

# Effect of Using Eye Mask on Sleep Quality in Cardiac Patients: A Randomized Controlled Trial

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Received 2015 February 28; Revised 2015 August 5; Accepted 2015 August 9.

## Abstract

**Background:** Patients in coronary care unit are at risk of sleep deprivation. Sleep deprivation can be associated with increased blood pressure and heart rate, raising the risk of developing cardiovascular problems among patients hospitalized in coronary care unit.

**Objectives:** This study was carried out to examine the effect of eye mask on sleep quality in cardiac patients.

**Patients and Methods:** In this randomized controlled trial, 60 patients who met the inclusion criteria were selected using a convenient sampling method and randomly allocated into the experimental and control groups. Patients in the control group received routine care. However, in the experimental group, patients received routine care and eye mask for three subsequent nights. In the both groups, the sleep quality was assessed using the Pittsburgh sleep quality index. Data were analyzed by the chi-square test, independent samples t-test, Mann-Whitney U, and Wilcoxon signed-rank tests.

**Results:** After the study, the median scores of the subjective sleep quality, the sleep latency, the sleep duration, the habitual sleep efficiency, and the sleep disturbances domains, as well as the median score of overall Pittsburgh sleep quality index in the experimental group were significantly lower than those in the control group ( $P < 0.05$ ). However, no significant differences were observed between the two groups in terms of the use of sleep medications and the daytime dysfunction domains ( $P > 0.05$ ).

**Conclusions:** Using eye mask can significantly improve the sleep quality in cardiac patients. Therefore, nurses are recommended to use eye mask in combination with current treatments for improving patients' sleep quality.

**Keywords:** Sleep, Coronary Care Unit, Nursing

## 1. Background

Sleep is a basic need for the human beings. High quality sleep is associated with better recovery from diseases (1). Sleep disorders are common in patients hospitalized in Coronary Care Units (CCU) (2). These disorders are associated with environmental factors such as noises, intervention-related pain and discomfort. Moreover, the psychological stress of having a life-threatening disease and disease complications may put patients at risk for development of sleep disorders (2, 3). The results of a study conducted in Shahrekord, Iran showed that about 51% of patients with congestive heart failure suffer from sleep disorders (4).

Sleep disorders can be associated with cardiovascular problems such as increased blood pressure and heart rate (1). Consequently, improving sleep quality in cardiac patients is a matter of great importance. Sedative and hypnotic medications can significantly increase the sleep quality. However, pharmacological agents are usually associated with different side-effects (5). Complementary therapies including aromatherapy, muscle relaxation,

and using eye mask and earplug can also improve the sleep quality without causing serious side-effects (2, 6, 7).

Eye mask, also called sleeping mask, is a device made from fabric that is intended to cover both eyes. The device has an elasticated strap that holds the mask on patients head. It is designed to keep all incoming light away from patient's eyes and to induce a state of pure darkness (8, 9). Using eye mask is one of the nursing interventions that can improve patients' sleep quality through decreasing the environment lights (9). However, research findings about the effectiveness of eye mask in improving sleep quality are conflicting. Jones and Dawson (7), Daneshmandi et al. (10) and Koo and Koh (11) found that eye mask enhanced sleep quality among cardiac patients. However, Bourne et al. found that patient willingness to use eye masks and/or earplugs was very low, which limits their routine clinical application (12). Arab et al. also found that eye mask enhanced some domains of sleep quality, but had no effect on other dimensions of sleep (13).

As mentioned above, there are inconsistent results

about the effect of eye mask on patients' sleep quality. Therefore, further studies are necessary to provide sufficient evidence in this area.

## 2. Objectives

This study aimed to investigate the effect of eye mask on sleep quality among patients hospitalized in CCU.

