Effectiveness of Cryotherapy on Pain Relief among Patients Receiving Intramuscular Injection

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Abstract

Background: Cryotherapy is one of the simplest and oldest therapeutic techniques used in physical rehabilitation; it involves the cooling of a target tissue to promote a decrease in local metabolism and to reduce injury symptoms. **The present study aimed to** assess the effectiveness of cryotherapy on pain relief among patients receiving intramuscular injection **Research design:** A quasi-experimental research design was utilized in this study.
 Setting: the study was carried out in medical departments at the Benha University Hospital. **subjects:**A convenience sample of (80) adult patients with vitamins intramuscular injection and divided into two equal groups: (control group who not received intramuscular injection and study group who received intramuscular injection 40 for each). **Tools for data collection:** Three tools were used in this study; **Tool 1:** A structure interview assessment sheet
 which included three parts; it was designed to assess patient demographic data and health data ; **Part I**: Patients' sociodemographic characteristics. **Part II:** Health data assessment. **Part III:** Questions related to factors that increase the severity of pain. **Tool 2**: Pain assessment sheet included two parts; **Part I-**Checklist of nonverbal pain indicators to assess the patients' pain level regarding intramuscular injection and the application of cryotherapy, **Part II-** Verbal pain assessment sheet to assess character of pain result from intramuscular injection and cryotherapy. **Tool 3:** Universal pain assessment scale to assess pain intensity marked by word descriptors. **Results:** Showed that highly significant difference regarding pain intensity between control & study post groups and between study pre group &study post group immediately and after ten minute .**Conclusion:** All the study group patients had positive effect of application of cryotherapy in pain relief; where the study group express lower pain intensity than control group during intramuscular injection, these results justified the research hypothesis of the present study. **Recommendations:** The study recommended that an instruction about the application of cryotherapy and its effect on minimizing the pain should be conducted for nursing staff and replication the current study on a large sample of different age groups of patients.

Keywords: Cryotherapy , Intramuscular injection , Pain.

I. Introduction

Intramuscular (IM) injections are a widespread and painful part of routine health care. Moreover, injection pain is a common complaint of patients especially chronic patients who are experiencing repeated injection that let them escape, sometimes faint, to keep away from visiting the physician, or even refuse essential treatments **(Mohammed et al., 2017).**

Intramuscular injection is a technique used to deliver a medication deep into the muscles. This allows the medication to be absorbed into the bloodstream quickly; intramuscular injections are a common practice in modern medicine. They're used to deliver drugs and vaccines. **(Weatherspoon , 2017).**

The current definition of pain is established by 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, or described in terms of tissue damage, or both." This definition is the culmination of centuries of ideas and work that have explored the concept of pain **(Moayedi & Karen, 2012).**

Cryotherapy is one of the simplest and oldest therapeutic techniques used in physical rehabilitation; it involves the cooling of a target tissue to promote a decrease in local metabolism and to reduce injury symptoms, aiding the healing process. **(Freire et al., 2016).**

The clinical application of low temperatures is recommended for inflammatory conditions, such as swelling and acute localized pain. It is essential to clarify the distinction and clear labeling of methods based on low temperature usage and the intended purpose, as the body's response to low temperature depends on the temperature, method of application, exposure time, method and rate of heat loss, humidity of the cooled air, and the characteristics and age of the subjects **(Lubkowska , 2012).**

Nurses are ethically and legally responsible for managing pain and reliving suffering.   Effective pain management not only reduces physical discomfort, but also improves quality of life. To prevent post-injection pain, nurses need to be knowledgeable of the assessment of pain, psychosocial and cultural factors affecting pain expression, genetic and ethnic determinants of pain threshold and pain tolerance and most importantly, current evidence-based practices regarding pain. However, although it is a common nursing practice, there is a paucity of research on IM injection **(Mohammed et al., 2017).**

Significant of the study:

According to **(WHO, 2011),** injections are the most frequently used medical procedures. Each year 16 billion injections are managed in developing countries. The vast majorities, around 95% are given in curative care, a large number of individuals are upset from fear of injections, chronic patients are experiencing repeated injection which let them escape, in some cases faint, to keep away from visiting the doctor, or even refuse essential treatments **(Ramadan et al., 2016).**

Therefore it was important to identify the effect of cryotherapy on pain relief among patients receiving intramuscular injection as a non-pharmacological pain management among patients. In this manner more studies are required to determine the effect of local cold therapy on pain management in patients receiving IM injection, so the present study will be conducted to determine the effectiveness of cryotherapy on pain management among patients receiving intramuscular injection.

