Current Sedation Practices in Procedures under Spinal Anaesthesia (SA)

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ABSTRACT

Introduction: Peri-operative anxiety and stress associated with procedures under Spinal anaesthesia (SA) is common and sedation may help improving compliance of the patient and quality of SA. There is no standard sedation protocol for SA. Study aimed to observe the various sedation protocols practiced in our institute during SA with regard to drugs used and their dosages, sedation levels, effect on the duration of SA and to assess the patient satisfaction level.

Material and methods: This was a prospective observational study comprised of patients undergoing elective surgeries under SA. IV sedation was given as per the attending anaesthesiologist's discretion after SA. We noted hemodynamic parameters, RSS, two-dermatomal regression time, Patient satisfaction scores etc. Epi Info 7.2 software was used for statistical analysis.

Results Total 500 patients received Dexmedetomidine (189), Midazolam (301) and Propofol (10) as IV sedation. Mean time required for regression of two-dermatomal sensory levels and for rescue analgesia requirement was prolonged in Dexmedetomidine (121.64, 203.75 mins resp.), as compared to Midazolam and Propofol. Mean Ramsay Sedation Score (2.4- 3) and Patient satisfaction scores (6-7.5) were comparable in all the drugs. Hemodynamic parameters were stable and comparable. No hypotension, respiratory depression seen except bradycardia (HR<50) noted in 4 patients of Dexmedetomidine.

Conclusion: Drugs used for sedation in 500 patients were Dexmedetomidine, Midazolam and Propofol. All the drugs provided optimum sedation without respiratory depression with stable hemodynamics and good patient satisfaction. In addition, Dexmedetomidine increased durations of sensory anaesthesia and post-operative analgesia.

Keywords: Sedation, Spinal Anaesthesia (SA), RSS, Patient Satisfaction

INTRODUCTION

Spinal anaesthesia (SA) is a very commonly used procedure in modern day anaesthesia practice. It has many advantages like cardiovascular and respiratory stability, preservation of protective airway reflexes, rapid postoperative recovery and early family contact.[1] Few drawbacks associated with SA are sympathectomy, fear and anxiety associated with the procedure and needles, recall and awareness during the surgical procedure.[1,2] Literature mentions that patients are often disinclined to be completely awake during procedure under SA and other regional anaesthesia (RA). Sedation and anxiolysis may improve patient's compliance and the advantages of SA may be fully appreciated. Advantages of sedation in SA as mentioned by authors in various studies are providing anxiolysis, sedation and amnesia increasing patient satisfaction and reducing postoperative recall.[3-6] Sedation helps to increase comfort, especially during uncomfortable positioning and decrease the stress responses to surgery and anesthesia and may help prolong the action of SA. Sedation has been shown to improve patient satisfaction during regional anaesthesia (RA) and thus, may be considered as a means to increase the patient's acceptance of procedures under SA.[5-8]

Drugs used for intravenous (IV) sedation include benzodiazepines such as Midazolam; alpha agonists such as Dexmedetomidine and Clonidine; anaesthetic drugs like Propofol and Ketamine in subanaesthetic doses; and opioids such as Fentanyl, Remifentanil and Pentazocine.[4] Many authors have studied variety of sedative drugs in SA and other RA and some found Propofol and Ketamine combination is best, others discovered Remifentanil infusion as very good. Some authors have found Dexmedetomidine as best agent for sedation under SA while others has mentioned Midazolam and Propofol are of choice.[3-10] However there is no consensus among authors and no standard ideal sedation protocol to be used in SA and these drugs are being used as per the attending anaesthesiologist's discretion.

In our Institute IV sedation in SA is given in some procedures at attending anaesthesiologist's discretion and no particular protocol is followed. Literature mentions awareness and anxiety during RA may lead to patient dissatisfaction and they may perceive it as low quality of anaesthesia as patient's perception regarding general and RA is not clear.[2,5,6] In today's era enhancing patient-doctor relationship being an important consideration and improvement upon patients comfort and satisfaction will go a long way. Hence we aimed to study the sedation practices in procedures under SA. This study may help in devising an ideal sedation protocol to be followed in cases of SA which has been our primary focus

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which may help in improving the quality of anesthesia by improving the level of patient satisfaction.

