

Effects of earplugs and eye masks combined with relaxing music on sleep, melatonin and cortisol levels in ICU patients: a randomized controlled trial——Crital Care

耳塞、眼罩联合轻音乐对ICU患者睡眠，褪黑激素和皮质醇水平的影响：随机对照临床试验。

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ICU 张耀丹

Abstract

Introduction: Intensive care unit (ICU) environmental factors such as noise and light have been cited as important causes of sleep deprivation in critically ill patients. Previous studies indicated that using earplugs and eye masks can improve REM sleep in healthy subjects in simulated ICU environment, and improve sleep quality in ICU patients.

引言：重症监护室（ICU）环境因素如噪音和灯光已被认为是导致危重病人睡眠不足的重要原因。既往研究表明在模拟的ICU环境中对健康者使用耳塞和眼罩能促进快速动眼睡眠，并能提高ICU患者的睡眠质量。

Abstract

This study aimed to determine the effects of using earplugs and eye masks with relaxing background music on sleep, melatonin and cortisol levels in ICU patients.

本研究的目的是确定使用耳塞和眼罩联合轻松的背景音乐对ICU患者睡眠，褪黑激素和皮质醇水平的影响效果。

Abstract

Methods: Fifty patients who underwent a scheduled cardiac surgery and were expected to stay at least 2 nights in Cardiac Surgical ICU (CSICU) were included. They were randomized to sleep with or without earplugs and eye masks combined with 30-minute relaxing music during the postoperative nights in CSICU.

方法: 选取接受心脏手术并预计在心脏外科ICU (CSICU) 至少停留两晚的50名患者。将他们随机分配到试验组和对照组，试验组患者术后在CSICU的夜晚佩戴耳塞和眼罩并听30分钟放松音乐，对照组没有采取以上措施。

Abstract

Urine was analyzed for nocturnal melatonin and cortisol levels. Subjective sleep quality was evaluated using the Chinese version of Richards-Campbell Sleep Questionnaire (a visual analog scale, ranging 0–100).

通过尿液分析夜间褪黑激素和皮质醇水平。并采用中文版的**Richards Campbell** 睡眠问卷（一种视觉模拟量表）来评估患者的主观睡眠质量。

Abstract

Results: Data from 45 patients (20 in intervention group, 25 in control group) were analyzed. Significant differences were found between groups in depth of sleep, falling asleep, awakenings, falling asleep again after awakening and overall sleep quality ($P < 0.05$).

结果: 从45名患者所得的数据进行分析（实验组20名，对照组25名）。两组患者在睡眠深度，入睡，觉醒，觉醒后再次入睡以及总体睡眠质量方面有明显差异（ $P < 0.05$ ）。

Abstract

Perceived sleep quality was better in the intervention group. No group differences were found in urinary melatonin levels and cortisol levels for the night before surgery, and the first and second nights post-surgery ($P > 0.05$). The urinary melatonin levels of the first and second postoperative nights were significantly lower than those of the night before surgery ($P = 0.01$). The opposite pattern was seen with urinary cortisol levels ($P = 0.00$).

试验组主观感知的睡眠质量更好。两组患者术前夜晚以及术后第一二个夜晚的尿液褪黑激素水平和皮质醇水平没有组间差异 ($P > 0.05$)。患者术后第一二个夜晚的尿液褪黑激素水平明显低于术前 ($P=0.01$)，尿液皮质醇激素则相反 ($P=0.00$)。

Abstract

Conclusion: This combination of non-pharmacological interventions is useful for promoting sleep in ICU adult patients; however, any influence on nocturnal melatonin levels and cortisol level may have been masked by several factors such as the timing of surgery, medication use and individual differences. Larger scale studies would be needed to examine the potential influences of these factors on biological markers and intervention efficacy on sleep.

结论：这种非药物联合干预措施有助于促进ICU中成人患者的睡眠；然而，对夜间褪黑激素水平和皮质醇水平的影响可能会被一些因素所掩盖，如手术时间、用药和个体差异。需要更大样本量的研究来检测这些因素对生物学标志和睡眠干预措施效果的潜在影响。

Abstract

Trial registration: Chinese

Clinical Trial Registry: ChiCTR-
IOR-14005511. Registered 21
November 2014.

临床试验注册: 中国

临床试验注册中心:
ChiCTR-IOR-14005511,
注册于2014.11.21。

Introduction

Sleep is a basic need for human beings and is especially important for healing and survival in critical illness [1,2]. Sleep deprivation impairs immune function, decreases inspiratory muscle endurance, negatively affects weaning from mechanical ventilation, prolongs ICU stay and has been associated with delirium and mortality in the ICU [1,3-6].

睡眠是人类的基本需求，对危重病患者的治疗和存活尤为重要【1，2】。睡眠不足会损害免疫功能，降低呼吸肌耐力，影响机械通气的脱机，延长ICU停留时间，并且与ICU患者谵妄的发生和死亡率相关【1，3-6】。

Introduction

Yet previous studies have been consistent in describing the poor sleep of ICU patients. A number of polysomnography (PSG) studies have shown that ICU patients commonly have broken, light sleep with a lack of slow-wave sleep and rapid eye movement (REM) sleep [6-9]. Meanwhile, surveys have identified poor sleep as one of the most frequent complaints among ICU survivors [5,10].

既往研究一致认为ICU患者睡眠差。许多关于多导睡眠监测（PSG）的研究已显示ICU患者通常缺乏慢波睡眠和快速动眼（REM）睡眠【6-9】。同时，调查研究已鉴定睡眠差是ICU幸存者中最频繁的抱怨之一。

Introduction

Numerous factors including sedation, environmental factors, disease and mechanical ventilation have been reported to contribute to sleep disturbance in ICU[5,11,12]. Evidence has suggested that excessive noise and continuous light exposure are common in ICU settings [4,8,13-15]. Noise has been widely cited as the most common cause of sleep disruption in the critically ill [14,16].

镇静，环境因素，疾病和机械通气等诸多因素已被报道为导致ICU患者睡眠障碍的原因【5，11，12】。证据表明过度的噪音和持续的灯光照射在ICU中很普遍【4，8，13-15】。噪音被广泛认为是导致重症患者睡眠中断的最常见的原因。

Introduction

The World Health Organization (WHO) has recommended that the average noise levels in hospital wards should not exceed 30 dB (A) during day or night, and peak levels should not exceed 40 dB (A) during the night [17]. Unfortunately, most studies have shown that noise levels in the ICU are much higher than these recommendations. The peak noise levels in the ICU routinely exceed 80 dB (A) [4,8,13,14,16].

世界卫生组织（WHO）推荐医院病房日间和晚间的平均噪声级不应该超过30分贝（A），并且夜间的最高值不应该超过40分贝（A）【17】。不幸的是，绝大多数研究显示ICU的噪声级比这些推荐值要高的多。ICU的最高噪声水平通常超过80分贝（A）【4， 8， 13， 14， 16】。

Introduction

The equivalent sound pressure level exceeding 30 dB (A) indoors for continuous noise and peak noise levels at 45 dB (A) or less may negatively affect sleep and result in sleep disturbance [17]. More than 70 dB (A) of noise may result in vasoconstriction, increased heart rate, hypertension and even arrhythmias [18].

