

Effect of *Matricaria Recutita* Drop on Sleep Quality in Patients with Chronic Heart Disease: A Randomized Controlled Trial

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Abstract

Context: Heart failure is a common endpoint of all cardiac disorders. Its deep effects on the patient's individual and social life and its chronic, progressive, and irreversible nature are one of the most important reasons for decreasing the quality of life. Sleep disorders are among the most common problems associated with heart failure. Sleep disorders can be treated and improved, but the treatment is not just through sleeping pills. Due to the side effects of chemical drugs, researchers are now seeking to replace them with herbs such as chamomile plants. **Aims:** This study aimed to determine the effect of chamomile droplets on the quality of sleep in patients with chronic heart failure. **Settings and Design:** The study population included patients aged 40–70 years with a confirmed diagnosis of heart failure, an Ejection Fraction (EF) < 40 percent, no smoking and alcohol, a persistence of vital signs, no severe and disturbing pain Sleep, and lack of restless leg syndrome. Also, having any of the following conditions would exclude patients from the study: ill-sickness, patient death, Patient's transference to the other parts during the study, discharge, history of heart attacks in the last three months, and significant arrhythmia. **Methods and Material:** This is a double-blind and three-stage clinical trial that was performed on 67 patients with heart failure in two groups of intervention and control in the cardiac ward of the Shahid Chamran Hospital in Isfahan using an easy and accessible method. The intervention group and the control group received chamazule and placebo (including 1 cc of chamazule) and placebo per day for one week, respectively. **Statistical analysis used:** Data were collected using a questionnaire based on St. Mary's Hospital Standard Sleep Quality Index during one day, three days, and one week after the intervention. Data analysis was performed using descriptive and inferential statistics and SPSS ver16 software. **Results:** Patients were between 40-67 years old. The mean sleep disorder score before the intervention was not significantly different between the two groups ($P < 0.05$), but three days and one week after the intervention, it was significantly lower in the test group than that in the control group ($P < 0.05$). **Conclusion:** Chamomile drops can be used as an auxiliary treatment for sleep disorders and improve sleep quality in patients with heart failure.

Keywords: Sleep quality, Heart failure, *Matricaria recutita*

INTRODUCTION

Heart failure is a pathophysiological condition in the heart that can achieve adequate discharge and restrict adequate tissue metabolism ^[1]. This is a global and costly disease that is estimated to affect about 38 million people worldwide. A number that is growing as the population ages and medical science advances in rescuing patients with a heart attack. ^[2] The number of people who are suffering from heart failure is growing because of the aging population and advances in medical science in rescuing patients with myocardial infarction ^[2]. In Western societies (Europe and the United States) the prevalence of the disease has been reported between 2% to 4% ^[3]. The prevalence of heart failure is approximately 2% of the population and up to 10% in individuals over 75 years old. It is also estimated that the risk of heart failure at age 40 is approximately 20% for both men and women. Heart failure in developing countries has

increased due to lifestyle changes that have led to obesity, hypertension, and diabetes ^[2]. According to statistics published by the Center for Disease Management in 2001, the number of heart failure patients in 18 provinces of Iran was

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3337 per 100,000 population. In a study conducted in Iran in September 1998, 25% of patients who were admitted to cardiac care units had heart failure [4]. A 2014 study in Iran showed that heart failure was more prevalent in women than men, with the highest incidence in Khuzestan and Gilan provinces at 9.05 and 7.5 per 100 persons per year and the lowest incidence was seen in Zanjan, Kohgiluyeh and Boyer-Ahmad provinces at 47 in one hundred people in a year [5]. Moreover, a survey from March 2015 to September 2016 in Isfahan, Iran showed that there were 1195 patients with heart failure, including 61.9% male and 38.4% female [6]. Patients with congestive heart failure experience numerous physical and psychological symptoms such as shortness of breath, lacking energy and weakness, fatigue, edema, sleep disorders, depression, and chest pain [7].

