Efficacy of Localized Cryotherapy on Physiological Parameters associated with incentive spirometry Among Post Operative Cardiac Patients

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Abstract

Background: the use of incentive spirometry contributes to the patient's pain and reduces the patient's ability to perform important activities after CABG. This may be attributed to the fact that incentive spirometry takes a lot of time to be performed and may result in changes in muscle tension and activity in skeletal position, which may contribute to change in physiological parameters. Aim: evaluate the efficacy of localized cryotherapy on physiological parameters among postoperative cardiac patients. Design: Quasi experimental design was utilized. Setting: The study was conducted in cardiothoracic intensive care unit. Sample: A Purposive sample of 60 adult patients were included in the study. Tools of data collection: Two tools were used for data collection; Tool I Structured interview questionnaire, Tool II physiological parameters assessment. Results: There were statistically significant improvement in physiological parameters and return to normal 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 was effective for improving physiological parameters with incentive spirometry in patients post coronary artery bypass graft surgery. Recommendations: More research is necessary to examine the effectiveness of different types of localized cryotherapy, such as (ice pack, massage, and ice towel), on the incisional discomfort linked to incentive spirometry following CABG surgery.

Key words: Localized Cryotherapy, Physiological Parameters, Cardiac Patients

Introduction

Open-heart surgery is any type of surgery where the chest is cut open and surgery is performed on the muscles, valves, or arteries of the heart. According to the *National Heart, Lung, and Blood Institute* (*NHLBI*), coronary artery bypass grafting (CABG) is the most common type of heart surgery done on adults. During this surgery, a healthy artery or vein is grafted (attached) to a blocked coronary artery. This allows the grafted artery to "bypass" the blocked artery and bring fresh blood to the heart (*Gunther et al.,2019*).

Open-heart surgery is also done to repair or replace heart valves, which allow blood to travel through the heart, repair damaged or abnormal areas of the heart, implant medical devices that help the heart beat properly and replace a damaged heart with a donated heart (heart transplantation) (*Ozkan& Cavdar,2021*).

Mataning physiological parameters within normal after open heart surgery is

considered the foremost postoperative care strategy. Today the strong emphasis is on non-pharmacological pain relief methods including relaxation, touch therapy, music therapy, imagination, and applying heat and cold therapy.

These methods are easy to use and may be acceptable to the patients and nurses also are capable of implementing them independently and some nurses prefer non pharmacological techniques since they are low risk and they also give patients an active role in relieving their own pain. Cold therapy is a non-pharmacological and a cost-effective way of relieving pain (*Yarahmadi et al.,2018*).

Cold therapy is also known as cryotherapy. It works by reducing blood flow to a particular area, which can significantly reduce inflammation and swelling that causes pain, especially around a joint or a tendon. It can temporarily reduce nerve activity, which can also relieve pain. There are a number of different ways to apply cold therapy to an affected area such as ice packs or frozen gel pack, ice massage and ice bath (*Ozkan& Cavdar,2021*).

The beneficial effects of cold therapy for imporving physiological parameters have been widely documented and the side effects are minimal, yet its use remains limited in post-surgical cardiac patients. after open heart surgery, patients recover from anesthesia and they are encouraged to perform activities such as DB & C exercises or use incentive spirometry to maximize their recovery and to prevent pulmonary complications such as atelectasis and infections (*Ebrahimi-Rigi et al., 2016*)

Postoperative pulmonary complications (PPCs) are the most frequent and significant contributors to morbidity, mortality and cost associated with hospitalization following. Routine aspects of postoperative open heart surgery care have been recommended to improve patients' pulmonary functions beside decreasing PPCs. Most of these interventions focus on airway management include various and techniques of mechanical ventilation. endotracheal suctioning, extubation and physiotherapy, which involve the use of incentive spirometry (Aktaş, & Karabulut, 2019).

The incentive spirometry is typically associated with incisional pain. This relates to the fact that most patients having open heart surgery undergo a procedure termed sternotomy, the sternum is cut open medially to provide access to the heart, At the end of the surgery, the sternum is wired back together and the skin is sutured creating an incision line on the sternum (*Gorji et al.,2019*).

Unfortunately, the use of incentive spirometry contributes to the patient's pain and reduces the patient's ability to perform important activities after open heart surgery. This may be attributed to the fact that incentive spirometry takes a lot of time to be performed and may result in changes in muscle tension and activity in skeletal position, which may contribute to incisional pain (*Sajedi-Monfared et al.,2021*). Nurses play an important role in controlling and managing post-operative pain through good assessment and applying pharmacological and non-pharmacological methods for controlling the intensity of pain (**Ozkan&** *Cavdar*, 2021).

Significance of the study:

Effective pain management leads to earlier recovery, reduces the postoperative complications and duration of hospitalization, and increases patient satisfaction. Various pharmacologic and non-pharmacologic therapies have been developed for pain management (*Chailler et Al.*, 2020).

