phobia does and it can be very detrimental for patients who require any method demanding injections, Nurses have to play a significant role in mitigating the slightest post-operation discomfort. A study in the U.S Says that 12% of Americans are apprehensive about needles.

Even though with the use of extensive therapeutic and nursing action in the health care unit anxiety and discomfort related to the intramuscular injection continues to be an unanswered issue in the medical world. Thus, the investigator has taken up this analysis to assess the productiveness of cold needle in decreasing linked with Intramuscular injection.

CHAPTER II OBJECTIVES

The objectives of the study are:

1. To assess the level of pain intensity among adult patients.

2. To compare the level of pain intensity among adult patients in both controland experimental group.

3. To find the association between the level of pain intensity and selecteddemographic variables.

Hypothesis:

The hypothesis will be tested at a level of 0.05

H_1**:** The mean level of pain among the experimental group will be significantly lower than the mean pain levels between the control group at the time of intramuscular injection calculated by a visual analogue scale at 0.05level.

H_2: There will be a statistically significant association between the level of pain during the intramuscular injections and the selected sociodemographics between the participants in the experimental and control groups respectively at 0.05level.

Assumption:

• IM injection will cause pain.

• Cold Needle IM injection may have effect on reducing pain duringadministration of IM injection.

Delimitation:

The study is delimited to patients who are receiving IM injection.

Operational Definitions:

Cold needle

In this study, it refers to a 23-gauge needle made cold by keeping it in the freezing compartment of the refrigerator for about 2 hours at a temperature below 2- degree C.

Pain intensity

In this study, it refers to an unpleasant feeling shown by subjects using a ten- point numerical pain scale.

Intramuscular Injection

In this study it refers to a technique used to deliver a medication deep into the muscles.

Tertiary Care Hospital

In this study, KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi.

CONCEPTUAL FRAMEWORK

A conceptual framework is an instrument research workers employ to conduct their query or investigation of research, it is also regarded as a series of concepts and planned designs utilized to organize the research and a kind of map that may comprise the research questionnaire, the review, data examination and different methods.

Researchers implement a conceptual framework to conduct and pilot their data collection and analysis, this giving an insight and to resolve certain questions.

The sole aim of the study is to assess the efficacy of a frozen needle on intramuscular inoculation to lessen the pain in patients present at the Surgical and Medical units at the hospital.

The Donabedian model for quality of care is developed as a conceptual framework by the researcher for the study. The model has three crucial components that are Structure, Process and outcome. The main focus of this model is delivering quality health care to individuals.
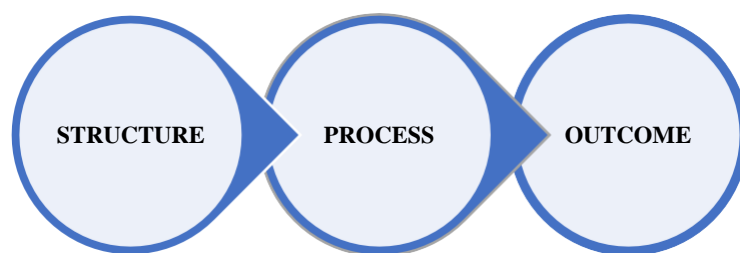
Donabedian represents the model with the aim of revamping the quality and enhancing the paradigm of

health care. The health care system providing health facilities and high care standards are considered in this study. The Nurse and the patient together cooperate so as to achieve the goal.

Donabedian Model has three parts:

- Structure

- Process

- Outcome

The structure is concerned with quality care given by the care provider this includes all the medical facilities, instruments, technologies, materials and resources.

The structure implies the Demographics in the study.

The process is a step that involves delivering care, in other words, which means the sort of care rendered to the patient, type of treatment followed, and the kindof health education given.

The process is concerned with the use of a cold needle for delivering an IM injection in Group 1(Exp group) followed by the normal method in Group 2 (control group).

The outcome implies the type of care provided by the clinics, medical centers, sanatorium, and emergency rooms in upgrading the quality of health care, improving physical, and mental health, and patient's well-being.

The outcome here is adult participants in Group 1 had reduced pain levels in comparison with adult participants from Group 2.
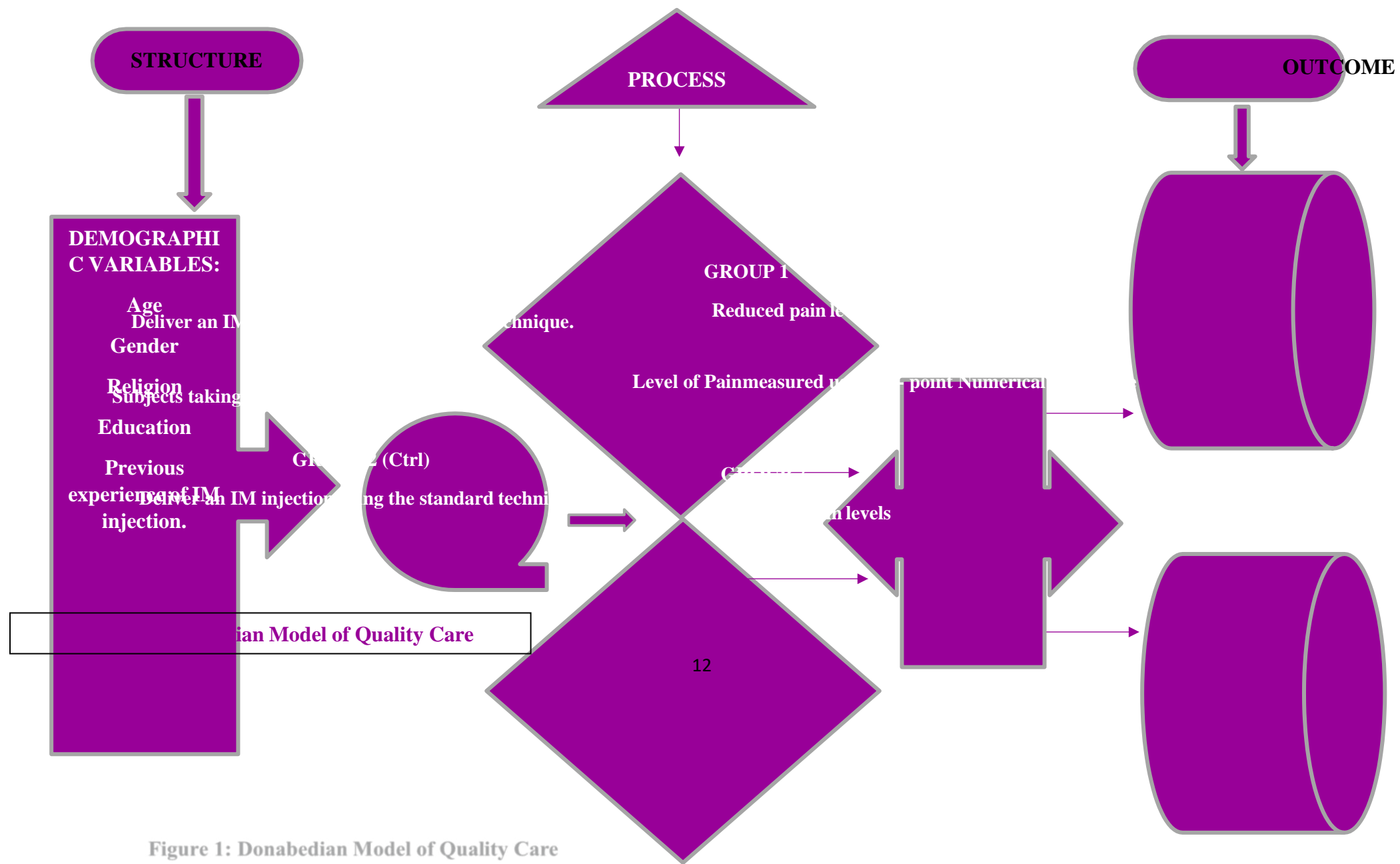
Figure 1: Donabedian Model of Quality Care

