

“BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY”

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LIST OF ABBREVIATIONS

ASA	-	American Society of Anaesthesiologists
BIS	-	Bispectral index
BP	-	Blood pressure
BT	-	Bleeding time
B.Urea	-	Blood Urea
CVS	-	Cardiovascular system
CMRO2	-	Cerebral metabolic rate of oxygen
CNS	-	Central nervous system
CPB	-	Cardiopulmonary bypass
CT	-	Clotting time
dB	-	Decibels
ECG	-	Electrocardiography
EEG	-	Electroencephalography
EMG	-	Electromyography
etc.	-	Etcetera
e.g.	-	Example
EtCO2	-	End tidal carbon dioxide
FEMG	-	Frontalis electromyogram
Hb	-	Hemoglobin
HR	-	Heart rate
hrs	-	Hours
HRV	-	Heart rate variability

i.e.	-	That is
IFT	-	Isolated forearm technique
IM	-	Intramuscular
IV	-	Intravenous
INJ.	-	Injection
kg	-	Kilogram
LOC	-	Lower Oesophageal contractility
MAC	-	Minimal alveolar concentration
MAP	-	Mean arterial pressure
min	-	Minutes
mg	-	Milligram
mg/dL	-	Milli gram per deciliter
mmHg	-	Milli meter of mercury
µg	-	Microgram
NIBP	-	Noninvasive Blood pressure
NMB	-	Neuromuscular blockers
N2O	-	Nitrous oxide
O2	-	Oxygen
PACU	-	Post anaesthesia care unit
PIC	-	Patient interface cable
PR	-	Pulse rate
PTSD	-	Post traumatic stress disorder
P/A	-	Per abdomen
RL	-	Ringer lactate
RS	-	Respiratory system

RR	-	Respiratory rate
RBS	-	Random blood sugar
RSA	-	Respiratory sinus arrhythmia
SBP	-	Systolic blood pressure
SD	-	Standard deviation
SEMG	-	Spontaneous surface electromyogram
SLOC	-	Spontaneous lower oesophageal contractility
SpO2	-	Oxygen saturation
SPSS	-	Statistical package for the social sciences
SQI	-	Signal Quality Index
S.Cr	-	Serum Creatinine
TC	-	Total count
VAS	-	Visual analogue scale
yrs	-	Years

ABSTRACT

BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY

INTRODUCTION:

Bis is a processed EEG in which electrodes are placed on the forehead, and BIS scores are continually presented, indicating the state of awareness.

AIM AND OBJECTIVES OF THE STUDY:

- A. To compare the time of recovery in post-operative period with and without the use of BIS (Bispectral Index).
- B. To compare the quality of recovery in the post-operative period with and without the use of BIS (Bispectral Index).

MATERIALS & METHOD:

Seventy-two patients of age group 18-60 years belonging to ASA I-II undergoing laparoscopic surgeries under general anesthesia were recruited in this prospective comparative study. **Thirty-six** patients in the BIS group were compared to 36 controls who received BIS monitoring in addition to standard monitoring. Pre-anesthetic evaluations were performed on all patients, and standard NPO protocols were observed. Routine anaesthetic drills are performed upon arrival in the operating room, and the patient's baseline measures such as blood pressure, heart rate, ECG, and pulse oximetry are documented. Intravenous access is established, and an IV infusion of Ringer lactate is started. Using a frontal-temporal montage, a BIS electrodes strip was placed on the forehead and temples. Patients were premedicated Intravenously (I.V.) with Inj. Midazolam 0.08-0.1 mg/kg, Inj. Glycopyrrolate 0.008-0.15 mg/kg, Inj. Ondansetron 0.15mg/kg 30 min before the procedure. Fentanyl 2-4 mcg/kg, I.V.

was used as an analgesic. IV Propofol 2 mg/kg was used to induce anaesthesia in the patients. To enable tracheal intubation with the proper size ETT, IV succinyl scholine 1-1.5 mg/kg was administered as a muscle relaxant. For anaesthetic maintenance, nitrous oxide (33 %:66 %), isoflurane was used, and vecuronium 0.08-0.12 mg/kg was administered for muscle relaxation. BIS score was displayed on the monitor. Beginning before the anaesthetic induction and continuing until patients were awake and responsive to vocal orders after extubation at the end of the surgery, the EEG was constantly monitored.

In both groups, depth of anesthesia was maintained by titrating Isoflurane by keeping BIS score between 40-60 in the BIS group. In contrast, in the Control group, it was held by titrating isoflurane according to heart rate and mean arterial pressure. The groups were compared as regards with recovery time at the end of anesthesia based on time for eye-opening and responds to verbal commands. Quality of recovery is assessed by orientation to time, place and person, swallow reflex, and cough reflex.

RESULT:

There were no significant differences in all the general characteristics. The mean time of recovery for opening eyes and responding to verbal commands is significant ($P = 0.0001$) in the BIS group. Orientation to time, place, and person, Swallow reflex, and Cough reflex was attained faster in the BIS group ($P=0.0467$). The difference in modified Aldrete scoring between the two groups was insignificant ($P = 0.468$), and both groups became eligible for discharge at around the same time.

CONCLUSION:

Addition of BIS monitoring to routine standard anesthesia care resulted in faster recovery of patients compared to the standard practice control group.

KEYWORDS:

Bispectral index monitoring, post-operative recovery, general anesthesia.

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INTRODUCTION

In today's age, Laparoscopic surgeries are one of the most commonly performed minimal access surgeries nationwide, safely done as a daycare procedure. Anesthetic techniques facilitating early recovery and home discharge have become the need of the hour. Hence, more emphasis is being given on providing balanced anesthesia to the patient, which includes adequate hypnosis, analgesia, and neuromuscular blockade. One of the aims of modern anaesthesia is to make sure adequate depth of anaesthesia in order to prevent consciousness without unnecessarily overdosing patients with powerful medications. The capacity to assess anaesthetic depth is one of contemporary anesthesiology's successes¹.

Surgery-related awareness is a major condition that affects 0.1–0.2% of all surgical patients. Patients who have had an intra-operative awareness experience regard it as the worst thing they have ever experienced, with such instances accounting for 2% of all legal claims against anaesthetists and can cause the patient to experience postoperative psychosomatic disorder and should be strictly avoided^{2,71}.

Pain, anxiety, and the helplessness to react due to neuromuscular paralysis frequently result in post-traumatic stress disorder (PTSD), which necessitates psychiatric intervention. To avoid such situations of consciousness, anaesthesiologists frequently utilize higher doses of anaesthetics, resulting in extended ventilation and post-operative sedation. On the other hand, it has been observed that "deep" anaesthesia is linked to a higher 1-year death rate, presumably due to immune system dysfunction^{3,71}.

The measurement of the depth of anesthesia is an unsolved problem because there is not yet a clear definition of depth of anesthesia. Commonly used parameters such as hemodynamic parameters during anesthesia, movement response to skin incision, or clinical

signs such as diaphoresis, lacrimation, and mydriasis cannot directly correlate to the level of consciousness.

Only bispectral index (BIS) monitoring has been demonstrated to be successful among all existing technologies for monitoring anaesthetic depth^{2,4-6}. The electroencephalogram (EEG) is recorded by BIS from 4 electrodes that are applied over the forehead, and after processing it with mathematic algorithms, it generates a number from 0 to 100. The patient is under profound anaesthesia when the BIS value is less than 40 and mild sedation when the value is greater than 80^{5,71}.

The use of BIS monitoring will most likely aid in the optimization of anaesthetic levels, ensuring that they are neither too light nor too deep. BIS monitoring has been shown to help minimize drug usage and awareness, as well as speed up recovery time⁷⁻¹⁰.

BIS monitoring offers various potential benefits over traditional intermittent patient evaluation procedures. Traditional evaluation is taking repeated readings of all vital signs to measure the level of anaesthesia and then adjusting the anaesthetic agent dosage accordingly. The bispectral index, a non-invasive approach, is used to overcome these constraints, and BIS scores are shown continuously and objectively in the monitor, indicating the state of awareness.

Hence, the present study aims to compare the post-operative recovery time and quality of recovery in 72 patients in whom laparoscopic surgeries were performed under general anaesthesia who had BIS monitoring in addition to standard monitoring against control group with standard monitoring alone.

AIMS AND OBJECTIVES OF THE STUDY

- A. To compare the time of recovery in post operative period with and without use of BIS (Bispectral Index).
- B. To compare the quality of recovery in post operative period with and without use of BIS.

REVIEW OF LITERATURE

GENERAL ANAESTHESIA HISTORY AND DEFINITIONS

The Greek philosopher Dioscorides used the term "anaesthesia" to describe the narcotic effect of the herb mandragora in the first century of the present era.

The term was reintroduced in the 1771 Encyclopedia Britannica, where it was characterized as a "sensory deprivation"¹¹. Following Morton's development of ether anaesthesia in 1846, Oliver Wendell Holmes developed the term "anaesthesia" to characterize the novel phenomena that allowed surgical procedures to be performed.

'Having inhaled the ether multiple times, I believe its effects may be split into three stages or degrees. The first is just a nice sense of half-intoxication; the second is a sensation of intense pleasure, akin to that generated by inhaling nitrous oxide or laughing gas.; The third stage, and, I believe, the only one in which procedures may be performed, is one of extreme drunkenness and insensibility. Plomley¹¹ wrote this remark in a letter to the Lancet in 1847, and it was one of the first definitions of the several phases of anaesthesia.

For ether anaesthesia, John Snow¹² identified "five degrees of narcotism." Induction of anaesthesia was covered in the first three phases, and surgical anaesthesia was covered in the last two. Snow¹¹ shifted his focus to chloroform eleven years later. The following indications were noted by Snow in his superb descriptions of ether and chloroform anaesthesia: conjunctival reflex; regular, deep, automatic breathing; movement of the eyes; and inhibition of the intercostal muscles. Many of these clinical indications were "re - discovered" years later¹³.

Guedel's classic account of the clinical symptoms of ether anaesthesia was published in 1937¹¹. He defined four phases using physical indications such as

1. breathing patterns,
2. ocular signals and
3. somatic muscle tone

- Slow, regular breathing with the diaphragm and intercostal muscles, as well as the existence of the lid reflex, characterise the first stage, analgesia. Complete amnesia, analgesia, and drowsiness are all experienced by the individual.
- The individual feels excitation, unconsciousness, and a dream state with unrestricted action in the second stage (delirium). The airflow is erratic and unexpected. The pupils dilate reflexively, the lid reflex remains intact, and the risk of clinically significant reflex activity (e.g., vomiting, laryngospasm, or arrhythmias) rises. The third stage (surgical anaesthesia) consists of four progressive planes.

-Slight somatic relaxation, regular periodic breathing, and active ocular muscles define Plane

1.

-In plane 2, inhalation becomes shorter than exhalation, and inhalation and exhalation are separated by a tiny gap. The eyes become frozen in place.

-Plane 3 has totally relaxed abdominal muscles and a strong diaphragmatic breathing pattern.

There is no eyelid response.

-The intercostal muscles are fully paralysed in plane 4, resulting in paradoxical rib cage movement. The pupils are dilated and breathing is erratic.

In Guedel's fourth stage (respiratory paralysis), muscles become flaccid, and the eyes widely dilate. Cardiovascular and respiratory arrest occurs, as does cardiovascular collapse.

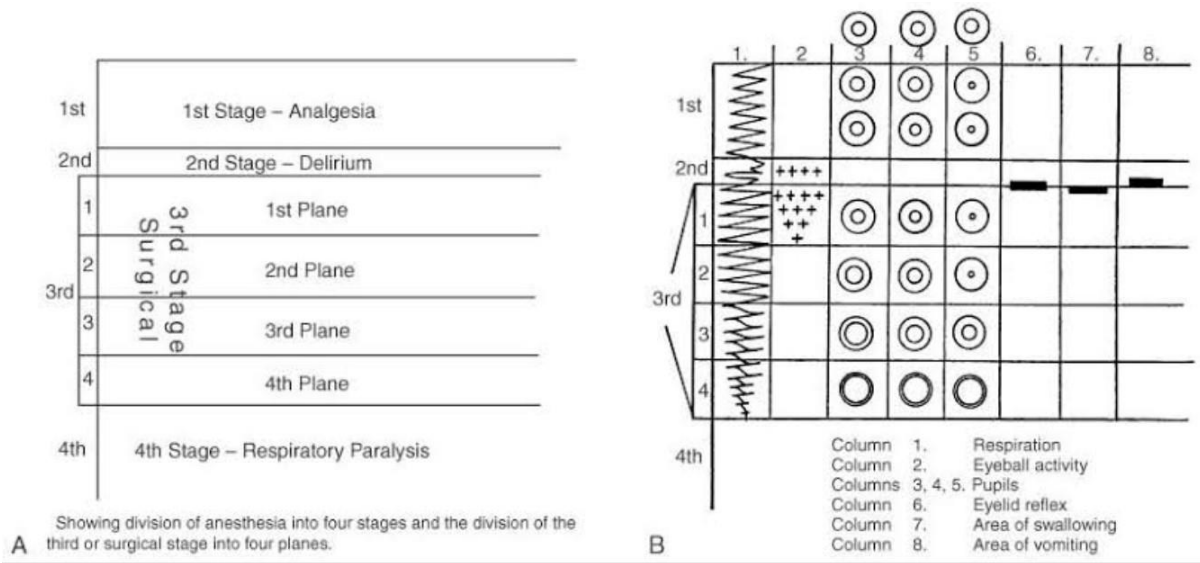


FIGURE 1: GUEDEL’S CLASSIC TEXT DESCRIBED THE STAGES AND PLANES OF ETHER ANAESTHESIA (A) AND THEN RELATED THEM TO CLINICAL SIGNS OR RELEVANT REFLEXES(B)

Muscles become flaccid and the eyes widen widely in Guedel's fourth stage (respiratory paralysis). Cardiovascular and respiratory arrest, as well as cardiovascular collapse, are all possible outcomes. Guedel and others identified clinical symptoms of level of anaesthesia that were extremely useful in the administration of cyclopropane, ether, and chloroform anaesthesia. The recognized hypnotic and analgesic effects of ether, which differ from those of the current inhaled anaesthetics employed in modern anaesthetic treatment, contribute to the effectiveness of employing clinical indicators to determine ether anaesthetic depth.

Small dosages of the muscle relaxant d-tubocurarine were used with deep levels of ether anaesthesia to generate planes 2 or 3 of Guedel's stage III beginning in 1942. When necessary, assistance with breathing was provided. As totally regulated breathing became more widespread, the dose of d-tubocurarine began to rise. Anaesthesiologists quickly learned that by combining controlled breathing, substantial doses of muscle relaxants, and low concentrations of inhaled anaesthetics, they might limit the danger of toxicity (cardiovascular

and respiratory depression) while also speeding up the recovery time. The use of muscle relaxants, on the other hand, abolished two important clinical indications of anaesthesia depth: the rate and volume of breathing, as well as the degree of muscular relaxation generated by the anaesthetic¹¹. Skeletal muscle activation was implicated in seven of Guedel's nine categorization components. When muscle relaxants are combined with ether anaesthesia, the only clinical indicators remaining are pupil size and lacrimation. Clinically, these symptoms are insufficient to determine anaesthetic depth¹¹.

The clinical concerns that muscle relaxants might cause were highlighted in a 1945 Lancet editorial, and examples of patient consciousness during surgery began to appear in the literature later¹⁴.

Woodbridge¹² investigated the various uses of anaesthetic medicines at the time in 1957. He characterised anaesthesia as a four-part process:

- (1) sensory afferent nerve impulse blockage
- (2) motor efferent impulses blockage
- (3) reflex blockage of the respiratory, cardiovascular, or gastrointestinal tract and
- (4) mental block, sleep, or unconsciousness.

Different drugs could be used to achieve each effect.

Woodbridge, on the other hand, made no attempt to specify procedures for evaluating any of these elements.

Prys-Roberts¹⁵ said in 1987 that there is no such thing as 'depth of anaesthesia.' He characterises loss of consciousness as an all-or-nothing phenomena in his editorial. As a result, there are no degrees of anaesthesia or varying depths of anaesthesia. Because pain is defined as a "conscious sense of painful stimuli," a "state of anaesthesia" is defined as a drug-induced unconsciousness in which the patient does not feel or recall pain. According to Kissin, anaesthesia comprises the avoidance of both bodily and psychological side effects of operation. Kissin, like Prys-

Roberts, sees anaesthesia as a series of distinct pharmacological responses elicited by one or more medications. One of the most helpful clinical markers of depth of anaesthesia is the deliberate movement of any portion of the body in response to painful perioperative stimuli. Eger et al¹⁶. established the minimum alveolar concentration (MAC) of inhaled anaesthetics as the concentration necessary to prevent 50% of individuals from reacting to painful stimuli based on this. MAC was further expanded to include other clinical end-points or stimuli, including as intubation (MAC intubation), incision (MAC incision), and beta adrenergic responses (MAC BAR).

