Effect of Cold Gel Pack Intervention on Controlling Pain Associated with Incentive Spirometry Post Open Heart Surgery

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Abstract

Background: After open heart surgery, considerable postoperative incisional pain is observed when incentive spirometry is used. As a result, the major postoperative treatment strategy for cardiac surgery is pain management. cold therapy is regarded as a quick, inexpensive, and non-pharmacological pain management technique. **Aim:** evaluate the effect of cold gel pack intervention on controlling pain associated with incentive spirometry post open heart surgery. **Design:** Quasi experimental design was utilized. **Setting:** The study was conducted in cardiothoracic intensive care unit and cardiothoracic department of Benha University Hospital. **Sample:** A Purposive sample of 60 adult patients were included in the study. **Tools of data collection:** Three tools were used for data collection; Tool I Structured interview questionnaire, Tool II Subjective pain assessment sheet, Tool III Objective pain assessment sheet. **Results:** There were statistically significant effects on pain intensity score, patients' perception and most of physiological indicators related to incisional pain associated with the use of incentive spirometry after cold gel pack application in study group compared to control group. **Conclusions:** Application of cold gel pack intervention was effective for reducing incisional pain and improving physiological parameters associated with incentive spirometry in patients post coronary artery bypass graft. **Recommendations:** Cold gel pack application should be promoted as a non-pharmacological treatment option before incentive spirometry for post-operative CABG patients,

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Key words: Cold Gel Pack, Pain, Incentive Spirometry, Open Heart Surgery

Introduction

Open heart surgery (OHS) is one of the treatment options for cardiovascular diseases. OHSs mainly include coronary artery bypass graft surgery (CABG), valvular heart surgery (VHS), heart transplantation, and congenital heart surgery. The aim of OHS is to eliminate the symptoms of cardiovascular diseases, restore cardiac function, and improve quality of life ***(Yeşiler et al.,2022).***

The number of patients undergoing OHS has gradually increased with the prolonged life expectancy and increasing medical developments. open heart surgery presents a lifesaving and life enhancing opportunity to thousands of patients. Many patients face significant challenges during the postoperative period including pain, anxiety and tension which can impair immune function and slow wound healing ***(Jensen et-al.,2020).***

open heart surgery includes opening the sternum from just below the jugular notch to below the xiphoid process to expose the heart. The heart is either stopped and a bypass (heart/lung) machine is utilized to replace the heart's function or the surgery is performed while the heart is still beating using stabilizers to

immobilize the area where the surgery is performed ***(Marzoog et-al.,2023)***

Sternal incision pain is the most common complaint after open heart surgeries. Since the sternum is cut open for the surgery, the movement of the rib cage during spirometry typically increases pain, creating breakthrough pain after cardiac surgery and patients need to perform these activities to optimize their recovery such as deep breathing and coughing exercises and spirometry***(Joseph& Garasiya.,2021).***

Control of pain in patients after heart surgery is one of the common problems in ICUs. Failure to treat the pain would deeply affect the quality of life and can have physical, psychological, social, and economic consequences. If acute pain is not properly managed, it can affect immune and nervous systems, and may progress and become chronic. Untreated pain can increase the risk of developing atelectasis, respiratory infections, myocardial ischemia, stroke, heart failure, and thromboembolic diseases in the patient ***(Jensen et-al.,2020).***

One of these activities that can create incident pain is spirometry. Patients who underwent these surgeries report having most severe pain during chest physio therapy procedure especially spirometry. using spirometer is very important in the prevention of respiratory complications such as hypoxemia, atelectasis, pneumonia. But, patient not likely to do this exercise if they are uncomfortable, or do not have strategies to control the break through pain ***(Feixiang et-al.,2023).***

Pain management requires a multidisciplinary approach (physician, nurse, pharmacist, physiotherapist, anesthesiologist). A nurse is a member who is facing the patient with pain and who often suffers from being unable to fully relieve their pain. More nurses should be given the opportunity to apply these practices by benefitting from the knowledge and experience of established nurses in this subject. ***(El-Nagaret-al.,2020.)***

Cold therapy is an effective and safe method with limited complications. cold leads to pain control and increases pain threshold. Cold Gel Packs are an economical treatment option that can be reused for multiple forms of therapeutic relief. They are made of high quality, durable materials that are intended to last through many uses and contrasting temperatures. The Gel Pack offers lasting cold therapy to the muscles. The pack is filled with large, moldable gel beads that remain flexible even when frozen. This provides cooling relief of pain and swelling to all body contours ***(Chen et-al.,2023)***

Many hospitals have postoperative standards of care that encourage patients to using incentive spirometry for deep breathing after open heart surgery at least every two hours while they are awake using incentive spirometry for deep breathing is typically associated with incisional pain because most cardiac surgical patients undergo a sternotomy (cut in sternal bone). (***El-Nagaret-al.,2020).***

Significance of the study

post open heart surgery patients frequently experience postoperative pulmonary problems (Decreased oxyhemoglobin saturation level, atelectasis, and pneumonia, etc.) which can occur in up to one-fifth of cases and are caused by general anesthesia, ischemia with consequences for the

extracorporeal circulation, sternotomy, and extended hypothermia ***(Tanner & Colvin 2020)***

In order to use incentive spirometry appropriately and efficiently and assist prevent PPCs, patients may have postoperative incisional pain. The result could be respiratory failure, hypoxemia, atelectasis, or pneumonia. Despite increased awareness of pain management on a global scale, cardiothoracic surgery units still face significant pain management issues. In patients who have undergone CABG, procedural pain has received limited attention. ***(Eid et al.,2022)***

Application of superficial cold gel packs is an efficient technique for pain relief because it slows down the speed of nerve conduction, which in turn lessens pain. However, **Çelik, & Özer., (2021)** who conducted a study about "Effect of Cold Application on Chest Incision Pain Due to Deep Breathing and Cough Exercises. recommended that there is a need for future studies to evaluate Effect of Cold Application on Chest Incision Pain Due to using incentive spirometry Therefore, the purpose of the current study was to evaluate the effect of cold gel pack intervention on controlling pain associated with incentive spirometry post open heart surgery.

