

Critical Review Form

Therapy

Miner JR, Biros MH, et.al Utility of BIS in Proc Sed with Propofol in the ED,
Acad EM 2005. 12:3;190-196

Objective: “To determine whether knowledge of the patient’s BIS (bispectral index)scores altered physician practice in performing PS (procedural sedation) in the ED (Emergency Department)” (p. 191). The authors tested three hypotheses: 1) Knowledge of the patient’s BIS score would alter the amount of propofol given during PS of ED patients for painful procedures; 2) Knowledge of the BIS score would increase the recognition of adequately sedated patients, thus reducing over sedation and the corresponding increased rate of respiratory depression (RD) and decreasing the rate of perceived pain or recall of the procedure; 3) Knowledge of the BIS score would have a greater effect in patients who were not sedated to a clinically adequate level after the first dose of propofol.

Methods: Prospective randomized study of PS in one urban county medical center (Hennepin County Medical Center) over about one year using adult patients undergoing PS with propofol in the ED. Exclusion criteria included age < 18 years, inability to provide consent including clinical intoxication, pregnancy, or known hypersensitivity to propofol. PS was performed by one physician while another completed the procedure. Attending emergency physicians were “reminded of prior research results suggesting that target BIS scores in the range of 70-85 are associated with adequate sedation and infrequent RD” (p. 191). RD was defined as oxygen saturation <90%, a change from baseline ETCO₂ of >10 mm Hg, or cessation of gas exchange at any time. The endpoint of sedation was return to baseline mental status and pain was assessed using a VAS.

Guide		Comments
I.	Are the results valid?	
A.	Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?	
1.	Were patients randomized?	YES , although the mechanism was not described
2.	Was randomization concealed (blinded)?	Physicians not blinded Data collectors not blinded Analysis not stated if blinded
3.	Were patients analyzed in the groups to which they were randomized?	NO . 5 pt’s excluded due to erroneous BIS exposure. Not stated which group they were from. MOST IMPORTANTLY, THERE WAS NO INTENTION TO TREAT ANALYSIS. When doing research, all subjects should optimally be analyzed in the group they were originally assigned to. This helps control unforeseen bias, complications, and statistical error. The B-AWARE trial (PGY 4 article) did this nicely.



4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Not stated. No demographic info given and no reporting of co-morbidities
B.	Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?	
1.	Were patients aware of group allocation?	Not stated
2.	Were clinicians aware of group allocation?	Yes, by necessity. Availability of BIS was the intervention.
3.	Were outcome assessors aware of group allocation?	Not stated, but data was theoretically objective.
4.	Was follow-up complete?	Of those that were not excluded, 100% had full data.
II.	What are the results (answer the questions posed below)?	
1.	How large was the treatment effect?	Significant reduction in chance for RD but no change in clinically significant RD.
2.	How precise was the estimate of the treatment effect?	Reasonably well, prospectively defined objective measures. Clinical relevance uncertain. Given the vague nature of the definition of respiratory depression, it is hard to be more precise. Optimally there would be a better consensus definition of RD, but the lack of one is not the authors fault.
III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	Yes. Adults needing RL in than ED. Similar monitoring parameters used. (similar setting)
2.	Were all clinically important outcomes considered?	Didn't evaluate procedural failure, or patient satisfaction. <u>Used unvalidated score for pain and recall.</u> This is a major problem. No measure of time of proc. No evaluation of efficacy of sedation. Therefore it is very hard to conclude anything about how well BIS affected the procedure, except as it applies to their definition of RD.
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3.	Are the likely treatment benefits worth the potential harm and costs?	Insufficient data. It appears that the BIS scores were equal between the groups, but RD differed, suggesting that the changes in RD were not due to the blinding of the MD to BIS. Also, no change in amount or doses of propofol but change in RD. Hard to figure out why there should be any difference in RD. Is this just statistical noise (i.e. a type 1 error)?
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Limitations

1) **Publication bias/Author bias: Biros authoring in Academic EM (she's the editor. Is there a bias towards publishing this?) Preferences to their own previous work (gratuitous, especially given that it was a weaker study.) There is lots of author bias here. Most notably is in the discussion, the lack of consistency or explainable results given no change in BIS or medication dose. Why don't they ever give thought to the possibility that the technology is being prematurely used to EM?**

2) **Used previously defined definitions of goal BIS (poor data – taken from their own work)**

3) **Used an unvalidated scale for recollection of pain and memory of procedure. This is a big problem and they used ad hoc analysis of the scale, not prospectively defined analysis.**

4) **Very high rate of respiratory depression (RD) by their definitions, but is this a clinically relevant number? There is a nice discussion of definitions for RD on p. 195**

Bottom Line

The technology is probably not ready for prime time. From the discussion and from Dr. DeWitt's experience, we might be able to use it in paralyzed patients (since clinical exam is unreliable), but using for brief procedures, associated with little clinically significant respiratory depression, isn't indicated, and could potentially cause harm.

