Original Article

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Comparing Patient Recovery after Laparoscopic Surgery for Women using Bispectral Index and Standard Clinical Method

M. Alimian (MD) [1], R. Safaeian (MD)[1], B. Zaman (MD)[1], H. Faiz (MD)[1], A. Azizi (MD) [*1]

1.Department of Anesthesiology, Faculty of Medicine, Iran University of Medical Sciences, Tehran, I.R.Iran

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ABSTRACT

BACKGROUND AND OBJECTIVE: Due to ever increasing demand for laparoscopic surgeries, the need for appropriate prescription of drug, faster recovery and decreasing the side effects seems more necessary than ever before. The present study was conducted to compare patient recovery after laparoscopic surgery for women using bispectral index (BIS) and standard clinical method.

METHODS: This clinical trial was conducted using women that underwent laparoscopic surgery in Rasool Akram Hospital. Patients were randomly divided into two groups: group A (standard clinical method) and group B (bispectral index monitoring). For group A, general anesthetic medication was administered according to body weight and hemodynamic status. In case of increase in hemodynamic changes for 20% more than the basic pressure, 20% was added to propofol dosage. For group B, if BIS was increased or decreased, BIS was kept in the range of 45-60 by increasing or decreasing propofol for 10% gradually or continuously. Discharge time, time of reaching aldrete score of 9 or more, the amount of narcotics used, pain intensity on admission, the incidence of nausea and vomiting, systolic/diastolic blood pressure and heart rate in every 5 minutes was recorded in recovery (IRCT: 2015122919715N2).

FINDINGS: No significant difference was observed between group A (51.95±27.9) and B (49.35±21.25) in terms of discharge time. There was also no significant difference between time of reaching aldrete score of 9 or more in group A (22.6±9.02) and B (27±14.63). There was also no significant difference between the amount of narcotics used in group A (18±7.68) and B (24.62±13.51).

CONCLUSION: According to the results of this study, there is no significant difference between bispectral index (BIS) and standard clinical method in managing anesthesia and enhancing patient recovery after laparoscopic surgery for women.

KEY WORDS: *BIS monitoring, Recovery, Depth of anesthesia, Laparoscopy for women*.

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[*]Corresponding author A. Azizi (MD)
Address: Department of Anesthesiology and Pain, Rasool Akram Hospital, SAttarkhan Ave., Tehran, I.R.Iran
Tel: +98 21 66515009
E-mail: draazizi@yahoo.com

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Introduction

Creating an appropriate depth of anesthesia and fast patient recovery and waking up are among the important issues of anesthesia. Nowadays, an appropriate patient anesthesia is as important as surgical skills in order to have a successful surgery. In conventional methods, the anesthesiologist administers a specified amount of anesthetics based on personal experience and skills, and gains an estimate of anesthetic depth by assessing patient's clinical symptoms and their changes (such as changes in blood pressure, heart rate, pupil status, the amount of sweating, tear shed, body movement, etc.). However, receiving medication more than the amount required to eliminate the above symptoms will delay waking up and will delay hospital discharge time (1).

Bispectral index (BIS) is an electroencephalogram-monitoring unit, which is divided into 0 to 100. The figure of BIS is commonly used at bedside as a criterion for showing the depth of general anesthesia and lack of response in patients who are under general anesthesia. BIS monitoring reduces the use of anesthetics and reduces the risk of waking up during surgery while reducing the recovery period (2). Several studies indicated that BIS monitoring provides the possibility for measuring anesthetic depth and precise titration of medications. While reducing drug use, this method can prevent the occurrence of unwanted complications such as nausea and vomiting and accelerate the process of waking up in patients and can be highly cost-effective (2).

