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A prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality in ICU

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ABSTRACT

Introduction: Despite the importance of the role of sleep, continuous assessment for both sleep quality and sleep disruptive factors in ICUs have not been considered in previous studies. Also, such assessment does not form part of standard clinical care in ICU. This study aimed to utilise continuous self-reported assessment of sleep quality and sleep disruptive factors on a daily basis, to acquire a more comprehensive overview of patients' sleep quality and identify the most disruptive factors. In addition, to evaluate the feasibility of implementing daily self-reports on sleep quality in ICU clinical practice.

Methods: An observational prospective-repeated assessment was conducted on n=120 patients in the ICU setting. Participants were both intubated and non-intubated.

Outcomes measures: Over a 3-month period, sleep quality was assessed on a daily basis using the Arabic version of Richards-Campbell Sleep Questionnaire (RCSQ-A), Sleep disruptive factors were identified using a modified Sleep in intensive Care-questionnaire (SICQ). Clinical factors, such as ICU interventions, and previously administered sedatives were also examined. Patients' acceptance of completing daily RCSQ-A reports was also assessed using various indicators of acceptability.

Results: A total of 381 self-reports (RCSQ-A) were collected for this analysis. Patients reported 34.4±5.60 indicating that they an average score of poor sleep quality. The group of intubated patients reported much poorer sleep quality during intubation than after extubation. In multivariate-analysis, factors which most significantly affected sleep [exp(b), p-value] were Midazolam [-6.424, p<0.0005], Propofol [-3.600, p<0.05], noise [-1.033, p<0.05], gender [1.836, p<0.05], daytime-sleepiness [0.856 p<0.05] and the presence of mechanical-ventilation [-1.218, p<0.05].

Conclusion: Sleep quality was reported as poor by all participants, factors affecting sleep were multiple and varied among patients. The findings from this study provided various recommendations for healthcare providers and researchers in terms of both examining and improving sleep quality in ICU patients.

Keywords: Intensive care unit, Richards-Campbell Sleep Questionnaire, sleep quality, factors affecting sleep, Self-report, Acceptability

STRINGTH AND LIMITATIONS OF THIS STUDY:

- This is the first study to assess both self-reported sleep quality and self-reported sleep disruptive factors that has included both intubated and non-intubated patients with data gathered on a daily basis until patients were discharged from the unit.

- The prospective repeated-assessment study design facilitated the reduction of recall bias, which also allowed sleep disruptive factors to be identified. These factors are constantly changing during patients' ICU stays and thus the study design permitted adequate statistical-power for analysis.

- The study provided a comparison of self-reported sleep quality during ventilation and after extubation within a group of intubated patients, reducing participant heterogeneity.

- The study was unable to study the effect of the patients' diagnoses and medications on sleep quality due to the variation in their medical-conditions and the combinations of medication-regimes between patients.

BACKGROUND

Sleep deprivation in critically ill patients has been studied for over 30 years. It is defined as a continued lack of restorative sleep over time, resulting in both physical and cognitive impairments.[1] Despite the importance of the role of sleep, continuous assessment of both sleep quality and sleep disruptive factors during ICU stays has not generally been considered in the previous studies. Also, assessment of such factors and outcomes does not form part of the standard clinical care given to ICU patients. Previous studies have assessed sleep quality and disruptive factors at one occasion during patient stays in the ICU or by means of retrospective reporting at the point of discharge.[2,3456,7]Evaluation of these types do not provide an accurate overview of patients' sleep quality or disruptive factors,[8,9]and thus are of little help in developing appropriate interventions for sleep promotion in ICUs. This may explain why there is no evidence of improvement in sleep in ICUs since the introduction of various sleep promoting interventions.[10,11,1213]

Sleep assessment in ICUs can be examined using objective tools such as polysomnography (PSG). While PSG is considered the gold standard for sleep measurement, it has certain drawbacks for use in the ICU environment; the electrodes must be worn continuously to collect data on sleep quality and the results require interpretation by experts.[314]The use of self-report instruments offers an alternative approach to sleep assessment in ICUs. Recent clinical practice guidelines for the management of pain, agitation, delirium, and sleep disruption in ICUs strongly recommend that patients' sleep should be continuously assessed by using a valid assessment tool such as the Richards-Campbell-Sleep Questionnaire (RCSQ).[15]

We thus adopted a method of prospective repeated assessment of both self-reported sleep quality and sleep disruptive-factors on a daily basis until patients discharge from the unit. Alongside developing a more comprehensive overview of patients' sleep quality and identifying those factors most disruptive to sleep from patients' perspectives. We also assessed the acceptability of ICU patients to complete daily self-reports on sleep quality using RCSQ during their ICU stays. This allowed for an understanding of the feasibility of implementing this method of assessment and its likely performance in clinical-practice and routine-care. This study enabled the development of various recommendations for healthcare providers and researchers in terms of both examining and improving sleep in ICU patients.

METHODS

Study design and settings

An observational prospective-repeated assessment was conducted in the ICU in Jeddah city, Saudi Arabia. The hospital has a 26-bed ICU facility that provides care for both medical and surgical critically ill patients. A single room was provided for each patient and there was a 1:1 registered nurse to patient ratio.

Patient involvement

A group of patients were involved in the design of the study at the stage of planning and piloting test. Those patients provided feedback on the modifications of one of the study tools (SICQ).

Study participants and recruitments

Participants eligible to take part in the study were adult patients (≥18 years) treated in the ICU for ≥24 hours who were alert and interactive, with Glasgow Coma Scale (GCS)[16] scores of 15, including those who were intubated. A convenience sample of all patients who met the eligibility criteria were invited to participate. Exclusion criteria included sedated or agitated patients with Richmond-Agitation and Sedation-Scores (RASS)**17** of <-1 or >+1, patients with pre-existing sleep pathologies; patients with cognitive-dysfunction, and patients who did not speak Arabic. All potential study participants were screened for eligibility at each morning using a study enrolment survey. Participants were assured that participation in the study was not obligatory and were reminded of their right to withdraw at any time. The study was reviewed and approved by the Institutional-Review-Board (IRB), King Abdul Aziz University Hospital, Saudi Arabia and the University of Glasgow, UK.

Data collection

Data collection was undertaken during May and August of 2018. Each included patient needed to be alert and calm, so patient consciousness levels were assessed daily; similarly, the presence of delirium was assessed using the Confusion-Assessment-Method for the ICU (CAM-ICU).

Outcome measures

Patient self-report assessment of sleep quality and sleep disturbance factors:

The RCSQ-A and the modified SICQ were administered each morning between 7.00 a.m. and noon until the day the patient was due to be discharged from the ICU. A table of study instruments can be found in the online supplementary-table-1. The five questions from the RCSQ-A were read aloud to the patients, and after each question, patients rated their previous night sleep by placing a mark on the answer line, which was 100 mm long (0 mm = poorest, 100 mm = optimum). This approach was chosen to limit the potential of recall-bias and to assure optimal reminiscence of the most recent night's sleep. Every attempt was made to ensure there were no missing or erroneous data by screening each patient's daily assessment-sheets. Missing RCSQ-A responses from patients who had declined to complete the questionnaire were not considered and not included in the analyses because the RCSQ total-score cannot be computed if the data are incomplete.[18] Patients who declined to complete the RCSQ-A were asked to clarify whether they not completing the questionnaire just on that individual occasion, or if they were withdrawing from the study. Patients who decided to withdraw from the study were not approached again; however, their consent for data they had already given to be analysed was retained. After every RCSQ-A completion, patients were also asked to rate their perception of the factors that disrupted their sleep during the previous night on the modified SICQ scale (1= no disruption to 10 = significant disruption). An open-ended question "What other activities were disruptive to your sleep last night?" was also used. Answers were communicated verbally by most patients and in writing and through actions by some.

Other measures: demographic and clinical data

Demographic and clinical variables were collected from patients' medical files. These included age, gender, ICU admission diagnosis, severity of critical illness (using the Acute-Physiology & Chronic Health-Evaluation (APACHE II) score23), ICU length of stay, nightly mechanical-ventilation statues (ventilated or non-ventilated), and medications administered during the study. None of the patients were on sedation during the assessment, though data on previously administered sedation medications were collected.

Patients' acceptance of daily self-reporting on sleep quality using RCSQ-A during their ICU stays:
The key elements of acceptability, including patient willingness, and perceived burden (ability to provide self-reports on a daily-basis) were assessed using several indicators of acceptability,[24] including withdrawal and dropout-rates, the total number of patients who decided to discontinue at some point during the assessment and the total number of completed reports. Participants were also asked: "How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?"

Sample size

G-Power software version 3.1.9.2 was used to perform regression-analysis to determine whether the sample size offered an effective power of at least 0.80 and a significance level of α = 0.05. This also determined the maximum number of variables to be included in the model. The power-analysis revealed that a sample size of 120 was adequate, given 16-variables to be included, with an effective-power of 0.88, assuming a moderate effect-size (f2 =0.22). Even supposing a much smaller-effect (f2 =0.19), the power remained 0.82, above the usual minimum-requirement of 0.80.[25]

Data management and analysis

Data were analysed using IBM-SPSS version-23.0. Data were first assessed for normality using the Shapiro-Wilk's test,26 then descriptive statistics were used to describe the continuous data (age, RCSQ-A scores). For categorical data (gender, admission diagnosis), frequencies and percentages were used. The total RCSQ-A score was converted into an estimate of the sleep efficiency-index (SEI) using the following formula: $SEI = 46.88 + (0.39 * RCSQ)$.[11,1827]
A paired-sample t-test was performed to check whether there was any significant difference in patients' sleep quality during ventilation and after extubation, and whether there were significant differences in self-reported sleep disruptive-factors during ventilation and after extubation that were explained by intubation status. The two-sided statistical significance level was set to 0.05 and 95% CIs were used. The correlation between daytime-sleepiness and length of ICU stay was assessed using a Bivariate (Pearson)-Correlation. A multiple-regression was run to assess the significance and relative contribution of each independent variable on predicting the dependent variable-sleep quality. To avoid overfitting the model, only factors rated most highly by the patients were included in the model in addition to variables of interest reflecting demographic and clinical characteristics derived from previous research. The majority of patients (87.5%) received non-opioid analgesics alongside opioid-fentanyl analgesics. To avoid multicollinearity, these two variables were therefore combined into a single-variable and entered as "analgesic". The appropriate modelling of continuous variables was confirmed by evaluating their linearity. There was no evidence of multicollinearity, as assessed by tolerance values greater than 0.1. Content analysis was used to interpret and synthesise the data collected in the open-ended questions.[28]

RESULTS

A total of 354 patients were screened, of whom 224 were excluded because they did not meet the study inclusion criteria (Figure-1). The remaining 130 patients met the inclusion criteria, but 10 patients declined to participate because of their unwillingness to participate in any research studies. Leaving 120 patients enrolled. The average age of patients was 59, and the majority (60%)

were male. The average APACHE II-score was 15.78 ±2.606, and 43 (35.8%) patients were on mechanical ventilation (MV). The average ICU-LOS was 9.35 days ±3.15 (Table-1).

Table 1 Demographic and clinical characteristics of patients (n=120)

Characteristics	Category	n (%)	Range
Age (Mean ±SD)	59.7±9.44		19.00- 75.00
Gender	Male	72 (60)	
	Female	48 (40)	
Admission diagnosis	Medical cardiac	21(17.5)	
	Medical respiratory	21 (17.5)	
	Gastrointestinal	11 (9.1)	
	Other	8 (6.7)	
	Surgical post-operative	59 (49.2)	
APACHE II score [b] (Mean ±SD)	15.78 ±2.606		10.00-24.00
Length of ICU stay (Mean ±SD)	9.35±3.15		4.00-21.00
Medications [a]	Beta blockers	75 (62.5)	
	Diuretics	76 (63.5)	
	Calcium channel blockers	99 (82.5)	
	Corticosteroids	45 (37.5)	
	Adrenergic	39 (32.5)	
	Non-Opioid and Opioid	105 (87.5)	
	Non-Opioid-Paracetamol	15 (12.5)	
Sedation	Propofol	54 (45)	
	Benzodiazepines (Midazolam)	40 (33.3)	
	Dexmedetomidine (Precedx)	26 (21.7)	
RASS score on enrolment [a]	Alert and calm (zero-score)	120 (100)	
GCS [b]	Fully conscious (15-score)	120 (100)	
Developed delirium	Positive CAM-ICU [c]	11 (9.2)	
Intubation statues	Intubated	43 (35.8)	
Method of ventilation	Invasive ventilation [d]	30 (69.8)	
	Non-invasive[e]	13 (30.2)	
Duration of MV (Mean ±SD)	6.26 ±3.381		2.00-17.00

[a] Richmond Agitation Sedation Scale, [b] Glasgow Coma Scale, [c] Confusion Assessment Method for the ICU, [d] ventilation applied via tracheotomy or endotracheal. [e] Ventilation applied via face or nasal mask.

Participants' self-report assessments of sleep and self-reported sleep disruptive factors

Average sleep quality as reported by the patients was poor, with mean scores for each of the RCSQ-A elements below 50 mm (Table-2). Furthermore, mean SEI was 60.3%, and a SEI less than 85% indicates poor sleep quality.[18] In contrast, average self-reported sleep quality at home was described as good, with a mean score 7.16 ±1.754. The average daytime-sleepiness score was 5.52 ±1.52, and daytime sleepiness did not change significantly over the course of any patient's ICU stay ($p>0.05$). Multiple factors were reported to disrupt patients' sleep (Table-3). Patients rated noise as the most disruptive extrinsic factor at 7.48±1.57, followed by clinical interventions at 5.95±1.57; the highest rated noise was talking at 6.80±1.25, while the highest-rated intrinsic disruptive factor was fear at 3.64±2.01. Supplementary-table-2 shows patients' comments on other factors that disrupted their sleep, including the categories and the sub-categories that emerged from content-analysis in accordance with Edéll-Gustafsson et al[29]

Table 2 Cohort patients' self-report of sleep quality, (n=120)

Richards-Campbell items	Mean ±SD	*Range*
(RCSQ-A.1) Sleep depth	31.82±7.03	19-56
(RCSQ-A.2) Falling asleep	33.07±6.73	21-54
(RCSQ-A.3) Awakenings	35.06±5.76	18-47
(RCSQ-A.4) Returning to sleep	36.29±5.36	25-50
(RCSQ-A.5) Overall sleep quality	35.36±5.34	22-51
Total RCSQ-A score [a]	34.41±5.60	23-48
SEI [b]	60.30	

[a] Total RCSQ-A = average of 5 items (Q1-Q5). The total RCSQ-A score was categorized, with a cut off-point of <26 indicating very poor sleep quality, a score of [26-50] indicating poor sleep quality, a score of [51-75] indicating good sleep quality, and a score of >75 indicating very good sleep quality. [b] SEI= Sleep efficacy index= < 85% indicates poor sleep quality.

Table 3 Self-reported sleep disruptive factors on modified SICQ, (n = 120)

Sleep disruptive factors in rank order	Mean ±SD	*Range*
Noise	7.48±1.57	3.00-9.00
Clinical interventions (i.e. blood samples, vital signs, etc.)	5.95±1.86	2.30-9.00
Light	2.36±0.94	1.00-5.00
Talking	6.80± 1.25	1.00-9.00
Machines' alarm (i.e. heart monitor, ventilator, etc.)	4.31±2.35	1.00-9.00
Telephone	1.12±0.36	1.00-7.30
Fear	3.64±2.01	1.00-8.25
Pain	2.30±1.10	1.00-7.30
Discomfort of being attached to the devices	2.26±1.18	1.00-5.75

Factors affecting sleep quality

The predictor variables included in the multiple-regression model were noise, clinical-interventions, talking, machine-alarms, and fear, along with the intrinsic factors of age, gender, daytime-sleepiness, APACHE II-score, ICU-LOS, analgesic use, MV status, and previous receipt of sedation using Midazolam, Propofol, and Precedx. The full model (Table-4) explained 39.3% of the variance in total sleep quality, a statistically significant predictor of total sleep quality, with the R^2 = 0.423, F (6.113) = 13.828, and p < 0.0005. Factors which negatively and significantly affected sleep quality (given as [exp(b)(95% CI), p value]) were Midazolam [-6.424 (-8.99– -3.86), p < 0.0005], Propofol [-3.600 (-5.71– -1.49), p<0.05], noise [-1.033, (-1.70– -0.364), p<0.05], and the presence of ventilator [-1.218 (-2.36- -0.077) p<0.05]. Total sleep quality was also significantly affected by differences in gender such that predicted sleep quality for female patients was greater than for male patients [1.836 (-1.70– -0.3640) p<0.05]. Daytime-sleepiness also significantly affected patients' sleep: using a daytime-sleepiness scale where 1 = unable to stay awake, and 10 = fully alert and awake, any increase on the scale was associated with a significant increase in total sleep quality [0.856 (-1.70– -0.3640) p<0.05].

Table 4 Model summary of the stepwise multiple regressions predicting total sleep quality from sleep disruptive factors with (adjusted $R^2 = 0.393$)

Variable	*B* [a]	R^2	ΔR^2	*F* [b]	*(95.0% CI)* [c]	*P*
Midazolam	-6.424	0.222	0.222	33.719**	(-8.99– -3.86)	<.0005**
Propofol	-3.600	0.287	0.065	23.541**	(-5.71– -1.49)	0.001*
Gender	1.836	0.340	0.053	19.914**	(0.157– 3.52)	0.032*
Noise	-1.033	0.373	0.033	17.097**	(-1.70– -0.364)	0.003*
Daytime sleepiness	0.856	0.401	0.028	15.236**	(0.175– 1.54)	0.014*
Nightly mechanical ventilation status	-1.218	0.423	0.023	13.828**	(-2.36– -0.077)	0.037*

[a] B= unstandardized regression coefficients, [b] F=test of overall significance, [c] CI=confidence interval, **highly significant; * p<.05

Self-reported sleep quality and sleep disruptive factors reported by participants during intubation and after extubation

The sub-sample of 43 patients who were placed on MV during the study reported sleep quality during intubation (31.88 ±6.16) as much poorer than after extubation (35.04±6.47); these differences were significant with p <0.0005. Patients reported sleep fragmentation as the greatest disturbance during intubation (30.63 ±5.79). Following extubation, the number of awakenings was significantly reduced, to a mean of 36.81±6.83 (Table-5). There were significant differences between the level of reporting for several sleep disruptive factors during ventilation and after extubation (p<0.05), as shown in Figure-2. During ventilation, machine alarms, clinical intervention, and fear were rated as causing high levels of sleep disruption (7.19±1.13, 7.04±2.04, and 6.32±1.81, respectively). However, after extubation, these levels of disruption were reduced significantly, causing only moderate to mild levels of disruption (4.68±1.37,6.07 ±2.34, and 2.72±1.34, respectively).

Table 5 Self-reported sleep quality of patients when they were intubated and after extubation, (n=43).

RCSQ-A items	Mean ±SD	Range	Mean ±SD	Range	P value [a]
Depth of sleep (RCSQ-A.1)	32.00±9.13	21-53	33.43±8.58	18-51	.001*
falling asleep (RCSQ-A.2)	33.00±8.67	19-53	34.38±8.41	22-56	.001*
Number of awakenings (RCSQ-A.3)	30.63±5.79	15-41	36.81±6.83	19-56	< .0005**
Returning to sleep (RCSQ-A.4)	31.85±5.50	21-40	36.20±5.99	28-49	< .0005**
Overall sleep quality (RCSQ-A.5)	32.14±5.51	21-41	34.40±5.54	25-47	< .0005**
Overall (RCSQ-A) Score [b]	31.88±6.16	20-45	35.04±6.47	24-49	< .0005

[a] Paired t test, *p< .05; **p< .0005 is highly significant.