One of the simplest and cheapest non pharmacologic ways to relieve pain is the use of cold. Cold therapy is an effective and safe method with few complications or no side effects. Studies show that cold leads to pain control and decrease pain threshold but there is a paucity of scientific evidence about the use of cold therapy in patients after open heart surgery (*Milgrom*, 2018).

after open-heart surgery, various complications require specific care, especially in the respiratory system. To reestablish it, several strategies should be used, such as respiratory muscle training, which aims to improve respiratory muscle strength, leading to a reduction in postoperative pulmonary complications in patients undergoing cardiac surgery.

The incentive spirometry creates stress and pain on the incision line over the sternum as the thoracic cage expands and puts pressure on the wound. The discomfort associated with incentive spirometry can prevent patients from performing these activities on postoperative days. (Seweid et al.,2021).

As well as from the clinical experience, observation for actual situations the researcher noticed that there is sever incisional pain during the use of incentive spirometry in post CABG patients at Benha University Hospital. The study of retrospective statistical record revealed that, the number of patient admitted to cardiothoracic intensive care unit at the last three years (2020, 2021, 2022) were approximately, 110, 130, 200 patients respectively (*Statistical Office in Benha University Hospital, 2022*). So this study is aimed 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 Localized Cryotherapy on Physiological Parameters Among Post Operative Cardiac Patients

Research hypotheses:

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

 H_2 : patient who will apply localized cryotherapy(cold gel pack) (intervention group) will have significantly improved in physiological parameters 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 setting:

The study was conducted in cardiothoracic surgery intensive care unit (ICU) and cardiothoracic department of Benha University Hospital. cardiothoracic intensive care unit includes four beds and it is well equipped by all necessary devices and man power needed for care of cardiothoracic patients and cardiothoracic department included three rooms, each room contains six beds.

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 within 6 months from the beginning of January till the end of June 2023 will be included in this study according to inclusion and exclusion criteria, the total number of patients participate in this study were (60) patients.

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.

Tools of data collection:

Three tools used to collect the data of the study:

<u>Tool I</u>: structured interviewing questionnaire .

This tool was developed by the researcher after reviewing related literature such as **Khalkhali et al.**, (2019), Çevik etal., (2020) and **El-Nagar et-al.**,(2020). It compromised two 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 Present medical history which included (3item), and past medical history (4 item).

Tool II: patients' perception (sensation and preference) about cold gel pack : It was developed by (Chailler, 20^{γ} .) and was used to assess patients' perception (sensation and preference) for cryotherapy (using cold gel pack) which included (8 items) such as:

- sensation during cryotherapy
- ➢ fear from side effects
- decreasing of pain sensation with cold gel pack application compared to analgesics
- changing levels of pain stimulating analgesics
- using cryotherapy can make breathing easier and expectorate more freely,
- cryotherapy is the easiest method for incisional pain relieving,

- prefer using of cryotherapy to decrease pain after CABG
- and patients' preference for cryotherapy using another time with incentive spirometry.

scoring system for Perception=10 scores

Low perception <70% = <7 scores,

High perception $\ge 70\% = \ge 7$ score

Tool III: Physiological indicators assessment sheet: The researcher developed it after considering the relevant articles (**Tang et al ., 2021& Seweid et-al .,2021**). It contained pulse rate, oxygen saturation, respiratory rate, and mean arterial pressure (4 items).

Tools validity and reliability: Tools validity

The face and content validity of the ascertained for tools were 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 pilot of the study the necessarv 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 admitted surgery patients 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.

III- Implementation phase of the procedure:

The implementation phase included the following steps:

Control group: (the group without localized cryotherapy) The researcher assessed the patients' baseline levels of of physiological parameters 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 physiological parameters assessment immediately upon completion.

study group: the group with localized cryotherapy (application of a cold gel pack intervention) physiological parameters 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 et-al.,2020 ,Manapunsopee 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 (Ceviket-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 physiological parameters and patient preference to use cold gel pack post intervention.

As soon as the 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.

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 nonparametric 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 pvalue < 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 $(40.27\pm0.74 \& 39.33\pm0.80)$ 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.

Table (2): This table describes the current health history among the studied patients (control and intervention groups), where there was no statistically significant difference between the two groups. pointing out that 76.7% and 66.7%, respectively, had comorbid disease, especially hypertension among 65.2 % and 80.0%, respectively. In addition, 76.7% and 66.7% of the studied patients follow a specific treatment regimen. while 65.2% and 80.0%. respectively, receive hypertension medications. Moreover, 36.7% and 43.3%, respectively, were diagnosed with cardiac problems in the past 1 - < 5 years.