Various factors, including sleep quality disorder, affect the quality of life of patients with heart failure [8]. Additionally, the quality of sleep, according to Rimmer, is intrinsically related to the quality of life [9]. Sleep quality is a term that consists of mental indicators of how sleep is experienced, such as the degree of sleep satisfaction that arises after getting up [10]. Sleep is a physiological and behavioral process that is essential for the preservation of human energy, ability, and life [11] and is important in the healing process of extremely ill patients [12]. Sleep is one of the most basic human needs that in addition to maintaining physical and mental health, reduces stress, strengthens reconciliation, and focuses on daily activities [13]. Researchers believe that sleep has a balancing and restorative function and is essential in regulating body temperature and energy conservation [14]. Furthermore, sleep plays an important role in cardiovascular function, and sleep deprivation aggravates anxiety and irritability. It can also increase the amount of oxygen demand by the heart muscle [15].

Improving the quality of life, reducing the length of hospitalization, and reducing mortality are among the therapeutic challenges for these patients [16]. Finding ways to improve the quality of life of these patients is an important aspect of current scientific advances in the field of cardiovascular disease in current research [17]. Many drugs have already entered the world market for the treatment of this disease. However, this disease has badly affected its patients' lifestyles. In this regard, congestive heart failure is the cause of death and shortening of life and the quality of life in most patients [18].

Traditional medicine with thousands of years of history can enter the field of study of cardiovascular diseases. It can also be considered as one of the most important research sources [19]. Due to the side effects and harmful effects of chemical drugs, returning to herbal and natural remedies has become more prominent in recent years. In this regard, the chamomile plant has a special place due to its wide therapeutic and clinical uses [20]. Chamomile is one of the most widely used and validated traditional medicine in Iran and the world [21]. It is a very important medicinal plant known from ancient times and used for the treatment of various diseases. While it

reduces pain, it has no side effects [22]. It is also one of the herbs that have been used in traditional medicine as a sedative and auxiliary to sleep [23]. Mohammad Hossein Aghili Khorasani Shirazi writes in his book entitled *Makhzanal-Adawiyyah* about chamomile flowers and says that it is well-known for its comforting and strengthening of nerves [24]. This plant belongs to the chicory family and its flowers are either dried or used for the treatment of diseases. Apigenin in chamomile extract is a ligand for benzodiazepine receptors and has anxiolytic and sedative effects but, unlike diazepam, it does not impair memory. Quercetin also has a monoamine oxidase inhibitory activity, so it has sedative effects [25]. Chamomile is a plant from the composite family known as *Matricaria recutita*. A wide variety of industrial products, as well as standard pharmaceutical, cosmetic, and brewing products, can be produced from this plant. Moreover, adults can consume 2 to 8 grams of this flower in a brewing solution. Additionally, 1 to 4 ml of its hydro-alcoholic solution can be consumed three times daily [26]. Among the medicinal traits of chamomile are anxiolytic, antispasmodic, anti-inflammatory, and soothing [21]. Chamomile is also a common treatment for diseases such as sleep disorders and anxiety [27]. Nowadays, it is used for treating bronchial tuberculosis, colds, fever, cough and sneezing, injuries, and burns. Moreover, no side effects are mentioned for its consumption. Regarding the effect of chamomile on sleep, Zick et al. showed that the consumption of chamomile extract, compared to chemical drugs, to some extent has positive effects on the patients who suffer from a sleep disorder [28].

Based on previous studies, the presence of sleep-disturbing factors and the importance of sleep and its negative effects on the quality of life of patients with heart failure lead to delayed recovery and long-term hospitalization. Also, previous studies show the irreversible side effects of chemical drugs compared to herbal remedies and the rising of people's interest in herbal and natural medicines in recent years. However, no research was found about the effect of chamomile on sleep quality in patients with chronic heart failure. Therefore, the present study aims to investigate the effect of chamomile on the sleep quality of these patients. The efficacy of chamomile may open a new window in helping to improve nursing care, reduce hospital stay, reduce the need for chemical drugs, and increase research richness in the nursing area.

