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Original article

MODERATE SEDATION IN SPINAL ANAESTHESIA: A COMPARATIVE STUDY OF EQUISEDATIVE INFUSIONS OF PROPOFOL AND DEXMEDETOMIDINE

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ABSTRACT

Background and Aims: There has been a paradigm shift of focus toward quality of spinal anaesthesia with sedation being an integral aspect of this regional anaesthesia technique. Thus, this study was designed to compare efficacy of intravenous dexmedetomidine and propofol for moderate sedation during spinal anaesthesia.

Material and Methods: A total of 60 patients of age group 18-50 years of American Society of Anaesthesiologists grade I & II, posted for surgeries under spinal anaesthesia were randomly divided in to two groups (*n* = 30 each); Group D received infusion of dexmedetomidine 1 μg/kg over 10 min followed by maintenance infusion of 0.5 μg/kg/h. Group P received infusion of propofol 5 mg/kg/h for 10 min followed by the infusion maintenance of 1.5 mg/kg/h. Level of sedation (using observer's assessment of alertness/sedation score), onset and recovery from sedation, hemodynamic changes, and overall patient's satisfaction were assessed.

Results: The onset and recovery from sedation were significantly earlier with propofol (15.57 ± 1.89 min vs. 27.06 ± 2.26 min; $P < 0.001$) however intra-operative sedation, and overall patient's satisfaction was significantly better with dexmedetomidine group ($p < 0.05$). Duration of postoperative analgesia was significantly prolonged with dexmedetomidine (225.53 ± 5.61 min vs. 139.60 ± 3.03 min; $P = 0.0013$). Mean heart rate and blood pressure were significantly lower in the propofol group ($P < 0.05$).

Conclusion: Dexmedetomidine with its stable cardio-respiratory profile, better sedation, overall patient's satisfaction, and post-Operative analgesia could be a valuable adjunct for intra-operative sedation during spinal anaesthesia.

Key words: Dexmedetomidine, moderate sedation, propofol

INTRODUCTION:

Spinal anaesthesia offers many advantages over general anaesthesia, however, the fear of surgery, the unfamiliar environment like operation room, the sight and sounds of sophisticated instruments, and the masked faces makes the patient panic. The intense sensory and motor block, continuous supine position and the inability to move the body also brings a feeling of discomfort and phobia in many patients [1].

Thus, sedation has been shown to increase patient satisfaction during regional anaesthesia. Moderate sedation is defined as "*A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by mild tactile stimulation. No intervention is required to maintain a patent airway and cardiovascular stability*." Earlier, this kind of sedation was popularly known as "*Conscious Sedation*" but Joint Commission on Accreditation of Healthcare Organization (JCAHO) in 2001 has coined the term *Moderate Sedation* [2].

Many agents have been used for this purpose. Continuous infusion of Propofol is an useful method for sedation because of the easy titratability and rapid emergence. Intravenous (i.v.) Dexmedetomidine prolongs the duration of spinal anaesthesia, provides sufficient sedation, with fewer side effects.

Hence we designed this study to evaluate the sedative, hemodynamic and side effects of i.v. dexmedetomidine and propofol when used for intra-operative moderate sedation along with spinal anaesthesia.

MATERIALS & METHODS

It was an observational analytical study in which effects of Moderate sedation in spinal anaesthesia was observed and analyzed by using two different drugs, Propofol versus Dexmedetomidine . The study was initiated after taking approval from hospital ethical committee. Patients included in this study were informed about the procedure in their own language, and a written informed consent was taken from all of them.

The study was carried out in 60 patients between 18 to 50 years of age, of both genders (male-42 and female-18), weighing 50 to 80 kgs having physical status of American Society of Anaesthesiologists (ASA) i.e. ASA–I (A normal healthy patient) and ASA–II (A patient with mild systemic disease). The Patients who were administered spinal anaesthesia were restricted to lower abdominal and orthopaedic elective surgical procedures which were anticipated to complete within 2 hours were included.

Patients with history of allergic reaction to the study drugs, those with significant cardiac , pulmonary, hepatic or renal dysfunction, Obese patients , those with history of chronic use of sedative drugs, full stomach patients, pregnant patients and epileptic patients were excluded from the study.

The patients were divided into two groups which were:

Group P (n=30) Patients who were administered Propofol for moderate sedation.
Group D (n=30) Patients who were administered Dexmedetomidine for moderate sedation.

