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A Quasi-Experimental Study to Evaluate the Effectiveness of Cold Application Prior to Intramuscular Injection on the Level of Needle Stick Pain among Adult Patients of a Selected Hospital, Gurgaon, Haryana

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Abstract: ***Introduction: Pain is highly unpleasant and very personal sensation. Every human being in the world has experienced some type or degree of pain during intramuscular injection. Among many non-pharmacological measures, application of cold reduces the ability of pain fibres to transmit pain impulses and reduce the pain associated with various types of injection. The main aim was to assess the effectiveness of cold application on the level of needle stick pain during intramuscular injection.The objectives of the study were: (1) To assess and compare the level of needle stick pain among patients undergoing intramuscular injection after cold application in the experimental group and without cold application in the control group. (2) To find association between the level of needle stick pain with selected demographic variables of experimental and control group. Methods: A quantitative approach using quasi-experimental post-test only control design was used.A non-probability purposive sampling technique had been used to select 60 subjects, out of which, 30 were assigned to experimental group and 30 to control group . Study was conducted at injection room of Civil Hospital, Gurgaon, Haryana. Results: The findings revealed that out of total 30 adult patients in experimental group 16 (53.3%) had no pain, 13 (43.4%) had mild pain and 1 (3.3%) had moderate pain while receiving intramuscular injection and whereas out of total 30 adult patients in control group ,15 (50.1%) had moderate pain, 11 (36.7%) had mild pain and 2 (6.6%) had severe pain and 2(6.6%) had no pain while receiving intramuscular injection. The level of needle stick pain mean score of experimental group was 0.933 ± 1.20 SD and the level of needle stick pain mean score in control group was 3.5 ± 1.97 SD which was found to be at significant at p<0.01 level with a 't' value of 6.153. There was a significant association found between educational background and post-test pain score while receiving intramuscular injection in control group. Conclusion Cold application was significantly effective in reducing the needle stick pain of patients in experimental group, as compared to patients in control group those who received IM injection without cold application.***

Keywords: Effectiveness, Cold Application, Pain, Intramuscular Injection, Adult Patient

1. Introduction

The International Association for the study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage[1]. The American pain society created the phrase "pain: as the fifth vital signs" to increase awareness of pain assessment among the health care professionals, especially nurses. [2]

US census bureau (2011) estimated that injections are among the most frequently used medical procedures with an estimated 12 billion intramuscular injections administered throughout the world on an annual basis , of these 5% or less are for immunization and rest are given for curative purposes. [3] In developing countries alone, some sixteen thousand million injections are administered annually, over 90%, are administered for therapeutic aims whereas 5 to 10% are administered for disease prevention, the foremost important side-effect associated with injections is that the related pain. Injection pain is associated with the penetration of the skin by the needle and to the mechanical and chemical effects of the drug during and after its injection.[4] Department of Health and Human Service, India (2010) stated that 96% of intramuscular injections given by private doctors were of antibiotics, vitamins, and analgesics. The prevalence of intramuscular injection range is between 1.7-11.3 injections per person per year. [5]Though Intramuscular injection is most frequently used injection but it causes painful experience for many individuals. [6]One of the basic human rights of patients is providing relief from pain, which is the responsibility of a nurse, who must use the most efficient procedures to control the pain and promote comfort. [7]There are several numbers of pharmacological and non-pharmacological measures to reduce pain.[2] Now the non-pharmacological interventions are gaining popularity.[8]Different methods are used by the nurses to reduce pain during Intramuscular injections such as taping the skin, Z- track technique, applying pressure, applying heat and cold. It is a challenge to the nurse to select a method that, the nurse can use and give painless injections provide relief from pain, especially for those patients who are scared of needles and injection.Among these non-pharmacological measures, application of cold reduces the ability of pain fibres to transmit pain impulses and studies

have shown that cold therapy has the ability to reduce the pain associated with various types of injection.[8]
Cold application, known as cryotherapy which is a simple and cheap therapy and has been accepted for decades as an effective nonpharmacologic intervention for pain management.

