

Bispectral index values during spinal anesthesia using hyperbaric bupivacaine with intrathecal or intravenous fentanyl for cesarean section

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BACKGROUND: It has been shown that bispectral index (BIS) may reduce during spinal anesthesia. The aim of this study was comparing BIS scores during spinal anesthesia using hyperbaric bupivacaine alone or with intrathecal or intravenous fentanyl for cesarean section. **METHODS:** In this double-blind randomized controlled clinical trial, 140 pregnant women with American Society of Anesthesiologists (ASA) class I or II were randomly assigned to receive 1-2.5 mL hyperbaric 0.5% plus normal saline (B), 2-2.5 mL hyperbaric 0.5% plus 20 µg fentanyl intrathecally (BF_{IT}), or 2.5 mL hyperbaric 0.5% plus 100 µg fentanyl intravenously (BF_{IV}). BIS was measured using electroencephalography (EEG) findings and recorded at the baseline and 5th, 10th, 15th, 30th, 45th, and 60th minutes after spinal injection. The heart rate (HR), mean arterial pressure (MAP), signal quality index (SQI), and temperature were also recorded during surgery. **RESULTS:** A total number of 140 subjects completed the study and underwent analysis. The recorded BIS was significantly different between the three groups at all time points ($p = 0.004$). At all the times, the BIS values were lower in the BF_{IV} group compared to other groups ($p < 0.05$). The BIS scores in group B were significantly higher in most time points compared to other groups. After spinal anesthesia, the changing trend of BIS reduced until the 30th minute for the BF_{IT} group and until the 45th minute for the B and BF_{IV} groups. **CONCLUSIONS:** Although the BIS scores began to decrease during spinal anesthesia using hyperbaric bupivacaine alone or with intrathecal or intravenous fentanyl for cesarean section, the greatest reduction from baseline BIS values occurred with adding intravenous fentanyl. Moreover, maximum reductions of BIS scores appeared at 30 and 45 minutes after induction of spinal anesthesia.

KEYWORDS: Anesthesia, Bispectral Index, Depth, Spinal

BACKGROUND

Bispectral index (BIS) is an electroencephalography (EEG)-derived parameter related to the level of sedation and loss of consciousness.^[1-4] It has also been recognized as the first method which enables anesthesiologists to determine the depth of anesthesia in high-risk surgeries.^[3-7]

Spinal anesthesia with a sedative drug may affect patient's consciousness. However, a previous study showed that patients undergoing spinal anesthesia without sedatives suffer decreased level of consciousness as well.^[8] Spinal anesthesia is widely used for cesarean section. Regional anesthesia techniques have several advantages including decreased risk of failed intubation and aspiration of gastric contents, avoidance of depressant agents, and the ability of the mother to remain awake and enjoy the birthing experience. In addition, it has been suggested that blood loss is reduced under regional anesthesia for cesarean delivery. Spinal anesthesia has been found to be faster and more cost-effective and to provide a superior block.^[9]

However, patients undergoing cesarean section have shown decreased levels of consciousness with spinal anesthesia.^[1]

Some factors, including pregnancy, additional drugs, and baricity, affect the depth of spinal anesthesia.^[2,4,6,10] Pregnant women demonstrate increased sensitivity to regional anesthetics. From early pregnancy, when neuraxial anesthesia is administered, women require less local anesthetic than non pregnant women do reach a given dermatomal sensory level.^[9,11,12] It has previously reported that BIS during spinal anesthesia with isobaric bupivacaine is reduced by intrathecal fentanyl but not by intravenous or epidural fentanyl.^[4] BIS values in patients who received intrathecal isobaric bupivacaine with fentanyl were lower than those under intrathecal hyperbaric bupivacaine and fentanyl.^[10] Intrathecal hyperbaric bupivacaine and fentanyl produce longer alertness than single hyperbaric bupivacaine.^[1]

No previous study has accurately compared the effects of hyperbaric bupivacaine alone and in combination with different routes of fentanyl on BIS values.

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The aim of this study was to evaluate BIS scores during spinal anesthesia using hyperbaric bupivacaine alone or in combination with intrathecal or intravenous fentanyl for cesarean section.