CHAPTER III

REVIEW OF LITERATURE

A test study was carried out at College of Nursing, Madras Medical College, Chennai to establish the efficacy of utilizing a cold needle (0-2°C) while giving an IM injection to reduce pain. Out of 60 samples acquired from the volunteers, 30 volunteers belonged to the Experimental group that received IM injection using the cold needle approach, and the rest of the 30 subjects used the routine technique. The severity of pain was computed soon after the dose by using Wong-Baker Faces Pain Scale and the mean pain score was calculated at 66.7% for experimental and 63.3% for the Control group (P=0.001) which deduces that the utilization of cold needle technique helps in curtailment of pain during IM injection.

Ruma Choudhury Bhattacharjee, an MSc Nursing intellectual based in Haryana, effectuated out a report with the purpose to establish the potency of the cold application prior to IM injection on needle stick pain, among individuals between the age of 18-60 years. An entirety of sixty patients was selected by "non-probability sampling technique" wherefrom 30 were experimental and the remaining 30 were of the control group. The pain was scrutinized by using a 0-10 Numerical Pain rating scale. The evaluation indicated that in the Experimental group out of 30 patients, 16 had no pain, 13 had mild pain, out of which only 1 patient had moderate pain, and in the control group 15 patients had moderate pain, 11 had mild pain and 2 had no pain during inoculation of IM injection.

Jancy J (2019) Cold needle is a well-organized structure in lessening the pain through an IM (intramuscular) injection. This analysis was conducted at a selected hospital Kerala and used the cold needle procedure for providing IM Diclofenac. A "non-probability sampling method" was implemented to choose 50 adults between the age range of (21-60 years) acquiring the injection. Individually each and every adult received 2 doses with a needle at room temperature on the first day followed by a cold needle (0-2°C) on the following day. The pain was diagnosed using a numbered pain rating scale and the study discovered that the mean pain score was 5.32 with a room temperature needle and 2.00 with a cold needle which is remarkably lower which reckons that the cold needle method is a coherent practice in pain perception during IM injection.

A True Experimental analytic review was done in Amritsar to assess the productiveness of cold application where 60 patients from selected hospitals were taken into consideration and divided into Experimental (thirty) and Control group (thirty) by "Probability Sampling Approach", the cold application was

carried out for five seconds just before conducting the injection and a Standardized Numeric scale for pain was applied to estimate the pain levels. The study results showcased that the Control group mean was 5.8 and Experimental group was 3.2. It reveals that the mean difference is 2.6, obtained "t" value is 10.8 significant at p<0.05 level. This presumed that cold application helps in scaling down pain associated with IM injection.

Mrs. S. Jayashree (2014) conducted a True Experimental Post-test only research with an intention to alleviate pain by application of ice in precedence to an IM injection in children under five years from a vaccination clinic in 2014. Random Sampling was used to select sixty samples and was divided among Experimental and Control groups, FLACC Scale was used to evaluate pain. An Ice pack was applied before providing an IM injection in the Experimental group and the test inferred those 26 children under five had mild pain, 4 had moderate pain and in the Control group, 25 had severe pain and 5 had moderate pain.

A. Farhadi and M. Esmailzadeh (2011) carried out a study in which Randomized sampling method was used to bifurcate, 60 patients into the Trial and comparison group, out of which 30 received cold ice for thirty seconds before giving penicillin benzathine IM injection and 30 received without cold ice application. The reaction was accumulated by means of a set of questions and using a VAS scale. The result revealed that applying cold ice has diminished pain in the trial group on par with the comparison group. This indicated that ice application can reduce pain attributable to the IM injection.

In 2007 a double-masked study was guided to test the frozen needle for decreasing pain. 80 healthy members above 18 years were picked randomly for the influenza vaccine. A 23G needle was used and the members were injected with 0.5 ml of influenza vaccine and 0.5 ml of saline. An email was forwarded or otherwise, a phone call was made after two-four days to ask which vaccine has caused slighter pain and to appraise the pain at the injection site, also to ask if they noticed whether a frozen needle was used for just one injection or both. This study revealed that using frozen needles reduced discomfort in accordance with IM injection.

A randomized crossover single-blinded study was carried forth on patients suffering from RHD. A sum of hundred (100) samples were chosen that involved antibiotic treatment i.e., Penicillin intramuscularly. A cold needle (0-2 degrees Celsius) and a room temperature needle were used arbitrarily. The pain was computed by the use of a 10-point pain scale. There was a notable axing of pain whilst using a cold needle (3.37 ±1.75) contrary to the routine technique (5.58 ±1.68), $P \leq 0.0001$).

Firas Al-Qarqaz (2011) conducted an RCT to determine the effect of using cold air for lessening the needle pain. clients experiencing skin injections were selected. 40 clients were applied cool air and again without cool air before administering a skin injection and quantified using a Visual Analogue Scale. It showed that 33 had mild pain, 5 had worst pain and 2 had no shift in pain using cold air which determines that using cold air is helpful.

A RCT was set up by means of cold therapy to scale down needle sting pain in connection to local anesthetic injection in the emergency department. The patients were unsystematically fractionated into two groups, one group received cold therapy. A dressing was done to cover the wound and cold therapy was given for 5 minutes at the site of the wound before the anesthesia was performed upon and the other group did not receive cold therapy. The pain levels were determined using 10 pt numerical pain scale thereafter. It showed that placing ice at the site can contribute to pain relief.

BJ Barnhill (1996) conducted an Experimental study that aimed at applying pressure prior to the administration of immunoglobulin injection Intramuscularly, in totality 48 patients were applied pressure out of 93 patients and 45 without applying pressure and were computed with a 100mm VAS scale that showed 13.6mm in Exp and 21.5mm in the control group. This summonses that applying pressure at the site minimizes needle prick pain.

