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Original Article

A multicentre point prevalence study of nocturnal hours awake and enteral pharmacological sleep aids in patients admitted to Australian and New Zealand intensive care units

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ABSTRACT

Objective: Critically ill patients suffer disrupted sleep. Hypnotic medications may improve sleep; however, local epidemiological data regarding the amount of nocturnal time awake and the use of such medications is needed.
Design: Point prevalence study.
Setting: Adult ICUs in Australia and New Zealand.
Participants: All adult patients admitted to participating Intensive Care Units (ICUs) on the study day.
Main outcome measures: Time awake overnight (22:00–06:00) was determined by structured nurse observation. The use of enterally administered sedative-hypnotic drugs prior to and during ICU admission was recorded, as was the use of a unit policy and non-pharmacological sleep promotion strategies.
Results: Data were available for 532 patients admitted to 40 ICUs (median age 60 years, 336 (63.2%) male, and 222 (41.7%) invasively ventilated). Forty-eight patients (9.0%) received an enteral pharmacological sleep aid, of which melatonin (28, 5.2%) was most frequently used. Patients not invasively ventilated were observed to be awake overnight for a median of 4.0 h (interquartile range (IQR): 2.5, 5.5), with no difference in those receiving an enteral hypnotic ($p = 0.9$). Non-pharmacological sleep aids were reportedly not offered or available for 52% (earplugs) and 63% of patients (eye masks). Only 7 (17.5%) participating ICUs had a policy informing sleep-optimising interventions.
Conclusions: Patients not receiving invasive ventilation appeared to spend many nocturnal hours awake. Pharmacological sleep aid administration was not associated with a greater observed time asleep. Most

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patients did not receive any non-pharmacological aid, and most ICUs did not have a local guideline or unit policy on sleep promotion.

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1. Introduction

Sleep is an essential physiological process that is frequently disrupted during critical illness.[1–3] Observational data suggest that patients in the Intensive Care Unit (ICU) suffer from frequent awakenings and a paucity of time in the deep, restorative phases of sleep.[4–7] The consequences of disturbed sleep during critical illness remain uncertain, but the available evidence suggests it is associated with substantial patient distress, increased risk of delirium and delayed liberation from mechanical ventilation in patients in the ICU, as well as anxiety, depression, and decreased quality of life in ICU survivors.[8–11]

Both pharmacological and non-pharmacological interventions to improve sleep have been evaluated with mixed results.[12–14] Pharmacological sleep aids are a diverse group of drugs with sedative-hypnotic properties prescribed with the specific intention of improving sleep quality and quantity.[15] While the efficacy of pharmacological sleep aids to improve objective and subjective sleep-related outcomes in patients with chronic insomnia has been demonstrated in the outpatient setting, this has not been replicated consistently in either general inpatient or critical care populations with acute sleep disturbances.[16–18]

The Society of Critical Care Medicine's 2018 clinical practice guidelines for the management of Pain, Agitation, Delirium, Immobility and Sleep disruption (PADIS) in the ICU recommend – on the basis of low-quality evidence - the implementation of multicomponent sleep protocols that include the offer of earplugs and eye masks, as well as ambient noise and light reduction strategies to improve ICU patient sleep.[12] While only a limited number of drugs were included in the PADIS guideline, no pharmacological agents for sleep promotion were recommended. Similar recommendations were made by the South Korean Society of Critical Care Medicine's 2021 PADIS guidelines.[19] Despite the absence of robust evidence to support their use, single-centre period-prevalence data suggest up to 20% of patients receive an enteral drug to promote sleep while in an Australian ICU.[15]

Gaining a clearer understanding of the current prescribing patterns for these drugs and the amounts of sleep loss in critically ill patients will help guide future practice by providing a foundation for quality improvement initiatives and identifying therapeutic targets for future research. Given the lack of data on the prescribing patterns of enteral pharmacological sleep aids in Australian and New Zealand ICUs, data were collected to determine the point prevalence of enteral pharmacological sleep aid use, and which classes and doses of enteral pharmacological sleep aids are prescribed.