Hence we started the study with objective to observe the various sedation protocols practiced in our institute during spinal anesthesia with regard to drugs used and their dosages, sedation levels, effect on the duration of SA and also to assess the level of patient satisfaction.

MATERIAL AND METHODS

This was an observational prospective study initiated after obtaining approval from the Institutional Ethics and Research Committee (Vide no. ECARP/2016/96) and written informed valid consent from all the patients conducted in a tertiary care teaching public hospital. The study spanned over a period of 12 months from December 2016 to December 2017. Study group comprised of patients undergoing elective infraumbilical surgeries of duration up to 90 minutes (general surgical, urological, gynaecologic and orthopaedic) under SA. We included 18 – 60 years both sexes and American Society of Anesthesiologists (ASA) I-II patients. Pregnant women, patients on sedatives, opioids, antidepressants, patients with anticipated difficult airway (Mallampatti Class III, IV) and patients given combined spinal epidural anaesthesia or any additives in the SA were excluded.

Being observational study patients received standard routine management for SA using 0.5% hyperbaric Bupivacaine as per the attending anaesthesiologist's discretion and sedation was administered once adequate spinal level was achieved and the patient was hemodynamically stable. Following parameters were noted: Age, sex, Surgical procedure, ASA grade, Duration of surgery, Highest sensory level achieved, Sedation drug used, Ramsay Sedation Score (RSS as mentioned in Table 1) was noted after sedation and post-operatively, Time for two- dermatomal regression, Time for rescue analgesia. Heart rate (HR), blood pressure (BP), SpO_2, respiratory rate was noted every 5 minutes for the first 30 minutes, followed by every 10 minutes intra-operatively and post-operatively every 30 minutes for 2 hours and complications if any were noted. At the end of the procedure, patients were asked to assess their level of satisfaction on a scale of 1-10 where 1- completely dissatisfied, and 10-completely satisfied and Patient satisfaction score was noted.

STATISTICAL ANALYSIS

Study population was selected by non-probability convenience sampling method. During the study period all the patients fulfilling inclusion criteria (500 patients) were included in the study.

Data was summarized in MS Excel. Quantitative data (Age, RSS, patient satisfaction score etc) was presented with the help of Mean, Standard deviation (SD), Median and Interquartile range (IQR). Qualitative data (sex, ASA grade, sedation drug etc) was presented with the help of frequency and percentage table. Epi Info 7.2 software was used for statistical analysis. Chi square test and unpaired t test were applied wherever required and 95% confidence interval was taken and p value less than 0.05 were considered as tests of significance. However, given that matching of study groups had not been done; this significance has its limitations.

RESULTS

Sedation score (RSS)	Clinical response
0	Paralyzed, unable to evaluate
1	Awake
2	Lightly sedated
3	Moderately sedated, follows simple commands
4	Deeply sedated, responds to non-painful stimulus
5	Deeply sedated, responds only to painful stimulus
6	Deeply sedated, unresponsive to painful stimulus

Table-1: Modified Ramsay Sedation Scale

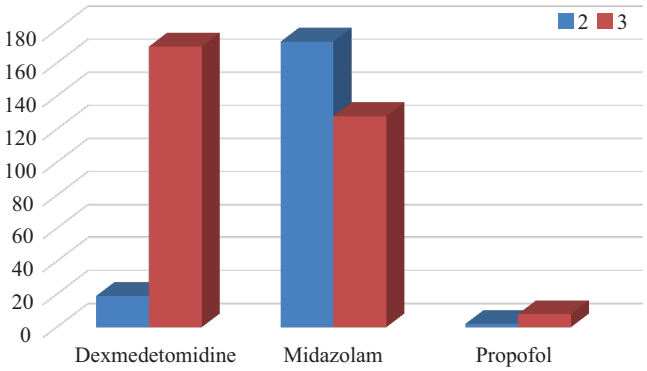

Figure-1: Distribution of patients according to drug and RSS (2, 3) after sedation

