



Evaluation of Propofol as a General Anesthetic Agent for Minor Oral Surgical Procedure

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ABSTRACT

Nausea and vomiting following anesthesia is a distressing problem for the patient as it increases the recovery time, intensity of nursing care and delays discharge. The aim of randomized controlled single blind study is to evaluate the efficacy and safety of subhypnotic doses of propofol for the prevention of post-operative nausea and vomiting (PONV) in day care management of cases in oral and maxillofacial surgeries. Twenty-five patient of ASA-1 with age ranging from 12 to 40 years were scheduled for various maxillofacial surgical cases like fracture, cyst enucleation, surgical removal of 3rd molar, etc. were given propofol at the dose of 2 to 2.5 mg/kg as induction dose and sedation was maintained with the dose 5 to 10 mg/min. There was no significant effect on heart rate, systolic and diastolic blood pressure, respiratory rate and oxygen saturation intra-operatively. In conclusion, a subhypnotic dose of propofol is fast acting, safe and easily controllable, short acting general anesthetic agent with rapid recovery. The study found that the PONV was significantly reduced in the patient with propofol, no hemodynamic derangements were noted in the postoperative period.

Keywords: Propofol, Postoperative nausea and vomiting, Total intravenous anesthesia, Amnesia, Sedation.

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INTRODUCTION

The Era of Barbarous world of 18th century medicine has been characterized as an age of agony. The sensation, fear and anxiety about pain are undoubtedly common reason for patient to delay dental care, not only many patient find dental treatment unpleasant but they also exhibit peripheral manifestation of excessive sympathetic activity such as xerostomia, tachycardia, sweating and tremors which in some instances may lead to anxiety and apprehension induced cardiac arrhythmias and vasovagal shock.

In anxious patient, anxiety control² is not attainable by regional analgesia alone. There is a constant threat of posting oral surgery procedure under long acting general anesthesia as patient is subjected to more stress and cost also, it takes long time to achieve street fitness. Economic constraints and lack of time have encouraged the expectations of day care surgeries. Fast recovery is also a key factor for the introduction of total intravenous anesthesia (TIVA), which can fulfill all the requirements as an adjunct to regional analgesia and long acting anesthetic drug.

This randomized controlled study was designed to evaluate TIVA as choice of anesthesia in terms of intra- and postoperative hemodynamic profile, postoperative recovery and undesirable sequel like PONV.

AIMS AND OBJECTIVES

The aim of the study was to determine the rate of recovery of the patient from the sedative effect of drug and fitness after recovery, quality of sedation and anxiolysis achieved. Parameters like profoundness of amnesia along with effect of drug on physiological parameters of patient like blood pressure, pulse, respiratory rate and oxygen saturation were monitored.

MATERIALS AND METHODS

The present study was conducted in Department of Oral and Maxillofacial Surgery. The study included 25 ASA one of either six with their age ranging from 12 to 40 years requiring day care surgery like extraction of impacted molars, frenectomy, enucleation of cysts, bone plating in fractures.

A record of detailed history of patient was maintained with their past exposure to anesthetic sedative drugs, previous surgical procedures, allergy to drugs and eggs. The cases for which surgery were expected to last at least for 20 minutes and not more than 60 minutes, were selected for the study.

Premedication received 0.6 mg of atropine sulfate (Tropin; Neon pharma) as preanesthetic medication followed by injection of xylocard (Astra IDL). In the study (TIVA), Propofol (Profol; Claris Pharma) in the dose of 2 to 2.5 mg/kg was given for the induction of sedation^{3,4} and maintenance of sedation was achieved with 5 to 10 mg/min and titrated to the required end point, i.e. phosis and slurred speech. Patients were given local anesthesia injection of 2% lignocaine 2 to 3 minutes after administration of propofol. In few cases intubation was needed,⁷ it was facilitated with succinyl choline 1 to 1.5 mg/kg and maintained with nitrous oxide and oxygen 60:40 and propofol.

Parameters evaluated were oxygen saturation, blood pressure, heart rate, onset on action of time, amnesia, recovery period, patient cooperation and level of sedation.

Side Effects

In the operative room multi para monitor was there for consistent monitoring of pulse, oxygen saturation and blood pressure. Real time monitoring of all the parameters was made at 15 minutes before surgical procedure and immediately after propofol infusion. Third reading was taken after local anesthetic administration. After this readings were recorded at regular intervals of 15, i.e. (15, 30, 45 and 60 min) last reading was recorded at the time of discharge.

