



Effects of Propofol and Midazolam on Newborns' Apgar Scores and Mothers' Hemodynamic under Spinal Anesthesia

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ABSTRACT

At present, cesarean section is the most prevalent surgical procedure in women and the anesthesia performed for it has turned into a selective technique. This study compared the effects of midazolam and propofol on newborns' Apgar scores and on the hemodynamic status of the mothers undergoing cesarean sections. This research, in the form of a double-blind clinical trial, was carried out on forty-two 15 - 35 year-old of class ASA I and II pregnant women who underwent cesarean section. Using the simple random method, they were divided into two groups of equal members: 21 in the Propofol and 21 in the midazolam groups. The newborns' Apgar scores were recorded 1 and 5 minutes after birth and the mothers' hemodynamic status 3, 5, 10, 15, 30, 60 minutes into the surgical procedure. The data was analyzed using SPSS, the repeated measurement test, and the independent t-test. One and five minutes after birth, there were no significant differences between the newborns' Apgar scores in the two groups ($p=0.08$), or between the two groups ($p=0.33$). Results showed there were no statistically significant differences between the Apgar scores of the newborns at low doses of midazolam and propofol.

Keywords: Midazolam, propofol, Newborns' Apgar scores

INTRODUCTION

The birth phenomenon is the most beautiful and, at the same time, the most sensitive phenomenon in creation. Nevertheless, we have occasionally encountered problems in the occurrence of this natural and important event, have realized its huge dimensions, and have searched for the best ways of making it the least dangerous and the easiest event. Since cesarean births constitute 25% of all deliveries, correct management of delivery and anesthetic techniques for creating analgesia and for ensuring the health of the mother and the fetus during cesarean section is of great importance [1]. From a series of extensive studies carried out on various aspects of the advantages and shortcomings in the methods of spinal and general anesthesia, and on their comparison, it has been estimated that less medicine reaches the mother and the fetus in the spinal anesthesia technique and the risks of aspiration [2-4] and hypoxia [5] for the mother are less. However, all anesthetic agents that weaken the mother's nervous system pass through the placenta and weaken the nervous system of the fetus [1]. Study of the newborn's status after birth can help us select the best method for creating analgesia in pregnant women undergoing cesarean section. Determination of the Apgar scores of newborns 1, 5, and 20 minutes after birth is one of the methods employed in evaluating their status [6]. Newborns' Apgar scores immediately after birth are one of the determining factors in their mortality rate after birth, and the type of drug used for anesthetizing pregnant women is one of the factors influencing the newborn's Apgar score [7]. The Apgar score 1 minute after birth determines whether there is an urgent need for resuscitation. The Apgar score 5 minutes after birth, and especially the change in Apgar score between the first and

fifth minute after birth, is an important index for the efficacy of resuscitation [6]. The increase in cesarean section rates in recent years has led to greater attention being paid to the complications of this method of delivery for the mother and the fetus [8]. Anesthesia drugs, narcotics, and tranquilizers used during cesarean operation are one of the factors influencing newborns' Apgar scores [6]. Propofol is an intravenous anesthesia drug that plays a part in the induction and continuation of anesthesia, but its anti-nausea effect at low doses, and the effect of its sub-hypnotic doses, has recently attracted interest [9-11]. Midazolam and benzodiazepines in general are among the drugs most frequently used as premedication before surgery [12]. Their most important effects are their performance as tranquilizers and sleep inducers and as drugs that cause amnesia. In addition, benzodiazepines act as an antispasmodic and are employed for treating spasms, and have anti-anxiety and muscle-relaxing properties at higher doses [13-14]. In some previous studies on the relationship between Apgar scores of newborns and the type of anesthesia employed, no correlation was found between the Apgar scores of newborns and the type of anesthesia used in their delivery [7-15]. However, in some other studies newborns delivered under general anesthesia had lower Apgar scores [18], and some researchers believed the type of anesthesia had no effect on the short-term outcome of newborn infants [19]. Considering the conflicting results of previous studies, this research intended to compare the effects of propofol and midazolam on Apgar scores of newborns and on their mothers' hemodynamic during spinal anesthesia for cesarean section.

