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Patient Safety Tip of the Week

January 4, 2022

Spin or Not: A Useful Secondary Finding in a Study

We ended 2021 with our December 21, 2021 Patient Safety Tip of the Week "Spinning Misinformation" discussing how publications often "spin" a study to show a positive result when the primary outcome was not met. Often, the authors do a post-hoc analysis and find a subgroup that seemed to have a benefit from the drug or procedure that was being studied. Such post-hoc analyses should be hypothesis-generating and lead to a randomized controlled trial in that subgroup population.

But sometimes a study that fails to meet its primary outcome may have another finding that was not even a secondary outcome parameter yet is clinically important. Case in point: a study just published in JAMA Internal Medicine. Najafi and colleagues (Najafi 2021) sought to see if an intervention promoting sleep would prevent delirium in hospitalized patients. Our many columns on diagnosis, prevention, and management of delirium (listed below) have emphasized that one of the factors contributing to development of delirium is lack of sleep or disruption of the normal sleep/waking cycle. We've also done many columns on promoting sleep in hospitalized patients and noted that waking the patients at night to take unnecessary vital signs is a major impediment to good sleep.

The Najafi study was a randomized controlled trial (RCT) on almost 1700 non-ICU patients on a general medical service at a tertiary care academic medical center. The intervention was a clinical decision support notification that informed the physician if the patient had a high likelihood of nighttime vital signs within the reference ranges based on a logistic regression model that used real-time patient data as input. The notification provided the physician an opportunity to discontinue measure of nighttime vital signs.

Results showed no significant difference between groups in the primary outcome, delirium incidence (11% in the intervention group vs 13% in the usual care group). But the study did show that nighttime vital signs can be reasonably safely discontinued in patients identified by their real-time data analysis tool. There was a significant decrease in the mean number of nighttime vital sign checks (0.97 in the intervention group vs 1.41

in the control group; P < .001) with no increase in intensive care unit transfers (5% in both groups) or code blue alarms (0.2% vs 0.9%; P = .07).

A secondary outcome, patient satisfaction with sleep was assessed by answers to the question on the HCAPS survey: "How often was the area around your room quiet at night?". But postdischarge HCAPS surveys were completed by only 5% of the patients and revealed no significant difference for this issue.

In our August 6, 2013 Patient Safety Tip of the Week "Let Me Sleep!" and several of our other columns on promoting sleep in the hospital we have pointed out that patients' sleep is often interrupted by blood drawing and/or taking vital signs and often there is no coordination between those doing either. And we've noted that we often fail to assess whether those nocturnal vital signs were even necessary. Rather, we often reflexly enter orders such as "Vital signs every 6 hours" without considering that such orders mean a patient will likely be wakened for such assessments. Don't get us wrong – patients who are unstable do need to be wakened to take vital signs. And some patients, such as head trauma patients or patients with some neurological emergencies, also need to be wakened in order to assess level of arousal. But a substantial number of inpatients don't need to be wakened for vital signs at night. The Najafi study showed that their algorithm predicting which patients were likely to have stable vital signs at night was, indeed, useful.

But their study also showed that some habits are hard to break. Physicians did not have to heed the clinical decision support notification. Some may have disagreed with the recommendation. But others may have simply ignored it. In fact, physicians did not order SPV (sleep promotion vitals) 40% of the time. Moreover, the SPV order, which would be carried out by the bedside patient-care assistant or nurse, was not carried out on 35% of the encounter-nights. The authors postulate that busy patient-care assistants and nurses may check vital signs out of habit without noticing that the order has changed for some of the patients. The authors also point out that other interruptions to sleep, such as phlebotomy, room cleaning, noise from another patient, etc., were not precluded by the SPV order. We'll add that we often order medications in a manner that requires the patient to be wakened at night.

Does the negative primary outcome (failure to reduce delirium incidence) mean we should not consider avoidance of nocturnal vital signs in our delirium prevention programs? Of course not. Note that Najafi study did not include an assessment of delirium risk on all patients. The average age of the patients was only 53, likely meaning that older patients who are at greater risk of delirium were likely underrepresented in the study. The authors note that a study of their intervention on an acute geriatric unit might better assess its value in preventing delirium. Also, we note that some of the other risk factors for delirium might preclude use of the SPV order. And note that our March 16, 2021 Patient Safety Tip of the Week "Sleep Program Successfully Reduces Delirium" highlighted a study which showed a structured sleep promotion program successfully reduced the occurrence of delirium on a medical oncology unit and a surgical spine unit (Gode 2021).

But use of the Najafi predictive algorithm could still be applied to most patients. The editorial accompanying the Najafi study (Cho 2021) notes that the algorithms predicted normal nighttime vital signs 84% of the time and abnormal vital signs 70% of the time, "thereby alleviating cognitive burden to the clinician about vital sign stability and reducing alert fatigue from inappropriate notifications. By including a prompt to change vital sign orders, they also made it easy for physicians to change to a schedule that would not interfere with sleep."