The sequence: MAC-awake < MAC-incision < MAC-intubation < MAC-BAR.

MAC curves for various intraoperative stimuli fall between MAC-incision and MAC-intubation because tracheal intubation represents more noxious stimuli than all surgical stimuli. At end-tidal concentrations of inhalational drugs equivalent to MAC-awake, both explicit and implicit memory may be absent in unstimulated individuals.

If general anaesthesia is viewed as a spectrum of distinct pharmacologic activities that vary depending on the anaesthetic aims, some inferences about anaesthetic potency and depth of anaesthesia may be drawn. "It's practically impossible to assess the efficacy of many activities using a single metric due to the range of pharmacological effects that, when combined, cause anaesthesia," Kissin said¹⁷".

TABLE 1: COMPONENTS REQUIRED TO DETERMINE ANAESTHESIA DEPTH

COMPONENTS REQUIRED TO DETERMINE ANAESTHESIA DEPTH
Afferent stimulation
Efferent reaction
Analgesic drug concentrations that are Equilibrated
hypnotic drug concentrations that are Equilibrated
Other relevant medications (e.g., -blockers, muscle relaxants, local anaesthetics) at equilibrated concentrations
Drug concentrations are related to the likelihood of a particular reaction to a given stimulus on an interaction surface.

TABLE 2: METHODS TO ASSESS DEPTH OF ANAESTHESIA¹⁸

COMPONENTS REQUIRED TO DETERMINE ANAESTHESIA DEPTH ¹⁸
1. Subjective Techniques
a. Autonomic response <ul style="list-style-type: none">• Hemodynamic response• Pupillary dilatation• Lacrimation• Sweating
b. Forearm Isolation Method
2. Objective Techniques
a. Spontaneous surface electromyogram (SEMG)
b. Lower oesophageal contractility (LOC)
c. Variability in Heart Rate
d. Electroencephalogram and indices generated from it <ul style="list-style-type: none">• Bispectral index• Spectral edge frequency• Median frequency
e. Evoked potentials <ul style="list-style-type: none">• Somatosensory evoked potentials• Auditory evoked potentials• Visual evoked potentials• Auditory evoked potential index

1. SUBJECTIVE TECHNIQUES:

a. AUTONOMIC RESPONSE

In common practise, these are frequently employed as clinical markers of anaesthetic depth. Sudden hypertension and/or tachycardia, sweating, lacrimation, or mydriasis are all signs of anaesthesia lightening. Hypotension, dehydration, hypoxia, hypo or hyperthermia, and high amounts of blood loss are just a few of the other conditions that can affect hemodynamics. Blood pressure and heart rate can be affected by factors such as the patient's build, baseline tone, and cardiac medicines such as beta-blockers, other anti-hypertensive agents, inotropes, and vasodilators. Apart from that, anaesthetic medicines such as muscle relaxants and opioids may decrease these reactions but not cause hypnosis.

The PRST score, which is based on autonomic alterations in response to surgical stimulation, is a poor predictor of anaesthetic depth, as demonstrated in table 3¹⁹. It has been established that hemodynamic reactivity to noxious stimuli does not always imply awareness, and that the absence of hemodynamic changes does not always imply unconsciousness. There was no accompanying autonomic sign²⁰ in the majority of ASA closed claims for recall during anaesthesia. Only 2% of individuals with anaesthetic recollection had movement²⁰, whereas 15% had hypertension, 7% had tachycardia, and 15% had hypertension. Vernon et al²¹ found that pre-incision hemodynamic factors did not influence the outcome of the surgery.

**TABLE 3: PATIENT RESPONSE TO SURGICAL STIMULUS (PRST) SCORING
SYSTEM¹⁸**

Index	Condition	Score
Systolic blood pressure	< 15mm Hg from baseline	0
	15-30mm Hg from baseline	1
	>30mm Hg from baseline	2
Heart rate	<15 beats per min from baseline	0
	15-30 beats per min from baseline	1
	>30 beats per min from baseline	2
Sweating	Nil	0
	Skin moist	1
	sweat beads visible	2
Tears	No excessive tears in open eyes	0
	Excessive tears in open eyes	1
	Tears over flowing	2

b. Isolated Forearm Technique (IFT)¹⁸

Light anaesthesia is indicated by intentional movement in response to a vocal order. To avoid the impact of a muscle relaxant, a tourniquet is placed on the patient's arm and inflated above systolic blood pressure. As a result, the arm is free to move during anaesthesia. Ischemia must be avoided by removing the tourniquet at regular intervals, generally before filling up the muscle relaxant. After that, the patient may be requested to wiggle his fingers to verify the depth of anaesthetic. Despite its simplicity, IFT has certain drawbacks as a depth of anaesthesia monitor, including as –

- 1) An indiscriminate startle reaction might be mistaken for awareness.
- 2) Since the invention of muscle relaxants, the doses of anaesthetic required to inhibit movement in patients utilising IFT have been substantially greater than those commonly utilised.
- 3) Patients have described hearing orders to move the isolated arm but being unable to do so, despite the fact that the arm was not paralysed according to the nerve stimulator.

2. OBJECTIVE METHODS¹⁸

a. Spontaneous Surface Electromyogram (SEMG)

In those who aren't completely paralysed, a spontaneous surface electromyogram (SEMG) can be recorded from numerous muscle groups, including the facial, abdomen, and neck muscles. A branch of the facial nerve innervates the frontalis muscle, which is less impacted by the neuromuscular blockade. The frontalis Electromyogram (FEMG)¹⁸ can be recorded with a stick-on electrode placed across the muscle. FEMG levels have been reported to decline during anaesthesia before returning to pre-anaesthetic levels shortly before awakening²². In 28 of 30 patients, a 30% rise in neck muscular EMG activity preceded movement responses after purposeful lighting from enflurane – nitrous oxide anaesthesia. The scales, however, were not comprehensive, and there may be some variation in response. When used with EEG, the FEMG yields superior results. The ABM monitor system (Datex) uses the same electrodes to capture both EEG indices and FEMG.

b. Lower Oesophageal Contractility (LOC)

The non-striated muscles in the lower portion of the oesophagus retain their potential activity even after total skeletal muscle paralysis by neuromuscular blocking drugs. As a result, there are two important derivatives from LOC measurements.

- i. Spontaneous Lower Oesophageal Contractions (SLOC): These contractions are mediated by the vagal motor nuclei and reticular activating system in the brain stem. It usually controls non-propulsive spontaneous contractions of the lower oesophagus. The frequency of these movements increases when the anaesthetic dosage is reduced.
- ii. Lower Oesophageal Contractions Induced

To get them, a small balloon is inflated in the lower oesophagus. A secondary pulsatile response is induced by the short inflating of a tiny balloon, which grows in amplitude as the anaesthetic depth decreases. Evans and colleagues²³ were the first to propose that the degree of spontaneous lower oesophageal contractions may be utilised to evaluate anaesthetic level. During powerful inhaled anaesthetics like halothane, the frequency of such contractions can predict movement on reaction to skin incision, but not with N₂O/opioid anaesthesia, according to Sessler et al²⁴. In participants administered halothane anaesthesia, the lack of spontaneous contractions of the lower esophageal sphincter 6 minutes before skin incision corresponded well with no movement on incision. In patients administered alfentanil and nitrous oxide, however, there was no association between spontaneous contraction of the lower esophageal sphincter and movement²⁴.

c. Heart rate variability (HRV)¹⁸

Recent animal studies have revealed that anaesthetics operate on the brain stem first, either directly or indirectly, and subsequently block the cerebral cortex via ascending efferent projections from the midbrain²⁵. As a result, objective assessment of brainstem-mediated autonomic tone that is unaffected by everything but anaesthetic depth may be a reliable indication of anaesthesia depth.

Kiode²⁶ looked into heart rate variability from beat to beat and discovered that it might give information that could be beneficial for monitoring anaesthetic depth. HRV was divided into the following components after a thorough examination.:

- 1) Circadian variations with low frequency fluctuations.
- 2) Baroreceptor reflex causes medium frequency fluctuations.
- 3) Variations with a high frequency

HRV corresponds with the frequency of breathing, with heart rate increasing during inspiration and decreasing during expiration, thanks to a predominantly parasympathetic response

connecting stretch receptors in the lungs and aorta to vagal motor neurons innervating the heart. Pomfrett and coworkers²⁷ discovered a decrease in RSA during anaesthesia and an increase in RSA after recovery using on-line RSA analysis. In various studies, RSA levels were observed to be related to anaesthetic depth^{28,29}. Furthermore, surgical stimulation during light anaesthesia results in a higher rise in RSA than light anaesthesia alone¹⁸.

DEVELOPMENT AND CLINICAL APPLICATION OF BISPECTRAL INDEX

The electroencephalogram (EEG) is gaining popularity as a clinical monitoring tool for anaesthesia and sedation. This resurgence is the consequence of two recent events: first, a shift in the use of EEG from verifying deep surgical anaesthesia to assessing lighter or sedative levels, and second, technological advances that have resulted in significant progress in the construction of an "anaesthetic depth monitor."

Richard Caton³⁰, a Liverpool physician, initially characterised the EEG in 1875 after seeing electrical oscillations on the exposed brain surface of animals. Hans Berger, a psychiatrist at Jena, began a series of reports³¹ in 1929 that are now widely recognised as the initially reported human EEG in a descriptive systemic way.

EEG monitoring is being utilised to determine the state of "wellbeing" of the upper central nervous system (CNS) or the pharmacodynamic action of an anaesthetic medication in real time. EEG monitoring has been frequently employed for this purpose during carotid surgery since it is universally acknowledged as a highly sensitive, somewhat specific indication of CNS ischemia or hypoxia. EEG monitoring for drug effect has three applications: as a quantitative tool for the pharmacologic study of CNS active agents; as a tool for assessing metabolic suppressive effect (e.g., dose control of thiopental for EEG burst suppression); and, more recently, as a tool for assessing CNS functional suppression (depth of sedation or anaesthesia). The physiological outcome used to correlate or assess the EEG has so far been crucial. The first study correlated EEG to changes in blood pressure following noxious stimulation. The extent of hemodynamic change following intubation was proportional to the degree of EEG depression before laryngoscopy^{32,33}. Later attempts to link EEG to gross deliberate movement in response to surgical incisions, however, have yielded mixed results^{34,35}. The anatomic and maybe pharmacologic isolation of the neural circuits responsible for movement responses (spinal cord) from those responsible for the creation of the EEG signal could explain the

discrepancies (cerebrum). EEG is a phenomenon of the rostral structures, notably the cerebral cortex, as will be detailed. Monitoring spinal reflexes such as F waves can reveal anesthetic-induced inhibition of spinal function, i.e. surgical immobility. More trustworthy, therapeutically relevant results are achieved when EEG is connected with brain processes linked to the cortex, such as consciousness or memory.

THE BISPECTRAL INDEX⁴²

Bispectral analysis is a statistical approach that allows nonlinear phenomena like surf beats and wave breaking to be studied³⁶. Bispectral analysis is an alternative to other traditional power spectral analysis approaches developed from rapid Fourier transformation for describing a continuous pseudo-randomly fluctuating signal (e.g., EEG). In 1971³⁷, the first research on EEG bispectral analysis were published. Bispectral analysis is computationally demanding, and online bispectral analysis of the EEG in the operating room was not practical until fast microprocessors were created.

The strength, frequency, and phase of the EEG signal are all determined via conventional EEG analysis utilising rapid Fourier transformation. Power and frequency information are graphed in typical displays, such as the compressed spectral array, but phase information is ignored³⁸. The bispectrum quantifies relationships among the underlying sinusoidal components of the EEG³⁸, but bispectral analysis offers a distinct description of the EEG in that inter frequency phase relations are quantified. The unique parameter of the bispectral index, or BIS, is created using data from both bispectral and traditional frequency-power studies of the EEG^{38,39}. BIS is a dimensionless number ranging from 100–0, with 100 indicating a completely conscious EEG and 0 indicating complete electrical silence (cortical suppression)⁴². BIS went through several revisions during evolution (table 4) and the currently available versions (versions 4.0) are shown in figure 2.

Table 4: BISPECTRAL INDEX DEVELOPMENT

BIS Version	Release Date	Clinical Endpoint	Comment
1.0	1992	MAC/Hemodynamic	Agent-specific, with analgesic dosage modifying the effect
2.0	1994	Hypnosis/Awareness	Agent-independent index reformulation
2.5	1995	Hypnosis/Awareness	“Awake” artifact identification/removal
3.0	1995	Hypnosis/Awareness	Sedation performance has improved.
3.1	1996	Hypnosis/Awareness	The identification of EEG burst suppression improved
3.2	1997	Hypnosis/Awareness	EMG detection and removal is enhanced
3.3	1998	Hypnosis/Awareness	enhanced EMG and "near" suppression handling
3.4	1999	Hypnosis/Awareness	on emergence patterns, 15 s Smoothing, decreased vulnerability to “arousal delta”
4.0 (XP)	2001	Hypnosis/Awareness	Resistant to electrocautery, improved performance in sedation range and handling of near suppression states 4 lead sensor, upgraded DSC, advanced error handling 2 nd bipolar EEG rejects eye movement artifact
4.1	2004	Hypnosis/Awareness	Improved performance in sedation range

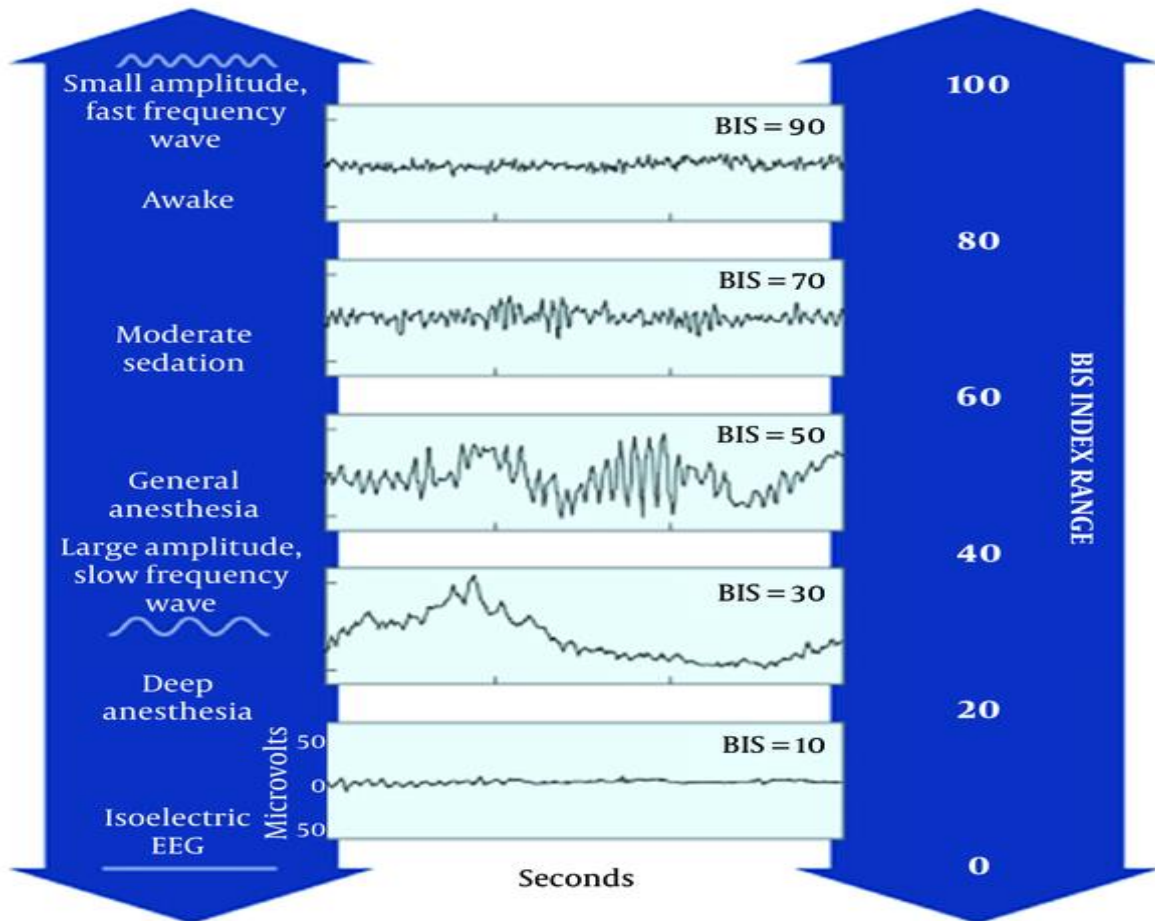


FIGURE 2: CLINICAL CORRELATION OF BISPECTRAL INDEX

The BIS is a single metric that incorporates a variety of various EEG properties. A combination of EEG activity subparameters^{13,42} was constructed using a prospectively collected database of anaesthetized volunteers with measurements of clinically significant sedative endpoints and hypnotic drug concentrations. The procedure of obtaining BIS is depicted graphically in figure 3. When clinical outcomes and drug concentrations were known, the EEG was recorded on a computer and time-matched to them. After reviewing the unprocessed EEG data and eliminating areas with artefacts, spectrum calculations were performed to get bispectral and power spectral variables. The factors that best correlate with the clinical objective were chosen after statistical ranking. The maximum likelihood answer to a logistic regression analysis was then used to fit these to a multivariate statistical model, resulting in a continuous sequence of BIS values. This index was then tested offline on a fresh database in a prospective way, and studies were conducted to assess its clinical value. Rampil has written a full description of the parameters utilized in current BIS implementations^{38,42}.