MATERIALS AND METHODS

After the Research council of Jahrom University of Medical Sciences and the Ethics Committee approved this double-blind clinical trial with the code of jums.rec.1392.005, it was carried out on forty-two 15-35 year-old ASA Class I and II (American Society of Anesthesia Score) pregnant women who underwent cesarean section. The simple random sampling method was used in selecting the statistical population from among pregnant women who visited the Mottahhari Hospital in Jahrom and underwent cesarean section under spinal anesthesia. The 42 pregnant women were randomly divided into two 21-member groups (the midazolam and propofol groups) using the numbers on the women's health files. The inclusion criteria were that the pregnant women had to submit their written consent to participate in the research, be 15-50 years of age, belong to anesthesia Class I or II, be candidates for elective cesarean section, have no known history of physical and mental illnesses, and do not take analgesics, antidepressants, sleeping pills, or psychotropic drugs. The criteria for exclusion from the research were weight of over 100 kilograms, age of more than 50 or less than 15 years, use of narcotics or alcohol, treatment with antidepressants, and use of sleeping pills or psychotropic drugs. Pregnant women who required postoperative stay at ICU, had a history of sensitivity to propofol or midazolam, needed additional treatment measures, and became critically ill during the operation were also excluded from the study. So were those who experienced rising anesthesia level and reduction or loss of breathing, were of anesthesia Class III and IV (based on the American Society of Anesthesia Score), and suffered from hemodynamic disorder. Before entering the operating room, the pregnant women did not receive any preoperative medication. Prior to their entry into the research, the method of conducting the study, the reason for carrying it out, and its complications were verbally explained to the pregnant women and, if were willing to take part in the study, they handed in their informed consent. After the pregnant woman lay on the operating bed, the suitable route of venous injection was selected, the electrocardiography leads were attached on her chest, the pulse oximeters were attached, and blood pressure cuffs were tied to her arm, and her blood pressure and heart rate were displayed on the monitor and recorded. Both groups received Ringer's solution at 7cc/kg as fluid therapy. Before injecting propofol or midazolam, blood pressure and heartbeat rate were recorded, spinal anesthesia was applied using 65 mg of 5% lidocaine, and group A received 1.5 mg midazolam and group B, simultaneously, 2 cc (equivalent to 20 mg) of propofol. Blood pressure, heartbeat rate, and number of breaths were measured 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia was applied. The newborns' Apgar scores were measured 1 and 5 minutes after delivery. During the surgery, if blood pressure dropped, ephedrine was administered. When the operation ended, the women were transferred to the recovery room and kept there for at least one hour. The women, and the person responsible for follow up after surgery, did not know which initial drug had been prescribed for them.

RESULTS

In this study, 42 pregnant women were divided into two 21-member groups. Group A were injected with midazolam and group B with propofol. These two groups are compared below using diagrams and bar charts.

The diagram below shows differences in systolic pressure between the midazolam and propofol groups 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia. The repeated measurement test (repeated measures ANOVA) was used to study the trend of changes in systolic blood pressure, and the descriptive table shows there were significant differences in systolic blood pressure in both groups from the first to the 60th minute after spinal anesthesia ($p=0.001$), but there were no significant differences between the two groups ($p=0.42$).