A RCT was run in Turkey in 2009 on patients receiving inj Diclofenac intramuscularly. The study aimed to test if changing the needle before administering the injection would cause less discomfort. 100 patients were chosen and two distinct approaches were implemented to patients who received two injections The patients were indiscriminately allotted and a numerical scale was used for quantifying pain after each injection. The results confirm that switching the needle before giving an injection into the muscle significantly minimizes pain intensity.

A research study was concluded in Korea in order to dictate the pain from IM injection in adults in February 2006. A 24-gauge needle was used to carry out Hepatitis B vaccine in 160 clients of which 65 were males and 95 were females. A VAS scale was utilized soon after administration to calculate pain. The results showedthat the average score in males was 20.8 ± 17.1 and 34.4 ± 19.7 in females which proposes that gender is linked with the VAS scale and seems to be a decisive constituent in influencing pain coupled with IM

injection. Hence pain-reducing techniques should be executed in this procedure.

A RCT was impelled to find out the reaction on pain by using three different techniques i.e., Z technique, internally for giving an IM injection. 75 patients were selected at a university hospital in Zonguldak, Turkey. And each patient received 3 injections given by the same researcher with 3 different methodologies. The patients had been assigned randomly. After each injection, the pain levels were measured using a VAS scale. The research determined that pointing the toes downward did not prove to have a significant reduction in pain but the Z track technique and internally rotated foot showed noticeably less pain.

Dilek K Yilmaz executed a study in 2013 at the Department of Brain Surgery, Cekirge State Hospital, Bursa, Turkey to know the developments of using two different techniques on pain associated with an IM injection into two different injection sites i.e., dorsogluteal and ventrogluteal sites. The study comprised of 60 samples that were unpredictably split into halves. Both the groups received two injections one using the airlock method and the other not using it on the ventrogluteal site and the other group on the dorsogluteal site. The pain experienced sustained was assessed right away using a VAS scale. The mean scores were 3.30 ± 2.70 for

Dorsogluteal using the Airlock method and 2.53 ± 2.52 for ventrogluteal respectively.
In spite of the fact that the study showed that there is no major difference in the methods, the results resolved those injections to the VS using the airlock method were painful to a smaller extent than to the dorsogluteal site.

A semi-experimental study was achieved wherein hand pressure was applied for about 10 seconds prior to administering an IM injection into the deltoid muscle. A total of 193 first-year students from a university were considered as they were proposed for hepatitis A and B and divided randomly into two groups. Group 1 underwent hand pressure previously to the injection and group 2 was not given any pressure and perceived pain was recorded using a numerical pain scale. The accumulated data proved that using hand pressure before administering an IM injection was helpful in reducing post-vaccination pain.

An experimental study was completed to measure the effectiveness of using distraction cards in lessening pain and anxiety after being provided with an IM injection. The study was concentrated on children between the ages of 6 to 11 years. Sixty children were picked and randomly assigned to two groups. One group used distraction cards while performing the procedure and the other group did not comprise of any

distraction method but were allowed to have their family during the procedure. The pain was assessed using Wong Bakers FACES Pain Scale which was completed by the children, parents, and the observer. The group that involved distraction showed less pain which culminates that integrating distracting methods is very supportive in children.

A Prospective, randomized controlled study was concluded at a school of Medicine, Istanbul, Turkey in 2018 in adult patients undergoing an IM injection of diclofenac and were divided into three groups of 40 patients each. Each group went hrough a different technique i.e., shot-blocker technique, cold spray, and a routine procedure in reducing pain during inoculation. All the patients were instructed to rate the severity of pain using a 100 mm numerical pain scale. The level of pain was the lowest in the shot block technique (11mm) and cold spray (10mm) other than the control group (31 mm) (p=0.001). which comes to the point that, using shot block andcold spray is effective as a pain management technique.

Leanne M Hall guided a study using RCT to decide the outcome of the employment of dermis cooling approach on pain correlated with immunization. The study involved 689 children and 829 adults and a cold spray or ice pack was used as a mediation. In the comparative group, local anesthetic cream and diversional techniques were used. The test resulted that adopting the cold spray in adults reduced pain drastically although using skin cooling techniques in children was not so of a success. Hence the study achieved the purpose, that the use of cooling techniques is able to cut back the injection pain in patients.

A quantitative post-test-only study was conducted with an aim to observe the perks of using the blunt pressure technique rather than using the regular technique. Clients receiving IM injections in a tertiary care hospital were preferred and aimlesslyassigned to Experimental and control groups, the control group followed routine technique and experimental group used blunt pressure technique followed by measuring the pain with a numerical pain scale. The mean pain ratings for normal technique has been 3.15 ± 1.44 and 1.01 ± 0.98 for using blunt pressure subsequently which shows that blunt pressure is said to have reduced injection pain.

CHAPTER IV RESEARCH METHODOLOGY

Research methodology is an organized and conceptual procedure to accumulate and assess data through the research procedure. It acknowledges researchers to authenticate a study's thoroughness to gain new data and to prove the reliability, viability and dependability of a particular research purpose.

This chapter discusses the elucidation of methodology taken for the research and is given as under:

1. Research approach:

Taking into account the outlook of the issue chosen and the purpose to be attained, the evaluative perspective was regarded as relevant for the research. The evaluative approach is an applicable method of research and implicates how efficienta particular application, method, strategy or approach is functioning. The Quantitative Approach is considered.

2. Research Design:

A Research design is merely a systematic structure of numerous research methods and approaches that are made use of by the researcher. The research design is planned to provide a suitable structure for the intended purpose of study and it can also prove how pertinent and credible a study determines. The Research Design considered here is True experimental -post-test only control research design

This design is used as it best suits the study since the study calls for assessing the efficacy of using a cold needle in minimizing the needle prick pain while administering an IM injection. A random sampling method was used.

GROUP	RANDOM ALLOCATION	INTERVENTION (A cold needle technique)	POST TEST (Pain Scores)
EXP	R	X	O_1
CTRL	R	-	O_1

Key:

EXP-Experimental Group

CTRL- Control Group

R- Randomly allocated the samples

X-Intervention is/in using a cold needle

O₁-Post-test evaluation of pain.

Variables:

In experimental studies, elements that possess any varied attribute (quality) or quantity is known as a variable. Conceptions are generally cited as variables, which proves to be the core constituents of a discourse or study.

The current study is oriented towards comprehending the validity of the intervention.

Independent variable: In this study is the cold needle that is used to give an IMinjection.

Dependent variable: In this study is pain.

The demographic variable: In this study are Age, Gender, Religion, Education andPrevious experience of being injected intramuscularly.

3. **Research setting:**

Research setting is the site, where the research occurs or happens, the setting under which studies are conducted, proves vital for the investigation or experimentalmotif.

The setting for conducting the study was a tertiary care hospital, Belagavi. Thebasis for choosing the setting is the practicability for carrying out the study.

4. Population:

The population is interpreted as a distinct, clear and distinct assemblage of people or entities known to have similarities or generally a massive group of individuals that is the principal focus of a research study.