Aim of the study

The aim of this study is to evaluate the effect of cold gel pack on controlling pain associated with incentive spirometry post open heart surgery.

Research hypotheses:

To achieve the aim of this study the following research hypothesis will be formulated:

H1: patient who will apply cold gel pack (intervention group) will have decreased intensity of pain associated with incentive spirometry than patients who will receive routine care (control group).

Subjects and Methods

Research Design:

Quasi-Experimental research design (pre and posttest) was used to achieve the aim of the study.

Study variables:

The independent variable in this study was the cold gel pack intervention, while the dependent variables were: pain level and physiologic parameters

Study setting:

The study was conducted in cardiothoracic surgery intensive care unit (ICU) and cardiothoracic department of Benha University Hospital.

Subjects:

A Purposive sample of post-operative coronary artery patients newly admitted to cardiothoracic intensive care unit and cardiothoracic department will be divided into two equal groups, control group and intervention group

Inclusion criteria:

Age from 20 to 60 years.

Patients scheduled to coronary artery bypass graft surgery. and haven't any complications.

Exclusion criteria

- Mechanically ventilated patients, as the patient will not be conscious and can't express his pain.
- Patients with diseases that affect pain measurement (delirium, dementia, or major depression.
- patient with Contraindicated to cold therapy such as Reynaud's disease, sickle cell anemia, cold allergic conditions.
- Patients with diabetes mellitus.
- Patients experienced post-operative complications such as infection, bleeding and

uncontrolled atrial fibrillation excluded from the study as identified from related literatures such as **(Weheida et-al.,2021)**

Tools of data collection:

Three tools used to collect the data of the study:

Tool I: structured interviewing questionnaire.

This tool was developed by the researcher after reviewing related literature such as **Khalkhali et al., (2019), Çevik et-al., (2020)** and **El-Nagar et-al.,(2020).** It compromised three parts;

Part one: Demographic characteristics of the studied patients: It was concerned with the demographic characteristics of patients which included (6 items) such as patient's age, sex, marital status, educational level, nature of work and the place of residence.

Part two: patient's medical health history: which include two items about assessment of the preoperative pain assessment (6items) and patients life style (6 items).

Tool II: Subjective pain assessment sheet : It compromised two parts:

Part one: "Pain Intensity Scale": it was adopted from **(McCaffery et al., 1994)**. for adults who had undergone postoperative coronary artery bypass graft surgery and were completely aware and oriented, it was utilized to measure pain intensity (5 item).

Scoring system: This scale consists of a 10-point numeric scale, where **"0"** denotes no pain, "**1-3"** mild pain, "**4-6"** moderate pain, **"7-9"** severe pain, and **"10"** representing unbearable pain. With a total score between **0 (no pain)**, and **10 (worst possible pain).**

part two: Patient self- report of pain (Pain characteristics):

It was developed by the researcher after extensive reviewing the relevant literature such as **(Berman et al., 2016; Peate & Wild, 2018; Zaccagnino & Nedeljkovic, 2017).** It was used mainly to describe and assess the quality of pain which was self-reported by postoperative coronary artery bypass grafting patient. It consists of different characteristics of pain **such as** Onset, Radiation, Location, Quality, Frequency, duration and associated symptoms

Tool III: Patients' behavioral pain scale it was adopted from ***Gélinas et al. (2006).*** It is one of the few pain scales to mainly assess and measure objective behavioral indicators of pain. It includes four domains, facial expression, body movement, vocalization and muscle tension.

Scoring system: Each of the four domains is scored as **0, 1, or 2** points, giving an overall score ranging from **0 (no pain) to 8 (maximum pain)**. Descriptions are consistent scoring within each domain.

Tools validity and reliability: (Appendix II)

Tools validity

The face and content validity of the tools were ascertained for comprehensiveness, relevance, simplicity, clarity and ambiguity through a jury of five experts (2 professors , 2 assisstant professors and one lecture from medical surgical nursing department, faculty of nursing, Benha University. Based on the opinion of panel of expertise some modifications were done and then the final form was developed based on newest current literature and used for data collection.

Tools reliability

Reliability was testing statistically to assure that the tools were reliable before data collection and it was evaluated using test-retest method by the Cronbach's alpha test which is used to measure the internal consistency. It was found that Chronbach's Alpha test for the tool I was 0.906, 0.8 for Tool II, and 0.7 for tool III which reflects reliable tools.

Ethical considerations:

Official permissions for data collection were generated from Hospital directors and head managers of the cardiothoracic surgery intensive care unit (ICU) and cardiothoracic department of Benha University Hospital. by the submission of a formal letter from the dean of Faculty of Nursing at Benha University. Also, the study approval was obtained from the ethical committee of Faculty of Nursing before initiating the study work. Oral approval from patients was taken after explanation the aim of the study; they were also informed that their participation is optionally, and that they have the right to withdraw at any time without any consequences. The researcher was assured maintaining anonymity and confidentiality of data and information gathered used only for patients benefit and for the purpose of the study.

Pilot Study

Pilot study was conducted on 10% (6 patients) before data collection of all patients in ICU department at Benha University Hospital in order to test the clarity and applicability of the study tools and the guidelines, to estimate time needed for each tool to be filled in as well as to identify any possible obstacles that may hinder data collection. Based on the results of the pilot study the necessary modifications were done to be more applicable tools for data collection. Patients involved in the pilot study were excluded from the study. The pilot study was done two weeks before starting the study (16 December 2022).

- **Preparatory phase:**

It includes extensive reviewing literature and studies related present study using local and international books, magazines, and periodical to get acquainted with the study problem to develop the study tools and the content of the educational booklet.

The participants were given a clear explanation and were informed regarding the aims of the study, protocols, measurements, benefits and risks, and the right to withdraw from the study. After receiving permission with written informed consent, clinical data were collected from their medical records.

III: Field Work

Data will be collected in the following sequence:

Data were collected from the beginning of January to the end of July 2023. All postoperative coronary artery bypass graft surgery patients admitted to the Cardiothoracic Surgical ICU and Cardiothoracic Surgery Department at Benha University Hospital who met the inclusion criteria were enrolled in this study. The researcher used tools II and III to thoroughly analyze the pain of postoperative coronary artery bypass graft surgery patients. The process of data collection was achieved three times first day, second day and after one week after surgery

I- Assessment phase:

- Patients' Socio demographic characteristics and medical health history should be done pre-operative by using tool I.
- Pain scores and physiological parameters should be assessed to control group and intervention group pre, and post using of incentive spirometry by using

tool II and tool III.