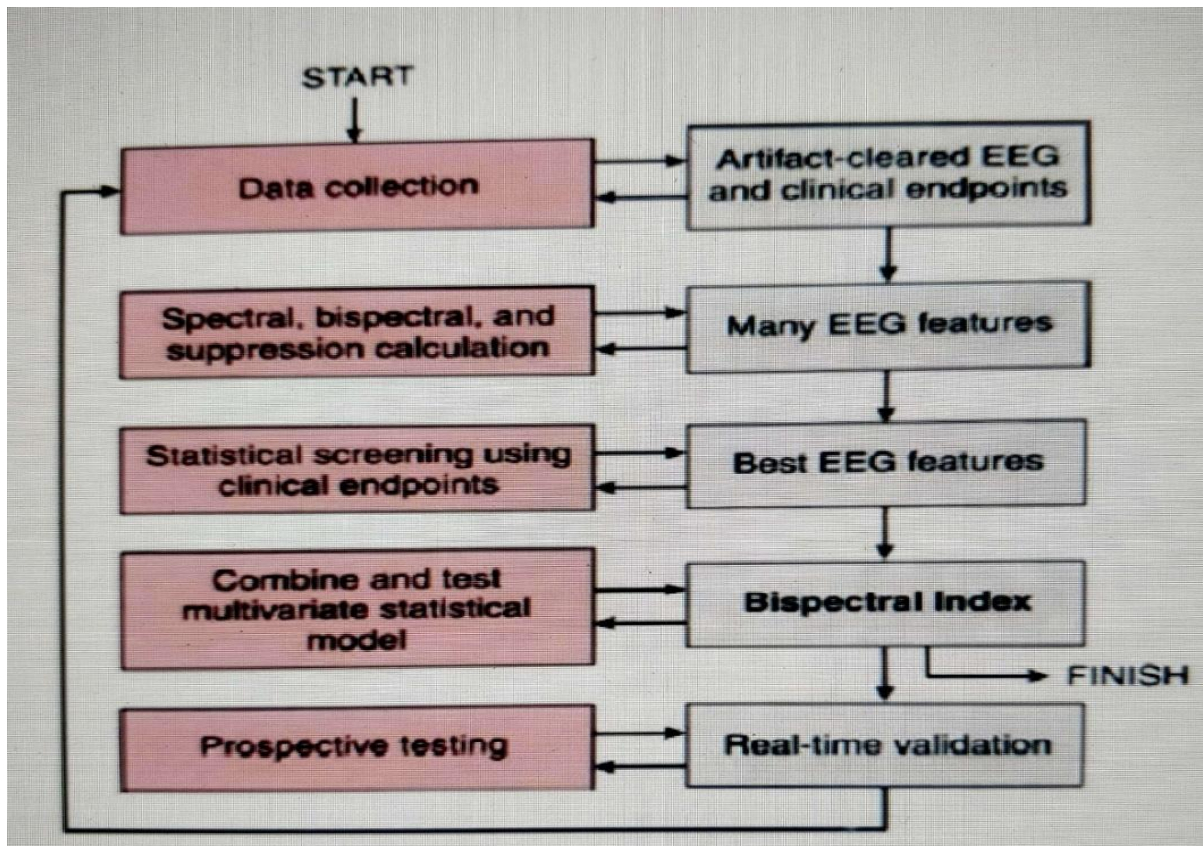


FIGURE 3: STEPS USED DURING DEVELOPMENT OF BISPECTRAL ALGORITHM

The BIS monitor is a good example of a successful EEG vs. behavioural response paradigm. Bispectral analysis and derivatives from classic EEG power spectral analysis are combined in the BIS approach⁴².

The so-called "triad" of anaesthesia (Gray and Rees, 1952) represented in figure 4 is now considered to be mainly distinct processes, and current anaesthesia is frequently achieved by mixing medicines that specifically elicit each of these effects.



FIGURE 4: COMPONENTS OF BALANCED ANESTHESIA: SEPARATION OF ANALGESIA, HYPNOSIS, AND AREFLEXIA.

BISPECTRAL INDEX MONITOR

In addition to the numeric BIS value, the BIS monitor has a touch screen that shows the SQI, EMG, burst count, and suppression ratio (Figure 5 & 6). The BIS, like the majority of parameters, is updated on a frequent basis, allowing the value to be presented in real time. The signal quality indicator (SQI) is a computation that estimates the signal quality of the EEG channel source based on impedance data, artefact, and other features. Higher SQI values indicate a more reliable and accurate BIS value, which can be shown as a bar or numerical number. If the signal quality is low, the BIS value may or may not be displayed alongside the other trend variables and parameters, depending on the explanation or artefact.

The bar graph indicates an electromyograph that depicts the power generated by muscle activity (i.e., EMG in the 70–110 Hz frequency range) and indicates whether or not there is muscular activity or other high-frequency aberrations (oscillating ventilator modes, convective warming blanket, fluid warmer, oscillating air mattress). The BIS monitoring conditions are optimal when the bar is empty. A surge in EMG might be caused by pain or other unpleasant stimuli, lightening sedation, or the wearing off of a neuromuscular blocking medication (NMB). The electrical power of muscle activation and high frequency artefacts are shown in the EMG bar graph. The lowest possible EMG is at 25 decibels. The acceptable EMG should be less than 55 dB. $EMG \leq 30$ dB: this is an ideal EMG.

The suppression ratio value represents the percentage of time the EEG signal has been suppressed over the last 63 seconds. It's a computed parameter that tells you if you're in an isoelectric (flat line) state.

When the BIS extend sensor is used, the burst count (burst or minute) is another technique of assessing suppression. It is measured as the number of EEG bursts per minute and presented.

A single or multichannel EEG may be presented depending on the monitor and the type of sensor used. A graph showing the BIS trend, which plots BIS values over time with a targeted

range indication, may also be produced. When a new sensor is connected to the PIC, a distinct case identification number is assigned and shown for each individual case when the sensors check passes. Data transmission to a USB drive or a patient monitoring or recordkeeping system, printing, and software upgrades as permitted by the manufacturer are all possible through three ports on the rear of the machine. For around 72 hours, the monitor saves recorded trend data together with the time and date of capture.

Advanced monitoring capabilities with identification of hemisphere variations in the brain are available with the newer BIS Vista™ bilateral monitoring system. It has a four channel EEG monitor, an asymmetry indicator for hemisphere EEG activity differences, and a density spectral array.



FIGURE 5: BISPECTRAL INDEX MONITOR DISPLAY

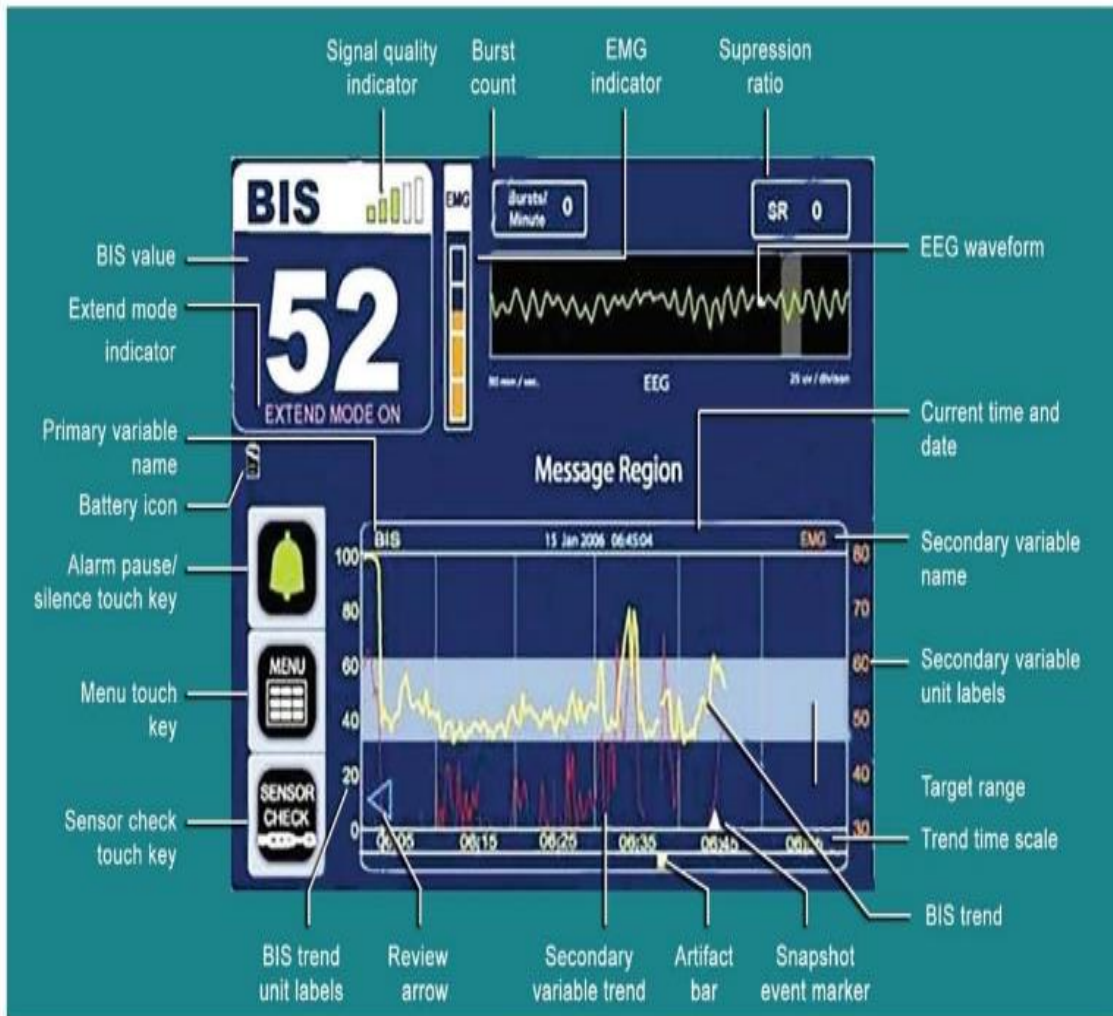


FIGURE 6: BISPECTRAL INDEX MONITOR

Bispectral Index-X Device

The digital signal converter of the BISx device (Figure 7) is the component that continually collects and processes the patient's EEG data. It computes data using the BIS method while filtering observed artefacts in order to determine the BIS. Other metrics such as signal quality indicator (SQI), EMG, burst count, and suppression ratio are also calculated (discussed in BIS monitor). The monitor interface cable, which connects to the front of the monitor, is used to transport and show them on the BIS monitor. For about 1,200 hours, the BISx retains EEG characteristics, including the BIS value, as well as the time and date of collection, and the data may be acquired to see the BISx history for a given instance. The BISx gadget is placed near to the patient's head to avoid other medical equipment from interfering with the EEG signal.



FIGURE 7: BISPECTRAL INDEX- X DEVICE

BIS SENSORS:



FIGURE 8(A): BIS SENSOR (QUATRO)

The EEG information is collected by placing the Sensor on the patient's forehead, which may be placed on either side of the patient's forehead and links to the patient interface cable, from which the BIS value is calculated.

THE SENSOR: Figure 8(a), (b) & 9

- Is an electrode strip that is intended to perceive the typically small amplitude, or very tiny, EEG signal
- Is has an adhesive to give perfect contact with the skin of patient
- Has self-prepping electrodes, doesn't require general skin preparation. A pre-filled conductive gel is present in each electrode to allow the EEG signal conduction.
- Has a 4th electrode inserted above the frontalis muscle and monitors the EMG of frontalis muscle.
- single channel EEG- Reads the frontal montage
- can be used only once, to be changed for each patient.
- free of latex

SENSOR APPLICATION:

- after preparing the skin with spirit, apply sensor on forehead at angle.
- 1-channel based EEG
- Either left hemisphere or right hemisphere
 - Circle 1: Center, 2 inches just-above the nose
 - Circle 4: Above/next to the eyebrow

- Circle 3: Either temple in-between corner of hairline and eye
 - Press the borders of the sensor
- Press each circle for 5 seconds
- with fingertip
 - apply pressure firmly



FIGURE 8(B): BIS SENSOR (QUATTRO)



FIGURE 9: BIS SENSOR APPLIED ON THE FOREHEAD OF PATIENT

LIMITATIONS OF BISPECTRAL INDEX MONITORING

MONITOR-RELATED SITUATIONS

1. All existing monitors need various times to compute and update the index in response to changes in anaesthetic depth. The time it takes to update BIS records might be anything from 14 and 155 seconds⁴¹. The delay of the bispectral index may imply that this monitor's usefulness in preventing intraoperative recollection and transitioning from awareness to unconsciousness is limited.
2. When electrode impedance is high owing to erroneous placement or decreased adherence⁴², falsely inflated BIS can ensue. The bispectral index necessitates the use of certain electrodes that, while pleasant, simple to use, and ensuring low resistance when obtaining the EEG data, and are also very costly
3. BIS monitoring can be influenced greatly by electromyographic (EMG) activity and neuromuscular blockers (NMB). BIS is increased by increased EMG activity, but it is reduced by NMB administration⁴³. There is no link between the EMG and the erroneous elevation of the BIS. Before making any judgments, the anaesthesiologist should be aware of signal quality (SQI), EMG activity, and the trend of BIS values in relation to the patient's clinical situation.

INTERFERENCE FROM ELECTRICAL EQUIPMENT

1. Aside from the electric scalpel, a variety of electrical gadgets might impair BIS monitoring. During heart surgery, there was a spike in BIS of up to 90 when an atrial pacemaker was used, which then reduced when the pacemaker was switched off.
2. False increases in BIS have been reported⁴⁴ when the thermal blanket was turned on and put directly on the patient's face. When the gadget was switched off, the bispectral index restored to 35 to 60. Similarly, BIS rose abruptly after shoulder arthroscopy as the shaver's oscillations began⁴⁵. These electrical gadgets can induce BIS electrodes to

vibrate or have a low frequency, replicating EEG signals seen during superficial anaesthesia or awareness. The monitor did not recognise the signal interferences as interferences. As a result, circumstances for unintended anaesthetic overdose are formed once more.

CHANGES IN BIS SECONDARY TO ABNORMAL EEG PATTERNS

1. Some patients have a genetically determined EEG variation that presents itself as low voltage⁴⁶. This is a common variation that affects 5 to 10% of the population and is not linked to any cognitive impairment. The monitor does not identify this aberrant EEG pattern since the BIS algorithm was designed on subjects with normal EEG. As a result, verifying the BIS in all patients prior to anaesthesia induction is critical.
2. Since the BIS algorithm was built using data from people with normal EEG, neurologic diseases that cause irregular EEG patterns are likely to influence BIS monitoring. Because neurological dysfunction impairs the BIS' ability to evaluate depth of consciousness, it is an unreliable instrument for measuring consciousness in this patient population. BIS levels are lower in neurologically damaged people in general. The activity of the cortical structure of the brain is represented by BIS values, but not that of subcortical areas such as the spinal cord⁴⁷.
3. Dementia patients' alertness was lower than that of those in the same age group who served as controls. Reduced BIS levels in dementia patients are linked to the Mini Mental State Examination⁴⁸.

ANAESTHETIC EFFECTS OF CERTAIN DRUGS

1. BIS levels are affected by the anaesthetics administered. With the same score, a patient anaesthetized with one anaesthetic drug may be more sedated than a patient anaesthetized with a different combination of medications. The BIS monitor is incorrect when certain anaesthetics, such as ketamine and nitrous oxide, are used (N₂O). In 2017,

Mishra et al. researched the effect of nitrous oxide on the bispectral index and observed that when nitrous oxide is introduced, the BIS value increases. This result might be explained by N₂O's neurostimulant properties and the fact that it reduces the suppressive effects of inhalational anaesthetic medications on EEG. N₂O increases cerebral blood flow rates, while also raising oxygen consumption in the cerebrum of brain (CMRO₂)⁴⁹.

