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Effect of Cryotherapy on Pain Intensity among Adult Patients Receiving Intramuscular Injections

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Abstract
Background: *Intramuscular injection (IMI) ismost frequently used but causing painful experience for many individuals. Chronic patients are experiencingrepeated injection which let them escape, sometimes faint, to keep away from visiting the doctor, or even refuse essential treatments. Cryotherapy is generallynamed as cold application which is a simple and cheap therapy,and has been accepted for decades as an effective non-pharmacologic intervention for pain management. Aim of the current study wasto evaluate the effect of cryotherapy on pain intensity among adult patients receiving IMI.*
Subject and Methods: *Quasi–experimental time-series design was carried out in this study. The study was conducted in medical departments at MansouraUniversity Hospital. Total number of (100) participants were recruited for the purpose of the current study, using power analysis that correspond inclusion criteria. Structured interview questionnaire was used to collectdata. (1) The socio-demographic and health data, (2) Universal pain assessment tool and (3) ObservationChecklist of nonverbal pain indicator (OCNPI).*
Results *showed significant positive relation of pain scores before and after the intervention. The study* ***concluded*** *thatthere wasa significant positive effect of cryotherapy on reducingIMI pain. The hypothesis of the present study was accepted whereaspatients who gotcryotherapy communicated lower pain intensity incontrast with patients who did not getcryotherapy during IMI insertion.It wasrecommended thatmedical departments can apply cryotherapy technique toreduce needle puncture pain for IMI in routine care.*
Keyword: *Intramuscular Injection, Cryotherapy, Pain*

I. Introduction

Pain is a multidimensional phenomenon, it is difficult to define, it is an individualand subjective experience, and no two individualsexperience pain is thevery same way. The international association for study of pain (IASP) defines pain as "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or describe in terms of such damage (Hinkle and Cheever, 2014).

Pain is standout amongst the most widely recognized reasons forhuman sufferings, which is considered as a major health problem among adults.There are 16 billion Intramuscular injections(IMI) administeredannually throughout the world(WHO, 2011). Pain resultingfrom IM injection should not be underrated, in light of the fact that a painful injection might affect serious apprehensionof injection, which may lead a patient to postpone looking medical help. Decreasing patients' pain is critical for all nurses in light of numerousreasons. Unnecessary pain can harm the nurse-patient relationship (Ozdemir, Pinarci, Akay and Akyol, 2013).

Intramuscular injections (IMI) are regular complexprocedure used to deliver medication profoundinto the vast muscle of the body(Potter, Perry,Stockert and Hall,2013). It isevaluated that around 10% of American adults are trypanophobic (fear of injections) and 1-3% U.K. population has some sortof fearabout needles (aichmophobia) or injections (trypanophobia) in the light of fact thatthey are deliveringpain(D'costa, 2014).

Many studies are currently available in this field to reduce pain due to injection. A study was conducted to assess the effect of local cold on intensity of pain during IMI due to penicillin benzathin. Resultsdemonstratedthat local cold significantly diminishedseverity of pain in contrastwith control group (Farhadi and Esmailzadeh, 2011).

There are variouspharmacological and non-pharmacological measures to lessen pain. As of late, the non-pharmacological measures of pain management strategyare picking up the prominence, for example cryotherapy, acupressure, massage, acupuncture etc.... (Demir, 2012).Research evidences demonstratedthat non-pharmacological measures complimentary or alternative nursing interventions, which were advocated to minimize pain in patients (Sahngun et al., 2012).

An experimental study was conducted in New Delhi on effect of cryotherapy on arteriovenous fistula puncture related pain in haemodialysis patients, outcomes demonstratedthat the objective and subjective pain scores were observedto be significantly (P= 0.001) reduced within the study group with the use of cryotherapy.

The study inferredthat there was a requirementfor adopting alternative therapies such as cryotherapy for effective pain management in hospital (Sabitha et al., 2008)

Cryotherapy is one of the non-pharmacological techniques utilizedand acted through local skin allotments as indicated bygate – control theory. While utilizingthe body's own nervous system, the GATE control theory mentionsthe ideathat the last normalpathway for sharp pain to the brain can be hinderedby the nerves that transmit cold (Costello and Donnelly, 2010).

