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The Effect of Use of Earplugs on Sleep Quality in Coronary Care Units Patients

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ABSTRACT

Introduction: Sleep deprivation along with subsequent increased blood pressure and heart rate can lead to higher risk among patients admitted to Coronary Care Units (CCUs).

Objective: The aim of this study was to determine the effect of use of earplugs on sleep quality and its domains (sleep disturbance, supplementary sleep and the effectiveness of sleep) in CCU patients.

Materials and Methods: This cross-over randomized clinical trial study was carried out on 92 CCU patients in 2 groups of A (using earplugs at the first night and no earplugs at the second night) and B (no earplugs at the first night and using earplugs at the second night). Data collection was done using a two-part tool including a researcher-made questionnaire on individual and socio-demographic information related to disease and standard scale of Verran and Snyder-Halpern Sleep Scale (VSH Sleep Scale). Earning higher scores was described as poor sleep quality in the overall quality of sleep and its domains. Data analysis was performed using descriptive and inferential statistical methods, ANOVA and Generalized Estimating Equations (GEE) logistic regression.

Results: The results revealed that the female participants made up the majority of samples in both groups A and B (54.2 and 60.4%). The use of earplugs significantly reduced the quality of sleep disturbance domain in both groups A and B (P=0.0001 and P=0.021, respectively), and the supplementary sleep domain in group A (P=0.027). There was no significant difference between the two groups in terms of mean change in overall sleep quality score and its domains within the two nights. Finally, the GEE-based regression test based on controlling the individual and social and disease-associated factors indicates the effect of use of earplugs in reducing the quality of sleep (B=3.1 and P=0.0001) and its domains, including sleep disturbance (B=-5.59 and P=0.021), supplementary sleep (B=3.33 and P=0.0001) and sleep effectiveness (B=-1.43 and P=0.027).

Conclusion: The negative effects of using earplugs on overall sleep quality and its domains in this study highlights the need to carry out further researches in order to find an effective method to improve sleep quality in CCU patients.

Keywords:
Ear protective devices, Sleep, Inpatients, Coronary care units

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Introduction

Sleep is one of the basic human needs that is essential for energy conservation, stress adaptation, and restoration of physical and mental health. However, Sleep deprivation can reduce the ability to perform daily activities [1]. Furthermore, sleep deprivation can lead to higher risk of hypertension, diabetes [2], increased sensitivity to pain and the risk of heart attacks [3]. There is also evidence regarding a relationship between sleep disturbance and coronary artery diseases [4]. The significance of this problem is highlighted considering the high prevalence of short sleep duration among hospitalized patients, especially in intensive care units [5]. Thus, ICU patients are at risk of sleep disturbance due to the stress of being involved in the severe disease as well as the experience of specific environmental factors in ICUs [6]. Measuring the noise levels in the ICUs also shows noise levels of 50 to 75 dB and even up to 130 dB [7] which is much higher than the standard noise level in the hospital wards (maximum level of 30 dB) advised by the World Health Organization (WHO) [8]. Thus, this high noise accounts for large proportion of sleep disturbances in ICU patients [9]. Xie also described the noise as the strongest indicator of the sleep situation of ICU patients [10]. The results of a study on CCU patients revealed that the mean and standard deviation of the night sleep duration in these patients was 5.6±2.2 hours less than those admitted in other wards of the hospital. This difference has been observed especially in patients with acute coronary syndrome in the first 3 days of admission [11].

Thus, sleep deprivation and its impact on delay in patient recovery should be taken into consideration [12]. Therefore, nurses should consider appropriate measures to promote rest and sleep in their care planning and give high priority to supporting the patient sleep [13]. Since the available evidence indicates the effectiveness of interventions eliminating unnecessary noise on the promotion of sleep in ICU patients [14], several researchers have focused on noise reduction techniques in these areas. The researchers are showing increasing level of interest to the use of earplugs as a simple and cost-effective intervention to reduce the noise experienced by patients in the ICU setting. However, there are still controversial results in this regard. For instance, the results of some studies have referred to longer sleep duration and the effectiveness of using earplugs on the quality of night sleep in CCU patients [3, 15]. Nevertheless, Martin reported different results in his study [16].