2. EEG abnormalities can be caused by a variety of inhalational anaesthetics. As a result, BIS readings with equipotent amounts of various anaesthetics are not the same. The bispectral index of halothane was substantially higher than that of sevoflurane⁵² or isoflurane⁵⁰ at equipotent dosages. As a result, while using BIS to monitor halothane anaesthesia, care should be taken to avoid unintended anaesthetic excess.
3. Ketamine, when used with propofol during sedation, boosted hypnosis without decreasing BIS levels⁵¹.
4. Opioids generate only minor modifications in the cerebral cortex's electrophysiology. The mechanism of action of opioids is mediated through subcortical regions, which are not detectable by the EEG.

CHANGES IN BIS ACCORDING TO AGE:

It's difficult to use BIS to titrate anaesthetic drugs in babies younger than 6 months old; this might be owing to a variation in EEG in this population compared to older children, since brain development and synapse creation occur during that time. Bannister et al. reported no significant changes in anaesthetic usage or recovery parameters in children of age group among 6 months to 3 years between the conventional practice and BIS groups in 2001⁵³.

CHANGES IN BIS DUE TO HYPOTHERMIA:

Doi et al⁵⁴. assessed on 12 patients who were undergoing a surgery for a cardiac bypass had hypothermia and noted a broad range of BIS values as their body temperature dropped. For each degree Celsius drop in body temperature, the BIS drops by 1.12 units. Reduced brain metabolic rate for oxygen is represented on the EEG by the transition to an isoelectric/burst suppression pattern characterised by isoelectric periods when the temperature is lowered. EEG slows after aortic cannulation. Because the brain is perfused with a crystalloid prime solution, the commencement of cardiopulmonary bypass causes a brief EEG depression. Reduced cardiopulmonary bypass flow rates with the aorta crossing and clamp release cause EEG slowing that may last throughout the post-cardiopulmonary bypass phase. Reduced CPB flow rates recommended by the surgeon during aorta crossing and clamp release were frequently associated with EEG slowing that lasted well after the CPB was removed⁵⁵.

MODIFIED ALDRETE SCORING SYSTEM:

The Aldrete scoring system is a widely used scale for assessing when patients can safely be released from the post-anesthesia care unit (PACU) to the postsurgical ward or the second stage (Phase II) recovery area^{56,57}. The goal of Aldrete's grading system is to figure out when patients may safely leave the post-anesthesia care unit.

Jorge Antonio Aldrete [de], a Mexican anesthesiologist, developed the Aldrete Scoring System while working at the Denver Veterans Affairs Hospital in 1970^{56,58}. In 1988, he created the Combined Spinal Epidural Anesthesia, a well-known anaesthetic administration system that is currently utilised in major operating theatres throughout the world, and in 1989, he founded a well-known pain treatment clinic in Florida.

Instead of colour, the updated Aldrete Scoring System employs SpO₂. Wiley et al. (2002) evaluated the usefulness of this rating system⁵⁹.

TABLE 5: MODIFIED ALDRETE SCORE

Criteria	Score
1. ACTIVITY	
Moves all extremities	2
Moves two extremities	1
No movement	0
2. RESPIRATION	
Breathes deeply, coughs freely	2
Dyspnic, shallow or limited breathing	1
Apneic	0
3. CIRCULATION (BLOOD PRESSURE)	
20 % \pm preanaesthetic level	2
20 – 49% \pm preanaesthetic level	1
50 % \pm preanaesthetic level	0
4. CONSCIOUSNESS	
Fully awake	2
Arousable on calling	1
Not responding	0
5. OXYGEN SATURATION	
SpO ₂ > 92 % on room air	2
Supplemental oxygen requirement to maintain SpO ₂ > 90%	1
SpO ₂ < 90% with oxygen supplementation	0
TOTAL SCORE	

There are alternatives to this criterion for discharge. These discharge criteria have recently been employed in the operating room (OR) to decide whether outpatients having ambulatory surgery are eligible for a fast-track procedure.^{60,61}

MATERIAL AND METHODS

Source of data:

The study was conducted in Department of Anesthesiology, SHRI B M PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTER during the period from 22-11-2019 to 31-05- 2021 after ethical committee approval. Seventy-two (72) ASA Grade I and II patients between the ages of 18 and 60 were chosen for the research. Each patient gave their informed permission. The research comprised patients who were undergoing elective Laparoscopic surgeries under general anaesthesia. A thorough pre-anaesthetic examination was performed, which included a thorough history, physical examination, and airway assessment.

Investigations: The following investigations are requested pre-operatively:

- Blood investigations: Hemoglobin%, bleeding time, clotting time, Blood grouping and Rh typing, Blood sugar, Blood urea and Serum Creatinine.
- Urine: albumin, sugar & microscopy.
- ECG, chest X- ray.
- And other investigations - when indicated.

Inclusion criteria

- Patients of either gender, ages 18 to 60, who have been referred for elective laparoscopic surgical operations that will take at least one hour and will be performed under general anaesthesia.
- Patients of ASA grade I & II

Exclusion criteria

- Patient refusal for the procedure.
- Patients of III & IV ASA grade.
- Patients with established cardiac, renal, hepatic, neurological disorders, as well as any other major medical condition that would make response evaluation difficult.
- Anticonvulsants, benzodiazepines, opioids, alcohol, or other psychotropic medicines have been used (chronically or within 24 hours before the induction of anaesthesia).

STUDY PROCEDURE:

Seventy-two (72) patients were randomly allocated into two groups as follows: **36** patients in the BIS group who received BIS monitoring in addition to standard monitoring were compared to 36 controls. Pre-anesthetic evaluations were performed on all patients, and standard NPO protocols were observed.

Preliminaries:

- Written informed consent.
- Intravenous access with a 20 gauge I.V cannula under aseptic techniques

Procedure:

- When the patient arrives in the operating room, routine anaesthesia exercises are conducted, and baseline measurements such as blood pressure, heart rate, ECG, and pulse oximetry are recorded.
- Intravenous access was obtained, and a Ringer lactate IV infusion was commenced.
- The following monitors were attached:
 - Pulse oximetry – SpO₂
 - NIBP
 - ECG monitor
- After skin preparation, using a frontal – temporal montage, BIS electrodes strip was placed on the forehead and temples and connected to BIS monitor through BIS-X device. The EEG was constantly recorded from before anaesthetic induction until the patients were awake and responsive to vocal directions after extubation at the end of operation.

Patients were premedicated intravenously (IV) with Inj. Midazolam 0.08-0.1 mg/kg, Inj. Glycopyrrolate 0.008-0.15 mg/kg, Inj. Ondansetron 0.15 mg/kg half-an-hour before the procedure.

- Patients were pre-oxygenated for 3 min with 100% O₂.
- Inj.Fentanyl 2-4 mcg/kg I.V. was used as an analgesic.
- Induction: Inj.Propofol 2 mg/kg IV.
- Muscle relaxant: After ensuring the adequacy of mask ventilation Inj. Succinyl scholine 1-1.5 mg/kg IV to facilitate intubation of the trachea with appropriate size tube.
- Maintenance: Oxygen (O₂): Nitrous oxide (N₂O) (33%:66%), controlled ventilation along with isoflurane 0.5- 1 %. Muscle relaxation was maintained using intermittent doses of Vecuronium 0.08-0.12 mg/kg.
- Intra-operative monitoring is done with – pulse oximetry, non-invasive blood pressure, electrocardiogram, end-tidal carbon dioxide continually. Mechanical ventilation has been used to keep ETCO₂ levels between 35 and 40mm Hg in all of the patients.
- Intraoperative hypotension was described as a MAP less than 25% of baseline or an absolute value less than 60 mmHg, and it was treated with a fluid bolus and an IV bolus of mephentermine 6 mg. Bradycardia was defined as a heart rate of less than 50 beats per minute, and all patients with symptomatic bradycardia were given IV atropine 0.6 mg boluses.
- Tachycardia was defined as a heart rate more than 20% of baseline and intraoperative hypertension as a blood pressure greater than 25% of baseline (Orhon et al., 2013)⁶². During intraoperative hypertension episodes, the depth of anaesthesia was modified by raising the concentration of isoflurane or by boluses of fentanyl 25–50g with subsequent top-up doses of 0.02 mg/kg of vecuronium, as determined by the primary anaesthetist.
- In both the groups, depth of anaesthesia was maintained by titrating isoflurane, by keeping BIS score between 40-60 in BIS group, while in the Control group, it was

maintained by titrating isoflurane according to heart rate and mean arterial pressure (MAP).

- Inhalational agents and anaesthesia drugs used for maintenance of anaesthesia were discontinued towards the end of surgery to facilitate rapid recovery in both groups and to achieve a BIS score of 60-75 range in BIS group. Port site infiltration was done with 0.25% bupivacaine. Fresh gas flow rate was increased to 8–10 l/min with 60% N₂O in O₂. N₂O was discontinued after application of the last skin suture.
- The neuromuscular block was restored by intravenous injections of glycopyrrolate 0.008 mg/kg and neostigmine 0.05 mg/kg.
- The endotracheal tube was withdrawn once they met the subjective and objective criteria for extubation. The patient's recovery profile was observed at this time in terms of the following:
 - Recovery time is assessed in terms of
 - 1) time for eye opening and 2) responds to verbal commands.
 - Quality of recovery is assessed by
 - 1) swallow reflex 2) cough reflex and 3) orientation to time place and person and noted.
- Patients were shifted to post anaesthesia care unit (PACU). In PACU, Modified Aldrete score was noted. Modified Aldrete score comprise level of consciousness, physical activity, respiratory instability, oxygen saturation status, circulation (BP) with a total score of 10 [Table 1]. Time of achieving score of ≥ 9 was considered sufficient for discharge from PACU to ward.
- To maintain the visual analogue scale score (VAS) below 3, all patients got appropriate post-operative analgesia with sufficient dosages of inj. diclofenac, inj. paracetamol, or inj. tramadol, either given alone or administered together.

Statistical analysis:

All characteristics will be summarized descriptively. For continuous variables, the summary statistics of N, mean, standard deviation (SD) was used. For categorical data, the number and percentage were used in the data summaries and data was analyzed by Chi square test for association, comparison of means unpaired t test, Mann-Whitney U test and diagrammatic presentation.

Sample size: To do a comparative analysis for quality of recovery with and without BIS guidance, 72 (36per group) patients are required to have a 90% chance of detecting, as significant at the 5% level, an increase in the mean BIS monitor value from 90.6 in the control group to 91.8 in the experimental group with anticipated SD as 1.55.

Calculation based on the formula:

$$n = f(\alpha/2, \beta) \times 2 \times \sigma^2 / (\mu_1 - \mu_2)^2$$

Where μ_1 and μ_2 are the mean outcome in the study groups respectively, σ is the standard deviation

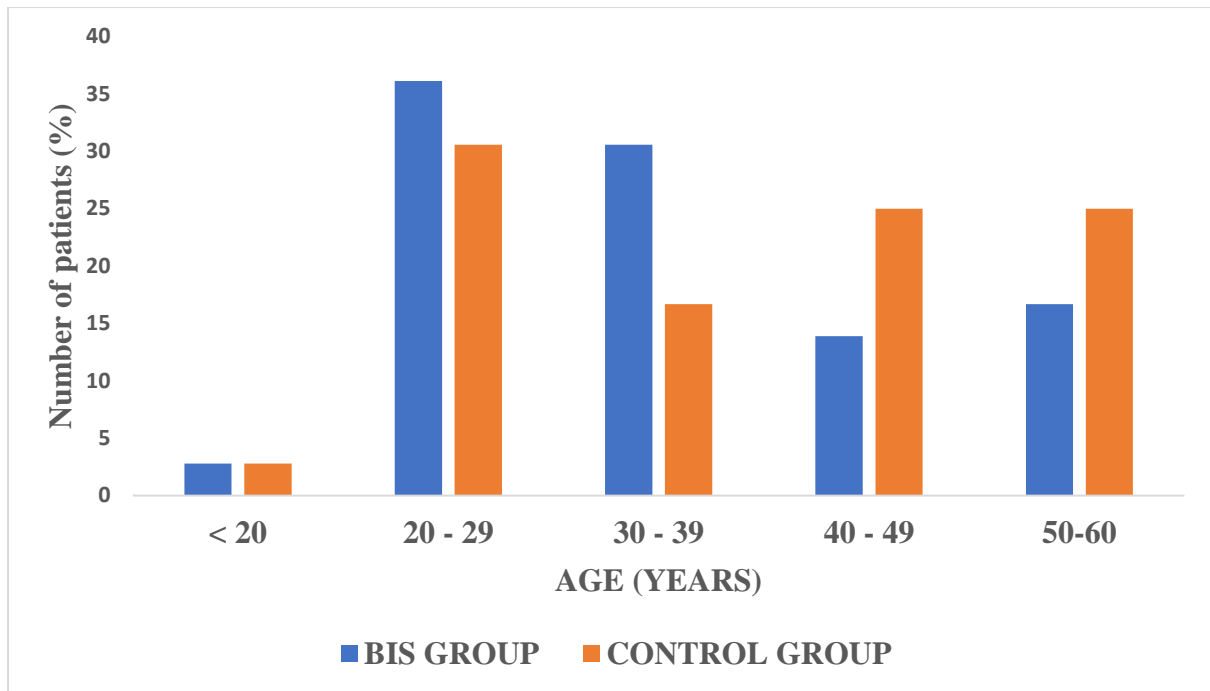
STATISTICAL SOFTWARE: The Statistical software namely Statistical Program for Social Science (SPSS) version 21.0 was used to analyse the data, while Microsoft Word and Excel were utilised to create graphs, tables, and other graphics etc.

OBSERVATION & RESULTS

This prospective comparative study was carried out on 72 patients between the age group of 18-60 years at Shri B M Patil medical college, hospital and research center, Vijayapur by comparing the recovery time and quality of recovery using the bispectral index monitor in BIS group against the Control group in patients undergoing elective laparoscopic surgeries.

TABLE 6: AGE DISTRIBUTION OF PATIENTS STUDIED

Age in years	BIS GROUP		CONTROL GROUP		P value
	N	%	N	%	
< 20	1	2.78	1	2.78	P=0.180
20 - 29	13	36.11	11	30.56	
30 - 39	11	30.56	6	16.67	
40 - 49	5	13.89	9	25.0	
50 - 60	6	16.67	9	25.0	
Total	36	100.0	36	100.0	

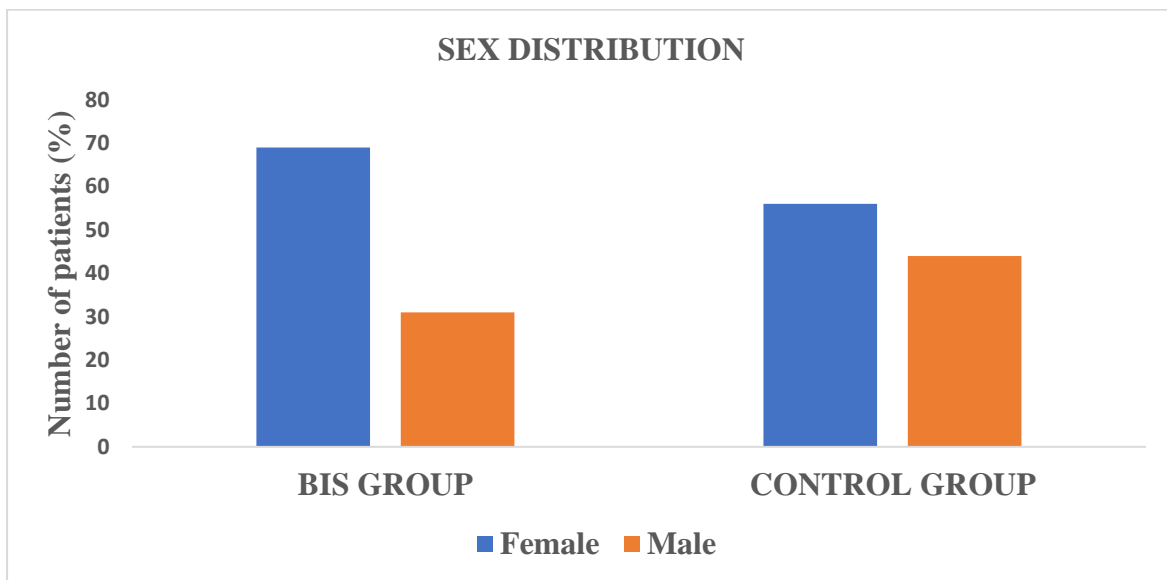


GRAPH 1: AGE DISTRIBUTION

The patients took part in the study belonged to the age group of 18 -60 years, 36.11 % of patients in BIS group and 30.56 % in control group were between 20 -29years. Mean age in BIS group and Control group was 35.89 ± 12.517 and 39.89 ± 12.328 respectively and were comparable among two groups ($p>0.05$).