## 3. Patients and Methods

### 3.1. Study Design and Participants

This was a non-blind randomized controlled trial conducted since September to December 2013. The study setting included the two CCUs of Shahid Beheshti Hospital in Kashan, Iran. The study population comprised all patients hospitalized in the study setting. The inclusion criteria were being oriented to time, place, and person, having a cardiac ejection fraction of at least 40%, having no known sleep-disturbing diseases (such as rheumatoid arthritis and migraine), having no known sleep disorders (as mentioned by participants) and receiving no medical treatment during sleeping hours (22:00 - 6:00). The exclusion criteria included patient's reluctance to remain in the study, decreased consciousness, cardiac arrest, and using over-the-counter tranquilizers or hypnotic-seda-

tive agents. Sample size was calculated using the results of a local study conducted by Daneshmandi et al. (10). Based on the results of Daneshmandi et al. the post intervention means  $\pm$  standard deviations of daytime dysfunction dimension were  $1.63 \pm 0.70$  and  $0.66 \pm 0.47$ , in the control and experimental groups, respectively. Accordingly, with a type I error probability of 0.05 and a power of 0.80, the sample size was determined to be 15 patients for each group. However, for compensating probable attritions and achieving more reliable results, we recruited 30 patients for each group. Patients were recruited to the study by using the convenience sampling method.

We randomly assigned the study participants to the study groups by using the permuted block randomization technique. Primarily, the six-block size of five was formed for each group. Then, the sequence of blocks was determined using a table of random numbers. All the study interventions were implemented by the same researcher who was not blind to the study.

Two hundred and thirty-six patients were assessed for eligibility. One hundred and seventy-six patients excluded according to the inclusion criteria ( $n=169$ ) and declining to participate ( $n=7$ ). Therefore, thirty patients were enrolled in each group. None of the patients excluded from the study (Figure 1).