Cryotherapy is generally named as cold applicationwhichis a simple and cheap treatmentand has been acknowledged considerable length of timeas acompellingnon-pharmacologic intervention for pain management.Cold applicationexpands the pain threshold and decreases the inflammatory responseand spasm. Cold application is regularly utilized as a part of the treatment of acute soft tissue injuries and has been appeared to reduce pain effectively in the IMI pain management (Serena, 2010).Toreduce pain, ice only needed to be applied for 30 seconds, though paststudies prescribed 2 to 15 min cold (FarhadiandEsmailzadeh, 2011)

The most well-known techniquesfor cold application incorporatecold packs, cold immersion, and ice massage. Spray and stretch is an application of cryotherapy with a vapocolant spray, which then is followed by stretching of the includedmuscles. Contingent onthe application technique and length of time, the essentialphysiologic impact incorporates,diminishlocal metabolism, vasoconstriction, reactive hyperaemia, lessenedoedema, decreased haemorrhage and reduced muscle effectiveness(Black and Hawks, 2009). In this manner, the present study will be conductedto evaluate the effect of cryotherapy on pain intensity among adult patients receiving intramuscular injections.

II. Significance Of The Study

According toWHO(2011), injections are the most frequently used medical procedures. Each year 16 billion injections are managed in developing countries. The vast majority, around 95% are given in curative care. Immunizations arrange for around 3 % of all injection. A large numberof individualsare upset from fear of injections.Chronic patients are experiencingrepeated injection which let them escape,in some cases faint, to keep away from visiting the doctor, or even refuseessential treatments(Costello and Donnelly, 2010).

Nurses as advocates for adults, are committed to minimize the emotional and physical impactsof painful procedures. Providing pain relief is considered a most basic human right and it is the obligation of the nurse to utilize best way to deal withpain control.

Diverse strategies are utilizedby the nurses to reduce pain during intramuscular injections such as applying pressure, taping the skin, applying heat and cold. Every strategy will have contrastsin their impact on the level of pain during intramuscular injection. Since several studies have been done in this field, it is demanding tocarry on such a study to evaluate the effectiveness of cryotherapy on pain intensity among adult patients receiving intramuscular injection as a non-pharmacological pain management among Egyptian patients.

Hypothesis

Patients who receive cryotherapy will express lower pain intensity compared to patients who do not receive cryotherapy during IMI insertion.

Aim of the Study

To evaluate the effect of cryotherapy on pain intensity among adult patients receiving intramuscular injections.

Research design

Quasi–experimental time-series design was used in this study.The researcher periodically observed the subjects to measure patients' pain intensity with the use of cryotherapy. The experimental treatment is administered before observations to determine if cryotherapy is effective in reducing IMI pain, and if the effectiveness of the cryotherapy persists. Time-series design with its numerous observations or measurements of the dependent variable helps strengthen the validity of the design (Nieswiadomy, 2012).

Setting

The study was conducted in medical departments at Mansoura University Hospital.

Subject

Total number of (100) participants were recruited for the purpose of the current study using power analysis. The power analysis indicated that (85)participants with a power of .80 ($\beta = 1-.80 = .20$) at alpha .03 (one-sided) was used as the significance level, because these levels had been suggested for use in the most areas of behavioural science research (Ellis, 2010).

In addition, the medium effect size (0.3) is conventional effect size in behavioural science that will be used when the new area of research and when instruments have not well been tested (Murphy andMayors, 2004). Although the minimum numbers of 85 subjects were required by power analysis, the researcher was aimed to obtain 100 subjects in this study because ten percent of non-response rate were expected to be dropfrom the subjects.

Data was collected for three months started from July till October 2014.

Inclusion criteria

1) Age:Adult patients> 18 years old
2) Sex: Both sexes
3) Medication:Receiving Neurovit intramuscular injection.