Aim of the study:

The aim of the present study was to assess the effectiveness of cryotherapy on pain relief among patients receiving intramuscular injection.

Research Hypothesis:

Patients who receive cryotherapy will be express lower pain intensity than the patients who don't receive cryotherapy during administration of intramuscular injection.

II. Subjects and Methods

Research Design:

A Quasi –experimental design was utilized to meet the aim of this study.

Study setting:

The study was carried out in medical departments at the Benha University Hospital.

Subjects:

A convenience sample of (80) adults from both sex was taken receiving vitamins intramuscular injection who accepted to participate in this study within 6 months in the above mentioned setting was recruited and divided into two equal groups: (control group who not received cryotherapy before intramuscular injection and study group who received cryotherapy before intramuscular injection 40 for each), the patients had been selected according to the following criteria:

The exclusion criteria:

- Patients who have disease with chronic pain.

- Unconscious patients who take (sedation, addiction, alcoholism and drug abuse patient).

- Patients who have impairment in circulation or have peripheral vascular disease.

- Patients who have local infection and inflammation in the site of injection.

Tools of Data Collection
Three tools were used to collect study data:

Tool 1: Structure interview assessment sheet:
    It was adapted by the researcher based on recent literature review in a simple Arabic and English language. It was based on **(Holle et al., 2014)** It was designed to assess patient demographic data and health data and consisted of three parts as the following:
Part I: Demographic data: It involved 5 items related to, age, gender, level of education, occupation and place of resident.
Part II: Health data assessment: It included 7 items related to present history and physiological assessment data.
A) Present history, which included 5 Items related to hospitalization, diagnosis, current IM vitamin medication, current complaint, changing sleep patterns.
B) Physiological assessment data (respiratory rate, pulse and blood pressure).
Part III: Questions related to factors that increase the severity of pain: It included 8 closed ended questions.

Scoring system for factors that increase the severity of pain questionnaire:
The answer for each question included 2 options either yes or no. If the patient answer was no it was scored (zero). If his answer was yes it was scored (1) grade.
The 1st and 2nd questions state degree if the answer yes the degree was categorized into Mild =1, Moderate =2, Sever =3 and Extreme =4

Tool 2: Pain assessment sheet: It included 2 parts as following:

Part I-Checklist of nonverbal pain indicators (CNPI): This tool was adopted from (**Pollack ,2016) an observational tool,** is a modified version of the University of Alabama Pain Behavior Scale to assess the patients' pain level regarding intramuscular injection and the application of cryotherapy, This tool consists of 6 behaviors that are commonly considered to be associated with pain: vocal complaints (non verbal) as moans, facial grimaces, bracing, rubbing, restlessness and vocal complaints(verbal) as ouch.

Scoring system for Checklist of nonverbal pain indicators: (CNPI):
Each of these categories is scored from 0-2 as the following:
Score 0= behavior not observed.
Score 1= behavior is observed immediately after injection either during rest or movement.
Score 2= behavior is observed after ten minute of injection either during rest or movement.

Part II- Verbal pain assessment sheet: It was adapted by the researcher after reviewing the related literature **(Doyle &Cutcheon, 2015) & (Cryoaction , 2016):** It was devoted to assess character of pain result from intramuscular injection and cryotherapy it includes 3 parts as the following:

Part A: Questions related to intramuscular injection pain: This part consisted of 10 closed ended questions.

Part B: Questions for patients about the character of pain: which consist of 6 closed ended questions.

Part C: Questions for patients' knowledge about application of cryotherapy: it consists of 11 closed ended questions.

Scoring system for verbal pain assessment sheet:
Part A: The answer for each question included two options either yes or no. If the patient answer was no it was scored (zero). If his answer was yes it was scored (1) grade. Except 2nd part in the 1st question it include another score : state degrees if the answer yes the degrees was categorized into Mild =1 , Moderate =2 and sever =3.
Part C: The answer for each question included two options either yes or no. If the patient answer was no it was scored zero. If his answer was yes it was scored 1 grade, state degree was categorized as the following: Complete right answer =2 , Incomplete right answer =1 and Wrong answer =0 The total score for every question was calculated and converted into percent. These scores were summed-up and converted into a percent score, then categorized as follow:
❖ Score < 60 % referred to inadequate.
❖ Score ≥ 60 % referred to adequate.