Onset of action was calculated by the time of induction to the loss of eyelid reflexes (Guedel stage III phase 1), anterograde amnesia was graded according to complete or partial failure to recall any stimuli applied. Recovery of the patient was calculated as immediate recovery and complete recovery, which was calculated from the last dose to the first sign of response (Phase 1) or till the complete recovery (Phase 2). Patients were cooperative (Ramsay Sedation score) and criteria for operative condition and surgeons convenience, was accessibility to operating field, body or tongue movement.

RESULT AND OBSERVATIONS

The study includes 25 patients from who did not have any drug history or hypersensitivity.

Induction: Loss of eyelid reflexes was considered to be the point of unconsciousness with in 30 to 40 seconds of starting of bolus dose. Maximum time taken by a patient was 60 seconds and minimum was 25 seconds, mean induction time was 35.6 ± 6 . This shows propofol takes less induction time which is an ideal requisite of general anesthetic agent.

Heart rate in our study we found a 3% decrease by baseline value ranging from 87.4 ± 4.7 beats per minute this shows there is no significant change on the heart rate at the time of induction or during surgical procedures shown in Table 1.

Respiratory rate was measured when patient was calm in preanesthetic room, in this study there was 27% reduction in the respiratory rate no patient had apnea. At the time of arrival in the recovery room there was increase in respiratory rate by 1.1% by the baseline value which was 18.4 with a mean of 18.6 ± 1.1 , shown in Table 2.

Systolic blood pressure just before induction was in the range of 110 to 130 mm Hg with the mean value of 117.7 ± 5.7 mm Hg, after induction there was 11.2% increase in systolic blood pressure with a mean of 104.5 ± 5.4 mm Hg. During discharge it was almost equal to baseline value, shown on Table 3.

Diastolic blood pressure, propofol in all previous studies have shown decrease in blood pressure at induction and through out the infusion. In our study also there was decrease in blood pressure from baseline. Preinduction value was 77.1 ± 4.7 mm Hg after induction 15.2% fall in diastolic blood pressure was noted by the baseline value, all the parameter were noted after 15, 30, 45 and 60 minutes, and time of discharge detailed reading are shown in Table 4.

Oxygen saturation: Preinduction was having a mean value of 99.4 ± 0.8 , after induction there was 4.8% decrease with mean value of 94.6 ± 1.1 . At the time of discharge oxygen saturation was 99.8 ± 0.4 detailed reading shown in Table 5.

Recovery time: Mean recovery period was 7.5 ± 1.4 earliest recovery was 4 minutes and maximum time taken was 10 minutes.

Table 1: Heart rate

	Mean \pm SD	Reduction from base line	Percentage reduction	t-value	p-value
On reporting (base line)	87.4 ± 4.7	–	–	–	–
On induction	84.8 ± 4.8	2.6	3.0	12.10	<0.001
After local anesthesia	87.1 ± 4.9	0.3	0.3	0.80	NS
After 15 minutes	86.29 ± 4.6	1.2	1.4	4.65	<0.001
After 30 minutes	86.1 ± 4.3	1.3	1.5	3.57	<0.001
After 45 minutes	85.6 ± 4.5	1.8	2.1	4.87	<0.001
After 60 minutes	85.7 ± 4.7	1.7	1.9	5.16	<0.001
After ARR	88.4 ± 4.4	(–) 1.4	(–) 1.6	4.10	<0.001
During discharge	86.2 ± 4.1	1.2	1.4	2.48	<0.05

Paired t-test; SD: standard deviation; ARR: arrival in recovery room

Pain on injection site: Only one patient complain of pain¹⁷ at the site of injection.

Postoperative nausea and vomiting (PONV):^{5,18} In our study only one patient had an episode of emesis, who was given ondansetron 4 mg iv stat and there was no episode later.

Operating condition: Surgeons had excellent operating condition for 21 patients and good for four patients.