TABLE 7: SEX DISTRIBUTION OF PATIENTS STUDIED

Gender	BIS GROUP		CONTROL GROUP		P value
	N	%	N	%	
Female	25	69	20	56	P=0.4884
Male	11	31	16	44	
Total	36	100.0	36	100.0	

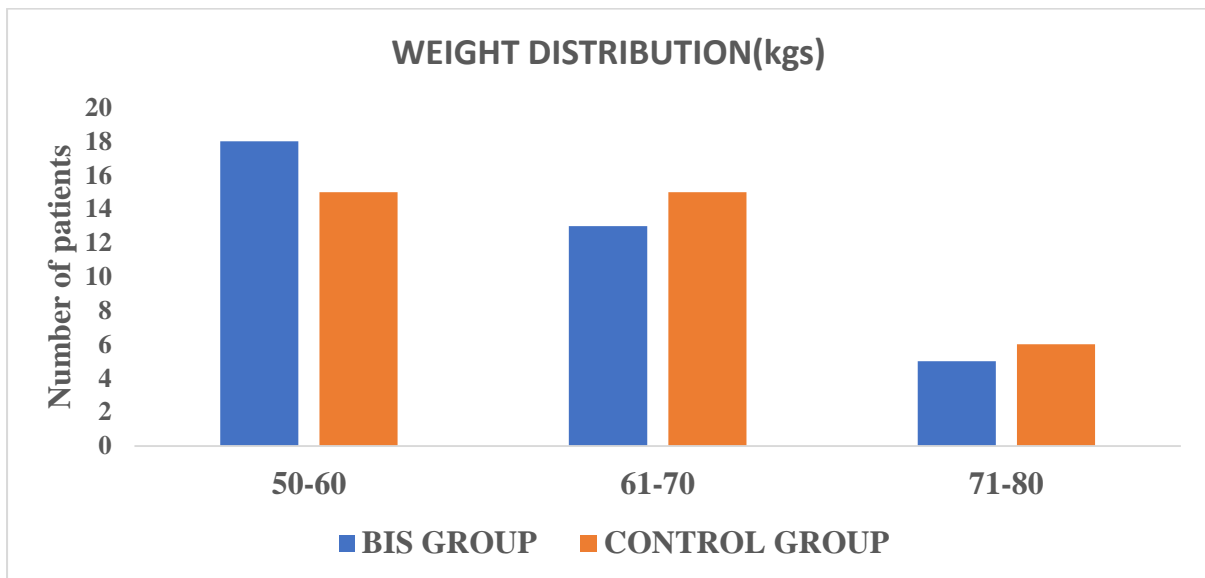


GRAPH 2: SEX DISTRIBUTION

Majority of the patients in our study were female accounting for 69% in BIS Group and 56% in Control group of the total. There were no significant differences between males and females in relation to post operative recovery.

TABLE 8: WEIGHT DISTRIBUTION OF PATIENTS STUDIED

WEIGHT (kgs)	BIS GROUP		CONTROL GROUP		TOTAL %	P value
	N	%	N	%		
50-60	18	50.00 %	15	41.67%	45.83%	P=0.193
61-70	13	36.11%	15	41.67%	38.89%	
71-80	5	13.89%	6	16.67%	15.28%	
TOTAL	36	100%	36	100%	100.00%	

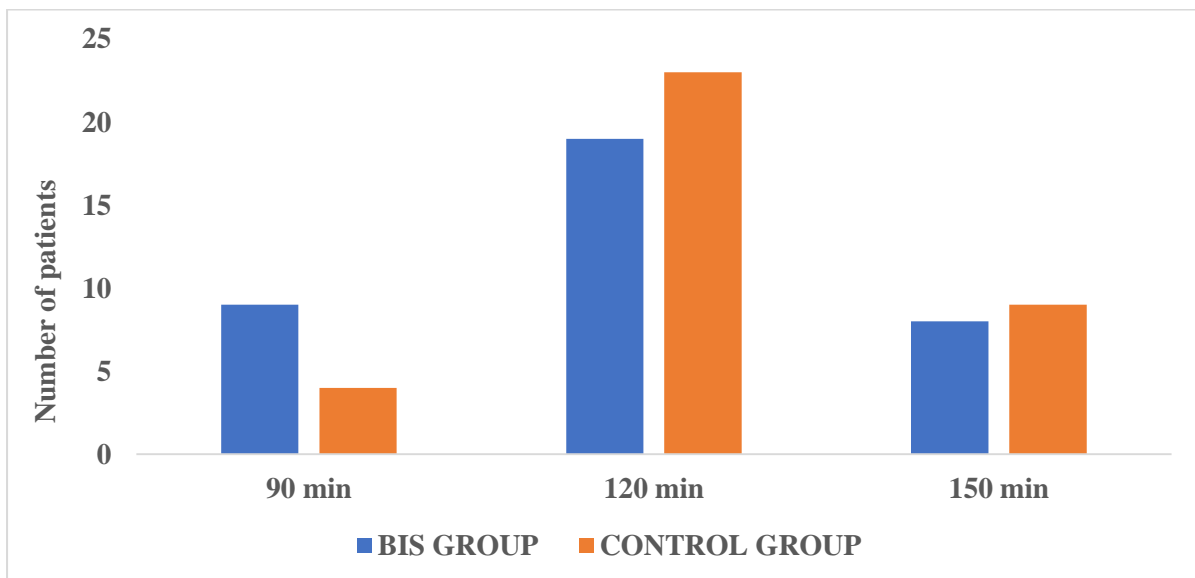


GRAPH 3: WEIGHT DISTRIBUTION

Both the groups predominantly weighed between 50-60 kgs i.e 45.83% in each group and mean weight in BIS group and Control group was 61.22 ± 7.672 and 63.56 ± 7.385 and were comparable among two groups ($p>0.05$).

TABLE 9: DISTRIBUTION OF PATIENTS STUDIED ACCORDING TO DURATION OF ANAESTHESIA

DURATION OF ANAESTHESIA (min)	BIS GROUP		CONTROL GROUP		P value
	N	%	N	%	
90	9	25.00%	4	11.11%	P=0.278
120	19	52.78%	23	63.89%	
150	8	22.22%	9	25.00%	
TOTAL	36	100%	36	100%	

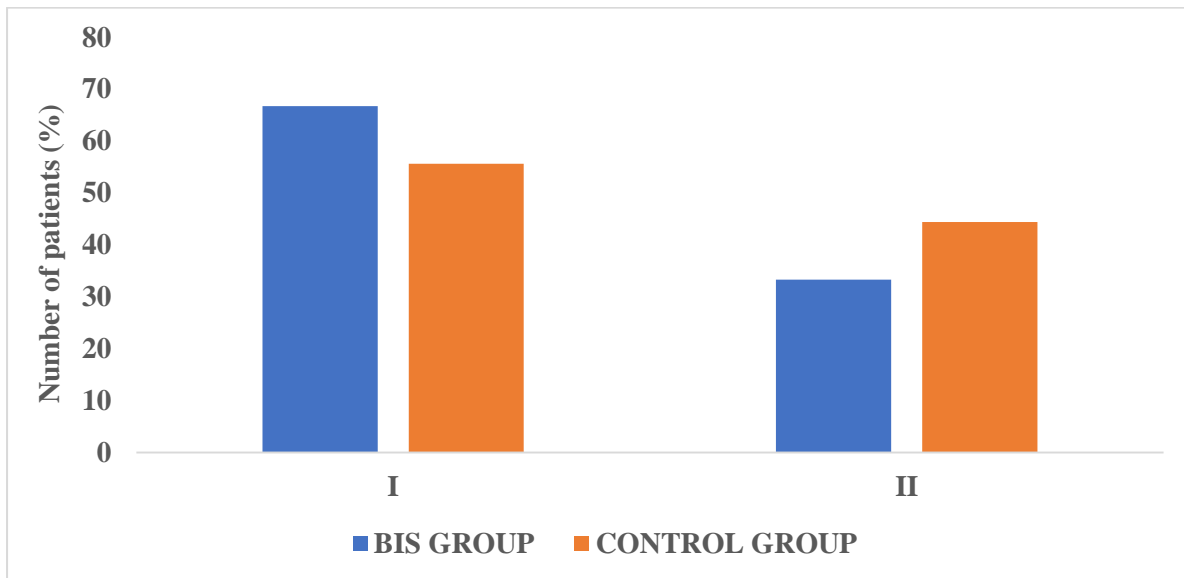


GRAPH 4: DISTRIBUTION ACCORDING TO DURATION OF ANAESTHESIA (IN MINUTES)

Mean duration of anaesthesia in BIS group and Control group was 119.17 ± 20.891 and 124.17 ± 17.788 respectively and were comparable among two groups ($p > 0.05$).

TABLE 10: DISTRIBUTION OF PATIENTS STUDIED ACCORDING TO ASA

ASA grade	BIS GROUP		CONTROL GROUP		P value
	N	%	N	%	
I	24	66.7	20	55.6	P=0.4884
II	12	33.3	16	44.4	
Total	36	100.0	36	100.0	

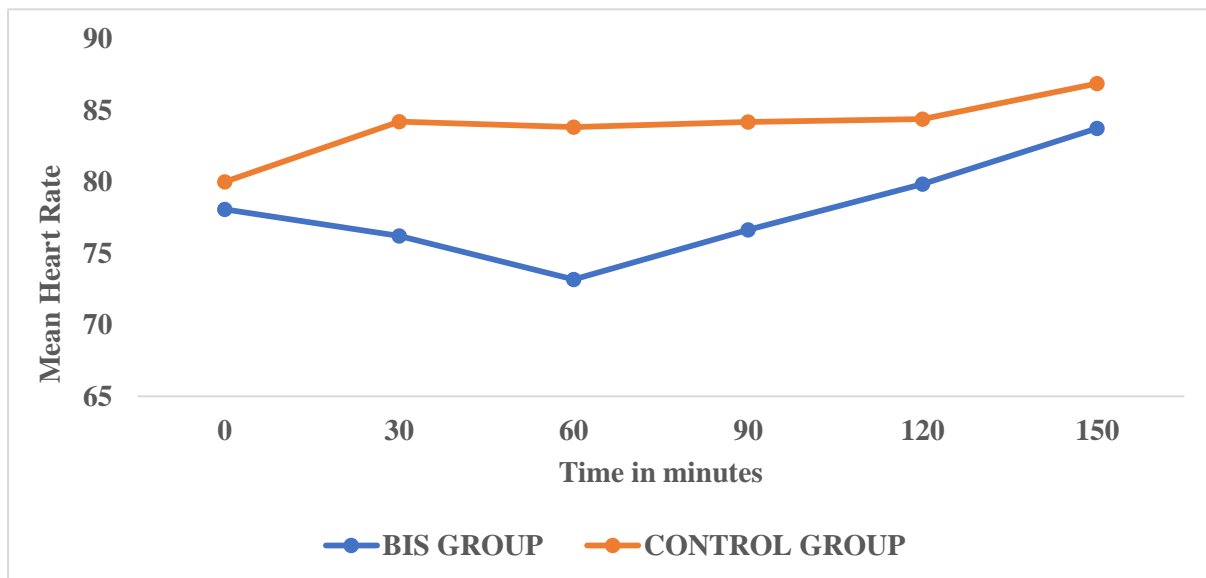


GRAPH 5: DISTRIBUTION ACCORDING TO ASA

Both the groups predominantly belonging to ASA grade I with 61.11 % in each group and both groups were comparable ($p > 0.05$).

**TABLE 11: PERI-OPERATIVE HEART RATE (HR) OF PATIENTS AT
DIFFERENT TIME INTERVALS**

Time in min	BIS GROUP		CONTROL GROUP		P value
	MEAN	±SD	MEAN	±SD	
0	78.08	10.777	80.00	10.744	P=0.452
30	76.22	9.084	84.22	12.206	P=0.002
60	73.17	8.185	83.83	12.230	P=0.001
90	76.64	10.387	84.19	10.810	P=0.003
120	79.85	7.541	84.40	10.11	P=0.05
150	83.75	6.571	86.89	11.704	P=0.51

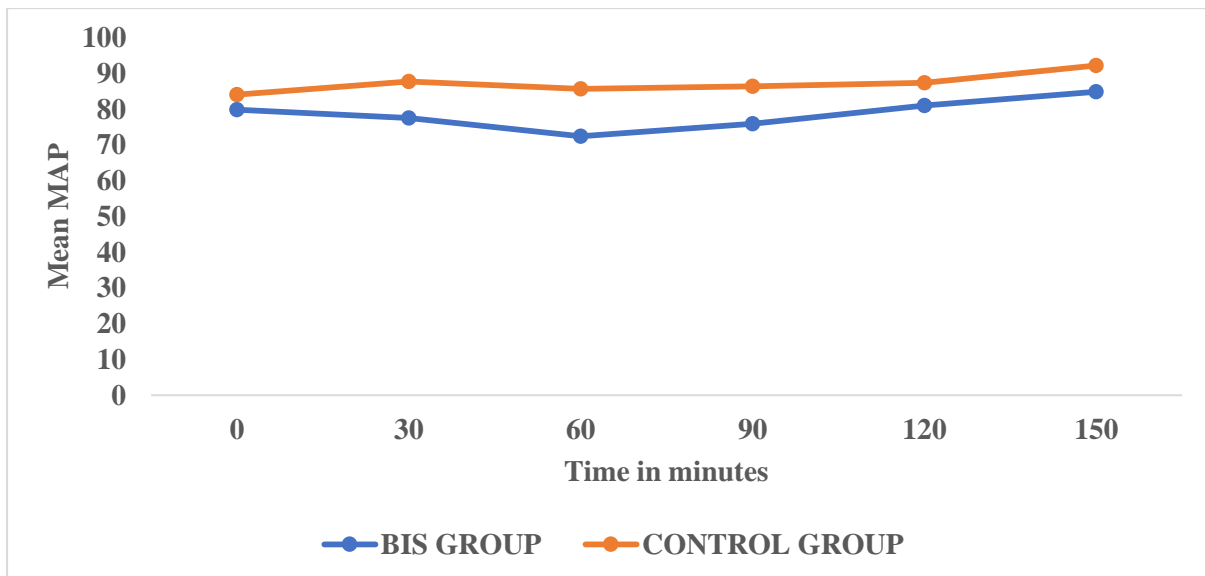


**GRAPH 6: PERI-OPERATIVE HEART RATE OF PATIENTS AT DIFFERENT
TIME INTERVALS IN BOTH GROUPS**

Inter-group, intra-operative HR was analysed using “unpaired t-test” and the variation in HR was statistically significant except at 0th and 150th min time interval where P value was insignificant (p>0.05).

TABLE 12: PERI-OPERATIVE MAP OF PATIENTS AT DIFFERENT TIME INTERVALS

Time in min	BIS GROUP		CONTROL GROUP		P value
	MEAN	±SD	MEAN	±SD	
0	79.89	10.777	84.08	7.358	P=0.025
30	77.53	9.084	87.72	8.736	P=0.001
60	72.42	8.185	85.72	7.814	P=0.001
90	75.94	7.808	86.36	6.039	P=0.001
120	81.03	8.234	87.37	6.163	P=0.001
150	84.87	7.769	92.33	2.708	P=0.016

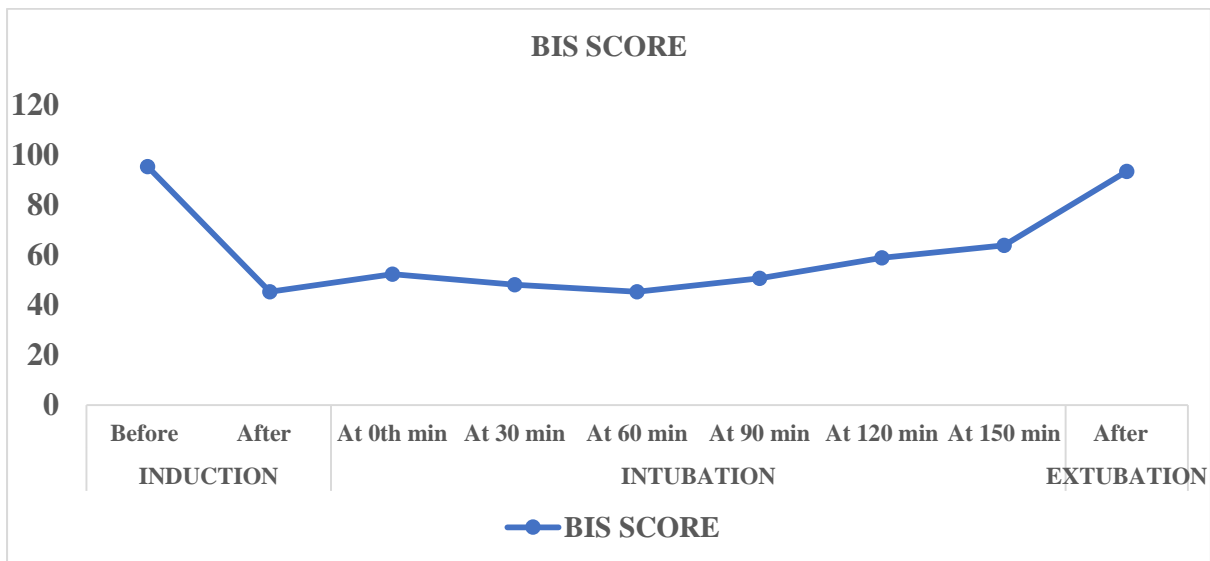


GRAPH 7: PERI-OPERATIVE MAP OF PATIENTS AT DIFFERENT TIME INTERVALS IN BOTH GROUPS

Inter-group, intra-operative MAP was analysed using “unpaired t-test” and the variation in MAP had a statistically significant P value ($p < 0.05$).