室内持续性噪音超过30分贝和最高噪声值在45分贝或稍低的声压级会负面影响睡眠及导致睡眠障碍【17】。大于70分贝的噪音可能导致血管收缩，心率增快，高血压甚至心律失常。

Introduction

Moreover, continuous light exposure is another noxious and disruptive environmental factor affecting sleep in the ICU. Light plays a vital role in synchronization of the circadian rhythm. Chang et al. found that light levels of the range of approximately 30 to 50 lux in the angle of gaze delayed the circadian clock, acutely suppressed melatonin and disrupted sleep [19].

另外，持续性灯光暴露是ICU中另一种影响睡眠的有害的环境因素。光线在昼夜节律的同步中起着重要作用。

Chang等人发现大约30~50lux范围的光照水平会延迟生物钟，强烈抑制褪黑激素并干扰睡眠【19】

Introduction

Chellappa et al. reported that light can impact directly upon sleep structure at low light levels (40 lux) [20]. Continuous light measurements made in four ICUs show that the mean maximum nocturnal level ranges from 128 to 1,445 lux, which is high enough to suppress melatonin, and may affect sleep and biological rhythm [4].

Chellappa等人报道光照在较低的水平（40lux）直接影响睡眠结构【20】。在四个ICU中的持续光照测量显示夜间最高水平的平均值在128~1445lux范围，这足够高抑制褪黑激素，也会影响睡眠和生理节律【4】。

Introduction

In the past 20 years, multiple strategies have been proposed to optimize sleep in the ICU. A number of studies have been carried out on the effects of nonpharmacologic interventions for sleep promotion in ICU patients [21-25]. Using protective devices such as earplugs and eye masks and listening to music are important options in this field [23-25], although no clinical studies have been published that used all three strategies in combination. Several studies have investigated applying protective earplugs and eye masks in ICU patients or in an ICU simulated environment [24-28].

在过去的20年中，已提出多种策略来优化ICU患者的睡眠。进行了许多关于促进ICU患者睡眠的非药物干预措施的研究【21-25】。使用防护装置如耳塞眼罩和听音乐是这个领域中的重要措施【23-25】，然而没有关于这三者联合应用的临床研究。已有一些关于在ICU患者中或在一个ICU模拟环境中应用保护性耳塞和眼罩的研究【24-28】

Introduction

We hypothesized that a reduction of noise and light during the night using earplugs and eye masks combined with listening to sleep-inducing music could be beneficial in sleep promotion and the protection of nocturnal melatonin and cortisol secretion in ICU patients. To test this hypothesis, a randomized controlled clinical trial (RCT) was conducted in cardiac surgical patients during postoperative nights in an ICU.

我们假设使用耳塞和眼罩联合睡眠诱导音乐以减少夜间噪音和光照能够促进ICU患者睡眠和保护夜间褪黑激素及皮质醇的分泌。为了检验这个假设，对心脏手术患者在术后入住ICU的晚上进行一项临床随机对照试验（RCT）。

Materials and methods

This study was a prospective single-center randomized controlled parallel-group clinical trial performed within a 21-bed Cardiac Surgical Intensive Care Unit (CSICU) of Fujian Medical University Union Hospital, Fuzhou, China.

资料与方法

本研究是一个前瞻性单中心随机对照临床试验，在中国福州福建医科大学附属医院的一个21张床位的心脏外科重症监护病房（CSICU）中进行。

Materials and methods

It was approved by the Hospital and Fujian Medical University Research Ethics Boards. The trial was registered in the Chinese Clinical Trials Registry (ChiCTR-IOR-14005511).

Written informed consent for participation in the study was obtained before surgery.

该研究被这个医院和福建医科大学研究伦理委员会批准。本试验注册于中国临床试验注册中心(ChiCTR-IOR-14005511)。参与本研究的书面知情同意在术前获得。

Materials and methods

Participants and study settings

Study participants were recruited from March 2009 and September 2009. The inclusion criteria were:

- (1) primary and elective cardiac surgery;
- (2) age ≥ 40 years;
- (3) with normal liver, kidney and lung preoperative function and without history of diabetes;
- (4) no history of neurological or Psychiatric;

参与者与研究设置

研究参与者来自于2009年3月和9月。纳入标准是：

- (1) 原发性择期心脏手术；
- (2) 年龄 ≥ 40 岁；
- (3) 术前肝、肾、肺功能正常且没有糖尿病史；
- (4) 没有神经性或精神性疾病史；

Materials and methods

(5) ability of patients to communicate verbally and understand the sleep questionnaires administered before surgery and after being transferred from the ICU;

(6) length of ICU stay ≥ 48 hours;

(7) Glasgow coma score (GCS) > 10 in the first and second postoperative days;

and (8) stable hemodynamics postoperatively.

(5) 患者有语言沟通能力并能理解在术前和从ICU转出后发放的睡眠调查问卷;

(6) ICU停留时间 ≥ 48 小时;

(7) 术后第一二天格拉斯哥昏迷评分 (GCS) > 10 分;

(8) 术后血流动力学稳定。

Materials and methods

Exclusion criteria were:

- (1) severe sleep disorder requiring daily treatment before surgery;
- (2) patients with severe postoperative complications;
- (3) presence of postoperative renal failure;
- (4) presence of thoracic aortic dissection;

排除标准有：

- (1) 术前有需要日常治疗的严重睡眠障碍；
- (2) 有严重术后并发症的患者；
- (3) 存在术后肾功能衰竭；
- (4) 存在胸主动脉夹层动脉瘤；

Materials and methods

(5) Postoperative unconsciousness, coma or delirium;
and (6) cardiac valve replacement or congenital heart disease requiring sedation and analgesics after surgery. Staff members were asked to continue all usual routines and care practices and to make no special attempts to decrease noise during the study.

(5) 术后意识不清，昏迷或谵妄；

(6) 术后需要镇静镇痛的心脏瓣膜置换或先天性心脏病。

工作人员被要求继续进行所有的常规治疗和护理措施而没有采取降低噪声的特殊措施。

Materials and methods

Intervention and randomization

Patients were randomly assigned to two different groups using the closed-envelope method. The control group received routine care during the nights after surgery and the experimental group received protective devices (wearing earplugs and eye masks during nocturnal sleep) with 30 minutes of relaxing music on the basis of routine care.

干预和随机化

采用密封的信封法将患者随机分配到两组。对照组术后夜晚接受常规护理，试验组在接受常规护理的基础上使用防护装置（夜间睡眠时佩戴耳塞和眼罩）配合30分钟的放松音乐。

Materials and methods

After randomization, earplugs (3 M Corporation, Beijing, China) and eye masks were provided 2 to 3 days before surgery and patients in the intervention group were asked to wear them. Meanwhile, the researcher explained to them that they should wear the earplugs and eye masks during their postoperative stay in ICU to ensure rest and instructed patients to use them properly.

随机分组后，耳塞（中国北京3M公司）和眼罩在术前两到三天要求试验组患者佩戴。同时，研究者向他们解释术后入住ICU的过程中需要佩戴耳塞和眼罩以保证休息并指导患者正确使用这些工具。

Materials and methods

The patients chose from three types of eye mask provided.

Providing the earplugs and eye masks preoperatively allowed patients to adapt to wearing earplugs and eye masks, and it also helped to play a role in establishing a time cue.

