ClinicalPractice

# The effects of eye masks and earplugs on the sleep quality and anxiety of hospitalized patients-a randomised controlled trial

**Background & Objectives:** A randomized controlled trial was performed with the purpose of exploring the effects of eye masks and earplugs on the sleep quality and anxiety of hospitalized patients.

**Methods:** The sample consisted of 86 hospitalized patients who were undergoing some kind of cardiovascular operation. Patients were assigned either to the experimental group or the control group. A Patient Identification form, the Pittsburgh Sleep Quality Index, and the State Anxiety Inventory were administered to patients' one day before the operation. After surgery, patients in the treatment group were admitted to the clinic and given masks and earplugs to put on.

**Results:** The quality of sleep of patients in the experimental group was found not to have changed and remained at the same level as in the preoperative period. The quality of sleep of patients in the control group was found to have decreased compared to the preoperative period. Patients in both groups experienced moderate anxiety levels preoperatively and mild anxiety levels postoperatively. In conclusion, eye masks and earplugs were effective in promoting sleep but did not affect anxiety levels.

**Conclusions:** It is recommended that eye masks and earplugs be used in patients undergoing cardiovascular operations in order to promote sleep.

**Keywords: sleep quality, earplugs, eye masks, patient**

Ayşe Demiray* &
Leyla Khorshid

*Ege University Nursing Faculty, Turkey*

**Author for correspondence:*
*aysedemiray2008@hotmail.com*

## Introduction

Sleep is essential for people to stay in good health and for the prevention of disease [1,2]. Motivation, culture, lifestyle, dietary habits, alcohol intake, caffeinated beverages, smoking, environmental factors, psychological stress, illness, and medications are some of the factors which can affect the quantity of sleep [2,3]. Sleep deprivation is common in individuals with acute and chronic illnesses [4]. At times of illness, the need for sleep increases [1], and sleep promotion is important for recovery [1,5-7].

Hospitalization can have a negative effect on a patient's sleep [2,7]. The pain due to illness; primary sleep disorders; psychological stress; physical discomfort; mood problems such as anxiety or depression; the environment of the hospital; the activities of the health care personnel; medical treatment; some medications; and chronic conditions that cause respiratory problems, difficulty moving, or pain may also affect the sleep of hospitalized patients [2-4,7,8]. A study indicated that the majority of patients (69.5%) experienced changes in their sleep behavior in the hospital, and factors affecting the patients' sleep included environmental factors such as poor ventilation of hospital rooms, treatment and assessments during sleeping hours, frequent visits, and individual factors such as pain [9]. The surrounding environment can affect sleep, and changes in the environment can hinder sleep. Unfamiliar stimuli can prevent people from sleeping [10]. In hospitals, patients' sleep is frequently disrupted due to new or strange noises [2,6,11]. The sources of noise in hospitals include staff's conversations with each other [1,7,10], paging systems, telephones, call lights, intravenous and cardiac monitor alarm signals, doors closing, elevator chimes, furniture squeaking, and linen carts being wheeled through corridors [10]. Patients can experience sleep fragmentation during care interventions such as the measurement of blood pressure, pulse, and temperatures; phlebotomy; and medication administration [7,11,12]. In one study, the authors concluded that critical care unit sound levels negatively impacted subjective sleep [6].

Some patients who are used to darkness while



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sleeping may find it difficult to sleep in the light [2,10], and therefore light levels in the room may affect the ability to go to sleep [2,10,12]. Stress, pain, and anxiety can disrupt sleep and interfere with biological processes linked to a normal 24-hour sleep-wake cycle [13]. Anxiety has a negative effect on sleep because of feelings about the severity of the illness [1] and because of frequent treatment and monitoring [13]. Anxiety is common in patients who undergo cardiac surgical procedures, and those patients may report more disturbed sleep than other patients [4]. In one study, it was shown that there was a significant association between decreased quality of sleep and abnormal anxiety in coronary artery disease patients [14].