Table (3): This table shows the previous health history among the studied patients (control and intervention groups), where there was no statistically significant difference between the two groups. Noting that (53.3% & 43.3%, respectively) had previous surgery especially Uro surgery among (43.8% & 53.8%) of them, where (43.8%) &83.4%, respectively) were hospitalized for 5-<10 day. Only 6.7% of patients in both groups had used cold gel in order to treat neck and knee pains, whereas 50.0% of the control group reported experiencing numbness, nausea. and vomiting. And 50.0% of the intervention group reported experiencing numbness only, after cold gel application.

Table (4): Displays patients' cryotherapy perceptions of among intervention group, where there was a highly significant statistical difference between first day with second day and post one-week intervention periods $(p = < 0.001^{**})$, and it was noted that 86.7% of patients in first day had a fear of the treatment's side compared to 30% in second day and 16.7% post week. while 86.7% of studied patient didn't prefer to use cryotherapy in order to decrease pain during first day compared to 13.3% in second day and 6.7% post week. However, it was also perceived that cryotherapy is a preferred method to decrease pain after CABG in second day among 86.7% to be 93.3% post one week of intervention as well as 90.0% reported that cryotherapy can make breathing easier and expectorate more freely.

Table (5): Shows the comparison of physiological indicators of pain between control and intervention groups, displaying that there was a significant statistical difference post each intervention period. Where 86.7% of control group had arrhythmic pulse, comparing by 66.7% of intervention group had rhythmic pulse during first day post intervention with p value = $<0.001^{**}$, also during the second day 73.4% of control group had pulse rate >100 b/m comparing by 66.7% of intervention group had 60-100 b/m with p value= <0.001**, concerning one-week period post intervention 63.3% of control group had \geq 95% of O2 saturation, comparing by 86.7% of intervention group with p value = 0.037^* .

Table (6): This Table shows correlation between studied variables among studied groups during one-week post intervention, it was noticed that there were a significant and negative correlation between pain intensity with respiratory rate and partial pressure of oxygen saturation but there was a significant positive correlation between pain intensity and behavioral indicators.

Table (7): Multivariate linear regression table model in this presents that physiological indicators in the control group was best predicted by presence of comorbid diseases and pain intensity ($p=0.015^*$, and <0.001**, respectively), accounting for 67.7% of the variance of physiological indicators. While regarding intervention group it was best predicted by age, pain intensity, and behavioral indicators (p= 0.007*, 0.038*, and 0.009*, respectively), accounting for 65.1% of the variance of physiological indicators.

| Patients' sociodemographic | Variables | Control N=3 | group 30 | Intervention g | roup N=30 | Test | | |
|----------------------------|----------------------------|----------------|-------------|----------------|--------------|----------------|----------------------|--|
| characteristics | | No. | % | No. | % | \mathbf{X}^2 | P value | |
| Age (year) | 20-<30 | 5 | 16.7 | 6 | 20.0 | 1.201 | 0.548 ^{n.s} | |
| | 30-<40 | 12 | 40.0 | 8 | 26.7 | | | |
| | 40-60 | 13 | 43.3 | 16 | 53.3 | | | |
| | Mean ± SD | 40.27 | ±0.74 | 39. | .33±0.80 | 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-<' • hrs | ۲۱ | ٥.٠٩ | ۲۸ | ٩٣.٣ | | | |
| | 10-12 hrs | 2 | 6.7 | 2 | 6.7 | | | |
| Residence | Urban | 21 | 70.0 | 22 | 73.3 | 0.082 | 0.774 ^{n.s} | |
| | Rural | 9 | 30.0 | 8 | 26.7 | | | |

Table (1): Distribution of studied patients (control & intervention groups) according to their sociodemographic characteristics (n=30).

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

| Pain assessment | Variables | Control N=3 | group 30 | Interve gro N= | ention up 30 | X ² test | P value |
|-------------------------|------------------------|----------------|-------------|----------------------|--------------------|------------------------|----------------------|
| | | No. | % | No. | % | | |
| Presence of chest pain | Yes | 30 | 100.0 | 30 | 100.0 | .a | N.A |
| Tresence of enest pain | No | 0 | 0.0 | 0 | 0.0 | | |
| Incidence of nain | Sudden | 19 | 63.3 | 17 | 56.7 | 2.411 | FE |
| incluence of pain | Gradual | 11 | 36.7 | 13 | 43.3 | | 0.195 ^{n.s} |
| Time of noin consection | Sleeping | 2 | 6.7 | 3 | 10.0 | 1.470 | 0.832 ^{n.s} |
| | Rest | 5 | 16.7 | 4 | 13.3 | | |
| # | Walking | 18 | 60.0 | 15 | 50.0 | | |
| | Climbing upstairs | 7 | 23.4 | 9 | 30.0 | | |
| | Continuous | 10 | 33.3 | 8 | 26.7 | 0.317 | FE |
| Intervale of pain | Intermittent | 20 | 66.7 | 22 | 73.3 | | 0.779 ^{n.s} |
| | Emergent (till 7 days) | 11 | 36.7 | 9 | 30.0 | 1.744 | 0.418 ^{n.s} |
| Type of noin | Acute (7days- 6 | 13 | 43.3 | 16 | 53.3 | | |
| Type of pain | weeks) | | | | | | |
| | Chronic (> 6 weeks) | 6 | 20.0 | 5 | 16.7 | | |
| | Tingling | 10 | 33.3 | 4 | 13.3 | 5.796 | 0.327 ^{n.s} |
| | Burning | 14 | 46.7 | 16 | 53.3 | | |
| Nature of pain # | Numbness | 1 | 3.3 | 2 | 6.6 | | |
| | Stabbing | 5 | 16.7 | 6 | 20.0 | | |
| | Pressure | 1 | 3.3 | 3 | 10.0 | | |