SUBJECTS AND METHODS:

The present study is a two-group and three-stage clinical trial in which patients with heart failure were hospitalized in the heart wards of the Shahid Chamran Hospital. The patients had various degrees of sleep disorders. Furthermore, their heart failure and sleep disorders were approved by the physician. The selection of samples was done in a non-probable manner by taking into account the entry criteria and after obtaining consent and filling in the questionnaire. Then, samples (67 Patients) were randomly divided into two groups of 32 intervention and 35 control. The study population included patients aged 40–70 years with a confirmed diagnosis of heart

failure, an Ejection Fraction (EF) < 40 percent, no smoking and alcohol, persistence of vital signs; no severe and disturbing pain Sleep, and lack of restless leg syndrome. Also, having any of the following conditions would exclude patients from the study: ill-sickness, patient death, Patient's transference to the other parts during the study, discharge, history of heart attacks in the last three months, and significant arrhythmia.

The questionnaire of St. Mary's Hospital Standard Sleep Quality Index was used to assess the sleep quality of hospitalized patients and included 11 questions and four options (1 for never and 4 for always) on the Likert scale. The range of the questionnaire score is between 11 and 44. A score less than 11 is regarded as a lack of sleep disorder, a score between 12 to 22 is a mild sleep disorder, a score between 23 to 33 is a moderate sleep disorder, and a score between 34 to 44 is a severe sleep disorder.

The validity and reliability of this tool have been confirmed by studies conducted in Iran. The Validity of this questionnaire was confirmed by Abolhassani (2003), 0.91, and Elise *et al.* (1986), 96/0. Moreover, the reliability of the questionnaire was confirmed by Eshvandi *et al.* (2014) using Cronbach's alpha of 0.83^[29]. Ethical points were considered at all stages of the research. To this end, the project was first approved by the Research Council and the Ethics Council of Isfahan University of Medical Sciences and then referred to the Shahid Chamran Hospital. Before responding, written consent was obtained from each participant and all patients' information remained confidential. The researcher provided the participants with enough information about the research objectives and assured them about the confidentiality of their personal information and responses. After selecting the samples through an accessible method, a questionnaire containing demographic information and a standardized questionnaire based on the quality of sleep in the St. Mary's Hospital was given to them. After collecting the questionnaires, those who had a sleep quality score of 12 and above and had other criteria for entering the study were included. Then they were randomly assigned to two groups of test and control. Thirty-two cards with number one and 35 cards with number two were packed in envelopes. On the day of the random division of the research units, they were asked to select a card. The people with number one were assigned to the intervention group, and the people with number two were assigned to the control group. The intervention period was considered one week, so that the intervention in the test group included receiving chamomile drops, called chamazule (containing the whole extract of chamomile extract), at 30 drops (about 2 ccs), made by Sina Faravar Pharmaceutical Company in Isfahan, in half a glass of water, with half a cube of sugar, under the doctor's supervision at the heart ward of the hospital before bedtime at 9 pm for one week. Moreover, the control group was under the doctor's supervision for one week and received a placebo or chamazule at the same time applied to the intervention group. The placebo contained 1 / cc of chamazule. It means that there was 1 cc of chamazule

in 10 ccs hydrochloric acid solution. Furthermore, the placebo was not different from chamazule in terms of color, odor, appearance, and packaging, but it was distinguished from chamazule medicine by its code. Possible effects (unwanted side effects of the medicine and drug allergy) were predicted. Consultant physicians and pharmacists were available throughout the project for potential side effects of the medicine and prevention of drug interactions. To monitor drug use, the researcher monitored the use of drugs by phoning the samples and asked the samples to inform the researcher of any problems with the use of drugs. After the end of the intervention period, the questionnaire was completed by the researcher through in-person interviews with the studied units. In the interviews and questionnaires, simple and understandable sentences and statements were used with respect to the possibility of low literacy or illiteracy. Also, to remove individual factors in the results, the study was carried out as three-way research, so that the samples did not know which group was used. Moreover, two colleagues were employed for the sampling of the research. In this way, one of them provided the samples with the medicine and the other person provided them with the questionnaires. The statistician did not know the treatment groups.

