54

Abstract

Background: Current strategies to control pain and anxiety of chest tube removal are not efficacious. The aim of this study is to determine the effects of cold therapy and respiratory relaxation exercise on pain and anxiety of chest tube removal. Materials and Methods: A parallel single-blind clinical trial study was conducted in Imam Khomeini Hospital, Iran, on 120 patients. Participants were randomized into 4 groups of 30. Numeric Rating Scale was used to assess pain and anxiety. One-way ANOVA test and Fisher's exact test were used to analyze demographic data. The Kruskal-Wallis test was used to compare the severity of pain and anxiety between groups; the Friedman and Mann-Whitney test were used to compare the severity of pain and anxiety within groups with a significance level of 0.05. Results: Pain intensity was weak before chest tube removal and there was no significant difference in basal pain. Pain immediately after chest tube removal was significantly higher than other times in each group ($\chi^2 = 57.16$, $\chi^2 = 63.70$, $\chi^2 = 46.49$, $\chi^2 = 59.04$, df = 3, p < 0.001). There was no significant difference in pain score immediately (p = 0.052) and 15 min (p = 0.329) after Echest tube removal in experimental groups compared to the control group. No significant difference was found between control and experimental groups in anxiety score immediately (p = 0.995) and 15 min (p = 0.976) before chest tube removal. **Conclusions:** Mentioned methods were not effective in reducing pain and anxiety. It is suggested to investigate effects of different methods of removing chest tubes and applying cold with a larger sample size.

Keywords: Anxiety, chest tubes, cryotherapy, Iran, pain, relaxation

Introduction

Chest tubes are usually inserted after cardiac surgeries and other circumstances to drain air, blood, pus, and other secretions from the mediastinum and pleural cavity.^[1,2] Chest Tube Removal (CTR) has been reported as a painful and frightening procedure for patients in intensive care units.^[3] Beyond the association between cardiorespiratory pain and anxiety, pain can cause feelings of anxiety that in turn can increase the sensitivity of the patient to the pain.^[4] So, it seems that by controlling pain, anxiety can also be controlled. Although the American Society for Pain Management Nursing indicates that optimum pain management before, during, and after every procedure is everyone's right, the pain of CTR is poorly and inefficiently managed.[5-7] Payami et al. quoted from Tylor et al. that "Nurses are responsible for patients' rest and pain."[8] To control pain, nonpharmacological methods having no analgesic side effects confer

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higher priority than pharmacological ones because they can be used independently by nurses and are easily accepted by patients.^[3,9,10] Cold therapy is an efficient nonpharmacological method in pain control since it slows nerve conduction velocity that increases pain threshold.^[9,11] It also decreases edema, cellular metabolism, muscle spasms, and blood flow and causes numbness around the chest tube.[12,13] Another nonpharmacological method that can physiologically and psychologically decrease pain and anxiety is relaxation exercise, which is defined as the absence physical. mental, and emotional of tension.^[3,14] Relaxation physiologically reduces sympathetic response to pain leading to reduction of oxygen consumption, blood pressure, heart rate, respiratory rate, and muscular tension and psychologically distracts patients from the pain.^[3,15]

Previous studies have yielded conflicting results about the efficacy of cold therapy and

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respiratory exercise on reducing pain and anxiety related to CTR; some of these studies like Demir, Gorji et al., and Mokadem et al. found that mentioned methods were effective in reducing pain.^[9,14,16] Chen and Hsieh evaluated the effectiveness of cold application for pain associated with CTR in a systematic review. The researchers reported that cold application was effective in reducing pain but there was a need to do further studies to support these results.^[17] About anxiety, there was a significant difference in anxiety score between groups in a study by Aktas et al. and Mokadem et al.^[6,16] On the other hand, Aktas et al., who examined the effects of cold therapy in a double-blind, four-group experimental study, believed that cold therapy was not effective in reducing pain.^[6] About effects of relaxation exercise, Houston and Jesurum, who examined the effect of Quick Relaxation Technique (QRT), stated that QRT did not significantly decrease pain caused by CTR.^[15] Demir found that cold therapy was insufficient to reduce anxiety related to CTR.[9]

To our knowledge, no study was found that examined the effects of cold therapy and respiratory exercises separately and together on pain and anxiety associated with CTR. Regarding the insufficient management for CTR pain and anxiety, previous conflicting studies about the efficacy of mentioned methods and limitation of using analgesics by nurses to control pain and anxiety, this study was conducted to determine the effects of cold therapy and respiratory relaxation exercise on the pain and anxiety related to CTR.