患者从提供的三种眼罩中选择一种。术前提供耳塞和眼罩让患者适应佩戴，同时也有助于患者建立时间提示线索。

Materials and methods

During the postoperative ICU stay, ICU nurses assisted patients with wearing earplugs and eye masks from 9:0 pm every night until the next morning. Pieces of music for relaxing and implying time of day were collected and recorded on an MP3 player. Sounds of nature and bird songs were selected to imply morning. Sounds of frogs and waves were selected to imply evening.

术后入住ICU时，ICU护士协助患者佩戴耳塞和眼罩从每晚9:00到第二天早上。令人放松并暗示时间的音乐被收集并录制于MP3播放器中。大自然的声音和鸟叫声暗示是早晨。蛙叫声和浪声暗示夜晚。

Materials and methods

Pieces of classical music, including Blue Danube, Morning Song, Lofty Mountains and Flowing Water, Clouds Chasing the Moon, Lotus Emerging out of Water, and Moonlight Sonata, et cetera, were selected as relaxing music. Patients used earphones to listen to the corresponding music at 8:00 to 9:00 pm and 7:30 to 8:30 am every day after surgery. The duration of listening to music was 30 minutes.

古典音乐，包括蓝色多瑙河，晨曲，高山流水，彩云追月，出水芙蓉，月光奏鸣曲等，选作放松音乐。术后患者在晚上8:00到9:00和早上7:30到8:30用耳机听相应的音乐。听音乐的时间是30分钟。

Materials and methods

The music volume was set at a comfortable level for each participant. The MP3 music was supplied through earphones to the participants. Sometimes listening to music had to be stopped due to need for immediate care; when this occurred, the period of listening to music was shifted, although the range remained within the period of 9:00 pm and 8:30 am.

音量设置在对每个患者感到舒适的水平。MP3音乐通过耳机传递给受试者。有时因为需要即时护理而不得不暂停音乐，当这种情况发生时，听音乐的时间被改变，然而时间范围仍保持在晚上9:00和早上8:30之间。

Materials and methods

During the night when care-givers needed to interact with the patients, whether or not the earplugs and eye masks were retained was left up to the nurses' judgment, patients' request and specific circumstances. For patients who did not like the music that was provided, we reselected other pieces of music for them on the basis of the requirement to relax the patients and help them sleep.

夜晚，当护患之间需要沟通时，耳塞和眼罩是否继续使用取决于护士的判断，以及患者的要求和具体情况。对于不喜欢提供的音乐的患者，我们为他们重新选择其他音乐基于能使其放松并有助于睡眠。

Materials and methods

Those who were strongly disinclined to listen to music were withdrawn from the study. In the control group, no interventions mentioned above were offered to the patients and routine preoperative and postoperative medical care was provided.

那些强烈不愿意听音乐的患者退出本研究。对照组中，没有以上的干预措施提供给患者，仅提供常规的术前和术后治疗。

Materials and methods

Reasons for study termination

criteria were:

- (1) Disease aggravation threatening the patient's life;
- (2) death;
- (3) patient request for withdrawal;
- (4) transfer out of the ICU less than 2 nights postoperatively;
- and (5) serious adverse reactions.

研究终止的标准为：

- (1) 疾病恶化威胁患者生命；
- (2) 死亡；
- (3) 患者要求退出；
- (4) 术后ICU停留时间不足两晚；
- (5) 严重不良反应。

Materials and methods

Data collection and measures

Demographic and clinical data were collected from the patient's record. Acute physiology and chronic health evaluation (APACHE) II severity-of-illness scores for the initial 24-hour period of admission to the ICU and preoperative cardiac function were calculated to assess severity of illness.

数据收集和测量

人口学和临床数据从病历中收集。患者进入ICU的最初24小时的急性生理与慢性健康（APACHE）II 疾病严重程度评分与术前心功能综合起来评估疾病的严重程度。

Materials and methods

Assessment of sleep perception

Subjective sleep quality during the ICU stay was evaluated 1 to 2 days following transfer out of the ICU, using the Chinese version of the Richards-Campbell sleep questionnaire (RCSQ). The original RCSQ had six items and evaluated aspects of nighttime sleep including: (1) depth; (2) latency (time to fall asleep); (3) number of awakenings; (4) efficiency (percent of time awake);

睡眠感知的评估

在患者转出ICU后的1到2天，使用中文版的Richards-Campbell睡眠量表（RCSQ）对ICU停留时的主观睡眠质量进行评估。原始的RCSQ有六个项目，关于夜间睡眠的评估包括：（1）睡眠深度；（2）入睡（入睡的时间）；（3）觉醒的次数；（4）效率（觉醒时间的百分比）；

Materials and methods

(5) quality;

and (6) perceived nighttime noise measured on a 100-mm visual-analog scale (VAS) [29].

The RCSQ was pilot-tested in a medical ICU [30] and validated with overnight polysomnography (PSG) in medical ICU patients [29].

(5) 睡眠质量;

(6) 通过100mm视觉模拟量表 (VAS) 测量主观感知的夜间噪声【29】。睡眠量表在一个内科ICU进行试点测试【30】并经过对内科ICU病人整晚的多导睡眠监测验证【29】。

Materials and methods

Cronbach's alpha value of the Chinese RCSQ in this study was 0.84; higher scores indicate poorer perceived sleep quality in this Chinese version of the RCSQ. The patients filled out the Pittsburgh sleep quality index questionnaire (PSQI) [31] before surgery to evaluate the quality of sleep one month before surgery.

本研究中的中文版的睡眠量表的克朗巴哈系数为0.84；量表得分越高表示主观睡眠质量越差。患者术前填写匹兹堡睡眠质量指数问卷（PSQI）【31】以评估术前一个月的睡眠质量。

Materials and methods

Nocturnal melatonin and cortisol levels

Nocturnal urine (12-hour) was collected between 8:00 pm and 8:00 am on the day before surgery and the first and second days after surgery. The containers were wrapped with black plastic to protect the urine from light. The total volume was recorded and two 2-ml samples were frozen to -20°C for later analysis.

夜间褪黑激素和皮质醇水平收集术前和术后第一二天晚上8:00到早上8:00之间的夜间尿（12小时）。容器用黑色塑料覆盖以防止尿液受光照。记录尿液总量，并取2ml尿液标本各两份冷冻至 -20°C 为之后的分析所用。

Materials and methods

Concentrations of 6-sulphatoxymelatonin (6-SMT), the stable metabolite of melatonin, were measured by ELISA (IBL, Hamburg, Germany) in duplicate. Concentration of cortisol, a stress-related hormone, was measured in another urine sample by radioimmuno assay (RIA) (Beijing North Institute of Biological Technology, Beijing, China).

褪黑激素的稳定代谢物6-羟基硫酸褪黑素（6-SMT）的浓度，通过酶联免疫吸附试验测定。皮质醇，一种压力相关的激素，通过对另一个尿液标本进行放射免疫检验（RIA）测定其浓度。

Materials and methods

Nocturnal noise and light levels

The nocturnal 12-hour (from 8:00 pm to 8:00 am) noise level in the ICU was monitored continuously using a digital sound level meter (model AWA5610, AWA, Hangzhou, China.) The light intensity between 8:00 pm and 8:00 am in the ICU was measured at the eye level of the patient once every two hours using a light detector (model TES1332, Taiwantes, Shenzhen, China).

