Bispectral Index System Assessment of a Propofol Infusion Kinetic-Based Program: A Pilot Study

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Introduction

Bispectral index monitoring (BIS), an FDA approved monitor, has been introduced as an objective method for monitoring the level of consciousness in patients under sedation and general anesthesia. BIS records electrocephalogram waveforms which provide an objective measurement of brain activity. It has a numerical range of 0-100, with 0 indicating coma and 100 demonstrating total consciousness. BIS monitoring has displayed a significant association to sedation scales; therefore, it may be used to determine depth of sedation without the need for patient stimulation. Previous research with a similar protocol was published in 2018 for deep sedations utilizing propofol bolus-based protocols for teenagers during oral surgery procedures. The sedation algorithm now consists of a pharmacokinetic-based propofol infusion technique to provide deep sedation. This technique has led to smoother sedation with fewer respiratory complications. Further studies identifying the correlation between the BIS level and depth of sedation will help determine whether BIS analysis has a definitive role for pediatric and adolescent patients undergoing sedation for oral surgery procedures.

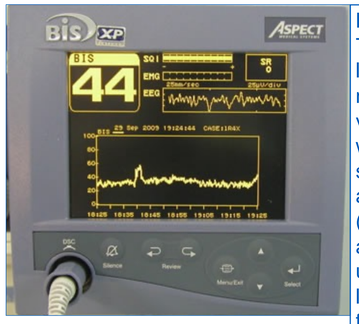

Figure 1: BIS monitor. The number on the top left corner of the BIS monitor depicts the BIS value. The BIS monitor will also measure both signal quality (SQI) and muscle activity (EMG) artifact as well as displaying the raw unprocessed EEG. The lower figure is the BIS trend over the last hour.

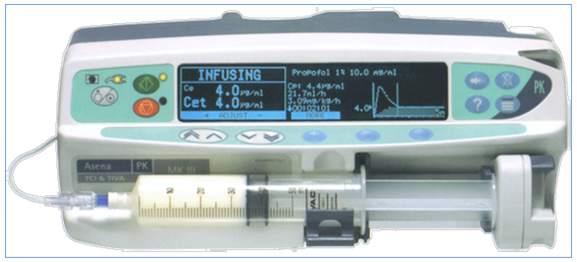

Figure 2: Propofol Infusion Pump. A medical device used to deliver measured quantities of medications to patients. The patient's weight , dose and drug concentration are entered and the infusion rate is calculated and displayed.

Materials and Methods

After IRB approval, those patient's ages 13-21 scheduled for third molar extractions during the pre-operative screening process were recruited. Exclusion criteria included patients with: ADHD, autism, multiple seizure or psychotropic medications, regular marijuana or ETOH use, ASA >2, BMI > 30. Research consent was taken on the day of procedure prior to IV placement. Patient's were divided into two groups: Group A (13-17 years of age) and Group B (18-21 years of age). The probe was placed on the patient's forehead per manufacturer's recommendations. The BIS monitor requires the use of a probe/electrode similar in nature to that for an EKG, however, it does have a slightly course surface that may cause mild discomfort when applied. Appropriate monitors (pulse oximeter, blood pressure cuff, ETCO2 nasal canula, ECG leads) were also placed on the patient. The BIS monitor was then calibrated to the applied probe to determine adequate signal acquisition. The BIS monitor was connected to a laptop computer using a serial USB cable and the data from the BIS monitor was collected in real time into an Excel readable file for analysis. The BIS monitor screen (Figure 1) was partially occluded so that the research team/providers are unable to see the BIS score or data during the procedure. The screen visible ensured that the BIS monitor was reading appropriately (RAW EEG tracing and error codes only). The BIS probe remains on the patient until the patient is awake and can be transferred to recovery. Patient's completed participation once the BIS probe was removed. Data collected included: BIS Score, Artifact, Signal Quality, EMG interference.

Sedation

A propofol infusion based sedation algorithm (Table 1) is our current standard of practice. It consists of a combination of sedation medications (Propofol, Midazolam and Fentanyl) to reach a desired depth of sedation. The propofol is administered through an infusion pump (Figure 2). The amounts are weight-based and have been adapted and structured from published pharmacokinetic models of propofol.

AGE / WEIGHT BASED PROPOFOL INFUSION DOSING FOR DEEP SEDATION		DOSING: mcg/kg/minute					
		T=1	T=2	T=3	T=4	T=5	T=6
AGE (years)	Kinetic Model	DOSE1	DOSE2	DOSE3	DOSE4	DOSE5	DOSE6
13	PAEDFUSOR	260	155	140	125	110	100
14	PAEDFUSOR	220	140	125	110	100	90
15	PAEDFUSOR	190	125	110	100	90	85
16	PAEDFUSOR	160	110	100	90	80	75
17+	DIPRIFUSOR	155	110	95	85	80	75

Table 1: Propofol Kinetic Model.
The initial infusion rate is continued until clinical depth of achieved, use step down dosing model to maintain constant plasma sedation level.