- Data will be collected in morning and afternoon shifts. the first day to patient is the zero day to researcher.

II-Planning phase:

The researcher was collected data about the study setting to put plan for carrying out the study. The researcher will put plan for implementation of the cold gel pack during the use of incentive spirometry for deep breathing exercises post coronary artery bypass graft surgery after collection of basic data related to physiological parameters and level of pain among patients.

Educational booklet regarding cold gel pack intervention and spirometry (Appendix III)

The general objective of the patients' booklet was improving patients' knowledge and practices regarding cold gel pack intervention and spirometry

It was included two parts:

1-Theoritical part: It included knowledge related to definition, benefits, indications, precautions and types of cold therapy.

2- Practical part: It contained demonstration of steps of using spirometer for deep breathing postoperative and how to use cold gel pack for later use.

Implementation phase of educational booklet:

-The researcher attended two days/week, meet with patient the day before surgery as the patient hospitalized one day before surgery to establish good relation with patient and cooperation

- The technique of implementation was carried out for each group through the conduction of three sessions, one theoretical session pre-operative and two practical sessions during their hospital stay and each session lasted about 25-30 minutes.

-Different teaching and learning methods were used during the sessions which included; videos, group discussions, demonstration and re-demonstration to educate patients about spirometry for deep breathing exercise.

III- Implementation phase:

The implementation phase included the following steps:

Control group: (the group without cold gel pack intervention) The researcher assessed the patients' baseline levels of pain before procedure. then providing them with a thorough description of the incentive spirometry, patients were prepared to use it. The patient was instructed to exhale normally, secure their lips over the mouthpiece, and then take a slow, deep breath without using their nose. or patient can take deep breath from nose and exhale in the incentive spirometry. To support sternal wound, a folded blanket or pillow was placed over the chest incision. Patients were asked to hold their breath and count to three once they were no longer able to inhale. Patients were told to conduct three cycles with the gadget their lips out of the mouthpiece and exhaling properly. The researcher make a pain assessment immediately upon completion.

Intervention group: the group with application of a cold gel pack intervention, baseline pain assessment was performed by the researcher (pre intervention assessment), then patients were elevated to stay in the upright position and skin sensitivity was tested at the sternotomy wound area.

A reusable gel pack, size 10.0x26.5 cm was used as the cold source. It is manufactured of a soft, naturally drug-free, nontoxic, biodegradable gel held in a flexible plastic contour. **(Kwiecien,& McHugh ., 2021**

,Manapunsopee et-al.,2020) The temperature of the gel pack was tested using the same digital thermometer each time before the cold therapy session started. , the cold gel pack that would be used for localized cryotherapy was placed in the freezer for 30 to 40 minutes. According to advice from other studies **(Çeviket-al., 2020)** the researcher immediately put the cold gel pack over the median sternotomy incision of the patients for 20 minutes after bringing it from the freezer to their bedside and wrapping it in a washcloth or towel. to achieve the therapeutic effect of cold therapy its required to cool down the tissues for at least 12 minutes, therefore 15-min use time was suitable in this study to attain the wanted results **(Awad et-al.,2022)** The cold gel pack was left for 20 minutes on place until it was time to remove it, and the researcher remained beside each patient bed to confirm this and observe any changes on patient. Patients were prepared for the use of incentive spirometry (three cycle). Patients acquired instruction on how to utilize incentive spirometry (three cycle). The researcher then used data collection tools II and III to evaluate pain post intervention.

As soon as the pain evaluation was done, the cold gel pack was cleaned in accordance with hospital infection control procedures and put back into the freezer for future usage. the researchers applied localized cryotherapy for maximum 20 minutes to attain therapeutic effects and avoid side effects at the same time. The most severe side effects of localized cryotherapy according to previous studies include injuries to the skin and tissues that may occur if localized cryotherapy applied longer than 30 minutes **(Mohammadi et al., 2018 and Aktaş¸& Karabulut,2019).** Therefore, in this study, the dressing layer over the chest incision was separated from the cold gel pack by a piece of cloth or a towel.

IV: Evaluation phase:

For intervention group the researcher applies cold gel pack on first day, second day and one week post operatively after cold application the patient prepared to use the incentive spirometry, then the researcher assesses patient pain intensity by tool II and tool III. For control group pre and posttest done only after using the incentive spirometry and compare between them.

Statistical Analysis:

Data analysis was performed using the SPSS software (version 25). For determining the normal distribution of quantitative variables was used to Kolmogorov-Smirnov test. Chi-square tests were used to compare nominal variables in the two groups and compare between different periods. Fisher's exact test was applied on smaller sample sizes, alternative to the chi-square test, when the frequency count is < 5 for more than 20% of cells. For comparing the mean scores in two groups were used to the independent t-tests, Mann Whitney test for non-parametric quantitative data. Friedman test to compare between more than two periods or stages. spearman method was used to test correlation between numerical variables. Linear regression was used for multivariate analyses on physiological indicators as dependent factor A p-value < 0.05 was considered significant, and <0.001 was considered highly significant.

Results

Table (1): Displays the sociodemographic distribution of the studied patients (control and intervention groups), where there was no statistically significant difference between the two groups. Clarifying that (43.3% & 53.3%, respectively) had 40-60 years old with a mean age of (40.27±0.74 & 39.33±0.80) years, while (73.3% & 70.0%) of them were males, (46.7 % & 43.3%) were

married. In addition, (40.0% & 43.3%) of the studied patients had an intermediate qualification. Moreover, (33.3% &36.7%) of them had sedentary work, with working hours of 6-<8 hour among 60.0% and 66.6%, respectively. Moreover (70.0% & 73.3%, respectively) were residing urban area.

Figure 1: This figure illustrates that, there was no significant changes among control and intervention groups regarding their nature of pain (p value = 0.0327 n.s), where (46.7% & 53.3%, respectively) reported a burning sensation.