夜间噪声和光线水平

使用数字声级测量计（中国杭州，型号AWA5610，AWAI）持续监测ICU夜间12小时（从晚上8：00到早上8：00）的噪声水平。ICU晚上8：00到早上8：00的光线强度用光探测器（型号TES1332，Taiwantes，中国深圳）在患者视线水平位置每两小时测量一次。

Materials and methods

Statistical analysis and sample size

Data were analyzed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA).

Measurement data were expressed as mean \pm standard deviation and count data were expressed as ratios. The independent samples t-test or nonparametric Wilcoxon rank sum test were used for comparison of the groups, and the chi-square (χ^2) test was used for comparison of count data.

统计分析和样本量

用SPSS 16.0版进行数据分析。计量资料用均数 \pm 标准差表示，计数资料用比率表示。用独立样本T检验或非参数秩和检验进行组间比较，用 χ^2 检验比较计数资料。

Materials and methods

One-way repeated measures analysis of variance (ANOVA) was used to determine differences in 6-SMT and cortisol concentrations at different points in time. An alpha of 0.05 was considered significant.

用单向重复测量方差分析（ANOVA）确定不同时间点的6-SMT和皮质醇浓度的差异。 α 0.05认为差异显著。

Materials and methods

The sample size was calculated based on our pilot study, which found that the estimated standard deviation of mean sleep score in ICU patients was 27. We hypothesized that the non-pharmacological intervention could improve the sleep quality by inducing a 28-point difference of total mean sleep score between groups. Using an effect size of 0.8 and a P-value ≤ 0.05 , the required sample size for each group was calculated as 20 per group, but 25 per group were recruited after considering a 10% dropout rate.

样本量的计算基于我们的试点研究，ICU患者平均睡眠分数的估计标准差为27。我们假设这种非药物干预措施能提高睡眠质量，引导组间睡眠分数总体均值之间差异为28分。通过0.8的效应量和P值 ≤ 0.05 计算，每组的必要样本量为20，但是考虑到10%的脱试率，每组选取25名患者。

Results

Sample characteristics

In total 50 patients who met the inclusion criteria were enrolled and randomly divided into the two groups (intervention = 25; control = 25). In the intervention group, five patients were withdrawn due to serious postoperative complications (n = 2), refusal to wear earplugs and eye masks (n = 2), and refusal to listen to music (n = 1).

样本特征

符合纳入标准的50名患者被随机分配到两组（实验组25名；对照组25名）。在试验组中，5名患者退出研究，其中包括由于严重的术后并发症退出研究（n=2），拒绝佩戴耳塞和眼罩（n=2），拒绝听音乐（n=1）。

Results

Thus, data analyses were carried out for 20 cases in the intervention group and 25 cases in the control group (Figure 1). The findings of patients' demographic analysis are shown in

Table 1. Both study groups were comparable at baseline, with no significant differences in age, gender, operative time, presence of cardiopulmonary bypass, preoperative cardiac function, APACHE II scores, PSQI scores, duration of mechanical ventilation, length of ICU stay or length of hospital stay ($P > 0.05$).

因此，对试验组20例和对照组25例进行数据分析（图1）。患者的人口分析如表1所示。两组进行基线对比，在年龄、性别、术前心功能、APACHEII评分、PSQI评分、机械通气时间、ICU停留时间或住院时间上无显著差异（ $P > 0.05$ ）。

Results

All of the seven coronary artery bypass graft (CABG) patients used midazolam (0.05 mg/kg/h) plus fentanyl (1 μ g/kg/h) for sedative and analgesic during the first 48 hours post surgery.

七名冠状动脉旁路搭桥术（CABG）患者在术后头48小时内使用咪达唑啉（0.05mg/kg/h）加芬太尼（1 μ g/kg/h）镇静镇痛。

Results

图1 本研究的流程图

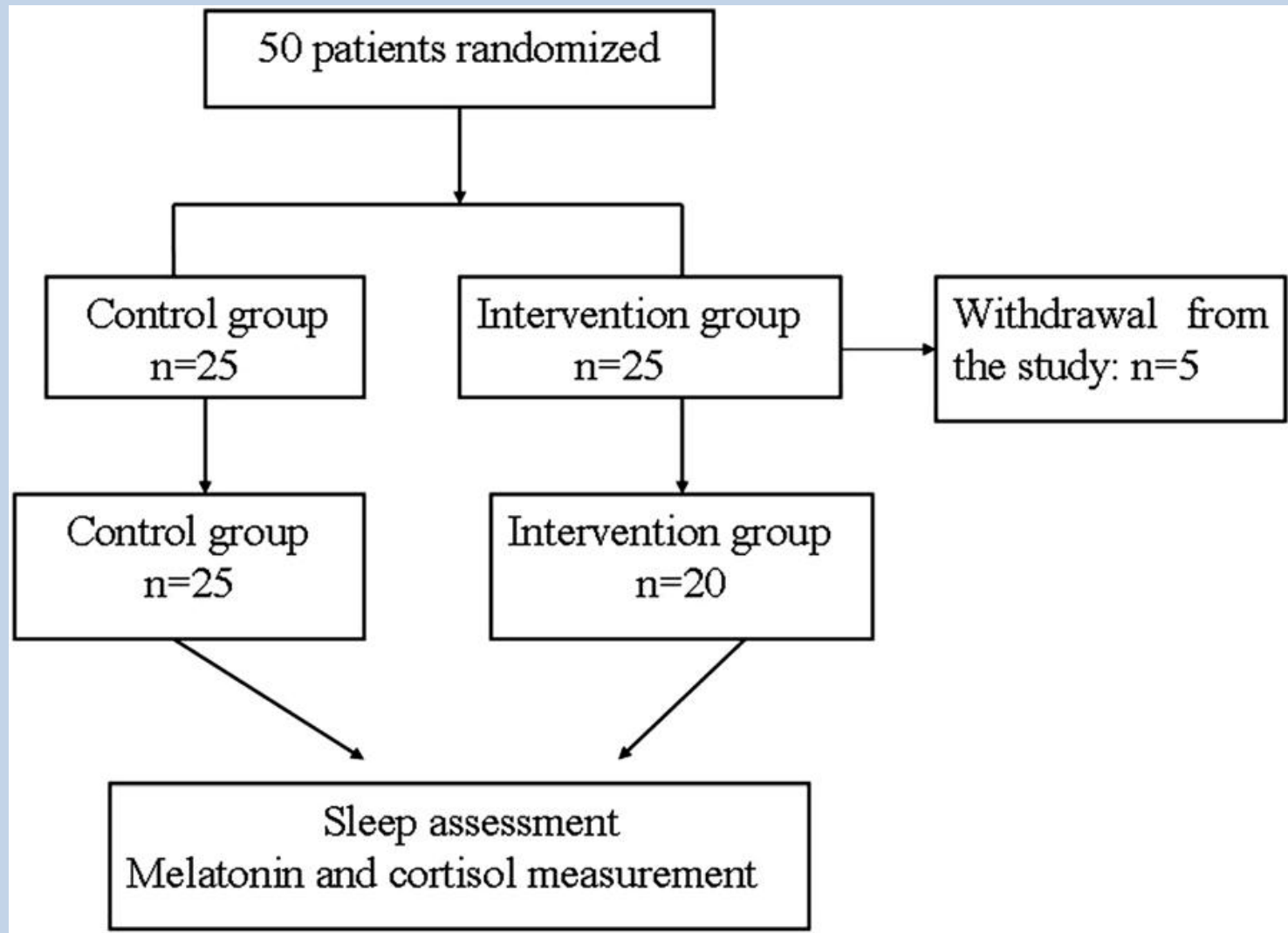


Figure 1 Flow chart of the study.

