Original Article

Effect of cold application in combination with Indomethacin suppository on chest tube removal pain in patients undergoing open heart surgery

Mitra Payami B[1], Nahid Daryei[2], Nouraddin Mousavinasab[3], Eskandar Nourizade[4]

Abstract

Background: Chest tube removal is a painful procedure. The goal of this study was to evaluate the effect of cold application in combination with Indomethacin suppository on chest tube removal pain in patients undergoing open heart surgery.

Materials and Methods: This single-blind, double-group clinical trial was performed on 66 patients aged 18-68 years with the chest tube in pleural space. The Indomethacin suppository (100 mg) was administered 1 h before the chest tub removal in both groups. In the intervention group, we applied a 4°C cold pack in the chest tube side for 20 min. In the placebo group, the applied pack was at room temperature. Pain intensity was measured by Visual Analog Score 20 min before, immediately after, and 15 min after the chest tube removal.

Results: Immediately after the CTR, the mean pain score was 2.67 ± 0.79 and 3.9 ± 0.76 in the intervention and placebo groups, respectively. The pain scores measured before and 15 min after the CTR were not statistically different between the two groups.

Conclusion: Application of cold in combination with Indomethacin suppository during the CTR was a suitable, low-risk, and easy method for pain control in open heart patients.

Key words: Chest tube, cryotherapy, indomethacin, Iran, pain

Introduction

Heart diseases are rapidly growing due to physical and mental pressures, anxiety, and unhealthy lifestyle. Most of the patients do not respond to medical treatments and are candidates of heart surgery.[1] According to Iran's Health Ministry official statistics, every year, 35,000-50,000 cases of heart surgery are done in Iran.[2] Following heart and chest surgery, chest tubes are placed in the thorax for taking fluid or air out of the chest.[3] The chest tubes are removed after reduction of drainage and lung dilation on the second or third day after open heart surgery.[4] Removing the chest tube is a relatively painful and distressful procedure.[5] The pain is caused by damaged intercostal nerves at the incision site, irritation and incitation of pleura during catheter placement and removal.[1] Several studies have shown that chest tube removal (CTR) is a painful procedure, the palliative treatments are not effective,[6] and only 16% of patients received pain relievers before the CTR.[7]

In different studies, medical treatments have been examined in order to relieve the CTR pain, including Remifentanil,[4] Morphine, Acetaminophen codeine and Percocet,[8] intravenous form of Paracetamol,[5] and local/topical pain relievers.[9] Due to the side effects of medications, especially on heart surgery patients, these medications have not been widely used.[10] In addition to medical therapies, the effects of complementary therapies, alone or in combination with medical treatments, have been studied for relieving pain during CTR. Some of these methods are: Ice pack,[3] cold pack and intravenous Paracetamol,[5] rapid muscle relaxation techniques with 50-75 mg Meperidine,[7] relaxation techniques with deep breathing, and Morphine Sulfate and Acetaminophen.[8] The results of the studies have shown that using cold alone and muscle relaxing technique as well were not effective in the CTR pain relief.[3,7] Other methods including cold pack and Paracetamol,[5] relaxation techniques with deep breathing, and Morphine Sulfate and Acetaminophen[8] were effective. However, these methods have some limitations; getting the patients acquainted with the relaxing techniques before surgery, patients' cooperation, related risks of the opioid drugs, and injecting intravenous

[1]Department of Nursing, School of Nursing and Midwifery, Zanjan, Iran, [2]Department of Nursing, Allinasab Hospital, Tabriz, Iran, [3]Department of Community Medicine, School of Medicine, Zanjan University of Medical Sciences and Health Services, Zanjan, Iran, [4]Subspecialist of Cardiovascular Surgery, Allinasab Hospital, Tabriz, Iran

Address for correspondence: Prof. Mitra Payami, Nursing and Midwifery, Faculty of Zanjan University of Medical Sciences and Health Services, Zanjan, Iran.
E-mail: payami@zums.ac.ir

Paracetamol are the practical barriers for using these methods broadly. Among these methods, applying cold seems to be a noninvasive and safe way of reducing pain.