This includes all Patients present at Med Surg units at a tertiary care hospital, Belagavi.

5. Sample:

The procedure of choosing a group of individuals for research in a corresponding manner such that the people constitute the sizeable group from which they are selected.

Potential samples are who are all experiencing an IM injection at a tertiarycare hospital, Belagavi.

Sample size

The study contained sixty (60) samples and further divided into 30 Exp groupand 30 Ctrl group.

Sampling technique

The Random sampling technique or Lottery method was used for the study

Eligibility Criteria for selecting the samples:

Inclusion criteria are attributes that the proposed participants should possess ifthey are included in the study or research.

Exclusion criteria are particular characteristics that the participants don't have

or lack the same and prove ineligible if they don't fit the criterion.

The researcher determines the features of the populace under research bymeans of inclusion and exclusion criteria in the study.

The basis used to specify the masses for a research study bears consequencefor the explanation of the outcome and the inference of data.

Addition Criteria:

Adults' patients who are:

- Admitted to the medical and surgical wards

- Experiencing an IM injection.
- Competent in responding to pain.

- Present during the study and consenting to cooperate in the study

Omission Criteria:

- Insentient and terminally ill patients.

- Taken sedating drugs or analgesics an hour prior

- Life-threatening conditions like Epilepsy, Alzheimers, DM.

- Unwilling to cooperate in the study

6. Development and description of tool:

Following a substantial analysis of reports regarding the research, a systematic mode of standardization instrument of measurement was selected for evaluating the perception of pain.

Description of tool

Visual Analogue Scale (VAS)

The visual analogue scale necessitates a patient to measure pain on a calibrated system of 0-10 by means of a 10-point Numerical Pain scale of which 10 is the maximal score and 0 is the minimal score which is divided as follows:

0 - denotes No pain1-3 is Mild pain

4-6 is Moderate pain

7-10 resembles Severe pain

The straight line depicts a continuity of intensity. A patient reports pain by marking the suitable point on the VAS. This scale showcases the patients compete liberty to recognize pain levels.

7. Pilot study:

The pilot study is a pivotal constituent of a proficient study invent and it executes a scale of major results, giving and accurate and deep understanding to researchers.

The pilot study was carried out following approval from the ethical clearance committee. The setting was a tertiary care hospital, Belagavi and included 10 participants that were receiving IM injection and were randomly assigned to Experimental (5) and Control Group (5) discretely and the severity was calculated with a VAS scale. The data was collected between 6th December 2021 to 15th December 2021. The outcome of the pilot study reveals that, the experimental group mean scores after intervention is 4. The control group mean score excluding the intervention is 6. Therefore, the pilot study was confirmed to be successful in scaling down pain in accordance with IM injection.

8. Process for data collection

The data was gathered over a period of one and half months from 8th January 2022 to 23rd February 2022 after attaining permission from the college and the hospital authorities for carrying out the research study. The importance, objectives and details of the procedure were elucidated to the participants, and were encouraged to ask questions about the study. Informed consent was obtained thereafter. A cold needle was used in the Experimental group during inoculation and the standard procedure for the control group was followed. The Demographics were collected and the levels of pain was measured in both groups by using a VAS scale. The Evaluation of data was carried out using Descriptive and Inferential measures.
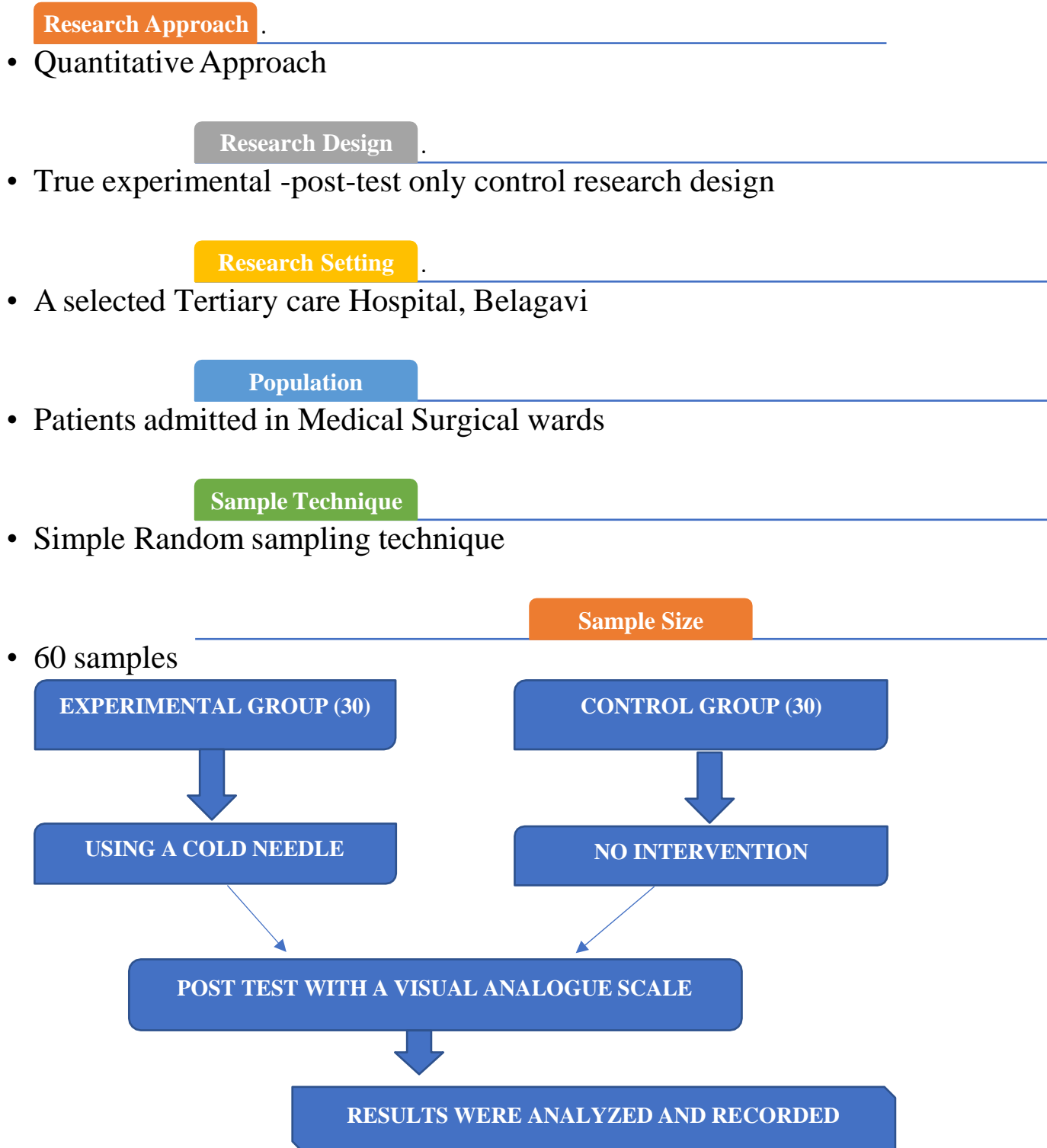
9. Plan for data analysis

Specialists in the area of nursing and statistics are guided in the direction in growth of data research strategies, which are demonstrated as

The data gathered was arranged and tabulated on a master sheet. The demographics were observed by descriptive and inferential analysis. Descriptive analysis was carried out by frequency, proportion, mean and SD for categorical variables. Inferential analysis used was unpaired t-test to compare the categorical outcomes between experimental and control group.