表1 患者人口学特征

Table 1 Patients demographic characteristics

Variable	Control group (n = 25)	Intervention group (n = 20)	P-value
Age, years, mean + SD	56.8 + 11.2	56.6 + 11	0.97
Gender, number of patients			0.5
Male	16	11	
Female	9	9	
Weight, kg, mean + SD	61.6 + 11.7	60.5 + 12.9	0.6
Surgery, number of patients			
CABG	4	3	0.94
Cardiac valve replacement	17	13	
Congenital heart disease	4	4	
Operative time, hours, mean + SD	3.3 + 1.2	3.3 + 0.7	0.96
Cardiopulmonary bypass, number of patients			
Yes	19	14	0.7
No	6	6	
APACHE II scores on admission, mean + SD	20 + 3.1	21.2 + 2.9	0.75
Preoperative cardiac function score, number of patients			
II	3	3	0.6
III	21	17	
IV	1	0	
Duration of mechanical ventilation, hours, mean + SD	22 + 10.1	22.7 + 9.5	0.8
Length of ICU stay, hours, mean + SD	58.9 + 20	53.0 + 16	0.29
Length of hospital stay, days, mean + SD	22.6 + 10.8	20.7 + 6.1	0.5
Preoperative PSQI, mean + SD	7.5 + 3.7	8.6 + 4.5	0.3
Discharge outcomes of hospital, number of patients			
No death	23	20	0.4
mortality	2	0	

CABG, coronary artery bypass surgery; PSQI, Pittsburgh sleep quality index; APACHE, acute physiology and chronic health evaluation scoring system.

Results

Perception of sleep quality

The independent samples t-test showed subjective sleep quality in the intervention group was significantly higher than in the control group ($P < 0.05$). Significant differences were also found between groups in the five items of sleep scoring. Patients' perceptions of nighttime noise were significantly lower in the experimental group than in the control group ($P < 0.05$) (Table 2).

对睡眠质量的感知

独立样本T检验显示试验组的主观睡眠质量明显高于对照组 ($P < 0.05$)。睡眠量表的五个项目的评分同样存在明显的组间差异。试验组患者感知到的夜间噪音明显低于对照组 ($P < 0.05$) (Table 2)。

Results

表2 睡眠分数的组间比较

Table 2 Comparison of sleep scores between groups

Variables, mean \pm SD	Intervention group	Control group	<i>P</i> -value
Depth	26.7 \pm 21.5	55.5 \pm 27.4	0.00
Latency (time to fall asleep)	23.7 \pm 17.4	60.4 \pm 25.9	0.00
Number of awakenings	25.3 \pm 16.2	51.2 \pm 26.7	0.00
Efficiency (percent of time awake)	21.7 \pm 20.9	63.4 \pm 21.9	0.00
Perceived quality	23.7 \pm 20.6	54.0 \pm 25.5	0.00
Perceived nighttime noise	25.0 \pm 24.0	40.2 \pm 28.8	0.047

Results

Nocturnal urinary excretion of 6-SMT and cortisol

Total 12-hour urinary excretion of 6-SMT and cortisol (8:00 pm to 8:00 am) in patients during the night before surgery, and the first and second postoperative nights are shown in **Figures 2 and 3**, respectively.

夜尿排泄的6-SMT和皮质醇患者术前和后术后第一二个夜晚的夜间12小时（晚8:00-早8:00）排泄的6-SMT和皮质醇分别如图2和图3所示。

Results

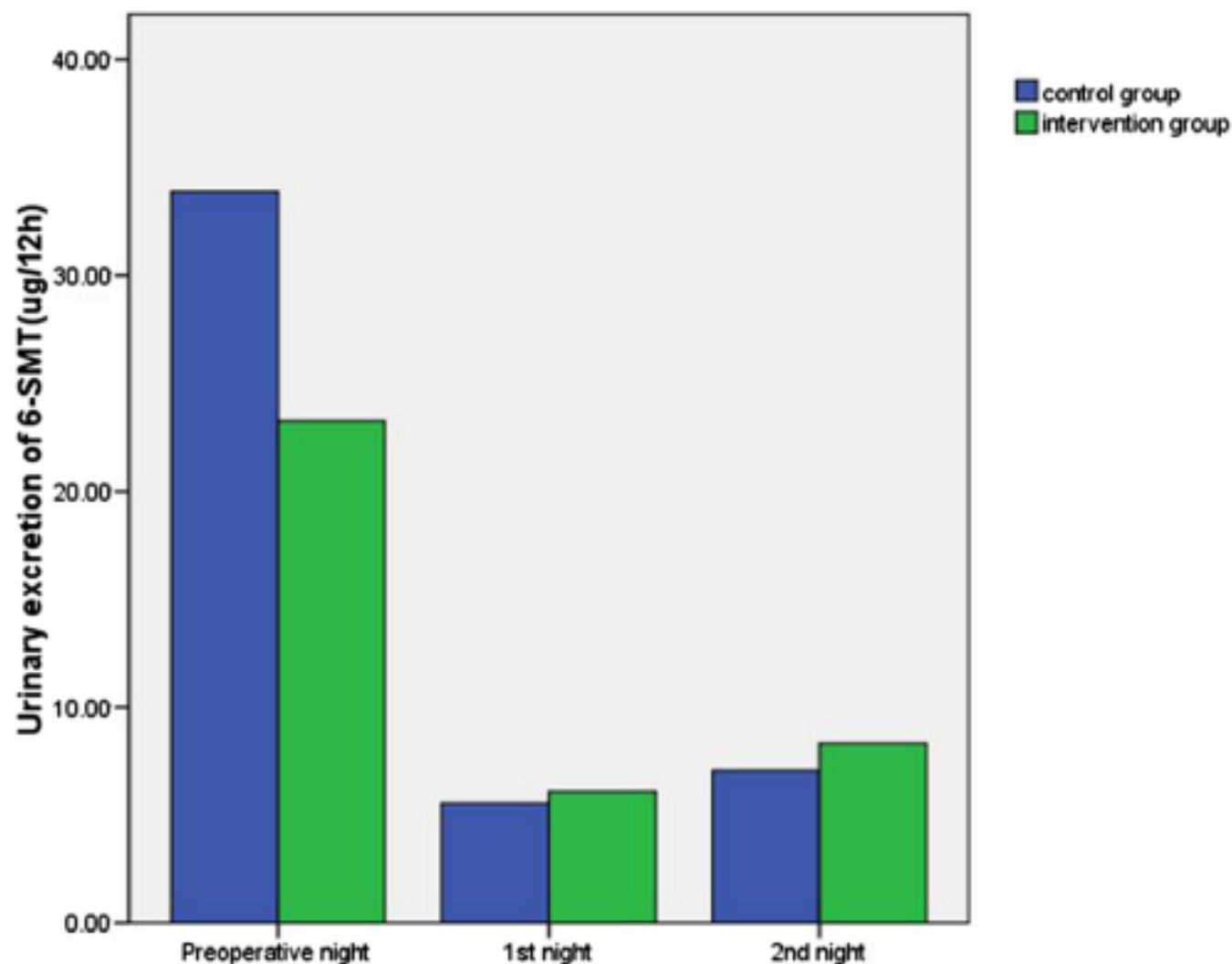


Figure 2 Comparison between groups of urinary excretion of 6-SMT during the night before surgery, and the first and second postoperative nights. No significant differences were found between the two groups in 6 SMT levels during the night before surgery, or the first and second postoperative nights ($P > 0.05$). 6 SMT, 6 sulphatoxymelatonin.