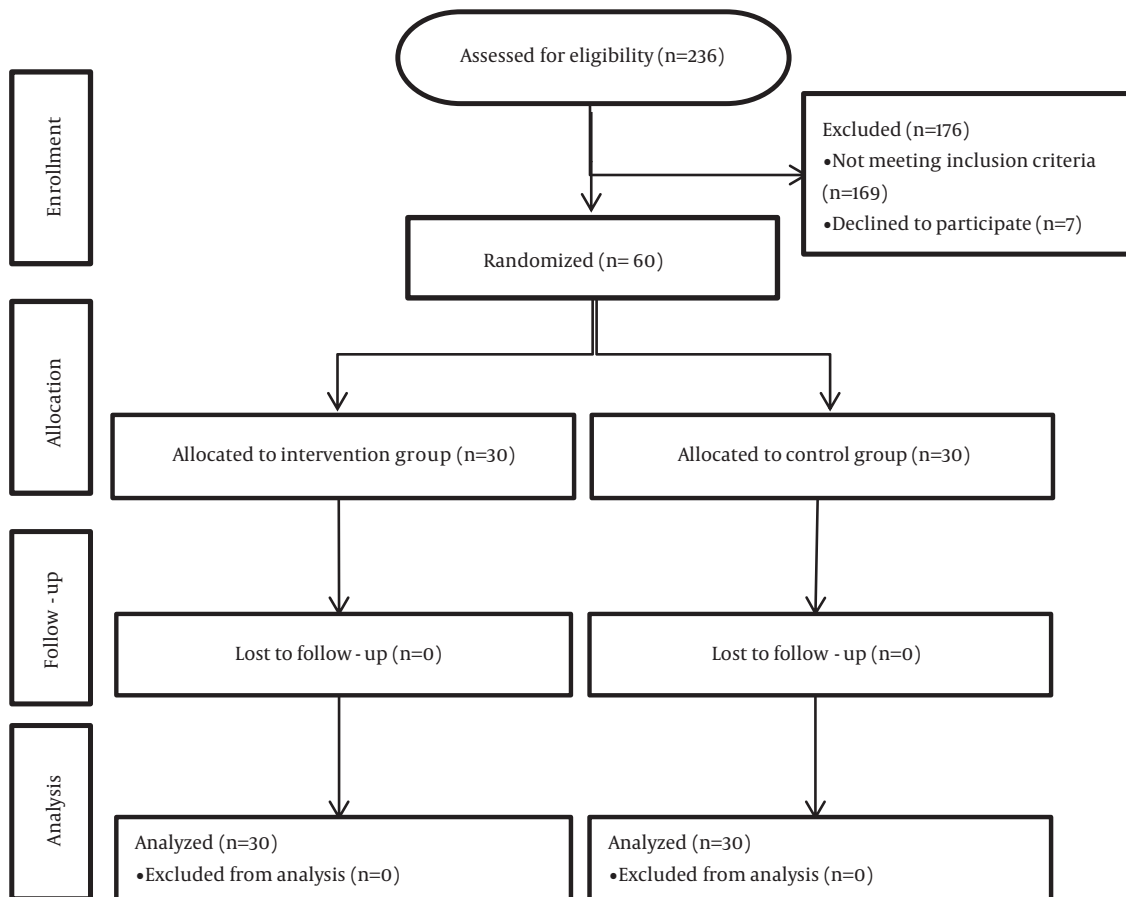


Figure 1. Consort Flow Diagram

### 3.2. Instruments

The study instrument comprised two parts including a demographic questionnaire and the Pittsburgh sleep quality index (PSQI). The demographic questionnaire consisted of questions about participants' demographic and clinical data including age, gender, marriage, employment, education level, history of hospitalizations, and medical diagnosis. The PSQI is a self-report questionnaire developed for evaluating sleep quality (14, 15). The PSQI consists of 7 components subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. The score for each component ranges from 0 to 3, resulting in a total PSQI score of 0-21. Higher scores represent lower sleep quality (16, 17). In this study we used Farsi version of PSQI, which has yielded satisfactory validity and reliability. Cronbach's alpha coefficient was 0.77 and corrected item-total correlations ranged from 0.30 to 0.7 for the seven components of the PSQI (14).

### 3.3. Procedures

We went to the CCU at 7:00, when the patients were at rest after breakfast. At the start of the study (in the second day of hospitalization) we asked all the patients in both groups to respond the PSQI. In the illiterate subjects, the questions were read by the researcher and the subjects answers were recorded in the questionnaire. Moreover, we gathered patients' demographic and clinical data through their medical records. The onset of intervention was the second night of hospitalization. In the control group, patient received the sleep care routinely provided in the study setting. The routine sleep care included of reducing environmental noise, decreasing indoor lighting level, and providing nursing care during daytime to avoid interrupting patients' sleep for nighttime. Patients in the experimental group received routine sleep care as well as eye mask for eight hours (22:00 - 6:00) each night. During this period, eye masks were applied on the patients' eyes and its correct usage was checked by the first researcher. In the morning of the fourth day of the study (i.e. after the third eye mask session), we asked patients in both groups to fill out the PSQI again.

### 3.4. Ethical Considerations

The ethics committee of Kashan university of medical sciences approved the study. Also, permissions were obtained from the hospital and the wards authorities. We informed the study participants about the aim and the course of the study, being free to participate in the study, being free to withdraw from the study at any stage, confidentiality of personal information, and the lack of adverse effects of eye mask. Then, we obtained a written informed consent from them.

### 3.5. Data Analysis

Study data were analyzed using the SPSS version 11.5 (SPSS, Inc., Chicago, Illinois, USA). Kolmogorov-Smirnov test was used to test the normal distribution of the age and sleep quality scores. The results of this test revealed that the age had a normal distribution; however, the scores of PSQI and its domains did not have a normal distribution. The independent samples T-test and chi-square test were used to compare the demographic and clinical data between the two groups. Accordingly, we used the nonparametric Wilcoxon signed-rank and Mann-Whitney U tests, respectively for within- and between-groups comparisons. The level of significance was set at below 0.05.

## 4. Results

The mean and standard deviation of patients' age in the experimental and the control groups were  $61.40 \pm 11.64$  and  $63.9 \pm 10.23$  years, respectively. Most of the patients were married (88.3%), literate (61.70%), and male (58.30%). The medical diagnosis for most patients was acute coronary syndrome (66.70%). Most of the patients (68.30%) had been previously hospitalized for at least one time. The statistical analysis showed no significant differences in age, gender, marriage, employment, educational status, history of hospitalization, and established medical diagnosis between the two groups ( $P > 0.05$ ; Table 1).

