Original Article

Awareness and apgar score in elective Cesarean section under general anesthesia with propofol or Isoflurane: A prospective, randomized, double-blinded clinical trial study

Somayeh Khanjani, Khosrou Naghibi[1], Hamed Azarnoush[2]

Departments of Obstetrics and Gynecology, [1]Anesthesiology and Intensive Care, Isfahan University of Medical Sciences, [2]Azad University of Medical Sciences, Isfahan, Iran

Abstract

Background: Awareness is a postoperative recall of events experienced under general anesthesia. In this study, we compared the incidence of awareness between two routine methods used, inhalation (Isoflurane) and intravenous protocol (Propofol), in elective Cesarean section, and also evaluated the effect of these two different methods on the apgar score of newborns.

Materials and Methods: In this prospective, clinical trial study, 90 pregnant women candidates for elective Cesarean section were randomly enrolled, after taking written consent. Induction of anesthesia in both groups was provided by propofol and succinylcholine in the same manner, and maintenance of anesthesia in Group 1 was provided by propofol 100 μg/kg/minute and in Group 2 with isoflurane 1 MAC, to maintain the bispectral index (BIS) between 45 and 60. Blood pressure, heart rate, electrocardiography (ECG), and also Etco2 and o2sat were recorded throughout the surgery and finally analyzed and compared.

Results: From 90 patients, four cases of confirmed awareness were found in the propofol group and three cases in the Isoflurane group (8/9% vs. 6/7%), but the apgar scores were comparable between the two groups. Meanwhile there were no significant differences between the two groups in basic information, neonatal apgar scores, hemodynamic changes, and BIS, *Electromyography* (EMG), and *signal quality index* (SQI) values.

Conclusion: According to the patient's state, diagnosis of the anesthesiologist, and other criteria like price and its availability, we could use these drugs in general anesthesia during Cesarean section, although it is recommended that more studies be done to compare the effect of these two drugs in larger groups.

Key Words: Apgar score, awareness, BIS, Isoflurane, propofol

Address for correspondence:
Dr. Khosrou Naghibi, Department of Anesthesiology and Intensive Care, Isfahan University of Medical Sciences, Isfahan, Iran.
E-mail: Naghibi@med.mui.ac.ir
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INTRODUCTION

Awareness is postoperative recall of events experienced under general anesthesia and most frequently patients remember an auditory perception, the feeling of motor function loss, pain, helplessness, anxiety, panic, impending death.[1] The prevalence of awareness in non-obstetric and non-cardiac surgical cases is 0.1-0.2%, but the prevalence is higher in

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cardiac surgery, obstetric, and major trauma cases, and according to the results of many studies light anesthesia is the most common cause of the awareness. Posttraumatic stress disorder (PSD) occurs in 33-56% of the patients who have experienced awareness during general anesthesia.[1] Choosing the anesthesia technique in Cesarean cases depends on several factors, such as, the emergency rate, the status of the mother and fetus, and mother's request.[2] General anesthesia is selected more in emergency cases, such as, fetus distress and severe bleeding or in cases where local anesthesia is contraindicated.[3,4] On the other hand, due to its effect on the fetus, the type of anesthetic drug is very important and now, two anesthetic drugs — propofol (Infusion) and isoflurane (inhalation) — are usually used in the anesthetic process.[5,6]

The aim of general anesthesia includes preventing intraoperative pain and creating relaxation, sleep and anesthesia, so that the patient does not remember the surgery, but if the depth of anesthesia is not appropriate, it leads to awareness during surgery.[7] If the depth of anesthesia is high, complications of anesthesia occur in the patient; therefore, it is necessary to maintain an appropriate depth of anesthesia, especially during the Cesarean section.