Exclusion Criteria

1) Patients with chronicpain associated with other disease condition
2) Sedated and unconscious patients
3) Adult patients who are receiving intramuscular injection for the first time.
4) Patients have impaired circulation, peripheral vascular disease
5) Local infection

Tools

The data was collected throughout the following tools:

1- A structured interview questionnaire developed by the researcher was used to collect the following data:

A- The socio-demographic data of adult patients such as age, gender, educational status, marital status, and place of residence.

B- Health data include height, weight and body mass index.

2- Universal pain assessment tool:developed by Dalton andMcNaull (1998)

This tool includes integrationamong Verbal Descriptor Scale or Numerical Rating Scale (NRS),Wong-Baker Facial Grimace Scale or Visual Analog Scale (VAS) and Activity Tolerance Scale. Through which the patient indicated the level of pain.

A- Verbal Descriptor Scale (VDS)or Numerical Rating Scale (NRS) is a 0-10 scale whereas (zero)=no pain, (1-2)= mild pain, (3-6)=moderate pain, (7-8)=sever pain,(9-10)=worst pain.

B- Wong-Baker Facial Grimace Scale (WFGS) or Visual Analog Scale (VAS)uses the patient's facial expression for assessment whereas (zero)=alert smiling, (1-2)= no humor – serious – flat,(3-4)=furrowed brow – pursed lips – breath holding, (5-6)=wrinkled nose – raised upper lips – rapid breathing,(7-8)=slow blink – open mouth, (9-10)=eye closed – moaning – crying.

C- Activity Tolerance Scale (ATS) uses the patient's self-assessment activities whereas (zero)=no pain, (1-2)=can be ignored, (3-4)=interferes with tasks, (5-6)= interferes with concentration, (7-8)= interferes with basic needs, (9-10)=bedrest required.

3- Observationchecklist of nonverbal pain indicator (OCNPI): It is a modified version of the University of Alabama Pain Behaviour Scale (Richards,Nepomuceno, Riles and Suer,1982).

This tool describes behavioral observation to interpret expressed pain when patient cannot communicate his/her pain intensity. The tool consists of 6 items as: 1.Vocal complaints: nonverbal (Sighs, gasps, moans, groans, cries), 2. Facial Grimaces/Winces (Furrowed brow, narrowed eyes, clenched teeth, tightened lips, jaw drop, distorted expressions), 3. Bracing (Clutching or holding onto furniture, equipment, or affected area during movement),4.Restlessness (Constant or intermittent shifting of position, rocking, intermittent or constant hand motions, inability to keep still), 5.Rubbing (Massaging affected area), 6. Vocal complaints: verbal words expressing discomfort or pain [e.g., "ouch," "that hurts"]; cursing during movement; exclamations of protest [e.g., "stop," that's enough”].

Scoring System:

Score"0" if the behavior was not observed. Score "1" if the behavior was observed even briefly during activity or at rest. The total number of indicators is summed for the behaviors observed at rest, with movement and overall.

Validity and Reliability of the tools

Content Validity has been done by fiveexperts in the field of medical-surgical nursing specialty.

In a study done by Hawker,Mian, Kendzerska and French (2011) among patients suffering from rheumatic arthritis pain, reliability of the universal pain assessment tool(Which includes numerical rating scale “NRS” and visual analog scale “VAS”): The NRStest–retest reliability was ranging between r = 0.95 and 0.96, while the VAS test–retest reliability was ranging between r = 0.86 and 0.95.

The observationchecklist of non-verbal pain indicators (OCNPI)tool has been shown to be a reliable among adults with acute or chronic pain, in critical care units.This tool was previously tested byTybergandChlan(2006),NygaardandJarland(2006) and Feldt(2000).

Pilot study

A pilot study was conducted on 10 % of total number of patients to investigate and ensure the feasibility, objectivity, applicability, clarity, adequacy, content validity, and internal consistencyof the study tools and to determine possible problems in the methodological approach or instrument. The results of the pilot study were used to test the proposed statistical and data analysis methods. Subjects involved in the pilot study were excluded from the main study sample.

