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Correlation of Bis Index with Clinical Sedation Score During Mechanical Ventilation in Intensive Care Unit Patients

[*]Dr. Virendra Kumar[1],Dr. Manoj Tripathi[1],Dr. Shamshad Ali[2],
Dr. Deepak Malviya[3],Dr. Amit Tyagi[4],Dr. Mahendra Singh[4]

[1]*Assisitant Professor, Department of Anesthesia & Critical Care, Dr. Ram Manohar Lohia Institute of Medical Sciences Lucknow, UP*
[2]*Consultant, Main Hospital, BHEL, Haridwar*
[3]*Professor & Head ,Department of Anesthesia & Critical Care, Dr. Ram Manohar Lohia Institute of Medical Sciences Lucknow, UP*
[4]*Senior Resident, Department of Anesthesia & Critical Care, Dr. Ram Manohar Lohia Institute of Medical Sciences Lucknow, UP*
Corresponding Author: Dr.Manoj Tripathi,

Abstract
Background: *Mechanical ventilation and sedation are inextricably linked components of critical care that represent, what we do for the patients during their vulnerable course in ICU.*
Aims: *The aim of the present study is to evaluate the use of BIS for monitoring sedation in mechanically ventilated ICU patients and correlation of BIS with Sedation Agitation Scale.*
Settings and Design: *Prospective Observational study.*
Methods and Material: *In this study, recruited patients were allocated into two groups of 10 patients each. Group A(Non-surgical) and Group B (Surgical) patients received Inj. Propofol and Inj. Midazolam for sedation. Hemodynamic parameters, correlation of BIS with SAS, duration of mechanical ventilation and mortality were assessed in both groups.*
Statistical Analysis: *Mean and standard deviation was calculated. We applied correlation technique that is Pearson Product-moment correlation coefficient (r) to assess correlation between BIS and SAS. It varies from +1 to 0 to -1.*
Results: *In this study in non surgical group 8 patients shown moderate to strong correlation while in group B, 9 patients had shown moderate to strong correlation between BIS and sedation agitation scale*
Conclusion:*. BIS monitor may be effectively used for prolonged periods in sedated, mechanically ventilated ICU patients and BIS correlates with clinical sedation scores.*

Keywords: *Propofol, Midazolam, Sedation Agitation Scale, Bispectral Index, ICU sedation*

I. Introduction

Patients admitted to the ICU are usually in need of invasive and uncomfortable interventions such as mechanical ventilation. To reduce anxiety, increase tolerance, and improve outcomes of such interventions, sedation is common practice.[1] Traditionally, sedative agents administered in the ICU are g-aminobutyric receptor agonists (GABA) which include the benzodiazepines (usually midazolam) and propofol.[2] Optimum sedation is vital in striking a balance between providing pain relief and maintaining patient calm while preventing over-sedation and unnecessarily lengthy ICU stays.[3] Many protocols advise daily sedation interruptions to assess the level of sedative in the patient and to avoid oversedation.[4] Because of limitation of subjective sedation scales to assess ICU sedation, over sedation and under sedation are the major challenges in the ICU management. To overcome this, Bispectral Index, an objective tool to assess sedation and consciousness is now being used in critical care setting.[5]

Clinically, use of BIS monitor may help standardize clinical practice and improve patient's care. Having an objective BIS as a guide for adjusting doses of sedating agents could also minimize medical complications such as pancreatic, liver, and renal injuries, depressed cardiac contractility and blunting of protective reflexes associated with excessive use of sedatives and their metabolism. Use of BIS monitor can also provide financial benefits by limiting excessive use of costly sedatives and decreasing the time of extubation.

The Aims Of Present Study Are –

- To describe the level of sedation for a cohort of mechanically ventilated intensive care unit (ICU) patients using validated subjective and objective tools.
- To evaluate the use of BIS for monitoring sedation in mechanically ventilated ICU patients.

