

Comparison of Midazolam and Propofol for BIS Guided Sedation during Regional Anaesthesia

Shailendra D. Chauhan*, Vinayak S. Sirsat*, Satish Deshpande**

Abstract

Bispectral Index (BIS) was introduced by Aspect Medical Systems, Inc in 1994 as a novel measure of level of consciousness by algorithmic analysis of patient's encephalogram during anaesthesia. Besides providing an idea about the hypnotic state of the patient, it also enables titration of anaesthetic agents so as to avoid adverse effects as awareness and side effects of over doses. The ideal sedative medication should provide an early titratable level of sedation, predictable amnesia, decreased anxiety and a rapid recovery with minimal side effects.

In the present study, 60 patients of either sex belonging to ASA grade I and II between age range of 20-60 years posted for elective operative procedures performed under spinal anaesthesia were selected.

All these patients were preanaesthetically evaluated and written valid consent was obtained. All monitors were attached and baseline parameters as pulse rate, mean arterial pressure, respiratory rate and SpO₂ were noted. These 60 patients were divided into 2 equal groups of 30 patients each. In Group M, Midazolam 1% intravenous infusion in 5% Dextrose was started in dose of 0.5mg/kg/hr till BIS value more than 75 was maintained with infusion via syringe pump at 65-85 range and

In group P, Propofol 1% infusion in 5% Dextrose was started in dose of 6mg/kg/hr. Intraoperatively, mean pulse rate, mean arterial pressure, respiratory rate, SpO₂ were monitored and noted at various time intervals. These patients were monitored intra and postoperatively for any side effects. These patients were evaluated for time taken to reach required level of sedation, time taken for recovery, dose required for level of sedation, haemodynamic stability and Alderate score. It was observed that, there was no significant difference in groups M and P at various time intervals but there was statistically significant difference in mean pulse rate, mean arterial pressure amongst the groups at various time intervals. When compared to baseline readings. This difference was more significant in Propofol group as compared to Midazolam group. BIS value in both groups at various time intervals, there was significant difference. Mean time taken to reach required level of sedation was significantly greater in group M as compared to group P. Mean time taken for recovery in group M was significantly greater as compared to group P. The incidence of dreadful complications was comparatively less in both groups. Mean Alderate score on arrival in recovery room in both groups was significant and

insignificant at 1 hour.

Keywords: Regional Anaesthesia; Bispectral Index; Midazolam; Propofol; Less Side Effects.

Introduction

Monitored Anaesthesia care has been new concept developed in modern era of Anaesthesia practice. It has replaced old trend of standby practice for critical ill patients, radio diagnostic procedures, ophthalmic procedures or along with local anaesthesia procedures [1].

Conscious sedation is a minimally depressed level of consciousness that retains the patient's ability to maintain the airway and response to appropriate physical stimulation, verbal command [2]. With conscious sedation only some of the centers in medullary reticular formation and thalamus are depressed in dose dependent manner [3]. Thus, the level of

Author's Affiliation:

*Associate Professor **Professor,
Dept. of Anaesthesiology, Government
Medical College, Latur (Maharashtra).

Corresponding Author:

Satish Deshpande, Professor,
Dept. of Anaesthesiology Government
Medical College Latur, Maharashtra
- 413512.

E-mail:

satdeshpande@rediffmail.com

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sedation additionally provides the benefit of prevention of preservation of protective airway reflexes as in monitored anaesthesia care [3].

Regional anaesthesia techniques most popularly administered has its benefits as less chances of airway compromise, aspiration, facilitation of postoperative analgesia, utility in some medical conditions and operation theater pollution [4].

The concept of monitored anaesthesia care has come to highlight the fact that a vigilance on patient's vital parameters, level of sedation and regional anaesthesia monitoring are as important as in general anaesthesia [5]. From olden days to recent era there was a need of system which measures the depth and level of anaesthesia useful for titration of high dose or low dose administration of anaesthesia drugs [1].

Bispectral Index (BIS) was introduced by Aspect Medical Systems, Inc in 1994 as a novel measure of level of consciousness by algorithmic analysis of patient's encephalogram during anaesthesia and got FDA approval in 1996 [7]. Besides providing an idea about the hypnotic state of the patient, it also enables titration of anaesthetic agents so as to avoid adverse effects as awareness and side effects of over doses. The ideal sedative medication should provide an early titratable level of sedation, predictable amnesia, decreased anxiety and a rapid recovery with minimal side effects.

