ARTICLE

ASSESSMENT OF THR EFFECT OF BISPECTRAL INDEX (BIS) MONITORING ON AWARENESS DURING ANESTHESIA IN PATIENTS CANDIDATES FOR NON EMERGENCY CESAREAN SECTION

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ABSTRACT

Background: *Awareness during general anesthesia is potentially an unpleasant experience among patients undergoing surgical procedures. Despite the loss of consciousness induced by anesthesia, patients may experience pain during surgical processes due to their sensory perceptions and improper pain management. Anesthesiologists can estimate the level of patients' unconsciousness, based on their clinical experience and skills, as well as such as changes in patients' clinical signs (e.g., blood pressure, heart rate, sweating and tears in the eyes). However, since this sign is neither accessible nor reliable at all times, bispectral index (BIS) monitoring is required during the general anesthesia, particularly in the cesarean section. Methods: This double-blinded, randomized, clinical trial was performed on 214 women (> 15 years of age) with (American Society of Anesthesiologists) ASA class I and II, undergoing cesarean section at Taleghani Hospital of Arak, Iran. The participants undergoing general anesthesia were randomly divided into intervention (with BIS monitoring) and control groups (without BIS monitoring). The level of subjects' awareness during anesthesia was determined by interviews (using specific structured questions) within 24 hours after the surgery and 3-6 days following the procedure at the post-anesthesia care unit.* ***Results:*** *Awareness during anesthesia was reported in 8 out of 107 cases (7.4%) in the control group (awareness score ≥ 2). However, this event was observed in none of the participants (0%) in the intervention group. Based on Kruskal-Wallis test results, level of awareness during anesthesia in the control group was higher than the intervention group (P<0.001).* ***Conclusion:*** *Based on the finding, level of awareness during anesthesia was dramatically lower in subjects with BIS monitoring, compared to those without BIS monitoring (traditional anesthetic induction).*

KEY WORDS
Awareness, BIS monitoring, Non-emergency Cesarean Section

INTRODUCTION

Awareness during general anesthesia is a potential and major concern among patients and anesthesiologists during surgical processes. As estimated, over 50% of patients are concerned about this unpleasant event. Awareness during anesthesia can cause various side-effects such as neuroticism, anxiety and irritability among patients. Despite the loss of consciousness induced by anesthesia, patients may experience pain during surgery due to their sensory perceptions and improper pain management [1, 2].

Commonly, anesthesiologists prescribe a dose of analgesic medications for the patients, based on their medical experience and expertise. They can estimate the level of patients' unconsciousness by evaluating their clinical signs (e.g., blood pressure, heart rate, sweating, tears in the eyes and body movements). Since evaluation of the majority of these signs is neither accessible nor reliable at all times, bispectral index (BIS) monitoring during general anesthesia, particularly in abdominal surgeries, is essential [3].

BIS is a statistical index, derived from electroencephalographic parameters, which categorizes the level of patients' consciousness as follows: burst suppression: 0-30, deep hypnosis: 30-40, general anesthesia: 40-65, sedation: 65-85 and awake: 85-100.

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Although intraoperative awareness with explicit recall of sensory perceptions during surgery is a rare event, it can lead to post-traumatic stress disorder (PTSD) among patients with such an experience [1, 2, 4]. Initially, monitoring devices for evaluating the depth of anesthesia were introduced in the developed countries, especially in the United States. In these countries, use of such systems has been recommended by medical authorities, considering the high reported rate of awareness during surgery, deep anesthesia and uncontrolled use of analgesics. Use of these devices is increasing in other countries, although the available technologies are quite restricted, given the complexity of anesthetic induction.

According to published approved data, BIS monitoring, as the main introduced technology in this area, is applied in approximately 73% of most prominent hospitals and 53% of operating rooms in the United States. Today, use of this technology has been reported in almost 160 countries around the world. Factors such as high cost, unfamiliarity, unawareness of BIS advantages and low quality of care provision have led to the slow development of this technology in developing countries [5-7].