- To correlate BIS with clinical sedation score in mechanically ventilated ICU patients

II. Material And Methods

The present study was conducted on 20 patients of either sex ranging from 20-60 years requiring mechanical ventilator support in I.C.U. at Dr. RMLIMS, Lucknow Patients admitted to I.C.U. requiring mechanical ventilatory support were eligible for enrolment. Exclusion criteria for the study was Pregnancy, Transfer from an outside institution where sedatives had already been administered, Admission after resuscitation from cardiac arrest, Head injury patients, Impaired hearing, Impaired visual acuity such as blindness or facial or eye trauma. The patients were divided into two groups (10 patients each) –

Group-A : Non-surgical patients

Group-B : Surgical patients (All post-operative)

Written consent was taken from every patient's relative. All the patients were examined thoroughly and relevant routine investigations such as hemoglobin, total and differential leucocyte counts, platelet count, serum creatinine, serum urea, blood urea nitrogen, serum bilirubin, serum electrolytes including sodium, potassium and calcium . ABG were done in all patients. Choices of sedation and or analgesic regimens were made at the discretion of the attending physician, independent of the BIS. After wiping the patient's forehead and temple with alcohol and drying the skin to ensure that a quality signal will be obtained, sensor placed across the patient's forehead and over the left or right temple. The BIS index displayed on the monitor as a number; recorded.

In addition to a numeric BIS index, the monitor displays other significant data. The BIS trend is a graphical representation of BIS index values over time. Continuous intravenous sedatives infusion (midazolam or propofol) were given for first 8 hours to every patient, who had SAS score ≥ 4; then sedatives were interrupted and restarted on as and when required basis. The doses of sedatives and analgesics were adjusted to achieve a score of 3 or 4 on SAS scale. Injection tramadol (intramuscular) was given to ensure adequate analgesia, it was administered to all patients according to the need, based on nurses assessment of the level of analgesia, which is as follows-

1- Denotes extreme pain
2- Severe pain
3- Moderate pain
4- Slight Pain
5- No pain

Tramadol was administered in response to a score of 1 to 4 and was continued until the pain was considered to be adequately controlled. Simultaneous recording of the clinical sedation scale (Riker's Sedation-Agitation Scale), sedative drugs and BIS index done at every 4 hours for first 24 hours, then every 8 hourly. Sedation assessment was performed before recording the BIS value to avoid bias. Data were collected for a maximum of 3 days, but if prolonged (>3 days) ventilation required then until extubation. Duration of total ICU stay also noted. Hemodynamic parameters like PR, BP, SpO2 and ECG, temperature were also monitored. A thorough assessment of patient's condition eg chest, cardiovascular system, urine output, mental status, PaO2/FiO2 ration to see lung injury was done on daily basis after interruption of sedation. Sedation Agitation Scale (Riker et al, 1999)[6] was applied to see clinical sedation score which is as follows-

7 - Dangerous agitation
6 - Very agitated
5 - Agitated
4 - Calm and co-operative
3 - Sedated
2 - Very sedated
1 - Unarousable

Midazolam was started as a intravenous bolus of .5-5 mg every 1-5 minutes as needed and continuous infusion at 1-2 mg/hour, doses to be increased in increments of 1-2 mg/hour until adequate sedation is acquired. Propofol started as continuous infusion at 5ug/kg o/min; dosage to be increased in increments of 5-10ug/min every 2 minutes until adequate sedation is achieved. On the basis of observations, relationship between Bispectral index and sedation-Agitation Scale measured by "correlation coefficient". We applied correlation technique that is Pearson Product-moment correlation coefficient (r) . It varies from +1 to 0 to -1.

$r \geq .8$: High correlation coefficient
$r = 0.4$ to .7 : Moderate correlation coefficient
$r \leq .3$: Low correlation coefficient

r = 0 : Absolutely no correlation

III. Observations And Results

No significant difference was found in sex distribution of cases between groups. Male : Female ratio was found to be 1.5:1 in each group. Age of patients varied from 20-60 years. Majority of patients (50%) were between age group 31-50 years. No significant difference was found in regard of age between two groups

Table1 Showing Diagnosis, Duration Of Mechanical Ventilation, Duration Of Icu Stay And 24 Hours Consumption Of Sedation/Analgesics Of Group A

				24 hour consumption		
Patient	Diagnosis	Duration of Mechanical ventilation(Days)	Duration of ICU stay(Days)	Propofol(mg)	Midazolam(mg)	Tramadol (mg)
P1	Septicemia	3.2	5.5	1120	-	100
P2	Hypokalemic period paralysis	3.0	5.0	-	30	100
P3	Bacterial meningitis	2.3*	-	-	-	-
P4	Septicemia	2.5*	-	1060	-	100
P5	Snake bite	2.3	3.5	-	35	100
P6	Organophosphorus Poisoning	3.0	4.0	-	42	100
P7	COPD	2.7	6.0	1630	-	100
P8	COPD	3.0	6.5	1710	-	100
P9	TBM	2.7*	-	-	-	-
P10	Snake bite	2.7	4.0	-	37	100
			Mean=4.93			

* indicates patient expired during treatment before extubation.