Propofol has many ideal properties of sedation/hypnosis for use for sedation/analgesia. The context sensitive halftime of Propofol remains short even after

prolonged intravenous infusion (in contrast to Midazolam) and it is easily titratable drug which has an excellent recovery profile. Midazolam is short acting produces sedation, anxiolysis and amnesia, with side effects as significant respiratory depression and prolonged psychomotor impairment [9].

Regional anesthesia is becoming more popular even for day care surgery. Many patients prefer being sedated during operative procedures under regional anaesthesia. Sedation increases patient's acceptance for regional anesthesia and improve patient's well being.

The present study was aimed to compare the efficacy of Midazolam and Propofol as sedative using Bispectral Index (BIS) in patients undergoing operative procedures under spinal anaesthesia to optimize patient comfort.

Material and Method of Study

The present study was a prospective, randomized single blind study carried out to evaluate the efficacy of Midazolam and Propofol in terms of haemodynamic stability, dose requirement as adjuvant to spinal anaesthesia and side effects. 60 patients belonging to ASA grade I and II of either sex with age range between 20-60 years posted for elective operative procedures below umbilicus were studied.

The demographic data was as shown in Table 1.

Table 1: Showing demographic data

Variables	Group M	Group P	t value	p value	Significance
Age in years	41.43 ± 9.69	38.40 ± 11.27	1.11	0.26	NS
Height in cm	158.5 ± 7.01	151.7 ± 7.11	0.98	0.33	NS
Weight in Kg	57.10 ± 6.47	55.33 ± 6.01	1.09	0.28	NS

Mean age in Group M (Midazolam) was 41.43 ± 9.69 years and in Group P (Propofol) was 38.40 ± 11.27 years. Mean height in Group M was 158.5 ± 7.01cm and in Group P was 156.7 ± 7.15cm. Mean

weight was 57.10 ± 6.47 kg In group M and 55.33 ± 6.01 kg in Group P. All these parameters were not statistically significant in both groups.

Sex distribution was as shown in Table 2.

Table 2: Showing sex distribution

Gender	Group M	Group P	X ²	p value	t value
Male	17(56.67%)	16(53.33%)	0.06	0.79	NS
Female	13(43.33%)	14(46.67%)			
Total	30(100%)	30(100%)			

In group M, there were 17 male (56.67%) and 13 female patients (43.33%). In group P, there were 16 (53.35%) male and 14 (46.67%) female patients. There was no significant difference in sex distribution in

both groups.

All these patients were preanaesthetically evaluated for fitness according to ASA grading as

shown in Table 3.

There was no significant difference as far as ASA grading I and II was concerned in both groups.

All these patients were posted for various elective operative procedures which can be performed under spinal anaesthesia as shown in Table 4.

The distribution of operative procedures in 2 groups was almost identical and there was no significant difference.

In both groups, mean total duration of operative procedure as time start of operation to the end of

operation was noted as shown in Table 5.

Mean duration of surgery was 83.00 ± 11.85 minutes in group M and 80.07 ± 15.30 mints in group P. In group M, maximum duration of surgery was 108 minutes and minimum duration was 64 minutes. In group P, maximum duration of surgery was 114 minutes and minimum 55 minutes. The difference in both groups was statistically significant.

All these patients were monitored for changes in vital parameters Intraoperatively. Preoperative (Baseline) mean pulse rate and mean arterial pressure were noted as shown in Table 6.

Table 3: Showing distribution according to ASA grading

ASA Grade	Group M	Group P	X ²	p value	t value
I	24(80%)	25(83.3%)	0.11	0.74	NS
II	6(20%)	5(16.6%)			
Total	30(100%)	30(100%)			

Table 4: Showing operative procedures in both groups

Type of Surgery	Group M	Group P	Total
Vaginal Hysterectomy	8(26.67%)	9(30%)	17(28.33%)
# Femur Shaft	6(20%)	5(16.67%)	11(18.33%)
# Tibia-Fibula	4(13.33%)	5(16.67%)	9(15%)
Inguinal Hernia	9(30%)	8(26.67%)	17(28.33%)
Incisional Hernia	3(10%)	3(10%)	6(15%)
Total	30(100%)	30(100%)	60(100%)