It has also been observed over a period of clinical practice in Medical Surgical departments that there are a number of patients who complained pain duringadministration of intramuscular injections as well as some patients may complain from swelling or tissue trauma at the site of injection despite using standard traditional technique of intramuscular injection. This motivated the researcher to search the current literature to find out the non-pharmacological therapy to reduce pain of IM injection. There are many researches done to assess the effectiveness of cold application on the pain level from IM injection in children, that too in foreign settings but very few studies have been done in adults in Indian setting.

2. Review of Literature

A study was undertaken **by Ramadan RH et al [9](2016) to** evaluate the effect of cryotherapy on pain intensity among 100 adult patients receiving Intramuscular Injection in medical departments at Mansoura University Hospital. Quasi–experimental time-series design was carried out in this study. Structured interview questionnaire was used to collect data. The result showed that the patients who got cryotherapy communicated significant lower pain intensity in contrast with patients who did not get cryotherapy duringIntramuscular Injection insertion. The study concluded that there was a significant positive effect of cryotherapy on reducing Intramuscular Injection pain.

Kalyan K, Shahji J Kumari S, Kumari R[10](2019) conducted a true experimental study in Hargun Hospital and The Corporate Hospital, Balata Road Amritsar, to assess the effectiveness of local cold application prior to intramuscular injection to reduce the intensity of the pain. The sample size consisted of 60, 30 in control group and 30 in experimental group are selected from medical, surgical, emergency wards and antenatal clinic. Probability sampling simple random technique was used to select the sample. Cold application was applied for 5 seconds just prior to inserting the needle Standardized Numerical pain scale was used to assess the pain level. To compare the pain level in both groups the control group mean (5.8) is higher than the experimental group (3.2), mean difference is 2.6, obtained "t" value is 10.8 significant at $p<0.05$ level. The study concluded that ice application had effect on reducing the pain during intramuscular injection.

Pande P[11](2017) conducted a true experimental study to assess the effectiveness of cold application prior to intramuscular injection on the intensity of pain among adults admitted in selected hospitals of the city. Post-test only control design was used for the study. 60 adults (30experimental group and 30 control group) were selected by using probability simple random sampling technique. Lottery method was used for the selection of sample. The data was collected by using interview scheduled & modified numerical pain intensity scale. The comparison of intensity of pain in the experimental group & control group reveal that the mean difference score of the experimental group was 3.93 & the control group Was 6.40. Thus, the study concluded that the mean pain was less in experimental group as compared to control group, hence cold application was very effective.

3. Materials and Methods

Research Approach -Quantitative
Research Design- Quasi-experimental post-test only control design.
Target Population- Adult patients receiving IM injections Voveron, age 18-60 years.
Setting- The injection room at civil hospital, Sec.10, Gurgaon, Haryana.
Sampling Technique- Non-probability purposivesampling
Sample size-A total of 60 subjects were selected, 30 in experimental group and 30 in control group.

Variables of The Study
Dependent variables: Level of needle stick pain associated with intramuscular injections.
Independent variable: Cold application

Table 1: Research design

Group	Intervention (before giving IM injection)	Level of needle stick pain (assessed after 1 minute of administering IM injection)
Experimental group (30)	cold application X	O1
Control group (30)	no intervention	O1

Operational Definition
1) Effectiveness: It refers to the level of pain reduction while giving intramuscular injection after a cold application as assessed by Numerical Rating Scale.
2) Cold application: In this study cold application refers to the application of ice cube (5×5cm), covered with gauze and applied on the site of intramuscular injection for a period of 1minute prior to intramuscular injection by researcher.
3) Pain: Pain is an unpleasant subjective sensational experienced by patients while receiving intramuscular injection and measured by Numerical Rating scale after the withdrawal of needle within time interval of 1minutes.
4) Intramuscular injection: It refers to introduction of needle into Dorso gluteal muscle to administer injection voveron/ on adult patients in the selected hospital, Gurgaon.

Inclusion criteria
1) Patients who are willing to participate in the study and are in the age group of 18-60 years.
2) Medication: Receiving Inj. Voveran Intramuscular injection in a selected hospital, Gurgaon.

