A BIS Assessment of a Propofol Infusion Kinetic-Based Program: A Pilot Study

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Introduction

In our dental sedation suite we use a deep sedation technique that includes midazolam, fentanyl (Figure 1) and a Propofol infusion. The Propofol infusion is based upon published kinetic models (Diprifusor & Paedfusor) that are used in proprietary computerized propofol infusion pumps to deliver TIVA. The anesthesiologist selects an appropriate propofol blood level and these infusion pumps control the sedation infusion rates. We use a set of pre-calculated infusion rates based upon the patients age (Figure 2). A Propofol infusion dose adjustment is made for younger patients due to greater sedation needs as well as an altered pharmacokinetic profile. We achieve the desired clinical sedation using infusion rate Dose-1, and then rates Dose-2 to Dose-6 are designed to keep the propofol level constant (Figure 3).

We have used this sedation regimen for several years, with good clinical success. The aim of this study was to:

1) Evaluate the effectiveness of using the BIS monitor. This BIS monitor uses EEG analysis algorithms to determine the depth of sedation and provides a continuous, non-subjective assessment of sedation.
2) Does our Age/Weight pharmacokinetic modelled propofol infusion dosing regimen provide a similar depth of sedation for the different aged children, using the BIS monitor as the determinant.

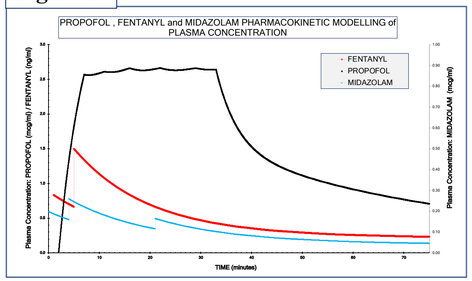
Figure 1.

2022 DEEP PED/ADULT IV SEDATION REGIMEN, GUIDE, DOSING ALGORITHM									
	STARTING DOSING				*OPTIONAL*	ADDITIONAL DOSING		MAXIMUM DOSING	
WEIGHT	FIRST	SECOND	FIRST	SECOND	THIRD	SUBSEQUENT	SUBSEQUENT	TOTAL	TOTAL
(kg)	MID (mg)	MID (mg)	FENT (mcg)	FENT (mcg)	FENT (mcg)	MID (mg)	FENT (mcg)	MID (mg)	FENT (mcg)
15 to 20	1	1	12.5	12.5	-	0.5	12.5	4	37.5
21 to 25	1	1	25	12.5	-	0.5 or 1	12.5	5	50
26 to 30	1.5	1	25	12.5	12.5	0.5 or 1	12.5	6	62.5
31 to 35	2	1	25	12.5	12.5	1	12.5	7	75
36 to 40	2	1	25	25	25	1	12.5	7	87.5
41 to 45	2	1.5	25	25	25	1	12.5	7	100
46 to 50	2	1.5	50	25	25	1	12.5	8	112.5
51 to 60	2	2	50	25	25	1 or 2	12.5	8	125
61+	2	2	50	25	25	1 or 2	25	8	150

Figure 2.

AGE / WEIGHT BASED PROPOFOL INFUSION DOSING FOR DEEP SEDATION							
AGE (years)	MODEL	DOSE1	DOSE2	DOSE3	DOSE4	DOSE5	DOSE6
5	PAEDFUSOR	370	220	200	175	155	140
6	PAEDFUSOR	**350**	**205**	**185**	**160**	**140**	**125**
7	PAEDFUSOR	350	205	185	160	140	125
8	PAEDFUSOR	330	190	165	145	125	110
9	PAEDFUSOR	330	190	165	145	125	110
10	PAEDFUSOR	**310**	**180**	**160**	**140**	**120**	**105**
11	PAEDFUSOR	310	180	160	140	120	105
12	PAEDFUSOR	290	165	145	130	115	100

Figure 3.



Methods

After IRB approval, consent and assessment as indicated, patients between the ages of 5-13 who report for dental procedures under deep sedation were recruited. The patient were sedated to the desired level of deep sedation (RASS -4) using a combination of Midazolam, Fentanyl and the kinetic based Propofol infusion. Due to some BIS monitor probe discomfort the probe is placed on the patient's forehead after the child is asleep (RASS -4). BIS data was recorded every 5 seconds and transferred to a computer using HyperTerminal and stored in an Excel readable file. The procedure and sedation staff were blinded to the BIS score throughout the procedure.

