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"Sedation with Intra Venous Propofol as an adjunct to regional anaesthesia: A clinical study ''

KEYWORDS: Propofol, regional anaesthesia,sedation.

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ABSTRACT *The aim of study was to assess the effectiveness of sedation with Intravenous Propofol as an adjunct to the regional anaesthesia. We have included 50 patients of age group 5 to 50 years, of ASA grade I and II and posted for both elective as well as emergency surgeries.Patients were anaesthetized with suitable regional technique. After the adequate level of analgesia, the bolus dose of Propofol, 1mg/kg was given and sedation was maintained with intermittent doses of Propofol in dose of 0.2mg/kg. During the whole procedure, patient's hemodynamic status was observed and vital parameters were recorded. Level of sedation was assessed and any undesirable side effects like involuntary movements, muscles twitching were observed. In the post operative period higher CNS functions were observed in the form of mental status, reflexes and co-ordination.*

All patients had satisfactory level of sedation throughout the procedure with stable hemodynamic condition.No undesirable side effects were observed intraoperatively as well as postoperatively. To conclude Propofol is an excellent agent and can be used safely and conveniently for the sedation as an adjunct to regional anaesthesia.

Introduction:
Patients about to undergo surgery can be quite frightened. What seems like a minor procedure to the anaesthesiologist and surgeon may represent a major ordeal to the patient. Anxiety is also associated with significant adverse physiological responses like tachycardia, hypertension leading to increased myocardial oxygen consumption, intracranial hypertension and persistent catabolism which may affect post operative recovery. So the reduction of anxiety to tolerable levels is a human goal and should be attempted for every patient. (Johnston M).

Regional anaesthesia techniques can be used for a variety of surgical procedures and may offer certain advantages over general anaesthesia. In order to improve patient's acceptability and comfort and to reduce stress it is necessary to provide some form of sedation during the operation. Sedation can be provided by different methods like inhalation, intravenous techniques, either by repeated bolus doses or patient controlled sedation which is most widely used.

The suitable agents include the Benzodiazepines, the intravenous Induction agents and the opioids. Midazolam and Propofol are considered to be the most suitable drugs. Propofol is 2, 6 di-isopropyl phenol with rapid onset of action and rapid recovery. Pharmacokinetic properties and recovery characteristic of Propofol have led to its use for sedation (Ronald M).

In this study we observed sedative properties and recovery characteristics of Propofol by using its bolus doses in patients posted for surgeries under regional anaesthesia.

Material and Methods:
Approval was taken from institutional ethical committee and informed consent was taken from 50 patients posted for both elective and emergency surgeries under regional anaesthesia. Inclusion criteria were patients of ASA gr I and II, of age group between 5 to 50 yrs and of either sex. Exclusion criteria were patients having severe systemic disease. Preoperatively necessary investigations were done. Patient's vital parameters such as pulse blood pressure, respiratory rate as well as patient's weight were recorded. In the operation theater monitors were attached to the patients and patients were anaesthetized with suitable regional technique appropriate for that patient and type of surgery. Intraoperatively after the adequate level of analgesia was achieved and patient's hemodynamic condition became stable, the bolus dose of inj. Propofol 1mg/kg was given to the patients. Sedation was maintained throughout the procedure with the intermittent doses of Propofol 0.2 mg/kg. Intraoperatively,patient's vital parameters as well as level of sedation was observed at the interval of 5 minutes. Sedation level was assessed and scoring was done according to "Modified Stewards Criteria" which is given below.

"Modified Stewards Criteria"

I] Consciousness	Points
* Fully awake, eyes open conversive	4
* Lightly asleep eyes open intermittently	3
* Eyes open on command or in response to name	2
* Responding to ear pinching	1
* Not responding	0

II] Airway

*Opening mouth with or without coughing on command	3
* No voluntary cough but airway clear without support	2
* Airway obstruction on neck flexion but clear without Support on extension	1
*Airway obstruction without support	0

III] Activity

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*Raising one arm on command	2
*Non purposeful movement	1
* Not moving	0

Sedation scoring was done by addition of points under the above three headings and according to the total scoring, quality of sedation was decided.