Cold desensitizes sensory nerve terminals and reduces the transmission of pain. Local application of cold causes vasoconstriction, reduces blood flow to tissues and muscle spasms, reduces the secretion of histamine, serotonin, and bradykinin, and also reduces the severity of inflammation and edema.[11] Although some studies have shown that cold alone is not effective on the CTR pain,[3] it has been shown that combining cold with an analgesic drug such as intravenous Paracetamol can reduce CTR pain.[5]

Regarding the risks of intravenous drugs, it seems that using other forms of medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) with similar effects lowers the risks for patients. Indomethacin is one such NSAID that is available in different forms including as a suppository. Indomethacin is an analgesic with little side effects, relieves central and peripheral pain, and has anti-inflammatory effects.[10] Despite most prescribed medications being oral, some intolerable oral NSAIDs can be administered through the rectum.[12] The suppositories are safe, and because of elimination of the drug passage from mouth to rectum, have operational capabilities including high absorption compared to oral forms and show their peak effect within an hour.[10] Previous studies on Indomethacin have shown its effect on Colles fracture,[13] open cholecystectomy surgery,[14] and Cesarean surgery.[15]

Nurses are responsible for patients' rest and pain.[11] Regarding insufficient palliative treatments for reliving the CTR pain,[6,7] the limitations of using intravenous drugs, especially in heart surgery patients, and the necessity of applying a safe and simple strategy to reduce the CTR pain efficiently, this study was conducted to assess the effect of using cold in combination with Indomethacin suppository on the CTR pain in patients undergoing open heart surgery.

Materials and Methods

This single-blind, double-group clinical trial was carried out from May 2011 to August 2011. All open heart surgery patients hospitalized in the open heart ICU of Alinasab hospital in Tabriz were recruited to the study. From a total of 146 patients who underwent open heart surgery during the study period, 68 patients who were eligible were selected using convenience sampling method. The inclusion criteria were: Patients undergoing open sternotomy surgery, of age 18-69 years, being aware of time and place, being able to cooperate and self-report pain, with no contraindication for Indomethacin suppositories, no addiction to opioids, drugs, and cigarettes, having not received Indomethacin suppositories or other types of analgesics 6 h before the intervention and sedative drugs at least 12 h before the study, with body mass index (BMI) less than 30 kg/m^2, having at least one chest tube (CT) from the pleural space and no contraindication for removing chest tube 24 h after the surgery. The exclusion criteria were: Sudden change in the patients' condition during the intervention and pain in other organs that affect the pain in chest tube location, such as angina. The participants were randomly allocated to the intervention and placebo groups. The patients were not aware of being in the intervention or placebo group. The study purpose was explained to the participants and informed consent was obtained from them. Visual Pain Scale (VAS) was used to measure the perceived pain intensity. This instrument measures mental traits and attitudes to pain, which are not directly measurable. The pain perceived from a painful experience is classified in the median 10 cm line from analgesia on one side to possible severe pain on the other side of the spectrum. Patients mark the point at which they feel the intensity of pain. The distance from the beginning of the line to the location marked is measured with a metal scaled ruler.[16] Patients eligible for the study were aware of how to use the tools. One hour before the CTR, patients in both groups received 100 mg Indomethacin suppository. In the intervention group, cold gel at a temperature of +4°C wrapped in gas pack was applied to cool down the area for 20 min before removing the chest tube. Patients in the placebo group received usual care with similar gel pack at room temperature. The perceived pain intensity was measured using the VAS 20 min before, immediately after, and 15 min after the CTR. Taking CT out in all patients was carried out by one person.

Although VAS is a reliable and valid instrument, compared to 11-point and 21-point numerical box scales, patients made more mistakes using VAS.[16] For reliability, VAS and Numerical Ratig Scale (NRS) were performed for a group of eligible patients in a short interval ($r = 0.96$). Content validity was confirmed by nursing and other related scientific committee members of Zanjan University of Medical Sciences.

