Clinical Investigation

Arousal time from sedation during spinal anaesthesia for elective infraumbilical surgeries: Comparison between propofol and midazolam

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Access this article online
Website: www.ijaweb.org
DOI: 10.4103/0019-5049.138972
Quick response code

ABSTRACT

Background and Aims: Studies have already compared propofol and midazolam as sedatives during regional anaesthesia. A few studies have focused on recovery characteristics and very few have utilised both instrumental and clinical sedation monitoring for assessing recovery time. This study was designed primarily to compare arousal time from sedation using propofol with that of midazolam during spinal anaesthesia for infraumbilical surgeries, while depth of sedation was monitored continuously with bispectral index (BIS) monitor. The correlation between the BIS score and observer's assessment of awareness/sedation (OAA/S) score during recovery from sedation was also studied. **Methods:** A total of 110 patients were randomly assigned to receive either propofol (Group P, n = 55) or midazolam (Group M, n = 55). Patients in the Group P received bolus of propofol (1 mg/kg), followed by infusion at 3 mg/kg/h; Group M received bolus of midazolam (0.05 mg/kg), followed by infusion at 0.06 mg/kg/h and titration until BIS score 70 was achieved and maintained between 65 and 70. OAA/S score was noted at BIS 70 and again at BIS 90 during recovery. The time to achieve OAA/S score 5 was noted. Spearman's correlation was calculated between the arousal time from sedation and the time taken to reach an OAA/S score of 5 in both the study groups. **Results:** Arousal time from sedation was found lower for Group P compared to Group M (7.54 ± 3.70 vs. 15.54 ± 6.93 min, respectively, P = 0.000). The time taken to reach OAA/S score 5 was also found to be lower for Group P than Group M (6.81 ± 2.54 min vs. 13.51 ± 6.24 min, respectively, P = 0.000). **Conclusion:** A shorter arousal time from sedation during spinal anaesthesia can be achieved using propofol compared with midazolam, while depth of sedation was monitored with BIS monitor and OAA/S score. Both objective and clinical scoring correlate strongly during recovery from sedation.

Key words: Bispectral index monitoring, midazolam, propofol, sedation, spinal anaesthesia

INTRODUCTION

Stress factors in operation room and block level mismatch with surgical area may contribute to discomfort, anxiety and restlessness in patients under spinal anaesthesia.[1] Sedation is a valuable tool to provide general comfort for the patient. It may provide freedom from specific discomfort and can impart some amnesia for the block procedure and surgical operation. Thus, judicious use of sedation can make surgeries under spinal anaesthesia more comfortable for the patient, the surgeon and the anaesthetist. Thus, it can increase the patient's acceptance of regional anaesthetic technique.[2] Spinal anaesthesia itself can impart some sedative effects.[3] The interaction between spinal local anaesthetics and sedatives can lead to an augmentation of sedation, thereby decreasing the requirement of propofol or midazolam to obtain a desired level of sedation.

How to cite this article: Bagchi D, Mandal MC, Basu SR. Arousal time from sedation during spinal anaesthesia for elective infraumbilical surgeries: Comparison between propofol and midazolam. Indian J Anaesth 2014;58:403-9.

Oversedation may jeopardise the safety of the patient. While levels of sedation progress in a dose-response continuum, it is not always possible to predict precisely how an individual patient will respond to a particular dose.[4] Oversedation may be associated with untoward effects of respiratory and cardiovascular depression resulting in higher chances of airway instrumentation and hypotension leading to a prolonged stay in the post-anaesthetic care unit, entailing increased burden on staff, bed availability and associated costs.[5] Appropriate monitoring of depth of sedation thus remains important, as also the search for an agent with a shorter recovery time. Midazolam, a short-acting benzodiazepine, is frequently used as a sedative during procedures under spinal anaesthesia. It has a property of rapid onset and offset of action after intravenous (IV) injection. It has the advantage of producing anxiolysis and amnesia. Propofol, a non-benzodiazepine anaesthetic agent, is frequently being used as an IV sedative agent during regional anaesthetic procedures, as it has a quick onset and offset of action with easy arousability. Lower doses of propofol as sedative also produces amnesia and anxiolysis, but has the propensity of greater cardiovascular and respiratory depression when used in higher doses.[6] There are studies comparing sedation with propofol and midazolam during regional anaesthesia.[6-8] However, only a few studies have focused on their recovery characteristics.[7,8] Bispectral index (BIS) monitoring may be helpful when oversedation has to be avoided because clinical scales do not allow a discrimination of deep sedation.[5] Only one study[8] has utilised the BIS monitor for assessing the recovery time.