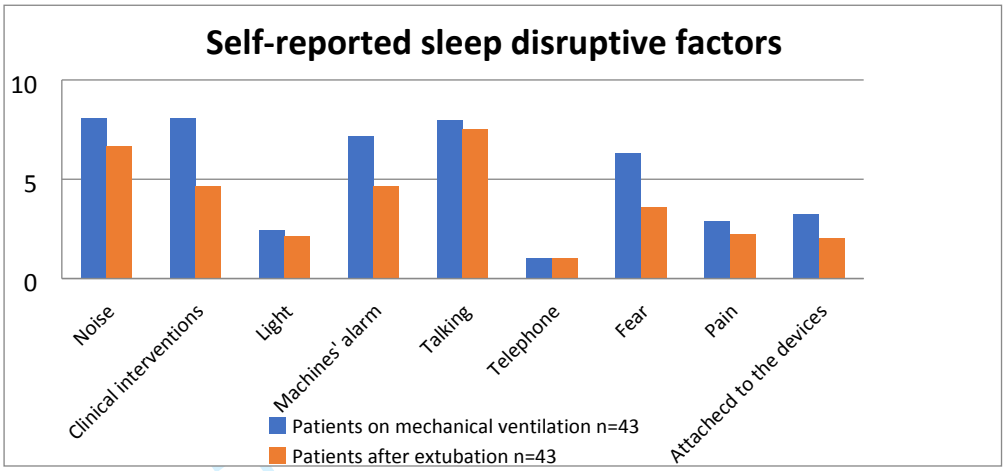

Figure 2. Significance of changes in the self-reported sleep disruptive factors

Patients' acceptance of making daily self-reports on sleep quality using RCSQ-A during ICU stays

Dropout and withdrawal rates: The number of patients who dropped out by choosing to stop taking part was very small at n=3 (2.5%). No reasons for such cessations were provided. The number of withdrawals was also very small at n=11 (9.2%). The reason for withdrawal for these patients was that they no longer met the study's inclusion criteria, as they had become agitated and developed delirium. The majority of participants, n=106 (88.4%), were able to complete study participation in full.

Number of completed self-reports (RCSQ-A): In total, 381 reports were collected from 120 participants. The answers to the open-ended question confirmed that most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stays in the ICU. However, some of the participants, n=17 (16.1%), at some point during the repeated-assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored (Supplementary-material-3).

***Experiences of completing the RCSQ-A*:** The time taken to complete RCSQ-A was between two and three minutes. Participants provided the RCSQ-A between one and six times, with the average being three times. N=111 (92.5%) provided more than one RCSQ-A, while only nine participants (7.5%) provided a single self-report. Four of the participants became delirious and agitated on the second day of assessment, while three patients asked to stop taking part; two patients were also discharged from the ICU on their second day of assessment. Among the study participants, n= 68 (56.7%) were unable to set a mark on the VAS themselves, requiring assistance due to physical barriers such as hand tremors and muscle weakness. These patients were only able to point at their chosen spots on the scales.

DISCUSSION

A review of the literature suggests that, this is the first study assessing both self-reported sleep quality and self-reported sleep disruptive factors that has included intubated and non-intubated patients on a daily basis until patients discharge from the unit. We considered it is important to study sleep quality and sleep disruptive-factors simultaneously in order to develop a comprehensive view of patients' sleep and the factors that disrupt it. We considered that this would inform the future development of strategies to improve patients' sleep in ICU. This is also

the first study assessing ICU patients' acceptance of completing daily self-reports (RCSQ-A) on the quality of their sleep. Despite the growing awareness of the role of sleep in ICU patients' recovery, it is somewhat surprising that this is also the first study that has assessed self-reported sleep using a valid tool (RCSQ-A) in ICU patients in an Arabic-speaking country in the Middle-East.

There was evidence of general poor sleep quality in this cohort of ICU patients. The overall quality of sleep from the patient perspective was 34.41, much lower than reported findings in some previous studies[4,11,30,31]and slightly lower than in others.[7,20,2732]The SEIs emerged at 60.3%, matching the results from a group of ICU patients in the United Kingdom10 used as a control, in which the SEIs were 60.8%, and slightly lower than reported in the repeated self-report assessment study from Australia (60.3% vs. 65%).27 In this study, patient perception of sleep varied between poor to very poor in contrast to other self-report assessment studies in which patients' sleep varied from very good to very poor.[4,72011,31]Reasons for these differences may include the different treatment characteristics of the patients, as this study included intubated patients, as well as the different ICU environment. Differences in the method of sleep quality assessment could also have influenced these results. The current results are based on continuous assessment to discharge from the ICU, while the majority of previous studies limited assessment to a single night.[23,4,11]Only three studies used RCSQ for repeated-assessment,[2730,32]and their assessments were limited to non-intubated patients. The finding that patients' sleep is reported as worse in the ICU than at home is consistent with previous studies.[2,36,11]This indicates that there are factors within these environments which may lead to changes in and disruption to patients' sleep.

The results demonstrated that daytime-sleepiness was consistent with lack of sleep during the night and that perceived daytime-sleepiness did not improve over the course of patients' ICU stays. These results are consistent with previous polysomnographic and self-report studies,[25]which showed that between 40 to 50% of total sleep time in an ICU occurs during the day, and that this altered sleep pattern did not improve over the course of stays. It is known that female subjects experience additional slow wave, and this is reflected in the observed gender differences in patients' sleep in this study: female patients slept better than male patients. This concurs with a recent study that found that female patients had better sleep than males.[2]Our results showed that multiple sleep disrupting-factors were identified by the entire sample, which substantiates other results. Of the extrinsic-factors, patients rated noise as the most disruptive, supporting the findings of previous studies.[2,333,34]Peak noise levels in the ICU were documented at 41dB and 68 dB,[34,35,36] exceeding the World-Health-Organization (WHO) recommendation for sound levels in an ICU not to exceed 35 dB during the day and 30 dB at night.37The current results also support the idea that interruptions of sleep in the ICU caused by clinical-interventions are important. This finding is consistent with the results of Celik et al,38 who found that patients had their sleep interrupted by human-interventions an average of 51-times each per night. However, in addition to these, psychological factors cannot be ignored. Patients reported fear factors to be the most disruptive intrinsic-factor, though patients also referred to nightmares and worries, corroborating previous study findings.[7,2027]

The effects of sedations have not been studied sufficiently in the ICU. None of the patients were on sedation during this assessment, though data on previously administered sedations were gathered. Sedatives, especially benzodiazepines, are commonly used to induce sleep but these have been known to supress slow-wave (SWS) and rapid-eye-movement sleep (REM) after

withdrawal.[39] Propofol has shown to increase SWS while suppressing REM sleep.15 Interestingly, patients who received benzodiazepines had worse sleep quality than patients who received Propofol. However, both forms of sedation significantly affected patients' sleep quality. The adverse effects of many sedatives have been well determined, and thus sedatives should not be used for sleep promotion in most cases;15 in addition, patients receiving these drugs should be carefully monitored with regard to the quality of their sleep.

The negative effects of the presence of MV on patients' sleep quality has been reported previously in several polysomnographic studies.[5,4041]However, this is the only self-report study including intubated patients and assessing their perception of sleep quality alongside their perceptions of sleep disruptive-factors on a daily basis both during intubation and after extubation to find out whether the ventilator has an effect on patients' perception of sleep and factors that disrupt their sleep. We found that intubated patients reported better sleep quality after extubation. They also reported sleep fragmentation to be greater during intubation than after extubation; furthermore, during ventilation, the factors of machine-alarms, clinical-interventions, and fear were rated by the patients as the most disruptive factors, while after extubation, the level of disruption reduced significantly. One possible explanation for high sleep-fragmentation during intubation is the disruptive factors that arise from or are increased by the presence of the ventilator, such as alarms, clinical interventions and feelings of fear. A study by Freedman et al.5assessed the sleep quality of ventilated patients, which demonstrated that sleep was highly fragmented; they suggested that this may be due to the multiple human-interventions during ventilation. Our findings stress the need for attention to be paid to the sleep quality of this group of patients, with close monitoring for factors that may adversely affect sleep. In particular, environmental factors such as noise from alarms should not be overlooked; such impacts should be handled properly by following guidelines such as the Joint Commission (JCI) policies on safely managing clinical alarm systems to avoid false alarms.43 Clustering patients' care activities as much as possible during the night and avoiding performing unnecessary care activities during the night is also important for managing these factors. Where MV is present, patients may experience distressing psychological side effects such as fear,[4445] and thus it is also important to consider the individual patient's psychological needs.

Our results demonstrated that daily self-report assessments on sleep-quality by using (RCSQ-A) was non-burdensome to the majority of participants. It is therefore somewhat surprising that the use of RCSQ for repeated assessment in ICUs is only infrequently published, with only three main studies of this type.[27,30,32]Two were conducted in Australia,[2732] with one featuring 151 participants reporting on their sleep using the RCSQ 356 times where 50% of participants were able to report on two or more days;[27] the other Australian study[32] featured 50 patients reporting, and the completion rate was 72%. The other study, in North America,30 featured 33 patients over 137 days completing 121 self-reports, giving a rate of 88%. These studies and our own completion rate of 92.5% provide evidence to support the tool's feasibility for routine assessment of patients' sleep in ICUs. Patients in this study also described their experience of completing the RCSQ-A during their stays generally positively. Patients were happy, reporting various psychological and social needs being met by this method of assessment. For example, they felt a sense of security, enhanced communication levels, reduced feelings of loneliness, and a sense that someone respected and cared about their needs for sleep. These results are in agreement with a recent qualitative study46 that found that patients who felt well taken care of reported felt more relaxed and that their sleep was affected in a positive way.

Based on the daily self-report assessment of both sleep quality and sleep disruptive-factors, sleep disruptive-factors were evaluated by the patients differently from day to day and from patient to patient despite the constant setting. The findings thus do not support the hypothesis that ICU noise is the main factor responsible for sleep disturbance for all ICU patients.47 Patients' sleep disruption is influenced by several interrelated factors that constantly change due to the nature of the ICU environment. Sensitivity to sources of sleep disruption also vary from patient to patient.[5] Unfortunately, individual differences have not been considered in most recent interventions studies that have aimed to improve sleep in ICU by developing and applying protocols.[10,11,12,13] Recent guidelines15also revealed problems with methodology in these intervention studies, highlighting the need for well-designed nonpharmacological-measures and improved methods for measuring sleep to allow implementation of interventions with individualised approaches.

Our findings demonstrate the acceptability and feasibility of using repeated, self-reported RCSQ assessments of sleep quality in ICU environments. Such assessments can be performed whenever patients are sufficiently alert, and they do not need to be able to communicate verbally. The findings also encourage clinicians routinely inquiring about patients sleep, implementing routine early documentation of sleep patterns using RCSQ in the patient care-plans. Patient perceptions of factors disrupting sleep should be identified individually to determine the patient-specific needs to address sleep disturbances with treatment-decisions. Furthermore, patients should be involved in their care; this corresponds with the Institute for Healthcare-Improvement's (IHI) identification of patient-safety as one driver of exceptional patient-centred care.[4849]However, it would be valuable to further validate the RCSQ in intubated ICU populations, as the original validation was performed using PSG in non-intubated patients.[18]This additional validation would enhance the promotion and use of this instrument for the purposes of ongoing assessment over various points of patient ICU stays. Further studies are required to test acceptability in other populations of ICU patients in different countries and regions. Further work is also required to assess perceptions of and acceptability by health care providers in ICUs in terms of implementation. The quality of sleep was poor in all participants in this case, highlighting the need for further testing in the Middle-East countries, as well as the need to implement greater care concepts with regard to managing the sleep in ICUs.

The current study had several limitations, which must be acknowledged. Selection bias is possible, as all patients selected to participate were non-sedated; this was necessary, as sedations affect cognitive abilities, and thus would affect the validity of results. However, this means that the results are not generalisable to the whole ICU-patient population. Nevertheless, this is a very important patient population to study, especially as it includes patients in the period after sedation cessation, when regular-assessment of sleep quality that may be affected by the previously received sedation is necessary. In addition, the aim was to identify such factors subjectively from a patient perspective subject to patient experience, and thus changes in sleep-architecture were not observable, due to the use of a self-report tool. However, routine-use of objective-methods of assessment such as PSG-monitors during patient care is not feasible, and the clinically meaningful outcome of sleep quality is the patient's experience.[15,27]

CONCLUSION

Sleep quality was reported as poor by all participants, though factors affecting sleep were multiple and varied from patient to patient, stressing the need to regularly and individually assess patients' sleep quality, and the importance of adopting patient-centred care, including an individual sleep care plan for each patient. The results also demonstrated the feasibility and the acceptability of ICU patients making daily self-reports of their sleep quality using RCSQ-A during their ICU stays.

REFERNCES

1. Parthasarathy S, Tobin MJ. Sleep in the intensive care unit. *Intensive Care Med* 2004;30:197–206
2. Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.7.
3. Elliott R, McKinley S, Cistulli P, Fien M. Characterisation of sleep in intensive care using 24-hour polysomnography: an observational study. *Crit Care* 2013;17:R46.
4. Nicolás A, Aizpitarte E, Iruarrizaga A, Vázquez M, Margall A, Asiain C. Perception of night-time sleep by surgical patients in an intensive care unit. *Nurs Crit Care* 2008;13:25–33.
5. Freedman NS, Gazendam J, Levan L, et al. Abnormal sleep/ wake cycles and the effect of environmental noise on sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 2001;163:451–7. 5
6. Freedman NS, Kotzer N, Schwab RJ. Patient perception of sleep quality and etiology of sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 1999;159:1155–1162.
7. Frisk U, Nordström G. Patients' sleep in an intensive care unit: patients' and nurses' perception. *Intensive Crit Care Nurs* 2003;19:342–349.
8. Hoey LM, Fulbrook P, Douglas JA. Sleep assessment of hospitalised patients: a literature review. *Int J Nurs Stud* 2014;51:1281–1288.
9. Jeffs EL, Darbyshire JL. Measuring sleep in intensive care unit: a critical appraisal of the use of subjective methods. *J Intensive Care Med* 2017;1–10.
10. Patel J, Baldwin J, Bunting P, et al. The effect of a multicomponent multidisciplinary bundle of interventions on sleep and delirium in medical and surgical intensive care patients. Anaesthesia 2014;69:540–549.
11. Li SY, Wang TJ, Vivienne Wu SF, et al. Efficacy of controlling night time noise and activities to improve patients' sleep quality in a surgical intensive care unit. *J Clin Nurs* 2011;20:396–407.
12. Kamdar BB, King LM, Collop NA, *et al*. The effect of a quality improvement intervention on perceived sleep quality and cognition in a medical ICU. *Crit Care Med* 2013;41:800–809.
13. Elliott R, McKinley S. The development of a clinical practice guideline to improve sleep in intensive care patients: a solution focused approach. *Intensive Crit Care Nurs* 2014;30:246–256.
14. Knauert MP, Yaggi HK, Redeker NS, et al. Feasibility study of unattended polysomnography in medical intensive care unit patients. *Heart Lung* 2014;43:445–452.
15. Devlin JW, Skrobik Y, Gélinas C, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Crit Care Med* 2018;46:825-873.
16. Fischer M, Rüegg S, Czaplinski A, et al. Inter-rater reliability of the Full Outline of Unresponsiveness score and the Glasgow Coma Scale in critically ill patients: a prospective observational study. *Crit Care*. 2010;14:R64.

17. Sessler CN, Gosnell MS, Grap MJ. Et al. The Richmond Agitation–Sedation Scale. *Am J Respir Crit Care Med* 2002;166:1338–1344.
18. Richards KC, O'Sullivan PS, Phillips RL. Measurement of sleep in critically ill patients. *J Nurs Meas* 2000;8:131–44.
19. Al-Sulami G, Rice AM, Kidd L, et al. An Arabic translation, reliability, validity and feasibility of the Richards-Campbell Sleep Questionnaire for Sleep Quality Assessment in Intensive Care Unit: Prospective-Repeated Assessments. *J Nurs Meas* (forthcoming).
20. Krotsetis S, Richards KC, Behncke A, et al. The reliability of the German version of the Richards-Campbell sleep questionnaire. *Nurs Crit Care* 2017;22:247–252.
21. Chen, LX, Ji DH, Zhang F, et al. Richards-Campbell sleep questionnaire: psychometric properties of Chinese critically ill patients. *Nurs Crit Care* 2018; doi:10.1111/nicc.12357
22. Burns KEA, Duffett M, Kho ME, et al. A guide for the design and conduct of self-administered surveys of clinicians. *CMAJ* 2008;179:245–252.
23. Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. *Crit Care Med* 1985;13:818–29.
24. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
25. Cohen J. A power primer. *Psychol Bull* 1992;112:155–9.
26. Shapiro SS, Wilk MB. An Analysis of Variance Test for Normality (Complete Samples). *Biometrika* 1965;*52*:591-611.
27. Aitken LM, Elliott R, Mitchell M, et al. Sleep assessment by patients and nurses in the intensive care: an exploratory descriptive study. *Aust Crit Care* 2016; 30: 59–66.
28. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15:398-405.
29. Edéll-Gustafsson U, Arén C, Hamrin E, et al. Nurses' notes on sleep patterns in patients undergoing coronary artery bypass surgery: a retrospective evaluation of patient records. *J Adv Nurs* 1994; *20*:331-336.
30. Kamdar BB, Shah PA, King LM, Kho ME, Zhou X, Colantuoni E, Collop NA, Needham DM. Patient-nurse interrater reliability and agreement of the Richards-Campbell sleep questionnaire. *Am J Crit Care* 2012;21:261–269.
31. Ritmala-Castren M, Axelin A, Kiljunen K, et al. Sleep in the intensive care unit-nurses' documentation and patients' prespectives. *Nurs Crit Care* 2014;22:238-246.
32. Aitken LM, Elliott R, Mitchell M, et al. Sleep assessment by patients and nurses in the intensive care: An exploratory descriptive study. *Nurs Crit Care* 2017;30:59.
33. Salandin A, Arnold J, Kornadt O. Noise in an intensive care unit. *J Acoust Soc Am* 2011;130:3754–3760.
34. Simons KS, Verweij E, Lemmens PM, et al. Noise in the intensive care unit and its influence on sleep quality: a multicenter observational study in Dutch intensive care units. *Crit Care* 2018;22:250.
35. Park M, Kohlrausch A, de Bruijn W, et al. Analysis of the soundscape in an intensive care unit based on the annotation of an audio recording. *J Acoust Soc Am* 2014;135:1875–1886.
36. Darbyshire JL, Young JD. An investigation of sound levels on intensive care units with reference to the WHO guidelines. *Crit Care* 2013;17:R187.
37. Berglund B, Lindvall T, Schwela DH & World Health Organization Occupational and Environmental Health Team. Guidelines for community noise. 1999. http://www.who.int/iris/handle/10665/66217
38. Celik S, Oztekin D, Akyolcu N, et al. Sleep disturbance: the patient care activities applied at the night shift in the intensive care unit. *J Clin Nurs* 2005;14:102–6.

39. Pisani MA, Friese RS, Gehlbach BK, et al. Sleep in the intensive care unit. *Am J Respir Crit Care Med* 2015;191:731–8.
40. Cooper AB, Thornley KS, Young GB, et al. Sleep in critically ill patients requiring mechanical ventilation.***Chest*** 2000;117:809–818.
41. Beecroft JM, Ward M, Younes M, et al. Sleep monitoring in the intensive care unit: comparison of nurse assessment, actigraphy and polysomnography**. *Intensive Care Med*** 2008;34:2076–2083.
42. Elliott R, Rai T, McKinley S. Factors affecting sleep in the critically ill: an observational study. *J Critc Care* 2014;29:859-63.
43. The Joint Commission. The Joint Commission announces 2014 national patient safety goal, 2013. Available from. http://www.jointcommission.org/assets/1/18/jcp0713_announce_new_nspg. pdf2016.
44. McKinley S, Fien M, Elliott R, et al. Sleep and psychological health during early recovery from critical illness: an observational study. *J Psychosom Res* 2013;175:539-45.
45. Rotondi AJ, Chelluri L, Sirio C, et al. Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. *J Crit Care Med* 2002;30:746-52.
46. Ding Q, Redeker NS, Pisani MA, et al. Factors influencing patients' sleep in the intensive care unit: perceptions of patients and clinical staff. *Am J Crit Care* 2017;26:278.
47. Gabor JY, Cooper AB, Crombach SA,et al. Contribution of the intensive care unit environment to sleep disruption in mechanically ventilated patients and healthy subjects. *Am J Respir Crit Care Med* 2003;167:708–715.
48. Perlo J ,Balik B , Swensen S , *et al* . *IHI framework for improving joy in work*. Cambridge, MA: Institute for Healthcare Improvement, 2017.
49. Gandhi TK, Kaplan GS, Leape L, et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf* 2018;27:1019-26.