Materials and Methods

This study was a parallel single-blind four-group clinical trial (IRCT20170827035918N2) that was conducted on 120 patients in ICU open-heart ward of Imam Khomeini Hospital, Tehran, Iran from July 2018 to March 2019. The sample size with a statistical power of 95% and a power of 80% was obtained [120 (30 for each group)] according to a similar study by Hasanzadeh.^[12] According to the standard deviation of pain intensity in the experimental and control group (1.8 and 2, respectively) and assuming an attrition rate of 10%, this sample size was obtained.

Patients were selected with convenience sampling methods. Inclusion criteria included undergoing open-heart surgery, having two chest tubes, complete consciousness, age >18, Body Mass Index (BMI) <35, stable vital signs, no drug addiction, ability to report pain, absence of any mental, communicative, and psychotic disorders, not receiving analgesic and sedatives 4 h before the intervention, and willingness to participate. The exclusion criteria consisted of sensitivity to ice and withdrawing from the study. Permuted block randomization with a size of four was used to randomly allocate participants to one of four groups: control group, group 1 (cold therapy), group 2 (respiratory relaxation exercise), group 3 (respiratory exercise in combination with cold therapy). To explain in detail the randomization technique: a group of the participants were

randomly defined using the letters A, B, C, D. Then, two series of 24 possible permutations were written in different pieces of papers, for example, ABCD and ADBC. Then, 30 permutations were randomly selected; in this way, sequences of blocks were determined. The assignments of the patients were determined according to permutation order in the block. For example, the first patient's group was determined according to the first permutation in the first block.

The procedures for each group are as follows: in the control group, no intervention was done for the patients and the chest tubes were removed according to the ward policies. Chest tubes were removed without any interventions or medications every day at 7 except Sundays. In group 1, three equal ice cubes were put in a one-use nylon cylindrical bag with a length of 0.25 m and width of 0.07 m for each patient. After putting patients in a semi-fowler position with a pillow under their head, ice bags, which were wrapped in a dressing gauze, were applied on either side of the chest tubes. According to previous studies, ice bags were applied for about 20 min until the skin temperature reached to 13°C.^[6,9,15] Gorji et al. quoted from Forouzan et al. and Janwatanakul that ice application can relieve pain when the skin temperature is under mean 13.6.[14] Because one ice bag was not long enough to cover around the chest tubes completely, two curved ice bags which were attached to each other were applied around chest tubes. An infrared thermometer which was calibrated was used to measure skin temperature. One-use bag and an infrared thermometer reduced significantly the risk of infections through patients. After 20-min chest tubes were removed. In group 2 after providing privacy and a quiet environment, the patients were instructed on how to perform the respiratory exercises by the researchers. Respiratory exercises were inhaling slowly from the nose and exhaling through semiclosed lips two times slower than inhalation with closed eyes until feeling relaxed and after 15-min chest tubes were removed by the physician.^[3,14] In group 3, both interventions were done for the patient at the same time. Designed ice bags were applied 20 min before CTR according to the method of experimental group 1, then the patients were asked to simultaneously do relaxation exercises according to the method of experimental group 2 for about 15 min, then chest tubes were removed. The same physician removed chest tubes for all of the patients. According to the ICU policies, the physician removed the two chest tubes together at the same time. The interventions were done before the physician's presence in the ward, so the physician was blind to the type of groups. Because only one physician removed the chest tube and all participants were in an equal situation, the effect of physician's technique was controlled in this study. In all groups, the pain severity score was measured in 4 points of time: 20 min and immediately before CTR, immediately and 15 min after CTR. The anxiety intensity was measured in 2 points of time: 20 min and immediately before CTR.