Sleep problems are common in patients with heart failure [15]. In a study with the aim of describing the factors influencing the sleep quality of patients (n:101) with heart failure, it was found that 81% of participants reported poor sleep quality, and 31% were dissatisfied with the quality of their sleep [15,16]. Kociuba et al. (2010) carried out a study with the aim of determining the prevalence of sleep difficulties and their impact on the cognitive function of 77 persons at an outpatient cardiology center and reported that approximately 94% of participants met the criteria for "poor" sleep and that sleep problems were commonly associated with cardiovascular disease. In a study on patients who were hospitalized in surgery clinics, it was determined that pain, anxiety, and noise influenced the quality of sleep [17]. In a study by Yalçın Atar et al. (2012), it was determined that pain (37.4%), poor ventilation of hospital rooms (32.7%), and noise (24.3%) were the three main factors affecting patients' sleep during hospitalization [18].

Sleep discomfort is prevalent during [4] and after heart surgery and can result in delayed recovery [6,19] and poor quality of life [19]. Postoperative sleep disturbance can cause changes in mental state, development of episodic hypoxemia, and hemodynamic instability [7]. Results of a study with 38 male patients showed that in the period immediately following coronary artery bypass grafting, there was a change in sleep distribution with a reduction in sleep duration and an increase in daytime sleep [20]. In a systematic review with the aim of describing sleep patterns in adults during recovery from heart surgery, it was concluded that during the three postoperative weeks, serious sleep problems often occurred such as low sleep efficiency and difficulty in maintaining sleep and that sleep disturbances are associated with individual, physiological, psychological, and environmental factors [19]. In another study, the researchers evaluated the effect of cardiopulmonary bypass on neurocognitive functions in patients (n=36) undergoing coronary bypass surgery. In this study, the patients were administered a neurocognitive test battery before and one month after surgery, including the Pittsburgh Sleep Quality Index. Compared to the postoperative scores, there was a decrease in the Pittsburgh Sleep Quality Index, but this did not reach a significant level [21].

Researchers have investigated the effect of aromatherapy [22-24], Taichi exercise [25], music therapy [15,26], valerian acupressure [27], and standard acupressure [28] on sleep quality in different healthy and sick populations. However, there have been few studies which evaluated the effect of earplugs in improving sleep. Scotto et al. (2009) implemented a study of critical care [n=88], and they concluded that using earplugs improved the subjective experience of sleep [29]. Wallace et al. (1999) measured the effect of earplugs on sleep in healthy volunteers who were exposed to a simulated intensive care unit for five nights, and they concluded that earplugs caused an increase in the percentage of rapid eye movement sleep [30].

Only three studies have examined the effect of both earplugs and eye masks on sleep. Hu et al. (2010) examined the efficacy of earplugs and eye masks on sleep quality and anxiety level in 14 healthy subjects exposed to simulated intensive care unit noise and light and found that earplugs and eye masks improved sleep [31]. Jones and Dawson (2012) examined the effect of using eye masks and earplugs on self-reported sleep experience and factors affecting sleep quality in 100 patients and concluded that the intervention group identified earplugs (22%) and eye masks (28%) as factors promoting sleep [32]. Another study carried out by Richardson et al. (2007) evaluated the practicality of using eye masks and earplugs with 64 critical care patients and found that some patients using earplugs and eye masks reported longer periods of sleep than those without and also that patients' experience of wearing earplugs and eye masks varied from very comfortable to very uncomfortable [33,34]. Reducing anxiety may also lead to an improvement of sleep. There are few studies relating the effect of eye masks and earplugs on sleep promotion during hospitalization in patients who have undergone cardiovascular surgery.

## Method

### Study design

A randomized controlled design was used to assess the effects of earplugs and eye masks on sleep quality and anxiety in patients who has undergone cardiovascular surgery.