If total score was

< 6 – Deep level of sedition

6 to 8 – Satisfactory level of sedation

>8 – Light sedation

Other undesirable side effects such as involuntary movements, muscle twitching and airway obstruction were also noted during the procedure.

Time of recovery was observed as the time from the last top up dose of Propofol to the end point of sedation when the patient was fully conscious and oriented with respect to time, place and person. In the post operative period patients higher CNS functions were observed in the form of mental status, reflexes and co-ordination at the interval of ½ hr,1hr, 2hr& 4hrs and also observed for any side effects like nausea and vomiting.

Results:
Study was conducted among 50 participants (40 male and 10 female) among age group 5 yrs to 50 yrs.. Mean weight of study participants was 59.g Kg (SD ±11.24).Patients with their onset time of sedation was mentioned in Table 2.Average time of onset of sedation was 34.43±13.93 seconds.

Table 1. Time of onset of sedation (n=50)

Time in seconds	No. of patients	Percentage
30-40	30	60%
41-50	18	36%
51-60	2	4%

Table 2. Changes in Intraoperative vital parameters like pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate among patients in relation to time.(n=50)

Time in minutes	Changein pulse rate per minute from the earlier pulse rate (before sedation) (Mean ± SD)	Change in systolic blood pressure (mmHg) from earlier blood pressure (before sedation) (Mean ± SD)	Change in diastolic blood pressure (mmHg) from the earlier blood pressure (before sedation) (Mean ± SD)	Change in respiratory rate per minute from the earlier respiratory rate (before sedation) (Mean ± SD)
5	1.87 ± 0.5696	13.38 ± 4.8511	8.56 ± 2.5241	2.32 ± 0.8336
10	1.93 ± 0.3935	13 ± 5.0606	8.44 ± 2.8078	2.14 ± 1.0303
15	1.72 ± 0.4521	11.91± 5.0490	7.52 ± 3.7375	1.72 ± 1.4002
20	1.62 ± 0.4866	11.79 ± 5.5714	6.68 ± 4.2303	1.62 ± 1.4126
25	1.42 ± 0.6454	10.52 ± 5.9632	6.12 ± 4.3968	1.49 ± 1.4334
30	1.34 ± 0.7002	9.62 ± 4.6977	6.12 ± 4.4128	1.37 ± 1.4384
35	1.33 ± 0.6396	10 ± 5.1467	6.04 ± 4.3714	1.33 ± 1.4770
40	1.31 ± 0.5253	11.68 ± 6.0898	6.56 ± 4.4235	1.21 ± 1.1890
45	1.26 ± 0.5832	10.38 ± 6.8003	6.90 ± 4.4970	1.29 ± 1.1240
50	1.22 ± 0.5284	8.55 ± 6.4119	6.68 ± 4.5755	1.24 ± 1.2437
55	1.00 ± 0.5671	8.95 ± 6.1194	5.71 ± 5.0709	1.42 ± 1.2873
60	1.33 ± 0.5	8.42 ± 6.4773	5.71 ± 5.1355	1.71 ± 1.3259
65	1.42 ± 0.5345	6.66 ± 7.0710	5.55 ± 5.2704	1.55 ± 1.3333
70	1.2 ± 0.4472	0.6 ± 5.4772	6 ± 5.4772	1.6 ± 1.6733

As shown in table 2, there was reduction in the pulse rate from the rate before sedation and average reduction in pulse rate was by 1.24±0.26 beats/min. The volume and the rhythm of pulse remained normal. There was reduction in systolic blood pressure after sedation with Propofol and the average reduction was by 10.60 ± 2.16 mmHg i.e. 10.17%. With the intermittent doses of Propofol the fall in systolic blood pressure was less than the fall which was observed after giving bolus dose. The fall was not very severe and no patients required any vasopressor therapy. There was also fall in diastolic blood pressure after sedation with Propofol and the average fall was by 8.22 ± 2.5 mm Hg i.e. by 10.74%. The reduction in systolic and di-

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astolic blood pressure occurred approximately in same proportion. The respiratory rate was reduced after sedation and the average reduction was by 1.57±0.32 breaths / min i.e. by 8.51%. Maximum reduction was observed during the first 5 minutes after the bolus dose. There was no instances of apnea or laryngospasm but airway obstruction was developed in 2[4%] of patients. Peripheral oxygen saturation remained stable throughout the procedure. Total sedation score ranged between 5.06 to 6.7 (Table 3) .Overall satisfactory level of sedation was maintained among patients.The average time of recovery was 2.72 ± 0.46 minutes (Table 4).