Data were collected with a questionnaire that consisted of two parts. The first part included demographic information, such as age, gender, weight, BMI, marital status, education level, occupation, economic status, and ethnicity, and information about a disease such as the type of the surgery, number of days with chest tube, and previous medical history; all information were collected from medical records and interviews with patients. The second part included Numeric Rating Scale (NRS) to measure pain and anxiety. It is important to admit that first Visual Analogue Scale (VAS) was used to measure pain and anxiety, but old patients couldn't fill them properly and had difficulty with them. Also, other pain and anxiety questionnaires, which 5–10 min are needed to fill them, were not found suitable for our study goal because the aim of this study was to measure pain and anxiety at the time of removing chest tube. Regarding mentioned reasons, we decided to use NRS. Patients reported their pain from 0 (without pain) to 10 (worst pain). VAS is a common and standard tool to assess the intensity of pain because there is a strong correlation between NRS and VAS; the validity and reliability of NRS in measuring pain is confirmed.^[18] Anxiety was measured by NRS ranging from 0 (no anxiety) to 10 (worst anxiety). Validity and reliability of NRS in assessing anxiety have been confirmed by previous studies.^[19,20] One-way ANOVA tests and Fisher's exact test were used to analyze demographic data with SPSS System for Windows (version 23; IBM Corporation, Somers, NY). With a significant level of 0.05, the Kruskal–Wallis test was used to compare the severity of pain and anxiety between groups and the Friedman and Mann-Whitney tests were used to compare the severity of pain and anxiety within groups. The method part was written according to consort checklist (2010).

Ethical considerations

Ethical approval from the Ethics Committee of Tehran University of Medical Sciences with the number of IR.TUMS.VCR.REC.1396.4155 was obtained. The aim and goal of the study were explained to the participants before interventions and they were assured about confidentiality and anonymity of their information. They were assured that participation in this study is voluntary and they can leave the study at any time. Verbal and written informed consents were obtained from patients who accepted to participate in the study.

Results

From a total of 150 patients who had open-heart surgery, 20 patients did not meet inclusion criteria and 10 patients declined to participate in the study. Finally, 120 (30 patients in each group) patients were enrolled in the study in each of the experimental and control groups. The age range of participants was from 18 to 78 with mean (SD) 57.70 (10.16), 59.43 (11.78), 51.26 (15.77), and 53.83 (12.25) in the control group and experimental

groups 1, 2, and 3, respectively ($F_{3,116} = 2.55$, p = 0.059). The percentage of men who participated in the present study was 56.70, 56.70, 66.70, and 70 in the control group and experimental groups, respectively ($\chi 2= 1.81$,df=3, p = 0.61). The majority of patients were married with percentages of 93.10, 96.70, 86.70, 83.30 in the control group and experimental groups, respectively (p = 0.33). No statistically significant difference was found between groups in demographic characteristics (p > 0.05). A comparison of other demographic characteristics of participants in the study groups is shown in Table 1.

Mean (SD) scores for pain and anxiety in different times are shown in Tables 2 and 3. As shown in Table 2, pain intensity was weak in all groups before CTR and there is no significant difference in pain intensity 20 minutes before CTR (0.816) and immediately before CTR (0.592). Pain intensity immediately after CTR was significantly higher than other times in each group ($\chi^2 = 57.16$, $\chi^2 = 63.70, \, \chi^2 = 46.49, \, \chi^2 = 59.04, \, df = 3, \, p < 0.001$). The difference in pain intensity score immediately (p = 0.052)and 15 min (p = 0.329) after CTR between control and experimental groups was not statistically significant. As shown in Table 3, the anxiety score was mild within all groups before CTR without any significant difference within control group (p = 0.655), group 1 (p = 0.829), group 2 (p = 0.666), and group 3 (p = 0.073), and no significant difference was found between control and experimental groups in anxiety score 20 min (p = 0.995) and immediately before CTR (p = 0.976).