Summary

This section on research methodology incorporates numerous strides taken on by the research investigator during the course of the thesis.

FIGURE 2: DIAGRAMATIC PRESENTATION OF DATA COLLECTIONPROCESS

Research Approach .

- Quantitative Approach

Research Design .

- True experimental -post-test only control research design

Research Setting .

- A selected Tertiary care Hospital, Belagavi

Population

- Patients admitted in Medical Surgical wards

Sample Technique

- Simple Random sampling technique

Sample Size

- 60 samples

EXPERIMENTAL GROUP (30)	CONTROL GROUP (30)
USING A COLD NEEDLE	NO INTERVENTION

POST TEST WITH A VISUAL ANALOGUE SCALE

RESULTS WERE ANALYZED AND RECORDED

CHAPTER VRESULTS

The following part introduces the audit and explanation of the data gathered, toevaluate the efficacy by using a cold needle for minimizing the pain in patients experiencing an IM injection in surgical and medical wards at a selected tertiary care hospital Belagavi.

Analysis is defined as the procedure of effectively executing multivariate and methodical procedures to explain and emphasise, summarise and outline and assess data.

The details of the data were examined in accordance with the objectives whichare as follows:

1. To assess the level of pain intensity among adult patients.

2. To compare the level of pain intensity among adult patients in both control and experimental group.

3. To find the association between the level of pain intensity and selected demographic variables.

The researcher gathered the data for examining and elucidating using a standardized calibrated system like a VAS scale. For further analysis the data was arranged and tabulated systematically using statistical tests and is given as under:

Table 1: Comparison of mean of pain score between study group(N=30+30)

Parameter	Study group (Mean± SD)		P value
	Case (N=30)	**Control (N=30)**	
Pain score	1.73 ± 1.08	7.17 ± 1.05	<0.001

The table above interprets that the Mean pain score after intervention in Case group is 1.73 and the Mean pain score without intervention in Control Group is 7.17

Thus, H_1 was acknowledged that the mean level of pain among the experimental group will be significantly lower than the mean pain levels between the control group at the time of intramuscular injection calculated by a visual analogue scale at 0.05level.

Table 2: Comparison of pain scores between the experimental and control groupby using Unpaired t test (N=30+30)

	Unpaired t test					
	Mean difference	**andard error**	**alculatedt value**	**abulatedt value**	**d.f**	**P value**
ost Test values	5.43	0.2755	19.722	1.95	58	<0.001

The post-test mean values of pain among the experimental and control group were obtained at p<0.001. which proposes that reduced levels of pain in experimental group at the time of IM inoculation was because of using cold needle as an intervention and not accidental or by luck. A significantly high difference was detected.
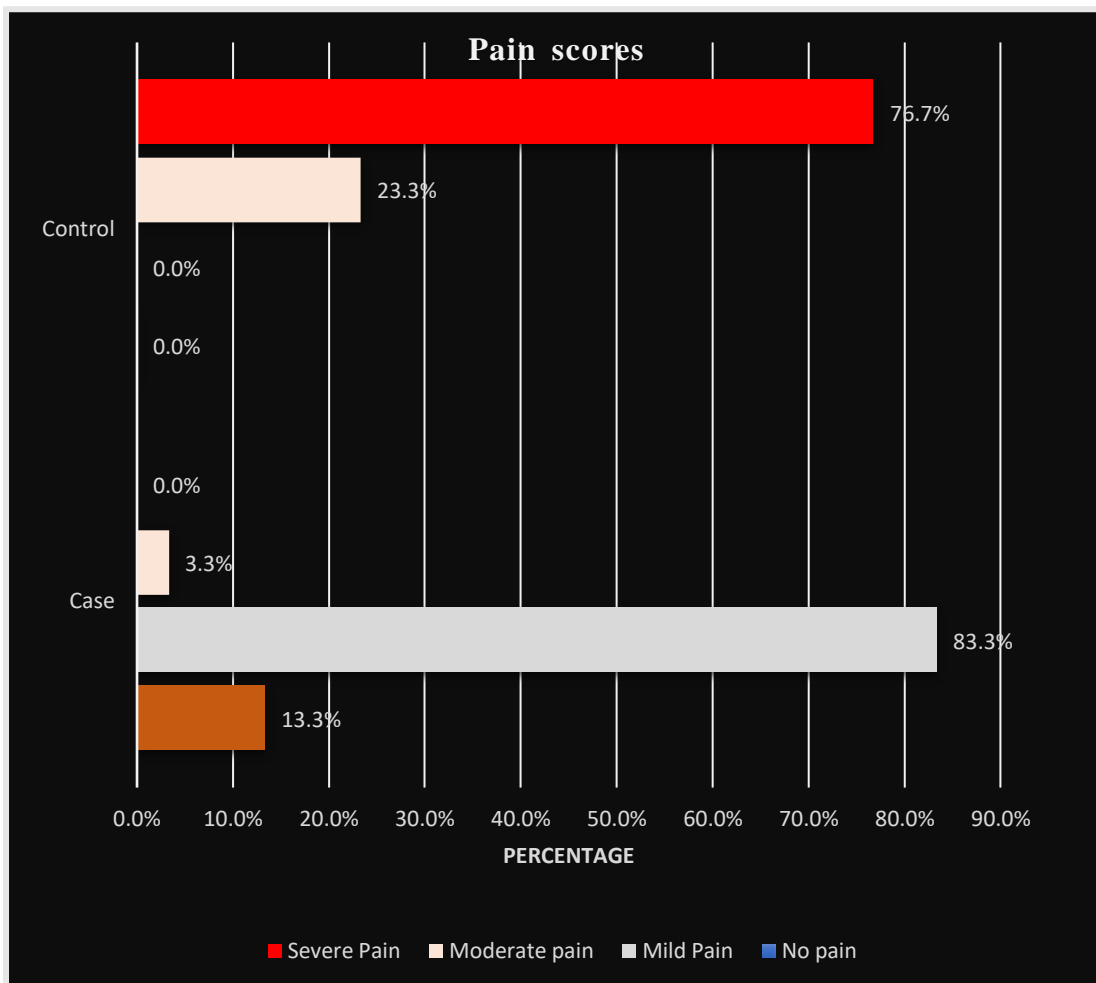
Table 3: Comparison of pain score between study groups (N=30+30)

Pain Score	Study Group	
	Case (N=30)	**Control (N=30)**
No Pain (0)	4 (13.33%)	0 (0%)
Mild Pain (1-3)	25 (83.33%)	0 (0%)
Moderate Pain (4-6)	1 (3.33%)	7 (23.33%)
Severe Pain (7-10)	0 (0%)	23 (76.67%)

*No statistical test was applied- due to 0 subjects in the cells

Amidst the participants in Case group none experienced severe pain, 25 (83.33%) had mild pain, 1 (3.33%) had moderate pain, 4 (13.33%) experiencedabsolutely no pain at all. Moreover 23 (76.67%) of them had severe pain and 7 (23.33%) had moderate pain in the control group.