The conventional and common methods of examining the depth of anesthesia in operating rooms rely on changes in blood pressure, heart rate, changes in the pupil size, tear shed, sometimes the movement of organs and changes in breathing pattern. This is not a reliable technique and while patient's pain is being relieved, which is sometimes done hastily, the anesthetic depth cannot yet be calculated accurately (3). Several studies have been conducted to investigate the effect of BIS monitoring and the reported results were pretty much the same (4-10). However, there are disagreements among researchers regarding the fact that BIS monitoring accelerates patient recovery from anesthesia compared with standard methods (11-20). In a review article regarding BIS integration in the standard method, Punjasawadwong et al. found that BIS reduces patients' recovery period after surgery (17). In the first meta-analysis study by Park et al. comparing the standard and BIS monitoring, they did not observe a significant difference between the two groups in terms of recovery period (20). Moreover, several other studies indicated that administration of hypnotic drugs such as propofol and sevoflurane leads to faster recovery from anesthesia in patients (7-8, 14). In recent years, several studies were conducted regarding anesthesia and recovery in obese patients who underwent various laparoscopic surgeries. This method is accompanied by less pain after surgery and minimizes the need for narcotics. At the same time, this technique benefits from better oxygenation and lower prevalence of nausea and vomiting after surgery. As a result, patients can very soon come back to normal life (16, 19, 21-23). Given the contradictory results of previous studies regarding efficiency of BIS monitoring technique in monitoring the depth of anesthesia and the ever-increasing demand for laparoscopic surgeries, particularly women's surgery, and since most of them are outpatient surgeries, the need for appropriate administration of medications, reduction of recovery complications and faster patient recovery is felt more than ever.

This study aims to compare both techniques of anesthesia including BIS monitoring and the standard clinical method in regard with laparoscopic surgery in women and their effect on patient recovery and complications such as pain, nausea and vomiting after surgery.

Methods

This clinical trial was carried out after being approved by Ethics Committee of Iran University of Medical Sciences with registration code IRCT: 2015122919715N2. A sample size with 95% confidence interval and 80% power and assuming 84% success rate for BIS technique and 56% success rate for standard clinical technique (16) was calculated with minimum sample size of 40 people.

In this study, all patients admitted to Rasool Akram Hospital from March 2015 to October 2015 for laparoscopic surgeries in women's field with class I and class II according to The American Society of Anesthesiologists (ASA) and were consented to enter the plan were included in the study. Patients under 18 years old, patients with a history of chronic obstructive pulmonary, patients with kidney dysfunction with creatinine higher than 2 mg/dL or liver dysfunction, neurologic diseases, patients with difficult airway (by direct laryngoscopy or fiberoptic), patients with a

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history of drug abuse, alcohol addiction and psychotropic drugs, chronic use of analgesics anticonvulsants and antidepressants, patients with untreated hypertension, heart failure and drug allergy and finally patients with emergency surgery were excluded from the study.

In this triple-blinded randomized trial, standard monitoring (ETco2, POM, NIBP, and ECG), BIS Vista Monitoring System of Aspect Medical systems Inc. and venous catheter No. 20 (3 cc/KG) from Ringer's solution infusion were used for patients who entered the operation room. Then, premedication for both groups was done as follows: administration of fentanyl 4 micrograms (mcg) per kilogram (kg) of body weight and administration of midazolam 0.02 micrograms (mcg) per kilogram (kg) of body weight. For induction of anesthesia, propofol 2 mg/kg and cis-atracurium 0.2 mg/kg was administered and patients were intubated by proper size cuffed tube.

Then, in group A (standard clinical method), administration of propofol 100 micrograms (mcg) per kilogram (kg) of body weight started, and during anesthesia, cis-atracurium 0.03 mg/kg was administered every 30 minutes and intravenous fentanyl 50 µg was injected every 40 minutes. During the operation, in case of 20% increase in blood pressure and heart rate, 20% was added to propofol dosage and in case of unresponsiveness, 50 µg fentanyl was injected intravenously. If blood pressure did not decrease, TNG infusion started from 5 µg per minute and increased up to 20% of the baseline. If blood pressure decreased up to 20% of the baseline, 20% to 30% of propofol dosage was decreased.

