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The effect of local heat therapy on physiologic parameters of patients with acute coronary syndrome: a randomized controlled clinical trial

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ABSTRACT

Aims: Acute Coronary Syndrome (ACS) is a common cardiovascular disease. In patients with this disease, symptom management is performed both pharmacologically and non-pharmacologically. One of the non-pharmacologic symptom management interventions is chest local heat therapy. The aim of this study was "to determine the effect of chest local heat therapy on physiologic parameters in patients with ACS".

Methods: We conducted this randomized double-blind placebo-controlled clinical trial in 2013—during six months in Cardiac Care Unit of 22 Bahman hospital in Gonabad, Iran. In this study, we randomly allocated 66 patients with ACS to two placebo and experimental groups. Patients in the experimental and control groups received chest local heat therapy by using a hot pack warmed to 50°C and 37°C respectively. Local heat therapy was administered for four 23-minute sessions in the anterior part of the chest. The levels of patients' heart rate, respiratory rate, arterial blood pressure and blood oxygen saturation were measured both before and after the intervention. Data collection tools consisted of a demographic questionnaire and a data sheet for recording physiologic parameters. Data were analyzed by using SPSS 16 software and descriptive and inferential statistical tests.

Results: There was no significant difference in the two groups before and after the intervention in terms of systolic and diastolic blood pressure as well as heart rate. However, in compare with before the intervention, systolic and diastolic blood pressure in the experimental group were decreased significantly ($p<0.05$). Moreover, before the intervention, there was no significant difference in the two groups in terms of respiratory rate and oxygen saturation. However, after the intervention, respiratory rate in the experimental group in compare with before the intervention and placebo group were decreased significantly and oxygen saturation was increased significantly ($p<0.05$).

Conclusions: The study findings confirmed the effectiveness of local heat therapy in improving physiologic parameters in patients with ACS.

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1. Introduction

Cardiovascular diseases are among non-communicable diseases that have been greatly spreading due to new technologies and equipment, change in lifestyle and modern lifestyle, switching to urbanization and unsuitable food habits [1]. These diseases are now the most common diseases in the developed countries and their outbreak is increasing in the developing countries, so that; they are still the most common cause of death and they cause 35% of all the death in the world (almost one million deaths every year), this amount is close to 40% in high-income countries and in low to middle-income countries it is about 28% [2]. Coronary artery diseases are the most common cardiac diseases [3]. About 46% of deaths are related to coronary artery diseases [4].

Acute Coronary Syndrome (ACS) is said to a group of cardiovascular disorders which is determined with different degrees of ischemia, the most common type of that is Unstable Angina (UA), Myocardial Infarction with ST-segment Elevation (STEMI) and Myocardial Infarction without ST-segment Elevation (NSTEMI) [5]. ACS happens because of decrease in myocardial oxygen supply (atherosclerosis and coronary artery spasm) or increase in myocardial oxygen demand (tachycardia or severe anemia) [2]. The four main modifiable risk factors in these patients include; atherosclerosis, smoking, hypertension and mellitus diabetes and complications due to them that all of them lead to increase of vascular injury and finally coronary syndrome [5].

Clinical manifestations in these patients include; chest pain, perspiration, dyspnea and a feeling of choking, tachycardia, vomiting, changes in blood pressure often in the form of hypertension, anxiety and the feeling of being on the verge of death that all of them deteriorate myocardial oxygen supply and demand balance and intensifies ischemia process. Vascular endothelium dysfunction can be seen in the patients with ACS because of different reasons that the most common reason is atherosclerosis that is because of arteriole dilation reduction and finally increase of blood pressure. Also, in these patients, vascular injuries causes release of inflammatory mediators such as; bradykinin and histamine which is because of contraction of smooth muscle in the vessels wall, increased vascular resistance and increased blood pressure [2].

From the other side, patients with ACS experience different levels of anxiety during hospitalization. About 50% of these patients report anxiety symptoms which can be because of hospitalization, fear of death and also fear of further MI and totally fear of unknowns [6] which can cause release of catechol amines and physiologic reactions such as; increased blood pressure, heart rate, increased number of respiratory and dyspnea and as the result development of myocardial ischemia [7].

Treatment and management of the symptoms is very important in ACS stage and decreases patients' death complications to the high extent. The main aims in treatment and taking care of these patients is myocardial blood flow, symptoms management, preventing development of myocardial ischemia, and decreasing their anxiety [5].