Table 5: Showing Mean Duration of Surgery

Mean Duration in Minutes	Group M	Group P	t value	p value	Difference
Mean Duration	83.00 ± 11.85	80.07 ± 15.30	0.83	0.43	NS

Table 6: Showing preoperative mean pulse rate and mean arterial pressure

Preoperative	Group M	Group P	T value	P value	Difference
Pulse rate Beats/min	83.57 ± 8.65	82.90 ± 10.95	0.27	0.79	NS
Mean arterial pressure	80.40 ± 4.53	82.27 ± 4.88	1.54	0.13	NS

Table 7: Showing mean pulse rate at various time intervals

Time Interval	Group M	Group P	T value	P value	Difference
Preop	83.40 ± 8.07	82.50 ± 10.98	0.36	0.72	NS
2 min	82.40 ± 8.07	79.0 ± 10.81	1.38	0.17	NS
5/6 min	76.67 ± 7.96	73.5 ± 9.90	1.35	0.18	NS
10 min	76.17 ± 7.95	73.88 ± 9.51	1.00	0.31	NS
30 min	74.23 ± 8.65	72.80 ± 9.51	0.61	0.54	NS
60 min	80.40 ± 8.76	75.76 ± 9.08	1.98	0.08	NS
90 min	83.82 ± 9.90	87.18 ± 10.63	0.81	0.42	NS

In group M, preoperative mean pulse rate was 83.57 ± 8.45 and mean arterial pressure was 80.40 ± 4.53 mm of Hg. In group P, mean pulse rate was 82.90 ± 10.95 and mean arterial pressure was 82.27 ± 4.88 mm of Hg. These preoperative mean pulse arte and mean arterial pressure were not statistically

significant.

Intraoperatively, mean pulse rate and mean arterial pressure at various time intervals were noted in both groups as shown in Table 7.

It was observed that, in group M mean pulse rate

was 83.40 ± 8.07 beats/min (at preoperative) gradually decreased to 74.23 ± 8.65 beats/min at 35 minutes. In group P, initial mean pulse rate 82.50 ± 10.98 beats/min gradually decreased to 75.33 ± 10.25 beats/min at 25 minutes. The difference in mean pulse rate at various time intervals was not statistically significant at all time intervals. When mean pulse rate at various time intervals was compared to preoperative pulse rate, it was highly significant with p value <0.01 at 5 minutes and continued to remain till 45 minutes. At 60 minutes the difference was statistically significant p value <0.05 to become non significant at 60 minutes onwards. In groups P, when preoperative mean pulse rate was compared with various time intervals, it was observed that, the difference was highly significant with p value <0.01 at 5 minutes and continued till 45 minutes except 10 and 15 minutes. Again it was statistically significant with p value <0.05 at 60 and 75 minutes and not significant at 90 minutes.

Mean arterial pressure at various time intervals was as shown in Table 8.

In group M, mean arterial pressure at preoperative was 80.27 ± 4.32 mm of Hg decreased to 73.17 ± 6.21

mm at 60 minutes and in group P from 82.07 ± 4.91 mm gradually decreased to 68.37 ± 4.64 mm at 60 minutes.

In group M, maximum mean arterial pressure was 80.32 ± 6.77 at 90 minutes and minimum was 73.17 ± 6.21 mm around 60 minutes. In group P, maximum mean arterial pressure was 82.07 ± 4.91 at preoperative and minimum 68.37 ± 4.64 at 60 minutes. In both groups mean arterial pressure was not statistically significant upto 25-30 minutes but became highly significant at 30 minutes and continued upto 90 minutes. In group M, mean arterial pressure at preoperative reading when compared to various time intervals, at 2 minutes it was not significant but highly significant at 5 minutes and continued to remain high upto 60 minutes, It became significant at 75 minutes and non significant at 90 minutes. In group P, mean arterial pressure at various time intervals upto 90 minutes was highly significant when compared to preoperative readings.

Bispectral index (BIS) value at various time intervals was as shown in Table 9.