The patients were connected to multipara monitors for monitoring non-invasive blood pressure,SpO2, and electrocardiogram. Baseline measurements were recorded. A large vein was chosen for intravenous i.v. access and 18G cannula was secured. Another wide bore intravenous access was established on the forearm of the other limb, for administration of the study drug infusion. All the patients were preloaded with 15 ml/kg of ringer's lactate prior to spinal anaesthesia. Under aseptic precautions, lumbar puncture

was performed at L3-L4 inter vertebral space with 23G Quincke type spinal needle. After free flow of CSF had been obtained, 3.5 ml dose of 0.5% Bupivacaine heavy was injected into the subarachnoid space. Patients were then made to lie in the supine position. Study drugs were started according to the group allocated, after assessment of maximum sensory blockade. Sedative premedication was not given to any patient to avoid interference with results.

Group D (dexmedetomidine group) received an initial dose of 1 mg/kg
infused over 10 min, followed by maintenance of 0.5 mg/kg/h. Group P (propofol group) received an initial dose of 5 mg/ kg/h infused over 10 min followed by maintenance of 1.5 mg/ kg/h. Standardized anaesthetic protocol was followed in all the patients. Heart rate, mean arterial pressure, SpO2 , respiratory rate and sedation score were recorded initially at 5 minute intervals for 10 minutes and later at 15 minute intervals till the end of procedure. Patients were informed to communicate about the perception of any pain or discomfort during surgery. Intra-operative sedation level was assessed using modified observer's assessment of alertness/ sedation scale (OAA/S) [3].

Observer assessment of alertness/sedation scale (OAA/S)

Scores	Descriptions
5	Responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly and/or repeatedly
2	Responds only after mild prodding or shaking
1	Responds only after painful trapezius squeeze
0	No response after painful trapezius squeeze

The onset of sedation was taken as time taken to reach OAA/S score of 4 as it most closely meets the condition of moderate sedation. The infusion of propofol and dexmedetomidine was continued at a constant rate throughout the procedure and was not altered till a sedation score of 3. Level of sedation was assessed at every 5 min interval for the first 10 minutes and later at 15 minute intervals till the end of procedure. The infusion was stopped at time of skin closure.

Duration of effective analgesia (time interval between administration of spinal to first request for supplementary analgesics) and recovery time (time taken to return to sedation score 4 or more on modified OAA/S scale after stopping the infusion of study drugs) was recorded in all the patients studied. Overall satisfaction of patients was also assessed.

All patients were watched for side effects such as nausea, vomiting, hypotension, respiratory depression, shivering, motor weakness, and seizures both intra-operatively and postoperatively. During the procedure, if bradypnea (RR <10) or SpO2 92% or less were recorded, 4 L/min of supplemental oxygen was administered via a nasal cannula and rate of infusion of the drug is reduced, aiming to awaken the patient and to resume his normal breathing. Hypotension (MBP <50) was treated with fast 0.9% normal saline and i.v. bolus of mephenteramine 6 mg and bradycardia (HR <50) with 0.5 mg of i.v. atropine stat, with a reduction in the rate of infusion.

RESULTS

VARIETY OF SURGICAL PROCEDURES	
Indications	**Frequency**
Hernia / Hydrocele	15
Orthopaedic Surgery	12
Apppendicectomy	15
Ovarian Tumours and Mass	03
Tubal ligation	05
Vaginal hysterectomy	10
Total	**60**

All the 60 patients who were enrolled in the study completed the study protocol and included in the data analysis. No spinal anaesthesia failure was observed. There were no significant differences between the groups with respect to patient age, weight or sex. The mean duration of the procedure was similar in the Group D and Group P. The mean time to reach the required level of sedation (OAA/S-4) was observed at 5min in Group P and 10 Min in group D .Recovery time to OAA/S score 4 or more was significantly prolonged in Group D as compared to Group P ($P < 0.001$) .Duration of effective post-op analgesia was significantly prolonged in Group D as compared to Group P.

Demographic and recovery profile		
Demographic and recovery profile	**Group D**	**Group P**
Number of patients	30	30
Age (years)	36.70±9.29	38.40±9.04
Sex (male/female)	20/10	22/8
Weight (kg)	55.53±5.31	55.05±6.05
Mean duration of surgery (min)	62.85±16.18	60.03±18.81
Mean time to reach target level of sedation (Min)	5±1.13	10±0.72
Mean duration of effective analgesia (min)	225.53±5.61	139.60±3.03
Recovery time to OAA/S* score 4 or more (min)	27.06±2.26	15.27±1.89
OAA/S = Observer's Assessment of Alertness/Sedation		

Overall satisfaction was significantly higher in Group D patients(77.50%) as compared to Group P patients(55.0%).All patients in the dexmedetomidine group were satisfied with their anaesthesia and would choose the same technique again. Two patients in the Propofol group would prefer an alternative technique in the future. Baseline MBP was comparable in both the groups. Significant fall in MBP was observed at 5 min in Group P as compared to Group D and this fall persisted throughout the study period. Group D had no significant change observed from baseline. The baseline mean HR was comparable

among both the groups. Significant decrease in HR was observed in group D at 5 min that persisted throughout the procedure as compared to Group P. Mean HR in Group P had no significant change from baseline.