METHODS

This randomized, double-blind clinical trial was conducted in Beheshti Medical Center, Isfahan, Iran, from spring 2008 to summer 2009. After obtaining approval from the Ethics Committee of Isfahan University of Medical Sciences, we recruited 140 parturients with American Society of Anesthesiologists (ASA) physical status I or II who were scheduled for elective cesarean delivery under spinal anesthesia. Written informed consents were obtained from all parturients after full explanation of the goals and procedures of the study.

The inclusion criteria were ASA I or II, absence of cardiovascular diseases, no history of diabetes, no previous pregnancy complications, and no history of twin pregnancies. The exclusion criteria were any significant history of maternal medical or obstetric diseases. All patients had fasted for 8 hours preoperatively and were infused with an intravenous preload of 10 cc/kg of Ringer's lactate solution before surgery. Intraoperative monitoring included pulse oximetry, automated blood pressure cuff, lead II electrocardiogram, and capnograph.^[13-15]

An operating theatre nurse used randomization protocol to assign participants to their respective groups. Patients were randomly assigned to receive hyperbaric bupivacaine alone or in combination with intrathecal or intravenous fentanyl. Randomization was performed using a table of random numbers with minimization for age and medical and psychiatric status. Both the patients and the anesthetist were blind to treatment.

Before spinal anesthesia, the cerebral state monitoring (CSM) electrodes were placed on the fronto-temporal regions as recommended by the manufacturer (Danmeter Co., Denmark). The system was used for measurement of BIS values and signal quality index (SQI). To reduce skin/electrode impedance, the skin over the forehead was cleaned with an alcohol-impregnated wipe. BIS values were only considered valid when SQI was above 50%. If SQI was < 50% for longer than 20% of the total study period, all data for the patient was excluded from analysis.

Lumbar puncture was performed in the sitting position. A 25-gauge (pencil point, Pajunk, Germany) spinal needle was introduced into the subarachnoid space

at the L3-L4 lumbar level midline approach with the needle orifice cephalad. Cerebrospinal fluid was aspirated and the ready fluid 2.5 mL hyperbaric 0.5% dissolved in 8.25% glucose solution^[13] (Marcaine 5%, Mylan, France) was injected to subarachnoid space over the period of 15 second, with no barbitage as bellow:

1-2.5 mL hyperbaric 0.5% plus normal saline (B)

2-2.5 mL hyperbaric 0.5% plus 20 micrograms fentanyl intratechally (BF_{IT})

3-2.5 mL hyperbaric 0.5% plus 100 micrograms fentanyl intravenously (BF_{IV})

Patients were set to left lateral position. The maximum level of sensory motor block was assessed by pin prick test after spinal anesthesia. Motor block was assessed by modified bromage score (0: motorless, 1: inability to flex the hip, 2: inability to flex the knee, and 3: inability to flex ankle). After the establishment of T4 block with pin prick test and confirmation of anesthesia, cesarean section was initiated.

The study solution was prepared by another researcher who was not involved in patient care. The solution was then injected immediately. The spinal needle was withdrawn and the patients were repositioned to supine position with elevated head (for 15-20 degrees).

BIS, SQI, heart rate (HR), mean arterial pressure (MAP), and the core temperature were recorded at the baseline and 5, 10, 15, 30, 45, and 60 minutes after spinal injection. Core temperature was measured by a tympanic thermometer (Braun IRT 3020 ThermoScan, Kronberg, Germany).

If systolic blood pressure (SBP) was < 20% below baseline or < 100 mmHg, 5 mg intravenous (IV) ephedrine was given incrementally. If HR was less than 50 beats/min, 0.5 mg IV atropine sulfate was administered.^[1,13,14]

Based on previous studies, power of 0.95, and α error of 0.05, the sample size was calculated as 140. Data was analyzed by one-way analysis of variance (ANOVA), general linear model (GLM) repeated measures ANOVA, and chi-square test. All analyses were performed in SPSS¹⁸ (SPSS Inc., Chicago, IL, USA).^[16] P values less than 0.05 were considered as statistically significant. The quantitative data was presented as mean \pm standard deviation (SD).

RESULTS

All subjects completed the study and underwent anal

ysis (Figure 1). The 3 groups did not have significant differences in baseline characteristics and baseline conditions (Table 1). HR, MAP changes, temperature,

and SQI of the 3 groups were not significantly different at baseline and 5, 10, 15, 30, 45, and 60 minutes after spinal injection.