DISCUSSION

Intravenous anesthesia has evolved from being primarily for induction of anesthesia to provide unconsciousness and amnesia for the surgical procedure performed under general anesthesia. New insights into the pharmacokinetics¹⁶ and dynamics of intravenous anesthetic technique, as well as development of computer technology to facilitate IV drug delivery have greatly enhanced the use of TIVA. Day care

oral and maxillofacial surgery is cost¹⁹ effective, multiple factor contributing to this transition by improved surgical and anesthetic technique, better preoperative planning, better patient education and an enhanced ability to deliver adequate analgesia to patient. Ambulatory surgeries have undergone tremendous growth over the last decade and surgeons have to respond to this trend by adapting the unique demands posed by ambulatory anesthesia. Patients are adequately anesthetized for surgery yet they recover quickly and they may be discharged shortly after surgery. Propofol is now widely used to provide safe and effective general anesthesia for ambulatory procedures it is currently considered as a choice of intravenous anesthetic drug because of its short duration of action allows patient to be discharge home sooner then those anesthetized with other anesthetic agent, the sedative drug used over in the past had disadvantages of intraoperative complications, such as

Table 2: Respiratory rate

	Mean \pm SD	Reduction from base line	Percentage reduction	t-value	p-value
On reporting (base line)	18.4 \pm 1.3	–	–	–	–
On induction	14.6 \pm 1.2	3.8	20.7	24.87	<0.001
After local anesthesia	16.5 \pm 1/4	1.9	9.2	8.32	<0.001
After 15 minutes	16.5 \pm 1.1	1.9	10.3	7.10	<0.001
After 30 minutes	17.1 \pm 1.3	1.3	7.1	4.39	<0.001
After 45 minutes	17.1 \pm 1.1	1.3	7.1	5.02	<0.001
After 60 minutes	16.7 \pm 1.1	1.7	9.2	5.09	<0.001
After ARR	18.6 \pm 1.1	(–) 0.02	(–) 1.1	0.77	NS
During discharge	16.5 \pm 1.1	1.9	10.3	6.35	<0.001

Paired t-test; SD: standard deviation; ARR: arrival in recovery room; NS: nonsignificant

Table 3: Systolic blood pressure

	Mean \pm SD	Reduction from base line	Percentage reduction	t-value	p-value
On reporting (base line)	117.7 \pm 5.7	–	–	–	–
On induction	104.5 \pm 5.4	13.2	11.2	16.46	<0.001
After local anesthesia	108.1 \pm 5.3	9.6	8.2	9.07	<0.001
After 15 minutes	110.4 \pm 3.7	7.4	6.3	7.76	<0.001
After 30 minutes	111.3 \pm 4.5	6.4	5.4	5.71	<0.001
After 45 minutes	112.8 \pm 2.9	4.9	4.2	5.17	<0.001
After 60 minutes	114.6 \pm 3.3	3.1	2.6	3.42	<0.01
After ARR	117.2 \pm 3.5	0.5	0.4	0.71	NS
During discharge	117.4 \pm 5.0	0.3	0.2	0.41	NS

Paired t-test; SD: standard deviation; ARR: arrival in recovery room; NS: nonsignificant

Table 4: Diastolic blood pressure

	Mean \pm SD	Reduction from base line	Percentage reduction	t-value	p-value
On reporting (base line)	77.1 \pm 4.7	–	–	–	–
On induction	65.4 \pm 5.8	11.7	15.2	12.27	<0.001
After local anesthesia	66.5 \pm 4.0	10.6	13.7	14.72	<0.001
After 15 minutes	68.4 \pm 2.4	8.7	11.3	8.14	<0.001
After 30 minutes	69.6 \pm 2.1	7.5	9.7	9.47	<0.001
After 45 minutes	71.2 \pm 2.5	5.9	7.7	6.58	<0.001
After 60 minutes	74.1 \pm 3.3	3.0	3.9	3.68	<0.01
After ARR	76.4 \pm 3.8	0.7	0.9	0.99	NS
During discharge	76.9 \pm 4.2	0.2	0.3	0.68 S	NS

Paired t-test; SD: standard deviation; ARR: arrival in recovery room; S: significant; NS: nonsignificant

Table 5: Oxygen saturation

	Mean \pm SD	Reduction from base line	Percentage reduction	t-value	p-value
On reporting (base line)	99.4 \pm 0.8	–	–	–	–
On induction	94.6 \pm 1.1	4.8	4.8	18.31	<0.001
After local anesthesia	98.0 \pm 1.5	1.5	1.5	4.98	<0.001
After 15 minutes	99.0 \pm 1.0	0.5	0.5	2.32	<0.05
After 30 minutes	99.3 \pm 0.7	0.2	0.2	0.81	NS
After 45 minutes	98.9 \pm 0.9	0.6	0.6	2.50	<0.05
After 60 minutes	99.1 \pm 1.1	0.4	0.4	1.47	NS
After ARR	99.6 \pm 0.6	(–) 0.1	(–) 0.1	1.00	NS
During discharge	99.8 \pm 0.4	(–) 0.4	(–) 0.4	2.82	<0.01

Paired t-test; SD: standard deviation; ARR: arrival in recovery room; NS: nonsignificant

hypoxia, hypotension^{6,10,14} and oxygen desaturation, and postoperative complication such as hypoxia in recovery room, postinjection thrombophlebitis, prolonged recovery, nausea, vomiting and hypotension. Propofol, an alkyl phenol, is fast acting sedative hypnotic agent with a short duration of action, rapid recovery^{8,15} profile and low incidence of excitatory effect.