Incidence of side effects and complications among two groups

Complication	Number of patients (%)	
	Group D	Group P
Nausea/vomiting	03 (10.0)	01(3.30)
Bradycardia	04 (13.3)	03 (10.0)
Shivering	01 (3.30)	01(3.30)
Hypotension	02 (6.60)	07 (23.3)
Dry mouth	02 (6.60)	01(3.30)
Pain at site of injection	01(3.30)	08(26.6)
Neurological	00 (0.0)	00 (0.0)

Higher incidence of bradycardia, nausea and vomiting were noted in Group D compared to hypotension and pain at the site of injection in Group P. None of patient required to stop or reduce the rate of infusion of propofol and dexmedetomidine for management of hypotension and bradycardia. Neurological complications were not noted among any of the groups.

Discussion

During surgery under spinal anaesthesia unpleasant sensory sensations occur as afferent sensory supply to gut is not blocked. Vagal afferent is also not blocked and severe discomfort occurs while manipulating abdominal structures. Sedation besides relieving the above mentioned problems provides additional relief from anxiety and apprehension. Similarly listening to noises of cutting instruments is very disturbing for the patient and he is relieved of this agony by Moderate sedation.

The most widely used technique for administering sedation in regional anaesthesia is the *intermittent intravenous bolus dose technique*. This technique has been shown to be associated with peaks and troughs in plasma concentration producing *significant side effects and delayed recovery*. *Continuous infusions* have been proved to produce, lesser side effects, faster recovery, easy controllability over the desired depth of sedation and, should the regional block prove to be ineffective, easy conversion to general anaesthesia [6].

The early onset time of sedation in the propofol group compared to dexmedetomidine group occurs because propofol is highly lipophilic and distributes rapidly into the central nervous system. Arain, *et al [4]*. noted that the targeted sedation was achieved within 10 min with propofol but took 25 min with dexmedetomidine [4]. Both Groups D and P had significantly deeper level of sedation. Group D when compared with Group P has significantly deeper level of sedation throughout the procedure.

The mean recovery time was shorter in Group P as compared to Group D possibly due to rapid metabolism and excretion of propofol. Mean duration of effective analgesia was significantly prolonged in the dexmedetomidine group as compared to propofol group. Dexmedetomidine produces analgesia by binding to adrenoreceptors in the spinal cord. Jorm and Stamford, observed that dexmedetomidine has an inhibitory effect on the locus coeruleus which is located at the brain stem.[5] This supraspinal action

could explain the prolongation of spinal analgesia after i.v. administration of dexmedetomidine. In our study, a significant decrease in mean HR with dexmedetomidine was observed at 5 min of starting the infusion.

This difference persisted throughout the procedure and could be attributed to sympatholytic properties and vagal mimetic effects of dexmedetomidine. The results of our study correlate well with Al-Mustafa, *et al*.[7] MBP was significantly decreased in Group P at 5 min after starting infusion and persisted throughout the procedure as compared to Group D. There was no significant difference in MBP from baseline value in Group D throughout the whole duration of procedure. The fall in MBP in patients receiving propofol could be attributed to direct powerful inhibitory effect of propofol on sympathetic outflow causing vasodilatation. Dexmedetomidine is also known to decrease sympathetic outflow and circulating catecholamine levels and would, therefore, be expected to cause a decrease in MBP. However, larger doses of dexmedetomidine have a direct effect at the postsynaptic vascular smooth muscle to cause vasoconstriction, and it is possible that the sympathoinhibitory effects of dexmedetomidine were slightly opposed by direct α-2 mediated vasoconstriction [4] [7].

Both propofol and dexmedetomidine are known to have minimal respiratory depression when used as sedative agents which is evident for our results wherein the SpO2, RR did not differ significantly from baseline. Ryu, *et al*.[8] observed that dexmedetomidine was associated with fewer incidents of oxygen desaturation and
a reduced need for the oral cavity suction than Remifentanil during flexible bronchoscopy. Postoperative shivering was significantly reduced in the dexmedetomidine.

The above factors such as better sedation, stable cardio-respiratory profile and post operative analgesic effect resulted in significantly better overall patient satisfaction in the dexmedetomidine group.

Conclusion

The present study shows that both dexmedetomidine and propofol produce adequate level of sedation but dexmedetomidine could be used as BETTER alternative to propofol for intra-operative moderate sedation for surgeries under spinal anaesthesia.

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