Graph 1: Stacked bar chart of comparison of pain score between study group(N=30+30)

Association of Sociodemographics and level of pain between Case and Control group(N=30+30)

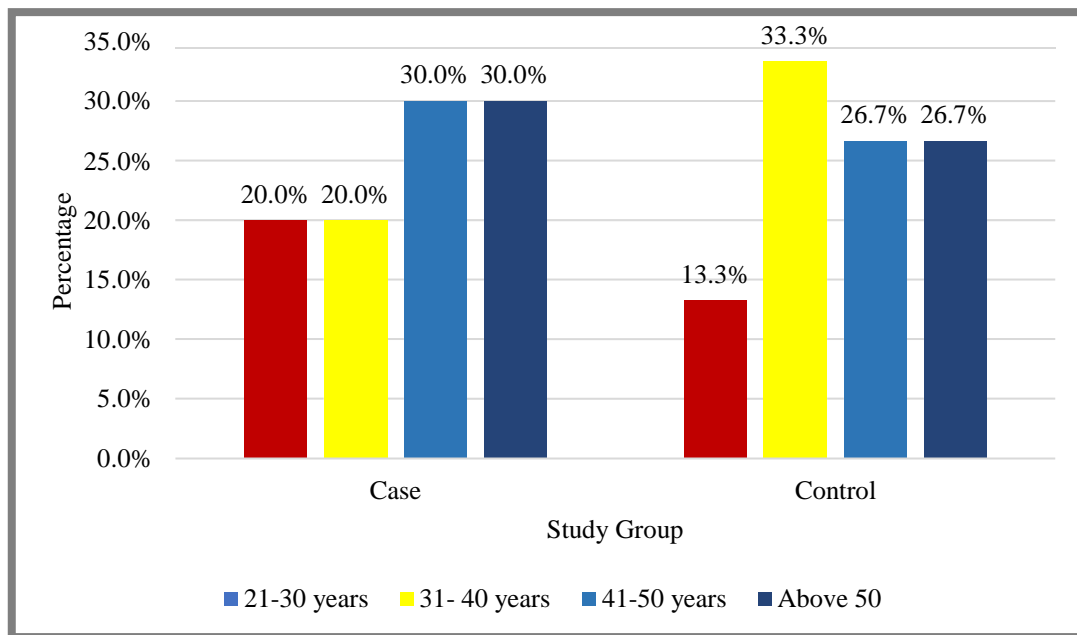**Table 4: Comparison of age between study group (N=60)**

Age	Study Group		Chi square	P value
	Case (N=30)	Control (N=30)		
21-30 Years	6 (20%)	4 (13.33%)		
31- 40 Years	6 (20%)	10 (33.33%)	1.518	0.678
41-50 Years	9 (30%)	8 (26.67%)		
Above 50	9 (30%)	8 (26.67%)		

Among the participants in Case group, 6 (20%) were in the age group of 21-30 years, 9 (30%) were

between of 41 to 50 years, around 6 (20%) in 31-40 years and

9 (30%) were > 50, In control 4(13.33%) were in the middle of 21-30 years, 31-40

age group had 10 (33.33%) of them, 8(26.67%) belonged to 41-50 years and >50 had 8(26.67%) participants.

The difference in proportion of study group across age groupwas not statistically significant. (P value 0.678)

Graph 2: Cluster bar chart of comparison of age between study groups (N=60)

Table 5: Comparison of gender between study groups (N=60)

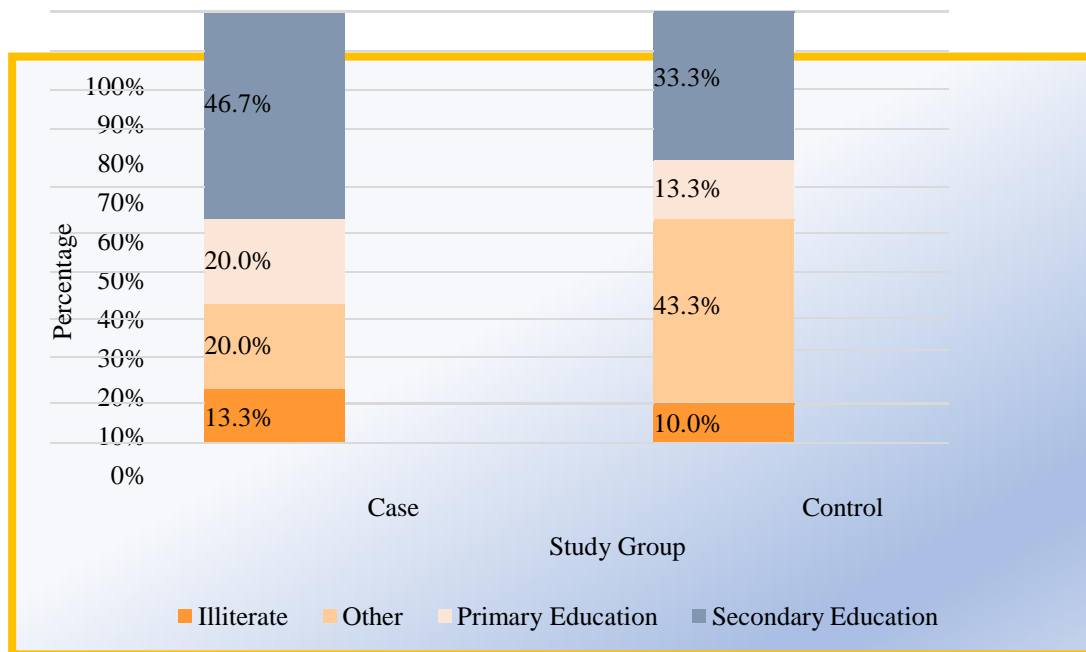| Gender	Study Group		Chi square	P value
	Case (N=30)	Control (N=30)		
Female	16 (53.33%)	18 (60%)	0.271	0.602
Male	14 (46.67%)	12 (40%)		

In Case group, Majority were females that is 16 (53.33%), 14 (46.67%) were males and majority were females in control group as well that is 18 (60%) and 12 (40%) of them were males. The difference in proportion of study group and gender was not statistically significant. (P value 0.602)