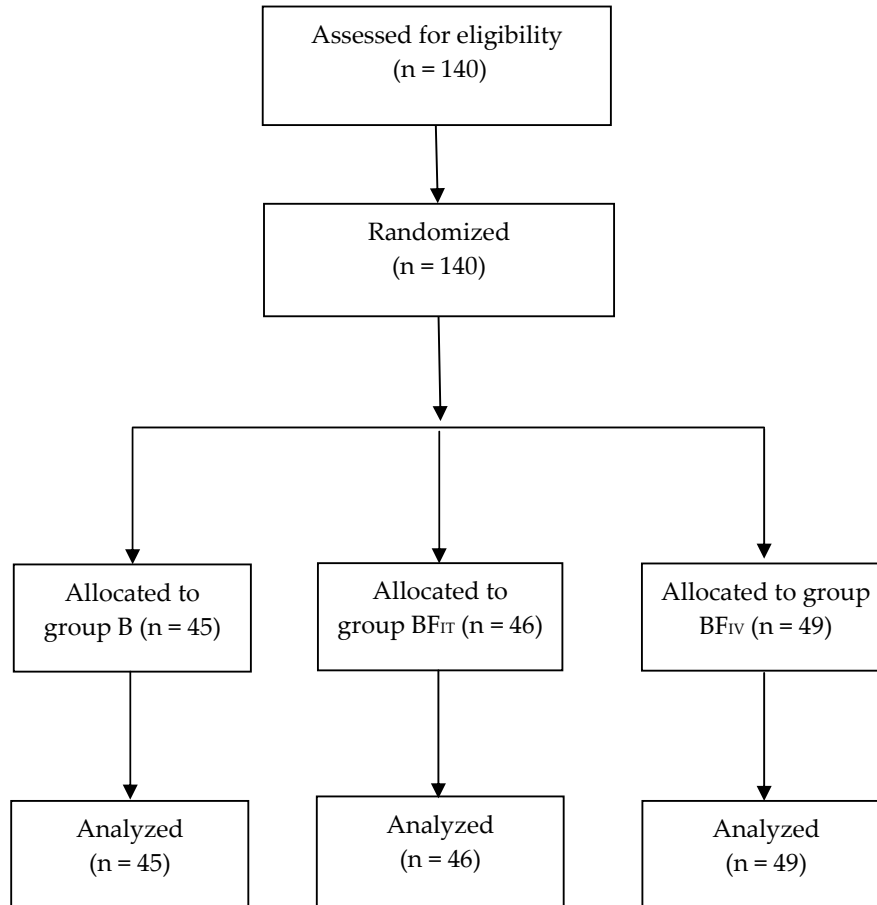


Figure 1. Flow diagram of the enrolled study patients (B: Hyperbaric bupivacaine; BF_{IT}: Hyperbaric Bupivacaine plus intrathecal fentanyl; BF_{IV}: Hyperbaric bupivacaine plus intravenous fentanyl)

Table 1. Baseline characteristics and drugs consumptions in the 3 groups

	B (n = 45)	BF_{IT} (n = 46)	BF_{IV} (n = 49)	p
Age (y)	27.3 ± 4.0	27.9 ± 4.0	27.5 ± 4.0	0.88*
Height (Cm)	162.9 ± 6.0	162.8 ± 5.0	163.9 ± 5.0	0.57*
Weight (Kg)	74.0 ± 9.0	76.6 ± 8.0	76.1 ± 7.0	0.07*
SBP(mmHg)	116.7 ± 18.0	111.3 ± 7.0	114.8 ± 11.0	0.16*
HR (beat/min)	88.0 ± 23.0	86.0 ± 115.0	88.0 ± 22.0	0.24*
Parity (nulipara/multipara)	26/20	26/18	31/18	0.22**
ASA I/II	41/5	41/4	44/5	0.81**
Duration of surgery(min)	45.0 ± 10.0	43.0 ± 12.0	44.0 ± 8.0	0.31*
Ephedrine consumption(mg)	10.2 ± 6.0	13.6 ± 7.0	10.0 ± 6.0	0.24*
Atropine consumption (mg)	0.3 ± 0.01	0.26 ± 0.02	0.28 ± 0.02	0.11*

SBP: Systolic blood pressure; HR: Heart rate; B: Hyperbaric bupivacaine; BF_{IT}: Hyperbaric bupivacaine plus intrathecal fentanyl; BF_{IV}: Hyperbaric bupivacaine plus intravenous fentanyl

Data is shown as mean ± SD or numbers.

