A Prospective, double-blinded randomized controlled study comparing two different Trendelenburg tilts in laparoscopically assisted vaginal hysterectomy positioning

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Abstract

Background: Bispectral index (BIS) used for intra-operative depth assessment under general anesthesia (GA) can be altered by different factors. This study was designed to detect the alteration in BIS reading with two different Trendelenburg (TBG) tilt in laparoscopically assisted vaginal hysterectomy (LAVH) procedure. **Materials and Methods:** A prospective, double-blinded, randomized controlled study was designed involving 40 American Society of Anesthesiologists Grade I and II female patients, aged 35-60 years, scheduled to undergo LAVH under GA. Patients were divided into two groups with TBG >30° and TBG <30°. BIS readings; systolic and diastolic blood pressure, heart rate were recorded in supine position. Patients were then shifted to desired TBG position either (>30°) or (<30°) as per group allotment. Data were recorded at 30 min intervals and all the patients were followed upto 24 h postoperatively for any recall. **Results:** A rise in BIS value was noticed, when position was changed from supine to head down in both groups. During comparison between two groups with different angulations, TBG >30° showed a higher BIS value than TBG <30°. This statistically significant ($P < 0.05$) trend was observed at all the 30, 60, 90, and 120th min interval. Interestingly, BIS values returned to preoperative levels following adopting final supine position. No incidence of awareness was reported in both the series throughout the study. **Conclusion:** Though awareness remains unaltered BIS value gets increased with higher angle of inclination in TBG position during LAVH operation.

Key words: Bispectral index, general anesthesia, laparoscopically assisted vaginal hysterectomy, post anesthesia care unit, Trendelenburg

INTRODUCTION

Anesthesia is a state of drug induced unconsciousness in which patient neither perceives nor recalls noxious stimulation.[1] Awareness during anesthesia is defined as postoperative recall of events occurring under general anesthesia (GA). Incidence of awareness is approximately 0.1-0.2% during general non high risk surgery.[2-4] Traditionally, depth of anesthesia had long been monitored clinically by assessing autonomic parameters (Evan's score) or patient response to surgical stimulus such as systolic blood pressure (SBP), heart rate, sweating and tear.[5] Aspect electroencephalogram (EEG) monitor or the bispectral index (BIS) is used to assess central nervous system (CNS) depression during GA with the help of changing amplitude and frequency of cortical surface EEG. It is a statistical system to analyze EEG and compute an index ranging from

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0 to 100 to quantify level of CNS depression where 0 is an isoelectric EEG and 100 is fully awake state.[6]

Laparoscopic surgery is a minimally invasive technique[7] and laparoscopic assisted vaginal hysterectomy (LAVH) is a surgical alternative to the classical transvaginal and transabdominal approaches.[8] Although LAVH has also been associated with benefits such as better postoperative pain control and shorter length of hospital stay,[9] its impact on perioperative metabolic and hormonal responses has received little attention. Prolonged dorsolithotomy[10] position coupled with exaggerated Trendelenburg (TBG) tilt related complications[11-13] are also not very uncommon. Change of position during GA is often demanded for better surgical exposure. In LAVH, patients must be placed in a maximum TBG position to facilitate the fall of bowels away from the pelvic organs. This position change has been associated with changes in important physiological parameters like hemodynamics, which is a consequence of metabolic and hormonal responses, raised intra cranial pressure (ICP), and decreased functional residual capacity.[14]

Kaki and Almarakbi[15] detected the influence of patient positioning on BIS readings; they reported that changes in BIS values consequent to the changes in position of head. However, the change of BIS value and its correlation with intra-operative awareness is not known. Hence, this study was designed to observe the effect of TBG positioning on BIS monitoring in patient undergoing LAVH under GA.

MATERIALS AND METHODS

After getting approval from Institutional Ethics Committee, written informed consent was obtained from 40 adult female patients of American Society of Anesthesiologists (ASA) physical Status I or II, aged 35-60 years scheduled to undergo LAVH under GA of expected OT duration over 120 min.