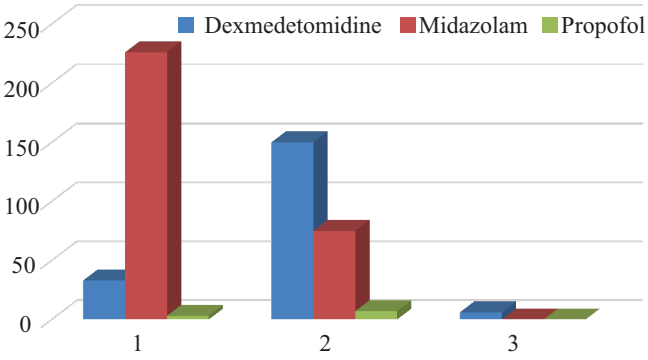

Figure-2: Distribution of patients according to drug and RSS (1, 2, 3) in the postoprative period.

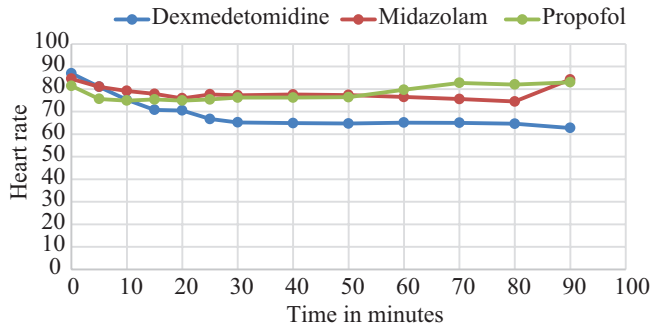

Figure-3: Comparison of intraoperative Heart rate among sedative drugs

Study parameter		Drug Used			p
		Dexmedetomidine	Midazolam	Propofol	
Time for two- dermatomal regression in minutes	Mean	121.64	101.98	103	<0.01
	SD	3.55	3.36	3.68	
Comparison of mean time for rescue analgesia in minutes	Mean	203.75	180.57	182.20	<0.01
	SD	5.21	5.44	6.40	
RSS after sedation	Mean	2.89	2.42	2.80	<0.01
	SD	0.30	0.49	0.42	
Postoperative RSS	Mean	1.85	1.24	1.70	<0.01
	SD	0.43	0.43	0.48	
Patient satisfaction score	Mean	7.05	6.56	6.40	<0.01
	SD	0.58	0.64	0.48	
Intraoperative mean heart rate	Mean	69.49	78.37	77.98	<0.01
	SD	7.37	3.12	3.23	
Postoperative mean heart rate	Mean	76.41	81.44	80.92	<0.01
	SD	5.95	1.63	1.37	
Intraoperative mean arterial pressure	Mean	84.98	84.74	86.63	0.75
	SD	7.11	8.87	5.06	
Postoperative mean arterial pressure	Mean	94.18	93.61	93.92	0.37
	SD	4.75	4.20	3.69	

Table-2: Comparison various study parameters according to sedation drug used

Total 500 patients were studied, out of them 185 (37%) were males and 315 (67%) were females. Dexmedetomidine was administered in 189 patients (37.8%), including 78 males (15.6%) and 111 females (22.2%). 301 patients (60.2%) were given Midazolam, including 104 males (20.8%) and 197 females (39.4%). Propofol was given to 10 patients (2%), consisting of 3 males (0.6%) and 7 females (1.4%). The mean age of patients receiving Dexmedetomidine was 39.15 years (+/- 12.58), Midazolam was 39.21 (+/- 12.46), and Propofol was 26.30 years (+/- 9.93). Drugs used for sedation were in standard dosages as Midazolam (1 mg IV bolus), Dexmedetomidine (0.5 µg/kg over 20 minutes followed by 0.5 µg/kg/hr infusion) or Propofol (50 µg/kg/min infusion which is equivalent to 3 mg/kg/hr). Mean duration of surgery in all the groups were comparable from 55-65 min.