Table (2): This table reveals the comparison of pain intensity between control and intervention groups, pointing out that there was a significant statistical difference post each intervention period. Where 36.7% of control group had severe pain and 33.3% of intervention group had a moderate pain during first day post intervention , while during the second day 63.3% had moderate pain and 53.3% had mild pain, respectively to be post one week moderate level among 50.0% of control group and mild level among 73.3% of intervention group, with a significant overall change in pain score within the control group p=0.040*) and highly significantp=<0.001**) within the intervention group throughout post intervention phases.

Table (4): reveals the comparison of pain characteristics between control and intervention groups, displaying that there was a significant statistical difference post each intervention period. Where 86.7% of control group had radiating pain during first day post intervention as well as 83.3% during the second day, while regarding intervention group, 56.7% had radiating pain during the post first day and 40.0% during the second day with p value= 0.045* and 0.038*, respectively, concerning one week period post intervention 93.3% of control group and 20.0% of intervention group reported incidence of sharp pain with p value = 0.025*.

Table5: This table reveals that, there was significant statistical relation during pre-intervention period with age, sex, occupation and residence while the relation during post one-week intervention period was significant age, marital status, education level and residence.

Table (1): Distribution of studied patients (control & intervention groups) according to their sociodemographic characteristics (n=٦0)

Patients' sociodemographic characteristics	Variables	Control group N=30		Intervention group N=30		Test	
		No.	%	No.	%	X^2	P value
Age (year)	20-<30	5	16.7	6	20.0	0.310	0.857 n.s
	30-<40	12	40.0	10	33.3		
	40-60	13	43.3	14	46.7		
	Mean ± SD	**40.27±0.74**		**39.27±0.78**		t= 0.335	0.739 n.s
Sex	Male	22	73.3	21	70.0	0.082	0.774 n.s
	Female	8	26.7	9	30.0		
Marital status	Single	4	13.3	3	10.0	0.430	0.934 n.s
	Married	14	46.7	13	43.3		
	Widowed	7	23.3	9	30.0		
	Divorced	5	16.7	5	16.7		
Educational level	Illiterate	6	20.0	6	20.0	0.437	0.933 n.s
	Read and write	4	13.3	5	16.7		
	Intermediate qualification	12	40.0	13	43.3		
	University qualification	8	26.7	6	20.0		
Nature of work	Manual work	6	20.0	5	16.7	0.282	0.963 n.s
	Sedentary work	10	33.3	11	36.7		
	House wife	6	20.0	7	23.3		
	Not working	8	26.7	7	23.3		
Working hours	< 6 hrs	1	3.3	0	0.0	1.419	0.841 n.s
	6-<8 hrs	18	60.0	20	66.6		
	8-<10 hrs	9	30.0	8	26.7		
	10-12 hrs	2	6.7	2	6.7		
	Mean ± SD	**6.43±0.747**		**6.50±0.77**		t= 0.333	0.740 n.s
Residence	Urban	21	70.0	22	73.3	0.082	0.774 n.s
	Rural	9	30.0	8	26.7		

(n.s) Not significant (p > 0.05)

Figure 1: Distribution of nature of pain among studied patients (control & intervention groups) (n=30)

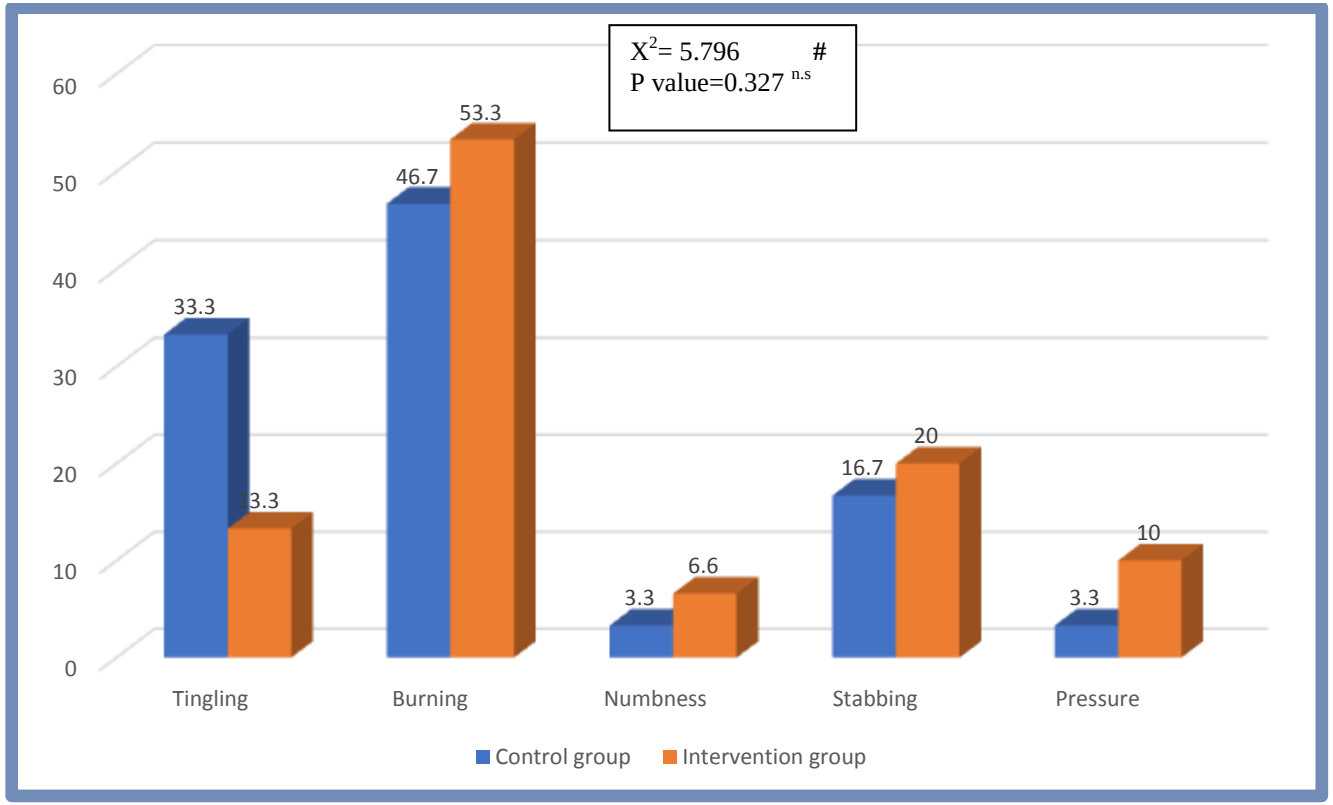

Table (2): Comparison of patients' pain intensity between control and intervention groups throughout post intervention phases (n=60).