Therefore, the researchers seek to conduct a research aimed at determining the effect of earplugs on the quality of sleep and its three domains in hospitalized patients (disturbance, effectiveness, and supplementary sleep) in the CCU wards. This research comprises four hypotheses with themes of the effect of earplugs in reducing the mean score of the domains of sleep quality, supplementary sleep, and overall sleep quality of the subjects by controlling the effects of individual, social and variables and disease-related factors, as well as the effect of earplugs on the increasing mean score of the effectiveness of sleep quality.

Materials and Methods

The present study was a cross-over clinical trial. The study samples included patients with acute coronary syndrome who were admitted to the CCU wards of one of the educational centers in the city of Rasht, Iran. The inclusion criteria included age of at least 18 years, being admitted during morning until 6:00 p.m. of the sampling day, signing the written consent form, probability of admission to the CCU ward for at least 2 nights with the observation of acute changes in the T wave or ST segment in the electrocardiogram, complete consciousness and orientation to time, place and person, ability to read and write, and understanding the Persian language; lack of visual impairment, hearing loss as well as lack of using earplugs according to the patient's statement, lack of forgetfulness based on the patient's statements, lack of use of sedative drugs in the past 24 hours and lack of use of opioids at 12 hours before the first night of intervention based on the patient's medical records data and the patient's statements. The samples were selected gradually and randomly placed into two groups A and B in equal proportions (by random selecting of even and odd numbers of patients' bed). The selected samples were excluded from the study in the event of any change in the care process such as transfer from the wards at any time of the trial period, the need to remove the earplugs or its accidental removal, wearing the earplugs for less than 6 hours as well as the reluctance to continue participating in the research and sampling was continued until the desired sample size was reached.

The sample size for each group (n=44) and total sample size in the present study was determined (n=88) based on the results of the mean and standard deviation of supplementary sleep domain scores before and after using the earplugs in a Mashayekhi's study (the pre and post-intervention mean of 25.5±27.06 and 23.64±40.8) titled the effect of earplugs on sleep perception in CCU patients

[3] with CI=95% and power=80%. This cross-over study was performed on two groups of 48 patients and the total number of samples 96.

The data collection was done using a two-part tool consisting of a researcher-made questionnaire on personal, disease and treatment information (age, gender, marital status, level of education, occupation, sleep duration habits, comorbidities, diagnosis, history of admission in the CCU, a person's experience of sleep quality in the case of a history of admission to the ICU wards, routine sleep quality outside the hospital, average night-duration sleep, average sleep time, level of left ventricular drainage, use of opioids during the 12 hours before the participation in the study, the history of drugs affecting the nervous system and the Veran and Snyder-Halpern Sleep Scale (VSH Sleep Scale).

The VSH scale is a visual scale with 15 interrogative sentences and one computational term that evaluates the three domains of sleep disturbance (7 items), effectiveness (5 items) and supplementary sleep (4 items) with separate scoring. Each item is answered by marking the samples on a graded vector with scores ranging from 0-100 mm. Higher scores in sleep disturbance and supplementary sleep and lower scores in the effectiveness of sleep domains indicated poor sleep quality [3]. In this research, the total scores obtained from each of the sleep domain were presented for the formal matching of the results after being divided by the number of items in each domain. All sleep domains were reported with a score range of 0-100. In this study, the overall score of sleep quality was also calculated using the following formula:

Overall sleep score=Sleep score in effectiveness domain (Sleep score in disturbance domain + sleep score in supplementary sleep)