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Supplementary-1: Study instruments

1- The Arabic version (RCSQ-A) of RCSQ was used to assess patients' perceptions of their sleep quality. This questionnaire is a brief self-report tool that asks respondents to rate the previous nights' sleep on a five-item visual analogue scale (VAS).[18] Each VAS represents a different aspect of sleep: sleep depth, falling asleep, number of awakenings, returning to sleep, and overall quality of sleep. The RCSQ has been validated against the PSG and demonstrates a reliability coefficient of 0.90.[18]It also demonstrates good internal consistency, with scores of 0.88 to 0.92, throughout numerous translations including Arabic, German, Chinese, Spanish, and Swedish[19,20,21,4,7]

2- To identify factors disrupting patients' sleep, a modified Sleep in Intensive-Care Unit Questionnaire (SICQ)[6] was used. The SICQ has 27 items under the headings sleep quality (five-items), daytime sleepiness (four-items), and sleep disruptive factors (18-items). The SICQ was developed in the 1990s by researchers who performed factor-analysis and reported that the questionnaire appears to be internally valid. While this requires further validation with the PSG monitor, it has nonetheless been used in many studies.[2,3,10,11]In the current study, measures of content and face validity, including peer review by an expert-panel (healthcare providers expert in ICU work) were completed, followed by a pilot test of the SICQ with 56 patients. Subsequently, the items that required participants to retrospectively rate their sleep quality on discharge were removed to prevent recall bias. The items for sleep interruptions from television noise and doctor pagers were also removed as these were not used in the ICU. Items regarding several similar sources of noise (heart monitor alarms, ventilator alarms, I.V. pump alarms) were collated into one category item (machine alarms), and diagnostic-testing, vital-signs, blood-samples, and administration of medication were similarly collated into the category item clinical interventions. The decision to categories these items was made to ensure that the self-administered SICQ was short and simple, which was particularly important for critically ill patients to lessen the burden of the questionnaire.[22] In addition, it was considered that patients might not accurately remember or detect the source of an alarm that caused sleep disturbance during the previous night, as the ICU environment has many complicated machines. Factors of fear, pain and being attached to machines were, however, added, based on patient answers in the pilot-test. The questionnaire demonstrated good face validity and was easily understandable for patients, as judged by a lack of comments on difficult or ambiguous items.

Supplementary-2 Categories arising from the comments of patients in relation to the open-ended question in the modified SICQ "What other factors or activities were disruptive to your sleep during last night?

Category	Subcategories	NO. patients
Environmental factors	**(Noise disruption)**	
	-Voices of other patients *'I wok every time because of the sounds of suction of patient next to me'* *'I could not sleep last night because of the man who was moaning all night'*	28
	-Sounds of footsteps/moving equipment *'I slept on and off, there was footsteps sounds along the night'* *'Sometimes I could hear moving of equipment, sounds of people steps, I did not sleep well because all of that'*	9
Patient factors	**(Psychological factors)**	
	-Worries *'I did not sleep until the morning, I was worried'* *'I was worried about whether I'd be better or not'* *'I was concerned and thinking all night about my family'*	20
	-Nightmares *'I wok every time last night of bad dreams'* *'I was so scared, and I could not sleep of a terror dream'*	15
	Clinical condition factors	
	-Coughing *'I did not sleep because of the coughing all night'* *'I have a very bad cough which keeping me awake'*	18
	- Choking sensation *'I could not sleep of a chocking feeling I was breathing through my mouth'* *'I woke up of sudden chocking feeling and I could not get back again to sleep'*	10 7
	-Nausea *'I had bad sleep of unpleasant nausea'* *'I had feeling of throwing up all night, I could not sleep'*	

Supplementary-3 Patient perception in making daily-self-reports using RCSQ-A
Most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stays in the ICU. Most of them found the questionnaire simple to complete and easy to understand *"It was easy to answer the questionnaire, I was just pointing".* *"The questionnaire was simple and short".*
Some patients noted that answering made them feel safe, suggesting that someone was paying attention to their needs with regard to sleep quality *"I felt safe having someone asking about my sleep"* *"I felt happy to find someone asking about my sleep, especially at that time no one was caring about this problem I have".*
Some patients found the daily self-report assessment enhanced their communication levels and reduced feelings of loneliness. *"I was feeling happy at that time when I was on the ventilator machine, unable to talk and when you come to me and try to communicate with me"* *"I was feeling lonely most of the time, everybody was busy, so I was pleased that I had opportunity to interact with someone"*
Other patients found that daily assessment of their sleep quality improved their awareness of the importance of adequate sleep for health, causing them to pay more attention to their sleep. *"It is really opened my eyes on how is important to my health to get enough sleep"* *"The assessment was at each morning which gave me attention that my sleep is important to me"*
Some of the participants, n=17 (16.1%), at some point during the repeated assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored *"I felt tired at sometimes and I did not want to do any activity"* *"I was feeling bored and empty at sometimes, and I did not want to do anything"*

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	In the title and abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	In the 2nd page
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	In the 4th page
Objectives	3	State specific objectives, including any prespecified hypotheses	Last paragraph in the background
Methods			
Study design	4	Present key elements of study design early in the paper	Under study design and settings page 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Under study design and settings page 4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Under study participants and recruitments page5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, and effect modifiers. Give diagnostic criteria, if applicable	Under outcome measures page 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Under outcome measures page 5
Bias	9	Describe any efforts to address potential sources of bias	Under outcome measures page 5
Study size	10	Explain how the study size was arrived at	Sample size page 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Under data management and

			analysis page 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Under data management and analysis page 6
		(*b*) Explain how missing data were addressed	Under outcome measures page 5
		(*c*) If applicable, explain how loss to follow-up was addressed	N/A
		(*d*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	First paragraph in the result and Table1. Page 6-7
		(b) Give reasons for non-participation at each stage	First paragraph in the result page6. And under Patients' acceptance of making daily self-reports page 10
		(c) Consider use of a flow diagram	Page 6 (Figure-1).
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures	First paragraph in the result and Table1. Page 6-7
		(b) Indicate number of participants with missing data for each variable of interest	Under Patients' acceptance of making daily self-reports page 10
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	In the result part Page 8,9
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	In page 11,12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Last two paragraphs page 13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Last paragraph page 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	After references page16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality

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A prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality

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ABSTRACT

Introduction: Despite the importance of sleep, the assessment of sleep quality does not form part of standard clinical-care in ICU. Continuous assessment of self-reported quality of ICU patients' sleep has been strongly recommended. Prior to implementing such an assessment in the ICU, it is important to assess the acceptability of this method of assessment to the ICU's patients. The aims of this study were to assess the acceptability to ICU patients of completing daily self-reports on sleep quality during their ICU stay and to assess ICU patients' self-reported sleep quality and sleep-disruptive factors during their time in ICU.

Methods: An observational prospective-repeated assessment was conducted on n=120 patients in an ICU in Saudi Arabia. The participants were both intubated and non-intubated.

Outcomes measures: Over a three-month period, sleep quality was assessed using the Arabic version of the Richards Campbell Sleep Questionnaire (RCSQ-A), and self-reported sleep-disruptive factors were identified. Clinical-factors, such as ICU interventions, and previously administered sedatives were also examined. The patients' acceptance of completing daily RCSQ-A reports was assessed using various indicators of acceptability.

Results: A total of 381 self-reports (RCSQ-A) were collected for this analysis. The patients reported 34.4±5.60, indicating that sleep quality was poor on average. The group of intubated patients reported much poorer sleep quality during intubation than after extubation. In the multivariate-analysis, factors which most significantly affected sleep [exp(b), p-value] were Midazolam [-6.424, $p<0.0005$], Propofol [-3.600, $p<0.05$], noise [-1.033, $p<0.05$], gender [1.836, $p<0.05$], daytime-sleepiness [0.856 $p<0.05$] and the presence of mechanical-ventilation [-1.218, $p<0.05$].

Conclusion: The acceptability and feasibility of using daily RCSQ-A for sleep quality assessment was demonstrated. Sleep quality was reported as poor by all participants and the factors affecting sleep were varied. This study provided various recommendations for healthcare-providers and researchers in terms of evaluating and improving sleep quality in ICU patients.

Keywords: Intensive care unit, Richards Campbell Sleep Questionnaire, sleep quality, factors affecting sleep, Self-report, Acceptability

STRINGTH AND LIMITATIONS OF THIS STUDY:

- This is the first study to assess ICU patients' acceptability of completing daily self-reports on the quality of their sleep.
- The prospective repeated-assessment study design facilitated the reduction of recall bias, which allowed sleep disruptive factors to be identified. These factors are constantly changing during patients' ICU stays and thus the study design permitted adequate statistical-power for analysis.
- The study provided a comparison of self-reported sleep quality during ventilation and after extubation within a group of intubated patients, reducing participant heterogeneity.
- The study was unable to study the effect of the patients' diagnoses and medications on sleep quality due to the variation in their medical-conditions and combinations of medication-regimes.

BACKGROUND

Sleep disruption in critically ill patients has been studied for over 30 years. It is defined as a continued lack of restorative sleep over time, resulting in both physical and cognitive impairments.[1] Studies suggest a number of extrinsic and extrinsic sleep disruptive factors are associated with disrupted sleep in ICU patients.[2,3] Extrinsic factors (environmental) include environmental sounds, light and nurses' activities. Intrinsic factors (factors related to the patients) include the severity of the illness, pain, fear or medical treatments. Despite the importance of sleep, continuous assessment of sleep quality during ICU stays does not form part of the standard clinical care given to ICU patients. Assessment is the first critical process in the nursing care plan, which enables nurses to develop an appropriate intervention and evaluate its effectiveness. Regular assessment is important in early identification of any sleep problems that ICU patients may have which in turn, lead to identifying the cause of the problem and implementing the proper interventions to improve the patients' sleep. [4,5]

Sleep assessment in ICUs can be examined using objective tools such as polysomnography (PSG). While PSG is considered the gold standard for sleep measurement, it has certain drawbacks for use in the ICU environment; the electrodes must be worn continuously to collect data on sleep quality and the results require interpretation by experts. [6,7] The use of self-report instruments offers an alternative approach to sleep assessment in ICUs. Recent clinical practice guidelines for the management of pain, agitation, delirium, and sleep disruption in ICUs, the Society of Critical Care Medicine strongly recommend that patients' sleep should be continuously assessed using a valid assessment tool such as the Richards-Campbell-Sleep Questionnaire (RCSQ).[8] However, prior to implementing self-reports on the quality of patient's sleep as part of the daily routine in the ICU, it is important to determine whether this is acceptable to the patients. Sekhon et al. [9] stated that successful implementation of new measures depends on the acceptability of the proposed measures to the recipients. They defined acceptability as a multi-faceted construct that reflects the extent to which people participating in new proposed measures consider it to be appropriate, based on their experienced cognitive and emotional responses. A few recent studies have used RCSQ in repeated assessment and throughout the patient's stay in the ICU.[10,11,12] They provided data on the completion rate of RCSQ by the participants,[10,11,12] and reasons for not completing the RCSQ by some participants.[12] However, there is no data on the patients' acceptability of this daily assessment (i.e. patients' experience of completing RCSQ on a daily basis during their ICU stay).

Despite the growing awareness of the role of sleep in ICU patients' recovery, there is little literature concerning any aspect of ICU patients' sleep quality and sleep disruptive factors in Middle East countries. In particular, the RCSQ is empirically valid and highly recommended for assessing the quality of ICU patients' sleep, there is a lack of knowledge about patients' sleep quality and sleep disruptive factors in Saudi Arabian ICUs, as no study has previously assessed patients' perception of sleep quality and sleep disruptive factors in Saudi Arabian ICUs. Therefore, we adopted a method of prospective repeated assessment of both self-reported sleep quality and sleep disruptive-factors on a daily basis until the patients' discharge from the unit. The primary aims of this study were to: 1) assess the acceptability of ICU patients to complete a daily self-report on sleep quality using the RCSQ during their ICU stay, and 2) assess the ICU patients' self-reported sleep quality during their stay in the ICU. The secondary aims were to 3) identify the self-reported

factors that disrupt ICU patients' sleep during their ICU stay, and 4) evaluate the effects of self-reported sleep disruptive factors and clinical factors on the patients' self-reported sleep quality.

These study aims were designed in the purpose to understand the feasibility of implementing daily self-report assessment of patients' sleep quality in Saudi Arabian ICU clinical practice and its likely performance in national ICU clinical-practice and routine-care, and to provide a comprehensive view of the quality of ICU patients' sleep and sleep disruptive factors in the Saudi Arabian ICU population. This may help to develop recommendations for healthcare providers and researchers in terms of both examining and improving sleep in ICU patients if necessary.

METHODS

Study design and settings

An observational prospective-repeated assessment was conducted at King Abdul Aziz University Hospital (KAUH) ICU. The hospital is a tertiary referral hospital in the western region of Jeddah, Saudi Arabia (KSA). During the study period, the hospital had a total capacity of 845 beds, of which 26 beds were in the ICU facility that provides care for both medical and surgical critically ill patients. A single room was provided for each patient and there was a 1:1 Registered Nurse (RN) to patient ratio. The patients' rooms were arranged around a centrally located nursing station.

All rooms featured small windows fitted with blinds. There were no policies in place to schedule the opening and closing of blinds to aid maintenance of circadian rhythm by altering natural light levels according to time of day. Patients' room lights were switched off during the night while the bed lights and corridor lights remained on. There were no set policies or guidelines regarding the patients' sleep quality within the hospital.

Patient involvement

A group of patients were involved in the design of the study at the planning and piloting test stages. Those patients provided feedback on the study tools.

Study participants and recruitments

Participants eligible to take part in the study were adult patients (≥18 years) treated in the ICU for ≥24 hours who were alert and interactive, with Glasgow Coma Scale (GCS) [13] scores of 15, including those who were intubated. A convenience sample of all patients who met the eligibility criteria were invited to participate. Exclusion criteria included sedated or agitated patients with Richmond-Agitation and Sedation-Scores (RASS) [14] of <-1 or >+1, patients with pre-existing sleep pathologies; patients with cognitive-dysfunction, and patients who did not speak Arabic. All potential study participants were screened for eligibility at each morning using a study enrolment survey. The participants were assured that participation in the study was not obligatory and were reminded of their right to withdraw at any time. The study was reviewed and approved by the Institutional-Review-Board (IRB), King Abdul Aziz University Hospital, Saudi Arabia (Ref number: 612-17), and the University of Glasgow, UK (Ref number: 200170066).

Data collection

Data collection was undertaken during May to August of 2018. Each participant needed to be alert and calm, therefore, patient consciousness levels were assessed daily; similarly, the presence of delirium was assessed using the Confusion-Assessment-Method for the ICU (CAM-ICU).

Outcome measures

Patient self-report assessment of sleep quality and sleep disturbance factors:

The Arabic version of RCSQ (RCSQ-A) [15] and the modified Sleep in intensive Care Questionnaire (SICQ) [16] were administered each morning between 7.00 a.m. and noon until the day the patient was due to be discharged from the ICU. Details of study instruments can be found in online supplementary-table-1. The five questions from the RCSQ-A were read aloud to the patients and, after each question, the patients rated their previous night sleep by placing a mark on the answer line, which was 100 mm long (0 mm = poorest, 100 mm = optimum). This approach was chosen to limit the potential of recall-bias and to assure optimal reminiscence of the most recent night's sleep. Every attempt was made to ensure that there were no missing or erroneous data by screening each patient's daily assessment-sheets. Missing RCSQ-A responses from patients who had declined to complete the questionnaire were not considered and not included in the analyses because the RCSQ total-score cannot be computed if the data is incomplete.[17] The patients who declined to complete the RCSQ-A were asked to clarify whether they were not completing the questionnaire on that individual occasion, or if they were withdrawing from the study. The patients who decided to withdraw from the study were not approached again; however, their consent for data they had already given for analysis was retained. After every RCSQ-A completion, the patients were asked to rate their perception of the factors that disrupted their sleep during the previous night on the modified SICQ scale (1= no disruption to 10 = significant disruption). An open-ended question, "What other activities were disruptive to your sleep last night?" was also used. The answers were communicated verbally by most patients and in writing and through actions by some.

Other measures: demographic and clinical data

Demographic and clinical variables were collected from the patients' medical files. These included age, gender, ICU admission diagnosis, severity of critical illness using the Acute-Physiology & Chronic Health-Evaluation (APACHE II) score,[18] length of stay in ICU (ICU-LOS), nightly mechanical-ventilation statues (ventilated or non-ventilated), and medications administered during the study. None of the patients were on sedation during the assessment, however, data on previously administered sedation medications was collected.

Patients' acceptance of daily self-reporting on sleep quality using RCSQ-A during their ICU stays:

The key elements of acceptability, including patient willingness, and perceived burden (ability to provide self-reports on a daily-basis) were assessed using several indicators of acceptability, [9] including withdrawal and dropout-rates, the total number of patients who decided to discontinue at some point during the assessment and the total number of completed reports. The participants were also asked: "How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?"

Sample size

A post-hoc power analysis was conducted using G-Power software version 3.1.9.2 to perform regression-analysis for the total sample n=120 patients and to determine whether the sample size offered an effective power of at least 0.80 and a significance level of $\alpha = 0.05$. This also determined the maximum number of variables to be included in the model. The power-analysis revealed that

a sample size of 120 was adequate, given the inclusion of 16-variables, with an effective-power of 0.88, assuming a moderate effect-size (f2 =0.22). Even supposing a much smaller-effect (f2 =0.19), the power remained 0.82, which is above the usual minimum-requirement of 0.80. [19] A post-hoc power analysis was also used to perform a paired samples t-test for the sub-sample of n=43 patients who were placed on a ventilation during the study assessment. The analysis revealed that on the basis of the mean, between-two different conditions (during ventilation and after extubation), a sample size of 43 patients was adequate to obtain a statistical power of 0.89 with an effect size (d=0.5) and a significance level of $\alpha = 0.05$.

Data management and analysis

The data was analysed using IBM-SPSS version-23.0. The data were first assessed for normality using the Shapiro-Wilk's test. [20] Descriptive statistics including frequencies and percentages were used to describe the categorical data e.g. gender, admission diagnosis. The mean, range and standard deviation were used to describe the continuous data for the total sample of n=120 patients' sleep quality and sleep disruptive factors which the participants rated on a modified SICQ. Descriptive statistics were also used to describe a sub-sample of n=43 patients who had been placed on a ventilator at some point during the study period. The description included their self-reported sleep quality and sleep disruptive factors when they were on the ventilation and after they were extubated. A paired-sample t-test was performed to determine whether there was a significant difference in patients' sleep quality during ventilation and after extubation, and whether there were significant differences in self-reported sleep disruptive-factors during ventilation and after extubation that were explained by intubation status. The two-sided statistical significance level was set to 0.05 and 95% CIs were used.

The total RCSQ-A score for the total sample n=120 was converted into an estimate of the sleep efficiency-index (SEI) using the following formula: $SEI = 46.88 + (0.39 * RCSQ)$.[10,17, 21]

The correlation between daytime-sleepiness and ICU-LOS, was assessed using a Bivariate (Pearson)-Correlation. A multiple-regression was conducted for the total sample to assess the significance and relative contribution of each independent variable on predicting the dependent variable-sleep quality. To avoid overfitting the model, only the factors rated most highly by the patients were included in the model in addition to the variables of interest, reflecting the demographic and clinical characteristics derived from previous research. The appropriate modelling of continuous variables was confirmed by evaluating their linearity. The intercorrelation between independent variables for this repeated assessment was assessed using variance inflation factor (VIF) values less than 10, and tolerance values greater than 0.1. It was addressed by re-categorizing the relevant collinear variables. The majority of patients (87.5%) in this study received non-opioid analgesics alongside opioid-fentanyl analgesics. To avoid multicollinearity, these two variables were combined into a single-variable and entered as "analgesic". The independence of observation (residuals) was assessed by Durbin-Watson statistic values of 1.299. Content analysis was used to interpret and synthesise the data collected in the open-ended questions.[22]

RESULTS

A total of 354 patients were screened, of whom 224 were excluded because they did not meet the inclusion criteria (Figure-1). The remaining 130 patients met the inclusion criteria, however, 10 patients were unwilling to participate in any research studies and declined to participate, leaving 120 patients enrolled. The average age of the patients was 59, and the majority (60%) were male. The participants' APACHE II-score within 24 hours of ICU admission ranged from 10-24 with an average of 15.78 ±2.606. More than half the participants had an APACHE-II score between 10 and 16 n=71 (59.2%); meanwhile 49 participants (40.8%) had a higher score between 17-24. The average ICU-LOS was 9.35 days ±3.15. Patients who had an APACHE-II score between 10 and 16 stayed in the ICU for 4-12 days. In addition, patients who had a score between 17-24 stayed in the ICU for 6-21 days. Of the study sample, 43 (35.8%) patients were on mechanical ventilation (MV). Table 1 provides a summary of the sample demographic and treatment characteristics during the study assessment.