After collecting the data, they were encrypted and entered the computer. For analyzing the data, spssver16 software, descriptive and inferential statistics were used. Frequency tables and central indicators and dispersion were used in descriptive statistics, independent t-test, analysis of variance, and LSD test for inferential statistics.

RESULTS

In this research, 67 Patients in an easy and accessible form, randomly divided into two groups of intervention and control, were entered into the study. The age range of patients in the test group was 40 to 65 years old, 40% were retired, 87.6% were married, 81.2% lived in the city, 78.1% had previous hospitalization, and 18.8% consumed tobacco. Moreover, in the control group, the age range of the patients was 41 to 67 years old, 82.9% were male, 57.1% were employed, 94.2% were married, 94.3% lived in urban, 71.4% had previous disease history and 8.6% had a smoking history. Regarding the level of education and the economic situation of the patients in the test group, 22.6% of them had a high school diploma and 64.5% of them had a poor economic situation. Similarly, in the control group, 37.2% of them had a high school diploma and 68.6% were economically weak.

According to the findings, independent t-test showed that the mean score of sleep disorders before the intervention was not significantly different between the two groups ($P < 0.05$), but three days and one week after the intervention in the test group, it was significantly less than that in the control group ($P < 0.05$) (Table 1).

The ANOVA test with repeated observations showed that the mean score of sleep disorders in the control group was not

significantly different between the three times ($P > 0.05$), but there was a significant difference between the three groups in the test group ($P < 0.05$) (Table 2).

The LSD post hoc test showed that the mean score of sleep disorder in the test group was significantly reduced over time ($P < 0.001$) (Table 3).

Independent t-test showed that the mean changes in sleep disorders of the patients were significantly more in the test group three days and one week after the intervention compared to that in the control group ($P < 0.05$) before the intervention (Table 4), (Diagram 1).

Table 1: Comparison of the mean score of sleep disorders in patients between the two groups in each of the three times

Time	Test group		Control group		Independent t-test	
	mean	Standard deviation	mean	Standard deviation	t	p
before intervention	22.37	4.08	21.80	2.13	0.71	0.47
three days after intervention	17.13	2.62	22.16	2.43	8.16	<0.001
one week after intervention	14.15	2.27	22.60	2.52	14.36	<0.001

Table 2. Comparison of the mean score of sleep disorders in patients in each of the two groups between the three times

Time	Test group		Control group	
	mean	Standard deviation	mean	Standard deviation
before intervention	22.37	4.08	21.80	2.13
three days after intervention	17.13	2.62	22.16	2.43
one week after intervention	14.15	2.27	22.60	2.52
ANOVA analysis test with repeating views	F	70.44		2.60
	P	0.09		<0.0001

Table 3: Comparison of the mean score of sleep disorders in patients in the test group between two to two times using the LSD post hoc test

Times	P
Before intervention and three days after the intervention	<0.001
Before intervention and one week after intervention	<0.001
Three days after intervention and one week after intervention	<0.001

Table 4: Comparison of mean changes in sleep disorders of patients in three days and one week after the intervention compared with the pre-intervention between the two groups.

Time before the intervention	test group		control group		independent t-test	
	mean	Standard deviation	mean	Standard deviation	mean	Standard deviation
Three days after intervention	-5.24	0.60	0.36	0.45	7.57	<0.001
One week after intervention	-8.22	0.71	0.80	0.37	11.59	<0.001