2. Methods

A binational, multicentre, observational point prevalence study was conducted as part of the 2020 Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS-CTG) Point Prevalence Programme, coordinated by the George Institute for Global Health.[20] All Intensive Care Units in Australia and New Zealand were invited to participate. Human research ethics committee or institutional waiver of consent was obtained for all participating sites.

All adult patients admitted to an ICU bed at 10:00 h on the assigned study day (June 2020) were included in the data collection. Clinical and demographic data were obtained from patient records. Site-specific data collectors recorded information on the use and dosage of enterally administered sedative-hypnotic drugs that may promote sleep, irrespective of their indication. The list of included drugs was based on prior work by Wong and colleagues that identified eleven drugs commonly used as enteral sedative-hypnotic drugs in the ICU (Supplemental Table 1).[15] To increase specificity, this list of included agents was limited post hoc to those with a primary indication of sleep promotion to include only melatonin, temazepam, zolpidem and zopiclone.[21,22] No intravenous sedative agents were included. Data on the use of non-pharmacological interventions, including the availability, offer and acceptance of eye masks and earplugs, and the type of room used by the patient on the study day, was collected. On the study day, between 20:00 and 06:00, the bedside nurse used the Edwards-Schuring Sleep Observation Tool to measure the sleep-wake state at 15-min intervals. This tool has previously been validated against polysomnography in the ICU setting.[23] Patients receiving invasive ventilation were excluded from this analysis as most were presumed to be receiving intravenous sedation, and the effect of intravenous sedation on the Sleep Observation Tool's validity has not been reported. Unit-level data on the presence of a unit sleep protocol and its constituent elements were also recorded.

Study data collected at each site were entered into a REDCap electronic database hosted by the George Institute.[24,25] Patient data were deidentified prior to release by each site.

The statistical analysis was performed using Stata release 18 (StataCorp, Texas, USA). Categorical variables were compared using Chi-squared and Fisher's exact tests. No adjustments were made for missing data. The observed hours awake overnight were non-normally distributed, and between-group effects were analysed using Poisson regression with robust standard errors.[26]

3. Results

Forty units across Australia (33, 82.5%) and New Zealand (7, 17.5%) participated in the study. Most ICUs were located in public (35, 87.5%), tertiary (24, 60%), and teaching (31, 77.5%) hospitals (Supplemental Table 2).

Data were available for analysis from 532 patients (Table 1). Patients had a median age of 60 years (interquartile range (IQR): 45.0, 71.5), 336 (63.2%) were male and 222 (41.7%) were invasively ventilated.

3.1. Hours awake overnight

On the study day, data for the duration of time awake overnight were available for 182 of 310 (59%) patients not being invasively ventilated. The median nurse observed time awake between 22:00 and 06:00 was 4.0 h (IQR: 2.5, 5.5). There was no difference in the time awake for patients who received a pharmacological sleep aid of 4.0 h (2.3, 5.5) compared to 4.0 (2.5, 5.5) hours for those who did not ($p = 0.90$).

Table 1
Patient characteristics.