In group B, administration of propofol started after induction with a dosage of 100 micrograms (mcg) per kilogram (kg) of body weight and during anesthesia, cis-atracurium 0.03 mg/kg was administered every 30 minutes and intravenous fentanyl 50 µg was injected every 40 minutes and was kept in the range of 45-60. In case of BIS increase or decrease, we kept BIS in the range of 45-60 by increasing and decreasing 10% propofol gradually and continuously. In the case of increased blood pressure despite increased dosage of propofol, fentanyl injection and if untreated, TNG were used based on group A protocol. At the end of operation, the drugs were stopped, the gas was extracted and the patient was extubated by reversing the relaxant effects using 0.04 mg/kg neostigmine and 0.02 mg/kg atropine, respiration and acceptable criteria. The time of reaching Aldrete score 9 and higher was recorded during recovery. In addition, nausea and vomiting during recovery were recorded as mild (only nausea), medium (nausea and vomiting once) and severe (vomiting more than once). Patient's pain was recorded using numerical rating scale and if exceeding 3, 0.5 mg/kg pethidine was administered. The vital signs were recorded and if Aldrete score was 9 or higher and the patient had stable blood pressure without a sign of nausea and vomiting for half an hour and if pain NRS was lower than 4, this was recorded as the proper time of discharge. Then, all the gathered data were recorded in SPSS software and were analyzed using independent t-test, Mann-Whitney U test, chi-square and Fisher exact test, while $p<0.05$ was considered significant.

Results

In this study, patients were 15 to 53 years old with a mean age of 31.32±8.57. 26 patients (32.5%) underwent ovarian cyst surgery, 10 patients (12.5%) underwent endometriosis, 13 patients (16.25%) underwent hysteroscopy, 9 patients (10.25%) underwent myomectomy, 11 patients (12.75%) underwent diagnostic laparoscopy, 7 patients (9.75%) underwent TAH surgery, 2 patients (2.5%) underwent surgery for fistula closure and 2 patients (2.5%) underwent surgery for dermoid cyst. The duration of surgeries was between 30 to 270 minutes; an average of 131.75±55.77 minutes. Bleeding was 50-500 cc; an average of 145.16±147.96. Based on patients' comments according to NRS, 4 patients (5%) did not feel pain, 72 patients (90%) felt mild pain, 2 patients (2.5%) felt medium pain and 2 patients (2.5%) felt severe pain.

The frequency of nausea and vomiting was as follows: 4 patients (5%) without nausea and vomiting, mild in 72 patients (90%), medium in 2 patients (2.5%) and severe in 2 patients (2.5%). The period to reach Aldrete score 9 and higher was between 5 to 60 minutes: an average of 24.47±11.77 minutes. The average consumption of narcotics was 20.4±10.39 mg. The duration of discharge was between 13 to 110 minutes with an average of 50.85±25.02 minutes. There was no significant difference between groups A and B regarding age, type of surgery, duration of surgery and level of bleeding among women who underwent laparoscopic surgery (table 1). Therefore, these variables did not have confounding effects on the results of the study. There was no significant

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difference between the time of discharge from recovery and the time to reach Aldrete score 9 and higher after laparoscopic surgery in the two groups. Moreover, there was no significant difference between nausea and vomiting and level of narcotics consumption during recovery (table 2).

There was also no significant difference in groups A and B in terms of systolic blood pressure of women undergoing laparoscopic surgery in each 5 minutes. However, there was a significant difference in systolic blood pressure of women undergoing laparoscopic surgery in group A in each 5 minutes (p=0.002 and X^2=30.08). There was no significant difference in systolic blood pressure of women undergoing laparoscopic surgery in group B in each 5 minutes (p=0.749 and X^2=7.59). There was no significant difference in diastolic blood pressure of women undergoing laparoscopic surgery in groups A and B in each 5 minutes. There was also no significant difference in diastolic blood pressure of women undergoing laparoscopic surgery in group A in each 5 minutes (p=0.674 and X^2=8.43). There was also no significant difference in diastolic blood pressure of women undergoing laparoscopic surgery in group B in each 5 minutes (p=0.898 and X^2=7.61). There was no significant difference in heart rate of women undergoing laparoscopic surgery in groups A and B in each 5 minutes. There was also no significant difference in heart rate of women undergoing laparoscopic surgery in group A in each 5 minutes (p=0.336 and X^2=12.38). There was also no significant difference in heart rate of women undergoing laparoscopic surgery in group B in each 5 minutes (p=0.092 and X^2=17.59).

Table 1. The descriptive characteristics and comparison of age and type of surgery in women undergoing laparoscopic surgery in the two groups of standard clinical method and BIS monitoring.