Table 8: Showing mean arterial pressure at various time intervals

Time Interval	Group M	Group P	t value	p value	Difference
Preop	80.27 ± 4.32	82.07 ± 4.91	1.51	0.14	NS
2 min	78.27 ± 4.31	78.57 ± 4.91	-0.22	0.83	NS
5/6 min	75.30 ± 4.29	75.00 ± 4.50	0.26	0.79	NS
10 min	76.20 ± 4.50	74.07 ± 4.39	1.86	0.07	NS
30 min	74.23 ± 4.83	68.87 ± 5.15	4.15	0.00	HS
60 min	73.17 ± 6.21	69.00 ± 4.69	2.90	0.00	HS
90 min	78.57 ± 6.10	70.73 ± 4.32	3.60	0.00	HS

Table 9: Showing BIS at various time intervals in both groups

Time Interval	Group M	Group P	t value	p value	Difference
Preop	97.70 ± 0.75	97.30 ± 1.23	1.52	0.13	NS
2 min	94.07 ± 1.45	91.50 ± 2.06	7.54	0.00	HS
5/6 min	85.20 ± 3.53	75.93 ± 3.06	10.86	0.00	HS
10 min	76.87 ± 3.19	72.03 ± 0.91	7.93	0.00	HS
15 min	72.20 ± 0.89	71.67 ± 0.89	2.18	0.03	Significant
25 min	71.83 ± 0.87	70.30 ± 1.51	4.80	0.00	HS
35 min	70.13 ± 0.97	70.17 ± 1.74	-0.10	0.91	NS
45 min	69.20 ± 1.30	71.00 ± 1.72	-4.57	0.00	HS
60 min	71.87 ± 1.59	71.86 ± 2.86	0.02	0.99	NS
90 min	76.50 ± 2.53	74.36 ± 3.04	1.92	0.07	NS

Table 10: Showing incidence of side effects

Side Effects	Group M	Group P	P value	Association
Nausea & Vomiting	4(13.33%)	2(6.66%)	0.67	NS
Restlessness	2(6.66%)	4(13.33%)	0.67	NS
Pain in Arm	0(0%)	2(6.66%)	0.49	NS
Awareness	6(20%)	5(16.67%)	0.99	NS
Hypotension	4(13.33%)	6(20%)	0.73	NS
Bradycardia	4(13.33%)	7(23.37%)	0.51	NS

In group M, BIS value at preoperative level was 97.70 ± 0.75 which gradually decreased to 69.20 ± 1.30 at 45 minutes. In group P, initial BIS value was 97.30 ± 1.23 which gradually decreased to 70.17 ± 1.74 at 35 minutes. There was statistically significant difference in BIS value at 2, 5, 10, 25, 35, 45 minutes when compared to preoperative value in both groups.

Mean time required to reach level of sedation was 10.83 ± 2.26 mint in group M and 6.40 ± 1.2 mints in group P which was significantly less where $p > 9.48$, $t = 0.00$

Mean time required for recovery (BIS value ≥ 90) was 18.03 ± 4.27 mints in group M and 10.13 ± 1.78 mints in group P, significantly less $f = 9.35$, $p = 0.00$

Intraoperatively and postoperatively, all patients were monitored to note side effects related to drugs or technique of anaesthesia and the incidence of side effects was as shown in Table 12.

Overall, the incidence of intraoperative and postoperative side effects / complications was not significant in both groups. Only 23.33% of patients in group P had bradycardia and 20% had hypotension.

Mean Alderate score was noted in both groups. In group M on arrival in recovery room, Alderate score was 8.03 ± 0.32 and after 1 hour it was 9.07 ± 0.25 . In group P, Alderate score on arrival was 8.33 ± 0.61 and at 1 hour was 9.20 ± 0.41 . The difference was significant at arrival and not significant at 1 hour in both groups.

Discussion

Regional anaesthesia offers many advantages over general anaesthesia with some disadvantages as pain at puncture site, fear of pin prick and recall of procedure. These factors stress the importance of sedation with analgesia, anxiolysis and amnesia [8].

Conscious sedation term is used for sedation as for therapeutic or diagnostic procedures and monitored anaesthesia care for sedation to supplement local or regional anaesthesia [10]. Sedation has been shown to increase patient's satisfaction during regional anaesthesia and may be considered as means of increase in patient's acceptance for regional anaesthesia technique [8].

Bispectral index (BIS), is a score derived from the frontal EEG. The property algorithm to determine this score was developed empirically by a computer aided search for statistical correlation between EEG

characteristics and state of consciousness. It provides additional information for standard monitoring techniques that helps to guide the administration of sedative / hypnotic agents. It helps to titrate the level of sedation so that minimum drugs can be used to maintain desired level of sedation [9].