### Setting and sample

The setting for the study was the Cardiovascular Surgery Clinic of a university hospital in Izmir. A sample size of 86 was determined based on One-Way ANOVA Power Analysis to achieve a power of 0.849. The study was implemented in the Cardiovascular Surgery Clinic of Ege University School of Medicine Research and Training Hospital. A convenience sample of 86 patients undergoing a cardiac operation was obtained from the Cardiovascular Surgery Clinic of the hospital. The data were collected between May 25, 2011 and January 31, 2013. Patients were chosen who were between 18 and 70 years of age and who could speak and understand Turkish; who had no previous diagnosis of any neurological or psychiatric disease; who had no problems with speech, hearing, or vision; who had been hospitalized at least 24 hours; who had not received intravenous sedation or general anesthetics; who could put on and remove eye masks and earplugs; and who had no previous substance addiction.

### Ethical considerations

The patients were informed about the aim of the study, and they participated in the study on a voluntary basis. The study was approved by the Ethics Committee for Human Research of the hospital, and written informed consent to conduct the study was obtained from the patients themselves and from the hospital.

### Measurements and instruments

To assess the subjective sleep of patients, a patient introduction form, developed by the authors, was used. The patient information form was composed of questions related to demographic characteristics and sleep habits prior to hospitalization. Experts' opinions were taken into consideration in developing this questionnaire. The Pittsburgh Sleep Quality Index (PSQI) which was developed in 1989 by Buyssee et al. was also administered to patients. The validity and reliability study of the PSQI for Turkey was performed by Ağargün et al. (1996). This scale evaluates subjective sleep quality and consists of 19 items and seven components. Each is weighted from 0 to 3. The seven component scores are added to obtain a global score ranging from 0 to 21. Higher scores indicate worse sleep quality [35]. In this study, the reliability coefficient (Cronbach's Alpha) of PSQI was p=0.537 in the preoperative term, and in the postoperative term it was r=0.655. The State Anxiety Inventory Form (STAI) consists of 20 questions, and every question has four options. The total score acquired from the scale ranges between 20 and 80, and a higher score indicates higher anxiety. In this study, the reliability coefficient (Cronbach's Alpha) of the STAI in the preoperative term was r=0.836, and in the postoperative term it was r=0.875. Simple randomization sampling was used in this research.

The patients were allocated to one of the two groups, control or experimental. While the patients in the control group were subjected to the normal procedure, the patients in the experimental group used eye masks and earplugs during night time. In the experimental group, patients were instructed on how to put on and take off commercially available earplugs. They were manufactured by Minnesota Mining & Manufacturing Company (3M) and cost 2.69 $ per pair. The questionnaire before and after the operation took approximately 30 minutes to complete. The PSQI and STAI were administered to the patients in both groups on the days before and following the operation.

### Data analysis

Statistical analyses were performed using Statistical Package for the Social Sciences for Windows Version 15.0. Frequency was calculated for all the variables, and Fisher's exactest was used to compare differences among proportions. Repeated measured ANOVA, a paired sample t test, the Wilcoxon Signed Ranks test, The Mann-Whitney test, and the Kruskal-Wallis test were used to test for differences in mean PSQI and STAI scores in the patients.

## Results

Eighty-six patients were enrolled in the study. There was no significant difference between the mean age ($x^2$=0.674, p=0.097) or gender ($x^2$=0.486, p=0.486) of the patients in the two groups **(TABLE 1).** In total, 55.8% of the patients were educated to elementary level or less, 90.6% were married, and 67.4% were not working full- or part-time. The mean PSQI score in the experimental group after the operation was found to be 6.2791 ± 3.64055, and in the control group it was found to be 8.1395 ± 3.50905. This difference was found to be statistically significant **(TABLE 2).** Differences between the mean PSQI score in the experimental group before and after the operation and the mean PSQI score in the control group before and after the operation were found to be statistically significant **(TABLE 3).** The differences between the mean STAI score in the experimental group and that in the control group before the operation (p=0.139), and the differences between the mean STAI score in the experimental group and that in the control group after the operation (p=0.060) were not found to be statistically significant **(TABLE 4).** Differences between the mean STAI score in the experimental group before and after the operation and the mean STAI score in the control group before and after the operation were found to be statistically significant (p=0.701) **(TABLE 5).**