Graph 3: Cluster bar chart of comparison of gender between study groups (N=60)
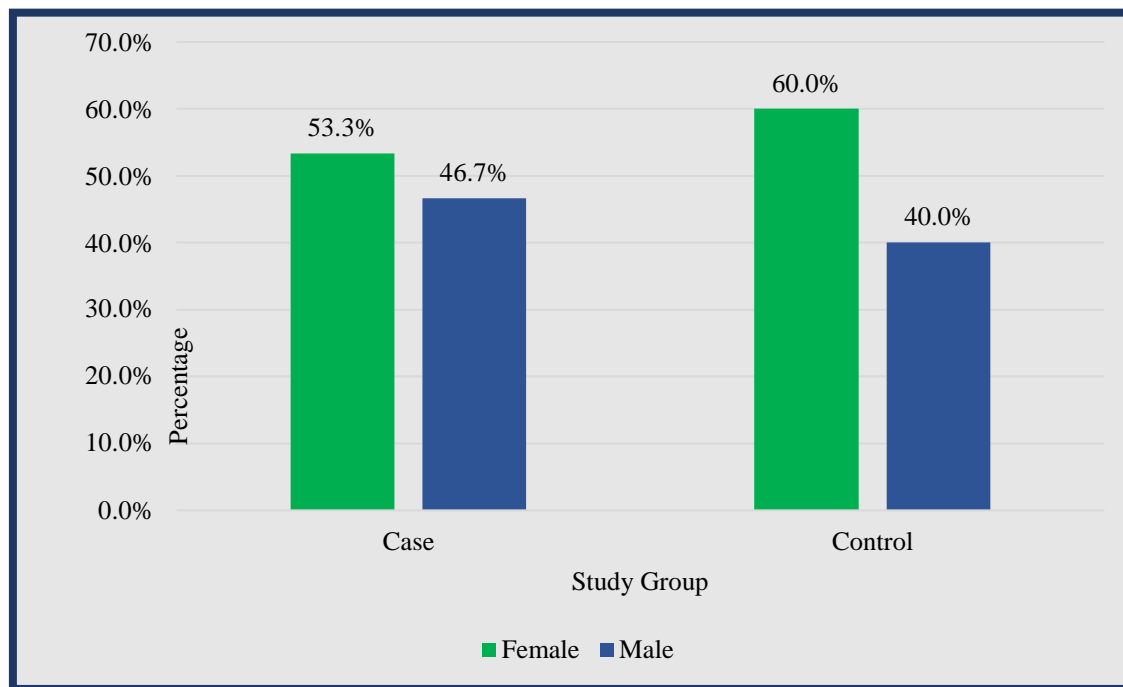
Table 6: Comparison of education between study groups (N=60)

Education	Study Group		Chi square	P value
	Case (N=30)	Control (N=30)		
Illiterate	4 (13.33%)	3 (10%)	3.788	0.285
Other	6 (20%)	13 (43.33%)		
Primary Education	6 (20%)	4 (13.33%)		
Secondary Education	14 (46.67%)	10 (33.33%)		

With regards to the table above majority of participants completed Secondary Education that is 14 (46.67%), 6 (20%) completed Primary Education, 6(20%) had either a diploma or degree, 4 (13.33%) were Illiterate and belonged to the Case group, whereas in Control group 10 (33.33%) completed Secondary Education, 4 (13.33%) have Primary Education, 13(43.33%) completed either degree or diploma, 3 (10%) were illiterate. The difference in proportion of study group and education was not statistically significant. (P value 0.285)

Graph 4: Stacked bar chart of comparison of education between study groups (N=60)

Table 7: Comparison of religion between study group (N=60)

Religion	Study Group		Chi square	P value
	Case (N=30)	Control (N=30)		
Christian	2 (6.67%)	2 (6.67%)	0.186	0.980
Hindu	13 (43.33%)	13 (43.33%)		
Muslim	11 (36.67%)	12 (40%)		
Other	4 (13.33%)	3 (10%)		

In comparison with the case and control group, 11 (36.67%) were Muslims, 4 (13.33%) belonged to other religions in the case group, 12 (40%) were Muslims, 3 (10%) were from other religions, 13 (43.33%) each belonged to Hinduism and 2 (6.67%) each were Christians in both the groups. The difference in proportion of study group and religion was not statistically significant. (P value 0.980).

Graph 5: Stacked bar chart of comparison of religion between study groups (N=60)
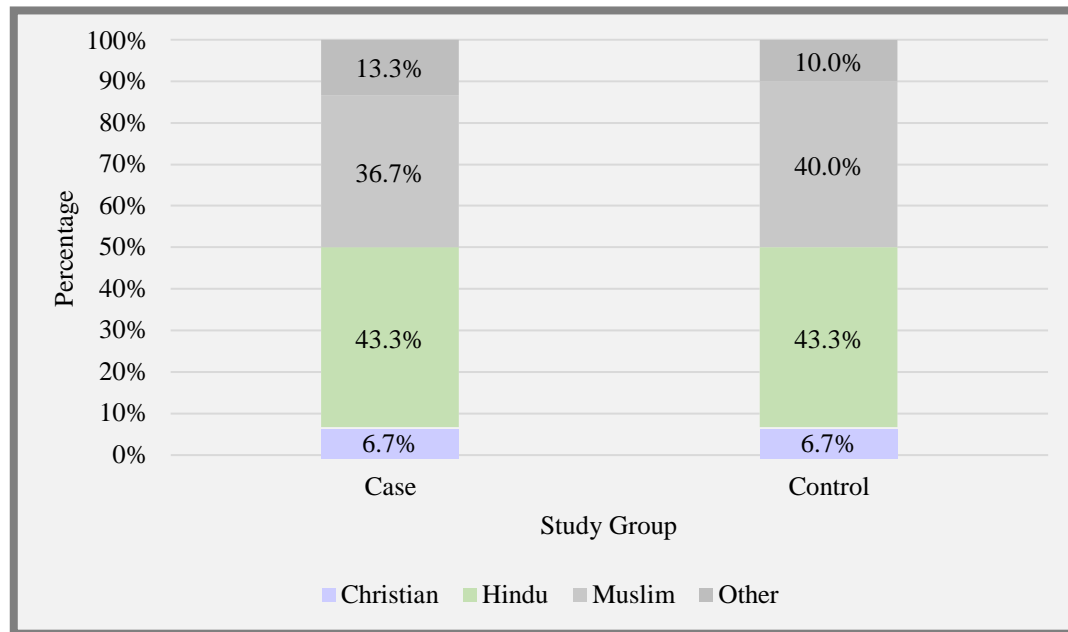
CHAPTER VIDISCUSSION

With regards to the reviewer this chapter emphasizes with the outline of the contemporary analysis and incapsulates the research data in contrast with the preceding study The current study is committed to evaluate the efficacy of using a cold needle for giving an intramuscular injection to minimize the pain intensity among patients admitted at selected tertiary care hospital Belagavi"

The major findings about this study are formulated as under:

➢ Conclusions linked to basic data of the participants

➢   Matching the outcome of the post test results of needle prick pain with theControl and Exp group.