Table 2- Showing Diagnosis, Duration Of Mechanical Ventilation, Duration Of Icu Stay And 24 Hours Consumption Of Sedation/Analgesics Of Group B

				24 hour consumption		
Patient	Diagnosis	Duration of Mechanical ventilation(Days)	Duration of ICU stay(Days)	Propofol(mg)	Midazolam(mg)	Tramadol (mg)
P1	Perforative peritonitis	2.3*	-	1020	-	300
P2	Septic abortion	2.7*	-	-	28	300
P3	Intestinal obstruction	3.0	5.0	1060	-	300
P4	Blunt trauma abdomen	2.3*	-	-	30	300
P5	Perforative peritonitis	2.3	4.5	960	-	300
P6	Gunshot abdomen	2.3*	-	-	-	100
P7	Intestinal obstruction	3.0	4.5	740	-	300
P8	Eclampsia	2.7	4.5	-	35	200
P9	Ruptured uterus	2.3	5.0	880	-	300
P10		3.5	5.0	-	25	300

	Septic abortion					
			Mean=4.75			

Table3- Showing Median, Mean Bis Value Recorded For Sas Score In Non-Surgical Patients (Group A)

Sedation Score (SAS)	BIS index					
	Sample size	Minimum	Maximum	Median	Mean	S.D.
1	19	26	48	33	34.63	05.52
2	02	42	50	46	46.00	05.65
3	06	60	80	72	71.66	06.86
4	62	70	98	78	79.93	07.25
5	21	80	98	90	91.05	04.66
6	02	80	90	85	85.00	07.07
7	-	-	-	-	-	-

Total 112 observations were made in non-surgical group. Maximum observations (62) were falling in SAS-4 and minimum (2) were falling in SAS-2 and SAS-6 (2 each). Table also shows that median BIS value increased as the sedation score increases except SAS-6.

Table 4 Showing Median, Mean Bis Value Recorded For Sas Score In Surgical Patients (Group B)

Sedation Score (SAS)	BIS index					
	Sample size	Minimum	Maximum	Median	Mean	S.D.
1	05	40	56	50.0	48.40	05.89
2	07	64	70	68.0	67.57	02.29
3	03	56	79	70.0	68.33	11.59
4	79	70	98	78.0	79.00	07.05
5	12	80	97	89.5	89.58	04.31
6	02	88	96	92.0	92.00	05.65
7	-	-	-	-	-	-

Total 108 observations were made in non-surgical group. Maximum observations (79) were falling in SAS-4 and minimum (2) were falling in SAS-2. It is also observed that median BIS value increased as the sedation score increases

Table 5 Showing Correlation Coefficient Between Bis Index And Clinical Sedation Score (Sas) In Each Group

Non-surgical (Group A)			Surgical (Group B)		
Patient	'r' value		Patient	'r' value	
P1	0.69	MC	P1	0.30	LC
P2	0.45	MC	P2	0.84	HC
P3	0.00	NC	P3	0.81	HC
P4	0.23	LC	P4	0.48	MC
P5	0.87	HC	P5	0.82	HC
P6	0.78	HC	P6	0.92	HC
P7	0.58	MC	P7	0.73	MC

P8	0.60	MC	P8	0.42	MC
P9	0.87	HC	P9	0.53	MC
P10	0.95	HC	P10	0.38	MC

HC = High correlation MC = Moderate correlation
LC = Low correlation NC = No correlation
Above table shows that 4 patients in each group showed high correlation, 4 patients in Group-A and 5 patients in Group-B showed moderate correlation, one patient in each group showed low correlation, while 1 patient in Group-A showed no correlation.