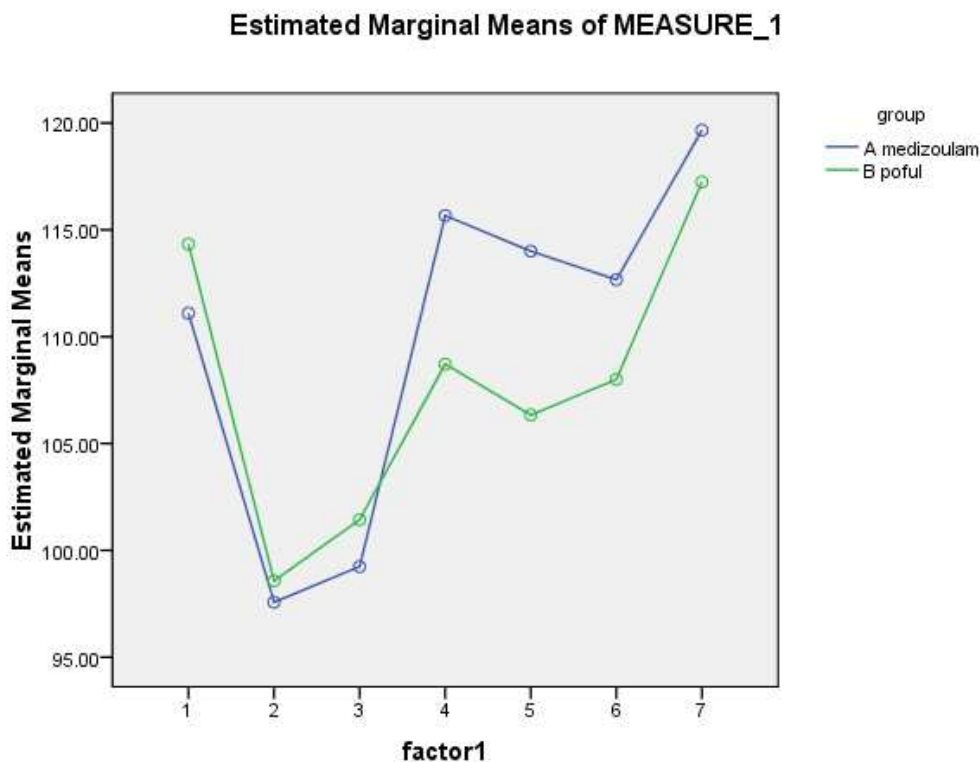


Diagram 1: Comparison of systolic pressure between the midazolam and propofol groups 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia

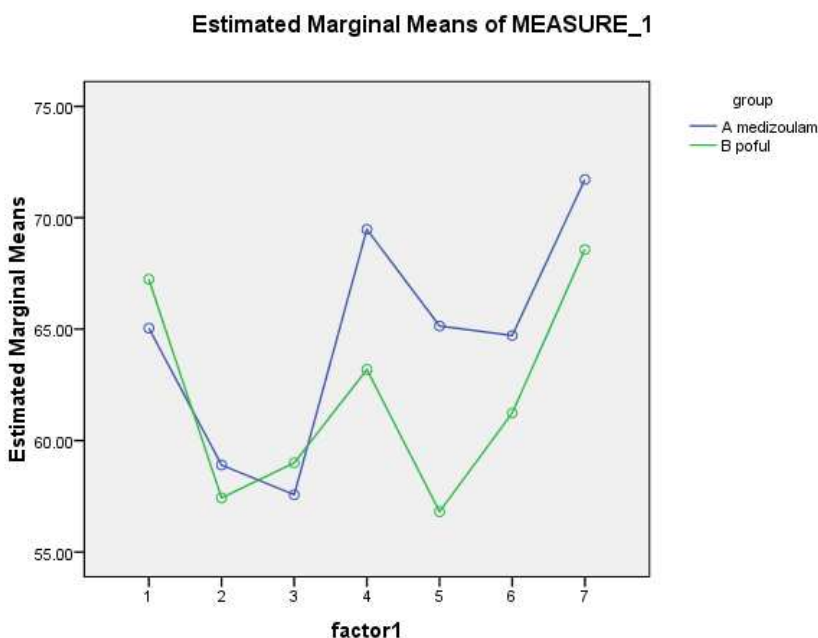


Diagram 2: Comparison of diastolic blood pressure in the midazolam and propofol groups 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia

The diagram below shows differences in diastolic blood pressure in the two groups 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia was applied. Repeated measure ANOVA was employed to study the trend of changes in diastolic blood pressure. Values of the means and standard deviations indicate there were significant differences in diastolic blood pressure in both groups from the first to the 60th minute after the spinal anesthesia ($p=0.001$).