Hence, we envisaged this study to compare the characteristics of recovery from sedation while patients were sedated either with propofol or midazolam under BIS monitoring during spinal anaesthesia for infraumbilical surgeries. The two drugs have been evaluated with respect to arousal times from sedation (primary outcome). Correlation between the observed BIS and observer's assessment of awareness/sedation (OAA/S) scores was also analysed.

METHODS

The present study compared the two drugs propofol and midazolam for intra-operative sedation during spinal anaesthesia in respect to 'arousal time from sedation' following stoppage of infusion. The arousal times were assessed by utilising BIS score[9] and OAA/S score.[10] We also analysed the correlation between the two observed arousal times. Intra-operative haemodynamic changes and patients' satisfaction regarding quality of intra-operative sedation by utilizing 7-point Likert-like verbal rating scale[11] were also noted.

Patients of either sex with age between 18 and 60 years complying with American Society of Anesthesiologists (ASA) physical status I and II criteria, posted for elective infraumbilical operations (surgical, gynaecological, or orthopaedic) of approximate 90 min duration were selected. Patients not willing to accept spinal anaesthesia, those not willing to receive sedation during surgery, or having any contraindication to spinal anaesthesia were excluded. The study commenced after getting the permission from the Institute's Ethics Committee. Informed consent was taken from individual before the inclusion.

Considering a difference of 30% regarding the arousal time to be clinically significant and taking an α error of 0.05 and power of the study (1-β) to be 80%, the number of patients was calculated to be 44 in each group. Expecting a dropout of 20%, a total of 110 patients were recruited. Using lottery method, they were randomly assigned to receive either propofol (Group P, $n = 55$) or midazolam (Group M, $n = 55$). The weight and height of all patients were noted during the pre-anaesthetic checkup. They were also given a demonstration about the use of the 7-point Likert-like verbal rating scale to express their satisfaction about the quality of sedation they would receive during the intra-operative period. This randomised controlled study was registered with Clinical Trial Registry of India with number 'CTRI/2012/08/002934'.

In the pre-operative room, one large bore (18G) IV cannula was established and an infusion started with Ringer's lactate at 15 ml/kg over 30 min. Premedication was given with injection ranitidine 50 mg, injection ondansetron 4 mg and injection. tramadol 50 mg IV slowly. After shifting the patient to the operating room, multichannel monitor (non-invasive blood pressure, electrocardiogram, pulse oximeter) was attached and the baseline parameters (mean arterial pressure [MAP], heart rate [HR] and peripheral arterial oxygen saturation [SpO_2]) were recorded. The anaesthesia machine with resuscitating facilities was kept ready for use in emergency.

The forehead and both the temples of the patient were cleaned with spirit and the four electrodes of BIS®

monitor (Aspect Medical Systems, Inc., Boston; A-2000 BIS XP Model) were attached following standard recommendations.[12] The infusion pump was readied with injection propofol or injection midazolam as per the study group. Spinal anaesthesia was given in the left lateral decubitus position with 2.5–3.0 ml of 0.5% bupivacaine heavy using Quincke needle (26G) at the L3–L4 interspinous space. After a sensory block to T6, sedation was initiated as appropriate for the group of study and the surgery was started.

The patients in the Group P were given a bolus of propofol (1 mg/kg) followed by infusion of propofol (at 3 mg/kg/h). The Group M received a bolus of midazolam (0.05 mg/kg), followed by infusion of midazolam at 0.06 mg/kg/h. The infusion was continued until a BIS score of 70 was reached. At this point, the OAA/S score was also noted as a clinical measurement of the patient's sedation status. The infusion was then titrated to maintain the BIS score between 65 and 70. MAP was measured continually at 5 min intervals and HR, SpO_2 were monitored continuously throughout the surgery. All parameters were documented at 10 min intervals until arousal of the patient. Infusion was stopped approximately 5 min before the end of surgery.