Tool 3: Universal pain assessment scale:
It was adopted from **(Belcheva & Shindove, 2014).** There are six levels of pain quality and intensity marked by word descriptors, each patient was asked to point to the face or choose the number which most closely depicted its pain perception during procedure.

Scoring system for Universal pain assessment scale:
0= No pain, 1-3= Mild pain, 4-6= Moderate pain, 7-8= Sever pain and 9-10 = Worse pain.

Methods

Ethical Consideration

Human rights must be considered by explaining the aim and benefits of the study as well as the procedure of data collection to all participants clearly. The participants' approvals were taken after informing them that their participation is optionally, and that they have the right to withdraw at any time without any consequences. Then, Verbal and written consent was obtained from each patient enrolled into the study. They were reassured that all information would be anonymous, confidential and it would be used only for their benefit and for research purposes.

Pilot study

Pilot study was conducted on (10 %) of the study sample (8 patients) taking intramuscular vitamins injection in 7 days to test the applicability of the study and the clarity, feasibility, objectivity of the developed tools, as well as to estimate the time needed for data collection. According to the results obtained from pilot study. The minor modifications were done in two weeks before starting the study. Patients who participated in the pilot study were excluded from the main study sample.

Field of work

➢ An official letter was forwarded from the dean of the Faculty of Nursing; Benha University requesting a permission to conduct the study, and a written official permission were obtained from the administrative director of Benha University Hospital and from Head of the Departments to carry out the study.

➢ Data collection of this study was carried out through six months, during the period from the beginning of April 2018 to end of September 2018.

➢ Structured interview was conducted individually for each patient eligible for the study in order to explain the purpose study, assure confidentiality and obtained patient's consent to participate in the study.

➢ Patients allocated to the study group was applied cryotherapy then given intramuscular injection). While patients in control group (was given intra intramuscular injection only).

A- Assessment phase:

This was the first phase, where data were collected from the patients and from their current medical records using **tools 1** which include: Demographic, Health data assessment and Questions for patients about the factors that may increase the severity of pain.

B- Planning phase:

Proposed Cryotherapy procedure was prepared based on relevant literatures and researches.

C-Implementation phase:

- The researcher visited the study setting 3days weekly at morning shift to collect data and implement this study.

-Unifying factors that may affect intramuscular injection pain include:

❖ Drug: neurovit vitamins

❖ Needle size: 20-22 gauge

❖ Site: dorsogluteal site

❖ Insertion angle : 90º

❖ Aspiration: Aspirated

❖ Injection amount: 3ml

❖ Needle withdrawal :At the same angle as insertion

❖ After the injection**:** Applying a light pressure at the injection site after the injection and not massaging the site

- The researcher was measured physiological data (respiratory rate, pulse and blood pressure) to control and study group, Then the researcher and the nurse in the ward was given intramuscular injection to control group patients (aspect technique followed during procedure according the hospital policy) without applying cryotherapy and the pain score was be recorded through using of **tool 3 , tool 2 Part I & part II (A & B)** and through measuring physiological data (respiratory rate, pulse and blood pressure) by using health data assessment sheet immediately after injection then use **tool 2 Part II(part C)** to assess the patients' knowledge about cryotherapy.

 -The researcher was given intramuscular injection to study group patients without applying cryotherapy and made pre- test, the pain score was be recorded through the using of **tool 3, tool 2 Part I & Part II (A & B)** and through measuring physiological data (respiratory rate, pulse and blood pressure) by using health data assessment sheet immediately after injection then use **tool 2 Part II (part C)** to assess the patients' knowledge about cryotherapy.

   -Then the researcher was applied cryotherapy to the study group patients by applying ice pack (ice of a frozen distal water inside plastic bag by slow circular motion) on site of injection for at least 20 seconds or until skin numbness felt (replacing the frozen ice bag occurred when necessary if ice melting start), then the intramuscular injection was given and made post- test the pain score was be recorded through the using of **tool 3 , tool 2 Part I & Part II (A & B)** and through measuring physiological data (respiratory rate, pulse and blood pressure) by using health data assessment sheet immediately after injection then use **tool 2 Part II(part C)** to assess the patient's knowledge about cryotherapy.