However, estimates of the degree of difference between each mean blood pressure showed there were no significant differences between the two groups with respect to diastolic blood pressure ($p=0.37$).

To determine changes in heartbeat rates in the two groups, repeated measures ANOVA was used. Based on the values of the means and standard deviations, there were no significant differences between the two groups regarding changes in heartbeat rates ($p=0.37$).

Repeated measure ANOVA was also used to study changes in O_2 saturation in the midazolam and propofol groups. According to the values of the means and standard deviations, there were no differences in the two groups ($p=0.64$), or between the two groups ($p=0.63$), with respect to O_2 saturation 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia.

To investigate differences in the trend of changes of number of breaths in the two groups, repeated measures ANOVA was used. Considering the values of the means and standard deviations, there were no significant differences in the two groups ($p=0.40$), or between the two groups ($p=0.37$), with respect to the trend of changes in the number of breaths from the first to the 60th minute after spinal anesthesia.

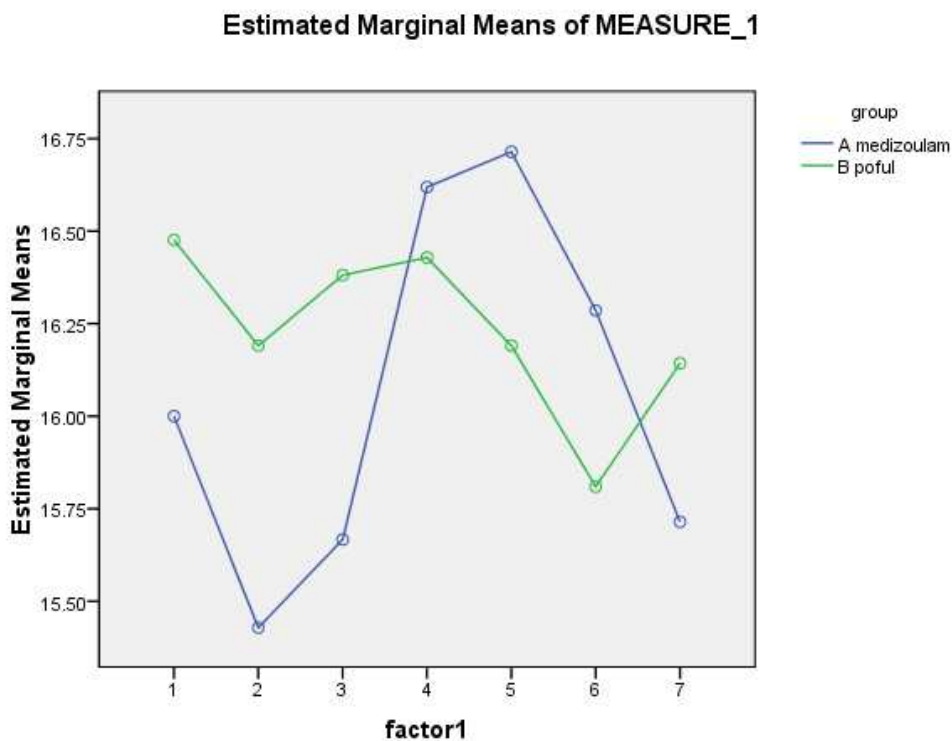


Diagram 3: Comparison of the number of breaths in the midazolam and propofol groups 1, 3, 5, 10, 15, 30, and 60 minutes after spinal anesthesia

In the diagram below, differences in Apgar scores of the newborns in the two groups were examined. Repeated measures ANOVA was used to determine the trend of changes in the Apgar scores. Based on the values of the means and standard deviations, there were no significant differences in the two groups ($p=0.08$), or between the two groups ($p=0.33$), with respect to Apgar scores 1 and 5 minutes after birth.