A dose related sedative effect has been demonstrated and non-dose related anxiolysis with Propofol. Amnesia is less with Propofol as compared to Midazolam. Propofol has quicker onset of action, quick induction, easy alteration of sedation level and early recovery. In high doses it causes severe hypotension and bradycardia with some haemodynamic instability. It is ideal agent for sedation during regional anaesthesia [9].

Midazolam has rapid onset of action, produces sedation, excellent amnesia but depresses respiration and arterial pressure only in high doses. It has no specific analgesic action.

In group M, intravenous infusion of Midazolam 1% was started with 0.5mg/kg/hr till BIS value reached upto 75 and titrated infusion was continued to maintain BIS in range of 65-85 via syringe pump. In group P, intravenous infusion of Propofol 1% was started with 6mg/kg/hr till BIS reached 75 and continued with titrated doses to maintain BIS value in range of 65-85. Our technique of administration of drugs was in accordance with Win Ni Ni et al (2005) [10], Khurana P et al (2009) [3] and Patki P et al (2011) [11].

In group M, mean age of patients was 41.43 ± 9.69 years, mean height was 158.5 ± 7.01 cm and mean weight was 57.11 ± 6.47 kg. In group P, mean age of patients was 38.47 ± 11.27 years, mean height was 156.7 ± 7.15 cm and mean weight was 55.33 ± 6.01 kg. There was no statistical difference in these demographic data in both groups. All operative procedures performed were below umbilicus under general surgery or gynecology.

In group M, mean duration of surgery was 83.00 ± 11.85 mints and in group P was 80.07 ± 15.30 mints and there was no significant difference in both groups as far duration of surgery was concerned. Our observations were in accordance with Win Ni Ni et al (2005) [10], Khurana P et al (2009) [3] and Patki A et al (2011) [11]. All preoperative vital parameters were almost similar in both groups and there was no statistical significant difference.

In group M, mean BIS value was 98.43 ± 0.57 where as in group P mean BIS value was 98.27 ± 0.69 and the difference was not significant. These observations were similar to studies of Atanassoff PG et al (1993)

[12], Win Ni Ni et al (2005) [10] and Patki A et al (2011) [11].

Overall, in between groups comparison of mean pulse rate at various time intervals revealed the difference was not significant at all time intervals. But the comparison of mean pulse rate at various time intervals with base line readings within same group showed significant difference in both groups. In between groups, In group P when mean arterial pressure was compared, there was no significant difference upto 30 minutes but it became highly significant at 35 minutes and continued to remain upto 90 minutes. The changes in mean arterial pressure between 2 groups being statistically significant at various time intervals indicated haemodynamic stability in group M as compared to group P.

In the present study, In group M mean BIS value at preoperative was 97.70 ± 0.75 which gradually decreased to 69.20 ± 1.30 at 45 minutes. In group P, BIS value decreased from 97.30 ± 1.23 to 70.17 ± 1.74 at 35 minutes. The difference in mean BIS value in both group at various time intervals was statistically not significant at baseline value but became highly significant at 5 minutes and continued to remain till 15 minutes, then at 25, 45 and 90 minutes. Our observations were comparable with studies of Conard B et al (1900) [13], Hofmann C et al (1999) [14], Gasoarovic S et al (2003) [15], Win Ni Ni et al (2005) [10], Hidaka S et al (2005) [16] and Khurana P et al (2009) [3]. They explained that cardiovascular effects of both drugs minimal when given in slow intravenous infusion with titrated doses. Both of these drugs have cardiac autonomic nervous system depression action during combined spinal-epidural anaesthesia. They observed that, Propofol to be more potent than Midazolam in resulting sympatholytic activity during regional anaesthesia. Our observations can be explained on above grounds as we have used minimum titrated doses of both drugs.

In group M, mean time taken to reach required level of sedation was 10.83 ± 2.26 minutes and in group P it was 6.4 ± 1.2 minutes. The difference was statistically highly significant as more time was required in group M as compared to group P. In group M, mean time required for recovery (BIS) was 18.03 ± 4.27 and in group P it was 10.13 ± 1.78 mints and the difference was statistically significant. The of recovery was more in group M as compared to group P. Fanard L et al (1988) [17], Wilson E et al (1990) [18], Pratila MG et al (1993) [19] Atanssoff PG et al (1993) [12], Takeshita M et al (1998) [20], Gasparovic S et al (2003) [15], Yaddanapudi S et al (2007) [21], Khurana P et al

(2004) [3], Patki A et al (2011) [11], Weinbroum AA et al (1997) [22], Sasaki T et al (2001) [23] and Nishiyama M et al 2004) [24] have all observed that recovery was faster with Propofol as compared to Midazolam. Our observations correlate to above authors.