**Table 1.** Patients' Demographic Characteristics

Variable	Group <sup>a</sup>		P Value (Chi-Square Test)
	Experimental	Control	
<b>Gender</b>			0.067
Female	14 (46.67)	21 (70)	
Male	16 (53.33)	9 (30)	
<b>Marital status</b>			0.688
Married	26 (86.67)	27 (90)	
Single	4 (13.33)	3 (10)	
<b>Education level</b>			0.728
Illiterate	13 (43.33)	10 (33.34)	
Primary school	11 (36.67)	13 (43.33)	
High school or higher	6 (20)	7 (23.33)	
<b>Previous history of hospitalization</b>			0.500
No	10 (33.33)	9 (30)	
One time or more	20 (66.67)	21 (70)	
<b>Medical diagnosis</b>			0.682
Acute coronary syndrome	21 (70)	19 (63.33)	
Dysrhythmia	2 (6.67)	4 (13.34)	
Congestive heart failure	7 (23.33)	7 (23.33)	

<sup>a</sup>Data are presented as No. (%).

The Wilcoxon signed-rank test showed that in the experimental group, the median scores of the subjective sleep quality, the sleep latency, the sleep duration, the habitual sleep efficiency, the sleep disturbances, and the daytime dysfunction domains as well as the median score of overall PSQI were significantly decreased after the intervention ( $P < 0.05$ ; Table 2). However, the median scores of the use of sleep medications domain in the experimental group showed no significant change after the intervention ( $P > 0.05$ ; Table 2). On the other hand, neither the scores of the domains nor the total score of PSQI changed significantly at the end of

the study in the control group ( $P > 0.05$ ; Table 2).

At baseline, there was no significant difference between the study groups in terms of the median score of overall PSQI as well as all the median scores of PSQI domains ( $P > 0.05$ ; Table 2). However, at the end of the study, the median scores of five domains of PSQI (including the subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, and sleep disturbances) as well as the median score of overall PSQI in the experimental group were significantly lower than those in the control group ( $P < 0.05$ ; Table 2).

**Table 2.** Sleep Quality in the Experimental and Control Groups

PSQI Domains/Groups	Before Intervention	After Intervention	P Value <sup>a</sup>
	Median (Q3-Q1)	Median (Q3-Q1)	
<b>Subjective sleep quality</b>			< 0.001
Experimental	1 (2 - 0)	0 (1 - 0)	
Control	1 (2 - 1)	1 (2 - 1)	
p <sup>b</sup>	0.400	0.001	
<b>Sleep latency</b>			< 0.001
Experimental	3 (3 - 3)	1 (2 - 0)	
Control	3 (3 - 2)	3 (3 - 2)	
p <sup>b</sup>	0.459	0.001	
<b>Sleep duration</b>			< 0.001
Experimental	2 (2.25 - 1)	0 (1 - 0)	
Control	2 (2 - 1)	2 (3 - 0.75)	
p <sup>b</sup>	0.817	0.001	
<b>Habitual sleep efficiency</b>			< 0.001
Experimental	2 (3 - 0)	0 (0.25 - 0)	
Control	2 (3 - 0.75)	3 (3 - 0)	
p <sup>b</sup>	0.862	0.001	
<b>Sleep disturbances</b>			0.005
Experimental	1 (1 - 1)	1 (1 - 0)	
Control	1 (1 - 1)	1 (1 - 1)	
p <sup>b</sup>	0.467	0.038	
<b>Use of sleep medications</b>			0.564
Experimental	1 (1 - 1)	1 (1 - 1)	
Control	1 (1 - 1)	1 (1 - 1)	
p <sup>b</sup>	0.999	0.305	
<b>Daytime dysfunction</b>			0.034
Experimental	0 (0 - 0)	0 (0 - 0)	
Control	0 (0 - 0)	0 (0 - 0)	
p <sup>b</sup>	0.864	0.643	
<b>Overall PSQI score</b>			< 0.001
Experimental	10 (12 - 7)	3 (5 - 2)	
Control	10 (11.25 - 7.75)	10 (12 - 7)	
p <sup>b</sup>	0.858	0.001	

Abbreviations: Q1, first quartile; Q3, third quartile; PSQI, Pittsburgh sleep quality index.

<sup>a</sup>The results of the Mann-Whitney U test for between-groups comparison.

<sup>b</sup>The results of the Wilcoxon signed-rank test for within-groups comparison.