TABLE 13: MEAN BIS VALUES OF PATIENTS AT DIFFERENT TIME INTERVALS

BIS VALUES	BIS GROUP
Before induction	95.33
After induction	45.33
At 0th min	52.33
At 30 min	48.06
At 60 min	45.33
At 90 min	50.64
At 120 min	58.81
At 150 min	63.87
After Extubation	93.33



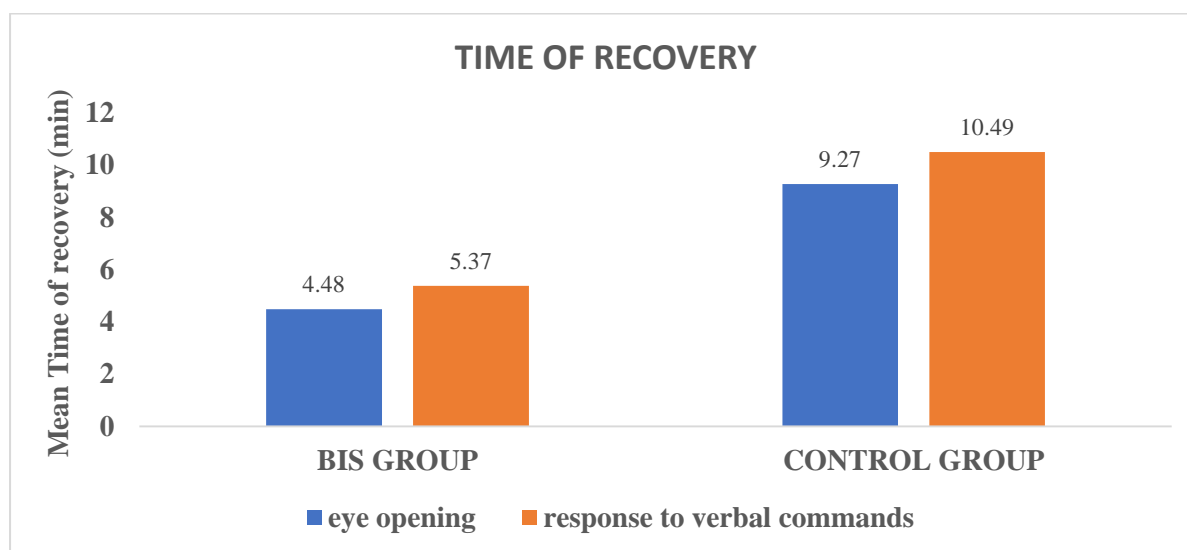
GRAPH 8: MEAN BIS SCORES OF PATIENTS IN BIS GROUP AT DIFFERENT TIME INTERVALS

Peri-operative mean BIS score at various time intervals is analysed and BIS values are well maintained between 40-60 during the procedure and values increased towards the end of procedure.

TABLE 14: DISTRIBUTION OF PATIENTS ACCORDING TO TIME OF RECOVERY

Time of recovery	BIS GROUP		CONTROL GROUP		Mann Whitney U test	P value
	Mean	±SD	Mean	±SD		
Opening of eye	4.48	0.89	9.27	0.668	U=0.000	P=0.0001*
Responds to commands	5.377	0.647	10.491	0.775	U=0.000	P=0.0001*

*: Statistically significant

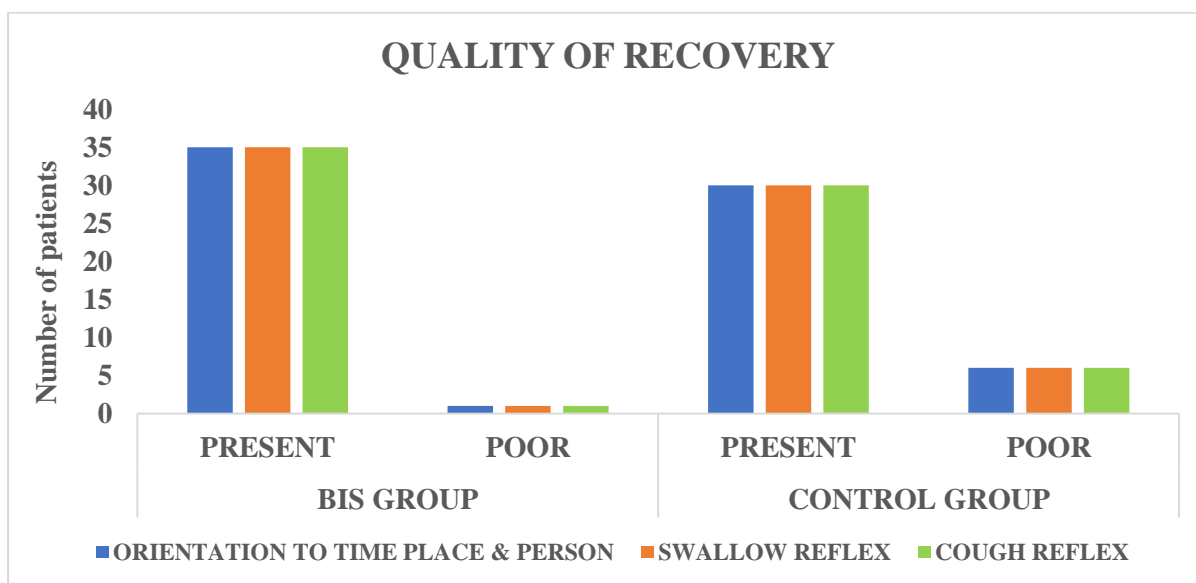


GRAPH 9: POST-OPERATIVE MEAN RECOVERY TIME OF PATIENTS IN BOTH GROUPS

Post-operative Mean Recovery time was analysed using “Chi- square test” and the variation in time of eye-opening and time of response to verbal commands was statistically significant (p<0.05).

TABLE 15: DISTRIBUTION OF PATIENTS ACCORDING TO QUALITY OF RECOVERY

Quality of recovery	BIS GROUP		CONTROL GROUP		P value
	PRESENT	POOR	PRESENT	POOR	
ORIENTATION TO TIME PLACE & PERSON	35	1	30	6	P=0.0467
SWALLOW REFLEX	35	1	30	6	
COUGH REFLEX	35	1	30	6	

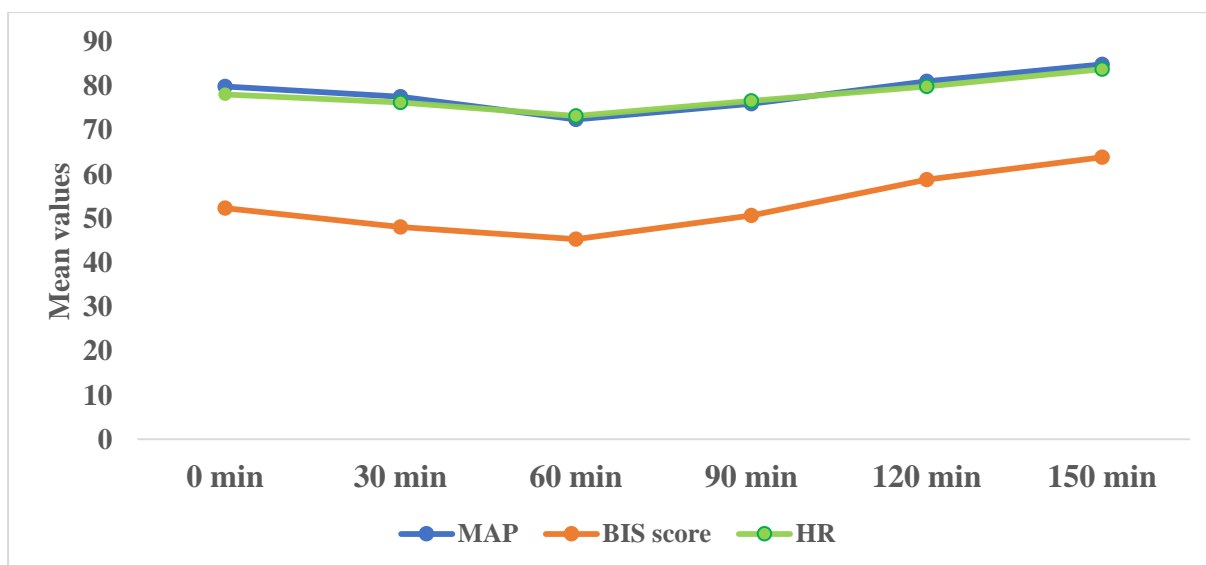


GRAPH 10: POST-OPERATIVE QUALITY OF RECOVERY OF PATIENTS IN BOTH GROUPS

Post-operative Quality of recovery was analysed using “Chi- square test” and orientation to time place & person, swallow reflex & cough reflex was statistically significant ($p < 0.05$).

TABLE 16: PERI-OPERATIVE MEAN VALUES OF MAP, BIS SCORES AND HR OF PATIENTS AT DIFFERENT TIME INTERVALS IN BIS GROUP

Time in min	MAP		BIS SCORE		HR	
	MEAN	±SD	MEAN	±SD	MEAN	±SD
0	79.89	10.777	52.33	3.118	78.08	10.777
30	77.53	9.084	48.06	3.179	76.22	9.084
60	72.42	8.185	45.33	2.581	73.17	8.185
90	75.94	7.808	50.64	7.871	76.64	10.387
120	81.03	8.234	58.81	7.107	79.85	7.541
150	84.87	7.769	63.87	2.315	83.75	6.571



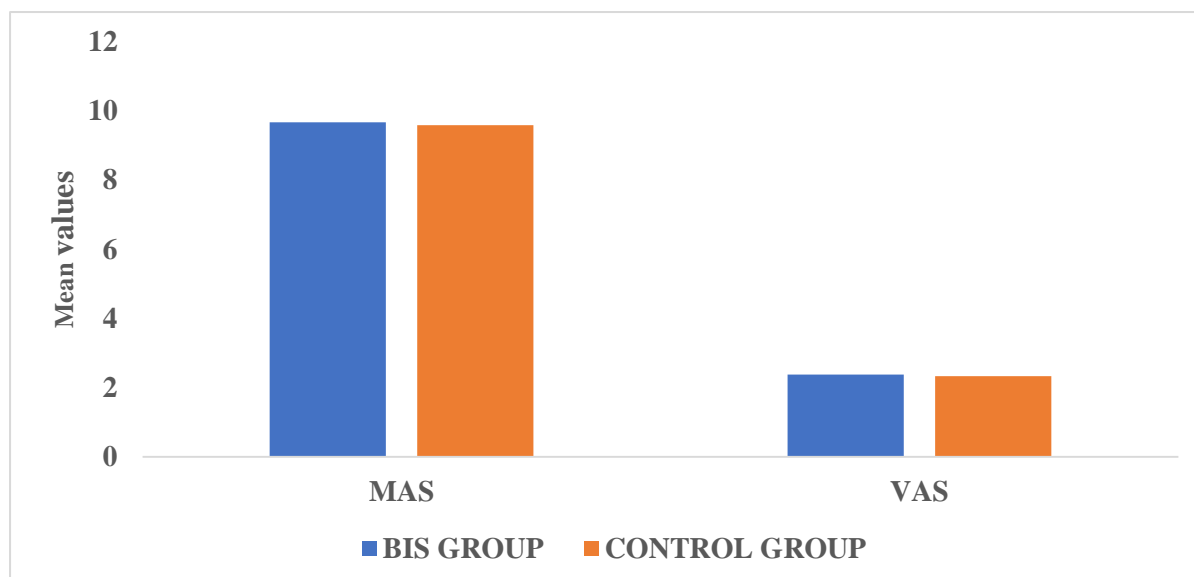
GRAPH 11: COMPARISION OF MAP, BIS SCORE & HR IN BIS GROUP

Despite the fact that there is no statistical link between BIS scores and hemodynamic parameters. As can be seen, the Bispectral index score fluctuates depending on the stage with various stages of anaesthesia, almost simultaneous changes in mean arterial blood pressures

and Heart rate occurred. When there is a rise in blood pressure on intubation, similarly there is increase in BIS scores at intubation. During maintenance phase, heart rate, blood pressure and BIS are maintained at a constant level throughout the period and at extubation, there is again raise in the BIS scores along with the heart rate and blood pressure.

TABLE 17: DISTRIBUTION OF PATIENTS ACCORDING DISCHARGE CRITERIA

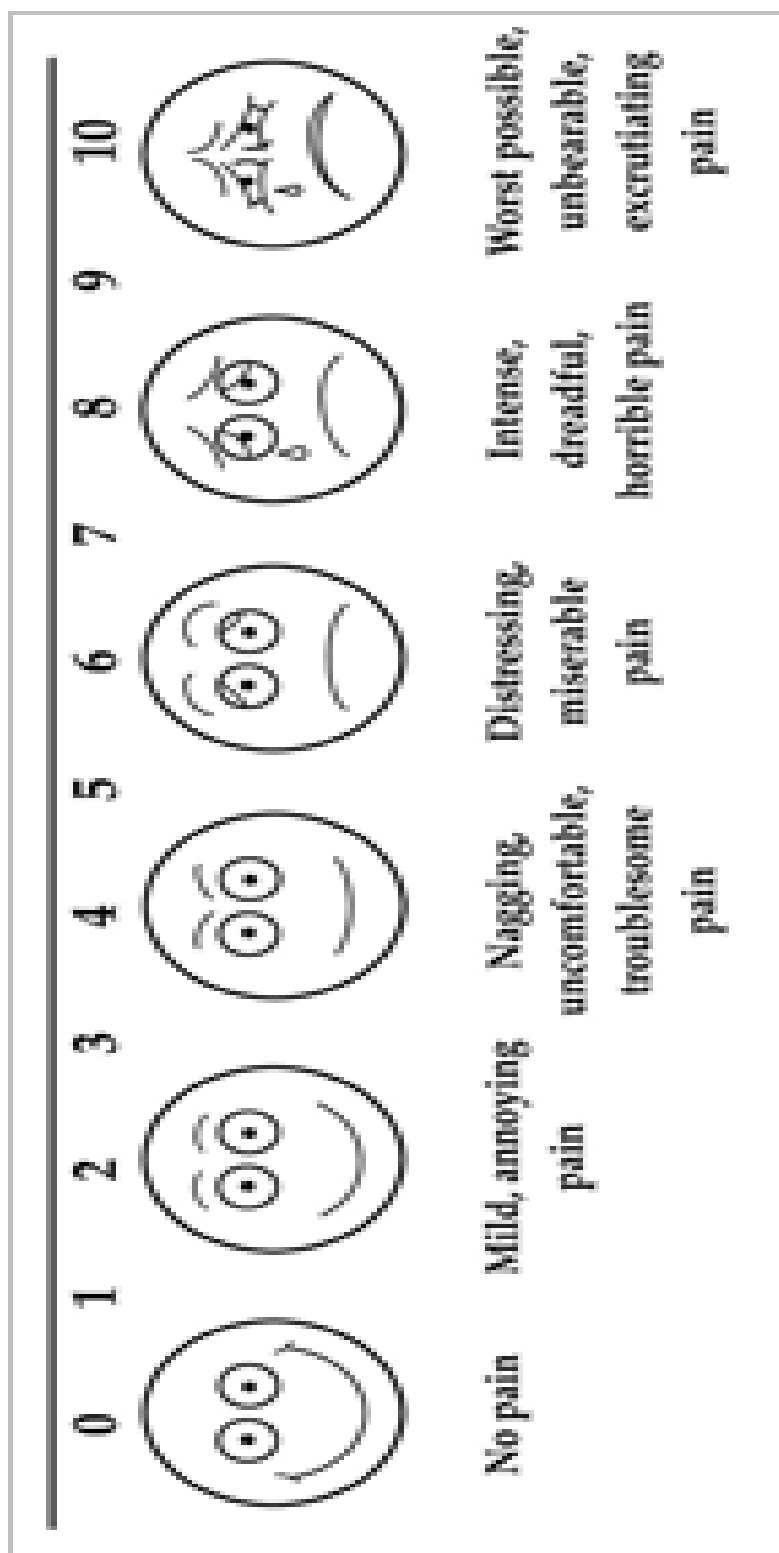
DISCHARGE CRITERIA	BIS GROUP		CONTROL GROUP		P value
	Mean	±SD	Mean	±SD	
Modified Aldrete score	9.67	0.478	9.58	0.500	P=0.468
VAS score	2.38	0.487	2.33	0.478	P=0.626



GRAPH 12: DISTRIBUTION OF PATIENTS ACCORDING DISCHARGE CRITERIA

Difference in modified Aldrete score (P=0.468) and visual analogue score (P=0.626) was not statistically significant between the two groups (Table 13) (Fig. 12) and both patients were eligible for discharge sooner.