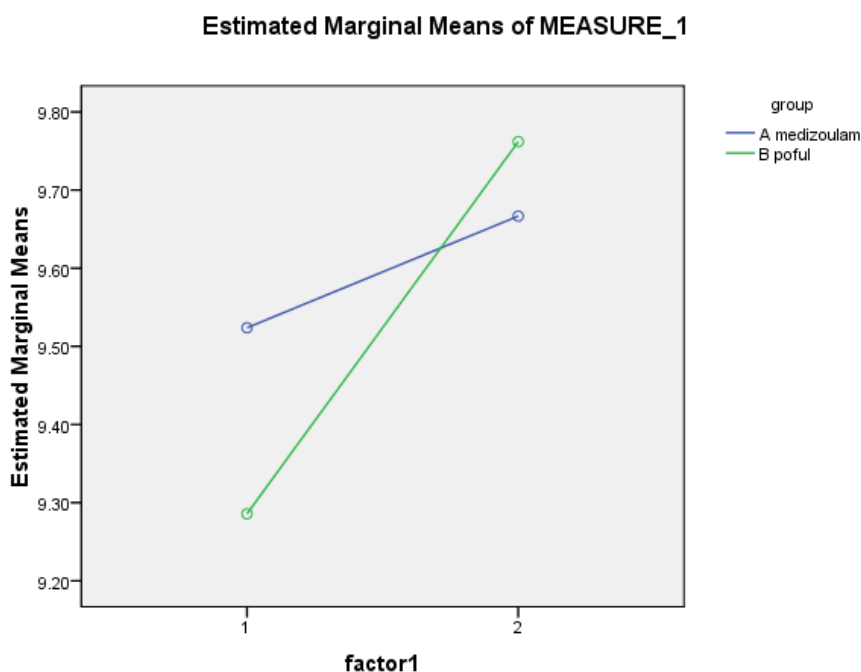


Diagram 4: Study of the trend of changes in Apgar scores of newborns in the midazolam and propofol groups 1 and 5 minutes after birth

DISCUSSION

At present, cesarean section is one of the most prevalent surgical procedures carried out all over the world. Therefore, the drug used in anesthesia for these operations must have the minimum effect on the fetus and on its Apgar score because changes and reduction in Apgar scores are one of the factors that increase mortality rates in newborns. Results of this research indicated Apgar scores of the newborns in the midazolam and propofol groups were not significantly different, and this result is similar to those found by Djordjevic *et al.* in their comparison of thiopental and propofol (20), and in agreement with results of other studies (21-22). The effect of propofol in reducing blood pressure in pregnant women during cesarean section, which was observed in this research, has been confirmed in other studies (23). However, as indicated in this study, this drop in blood pressure had no effects on the fetus. Results of studies conducted by Norouzi *et al.* showed that Apgar scores of newborns delivered under spinal anesthesia were higher compared to those delivered under general anesthesia (18). In 2001, in a study carried out in Jordan, it was found that 1 and 5 minutes after birth there were no differences between Apgar scores of newborns delivered under general anesthesia and those of newborns delivered under spinal anesthesia (15).

CONCLUSION

Considering the mentioned advantages, and since results of this research indicate Apgar scores 1 and 5 minutes after birth were higher in newborns delivered under spinal anesthesia compared to those delivered under general anesthesia, it seems reasonable that spinal anesthesia should be used in most cases. In the final analysis, the important thing is to create desirable conditions that are close to the physiological conditions for the fetus. Preserving these conditions, and hence keeping the Apgar scores of the newborns high, provides a better prognosis for the start of life.

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