Ethical consideration

A written approval was obtained from the ethics and research committee of the Faculty of Nursing, Cairo University. Informed consent was sought and obtained from each participating subject after explaining the nature and objectives of the study. Each assessment sheet was coded; subjects' names were not appeared on the sheets for the purpose of anonymity and confidentiality. Subjects were free to withdraw from the study at any time.

Procedure

Once permission was granted to proceed with the proposed study from the hospital director, heads and nursing supervisors of the medical departments, Patients were interviewed individually to explain nature and purpose of the study. Measures were taken to protect subjects' ethical rights. Each potential subject signed an informed consent. Voluntary participation, confidentiality and anonymity were assured.

Work plan was done as the following:

1- Patient was interviewed by the researcher to fill out the socio-demographic characteristics sheet before starting the study.

2- The plan of work before intervention:

a. Several factors might affect pain during injection, such as drug and amount injected, technique used, needle size, patient position, speed of delivery. Therefore standardization of these factors would manipulate all patients in the same manner.

b. Unifying factors affecting pain due to injection as follow:

- Drug = Neurovit.
- Amount of drug=1ml.
- Technique = angle (90^o) degree in dorso gluteal muscle.
- Needle size = 20-22 gauge.
- Position= right/ left side-lying position with knee flexed.
- Speed = rapid.
- Researcher = one

3- In the first time, patient was served as a control group where no intervention (no cryotherapy), the researcher administered IMI of Neurovit vitamin to patient in dorso gluteal muscle with patient in side-lying witha flexed knee, and the pain was recorded onuniversal pain assessment tooland observationchecklist of nonverbal pain indicator just immediately after IMI and then at different time intervals, i.e., 30 minutes and 1 hour interval after the administration of a single injection.

4- Insecond time,after one week or 3days the same patient was served as astudy group where cryotherapy intervention was applied. The researcher positioned the patient in side-lying (right or left site) with a flexed knee, and then applies ice gel (with 2-3cm) on dorso-gluteal muscle for at least 30 seconds. Then inject Neurovit vitamin with needle gauge 20-22. After injection the pain was recorded onuniversal pain assessment tooland observation checklist of nonverbal pain indicator just immediately after IMI and then at different time intervals, i.e., 30 minutes and 1 hour after the administration of a single injection.

III. Results

The results were presented in the following sequence: Description of socio-demographic data and health data of the study subjects, universal pain assessment and observationchecklist of non-verbal pain indicators (OCNPI) before and after intervention.Figure (1a, b, c, d, e, and f) revealed the study subjects' age ranged from 22 to 56 yrs. with mean 40.8±7.0 and median 40. The highest proportions in socio-demographics of study subject were to female gender (65%), basic/ intermediate educated (47%) married status (66%) and rural resident (91%). In relation to health dada, the body mass index range from 19.80 to 42 with mean 31.0±4.3 and median 30.90.

Table (1) Presented comparison of verbal descriptivepain scaleorNRSbefore and after the intervention in first, second, third time and average of 3 times. First time: pain ranged4.0-9.0, mean ±SD 7.5±1.0 and median 8.00 before intervention compared to 0.0-7.0, 0.2±0.8 and 0.00 after intervention with significant positive relation P <0.001. Second time: pain ranged 1.0-6.0, mean ±SD 2.7±1.0 and median 2.00 before intervention compared to 0.0-6.0, 2.1±1.0 and 2.00 after intervention with significant relation P <0.001. Third time: pain ranged 0.0-2.0, mean ±SD 0.3±0.6 and median 0.00 before intervention compared to 0.0-3.0, 0.5±0.7 and 0.00 after intervention with significant positive relation P 0.04. Average of 3 times: pain ranged 2.3-4.7, mean ±SD 3.5±0.6 and median 3.33 before intervention compared to 0.0-4.7, 0.9±0.5 and 1.00 after intervention with significant positive relation P <0.001.