For symptoms management in these patients, some drugs such as; nitrates, beta blockers, opioids and calcium blockers are being used which have considerable complications [2]. Nowadays, weakness of medical academic knowledge in many aspects, alternative non-pharmacological therapy methods are more considered since they have fewer complications and they are available and effective. One of the recommended non-pharmacological methods for symptoms management in these patients is heat therapy, this method can improve symptoms of these patients with different mechanisms.

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Heat therapy keeps toxic metabolites such as; histamine and bradykinin away from the area and improves oxygen supply through dilating vessels and increasing blood flow to the inflamed and damaged area, as the result; improvement of these patients' symptoms can be expected [8]. From the other side, heath therapy decreases contraction of smooth muscle in the vessels wall by stimulating heat receptors and as the result enlarges the vessels wall and improves the symptoms in this way. Also heat therapy decreases activity of the sympathetic nervous system and decreases smooth muscle contraction of the vessels wall and improves symptoms [9].

Different methods are used for heath therapy that one of them is local heat therapy with hot pack. Hot pack is a special hot water bag that produces moist heat and in addition to heating and increasing blood flow of the area, transfers heat to the deeper tissues too [10].

Methods of heat therapy are assessed generally in other heart diseases and appropriate results have been achieved. Studies have shown that; sauna and heat therapy of the whole body improves hemodynamic situation, ventricular arrhythmias, vascular endothelial performance, neurological and hormonal factors, autonomic nervous system performance and symptoms in patients with Congestive Heart Failure (CHF) [11]. From the other side according to other studies, heat therapy increases Nitric oxide synthesis in vascular endothelium and as the result; vasodilatation effects on blood pressure and growth of new blood vessels [12].

Considering situation of the patients with ACS, using Sauna and heat therapy of the whole body in the acute stage of the disease is not possible. It is possible to do local chest therapy with hot water bag for symptoms improvement of these patients; it may have the same effect as the whole body heat therapy. According to the clinical experiences it has been observed that some physicians and nurses use hot water bag with different temperatures and different times sporadically for improving these patients' symptoms, but scientific and valid studies which determine its positive and probable effects at special temperature and time are less considered by the researchers and the present study is done for this purpose with the aim of "determining the effect of local heat therapy on physiologic indicators of the patients with ACS".

2. Methods

This is a randomized double-blind placebo-controlled clinical trial study which was done in 2013 for six months in Cardiac Care Unit of 22 Bahman hospital in Goanbad. Samples of the study were the patients with definite diagnosis of ACS. Sample size was determined 32 patients by using Pilot study based on the formula of comparing the mean of the two groups with power test of 80% and the confidence of 99% for every group and by considering the probability of losing samples, the final sample size was considered 33 patients for every group.

Inclusion criteria included: definite diagnosis of ACS by a specialist, stable physiologic situation for answering the questions, lack of alcoholism and drug addiction, lack of suffering from diabetes, lack of chest muscular and skeletal or digestive diseases at the time of the disease, the ability of speaking and complete understanding of Persian language, lack of psychological disorders, lack of inflammation, wounds, abrasions and redness on chest, heart rate over 60 beats per minute, systolic blood pressure above 90 mmhg and BMI between 18.5 to 25. Exclusion criteria included; unwillingness to continue participation in the study and every kind of clinical conditions that need any specific diagnostic and therapeutic procedures and with a cardiologist's diagnosis, local heat therapy is not possible for the patient.

For data collection; a two-part questionnaire was used; the first part included; demographic information related to the disease and the

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second part included; recording sheet of systolic and diastolic blood pressure, heart and respiratory rate and arterial oxygen saturation. For measuring these cases SADAT monitoring made in Iran that is a standard device was used, for increasing reliability of this device, before using the tools and during the study, these cases were checked by another standard monitoring device and the results were compared.

After the approval of ethic committee of the university and getting written permission from the authority of the 22 Bahman hospital of Gonabad, from the 22 of March to 30 October 2013, every day referring to the hospital was done and the necessary explanations regarding the research project was given to the patients who had the inclusion criteria and in the case of their satisfaction, the informed consent form was filled by them for participating in the study.

After getting written consent from the samples of the study, samples were divided into two experimental and placebo groups (every group with 33 patients) through randomized allocation sampling by using permutation blocks of 4 pieces. Patients did not know about being whether in the placebo or experimental group. The main researcher made the randomized allocation list and encoded the hot packs. Then, routine treatments of the disease was done in the both groups according to cardiologist's prescription and two hours after the patient's

Table 1: Comparison of demographic, related to disease in two placebo and experimental groups.

