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Safety of implementing a sleep protocol in hospitalized patients

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ABSTRACT

Background: Although good sleep during hospitalization may promote positive outcomes, some patients and clinicians may have concerns about nursing interventions designed to reduce night-time sleep disturbances.
Methods: A randomized prospective trial of an intervention to promote sleep was conducted with stable, post-operative oncology patients. Eligible patients were randomized to receive usual nursing care overnight or sleep-promoting interventions.
Results: All thirty-seven surgeons in the organization agreed to let their qualified patients participate. One hundred and forty-four patients met the study criteria. Of those, 117 (81%) consented to participate, while 27 (19%) declined. The primary reason for non-enrollment was wanting to be checked on throughout the night (n = 21, 78%). There were no adverse events during the study period. Patients' perceptions of pain and nausea control among the two groups were equivalent.
Conclusion: An intervention to decrease sleep disturbances can be safely executed in a post-operative population while maintaining adequate symptom management.

Introduction

While healthcare providers implement multiple best practices to improve outcomes for surgical patients, an often-overlooked area is adequate sleep. The idea of promoting quality sleep during hospitalization is not new. Redeker[1] showed that interrupted sleep leads to increased stress, negative outcomes, however, to date limited research has been conducted on interventions to reduce night-time interruptions and improve sleep quality during a hospital stay in an acute care setting. In a systematic review performed by Hellström and Willman,[2] findings showed that interventional based projects were limited on nursing care and sleep hygiene methods.

To improve patient care and to follow with the Institute of Medicine's desire to bridge the quality chasm, practitioners need to progress past the habituated practices and traditions that contradict evidenced-based practices. Yoder et al.[3] explored the consequences associated with frequent night time interruptions leading to negative outcomes for the patient. Hospital interventions such as indwelling urinary catheters, surgical drains and intravenous catheters are defined by Yilmaz, Sayin and Gurler[4] as added stressors to a noisy, bright hospital environment that can add to diminished sleep in the acute care setting. The conclusions drawn by Yilmaz, Sayin and Gurler was that if care interactions controllable by medical and nursing staff could be adjusted around typical sleep hours, the stress impact of hospitalization and surgery could be reduced, better sleep quality attained, and timely discharge home could occur.

The goal of this research study was to evaluate a comprehensive intervention to help promote sleep in post-operative patients, while maintaining quality, patient-centred care. The specific aims were to: 1) examine the safety of an intervention to reduce night time sleep disturbances following surgery and 2) examine why post-operative oncology patients might elect not to participate in this type of intervention.

Methods

With Institutional Review Board approval, a 10-month study was conducted on post-operative patients admitted to an inpatient surgical oncology unit at a comprehensive cancer center.

This project was a prospective randomized trial of a comprehensive sleep intervention where patients were randomized into the control or intervention group. All patients who meet the

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inclusion criteria were screened for participation (Table 1). The exclusion criteria screened out complex flap surgeries (Table 1), conditions or use of medications requiring frequent assessment, altered mental status, and those at risk for poor oxygenation. All thirty-seven surgeons within the organization agreed to allow their patients to participate, having reviewed the inclusion and exclusion criteria. Surgeons, nurses and patients could request withdrawal from the study at any time or for any change in status. Patients who declined to participate were asked to provide a reason for their decision so that there could be understanding of the characteristics of patients who might not want to be left undisturbed during the night and concerns that patients might have about the intervention.

After obtaining informed consent, participants completed a demographic and baseline sleep quality questionnaire delivered on an iPad using REDCap (8UL1TR000105 (formerly UL1RR025764) NCATS/NIH). Patients in the control group were woken by the nursing staff every two to 4 h for usual nursing care, which included vital sign measurements at 21:00 and 04:00, body fluid output measurement, scheduled medications, intravenous fluid administration and laboratory or radiological tests. Participants in the intervention group were provided earplugs and an eye mask and given the opportunity to be "tucked in" (see Fig. 1). The patients in intervention group had no vitals signs obtained between 9:00p.m. and 6:00 a.m., with the last set of vitals obtained just before 9:00p.m., to confirm the patient was stable enough to participate. The nursing staff worked with the hospital pharmacy to schedule medications before 22:00 and after 05:00. Laboratory personnel were asked to draw blood from these patients last, radiology technicians were instructed to obtain X-rays before bed time or upon waking if possible, and the patients' rooms were marked with signage asking staff and visitors to check with the nurse prior to entering the room. Night shift nurses were empowered to withdraw patients from the intervention group if they did not meet the inclusion criteria by bedtime.