Results

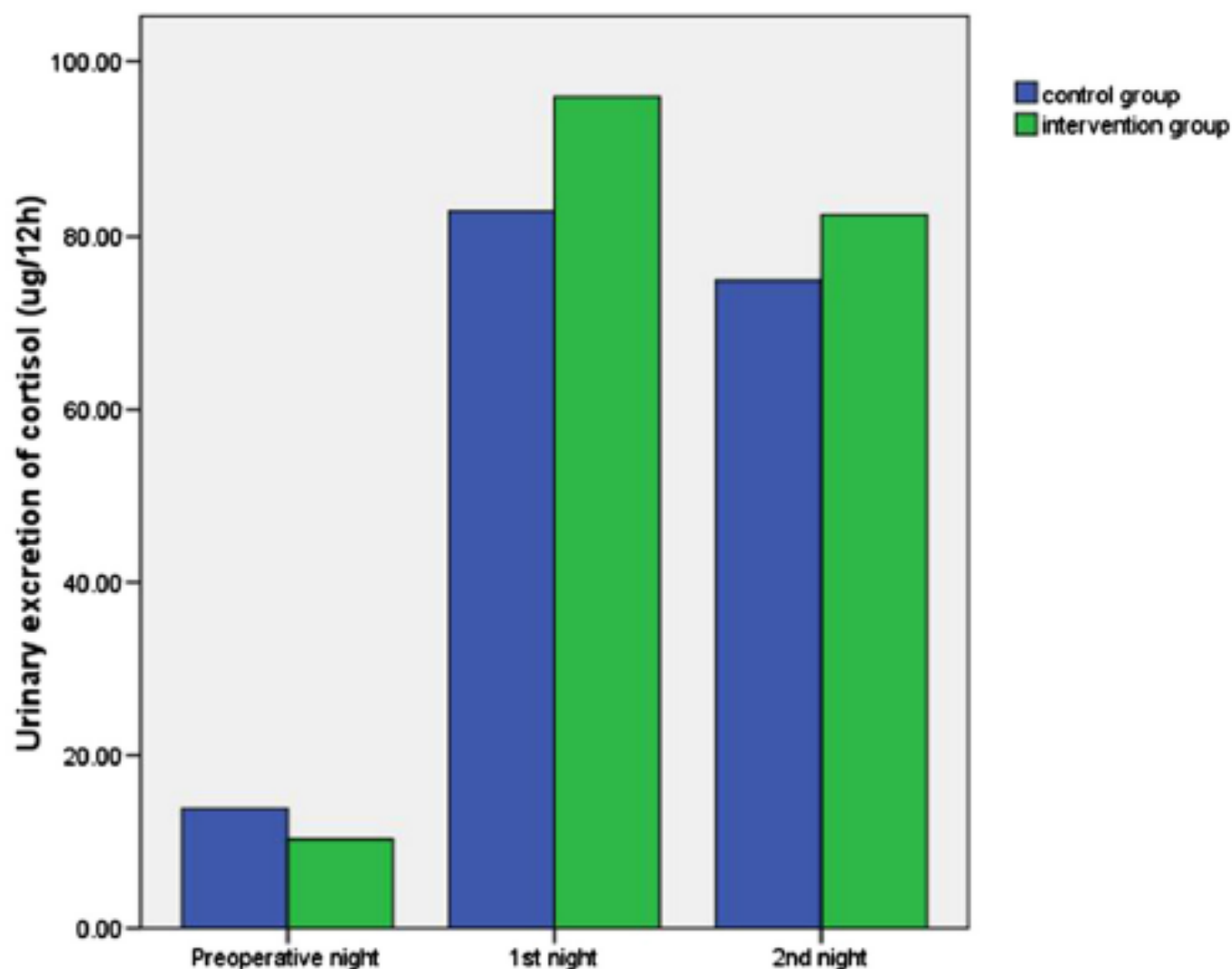


Figure 3 Urinary excretion of cortisol of the night before surgery, the 1st and 2nd postoperative nights between groups. No significant differences were found in cortisol levels between the two groups during the night before surgery, and the first and second postoperative nights ($P > 0.05$).

Results

The Wilcoxon rank sum test showed no significant differences were found between the two groups in 6-SMT levels during the night before surgery ($Z = -1.27$, $P = 0.22$), or the first ($Z = -0.52$, $P = 0.61$) and second postoperative nights ($Z = -0.03$, $P = 0.97$). There were also no significant differences in cortisol levels between the two groups during the night before surgery ($t = 0.99$, $P = 0.33$), or the first ($t = -0.64$, $P = 0.53$) and second postoperative nights ($t = -0.45$, $P = 0.65$) (Table 3).

秩和检验得出术前、术后第一天和第二天的夜间的6-SMT水平试验组与对照组无明显组间差异，术前夜间（ $Z = -1.27$ ， $P = 0.22$ ），术后一晚（ $Z = -0.52$ ， $P = 0.61$ ），术后第二晚（ $Z = -0.03$ ， $P = 0.97$ ）。两组的皮质醇水平在术前夜晚和术后第一二天夜晚同样也没有明显的组间差异，术前晚（ $t = 0.99$ ， $P = 0.33$ ），术后第一晚（ $t = -0.64$ ， $P = 0.53$ ），术后第二晚（ $t = -0.45$ ， $P = 0.65$ ）（表3）。

Results

Table 3 Urinary melatonin and cortisol levels in the groups during the night before surgery, and the first and second nights after surgery

Variables	Intervention group				Control group			
	Pre-surgery night	First night post surgery	Second night post surgery	P-value	Pre-surgery night	First night post surgery	Second night post surgery	P-value
6-SMT, μ g	23.3 + 24.3 ^a	6.1 + 9.9 ^a	8.3 + 12.6 ^a	0.01	33.9 + 99.9 ^a	5.6 + 12.7 ^a	7.1 + 9.8 ^a	0.00
Cortisol, μ g	10.3 + 8.3 ^b	95.9 + 71.2 ^b	82.5 + 47.3 ^b	0.00	13.8 + 8.8 ^b	82.9 + 56.9 ^b	74.9 + 56.3 ^b	0.00

^aNo significant differences were found between the two groups in 6-SMT levels during the night before surgery ($P=0.22$), or the first ($P=0.61$) and second postoperative nights ($P=0.97$). ^bNo significant differences were found in cortisol levels between the two groups during the night before surgery ($P=0.33$), or the first ($P=0.53$) and second postoperative nights ($P=0.65$).

Results

Repeated measures ANOVA showed the 6-SMT levels of the first and second postoperative nights were significantly lower than those of the night before surgery ($F = 7.53$, $P = 0.01$). The cortisol levels of the first and second postoperative nights were significantly higher than those of the night before surgery ($F = 88.63$, $P = 0.00$).