Table (2) represents comparison of Wong-Bakerpain scaleor VASbefore and after the intervention in three time interval: First time: pain range was1.0-4.0,mean1.9±0.5 and median2.00 before intervention compared to 0.0-0.0,0.3± 0.5 and 0.00 after intervention with significant positive relation p-value was<0.001.Second time:pain range was0.0-4.0,mean1.0±0.3 and median1.00 before intervention compared to0.0-1.0,0.9±0.3 and1.00 after intervention with significant positive relation p relation 0.007. Third time:pain range was0.0-1.0,mean0.1±0.2 and median0.00 before intervention compared to 0.0-1.0,0.2±0.4 and 0.00 after intervention with significant positive relation p relation was 0.002.Average of 3 times:pain range 0.3-1.7,mean1.0±2.0 and median1.00 compared to 0.3-1.0,0.4±0.2 and 0.33 with significant positive relation p-value was<0.001.

Table (3) Indicates significant positive relation of activity tolerance scale before and after the intervention in first, third and average of 3 times P <0.001

Table (4) Showed comparison of observednon–verbal pain indicators scores during resting and moving. During resting, there is significant positive relation of observed non–verbal pain indicators scores before and after the intervention in relation to vocal non-verbal complaints (P 0.03), bracing (P <0.001), restlessness (P 0.03), total first time measurement (immediately after injection) (P 0.003) and the total non-verbal (average of 3 times) presence of pain (P 0.007)

During moving, there is significant positive relation of observednon–verbal pain indicators scores before and after the intervention in relation to vocal non-verbal complaints (P <0.001), facial grimaces (P <0.001), bracing (P <0.001), restlessness (P <0.001), total first time measurement (immediately after injection) (P <0.001), and the total non-verbal (average of 3 times) presence of pain (P 0.007).

IV. Discussion

The aim of the present study was to evaluate the effect of cryotherapy on pain intensity among adult patients receiving intramuscular injections. To fulfill the aim of this study, a structured interview was used to collect the socio-demographic, health data questionnaire, universal pain assessment and observation checklist of non-verbal pain indicator questionnaire. The study was conducted with 100 adult patients receiving Neurovit intramuscular injection in medical departments at Mansoura University Hospital.

Regarding socio-demographic characteristics, the study subject age ranged from 22 to 56yrs. with mean 40.8±7.0 and median 40. The majority of study sample were patients diagnosed with liver disease which are common in this age group. Series of studies assessed pain after IMIworks on the same age group. Güneş, Kara, Arı and Ceyhan (2013);Kanika, Rani, and Prasad (2011), and Ağaç&Güneş (2010) agreed the same result. These in addition, the study done by Lakhani et al., (2014), who worked on the intensity of pain experienced by respondents given IMI with/without skin tapping technique mentioned that the age group was 20- 50 years.

According to gender, more than half of study subject were female. That is the majority of study sample were patients diagnosed with liver disease which are common in female.According to Guy and Peters (2013), reported thatacute liver failure, autoimmune hepatitis, benign liver lesions, primary biliary cirrhosis, and toxin-mediated hepatotoxicitywere more commonlypresent in women.On the same theme, Manns et al., (2010) confirmed that women are 10 times more prone to have primary biliary cirrhosis (PBC) than men and 4 times as liable to have autoimmune hepatitis.In this regard, series of studies assessed pain intensity after IMI and found that more than half of study subjects were females(Lakhani et al., 2014;Güneş, Kara, Ari and Ceyhan, 2013;Zoreand Dias,2014;Kanika, Rani and Prasad,2011).

In relation to marital status and educational level of current study subjects, more than half of patients, were married, and about half of them had basic/intermediate education that is related to Egyptian culture. These subjects' educational characteristic wassimilar toLakhani et al., (2014);Zoreand Dias (2014) and Kanika, Rani and Prasad (2011). In relation to residence, the majority of study subjects were from rural region that affiliate and receive medical treatment in Mansoura Universityhospital, whereas the study sample was from Mansoura city.