So, are we (and the authors of the study) spinning results of a study that did not meet its primary outcome? Perhaps. But it does mesh with a commonsense approach to do away with our age-old practice of ordering vital signs to be taken at night without thinking about their actual necessity. We like the introduction of the predictive algorithm used by Najafi et al. and the clinical decision support notification. The latter would be considered non-interruptive since it did not require an action or explanation from the clinician. Risking alert fatigue, perhaps requiring a response to the CDS notification would improve upon the substantial number of times clinicians did not comply with the suggested action.

We often do a disservice to our patients by practices that interrupt their natural sleep unnecessarily. This study is a step in the right direction.

Some of our previous columns on safety issues associated with sleep meds and promoting sleep in inpatients:

August 2009	"Bold Experiment: Hospitals Saying No to Sleep Meds"
March 23, 2010	"ISMP Guidelines for Standard Order Sets"
May 2012	"Safety of Hypnotic Drugs"
November 2012	"More on Safety of Sleep Meds"
March 2013	"Sedative/Hypnotics and Falls"
June 2013	"Zolpidem and Emergency Room Visits"
August 6, 2013	"Let Me Sleep!"
June 3, 2014	"More on the Risk of Sedative/Hypnotics"
May 15, 2018	"Helping Inpatients Sleep"
June 2018	"Deprescribing Benzodiazepine Receptor Agonists"
November 6, 2018	"More on Promoting Sleep in Inpatients"
June 2019	"FDA Boxed Warning on Sleep Meds"
August 2019	"Tools for Reducing Sleep Meds in Hospitals"
March 16, 2021	"Sleep Program Successfully Reduces Delirium"

Some of our prior columns on delirium assessment and management:

- October 21, 2008 "Preventing Delirium"
- October 14, 2008 "Managing Delirium"
- February 10, 2009 "Sedation in the ICU: The Dexmedetomidine Study"

- March 31, 2009 "Screening Patients for Risk of Delirium"
- June 23, 2009 "More on Delirium in the ICU"
- January 26, 2010 "Preventing Postoperative Delirium"
- August 31, 2010 "Postoperative Delirium"
- September 2011 "Modified HELP Helps Outcomes in Elderly Undergoing Abdominal Surgery"
- December 2010 "The ABCDE Bundle"
- February 28, 2012 "AACN Practice Alert on Delirium in Critical Care"
- April 3, 2012 "New Risk for Postoperative Delirium: Obstructive Sleep Apnea"
- August 7, 2012 "Cognition, Post-Op Delirium, and Post-Op Outcomes"
- February 2013 "The ABCDE Bundle in Action"
- September 2013 "Disappointing Results in Delirium"
- October 29, 2013 "PAD: The Pain, Agitation, and Delirium Care Bundle"
- February 2014 "New Studies on Delirium"
- March 25, 2014 "Melatonin and Delirium"
- May 2014 "New Delirium Severity Score"
- August 2014 "A New Rapid Screen for Delirium in the Elderly"
- August 2014 "Delirium in Pediatrics"
- November 2014 "The 3D-CAM for Delirium"
- December 2014 "American Geriatrics Society Guideline on Postoperative Delirium in Older Adults"
- June 16, 2015 "Updates on Delirium"
- October 2015 "Predicting Delirium"
- April 2016 "Dexmedetomidine and Delirium"
- April 2016 "Can Antibiotics Lead to Delirium?"
- July 2016 "New Simple Test for Delirium"
- September 20, 2016 "Downloadable ABCDEF Bundle Toolkits for Delirium"
- January 24, 2017 "Dexmedetomidine to Prevent Postoperative Delirium"
- March 21, 2017 "Success at Preventing Delirium"
- July 2017 "HELP Program Reduces Delirium Rate and LOS"
- January 2018 "What Happens After Delirium?"
- February 20, 2018 "Delirium and Falls"
- October 2018 "Rapid Screening for Delirium"
- November 13, 2018 "Antipsychotics Fail in ICU Delirium"
- February 12, 2019 "2 ER Drug Studies: Reassurances and Reservations"
- September 17, 2019 "American College of Surgeons Geriatric Surgery Verification Program"
- March 2021 "The Fiscal Costs of Delirium"
- March 16, 2021 "Sleep Program Successfully Reduces Delirium"

References:

Najafi N, Robinson A, Pletcher MJ, Patel S. Effectiveness of an Analytics-Based Intervention for Reducing Sleep Interruption in Hospitalized Patients: A Randomized Clinical Trial. JAMA Intern Med 2021; Published online December 28, 2021 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2787642

Gode A, Kozub E, Elizabeth Joerger K, et al. Reducing Delirium in Hospitalized Adults Through a Structured Sleep Promotion Program. Journal of Nursing Care Quality 2021; 36(2): 149-154 https://journals.lww.com/jncqjournal/Abstract/2021/04000/Reducing_Delirium_in_Hospitalized_Adults_Through_a.11.aspx

Cho HJ, Katz M. A Good Night's Sleep in the Hospital. JAMA Intern Med 2021; Published online December 28, 2021 https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2787646

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