Recollection of intraoperative events, which may be spontaneous or by asking questions of the patient, can be very uncomfortable, and in the most severe cases, it may lead to posttraumatic stress disorders.[8,9] In recent studies, the incidence rate of awareness during general anesthesia, in Cesarean section has been reported to be between 0.1 and 7%, which can exert extensive psychological consequences on the patient.[10,11] Therefore, by using various drugs, minimization of these events has been tried, while the appropriate depth of anesthesia is also maintained.[12,13]

Several studies have shown that in intravenous anesthetic drugs (propofol), for maintaining anesthesia, the incidence rate of intraoperative awareness is higher than in inhalation drugs (isoflurane).[14] On the other hand, given the concern of the crossing of drugs from the placenta and their effect on the infant, anesthesia induction has particular significance in patients undergoing Cesarean section.[9] The apgar index system is one of the clinically useful techniques to identify infants requiring resuscitation and also to assess the quality of resuscitation techniques based on five parameters, which are evaluated in the first and fifth minutes after birth.[15,16]

The anesthesiologist must diagnose the risk of intraoperative awareness under general anesthesia; and reducing neonatal complications must be balanced with this risk.[10,17]

The lack of using opioids and benzodiazepines before induction of anesthesia, the restricted consumption of inhalational agents, and applying rapid induction techniques are reasons that cause this group of patients to be exposed to the complication of intraoperative awareness.[10,18]

Some experts offer BIS (Bispectral Index), as an assessment process of the electroencephalogram, allowing the anesthesiologists to regulate the dose of the anesthetic drug during surgeries, so that he/she assures enough depth of anesthesia, without increasing the risk of awareness, as also neonatal complications.[19] Thus, the type of anesthetic drug used in Cesarean section is very significant. Hence, the present study aims to determine and compare the effect of two anesthetic techniques — propofol and isoflurane — on the incidence rate of intraoperative awareness and the Apgar index of infants, in an elective Cesarean section, in the Alzahra University Hospital, Isfahan, Iran.

MATERIALS AND METHODS

The present study is a clinical trial study conducted in the Isfahan Alzahra Hospital, in 2011.

Prior to the study, all the patients signed an informed written consent.

In this project 90 pregnant women, 18-35 years old, were included for elective Cesarean section, with normal Body Mass Index (BMI) and American Society of Anesthesiologists (ASA) classes 1 and 2.

The sample size was estimated based on a power calculation, which showed that at least 43 patients per group were necessary to achieve 80% power, to detect a 20% difference between the groups. We recruited 45 patients per group, to compensate for any exclusion.

Patients were randomly entered into one of the two groups (by random allocation software prepared in a sealed envelope) for receiving isoflurane (manufactured by Piramol Critical Care Inc., USA) and propofol (manufactured by Claris Lifescience Limited, India), by one of the investigators who was not related to data collection, monitoring or conduct of anesthesia. In cases where the patients had a history of seizure or neurological problems, were with the need for sedative drugs, with head trauma requiring hospitalization, surgical procedures, previous brain surgery or addiction, they were not taken into the

groups. Also, mothers who suffered from severe changes in hemodynamics (20% higher than the initial condition) during anesthesia or if the dose of the prescribed medications was changed for any reason, they were excluded from the study (one patient was excluded due to profound hypotension, from the Isoflurane group) [Flow Chart 1].

In both groups, the same anesthesia induction was done with 1.5 mg/kg propofol and 2 mg/kg succinylcholine, following and maintaining anesthesia was performed with 100 Propofol in Group 1 and 1 Isoflurane MAC in Group 2.

In both groups, the patients' hemodynamic status was evaluated before and immediately after anesthesia induction, and every 15 minutes during surgery and after end of surgery, till the time of recovery.

In both groups, the frequency of the incidence of hypotension (SBP < 90), bradycardia (HR < 60), hypertension (BP > 140/90), and tachycardia (HR > 100) were recorded and compared. Hemodynamic parameters were recorded according to the standard monitors in the surgery room.

At the end of the operation and after the last suture, the anesthetic drugs were stopped and atropine (0/02 mg/kg) and neostigmine (0/04 mg/kg) were used to reverse the neuromuscular effects. When the spontaneous breathing was acceptable, and if there was no any sign of hypoxia, the patient was extubated and transferred to the Recovery Room.