Mean time required for regression of two-dermatomal sensory levels, Mean time for rescue analgesia requirement, RSS after sedation and postoperative RSS and Patient satisfaction score among all the patients in the three drug groups have been depicted in Table 2. This difference among the drugs used was statistically significant with $p<0.01$. However, being observational study since matching of study groups have not been done, this significance has its limitations. Mean heart rate and mean arterial pressure (MAP) in the intra-operative and post operative period has been summarized in table 2. In the Dexmedetomidine group out of 189 patients 170 (89.95%) had a RSS score of 3 after sedation while 19 (10.05%) had a RSS score of 2. With Midazolam, 128 (42.52%) out of 301 patients had a RSS score of 3, while 173 patients (57.48%) had a RSS score of 2. In the Propofol group, 8 (80%) out of 10 patients had a RSS score of 3 and 2 patients (20%) had a RSS score of 2 (Figure 1). Figure 2 shows details of postoperative RSS. No major complications were observed. Intraoperative mean HR was on the lower range in Dexmedetomidine and bradycardia (HR<50) requiring intervention was noted in 4 patients. (Figure 3) No episodes of hypotension, respiratory depression (RR< 10) or desaturation (SpO_2<90%) or nausea, vomiting were seen in any of the patients.

DISCUSSION

In the present study we analysed current sedation practices in procedures under SA. Among 500 patients studied, 189 patients (37.8%) were given Dexmedetomidine, 301 (60.2%) were given Midazolam and 10 (2%) were given Propofol in standard doses. Höhener et al in a review article mentions the use of various sedative drugs in RA, such as Midazolam, Dexmedetomidine, Propofol, Ketamine and opioids such as Fentanyl, Remifentanil and Pentazocine of which Propofol and Remifentanil were found to be the combination of choice for sedation in RA.[4] Dinesh CN et al mentions Dexmedetomidine, Patki et al mentions propofol and midazolam, Güleç H mentions Ketofol as sedative of choice in SA.[9-12] In the current study we observed that Midazolam followed by Dexmedetomidine were preferred drugs for sedation in SA. When attending anaesthesiologist's were asked about choice of particular drug for sedation in SA, they mentioned type and duration of surgery, hemodynamic parameters, preoperative anxiety level and availability of drugs as deciding factors. The demographic parameters of the patients and average duration of surgery were comparable among all the drugs used for sedation in this study.

In the current study the mean time required for regression of two-dermatomal sensory levels was prolonged in Dexmedetomidine (121.64 mins), as compared to Midazolam (101.98 mins) and Propofol (103 mins). Dinesh CN et al (137.4 min), Harsoor et al, Lee et al observed similar finding in dexmeditomidine.[9,12,13] Kaya et al concluded that IV Dexmedetomidine and not Midazolam prolongs the duration of SA and Talakoub et al found no effect of Midazolam on duration of sensory block.[14,15]

Our study also showed that duration of analgesia was

prolonged with Dexmedetomidine as the mean time for rescue analgesia requirement was 203.75 mins, as compared to Midazolam (180.57 mins) and Propofol (182.20 mins). Harsoor et al, Kaya et al Gupta et al and many authors found that duration of analgesia was significantly prolonged with Dexmedetomidine as compared to Midazolam.[9-16] Similar studies by some authors have shown prolongation of sensory anaesthesia and post-operative analgesia in patients receiving intravenous sedation mainly Dexmedetomidine.[12-14]