Group / Characteristics	Standard clinical method N(%)	BIS Monitoring N(%)	P-value
Age (Mean±SD)	30.86±8.49	32.27±9.07	0.662
Duration of surgery (minutes) (Mean±SD)	134.34±57.82	128.23±54.42	0.725
Bleeding (cc) (Mean±SD)	133.33±132.6	170±181.35	0.983
Type of surgery			
ovarian cyst	14 (35)	12 (30)	
endometriosis	10 (25)	0 (0)	
hysteroscopy	3 (7.5)	10 (25)	
myomectomy	7 (17.5)	4 (10)	0.116
diagnostic laparoscopy	2 (5)	7 (17.5)	
TAH surgery	2 (5)	5 (12.5)	
fistula closure	2 (5)	0 (0)	
dermoid cyst	0 (0)	2 (5)	

Table 2. The descriptive characteristics and comparison of narcotics consumption in recovery in the two groups of standard clinical method and BIS monitoring after laparoscopic surgery.

Group / Characteristics	Standard clinical method N(%)	BIS Monitoring N(%)	Test statistics	P-value
The proper time of discharge from recovery (Mean±SD)	51.95±27.9	49.35±21.25	0.248	0.808
The time of reaching Aldrete Score 9 or higher (Mean±SD)	22.6±9.02	27±14.63	0.472	0.481
Narcotics consumption during recovery (Mean±SD)	18±7.68	24.62±13.51	1.43	0.188
Nausea and vomiting during recovery				
Without nausea	3 (7.5)	0 (0)		
Mild (only nausea)	35 (87.5)	38 (95)	3.62	0.305
Medium (nausea and vomiting once)	2 (5)	0 (0)		
Severe (vomiting more than once)	0 (0)	2 (5)		
Pain in recovery				
Mild (4-5)	12 (30)	12 (30)	0.164	0.921
Medium (6-7)	22 (55)	21 (52.5)		
Severe (8-10)	6 (15)	7 (17.5)		

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Discussion

In this study, there was no significant difference between discharge time from recovery in the two groups of standard clinical method and BIS monitoring after laparoscopic surgery. Kreuer et al. also did not find a significant difference between duration of recovery in different groups (11). Recart et al. randomly divided 90 patients who underwent laparoscopic surgery into three monitoring groups (the standard clinical method as contolr group, BIS and auditory evoked potentia=AEP) and based on results inconsistent with our study found that the quality of recovery in the two monitoring groups was significantly higher than the control group (12). This inconsistency may be related to difference in study design and different effects of anesthetic drugs on the recovery process and outcome of patients.

Investigating the effect of using BIS monitoring on the recovery of 50 patients undergoing urological surgery, Zohar et al. did not observe a significant difference in recovery time of patients in BIS monitoring and standard clinical method groups, which was in line with our study (13). Studying 30 obese patients undergoing laparoscopic gastric banding, Ibraheim et al. concluded that BIS monitoring reduces recovery time after surgery, which was inconsistent with our results (7). This contradiction may be due to using different anesthesia techniques; that is, using sevoflurane anesthesia gas instead of muscle relaxant. In a study by Liao et al. among 106 children aged 6-12 who underwent outpatient urological surgery, two groups using standard clinical method and BIS monitoring were studied and contrary to our study, the recovery time in BIS monitoring group was significantly shorter (14). This inconsistency may be attributed to the difference in the age range of samples or using sevoflurane anesthesia gas.

In the study of Fritz et al., patients at risk of consciousness were divided into two groups of BIS monitoring and general anesthesia and similar to our results, there was not a significant difference between the period of recovery after surgery in the two groups (15). Contrary to our results, recovery time in BIS group was shorter than the standard group in the study of Golmohammadi et al. (16). This difference might be related to the use of isoflurane for anesthesia. In a review article, Punjasawadwong et al. assessed 36 clinical trials about integrating BIS in the standard method for managing anesthesia and their results were not in line with our study. According to their results, BIS decreases the recovery time after deep anesthesia after surgery (17). According to the study of Arbabpour et al., which was inconsistent with our results, BIS monitoring accelerated the time of discharge from recovery (18).