Accordingly, the higher overall sleep score indicates poor sleep quality. The VSH scale in the current research was provided to 12 nursing faculty members after being translated and re-translated and approved with CVI=0.8 to 0.9 and CVR=0.99. The internal consistency of the instrument was confirmed based on the results of the pilot study carried out on 20 subjects who met the criteria specified for the research and Cronbach's alpha coefficients of 0.71, 0.82 and 0.798, obtained respectively, for the sleep disturbance, effectiveness, and secondary sleep domains. The data collection was carried out by the researcher in the first night, 4 hours prior to the intervention (between 6:00 p.m. to 10:00 p.m.) using interviews and recording the data contained in the medical records) and a researcher assistant using self-reporting method (recording data related to sleep quality) between 6:00 a.m. and 8:00 a.m., when the ICU lamps were turned on up and the patients were awakened. The researcher started the data collection process after receiving the written approval of the Vice-Chancellor of Research of Ethics Committee of the Guilan University of Medical Sciences and registering it at the Iranian Center for Clinical Trials (ICCT) as well as obtaining essential letters of introduction and signing the informed consent form.

The research subjects were place in A Group (48 individuals laying down on the even-numbered beds with earplugs on the first night and without earplugs in the second night) and B Group (48 individuals laying down on the odd-numbered beds with earplugs on the first night and without earplugs in the second night). The earplug used in the present study was of sponge-type

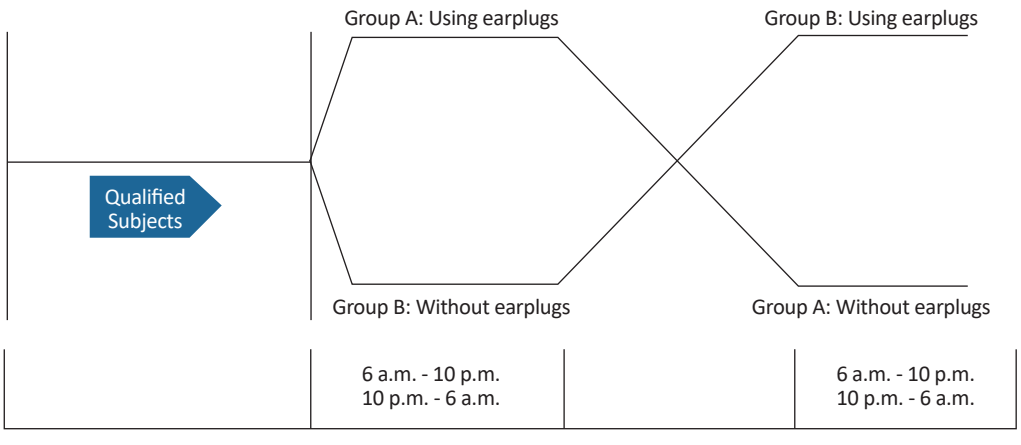

Figure 1. The model of intervention implementation in the studied groups

(JSP model, UK) with a noise reduction rate of up to 37 dB (SNR 37) and with European Conformity standard.

The sampling lasted for 3 months in 2014. During this period, 106 subjects were enrolled in the study, 4 and 6 of whom were excluded respectively due to being transferred from the women's intensive care unit to the Department of Women's Heart Surgery and changes in physical conditions and intolerance to the earplugs and early withdrawal (Figure 1).

Data collection was performed using descriptive (descriptive and mean, standard deviation and frequency of data) and inferential statistics (Chi-square, independent t-test, regression of GLM general linear model using GEE method to test the research hypotheses in SPSS software ver. 21). After confirmation of the normal distribution of the research data, the Kolmogorov–Smirnov test was analyzed. P-value of less than 0.05 was considered as the significant level in all of the data in this study.