Table 1 Demographic and clinical characteristics of patients (n=120)

Characteristics	Category	n (%)	Range
Age (Mean ±SD)	59.7±9.44		19.00- 75.00
Gender	Male	72 (60)	
	Female	48 (40)	
Admission diagnosis	Medical cardiac	21(17.5)	
	Medical respiratory	21 (17.5)	
	Gastrointestinal	11 (9.1)	
	Other	8 (6.7)	
	Surgical post-operative	59 (49.2)	
	Cardiothoracic	37 (30.9)	
	Thoracic traumatic	12 (10)	
	Abdominal	10 (8.3)	
APACHE II score (Mean ±SD)	15.78 ±2.606		10.00-24.00
	Low	71 (59.2)	10.00-16.00
	Medium	49 (40.8)	17.00-24.00
Length of ICU stay (Mean ±SD)	9.35±3.15		4.00-21.00
Medications [a]	Beta blockers	75 (62.5)	
	Diuretics	76 (63.5)	
	Calcium channel blockers	99 (82.5)	
	Corticosteroids	45 (37.5)	
	Adrenergic	39 (32.5)	
	Non-Opioid and Opioid	105 (87.5)	
	Non-Opioid-Paracetamol	15 (12.5)	
Sedation	Propofol	54 (45)	
	Benzodiazepines (Midazolam)	40 (33.3)	
	Dexmedetomidine (Precedx)	26 (21.7)	
RASS score on enrolment [b]	Alert and calm (zero-score)	120 (100)	
GCS [c]	Fully conscious (15-score)	120 (100)	
Developed delirium	Positive CAM-ICU [d]	11 (9.2)	
Intubation statues	Intubated	43 (35.8)	
Method of ventilation	Invasive ventilation [e]	30 (69.8)	
	Non-invasive[f]	13 (30.2)	
Duration of MV (Mean ±SD)	6.26 ±3.381		2.00-17.00

[a] Beta blocker=Metoprolol, Carvedilol; Diuretics= metolazone, furosemide, amiloride; Calcium channel blockers= amlodipine, verapamil; Corticosteroids = prednisolone, dexamethasone, hydrocortisone; Adrenergic= noradrenaline, adrenaline or dopamine [b] Richmond Agitation Sedation Scale, [c] Glasgow Coma Scale, [d] Confusion Assessment Method for the ICU, [e] ventilation applied via tracheotomy or endotracheal. [f] Ventilation applied via face or nasal mask.

Participants' self-reported assessments of sleep and sleep disruptive factors

The average sleep quality as reported by the patients was poor, with mean scores for each of the RCSQ-A elements below 50 mm (Table-2). Furthermore, the mean SEI was 60.3%, and a SEI less than 85% indicates poor sleep quality. [17] In contrast, the average self-reported sleep quality at home was described as good, with a mean score of 7.16 ±1.754. The average daytime-sleepiness score was 5.52 ±1.52, and daytime sleepiness did not change significantly over the course of any patient's ICU stay (p>0.05). Multiple factors were reported to disrupt patients' sleep (Table-3). Patients rated noise as the most disruptive extrinsic factor at 7.48±1.57, followed by clinical interventions at 5.95±1.57; the highest rated noise was talking at 6.80±1.25, while the highest-rated intrinsic disruptive factor was fear at 3.64±2.01. Supplementary-table-2 shows patients' comments on other factors that disrupted their sleep, including the categories and the sub-categories that emerged from content-analysis in accordance with Edéll-Gustafsson et al. [23]

Table 2 Cohort patients' self-report of sleep quality, (n=120)

Richards-Campbell items	Mean ±SD	*Range*
(RCSQ-A.1) Sleep depth	31.82±7.03	19-56
(RCSQ-A.2) Falling asleep	33.07±6.73	21-54
(RCSQ-A.3) Awakenings	35.06±5.76	18-47
(RCSQ-A.4) Returning to sleep	36.29±5.36	25-50
(RCSQ-A.5) Overall sleep quality	35.36±5.34	22-51
Total RCSQ-A score [a]	34.41±5.60	23-48
SEI [b]	60.30	

[a] Total RCSQ-A = average of 5 items (Q1-Q5). The total RCSQ-A score was categorized, with a cut off-point of <26 indicating very poor sleep quality, a score of [26-50] indicating poor sleep quality, a score of [51-75] indicating good sleep quality, and a score of >75 indicating very good sleep quality [24,25]

[b] SEI= Sleep efficacy index= < 85% indicates poor sleep quality.

Table 3 Self-reported sleep disruptive factors on modified SICQ, (n = 120)

Sleep disruptive factors in rank order	Mean ±SD	*Range*
Noise	7.48±1.57	3.00-9.00
Clinical interventions (i.e. blood samples, vital signs, etc.)	5.95±1.86	2.30-9.00
Light	2.36±0.94	1.00-5.00
Talking	6.80± 1.25	1.00-9.00
Machines' alarm (i.e. heart monitor, ventilator, etc.)	4.31±2.35	1.00-9.00
Telephone	1.12±0.36	1.00-7.30
Fear	3.64±2.01	1.00-8.25
Pain	2.30±1.10	1.00-7.30
Discomfort of being attached to the devices	2.26±1.18	1.00-5.75

Factors affecting sleep quality

The predictor variables included in the multiple-regression model were noise, clinical-interventions, talking, machine-alarms, and fear, in addition to the intrinsic factors of age, gender, daytime-sleepiness, APACHE II-score, ICU-LOS, analgesic use, MV status, and previous receipt of sedation using Midazolam, Propofol, and Precedx. The full model (Table-4) explained 39.3% of the variance in total sleep quality, a statistically significant predictor of total sleep quality, with the R^2 = 0.423, F (6.113) = 13.828, and p < 0.0005. The factors which negatively and significantly affected sleep quality (given as [exp(b)(95% CI), p value]) were Midazolam [-6.424 (-8.99– -3.86), p < 0.0005], Propofol [-3.600 (-5.71– -1.49), p<0.05], noise [-1.033, (-1.70– -0.364), p<0.05], and the presence of a ventilator [-1.218 (-2.36- -0.077) p<0.05]. Total sleep quality was also significantly affected by differences in gender such that predicted sleep quality for female patients was greater than for male patients [1.836 (0.157– 3.52) p<0.05]. Furthermore, daytime-sleepiness significantly affected the patients' sleep: using a daytime-sleepiness scale where 1 = unable to stay awake, and 10 = fully alert and awake, any increase on the scale was associated with a significant increase in total sleep quality [0.856 (0.175– 1.54) p<0.05].

Table 4 Model summary of the stepwise multiple regressions predicting total sleep quality from sleep disruptive factors with (adjusted R^2 = 0.393)

Variable	*B* [a]	R^2	ΔR^2	*F* [b]	*(95.0% CI)* [c]	*P*
Midazolam	-6.424	0.222	0.222	33.719**	(-8.99– -3.86)	<.0005**
Propofol	-3.600	0.287	0.065	23.541**	(-5.71– -1.49)	0.001*
Gender	1.836	0.340	0.053	19.914**	(0.157– 3.52)	0.032*
Noise	-1.033	0.373	0.033	17.097**	(-1.70– -0.364)	0.003*
Daytime sleepiness	0.856	0.401	0.028	15.236**	(0.175– 1.54)	0.014*
Nightly mechanical ventilation status	-1.218	0.423	0.023	13.828**	(-2.36– -0.077)	0.037*

[a] B= unstandardized regression coefficients, [b] F=test of overall significance, [c] CI=confidence interval, **highly significant; * p<.05

Self-reported sleep quality and sleep disruptive factors reported by participants during intubation and after extubation

The sub-sample of 43 patients who were placed on MV during the study reported sleep quality during intubation (31.88 ±6.16) as much poorer than after extubation (35.04±6.47); these differences were significant with p <0.0005. Patients reported sleep fragmentation as the greatest disturbance during intubation (30.63 ±5.79). Following extubation, the number of awakenings was significantly reduced, to a mean of 36.81±6.83 (Table-5). There were significant differences between the level of reporting for several sleep disruptive factors during ventilation and after extubation (p<0.05), as shown in Figure-2. During ventilation, machine alarms, clinical intervention, and fear were rated as causing high levels of sleep disruption (7.19±1.13, 7.04±2.04, and 6.32±1.81, respectively). However, following extubation, these levels of disruption reduced significantly,

causing only moderate to mild levels of disruption (4.68±1.37,6.07 ±2.34, and 2.72±1.34, respectively).

Table 5 Self-reported sleep quality of patients when they were intubated and after extubation, (n=43).

RCSQ-A items	*Patients on ventilation n= (43)*		*Patients after extubation n= (43)*		P value [a]
	Mean ±SD	Range	Mean ±SD	Range	
Depth of sleep (RCSQ-A.1)	32.00±9.13	21-53	33.43±8.58	18-51	.001*
falling asleep (RCSQ-A.2)	33.00±8.67	19-53	34.38±8.41	22-56	.001*
Number of awakenings (RCSQ-A.3)	30.63±5.79	15-41	36.81±6.83	19-56	< .0005**
Returning to sleep (RCSQ-A.4)	31.85±5.50	21-40	36.20±5.99	28-49	< .0005**
Overall sleep quality (RCSQ-A.5)	32.14±5.51	21-41	34.40±5.54	25-47	< .0005**
Overall (RCSQ-A) Score [b]	31.88±6.16	20-45	35.04±6.47	24-49	< .0005

[a] Paired t test, *p< .05; **p< .0005 is highly significant.

Patients' acceptance of making daily self-reports on sleep quality using RCSQ-A during ICU stays

Dropout and withdrawal rates: The number of patients who dropped out by choosing to stop participating was very small at n=3 (2.5%). No reasons for such cessations were provided. The number of withdrawals was also very small at n=11 (9.2%). These patients were withdrawn because they no longer met the study's inclusion criteria, as they had become agitated and developed delirium. The majority of participants, n=106 (88.4%), were able to complete study participation in full.

Number of completed self-reports (RCSQ-A): In total, 381 reports were collected from 120 participants. The answers to the open-ended question confirmed that most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stay in the ICU. However, some of the participants, n=17 (16.1%), at some point during the repeated-assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored (Supplementary-material-3).

***Experiences of completing the RCSQ-A*:** The time taken to complete RCSQ-A was between two and three minutes. The participants completed the RCSQ-A between one and six times, with the average being three times. In total 111 patients (92.5%) provided more than one RCSQ-A, while only nine participants (7.5%) provided a single self-report. Four of the participants became delirious and agitated on the second day of assessment, while three patients asked to stop participating; two patients were discharged from the ICU on their second day of assessment. Among the study participants, 68 (56.7%) were unable to set a mark on the VAS themselves, requiring assistance due to physical barriers such as hand tremors and muscle weakness. These patients were only able to point at their chosen spots on the scales.

DISCUSSION

This study was designed to assess the acceptability of ICU patients' completion of daily self-reports (RCSQ-A) on their sleep quality throughout their ICU stay and to assess self-reported sleep quality and sleep disruptive factors on a daily basis until patients were discharged from the unit. It is important to study sleep quality and sleep disruptive factors simultaneously to develop a comprehensive picture of the patients' sleep quality and the factors that disrupt it. We considered that this would inform the future development of strategies to improve patients' sleep in the ICU. A review of the literature suggests that this is the first study on ICU patients' experience of completing daily self-reports on their sleep quality during their ICU stay. It is also the first study that has assessed self-reported sleep quality using a valid tool (RCSQ-A) and self-reported sleep disruptive factors in ICU patients in an Arabic-speaking country in the Middle-East.

There was evidence of general poor sleep quality in this cohort of ICU patients. The overall quality of sleep from the patient perspective was 34.41, which is lower than the reported findings in previous studies.[10, 12, 26,27,28,29,30] The SEIs emerged at 60.3%, matching the results from a group of ICU patients in the United Kingdom[29] used as a control, in which the SEIs were 60.8%, and slightly lower than reported in the repeated self-report assessment study from Australia (60.3% vs. 65%).[10] In this study, patient perception of sleep varied between poor to very poor in contrast to other self-report assessment studies in which patients' sleep varied from very good to very poor.[12,26,24,25,30] These differences may be due to the different treatment characteristics of the patients, as this study included intubated patients, and the different ICU environment. Differences in the method of sleep quality assessment could also have influenced these results. The current results are based on continuous assessment until discharge from the ICU, while the majority of previous studies limited assessment to a single night. [6,21,26,31] Only three previous studies used RCSQ for repeated-assessment, [10,11,12] and their assessments were limited to non-intubated patients. The finding that patients' sleep is reported as worse in the ICU than at home is consistent with previous studies. [6,16,21,31] This indicates that there are factors within these environments which may lead to changes in and disruption to patients' sleep.

The results demonstrated that daytime-sleepiness was consistent with lack of sleep during the night and that perceived daytime-sleepiness did not improve over the course of patients' ICU stay. These results are consistent with previous polysomnographic and self-report studies, [31,32] which showed that between 40 and 50% of total sleep time in an ICU occurs during the day, and that this altered sleep pattern did not improve over the course of the stay. It is known that female subjects experience additional slow wave sleep, and this is reflected by the observed gender differences in patients' sleep in this study: female patients slept better than male patients. This supports a recent study that found that female patients had better sleep than males.[31] Our results showed that multiple sleep disrupting-factors were identified by the entire sample, which substantiates other results. Of the extrinsic-factors, patients rated noise as the most disruptive, supporting the findings of previous studies. [3,16,33,34] Peak noise levels in the ICU were documented at 41dB and 68 dB, [34,35,36] exceeding the World-Health-Organisation's (WHO) recommendation for sound levels in an ICU not to exceed 35 dB during the day and 30 dB at night.[37]The results also support the idea that interruptions of sleep in the ICU caused by clinical-interventions are important. This finding is consistent with the results of Celik et al,[38] who found that patients had their sleep interrupted by human-interventions an average of 51-times each per night. However, in addition to these,

psychological factors cannot be ignored. Patients reported fear to be the most disruptive intrinsic-factor; they also referred to nightmares and worries, corroborating previous study findings. [24,25,10]

The effects of sedation in the ICU have not been studied sufficiently. None of the patients were on sedation during this assessment, however, data on previously administered sedation were gathered. Sedatives, especially benzodiazepines, are commonly used to induce sleep, however, these have been known to supress slow-wave (SWS) and rapid-eye-movement sleep (REM) after withdrawal.[39] Propofol has shown to increase SWS while suppressing REM sleep.[32] Interestingly, patients who received benzodiazepines had worse sleep quality than patients who received Propofol. However, both forms of sedation significantly affected patients' sleep quality. The adverse effects of many sedatives have been well documented, and thus sedatives should not be used for sleep promotion in most cases;[8] in addition, patients receiving these drugs should be carefully monitored with regard to the quality of their sleep.

The negative effects of the presence of MV on patients' sleep quality have been reported in several polysomnographic studies. [32,40,41] However, this is the only self-report study include intubated patients and assessed their perception of sleep quality alongside their perceptions of sleep disruptive-factors on a daily basis both during intubation and after extubation to determine whether the ventilator has an effect on the patients' perception of sleep and the factors that disrupt their sleep. Intubated patients reported better sleep quality following extubation and the differences were statistically significant. However, to date there is no information which provides guidance about clinically important changes in the RCSQ scores, and thus it is difficult to make too much of the result. The patients also reported sleep fragmentation to be greater during intubation than after extubation. Furthermore, during ventilation, the factors of machine-alarms, clinical-interventions, and fear were rated by the patients as the most disruptive factors, while after extubation, the level of disruption reduced significantly. One possible explanation for high sleep-fragmentation during intubation is the disruptive factors that arise from or are increased by the presence of the ventilator, such as alarms, clinical interventions and feelings of fear. Freedman et al.[5] assessed the sleep quality of ventilated patients and demonstrated that sleep was highly fragmented; they suggested that this may be due to the multiple human-interventions during ventilation. Our findings stress the need for attention to be paid to the sleep quality of this group of patients, with close monitoring for factors that may adversely affect sleep. In particular, environmental factors such as noise from alarms should not be overlooked. Such impacts should be handled properly by following guidelines such as the Joint Commission (JCI) policies on safely managing clinical alarm systems to avoid false alarms. [42] Clustering patients' care activities as much as possible and avoiding performing unnecessary care activities during the night is also important for managing these factors. Where MV is present, the patients may experience distressing psychological side effects such as fear, [43,44] therefore, it is important to consider the individual patient's psychological needs.

Our results demonstrated that daily self-report assessments on sleep-quality using the RCSQ-A was non-burdensome to the majority of participants. Therefore, it is somewhat surprising that the use of RCSQ for repeated assessment in ICUs is only infrequently published, with only three main studies of this type. [10,11,12] Two were conducted in Australia, [10,12] with one featuring 151 participants reporting on their sleep using the RCSQ 356 times where 50% of the participants were able to report on two or more days;[10] the other Australian study [12] featured 50 patients reporting, and the completion rate was 72%. The third study, in North America, [11] featured 33 patients over

137 days completing 121 self-reports, giving a rate of 88%. These studies and our own completion rate of 92.5% provide evidence to support the tool's feasibility for routine assessment of patients' sleep in ICUs. The patients in this study generally described their experience of completing the RCSQ-A during their stays positively. The patients were happy and reported that various psychological and social needs were met by this method of assessment. For example, they felt a sense of security, enhanced communication levels, reduced feelings of loneliness, and a sense that someone respected and cared about their need for sleep. These results support a recent qualitative study [45] that found that patients who felt well taken care of felt more relaxed and reported that their sleep was positively affected.

According to the daily self-report assessment of both sleep quality and sleep disruptive-factors, sleep disruptive-factors were evaluated differently from day to day and patient to patient despite the constant setting. Therefore, the findings do not support the hypothesis that ICU noise is the main factor responsible for sleep disturbance for all ICU patients. [46] Patients' sleep disruption is influenced by several interrelated factors that constantly change due to the nature of the ICU environment. Sensitivity to sources of sleep disruption also varies from patient to patient.[32] Unfortunately, individual differences were not considered in most recent intervention studies that aimed to improve sleep in the ICU by developing and applying protocols.[21,27,29,30] Recent guidelines[8] also revealed problems with the methodology in these intervention studies, highlighting the need for well-designed nonpharmacological-measures and improved methods for measuring sleep to allow the implementation of interventions with individualised approaches.

Our findings demonstrate the acceptability and feasibility of using repeated, self-reported RCSQ assessments of sleep quality in ICU environments. Such assessments can be performed whenever the patients are sufficiently alert, and they do not need to be able to communicate verbally. The findings also encourage clinicians routinely inquire about patients' sleep and, implement routine early documentation of sleep patterns using RCSQ in the patient care-plans. Patient perceptions of the factors disrupting sleep should be identified individually to determine the patient-specific needs to address sleep disturbances with treatment-decisions. Furthermore, patients should be involved in their care; this corresponds with the Institute for Healthcare-Improvement's (IHI) identification of patient-safety as one driver of exceptional patient-centred care.[47,48]However, it would be valuable to further validate the RCSQ in intubated ICU populations, as the original validation was performed using PSG in non-intubated patients.[17] This additional validation would enhance the promotion and use of this instrument for the purposes of ongoing assessment over various points of the patients' ICU stays. Further studies are required to test acceptance in other populations of ICU patients in different countries and regions. Further work is also required to assess the perceptions and acceptance of health care providers in ICUs in terms of implementation. The quality of sleep was poor in all participants in this case, highlighting the need for further testing in Middle-Eastern countries. The facilitation of high-quality sleep for ICU patients is often overlooked by healthcare professionals. However, the results of this study suggest that better education should be provided regarding the negative effects of poor sleep for patients, and training should be established to allow healthcare providers to mitigate these effects. Additionally, to ensure high standards of care in the ICU, hospitals should not only introduce policies to avert sleep disturbances but should also regularly assess the sleep quality of patients, aiming to allow patients sufficient rest periods of a minimum of 90 mins to experience a full sleep cycle. To meet these aims, individual patient planning may be required.