**Table 1. Some demographic characteristics of population.**

| | Study Group | | Control Group | |
|---|---|---|---|---|
| Age Group | N | % | N | % |
| 18–38 | 3 | 37.5 | 5 | 62.5 |
| 39–58 | 28 | 60.9 | 18 | 39.1 |
| 39–58 | 12 | 37.5 | 20 | 62.5 |
| Gender | | | | |
| Male | 12 | 44.4 | 15 | 55.6 |
| Female | 31 | 52.5 | 28 | 47.5 |
| Mean Age | 55.11 ± 9.17 year | | 53.88 ± 12.47 year | |

**Table 2. Comparison of mean PSQI difference scores of patients between the experimental and control groups before and after the operation.**

| | Experimental Group (n:43) | | Control Group (n:43) | Test |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | | |
| Pre-op PSQI | 6.76 ± 3.13 | 5.79 ± 2.48 | MWU: 757.0 | p=0.146 |
| Post-op PSQI | 6.27 ± 3.64 | 8.13 ± 3.50 | MWU: 647.5 | p=0.016 |

**Table 3. Distribution of mean PSQI difference scores before and after the operations of patients in the experimental and control groups.**

| Difference in PSQI score | n | Mean Difference | Standard Deviation | Test |
|---|---|---|---|---|
| Experimental Group | 43 | -0.48 | 4.47 | t=-3.10, p=0.003 |
| Control Group | 43 | 2.34 | 3.98 | |

**Table 4. Comparison of mean STAI difference scores of patients between the experimental and control groups before and after the operation.**

| | Experimental Group (n:43) | | Control Group (n:43) | Test |
|---|---|---|---|---|
| | Mean ± SD | Mean ± SD | | |
| Pre-op STAI | 40.18 ± 6.18 | 41.58 ± 4.80 | MWU: 753.0 | p=0.139 |
| Post-op STAI | 35.16 ± 6.03 | 37.20 ± 5.35 | MWU: 707.0 | p=0.060 |

**Table 5. Distribution of mean STAI difference scores before and after the operations of patients in the experimental and control groups.**

| Difference in STAI score | n | Mean Difference | Standard Deviation | Test |
|---|---|---|---|---|
| Experimental Group | 43 | -5.02 | 9.01 | t= 3.38, p=0.701 |
| Control Group | 43 | -4.37 | 6.46 | |

## Discussion

Sleep disturbances may be present before cardiac surgery and may be related or unrelated to cardiovascular disease [4], but they are a cause of major physical distress after heart surgery and represent an unmet physical need [19]. In our study, 50.9% of patients in the environmental group and 49.1% of patients in the control group stated that noise affected their sleep. Also, 55.9% of patients in the experimental group and 44.1% of patients in the control group stated that light affected their sleep. In a study by Jones and Dawson (2012), noise was determined to be the factor most affecting sleep. In both groups, light and environment were also described as factors which affected sleep [32]. In a systematic review by Liao et al. (2011) with the aim of describing sleep patterns in adults during recovery from heart surgery, it was concluded that during the first postoperative week serious problems often occurred such as low sleep efficiency and difficulty in maintaining sleep, and sleep disturbances were associated with individual, physiological, psychological, and environmental factors [19]. Our results support the results of the studies by Jones and Dawson (2012) and Liao et al. (2011). In a study by Yalçın Atar et al. (2012) with the aim of determining the sleep quality of patients hospitalized in a surgical clinic, it was determined that pain (37.4%), poor ventilation of hospital rooms (32.7%), and noise (24.3%) were the three main factors affecting patients' sleep during hospitalization [18].