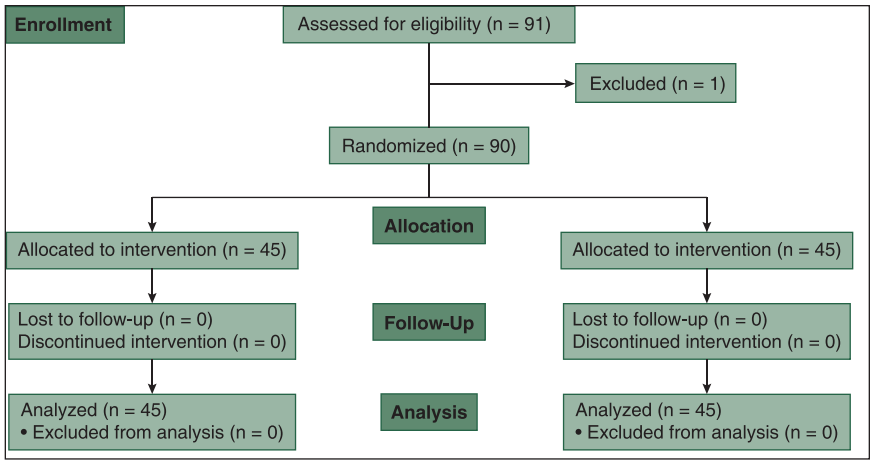
In both groups, the extubation duration was recorded and compared. The incidence of intraoperative awareness was recorded during recovery, with a few short questions based on recalling the intraoperative events in both groups, and for its assessment, the index of BIS, EMG, and SQI were used every five minutes from the time of anesthesia induction to the end of the surgery. The apgar indices were evaluated and recorded in both groups at the first and fifth minutes after birth, according to the related table. The duration of recovery time was assessed based on the Aldrete criteria and patient satisfaction was recorded using the Likert scale in both groups.

Subsequently, by collecting the statistical results gathered during and after surgery to the end of recovery, the obtained data were analyzed with the help of the SPSS software Version 20, the statistical Chi-square, t-test, and Analysis of Variance (ANOVA) test, or the replication of the observations.

RESULTS

In this study, 90 pregnant women candidates for elective cesarean section were randomly enrolled into two groups (of 45 each). In both groups, the mean age of the patients were 26.6 ± 4.3 and 27 ± 4.3 years, respectively, and there were no significant differences between them according to the t-test (P = 0.64). Also, the mean age of pregnancy was 37.9 ± 1.4 and 37.6 ± 1.4 weeks, respectively, in the two groups, and according to the mentioned test, no significant difference was observed (P = 0.25). From the propofol group, 42 patients (93.3%) and from the isoflurane group, 43 patients (95.6%), had ASA I and the others had ASA II (P = 1).

With regard to recollection of the intraoperative events during surgery, four cases from the propofol group and three cases from the Isoflurane group recalled their own surgeries (8.9 vs. 6.7%); however, no significant difference was observed between the two groups. Also, the Apgar index of the infant had no significant difference at the first and fifth minutes. In



Flow Chart 1: Study flowchart

Table 1, the frequency distribution of the recollection of intraoperative events and Apgar index of the infant at the first and fifth minutes has been shown.

In Table 2, the mean and standard deviation of the SQI, EMG, and BIS indices have been shown. According to the table, changes of all the three above-mentioned variables are balanced from the fifth to the sixtieth minute, in both groups. Conducting the ANOVA test, with repeated observations also showed that the mean of the changes in SQI, EMG, and BIS had no significant differences in the two groups receiving propofol and isoflurane ($P > 0.05$). The process of changes in the three mentioned variables has been shown in Figures 1-3, in both groups, from the fifth to the sixtieth minute.