Pain intensity	Control group (n=30)						Intervention group (n=30)						X^2 test P value (1)	X^2 test P value (2)	X^2 test P value (3)
	First day		Second day		After One week		First day		Second day		After One week				
	baseline	After intervention	baseline	After intervention	baseline	After intervention	Baseline	After intervention	baseline	After intervention	baseline	After intervention			
No pain (0)	2(6.7)	0(0.0)	0(0.0)	0(0.0)	1(3.3)	1(3.3)	0(0.0)	5(16.7)	0(0.0)	3(10.0)	0(0.0)	8(26.7)			
Mild pain (1-3)	5(16.7)	0(0.0)	9(30.0)	0(0.0)	15(50.0)	0(0.0)	5(16.7)	6(20.0)	5(16.7)	16(53.3)	14(46.7)	22(73.3)			
Moderate pain (4-6)	13(43.3)	9(30.0)	18(60.0)	19(63.3)	14(46.7)	15(50.0)	8(26.7)	10(33.3)	15(50.0)	10(33.3)	16(53.3)	0(0.0)	17.275 0.002*	30.238 <0.001**	56.444 <0.001**
Severe pain (7-9)	10(33.3)	11(36.7)	3(10.0)	8(26.7)	0(0.0)	14(46.7)	13(43.3)	7(23.3)	10(33.3)	1(3.3)	0(0.0)	0(0.0)			
Unbearable pain (10)	0(0.0)	10(33.3)	0(0.0)	3(10.0)	0(0.0)	0(0.0)	4(13.3)	2(6.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
Mean ± SD	8.03±0.89	9.03±0.80	4.80±0.61	6.47±0.68	4.43±0.57	5.40±0.68	8.53±0.94	6.83±1.17	5.17±0.69	4.30±0.70	2.53±0.51	0.73±0.45	U1= 703.500 <0.001**	U2= 782.000 <0.001**	U3= -874.000 <0.001**
Fr test P value (4)	6.424 0.040*						22.978 < 0.001**								

Table (3): Comparison of patients' pain characteristics between control and intervention groups throughout post intervention phases **(n=٦0).**

Pain characteristics	Response	Control group (n=30)						Intervention group (n=30)						X^{2} test P value (1)	X^{2} test P value (2)	X^{2} test P value (3)
		First day		Second day		After One week		First day		Second day		After One week				
		Baseline	After intervention	baseline	After intervention	baseline	After intervention	Baseline	After intervention	baseline	After intervention	baseline	After intervention			
Onset	Sudden	10(33.3)	11(36.7)	6(20.0)	9(30.0)	4(13.3)	6(20.0)	4(13.3)	4(13.3)	3(10.0)	2(6.7)	2(6.7)	1(3.3)	4.356 0.037*	5.455 0.020*	4.043 0.044*
	Gradual	20(66.7)	19(63.3)	24(80.0)	21(70.0)	26(86.7)	24(80.0)	26(86.7)	26(86.7)	27(90.0)	28(93.3)	28(93.3)	29(96.7)			
Radiation	Yes	24(80.0)	26(86.7)	24(80.0)	25(83.3)	28(93.3)	22(73.3)	26(86.7)	17(56.7)	24(80.0)	12(40.0)	2(6.7)	2(6.7)	6.648 0.010*	4.022 0.045*	4.320 0.038*
	No	6(20.0)	4(13.3)	6(20.0)	5(16.7)	2(6.7)	8(26.7)	4(13.3)	13(43.3)	6(20.0)	18(60.0)	28(93.3)	28(93.3)			
Location #	Sternum	20(66.7)	22(73.3)	25(83.3)	12(40.0)	24(80.0)	9(30.0)	30(100.0)	10(33.3)	26(86.7)	24(80.0)	28(93.3)	29(96.7)	26.297 <0.001 **	15.000 0.010*	53.133 <0.001 **
	Arm	21(70.0)	7(23.3)	28(93.3)	16(53.3)	29(96.7)	19(63.3)	1(3.3)	6(20.0)	28(93.3)	6(19.9)	2(6.6)	1(3.3)			
	Back	28(93.3)	8(26.6)	5(16.7)	7(23.3)	3(10.0)	7(23.3)	8(26.7)	0(0.0)	0(0.0)	5(16.6)	1(3.3)	1(3.3)			
	Jaw	21(70.0)	11(36.7)	0(0.0)	4(13.3)	3(10.0)	9(30.0)	1(3.3)	0(0.0)	4(13.3)	3(6.6)	1(3.3)	0(0.0)			
	Neck	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	14(46.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
Quality	Sharp	5(16.7)	11(36.7)	3(10.0)	8(26.7)	21(70.0)	28(93.3)	0(0.0)	3(10.0)	2(6.7)	0(0.0)	21(70.0)	6(20.0)	9.138 0.028*	10.884 0.012*	9.333 0.025*
	Dull	7(23.3)	7(23.3)	12(40.0)	17(56.7)	1(3.3)	2(6.7)	15(50.0)	17(56.7)	17(56.7)	26(86.7)	1(3.3)	15(50.0)			
	Aching	10(33.3)	6(20.0)	9(30.0)	4(13.3)	3(10.0)	0(0.0)	7(23.3)	6(20.0)	5(16.7)	2(6.7)	3(10.0)	7(23.3)			
	Burning	8(26.7)	6(20.0)	6(20.0)	1(3.3)	5(16.7)	0(0.0)	8(26.7)	4(13.3)	6(20.0)	2(6.7)	5(16.7)	2(6.7)			
Frequency	Constant	11(36.7)	10(33.3)	22(73.3)	24(80.0)	11(36.7)	14(46.7)	20(66.7)	16(53.3)	3(10.0)	4(13.3)	8(26.7)	6(20.0)	11.462 0.003*	11.290 0.004*	4.320 0.038*
	Frequent	8(26.6)	9(30.0)	8(26.7)	6(20.0)	9(30.0)	7(23.3)	7(23.3)	14(46.7)	7(23.3)	3(10.0)	0(0.0)	0(0.0)			
	Infrequent	11(36.7)	11(36.7)	0(0.0)	0(0.0)	10(33.3)	9(30.0)	3(10.0)	0(0.0)	20(66.7)	23(76.7)	22(73.3)	24(80.0)			
Duration	Continuous	11(36.7)	25(83.3)	12(40.0)	12(40.0)	22(73.3)	24(80.0)	22(73.3)	18(60.0)	13(43.3)	4(13.3)	8(26.7)	5(16.7)	4.022 0.045*	5.455 FE 0.039*	24.093 <0.001 **
	Intermittent	19(63.3)	5(16.7)	18(60.0)	18(60.0)	8(26.7)	6(20.0)	8(26.7)	12(40.0)	17(56.7)	26(86.7)	22(73.3)	25(83.3)			
Associated symptoms #	Nausea	13(43.3)	5(16.7)	8(26.7)	6(20.0)	20(66.7)	6(20.0)	18(60.0)	6(20.0)	20(66.6)	7(23.3)	20(66.7)	6(20.0)	31.867 <0.001 **	15.303 0.009*	7.838 0.049*
	Vomiting	15(50.0)	8(26.7)	6(20.0)	7(23.3)	9(30.0)	5(16.7)	5(16.7)	5(16.7)	7(23.3)	6(20.0)	9(30.0)	2(6.6)			
	Diaphoresis	2(6.7)	2(6.7)	0(0.0)	1(3.3)	0(0.0)	0(0.0)	4(13.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
	Breathlessness	3(10.0)	14(46.7)	0(0.0)	10(33.3)	0(0.0)	0(0.0)	5(16.7)	0(0.0)	2(6.7)	0(0.0)	0(0.0)	0(0.0)			
	Dizziness	3(10.0)	1(3.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
	Light headedness	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
	None	9(30.0)	27(90.0)	26(86.7)	26(86.7)	27(90.0)	27(90.0)	0(0.0)	28(93.3)	26(86.7)	26(86.7)	27(90.0)	29(96.7)			