Figure 10: VISUAL ANALOGUE SCORE



DISCUSSION

Prys-Roberts¹⁵ defined anesthesia as the state in which, as a result of drug induced unconsciousness, the patient neither perceives nor recalls noxious stimuli. He further stated that analgesia, muscle relaxation, and suppression of autonomic activity are not the components of anesthesia, but should be considered as desirable supplements to the state of anesthesia as a means to enable surgery to be performed. Anesthetic drug effects have traditionally been measured by the observation of heart rate, blood pressure, breathing pattern, lacrimation, sweating and the presence or absence of movement and many anesthesiologists rely on these clinical signs to direct anaesthetic agent dose in order to fulfil the core goals of anaesthetic management, which include unconsciousness (hypnotic effects), blocking of somatic motor responses, and suppression of autonomic reactions to unpleasant stimuli. These clinical indications, on the other hand, are not trustworthy indicators of the conscious state of sedated individuals. Awareness during general anesthesia can be a horrifying experience and may cause acute psychological trauma⁶⁴. Clearly, patients can experience intraoperative awareness in the absence of clinical signs of light anesthesia, such as changes in heart rate or blood pressure, or even movement. Therefore, a more direct and reliable method that would allow optimization of drug and measuring anesthetic drug effects on the brain is highly desirable and has been the object of research for many years.

Subsequently, electroencephalography (EEG) and processed EEG were used to relate drug concentration and clinical depth of anesthesia.

The bispectral index (BIS) is an objective method of assessing the depth of anesthesia. In October 1996, The BIS system was certified by the Food and Drug Administration as the first anaesthetic effect monitor based on electroencephalogram (EEG) that measures the depth

of anaesthesia. The Bispectral index (BIS) is a mathematically calculated statistic that lowers complicated EEG processing to a single value between 0 and 100. It measures the hypnotic component of the anesthetic and is a potentially useful adjunct for monitoring the depth of anaesthesia. The BIS is close to 100 in the conscious state, and it drops as the depth of anaesthesia increases; an appropriate degree of anaesthesia is attained with a BIS of 40 to 60. BIS monitoring appears to shorten the time it takes for patients to emerge and recover by reducing the overall quantity of anaesthetic they are exposed to. BIS monitor helps in reducing the incidence of awareness. Recommended level of surgical anaesthesia is between 40 and 60^[65,21,66]. This could result in preventing delayed recovery of the patients facilitating early discharge from the PACU set up leading to a decrease in anxiety and a decrease in the total costs incurred by the patient as well. Furthermore, BIS has the potential to diminish the occurrence of peri-operative recollection in surgical patients with a high risk of becoming conscious.⁶⁷.

In the present randomized prospective study, we compared time of recovery (time of eye opening and time to respond to verbal commands) and quality of recovery (cough reflex, swallow reflex and orientation to time, place and person) following general anaesthesia in patients undergoing elective laparoscopic surgeries with and without the use of BIS monitoring.

Seventy-two patients (ASA I-II) undergoing elective laparoscopic surgeries under GA were randomly divided into two groups of 36 each with (BIS group) and without (Control group) the use of Bispectral index monitoring. Patient refusal for the procedure, ASA grade III & IV, Patients with known cardiac, renal, hepatic, neurological disorders, or any serious medical condition that would interfere with response assessment and utilisation of benzodiazepines, anticonvulsants, alcohol, opioids or other psychotropic drugs (chronically or

within 24 hrs before the induction of anaesthesia) were excluded from the study so as to make the groups comparable.

The two groups were comparable with regard to all demographic data like age, weight, sex, Duration of anesthesia and ASA grade (Table 6-10 & Graph 1-5). The mean duration of anesthesia in BIS group was 119.17 ± 20.891 in whom anesthesia was given as per BIS values (BIS group) and in Control group it was 124.17 ± 17.788 in whom anesthesia was given as per the clinical parameters (Control group).

Electrodes of the Bispectral index monitor were attached to forehead and temple of the patients in BIS group. The EEG was constantly recorded from before anaesthetic induction until the patients were awake and responsive to vocal directions after extubation at the end of operation.

All the subjects received IV Glycopyrrolate 0.008 – 0.15mg/kg, IV Midazolam 0.08-0.1 mg/kg and IV Ondansetron 0.15 mg/kg IV as premedication 30min before the procedure. Fentanyl 2ug/ kg was used as analgesic. Induction was done with IV Propofol 2 mg/kg. After ensuring the adequacy of mask ventilation IV Succinyl scholine 1-1.5 mg/kg is given to facilitate intubation of the trachea with appropriate size tube. In the BIS group depth of anesthesia was maintained by keeping BIS score between 40-60 by titrating isoflurane, while in the Control group, it was maintained isoflurane was titrated using heart rate and mean arterial pressure (MAP). Maintenance of anesthesia was done with Oxygen (O₂): Nitrous oxide (N₂O) (33%:66%), controlled ventilation along with isoflurane 0.5 -1 %. Muscle relaxation was maintained using intermittent doses of IV Vecuronium 0.08-0.12 mg/kg. Inhalational agents and anesthesia drugs used for maintenance of anesthesia were discontinued towards the end of surgery to facilitate rapid recovery in both groups. After ensuring a regular breathing reversal of Neuromuscular block was done with injection glycopyrrolate 0.008 mg/kg and injection

neostigmine 0.05 mg/kg IV and patients were extubated. The patient's recovery profile was observed at this time in terms of the following:

- Recovery time is assessed in terms of
 - a) time for eye opening (from time of discontinuation of inhalational agent to eye opening)
 - b) responds to verbal commands (from time of discontinuation of inhalational agent to the time to respond and follow verbal commands)
- Quality of recovery is assessed by
 - a) swallow reflex (whether patient is able to swallow freely and properly or having a poor swallow reflex)
 - b) cough reflex (whether patient is able to breathe freely, cough freely or having a poor cough reflex) and
 - c) orientation to time place and person (whether patient is conscious, oriented and able to tell his/her own name or not) are noted.

The BIS patients recovered from anaesthesia faster than the Control patients. When it comes to comparing mean values, BIS group patients opened eyes and had verbal response faster than the Control group with a significant p value ($P=0.0001$). Mean time for eye opening and responds to verbal commands in patients of BIS group was 4.48 ± 0.89 min and 5.377 ± 0.647 compared to the Control group where mean time for eye opening and responds to verbal commands was 9.27 ± 0.668 min and 10.491 ± 0.775 (Table 14 and Graph-9).

In our study, there were seven patients (one in BIS group and six in control group) who had poor swallow and cough reflex with minimal confusion and disorientation in post operative period. There was a significant difference between the two groups when the above said parameters were assessed for quality of recovery showing a p value <0.05 ($P=0.0467$). Only 83.3% of control group have achieved a good quality of recovery while 16.7% had failed

to achieve good quality of recovery when anesthesia was maintained based on clinical signs whereas 97.2% of patients had achieved a good quality of recovery when anesthesia was maintained under BIS guidance. (Table 15 and Graph-10).

- Patients were shifted to post anaesthesia care unit (PACU). In PACU, Modified Aldrete score and visual analogue criteria were noted. Modified Aldrete score comprises level of consciousness, physical activity, respiratory instability, oxygen saturation status, circulation (BP) with a total score of 10 [Table 5]. Time of achieving score of ≥ 9 was considered sufficient for discharge from PACU to ward. To maintain the visual analogue scale score (VAS) below 3, all patients got appropriate post-operative analgesia with optimum dosages of inj. diclofenac, inj. paracetamol, or inj. tramadol, either alone or in combination. (Fig. 10)

Manisha et. Al⁶⁸ using Bispectral index monitor in their study showed that the mean recovery time between propofol group and isoflurane group was significantly different ($P < 0.001$). Incidence of postoperative nausea and vomiting was 35% lower in propofol group. The quality of surgical field was acceptable in both groups but slightly better in the propofol group.

Archana Nair et. Al⁶⁹ had done research on the effect of BIS monitoring on sevoflurane consumption, finding that in the BIS group, mean sevoflurane consumption was lower ($P = 0.019$) than in the control group, where acceptable depth of anaesthesia was maintained using normal clinical measures. Time for eye opening (TEO) ($P = 0.001$), time for motor response (TMR) ($P = 0.0001$), and time for extubation (TE) (0.003) were shorter in the BIS group. Difference in modified Aldrete scoring (MAS) between the 2 groups was not statistically significant ($P = 0.085$).

Divya Gahlot et. Al⁷⁰ in their study of 60 patients used showed early recovery parameters i.e., Time of removal of airway device (TD), Time to eye opening (TE), Time to follow verbal commands (TC), Time to orientation (TO), were achieved faster in patients receiving desflurane as compared to sevoflurane with no difference in time to achieve intermediate recovery and home readiness. The bispectral index (BIS) monitor was used for monitoring depth of anesthesia. Despite a faster early recovery with desflurane, no additional benefit in terms of home discharge and patient satisfaction was found, thus making use of either of the agents suitable for laparoscopic cholecystectomy on a day care basis.

Jasminka Persec et. Al⁷¹ studied that the use of BIS to guide anaesthesia will result in a much faster recovery time following anaesthesia.. When compared to the BIS-guided group, BIS levels in the nonBIS-guided group were considerably lower from 30 minutes through the completion of the operation ($p>0.05$). Extubation time was substantially reduced in the BIS-guided group. ($p<0.001$).

Carlos Rogerio Degrandi Oliveira et. Al⁷² have done a research comparing the benefits of GA monitoring based on the BIS Index versus monitoring based only on clinical indicators. The study was shown benefits in reducing time to extubation, orientation in time and place and discharge from operating room and post anaesthetic care unit.

The modified Aldrete scoring method did not show a statistically significant difference between the two groups in our investigation. Song et al⁷³., 1997; Guignard et al⁷⁴., 2001; Pavlin et al⁷⁵.

Berkenbosch⁷⁶ and coworkers suggested that BIS values of 50 – 70 correlated with moderate level of sedation, and deep sedation at levels below 50. BIS values of 45 -60 reflect adequate hypnotic effect for general anesthesia during surgery and 60 -75 during final 15 min of anesthetic regimen for rapid recovery of consciousness.

Studies of Kearse ⁶⁶ and **Vernon**²¹ attempted to correlate the BIS index to predict movement in response to skin incision with propofol/ nitrous oxide or propofol/alfentanil anesthesia respectively.

Flaishon⁷⁷ and colleagues in their study of 40 patients given general anesthesia found that BIS could estimate the likelihood of regaining consciousness following thiopental or propofol induction.

Gan et. Al⁷⁸ and others in another study of 302 patients receiving general anesthesia with propofol, nitrous oxide, alfentanil –concluded that titrating the dose of propofol with BIS monitoring decreased propofol use and improved recovery.

Our findings are comparable to those of **Lindholm et al**⁶³. and **Pavlin et al.**, who likewise found no effect on medication efficacy dosing and gas delivery using BIS, with fentanyl and sevoflurane anaesthesia.

Furthermore, according to **Klopman**⁴⁰ et al., claim that titrating anaesthesia using BIS level will result not only in faster waking times, but also reduced stays in the ICU, the possibility of meeting criteria to bypass the ICU, and lower medication expenses.

CONCLUSION

Bispectral index is a simple, objective measure to assess depth of anaesthesia. The study entitled “Bispectral index analysis for the quality of recovery in patients undergoing elective laparoscopic surgeries: a comparative study” concludes that Bispectral index monitoring is a very useful method in General anesthesia to ensure optimization of drug delivery to the needs of the individual patients in order to avoid unnecessarily too deep or too light anesthesia with their adverse effects. The amount of anesthetic required is optimized which translates into faster recovery and discharge times. This can lead to a better utilization of theatre time, decrease in PACU and hospital stay with reduction in costs. This can translate into an increased capacity to treat a greater number of patients which is especially useful in a day care set-up.

The information provided by the BIS monitor allows for improved anaesthetic management adjustments in addition to measuring consciousness during anaesthesia. Patients will be able to go home earlier with less leftover medication effects because to drug savings paired with enhanced recovery. As a result of our research, we discovered that with BIS monitoring, recovery variables were shorter, which impacted the pace of recovery following Laparoscopic procedures under general anaesthesia.

In general, certain groups of patients who have increased risk of awareness (Critically ill patients, Caesarean section, trauma patients) due to decreased dosage of anesthetic drugs could be provided with better operative and post operative care. These patients could benefit with optimized anesthetic drug delivery to prevent awareness using this BIS monitor.

However, as of now, the cost of the sensor is very high which can be a limiting factor for its wider usage. A reduction in the cost could prove to be very useful for its addition in the armamentarium of a large number of hospitals.

SUMMARY

A Prospective randomized study entitled “Bispectral index analysis for the quality of recovery in patients undergoing elective laparoscopic surgeries: a comparative study” was undertaken at Shri B M Patil medical college, hospital and research center.

Study population consisted of 72 patients of ASA physical status I/II patients in the age group of 18- 60 years belonging to both sexes scheduled for elective laparoscopic surgeries under general anaesthesia.

The BIS group was compared to the control group, which consisted of 36 patients in each group who received BIS monitoring in addition to conventional monitoring while the control group received only conventional monitoring. Routine anaesthetic drills are performed upon arrival in the operating room, and the patient's baseline measures such as blood pressure, heart rate, ECG, and pulse oximetry are documented. Intravenous access is established and an IV infusion of Ringer lactate started. After skin preparation, BIS electrodes were applied to the forehead and temple and BIS score was displayed on the monitor.

Patients were premedicated Intravenously (IV) with Inj. Midazolam 0.08-0.1 mg/kg, Inj. Glycopyrrolate 0.008- 0.15 mg/kg, Inj. Ondansetron 0.15 mg/kg 30 min before the procedure. Fentanyl 2-4 mcg/kg IV was used as an analgesic. IV Propofol 2 mg/kg was used to induce anaesthesia in the patients. To enable tracheal intubation with the proper size ETT, IV succinylcholine 1-1.5 mg/kg was administered as a muscle relaxant. For anaesthetic maintenance,

nitrous oxide (33 %:66 %), isoflurane, and vecuronium 0.08-0.12 mg/kg were administered. In the BIS group depth of anesthesia was maintained by keeping BIS score between 40-60, while in the Control group, it was maintained by titrating isoflurane using heart rate and mean arterial pressure (MAP). Inhalational agents and anesthesia drugs used for maintenance of anesthesia were discontinued towards the end of surgery to facilitate rapid recovery in both groups and to achieve a BIS score of 60-75 range in BIS group. Patient was reversed with IV Neostigmine 0.05mg/kg and IV Glycopyrrolate 0.04 mg/kg. The EEG was constantly recorded from before anaesthetic induction till the subjects were awake and responsive to vocal directions.

The groups were compared in terms of recovery time after anaesthesia, including eye opening time and responses to vocal orders. Quality of recovery is assessed by orientation to time place and person, swallow reflex and cough reflex.

- At this stage, the patient's recovery profile was observed in terms of the following:
 - A. Recovery time is assessed in terms of
 - 1) time for eye opening and
 - 2) responds to verbal commands.
 - B. Quality of recovery is assessed by
 - 1) swallow reflex
 - 2) cough reflex and
 - 3) orientation to time place and person and noted.

Patients were shifted to post anaesthesia care unit (PACU). In PACU, Modified Aldrete score was noted. Modified Aldrete score comprise level of consciousness, physical activity, respiratory instability, oxygen saturation status, circulation (BP) with a total score of 10 [Table 1]. Time of achieving score of ≥ 9 was considered sufficient for discharge from PACU to ward.