Exclusion criteria

Patient refusal, ASA Status III or more, any known allergy or contraindication to propofol and atracurium, any kind of neurological deficit, head injury or suggestive past history, hepatic, renal or cardiopulmonary abnormality, alcoholism, diabetes, gastro esophageal reflux disease were excluded. Patients with hypertension, glaucoma, and retinal detachment were also excluded from study. Pelvic malignancy, tubo-ovarian abscess, endometriosis or postinflammatory disorders, documented pelvic adhesion, uterus size >16-week pregnancy or maximum uterine width >12 cm or weight >800 g (as assessed by transvaginal ultrasonography) were excluded from the study.[16,17]

In preoperative assessment, patients were enquired about h/o previous exposure to anesthesia and prolonged drug treatment. General, systemic examinations and assessment of the airway were performed. Preoperative fasting of minimum 6 h was ensured. All patients received premedication of diazepam 5 mg orally the night before surgery as per preanesthetic checkup direction to allay anxiety, apprehension and for sound sleep. The patients also received ranitidine 150 mg orally in the previous night and in the morning of operation with sips of water.

After intravenous (IV) cannulation (18G) infusion of ringer's lactate was initiated. On arrival in the operation theatre monitors were attached to note the baseline parameters including noninvasive blood pressure, heart rate, SpO_2 and temperature. Skin was cleaned with alcohol and disposable BIS sensor electrodes were applied to the patient's forehead. The sensor consisted of four connected parts: Part 1 was applied at the center of the forehead approximately 5 cm above the nasal bridge, Part 4 was applied directly above the eyebrow, Part 2 was applied between Part 1 and 4, and Part 3 attached at the temple area between the corner of the eye and the hairline. The sensor was attached with the BIS monitor.

After preoxygenation with 100% oxygen for 5 min, fentanyl (2 μg/kg) and glycopyrrolate (0.01 mg/kg) were given intravenously administered 3 min before induction of anesthesia. All the patients were induced with 1% IV propofol (2 mg/kg). Atracurium (0.5 mg/kg) was used to facilitate laryngoscopy and intubation. Following intubation and inflating the cuff of endotracheal tube, controlled ventilation was maintained with 33% oxygen in 67% nitrous oxide and 1% isoflurane using Boyle's apparatus. Laryngoscopy, intubation and cuff inflation were completed within 15 s in all cases. Muscle relaxation was maintained with intermittent IV atracurium (0.2 mg/kg) as required. Intra-operative analgesia was maintained with incremental dose of fentanyl citrate. Intra-operatively pulse rate, respiratory rate, arterial oxygen saturation, electrocardiogram, capnography, SBP and diastolic blood pressure (DBP), were monitored continuously. Nitroglycerine infusion was administered with help of syringe pump to maintain SBP <130 mmHg, DBP <90 mmHg particularly after pneumoperitoneum and exaggerated TBG position. Ventilation was controlled manually and adjusted to maintain the end tidal CO_2 pressure ($EtCO_2$) between 35 and 45 mmHg. All the patients received tramadol 2 mg/kg IV 20 min before the end of surgery.

Each patient was put at dorsolithotomy position after creation of pneumoperitoneum at supine position. Intraperitoneal preset pressure was kept below 15 mmHg to avoid cardiovascular compromise during CO_2 insufflation. After pneumoperitoneum and dorsolithotomy position TBG inclination (either >30° or <30°) was made randomly using a computer-generated random number table and to facilitate the fall of bowels away from the pelvic organs and proper exposure of uterus and surrounding structure.

At the completion of surgery, residual neuro-muscular blockade was antagonized at train-of-four ratio >0.7 with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg intravenously and patients were extubated in awake condition. After recovery, patients were extubated and shifted to postanesthesia care unit (PACU). Postoperative analgesia was provided with diclofenac suppository 100 mg per rectally. Before discharge from the surgical PACU, all patients were assessed regarding intra-operative recall. Patients were again enquired about any recall after 24 h in the postoperative period.