➢ Efficiency of using a cold needle technique in the experimental group.

Basic data on Socio-demographics of the participants:

Among the participants in Case group, 6 (20%) were in the age group of 21-30 years, 9 (30%) were between of 41 to 50 years, around 6 (20%) in 31-40 years and 9 (30%) were > 50, In control 4(13.33%) were in the middle of 21-30 years, 31-40 age group had 10 (33.33%) of them, 8(26.67%) belonged to 41-50 years and >50 had 8(26.67%) participants.

In Case group, Majority were females that is 16 (53.33%), 14 (46.67%) were males and majority were females in control group as well that is 18 (60%), 12 (40%) of them were males.

With regards to the table above 14 (46.67%) participants completed Secondary Education, 6 (20%) completed Primary Education, 6(20%) had either a diploma or degree, 4 (13.33%) were Illiterate and belonged to the Case group, whereas in Control group 10 (33.33%) completed Secondary Education, 4 (13.33%) have Primary Education, 13(43.33%) completed either degree or diploma, 3 (10%) were illiterate.

In comparison with the case and control group, 11 (36.67%) were Muslims, 4 (13.33%) belonged to other religions in the case group, 12 (40%) were Muslims, 3 (10%) were from other religions, 13 (43.33%) each belonged to Hinduism and 2 (6.67%) each were Christians in both the groups.

Comparing post-test results of needle prick pain between patients in both the experimental and the control group:

The post-test mean values of pain among the experimental and control group were obtained at $p < 0.001$. which proposes that reduced levels of pain in experimental group at the time of IM inoculation was because of using cold needle as an intervention and not accidental or by luck. A significantly high difference was detected.

The results in the experimental group after using the unpaired t-test revealed that the t value = 19.72 which is significant at $p < 0.0001$. This concludes that using the cold needle technique was successful in lowering pain.

Comparing Mean post-test values and SD of pain following IM injection withand without intervention in both the Case and control group.

Parameter	Study group (Mean± SD)		P value
	Case (N=30)	Control (N=30)	
Pain score	1.73 ± 1.08	7.17 ± 1.05	<0.001

The table above interprets that the Mean pain score after intervention in Case group is 1.73 ± 1.08 and the Mean pain score without intervention in Control Group is 7.17 ±1.05

CHAPTER VIICONCLUSION

NURSING IMPLICATIONS

The conclusions of this following study have an inference for the nursing diaspora, nursing teaching and learning, nursing management, and nursing analysis and assessment.

NURSING SERVICE

This study accentuates the significance of clientle who are taking IM injection. It provides for the nurses to strategize and to systematically provide care during IM injection. Furthermore, helps enhance the adroitness of pain evaluation utilizing the VAS. By means of dispensation of cold needle technique, thereby reducing the patient's pain during IM injection.

NURSING EDUCATION

The results of the research study can be of vital significance to the nurse tutors. Pain also being a considerable indicator, compels the patient to heed the advice of the doctor. It demonstrates that patients with pain need instantaneous medical aid. This research will assist the nurse tutor to understand the pain in the course of the IM injection and hence paves a way to convey the understanding in relation to pain and its evaluation and therapy.

This research can prove to be as an illuminative specimen for students and personnel who can benefit and productively use this organized nursing involvement in

the patients who all are undergoing IM injection.

NURSING ADMINISTRATION

The research results of the study may be utilized by the nurse administrator so as to enhance nursing care. Strategies and conventions can be put to use by the nurse administrator concerning the pain evaluation whilst administration of IM injection, also the health nurse administrator can give in-service education to the staff. This in turn can prove vital so as to assist and to provide issue superior pain management careduring IM injection, thereby giving the required treatment and help relieve pain.

NURSING RESEARCH

Nursing research grants an improved direction for advanced studies in the field of nursing. This study will prompt the researcher to investigate and explore in multiple health management and healthcare services thus accentuating and promoting excellent attentiveness and quality care methods to the patients. Evidence-based nursing will get as far and have a larger and over the edge possibilities in the nursing environment.

LIMITATIONS:

1. This research study was confined to surgery, medicine wards of a selectedtertiary care hospital Belagavi.

2. The study was further narrowed down to patients experiencing an IMinjection.

3. The study was restricted to just sixty patients.

4. It was considered impossible by the researcher to control the extrinsicvariables

SUGGESTIONS:

1. The same study deserves to be carried out on a larger sample.

2. A similar experiment can be done in a different environment

3. The same study can be redone for a longer duration to be more relevant andget a broad view.

4. A descriptive study can be directed on knowledge and practices regarding coldtherapy.

5. A comparative study can be conducted between different nonpharmacological(drug-free) methods in reducing pain resulting from IM injection.

CHAPTER VIIISUMMARY

The sole intention of carrying out the trial was to ascertain the effectivity of practicing the use of a frozen needle in adult patients to decrease pain while experiencing an Intramuscular injection at medical, surgical units of a selected tertiary care hospital at Belagavi.

The objectives of the study are:

1. To assess the level of pain intensity among adult patients.

2. To compare the level of pain intensity among adult patients in both the controland experimental group.

3. To find the association between the level of pain intensity and selecteddemographic variables.

The hypothesis developed stated:

H_1: The mean level of pain among the experimental group will be significantly lower than the mean pain levels between the control group at the time of intramuscular injection calculated by a visual analogue scale at 0.05level.

H_2: There will be a statistically significant association between the level of pain during the intramuscular injections and the selected sociodemographics between the participants in the experimental and control groups respectively at 0.05level.

The independent, dependent and extrinsic variables are given along the following lines.

Independent variable as a Cold Needle technique, Dependent variable as pain and the Extrinsic variables as Age, Qualification, Gender, Religion and Previous experience of an IM injection.

The present study is focused on evaluating the efficacy of using a cold needle for giving an intramuscular injection to reduce the pain intensity in patients admitted at selected tertiary care hospital Belagavi.

The Donabedian model for quality of care is developed as a conceptual framework by the researcher for the study. The model has 3 major parts that is Structure, Process and Outcome which helps in identifying the efficacy of the cold needle method in lessening the pain while experiencing an IM injection.

The pilot study was performed at Credit general ward and involved ten patients of a selected tertiary care hospital Belagavi. The main study was carried out at the surgical and medical wards, the number of subjects included in the study was 60 and were picked using the non-probability random sampling method and the research setting was a tertiary care hospital Belagavi.

The levels of pain were measured after the intervention with the VAS scale. The results were analyzed, understood and recorded. Descriptive analysis was carried out by frequency, proportion, mean and SD for categorical variables. Inferential analysis used was an unpaired t-test to compare the categorical outcomes between the experimental and control group.

The results in the experimental group after using the unpaired t-test revealed that $t = 19.72$ which is significant at $p < 0.0001$. This concludes that using the cold needle technique was successful in lowering pain.

So accordingly, there is an association between cold needle technique to alleviate the pain while experiencing an IM Injection. The study was evident in minimizing needle stick pain related to IM injection.

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