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Use of BIS monitoring will be necessary in near future without any doubts. In addition to enhancing the quality of care provision via proper anesthesia management, this technology could prevent patients' awareness during surgery, reduce the risk of drug poisoning/overuse and distinct anesthetic-induced sleep from loss of consciousness (i.e., coma) [4]. In fact, as previously mentioned, these problems are quite common in Iranian hospitals [1].

Considering the risk of post-traumatic stress disorder (PTSD) in patients under anesthesia and the rarity of information on the complexity of this issue [2], the level of patients' awareness during general anesthesia and the effects of BIS monitoring need further studies [8]. Given the specific circumstances required for the administration of some analgesic medications, this study aimed to determine the level of awareness among 214 women (> 15 years of age) with ASA class I and II, undergoing abdominal surgery at Taleghani Hospital of Arak, Iran.

MATERIALS AND METHODS

This double-blinded, randomized, clinical trial was performed on 214 patients, candidates for cesarean (aged 15-45 years) with ASA class I and II, referring to Taleghani Hospital of Arak, Iran. The study samples were randomly divided into groups A and B. The sample size was calculated at 107 cases per group. Unlike group B (control group), BIS monitoring was employed in group A (intervention group). The number of cases was equal in the two groups.

These patients are randomized with sample randomized sample size.

$$n = \frac{\left[Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right]^2 [P_1(1-P_1) + P_2(1-P_1)]}{(P_1 - P_2)^2}$$

$$n = \frac{(1.93 + 2.33)^2[0.2(1-0.2) + 0.1(1-0/1)]}{(0.2-0.1)^2}$$

N= 107

$Z_{1-\frac{\alpha}{2}} = 1.96$

$Z_{1-\beta} = 2.33$

$P_1 = 0.2$

$P_2 = 0.1$

The inclusion criteria were as follows: 1: Being a candidate for non-emergency cesarean section; 2: gestational age of 37-42 weeks; 3: Lack of any systemic disorders; 4: ASA class I or II; 5: age range of between 15-45 years-old; 6: No chronic drug abuse; 7: no prior history of heart, liver or kidney disorders; 8: maximum surgery duration of 60 min; and 9: undergoing surgery by one single surgeon.

On the other hand, the exclusion criteria were as follows: 1: intubation for more than 35 sec (since problematic intubation is one of the causes of intraoperative awareness); 2: preeclampsia or chronic hypertension; 3: morbid obesity (BMI>35 kg/m2); 4: ASA class > II; 5: systemic or mental disorders; and 6: duration of surgery > 90 min.

In this study, the subjects were blind to the group they were assigned to. Also, considering the double-blind study, awareness during anesthesia was not evaluated by an anesthesiologist. Instead, trainees were instructed to assess the level of awareness during anesthesia in educational classes. The assigned classes were held by an anesthesiologist and the project manager before implementing the intervention.

In this study, all subjects underwent general anesthesia by thiopental (2-4 mg/kg) and succinylcholine (1-2 mg/kg). Afterwards, the subjects were mechanically ventilated and received 50% O2, 50% N2O and 1% isoflurane under anesthesia and. if required, muscle relaxants (0.2-0.5 mg/kg of atracurium) were used, as well. After delivery, 50-150 μg of fentanyl was prescribed for the patient.

In the intervention group, BIS monitoring was performed every 15 min during anesthetic induction alternatively, laryngoscopy, intubation, surgical incision, extubation and the end of the procedure. In the intervention group, in case of increased blood pressure or heart rate or BIS > 60 was reported, use of narcotics, anesthetic gases and medications was improved to increase the depth of anesthesia. In the control group, in case of increased blood pressure or heart rate, tears in the eyes or limb movements, the mentioned medications were prescribed.

At 12 and 24 hours after the surgery, a questionnaire on the level of awareness during anesthesia was completed. Additionally, the level of subjects' awareness during anesthesia was measured via interviews and the designed questionnaire. All of the questionnaire and interviews data were kept secret. In order to analyze the obtained findings, statistical tests including Kurskal-Wallis test, Chi-square, parametric tests and ANOVA were performed, using SPSS version 16.

RESULTS

Awareness during anesthesia was reported in 8 out of 107 cases (7.4%) in the control group (awareness score ≥ 2). However, awareness during anesthesia was observed in none of the participants in the intervention group (0%). Based on Kruskal-Wallis test results, level of awareness during anesthesia in the control group was higher than the intervention group (P<0.001) [Fig. 1].