Variable		Experimental group (33 patients)	Placebo group (33 patients)	p- value
Age (standard deviation ± mean)		66.61±12.79	62.30±13.94	p=0.19*
Age	Male	21(63.6)	18(54.5)	p=0.45**
number (percent)	Female	12(36.4)	15(45.5)	
History of hospitalization	Have	18(54.5)	18(54.5)	p=1**
number (percent)	Don't' have	15(45.5)	15(45.5)	
Family history	have	11(33.3)	9(27.3)	p=0.59**
number (percent)	Don't' have	22(66.7)	24(72.7)	
Type of disease	Unstable angina	23(69.7)	28(84.8)	p=0.14**
number (percent)	MI	10(30.3)	5(15.2)	
Drugs	Nitrates	32(97)	33(100)	p=0.31**
number (percent)	Beta blockers	28(84.8)	26(78.8)	p=0.52**
	ACE inhibitors	13(39.4)	8(24.2)	p=0.19**
	Diuretics	10(30.3)	6(18.2)	p=0.25**
	Calcium blocker	3(9.1)	3(9.1)	p=1†

*The results of the independent sample t-test.
**The results of the chi-square test.
† The results of the Fisher's Exact test

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entry to Cardiac Care Unit (CCU), the intervention was started. Hot pack (standard size of 25×35) was heated by hot pack devices in the 75 ° C water and then, it was in the special towel and it was put on the anterior part of the chest (in the first to sixth intercostal space) and in the end transferred temperature of 50 degrees to the patient.

Heat therapy period was 23 minutes. Simultaneously in the placebo group, the same hot pack as the experimental group with the temperature of 37 ° C was used too. Heat therapy was done for the patient every twelve hours for two days. Before and after heat therapy, systolic and diastolic blood pressure, heart and respiratory rate and arterial oxygen saturation were measured in the two groups and recorded.

The clinical nurse who puts the hot pack on the patient's chest did not have any other role in this study and was blinded to the study hypothesis. The researcher assistant who measured and recorded heart rate, blood pressure and respiratory rate and pulse oximetry was not informed about having the patient in the experimental or placebo groups.

Data were analyzed by SPSS 16 software. Descriptive statistic (mean, standard deviation and frequency) were used for describing data, for comparing demographic information of the two groups, independent statistical test, Chi-square and Fisher's exact test were used. For determining data normality, Kolmogorov Smirnov test was used. For comparing quantitative variables between the two experimental and placebo groups before and after intervention, in the case of normality, independent t-test and in the case of lack of normality of the data distribution, non-parametric Mann-Whitney test were used. For comparing quantitative variables before and after intervention in every group, in the case of normality of the data distribution, paired t-test and in the case of lack of normality, Wilcoxon non-parametric test were used. P amounts less than 0.05 was considered significant.

3. Results

Findings showed that; the age range of the samples was from 32 to 90 years old and their age mean in the control group and experimental group were respectively 62.30±13.94 and 66.61±12.79. Most of the patients (59.1%) were women and also 54.5% of the patients had the history of hospitalization. Results of chi-square and independent t-test in terms of demographic information and information related to disease such as; age, gender, history of hospitalization, family history of heart disease and type of coronary syndrome between the two placebo and experimental groups did not show any significant statistical difference ($p>0.05$). also results of Chi-square test and Fisher's exact test did not show any significant statistical difference between the two groups in terms of the using drugs ($p>0.05$) and the two groups had the similar characteristics (table 1).

Results of Wilcoxon test did not show any significant statistical difference in systolic blood pressure, respiratory rate and oxygen saturation percent before and after intervention in placebo group ($p>0.05$), but according to the results of this test, heart rate before and after intervention was significantly different in placebo group ($p<0.05$), so that heart rate after intervention was increased. According to the results of this test, heart rate before and after intervention did not have significant statistical difference in experimental group ($p>0.05$). according to the results of paired t-test in placebo group, no significant statistical difference was observed in diastolic blood pressure before and after intervention ($p>0.05$), but according to the results of this test, there was significant statistical difference in diastolic blood pressure before and after intervention in experimental group ($p<0.05$), so that diastolic blood pressure after intervention in this group was decreased. Also results of Wilcoxon test

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showed that; in experimental group, systolic blood pressure and respiratory rate had significant statistical decrease after heat therapy and oxygen saturation percent was increased significantly ($p<0.05$) (table 2).