Results

Demographics						
	Total Recruited	Average Age (years)	Gender (F)	Gender (M)	Average Weight (kg)	Average BMI
Group A	12	16.0	4	7	68.2	23.4
Group B	12	18.6	8	3	63.5	22.6

Table 2: Patient Demographics. A total of 24 patients have been recruited. Two patients were excluded due to disruptions in BIS monitor data capturing (One from Group A and one from Group B).

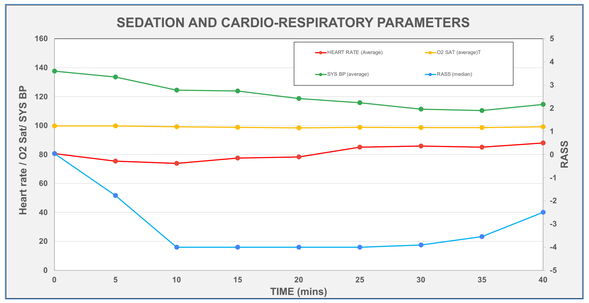

Figure 3: Sedation and Cardio-Respiratory Parameters. Demonstrates average hemodynamic values including heart rate, oxygen saturation and systolic blood pressure. The Richmond Agitation Sedation Score (RASS) was used to assess depth of sedation.

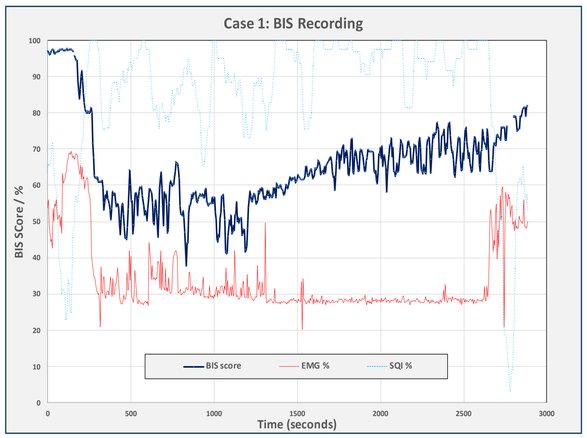

Figure 4: Case 1 Recording
This figure depicts BIS scores in association with the SQI and EMG recordings. Signal Quality Index (SQI) measures the reliability of the signal. Electromyographic readings (EMG) indicate the level of muscle activity or movement.

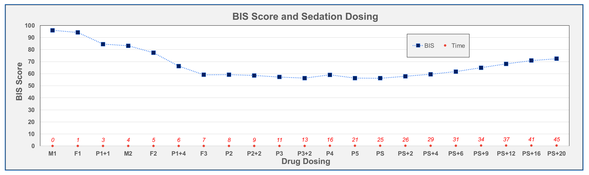

Figure 5: Bis Score and Sedation Dosing. Compares the sedation dosing (Average Dose/Times for all cases) at specific time intervals with BIS values. (M1: MID dose 1, F1 FENT Dose 1, P1 Start PROP, P2 PROP Dose change 2, PS PROP Stop, PS+ Mins after PROP stop)

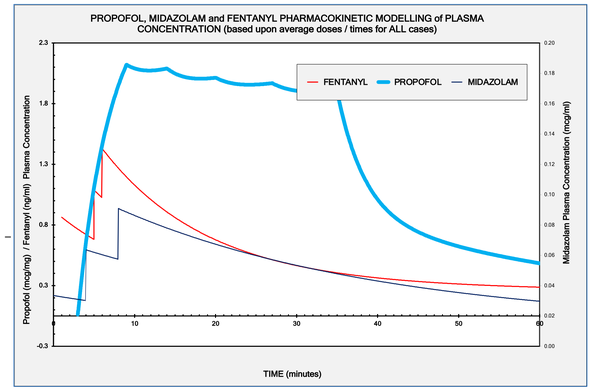

Figure 6: Pharmacokinetic model of Propofol plasma concentration. The dosing algorithm was used to maintain a steady conc. after the desired clinical effect was obtained. Superimposed are the MID and FENT plasma concentrations.

Conclusion

Initial results from this pilot study support the propofol infusion- based sedation protocol as a safe and reliable method for administering in-office intravenous deep sedation. A stable BIS level (60 - 65) during the procedure matches the predicted stable propofol concentration (1.9 - 2 mcg/ml). Overall the BIS signal quality was sufficient for data collection and the BIS values were consistent with stable cardiovascular outcomes and RASS average of -4. This pilot study serves as a baseline for future research, in which a power analysis will be prepared and applied for diverse pediatric and adolescent patient populations undergoing deep sedation.

References

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