The mean score of awareness in the control group was 1.64 in 8 subjects experiencing awareness during anesthesia. The mean blood pressure during anesthesia was 8.1 in the intervention group and 9.5 in the control group. Based on Kruskal-Wallis test results, the mean blood pressure was significantly lower in the intervention group, compared to the control group (P<0.01) [Fig. 2].

The mean heart rate was estimated at 94.6 bpm in the intervention group and 102.1 bpm in the control group. Based on Kruskal-Wallis test results, there was a significant difference between the two groups, and the mean heart rate in the intervention group was lower than the control group (P<0.01) The mean heart rate was 94.6±3.4 in the intervention group and 102.1±4.5 in the control group. There was a significant difference between the two groups and the mean heart rate was lower in the intervention group, compared to the control group (P<0.01) [Fig.3].

Moreover, according to Kruskal-Wallis test results, there was no significant difference between the two groups in terms of oxygen saturation (SpO2); in fact, the mean SpO2 was almost equal in the two groups (96%) (P<0.05).

Additionally, according to Kruskal-Wallis test results, age and duration of surgery were not significantly different between the two groups (P>0.05). The mean age of the participants was 27.3±2.4 years, which was almost similar in the two groups (P>0.05).

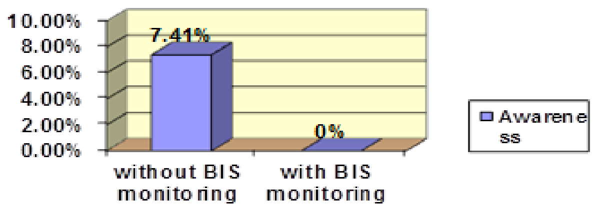

Fig. 1: The frequency distribution of awareness during anesthesia in subjects with and without BIS monitoring.

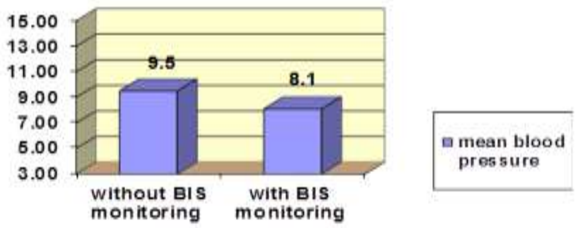

Fig. 2: The mean blood pressure in subjects with and without BIS monitoring.

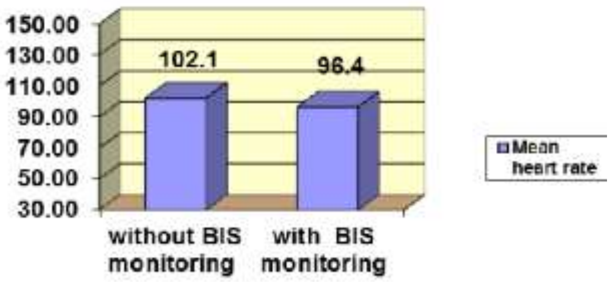

Fig. 3: The mean heart rate in subjects with and without BIS monitoring.

Based on the findings, the mean minimum alveolar concentration (MAC) of isoflurane was 0.5±0.1 in the intervention group and 1±0.2 in the control group (P≤0.01); there was a significant difference between the two groups and MAC of isoflurane was lower in the intervention group, compared to the control group [Table 1].

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Table 1: The mean minimum alveolar concentration (MAC) of isoflurane in the intervention and control groups

Groups	Mean	SD	P-value
Intervention group	0.5	0.1	≤0.01
Control group	1	0.2	

DISCUSSION

Characterization of the difference between the incidence and level of awareness during anesthesia in patients with and without BIS monitoring could cause enhancement in the condition of patients who experienced awareness during anesthesia. This event is dependent on the condition of patients and use of anesthetics. Awareness during anesthesia can cause various problems such as neuroticism, anxiety, irritability, depression and even suicide in some cases. Despite the loss of consciousness induced by anesthesia, patients may experience pain during surgical procedures due to their sensory perceptions and improper pain management. Anesthesiologists can estimate the level of patients' unconsciousness, based on their clinical experience and expertise, such as changes in patients' clinical signs (e.g., blood pressure, heart rate, sweating and tears in the eyes).