Hemodynamic changes in patients included systolic, diastolic, and mean arterial blood pressure, as also heart rate before anesthesia to sixty minutes after entering the patient in Recovery. These changes have been shown in Table 3. According to the table, changes in hemodynamic parameters have also had a balanced process in both groups and according to the ANOVA test, with repeated observations, the mean of changes have no significant differences in the two groups ($P > 0.05$). Also, the process of changes in the hemodynamic parameters in both groups has been shown in Figures 4-7.

In the two groups under anesthesia with propofol and isoflurane, the mean duration of extubation was 12 ± 6.7 and 11.5 ± 6.5 minutes, respectively. Moreover, there was no significant difference between the two groups according to the t-test ($P = 0.78$), and also, the mean duration of recovery time was 34.1 ± 13.4 and 35.6 ± 15.7 minutes, respectively. According to the mentioned test, there was no significant difference between the two groups ($P = 0.65$). The time

Table 1: Distribution of demographic characteristics of both groups

Characteristic	Group	Propofol	Isoflurane	*P*
Awareness	Yes	4 (8/9)	3 (6/7)	1
	No	41 (91/1)	42 (93/3)	
Apgar index (First minute)	Mean	8/24±1/15	8/18±1/09	0.78
Apgar index (Fifth minute)	Mean	9/2±0/76	9/22±0/79	0.89