Table (4): Comparison of patients' behavioral indicators of pain (Control & intervention) groups throughout intervention phases. (N=60).)

Behavioral indicators	Response	Control group (n=30)						Intervention group (n=30)						X^2 test P value (1)	X^2 test P value (2)	X^2 test P value (3)
		First day		Second day		After One week		First day		Second day		After One week				
		Baseline	After intervention	baseline	After intervention	Baseline	After intervention	baseline	After intervention	baseline	After intervention	Baseline	After intervention			
Facial expressions (0-2)	Relaxed, neutral	3(10.0)	2(6.7)	0(0.0)	8(26.7)	10(33.3)	9(30.0)	0(0.0)	13(43.3)	5(16.7)	10(33.3)	17(56.7)	20(66.7)	8.583 0.014*	12.222 0.002*	10.557 0.005*
	Tense	20(66.7)	19(63.3)	24(80.0)	12(40.0)	16(53.3)	16(53.3)	16(53.3)	12(40.0)	22(73.3)	20(66.7)	13(43.3)	10(33.3)			
	Grimacing	7(23.3)	9(30.0)	6(20.0)	10(33.3)	4(13.4)	5(16.7)	14(46.7)	5(16.7)	3(10.0)	0(0.0)	0(0.0)	0(0.0)			
Body movements (0-2)	Absence of movement or normal position	10(33.3)	5(16.7)	4(13.4)	7(23.3)	10(33.3)	10(33.3)	8(26.7)	15(50.0)	13(43.3)	20(66.7)	17(56.7)	20(66.7)	7.597 0.022*	11.759 0.003*	8.148 0.017*
	Protection	17(56.7)	21(70.0)	22(73.3)	22(73.4)	18(60.0)	17(56.7)	14(46.7)	12(40.0)	16(53.3)	10(33.3)	13(43.3)	10(33.3)			
	Restlessness	3(10.0)	4(13.3)	4(13.3)	1(3.3)	2(6.7)	3(10.0)	8(26.7)	3(10.0)	1(3.3)	0(0.0)	0(0.0)	0(0.0)			
Muscle tension (0-2)	Relaxed	8(26.7)	3(10.0)	8(26.6)	8(26.7)	19(63.3)	14(46.7)	4(13.3)	19(63.3)	19(63.3)	19(63.3)	11(36.7)	22(73.3)	19.036 <0.001**	8.606 0.014*	6.578 0.037*
	Tense, rigid	16(53.3)	21(70.0)	17(56.7)	21(70.0)	9(30.0)	12(40.0)	17(56.7)	7(23.3)	9(30.0)	11(36.7)	19(63.3)	8(26.7)			
	Very tense or rigid	6(20.0)	6(20.0)	5(16.7)	1(3.3)	2(6.7)	4(13.3)	9(30.0)	4(13.3)	2(6.7)	0(0.0)	0(0.0)	0(0.0)			
Compliance with ventilator (intubated patient) Or Vocalization (extubated patient)(0-2)	Talking in normal tone or no sound	12(40.0)	10(33.3)	12(40.0)	11(36.7)	7(23.3)	9(30.0)	17(56.7)	18(60.0)	19(63.3)	25(83.3)	22(73.3)	24(80.0)	4.286 0.038*	14.444 0.001**	15.578 <0.001**
	Sighing, moaning	16(53.3)	20(66.7)	18(60.0)	15(50.0)	20(66.7)	19(63.3)	13(43.3)	12(40.0)	11(36.7)	5(16.7)	8(26.7)	6(20.0)			
	Crying out, sobbing	2(6.7)	0(0.0)	0(0.0)	4(13.3)	3(10.0)	2(6.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)			
Total		3.60±1.71	3.60±1.07	2.33±1.06	3.40±1.75	2.17±0.94	3.07±1.82	4.07±1.23	2.50±1.19	3.70±1.49	1.53±0.82	2.90±1.03	1.13±0.86	U1= 229.500 <0.001**	U2= 169.000 <0.001**	U3= 163.000 <0.001**
Fr test P value (4)		1.271 0.530 n.s						14.935 0.001**								