According to the results of Mann-Whitney and independent t-test before and after intervention, there was no significant statistical difference in terms of systolic and diastolic blood pressure between the two placebo and experimental groups ($p>0.05$). also according to the results of Mann-Whitney test before intervention, respiratory rate and oxygen saturation percent did not have any significant difference in the two groups ($p>0.05$), but after intervention, respiratory rate in experimental group decreased significantly in compare with placebo group ($p<0.05$). also results of this study showed that oxygen saturation percent in experimental group increased significantly in

Table 2: Comparison of blood pressure, heart rate, respiratory rate and percentage of arterial oxygen saturation in two placebo and experimental groups.

	Group	Before intervention	After intervention	p-value
		Mean±SD	Mean±SD	
Systolic blood pressure	Experimental group	127.14±24.65	121.99±22.11	p<0.001*
	Placebo group	121.01±18.34	121.65±17.26	p=0.12*
p-value		p=0.07**	p=0.88†	
Diastolic blood pressure	Experimental group	78.23±14.99	75.40±15.21	p= 0.003††
	Placebo group	75.70±11.44	75.59±10.76	p=0.80††
p-value		p=0.12†	p=0.90†	
Heart rate	Experimental group	67.53±.48	71.96±17.35	p=0.22*
	Placebo group	64.34±9.85	66.03±9.57	p<0.001*
p-value		p=0.19**	p=0.11**	
Respiratory rate	Experimental group	18.89±4.68	16.62±3.75	p<0.001*
	Placebo group	17.87±3.53	18.41±4.38	p=0.17*
p-value		p=0.208**	p=0.001**	
Oxygen saturation percent	Experimental group	94.46±4.61	95.34±2.80	p=0.003*
	Placebo group	95.25±2.39	94.53±2.73	p<0.001*
p-value		p=0.59**	p=0.006**	

* The results of the Wilcoxon signed rank test
** The results of the Mann-Whitney test
† The results of the independent sample t-test
†† The results of the paired sample t -test

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compare with placebo group after intervention ($p<0.05$). according to the results of Mann-Whitney test, there was not any significant statistical difference in the two experimental and placebo groups in terms of heart rate before and after intervention ($p>0.05$) (table 2).

4. Discussion

The present study was done with the aim of determining the effect of chest local heat therapy on physiologic indicators of the patients with ACS. Results showed that local chest heat therapy in patients with ACS decreases systolic and diastolic blood pressure, but does not change heart rate.

Results of the study of Soubajima et al. showed that; sauna after MI increases vascular endothelial growth factor and improves vascular endothelial cell performance and subsequently increases release of Nitric oxides and prostacyclins by endothelial cells and as the result increases angiogenesis and improves myocardial perfusion and prevents heart failure [12]. Results of this study confirms the positive effect of heart therapy on cardiovascular. Indeed Nitric oxide is a vasodilator factor and causes inhibition of platelet aggregation and white blood cells and inhibition of migration and cell proliferation and it has a protective effect on cardiovascular performance in this way [13]. Local heat therapy can also cause the above mechanism similarly.

In addition, Kihara et al. also achieved that; repeating sauna can improve vascular endothelial performance and improves clinical symptoms in the patients with Chronic Heart Failure (CHF). Results of this study showed that; systolic blood pressure was decreased after two weeks of heat therapy, but there was no change in diastolic blood pressure and heart rate [14]. In this regard, results of the study of Imamora et al., also showed that; sauna improves vascular endothelial performance in the patients with coronary artery risk factors and it has a therapeutic role in these patients, results of this study showed that; systolic and diastolic blood pressure was decreased after sauna therapy, but there was no change in heart rate in this study too [15].

In addition to that, also in the study of Miyamota et al., sauna therapy decreases systolic blood pressure without changing heart rate. From the other side, sauna increased left ventricular ejection fraction, also the level of Norepinephrine was decreased remarkably after sauna. Results of this study showed that, frequent sauna improves the symptoms and exercise tolerance in the patients with CHF [16].

In this regard Miyata et al. and Suk Sohn et al. also in their study achieved that; sauna therapy in the patients with CHF decreases systolic and diastolic blood pressure but does not make any change in heart rate. In these studies, despite decrease in systolic and diastolic blood pressure in sauna therapy group, there was no significant statistical difference between the two sauna therapy and control groups in this regard. Findings of these studies are in consistent with the results of the present study.