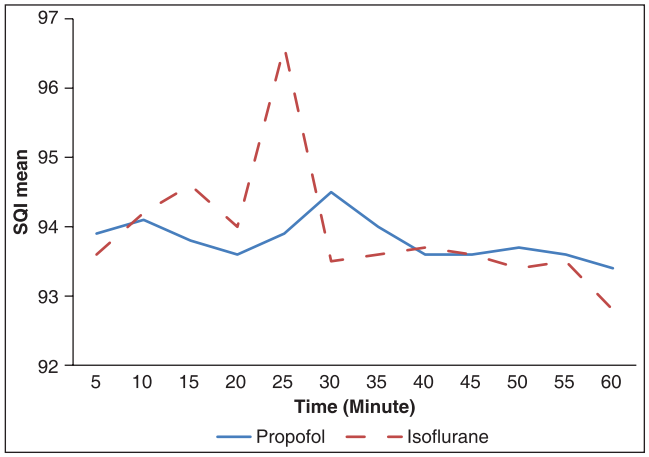


Figure 1: SQI changes in the two groups

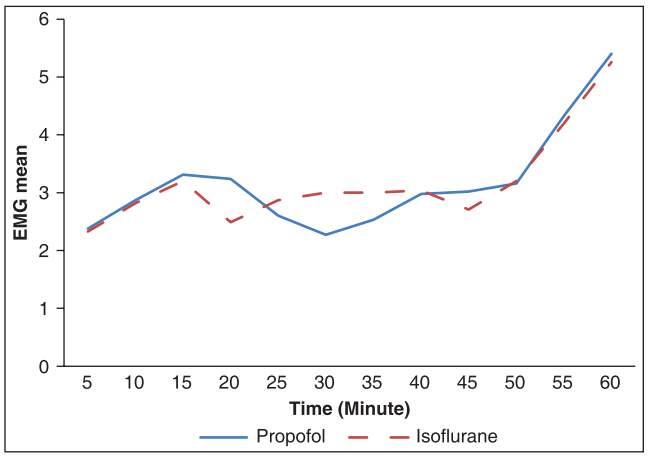


Figure 2: EMG changes in both groups

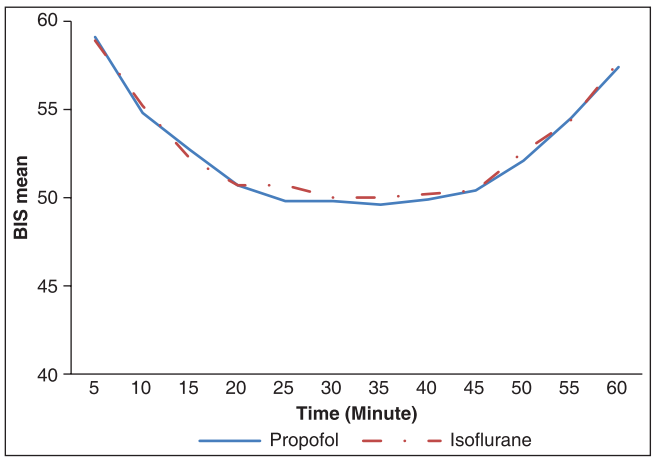


Figure 3: Changes in the BIS group

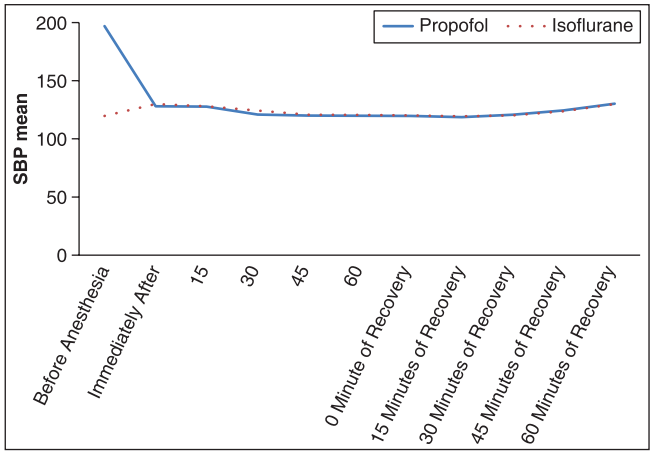


Figure 4: Change in systolic blood pressure in both groups

Table 2: Mean and standard deviation of SQI indices, EMG, and BIS percentage in both groups from fifth to sixtieth minute

Time	Index SQI		EMG %		Index BIS	
	Propofol	Isoflurane	Propofol	Isoflurane	Propofol	Isoflurane
5 minutes	93/9±2/3	93/6±2/1	2/38±1	2/33±1/3	59/1±4/1	58/9±4/7
10 minutes	94/1±1/9	94/2±2/1	2/87±1/5	2/82±1/3	54/8±3/8	55/2±5/4
15 minutes	93/8±2/4	94/6±1/9	3/31±1/8	3/2±1/8	52/7±3/9	52/2±4/2
20 minutes	93/6±1/9	94±1/8	3/24±2/2	2/49±2	50/7±3/3	50/7±3/7
25 minutes	93/9±1/8	93/6±2/3	2/6±2/1	2/87±2/1	49/8±3/7	50/7±3/8
30 minutes	94/5±2/4	93/5±2	2/27±1/9	3±2/1	49/8±3/3	50±3/5
35 minutes	94±2/3	93/6±2/4	2/53±2/1	3±2/1	49/6±3/3	50±2/8
40 minutes	93/6±2/2	93/7±2/2	2/98±2/2	3/04±2	49/9±3/8	50/2±3/6
45 minutes	93/6±2/5	93/6±2/1	3/02±3/2	2/71±2/2	50/4±4/1	50/4±3/6
50 minutes	93/7±1/9	93/4±1/9	3/16±3/7	3/2±2/3	52/1±4/2	52/6±5
55 minutes	93/6±2/1	93/5±2/1	4/33±2/8	4/2±2/8	54/5±4/8	54/4±5/3
60 minutes	93/4±2/3	93/8±2/6	5/4±4/1	5/26±4	57/4±5/4	57/7±5/6
P	0.2		0.97		0.67	

Table 3: Mean ± SD and hemodynamic parameters before and 60 minutes after entering into the recovery from anesthesia in both groups