This study had several limitations, which must be acknowledged. Selection bias is possible, as all patients selected to participate were non-sedated; this was necessary, as sedations affect cognitive abilities, and, therefore, would affect the validity of the results. However, this means that the results are not generalisable to the whole ICU-patient population. Nevertheless, this is an important patient population to study, especially as it includes patients in the period after sedation cessation, when regular-assessment of sleep quality that may be affected by the previously received sedation is necessary. The other issue with the findings is generalisability; half of the study sample were post-operative surgical ICU patients and most of them were cardiac patients. This limits the study's findings to these particular patients. Future research will be required in a broader critical care population. The aim was to assess sleep quality subjectively from a patient perspective, consequently, changes in sleep-architecture were not observable, due to the use of a self-report tool. However, routine-use of objective-methods of assessment such as PSG-monitors during patient care is not feasible, and the clinically meaningful outcome of sleep quality is the patient's experience. [8,12]

CONCLUSION

Sleep quality was reported as poor by all participants. The factors affecting sleep were multiple and varied from patient to patient, stressing the need to regularly and individually assess patients' sleep quality, and the importance of adopting patient-centred care, including an individual sleep care plan for each patient. The results also demonstrated the feasibility and the acceptability of

ICU patients completing daily self-reports of their sleep quality using the RCSQ-A during their ICU stays.

REFERNCES

1. Parthasarathy S, Tobin MJ. Sleep in the intensive care unit. *Intensive Care Med* 2004;30:197–206.
2. Elliott R, Rai T, McKinley S. Factors affecting sleep in the critically ill: an observational study. *J Critc Care* 2014;29:859-63.
3. Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.7.
4. Jeffs EL, Darbyshire JL. Measuring sleep in intensive care unit: a critical appraisal of the use of subjective methods. *J Intensive Care Med* 2017;1–10.
5. Hoey LM, Fulbrook P, Douglas JA. Sleep assessment of hospitalised patients: a literature review. *Int J Nurs Stud* 2014;51:1281–1288.
6. Elliott R, McKinley S, Cistulli P, Fien M. Characterisation of sleep in intensive care using 24-hour polysomnography: an observational study. *Crit Care* 2013;17:R46.
7. Knauert MP, Yaggi HK, Redeker NS, et al. Feasibility study of unattended polysomnography in medical intensive care unit patients. *Heart Lung* 2014;43:445–452.
8. Devlin JW, Skrobik Y, Gélinas C, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Crit Care Med* 2018;46:825-873.
9. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
10. Aitken LM, Elliott R, Mitchell M, et al. Sleep assessment by patients and nurses in the intensive care: an exploratory descriptive study. *Aust Crit Care* 2017; 30: 59–66.
11. Kamdar BB, Shah PA, King LM, et al. Patient-nurse interrater reliability and agreement of the Richards-Campbell sleep questionnaire. *Am J Crit Care* 2012;21:261–269.
12. Menear A, Elliott R, L MA, et al. Repeated sleep-quality assessment and use of sleep-promoting interventions in ICU. *Nurs Crit Care* 2017;22:348-54.
13. Fischer M, Rüegg S, Czaplinski A, et al. Inter-rater reliability of the Full Outline of Unresponsiveness score and the Glasgow Coma Scale in critically ill patients: a prospective observational study. *Crit Care*. 2010;14:R64.
14. Sessler CN, Gosnell MS, Grap MJ. et al. The Richmond Agitation–Sedation Scale. *Am J Respir Crit Care Med* 2002;166:1338–1344.
15. Al-Sulami G, Rice AM, Kidd L, et al. An Arabic translation, reliability, validity and feasibility of the Richards-Campbell Sleep Questionnaire for Sleep Quality Assessment in Intensive Care Unit: Prospective-Repeated Assessments. *J Nurs Meas* (forthcoming).
16. Freedman NS, Kotzer N, Schwab RJ. Patient perception of sleep quality and etiology of sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 1999;159:1155–1162.
17. Richards KC, O'Sullivan PS, Phillips RL. Measurement of sleep in critically ill patients. *J Nurs Meas* 2000;8:131–44.
18. Knaus WA, Draper EA, Wagner DP, et al. APACHE II: a severity of disease classification system. *Crit Care Med* 1985;13:818–29.
19. Cohen J. A power primer. *Psychol Bull* 1992;112:155–9.
20. Shapiro SS, Wilk MB. An Analysis of Variance Test for Normality (Complete Samples). *Biometrika* 1965;*52*:591-611.
21. Li SY, Wang TJ, Vivienne Wu SF, et al. Efficacy of controlling night time noise and activities to improve patients' sleep quality in a surgical intensive care unit. *J Clin Nurs* 2011;20:396–407.

22. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15:398-405.
23. Edéll-Gustafsson U, Arén C, Hamrin E, et al. Nurses' notes on sleep patterns in patients undergoing coronary artery bypass surgery: a retrospective evaluation of patient records. *J Adv Nurs* 1994; *20*:331-336.
24. Frisk U, Nordström G. Patients' sleep in an intensive care unit: patients' and nurses' perception. *Intensive Crit Care Nurs* 2003;19:342–349.
25. Krotsetis S, Richards KC, Behncke A, et al. The reliability of the German version of the Richards-Campbell sleep questionnaire. *Nurs Crit Care* 2017;22:247–252.
26. Nicolás A, Aizpitarte E, Iruarrizaga A, et al. Perception of night-time sleep by surgical patients in an intensive care unit. *Nurs Crit Care* 2008;13:25–33.
27. Kamdar BB, King LM, Collop NA, *et al*. The effect of a quality improvement intervention on perceived sleep quality and cognition in a medical ICU. *Crit Care Med* 2013;41:800–809.
28. Ritmala-Castren M, Axelin A, Kiljunen K, et al. Sleep in the intensive care unit-nurses' documentation and patients' prespectives. *Nurs Crit Care* 2014;22:238-246.
29. Patel J, Baldwin J, Bunting P, et al. The effect of a multicomponent multidisciplinary bundle of interventions on sleep and delirium in medical and surgical intensive care patients. Anaesthesia 2014;69:540–549.
30. Elliott R, McKinley S. The development of a clinical practice guideline to improve sleep in intensive care patients: a solution focused approach. *Intensive Crit Care Nurs* 2014;30:246–256.
31. Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.7.
32. Freedman NS, Gazendam J, Levan L, et al. Abnormal sleep/ wake cycles and the effect of environmental noise on sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 2001;163:451–7. 5
33. Salandin A, Arnold J, Kornadt O. Noise in an intensive care unit. *J Acoust Soc Am* 2011;130:3754–3760.
34. Simons KS, Verweij E, Lemmens PM, et al. Noise in the intensive care unit and its influence on sleep quality: a multicenter observational study in Dutch intensive care units. *Crit Care* 2018;22:250.
35. Park M, Kohlrausch A, de Bruijn W, et al. Analysis of the soundscape in an intensive care unit based on the annotation of an audio recording. *J Acoust Soc Am* 2014;135:1875–1886.
36. Darbyshire JL, Young JD. An investigation of sound levels on intensive care units with reference to the WHO guidelines. *Crit Care* 2013;17:R187.
37. Berglund B, Lindvall T, Schwela DH & World Health Organization Occupational and Environmental Health Team. Guidelines for community noise. 1999. http://www.who.int/iris/handle/10665/66217
38. Celik S, Oztekin D, Akyolcu N, et al. Sleep disturbance: the patient care activities applied at the night shift in the intensive care unit. *J Clin Nurs* 2005;14:102–6.
39. Pisani MA, Friese RS, Gehlbach BK, et al. Sleep in the intensive care unit. *Am J Respir Crit Care Med* 2015;191:731–8.
40. Cooper AB, Thornley KS, Young GB, et al. Sleep in critically ill patients requiring mechanical ventilation.*Chest* 2000;117:809–818.
41. Beecroft JM, Ward M, Younes M, et al. Sleep monitoring in the intensive care unit: comparison of nurse assessment, actigraphy and polysomnography**.** *Intensive Care Med* 2008;34:2076–2083.

42. The Joint Commission. The Joint Commission announces 2014 national patient safety goal, 2013. Available from. http://www.jointcommission.org/assets/1/18/jcp0713_announce_new_nspg. pdf2016.
43. McKinley S, Fien M, Elliott R, et al. Sleep and psychological health during early recovery from critical illness: an observational study. *J Psychosom Res* 2013;175:539-45.
44. Rotondi AJ, Chelluri L, Sirio C, et al. Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. *J Crit Care Med* 2002;30:746-52.
45. Ding Q, Redeker NS, Pisani MA, et al. Factors influencing patients' sleep in the intensive care unit: perceptions of patients and clinical staff. *Am J Crit Care* 2017;26:278.
46. Gabor JY, Cooper AB, Crombach SA,et al. Contribution of the intensive care unit environment to sleep disruption in mechanically ventilated patients and healthy subjects. *Am J Respir Crit Care Med* 2003;167:708–715.
47. Perlo J ,Balik B , Swensen S , *et al* . *IHI framework for improving joy in work*. Cambridge, MA: Institute for Healthcare Improvement, 2017.
48. Gandhi TK, Kaplan GS, Leape L, et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf* 2018;27:1019-26.

Legend text

Figure 1 Flow diagram of patients screening , enrolment and participants RCSQ-A completions.

Figure 2 Significance of changes in the self-reported sleep disruptive factors during intubation and after extuabtion

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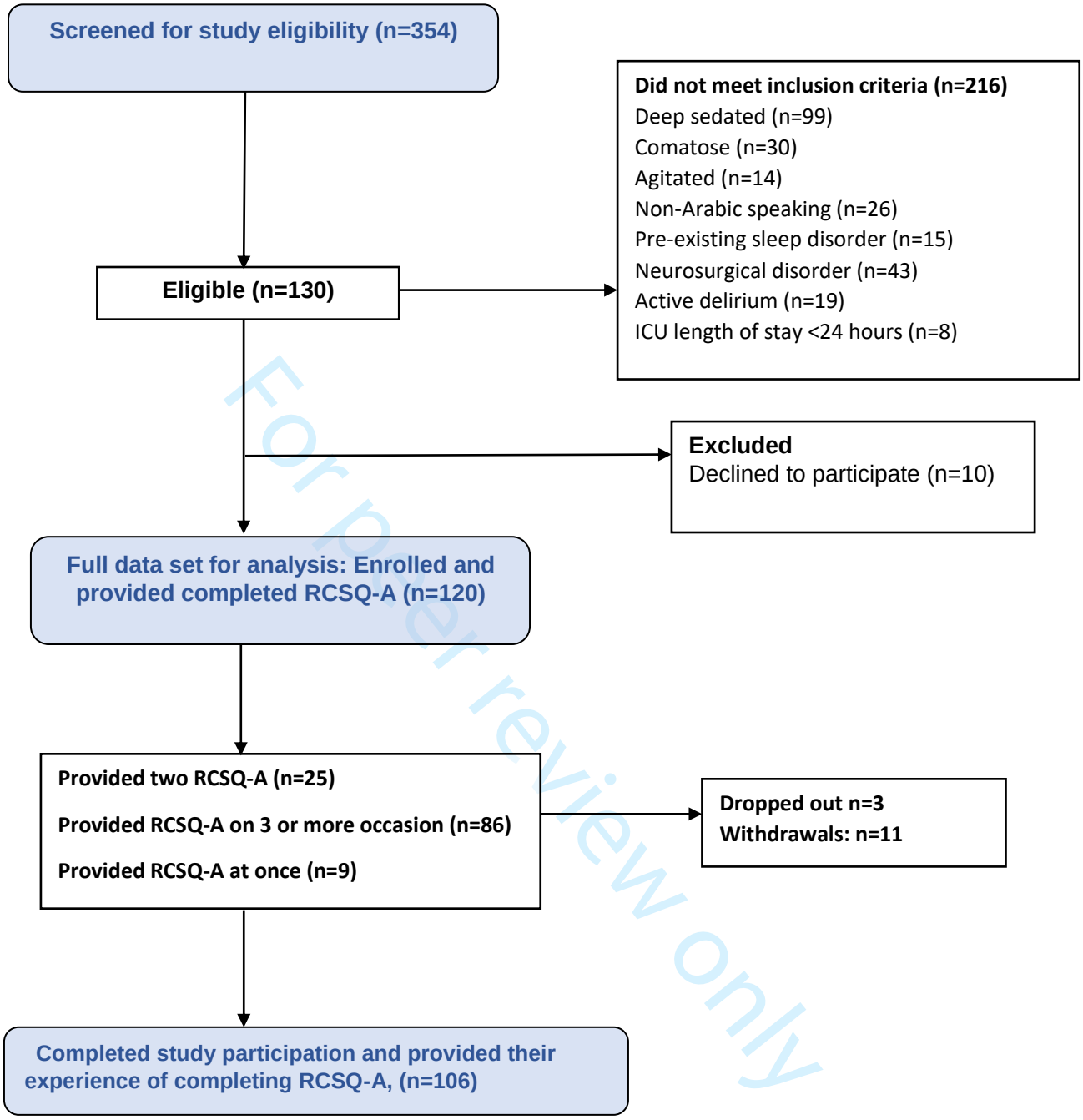

Figure 1. Flow diagram of patients screening, enrollment and participants RCSQ-A completions.

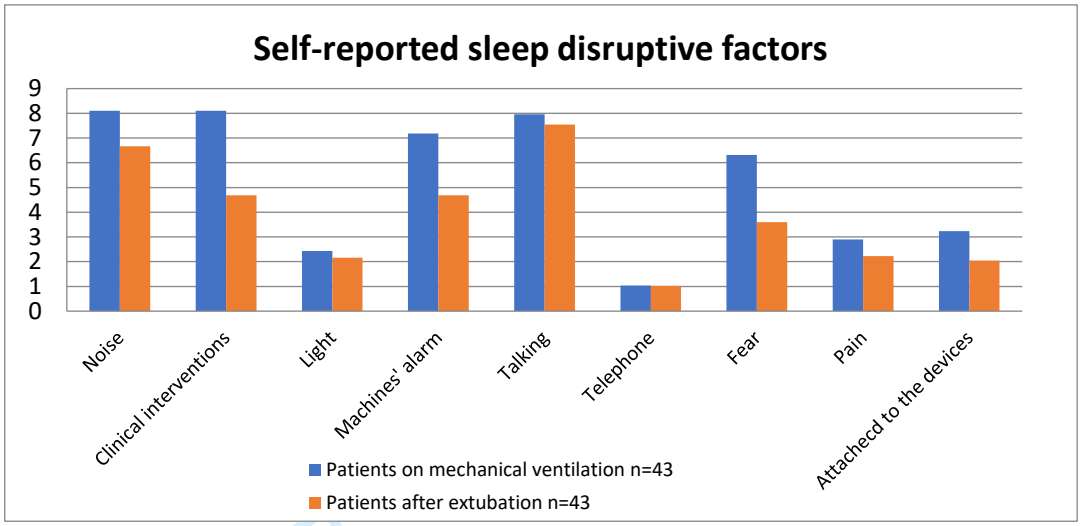

Figure 2. Significance of changes in the self-reported sleep disruptive factors during intubation and after extubation

Supplementary-1: Study instruments

1. The Arabic version of RCSQ (RCSQ-A) was used to assess patients' perceptions of their sleep quality. This questionnaire is a brief self-report tool that asks respondents to rate the previous nights' sleep on a five-item visual analogue scale (VAS).[17] Each VAS represents a different aspect of sleep: sleep depth, falling asleep, number of awakenings, returning to sleep, and overall quality of sleep. The RCSQ has been validated against the PSG and demonstrates a reliability coefficient of 0.90.[17] It also demonstrates good internal consistency, with scores of 0.88 to 0.92, throughout numerous translations including Arabic, German, Spanish, and Swedish.[15,24,25,26] The RCSQ total score is an overall assessment of sleep quality, with a higher total score relates to a higher quality of sleep experienced by the patient.[17] The cut-off scores for the RCSQ-A that used were based on the studies by Frisk Nordström et al.[24] and Krotsetis et al.[25] Patient responses were categorised into the following four classes; very poor = very low rating <26; poor = low rating, between 26-50; good = moderate, rating between 51-75; very good = high rating >57.

   The translation of the RCSQ was carried out by Alsulami et al.[15] according to translation guidelines laid down by the World Health Organisation (WHO), and with back-translations authorised by the RCSQ developer, Professor K. Richards.[17] The authors evaluated the clarity of the translated version (RCSQ-A) using cognitive debriefing methods to assess a sample of ICU patients' understanding of RCSQ-A 5-items. The RCSQ-A was shown to have a very good internal consistency, with a Cronbach's alpha measurement of 0.89 in 56 alert ICU patients, in Saudi Arabia. It also proved itself to be a simple tool with a scoring system that Arabic speaking ICU patients found easy to understand. [15]

2. To identify factors disrupting patients' sleep, a modified Sleep in Intensive-Care Unit Questionnaire (SICQ)[16] was used. The SICQ has 27 items under the headings sleep quality (five-items), daytime sleepiness (four-items), and sleep disruptive factors (18-items). The SICQ was developed in the 1990s by researchers who performed factor-analysis and reported that the questionnaire appears to be internally valid. While this requires further validation with the PSG monitor, it has nonetheless been used in many studies. [3,6,21,29] In the current study, measures of content and face validity, including peer review by an expert-panel (healthcare providers expert in ICU work) were completed, followed by a pilot test of the SICQ with 56 patients. Subsequently, the items that required participants to retrospectively rate their sleep quality on discharge were removed to prevent recall bias. The items for sleep interruptions from television noise and doctor pagers were also removed as these were not used in the ICU. Items regarding several similar sources of noise (heart monitor alarms, ventilator alarms, I.V. pump alarms) were collated into one category item (machine alarms), and diagnostic-testing, vital-signs, blood-samples, and administration of medication were similarly collated into the category item clinical interventions. The decision to categories these items was made to ensure that the self-administered SICQ was short and simple, which was particularly important for critically ill patients to lessen the burden of the questionnaire. In addition, it was considered that patients might not accurately remember or detect the source of an alarm that caused sleep disturbance during the previous night, as the ICU environment has many complicated machines. Factors of fear, pain and being attached to machines were, however, added, based on patient answers in the pilot-test. The questionnaire demonstrated good face validity and was easily understandable for patients, as judged by a lack of comments on difficult or ambiguous items.

Supplementary-2 Categories arising from the comments of patients in relation to the open-ended question in the modified SICQ "What other factors or activities were disruptive to your sleep during last night?