重测变异数分析显示术后第一二晚的6-SMT水平明显低于术前晚 ($F=7.53$, $P=0.01$)。术后第一二晚的皮质醇水平明显高于术前晚($F=88.63$, $P=0.00$)。

Results

Nocturnal noise and light levels

No significant differences between the groups were observed in the mean noise level during nighttime (intervention: 69.8 ± 2 dB(A); controls: 69.6 ± 2.2 dB (A)).

There were no significant differences between groups in nighttime noise ($P = 0.6$). Mean light level during nighttime also did not differ (intervention: 167.1 ± 5 lux; control: 170.2 ± 8 lux).

夜间噪音和光线水平

夜间平均噪音水平两组之间无明显差异（试验组：

69.8 ± 2 dB（A）；对照组：

69.6 ± 2.2 dB（A））。夜间

噪音无明显组间差异

（ $P=0.6$ ）。夜晚平均光线

水平两组间也无差异（实验

组： 167.1 ± 5 lux；对照组：

170.2 ± 8 lux）。

Discussion

Adequate sleep is a required condition for recovery after serious illness.

Previous studies have reported that patients suffer severe sleep disturbances after cardiac surgery [32,33]. It is essential in clinical practice to control or attenuate various factors disrupting sleep and thus, maximize patients' ability to experience restorative sleep.

充足的睡眠是重病后恢复的必需条件。有研究报道心脏术后患者遭受严重的睡眠障碍【32，33】。控制和减少影响睡眠的各种因素，以此让患者能很好的休息，在临床护理中极为重要。

Discussion

Overall, these results support the notion that using protective devices (earplugs and eye masks) plus listening to sleep-music during the night can significantly improve subjective sleep quality in an ICU setting.

总的来说，这些结果是支持夜晚使用防护装置（耳塞和眼罩）加听睡眠音乐能明显改善ICU患者的主观睡眠质量的观点。

Discussion

We found that the mean preoperative PSQI scores of the two groups were more than seven points in this study, indicating that the preoperative sleep quality of the participants in both groups were generally poor. Difficulty in falling asleep and difficulty in staying asleep were the two main symptoms, similar to data reported by Redeker [32].

我们发现本研究中术前两组患者的匹兹堡睡眠指数量表平均得分大于七分，表明两组参与者的术前睡眠质量普遍较差。入睡困难和保持睡眠状态困难是主要症状，与Redeker报道的资料相似【32】。

Discussion

It has been reported that ICU patients are exposed to an environment with high noise levels and continuous day-to-night lighting [4,8,13-15].

Continuous monitoring and care are commonly needed in the ICU and patients find themselves surrounded by medical and technological equipment.

有报道提出ICU患者暴露在高噪音水平和日夜持续照明的环境中【4，8，3-15】。ICU中需要持续监护，让患者觉得他们被医疗设备所包围。

Discussion

Aside from their presenting health problem, its treatment and care, the ICU environment may increase stress among patients [34]. Our previous study indicated that using earplugs and eye masks can improve REM sleep and sleep quality in healthy subjects in a simulated ICU environment [28]. The results are similar to those of other studies using earplugs and eye masks [24,35,36].

除了他们的健康问题，治疗和护理以外，ICU的环境会增加患者的压力【34】。我们之前的研究显示在一个模拟的ICU环境中健康者使用耳塞和眼罩能促进快速动眼睡眠，改善睡眠质量【28】。其结果和其他关于使用耳塞和眼罩的研究相似【24，35，36】。

Discussion

Patients' compliance with and tolerability of these interventions is critical. It has been reported that some ICU patients refuse to wear earplugs and eye masks because they feel uncomfortable, cannot see anything or feel pain after wearing them [35,37]. We found similar responses in three patients in this study.

患者对这些干预措施的依从性和耐受性很重要。有报道提出一些ICU患者拒绝佩戴耳塞和眼罩，因为他们觉得不舒服，看不见任何东西或佩戴后感到疼痛【35，37】。我们在本研究中的三个患者身上发现类似反应。

Discussion

One patient described nervousness, a feeling of panic and a sense of suffocation after wearing an eye mask and earplugs and another reported feeling pain in the ear canal with the earplugs. One patient withdrew after listening to music for only 5 minutes. The objective of protective intervention and music therapy is to help patients fall asleep and maintain sleep by reducing interference from potentially noxious environmental stimuli and relieving their anxiety with soothing music.

一名患者叙述他在佩戴耳塞眼罩后感到紧张，恐慌和窒息，另一名患者感到在耳孔里塞入耳塞很疼痛。一名患者只听了5分钟音乐后退出了本试验。保护性干预和音乐疗法的目的是通过减少潜在不良环境刺激的干扰和通过舒缓的音乐减轻患者的焦虑，从而帮助他们入睡并保持睡眠。

Discussion

Therefore, the prerequisite for applying a certain method must be that the patient readily accepts this kind of method. This suggests that the ICU staff must actively help patients to understand the benefits before applying the intervention. The nurses should assess individual variability in sensitivity or anatomy of the ears and patients' acceptability of the protective devices prior to using them.

因此，采取某一方法的先决条件必须是患者乐意接受这种方法。建议ICU工作人员在提供干预措施前必须积极的帮助患者理解它的好处。护士应评估患者耳朵的敏感度或解剖特点的个体差异，以及患者对防护装置的接受程度。

Discussion

Medical staff members should learn how to apply earplugs and eye masks properly to help patients benefit. For example, critical care nurses should help patients select the appropriate size of earplugs and eye masks, and provide accurate instructions and assistance for their use, especially for how to insert earplugs properly, and minimize any transient discomfort.

医务人员应掌握如何合理使用耳塞和眼罩。例如，重症监护护士应该帮助患者选择大小适当的耳塞和眼罩，并提供准确的使用指导和帮助，尤其是怎样合理的插入耳塞并使不适感降到最低。

Discussion

Melatonin is a major regulator of circadian rhythm in humans, which differs from evidence for circadian rhythm that melatonin is not secreted in specific strains of mice [38].

Melatonin is secreted from the pineal gland, while cortisol is one of the major glucocorticoid hormones secreted by the adrenal cortex. Both play a role in the regulation of the sleep-wake cycle.

褪黑激素是人类生理节律的重要调节物质，不同于褪黑激素不被老鼠这种特殊物种所分泌的有关生理节律的证据，【38】。褪黑激素分泌于松果体，然而皮质醇是肾上腺皮质分泌的一种重要的糖皮质激素。两者在睡眠-觉醒的周期调节中起重要作用

Discussion

Melatonin secretion follows the day-night cycle, with levels normally low during daytime, increasing soon after onset of darkness, and peaking in the middle of the night [39]. Cortisol levels tend to run in an opposite pattern, with peak levels occurring 30 minutes after awakening [40]. Several studies have suggested that sleep disorders and cognitive dysfunction in ICU patients may be associated with disruption of melatonin secretion [41,42].

褪黑激素的分泌遵循昼夜规律，其水平在日间通常较低，天黑后升高，在半夜时达到最高水平【39】。皮质醇水平则相反，最高水平出现在早上醒后的30分钟【40】。许多研究指出ICU患者睡眠障碍和认知紊乱可能和褪黑激素分泌紊乱有关【41，42】。

Discussion

Persistent high cortisol levels may affect metabolism, organ function, and immune function. These physiological sequelae are not conducive to recovery. In the present study no significant differences were found in 6-SMT levels and cortisol levels between the two groups during the three nights, yet the level of nocturnal melatonin secretion decreased significantly, while the level of cortisol secretion increased significantly on both postoperative nights.