Results

Findings on the demographic characteristics of the subjects indicate a mean age of 59.81±8.37 and 61.89±11.59 years for groups A and B, respectively. A total of 52.1% of them were admitted to the male CCU ward. Also, a majority of subjects in Groups A and B were female (54.2% and 60.4%), married (85.4% and 87.5%), individuals with elementary education (62.5% and 75%) and housewives (47.9% and 52.1%). A total of 39.7% of the subjects in A Group and the majority (62.5%) of the B Group had good sleep quality before admission. In addition, the majority of samples with a history of hospitalization in the CCU reported the quality of their previous experience of sleep as moderate (54.5 and 77.8%, respectively).

Most of the subjects had special pre-sleep habits (66.7% of the A Group and 56.2% of B Group), with the watching TV habit accounting for the highest percentage (31.3% of the A Group and 42.8% of the B Group). The subjects of A Group had a mean of sleep duration minute of 6±1.39 and the time spent from deciding to sleep of 36.66±32.83. The subjects in B Group had a mean of sleep duration of 6±1.41 hours, and the period from deciding to sleep of 31.56±21.11. Chi-squared test (in qualitative variables) and independent t-test (in quantitative variables) showed no significant difference between the two groups (Table 1).

Comparison of the mean of the score of the three domains of sleep disturbance, supplementary sleep and sleep effectiveness in the two A and B Groups in the first night indicates that the subjects in A Group in the first night of the study, had significant scores with higher mean in supplementary sleep compared to the B Group (75.30±18.46 and 65.74±20.4, respectively). Thus, sleep quality of subjects in A Group, despite the use of earplugs was weaker than those in B Group (first night + without earplugs) in this domain (P=0.02).

The mean score for sleep disturbance (67.57±16.77 and 66.19±16.10, respectively), effectiveness (54.45±16.18 and 55.54±17.6) and overall sleep quality (31.03±11.45 VS with 28.31±10.97) domains in A Group was slightly higher than the scores obtained in B Group (Figure 2). Comparison of the mean overall sleep score and the three domains of sleep disturbance, supplementary sleep and sleep effectiveness in the two A and B Groups in the second night showed that the mean score of sleep disturbance in B Group was significantly higher than A Group in the second night (70.52±11.90, VS with 60.61±13.79) (P=0.0001). The other more notable finding in Figure 3 is the higher mean scores of A Group samples in the supplementary sleep domain, VS to B Group (70.07±16.19 and 68.15±19.65, respectively) (Figure 3). The results of independent t-test show that the overall sleep quality was significantly better in A Group samples and those using earplugs (P=0.032), compared to B group or those using earplugs (26.99±8.66 and 31.15±9.99 respectively). While determining the effect of using earplugs on the sleep quality score in disturbance, supplementary sleep and sleep effectiveness, by controlling the effects of individual, social variables and disease-related factors using the regression model, the results indicate that there is a significant difference between the two groups in terms of sleep disturbance (B=-5.99 and P=0.0001) by controlling individual intervening and disease-associated variables (Table 2).

Table 2 shows that the lack of use of earplugs led to a lower sleep score than the time it was used in the supplementary sleep domain in such a way that the mean of sleep score of 3.33 obtained in the supplementary sleep domain in the night + no earplug state is less than the night and with the use of the earplugs, and the studied subjects had better sleep score in this domain. Based on the findings of this table, the lack of use of earplugs, by controlling the effects of individual and disease related variables significantly reduced the mean of the sleep effectiveness score of the samples (B=-1.438, P=0.027). Finally, the multiple regression analysis in this table shows that the lack of use of ear-