Category	Subcategories	NO. patients
Environmental factors	**(Noise disruption)**	
	-Voices of other patients *'I wok every time because of the sounds of suction of patient next to me'* *'I could not sleep last night because of the man who was moaning all night'*	28
	-Sounds of footsteps/moving equipment *'I slept on and off, there was footsteps sounds along the night'* *'Sometimes I could hear moving of equipment, sounds of people steps, I did not sleep well because all of that'*	9
Patient factors	**(Psychological factors)**	
	-Worries *'I did not sleep until the morning, I was worried'* *'I was worried about whether I'd be better or not'* *'I was concerned and thinking all night about my family'*	20
	-Nightmares *'I wok every time last night of bad dreams'* *'I was so scared, and I could not sleep of a terror dream'*	15
	Clinical condition factors	
	-Coughing *'I did not sleep because of the coughing all night'* *'I have a very bad cough which keeping me awake'*	18
	- Choking sensation *'I could not sleep of a chocking feeling I was breathing through my mouth'* *'I woke up of sudden chocking feeling and I could not get back again to sleep'*	10 7
	-Nausea *'I had bad sleep of unpleasant nausea'* *'I had feeling of throwing up all night, I could not sleep'*	

Supplementary-3 Patient perception in making daily-self-reports using RCSQ-A
Most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stays in the ICU. Most of them found the questionnaire simple to complete and easy to understand *"It was easy to answer the questionnaire, I was just pointing".* *"The questionnaire was simple and short".*
Some patients noted that answering made them feel safe, suggesting that someone was paying attention to their needs with regard to sleep quality *"I felt safe having someone asking about my sleep"* *"I felt happy to find someone asking about my sleep, especially at that time no one was caring about this problem I have".*
Some patients found the daily self-report assessment enhanced their communication levels and reduced feelings of loneliness. *"I was feeling happy at that time when I was on the ventilator machine, unable to talk and when you come to me and try to communicate with me"* *"I was feeling lonely most of the time, everybody was busy, so I was pleased that I had opportunity to interact with someone"*
Other patients found that daily assessment of their sleep quality improved their awareness of the importance of adequate sleep for health, causing them to pay more attention to their sleep. *"It is really opened my eyes on how is important to my health to get enough sleep"* *"The assessment was at each morning which gave me attention that my sleep is important to me"*
Some of the participants, n=17 (16.1%), at some point during the repeated assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored *"I felt tired at sometimes and I did not want to do any activity"* *"I was feeling bored and empty at sometimes, and I did not want to do anything"*

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	In the title and abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	In the 2nd page
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	In the 4th page
Objectives	3	State specific objectives, including any prespecified hypotheses	Last paragraph in the background
Methods			
Study design	4	Present key elements of study design early in the paper	Under study design and settings page 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Under study design and settings page 4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Under study participants and recruitments page5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, and effect modifiers. Give diagnostic criteria, if applicable	Under outcome measures page 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Under outcome measures page 5
Bias	9	Describe any efforts to address potential sources of bias	Under outcome measures page 5
Study size	10	Explain how the study size was arrived at	Sample size page 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Under data management and

			analysis page 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Under data management and analysis page 6
		(*b*) Explain how missing data were addressed	Under outcome measures page 5
		(*c*) If applicable, explain how loss to follow-up was addressed	N/A
		(*d*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	First paragraph in the result and Table1. Page 6-7
		(b) Give reasons for non-participation at each stage	First paragraph in the result page6. And under Patients' acceptance of making daily self-reports page 10
		(c) Consider use of a flow diagram	Page 6 (Figure-1).
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures	First paragraph in the result and Table1. Page 6-7
		(b) Indicate number of participants with missing data for each variable of interest	Under Patients' acceptance of making daily self-reports page 10
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	In the result part Page 8,9
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	In page 11,12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Last two paragraphs page 13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Last paragraph page 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	After references page16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality

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A prospective repeated assessment of self-reported sleep quality and sleep disruptive factors in the intensive care unit: acceptability of daily assessment of sleep quality

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ABSTRACT

Introduction: Despite the importance of sleep, the assessment of sleep quality does not form part of standard clinical-care in ICU. Continuous assessment of self-reported quality of ICU patients' sleep has been strongly recommended. Prior to implementing such an assessment in the ICU, it is important to assess the acceptability of this method of assessment to the ICU's patients. The aims of this study were to assess the acceptability to ICU patients of completing daily self-reports on sleep quality during their ICU stay and to assess ICU patients' self-reported sleep quality and sleep-disruptive factors during their time in ICU.

Methods: An observational prospective-repeated assessment was conducted on n=120 patients in an ICU in Saudi Arabia. The participants were both intubated and non-intubated.

Outcomes measures: Over a three-month period, sleep quality was assessed using the Arabic version of the Richards Campbell Sleep Questionnaire (RCSQ-A), and self-reported sleep-disruptive factors were identified. Clinical-factors, such as ICU interventions, and previously administered sedatives were also examined. The patients' acceptance of completing daily RCSQ-A reports was assessed using various indicators of acceptability.

Results: A total of 381 self-reports (RCSQ-A) were collected for this analysis. The patients reported 34.4±5.60, indicating that sleep quality was poor on average. The group of intubated patients reported much poorer sleep quality during intubation than after extubation. In the multivariate-analysis, factors which most significantly affected sleep [exp(b), p-value] were Midazolam [-6.424, $p<0.0005$], Propofol [-3.600, $p<0.05$], noise [-1.033, $p<0.05$], gender [1.836, $p<0.05$], daytime-sleepiness [0.856 $p<0.05$] and the presence of mechanical-ventilation [-1.218, $p<0.05$].

Conclusion: The acceptability and feasibility of using daily RCSQ-A for sleep quality assessment was demonstrated. Sleep quality was reported as poor by all participants and the factors affecting sleep were varied. This study provided various recommendations for healthcare-providers and researchers in terms of evaluating and improving sleep quality in ICU patients.

Keywords: Intensive care unit, Richards Campbell Sleep Questionnaire, sleep quality, factors affecting sleep, Self-report, Acceptability

STRINGTH AND LIMITATIONS OF THIS STUDY:

- This is the first study to assess ICU patients' acceptability of completing daily self-reports on the quality of their sleep.
- The prospective repeated-assessment study design facilitated the reduction of recall bias, which allowed sleep disruptive factors to be identified. These factors are constantly changing during patients' ICU stays and thus the study design permitted adequate statistical-power for analysis.
- The study provided a comparison of self-reported sleep quality during ventilation and after extubation within a group of intubated patients, reducing participant heterogeneity.
- The study was unable to study the effect of the patients' diagnoses and medications on sleep quality due to the variation in their medical-conditions and combinations of medication-regimes.

BACKGROUND

Sleep disruption in critically ill patients has been studied for over 30 years. It is defined as a continued lack of restorative sleep over time, resulting in both physical and cognitive impairments.[1] Studies suggest a number of extrinsic and extrinsic sleep disruptive factors are associated with disrupted sleep in ICU patients.[2,3] Extrinsic factors (environmental) include environmental sounds, light and nurses' activities. Intrinsic factors (factors related to the patients) include the severity of the illness, pain, fear or medical treatments. Despite the importance of sleep, continuous assessment of sleep quality during ICU stays does not form part of the standard clinical care given to ICU patients. Assessment is the first critical process in the nursing care plan, which enables nurses to develop an appropriate intervention and evaluate its effectiveness. Regular assessment is important in early identification of any sleep problems that ICU patients may have which in turn, lead to identifying the cause of the problem and implementing the proper interventions to improve the patients' sleep. [4,5]

Sleep assessment in ICUs can be examined using objective tools such as polysomnography (PSG). While PSG is considered the gold standard for sleep measurement, it has certain drawbacks for use in the ICU environment; the electrodes must be worn continuously to collect data on sleep quality and the results require interpretation by experts. [6,7] The use of self-report instruments offers an alternative approach to sleep assessment in ICUs. Recent clinical practice guidelines for the management of pain, agitation, delirium, and sleep disruption in ICUs, the Society of Critical Care Medicine strongly recommend that patients' sleep should be continuously assessed using a valid assessment tool such as the Richards-Campbell-Sleep Questionnaire (RCSQ).[8] However, prior to implementing self-reports on the quality of patient's sleep as part of the daily routine in the ICU, it is important to determine whether this is acceptable to the patients. Sekhon et al. [9] stated that successful implementation of new measures depends on the acceptability of the proposed measures to the recipients. They defined acceptability as a multi-faceted construct that reflects the extent to which people participating in new proposed measures consider it to be appropriate, based on their experienced cognitive and emotional responses. A few recent studies have used RCSQ in repeated assessment and throughout the patient's stay in the ICU.[10,11,12] They provided data on the completion rate of RCSQ by the participants,[10,11,12] and reasons for not completing the RCSQ by some participants.[12] However, there is no data on the patients' acceptability of this daily assessment (i.e. patients' experience of completing RCSQ on a daily basis during their ICU stay).

Despite the growing awareness of the role of sleep in ICU patients' recovery, there is little literature concerning any aspect of ICU patients' sleep quality and sleep disruptive factors in Middle East countries. In particular, the RCSQ is empirically valid and highly recommended for assessing the quality of ICU patients' sleep, there is a lack of knowledge about patients' sleep quality and sleep disruptive factors in Saudi Arabian ICUs, as no study has previously assessed patients' perception of sleep quality and sleep disruptive factors in Saudi Arabian ICUs. Therefore, we adopted a method of prospective repeated assessment of both self-reported sleep quality and sleep disruptive-factors on a daily basis until the patients' discharge from the unit. The primary aims of this study were to: 1) assess the acceptability of ICU patients to complete a daily self-report on sleep quality using the RCSQ during their ICU stay, and 2) assess the ICU patients' self-reported sleep quality during their stay in the ICU. The secondary aims were to 3) identify the self-reported

factors that disrupt ICU patients' sleep during their ICU stay, and 4) evaluate the effects of self-reported sleep disruptive factors and clinical factors on the patients' self-reported sleep quality.

These study aims were designed in the purpose to understand the feasibility of implementing daily self-report assessment of patients' sleep quality in Saudi Arabian ICU clinical practice and its likely performance in national ICU clinical-practice and routine-care, and to provide a comprehensive view of the quality of ICU patients' sleep and sleep disruptive factors in the Saudi Arabian ICU population. This may help to develop recommendations for healthcare providers and researchers in terms of both examining and improving sleep in ICU patients if necessary.

METHODS

Study design and settings

An observational prospective-repeated assessment was conducted at King Abdul Aziz University Hospital (KAUH) ICU. The hospital is a tertiary referral hospital in the western region of Jeddah, Saudi Arabia (KSA). During the study period, the hospital had a total capacity of 845 beds, of which 26 beds were in the ICU facility that provides care for both medical and surgical critically ill patients. A single room was provided for each patient and there was a 1:1 Registered Nurse (RN) to patient ratio. The patients' rooms were arranged around a centrally located nursing station.

All rooms featured small windows fitted with blinds. There were no policies in place to schedule the opening and closing of blinds to aid maintenance of circadian rhythm by altering natural light levels according to time of day. Patients' room lights were switched off during the night while the bed lights and corridor lights remained on. There were no set policies or guidelines regarding the patients' sleep quality within the hospital.

Patient involvement

A group of patients were involved in the design of the study at the planning and pilot testing stages. Those patients provided feedback on the study tools.

Study participants and recruitments

Participants eligible to take part in the study were adult patients (≥18 years) treated in the ICU for ≥24 hours who were alert and interactive, with Glasgow Coma Scale (GCS) [13] scores of 15, including those who were intubated. A convenience sample of all patients who met the eligibility criteria were invited to participate. Exclusion criteria included sedated or agitated patients with Richmond-Agitation and Sedation-Scores (RASS) [14] of <-1 or >+1, patients with pre-existing sleep pathologies; patients with cognitive-dysfunction, and patients who did not speak Arabic. All potential study participants were screened for eligibility at each morning using a study enrolment survey. The participants were assured that participation in the study was not obligatory and were reminded of their right to withdraw at any time. The study was reviewed and approved by the Institutional-Review-Board (IRB), King Abdul Aziz University Hospital, Saudi Arabia (Ref number: 612-17), and the University of Glasgow, UK (Ref number: 200170066).

Data collection

Data collection was undertaken during May to August of 2018. Each participant needed to be alert and calm, therefore, patient consciousness levels were assessed daily; similarly, the presence of delirium was assessed using the Confusion-Assessment-Method for the ICU (CAM-ICU).

Outcome measures

Patient self-report assessment of sleep quality and sleep disturbance factors:

The Arabic version of RCSQ (RCSQ-A) [15] and the modified Sleep in intensive Care Questionnaire (SICQ) [16] were administered each morning between 7.00 a.m. and noon until the day the patient was due to be discharged from the ICU. Details of study instruments can be found in online Supplementary-material-1. The five questions from the RCSQ-A were read aloud to the patients and, after each question, the patients rated their previous night sleep by placing a mark on the answer line, which was 100 mm long (0 mm = poorest, 100 mm = optimum). This approach was chosen to limit the potential of recall-bias and to assure optimal reminiscence of the most recent night's sleep. Every attempt was made to ensure that there were no missing or erroneous data by screening each patient's daily assessment-sheets. Missing RCSQ-A responses from patients who had declined to complete the questionnaire were not considered and not included in the analyses because the RCSQ total-score cannot be computed if the data is incomplete.[17] The patients who declined to complete the RCSQ-A were asked to clarify whether they were not completing the questionnaire on that individual occasion, or if they were withdrawing from the study. The patients who decided to withdraw from the study were not approached again; however, their consent for data they had already given for analysis was retained. After every RCSQ-A completion, the patients were asked to rate their perception of the factors that disrupted their sleep during the previous night on the modified SICQ scale (1= no disruption to 10 = significant disruption). An open-ended question, "What other activities were disruptive to your sleep last night?" was also used. The answers were communicated verbally by most patients and in writing and through actions by some.

Other measures: demographic and clinical data

Demographic and clinical variables were collected from the patients' medical files. These included age, gender, ICU admission diagnosis, severity of critical illness using the Acute-Physiology & Chronic Health-Evaluation (APACHE II) score,[18] length of stay in ICU (ICU-LOS), nightly mechanical-ventilation statues (ventilated or non-ventilated), and medications administered during the study. None of the patients were on sedation during the assessment, however, data on previously administered sedation medications was collected.

Patients' acceptance of daily self-reporting on sleep quality using RCSQ-A during their ICU stays:

The key elements of acceptability, including patient willingness, and perceived burden (ability to provide self-reports on a daily-basis) were assessed using several indicators of acceptability, [9] including withdrawal and dropout-rates, the total number of patients who decided to discontinue at some point during the assessment and the total number of completed reports. The participants were also asked: "How did you find completing the questionnaire on sleep quality on multiple days while you were an inpatient in the ICU?"

Sample size

A post-hoc power analysis was conducted using G-Power software version 3.1.9.2 to perform regression analysis for the total sample n=120 patients and to determine whether the sample size offered an effective power of at least 0.80 and a significance level of $\alpha = 0.05$. This also determined the maximum number of variables to be included in the model. The power-analysis revealed that

a sample size of 120 was adequate, given the inclusion of 16-variables, with an effective-power of 0.88, assuming a moderate effect-size (f2 =0.22). Even supposing a much smaller-effect (f2 =0.19), the power remained 0.82, which is above the usual minimum-requirement of 0.80. [19] A post-hoc power analysis was also used to perform a paired samples t-test for the sub-sample of n=43 patients who were placed on ventilation during the study assessment. The analysis revealed that on the basis of the mean, between-two different conditions (during ventilation and after extubation), a sample size of 43 patients was adequate to obtain a statistical power of 0.89 with an effect size (d=0.5) and a significance level of $\alpha = 0.05$.

Data management and analysis

The data were analysed using IBM-SPSS version-23.0. The data were first assessed for normality using the Shapiro-Wilk's test. [20] Descriptive statistics including frequencies and percentages were used to describe the categorical data e.g. gender, admission diagnosis. The mean, range and standard deviation were used to describe the continuous data for the total sample of n=120 patients' sleep quality and sleep disruptive factors. Descriptive statistics were also used to describe a sub-sample of n=43 patients who had been placed on a ventilator at some point during the study period. The description included their self-reported sleep quality and sleep disruptive factors when they were on the ventilation and after they were extubated. A paired-sample t-test was performed to determine whether there was a significant difference in patients' sleep quality during ventilation and after extubation, and whether there were significant differences in self-reported sleep disruptive-factors during ventilation and after extubation that were explained by intubation status. The two-sided statistical significance level was set to 0.05 and 95% CIs were used.

The total RCSQ-A score for the total sample n=120 was converted into an estimate of the sleep efficiency-index (SEI) using the following formula: $SEI = 46.88 + (0.39 * RCSQ)$.[10,17, 21]

The correlation between daytime sleepiness and ICU-LOS, was assessed using a Bivariate (Pearson)-Correlation. A multiple-regression was conducted for the total sample to assess the significance and relative contribution of each independent variable on predicting the dependent variable-sleep quality. To avoid overfitting the model, only the factors rated most highly by the patients were included in the model in addition to the variables of interest, reflecting the demographic and clinical characteristics derived from previous research. The appropriate modelling of continuous variables was confirmed by evaluating their linearity. The intercorrelation between independent variables for this repeated assessment was assessed using variance inflation factor (VIF) values less than 10, and tolerance values greater than 0.1. It was addressed by re-categorizing the relevant collinear variables. The majority of patients (87.5%) in this study received non-opioid analgesics alongside opioid-fentanyl analgesics. To avoid multicollinearity, these two variables were combined into a single-variable and entered as "analgesic". The independence of observation (residuals) was assessed by Durbin-Watson statistic values of 1.299. Content analysis was used to interpret and synthesise the data collected in the open-ended questions.[22]

RESULTS

A total of 354 patients were screened, of whom 224 were excluded because they did not meet the inclusion criteria (Figure-1). The remaining 130 patients met the inclusion criteria, however, 10

patients were unwilling to participate in any research studies and declined to participate, leaving 120 patients enrolled. The average age of the patients was 59, and the majority (60%) were male. The participants' APACHE II-score within 24 hours of ICU admission ranged from 10-24 with an average of 15.78 ±2.606. More than half the participants had an APACHE-II score between 10 and 16 n=71 (59.2%); meanwhile 49 participants (40.8%) had a higher score between 17-24. The average ICU-LOS was 9.35 days ±3.15. Patients who had an APACHE-II score between 10 and 16 stayed in the ICU for 4-12 days. In addition, patients who had a score between 17-24 stayed in the ICU for 6-21 days. Of the study sample, 43 (35.8%) patients were on mechanical ventilation (MV). Table 1 provides a summary of the sample demographic and treatment characteristics during the study assessment.

Table 1 Demographic and clinical characteristics of patients (n=120)

Characteristics	Category	n (%)	Range
Age (Mean ±SD)	59.7±9.44		19.00- 75.00
Gender	Male	72 (60)	
	Female	48 (40)	
Admission diagnosis	Medical cardiac	21(17.5)	
	Medical respiratory	21 (17.5)	
	Gastrointestinal	11 (9.1)	
	Other	8 (6.7)	
	Surgical post-operative	59 (49.2)	
	Cardiothoracic	37 (30.9)	
	Thoracic traumatic	12 (10)	
	Abdominal	10 (8.3)	
APACHE II score (Mean ±SD)	15.78 ±2.606		10.00-24.00
	Low	71 (59.2)	10.00-16.00
	Medium	49 (40.8)	17.00-24.00
Length of ICU stay (Mean ±SD)	9.35±3.15		4.00-21.00
Medications [a]	Beta blockers	75 (62.5)	
	Diuretics	76 (63.5)	
	Calcium channel blockers	99 (82.5)	
	Corticosteroids	45 (37.5)	
	Adrenergic	39 (32.5)	
	Non-Opioid and Opioid	105 (87.5)	
	Non-Opioid-Paracetamol	15 (12.5)	
Sedation	Propofol	54 (45)	
	Benzodiazepines (Midazolam)	40 (33.3)	
	Dexmedetomidine (Precedx)	26 (21.7)	
RASS score on enrolment [b]	Alert and calm (zero-score)	120 (100)	
GCS [c]	Fully conscious (15-score)	120 (100)	
Developed delirium	Positive CAM-ICU [d]	11 (9.2)	
Intubation statues	Intubated	43 (35.8)	
Method of ventilation	Invasive ventilation [e]	30 (69.8)	
	Non-invasive[f]	13 (30.2)	
Duration of MV (Mean ±SD)	6.26 ±3.381		2.00-17.00

[a] Beta blocker=Metoprolol, Carvedilol; Diuretics= metolazone, furosemide, amiloride; Calcium channel blockers= amlodipine, verapamil; Corticosteroids = prednisolone, dexamethasone, hydrocortisone; Adrenergic= noradrenaline, adrenaline or dopamine [b] Richmond Agitation Sedation Scale, [c] Glasgow Coma Scale, [d] Confusion Assessment Method for the ICU, [e] ventilation applied via tracheotomy or endotracheal. [f] Ventilation applied via face or nasal mask.