D-Evaluation phase:

It aims to reassess pain after intervention phase to identify the progress in term of differences in the level of response from baseline it was done after ten minutes of intervention using tools (**tool 1, tool 2 Part I & Part II (A & B) and tool 3).**

Statistical analysis

The data collected from the studied patients was revised, coded and entered into an excel sheet on the computer. Statistical analysis was fulfilled using the statistical package for social sciences (SPSS) version 20. Variety of statistical methods were used to analyze the data in this study as Qualitative variables were presented as number and percentage distribution. Chi-square test was used to examine the relation between qualitative variables. Quantitative variables were presented as Mean and standard deviation. Also Cronbach's alpha test was used to test the reliability of the tools. Cronbach's alpha test that was (0.62) for the patients' knowledge about application of cryotherapy questionnaire and (0.82) for the checklist of non-verbal pain indicator. The observed differences and associations were considered as the following: N0n significant (NS) P>0.05, Significant (S) P< 0.05*, highly significant (HS) P<0. 001**

III. Results

Table 1: illustrates frequency distribution of the studied sample according to their socio-demographic characteristics (study & control group). It revealed that; more than half (55%), (57.5%) of the control and study groups were females, with the mean age of control and study group (37.8±11.86 & 38.6±10.72) respectively. Concerning to their educational level one third of control group (35%) were University level and more than one third of the study group (37.5%) were Secondary level, Regarding to working the same table clarifies that, one third of control and study groups (35%) were house wife; and one third of the study group (35%) were Employee, The table also reveals that more than half of control group (55%), and the majority of study group (75%) were lived in Urban area.

Table 2: represents Mean and standard division of studied sample regarding physiological assessment data (study & control group). It shows that the shows that, there were high statistically significant differences regarding to systolic & diastolic pressure and pulse between control and study post group Immediately &After ten min and between control, study post & study pre group in relation to pulse Immediately &After ten min, while was non statistically significant difference in relation to systolic & diastolic pressure and respiration between groups study pre and control and between study pre and study post group (before, immediate and after ten min) of intramuscular injection.

Table 3a: illustrates frequency distribution of studied groups regarding to Checklist of nonverbal pain indicator (study & control group). It showed that comparison between control and study group regarding to CNPI;, There were high statistically significant difference between control & study post immediately in relation to vocal complaints(nonverbal) , facial grimaces and bracing immediately after intramuscular vitamins injection and after 10min in relation to Bracing , While there was no statistically significant difference between control group & study pre group in relation to vocal complaints, facial grimaces and bracing immediately of intramuscular vitamins injection.

Table 3b: illustrates frequency distribution of studied group regarding to CNPI (study & control group). It revealed that, comparison between control group and study group regarding to CNPI; There were high statistically significant differences between control & study pre group immediately , between control & study post group immediately and between control & study post group after 10 minutes in relation to Rubbing, Restlessness and Vocal complaints (verbal), While there was no statistically significant difference between control group , study pre group & post group immediately and after 10 minutes after intramuscular injection regarding to Vocal complaints (verbal).

Table 4: displays frequency distribution of studied sample regarding universal pain scale (study & control group). It showed that comparison between study and control groups regarding universal pain scale was highly significant difference between control & study post groups (60%) of patients' had score (7) and (60.0%) of patients' had score (2) respectively immediately, and between study pre group &study post group (57.5%) of patients' had score (2) and (72.5%) of patients' had score (0) respectively after ten min.

Figure 1: Illustrated that, the majority of control group and study pre group had inadequate knowledge about cryotherapy. While three quarters of study post group had adequate knowledge about cryotherapy.

Table 5: illustrates correlation between total pain score and gender, age, level of education & residence. Indicates that, there was a negative correlation between total pain score and socio-demographic characteristics regarding to age in study pre group immediately & post group after ten min and also there was statistically significant correlations regarding to occupation in study pre group &study post group immediately.

Table (1): Frequency distribution of the studied sample according to their socio-demographic characteristics (study & control group) (n=80).

