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RESEARCH ARTICLE

EFFECT OF EAR PLUGS & EYE MASK ON SLEEP AMONG ICU PATIENTS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Disturbed sleep and sleep deprivation is common among ICU patients. Use of eye masks and ear plugs may be a valuable to patients attempting to sleep in intensive care units. This randomized control trial aims to assess the efficacy of ear plugs and eye mask in improving the sleep pattern among critically-ill patients.

Method: The study was conducted in January 2014 in selected ICUs of a tertiary care hospital. 100 patients were selected by convenience sampling and were randomized to control and experimental group using parallel group design. The perception of patient's sleep with and without usage of ear plugs and eye mask was evaluated Using Verran and Snyder-Halpern Sleep Scale consists 16 items that include three main sleep sub scales: disturbance, effectiveness, and supplementation.

Results: The study revealed statistically significant difference in mean scores among experimental and control group as per sleep fragmentation (14.6±3.44 vs 4.19±3.58), sleep latency (6.05±1.88 vs 1.70±1.66), sleep quality (10.5±2.52 vs 2.14±2.29), sleep length (8.95±2.47 vs 2.36±2.46), sleep supplementation (11.8±3.26 vs 4.10±2.33).

Conclusion: Findings of the study revealed that ear plugs and eye mask has significantly increased the quality of sleep among critically ill patients at all three subscales (disturbance, effectiveness, and supplementation).

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INTRODUCTION

Sleep is one of the basic human needs required for health and energy conservation, appearance and physical well-being. During sleep, certain hormones such as serotonin and the growth hormone are released and chemical changes and increased cellular nutrition take place so as to make the body ready for the activities of the next day. It promotes repair, re-organization, memory enhancement, learning functions and causes reduction in stress, anxiety and neurological pressures and helps the individual in recovering energy for better focus, adaptability, adjustment and enjoying daily activities (Mohammad *et al.,* 2012). Sleep may not reach significance for an individual until it is lacking or disturbed. At that point, an individual may become short-tempered, irritable, over reactive and unable to cope effectively with situations or people. Sleep is a complex, active process that is programmed by man's circadian rhythm. This 24-hour biological clock is based on a day-night cycle, which programs human to sleep at night and be awake during the day (Honkus, 2003). The Intensive Care Unit (ICU) is the part of the hospital where highly specialized and intensive care, treatment and medicine is provided. When a patient's condition is life-threatening or fragile, they are assigned to the ICU. The ICU ensures constant and close technical and medical monitoring and support to maintain normal body levels. So environmental factors such as excess noise and lighting, the patient's acute illness itself, patient care activities or invasive nature of the ICU procedures and mechanical ventilation are detrimental to quality sleep in the ICU (Bourne and Mills, 2004).

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ICU patients were found to have poor sleep quality, which included severe irregularity in circadian rhythm and sleep cycle as well as decreased total sleep and sleep efficiency further compounding their illness (Shu-Yen *et al.,* 2012). Psychological stress alone can temporarily affect an individual's sleep patterns. Research findings has concluded that patients in critical care units may spend 40% to 50% of their sleep time awake and of the remaining sleep time only 3% to 4% in REM sleep (Honkus, 2003). However, Some patients will be predisposed to sleep disturbances in the ICU due to chronic illness. Patients with chronic obstructive pulmonary disease have increased sleep latency, reduced total sleep time and experience increased arousals. Cheyne-Stokes respiration is common in patients with chronic heart failure whose ejection fractions are less than 40% and is associated with sleep fragmentation and reduced sleep efficiency. Patients with acute neurological disorders (e.g. intracerebral haemorrhage, meningitis) may also suffer from Cheyne Stokes respiration. Asthmatic patients are known to experience sleep disorders including early awakening (Silveira *et al.,* 2012). The Prevalence of Obstructive sleep apnea is high in Congestive heart failure patients as well as in the general population. So, nursing interventions should be planned to improve sleep quality of Congestive heart failure patients (Patidar *et al.,* 2011).