In relation to health data, the body mass index ranged from 19.80 to 42 with mean 31.0±4.3 and median 30.90 that is two/third of study subjectswere obese,that is may related to Egyptian culture. In the same context,Nisbet (2006), studied intramuscular gluteal injections in the increasingly obese population, also

Zaybak, Gunes, Tamsel, Khorshid&Eşer(2007), evaluated"Does obesity prevent the needle from reaching muscle in IMI worked in obese patients". While Güneş, Kara, Ari and Ceyhan (2013) and Sartorius et al., (2010) found that mean BMI was 27.1 (SD=4.1) and 28.2 ± 0.4 respectively. In the opposite direction, Lakhani et al.,(2014) found that a large portion of the respondentshad a BMI ranging 18.5-24.9 which meant that they had normal weight. And Suhrabi and Taghinejad (2014), found that BMI:(23.74 ± 4.45 vs. 23.88 ± 5.74).

No significant relation was found between body mass index and IMI pain intensity probablybecause they were obese. This result disagrees with Ozdemir, Pinarci, Akay and Akyol, 2013)whospecifiedthat patients with typicaland/or low weight (BMI#24.9kg/m2) exhibited expanded pain severity compared with obese patients at 20 and 25 minutes after a 30-second injection.

Regarding universal pain assessment tool before and after the intervention,andaccording to the verbal descriptor pain scaleor NRS,the present study showed that there wasa significant positive relation of pain intensity before and after the intervention in the three time interval (first, second and third) and the average of three time.The findings of the current study was congruent with Sabitha et al., (2008) who agreed that the pain intensity on numerical rating scale& observation checklist were observed to be significantly (P =0.001) reduced within the studygroup by the useof cryotherapy.

Regarding to Wong-Baker's pain scale or VAS, the present study, showedasignificant positive relation of pain intensitybefore and after the intervention in the three time interval (first, second and third)and the average of three time. These findingswerein the same line withFarhadiand Esmailzadeh, (2011)whoanalyzed the impact of local cold on intensity of pain due to Penicillin Benzathin IMI, using VASresults demonstrated that the local cold therapy was compellingin diminishingintensity of pain due to penicillin benzathin IMI in experimentalgroup in contrastwith control group.In addition,Çelik et al., (2011)reported that, Vapocoolant sprayis compelling for preventing mild to moderate puncture pain in patients experiencinghemodialysis.

Concerning activity tolerance, the study results showed a significant positive relation of activity tolerance scores before and after the intervention in first, third and average of 3 times P <0.001, majority of patient had no pain specially immediately after intervention. These findingsweresupported by Sartorius et al.,(2010) who studied "Factors influencing time course of pain after depot oil intramuscular injection of testosterone undecanoat", they reported that pain required minimal pain relieving utilize and produced minimal interference in daily activities.

Regarding observation Checklist of Non–verbal pain indicators scores (OCNPI) before and after the intervention. There is significant positive relation of observationchecklist of non–verbal pain indicators scores before and after the intervention in the three time interval (first, second and third) and the average of three time. This accepts the research hypothesis that patients who receive cryotherapy expressed lower pain intensity compared to patients who did not receive cryotherapy. The present findings are supported by Sabitha et al., (2008), whowereutilizingobjective and subjective pain scoring using observation checklist and numerical pain rating scale. And found that objective and subjective pain scores significantly (p=0.001) reduced within the studygroup byuse of cryotherapy.

V. Conclusion

There is significant positive effect of cryotherapy on diminishingpain from intramuscular injection. The hypothesis of the present study was accepted thoughpatients who gotcryotherapy communicatedlower pain intensity in contrast withpatients who did not get cryotherapy during IMI insertion.

VI. Recommendations

The current study recommended the following:

- Medical departmentscanapplycryotherapy method toreduceneedle puncture pain forintramuscular injections inroutine care.

-Executethe same study on a larger group of adult with different age groups

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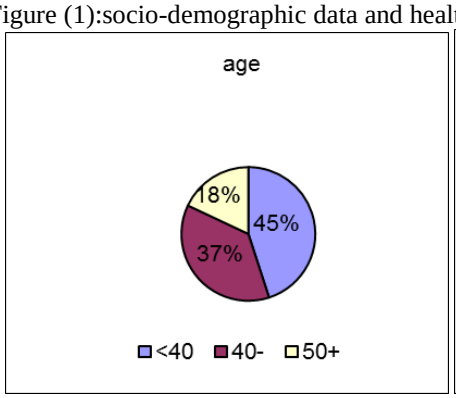
Figure (1):socio-demographic data and health data among patients of the study subject.