*One-way analysis of variance

**Chi-square

Table 2. Bispectral index (BIS), signal quality index (SQI), mean arterial pressure (MAP), heart rate (HR), and temperature changes at baseline and 5, 10, 15, 30, 45, and 60 minutes after spinal injection

	Group	Baseline	5 th minute	10 th minute	15 th minute	30 th minute	45 th minute	60 th minute	p*
BIS	B	97.4 ± 2.9	95 ± 5.9	94.8 ± 4.45	93.56 ± 4.69	93 ± 4.59	93±5.36	94.8 ± 3.9	0.004
	BF _{IT}	94.9 ± 2.3	93 ± 5.6	93 ± 3.73	92.91 ± 4.13	92.44 ± 3.17	93.15±3.41	94.22 ± 2.81	
	BF _{IV}	95.2 ± 2.3	92.2 ± 3	91.2 ± 3.38	90.26 ± 3.8	90.38 ± 3.34	90.73±3.99	92.24 ± 3.41	
SQI	B	81.5 ± 13.0	84.8 ± 12.2	83.26 ± 11.3	84.82 ± 10.13	84.5 ± 11.3	84.26±10.1	84 ± 7.83	0.07
	BF _{IT}	82.5 ± 13.6	85 ± 10.5	84.46 ± 11.2	85.22 ± 8.84	86 ± 7.23	85.71±7.97	86 ± 5.95	
	BF _{IV}	82.0 ± 8.3	84 ± 8.49	83.12 ± 10.8	83.91 ± 8	84 ± 9.99	84.81±7.18	85.91 ± 7.47	
MAP	B	83.7 ± 15.8	79.8 ± 14.3	79.56 ± 13.7	78.69 ± 13.7	77.1 ± 10.8	76.76±10.53	77.56 ± 10.18	0.29
	BF _{IT}	86.3 ± 11.4	80.75 ± 14	84.2 ± 10.2	81.35 ± 11.5	81.15 ± 9	81.36±8.76	81.54 ± 8.23	
	BF _{IV}	82.8 ± 10.1	80 ± 10.56	78.67 ± 9	78.73 ± 8.83	78.81 ± 8.39	81±8.37	80.7 ± 9.38	
HR	B	95.67 ± 16.25	92.36 ± 16	93.86 ± 14.2	94 ± 16.53	91.19 ± 12.8	88.69±12.65	87.23 ± 11.62	0.44
	BF _{IT}	93.64 ± 11.7	92.24 ± 17.7	90.6 ± 15.7	12.21	12.65	84.61±10.85	83.8 ± 10.62	
	BF _{IV}	93 ± 10.8	90.89 ± 13.43	89.48 ± 13.4	88.87 ± 12.41	86.63 ± 11.98	82.46 ± 8.9	82.46 ± 8.9	
Tympanic T(°C)	B	36.5 ± 0.1	36.5 ± 0.13	36.54 ± 0.12	36.52 ± 0.12	36.48 ± 0.14	36.5±0.15	36.52 ± 0.09	0.40
	BF _{IT}	36.54 ± 0.07	36.58 ± 0.06	36.53 ± 0.07	36.53 ± 0.07	36.54 ± 0.06	36.52±0.06	36.54 ± 0.07	
	BF _{IV}	37.5 ± 0.09	36.57 ± 0.1	36.53 ± 0.08	36.52 ± 0.1	36.51 ± 0.05	36.5±0.04	36.52 ± 0.06	

B: Hyperbaric bupivacaine; BF_{IT}: Hyperbaric bupivacaine plus intrathecal fentanyl; BF_{IV}: Hyperbaric bupivacaine plus intravenous fentanyl
Data is shown as mean ± SD.