### ■ Mean sleep points

The mean PSQI score in the experimental group after the operation was found to be 6.2791 ± 3.64055; in the control group it was found to be 8.1395 ± 3.50905. Wang et al. (2010) performed a study (n=101) with the aim of describing the factors influencing the sleep quality of patients with heart failure. They found that the mean score for sleep quality was 10.78 ± 4.78 as measured by PSQI [36]. A study by Hu et al. (2010) examined the effect of earplugs and eye masks on sleep; and the mean PSQI score for nights when the earplugs and eye masks were not used was found to be 4.1 ± 1.7, and for nights when the earplugs and eye masks were used it was found to be 2.3 ± 1.3 [31,34]. In a study by Yalçın Atar et al. (2012) with 107 patients from a surgery clinic, it was found that the sleep quality of 55.1% of patients was poor according to the PSQI. In that component of the PSQI, the subjective sleep quality score was 1.38 (SD=0.59), the sleep latency score was 1.22 (SD=0.90), the sleep disturbance score was 1.19 (SD=0.81), the sleep duration score was 0.85 (SD=1.24), the daytime function score was 0.54 (SD=0.87), the sleep efficiency score was 0.45 (SD=0.86), and the use of sleep medication score was 0.10 (SD=0.31) [18]. In our study, the mean PSQI score was found to be lower than those of these two studies. The results of a study examining sleep before and after coronary artery bypass grafting (CABG) with 38 male patients showed that there was a change a sleep distribution, with a reduction in sleep duration and an increase in daytime sleep in the period immediately following CABG. [20]. Kociuba et al. (2010) carried out a study to determine the prevalence of sleep difficulties and their impact on cognitive function in 77 persons at an outpatient cardiology center and reported that approximately 94% of participants met the criteria for poor sleep, and that sleep problems are common in cardiovascular disease [16]. Wang et al. (2010) performed a study (n=101) to describe the factors influencing the sleep quality of patients with heart failure and found that 81% of the participants reported poor sleep quality, and 31% were unsatisfied with the quality of their sleep [36].

### ■ The effects of earplugs and eye masks

The difference in mean PSQI score between patients in the control group and the experimental group before the operation was found not to be statistically significant (MWU=757.0, p=0.146). These results show that the study is reliable. The mean PSQI score in the control group after the operation was found to be higher than the mean PSQI score in the experimental group after the operation, and this difference was found as statistically significant (p=0.016) **(TABLE 2).** This result shows that wearing earplugs and eye masks was effective in increasing the sleep quality of patients in the experimental group. Only three studies have examined the effects of both earplugs and eye masks on sleep. Our results are similar to those of the studies by Jones and Dawson (2012), Hu et al. (2010), and Richardson et al. (2007). There have been few studies evaluating the effects of earplugs to improve sleep [29,30]. Our results are similar to the results of Scotto et al. (2009).

No statistically significant difference was found between the pre-application mean sleep quality scores of patients in the experimental group and their post-administration scores (Z=-0.469, p=0.639). That is, it was found that the sleep quality of patients in the experimental group did not change as a result of the application of earplugs and eye masks. The difference in mean sleep quality of patients in the control group before and after the application was found to be statistically significant (Z=-3.432, p=0.001). That is, it was found that the sleep quality of patients in the control group was reduced after the application compared with the pre-application level.

## Factors which did not affect sleep

The gender of patients in the experimental group did not affect the mean PSQI score before or after the operation (p>0.05). The gender of patients in the control group did not affect the mean PSQI score after the operation, but it did affect the mean PSQI score before the operation (p=0.016); the mean PSQI score before the operation in female patients in the control group was higher than that of male patients. This result showed that sleep quality was lower in female patients than in male patients before cardiovascular surgery. Liao et al. (2011) found that individual factors such as age and gender affected sleep quality. Our result supports the result of this study [19]. Wang et al. (2010) carried out a study with the aim of describing the factors influencing the sleep quality of patients with heart failure, and they found that age, religion, occupation, marital status, education level, and lifestyle were not related to sleep quality [36].

## ■ Factors which affected sleep

Wang et al. (2010) performed a study to describe the factors influencing the sleep quality of patients with heart failure, and they found that the factors related to sleep quality were gender, perceived health, depressive mood, and the number of comorbidities. Patients with heart failure who were female or who had self-perceived poor health, more comorbidities, and depressed mood were at higher risk of poor sleep quality than those who were not [36].