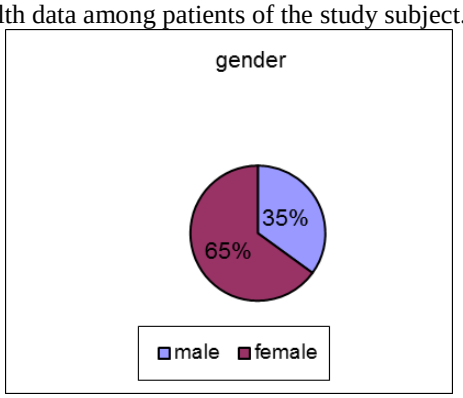
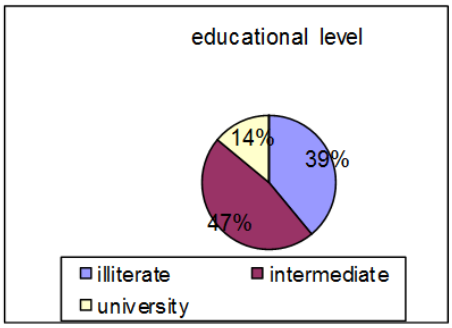


Figure (1a)age Figure (1b)gender



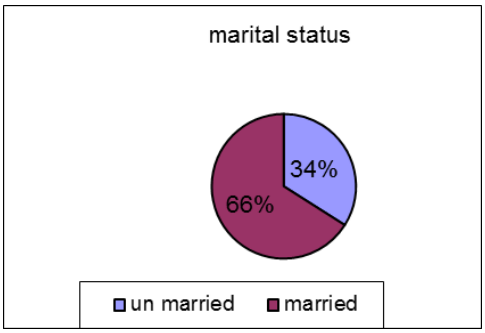
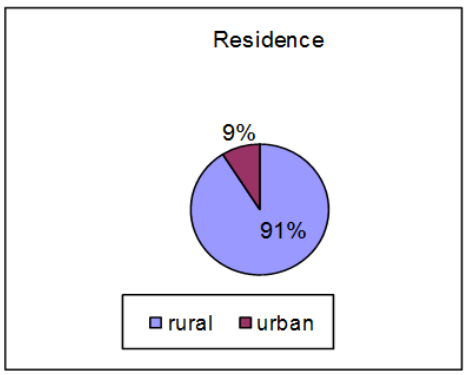


Figure (1c) educational level Figure (1d) marital status



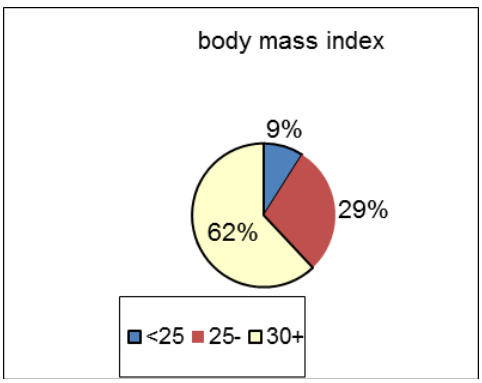


Figure (1e) residenceFigure (1f) body mass index

Table 1: Comparison ofVerbal Descriptive pain scaleor NRS before and after the intervention (n=100).

Verbal Descriptive painscale or NRS	Intervention		Mann-Whitney Test	p-value
	Pre	Post		
First time:				
Range	4.0-9.0	0.0-7.0		
Mean±SD	7.5±1.0	0.2±0.8	166.35	<0.001*
Median	8.00	0.00		
Second time:				
Range	1.0-6.0	0.0-6.0		
Mean±SD	2.7±1.0	2.1±1.0	13.61	<0.001*
Median	2.00	2.00		
Third time:				
Range	0.0-2.0	0.0-3.0		
Mean±SD	0.3±0.6	0.5±0.7	4.36	0.04*
Median	0.00	0.00		
Average of 3 times:				
Range	2.3-4.7	0.0-4.7		
Mean±SD	3.5±0.6	0.9±0.5	146.30	<0.001*
Median	3.33	1.00		

(*) Statistically significant at p<0.05

Table2: Comparison of Wong-Bakerpain scale or VAS before and after the intervention (n=100).