*General linear model repeated measures analysis of variance

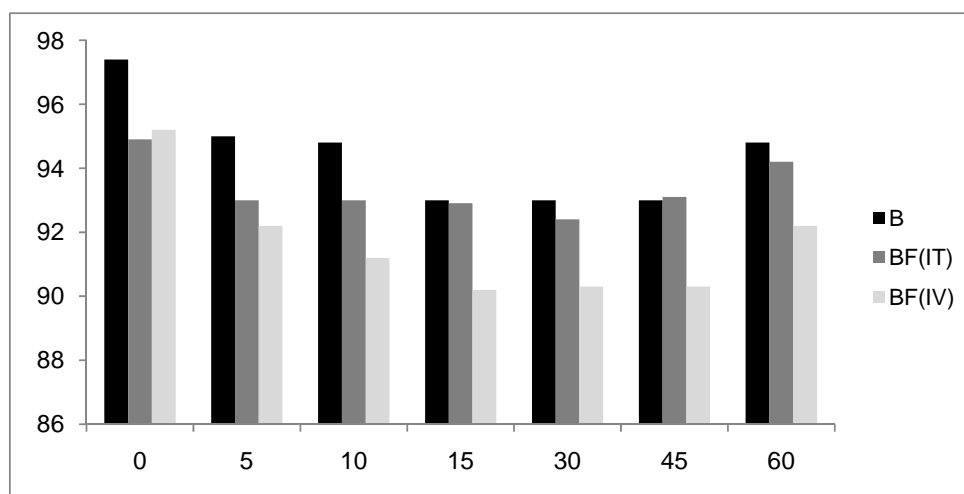


Figure 2. Bispectral index values during spinal anesthesia for cesarean section at baseline and 5, 10, 15, 30, 45, and 60 minutes after spinal injection in groups B (hyperbaric bupivacaine), BF_{IT} (hyperbaric bupivacaine plus intrathecal fentanyl) and BF_{IV} (hyperbaric bupivacaine plus intravenous fentanyl)

The recorded BIS values were significantly different between the 3 groups at all time points (Table 2) ($p = 0.004$). The BIS values in group B were significantly higher than other groups at all time points. However, 45 minutes after spinal anesthesia, BIS values of other groups were insignificantly higher than group B. The lowest BIS values at all times were observed in group BF_{IV} ($p < 0.05$).

In addition, BIS values decreased until the 30th minute in group BF_{IT} and until the 45th minute in

groups B and BF_{IV}. However, they increased at the 60th minute after spinal anesthesia in all groups (Figure 2).

DISCUSSION

Bupivacaine is widely used for spinal anesthesia. Although the effect of this drug on BIS score has been investigated, comparisons between the effects of hyperbaric bupivacaine alone and in combination with different routes of fentanyl on BIS values have never been made until now.^[5,6] Based on our results, the rec-

orded BIS values were significantly different between the 3 groups at all time points (Table 2) ($p = 0.004$). BIS values in group BF_{IV} were lower than other groups at all times ($p < 0.05$). After spinal anesthesia, BIS values reduced until the 30th minute in group BF_{IT} and until the 45th minute in groups B and BF_{IV}. However, the values increased at the 60th minute in all groups (Figure 2). Previous studies have proposed several theories, including a direct effect of the local anesthetic by either systemic absorption or rostral spread through the cerebrospinal fluid (CSF), and attenuating the stimulation of the reticular activating system in a situation where there is also decreased afferent input, to explain the sedative effects of spinal anesthesia. Pollock et al. reported that the greatest variations from baseline BIS values in non-sedated patients occurred at 30 and 70 minutes after induction of spinal anesthesia. They thus suggested that delayed rostral spread of local anesthetics might be responsible.^[17] A previous study in which high and low blocks (medians T3 *vs.* T10) were produced by the injection of different doses of hyperbaric bupivacaine (17.5 *vs.* 7.5 mg), reported that BIS values did not change until 20 minutes after the induction of spinal anesthesia. Propofol infusion had been started after 15 minutes in both groups. The authors suggested that 15-20 minutes were not long enough for local anesthetics to spread rostrally in concentrations sufficient to influence the electrical activity of higher neuronal centers.^[18] Although the possibility of rostral spread of the intrathecal local anesthetics cannot be excluded, it is not much probable, particularly in low block groups.^[6] The results of the present study supported these conclusions.