Noise was the most commonly cited interruption to patients' sleep. Environmental noise in ICU is due to a variety of causes, including ringing phones, talking, beepers and equipment sounds from suction apparatus and mechanical ventilation. Alarms from cardiac monitors, pulse oximeters and ventilators add to the noise pollution. It produces physiologic changes similar to what is seen in a generalized stress reaction, including vasoconstriction, elevated diastolic BP, dilated pupils and muscle tension. Because of adrenalin released by the sympathetic nervous system, these effects prevent the patient from relaxing and falling asleep (Honkus, 2003). The ICU environment makes patients sleep fragmented. A study on factor disturbing sleep found that 40% of ICU patients' awakenings are caused by noise generated by conversations and activities of patient care, which make these very significant factors for sleep disturbances (Silveira *et al.,* 2012).

The noise level in intensive care units (ICUs) ranges from 50 to 75 dB, with the highest night peak level even reaching 103 dB. Besides sensory overload from noise, lighting has also been identified as a factor preventing sleep. The normal light/dark cycles help to regulate the biological clock and play an important role in maintaining wake-sleep cycles. Alterations in the light and dark cycles have a major influence on sleep patterns because of melatonin secretion and signaling the body's internal clock that it is time to sleep or be awake. Bright lights from the nurses' station, lights that are not dimmed and lights that are turned on at night are all very disrupting to patient's sleep (Hui *et al*., 2009).

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Moreover, there are some adverse consequences of sleep disruption which include impaired immune function, decreased inspiratory muscle endurance and a possible association with delirium and severe morbidity (Rong-fang *et al.,* 2010). Patients in an intensive care unit (ICU) often become confused or delirious soon after or within a few days of admission in the ICU. A research published in Biomed Central's open access journal Critical Care shows that use of earplugs can result in better sleep (as reported by the patients), lower the incidence of confusion, and delay the onset of cognitive disturbances (Bourne and Mills, 2004). Moreover, ICU patients may also have more sleep disturbances caused by both the period of critical care and the high prevalence of concurrent diseases (Orwelius *et al.,* 2008). However, eye masks are also considered as one of the nursing intervention to improve sleep of the patients in CCU's to limit the environmental light as a study revealed that using eye mask, as an economical and uncomplicated method, can improve sleep quality in patients with acute coronary syndrome in the coronary care units and can be used as an alternative method of treatment instead of drug therapy (Mohammad *et al.,* 2012). In addition to this, there is an increasing number of patients have been requesting to use earplugs to help them sleep based on their experiences of wearing them at home or while travelling. Both earplugs and eye masks are regularly offered to travelers on long-haul night-time flights to improve sleep in aeroplanes light and noisy environment (Richardson *et al*., 2007).

Despite much emphasis on the combined effect of ear plugs and eye mask on improvement of sleep quality of patients admitted to ICUs, few studies have been done in this regard and most of conducted studies concerning this issue have particularly emphasized the use of ear plugs and eye mask separately. The present study aimed to determine the impact of ear plugs and eye mask on sleep pattern of patients admitted to ICU.

Hence, the incidence of disturbed sleep is increasing among ICU patients. So, there is urgent need to improve the sleep pattern. As some studies revealed that eye masks and earplugs helped to improve sleep pattern of critically-ill patients but in Indian scenario such studies are very limited. So, the present study has been undertaken in order to assess the efficacy of earplugs and eye mask which helps to improve the sleep pattern of critically-ill patients and to reduce the complication of sleep disruption.

MATERIALS AND METHODS

The study was conducted on 100 patients with 50 subjects in experimental group and 50 in control group in the selected ICU's of DMC & Hospital, Ludhiana. The data was collected during 1st January to 31st January 2014. The permission was taken from the ethical committee of DMC & Hospital to carry out the study. Informed consent was obtained from the patient.

