

Proposal

Postoperative Sleep Quality Following Total Joint Arthroplasty: A Prospective, Randomized, Controlled Trial of Diphenhydramine and Melatonin Versus Sleep Skills Training

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Background

Sleep disruption is a common, yet oft-ignored, problem in patients before and after total joint arthroplasty (TJA) with a postoperative prevalence as high as 50%.¹ Postoperative sleep disturbance is often reciprocal to night pain and mediates the association between early postoperative pain and functional recovery following TJA.² As such, optimizing sleep has potential to decrease pain and enhance a patient's mental status during daytime hours after TJA, which may improve functional outcomes and hasten postoperative recovery.³ Inversely, persistent sleep disturbance after TJA may increase pain and jeopardize the postoperative course while straining the physician-patient relationship.

The impact of sleep quality on postoperative functioning and recovery necessitates its optimization, especially in the context of exponentially increasing demand for TJA and an evolving healthcare landscape. By 2030, total hip arthroplasty (THA) utilization is projected to nearly triple from 2005 levels to almost 600,000 cases per year.⁴ Demand for total knee arthroplasty (TKA) is also expected to increase over 650% from 2005 levels to nearly 3.5 million cases annually.⁴ The utilization of patient satisfaction and outcome measures in reimbursement systems also continues to increase. Patient responses on such outcome measure tools can be impacted by their sleep quality, as it remains an important determinant of postoperative pain and functional recovery. This paradigm shift underlines the importance of optimizing all aspects of TJA patients' postoperative course, including sleep quality. While previous studies have demonstrated sleep disturbance in the weeks and early months following TKA,^{2, 5-7} there is a paucity of studies which prospectively assess interventions for sleep optimization after primary THA and TKA.

The purpose of this study is to compare the efficacy of non-prescription sleep medications (low-dose diphenhydramine and melatonin) to sleep hygiene education for improving sleep after primary elective total hip and knee arthroplasty.

Objective:

- To compare non-prescription sleep aids (low-dose diphenhydramine and melatonin) to sleep hygiene education for improving postoperative sleep quality after total joint arthroplasty

Study Design:

- Patient Population:
 - Sample size: 375
 - Inclusion criteria: all patients undergoing elective primary total hip or knee arthroplasty
 - Exclusion criteria: history of substance abuse, workman's compensation patients, revision joint replacement, history of prescription or over-the-counter sleep aid use
- Data To Be Collected:
 - Demographic data: gender, age, body mass index (BMI), alcohol consumption, tobacco use, narcotic use, previous diagnosis of sleep apnea
 - Perioperative data: Diagnosis, Operation, Laterality, American Society of Anesthesiologists (ASA) classification, Tourniquet time, Location of discharge (home vs rehabilitation facility), Length of stay
 - Postoperative data: Medications
 - Outcomes Data Collection Tools:
 - Epworth Sleepiness Scale (ESS) (Appendix 1)
 - Pittsburgh Sleep Quality Index (PSQI) (Appendix 2)
 - Visual Analogue Scale (VAS) for pain
 - Sleep Skills Handout (Appendix 3)
- Study Methods and Logistics
 - Consenting patients scheduled for primary THA or TKA who meet the "patient population" criteria as noted above will be enrolled in the study at their preoperative clinic visit
 - Patients will be randomized to one of three groups:
 - Control group (Usual Care)
 - Sleep Hygiene Education

- Over-the-counter sleep aids (25 mg Benadryl + 3mg melatonin) + Sleep Hygiene Education
- Data will be collected at: preoperative clinic visit at time of enrollment, and 3, 6, and 12 weeks postoperative (by phone or routine postoperative clinic visits)
- Logistics for Benadryl + Melatonin Group + Sleep Hygiene Education
 - This group will be given their full supply of Benadryl (25mg) and Melatonin before being discharged, but will not start them until the first day home each day until 12 weeks postoperative.
 - I can acquire department funding to supply the Benadryl and melatonin free of charge to patients, I met with pharmacy and they said the cost is nearly negligible for these medications.
 - This will be a handout (Appendix 3) that will be reviewed with patients at enrollment and 3, 6, and 12 weeks postoperative when the data is collected.
- Logistics Sleep Hygiene Education Group
 - This will be a handout (Appendix 3) that will be reviewed with patients at enrollment and 3, 6, and 12 weeks postoperative when the data is collected.