At the beginning of the operative procedure, when patients were in the supine position, monitoring was initiated and baseline hemodynamic parameters were recorded. After induction, intubation, and pneumoperitoneum, Hemodynamic parameters and BIS values were recorded. Intra-operative monitoring was performed every 30 min up to 120 min. Finally, before removal of 10 mm port in supine position the values were recorded. Entire laparoscopic dissection (lateral attachments of the uterus, the round ligaments, the infundibulopelvic ligaments and fallopian tubes are desiccated with bipolar forceps) and vault closure by intra-corporeal suturing were completed within 150 min. The table positioning and measurement of angulations was made with help of trigonometric table and done by a resident doctor completely unaware of the hemodynamic parameters and BIS value. Apart from these monitoring, other parameters such as urine output, end tidal carbon dioxide was also noted down throughout the period of the anesthesia. All the patients were closely observed continuously throughout the operative procedure for any untoward events like bradycardia and hypotension. Appearance of any of these adverse situations, were managed promptly with adequate and appropriate measures.

Statistical analysis

Assuming average BIS level just before the pneumoperitoneum as 50 (as under GA it ranges between 40 and 60), we decided to detect a difference of 10% (i.e., 5), at the $P < 0.05$ level, with a probability of detecting a difference this large, if it exists, of 80% ($1-\beta = 0.80$). Based on prior research, we estimated the average standard deviation as five in each group. Now from sample size calculator the minimum sample size comes as 17 in each group. We had started the work with 20 patients in each group. Finally, the raw data were entered into Microsoft excel spread sheet and analyzed by using Statistical version 6 (Tulsa, Oklahoma: Stat soft Inc., 2001) and Graph Pad Prism version 5 (San Diego, California: Graph Pad Software Inc., 2007). Categorical variables were compared using the Chi-square test or Fisher's exact test. Continuous variables were compared using independent *t*-test. Data are presented as mean ± standard deviation or as the number of patients and percentages. $P < 0.05$ was considered as statistically significant.

RESULTS

Both groups in terms of demographic characteristics of the patients namely age, body weight, ASA status, parity, duration of anesthesia and surgery [Table 1] were uniform. Indications of LAVH procedures were also similar [Table 2] in both the groups. Baseline hemodynamic parameters like SBP, DBP, mean arterial pressure (MAP), pulse rate and also hemoglobin were found to be comparable [Table 3] among two groups.

Table 1: Comparison of demographic data between the two study groups

Parameter	TBG <30°	TBG >30°	*P* value
Age (years)	44.40±16	41.60±14	0.474
Bodyweight (kg)	60±8.1	58.2±6.5	0.336
ASA physical status (I/II) (%)	12 (60):8 (40)	16 (80):4 (20)	0.168
Parity (multipara/ nullipara) (%)	16 (80)/4 (20)	15 (75)/5 (25)	0.50
Surgery time (min)	124.31±26.3	127.15±34.2	0.72
Anesthesia time (min)	137.7±30.1	146.5±27.5	0.34

ASA: American society of anesthesiologists, TBG: Trendelenburg

Table 2: Indications of LAVH procedures for randomized patient groups

Indications for LAVH	TBG <30° (*n* = 20)	TBG >30° (*n* = 20)
Multifibroid uterus	8 (40)	10 (50)
Menorrhagia	5 (25)	4 (20)
Early cervical intraepithelial neoplasia	3 (15)	2 (10)
Chronic pelvic pain	2 (10)	1 (5)
Dysmenorrhoea	2 (10)	3 (15)

Data are *n* (%), LAVH: Laparoscopically assisted vaginal hysterectomy, TBG: Trendelenburg

Table 3: Comparison of preoperative vitals between the study groups

Preoperative parameters	TBG <30°	TBG >30°	*P* value
Hemoglobin (g/dl)	10.9±1.3	10.5±1.4	0.20
SBP (mmHg)	122±10.81	118.95±9.07	0.33
DBP (mmHg)	82.05±10.30	78.3±7.76	0.20
MAP	95.36±10.20	91.85±8.20	0.29
Pulse rate (bpm)	79.4±10.10	77.0±15.36	0.38

TBG: Trendelenburg, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, MAP: Mean arterial pressure

Head down tilt was associated with a rising trend in SBP and DBP which was higher in TBG >30° than TBG <30° group however the results were not statistically significant [Table 4]. Interestingly, pulse rate decreased with head down tilt and fall was much higher in TBG >30° than TBG <30° group but without any statistical significance. All the values returned to normal after final supine posture.