持续的高皮质醇水平会影响褪黑激素，器官功能和免疫功能。这些生理后遗症不易于恢复。在目前的研究中，两组患者在三个夜晚的6-SMT水平和皮质醇水平没有明显的组间差异，然而术后两晚的夜间褪黑激素分泌量明显减少，而皮质醇分泌量明显增加。

Discussion

Previous studies indicated that medication (such as analgesics, sedative, and beta-blockers), surgery and anesthesia may influence the secretion of melatonin and cortisol [43,44]. Therefore, all of these factors may play a role in the melatonin and cortisol results and mask potential effects of the intervention in our study.

既往研究显示药物（如镇痛药，镇静剂，和 β 受体阻滞剂），手术和麻醉可能影响褪黑激素和皮质醇的分泌【43，44】。因此，这些因素可能对褪黑激素和皮质醇分泌结果起作用，同时掩盖本研究中干预措施的效果。

Discussion

Our levels of 6-SMT were found to be lower than those reported in a previous study of 40 patients in a surgical ICU [45]. There is great interpatient variability in absolute 6-SMT levels; indeed, we observed 20-fold inter-individual variability in 6-SMT levels [45-48] in our patient population.

本研究中的6-SMT水平比以往在外科ICU的40名患者进行的研究中得到的低【45】。患者6-SMT的绝对值存在较大的个体差异;确实,在我们患者中发现了6-SMT水平上存在20倍的个体差异【45-48】。

Discussion

Thus, large sample sizes are required to observe significant between-group differences.

Melatonin secretion varies with age and to some extent with gender [49]. Varying urine collection strategies also make it difficult to make cross-study comparisons.

因此，需要大样本量的研究来观察组间的显著差异。褪黑激素的分泌随年龄变化，同时在一定程度上受性别影响【49】。不同的尿液收集方法也使得现况研究对比变得困难。

Discussion

Environmental light is a main zeitgeber of the circadian rhythms, and can affect melatonin secretion [46].

Environmental factors such as ambient noise are also main synchronizers [50].

ICU usually requires continuous artificial lighting at night. Although we tried to reduce the influence of light and noise disturbance on patients by offering them earplugs and eye masks at night, and provided music therapy to relax and imply time of day and help patients sleep,

环境光线是生理节律的重要授时因子，并能影响褪黑激素的分泌【46】。环境因素如噪声也是重要的生理节律同步器【50】。ICU通常要求夜晚持续的照明。虽然我们试图通过在夜间给予患者耳塞和眼罩以降低光线和噪声对病人的影响，并提供音乐疗法来使患者放松，给予时间提示和改善患者睡眠，

Discussion

the results still showed that the effort did not significantly impact biological measures related to light-dark transitions. Our ICU has very few windows so artificial lighting is required for daytime lighting, which can result in loss of patients' accurate cognition of time and space, inducing disruption in patients' biological clocks and affecting sleep quality.

但是结果显示这些努力对明暗转变相关的生物措施没有显著的影响。ICU的窗户很少，所以在日间需要人工照明，这会导致患者丧失精确的时间和空间认知，引起患者生物钟的破坏并影响睡眠质量。

Discussion

The suprachiasmatic nucleus (SCN), the central circadian pacemaker in mammals, can be altered by cognition [51]. Our results are not entirely consistent with the results of our previous study in the sleep laboratory [28].

视交叉上核（SCN），哺乳动物的中央生理起搏器，可以通过认知来调节【51】。我们的研究结果与以往在睡眠实验室的研究结果并不完全一致【28】。

Discussion

Compared with healthy subjects, ICU patients' sleep, melatonin and cortisol secretion are not only affected by noise and light, but likely also by many other factors, including their disease, admission to an ICU, surgical intervention and medications, which may all contribute to the differences in results between the previous simulated experiment and the present clinical trial.

与健康受试者相比，ICU患者的睡眠，褪黑激素和皮质醇的分泌不仅受噪音和光线的影响，也可能受其他许多因素的影响，包括疾病，入住ICU，手术和药物，这些都可能导致之前的模拟实验和目前的临床试验之间结果产生差异。

Discussion

Limitations of the study and suggestions for future studies

Our study design has a number of limitations, which should be noted. First, the study only evaluated subjective sleep quality and did not carry out an objective sleep assessment. PSG is the gold-standard of sleep measurement.

研究的局限性和对未来研究的建议

我们的研究设计存在很多局限性，是应该注意的。第一，本研究仅评估了主观睡眠质量，并没有进行客观睡眠评价。PSG是睡眠测评的金标准。

Discussion

However, PSG application is limited in the ICU due to its high cost and inconvenient manipulation. Second, the study only assessed a 12-hour nocturnal period rather than over 24 hours during the first two nights in ICU. ICU patients experience circadian rhythm disturbances with sleep traversing day and night.

然而，PSG由于成本高和操作不便，在ICU的应用受限。第二，本研究仅评估入住ICU头两晚的12小时的夜间而不是整个24小时的时间范围。ICU患者经历日夜颠倒的昼夜节律紊乱。

Discussion

Therefore, an ideal study should measure the sleep pattern and circadian rhythm over multiple 24-hour periods. Moreover, this study included a specific population in a CSICU. Therefore, results may not be applicable to all settings and all patients. In addition, our sample sizes were small, which limited the power of our statistical analyses. Future studies with larger and more diversity of the participants would likely support these recommendations.

因此，理想的研究应该测量多个24小时期间的睡眠类型和生理节律。此外，本研究纳入了在CSICU中的一个特定人群。因此，结果可能不适用于所有病房及所有患者。另外，我们的样本量较小，使统计分析的权威性受到局限。未来样本量更大、更多样化的研究可能会支持这些措施。

Conclusions

In summary, our results clearly demonstrated the combination of using earplugs and eye masks with relaxing background music is useful for promoting sleep in CSICU adult patients, but the underlying mechanisms are more complex than simple changes in levels of 6-SMT and cortisol. Our pilot study provides a reasonable basis for promoting these non-pharmacological interventions for ICU patients.

总之，我们的研究结果证明了使用耳塞和眼罩联合放松的背景音乐对促进CSICU成人患者的睡眠是有效的，但是潜在的作用机制比6-SMT和皮质醇水平的简单变化更为复杂。我们的试点研究为这些非药物干预措施在ICU中使用提供了合理的依据。

Conclusions

Future study designs to replicate our results should consider including larger samples, include more diverse ICU populations, extend the time frame for data collection and post-discharge follow up to determine any longer-term benefits of this intervention.

未来的研究设计应该考虑更大的样本量，包含更多多样化的ICU人群，扩大数据收集的时间范围和出院随访以确定这项干预的远期利益。

Key messages

Using earplugs and eye masks with relaxing background music is useful for promoting the sleep perception of the patient

使用耳塞和眼罩配合放松背景音乐有助于促进患者的主观睡眠

Using earplugs and eye masks with relaxing background music does not influence the nocturnal melatonin or cortisol levels

使用耳塞和眼罩配合放松背景音乐对夜间褪黑激素和皮质醇水平没有影响

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