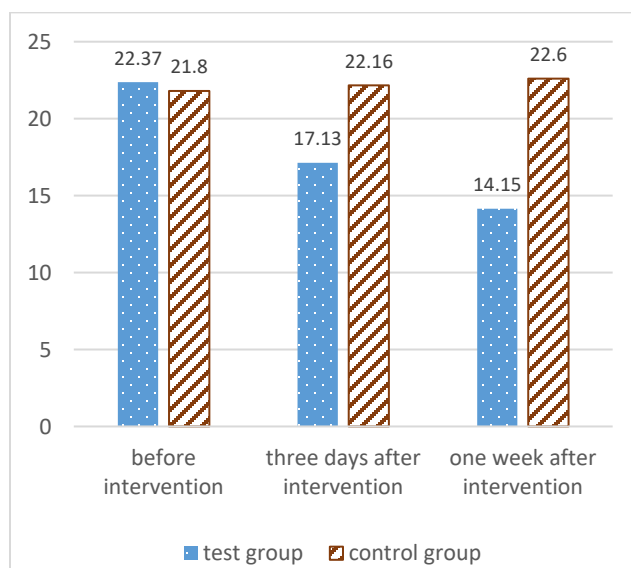


Diagram 1: Mean score of sleep disorders in patients in each of the three times in two groups

DISCUSSION

Chronic diseases are common health problems worldwide and patients with these diseases have many problems, such as sleep disorders^[30]. Inappropriate sleep has adverse effects on a person's physical, mental, psychological, and social performance. Therefore, it is important to study the factors affecting the quality of sleep. Among the non-chemical medicines improving the quality of sleep in patients is chamomile. Therefore, the present study was conducted to determine the effect of chamomile drops on sleep quality in patients with heart failure. The results indicate that consuming chamomile drops from three days to one week is effective in improving sleep quality in patients with heart failure in the Shahid Chamran Hospital. Chou et al. Study also suggested that aromatherapy with chamomile essential oil could reduce anxiety and improve sleep in patients admitted to special care units^[31]. Moreover, Zik et al. Showed that consuming oral chamomile extract for four weeks could

improve the symptoms of sleep disorders compared to placebo^[28]. The results of these studies were in line with the results of the present study on chamomile sleep ability in patients with heart failure.

Additionally, other studies have been done on the comforting effects of chamomile. For example, Amsterdam and colleagues^[27] in their research showed that the consumption of oral extract of chamomile reduces the symptoms of anxiety and depression in patients with an anxiety disorder. One of the most common problems in people with chronic illnesses is sleep disorders. The psychological effects of these diseases are gradually causing psychological problems such as anxiety in a person. And this anxiety also directly affects the quality of sleep in these patients. Therefore, it can be deduced that chamomile, with its sedative and anti-anxiety properties, can figure out sleep problems in individuals and can positively affect the quality of sleep^[30].

According to the findings, using chamomile drops improves the quality of sleep in patients with heart failure, but there is still a long way to reach the desired level, even in developed countries. Abbasinia *et al.*^[32] also achieved similar results in their research. Therefore, the results of the mentioned studies are in line with the present study and they refer to the significant role of chamomile in improving the quality of sleep. Thus, more attention should be paid to natural and herbal treatments than pharmaceutical treatments^[30]. Previous studies have shown the positive effects of complementary medicine and therapies on mental and psychological problems. They even state that some herbal remedies are as strong as medicines like diazepam and can reduce levels of anxiety in individuals. Thus, it seems to be necessary to replace chemical therapies with natural ones^[33]. Human health is associated with their sleep state and sleep disorders can affect their daily performance; however, sleep disorders are often not taken seriously into account and not sufficiently addressed. Because personality traits are relatively constant and predictable, if a relationship could be found between sleep patterns and personality traits, sleep disorders can be identified and managed more efficiently. Therefore, it is necessary to improve the quality of sleep in patients with heart failure and control some of the modifiable variables in these patients. King & Hinds^[34] and Howlett^[35] also achieved similar results and confirmed the effect of the aroma on the quality of sleep. However, it should be emphasized that this study was conducted under time and budget constraints, which is a major limitation in clinical practice studies. Therefore, to be more effective, the present study should focus on wider sample size and more time to intervene.

Key Messages: The results showed that there was a significant difference in the sleep quality of the chamomile consumer group after intervention. It means that chamomile drop has been able to improve sleep quality in patients with heart failure.

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