Appendix 1: Epworth Sleepiness Scale (ESS)

How likely are you to doze off or fall asleep during the following situations, in contrast to just feeling tired?

For each of the situations listed below, give yourself a score of 0 to 3, where 0 = Would never doze; 1 = Slight chance; 2 = Moderate chance; 3 = High chance.

Work out your total score by adding up your individual scores for situations 1 to 8. (If you have not been in the following situations recently, think about how you would have been affected.)

Situation	Score
Sitting and reading	
Watching television	
Sitting inactive in a public place (e.g. a theatre/meeting)	
As a passenger in a car for an hour with no break	
Lying down in the afternoon (when possible)	
Sitting and talking to someone	
Sitting quietly after lunch without alcohol	
In a car, while stopped for a few minutes in traffic	
Total	

Appendix 2: Pittsburgh Sleep Quality Index (PSQI)

Instructions:

The following questions relate to your usual sleep habits during the past month *only*. Your answers should indicate the most accurate reply for the *majority* of days and nights in the past month. Please answer all the questions.

1. During the past month, when have you usually gone to bed at night?

usual bed time_____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

number of minutes_____

3. During the past month, when have you usually got up in the morning?

usual getting up time_____

4. During the past month, how many hours of *actual* sleep did you get at night? (This may be different than the number of hours you spend in bed).

hours of sleep per night_____

For each of the remaining questions, check the one best response. Please answer *all* questions.

5. During the past month, how often have you had trouble sleeping because you.....

- (a) Cannot get to sleep within 30 minutes

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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- (b) Wake up in the middle of the night or early morning

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____
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- (c) Have to get up to use the bathroom

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(d) Cannot breathe comfortably

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(e) Cough or snore loudly

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(f) Feel too cold

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(g) Feel too hot

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(h) Had bad dreams

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(i) Have pain

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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(j) Other reason(s), please describe_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month_____	Less than once a week_____	Once or twice a week_____	three or more times a week_____
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6. During the past month, how would you rate your sleep quality overall?

Very good_____

Fairly good_____

Fairly bad_____

Very bad_____

7. During the past month, how often have you taken medicine (prescribed or “over the counter”) to help you sleep?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all_____

Only a very slight problem

Somewhat of a problem A

very big problem_____

10. Do you have a bed partner or roommate?

No bed partner or roommate _____

Partner/roommate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

11. How often do you feel tired during the following times during the day?

Morning:

0	1	2	3
most days	often	occasionally	never

Afternoon:

0	1	2	3
most days	often	occasionally	never

Evening:

0	1	2	3
most days	often	occasionally	never

Appendix 3: Sleep Hygiene Education Handout

<https://www.kramesstore.com/index.php/abcs-of-zzzs-the-basics-of-sleep-health-nsf.html>

- I will look into department funding to buy these brochures to use as our handout (~\$0.80 per brochure). They are published by the National Sleep Foundation and appear to be high quality.

References

1. Wylde V, Rooker J, Halliday L, Blom A: Acute postoperative pain at rest after hip and knee arthroplasty: Severity, sensory qualities and impact on sleep. *Orthop Traumatol Surg Res* 2011;97:139-144.
2. Cremeans-Smith JK, Millington K, Sledjeski E, Greene K, Delahanty DL: Sleep disruptions mediate the relationship between early postoperative pain and later functioning following total knee replacement surgery. *J Behav Med* 2006;29:215-222.
3. Hawker GA, Stewart L, French MR, et al: Understanding the pain experience in hip and knee osteoarthritis--an OARSI/OMERACT initiative. *Osteoarthritis Cartilage* 2008;16:415-422.
4. Kurtz S, Ong K, Lau E, Mowat F, Halpern M: Projections of primary and revision hip and knee arthroplasty in the united states from 2005 to 2030. *J Bone Joint Surg Am* 2007;89:780-785.
5. Krenk L, Jennum P, Kehlet H: Sleep disturbances after fast-track hip and knee arthroplasty. *Br J Anaesth* 2012;109:769-775.
6. Er MS, Altinel EC, Altinel L, Erten RA, Eroglu M: An assessment of sleep quality in patients undergoing total knee arthroplasty before and after surgery. *Acta Orthop Traumatol Turc* 2014;48:50-54.
7. Chen AF, Orozco FR, Austin LS, Post ZD, Deirmengian CA, Ong AC: Prospective evaluation of sleep disturbances after total knee arthroplasty. *J Arthroplasty* 2016;31:330-332.