The participants were randomly divided into two groups: with ear plugs and eye mask (experimental group) for 2 successive nights and without ear plugs and eye mask (control group). Then comparison was done to assess the efficacy of ear plugs and eye mask in improving the sleep pattern by taking pre test on 1st day and post test was taken on the 3rd day in both the groups (see Figure 1).

RANDOMIZED CONTROL TRIAL DESIGN
(Parallel group design)

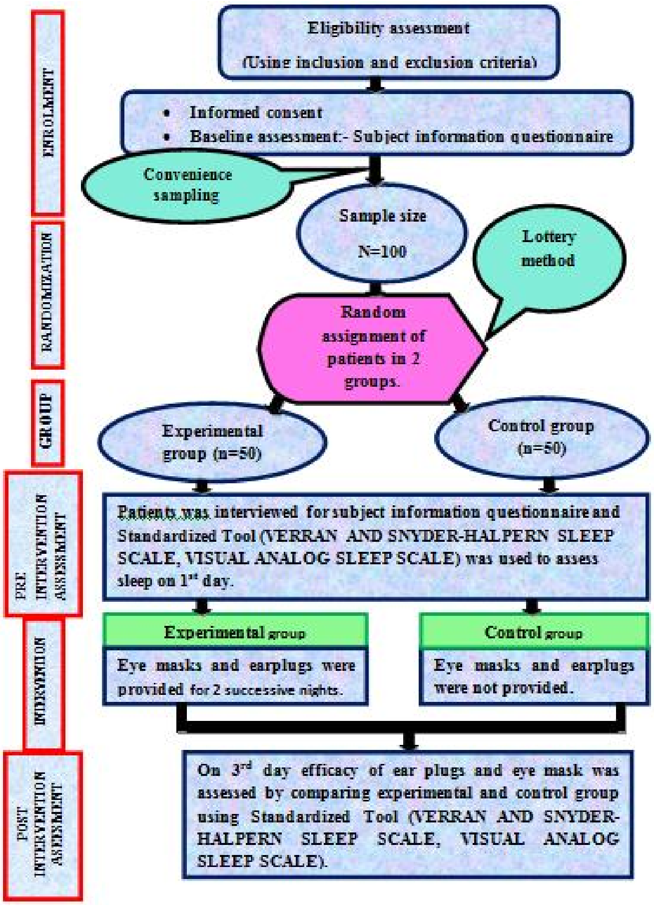

Figure 1. Consortium chart

Data collection tools used in the study way Snyder-Halpern Sleep Scale (VSH Sleep Scale). Using this questionnaire, patients provided an assessment of the quality of their previous night's sleep. This tool consists of 16 items which include three main sleep sub scales: "Disturbance" (interruptions and delays in sleep), "Effectiveness" (how well sleep refreshed the individual) and "Supplementation" (napping). Disturbance comprises items measuring subscales of 'fragmentation' (interruption of sleep) and 'latency' (delay in getting to sleep). Effectiveness comprises the subscales of 'quality' (restfulness and depth of sleep) and 'length' (hours of sleep while in bed). Supplementation contains four items about naps and falling back asleep after morning awakenings. Each characteristic is measured using a 10 cm or 100 mm visual analogue scale. Higher the mean difference ($Mean_D$) score better is the sleep pattern. Analysis of data was done in accordance with the objectives of the study using descriptive and inferential statistics. Calculation has been done using statistical software SPSS (19). Significance of effect or difference was established at the level of 0.05 levels.