	All patients	Pharmaco-logical sleep aid	No pharmaco-logical sleep aid	p-value
Total number of patients	532	48	484	
Age (years), median (IQR)	60 (45.0, 71.5)	53.5 (39.0,69.0)	60.5 (45.5, 72.0)	0.001
Male sex, n (%)	336 (63.2)	31 (64.6)	305 (63.0)	0.830
Weight (kg), median (IQR)	82.0 (67.0, 96.0)	79.0 (67.0, 96.6)	82.0 (67.1, 96.0)	0.755
Source of admission, n (%)				<0.001
- Emergency department	171 (32.1)	11 (22.9)	164 (33.9)	
- Theatre (elective)	113 (21.2)	7 (14.6)	106 (21.9)	
- Theatre (emergency)	96 (18.0)	7 (14.6)	89 (18.4)	
- Ward	85 (16.0)	11 (22.9)	74 (15.3)	
- Other hospital	33 (6.2)	3 (6.3)	28 (6.2)	
- Other ICU	30 (5.6)	9 (18.8)	21 (4.3)	
APACHE II score, median (IQR)	16.0 (12.0, 21.0)	15.0 (12.0, 18.0)	16.0 (12.0, 21.0)	0.210
Invasive ventilation, n (%)	222 (41.7)	23 (47.9)	199 (41.1)	0.362
Non-invasive ventilation, n (%)	143 (26.9)	14 (29.2)	129 (26.7)	0.708
Severe ARDS, n (%)	6 (1.1)	0 (0.0)	6 (1.4)	>0.99
COVID-19, n (%)	2 (0.4)	0 (0.0)	2 (0.40)	>0.99
Trauma, n (%)	72 (13.5)	5 (10.4)	67 (13.8)	0.660
Traumatic brain injury, n (%)	24 (4.5)	1 (2.1)	23 (4.8)	0.624
Patient room type, n (%):				0.071
- Single room, open door	163 (30.6)	11 (22.9)	152 (31.4)	
- Single room, closed door	44 (8.3)	6 (12.5)	38 (7.9)	
- Part of multi-bed area	206 (38.7)	21 (43.8)	185 (38.2)	
- Not known or available	119 (22.4)	10 (20.8)	109 (22.5)	
Pharmacological sleep aid prior to ICU admission, n (%)	26 (4.9)	8 (16.7)	18 (3.7)	<0.001

APACHE: Acute physiology and chronic health evaluation, ARDS: Acute respiratory distress syndrome, ICU: Intensive care unit, IQR: interquartile range, Kg: kilograms.

3.2. Pharmacological sleep aid use in ICU

Data on the use of enteral pharmacological sleep aids in ICU were available for 530 patients (99.6%), of which, forty-eight patients (9.0%) received an enteral pharmacological sleep aid on the study night. The most frequently prescribed of these drugs was melatonin in 28 patients (5.3%), and the most commonly recorded dose was melatonin 2 mg in 13 patients (2.4%) (Table 2). Patients who received an enteral pharmacological sleep aid in the ICU were younger and more likely to have been prescribed a drug to assist with sleep prior to ICU admission. Of the 48 patients who received a pharmacological sleep aid, 42 (88%) received a single drug, and 6 (13%) received two agents. There were no differences in prescribing patterns when comparing patients receiving invasive ventilation against those who were not (Supplemental Table 3).

The prevalence of unadjusted sedative-hypnotic agent prescription is summarised in Supplemental Table 4.

3.3. Pharmacological sleep aid use prior to ICU

Data on the use of enteral pharmacological sleep aids prior to ICU were available for 532 patients (100%) (Supplemental Table 5). For all patients, the most frequently prescribed pharmacological sleep aids prior to ICU admission were temazepam (13, 2.4%) and melatonin (8, 1.5%). In all relevant cases, the agent prescribed prior to ICU was the same as the agent prescribed in ICU. The use of an enteral pharmacological sleep aid prior to ICU admission was more common in the group prescribed these drugs in ICU compared to those that did not receive these medications (8/48 (16.7%) vs 18/484 (3.7%); $p < 0.001$).

Table 2
Prevalence of pharmacological sleep aid prescription by dose.

Agent	Dose	Frequency n (%) (N = 532)
Melatonin	2 mg	13 (2.4)
	Other dose	15 (2.8)
Temazepam	10 mg	8 (1.5)
	Other dose	0 (0)
Zolpidem	10 mg	1 (0.2)
	Other dose	1 (0.2)
Zopiclone	3.75 mg	11 (2.1)
	7.5 mg	3 (0.6)
	Other dose	2 (0.4)

3.4. Non-pharmacological sleep aid use

Data on the use of non-pharmacological sleep aids were reported as missing or unknown for 205 patients (39%) and 163 patients (31%) for earplugs and eye masks, respectively (Supplemental Table 6). Within these limitations, non-pharmacological sleep aids were found to be not offered or available for at least 280 patients (52%) for earplugs and 335 patients (63%) for eye masks. Missing data were not evenly distributed, with evidence of both inter and intra-unit variability. When data on non-pharmacological sleep aid use was missing, it was missing for all patients from that unit for 20–28% of patients. Data were missing more frequently when patients were not invasively ventilated compared to patients who were invasively ventilated for both earplugs (55, 26.8% vs 150, 73.2%) and eye masks (40, 24.5% vs 123, 75.5%) (Supplemental Table 7).