Time	Systolic blood pressure		Diastolic blood pressure		Mean arterial pressure		Heart rate	
	Propofol	Isoflurane	Propofol	Isoflurane	Propofol	Isoflurane	Propofol	Isoflurane
Before anesthesia	179±9/7	11/7±8/8	71/8±5/6	72/1±6/6	165/8±12/6	167/7±12/1	90/8±9/7	91/9±7/8
0 minute	128±6/9	129/9±6	77/5±5/8	77/1±6/9	179/6±9/8	181/3±9/7	102/5±12	105/1±10/1
15 minutes	127/8±7/4	128±7/2	76/3±6/3	75/7±6/3	178/7±10/5	178/5±10/3	107/2±10/9	109/9±7/8
30 minutes	120/9±8/3	124/4±7/2	71/9±5/3	74/3±6/4	168/9±11/1	173/9±10/4	105/3±11/3	107/5±7/2
45 minutes	120±8/2	120/8±6/5	72/7±5/3	72/9±5/2	168/4±10/7	169/4±8/7	103±11	105/3±7/2
60 minutes	119/9±8/3	120/6±6/4	70/6±5/2	72/7±5	167±11/4	169/1±8/7	101/1±10/7	101/8±6/7
0 minute of recovery	119/8±8/1	120/2±7/6	72/3±5/5	72/9±5/2	168±10/7	168/8±9/9	98/9±10/1	99/7±6/8
15 minutes of recovery	118/7±7/3	119/4±8/6	71/7±5/1	72/2±5/2	166/5±9/1	167/5±11	98±10/6	97/9±6
30 minutes of recovery	120/7±8/4	120/1±8/4	73/6±6/5	72/9±5	169/7±11/5	168/7±10/7	98/1±11/1	99/3±7/8
45 minutes of recovery	124/5±7/3	123/7±9	75/8±6	75/3±6/9	175±10/4	174±12/8	100/6±12/2	101/6±16/7
60 minutes of recovery	130/3±7/8	129/9±9/9	80/2±6/6	78/6±7/3	183/8±11/2	182/3±13/9	108/8±13/6	111±10/8
P	0.42		0.8		0.5		0.32	

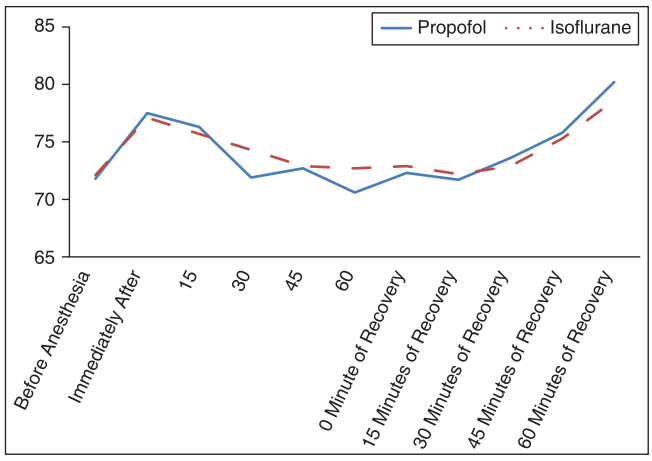


Figure 5: Change in diastolic blood pressure in both groups

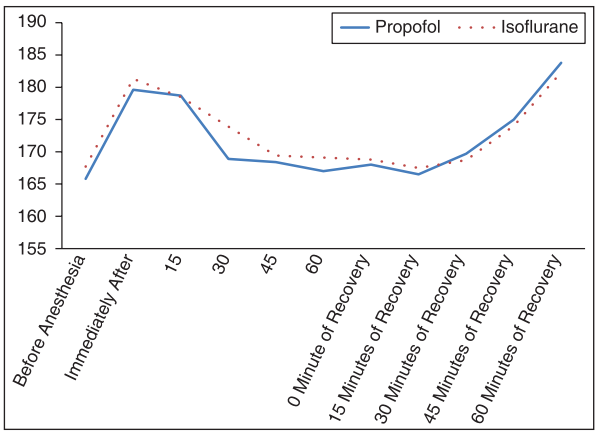


Figure 6: Change in mean arterial pressure in both groups

distribution of extubation and the length of recovery time have been shown in Figures 8 and 9.