We found that maximum patients (89.95%) receiving Dexmedetomidine had a RSS score of 3 after sedation. Mean RSS values after sedation were comparable in all the drugs with 2.89 in the Dexmedetomidine, 2.42 in the Midazolam and 2.80 in the Propofol group with satisfactory sedation. No episodes of over-sedation (RSS> 4) were noted in any of the study groups. Harsoor, Dere and Dinesh CN et al found that RSS scores with Midazolam were significantly lower compared to Dexmedetomidine.[9,12,17] However, Kaya et al observed contradictory results with RSS being lower in the Dexmedetomidine as compared with Midazolam.[14] Patki et al mentions equisedative infusion of propofol and midazolam offer good anxiolysis with Propofol having faster onset and recovery while midazolam provides better intraoperative amnesia.[11] Güleç H mentions Ketofol as a good sedative in spinal anesthesia with higher postoperative patient satisfaction and lower pain rates.[10]

Patient satisfaction scores in our study were were comparable among all the drugs as Dexmedetomidine (7.05), Midazolam (6.56) and Propofol (6.40). Bagchi et al, Kaya et al found comparable patient satisfaction scores in sedation in spinal anaesthesia.[7,14] Many authors mention that using understanding patient's expectations and allaying anxiety, providing sedation early in RA and continuous infusion provides better satisfaction scores in patients.[2,3,5,6,18-21]

Hemodynamic parameters were stable and comparable in all the groups with comparable systolic, diastolic BP, MAP and HR. However in the Dexmedetomidine group HR was observed in lower range as compared with those receiving Midazolam or Propofol, and bradycardia (HR<50) requiring intervention was noted in 4 patients. In the current study no other major complication was observed, no episodes of respiratory depression (RR< 10) or desaturation (SpO2<90%) or nausea, vomiting were seen. Bradycardia observed in some patients of Dexmedetomidine group was however not clinically significant and was given appropriate treatment and had no effect on the clinical outcome of the patients. Senses et al, Lee et al, Patki et al showed no significant hemodynamic difference between Midazolam and Dexmedetomidine sedation under spinal anaesthesia.[3,11,13] Dere et al did not observe a significant difference between Midazolam and Dexmedetomidine for MAP, however heart rates were significantly higher and SpO2 values were significantly lower in those who received Midazolam.[17] Bagchi et al found that the MAP and HR were significantly lower in patients receiving Propofol than Midazolam for sedation in spinal anaesthesia.[7] Harsoor et al found that there was a decrease in HR and MAP with Dexmedetomidine sedation during SA.[12]

Among complications many authors mentioned a higher incidence of bradycardia in Dexmedetomidine sedation and incidence of hypotension in Propofol and Midazolam.[10-16] Patki et al also showed the absence of clinically relevant bradycardia and hypotension.[11]

Thus, sedation was associated with good patient satisfaction and stable hemodynamics and also prolonged post-operative analgesia. Attri JP et al mention that use of sedation in RA has increased patient's acceptance and satisfaction. Also improved sedation delivery devices and monitoring of sedation depth has increased accuracy without compromising the safety.[21]

The study was not without limitations as this was an observational prospective study. Proper randomization and matching was not carried out, limiting the utility of comparison between drugs. Hence to generalize the results and improve validity, a multicentric randomized controlled study would be conducted.

CONCLUSION

To conclude, drugs used for sedation in 500 patients in our study during procedures under SA were IV Dexmedetomidine (189), Midazolam (301) and Propofol (10). Dexmedetomidine provided adequate sedation intra-operatively with good patient satisfaction, increased durations of sensory anaesthesia and post-operative analgesia leading to decreased rescue analgesia requirement and minimal occurrence bradycardia which was easily treatable. Midazolam and Propofol were found to be excellent alternatives for sedation during SA however having limited role in prolonging SA and prolonging the requirement of rescue analgesia. They were also associated with good patient satisfaction. Sedating the patient under SA was found to have significant advantages of allaying the anxiety of the patient, inducing sedation as well as amnesia without compromising safety. Patients are often unwilling to be aware during a procedure under SA. Sedation improved patient satisfaction and the patient's acceptance of SA and improvement in the quality of SA. All the three drugs in this study provided optimum sedation without respiratory depression with stable hemodynamics and good patient satisfaction. In addition, Dexmedetomidine increased durations of sensory anaesthesia and post-operative analgesia compared to Midazolam and Propofol.

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