Bispectral index score was observed continuously after the induction of spinal anaesthesia till the arousal of the patient. The arousal of the patient was defined as achieving a BIS score of 90. The arousal time from sedation (i.e. time from stoppage of infusion of study drug till a BIS score of 90 is achieved) was recorded. At this point, OAA/S score was observed. The time taken to reach OAA/S score of 5 (patient is awake clinically) was also noted. Correlation between the 2 times was derived from the recorded data to determine the correlation between electro-encephalogram (EEG) defined and clinical based recovery profiles.

The patient's satisfaction with the sedation was assessed by the 7-point 'Likert-like verbal rating scale' with some questions like 'where will you put your experience with this sedation on this scale?' in a language which the patient understands, at a point of time when the patient had a mental state suitable for communication.

Data were charted on the Excel Workbook (Microsoft Office Home and Student 2007, Microsoft Corporation, One Microsoft Way Redmond, WA 98052 USA) and analyzed using Statistical Package for the Social Sciences (SPSS) for Windows (version 12.0, SPSS Inc., Chicago, IL, USA). $P < 0.05$ was taken to be of statistical significance.

RESULTS

The study spanned from July 2011 to April 2012. In Group P, two patients had to be converted to general anaesthesia and in one, surgery ended much earlier than in the study protocol. In Group M, two patients needed general anaesthesia and two patients had surgeries of much shorter duration than in study protocol. These patients were excluded from data analysis. Thus, data from 103 patients (Group P [$n = 52$], Group M [$n = 51$]) were analysed. The Groups P and M were found to be comparable in respect of age, weight, height, sex distribution, the ASA physical status and duration of surgery [Table 1].

The intra-operative haemodynamic parameters (MAP and HR) and the peripheral oxygen saturation were compared at various time points. The MAP and the HR were lower in the Group P than in Group M, but the intra-group MAP and HR in both the groups were stable throughout. The MAP and HR [Figures 1 and 2] showed a slight rise nearing the end of surgery and recovery in both groups. In both groups, the SpO_2 values were distributed in an almost linear fashion with no wide variations.

The arousal time from sedation was significantly lower for the Group P when compared to Group M ($P = 0.000$); the time taken to reach an OAA/S score of 5 was also found to be lower for Group P ($P = 0.000$) as cited in Table 2.

Table 1: Demographic profile

Variable	Group P (*n*=52)	Group M (*n*=51)	*P* value
Age (years)	37.21±10.96	37.20±11.46	0.613
Height (cm)	165.88±7.60	164.48±8.48	0.091
Weight (kg)	58.38±9.03	56.61±7.49	0.075
Number of males* (%)	37 (71.2)	27 (52.9)	0.057
Number of females* (%)	15 (28.8)	24 (47.1)	0.057
ASA physical status I* (%)	43 (82.7)	41 (80.4)	0.763
ASA physical status II* (%)	9 (17.3)	10 (19.6)	0.763
Duration of surgery (min)	73.08±22.5	73.12±24.03	0.756

*Categorical data; analysis done with Chi-square test. Values are expressed in *n* (%). The rest are numerical data; analysis done with independent sample *t*-test. Values are expressed in mean±SD *P*<0.05 is taken to be statistically significant. Group P – Patients receiving injection propofol; Group M – Patients receiving injection midazolam. ASA – American Society of Anesthesiologists; SD – Standard deviation

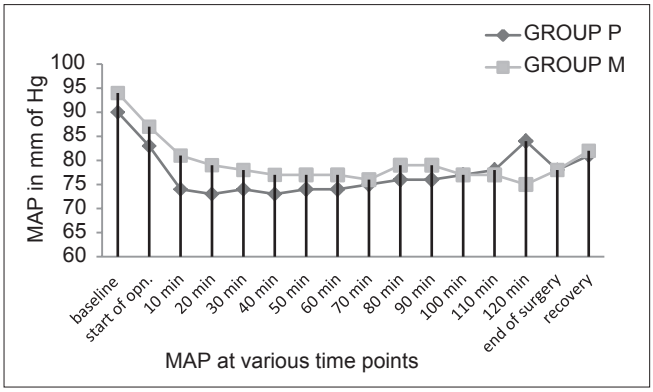

Figure 1: Haemodynamic parameters: Mean arterial pressure. Group P - patients receiving injection propofol; Group M - patients receiving injection midazolam