Exclusion Criteria

1) Patients with chronic pain associated with other disease condition
2) Patients have impaired circulation, peripheral vascular disease, Local infection.

Data collection tool and techniques

Tool I: Structured interview schedule for collecting demographic data.

Tool II: Numerical rating scale (NRS) for assessing level of needle stick pain.

Reliability

The 0-10 numerical pain scale (NPRS) is a valid and reliable scale to measure pain intensity. Reliability of the numerical rating scale "NRS" was tested by using test–retest measurement (r = 0.95) , thus found reliable. The permission to use this standardized tool was obtained from the author.

Validity of the tool

Content validity of the research tools were established in consultation with the guide, co-guide and experts in the field of medical -surgical nursing.

Ethical Considerations

The formal administrative permission was obtained from civil surgeon .The investigator explained the purpose of the study and assured confidentiality of all subjects. An informed consent was taken from the subjects.

Pilot Study

Pilot study was done on total of 10 respondents; Experimental Group (n1=5) and Control Group (n2=5). No major problem was faced during the pilot study.

4. Results

Table 2: Comparison of Demographic variables in both Experimental and control Groups, N=60

S. No.	Variable	Experimental group (n_1=30)	control Group (n_2=30)	't' value	df	p value
		Mean ± SD	Mean ± SD			
1	Age	34.13 ± 11.4	37.8 ± 13.2	t= -1.169	58	0.271

S. No.	Variables	Experimental Group (n_1=30)		Control Group (n_2=30)		Test value	df	p value
		f	%	f	%			
2.	Gender							
	a. Male	15	50	23	76.7	0.69	1	0.06
	b. Female	15	50	7	23.3	**(χ 2)**		
3.	Marital status							
	a. Single	5	16.7	8	26.7	0.86	1	0.532
	b. Married	25	83.3	22	73.3	**(χ 2)**		
4.	Educational Background							
	a. No formal education	4	13.3	13	43.3			
	b. Primary education	12	40	6	20	7.141		
	c. Secondary education	6	20	5	16.7	**(χ 2)**	3	0.68
	d. Graduate	8	26.7	6	20			
5.	Occupation							
	a. Business	1	3.3	4	13.3			
	b. Labourer	9	30	7	23.3	5.522		0.356
	c. Govt. service	0	0	3	10	**(Fisher exact**	5	
	d. Not working	10	33.3	8	26.7	**test)**		
	e. Health professional	1	3.3	1	3.3			
	f. Any other	9	30	7	23.3			
6.	Taken intramuscular injection before							
	a. Yes	28	93.3	29	96.7	0.351	1	1.00
	b. No	2	6.7	1	3.3	**(**Fisher exact test **)**		
7.	Fear of intramuscular injection							
	a. Yes	11	36.7	15	50	1.086 **(χ 2)**	1	0.435
	b. No	19	63.3	15	50			
8.	Previous Complication of intramuscular injection							
	a. Yes	0	00	1	3.3	1.01	1	1.00
	b. No	30	100	29	96.7	(Fisher exact test		

Table- 2 shows that the adult patients in both the group were homogeneous with respect to demographic characteristics as there was no statistically significant differences found between the experimental and control as calculated by Fisher exact test value and t- score (in case of age only).

Table 3 Comparison of frequency and percentage distribution of level of needle stick pain score ofpatients in experimental group and control group receiving IM Injection, N=60

Level of Needle Stick Pain	Experimental group n_1=30		Control Group Frequency n_2=30	
	Experimental Group Frequency	Experimental Group %	Control Group Frequency	Control Group %
No pain	16	53.3	2	6.6
Mild	13	43.4	11	36
Moderate	1	3.3	15	50
Severe	0	0	2	6.6

The above table 3 shows that out of 30 adults patients, 16 (53.3%) had no pain 13 (43.4%) had mild pain and 1 (3.3%) had moderate pain while receiving intramuscular injection in experimental group and patients in control group patients, 15 (50.1%) had moderate pain, 11 (36.7%) had mild pain and 2 (6.6%) had severe pain and 2(6.6%) had no pain while receiving intramuscular injection in control group.