The educational level of patients in the experimental group affected the mean PSQI score after the application of earplugs and eye masks. The mean PSQI score before the operation in patients who were educated to primary school level or lower was lower after the application than before. Also the mean PSQI score before the operation in patients who were educated to secondary school level or higher was higher after the application than before. This result showed that sleep quality was lower in patients in the experimental group who were educated to secondary level or more than that of patients who had a primary school or lower educational level. The educational level of patients in the control group did not affect their mean PSQI score after application. That is, sleep quality did not change in patients according to educational level in the control group. In a study by Wang et al. (2010), the authors found that education level was not related to sleep quality [36]. The results of the present study were similar to the results of this research.

## ■ Anxiety

Anxiety has a negative effect on sleep, and some ICU patients have stated that they were afraid to fall asleep because of not waking up again [1]. In this study, it was found that patients in both groups had a mild level of state anxiety before application and a moderate level of state anxiety after application. In a study by Hu et al. (2010), the mean state anxiety level before the application of earplugs and eye masks was found to be 32.5 ± 5.6, and after the application of earplugs and eye masks it was found to be 29.8 ± 6.4. In a study by Jones and Dawson (2012), 60% of patients in the experimental group and only 2% of patients in the control group defined state anxiety as a factor which prevented them from sleeping [32].

No significant difference in mean state anxiety scores was found before application between the two groups (p=0.139) **(TABLE 4).** This result showed that using earplugs and eye masks did not affect state anxiety due to operation. Also, no significant difference was found between the mean state anxiety score before and after application of the patients in the experimental group and control group (p=0.060) **(TABLE 4).** This result showed that the state anxiety level did not change in patients in the control group during hospitalization. This result may depend on continuing exposure to factors (noise, light) which cause state anxiety in both the pre- and post-operational period.

The difference between the mean state anxiety of patients in the experimental group before and after application was found to be statistically significant (p=0.001). That is, it was found that the state anxiety of patients in the experimental group after application was reduced compared with the pre-application level. This result may be connected with the use of earplugs and eye masks by patients in the experimental group.

The difference in the mean state anxiety of patients in the control group before and after application was found to be statistically significant (p=0.000). That is, it was found that the state anxiety of patients in the control group was lower after application. It is thought that this result may be connected with the elimination of a serious condition by surgery.

In a study by Kanan and Koca (2000), it was found that the state anxiety before the operation in the experimental group was higher than the state anxiety after the operation, and that this difference was statistically significant [37]. No significant difference was found between mean state anxiety according to gender in patients in either the experimental group or the control group after the operation (p>0.05). No significant difference was found between mean state anxiety according to gender in patients in the control group before the operation (p>0.05), but in the experimental group, such a difference was found (p=0.005). That is, female patients in the experimental group experienced a higher anxiety level before surgery. A weak correlation was found between anxiety scores before surgery and after surgery. It has been stated in many studies that the state anxiety level is higher in female patients [38-41]. Our study supported the results of these studies.

An operation is an important cause of loss of working time for patients; particularly for patients who have a profession in which money is earned on a daily basis, an operation means a loss of time and money [42]. No statistically significant difference was found in mean anxiety scores according to the profession or the educational level of patients in either the experimental group or the control group. These results are similar to the results of studies by Nayır (2012), Shevde and Panagopoulos (1991), and Yıldırım and Hacıhasanoğlu (2010).

## Conclusion

It can be concluded that eye masks and earplugs were not effective in reducing the state anxiety stemming from a cardiovascular operation but were effective in promoting sleep. These should be used in patients undergoing cardiovascular operations in order to promote sleep. Additional randomized clinical trials are required to determine the comparative effectiveness of eye masks and earplugs.

## Study limitation

The study was not blinded; this may be effected the results of the study.

## Author contributions

The study conception and design of the manuscript were made by AD and LK. AD performed the data collection. The data analysis and critical revision to the paper were performed by AD and LK.

## Ethical Approval

The ethical approval for this research was given by Ege University Faculty of Medicine Clinic Research Ethics Committee.

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