Table (2): Distribution of studied patients (control & intervention groups) regarding medical health history (preoperative pain assessment) (n=10).

Table (3): Distribution of studied patients (control & intervention groups) regarding medical health history (patients' lifestyle) (n=60).

| Life style | Variables | Control g N=30 | roup) | Study g N=3 | roup 60 | X ² test | P value |
|----------------------------------|-----------------------|-------------------|-----------|----------------|------------|------------------------|----------------------|
| | | No. | % | No. | % | | |
| | Yes | 14 | 46.7 | 20 | 66.7 | 3.321 | |
| Smoking | No | 13 | 43.3 | 8 | 26.6 | | 0.190 ^{n.s} |
| | Stopped smoking | 3 | 10.0 | 2 | 6.7 | | |
| | < 5 years | 0 | 0.0 | 2 | 10.0 | 2.424 | 0.489 ^{n.s} |
| | 5 - < 10 years | 2 | 14.3 | 3 | 15.0 | | |
| If yes, the period of smoking is | 10-15 years | 3 | 21.4 | 7 | 35.0 | | |
| | > 15 years | 9 | 64.3 | 8 | 40.0 | | |
| The smoked substance # | Cigarettes | 0 | 0.0 | 2 | 8.7 | 3.420 | 0.331 ^{n.s} |
| | Shisha | 8 | 57.1 | 10 | 43.5 | | |
| | Cigarettes and shisha | 2 | 14.3 | 5 | 21.7 | | |
| | Electronic cigarettes | 4 | 28.6 | 6 | 26.1 | | |
| | < 10/ day | 0 | 0.0 | 2 | 18.2 | 3.214 | 0.200 ^{n.s} |
| Times of cigarettes smoking / | 10-20 / day | 0 | 0.0 | 2 | 18.2 | | |
| uay | >20/day | 6 | 100.0 | 7 | 63.6 | | |
| | One time/ day | 0 | 0.0 | 6 | 40.0 | 1.283 | 0.526 ^{n.s} |
| Times of shisha smoking / day | 2-3 times / day | 5 | 50.0 | 3 | 20.0 | | |
| | >3 times/day | 5 | 50.0 | 6 | 40.0 | | |
| If stopped smoking, the time | < 1 year | 1 | 33.3 | 1 | 50.0 | 0.139 | FE |
| since stopping is | 1-3 years | 2 | 66.7 | 1 | 50.0 | | 1.000 |
| Toking opologies | Yes | 6 | 20.0 | 5 | 16.7 | 0.111 | FE |
| Taking analgesics | No | 24 | 80.0 | 25 | 83.3 | 1 | 1.000 ^{n.s} |
| | Anderal | 3 | 50.2 | 2 | 40.0 | 1.554 | FE |
| If yos, the type is # | Danetral | 1 | 16.6 | 1 | 20.0 |] | 0.817 ^{n.s} |
| If yes, the type is # | Paramol | 1 | 16.6 | 2 | 40.0 |] | |
| | Aspocid | 1 | 16.6 | 2 | 40.0 | | |

table (4) : Distribution of perception about cold gel back intervention among intervention group throughout different study phases