Table 4: Comparison of mean, standard deviation, standard error and t value on level of needle stick pain score of Experimental and controlled group, N=60

Group	Mean	Standard Deviation	Standard Error Mean	Test used	't' value	df	p-value
Experimental group	0.933	1.201	0.219	Independent 't' test	6.153	58	0.014**
Control group	3.5	1.97	0.361				

't'$_{(58)}$ = 2.06, p≤0.01 Significant
** highly significant atP≤0.01 ,*** very high significant at P≤0.001

Table 4. Data depicts thatthe level of needle stick pain mean score and SD of experimental group was 0.933± 1.20 and the level of needle stick pain mean score and SD in control group was 3.5 ± 1.97 which calculated 't' value was 6.153 which was greater than table value at p≤0.01 level

There was no statistical association between selected variables with level of needle stick pain score in experimental group. There was a highly significant association found between educational background with level of needle stick pain score in control group as the calculated value of educational background was F value of 7.183 and p value of 0.01, which was more than table value F=2.98.

5. Discussion

In this study the level of needle stick pain mean score and SD of experimental group was 0.933± 1.20 and the level of needle stick pain mean score and SD in control group was 3.5 ± 1.97 which calculated 't' value was 6.153 which were statistically significant at p<0.01 level. Hence, cold application was found highly significant in reducing the needle stick pain of IM injection in experimental group as compared to of IM injection in control group.

The finding was supported by similar study, which was done by Farhadi A and Esmailzadeh M. [12] to determine the effect of local cold application on severity of pain during penicillin benzathine (1/200/000 u) intramuscular injection.. Data was collected using questionnaire and visual analogue scale and analyzed with t-test. Results showed that local cold significantly decreased the severity of pain due to penicillin benzathine Intramuscular injection in case group as compared with control group (p=0/000). This concluded that local cold application could play an important role in decreasing pain during penicillin benzathine intramuscular injection.

There was a significant association found between educational background with level of needle stick pain score while receiving intramuscular injection in control group. Technique which projects F value of 7.183 and p value of 0.01. The findings are in congruence with the study conducted by P Pande[11]to assessof the effectiveness of cold application prior to intramuscular injection on the intensity of pain among adults' patients. The study revealed that in the experimental group there was a significant association of intensity of pain with educational status and there was no association found with age, gender, occupation, and previous experience of pain.

6. Conclusion

Based on the present study, there was significant reduction in the level of needle stick pain of patients receiving IMinjection with cold application, compared to IM injection without cold application.

7. Recommendations

From the findings of the present study, the following recommendations are offered for further research:

1) Similar kind of study can be conducted on a large sample size.
2) Similar study can be done to assess effectiveness of cryotherapy in reducing pain of IV injection, AV fistula and ABG etc.
3) A comparative study can be done between the effectiveness of various non -pharmacological measures for pain associated with intramuscular injection. .
4) The same study can be conducted in neonates, paediatrics and old age people.
5) The study can be conducted using true experimental design.

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Author Profile

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Dr. A Tamilselvi has done her Ph.D. in nursing from INC consortium in collaboration with WHO and RGUHS, Bangalore, post graduated from Saveetha College of Nursing, Tamil Nadu and graduated from College of Nursing, Madras Medical College, Tamil Nadu. She has been an expert in the field of Nursing for more than 21 years and has held various post in various esteemed hospitals and institutions and also a registered general nurse in Cork University Hospital, Ireland. A life time member of renowned professional bodies like TNAI ,She is also a member of the Editorial Board of many National and International Journals and certified for under taking various **online Continuing Nursing Education (CNE)** module on "nurses' guide to pain management, pulmonary system etc. She is actively involved in research presently PhD guide in Amity University Haryana, guided over 50 research projects in the field of Nursing and published research studies and books in peer reviewed journals. She has prepared protocols on different nursing procedures like care of patients during blood transfusion, ECG interpretation etc. Her function as Organizer, resource person, observer and delegate in more than 50 international and national conferences and workshops. In the year 2017 mam received the ***"PSG Faculty of the year award 2017"*** **f**rom the PSG Management.

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