Table 1. Distribution of studied subjects based on disease-related factors

Group / Variable		A Group N (%)	B Group N (%)	Sig.
History of heart risk factors	Hyperlipidemia	11(68.7)	12(63.1)	0.655*
	Cigarette	4(25)	4(21)	
	Hyperlipidemia and cigarette	1(6.2)	3(15.9)	
	Total	16(100)	19(100)	
Diagnosis	STEMT	16(33.3)	9(18.8)	0.343*
	NSTEMI	8(16.7)	7(14.6)	
	UAP	17(35.4)	21(43.8)	
	HF	7(14.6)	11(22.9)	
	Total	48(100)	48(100)	
The type of comorbidity	Yes	41(85.4)	42(87.5)	0.765*
	No	7(14.6)	6(12.5)	
	Total	48(100)	48(100)	
The type of comorbidity	Diabetes	11(26.8)	10(23.8)	0.249*
	Hypertension	13(31.7)	21(50)	
	Diabetes and hypertension	17(41.5)	11(26.2)	
	Total	41(100)	42(100)	
The history of admission to CCU	Yes	22(46.8)	18(37.5)	0.358*
	No	25(53.2)	30(62.5)	
	Total	47(100)	48(100)	
History of neuropsychiatric drugs use	Yes	3(6.3)	7(14.6)	0.181*
	No	45(93.8)	41(85.4)	
	Total	48(100)	48(100)	
Opioid consumption within 12 hours before the specified time limit	Yes	3(6.3)	7(14.6)	0.181*
	No	45(93.8)	41(85.4)	
	Total	48(100)	48(100)	
LVEF (%)		43.36±8.23	40.66±10.90	0.185**

* Chi 2; ** Independent t-test

plugs led to a significant reduction in the mean overall sleep score (P=0.0001) of the samples by 3.1 times. Therefore, the use of earplugs was associated with a lower sleep score.

Discussion

Findings show poor sleep quality using earplugs, taking into account the same clinical conditions with subjects wearing no earplugs, in sleep disturbance, supplementary sleep, sleep effectiveness domains, and overall sleep quality, which can demonstrate lack of comfort in using earplug and perceiving it as an external device in the ear and lack of inadaptability in this regard. Therefore, the use of earplugs is not likely to be comprehended as an advantage for patients and has even been experienced as an annoying and additional object.

Nevertheless, Yazdan Nick revealed in his study that the mean score of sleep disturbance in the second night in the group wearing no earplugs was higher than that of the group wearing earplugs [17]. This difference may be attributed to the difference in the hospitalization ward, because Yazdan Nick's study was conducted on ICU patients, patients with more severe pathological conditions and multiple systems might be hospitalized

Table 2. Determining the effect of earplugs on the sleep domains and total sleep quality by controlling individual, social variables, and disease-related factors

Variable		B	SE	95% CI		Sig.
				Lower	Upper	
Intercept		85.90	15.41	55.68	116.12	0.0001
Sleep disturbance	Without earplugs	-5.59	0.597	6.76	-4.42	0.0001
	With earplugs	Reference				
Effectiveness	Without earplugs	-1.43	0.651	-2.715	-0.162	0.027
	With earplugs	Reference				
Supplementary sleep	Without earplugs	-3.33	0.810	-4.93	-1.74	0.0001
	With earplugs	Reference				
Overall quality sleep score	Without earplugs	-3.100	0.413	-3.91	-2.28	0.0001
	With earplugs	Reference				

in these wards and exposed to higher noise levels of equipment and alarms since the quality and quantity of sleep are affected by various physical, psychological and environmental factors [2]. Moreover, the non-use of earplugs compared with usage state can be accompanied by a reduction in sleep disturbance score. This finding differs from the results of Yazdan-Nick's and Arab's studies, which indicate a positive and significant effect of the use of earplugs and eye mask on the quality of sleep [12, 17].

The difference may be attributed to the feeling of anxiety as a result of the existence of an unfamiliar and new device in the body by the present research subjects, as well as their low level of education. Martin has not confirmed the effect of use of earplugs on the effectiveness of sleep quality [16]. Existing differences highlight the need to further examine the impact of earplugs on the quality of sleep. It appears that the noise in the ICUs necessitates the use of effective strategies for improving the sleep quality. This point emphasizes the need to continue the studies in order to find the best and most practical solution. Improved quality of supplementary sleep of the subjects who participated in the present study in the case of non-use of earplug may indicate an uncomfortable feeling caused by the use of an external device in the patient's ears [18].