| | | | Inte | rventio | n group | o (n=30) | | | |
|------------------------------------|----------------------------|-----|-------------------|---------|-------------------|---------------|-------------------|----------------------|--------------------------------|
| | | (p | ore | imme | ediate | (most | 0.000 | $X^{2 \text{ test}}$ | X ^{2 test} |
| Patients' Perception | Variables | on) | | interv | ention | (post we | ek | P value | P value |
| | | | | | | intervention) | | (1) | (2) |
| | | No. | % | No. | % | No. | % | | |
| Sensation during cryotherapy | Experience cold | 24 | 80.0 | 2 | 6.2 | 1 | 5.0 | | |
| | feeling slight numbness | 1 | 5.0 | 15 | 50.0 | 7 | 21.7 | 63.29 | 23 49 |
| | comfort and less | _ | | 13 | 43.8 | | | <0.001 | <0.001** |
| | pain | 5 | 15.0 | | | 22 | 73.3 | | |
| Fear from side effect | Yes | 26 | <mark>86.7</mark> | 9 | 30.0 | 5 | 16.7 | 64.45 | 96.3 <0.001 ^{**} |
| | No | 4 | 13.3 | 21 | 70.0 | 25 | 83.3 | <0.001 | |
| Decrease pain level comparing to | Yes | 9 | 30.0 | 23 | 76.6 | 26 | 86.7 | 42.19 | 64.45 <0.001 ^{***} |
| analgesics | No | 21 | 70.0 | 7 | 23.4 | 4 | 13.3 | <0.001 | |
| Changing pain level makes you use | Yes | 6 | 20.0 | 25 | <mark>83.3</mark> | 26 | 86.7 | 78.51 | 87.57 <0.001 ^{**} |
| analgesics | No | 24 | 80.0 | 5 | 16.7 | 4 | 13.3 | <0.001 | |
| Cryotherapy can make breathing | Yes | 8 | 26.7 | 24 | 80.0 | 27 | <mark>90.0</mark> | 55.49 | 80.63 |
| easier and expectorate more freely | No | 22 | 73.3 | 6 | 20.0 | 3 | 10.0 | <0.001 | < 0.001*** |
| Cryotherapy is the easiest method | Yes | 6 | 20.0 | 21 | 70.0 | 25 | 83.3 | 48.51 | 60.8 |
| for pain relief | No | 24 | 80.0 | 9 | 30.0 | 5 | 16.7 | <0.001 | < 0.001 *** |
| Prefer using cryotherapy to | Yes | 4 | 12.5 | 26 | <mark>86.7</mark> | 28 | <mark>93.3</mark> | 106.46 | 128.66 |
| decrease pain after CABG | No | 26 | <mark>86.7</mark> | 4 | 13.3 | 2 | 6.7 | <0.001 ** | < 0.001** |
| Prefer using cryotherapy during | Yes | 4 | 12.5 | 24 | 80.0 | 25 | 83.3 | 89.42 | 98.2 |
| incentive spirometry | No | 26 | <mark>86.7</mark> | 6 | 20.0 | 5 | 16.7 | <0.001 | < 0.001** |