(Fr) Friedman test *(U) Mann witney test* *(n.s) Not Statistically Significant at >0.05* *(*) Statistically Significant at ≤0.05* *** Highly significant (p ≤ 0.001)*

(1) P1: p value for comparing post intervention behavioral indicators between control and intervention groups post first day
(2) P2: p value for comparing post intervention behavioral indicators between control and intervention groups post second day
(3) P3: p value for comparing post intervention behavioral indicators between control and intervention groups post one week
(4) P4: p value for comparing behavioral indicators scores within each group throughout post intervention phases

Table (5): **Relation between sociodemographic characteristics among intervention group with total score of pain intensity, throughout intervention phases (N=30).**

Demographic characteristics	Total Pain intensity of intervention group (n=30)					
	First day Post intervention	**Test P value**	**Second day Post intervention**	**Test P value**	**Post first week Post intervention**	**Test P value**
Age /year	□¯ ± SD		□¯ ± SD		□¯ ± SD	
20-<30	**2.00 ± 1.09**	H=0.177 0.915 n.s	**1.67 ± 0.51**	H=2.738 0.254 n.s	**0.83 ± 0.40**	H=0.474 0.789 n.s
30-<40	**1.88± 1.24**		**1.25± 0.70**		**0.75± 0.46**	
40-60	**1.75± 1.23**		**1.19± 0.75**		**0.69± 0.47**	
Gender						
Male	**1.76 ± 1.22**	U=85.500 0.689 n.s	**1.38 ± 0.66**	U=67.500 0.226 n.s	**0.86 ± 0.35**	U=55.500 0.077 n.s
Female	**2.00± 1.11**		**1.11± 0.78**		**0.44± 0.52**	
Marital status						
Single	**0.33± 0.57**	H=5.196 0.074 n.s	**0.33± 0.57**	H=5.647 0.059 n.s	**0.67± 0.57**	H=0.158 0.924 n.s
Married	**2.08 ± 1.38**		**1.54 ± 0.77**		**0.77 ± 0.43**	
Divorced	**2.00± 0.70**		**1.44± 0.52**		**0.78± 0.44**	
Widowed	**1.80± 1.09**		**1.00± 0.00**		**0.60± 0.54**	
Educational Level						
Illiterate	**1.33 ± 1.36**	H=11.425 0.010*	**1.33 ± 0.81**	H= 15.133 0.0.002*	**0.50 ± 0.54**	H=2.104 0.551 n.s
Read and write	**1.00± 0.70**		**0.60± 0.54**		**0.80± 0.44**	
Intermediate qualification	**1.77 ± 0.92**		**1.15 ± 0.37**		**0.77 ± 0.43**	
University qualification	**3.17± 0.75**		**2.17± 0.40**		**0.83± 0.40**	
Nature of Work						
Manual work	**1.20 ± 0.83**	H=3.016 0.389 n.s	**1.00 ± 0.70**	H=1.232 0.745 n.s	**0.40 ± 0.54**	H=5.221 0.156 n.s
Sedentary work	**2.18± 1.47**		**1.36± 0.92**		**0.73± 0.46**	
House wife	**2.00± 0.81**		**1.43± 0.53**		**0.71± 0.48**	
No work	**1.57 ± 1.13**		**1.29 ± 0.48**		**1.00 ± 0.00**	
Residence						
Rural	**1.74 ± 1.28**	U=68.500 0.896 n.s	**1.26 ± 0.73**	U=58.500 0.360 n.s	**0.74 ± 0.45**	U=65.500 0.585 n.s
Urban	**2.00± 1.19**		**1.50± 0.75**		**0.88± 0.35**	

Discussion:

Part I: Sociodemographic characteristics of studied patients.

Regarding age: the current study presented that there was no statistically significant difference between the two groups. Clarifying that near to half of both control and intervention group had 40-60 years old with a mean age of**(40.27year±0.74&39.27±0.78SD)** respectively, this might be this is the most affected age with coronary artery disease and this disease is common in middle and old age than young age as a result of aging process and the related physiological changes in the vascular system.

This result was agreed with the study conducted in turkey. **by Cevik et al., (2020)** who examined Effect of "Applying Cold Gel Pack to the Sternum Region on the Postoperative Pain after Open- Heart Surgery" and emphasized that the half of studied patients were aged between 50 and 60 years old. also this is consistent with **Ebrahimi-Rigi et al., (2016)** in astudy entitlled "Effect of cold therapy on the pain of deep breathing and coughing in patients after coronary artery bypass grafting in one of the hospital in Iran" and reported that the studied groups didn't differ significantly regarding age.

In contradiction with this study **Tanha et al., 2022,** whose study entitled " Effect of applying cold gel pack on the pain associated with deep breathing and coughing after open heart surgery". who stated that most of studied sample was young persons whose age ranged between 25-40 years old

As regard to gender, the present study revealed that more than two third of the control and study group patients were males. From the researcher point of view, this result might be because of stressors they face and unhealthy life style behavior they followed. This finding agreed with **Khan et al.,(2020**) who studied " Global Epidemiology of Ischemic Heart Disease", and reported that more than two third of studied patients were males. also this finding in the line with **Hallman et al., (2021).** who studied " Objective postoperative pain assessment using incentive spirometry values: a prospective observational study.", and reported that nearly three quarter of studied patients were males.

But this finding was in contradict with study by **El–Naggar et al., (2020)** who conducted a study in the Intensive care unit of open-heart surgery at the National Cardiac Institute, Imbabah, Giza Governorate, about " Effect of cold gel pack on controlling pain intensity associated with deep breathing and coughing exercise after cardiac surgery " they reported that the majority of the studied patients were female

Concerning to marital status, the present study finding revealed that more than one third of studied patients were married. From the researcher's point of view, this result might be due to the physical and social stress in their life and their families' responsibility. This finding was supported by the result of **Zencir& Eser, (2019).** who studied "Effects of cold therapy on pain and breathing exercises among median sternotomy patients". and reported that married patients who have ischemic heart disease represented the higher percentage of their study subject than single and widow patients.