Data for patient room-type allocation were available for 443 patients (78%). Approximately equal numbers of patients were in a multibed area (206 patients, 39%) compared to an individual room (207 patients, 39%) (Supplemental Table 8).

3.5. Intensive care unit sleep policy

Of the 40 participating Intensive Care Units, only 7 (17.5%) had a local policy or guideline to inform the use of sleep-optimising interventions. The components of the sleep-promotion policies are summarised in Table 3. Notably, the offer and use of earplugs and eye masks were described in 6 guidelines (85.7%), while only two guidelines (28.6%) referred to pharmacological sedative-hypnotic use. Logistic regression analysis did not find a significant association between the existence of a unit sleep policy and pharmacological sleep aid use ($p = 0.92$).

Table 3
Interventions included in unit protocols or guidelines.

Intervention	Frequency n	% of units using with sleep protocol (N = 7)	% of all units (N = 40)
Prescription of pharmacological sleep aids	2	28.6	5.0
Offer and use earplugs	6	85.7	15.0
Offer and use eye masks	6	85.7	15.0
Reduction of monitor alarm levels at night	5	71.4	12.5
Dimming lights at night	7	100	17.5
Avoidance of hygiene interventions between 22:00–06:00	4	57.1	10.0
Use of a validated sleep survey in competent patients	1	14.3	2.5

4. Discussion

4.1. Key findings

These findings suggest that patients not receiving invasive ventilation in Australian and New Zealand ICUs are awake for a substantial number of hours overnight. Enteral pharmacological sleep aids were prescribed in 9% of patients. Most patients were not offered non-pharmacological strategies, such as earplugs and eye masks, or they were not available. A minority of Australian and New Zealand ICUs have a local guideline or unit policy on sleep promotion.

4.2. Comparison with previous research

A prior point prevalence study of sound levels and sleep disruption conducted in 680 patients in 49 Australasian ICUs in 2015 by Litton and colleagues reported that patients were observed to spend a median of 3 (IQR: 1,4) nocturnal hours awake, similar to our findings.[27] Unpublished data from this study identified a similar infrequent offer or availability of earplugs 535 (79%) and eye masks 575 (85%), as well as the infrequent presence of a unit sleep policy (15%) (Supplemental Tables 9 and 10). This study reported that a pharmacological sleep aid was used in 56 patients (8.2%). However, the inclusion of more antipsychotic agents and fewer sedative-hypnotics compared to the current study limits direct comparison of these data.

The single-centre, period prevalence study of pharmacological sleep aid use in a metropolitan Australian ICU by Wong and colleagues reported that 17% of patients received a pharmacological sleep aid.[15] They identified the most frequently prescribed agents were melatonin (6.8%), temazepam (6.2%) and quetiapine (3%). A greater number and classes of included pharmacological agents, local prescribing habits and methodological differences may explain these differences.

Hamidi and colleagues conducted a retrospective chart review of the initiation of nocturnal neuroactive medication in ICU patients across two large North American institutions and reported that 9.7% of patients received these drugs.[28] While the definition of nocturnally neuroactive medications encompasses a more diverse range of medication classes, melatonin (5.1%) and anti-psychotics (4.0%) were the most frequently prescribed drugs. Methodological differences relating to study design and drugs included in the definition of a pharmacological sleep aid limit direct comparison with the current study.

4.3. Clinical implications

Enteral pharmacological sleep aids appear to be prescribed to around 10% of patients in the ICU on a given night. The reasons for this are likely multifactorial, involving clinician attempts to improve sleep and circadian rhythms, as well as requests by patients and families.[29] However, the available evidence does not support the use of these agents to improve sleep. A Cochrane review on the use of melatonin to improve sleep in the ICU found insufficient evidence to recommend its use.[30] In addition, the largest trial to date of melatonin in ICU patients, the ProMEDIC study, did not detect any statistically significant difference in subjective sleep quality or nurse-determined sleep duration.[31] A prospective, placebo-controlled, randomised trial of the effect of temazepam on sleep in ICU patients is currently underway (ACTRN12621000742875).