Table 2: Recovery characteristics

Variable (time taken in min)	Group P (*n*=52)	Group M (*n*=51)	*P* value
Arousal time from sedation (BIS 90)	7.54±3.70	15.54±6.93	0.000
Time taken to reach an OAA/S score of 5	6.81±2.54	13.51±6.24	0.000
OAA/S score 4 at BIS 90* (%)	13 (25)	12 (23.5)	0.862
OAA/S score 5 at BIS 90* (%)	39 (75)	39 (76.5)	0.862

Numerical data; analysis done with independent sample *t*-test. Values are expressed in mean±SD. *Categorical data; analysis done with Chi-square test. Values are expressed in *n* (%). *P*<0.05 is taken to be statistically significant. Group P – Patients receiving injection propofol; Group M – Patients receiving injection midazolam. SD – Standard deviation; BIS – Bispectral index; OAA/S – Observer's assessment of awareness/sedation

The mean arousal time from sedation (BIS score 90) with injection propofol was 7.54 ± 3.70 min, whereas, with injection midazolam it was 15.54 ± 6.93 min, the difference being statistically significant. The time taken to reach an OAA/S score of 5 was 6.81 ± 2.54 min with propofol versus 13.51 ± 6.24 min with midazolam. At BIS score of 90, the point of recovery, the number of patients with OAA/S score of 4 were 13 (in Group P) and 12 (in Group M) respectively, and those with OAA/S score of 5 were 39 (≥75% patients) in either of Groups P and M.

Spearman's correlation was calculated between the arousal time from sedation and the time taken to reach an OAA/S score of 5 in both the study groups. In Group P, the Spearman's correlation was 0.890 (P = 0.000), which was very strong, and in Group M, it was 0.837 (P = 0.000), which was also strong. This is also evident from the Figure 3 showing near-parallel graphs (within a group) when the 'arousal time from sedation' and the 'time taken to reach an OAA/S score of 5' was plotted on a scatter diagram.

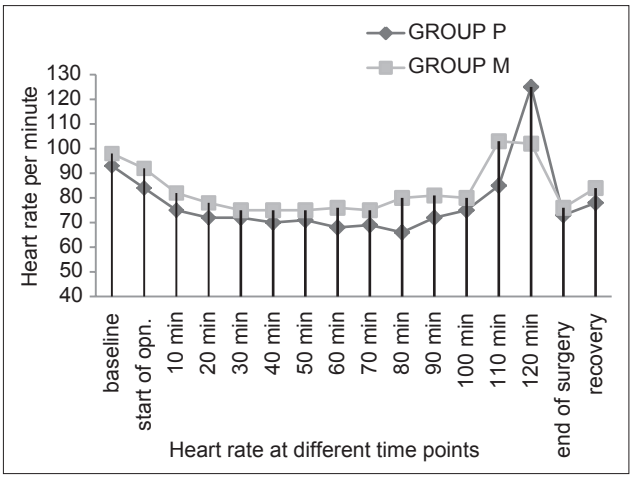

Figure 2: Haemodynamic parameters: Heart rate. Group P - patients receiving injection propofol; Group M - patients receiving injection midazolam

The patients' satisfaction scores on the 7-point Likert-like verbal rating scale were comparable in both the groups [Table 3].

DISCUSSION

In the present study, the time to reach BIS score of 90 (arousal time from sedation) was lower with injection propofol than midazolam (7.54 ± 3.70 min and 15.54 ± 6.93 min, respectively). Similarly, the patients became clinically awake (time taken to reach an OAA/S score of 5) earlier when sedated with propofol (6.81 ± 2.54 min with propofol vs. 13.51 ± 6.24 min with midazolam). Yaddanapudi *et al*.[6] found that the recovery was quicker with propofol (8.9 ± 2.8 min) than with midazolam (12.5 ± 3.5 min), monitoring sedation clinically. They also found the incidence of hypotension to be greater with propofol. Khurana *et al*.[8] found a recovery at 10.1 min with propofol compared with 18.6 min with midazolam. They also reported a greater fall in the MAP.