Discussion

The aim of this study was to determine the effects of cold therapy and respiratory relaxation exercise on the pain and anxiety related to CTR. Our findings revealed that these methods are not efficient to reduce pain and anxiety caused by CTR. According to our results, pain intensity increases significantly (p < 0.001) just after CTR in all groups; this finding is similar to previous studies by Abbasi Teshnizi, Demir, and Sauls.^[7,9,21] The pain intensity score immediately and 15 min after CTR in experimental groups was lower than that in the control group, but this reduction was not statistically significant; in another word, cold therapy and respiratory exercises were not effective in reducing pain and anxiety. This finding is similar to some of the previous studies.^[6,21,22] In all mentioned studies, cold therapy did not provide an effective pain and anxiety relief immediately and 15 min after CTR. The findings of our study are similar to some parts of the study conducted by Mohammadi et al.^[23] Mohammadi et al. examined effects of cold therapy and music therapy in a factorial randomized controlled trial.^[23] In the cold therapy group, 9-in. ice packs were applied for 20 min; cold therapy reduced pain intensity immediately after CTR, but as our study, there was no significant difference 15 min after CTR.^[23] This inconsistency can be explained by differences

Sajedi-Monfared, et al.: Cold application and respiratory relaxation exercise on the pain and anxiety related to chest tube removal

Characteristics		Control	Group 1	Group 2	Group 3	Statistical tests		
		group	•		•	F/χ^2	df	р
Body mass index, mea	26.45 (3.76)	26.74 (4.73)	28.14 (6.54)	25.56 (4.60)	1.32*	3*	0.271*	
Max-min		18.75-34.48	15.90-38.06	18.52-43.56	15.90-43.56			
Education level	Under diploma	20 (66.60)	15 (53.60)	17 (58.60)	14 (46.70)	7.22**	-	0.296**
no. (%)	Diploma	5 (16.70)	11 (39.30)	6 (20.70)	12 (40)			
	Postdiploma	5 (16.70)	2 (7.10)	6 (20.70)	4 (13.30)			
Occupation no. (%)	Employee	4 (13.40)	2 (6.90)	6 (20.70)	6 (20)	14.35**	-	0.087**
	Housewife	13 (43.30)	14 (48.30)	5 (17.20)	6 (20)			
	Jobless	0 (0)	1 (3.34)	4 (13.80)	3 (10)			
	Other***	13 (43.30)	12 (41.40)	14 (48.30)	15 (50)			
Type of surgery no. (%)	Valve surgeries	4 (13.30)	3 (10)	6 (20)	6 (20)	4.13**	-	0.919**
	Cardiovascular****	5 (16.70)	7 (23.30)	8 (26.70)	7 (23.30)			
	Coronary artery bypass graft	18 (60)	16 (53.30)	14 (46.70)	13 (43.30)			
	Coronary artery bypass graft and valve surgeries	3 (10)	4 (13.3)	2 (6.70)	4 (13.3)			
Past medical history no. (%)	Diabetes mellitus	3 (13.60)	13 (50)	10 (40)	14 (66.70)	15.56**	-	0.066**
	Hypertension	4 (18.20)	3 (11.50)	5 (20)	2 (9.50)			
	Diabetes mellitus and hypertension	7 (31.80)	5 (19.20)	3 (12)	3 (14.30)			
	Other****	8 (36.40)	5 (19.20)	7 (28)	2 (9.50)			
Number of days with	2 days	28 (93.30)	28 (93.30)	25 (83.30)	28 (93.30)	2.31**	-	0.542**
chest tube no. (%)	<2	2 (6.70)	2 (6.70)	5 (16.70)	2 (6.70)			

*ANOVA, **Fisher's exact test, ***Student, retired, self-employment, ****Heart transplant, aneurysm repair, arrhythmia surgery, *****Cerebrovascular accident, cancer, heart stroke, hyperlipidemia, thyroid disorders, chronic kidney disease