From the other side, results of these studies showed that; sauna increases left ventricular ejection fraction and decreases Brain Natriuretic Peptide (BNP) in these patients [17, 18]. BNP is a brain hormone that helps to regulate blood pressure and fluid volume in the body. This hormone is secreted mainly from the ventricles in response to pre-load increase as the result of increase in ventricular pressure [7]. In the study of Tie et al., systolic blood pressure was not changed in sauna therapy and warm bath groups after intervention, but diastolic blood pressure was decreased in both of the groups, also there was no significant statistical difference in the warm bath group. In this study heart rate was significantly increased in the both groups of the study during intervention and after intervention in compare with before that [19].

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In our study, systolic blood pressure in heat therapy group was significantly decreased, but there was no change in heart rate, the reason of the difference in the results of the study of Tie with the present study can be because of type of the intervention since the intervention in their study was warm bath and sauna and in our study, the intervention was local heat therapy.

Regarding scientific explanation of decrease in systolic and diastolic blood pressure in the present study, it can be said that; local heat therapy can decrease blood pressure and dilate vessels through increase in vessels blood flow in the area of heat therapy and removing inflammatory mediators and also stimulating heat receptors in the skin and deeper tissues. By considering this issue that; in patients with ACS, vascular endothelial performance is disrupted because of different factors such as; atherosclerosis due to prevention of making Nitric oxide [2], local heat therapy in these patients improves Vascular endothelial performance, increases production of Nitric oxide and as the result; dilates vessels and decreases systemic vascular resistance and blood pressure in this way.

In the present study, patients' respiratory rate and oxygen saturation percentage were improved remarkably after chest local heat therapy. Kihara et al. achieved that; sauna improves systolic and diastolic blood pressure, heart rate, BNP and Premature Ventricular Contraction (PVCs) number decrease remarkably in 24-hour Holter monitoring and finally they achieved that; sauna therapy has an important role in preventing the occurrence of ventricular arrhythmias in patients with CHF through decreasing sympathetic nervous activity.

In this study, despite decrease of systolic and diastolic blood pressure in the sauna therapy group, there was no significant difference in this regard between the two sauna therapy and control groups which is in consistent with the results of the present study [20].

In this regard Miyata et al. also stated that; sauna and heat therapy improves hemodynamic situation, heart performance, ventricular arrhythmias, hormonal and neural factors and symptoms of the patients with CHF [17]. In addition to that, Kuwahata et al. also achieved that; sauna decreases sympathetic nervous activity and activates parasympathetic nervous [21]. Local heat therapy with hot pack can also make the patient relax and decrease anxiety of the patients with ACS and it is because of it moist heat and they can decrease sympathetic nervous activity in this way and improve blood pressure, respiratory rate and oxygen saturation percentage in these patients.

Tie et al. in their study achieved that; sauna and warm bath in patients with CHF decreases systemic vascular and pulmonary resistance and also increases left ventricular ejection fraction [19]. Considering results of this study and this point that the positive effect of heat therapy on dilating vessels has been proven in different studies [12,14,15], regarding scientific explanation of increase in saturation percent, it can be said that; systemic vascular and pulmonary resistance and their dilation following heat therapy can increase exchange of oxygen between the alveoli in the lungs surface and blood and increase pressure of arterial oxygen contribution and as the result; increase of oxygen saturation percent.

Although the above studies mostly assessed the effect of sauna and heat therapy of the whole body on cardiovascular performance, the essential nature of these studies is about local or environmental heating. So all the above studies is somehow confirming results of the present study and shows the positive effect of heat therapy on heart and vessels and improvement of physiological indicators in these patients.

Among the limitations of this study, it can be pointed out to the low volume of sample size. It is recommended to do the same study with larger sample size by measuring BNP and Nitric oxide before and after local heat therapy

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for achieving more exact results and better understanding of the effect of local heat therapy on heart and vessels performance.

5. Conclusions

Local heat therapy improves systolic and diastolic blood pressure, respiratory rate and arterial oxygen saturation percent. These findings are clinically important in nursing cares. Since improvement of these indicators without using drugs is counted as an important care aim and can decrease complications related to pharmacological actions. From the other side, improvement of these symptoms in these patients is very important and it is because of decreased workload of the heart and decrease and prevention of myocardial ischemia development. So, based on the results of the present study and the important role that heat therapy has in improvement of the symptoms in these patients, also by considering high prevalence of these patients in all the societies, since local heat therapy is a simple and cheap nursing intervention , educating and using this method of treatment is recommended for the medical staff, especially for the nurses to do something in this regard for improvement of these patients apart from unwanted complications of the drugs and provide an opportunity for the medical team specially for nurses to have better care of these patients.

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