The major difference between this study and ours is related to the selected society and the type of surgery. In a study among 40 children and adolescents aged 6-16 who underwent dental surgery in two groups of general anesthesia with standard method and BIS monitoring, Sargin et al. contrary to our study found that there is a significant difference between recovery time and pain after surgery. Therefore, BIS monitoring may have favorable effects on recovery characteristics of children (19).

This difference may be related to the use of sevoflurane anesthesia gas or the type of surgery. In their first meta-analysis study, Park et al. investigated 11 clinical trials about the comparison between BIS monitoring and standard method and concluded that the time of recovery between the two groups was not significantly different (20). This result is in accord with our study. According to the results of this study, there was not a significant difference in reaching Aldrete score of 9 during recovery between the two groups of BIS monitoring and the clinical standard method after laparoscopic surgery in women. Similar to our results, Ibraheim et al. found that there is not a significant difference in reaching Aldrete score of 9 during recovery between the two groups (7).

Fritz et al. also found no significant difference in reaching Aldrete score of 9 during recovery between the two groups (15). In a similar study, Guignard et al. found that there is no significant difference in reaching Aldrete score of 9 during recovery between the two groups (21). According to our results, there was no significant difference in narcotics consumption during recovery between the two groups of BIS monitoring and the clinical standard method after laparoscopic surgery in women. BIS monitoring provides the possibility for measuring the status of brain based on ECG and reflects reduced brain metabolic rate by most sleep aids (22).

Therefore, it seems that using anesthetic drugs affects the function of BIS monitoring and cannot prevent narcotics consumption. Results of this study indicated that there was no significant difference between pain at the beginning of the recovery between the two groups of BIS monitoring and the standard clinical method after laparoscopic surgery in women.

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According to the study of Golohammadi et al., there was a significant relationship between the intensity of pain in the two groups. Medium pain was more observed in BIS group and severe pain was more observed in control group. However, the insignificance of difference in pain between the two groups may be attributed to more fentanyl reception in BIS group compared with control group (16).

Similar to our results, Fritz et al. found no significant difference in intensity of pain after surgery between these two groups (15). Contrary to our results, Sargin et al. found a significant difference in intensity of pain after surgery between these two groups (19). This may be due to difference in physiological characteristics of participants or difference in measurement scales.

The results of this study did not reveal a significant difference in nausea and vomiting between the two groups of BIS monitoring and the clinical standard method after laparoscopic surgery in women. According to the study of Liao et al., the incidence of nausea and vomiting was similar between the two groups of BIS monitoring and the standard clinical method (14), which was in accord with our study. Similar to our study, Fritz et al. did not observe a significant difference between the two groups in terms of incidence of nausea and vomiting (15). However, Lesile et al. found lower incidence of nausea and vomiting in the group with BIS monitoring, which was not in line with our results. This inconsistency can be attributed to the use of nitrous oxide and evaporator for anesthesia (23).

A study by Park et al. demonstrated that the side effects in the two groups were not significantly different, which was in accord with our study (20). The results of this study indicates that there is a significant difference between systolic blood pressure, diastolic blood pressure and heart rate in each 5 minutes during surgery in the two groups of BIS monitoring and the clinical standard method after laparoscopic surgery in women. Similar to the results of this study, Arbabpour et al. did not observe a significant difference between systolic and diastolic blood pressure in the two groups during surgery and recovery (18).

Similar to our results, Shafigh et al. found that hemodynamic parameters including systolic blood pressure, diastolic blood pressure and heart rate were identical in the two groups (6). The limitations of this study include small sample size which was due to limited facilities such as lack of BIS device and high cost of anesthetic depth sensors. Hence, after following the patients after surgery in this study, we came to the conclusion that monitoring anesthetic depth using Bispectral index as opposed to standard method could not decrease recovery period, the amount of narcotic during recovery, pain at the beginning of recovery, nausea and vomiting, systolic blood pressure, diastolic blood pressure and heart rate.

Therefore, monitoring anesthetic depth using Bispectral index as well as the standard clinical method after laparoscopic surgery in women provides almost identical results. According to the results of this study, it seems that BIS monitoring does not present a significant difference in managing laparoscopy candidates and their recovery after surgery, compared with the standard method. It seems that for proper use of BIS monitoring system in administering anesthetics, this system needs to be used accurately.

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