RESULTS

The mean age of patients was 58.7 ± 1.54 (Range: 22-88 years). Table 1 shows patients demographic characteristics which showed that out of 50 experimental 23 (46%) were found in age group 61-80 years as compared to control 23 (46%) were found in age group 41-60 years. Nearly half i.e. 51% of the individuals were male. It was found that maximum number of individuals i.e. 60% belonged to urban community. In experimental and control group 24 (48%) and 25 (50%) individuals had secondary level of education respectively. Maximum number of individuals i.e.71% were non-working and 72% individuals were vegetarian. Furthermore, it was found that maximum number of individuals was from ICCU i.e. 55%. In both the groups 20 (40%) of individuals were having 5-8 days of hospitalization and 24 (48%) of individuals were having 1-4 days of hospitalization and maximum number of individuals were present with cardio problems in both experimental and control group i.e. 49%.

Table 1. Distribution of subjects as per socio-demographic characteristics among experimental and control group

Variables	Experimental group (n=50)	Control group (n=50)	Total (n=100)	χ^2 statistics
	f (%)	f (%)	f (%)	
Age (in				
years)	06 (12)	08 (16)	14	$\chi^2 = 2.72$
21-40	18 (36)	23 (46)	41	df = 3
41-60	23 (46)	15 (30)	38	$p = 0.43^{NS}$
61-80	03 (06)	04 (08)	07	
81-100				
Gender				
Male	25 (50)	26 (52)	51	$\chi^2 = 0.04$
Female	25 (50)	24 (48)	49	df = 1
				$p = 0.84^{NS}$

NS: Not significant

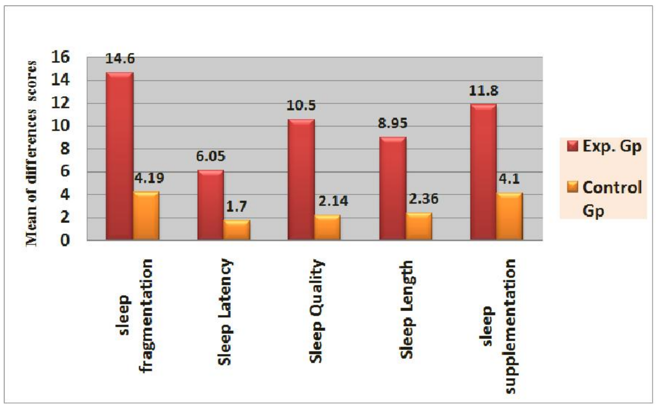

Fig. 2. Mean of differences in sleep pattern among experimental and control group

The mean difference scores as per sleep fragmentation in experimental and control group was 14.6 ± 3.44 vs 4.19 ± 3.58 respectively (p<0.001). Whereas, mean difference scores as per sleep latency in experimental and control group was 6.05 ± 1.88 vs 1.70 ± 1.66 respectively (p<0.001). Furthermore, sleep effectiveness is depicted by further two sub-categories i.e. sleep quality and sleep length. The mean difference scores as per sleep quality in experimental and control group was 10.5 ± 2.52 vs 2.14 ± 2.29 respectively (p<0.001). Whereas, mean difference scores as per sleep length in experimental and control group was 8.95 ± 2.47 vs 2.36 ± 2.46 respectively (p<0.001). Moreover, the mean difference scores as per sleep supplementation in experimental and control group was 11.8 ± 3.26 vs 4.10 ± 2.33 respectively (p<0.001). Mean difference scores of these sub scales have been shown in Figure 2.