This study was undertaken to estimate the usefulness of propofol and to assess propofol as how ideal general anesthetic it is. Its properties in terms of onset on action, recovery, amnesia, patient cooperation, surgeons convenience and side effects were assessed. Induction of anesthesia with propofol was found to be associated with a slight drop in heart rate and systolic blood pressure as compared to conventional inhalation although it was statistically not significant. In the intraoperative period TIVA was associated with better hemodynamic stability than conventional GA. Similar results was found in the study of Zacharias M et al and Meyer CJ et al. There was decrease in blood pressure at time of induction¹ but it was insignificant.

Arterial oxygen desaturation has always been a significant cause of concern during minor oral and maxillofacial surgical procedures. In this study, none of the patient experienced oxygen desaturation for more than 30 seconds with insignificant exception of one patient who had apnea for 60 seconds due to voluntarily reflex holding of breath¹² at the time of actual reduction of fractured segment Ryder W had concluded that occurrence of cardiac arrhythmias due to dental procedures with LA is not uncommon. In this study, no such arrhythmia at any time were monitored.

Recovery¹¹ from sedation was faster with propofol with no adverse effect, propofol has faster recovery time than diazepam corroborated by Valtonen and Polster MR et al.

In this study, the immediate recovery periods range from 4 to 10 minutes with a mean of 7.5 ± 1.4 minutes. A fast return of psychomotor was seen which was ranging from 40 to 60 minutes with a mean of 50 ± 5.4 minutes.

Patient cooperation in the present study and level of sedation was assessed on the Ramsay sedation score

21 (84%) patient come under excellent condition and 4 (16%) under good condition, in present study 12% of patient experienced pain at the site of injection, this is most common side effect of propofol.

Postoperative nausea and vomiting was observed in 4% of the patient which was treated by Ondansetron (Ondem; Alkem pharma) and no further episodes were noted.

In all propofol displayed good safety profile and excellent short acting GA in all the phases that were studied due to better recovery profile of patients. On TIVA, this technique is, therefore better suited for day care surgery as it allows discharge of patient immediately, who were well oriented.

CONCLUSION

The design of present study permitted qualitative assessment of propofol for short acting general anesthesia with regional analgesia, in minor oral surgical procedure. The ideal anesthetic agent should provide rapid onset of action, stable operating conditions, profound intraoperative amnesia while ensuring rapid recovery of protective reflexes, congestive and psychomotor functions.

The technique for sedation with propofol was safe, simple and versatile and caused no delay to surgery. Depth of anesthetic effect⁹ can be easily altered, by adjusting the infusion rate.¹³ Recovery was impressively rapid and devoid of side effects. Full orientation generally returned after 5 minutes after stopping the infusion.

Propofol produced no clinically significant effects on heart rate, respiratory rate, systolic and diastolic blood pressure and oxygen saturation. It proved to be reliable sedation, producing good operating conditions, stable vital signs and profound amnesia with minimum intra- and postoperative complications.

Its disadvantages of pain on injection and high cost which were of relatively no significance as compared to safety and other advantages such as rapid onset, profound amnesia, rapid recovery, less excitatory phenomenon and nil postoperative side effects. In our study, the only significant side effect was, postoperative nausea in one patient (4%),

where injection Ondansetron was given intravenously. Due to high level of safety and patient cooperation propofol can be considered as a drug of choice for day case oral and maxillofacial surgical procedures.

Propofol is fast acting, safe and easily controllable, short acting general anesthetic agent with rapid recovery. This offered the advantage of early patient discharge and better patient compliance.

Since, the patients in the present study were selected after careful inclusion and exclusion criteria, it is suggested that a larger randomized study covering even patients in high risk category be carried out, to assess the efficacy and safety profile of propofol as an agent for short acting general anesthetic agent in day case oral and maxillofacial surgical procedures.

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