To maintain the visual analogue scale score (VAS) below 3, all patients got appropriate post-operative analgesia with optimum dosages of inj. diclofenac, inj. paracetamol, or inj. tramadol, either alone or in combination.

The results can be summarized as follows:

1. Age of the patients, sex, weight, duration of anaesthesia and ASA grade were compared and there was no significant difference between them.
2. Patients in BIS group, had a faster recovery time when compared to control group. Mean time of recovery in BIS group was statistically highly significant with p value <0.05 ($P=0.0001$).
3. In our study, there were seven patients (one in BIS group and six in control group) who had poor swallow and cough reflex with minimal confusion and disorientation in post operative period that are used as indicators of quality of recovery [p value <0.05 ($P=0.0467$)].
4. Difference in modified Aldrete score ($P=0.468$) and visual analogue score ($P=0.626$) was not statistically significant between the two groups and both patients were eligible for discharge sooner.
5. Peri-operative mean BIS score at various time intervals is analysed and BIS values are well maintained between 40-60 during the procedure and values increased towards the end of procedure and reached a mean BIS score value of 93.33 after extubation.
6. Inter-group, intra-operative HR and MAP was analysed using and the variation in HR and MAP was statistically significant ($p<0.05$) except at 0th and 150th min time interval where HR among two groups was insignificant ($p>0.05$).

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ANNEXURE: I

ETHICAL CLEARANCE CERTIFICATE



IEC/NO-131/2019
22-11-2019

B.L.D.E. (DEEMED TO BE UNIVERSITY)

(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)
The Constituent College

SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE


INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The ethical committee of this college met on 13-11-2019 at 3-15 pm to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

Title: Bispectral index analysis for the quality of recovery in patients undergoing elective laparoscopic surgeries: a comparative study

Name of PG student: : Dr Madasetty Likitha Department of Anaesthesiology

Name of Guide/Co-investigator: Dr Vidya A Patil, Prof & HOD
Department of Anaesthesiology


DR RAGHVENDRA KULKARNI
CHAIRMAN

Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College, BIJAPUR-586103

Following documents were placed before Ethical Committee for Scrutinization:

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.



B.L.D.E.(Deemed to be University)
SHRI B.M.PATIL MEDICAL COLLEGE, VIJAYAPUR-586103
INSTITUTIONAL ETHICAL COMMITTEE

Date : 13-11-2019

1. Name of UG/PG Students/Researcher: Dr Madasetty Likitha
2. Department : Anaesthesiology
3. Title : Bispectral Index Analysis For The Quality Of Recovery In Patients Undergoing Elective Laparoscopic Surgeries: A Comparative Study
4. Guide/Co-Guide/Principle Researcher: Dr Vidya A Patil, Prof & HOD
5. Date of Admission (PG Only) :


Observation :


- There are no ethical issues.

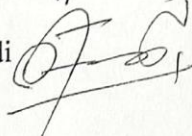
I.E.C. Remarks : Ethical Clearance accorded/be Chairman after corrected revised version is submitted by stipulated time.


1. Any alternation in Synopsis protocol should be intimated to E.C. in writing for review & approval.
2. Any adverse effects to subject of the study should be intimated in writing to E.C.
3. If study is stopped or an included patient is out of study inform E.C. the same with reason.


Signature of the Committee Members :

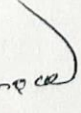
1. Dr Raghavendra Kulkarni, Chairman 

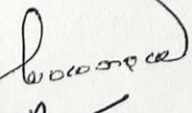
2. Dr Tejaswini Vallabha 

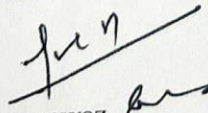
3. Dr Akram Naikawadi 


4. Dr P.B.Jaju 

5. Dr Chandrashekhar Bhuyyar 

6. Dr Pranesh Jahagirdar 

7. Dr Manjunatha Aithala 

8. Dr Satish Patil 

9. Dr Mohammed Shannawaz 

ANNEXURE –II

SAMPLE INFORMED CONSENT FORM

**BLDE (DEEMED TO BE UNIVERSITY), SHRI B M PATIL MEDICAL COLLEGE
HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA-586103, KARNATAKA**

TITLE OF THE PROJECT : BISPECTRAL INDEX ANALYSIS FOR THE
QUALITY OF RECOVERY IN PATIENTS
UNDERGOING ELECTIVE LAPAROSCOPIC
SURGERIES: A COMPARATIVE STUDY”

PRINCIPAL INVESTIGATOR : Dr MADASETTY LIKITHA
Department of Anaesthesiology
BLDE (Deemed to be University), Shri B M Patil
Medical College & Research Center, Sholapur
Road, Vijayapura.
E mail: likitha.madasetty@gmail.com

PG GUIDE : Dr VIDYA PATIL
M.D ANAESTHESIOLOGY
Professor & HOD
Dept of Anaesthesiology
BLDE (Deemed to be University), Shri B M Patil
Medical College & Research Center, Vijayapura,
Karnataka.

PURPOSE OF RESEARCH:

I have been informed that this study is BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY. I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice of either being included or not in the study.

PROCEDURE:

I understand that I will be participating in the study BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY.

RISKS AND DISCOMFORTS:

I understand that my ward may experience some discomfort during the procedure and I understand that necessary measures will be taken to reduce them

BENEFITS:

I understand that my ward participating in this study will help in finding out BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will **BISPECTRAL INDEX ANALYSIS FOR THE QUALITY OF RECOVERY IN PATIENTS UNDERGOING ELECTIVE LAPAROSCOPIC SURGERIES: A COMPARATIVE STUDY** be subjected to the confidentiality and privacy regulation of this hospital.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identities such as photographs and audio and video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr **MADASETTY LIKITHA** is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study ,or later I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. And that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand Dr. MADASETTY LIKITHA will terminate my participation in this study at any time after she has explained the reason for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely events of injury to me/my ward, resulting directly due to my participation in this study, such injury will be reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving my legal rights. I have explained to _____ the purpose of this research, the procedure required and the possible risk and benefits, to the best of my ability in patient's own language

DATE

Dr.MADASETTY LIKITHA

(investigator)

PATIENT/PARENT SIGNATURE

Witness

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. MADASETTY LIKITHA has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

(participant)

(date)

(witness to above signature)

(date)

ASA GRADE:

Investigations

Haemoglobin:

TLC:

Platelet count:

Urine routine:

HIV:

HbsAg:

S. Creatinine:

B.Urea:

Chest X-Ray:

ECG:

Anaesthesia start time:

Surgery start time:

Surgery end time:

Time of first complaint of pain in postoperative period:

Intra- operative events

TIME	PR/BP			
	AFTER INTUBATION		AFTER EXTUBATION	
0 min				
5 min				
10 min				

AFTER EXTUBATION

PARAMETERS	0 min	5 min	15 min
Spontaneous eye opening:			
Eye opening on verbal commands:			
Orientation to time, place and person:			
Swallow Reflex:			
Cough Reflex:			
Response to verbal commands:			

MODIFIED ALDRETE SCORE:

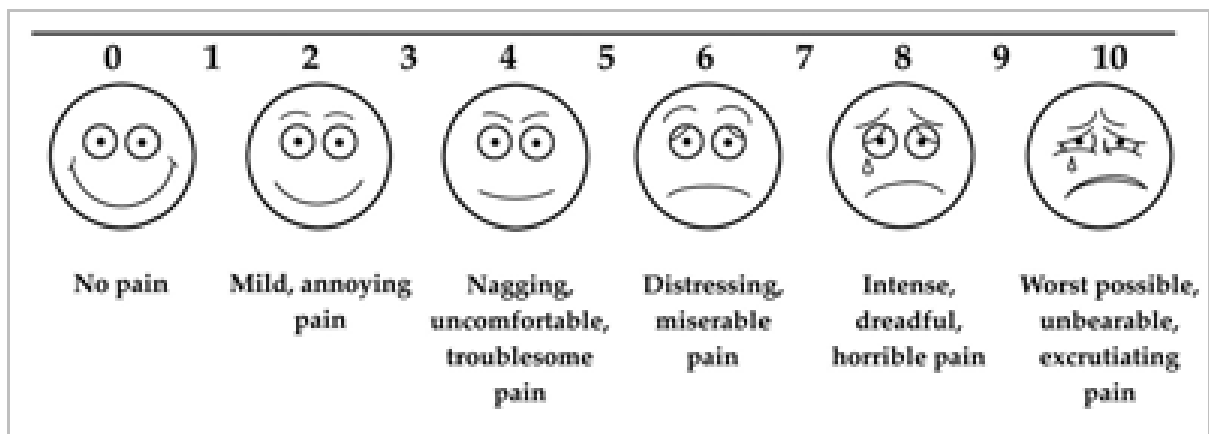
Criteria	Score
1. ACTIVITY	
Moves all extremities	2
Moves two extremities	1
No movement	0
2. RESPIRATION	
Breathes deeply, coughs freely	2
Dyspneic, shallow or limited breathing	1
Apneic	0
3. CIRCULATION (BLOOD PRESSURE)	
20 % \pm preanaesthetic level	2
20 – 49% \pm preanaesthetic level	1
50 % \pm preanaesthetic level	0
4. CONSCIOUSNESS	

Fully awake	2
Arousable on calling	1
Not responding	0
5. OXYGEN SATURATION	
SpO ₂ > 92 % on room air	2
Supplemental oxygen requirement to maintain SpO ₂ > 90%	1
SpO ₂ < 90% with oxygen supplementation	0
TOTAL SCORE	

CRITERIA OF THE PATIENT GOING FROM POST ANESTHESIA CARE UNIT

	YES	NO
Orientation to person, time and place		
Stable vital signs for 30-60 min		
Ability to ambulate unassisted		
Ability to tolerate oral fluids		
Ability to void		
Absence of significant pain or bleeding		

VISUAL ANALOGUE SCALE:



BIO-DATA

GUIDE NAME : Dr. VIDYA PATIL

DATE OF BIRTH : 23/09/1965

EDUCATION : M.B.B.S. – 1991 J.N.M.C., BELGAUM,
KARNATAKA UNIVERSITY DHARWAD,
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M.D ANAESTHESIOLOGY- 1997 J.N.M.C.,
BELGAUM, KARNATAKA UNIVERSITY
DHARWAD, KARNATAKA.

DESIGNATION : PROFESSOR
DEPARTMENT OF ANAESTHESIOLOGY

TEACHING : UG TEACHING-19YRS
PG TEACHING-19YRS

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(08352)261260, 94481 31260

BIO DATA

INVESTIGATOR NAME : Dr MADASETTY LIKITHA

QUALIFICATION : M.B.B.S,
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K.M.C.REG.NO : ANP 2018 0002311 KTK

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PATIL MEDICAL COLLEGE
HOSPITAL AND RESEARCH CENTRE,
VIJAYAPURA, KARNATAKA-586103.

MOBILE NO : 9676031719

EMAIL : likitha.madasetty@gmail.com

BIS

CONTROL GROUP

S.No	Dop	Age	Weight (kg)	ASA grade	Time of Duration anesthesia (hr)	at 10min			at 20min			at 30min			at 40min			at 50min			Quality of recovery	Discharge criteria							
						HR (bpm)	MAP (mmHg)	BS (values)	HR (bpm)	MAP (mmHg)	BS (values)	HR (bpm)	MAP (mmHg)	BS (values)	HR (bpm)	MAP (mmHg)	BS (values)	HR (bpm)	MAP (mmHg)	BS (values)			HR (bpm)	MAP (mmHg)	BS (values)				
1	MS	2F	70		120	82	90	100	94	94	88	90	88	90	88	90	88	90	88	90	94	91	820	930	present	present	10	2	
2	MS	2M	68		120	102	94	88	100	96	88	92	84	92	90	92	88	10	11	11	90	88	10	11	present	poor	9	3	
3	MS	4F	62		150	88	90	90	94	92	92	90	91	91	96	95	95	90	11	13	92	94	10	13	present	present	10	2	
4	MS	2F	55		120	90	80	102	86	104	90	88	88	102	94	90	90	90	102	102	96	94	920	1020	present	present	10	2	
5	MS	2F	58		120	84	78	82	78	90	82	84	78	88	90	88	90	88	90	90	90	91	830	940	present	present	10	2	
6	MS	2F	68		90	92	91	94	85	88	88	96	96	96	96	96	96	96	96	96	90	91	850	940	present	present	10	2	
7	MS	2F	62		78	84	84	82	86	88	90	90	91	90	91	90	90	90	90	90	92	92	920	1016	present	present	10	3	
8	MS	4F	69		120	96	94	102	98	90	88	94	93	94	93	98	96	98	98	94	91	100	100	1140	1140	present	present	9	2
9	MS	2M	75		150	88	91	94	97	102	95	100	94	94	98	92	92	98	98	93	90	93	930	1100	present	present	9	2	
10	MS	2M	72		120	84	80	82	78	88	79	82	81	81	88	88	88	88	88	88	88	92	810	920	present	present	10	2	
11	MS	4F	71		150	72	90	80	94	84	93	90	96	90	88	88	88	88	88	88	88	88	940	1030	present	present	9	3	
12	MS	4F	68		120	76	72	70	70	64	72	68	70	68	70	82	76	82	82	80	81	830	1030	present	present	9	2		
13	MS	3F	58		120	80	71	84	75	86	73	82	74	82	70	82	70	82	70	82	82	73	830	1116	present	present	9	2	
14	MS	3F	55		120	88	80	84	75	80	73	90	82	92	88	88	88	88	88	84	86	940	1030	present	present	10	2		
15	MS	3F	58		150	90	91	80	82	88	80	85	94	92	88	88	88	88	88	88	88	92	1020	1116	present	present	10	2	
16	MS	2F	63		120	82	90	88	98	78	89	78	80	80	81	81	78	81	81	84	94	840	1020	present	present	10	3		
17	MS	2F	51		150	64	89	70	85	66	64	62	88	66	65	66	66	66	66	70	92	94	9	1030	present	present	9	2	
18	MS	0F	65		150	70	88	82	78	66	80	64	82	68	80	74	86	80	74	86	78	90	9	11	present	poor	9	3	
19	MS	4F	55		120	74	72	84	88	80	88	78	89	78	89	70	80	80	80	80	80	85	100	1140	Yes	present	9	2	
20	MS	4M	62		120	60	70	88	75	58	64	78	90	82	82	82	82	82	82	88	91	10	1120	present	present	10	3		
21	MS	3M	60		120	66	90	60	88	64	65	70	88	78	85	88	88	88	80	97	830	930	1100	present	poor	9	3		
22	MS	3M	70		90	90	84	96	90	80	74	88	79	88	79	88	88	88	84	86	820	920	1016	present	present	10	2		
23	MS	4M	72		120	78	92	80	94	82	92	74	86	78	86	86	86	86	84	90	9	930	1016	present	present	10	2		
24	MS	2M	70		120	72	72	80	90	84	89	78	81	80	75	80	80	80	78	83	830	1010	1016	present	present	10	2		
25	MS	4F	68		120	70	91	84	94	88	93	82	90	90	94	88	88	88	81	90	910	1120	116	present	present	10	2		
26	MS	0F	50		120	84	79	90	89	92	85	88	91	85	86	86	86	86	88	89	10	1140	present	present	present	9	3		
27	MS	4F	75		150	98	88	105	92	104	98	110	91	108	90	108	90	108	104	92	100	920	1016	present	present	10	3		
28	MS	5F	50		120	72	80	78	90	74	88	78	85	80	87	88	88	88	84	88	10	1130	present	present	present	9	3		
29	MS	0F	60		150	62	90	70	94	68	95	71	92	70	96	70	88	88	72	94	60	930	1040	present	present	9	3		
30	MS	0F	58		90	96	87	110	93	106	91	102	89	88	92	88	88	88	92	88	820	910	910	present	present	10	2		
31	MS	2M	60		120	80	90	82	98	98	97	86	89	88	92	88	88	88	92	96	840	940	940	present	present	10	2		
32	MS	3M	75		120	70	81	90	98	84	90	86	82	84	88	88	88	88	88	91	100	1120	116	present	present	9	2		
33	MS	3M	70		120	74	80	76	82	80	85	82	84	84	90	88	88	88	88	85	10	1120	present	present	present	9	2		
34	MS	5F	55		120	64	72	70	74	72	80	78	82	88	81	88	81	88	81	74	81	930	1130	present	present	10	3		
35	MS	4F	70		120	86	80	82	78	88	81	85	86	86	88	88	88	88	88	88	89	940	1030	present	present	10	2		
36	MS	3F	68		150	80	85	72	80	74	81	78	83	83	86	86	86	86	90	91	89	93	10	1030	present	present	10	2	