SPSS-16 was used for data analysis. To determine the normal distribution of variables in the two groups, the Kolmogorov–Smirnov test was used. To compare the pain before and after the CTR in each group, paired *t*-test was used. To determine the effect of cold application in combination with Indomethacin suppositories in the intervention and placebo groups, independent *t*-test was used. To compare pain intensity in the two groups, in three rounds, statistical repeated measurements method (repeated measure mixed models) was used.

Results

From the total of 68 participants, 2 participants had respiratory difficulties and were withdrawn from the study. The presented results are for 66 patients: 32 (48.5%) in the intervention group and 34 (51.5%) in the placebo group. Mean age of the participants was 57.31 ± 7.8 years in the intervention group and 60.18 ± 6.2 years in the placebo group. Almost half of the patients (48.1%) in the intervention group underwent coronary bypass surgery (CABG) and 59.1% underwent valvular surgery and CABG. Twenty-nine patients (46.8%) in the intervention group and 33 patients (53.2%) in the placebo group had two chest tubes located in pleura and mediastinum space. There were no differences between the two groups with respect to the characteristics of sex, age, height, and weight at baseline ($P > 0.05$). Also, there were no statistical differences between the two groups at baseline regarding the study variables including type of surgery and the number of grafts, number and diameter of the CT, the time between surgery and CTR, and intensity of pain after surgery CTR ($P > 0.05$). Table 1 shows the comparison of participants' characteristics at baseline.

Comparison of the pain intensity before, immediately after, and 15 min after the CTR in both groups showed that pain was increased in both groups immediately after the CTR and was reduced 15 min after the CTR [Figure 1].

The paired *t*-test results showed a statistically significant difference in pain intensity immediately after and 15 min after the CTR in both intervention and placebo groups ($P = 0.0001$).

The mean pain intensity scores before, immediately, and 15 min after the CTR were compared in both placebo and intervention groups by the independent sample *t*-test. Results indicated that decrease in the pain intensity was more immediately after the CTR in the intervention group than in the placebo group. This difference was statistically significant ($P = 0.0001$). However, the pain intensity score 15 min after the CTR showed no statistically significant difference between the groups [Table 2].

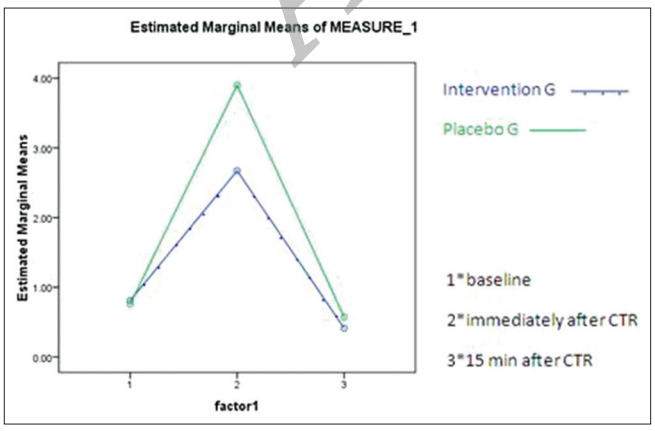

Figure 1: Pain scores before, immediately, and 15 min after removal of the chest tube in the intervention and placebo groups Green line = placebo group Blue dotted line = intervention group

Effects of gender, age, BMI, and number of grafts were assessed separately on pain intensity scores in the three phases. The results showed that gender, age, BMI, and number of grafts had a significant effect on pain intensity scores ($P > 0.05$).