Sleep disturbance is sub-divided into two parameters i.e. sleep fragmentation and sleep latency. Sleep fragmentation consist of five items i.e. WASO, SS, QD, MSA, MDS and each item represents sleep fragmentation of individuals. Mean difference scores as per item1 i.e. Wake after sleep onset (WASO) in experimental and control group was 2.96 ± 1.13 vs 0.80 ± 0.91 respectively (p<0.001). As per item7 i.e. Soundness of sleep (SS) mean difference score in experimental and control group was 2.87 ± 0.88 vs 0.52 ± 1.05 respectively (p<0.001) while mean difference score as per item8 i.e. Quality of disturbance (QD) in experimental and control group was 2.81 ± 1.19 vs 0.91 ± 0.94 respectively (p<0.001). Mean difference score as per item9 i.e. Mid sleep awakening (MSA) in experimental and control group was 2.99 ± 1.11 vs 1.16 ± 0.83 respectively (p<0.001) and mean difference score as per item11 i.e. Movement during sleep (MDS) in experimental and control group was 2.95 ± 1.20 vs 0.83 ± 0.73 respectively (p<0.001). Whereas, sleep latency consist of two items i.e. SL & QL and each item represents sleep latency of individuals. Mean difference scores as per item6 i.e. Sleep latency (SL) in experimental and control group was 3.02 ± 1.11 vs 0.76 ± 0.84 respectively (p<0.001) while mean difference score as per item10 i.e. Quality of latency (QL) in experimental and control group was 2.99 ± 1.20 vs 0.93 ± 0.98 respectively (p<0.001). (Table 3)

Furthermore, Sleep effectiveness is sub-divided into two parameters i.e. sleep quality and sleep length. Sleep quality consist of three items i.e. RUA, SQS, SSE and each item represents sleep quality of individuals. Mean difference scores as per item12 i.e. Rest upon awakening (RUA) in experimental and control group was 3.44 ± 0.92 vs 0.75 ± 0.76 respectively (p<0.001) while mean difference score as per item14 i.e. Subjective quality of sleep (SQS) in experimental and control group was 3.47 ± 1.18 vs 0.69 ± 1.03 respectively (p<0.001) and mean difference score as per item15 i.e. Sleep sufficiency evaluation (SSE) in experimental and control group was 3.67 ± 1.11 vs 0.71 ± 0.99 respectively (p<0.001). However, sleep length consist of two items i.e. TSP & TST and each item represents sleep length of individuals. Mean difference scores as per item1+2 i.e. Total sleep period (TSP) in experimental and control group was 2.96 ± 1.13 vs 0.80 ± 0.91 respectively (p<0.001) while mean difference score as per item2 i.e. Total sleep time (TST) in experimental and control group was 3.02 ± 0.92 vs 0.81 ± 0.84 respectively (p<0.001).

Moreover, sleep supplementation consist of four items i.e. DTS, AMS, PMS, WAFA and each item represents sleep supplementation of individuals. Mean difference scores as per item3 i.e. Day time sleep (DTS) in experimental and control group was 3.03 ± 1.06 vs 0.96 ± 0.98 respectively (p<0.001) while mean difference score as per item4 i.e. Morning sleep (AMS) in experimental and control group was 2.88 ± 1.16 vs 0.94 ± 0.86 respectively (p<0.001). Mean difference score as per item5 i.e. Afternoon sleep (PMS) in experimental and control group was 2.88 ± 1.17 vs 1.21 ± 0.91 respectively (p<0.001) and mean difference score as per item13 i.e. Wake after final arousal (WAFA) in experimental and control group was 3.04 ± 1.10 vs 1.03 ± 0.87 respectively (p<0.001). So, it was found that the sleep pattern mean difference score among experimental group was significantly higher as compared to control group (p<0.001).

Table 3. Item wise mean difference scores of sleep pattern among experimental and control group