In group M, mean maintenance dose for sedation was 0.12 ± 0.12 mg/kg/hr while in group P was 2.19 ± 0.31 mg/kg/hr. The dose requirement of Propofol was more as compared to Midazolam. Above authors also quotes less dose requirement with Midazolam than Propofol.

The incidence of dreadful side effects Intraoperatively as well as postoperatively was negligible in both groups as the doss used were therapeutically titrated and low doses. Many of the authors observed that Midazolam produced less side effects with effective amnesia while Propofol was associated with less postoperative sedation, drowsiness, confusion and amnesia with more rapid recovery.

In present study, on arrival in recovery room, mean Alderate score was 8.03 ± 0.32 in group M and 8.33 ± 0.61 in group P. The difference was significant. At one hour, mean Alderate score was 9.07 ± 0.25 in group M and 9.20 ± 0.41 in group P and the difference was not significant. Our observations were corresponding to Dortwine R et al (1988) [25], Murry LU et al (1989) [7], Wilson E et al (1990) [18], Conard B et al (1900) [13] and Pratik MG et al (1993) [19]. They noted Propofol to be superior to Midazolam due to shorter recovery time. With Propofol there is significantly faster restoration of higher mental functions as compared to Midazolam.

Summary

In the present study, 60 patients of either sex belonging to ASA grade I and II between age range of 20-60 years posted for elective operative procedures performed under spinal anaesthesia were selected. The patients with overall contraindications for spinal anaesthesia with central nervous system disorders were excluded from study.

All these patients were preanaesthetically evaluated and written valid consent was obtained. All monitors were attached and baseline parameters as pulse rate, mean arterial pressure, respiratory rate and SpO₂ were noted. Intravenous infusion was started with Ringer lactate and under all aseptic precautions spinal anaesthesia with 0.5% Bupivacaine 3-5ml was injected in subarachnoid

space. These 60 patients were divided into 2 equal groups of 30 patients each. In Group M, Midazolam 1% intravenous infusion in 5% Dextrose was started in dose of 0.5mg/kg/hr till BIS value more than 75 was maintained with infusion via syringe pump at 65-85 range. In group P, Propofol 1% infusion in 5% Dextrose was started in dose of 6mg/kg/hr till BIS d" 75 and titrated to maintain BIS value in range of 65-85. Intraoperatively, mean pulse rate, mean arterial pressure, respiratory rate, SpO₂ were monitored and noted at various time intervals. These patients were monitored intra and postoperatively for any side effects as nausea, vomiting, shivering, bradycardia, hypotension, respiratory depression etc. and treated accordingly. These patients were evaluated for time taken to reach required level of sedation, time taken for recovery, dose required for level of sedation, haemodynamic stability and Alderate score. It was observed that, there was no significant difference in groups M and P at various time intervals but there was statistically significant difference in mean pulse rate, mean arterial pressure amongst the groups at various time intervals. When compared to baseline readings. This difference was more significant in Propofol group as compared to Midazolam group. BIS value in both groups at various time intervals, there was significant difference. Mean time taken to reach required level of sedation was significantly greater in group M as compared to group P. Mean time taken for recovery in group M was significantly greater as compared to group P. The incidence of dreadful complications was comparatively less in both groups. Mean Alderate score on arrival in recovery room in both groups was significant and insignificant at 1 hour.

Conclusions

From the present study, it was concluded that Midazolam and Propofol both drugs are effective sedative agents during spinal anaesthesia. And can be easily titrated to maintain desired BIS value. The time taken to reach required level of sedation (BIS d" 75) was earlier with Propofol as compared to Midazolam.

The mean dose required to maintain level of sedation was 0.12 ± 0.02 mg/kg/hr for Midazolam and 2.19 ± 0.31 mg/kg/hr for Propofol. The mean time required for recovery was earlier with Propofol than Midazolam. Midazolam provided better haemodynamic stability as compared to Propofol as mean arterial pressure was significantly decreased in Propofol group than Midazolam group. The

incidence of dreadful side effects was less in both groups. So both of these are equivalent as far efficacy is concerned during regional anaesthesia (spinal anaesthesia) for BIS control.

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