The reversibility of sedation is more rapid with cessation of infusion of propofol. This may be due to the higher clearance rate of propofol (around 30 ml/kg/min) with respect to that of midazolam (6-11 ml/kg/min), which is claimed to be a result of extrahepatic metabolism of propofol. Furthermore, the concentration of propofol in the brain falls rapidly owing to its redistribution, leading to quick recovery. In comparison, the concentration of midazolam in the brain tissue has an initial phase of rapid decrease due to redistribution, which is followed by a slower

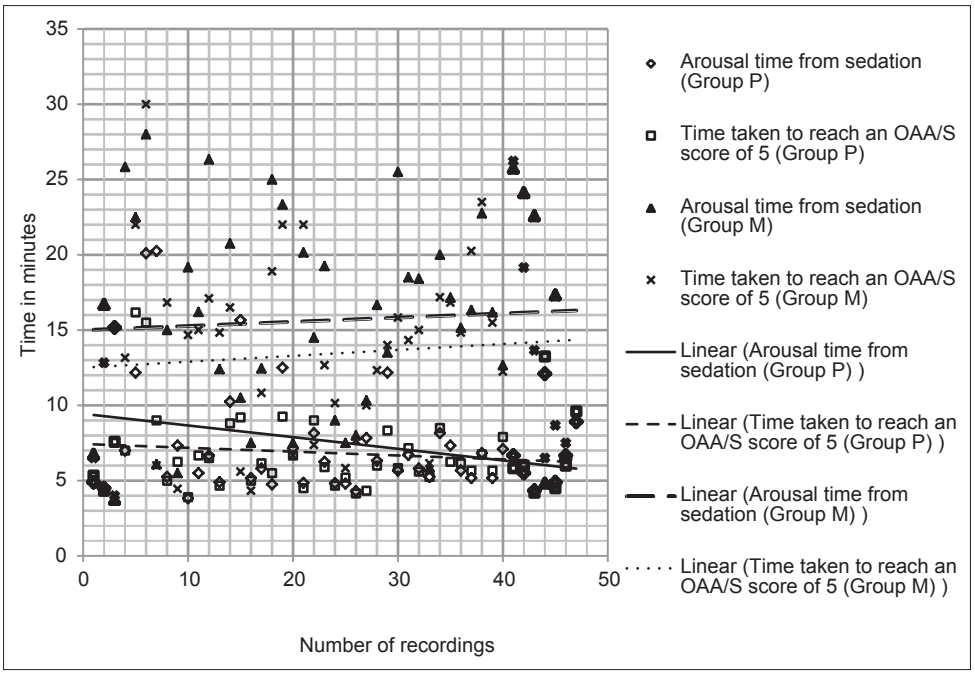

Figure 3: Scatter diagram showing the relation between the arousal time from sedation (bispectral index 90) and time taken to reach an observer's assessment of awareness/sedation score of 5 in both the study groups. Group P - patients receiving injection propofol and Group M - patients receiving injection midazolam

Table 3: Patients' satisfaction score

Variables	Group P (*n*=52) (%)	Group M (*n*=51) (%)	*P* value
Patient satisfaction score of 5	3 (5.8)	7 (13.7)	0.173
Patient satisfaction score of 6	13 (25)	17 (33.3)	0.352
Patient satisfaction score of 7	36 (69.2)	27 (52.9)	0.09

Categorical data; analysis done with Chi-square test. Values are expressed in *n* (%). *P*<0.05 is taken to be statistically significant. Group P – Patients receiving injection propofol; Group M – Patients receiving injection midazolam

phase resulting from the metabolism of the drug. Midazolam on metabolism in the liver produces an active metabolite, 1-hydroxy midazolam, which may be responsible for its delayed offset of action. The emergence time from sedation may thus depend on the total dose of midazolam infused as the metabolite accumulates on prolonged infusion. The metabolites of propofol have not been reported to have any such sedative-hypnotic activity. The context-sensitive half-time, which depends on the clearance of the drug from the body compartments when an infusion is given, is much lower for propofol than for midazolam. This perhaps explains the earlier recovery from sedation with propofol when compared with midazolam.[13]