The frequency distribution of the patients' satisfaction in both surgery groups has been shown in Table 4 and the frequency distribution of patients' satisfaction had no significant difference based on Fisher's exact test, in both groups ($P = 0.99$).

DISCUSSION

Awareness while under general anesthesia, and a later recall of what happened during surgery,

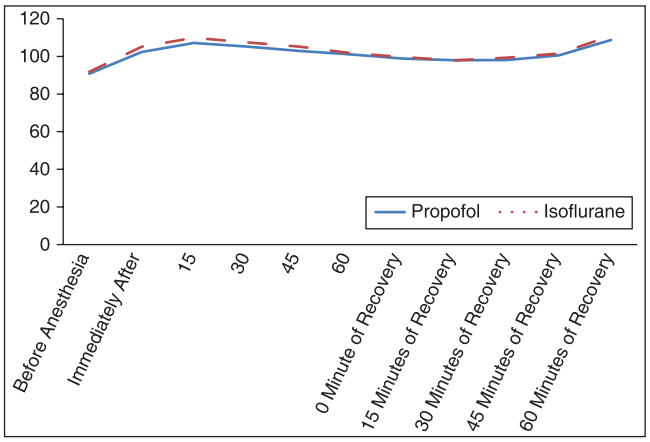


Figure 7: Change in the heart rate in both groups

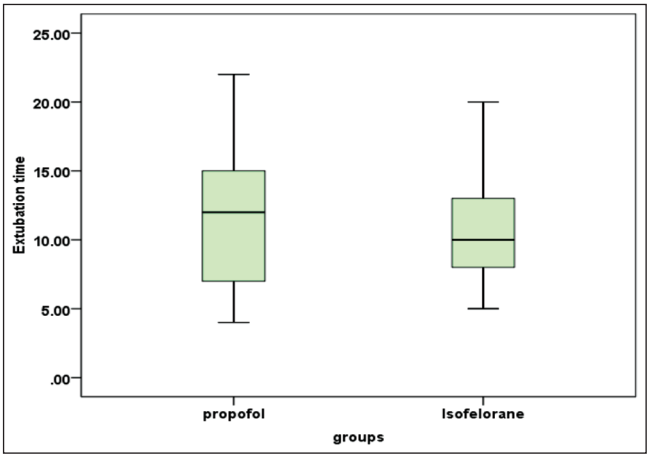


Figure 8: Median, range, and 25% percentile and 75% extubation time

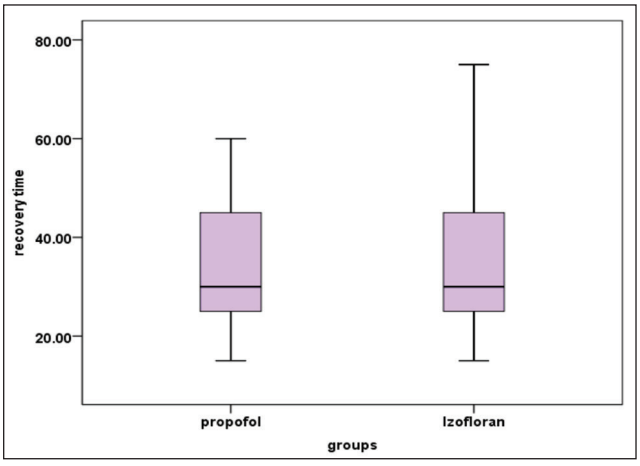


Figure 9: Median, 25% and 75% percentile range, stay in recovery

can be experienced by patients as horrific events and patients may have both auditory and tactile perception, potentially accompanied by feelings of helplessness, inability to move, pain, and panic, ranging to an acute fear of death.[10] For some patients, the experience of awareness under anesthesia has no sequels; for others, however, it can lead to