Jones and Dawson demonstrated that less than half of the subjects reported comfortable and easy use of earplugs [18]. Overall, the findings of this study are different from the results of a number of previous studies, such as the Neyses' study which showed a significant effect of use of earplugs on the overall sleep score of

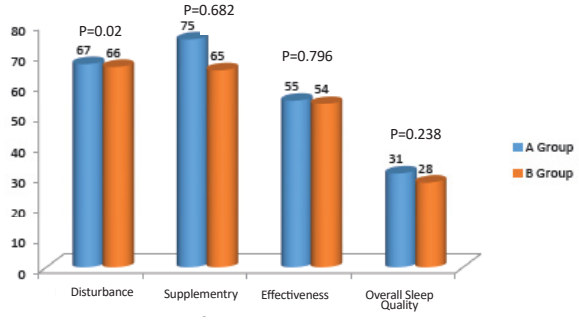

Figure 2. Comparing the quality of sleep and its domains in the groups A and B in the first night

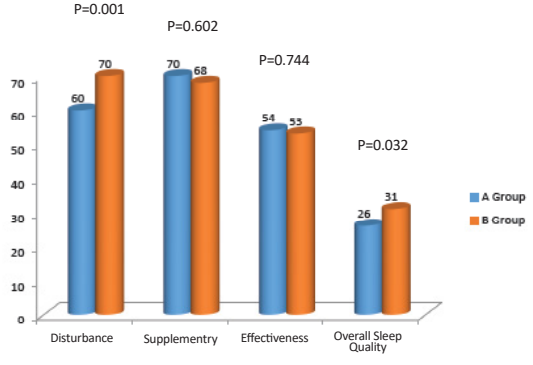

Figure 3. Comparison of sleep quality and its domains in the groups A and B on the second night

the studied subjects [1] which is perhaps due to the different tools used by these studies or different settings in the CCU wards. Patients with multiple disorders are usually admitted in these wards and are associated with a higher noise level considering the need for equipment such as artificial respiration and multiple alarms. Considering the results of this research, nursing managers should enhance the ability of nurses to provide a more quiet environment so as to improve the quality of sleep in CCU patients by organizing training programs for nurses, especially ICU nurses.

Furthermore, equipping the ICU wards with noise control facilities (such as acoustic ceilings and walls), and providing guidelines specifically designed to promote the sleep quality and precise supervision over their implementation are among the measures that should be considered by managers. In this regard, Hophius demonstrated that although the majority of nursing staff provided reports on the need to implement a specific sleeping pattern, the vast majority of Dutch ICU wards did not have this type of guideline [19]. CCU nurses can also play a more effective role in resolving this commonly occurring problem by planning for other sleep-promoting measures, such as reducing light and timely implementation of nursing care. In addition, examining the patients' routine sleep quality along with their special habits can provide a unique plan for improving the quality of sleep. In general, multidimensional approaches are required to improve the sleep of CCU patients because adequate sleep is associated with reduced pathogenesis and health recovery [20]. The subjective quality of sleep and the focus of the findings on the responsiveness of the subjects are the main limitations of the present research that were not controlled by the researcher.

Acknowledgments

The present study was approved by the Ethics Committee of the Vice-Chancellor of Research of Guilan University of Medical Sciences with the number of 2930252806 and registered at Iranian Registry of Clinical Trials (IRCT) with IRCT201403031118N. Therefore, researchers would like to appreciate all those who have supported the project. Also, the authors also express their gratitude to all nurses and patients admitted to this treatment center, which have had an undeniable contribution to this study. Department of Research and Technology in Guilan University of Medical Sciences has financially supported this article.

Conflict of Interest

No conflict of interest has been declared by the authors. All authors have agreed on the final version and meet at least one of the ICMJE authorship criteria, including substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content.

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