In the present study, the time to reach BIS score of 90 (arousal time from sedation) was found to tally with the time taken to reach an OAA/S score of 5, at which the patient was awake on clinical observation. There was a strong correlation between the 2 times when they were analysed statistically (Spearman's correlation was 0.890 in Group P and 0.837 in Group M). The OAA/S score was 5 in > 75% of patients in either group at a BIS score of 90, the point of recovery in the study. The above findings imply that both the EEG based monitoring (BIS monitoring) and clinical monitoring (OAA/S) techniques were equally effective in monitoring recovery from sedation, and thus either can be relied upon independent of the other. This is however in contrast to the finding that the BIS score and OAA/S score have poor correlation during onset of sedation while using the same two drugs, more so with midazolam.[14]

Bispectral index monitoring for assessing the level of sedation is appealing as it can help in better titration of propofol resulting in reduced dose requirement of propofol and potential economic benefits compared with clinical monitoring of depth of sedation. Verma *et al*.[2] reported that BIS monitoring reduced propofol requirement by 47% during combined spinal epidural anaesthesia for gynaecological surgeries. They reported that delayed recovery occurred in BIS monitored group as most of the patients maintained desired level of sedation (BIS value around 70), whereas earlier recovery occurred in control group (without BIS monitoring) due to frequent intra-operative awakening

as a result of clinical assessment. It is already established that BIS scores may vary for a particular level of clinical sedation and variable recovery pattern can be seen with different sedatives-hypnotics.[15,16] Hence, it can be said that relying solely on EEG-based monitor (like BIS) may not ensure the attainment of proper recovery. As clinical sedation is our area of interest, the combination of both methods of monitoring can provide complementary facts and can consolidate a better understanding of patient's response to sedation than when using either method singly.[14,16] At least, additional clinical assessment should be done after attainment of the desired instrumental score, if repeated stimulation is to be avoided with the concern of changing sedation level as might occur during clinical monitoring of depth of sedation.

The MAP and HR were found to be lower in patients receiving propofol. Bradycardia and hypotension are possible due to cephalic spread of spinal anaesthesia. Propofol does not change HR significantly and has a minimal action on the sinus node or atrioventricular node. Propofol may however blunt the reflex tachycardia in response to fall in blood pressure.[13] Blunting of the tachycardic response to hypotension may lead to a lower HR among those receiving propofol in the present study. Propofol can produce hypotension when given in bolus or infusion as a result of vasodilatation and negative inotropic action on the heart.[17] Midazolam also produces hypotension to a lesser magnitude, only when it is given as an induction agent which entails a higher dose over a short time. This hypotension may be due to its curtailing effect on sympathetic tone during onset of anaesthesia.[18] This difference in the mechanism of hypotension may have resulted in the lower MAP in patients receiving propofol compared with midazolam in this study. During recovery, the MAP and HR increased, probably due to cessation of infusion and thus waning of the effect.

The study was not blinded owing to limited availability of human resources. Use of target-controlled infusion with patient-controlled feedback was also not possible owing to lack of resources. Placebo-controlled study design was not followed because the authors considered it to be unethical to give sedation to one group while denying sedation in other group of patients. Further studies after elimination of these limitations may yield newer aspects of observation.

CONCLUSION

A shorter arousal time from sedation during spinal anaesthesia can be achieved using propofol compared with midazolam while monitoring the depth of sedation with BIS monitor. Similar findings were evident when clinical sedation score was analysed and both the monitoring systems were found to correlate strongly during the recovery from sedation.

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Source of Support: Nil, **Conflict of Interest:** None declared

Announcement

Conference Calendar Details

Name of the conference: 62nd Annual National Conference of the Indian Society of Anaesthesiologists, ISACON 2014
Date: 25th to 29th December 2014
Venue: Velammal Medical College "Velammal Village", Madurai – Tuticorin, Ring Road, Annupanadi, Madurai – 625009, Tamil Nadu, India
Organising Secretary: Prof. Dr. S C Ganesh Prabhu, ISACON 2014, Institute of Anaesthesiology, Government Rajaji Hospital, Panagal Road, Madurai – 625 020, Tamil Nadu, India
Contact: +91 93448 17143, 94434 96835
E-mail: isaconmadurai2014@gmail.com
Website: www.isacon2014.com

Name of the conference: ISA VISZAC 2014 - SOUTH ZONE
Date: 22nd to 24th August 2014
Venue: Amcosa Hall, Visakhapatnam
Organising Secretary: Dr. A Satyanarayana
Contact: +91 98491 26512
E-mail: isaconmadurai2014@gmail.com
Website: www.viszac2014.com