| | | Control group (n=30) | | | | | Intervention group (n=30) | | | | | | | \mathbf{v}^2 | \mathbf{X}^2 | |
|------------------|-------------|----------------------|---------------------------|----------|---------------------------|----------|---------------------------|----------|---------------------------|----------|---------------------------|----------|---------------------------|---------------------|------------------------------|--------------------|
| Physiological | | First | t day | Secon | d day | After O | ne week | Firs | t day | Secon | d day | After O | ne week | X ^{2 test} | A test D | rest P |
| indicators | Response | Baseline | After interven tion | baseline | After interven tion | baseline | After interven tion | Baseline | After interventi on | baseline | After interven tion | Baseline | After interven tion | (1) | value (2) | value (3) |
| Pulse rate b/m | < 60b/m | 9(30.0) | 0(0.0) | 10(33.3) | 1(3.3) | 1(3.3) | 7(23.3) | 2(6.7) | 3(10.0) | 2(6.7) | 6(20.0) | 1(3.3) | 1(3.3) | 26.269 | 22.292 <0.001** | 15 001 |
| | 60-100b/m | 10(33.3) | 8(26.7) | 14(46.7) | 7(23.3) | 16(53.3) | 11(36.7) | 5(16.6) | 6(20.0) | 5(16.6) | <mark>20(66.7)</mark> | 25(83.3) | 26(86.7) | <0.001** | | 15.981 <0.001** |
| | >100b/m | 11(36.7) | 22(73.3) | 6(20.0) | <mark>22(73.4)</mark> | 13(43.3) | 12(40.0) | 23(76.7) | 21(70.0) | 23(76.7) | 4(13.3) | 4(13.3) | 3(10.0) | (0.001 | (0.001 | (0.001 |
| Pulse volume | Weak | 6(20.0) | 3(10.0) | 6(20.0) | 2(6.7) | 3(10.0) | 17(56.7) | 4(13.3) | 2(6.7) | 4(13.3) | 2(6.7) | 3(10.0) | 0(0.0) | 8.270 | 7 170 | 14.206 |
| | Normal | 10(33.3) | 10(33.3) | 12(40.0) | 8(26.6) | 18(60.0) | 13(43.3) | 9(30.0) | 21(70.0) | 15(50.0) | 18(60.0) | 23(76.7) | 26(86.7) | | 0.028* | 0.001** |
| | Strong | 14(46.7) | 17(56.7) | 12(40.0) | 20(66.7) | 9(30.0) | 0(0.0) | 17(56.7) | 7(23.3) | 11(36.7) | 10(33.3) | 4(13.3) | 4(13.3) | 0.010 | 0.028 | |
| Pulse rhythm | Rhythmic | 14(46.7) | 4(13.3) | 18(60.0) | 11(36.7) | 17(56.7) | 12(40.0) | 8(26.7) | 20(66.7) | 6(20.0) | 22(73.3) | 25(83.3) | 27(90.0) | 17.778 | 39.65 | 16.569 |
| | Arrhythmic | 16(53.3) | 26 <mark>(86.7)</mark> | 12(40.0) | 19(63.3) | 13(43.3) | 18(60.0) | 21(70.0) | 10(33.3) | 23(76.7) | 8(26.7) | 5(16.7) | 3(10.0) | < 0.001** | < 0.001** | < 0.001** |
| Mean arterial | <70 MmHg | 4(13.3) | 8(26.7) | 6(20.0) | 6(20.0) | 6(20.0) | 4(13.3) | 4(13.3) | 8(26.7) | 3(10.0) | 6(20.0) | 3(10.0) | 3(10.0) | 0.001 | 12.094 | 14.509 |
| pressure | 70-100 MmHg | 20(66.7) | 6(20.0) | 18(60.0) | 5(16.7) | 5(16.7) | 11(36.7) | 9(30.0) | 16(53.3) | 7(23.3) | 17(56.7) | 22(73.3) | 25(83.3) | 9.091 | 12.084 0.002 [*] | |
| (MITH) | >100 MmHg | 6(20.0) | 16(53.3) | 6(20.0) | 19(63.3) | 19(63.3) | 15(50.0) | 17(56.7) | 6(20.0) | 20(66.7) | 7(23.3) | 5(16.7) | 2(6.7) | 0.011 | 0.002 | 0.001 |
| Respiratory rate | <12c/m | 7(23.3) | 3(10.0) | 6(20.0) | 2(6.7) | 7(23.3) | 0(0.0) | 4(13.3) | 6(20.0) | 4(13.3) | 4(13.3) | 1(3.3) | 1(3.3) | 6.924 | 0.002 | |
| c/m | 12-20c/m | 18(60.0) | 14(46.7) | 15(50.0) | 12(40.0) | 11(36.7) | 14(46.6) | 8(26.7) | 20(66.7) | 9(30.0) | 21(70.0) | 23(76.7) | 27(90.0) | 6.824 0.033* | 8.885 | 17.611 |
| | >20c/m | 5(16.7) | 13(43.3) | 9(30.0) | 16(53.30 | 12(40.0) | 16(53.4) | 18(60.0) | 4(13.3) | 17(56.7) | 5(16.7) | 6(20.0) | 2(6.7) | 0.055 | 0.012 | <0.001 |
| SpO2% | <95% | 11(36.7) | 19(63.3) | 9(30.0) | 15(50.0) | 9(30.0) | 11(36.7) | 7(23.3) | 10(33.3) | 6(20.0) | 7(23.3) | 3(10.0) | 4(13.3) | 5.406 | 4.593 | 4.356 |
| | ≥95% | 19(63.3) | 11(36.7) | 21(70.0) | 15(50.0) | 21(70.0) | 19 <mark>(63.3)</mark> | 23(76.7) | 20(66.7) | 24(80.0) | 23(76.7) | 27(90.0) | 26 <mark>(86.7)</mark> | 0.020* | 0.032* | 0.037* |

Table (5): Comparison of patients' physiological indicators of pain between control and intervention groups throughout post intervention phases (n=70).



Figure 1. Distribution of physiological indicators of pain among control and intervention groups after one week post intervention (n=3)

Table (6): Correlation between studied variables among the studied patients (control & intervention groups) after one week post intervention (n=10)

| Variables | Pain intensity | | | | |
|-------------------------------|--------------------|----------|----------------------|--|--|
| variables | r | P –value | | | |
| Pulse rate b/m | Intervention group | 0.378 | 0.039* | | |
| | 0.585 | 0.001** | | | |
| | Intervention group | 0.134 | 0.479 ^{n.s} | | |
| Pulse volume | Control group | 0.326 | 0.079 ^{n.s} | | |
| | Intervention group | 0.207 | 0.272 ^{n.s} | | |
| Pulse rhythm | Control group | 0.346 | 0.061 ^{n.s} | | |
| Mean arterial pressure (MmHg) | Intervention group | 0.473 | 0.008** | | |
| | Control group | 0.405 | 0.026* | | |
| Respiratory rate c/m | Intervention group | -0.449 | 0.013* | | |
| | Control group | -0.370 | 0.044* | | |
| SPO2 | Intervention group | -0.428 | 0.018* | | |
| | Control group | -0.677 | < 0.001** | | |
| Pahavioral indicator | Intervention group | 0.556 | 0.001** | | |
| Denavioral mulcator | Control group | 0.387 | 0.034* | | |