Table 4: The frequency distribution of patients' satisfaction in both groups

Group satisfaction	Propofol		Isoflurane		Total	
	Number	Percent	Number	Percent	Number	Percent
Completely satisfied	22	48/9	21	46/7	43	47/8
Satisfied	16	35/6	17	37/8	33	36/9
No comments	3	6/7	4	8/9	7	7/8
Dissatisfied	3	6/7	3	6/7	6	6/7
Completely dissatisfied	1	2/2	0	0	1	1/1
Total	45	100	45	100	90	100

$P = 0.99$

the development of posttraumatic stress disorder, consisting of complex psychopathological phenomena, such as, anxiety, insomnia, nightmares, irritability, and depression.[10] Several methods of anesthesia, monitoring and drugs have been introduced, to decrease the incidence of awareness.[10-23] The main objective of the present study was to determine the effect of the two anesthetic techniques, through propofol and isoflurane, on the incidence rate of intraoperative awareness and the Apgar score of infants, in the elective Cesarean section. In our study, two Cesarean section groups underwent general anesthesia by intravenous and inhaled techniques. They were compared, and both the mentioned groups were similar in terms of basic variables such as age distribution, pregnancy age, and ASA. However, in our study, the frequency distribution of intraoperative awareness had no significant difference in the two groups under anesthesia, either with propofol or isoflurane. However, except for the type of anesthetic drug, other factors such as the depth and duration of anesthesia also have an effect on intraoperative awareness. As anesthesia induction usually has side effects on the infant, care is taken to induce the most safe drug, with minimal depth of anesthesia, and for the least possible time, to the mother undergoing Cesarean, and for this reason, the intraoperative awareness in the Cesarean section is higher than in other surgical procedures. According to other studies, during general anesthesia, the incidence rate of awareness has been reported to be between 0.1 to 7% in Cesarean surgery.[10,11] However, in maintaining anesthesia with isoflurane or propofol, the incidence rate of intraoperative awareness is effectively reduced. In the study by Tsai *et al*., the effect of propofol and isoflurane anesthesia was examined, as the anesthesia was maintained by combining $O_2$33%-N_2O67%, in two groups of 12 pregnant mothers, who were candidates for Cesarean section. The results were similar to those obtained in our study, and according to it, the Apgar index, change in hemodynamic status, and BIS index were the same in both groups.[11]

In the Abboud *et al*. study, a comparison was performed between the effect of propofol and isoflurane as anesthesia maintenance on 74 pregnant women, who were candidates for Cesarean section, in two groups. In the study, the incidence rate of intraoperative awareness and duration of recovery did not differ. The Apgar index was good in both groups, but in the isoflurane group, the hypertension response at intubation was less than in the propofol group, and propofol was mentioned as a more reliable anesthesia than isoflurane.[22] In contrast, in the Ashworth and Smith study conducted on isoflurane and propofol in Outpatient surgeries, the intraoperative awareness was not seen in anesthesia with propofol and isoflurane, but sufficient depth of anesthesia could hardly be maintained by propofol.[23]

According to the results obtained in our study, the SQI indices, EMG percentage, and BIS did not show a significant difference from the fifth to sixtieth minute in the two groups. Also, the hemodynamic variables included blood pressure and heart rate, which showed no significant difference in both groups from before anesthesia to the sixtieth minute of recovery. On the other hand, due to weakening of the uterine contractions in 25% of mothers in the isoflurane group, the application of this drug for anesthesia maintenance in delivery is questioned.[11] However, ultimately, given that the incidence rate of intraoperative awareness, the Apgar index of the infant and the hemodynamic variables had no significant difference in the two groups under anesthesia with isoflurane and propofol. Each mentioned drug could be used in general anesthesia for Cesarean section according to the patient's condition, anesthesiologist's diagnosis, and other criteria, such as, the price and availability of drugs.

The *small sample size* is a significant *limitation* of this *study. This may cause some bias in our study,* so further work is required to determine the exact incidence of awareness, especially in high-risk patients.

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