Bispectral index values also gradually increased with head down tilt and TBG >30° group showed higher BIS value than TBG <30° [Table 5 and Figure 1]. Although the BIS values among two groups were statistically significant, the patients from either group didn't complain of its awareness (probably due to their anesthetic state). Nitroglycerine and fentanyl use in TBG >30° group was higher and statistically significant ($P < 0.05$) when compared with TBG <30° [Table 6]. Again PACU stay was longer ($P < 0.05$) in TBG >30° group compared to TBG <30° group [Table 6].

DISCUSSION

The excellence of anesthesia lies in the way to keep a person complete unaware of the distressful and painful experience of any surgical procedure as well as obnoxious surgical positioning, which is often demanded during some surgical procedures.[18,19]

Intra-operative awareness may produce many deleterious effects both during and post procedure period,[20] which can leave a patient with lifetime residual emotional and psychological problems. Moreover, anesthesiologists may face claims of compensation[21] as a consequence of intra-operative awareness of the patient. Hence, proper assessment of depth of anesthesia and prevention of awareness has become most fundamental and crucial step for safe anesthesia practice.

The introduction of BIS has regenerated considerable interest in the study of intra-operative awareness.[22] Our study was designed to observe the effect of dorsolithotomy position coupled with steep TBG inclination of OT table on BIS monitoring during surgery in patients under GA. Interestingly, the changes in hemodynamic parameters were clinically and statistically insignificant ($P > 0.05$) and are consistent with previous reports.[23] Kaki and Almarakbi[15] had also observed a remarkable increase in MAP 10 min after tilting the patient from neutral to head down position, which reached the highest value at the end of the head down position, this may be comparable with the SBP changes of our study and can be explained with the possible changes of end diastolic volume or preload, cardiac output in the head down position.[24]

Although, BIS values were within acceptable limits, a significant rise in BIS value was observed, when position was changed from supine to head down in both groups [Table 5]. Interestingly raising head down inclination of OT table in TBG >30° group caused a statistically significant ($P < 0.05$) rise in BIS value than TBG <30° group.

No incidence of awareness was reported in both the series, when patients were enquired on 1st postoperative day particularly during discharge from PACU which reflects adequate depth of anesthesia. However nitroglycerine and fentanyl consumption in TBG >30° was statistically higher ($P < 0.05$) when compared with TBG <30° [Table 6] and PACU stay is longer in TBG >30° compared to TBG <30° group [Table 6].

Kaki and Almarakbi[15] observed rise in BIS value at head down position and fall in head up position and associated this with alteration of cerebral hemodynamics, cerebral blood flow (CBF), ICP and cerebral perfusion pressure, which can affect the BIS reading. The alteration in cerebral

Table 4: Comparison of intraoperative hemodynamics between the study groups at fixed time interval