Socio demographic characteristics	Study (n=40)		Control (n=40)		X^2	p-value
	No	%	No	%		
Gender						
Male	17	42.5	18	45.0		
Female	23	57.5	22	55.0	0.05	0.82
Age (years)						
20-30	12	30.0	8	20.0		
> 30 - < 40	8	20.0	17	42.5	4.75	0.09
≥ 40 - 60	20	50.0	15	37.5		
Mean ± SD	38.6±10.72		37.8±11.86			
Level of Education						
Illiterate	5	12.5	5	12.5		
Primary	8	20.0	10	25.0	0.99	0.80
Secondary	15	37.5	11	27.5		
University	12	30.0	14	35.0		
Occupation						
Doesn't work	6	15.0	5	12.5		
Employee	14	35.0	8	20.0	5.52	0.35
Farmer	2	5.0	2	5.0		
Private work	2	5.0	3	7.5		
Worker	2	5.0	8	20.0		
Housewife	14	35.0	14	35.0		
Place Of Resident						
Rural	10	25.0	18	45.0		
Urban	30	75.0	22	55.0	3.51	0.06

Not significant at P > 0.05   * Significant at P < 0.05   ** High significant P < 0.01

Table (2): Mean and standard division of studied sample regarding physiological assessment data (study & control group) (n=80).

Variable	Control Mean ±SD	Study pre Mean ±SD	Study post Mean ±SD	t1 p-value	t2 p-value	t3 p-value
Systolic						
Before	120.2±9.33	119.7±10.85	119.1±10.85	0 .221 0.826	0.497 0.621	1.094 0.281
Immediately	125.8±8.15	126.1±8.95	122.1±10.49	0.131 0.896	1.78 0.07	6.676 0.000**
After ten min	121.1±6.04	122.2±8.00	119.3±8.4	0.710 0.480	1.069 0.289	5.387 0.000**
Diastolic						
Before	77.8±8.54	78.2±8.95	78.0±8.82	0.192 0.849	0.064 0.949	0.305 0.762
Immediately	83.6±7.42	85.1±7.29	79.5±7.82	0.912 0.365	2.41 0.018	7.579 0.000**
After ten min	80.6±6.11	85.1±7.29	79.0±7.77	0.695 0.489	1.039 0.302	3.920 0.000**
Pulse						
Before	82.2±10.23	72.0±7.30	70.6±6.28	5.105 0.000	6.097 0.000	1.303 0.200
Immediately	86.4±9.64	77.2±7.01	73.5±6.78	4.918 0.000**	6.91 0.000**	3.368 0.002*
After ten min	82.2±8.39	74.3±6.72	71.2±5.77	4.630 0.000**	6.794 0.000**	3.779 0.000**
Respiration						
Before	19.3±2.25	18.3±2.22	19.2±1.79	1.896 0.062	.055 0.956	2.481 0.018
Immediately	22.0±2.49	19.6±2.57	19.7±2.55	4.144 0.000	3.982 0.000	.264 0.793
After ten min	23.1±15.88	18.30±1.84	18.2±2.30	1.919 0.059	1.921 .058	.078 0.938

t1 independent t test between groups study pre and control
t2 paired t test between study pre and study post
t3 between control and study post

Table (3a): Frequency distribution of studied groups regarding to Checklist of nonverbal pain indicator (study & control group) (n=80).

Indicator	Control group Immediate		Control group After ten min		Study pre group Immediate		Study pre group After ten min		Study post group Immediate		Study post group After ten min		X^2_1	X^2_2	$X^2 3$
	No	%	No	%	No	%	No	%	No	%	No	%			
Vocal complaints: nonverbal															
Behavior not observed	0.0	0.0	30	75.0	0	0.0	37	92.5	3	7.5	36	90.0			
Observed during rest or movement	36	90.0	10	25.0	21	52.5	3	7.5	37	92.5	4	10.0	0.20	23.2	3.11
Observed during rest and movement	4	10.0	0.0	0.0	19	47.5	0.0	0.0	0.0	0.0	0.0	0.0	0.65	0.000**	0.07
Facial Grimaces															
Behavior not observed	0.0	0.0	32	80.0	0	0.0	32	80.0	5	12.5	38	95.0			
Observed during rest or movement	23	57.5	8	20.0	29	72.5	8	20.0	35	87.5	2	5.0	1.97 0.16	24.4 0.000**	4.11 0.04*
Observed during rest and movement	17	42.5	0.0	0.0	11	27.5	0	0.0	0.0	0.0	0.0	0.0			
Bracing															
Behavior not observed	0.0	0.0	10	25.0	0	0.0	9	22.5	27	67.5	39	97.5			
Observed during rest or movement	20	50.0	30	75.0	16	40.0	31	77.5	13	32.5	1	2.5	0.80 0.36	48.4 0.000**	44.2 0.000**
Observed during rest and movement	20	50.0	0.0	0.0	24	60.0	0.0	0.0	0.0	0.0	0.0	0.0			

Not significant at P > 0.05   * Significant at P < 0.05   ** High significant P < 0.01

X2 1 between control & study pre immediately
X2 2 between control & study post immediately
X2 3 between control & study post after 10 minutes

Table (3b): Frequency distribution of studied group regarding to CNPI (study & control group) (n=80).