Table 2: Comparison of pain intensity scores among the study groups at different times*										
Time (pain)		20-min before	Just before	Just after	15-min after	Statistical tests***				
Groups (pain)	CTR**		CTR	CTR	CTR	χ^2	df	р		
Control Group		1.80 (2.21)	1.70 (2.23)	6.33 (2.35)	1.76 (2.29)	57.16	3	< 0.001		
		0-7	0-7	0-10	0-10					
Group 1	1.46 (2.34)		0.96 (1.75)	5.83 (2.42)	1 (1.61)	63.70	3	< 0.001		
		0-10	0-7	0-10	0-5					
Group 2		1.66 (2.20)	1.33 (1.91)	4.70 (2.83)	1.16 (2.22)	46.49	3	< 0.001		
		0-8	0-7	0-10	0-10					
Group 3		1.85 (2.59)	1.30 (2.23)	5.90 (2.68)	1 (1.72)	59.04	3	< 0.001		
		0-10	0-8	0-10	0-7					
statistical test ****	\mathbf{X}^2	0.94	1.90	7.70	3.43					
	df	3	3	3	3					
	р	0.816	0.592	0.052	0.329					

*Data are presented as mean (SD), min-max, **Chest tube removal, ***Friedman test, ****Kruskal-Wallis

Time		Control group	Group 1	Group 2	Group 3	t different times* Statistical tests***		
						χ^2	df	р
20-min before CTR**		1.40 (2.58)	0.90 (1.49)	1.46 (2.66)	1.66 (3.16)	0.07	3	0.995
		0-10	0-5	0-10	0-10			
Immediately before CTR		1.43 (2.66)	0.90 (1.42)	1.43 (2.5)	1.10 (2.26)	0.21	3	0.976
-		0-10	0-5	0-10	0-10			
Statistical tests****	Ζ	-0.44	-0.21	-0.43	-1.79			
	р	0.655	0.829	0.666	0.073			

*Data are presented as mean (SD), min-max, **Chest tube removal, ***Friedman test, ****Kruskal wallis

in ice bag dimensions. In Mohammadi's study, larger ice packs (0.22 m) were used while in our study ice bags were 0.07 m. About the effects of relaxation exercises, our study

is similar to a study conducted by Houston *et al.*, in which the effects of QRT were evaluated. Houston concluded that QRT was not efficient in reducing pain during CTR.^[15]

The findings of the current study are different from what was reported by Hasanzadeh et al. and Mokadem et al. who both evaluated the effects of cold application and respiratory exercise on pain and anxiety in patients who had cardiac surgery.^[12,16] They demonstrated that mentioned methods can reduce pain and anxiety of removing chest tube. In both studies, all participants received 1 g acetaminophen intravenously before CTR and cold-gel packs were used to decrease skin temperature. Maybe this discrepancy is because of using analgesic and different methods of cooling skin. Payami et al., who examined the effect of cold application in combination with Indomethacin suppository on CTR in a single-blind, double-group clinical trial, reported that cold application is effective in reducing pain.^[8] It seems that this contradictory result is because of administrating Indomethacin suppository (100 mg) before CTR in both control and experimental group.

For a better concentration on respiratory exercises, a quiet environment is required because pain perception depends on different environmental factors such as noise, light, and procedures.^[9,16] In the current study, providing a quiet environment was difficult because this study was conducted in a busy ICU ward. Researcher lessened distracting factors by providing a private environment for each patient. Another limitation was lack of cooperation of some elderly people with respiratory exercises; for solving this problem, the researcher helped them in doing respiratory relaxation exercise correctly by accompanying them. Based on our findings, cold therapy and respiratory relaxation exercises are not sufficient for managing CTR-induced pain and anxiety. For future studies, it is suggested to explore and compare the effects of different methods of removing chest tubes and decreasing skin temperature with ice cubes or ice-gel packs with larger sample size.

Conclusion

The current study revealed that cold application and respiratory relaxation exercise were not effective in reducing pain and anxiety related to CTR and it is not suggested to use these methods for managing pain and anxiety during CTR. The results of this study can be generated, especially in ICU patients >50 years.

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Conflicts of interest

Nothing to declare.

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