Name of the conference: ISAWBCON 2014
Date: 19th to 21st September 2014
Venue: SILIGURI – WEST BENGAL
Organising Secretary: Dr. Sabyasachi Das
Contact: +91 98320 12131
E-mail: sabyasachi1968@gmail.com

Name of the conference: 17TH RAJASTHAN STATE CONFERENCE 2014
Date: 04th to 5th October 2014
Venue: Tantia General Hospital, Sukhadiya Marg, Sri Ganganagar, Rajasthan
Organising Secretary: Dr. Seema Maheshwari
Contact: +91 94621 78561
E-mail: info@rajisacon2014.in
Website: www.rajisacon2014.com

Name of the conference: KISACON 2014
Date: 9th to 12th October 2014
Venue: SDM College of Medical Sciences and Hospital, Dharwad
Organising Secretary: Dr. Shyam Sunder Kamath
Contact: +91 99004 13473
E-mail: kisacon2014@gmail.com
Website: www.kisacon2014.com

Name of the conference: ISACON KERALA 2014
Date: 10th to 12th October 2014
Venue: IMA House, Near J N I Stadium, Ernakulam, Kerala
Organising Secretary: Dr. Shyam Sundar
Contact: +91 98950 93011
E-mail: isaconkerala2014@gmail.com

Name of the conference: NEZACON 2014 - NORTH EAST ZONE
Date: 11th to 12th October 2014
Venue: Department of Anaesthesiology, AGMC & GBP Hospital, Agartala, Tripura
Organising Secretary: Dr. Biswajit Chakraborthi
Contact: +91 94364 68156
E-mail: chakrabortibiswajit2@gmail.com

Name of the conference: UPISACON – 2014
Date: 17th to 19th October 2014
Venue: M.L.N Medical College, Allahabad
Organising Secretary: Dr. P S Malviya
Contact: +91 94528 34286

Name of the conference: National CME ISAJAC 2014 & BJSAC 2014 - EAST ZONE CONFERENCE
Date: 7th to 9th November 2014
Venue: DSA City Branch – Dhanbad, Jharkand
Organising Secretary: Dr. Dinesh Kumar Singh
E-mail: dksdhn@gmail.com
Website: www.isajac2014.in

Name of the conference: 7th NATIONAL CONFERENCE, ASSOCIATION OF OBSTETRIC ANAESTHESIOLOGISTS (AOA)
Date: 17th to 19th October 2014
Venue: K N UDUPA Auditorium, Banaras Hindu University, Varanasi
Organising Secretary: Dr. P Ranjan
Contact: +91 94159 86684
E-mail: aoacon2014@gmail.com
Website: www.aoacon2014.com

Name of the conference: 17th MISACON and 11th WISACON 2014
Date: 31st October to 2nd November 2014
Venue: Hotel Grand International, Barshi Road, Latur, Maharashtra
Organising Secretary: Dr. Santosh Gitte
Contact: +91 98223 35235
E-mail: misaco2014@rediffmail.com
Website: www.misaco2014.com

Name of the conference: 15th Annual Conference of Indian Society of Anaesthesiologists-North Zone (NZISACON 2014)
Date: 31st October to 2nd November 2014
Venue: Acharya Srichander College of Medical Sciences and Hospital, Jammu
Organising Secretary: Dr. Nandita Mehta
Contact: +91 94191 95424
E-mail: drnanditamehta@gmail.com
Website: http://nzisacon2014.org

Name of the conference: RSAPCON 2014 - 24th Annual Conference of Research Society of Anaesthesiology Clinical Pharmacology
Date: 14th to 16th November 2014
Venue: Department of Anaesthesiology & Pain Management HIMS, HIHT University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand - 248140
Organising Secretary: Dr. J P Sharma
Contact: +91 94117 18466
E-mail: info@rsacpcon2014.com

Name of the conference: ICA CON - 2014
Date: 21st to 23rd November 2014
Venue: Narayana Hrudayala Hospitals #258/A, Bommasandra Industrial Area Anekal Tk, Bangalore, Karantaka
Organising Secretary: Dr. Muralidhar Kanchi
Contact: +91 99801 63108
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