Indicator	Control group Immediate No	%	Control group After ten min No	%	Study pre group Immediate No	%	Study pre group After ten min No	%	Study post group Immediate No	%	Study post group After ten min No	%	X^2_1	X^2_2	X^2_3
Rubbing															
Behavior not observed	23	57.5	3	7.5	5	12.5	6	15.0	38	95.0	37	92.5	25.4		
Observed during rest or movement	11	27.5	37	92.5	8	20.0	34	85.0	2	5.0	3	7.5	0.000**	15.9	57.8
Observed during rest and movement	6	15.0	0.0	0.0	27	67.5	0	0.0	0.0	0.0	0.0	0.0		0.000**	0.000**
Restlessness															
Behavior not observed	0.0	0.0	6	15.0	0	0.0	9	22.5	40	100.0	36	85.0	15.6		
Observed during rest or movement	17	42.5	34	85.0	34	85.0	31	77.5	0.0	0.0	4	10.0	0.000**	80.0	45.1
Observed during rest and movement	23	57.5	0.0	0.0	6	15.0	0.0	0.0	0.0	0.0	0.0	0.0		0.000**	0.000**
Vocal complaints: verbal															
Behavior not observed	0.0	0.0	32	80.0	0.0	0.0	0.0	0.0	0.0	0.0	0	0.0			
Observed during rest or movement	34	85.0	8	20.0	33	82.5	33	82.5	37	92.5	34	85.0	0.09	68.9	0.34
Observed during rest and movement	6	15.0	0.0	0.0	7	17.5	7	17.5	3	7.5	6	15.0	0.76	0.000**	0.55

Not significant at P > 0.05   * Significant at P < 0.05   ** High significant P < 0.01

X2 1 between control & study pre immediately
X2 2 between control & study post immediately
X2 3 between control & study post after 10 minutes

Table (4): Frequency distribution of studied sample regarding universal pain scale (study & control group) (n=80).

Indicator	Control				Study pre				Study post				X^2_1	X^2_2	$X^2 3$
	Immediate		After ten min		Immediate		After ten min		Immediate		After ten min				
	No	%	No	%	No	%	No	%	No	%	No	%			
0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	29	72.5	79.0 0.000**	1.53 0.67	64.7 0.000**
1	0.0	0.0	6	15.0	0.0	0.0	4	10.0	15	37.5	10	25.0			
2	0.0	0.0	21	52.5	1	2.5	23	57.5	24	60.0	1	2.5			
3	0.0	0.0	13	32.5	0.0	0.0	12	30.0	1	2.5	0.0	0.0			
4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
6	9	22.5	0.0	0.0	5	12.5	0.0	0.0	0.0	0.0	0.0	0.0			
7	24	60.0	0.0	0.0	20	50.0	1	2.5	0.0	0.0	0.0	0.0			
8	7	17.5	0.0	0.0	14	35.0	0.0	0.0	0.0	0.0	0.0	0.0			

Not significant at P > 0.05   *** Significant at P < 0.05**   **** High significant P < 0.01**

X^2 1 between immediately control and study immediate post
X^2 2 between control after 10 minutes and study pre after 10 minutes
X^2 3 between study pre after 10 minutes and study post after 10 minutes