Results

So far 16 patients have been recruited for this study, patient demographics are shown in table 1. Group A: patients age 5-7. Group B: patients 8-12. Sedation use is shown in table 2. The quality of BIS monitor recording was excellent in both groups, minimal data loss, good EEG signal, minimal artifact. The BIS values between the two groups were not BIS scores were different during different aspects of the dental procedure (Table 4). Also comparing the BIS values at the different Propofol infusion rate changes D2-D6 and propofol stop also did not show any difference between the groups (Figure 4). On overall analysis (n=14), Repeat One Way ANOVA analysis of the BIS scores at Dose-2 to Dose-6 did not demonstrate variability as the propofol rate was decreased as per the dosing algorithm. Figure 5 shows the predicted propofol levels as per kinetics calculation. The propofol level at all doses was significantly lower in Group B.

TABLE 1. PATIENT DEMOGRAPHICS / TIMES (Average / SD)

	AGE (years)	WEIGHT (kg)	BMI	DOSE WT (kg)	DUR SURGERY (mins)	DUR RECOVERY (mins)
GROUP A	5.8	24.5	17.1	23.2	24.1	49.7
N =12	0.8	5.8	2.5	3.7	4.4	18.2
GROUP B	9.3	34.9	19.0	34.2	18.3	40.0
N=4	0.8	9.8	3.2	9.8	11.5	7.1
P VALUE	*0.00*	*0.02*	*0.24*	*0.00*	*0.15*	*0.33*

TABLE 2. SEDATION USE (Average / SD)

	MIDAZOLAM (mg/kg)	FENTANYL (mcg/kg)	PROPOFOL (mg/kg)	PROPOFOL DURATION (mins)
GROUP A	0.049	1.83	6.0	29.2
	0.006	0.36	0.73	4.0
GROUP B	0.050	1.97	4.7	24.3
	0.007	0.38	1.32	9.7
P VALUE	*0.75*	*0.52*	*0.02*	*0.16*

TABLE 3. BIS QUALITY INDICES (Average)

	SQI AVERAGE	EMG AVERAGE	% BIS MISSING	% IMPED > 1000	% ARTI > 1000
GROUP A	91.2	17.2	0.1	0.7	4.7
GROUP B	90.0	17.0	0.0	1.2	3.9
P VALUE	*0.69*	*0.98*	*0.58*	*0.31*	*0.80*

TABLE 4. BIS VALUES DURING THE PROCEDURE (Average)

	MOUTH PROP	LA	START	FINISH	DC IV
GROUP A	60.5	61.9	62.2	61.8	77.6
GROUP B	56.2	57.9	59.9	67.7	76.2
P VALUE	*0.26*	*0.46*	*0.63*	*0.19*	*0.53*

Figure 4.

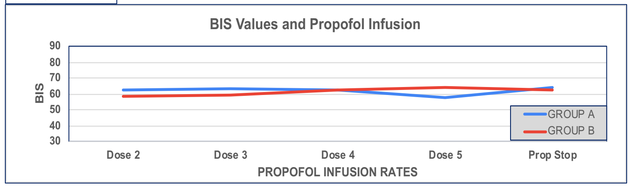
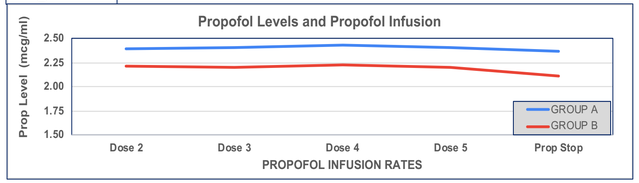


Figure 5.



Conclusion

The BIS monitor proved to be an effective tool to assess the sedation quality throughout a pediatric dental procedure. Data loss was minimal and data quality was excellent. The pharmacokinetic model of propofol infusion based on age and weight delivered similar and stable depths of sedation for the different groups of children. BIS values were stable from mouth prop placement until the procedure was completed, as well as at the time of removing the IV. These levels are consistent with that expected; deep sedation/GA.