Marucci et al. reported that in pregnant women undergoing cesarean delivery using spinal anesthesia, 12.75 mg hyperbaric bupivacaine 0.5% with fentanyl had more sedative effects than the same dose of this drug without fentanyl. They considered increased anesthetic block density to be responsible for such finding. Moreover, in the group that had only received bupivacaine, the peak sedative effect was seen 35-45 minutes after injection, while in women who had had bupivacaine plus fentanyl, the peak sedative effect was seen at 45-70 minutes ($p < 0.05$). Therefore, it was concluded that spinal anesthesia in cesarean was in association with loss of consciousness especially if two drugs were used simultaneously. Intrathecal spinal anesthesia has antianxiety effects in addition to spinal ganglion blockade and decreases afferent signals from the spinal cord.^[1] More recent data has indicated that reduced local anesthetic requirements predate the mechanical effects of the gravid uterus. In animal studies, chronically administered progesterone has been found to reduce anesthetic requirements. In addition, it has

been suggested that increased concentrations of endorphins and dynorphins found in pregnant rats may be related to altered pain threshold. This evidence led to a multifactorial explanation for the decreased anesthetic requirement.^[9,19]

In another study, 46 pregnant women were divided into five groups to receive 2.5 ml bupivacaine isobar 0.5% and 20 µg intrathecal fentanyl in group I, 2.5 ml intrathecal bupivacaine isobar 0.5% and 100 µg intravenous fentanyl in group II, 2.5 ml intrathecal bupivacaine isobar 0.5% and 100 µg epidural fentanyl in group III, 2.5 ml intrathecal bupivacaine isobar 0.5% in group IV, and finally 3 ml intrathecal bupivacaine isobar 0.5% in group V. BIS values of group I were lower than other groups ($p = 0.3$). In addition, the time in which the BIS scores were 80 or less was the highest in group I. Therefore, BIS value was significantly decreased only by intrathecal fentanyl for cesarean section.^[4]

Other than combination use of drugs, baricity is another known factor that affects consciousness in spinal anesthesia.^[6,10] No study has compared the effects of adding intrathecal or intravenous fentanyl to hyperbaric bupivacaine on BIS values. According to the present study, BIS values during surgery began to reduce after injection of both of these routes of fentanyl. Moreover, BIS values were lower in hyperbaric bupivacaine plus intravenous fentanyl group than the others. One study examined the effects of different levels of spinal anesthesia for varicose vein surgery, induced by solutions of different baricity but containing the same amount of local anesthetic agent, on the requirement for sedation with propofol through BIS assessment. The maximum levels of block in the control hyperbaric and isobaric groups were T4 (T3-T9) and T10 (T8-T11), respectively. Cumulative consumption of propofol to maintain BIS values was also less in the hyperbaric than in the isobaric group that was influenced by the block height, not the dose of local anesthetic used. However, this study did not demonstrate a correlation between block level and propofol requirement, because the block levels were not so diverse.^[6]

Conversely, another study investigated whether the specific gravity of bupivacaine combined with intrathecal fentanyl in spinal anesthesia for cesarean section effected the BIS values. The study allocated 31 women scheduled for cesarean section into two groups to receive 2 ml isobaric bupivacaine 0.5% plus 20 µg fentanyl (group I, $n = 14$) or 2 ml hyperbaric bupivacaine 0.5% plus 20 µg fentanyl (group H, $n = 17$). BIS values were recorded throughout the anesthesia. The lowest BIS val-

ues in groups I and H were 77 ± 13 and 87 ± 6 , respectively. The cumulative time for BIS values of or below 80 in group I was longer than that in group H. The number of decreased BIS cases, defined as the cases in which the BIS values continuously fell down to 80 or below for more than 10 minutes, in group I was higher than in group H. BIS values in patients who received intrathecal isobaric bupivacaine with fentanyl were lower than those with intrathecal hyperbaric bupivacaine and fentanyl.^[10]

In our study, there was no difference in ephedrine consumption during evaluation. Yentis et al. found that ephedrine, but not phenylephrine, increased BIS values during combined general and epidural anesthesia.^[19]

There have been two limitations to our study. First, the plasma concentrations of local anesthetics and fentanyl were not measured. Second, there was no control group where intrathecal local anesthetic was not given.

CONCLUSIONS

In conclusion, in this double-blind randomized controlled clinical trial on pregnant women undergoing elective cesarean section using spinal anesthesia, the BIS during surgery began to reduce when the patients were injected by both intrathecal and intravenous fentanyl plus intrathecal hyperbaric bupivacaine. However, the greatest reduction from baseline BIS values occurred with adding intravenous fentanyl. In addition, the highest reduction of BIS scores appeared at 30 and 45 minutes after induction of spinal anesthesia.

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