Table 3. Average time required for level of sedation intraoperatively (n=50)

Time interval in minutes	Total scoring for the level of sedation (Mean ± S.D)
5	5.06 ± 0.3136
10	6.47 ± 0.1941
15	6.42 ± 3.4217
20	6.52 ± 3.2923
25	6.56 ± 3.1757
30	6.59 ± 3.0751
35	6.62 ± 2.9882
40	6.64 ± 2.9224
45	6 .66 ± 2.8701
50	6.68 ± 2.8244
55	6.69 ± 2.7937
60	6.70 ± 2.7731
65	6.70 ± 2.7581
70	6.71 ± 2.7491

Table 4.Recovery time from sedation among patients (n=50).

Time in minutes	No. of patients	Percentage
2 to 3	40	80%
3.1 to 4	8	16%
4.1 to 5	2	4%

The undesirable sideeffects like pain on injection in 4 (8%) of patients, respiratory obstruction in 2 (4%) of patients were observed during the study. There was a completely normal higher CNS function in all the patients.

Discussion:

Regional anesthetic techniques can be used for a variety of surgical procedures and may offer certain advantages over general anesthesia.In order to improve patient acceptability and comfort and to reduce stress,it is necessary to provide some form of sedation during the operation.Propofol appears to have very rapid onset of action as observed in various studies (Osobrne G.A. et al; Patki A., Shelgaonkar VC). We also observed the same result in our study with average time of onset of sedation was 34.43 ± 13.93 seconds.Another study (WilsonE., David A)in 1990 observed slight decrease in pulse rate (by 5 beats per minute) and also reduction in systolic as well as diastolic pressure. However, a study conducted in 2011 observed no significant fall in pulse rate as well as mean arterial pressure (Irwin M.G., Thompson N; Patki A., Shelgaonkar VC). Considerable fall in blood pressure in majority of patients were observed in a study conducted in 2006 (Mubeen M, Mahmood S).In our study we also observed the reduction in pulse rate as well as systolic and diastolic blood pressure but no patient required vasopressor therapy.

Irwin et al observed reduction in respiratory rate with onset of sedation was reported in a study (Irwin M.G., Thompson N). No significant alteration in respiratory rate or SPO_2 throughout the procedure and none of the patients showed evidence of airway obstruction (Patki A., ShelgaonkarVC). This may be because they administered the Propofol in sub hypnotic doses. In our study we observed reduction in respiratory rate by 2 breaths per minute and airway obstruction in 4% of patients which developed after bolus dose of Propofol.

Level of sedation by Modified Steward's Criteria was assessed (Irwin M.G., Thompson N) and it was observed the satisfactory level of sedation throughout the procedure. Various studies (Patki A., Shelgaonkar VC; Mubeen M, Mahmood S) observed controllable sedation with clear headache recovery. In our study we also observed good sedation score ranging between 6 to8.

Intermittent injection technique supplementary doses will be required every 4 to 5 minutes. Adam H .K et al was also observed the same in a study, while very fast recovery was reported in other study (Wilson E., David A.; Irwin M.G., Thompson N). This study has also reported the same finding with mean time of recovery was 2.72 ± 0.46 minutes.

Pain on injection was also observed in 5% of patients (Wilson E., David A.) and1% of patients (Irwin M.G., Thompson N.) in studies. In our study we also observed pain on injection in 8% 0f patients which may be due to small veins on the dorsum of the hand. No side effects like involuntary movements or muscle twitching (Patki A., Shelgaonkar VC). In our study we observed involuntary movements in 4% of patients. It is well known that Propofol possesses significant antiemetic property (Miller R).In our study also there were no incidence of postoperative nausea and vomiting. In our study we observed completely normal higher CNS functions.

Hence we would like to conclude that Propofol is an excellent agent with its rapid onset and rapid recovery and can be used safely and conveniently for the sedation as an adjunct to regional anaesthesia with Proper vigilance over vital parameters.

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