Sleep pattern	Item no.	Experimental group (n = 50)		Control group (n = 50)		t value	p value
		$Mean_D$	SD	$Mean_D$	SD		
• Sleep disturbance:							
Sleep fragmentation							
Wake after sleep onset (WASO)	1	2.96	1.13	0.80	0.91	11.0	0.000*
Soundness of sleep (SS)	7	2.87	0.88	0.52	1.05	13.1	0.000*
Quality of disturbance (QD)	8	2.81	1.19	0.91	0.94	8.20	0.000*
Mid sleep awakening (MSA)	9	2.99	1.11	1.16	0.83	9.48	0.000*
Movement during sleep (MDS)	11	2.95	1.20	0.83	0.73	9.82	0.000*
Sleep latency							
Sleep latency (SL)	6	3.02	1.11	0.76	0.84	10.8	0.000*
Quality of latency (QL)	10	2.99	1.20	0.93	0.98	9.50	0.000*
• Sleep effectiveness:							
Sleep quality							
Rest upon awakening (RUA)	12	3.44	0.92	0.75	0.76	17.5	0.000*
Subjective quality of sleep (SQS)	14	3.47	1.18	0.69	1.03	12.5	0.000*
Sleep sufficiency evaluation (SSE)	15	3.67	1.11	0.71	0.99	15.4	0.000*
Sleep length							
Total sleep period (TSP)	1+2	2.96	1.13	0.80	0.91	11.0	0.000*
Total sleep time (TST)	2	3.02	0.92	0.81	0.84	13.1	0.000*
• Sleep supplementation:							
Day time sleep (DTS)	3	3.03	1.06	0.96	0.98	9.80	0.000*
Morning sleep (AMS)	4	2.88	1.16	0.94	0.86	10.8	0.000*
Afternoon sleep (PMS)	5	2.88	1.17	1.21	0.91	8.18	0.000*
Wake after final arousal (WAFA)	13	3.04	1.10	1.03	0.87	10.0	0.000*

DISCUSSION

Sleep is an important aspect of the healing process. However, sleep impairment is a common problem in hospitals. In order to evaluate the effects of ear plugs and eye mask in improving the sleep pattern of critically-ill patients. Our results showed that in general, patient's sleep pattern was significantly improved after use of ear plugs and eye mask in experimental group. Quality of sleep in hospitalized patients should be a routine part of patients assessment because the patients sleep quality may reveal more information about the patients overall well-being. The results of present study showed that the mean difference score was significantly increased in experimental group as compared to control group which means that sleep was improved after application of ear plugs and eye mask (p=0.000) this was in accordance with the study results of Mashayekhi F *et al.* (2013) Using ear plug statistically significantly increased the quality of sleep ($p<0.05$). This present study also showed that mean difference score of rest upon awakening (RUA) was 3.44 vs 0.75 (p=0.000), subjective quality of sleep (SQS) was 3.47 vs 0.69 (p=0.000), sleep sufficiency evaluation (SSE) was 3.67 vs 0.71 (p=0.000), total sleep period (TSP) was 2.96 vs 0.80 (p=0.000) and total sleep time (TST) was 3.02 vs 0.81 (p=0.000) among experimental and control group respectively. Hence, it was concluded that sleep quality and sleep length was significantly improved in experimental group as compared to control group.

Similar study conducted by Zolfaghari *et al.* (2013) revealed the effects of environmental modification on quality of sleep among CCU patients. They reported that interventions of decreasing excessive environmental light and noise; such as use of earplug and eye mask has improved the patient's nocturnal sleep in CCU. Neyse *et al.* (2010) reported that the use of earplug and eye mask could improve patients' sleep in critical care unit (Mashayekhi *et al*. 2013). In agreement with our finding, Richardson *et al.* (2007) depicted that majority of patients, in non-interventional group (65%) slept for 6 hours or less whereas, interventional group (56%) slept for longer hours than non-interventional group.

From the above discussion, it is concluded that application of ear plugs and eye mask shows significant effect in improving the sleep fragmentation, sleep latency, sleep quality, sleep length and sleep supplementation of critically-ill patients admitted in ICU's than the control group and it should be recommended for improving the sleep pattern in ICU patients.

Conclusion

Sleep is one of the important elements in human life which is associated with reconstruction of physical and emotional power. Maintaining regular sleep cycles is absolutely necessary in order to preserve fitness and health. Application of ear plugs and eye mask shows significant effect in improving the sleep fragmentation, sleep latency, sleep quality, sleep length and sleep supplementation of critically-ill patients admitted in ICU's than the control group (p=0.000) and is considered as cost-effective and un-complicated method that can improve sleep pattern of critically-ill patients admitted in ICU's.

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