 Table (7): Multiple Linear Regression Analyses for Predictor Variables physiological indicators among studied patients after one week post intervention (n=60).

| | | Cor | ntrol group | | Intervention group | | | | | | |
|------------------------------|-------------------------------------|------------|--------------|----------|--------------------|----------------|------------|--------------|--------|--------|--|
| Physiological indicators | Unstandardized S | | Standardized | | | Unstandardized | | Standardized | | | |
| i hysiological marcators | Coeffi | icients | Coefficients | | | Coef | ficients | Coefficients | | | |
| | В | Std. Error | Beta | t | Sig. | В | Std. Error | Beta | t | Sig. | |
| (Constant) | 1.332 | 0.135 | | 9.831 | 0.001** | 1.134 | 0.344 | | 3.299 | 0.004 | |
| Age | 0.028 | 0.085 | 0.044 | 0.328 | 0.746 | -0.114 | 0.038 | -0.564 | -2.991 | 0.007* | |
| Sex | -0.045 | 0.053 | -0.139 | -0.849 | 0.405 | 559 | .297 | 341 | -1.884 | .074 | |
| Presence of comorbid disease | .635 | .240 | .524 | 2.651 | 0.015* | -0.092 | 0.124 | -0.230 | -0.748 | 0.463 | |
| | | | | | | | | | | | |
| Time since diagnosis with | 347 | .519 | 125 | 669 | .510 | 269 | .259 | 190 | -1.036 | .312 | |
| cardiac problems | | | | | | | | | | | |
| Smoking | .767 | .438 | .381 | 1.751 | .095 | .213 | .729 | .065 | .293 | .773 | |
| Pain intensity | -0.086 | 0.019 | -0.556 | -0.4.481 | <0.001* | -0.027 | 0.030 | -0.136 | -2.881 | 0.038* | |
| | | | | | * | | | | | | |
| Behavioral indicators | -0.005 | 0.003 | -0.225 | -1.541 | 0.138 | 0.000 | 0.006 | -0.014 | 1.991 | 0.009* | |
| Adjus | Adjusted $R^2 = 0.651$ $P = 0.005*$ | | | | | | | | | | |

Discussion

Regarding age: the current study presented that there was no statistically significant difference between the two groups. Clarifying that more than one third of control group and more than half of study group had 40-60 years old with a mean age of (40.27±0.74 & 39.33±0.80) years, this might be because this is the most affected age with coronary artery disease and CAD is common in middle and old age than young age as a result of aging process. This result was agreed with the study conducted in Türkiye. by Çevik 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 majority of studied patients were aged between 50 and 60 years old.

In contradiction with this study **Tanha et al., 2014,** whose study conducted in Iran 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.

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's point of view, this result might be because of stressors they face and unhealthy life style behavior they followed. This finding agreed with Hallman et al., (2021). who studied " Objective postoperative pain assessment using incentive spirometry values: a prospective observational study.", and reported that more than three quarter of studied patients were males.

In addition to, **Brown, et al., (2022)** who studied "Risk Factors for Coronary Artery Disease ", and showed that the percentage of male is more than female So men had a higher prevalence of CHD than woman.

But this finding was in contradict with study by by **Mehtaet al.**, (2020), and found that more than three fifths were females and less than two fifth were males.

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, (2016). who studied Effects of cold therapy on pain and breathing exercises among median sternotomy patients. they reported that married patients who have ischemic heart disease represented the higher percentage of their study subject than single and widow patients.

In respect to the educational level, result of the 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 finding agreed with the finding of study by 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, in Turkey", who revealed that the majority of heart failure patients attained an intermediate education

results was consistence with the result of **Khan et al.,(2020)** As regard to residence, the finding of the current study represented that about three quarters of the studied patients were living in urban areas,

Results were similar 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. also in the same line.

Regarding current medical history. The result of this study revealed that there was no statistically significant difference between the two groups in present medical history while more than three quarters of studied patients had comorbid disease, From the researcher's point of view, this result might be due to the chronic disease are common in old age and connected positively with coronary artery disease. This result agreed with the result of study conducted by **Seweid et al.,(2021)** who found that more than half of studied sample had chronic disease especially hypertension

Also This result was in agreement with **Keawnantawat et al., (2018)** who conducted a study about "Effectiveness of Cold Therapy in Reducing Acute Pain among Persons with Cardiac Surgery" and illustrated that more than two -third of participants underwent CABG-surgery suffer from diabetes and hypertension and diagnosed with cardiac problems in past three years

Regarding to treatment regimen. the finding of the present study revealed that more than half of studied patients follow regimen (hypertensive treatment medication) because the chronic disease need compliance with treatment regimen to avoid complications. This result was congruent with Perdoncin & Duvernov. who studied "Treatment of (2019). Coronary Artery Disease in Women in the United States ", and showed that more than two thirds of studied patients follow specific medical regmin for chronic disease

As regard to diagnosis. The present study revealed that more than one third of studied patient were diagnosed with cardiac problem since less than five years. This result was supported by the result of **Mehta** et al., (2020), who reported that more than one third of studied patients were diagnosed with CHD since less than three years.