Figure (1): Frequency distribution of studied sample (control & study) regarding total knowledge score through phases
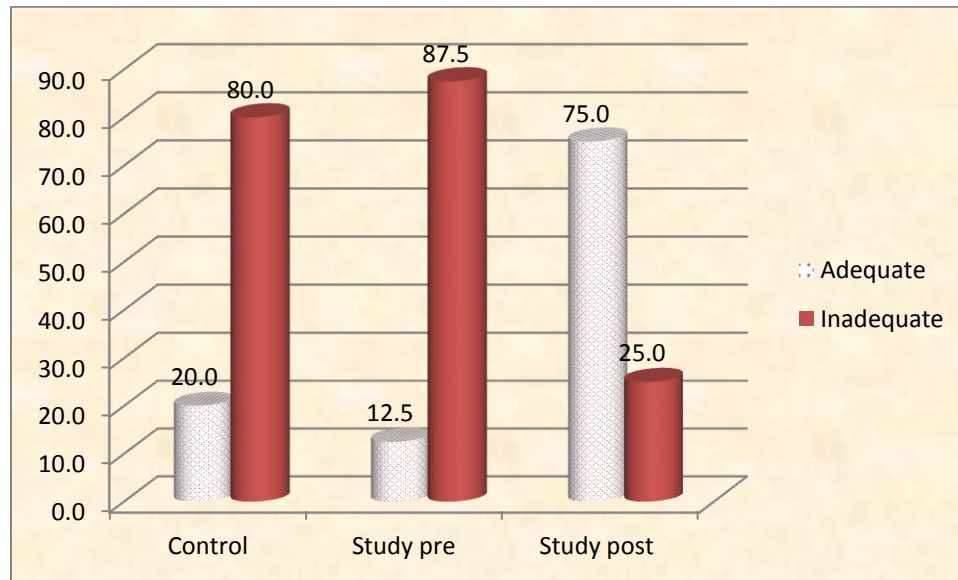
Table (5): Correlation between total pain score and gender, age, level of education & residence

Socio demographic characteristics	Control immediately		Study pre immediately		Study post immediately		Study post after10m		control after10m		Study pre after10m pre	
	R	p-value	r	p-value	r	p-value	r	p-value	r	p-value	r	p-value
Gender	0.09	0.57	-0.22	0.15	-0.17	0.26	0.17	0.28	-0.002	0.99	-0.05	0.71
Age	0.03	0.81	-0.33	0.03*	-0.17	0.27	-0.32	0.04*	-0.03	0.81	-0.02	0.87
Level of Education	-0.21	0.18	-0.28	0.07	0.09	0.55	-0.15	0.35	-0.15	0.35	-0.10	0.52
Occupation	0.05	0.72	-0.42	0.007*	-0.43	0.005*	0-0.05	0.74	0.20	0.19	-0.12	0.43
Residence	-0.13	0.39	0.23	0.14	0.01	0.92	-0.06	0.67	0.06	0.69	-0.05	0.71

Not significant at P > 0.05   * Significant at P < 0.05   ** High significant P < 0.01

IV. Discussion

Cryotherapy can effectively reduce the sensation of pain. It might be a simple, safe, and effective method of reducing hazards and physiologic responses that may arise from pain during intramuscular injection **Sundar et al., (2017).** The present study aimed to assess the effectiveness of cryotherapy on pain relief among patients receiving intramuscular injection.

Based on the results of this study, in relation to patients' socio demographic characteristic of both groups there were no statistically significant differences between study group and control group indicating that the randomized groups were reasonably well balanced , regarding to sex there where more than half in study and control groups were female .

This results supported by the finding of **Green et al., (2017)** who revealed the vitamin B12 deficiency can affect individuals at all ages, but most particularly elderly individuals. Infants, children, adolescents and women of reproductive age, This finding is inconsistent with **Ibraheem (2016)** who revealed the majority of participants were male in both control and study groups.

Regarding to age the present study revealed that, there were more than one third of control group and half of study group age ranged from 30:40 yrs & 40:60yrs respectively, this may due to women in reproductive age high risk of Vitamin B12 deficiency, and this finding agree with **Ramadan et al. (2016)** who emphasized that, the highest proportions in socio demographics of study subjects with Vitamin B12 deficiency were female and the study subjects age ranged from 22 to 56 years old.

Regarding level of education, the present study illustrated that, about one third of both groups under the study were Secondary & University education. This finding may be due to that the majority of control group and more than half of study group lives in Urban. This finding is in accordance with **Ibraheem (2016)** whose study results revealed that more than half in the study group and control group have secondary school &university graduates.

Concerning the occupation, the current study revealed that, one third of both groups were house wives. This finding may be due to that more than half of patients in the study and control groups were female also, one third of patients in control group were employee. this agree with **Taha et al. (2013)** who reported that most of both groups were house wives also, agree with **Ali et al. (2014)** who revealed that most of both groups were housewives.