## 5. Discussion

The findings revealed that eye mask significantly improved the participants' sleep quality. This is in line with the findings of studies conducted by Richardson et al. (18) and Hu et al. (9). Moreover, Koo and Koh found that eye mask improved sleep quality among cardiac patients (11). A previous study on the factors affecting the sleep quality among patients admitted to CCUs also reported that from the patients' perspective, the existence of too much light at night was one of the causes of low sleep quality (19). Therefore, it seems that improving the sleep quality in this study is associated with decreasing the environmental light to the patients' eyes.

In the present study, the baseline sleep quality was not significantly different in the two groups. However, the intervention could significantly improve the overall PSQI score and all dimensions of sleep except for the use of sleep medications and daytime dysfunction. In addition, although the median score of the daytime dysfunction was not significantly different between the two groups, however, in comparison with the baseline, a significant reduction in daytime dysfunction was occurred in the intervention group. According to the patients in this study, the intervention did not affect their use of sleep medications. This finding might be attributed to the fact that most patients in the CCU have doctor's orders of sleeping medication at night and the orders are routinely executed by nurses. Moreover, most patients are trusting in their physician's instructions such as sleep medications and do not change or discontinue their medications without the physician's authorization (20). Saeedi et al. also noted that complementary therapies had no significant effect on use of sleep medications in hospitalized patients (6). For instance, Neyse et al. found that earplug can significantly improve the majority of domains of sleep quality except for subjective sleep domain (21). Daneshmandi et al. (10) also found that eye mask significantly improved the mean scores of the sleep latency, the sleep duration, the habitual sleep efficiency, the daytime dysfunction and the use of sleep medications, but had no significant effect on subjective sleep quality domain. The contradiction between the results of Neyse et al. (21) and Daneshmandi et al. (10) with the results of the current study might be attributed to the differences in the interventions used. For example, in the study conducted by Neyse et al. (21) instead of eye mask, earplugs have been used. On the other hand, in the study conducted by Daneshmandi et al. (10) the duration of intervention was longer than this study. The duration of intervention in the study conducted by Daneshmandi et al. was at least four nights while our intervention lasted only for three nights (10).

In this study we did not assess the people's psychological conditions and sleep habits. However, such factors might affect the people's sleep quality. We also did not assess the actual amount of sleep medication used by the

patients and this variable such as other variables only assessed based on the patients self-report. Then further studies are suggested to assess the effect of people's psychological condition and sleep habits of their sleep quality. Moreover the effect of using eye mask on the actual amount of sleep medication used is suggested. In addition, daytime functioning might be affected by several factors that were not assessed in this study. Therefore, future studies with controlling other confounding factors such as environmental stimulators are suggested.

The findings of this study indicate that eye mask can significantly improve the sleep quality of cardiac patients hospitalized in CCU. Accordingly, healthcare providers can use eye mask either in combination with current treatments or alternatively for promoting patients' sleep quality without causing them the adverse side-effects of routine sleep medications.

## Acknowledgments

This article is the report of a Master's thesis funded by Kashan university of medical sciences with the number 9276. The recorded code in the registration center of clinical trials is IRCT2013052013403N1. We would like to gratefully thank the research administration of the funding university as well as the administrators and the staffs of the study setting who helped and supported us during the study. We also are thankful of the patients for their participation in this study.

## Footnotes

**Authors' Contribution:** Study concept and design: Atye Babaii and Ali Hajibagheri; acquisition of data: Atye Babaii and Mohsen Adib-Hajbaghery; Analysis and interpretation of data: Atye Babaii, and Mohsen Adib-Hajbaghery; Drafting of the manuscript: Atye babaii; Critical revision of the manuscript for important intellectual content: Mohsen Adib-Hajbaghery; Statistical analysis: Atye Babaii, and Mohsen Adib-Hajbaghery; administrative, technical, and material support: Atye Babaii and Mohsen Adib-Hajbaghery; study supervision: Mohsen Adib-Hajbaghery and Ali Hajibagheri.

**Financial Disclosure:** The authors declare that they have no competing interests.

**Funding/Support:** This project was funded by the research deputy of Kashan University of Medical Sciences, Kashan, IR Iran.

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