Participants' self-reported assessments of sleep and sleep disruptive factors

The average sleep quality as reported by the patients was poor, with mean scores for each of the RCSQ-A elements below 50 mm (Table-2). Furthermore, the mean SEI was 60.3%, and a SEI less than 85% indicates poor sleep quality. [17] In contrast, the average self-reported sleep quality at home was described as good, with a mean score of 7.16 ±1.754. The average daytime-sleepiness score was 5.52 ±1.52, and daytime sleepiness did not change significantly over the course of any patient's ICU stay (p>0.05). Multiple factors were reported to disrupt patients' sleep (Table-3). Patients rated noise as the most disruptive extrinsic factor at 7.48±1.57, followed by clinical interventions at 5.95±1.57; the highest rated noise was talking at 6.80±1.25, while the highest-rated intrinsic disruptive factor was fear at 3.64±2.01. Supplementary-material-2 shows patients' comments on other factors that disrupted their sleep, including the categories and the sub-categories that emerged from content-analysis in accordance with Edéll-Gustafsson et al. [23]

Table 2 Cohort patients' self-report of sleep quality, (n=120)

Richards-Campbell items	Mean ±SD	*Range*
(RCSQ-A.1) Sleep depth	31.82±7.03	19-56
(RCSQ-A.2) Falling asleep	33.07±6.73	21-54
(RCSQ-A.3) Awakenings	35.06±5.76	18-47
(RCSQ-A.4) Returning to sleep	36.29±5.36	25-50
(RCSQ-A.5) Overall sleep quality	35.36±5.34	22-51
Total RCSQ-A score [a]	34.41±5.60	23-48
SEI [b]	60.30	

[a] Total RCSQ-A = average of 5 items (Q1-Q5). The total RCSQ-A score was categorized, with a cut off-point of <26 indicating very poor sleep quality, a score of [26-50] indicating poor sleep quality, a score of [51-75] indicating good sleep quality, and a score of >75 indicating very good sleep quality [24,25]

[b] SEI= Sleep efficacy index= < 85% indicates poor sleep quality.

Table 3 Self-reported sleep disruptive factors on modified SICQ, (n = 120)

Sleep disruptive factors in rank order	Mean ±SD	*Range*
Noise	7.48±1.57	3.00-9.00
Clinical interventions (i.e. blood samples, vital signs, etc.)	5.95±1.86	2.30-9.00
Light	2.36±0.94	1.00-5.00
Talking	6.80± 1.25	1.00-9.00
Machines' alarm (i.e. heart monitor, ventilator, etc.)	4.31±2.35	1.00-9.00
Telephone	1.12±0.36	1.00-7.30
Fear	3.64±2.01	1.00-8.25
Pain	2.30±1.10	1.00-7.30
Discomfort of being attached to the devices	2.26±1.18	1.00-5.75

Factors affecting sleep quality

The predictor variables included in the multiple regression model were noise, clinical-interventions, talking, machine-alarms, and fear, in addition to the intrinsic factors of age, gender, daytime-sleepiness, APACHE II-score, ICU-LOS, analgesic use, MV status, and previous receipt of sedation using Midazolam, Propofol, and Precedx. The full model (Table-4) explained 39.3% of the variance in total sleep quality, a statistically significant predictor of total sleep quality, with the $R^2 = 0.423$, F (6.113) = 13.828, and p < 0.0005. The factors which negatively and significantly affected sleep quality (given as [exp(b)(95% CI), p value]) were Midazolam [-6.424 (-8.99– -3.86), p < 0.0005], Propofol [-3.600 (-5.71– -1.49), p<0.05], noise [-1.033, (-1.70– -0.364), p<0.05], and the presence of a ventilator [-1.218 (-2.36- -0.077) p<0.05]. Total sleep quality was also significantly affected by differences in gender such that predicted sleep quality for female patients was greater than for male patients [1.836 (0.157– 3.52) p<0.05]. Furthermore, daytime sleepiness significantly affected the patients' sleep: using a daytime-sleepiness scale where 1 = unable to stay awake, and 10 = fully alert and awake, any increase on the scale was associated with a significant increase in total sleep quality [0.856 (0.175– 1.54) p<0.05].

Table 4 Model summary of the stepwise multiple regressions predicting total sleep quality from sleep disruptive factors with (adjusted $R^2 = 0.393$)

Variable	*B* [a]	R^2	ΔR^2	*F* [b]	*(95.0% CI)* [c]	*P*
Midazolam	-6.424	0.222	0.222	33.719**	(-8.99– -3.86)	<.0005**
Propofol	-3.600	0.287	0.065	23.541**	(-5.71– -1.49)	0.001*
Gender	1.836	0.340	0.053	19.914**	(0.157– 3.52)	0.032*
Noise	-1.033	0.373	0.033	17.097**	(-1.70– -0.364)	0.003*
Daytime sleepiness	0.856	0.401	0.028	15.236**	(0.175– 1.54)	0.014*
Nightly mechanical ventilation status	-1.218	0.423	0.023	13.828**	(-2.36– -0.077)	0.037*

[a] B= unstandardized regression coefficients, [b] F=test of overall significance, [c] CI=confidence interval, **highly significant; * p<.05

Self-reported sleep quality and sleep disruptive factors reported by participants during intubation and after extubation

The sub-sample of 43 patients who were placed on MV during the study reported sleep quality during intubation (31.88 ±6.16) as much poorer than after extubation (35.04±6.47); these differences were significant with p <0.0005. Patients reported sleep fragmentation as the greatest disturbance during intubation (30.63 ±5.79). Following extubation, the number of awakenings was significantly reduced, to a mean of 36.81±6.83 (Table-5). There were significant differences between the level of reporting for several sleep disruptive factors during ventilation and after extubation (p<0.05), as shown in Figure-2. During ventilation, machine alarms, clinical intervention, and fear were rated as causing high levels of sleep disruption (7.19±1.13, 7.04±2.04, and 6.32±1.81, respectively). However, following extubation, these levels of disruption reduced significantly,

causing only moderate to mild levels of disruption (4.68±1.37,6.07 ±2.34, and 2.72±1.34, respectively).

Table 5 Self-reported sleep quality of patients when they were intubated and after extubation, (n=43).

RCSQ-A items	*Patients on ventilation n= (43)*		*Patients after extubation n= (43)*		P value [a]
	Mean ±SD	Range	Mean ±SD	Range	
Depth of sleep (RCSQ-A.1)	32.00±9.13	21-53	33.43±8.58	18-51	.001*
falling asleep (RCSQ-A.2)	33.00±8.67	19-53	34.38±8.41	22-56	.001*
Number of awakenings (RCSQ-A.3)	30.63±5.79	15-41	36.81±6.83	19-56	< .0005**
Returning to sleep (RCSQ-A.4)	31.85±5.50	21-40	36.20±5.99	28-49	< .0005**
Overall sleep quality (RCSQ-A.5)	32.14±5.51	21-41	34.40±5.54	25-47	< .0005**
Overall (RCSQ-A) Score [b]	31.88±6.16	20-45	35.04±6.47	24-49	< .0005

[a] Paired t test, *p< .05; **p< .0005 is highly significant.

Patients' acceptance of making daily self-reports on sleep quality using RCSQ-A during ICU stays

Dropout and withdrawal rates: The number of patients who dropped out by choosing to stop participating was very small at n=3 (2.5%). No reasons for such cessations were provided. The number of withdrawals was also very small at n=11 (9.2%). These patients were withdrawn because they no longer met the study's inclusion criteria, as they had become agitated and developed delirium. The majority of participants, n=106 (88.4%), were able to complete study participation in full.

Number of completed self-reports (RCSQ-A): In total, 381 reports were collected from 120 participants. The answers to the open-ended question confirmed that most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stay in the ICU. However, some of the participants, n=17 (16.1%), at some point during the repeated-assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored (Supplementary-material-3).

***Experiences of completing the RCSQ-A*:** The time taken to complete RCSQ-A was between two and three minutes. The participants completed the RCSQ-A between one and six times, with the average being three times. In total 111 patients (92.5%) provided more than one RCSQ-A, while only nine participants (7.5%) provided a single self-report. Four of the participants became delirious and agitated on the second day of assessment, while three patients asked to stop participating; two patients were discharged from the ICU on their second day of assessment. Among the study participants, 68 (56.7%) were unable to set a mark on the VAS themselves, requiring assistance due to physical barriers such as hand tremors and muscle weakness. These patients were only able to point at their chosen spots on the scales.

DISCUSSION

This study was designed to assess the acceptability of ICU patients' completion of daily self-reports (RCSQ-A) on their sleep quality throughout their ICU stay and to assess self-reported sleep quality and sleep disruptive factors on a daily basis until patients were discharged from the unit. It is important to study sleep quality and sleep disruptive factors simultaneously to develop a comprehensive picture of the patients' sleep quality and the factors that disrupt it. We considered that this would inform the future development of strategies to improve patients' sleep in the ICU. A review of the literature suggests that this is the first study on ICU patients' experience of completing daily self-reports on their sleep quality during their ICU stay. It is also the first study that has assessed self-reported sleep quality using a valid tool (RCSQ-A) and self-reported sleep disruptive factors in ICU patients in an Arabic-speaking country in the Middle-East.

There was evidence of general poor sleep quality in this cohort of ICU patients. The overall quality of sleep from the patient perspective was 34.41, which is lower than the reported findings in previous studies.[10, 12, 26,27,28,29,30] The SEIs emerged at 60.3%, matching the results from a group of ICU patients in the United Kingdom[29] used as a control, in which the SEIs were 60.8%, and slightly lower than reported in the repeated self-report assessment study from Australia (60.3% vs. 65%).[10] In this study, patient perception of sleep varied between poor to very poor in contrast to other self-report assessment studies in which patients' sleep varied from very good to very poor.[12,26,24,25,30] These differences may be due to the different treatment characteristics of the patients, as this study included intubated patients, and the different ICU environment. Differences in the method of sleep quality assessment could also have influenced these results. The current results are based on continuous assessment until discharge from the ICU, while the majority of previous studies limited assessment to a single night. [6,21,26,31] Only three previous studies used RCSQ for repeated-assessment, [10,11,12] and their assessments were limited to non-intubated patients. The finding that patients' sleep is reported as worse in the ICU than at home is consistent with previous studies. [6,16,21,31] This indicates that there are factors within these environments which may lead to changes in and disruption to patients' sleep.

The results demonstrated that daytime-sleepiness was consistent with lack of sleep during the night and that perceived daytime-sleepiness did not improve over the course of patients' ICU stay. These results are consistent with previous polysomnographic and self-report studies, [31,32] which showed that between 40 and 50% of total sleep time in an ICU occurs during the day, and that this altered sleep pattern did not improve over the course of the stay. It is known that female subjects experience additional slow wave sleep, and this is reflected by the observed gender differences in patients' sleep in this study: female patients slept better than male patients. This supports a recent study that found that female patients had better sleep than male. [31] Our results showed that multiple sleep disrupting-factors were identified by the entire sample, which substantiates other results. Of the extrinsic-factors, patients rated noise as the most disruptive, supporting the findings of previous studies. [3,16,33,34] Peak noise levels in the ICU were documented at 41dB and 68 dB, [34,35,36] exceeding the World-Health-Organisation's (WHO) recommendation for sound levels in an ICU not to exceed 35 dB during the day and 30 dB at night.[37]The results also support the idea that interruptions of sleep in the ICU caused by clinical-interventions are important. This finding is consistent with the results of Celik et al,[38] who found that patients had their sleep interrupted by human-interventions an average of 51-times each per night. However, in addition to these,

psychological factors cannot be ignored. Patients reported fear to be the most disruptive intrinsic-factor; they also referred to nightmares and worries, corroborating previous study findings. [24,25,10]

The effects of sedation in the ICU have not been studied sufficiently. None of the patients were on sedation during this assessment, however, data on previously administered sedation were gathered. Sedatives, especially benzodiazepines, are commonly used to induce sleep, however, these have been known to supress slow-wave (SWS) and rapid-eye-movement sleep (REM) after withdrawal. [39] Propofol has shown to increase SWS while suppressing REM sleep. [32] Interestingly, patients who received benzodiazepines had worse sleep quality than patients who received Propofol. However, both forms of sedation significantly affected patients' sleep quality. The adverse effects of many sedatives have been well documented, and thus sedatives should not be used for sleep promotion in most cases; [8] in addition, patients receiving these drugs should be carefully monitored with regard to the quality of their sleep.

The negative effects of the presence of MV on patients' sleep quality have been reported in several polysomnographic studies. [32,40,41] However, this is the only self-report study include intubated patients and assessed their perception of sleep quality alongside their perceptions of sleep disruptive-factors on a daily basis both during intubation and after extubation to determine whether the ventilator has an effect on the patients' perception of sleep and the factors that disrupt their sleep. Intubated patients reported better sleep quality following extubation and the differences were statistically significant. However, to date there is no information which provides guidance about clinically important changes in the RCSQ scores, and thus it is difficult to make too much of the result. The patients also reported sleep fragmentation to be greater during intubation than after extubation. Furthermore, during ventilation, the factors of machine-alarms, clinical-interventions, and fear were rated by the patients as the most disruptive factors, while after extubation, the level of disruption reduced significantly. One possible explanation for high sleep-fragmentation during intubation is the disruptive factors that arise from or are increased by the presence of the ventilator, such as alarms, clinical interventions and feelings of fear. Freedman et al.[5] assessed the sleep quality of ventilated patients and demonstrated that sleep was highly fragmented; they suggested that this may be due to the multiple human-interventions during ventilation. Our findings stress the need for attention to be paid to the sleep quality of this group of patients, with close monitoring for factors that may adversely affect sleep. In particular, environmental factors such as noise from alarms should not be overlooked. Such impacts should be handled properly by following guidelines such as the Joint Commission (JCI) policies on safely managing clinical alarm systems to avoid false alarms. [42] Clustering patients' care activities as much as possible and avoiding performing unnecessary care activities during the night is also important for managing these factors. Where MV is present, the patients may experience distressing psychological side effects such as fear, [43,44] therefore, it is important to consider the individual patient's psychological needs.

Our results demonstrated that daily self-report assessments on sleep-quality using the RCSQ-A was non-burdensome to the majority of participants. Therefore, it is somewhat surprising that the use of RCSQ for repeated assessment in ICUs is only infrequently published, with only three main studies of this type. [10,11,12] Two were conducted in Australia, [10,12] with one featuring 151 participants reporting on their sleep using the RCSQ 356 times where 50% of the participants were able to report on two or more days; [10] the other Australian study [12] featured 50 patients reporting, and the completion rate was 72%. The third study, in North America, [11] featured 33

patients over 137 days completing 121 self-reports, giving a rate of 88%. These studies and our own completion rate of 92.5% provide evidence to support the tool's feasibility for routine assessment of patients' sleep in ICUs. The patients in this study generally described their experience of completing the RCSQ-A during their stays positively. The patients were happy and reported that various psychological and social needs were met by this method of assessment. For example, they felt a sense of security, enhanced communication levels, reduced feelings of loneliness, and a sense that someone respected and cared about their need for sleep. These results support a recent qualitative study [45] that found that patients who felt well taken care of felt more relaxed and reported that their sleep was positively affected.

According to the daily self-report assessment of both sleep quality and sleep disruptive-factors, sleep disruptive-factors were evaluated differently from day to day and patient to patient despite the constant setting. Therefore, the findings do not support the hypothesis that ICU noise is the main factor responsible for sleep disturbance for all ICU patients. [46] Patients' sleep disruption is influenced by several interrelated factors that constantly change due to the nature of the ICU environment. Sensitivity to sources of sleep disruption also varies from patient to patient.[32] Unfortunately, individual differences were not considered in most recent intervention studies that aimed to improve sleep in the ICU by developing and applying protocols.[21,27,29,30] Recent guidelines[8] also revealed problems with the methodology in these intervention studies, highlighting the need for well-designed nonpharmacological-measures and improved methods for measuring sleep to allow the implementation of interventions with individualised approaches.

Our findings demonstrate the acceptability and feasibility of using repeated, self-reported RCSQ assessments of sleep quality in ICU environments. Such assessments can be performed whenever the patients are sufficiently alert, and they do not need to be able to communicate verbally. The findings also encourage clinicians routinely inquire about patients' sleep and, implement routine early documentation of sleep patterns using RCSQ in the patient care-plans. Patient perceptions of the factors disrupting sleep should be identified individually to determine the patient-specific needs to address sleep disturbances with treatment-decisions. Furthermore, patients should be involved in their care; this corresponds with the Institute for Healthcare-Improvement's (IHI) identification of patient-safety as one driver of exceptional patient-centred care.[47,48]However, it would be valuable to further validate the RCSQ in intubated ICU populations, as the original validation was performed using PSG in non-intubated patients.[17] This additional validation would enhance the promotion and use of this instrument for the purposes of ongoing assessment over various points of the patients' ICU stays. Further studies are required to test acceptance in other populations of ICU patients in different countries and regions. Further work is also required to assess the perceptions and acceptance of health care providers in ICUs in terms of implementation. The quality of sleep was poor in all participants in this case, highlighting the need for further testing in Middle-Eastern countries. The facilitation of high-quality sleep for ICU patients is often overlooked by healthcare professionals. However, the results of this study suggest that better education should be provided regarding the negative effects of poor sleep for patients, and training should be established to allow healthcare providers to mitigate these effects. Additionally, to ensure high standards of care in the ICU, hospitals should not only introduce policies to avert sleep disturbances but should also regularly assess the sleep quality of patients, aiming to allow patients sufficient rest periods of a minimum of 90 mins to experience a full sleep cycle. To meet these aims, individual patient planning may be required.

This study had several limitations, which must be acknowledged. Selection bias is possible, as all patients selected to participate were non-sedated; this was necessary, as sedation affect cognitive abilities, and, therefore, would affect the validity of the results. However, this means that the results are not generalisable to the whole ICU-patient population. Nevertheless, this is an important patient population to study, especially as it includes patients in the period after sedation cessation, when regular-assessment of sleep quality that may be affected by the previously received sedation is necessary. The other issue with the findings is generalisability; half of the study sample were post-operative surgical ICU patients and most of them were cardiac patients. This limits the study's findings to these patients. Future research will be required in a broader critical care population. The aim was to assess sleep quality subjectively from a patient perspective, consequently, changes in sleep-architecture were not observable, due to the use of a self-report tool. However, routine-use of objective-methods of assessment such as PSG-monitors during patient care is not feasible, and the clinically meaningful outcome of sleep quality is the patient's experience. [8,12]

CONCLUSION

Sleep quality was reported as poor by all participants. The factors affecting sleep were multiple and varied from patient to patient, stressing the need to regularly and individually assess patients' sleep quality, and the importance of adopting patient-centred care, including an individual sleep care plan for each patient. The results also demonstrated the feasibility and the acceptability of

ICU patients completing daily self-reports of their sleep quality using the RCSQ-A during their ICU stays.