Regarding residence, the results of this study revealed that, the majority of study group and more than half of control group lives in urban. These results agree with **Gudlavalleti et al. (2014)** who reported that the prevalence of hypertension was increasing with urban residence. This finding may due to increase stress, noise and lifestyle in urban, this study disagree with **Ramadan et al. (2016)** whose study results revealed that the majority of study subjects were from rural residence.

Regarding to physiological measurement, the current study revealed that, the study post group recorded high statistically significant differences regarding decrease pulse immediately and after ten minutes when comparing to the study pre group & control group and recorded high statistically significant differences regarding to decrease systolic and diastolic BP immediately & after ten min when comparing the control & study post group this may be related to decrease pain intensity after apply cryotherapy. These results were in accordance with **Khalil (2017)** who showed that heart rates were

significantly different between the both groups, as the study group recorded lower heart rate when compared to the control group. Also, these results disagree with **Attia & Hassan (2017**) whose study results reported that, the hemodynamic parameters including heart rate and blood pressure before and after cryotherapy were not statistically significant.

Regarding to the observational checklist of non-verbal pain indicators scores, between control ,study pre group & study post group in two time interval (immediate and after ten minute) the current study concluded that there were high statistically significant differences regarding to lower incidence of behavioral responses to pain, such as vocal complaints: nonverbal, facial grimacing, bracing, rubbing, vocal complain (verbal) and restlessness among patients exposed to intramuscular injection after cryotherapy (study post group). This is confirmed with **Ramadan et al. (2016)** whose study results stated that high statistically significant differences of observed non–verbal pain indicators scores before and after the intervention.

Regarding universal pain assessment tool, the present study showed that there were   high statistically significant difference regarding decrease pain intensity between control & study post immediate and between study pre & study post after 10 minutes .The findings of the current study was congruent with **Ramadan et al. (2016)** who found that the pain intensity on numerical rating scale was observed to be statistically significant reduced within the study group by the use of cryotherapy. This result also agree with **Jantaracharut et al. (2016)** who revealed that the patients who received cold compression had less pain score, inflammation, swelling and skin necrosis than those patients who did not receive cold compression.

 Regarding total knowledge about cryotherapy the present study indicated the majority of control group and study pre group had inadequate knowledge about cryotherapy. While three quarters of study post group had adequate knowledge about cryotherapy, this result due to the researcher give the needed information about cryotherapy to the study post group after applied cryotherapy during implementation phase, this agree with **Derewiecki et al. (2016)** who reported in his study more than half of the control group not have sufficient knowledge about cryotherapy.

 Regarding the correlation between total pain score and socio demographic characteristic, the present study reveal that there was no statistically significance correlation between patient gender and level of pain in control, study pre and study post group immediately and after minute and this agree with **Celik et al. (2011)** who revealed that there was no statistically correlation regarding pain and gender

 Regarding the correlation between total pain score and age, the present study found that there was a negative correlation between pain score and studied patients age in the study pre group immediately & study post and after ten min. This result corroborated with agree with **Alam et al. (2016)** who indicated that , statistical significant negative correlation between level of pain and studied patients age during turning procedure

 This result was in contrast with **Khalil (2017)** who reported in their study that the pain score was lower in younger patients than older patients in the study group when compared to control group so there was significant statistical positive correlation regarding perception of pain by their age.

Regarding the correlation between total pain score and level of education , the present study revealed that there was no statistically significant correlation between pain score and level of education ,this result was disagree **Afolayan et al. (2015)** who revealed in their study there was statistically significant correlation between level of education and pain perception

Regarding the correlation between total pain score and place of residence, the present study revealed that there was no statistically significant correlation between pain score and place of residence , this agree with **Lewandowsk & Łukaszewska (2014)** who found that The frequency and localization of Spinal pain are the same in youths living in villages and youths living in cities which indicated no correlation between them .

V. Conclusion

Based upon the results of this study, it could conclude that,   all the study group patients had positive effect of application of cryotherapy in pain relief where the study group express lower pain intensity than control group during intramuscular injection, these results justified the research hypothesis of the present study.

VI. Recommendations

This study recommended that should utilization of the cryotherapy or ice pack in needle puncture pain and on other painful procedures. Instructions about the application of cryotherapy and ice pack and its effect on minimizing the pain should be conducted for nursing staff. Replication the current study on a large sample of different age groups of patients. The hospital should supply various sizes of an ice pack application, or use ice gel.

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