But this finding was in contradict with study conducted by **Wong et al., (2018)** about "Marital status and risk of cardiovascular disease and

concluded that compared to married individuals, being unmarried was associated with increased CHD Similarly, observed a greater risk of death from CHD and stroke in divorced compared to married individuals this may due to marital status appears to influence CVD and prognosis after CVD.

Owing to educational level , the result of the present study revealed that more than one third of the studied patients had intermediate education this may be due to that the study was conducted in the governmental hospital which accommodates great numbers of patients with low socioeconomic levels with low educational level. This result is in the same line with **Girgin, et al., (2021)**, in a study about "The Effect of pulmonary rehabilitation on respiratory functions, and the quality of life, following coronary artery bypass grafting" and revealed that the majority of heart failure patients attained an intermediate education

This finding disagreed with the finding of study by **Ahmed et al., (2019**) entitled " Factors Affecting the Outcomes of Patients with Ischemic Heart Disease at Intensive Care Units in As-Salam International Hospital in Egypt " whose results indicated that, about half of patients were highly qualified education this might be because of the setting place were contracted with highly reputably health care sponsoring companies beside the nature of the high socioeconomic class of patients.

Regarding to nature of work, the result of the present study revealed that more than one third of studied patients was working. with working hours of 6-<8 hours .This results was consistence with the result of **Seweid et al.,(2021)** entitled “Effect of cold application on incisional pain associated with incentive spirometry after coronary artery bypass graft surgery in Alexandria” who reported that more than one third of studied subjects were working.

As regard to residence, the finding of the current study represented that about three quarters of both groups were living in urban areas, this Results were similar also to findings of study by Singh et al., (2020), who studied "Urban-Rural Differences in Coronary Heart Disease incidence in the United States ". They revealed that more than two third of studied group were living in urban areas.

On the other hand, this finding is disagree with **Bakitas et al., (2020)** in the study entitled "Effect of an early palliative care telehealth intervention vs usual care on patients with coronary artery disease, in New York", who showed that more than half of patients lived in rural areas

Second part: Comparison of self-reported pain assessment (intensity, &characteristics) between control and intervention groups throughout different post intervention phases.

The results of the current study show that the mean scores of pain associated with the use of incentive spirometry are significantly decreased with cold gel pack application in intervention group compared to control group. from the researcher point of view, the incentive spirometry increase pain in control group due to chest expansion and pressure fall on chest cage during usage. Also This might be related to the decrease in the sensory and motor nerve conduction with cold gel pack application which is known as the direct analgesic effect of cold application.

The results of the present study were in agreement with Chailler **et al., (2022)** whose study entitled "Cold therapy for the management of pain associated with deep breathing and coughing post-cardiac surgery". and founded that there was a significant reduction in pain scores between pre-and post-application of the gel pack These agrees with **Keawnantawat et al., (2018)** whose results showed that the experimental group had significantly lower mean pain than the control group. Thus, cold therapy was effective in reducing pain after cardiac surgery during the acute phase.

This result agreed with the study results by **Chauhan et al., (2021):** about effectiveness of cold application versus breathing exercises to reduce pain and anxiety during chest tube removal among postoperative cardiac surgery adult patient who stated that mean scores of pain intensity in cold application group was significantly decreased compared to breathing exercises group. **Second part: Comparison of objective pain assessment (behavioral indicators of pain) between control and intervention groups throughout different post intervention phases**

Regarding patients' behavioral indicators of pain, the results of the current study revealed that there was a significant statistical difference post each intervention period between control group and intervention group. from the researcher point of view, pain aggravating has negative effect on facial expression, body movement and muscle contraction these results could be related to that decreasing pain caused by cold gel pack leads to muscle relaxation and decrease muscle spasm.

These results are supported by **Seweid et al., (2021)** who found that there was significant reduction in pain scores in pain intensity and pain distress as well as critical care pain observation post cold gel application therapy in patient undergoing coronary artery bypass grafting

Also these results are consistent with a study conducted by, **Yaban, (2023)** about "Usage of non-pharmacologic methods on postoperative pain management by nurses "and found that cold application reliefs pain with the effects such as the decrease in edema by vasoconstriction as a result of sympathetic fiber activation, suppression of inflammatory reactions, decrease muscle spasm and contraction

on the other hand, these results are controverted by **El-Nagar et al., (2020)** who revealed that localized cryotherapy effective in reducing pain intensity but not change behavioral indicators because it is related to patient tolerance.

Regarding relationship between total pain score of studied groups and their demographic characteristics there was significant statistical relationship with educational level and marital status while there was no significant statistically relationship between total pain score and age , Gender and residence ,this result may be related to pain threshold differ from person to another person , married person may pear pain more than single one and pain intensity doesn't associated with residence. This result in the same line with **Milgrom et-al., (2022)** who stated that there was statistically significant relationship between pain intensity and educational level and marital status.

but on the other hand, the result of the present study was

disagreeing with the result of study conducted by **Weheida et al.,. (2021**) entitled"The Effect of Applying Superficial Cold Gel Packs on Incisional Pain during Different Patients Activities post Coronary Artery Bypass Graft in Egypt" who concluded that there were highly statistically significant relationship between pain intensity and patient age . **Finally,** the current study affirmed the hypotheses that post coronary artery bypass graft surgery patients who received cold gel pack intervention would experience reduced incisional pain related to the use of incentive spirometry

Conclusion

Based on the findings of the current study, it concluded that cold application is one of the non-pharmacological strategies that can be used beside pharmacological management by critical care nurses to alleviate incisional pain associated with the use of incentive spirometry in an easy, effective, and costless way.

Recommendations:

Based on the results of the present study the following recommendations are suggested:

- Cold gel pack should be used as an alternative non-pharmacological pain management method for open heart surgery patients as it is cheap, readily available and saves high costs of medication that used for pain relief and control.
- Evaluate the effectiveness of different types of localized cryotherapy, such as (chip, massage, and ice towel) on the incisional discomfort linked to incentive spirometry following CABG surgery.

- The study should be performed on a sizable, non-probability sample and in a different hospital setting from diverse geographical regions in order to generalize the study's findings.

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