An important aspect of the study was ensuring that intervention group patients were adequately monitored during the night. The hospital call light system and the pulse oximetry devices were compatible, so that when the pulse oximeter was plugged into the call light, any changes to oxygenation or altered heart rate above or below alarm limits turned on the call light, alerting the staff to check on the patient. Patients were able to contact the staff at any time using the call light system.

A tally sheet in the patients' room was used by nursing and ancillary staff to track the number of times the control and intervention participants were disturbed and whether it was staff initiated or a patient request via the call light. Each morning control and intervention participants were surveyed about their experience during the prior night. Patients were asked if noise, light or temperature kept them from sleeping using a five-point Likert scale (1 = Strongly disagree to 5 = strongly agree). The degree to which pain and nausea were controlled was evaluated using a Likert scale (1 = Strongly disagree to 5 = strongly agree). In addition to estimating the number of hours slept, participants were asked to complete the Richards-Campbell sleep questionnaire (RCSQ)[5] to assess sleep quality. The RCSQ is a five-item visual scale that evaluates patients' perception about sleep depth, sleep onset latency, number of awakenings, awake time and general sleep quality. Participants rated each item on an iPad with a sliding scale ranging from 0 to 100. Participants were also queried about their satisfaction with the nursing care provided. There was also an option for the patient to subjectively describe their night, and how they felt about their sleep, or lack thereof.

Results

Four hundred and fifty-four patients were screened in the ten-month study period. Two hundred and ten, or approximately half of patients met the inclusion criteria. Based on availability of research personnel to recruit and obtain informed consent, 144 (67%) were invited to participate. Of those, 117 (81%) were consented to participate, while 27 (19%) patients declined. Of those who declined to participate, 21 (78%) were attributed to patient or family insecurity, specifically, wanting to be monitored or checked on through the night, for concerns of safety or worry that their post-operative pain or symptoms might get out of control. The

Table 1
Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
Temperature <38.5° Celsius	Free flap procedure
Systolic blood pressure >90 and <160 mm Hg	Whipple surgeries
Heart Rate: 60–120 beats per minute	Craniotomy
Respiratory Rate: 10–30 breaths per minute	Neobladder
SPO_2 > 90%	Tracheostomy
Urine output: > 120 ml in 4 h or voided following operation mEWs[c] Score = 2 or below Glasgow Coma Score: eye response equal to 4, verbal response equal to 5, total score ≥14	Orthopedic surgeries with every 4-h neurological checks on affected limb
Ambulated following operation	On a Clinical Institute Withdrawal Assessment protocol for alcohol
	Drains with high output
	Epidural catheter
	Patient controlled analgesia/ketamine (or any other continuous intravenous pain medications requiring frequent assessment)
	Heparin or cardiac medication infusion
	Confusion/dementia, sundowning (change in mental status at night), impulsive behavior, developmental delay
	Diabetics on Q6, Q4 or 0300 blood glucose checks
	1:1 supervision or bed alarm
	Direct admissions or readmissions
	Procedures or interventions scheduled for nighttime
	On face mask or O_2 > 4L/minute on nasal cannula or new CPAP[a] or BiPAP[b]
	Non-English speaking

[a] Continuous positive airway pressure.
[b] Bilevel positive airway pressure.
[c] Modified Early Warning Score.