The published literature suggests that eye masks alone or in combination with earplugs, may improve sleep in ICU patients, while earplugs alone do not provide benefit.[32,33] However, heterogeneity across studies, small sample size and methodological inconsistency may have overestimated any effect size. In the current study, these non-pharmacological interventions were rarely offered or available.

The scarcity of evidence-based, sleep-promoting interventions may explain the low prevalence of a unit policy or guideline. More high-quality research that focuses on both objective measures and the subjective patient experience is required to understand how we can optimise sleep in the vulnerable ICU patient population.

4.4. Limitations

There are several limitations to our study. Determining which medications to include as pharmacological sleep aids poses an ongoing problem for research in this area. While many drugs are prescribed with the intent of promoting sleep, they frequently have multiple alternative indications. Determining the indication for a given agent is essential to identify it as a pharmacological sleep aid. The initial list of sleep aids, based on a prior study by Wong and colleagues, was not adequately specific for our study methodology, appearing to capture the use of antipsychotics and diazepam for indications other than sleep promotion. In contrast, the post-hoc revised list of pharmacological sleep aids may have been overly specific and insufficiently sensitive. Both definitions omitted emerging classes of hypnotic agents, including the orexin receptor antagonists and melatonin receptor agonists. Propofol, midazolam and dexmedetomidine have all been investigated as potential intravenous pharmacological sleep aids with mixed results.[34–38] As these agents are more commonly used for their sedative and anaesthetic properties, their use primarily as sleep aids is less well-defined and consequently, intravenous pharmacological sleep aids were not included in this study.

The Edwards and Schuring Sleep Observation Tool has been validated against polysomnography and found to have good agreement in a small study of 21 fully oriented adult patients. While the majority of these patients were invasively ventilated, the use of sedation is not reported. Intravenous sedative-anaesthetic agents are likely to confound the assessment of sleep-wake status, precluding the use of the Sleep Observation Tool in patients receiving these drugs. In the absence of data on intravenous sedation use, the use of invasive ventilation was used as a surrogate

for this variable, and we elected to exclude this cohort from the assessment using the Sleep Observation Tool in order to limit confounding. The lack of specific training for clinical staff completing this tool may also have limited the accuracy of this data.

The point prevalence design facilitates a large amount of data to be sampled from multiple ICUs simultaneously. However, this methodology posed a number of limitations. While we were able to collect information on which drugs were prescribed, it was not possible to determine the indication for their prescription. In addition, it was not possible to collect data on the concurrent use of enteral and intravenous sedative drugs or the incidence of delirium, which would have helped provide important context for our results.

Due to the amount of missing data, any conclusions regarding observed hours awake overnight, the use of non-pharmacological sleep aids, and patient room allocation are limited and further exploratory analysis of these parameters was deemed not to be appropriate. The patients' index ICU and their ventilation status appear to be associated with missing data for these parameters. Patients receiving invasive ventilation would typically have a higher nursing ratio, which may have facilitated data collection for this subpopulation. The impact of the patient's ICU on missing data may be indicative of site-specific compliance issues.

5. Conclusion

This study identified that around 1 in 10 patients admitted to Australian and New Zealand ICUs received an enteral pharmacological sleep aid. However, non-ventilated patients in Australian and New Zealand ICUs are awake for a substantial number of hours overnight. The most frequently prescribed drug was melatonin. Earplugs and eye masks were not available, or not offered, to more than half of all included patients. Only 17.5% of ICUs had a unit policy to guide the use of their pharmacological and non-pharmacological interventions to improve sleep. More high-quality research is required to assess whether pharmacological sleep aids can improve sleep and patient-centred outcomes in critically ill patients, as well as guiding policy development at unit, national and international levels.

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CRediT author statement

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Yasmine Ali Abdelhamid: Conceptualization, Methodology, Writing – Review & Editing, Supervision, Funding acquisition, Project administration.

Conflict of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

The following authors declare that they are part of the CC&R editorial team as associate editors:

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Appendix A. Supplementary data

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