Discussion

Table 1: Comparison of characteristics between intervention and placebo groups

Characteristics	Intervention group (*n*=32)	Placebo group (*n*=34)	*P* value
Sex *n* (%)			
Female	24 (49)	25 (51)	1.00
Male	8 (47.1)	9 (52.9)	
Age, years (mean±SD)	57.3±7.8	60.2±6.2	0.11
Length, m (mean±SD)	1.6±0.1	1.6±0.2	0.47
Weight, kg (mean±SD)	69.5±13.2	72.2±8.4	0.33
BMI, kg/m² (mean±SD)	24.5±3.5	26.1±2.01	0.02
Type of surgery *n* (%)			
CABG	26 (48.1)	28 (51.9)	1.00
CABG with changing valves	6 (50)	6 (50)	
Type of analgesic *n* (%)			
Codein	7 (35)	13 (65)	0.23
Indomethacin	16 (50)	16 (50)	
Diclofenac	9 (64.3)	5 (35)	
Graft no. *n* (%)			
1	4 (50)	4 (50)	0.9
2	7 (47.7)	8 (53.3)	
3	12 (46.2)	14 (53.8)	
4	8 (57.1)	6 (42.9)	
Chest tube diameter, French *n* (%)			
28	9 (64.3)	5 (35.7)	0.37
32	11 (47.8)	12 (52.2)	
36	12 (41.4)	17 (58.6)	
Vital sign			
Systolic BP, mm/Hg (mean±SD)	111±10.1	22.1±110	0.73
Diastolic BP, mm/Hg (mean±SD)	65.1±7.9	65.9±10.6	0.72
Heart rate *n* (%)	80±9.1	82±10.7	0.41
Respiratory rate *n* (%)	22.1±2.6	23.9±12.1	0.4

SD: Standard deviation

Table 2: Comparison of pain intensity scores before, immediately, and 15 min after removal of the chest tube in the intervention and placebo groups

Pain intensity	Intervention group (*n*=32)	Placebo group (*n*=34)	Results	
	Mean±SD	Mean±SD	*t* test	*P* value
Pain score before CTR	0.8±0.5	0.6±0.7	0.34	0.73
Pain score immediately after CTR	0.79±2.6	0.76±3.9	−6.45	0.001
Pain score 15 min after CTR	0.41±0.4	0.55±0.5	−1.34	0.18

CTR: Chest tube removal, SD: Standard deviation

In this study, we aimed to assess the effect of cold application in combination with the Indomethacin suppositories on the CTR pain in patients undergoing open heart surgery. The results showed that the application of cold in combination with Indomethacin suppositories was more efficient than Indomethacin alone in relieving pain in patients after open heart surgery ($P = 0.001$).

The results showed that the pain score in the placebo group was higher than that in the intervention group immediately after the CTR. The participants in the intervention group had reported less pain than the participants in the placebo group. In Demir *et al*. (2010) study, the effect of combination of cold and intravenous Paracetamol on pain of the CTR was investigated and similar results were obtained.[5] While the results of Sauls' study (2002) indicate that ice compression was ineffective in relieving the CTR pain.[3] The inconsistency of our results with those of Sauls' study may be due to some differences in the methodologies of the studies. In Sauls' study, the number of samples was small ($n = 50$), ice was applied for a short period of time (10 min), and palliative drugs were not used.

The severity of pain in both groups immediately after the CTR compared with the pain scores measured before and 15 min after the CTR showed that the CTR was a painful procedure for patients in both groups. In a study by G›elinas (2007) on management of pain in cardiac surgery ICU patients, the participants expressed that the CTR was painful.[17] Similar to our results both control and intervention groups of Sauls' s study experienced more pain immediately after CTR compared to before and 15 min after CTR.[3]

The results of pain scores 15 min after the CTR in the intervention and placebo groups showed that the intervention group experienced less pain than the placebo group. The difference was not statistically significant. In Sauls' study also, no significant difference was not found in the pain scores 15 min after the CTR between the intervention and placebo groups.[3] By the way, the pain intensity 15 min after the CTR were significantly reduced in both studied groups. Comparing the perceived pain intensity 15 min after the CTR with that before the CTR represents pain relief This difference was statistically significant, which indicates the continuing effects of Indomethacin.

This study was conducted among a limited number of patients undergoing open heart surgery. Therefore, the findings cannot be generalized to other patients who experience CTR. It is recommended to repeat the study with more patients who experience the CTR for other reasons. The present study was designed in two groups; so, the possible placebo effect was not identified on the patients' pain perception. It is recommended to conduct a similar study in three groups to exclude the placebo effect. In our study, patients might have responded differently to pain based on their physical condition, emotional and cultural states. Further studies in different settings are suggested.

Conclusion

Although Our findings showed application of cold in combination with Indomethacin suppository during the CTR was a suitable, low-risk, and easy method for pain control in open heart patients, further studies in different settings are suggested.

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