Table 6 Showing Distribution Of Mortality In Each Group

	Total Patients	Patients survived		Patients expired	
		No.	%	No.	%
Group-A	10	07	70	03	30
Group-B	10	06	60	04	40

Above table shows distribution of mortality in both groups. Mortality was observed more in Group-B (40%). Haemodynamic parameters recorded after putting the patients on ventilator at different interval for consecutive three days. Most of the patients required ionotropic support expired in both groups.

IV. Discussion

Sedatives and analgesics are administered to many patients who are critically ill in intensive care unit throughout the world. This is well known now that use of sedative medications can have substantial impact on duration of ICU has raised the awareness of the value of structured sedation evaluation.

Kress JP et al [7,8,9] studied on mechanically ventilated patients and concluded that BIS monitoring with adequate sedation reduced the median duration of mechanically ventilation by 33%, median length of ICU stay by 35% and median length by 21%.

Table 3 and 4 showing median, mean BIS value recorded for SAS score in non-surgical and surgical patients. It is observed that median BIS value increased as the SAS score increases both in surgical and non surgical patients except in SAS=6 in non surgical patients where it decreased from 90 to 85. Maximum number of observation were falling in SAS=4. Table 5 shows correlation coefficient between BIS index and clinical sedation score (SAS) in each group. In Group-A patients mean 'r' value was found to be 0.602, ranging from 0 to .95. Out of 10 patients, 4 showed strong correlation, 4 showed moderate correlation, 1 showed low correlation and in 1 patient no correlation was found. In Group B, out of 10 patients, 4 showed strong correlation, 5 showed moderate correlation and 1 showed low correlation.

Carmen Hernandez-Gancedo et al (2007) [10] evaluated sedation of intubated surgical critically ill patients by mean of the Ramsay Sedation score, Bispectral index and entropy and analyzed the correlation between these variables. They concluded that ENTROPY, BIS and Ramsay Score values correlate significantly in sedated poet-operative ICU patients. Entropy does not appear superior to BIS for the assessment of sedation in this context.In the present study we also observed moderate to strong correlation in 9 out of 10 patients during mechanical ventilation in post-operative patients between BIS index and Sedation Agitation Scale Score.

Riess ML et al (2002)[11] studied "To determine the reliability and possible confounding factors of the Bispectral index to assess sedation in surgical intensive care patients ".Following major surgery, Bispectral index, body temperature and electromyographic activity of 44 patients were recorded. Sedation levels were assessed with Ramsay Sedation Score. They concluded that Bispectral index correlated with Ramsay Sedation Score.[12,13] In present study, we also observed that in post-operative patients during mechanical ventilation, BIS index correlated well with Sedation Agitation Scale.

Dirk Frenzel et al (2002)[14] evaluated the role of BIS index in assessing the depth of sedation in mechanically ventilated surgical ICU patients. Out of 19 patients, there was a moderate correlation between BIS and sedation score in 11 patients and no correlation in 8 patients. They concluded BIS is correlated only in some ICU patients with sedation level. In present study out of 20 patients, only 2 patients had low correlation (one in each group) and one patient in non surgical group had no correlation between BIS index and SAS score ('r' = 0). This value was observed in patient of bacterial meningitis. This may be because a low BIS could reflect a neurological deterioration and just a deeper level of sedation, which in turn would mandate a different plan of action. Table 6 is showing mortality in each group. Mortality is seen more in surgical group of patients that is 40% in comparison to nonsurgical group where it is 30%. According to age distribution equal mortality seen in

all age groups. Almost all patients were hemodynamically stable during mechanical ventilation with adequate sedation and analgesia, except few patients who were very critical and were on ionotropic support. In patients having light sedation or no sedation, there pulse rate and blood pressure were found to be increased significantly.In non-surgical patients the requirements of sedatives were greater than the surgical patients, but analgesic requirement was increased in surgical patients. Here analgesics could have reduced the dose of sedatives in surgical patients. Thus, our study further strengthened the reports of various authors regarding correlation of Bispectral index and clinical sedation score during mechanical ventilation in intensive care unit.

V. Conclusion

In conclusion, moderate to high correlation were found between Bispectral index and Sedation-Agitation scale during mechanical ventilation in intensive care unit patients in both surgical and non-surgical group. Therefore, BIS monitor may be effectively used for prolonged periods in sedated, mechanically ventilated ICU patients and BIS correlates with clinical sedation scores; and the BIS may be a useful adjunct to monitor and guide sedatives when the clinical examination is not available.

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