Regarding past medical history. The result of this study revealed that there was statistically significant difference no between the two groups. Noting that more than half of control group and more than one third of study group had previous surgery especially cardiac catheterization surgery. From the researcher point of view, this may be due to the nature of coronary artery diseases which need for diagnostic or therapeutic cardiac catheterization .This result was agreed with the result of study by Taylor et al., (2022), who studied "The role of cardiac rehabilitation in improving

cardiovascular outcomes" and they revealed that more than two third of studied group had performed surgical operation.

On the other hand, the result of the present study was disagreeing with the result of study conducted by **Attia & Hassan (2017)** who stated that about half of the studied patients had no previous cardiothoracic surgery and Similarly

Third part: perception of studied patients about cold gel pack intervention

The finding of the present study showed that there was a highly significant statistical difference between pre, immediately post and after one-week post cold gel pack intervention and the majority of studied patients pre intervention had a fear of the treatment's side effects and didn't prefer to use cryotherapy or using it during incentive spirometry. but after one week of intervention it was noted that more than two third of studied patients feeling comfort and less pain ,from the researcher point of view this result about patient's perception of cold gel pack due to fear from the unknown which has been defined by researchers as a fear caused by a perceived lack of information .This result agreed with the result of study conducted by Dardier et al.,(2022) entitled "Efficacy of localized cryotherapy on incisional pain associated with incentive spirometry post coronary artery bypass graft surgery " show that more than two third of the studied patients experienced comfort and less pain after one week of localized cryotherapy application.

fourth part: comparison of physiological indicators of pain between control and intervention groups

As regard to patient's physiological indicators of pain between control and intervention groups, the present study revealed that there was a significant statistical difference between control group and intervention group regarding arterial pressure, pulse rate, respiratory rate and oxygen saturation and their values have been reduced to normal after cold gel pack intervention application.

where most of control group had arrhythmic pulse, while more than two third of intervention group had rhythmic pulse during first day post intervention with **p** value = $<0.001^{**}$, also during the second day about three quarters of control group had tachycardia after procedure while more than two third of intervention group had normal range of pulse at **p** value= $<0.001^{**}$

from the researcher point of view, this results mean that cold gel pack more effective in pain management thus there are improvement in physiological parameters in intervention group compared to control group also these results related to that increase pain may effect on physiological parameters

This result agreed with the result of study by **Seweid et al.**, (2021) about "Effect of cold application on incisional pain associated with incentive spirometry after coronary artery bypass graft surgery" who stated that physiological indicators of incisional pain associated with the use of incentive spirometry reduced with the use of cold gel pack application compared to without cold gel pack application.

The present study results were in the same line with **Bastani et al.**, (2019). who studied comparing the effect of acupressure and cryotherapy on the pain caused by removal of chest drain tube in the elderly patients undergoing open heart surgery and found that there was improvement in physiological indicators for cryotherapy group compared to acupressure group.

on the other hand, these results are controverted by **El-Nagar et al.**, (2020) who revealed that there was no significant difference in respiratory rate before and after cold application. In addition, the findings of the current study are disproved by **G'elinas &Arbour**, (2019) who revealed that pain reduction during recovery period has a significant effect on respiratory rate in comparison with nociceptive procedure.

correlation Regarding between studied variables among studied groups during one-week post intervention, it was noticed that there was a significant negative correlation between pain intensity with respiratory rate and partial pressure of oxygen saturation moreover it was positive and significant, moreover with, behavioral indicator. These results are matched with Seweid et al, (2021) who concluded that administering a cold treatment improved mean arterial blood pressure and respiratory rate but did not definitively enhance oxygen saturation. These results are controverted by El-Nagar et al., (2020) that there was significant positive correlation between pain intensity and respiratory rate before and after cold application.

Conclusion

According to the results of present study, it might be concluded that

Localized cryotherapy is one of the non-pharmacological strategies that can be used beside pharmacological management by critical care nurses to improve physiological parameters associated with the use of incentive spirometry in an easy, effective, and costless way.

Recommendations

In the light of the findings obtained from the current study the following recommendations can be suggested:

- Further studies may be needed to assess effect of using different nonpharmacological methods on improvement of Post CABG patients' outcomes.
- For post-operative patients who have CABG surgery, localized cryotherapy should be promoted as a nonpharmacological treatment option before painful activity such as incentive spirometry, deep breathing& coughing exercises and early mobilization.