Since the majority of these signs are not reliable at all times, use of bispectral index (BIS) during general anesthesia, particularly in abdominal surgeries, is required. It seems that BIS monitoring could lead to a substantial reduction in patients' awareness during anesthesia [8].

The risk of awareness during anesthesia is higher in some surgeries such as open heart, cesarean and trauma surgeries. In such surgeries, anesthesiologists cautiously prescribe analgesics in accordance with patients' specific conditions; these prescriptions may increase the risk of awareness during surgery in some cases [8-11].

In this study, awareness during anesthesia was assessed in patients, who were candidates for non-emergency cesarean. Based on our findings, awareness during anesthesia was reported in 8 out of 107 cases (7.4%) without BIS monitoring (awareness score ≥ 2). On the other hand, awareness during anesthesia was observed in none of the participants with BIS monitoring.

In the present study, based on Kruskal-Wallis test's results, level of awareness during anesthesia in patients without BIS monitoring was higher than those with BIS monitoring ($P<0.001$). Similar results have been reported in previous studies. In a study by Ekman et al. (2004) in Scandinavia on the effect of BIS monitoring on awareness during anesthesia, a 77% decline in awareness during anesthesia was reported [10].

Additionally, in a study by Avidan et al. (2008) on awareness during anesthesia and BIS monitoring, it was reported that this technology does not provide routine standard anesthesia. However, the incidence of awareness during anesthesia would decline if BIS value did not exceed 60 [12].

Moreover, Azemati et al. (2004) conducted a study in Iran in order to compare the incidence of awareness during anesthesia in 151 women undergoing cesarean section and anesthesia via propofol, thiopental and halothane. The results showed that awareness during anesthesia may cause some side-effects such as neurosis, anxiety and irritability, which can manifest in form of dreaming or complete recall of intraoperative events. Awareness during anesthesia was more common in some surgeries such as cardiac and cesarean [13]. This study was indicative of the relatively high incidence of awareness during anesthesia in cesarean section.

Additionally, Khalili et al. (2007) conducted a study at Isfahan University of Medical Sciences to compare the depth of anesthesia, based on BIS value in 114 cases, undergoing intravenous and inhalation anesthesia. As the findings indicated, clinical symptoms, which are commonly applied to evaluate the depth of anesthesia, are insufficient and inadequate. The depth of anesthesia could be correctly set by BIS monitoring; also, the required dose of anesthetics could be reduced in some cases via BIS monitoring [14].

In the present study, the mean MAC of isoflurane during surgery was 0.5±0.1 in cases with BIS monitoring and 1±0.2 in patients without BIS monitoring. As the results indicated, a significant difference was detected between the two groups and MAC of isoflurane was lower in the BIS monitoring group ($P\geq 0.01$). In other words, use of anesthetic gas in patients benefiting from BIS monitoring was lower than those with no BIS monitoring.

In a previous study accordance with the present research, the dose of required anesthetics was lower in patients with BIS monitoring, compared to those without BIS monitoring (traditional method) [14]. The results of the majority of these studies are in consistence with the present findings. According to literature review, BIS monitoring plays a basic role in decreasing awareness during anesthesia [9, 14, 15].

Application of BIS monitoring during general anesthesia in surgeries, particularly open heart surgery and cesarean, is effective in accurate administration of anesthetics. Accordingly, the accurate use of drugs can lead to a significant decline in the rate of intraoperative awareness (via accurate and timely administration of sufficient anesthetic doses), prevent the overdose of anesthetics and reduce the use of such drugs; it also can lead to a reduction in the costs and problems induced by anesthetics.

Further research is required to compare the depth of anesthesia in different anesthetic techniques and to evaluate the effect of BIS monitoring on reduced awareness during anesthesia in other surgeries such as open heart surgery.

CONCLUSION

In conclusion, this study showed that BIS monitoring could be effective in reducing awareness during anesthesia among pregnant women undergoing non-emergency cesarean.

CONFLICT OF INTEREST
The authors declare no competing interests in relation to the work.

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