- Ensure vital signs meet study criteria
- Fill up water mug
- Check and empty all drains, catheters, chest tubes etc.
- Pulse oximetry plugged into wall and attached to patient
- Change intravenous fluid bag if fluids will run out during the night
- Fill feeding tube bags with maximum allowed amount of formula
- Offer evening cares
- Offer toileting to patient
- Offer eye masks and ear plugs to patient
- Discuss/offer pain and/or nausea medications
- Ensure temperature in room is comfortable
- Give sleeping medication if ordered and requested

Fig. 1. Sleep study 'tuck in' check list for night shift nurses to use with patients in the sleep intervention group.

Table 2
Comparison of age of patients who agreed to participate in the sleep study versus those who declined.

Grouping	Mean Age (SD)	T	df	p
Agreed to participate	56.6 years (15.3)	-.065	154	.95
Refused to participate	56.8 years (12.5)			

remaining 6 (22%) declined to say why they chose to not to participate.

Demographic characteristics among patients who agreed to participate in the study and those who did not were similar. Although the range of ages in each group varied (18–93 years in the enrolled participants *vs.* 29–74 years in the refusal group), the mean ages were equivalent (Table 2). Among the 117 enrolled participants, 28 were over 70 and 4 were over 80 years of age. Similarly, males and females declined to participate at similar rates (Chi-square = 0.01, p = .92).

Among the 117 patients enrolled in the study, for a range of one to five nights, there were no adverse events; and therefore, no difference in medical outcomes between the control versus intervention groups. During the study period, no surgeon requested that a patient who met inclusion criteria, not participate or be withdrawn from the study. Three patients in the intervention group were withdrawn during the night by the nursing staff; one due to increased confusion and two due to medical instability (bradycardia/hypotension and tachycardia/hypertension with vomiting). The withdrawal of these patients demonstrated that the night time checklist was effective in ensuring patient safety and protocol adherence. Patients' reported perceptions of pain and nausea control among the control and sleep intervention groups were statistically equivalent (t = 0.30, p = .77).

Discussion

This prospective randomized trial of sleep intervention in post-operative patients shows that an intervention to decrease interruptions of sleep can be safely executed in a post-operative population with careful screening for strict inclusion criteria.

While no complications occurred in the study group, nearly 20% of the patients who were invited to participate declined because they were concerned about the negative consequences of being allowed to sleep without interruptions while in the hospital. Patients who became less stable overnight were either identified prior to the start of the intervention or were identified through the monitoring system. Yoder et al. demonstrated in their study that vital signs on medically stable patients could be adjusted to focus on higher acuity patients without adverse outcomes to low risk patients being allowed to sleep. The patients who declined to participate in the study cited family concerns about not being monitored, the perception that nursing care means being frequently checked on and the security associated with being checked on. Community and public perception, as well as expectation of historical care practices can impact opportunity for beneficial rest and symptom management in a safely monitored environment.

Despite a fear of inadequate pain control associated with not being 'checked on' overnight, patients who participated in the study and were in the sleep intervention group had equivalent pain (and nausea) control as those in the control group.

Further studies are necessary to evaluate whether sleep improvement may impact post-operative outcomes. Potential next steps for this research could be to expand the project to include non-surgical patients, evaluate length of stays between intervention and control groups, identify further inclusion and exclusion criteria, and work with physicians about preoperative teachings of sleep hygiene methods utilized in hospital. The literature on sleep protocols demonstrate challenges and areas for future studies to focus on. Norton et al. (ref #[6]) described limitations to their study due to no control group, and Yilamaz, Sayin and Gurler (ref #[4]) did not have sleep interventions to compare standard care practices to.

Additionally, opportunities exist for changing expectations and perceptions of quality care by better educating patients to the post-operative course of treatment during the hospital stay (?), including sleep options and strategies for managing symptoms while allowing restorative sleep. Pre-operative education by practitioners and nursing staff could impact and adapt a culture of care expectation by the patient creating improved outcomes. In conclusion, it is possible for physicians to authorize sleep protocols and have a positive impact on patients' outcomes, care perceptions and recovery.

Conflicts of interest

The authors have no conflict of interest to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2018.10.017.

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