Intraoperative parameters	Group	Supine (Su_0)	*P* value	Head down (Hu_30)	*P* value	Head down (Hd_60)	*P* value
SBP mmHg	TBG <30°	118.95±10.54	0.2610	119.9±6.39	0.0623	121.8±10.84	0.1294
	TBG >30°	122.50±9.07		124.15±7.58		127.1±10.83	
DBP mmHg	TBG <30°	78±10.26	0.1608	81.6±9.14	0.0600	82.2±10.68	0.3381
	TBG >30°	82.1±7.76		86±4.53		85.2±8.87	
Pulse (bpm)	TBG <30°	89±14.71	0.2573	85.4±14.86	0.2100	82.6±15.66	0.1756
	TBG >30°	83.75±14.10		80.05±11.93		76.4±12.49	
	Group	**Head down (Hd_90)**	***P* value**	**Head down (Hu_120)**	***P* value**	**Supine (Su_End)**	***P* value**
SBP mmHg	TBG <30°	120.4±10.30	0.5787	124.20±7.26	0.0782	120.1±10.46	0.5923
	TBG >30°	121.95±6.92		127.65±4.43		121.75±8.82	
DBP mmHg	TBG <30°	79.65±6.52	0.1031	83.55±9.23	0.1444	79.15±10.12	0.6410
	TBG >30°	82.75±5.15		87.70±8.34		80.7±10.92	
Pulse (bpm)	TBG <30°	86.15±14.83	0.1552	85.4±13.73	0.3381	82.65±11.43	0.8425
	TBG >30°	79.85±12.55		81.8±9.41		83.4±12.42	

TBG: Trendelenburg, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 5: Comparison of BIS values between two study groups at fixed time intervals

OT table position	TBG <30°	TBG >30°	*P* value
Supine (Su_0)	53±3.52	50.85±4.30	0.0900
Head down (Hu_30)	54.85±3.82	57.75±3.14	0.0125*
Head down (Hu_60)	55.0±2.93	57.15±2.20	0.0126*
Head down (Hu_90)	54.05±2.87	57±5.66	0.0443*
Head down (Hu_120)	53.8±3.01	56.2±2.58	0.0102*
Supine (Su_End)	52.80±7.30	50.25±2.59	0.1497

BIS: Bispectral index, TBG: Trendelenburg, OT: Operation Theatre, (*) means statistically significant

Table 6: Comparison of drugs to control hemodynamics and pain, duration of ICU stay

Perioperative supports used	TBG <30°	TBG >30°	*P* value
Nitroglycerine use (µg/kg/min)	4.1±1.4	6.6±1.2	0.04*
Fentanyl use (µg/kg)	6.8±0.3	10.5±0.8	0.03*
ICU stay (h)	7.3±6.4	10.7±8.2	0.03*

TBG: Trendelenburg, ICU: Intensive Care Unit, (*) means statistically significant

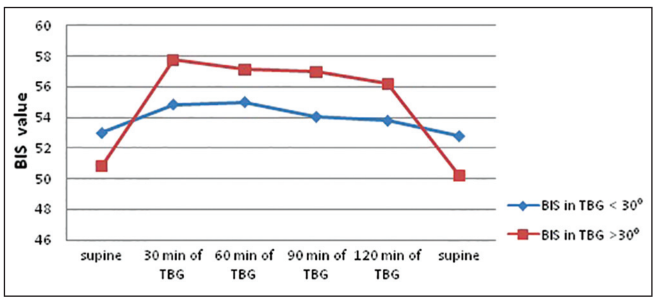

Figure 1: Comparison of bispectral index value in two different Trendelenburg position

hemodynamics has been confirmed by several studies[25-29] using magnetic resonance imaging to measure CBF and cerebrospinal fluid in both supine and upright positions. These large shifts in the distribution of intracranial blood can alter cerebral electrical activity and dipole responsible for EEG waveform changes.

The effect of dorsolithotomy position coupled with exaggerated TBG tilt on intra-operative awareness particularly in LAVH operation is not known. Our study demonstrates comparable change in hemodynamics, along with head down tilt in two different angulations (>30° and <30°) of OT table during LAVH. However, the BIS values were although raised with increase in angle of inclination of OT table this didn't influence patients complaint of intra-operative awareness during discharge from PACU.

CONCLUSION

Our study shows changing a patient's position from supine to TBG in LAVH significantly alters the BIS values despite no event of awareness being reported. Nevertheless, for medico-legal aspect, while interpretation to be made with BIS index in intra-operative period, this positioning effect on BIS readings is to be considered for correct measurement of anesthetic depth and ensuring real atraumatic anesthesia.

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