Wong-Baker pain scale or VAS	Intervention		Mann-Whitney Test	p-value
	Pre	Post		
First time:				
Range	1.0-4.0	0.0-0.0		
Mean±SD	1.9±0.5	0.3±0.5	153.73	<0.001*
Median	2.00	0.00		
Second time:				
Range	0.0-4.0	0.0-1.0		
Mean±SD	1.0±0.3	0.9±0.3	7.34	0.007*
Median	1.00	1.00		
Third time:				
Range	0.0-1.0	0.0-1.0		
Mean±SD	0.1±0.2	0.2±0.4	5.92	0.02*
Median	0.00	0.00		
Average of 3 times:				
Range	0.3-1.7	0.3-1.0		
Mean±SD	1.0±2.0	0.4±0.2	142.43	<0.001*
Median	1.00	0.33		

(*) Statistically significant at p<0.05

Table 3: Comparison of activity tolerance scale before and after the intervention (n=100).

Activity Tolerance scale	**Intervention**				**X^2 test**	**p-value**
	Pre		**Post**			
	No.	**%**	**No.**	**%**		
First time:						
0	0	0.0	79	79.0		
1	100	100.0	21	21.0	130.58	<0.001*
Second time:						
0	8	8.0	13	13.0		
1	92	92.0	87	87.0	1.33	0.25
Third time:						
0	98	98.0	83	83.0		
1	2	2.0	17	17.0	13.09	<0.001*
Average of 3 times:						
Range	0.3-1.0		0.0-0.7			
Mean±SD	0.6±0.1		0.4±0.2		84.97	<0.001*
Median	0.67		0.33			

(*) Statistically significant at p<0.05.

Table 4: Comparison of observation Checklist ofnon-verbal pain indicators scores before and after the intervention (n=100)

Non-verbal indicators of pain	Intervention				X^2 test	p-value
	Pre**		Post**			
	No.	%	No.	%		
Resting**:						
Vocal non-verbal complaints	14	14.0	5	5.0	4.71	0.03*
Facial grimaces	21	21.0	15	15.0	1.22	0.27
Bracing	45	45.0	20	20.0	14.25	<0.001*
Restlessness	81	81.0	68	68.0	4.45	0.03*
Rubbing	73	73.0	67	67.0	0.86	0.35
Vocal verbal complaints	73	73.0	67	67.0	0.86	0.35
Total:						
First time	13	13.0	2	2.0	8.72	0.003*
Second time	73	73.0	67	67.0	0.86	0.35
Third time	14	14.0	15	15.0	0.04	0.84
Total non-verbal (average of 3 times)						
Absent	7	7.0	20	20.0		
Present	93	93.0	80	80.0	7.24	0.007*
Moving**:						
Vocal non-verbal complaints	94	94.0	4	4.0	162.06	<0.001*
Facial grimaces	94	94.0	5	5.0	158.44	<0.001*
Bracing	95	95.0	6	6.0	158.44	<0.001*
Restlessness	97	97.0	32	32.0	92.26	<0.001*
Rubbing	26	26.0	30	30.0	0.40	0.53
Vocal verbal complaints	26	26.0	30	30.0	0.40	0.53
Total:						
First time	93	93.0	3	3.0	162.26	<0.001*
Second time	26	26.0	30	30.0	0.40	0.53
Third time	16	16.0	17	17.0	0.04	0.85
Total non-verbal (average of 3 times)						
Absent	7	7.0	20	20.0		
Present	93	93.0	80	80.0	7.24	0.007*

(*) Statistically significant at $p<0.05$

(**) numbers are not mutually exclusive