REFERNCES

1. Parthasarathy S, Tobin MJ. Sleep in the intensive care unit. *Intensive Care Med* 2004;30:197–206.
2. Elliott R, Rai T, McKinley S. Factors affecting sleep in the critically ill: an observational study. *J Critc Care* 2014;29:859-63.
3. Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.7.
4. Jeffs EL, Darbyshire JL. Measuring sleep in intensive care unit: a critical appraisal of the use of subjective methods. *J Intensive Care Med* 2017;1–10.
5. Hoey LM, Fulbrook P, Douglas JA. Sleep assessment of hospitalised patients: a literature review. *Int J Nurs Stud* 2014;51:1281–1288.
6. Elliott R, McKinley S, Cistulli P, et al. Characterisation of sleep in intensive care using 24-hour polysomnography: an observational study. *Crit Care* 2013;17:R46.
7. Knauert MP, Yaggi HK, Redeker NS, et al. Feasibility study of unattended polysomnography in medical intensive care unit patients. *Heart Lung* 2014;43:445–452.
8. Devlin JW, Skrobik Y, Gélinas C, et al. Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Crit Care Med* 2018;46:825-873.
9. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
10. Aitken LM, Elliott R, Mitchell M, et al. Sleep assessment by patients and nurses in the intensive care: an exploratory descriptive study. *Aust Crit Care* 2017; 30: 59–66.
11. Kamdar BB, Shah PA, King LM, et al. Patient-nurse interrater reliability and agreement of the Richards-Campbell sleep questionnaire. *Am J Crit Care* 2012;21:261–269.
12. Menear A, Elliott R, Aitken LM, et al. Repeated sleep-quality assessment and use of sleep-promoting interventions in ICU. *Nurs Crit Care* 2017;22:348-54.
13. Fischer M, Rüegg S, Czaplinski A, et al. Inter-rater reliability of the Full Outline of Unresponsiveness score and the Glasgow Coma Scale in critically ill patients: a prospective observational study. *Crit Care*. 2010;14:R64.
14. Sessler CN, Gosnell MS, Grap MJ. et al. The Richmond Agitation–Sedation Scale. *Am J Respir Crit Care Med* 2002;166:1338–1344.
15. Al-Sulami G, Rice AM, Kidd L, et al. An Arabic translation, reliability, validity and feasibility of the Richards-Campbell Sleep Questionnaire for Sleep Quality Assessment in Intensive Care Unit: Prospective-Repeated Assessments. *J Nurs Meas* (forthcoming).
16. Freedman NS, Kotzer N, Schwab RJ. Patient perception of sleep quality and etiology of sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 1999;159:1155–1162.
17. Richards KC, O'Sullivan PS, Phillips RL. Measurement of sleep in critically ill patients. *J Nurs Meas* 2000;8:131–44.
18. Knaus WA, Draper EA, Wagner DP, et al. APACHE II: a severity of disease classification system. *Crit Care Med* 1985;13:818–29.
19. Cohen J. A power primer. *Psychol Bull* 1992;112:155–9.
20. Shapiro SS, Wilk MB. An Analysis of Variance Test for Normality (Complete Samples). *Biometrika* 1965;*52*:591-611.
21. Li SY, Wang TJ, Vivienne Wu SF, et al. Efficacy of controlling night time noise and activities to improve patients' sleep quality in a surgical intensive care unit. *J Clin Nurs* 2011;20:396–407.

22. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15:398-405.
23. Edéll-Gustafsson U, Arén C, Hamrin E, et al. Nurses' notes on sleep patterns in patients undergoing coronary artery bypass surgery: a retrospective evaluation of patient records. *J Adv Nurs* 1994; *20*:331-336.
24. Frisk U, Nordström G. Patients' sleep in an intensive care unit: patients' and nurses' perception. *Intensive Crit Care Nurs* 2003;19:342–349.
25. Krotsetis S, Richards KC, Behncke A, et al. The reliability of the German version of the Richards-Campbell sleep questionnaire. *Nurs Crit Care* 2017;22:247–252.
26. Nicolás A, Aizpitarte E, Iruarrizaga A, et al. Perception of night-time sleep by surgical patients in an intensive care unit. *Nurs Crit Care* 2008;13:25–33.
27. Kamdar BB, King LM, Collop NA, *et al*. The effect of a quality improvement intervention on perceived sleep quality and cognition in a medical ICU. *Crit Care Med* 2013;41:800–809.
28. Ritmala-Castren M, Axelin A, Kiljunen K, et al. Sleep in the intensive care unit-nurses' documentation and patients' prespectives. *Nurs Crit Care* 2014;22:238-246.
29. Patel J, Baldwin J, Bunting P, et al. The effect of a multicomponent multidisciplinary bundle of interventions on sleep and delirium in medical and surgical intensive care patients. Anaesthesia 2014;69:540–549.
30. Elliott R, McKinley S. The development of a clinical practice guideline to improve sleep in intensive care patients: a solution focused approach. *Intensive Crit Care Nurs* 2014;30:246–256.
31. Bihari S, Doug McEvoy R, Matheson E, et al. Factors affecting sleep quality of patients in intensive care unit. *J Clin Sleep Med* 2012;8:8.7.
32. Freedman NS, Gazendam J, Levan L, et al. Abnormal sleep/ wake cycles and the effect of environmental noise on sleep disruption in the intensive care unit. *Am J Respir Crit Care Med* 2001;163:451–7. 5
33. Salandin A, Arnold J, Kornadt O. Noise in an intensive care unit. *J Acoust Soc Am* 2011;130:3754–3760.
34. Simons KS, Verweij E, Lemmens PM, et al. Noise in the intensive care unit and its influence on sleep quality: a multicenter observational study in Dutch intensive care units. *Crit Care* 2018;22:250.
35. Park M, Kohlrausch A, de Bruijn W, et al. Analysis of the soundscape in an intensive care unit based on the annotation of an audio recording. *J Acoust Soc Am* 2014;135:1875–1886.
36. Darbyshire JL, Young JD. An investigation of sound levels on intensive care units with reference to the WHO guidelines. *Crit Care* 2013;17:R187.
37. Berglund B, Lindvall T, Schwela DH & World Health Organization Occupational and Environmental Health Team. Guidelines for community noise. 1999. http://www.who.int/iris/handle/10665/66217
38. Celik S, Oztekin D, Akyolcu N, et al. Sleep disturbance: the patient care activities applied at the night shift in the intensive care unit. *J Clin Nurs* 2005;14:102–6.
39. Pisani MA, Friese RS, Gehlbach BK, et al. Sleep in the intensive care unit. *Am J Respir Crit Care Med* 2015;191:731–8.
40. Cooper AB, Thornley KS, Young GB, et al. Sleep in critically ill patients requiring mechanical ventilation.*Chest* 2000;117:809–818.
41. Beecroft JM, Ward M, Younes M, et al. Sleep monitoring in the intensive care unit: comparison of nurse assessment, actigraphy and polysomnography**.** *Intensive Care Med* 2008;34:2076–2083.

42. The Joint Commission. The Joint Commission announces 2014 national patient safety goal, 2013. Available from. http://www.jointcommission.org/assets/1/18/jcp0713_announce_new_nspg. pdf2016.
43. McKinley S, Fien M, Elliott R, et al. Sleep and psychological health during early recovery from critical illness: an observational study. *J Psychosom Res* 2013;175:539-45.
44. Rotondi AJ, Chelluri L, Sirio C, et al. Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. *J Crit Care Med* 2002;30:746-52.
45. Ding Q, Redeker NS, Pisani MA, et al. Factors influencing patients' sleep in the intensive care unit: perceptions of patients and clinical staff. *Am J Crit Care* 2017;26:278.
46. Gabor JY, Cooper AB, Crombach SA,et al. Contribution of the intensive care unit environment to sleep disruption in mechanically ventilated patients and healthy subjects. *Am J Respir Crit Care Med* 2003;167:708–715.
47. Perlo J ,Balik B , Swensen S , et al . *IHI framework for improving joy in work*. Cambridge, MA: Institute for Healthcare Improvement, 2017.
48. Gandhi TK, Kaplan GS, Leape L, et al. Transforming concepts in patient safety: a progress report. *BMJ Qual Saf* 2018;27:1019-26.

Legend text

Figure 1 Flow diagram of patients screening , enrolment and participants RCSQ-A completions.

Figure 2 Significance of changes in the self-reported sleep disruptive factors during intubation and after extuabtion

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Competing interests: None.

Data sharing statements: All data relevant to the study are included in the article or uploaded as supplementary information

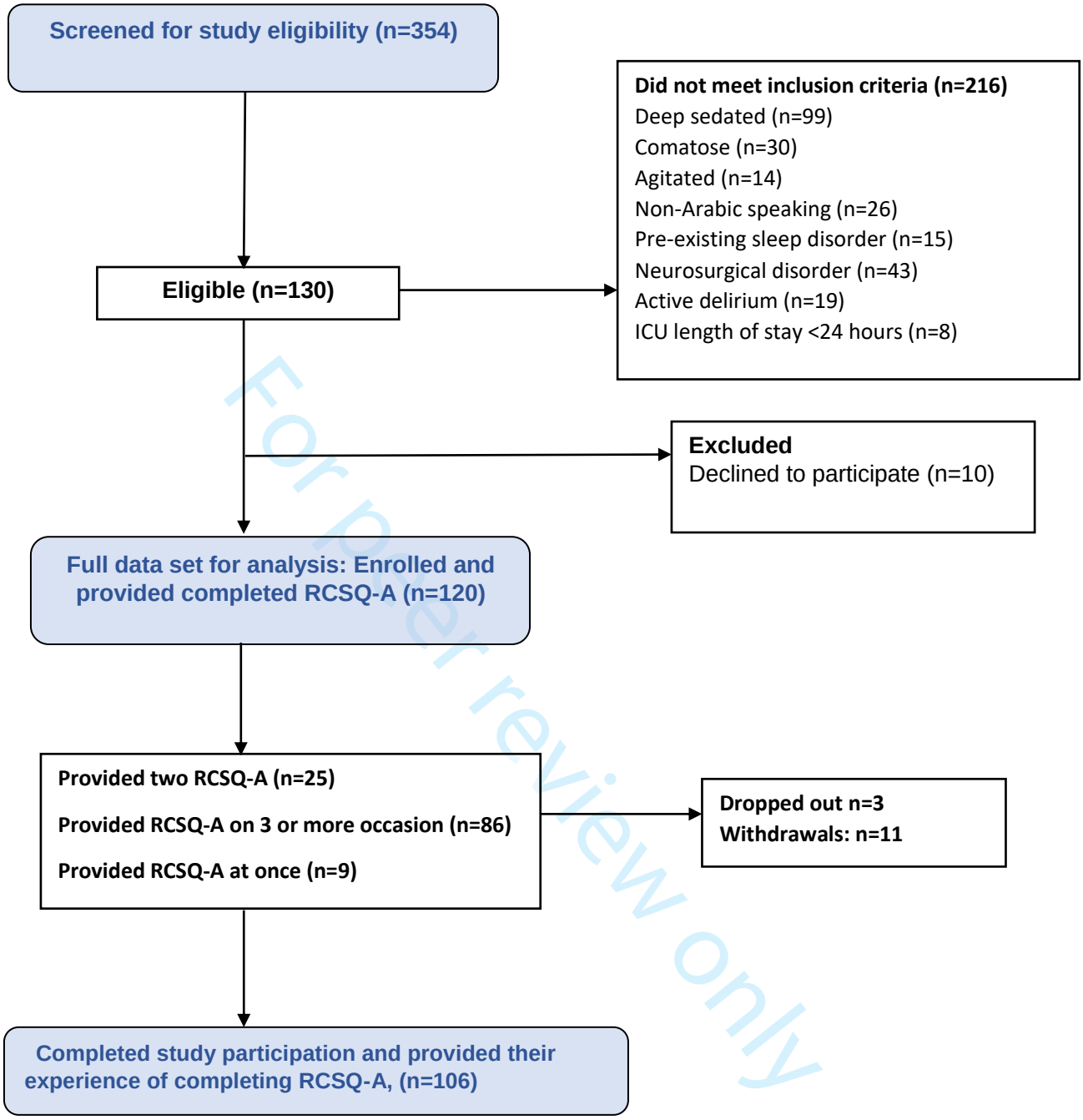

Figure 1. Flow diagram of patients screening, enrollment and participants RCSQ-A completions.

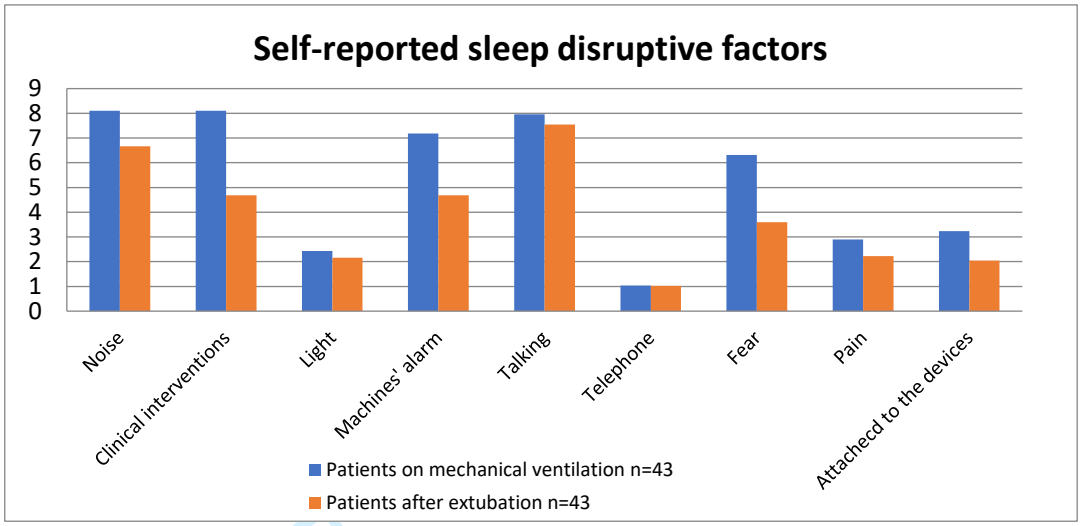

Figure 2. Significance of changes in the self-reported sleep disruptive factors during intubation and after extubation

Supplementary-1: Study instruments

1. The Arabic version of RCSQ (RCSQ-A) was used to assess patients' perceptions of their sleep quality. This questionnaire is a brief self-report tool that asks respondents to rate the previous nights' sleep on a five-item visual analogue scale (VAS).[17] Each VAS represents a different aspect of sleep: sleep depth, falling asleep, number of awakenings, returning to sleep, and overall quality of sleep. The RCSQ has been validated against the PSG and demonstrates a reliability coefficient of 0.90.[17] It also demonstrates good internal consistency, with scores of 0.88 to 0.92, throughout numerous translations including Arabic, German, Spanish, and Swedish.[15,24,25,26] The RCSQ total score is an overall assessment of sleep quality, with a higher total score relates to a higher quality of sleep experienced by the patient.[17] The cut-off scores for the RCSQ-A that used were based on the studies by Frisk Nordström et al.[24] and Krotsetis et al.[25] Patient responses were categorised into the following four classes; very poor = very low rating <26; poor = low rating, between 26-50; good = moderate, rating between 51-75; very good = high rating >57.

   The translation of the RCSQ was carried out by Alsulami et al.[15] according to translation guidelines laid down by the World Health Organisation (WHO), and with back-translations authorised by the RCSQ developer, Professor K. Richards.[17] The authors evaluated the clarity of the translated version (RCSQ-A) using cognitive debriefing methods to assess a sample of ICU patients' understanding of RCSQ-A 5-items. The RCSQ-A was shown to have a very good internal consistency, with a Cronbach's alpha measurement of 0.89 in 56 alert ICU patients, in Saudi Arabia. It also proved itself to be a simple tool with a scoring system that Arabic speaking ICU patients found easy to understand. [15]

2. To identify factors disrupting patients' sleep, a modified Sleep in Intensive-Care Unit Questionnaire (SICQ)[16] was used. The SICQ has 27 items under the headings sleep quality (five-items), daytime sleepiness (four-items), and sleep disruptive factors (18-items). The SICQ was developed in the 1990s by researchers who performed factor-analysis and reported that the questionnaire appears to be internally valid. While this requires further validation with the PSG monitor, it has nonetheless been used in many studies. [3,6,21,29] In the current study, measures of content and face validity, including peer review by an expert-panel (healthcare providers expert in ICU work) were completed, followed by a pilot test of the SICQ with 56 patients. Subsequently, the items that required participants to retrospectively rate their sleep quality on discharge were removed to prevent recall bias. The items for sleep interruptions from television noise and doctor pagers were also removed as these were not used in the ICU. Items regarding several similar sources of noise (heart monitor alarms, ventilator alarms, I.V. pump alarms) were collated into one category item (machine alarms), and diagnostic-testing, vital-signs, blood-samples, and administration of medication were similarly collated into the category item clinical interventions. The decision to categories these items was made to ensure that the self-administered SICQ was short and simple, which was particularly important for critically ill patients to lessen the burden of the questionnaire. In addition, it was considered that patients might not accurately remember or detect the source of an alarm that caused sleep disturbance during the previous night, as the ICU environment has many complicated machines. Factors of fear, pain and being attached to machines were, however, added, based on patient answers in the pilot-test. The questionnaire demonstrated good face validity and was easily understandable for patients, as judged by a lack of comments on difficult or ambiguous items.

Supplementary-2 Categories arising from the comments of patients in relation to the open-ended question in the modified SICQ "What other factors or activities were disruptive to your sleep during last night?

Category	Subcategories	NO. patients
Environmental factors	**(Noise disruption)**	
	-Voices of other patients *'I wok every time because of the sounds of suction of patient next to me'* *'I could not sleep last night because of the man who was moaning all night'*	28
	-Sounds of footsteps/moving equipment *'I slept on and off, there was footsteps sounds along the night'* *'Sometimes I could hear moving of equipment, sounds of people steps, I did not sleep well because all of that'*	9
Patient factors	**(Psychological factors)**	
	-Worries *'I did not sleep until the morning, I was worried'* *'I was worried about whether I'd be better or not'* *'I was concerned and thinking all night about my family'*	20
	-Nightmares *'I wok every time last night of bad dreams'* *'I was so scared, and I could not sleep of a terror dream'*	15
	Clinical condition factors	
	-Coughing *'I did not sleep because of the coughing all night'* *'I have a very bad cough which keeping me awake'*	18
	- Choking sensation *'I could not sleep of a chocking feeling I was breathing through my mouth'* *'I woke up of sudden chocking feeling and I could not get back again to sleep'*	10 7
	-Nausea *'I had bad sleep of unpleasant nausea'* *'I had feeling of throwing up all night, I could not sleep'*	

Supplementary-3 Patient perception in making daily-self-reports using RCSQ-A
Most participants, n=89 (83.9%), were happy to complete the RCSQ-A daily during their stays in the ICU. Most of them found the questionnaire simple to complete and easy to understand *"It was easy to answer the questionnaire, I was just pointing".* *"The questionnaire was simple and short".*
Some patients noted that answering made them feel safe, suggesting that someone was paying attention to their needs with regard to sleep quality *"I felt safe having someone asking about my sleep"* *"I felt happy to find someone asking about my sleep, especially at that time no one was caring about this problem I have".*
Some patients found the daily self-report assessment enhanced their communication levels and reduced feelings of loneliness. *"I was feeling happy at that time when I was on the ventilator machine, unable to talk and when you come to me and try to communicate with me"* *"I was feeling lonely most of the time, everybody was busy, so I was pleased that I had opportunity to interact with someone"*
Other patients found that daily assessment of their sleep quality improved their awareness of the importance of adequate sleep for health, causing them to pay more attention to their sleep. *"It is really opened my eyes on how is important to my health to get enough sleep"* *"The assessment was at each morning which gave me attention that my sleep is important to me"*
Some of the participants, n=17 (16.1%), at some point during the repeated assessment did not complete the daily RCSQ-A; these patients had some difficulties in completing the questionnaire for personal reasons such as feeling tired or bored *"I felt tired at sometimes and I did not want to do any activity"* *"I was feeling bored and empty at sometimes, and I did not want to do anything"*

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	In the title and abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	In the 2nd page
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	In the 4th page
Objectives	3	State specific objectives, including any prespecified hypotheses	Last paragraph in the background
Methods			
Study design	4	Present key elements of study design early in the paper	Under study design and settings page 4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Under study design and settings page 4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Under study participants and recruitments page5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, and effect modifiers. Give diagnostic criteria, if applicable	Under outcome measures page 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Under outcome measures page 5
Bias	9	Describe any efforts to address potential sources of bias	Under outcome measures page 5
Study size	10	Explain how the study size was arrived at	Sample size page 6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Under data management and

			analysis page 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Under data management and analysis page 6
		(*b*) Explain how missing data were addressed	Under outcome measures page 5
		(*c*) If applicable, explain how loss to follow-up was addressed	N/A
		(*d*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	First paragraph in the result and Table1. Page 6-7
		(b) Give reasons for non-participation at each stage	First paragraph in the result page6. And under Patients' acceptance of making daily self-reports page 10
		(c) Consider use of a flow diagram	Page 6 (Figure-1).
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures	First paragraph in the result and Table1. Page 6-7
		(b) Indicate number of participants with missing data for each variable of interest	Under Patients' acceptance of making daily self-reports page 10
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	In the result part Page 8,9
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	In page 11,12
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Last two paragraphs page 13
Generalisability	21	Discuss the generalisability (external validity) of the study results	Last paragraph page 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	After references page16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.