

Comparison of propofol with propofol -midazolam for I-gel insertion in spontaneously breathing patients for elective day care procedures

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Abstract

Background and Aim: Supraglottic airway devices (SGA) offer certain advantages over endotracheal intubation, making them appropriate for outpatient anesthesia. The I-gel® is the innovative second generation supraglottic airway device from Intersurgical. I-gel offers unique advantages of easy insertion, reduced trauma, superior sealing pressure, and gastric access. Drugs such as propofol, sevoflurane are commonly used for supraglottic device insertion. The pharmacokinetic characteristics of Propofol allows for rapid onset and offset of drug effect with better blunting of airway reflexes compared to thiopentone. Midazolam is a well-established anaesthetic pre-medicant for short surgical procedures. There are innumerable studies on insertion of classic LMA with propofol but only few with I-gel. This prompted us to inspect the efficacy of propofol, and propofol-midazolam co-induction for I-gel insertion in spontaneously breathing patients for elective day care procedures. The primary aim of the study is to compare propofol and propofol-midazolam for ease of I-gel insertion.

Methods: Eighty patients, aged 18-45, were divided into two groups group P and Group PM. They received anaesthesia induction with propofol and propofol -midazolam after pre-medicating with Inj.Fentanyl 2micrograms/kg respectively. Patients in (group P) received IV normal saline 2ml followed by Propofol 2.5mg/kg for induction. Patients in (group PM) received IV Midazolam 0.04mg/kg three minutes before induction with propofol.

The following conditions were assessed for ease of I-gel insertion such as number of insertion attempts, Jaw relaxation, coughing and gagging. The total dose of propofol, hemodynamic changes during induction were the other parameters recorded.

Results: I-gel was successfully inserted at first attempt in 33 patient's(80%) in group PM and 24 patients(60%) group P and it was statistically significant($p \leq 0.03$). The total dose of propofol consumed in group P(45.5±8.165) was more compared to group PM(44.65±6.483)($p \leq 0.002$).

Conclusion: I-gel insertion was swifter with better hemodynamic stability in propofol-midazolam than propofol alone for day care surgeries.

Keywords: Supraglottic devices, I-gel, Propofol, Midazolam

Introduction

Airway management is one of the critical duty of an anaesthesiologist. Recent advances in anaesthesia and pain management have provided a huge scope for ambulatory surgery. In day care surgeries patient needs a brilliant recovery profile which is made possible by new airway gadgets and short acting drugs. The tracheal intubation is the gold standard method for maintaining a patent airway during anesthesia. However, this maneuver requires skill and continuous training and practice in direct laryngoscopy. Supraglottic airway devices are promising alternative to endotracheal intubation. I-gel (Intersurgical Ltd., Workingham, England) is a supraglottic airway device designed for single-use that, unlike conventional LMAs, does not require an inflatable cuff. In addition, the I-gel, much like the Proseal LMA (PLMA), has a gastric drainage tube associated with an upper tube for decompression of the stomach, thereby avoiding acid reflux and decreasing the risk of pulmonary absorption.⁽¹⁾

Propofol (2,6-diisopropylphenol) is an intravenous short-acting anaesthetic widely used for inducing and maintaining anaesthesia.⁽²⁾ The desirable features of the

drug are rapid emergence from anaesthesia, lack of cumulation, lack of action on adrenal steroidogenesis, and has no adverse effect on liver and renal function.⁽³⁾ Propofol, when used alone, requires large doses and causes profound hemodynamic instability.⁽⁴⁾ To overcome this adverse effect of propofol we added midazolam as a coinduction agent.

Midazolam is an imidazobenzodiazepine, has an overall pharmacological potency similar to that of diazepam but a much shorter duration of action.⁽⁵⁾

Materials and Methods

After approval of the institutional ethical committee for a prospective randomized double blind study eighty patients of both sexes undergoing elective day care procedures were randomly allocated to two groups group P and group PM by sealed envelope techniques. Patients belonging to ASA physical status I and II were recruited for the study after obtaining informed written consent. The study was conducted over a period of one year.

Forty patients of both sexes undergoing surgical procedure were randomly allocated into two group Propofol (group P) and Propofol- Midazolam (group

PM) using opaque sealed envelope technique. Patients were advised over-night fasting. All patients were given tablet Ranitidine 150 mg and tablet metaclopramide 10mg on the night prior to surgery and on the morning of surgery. They were started on 18G IV cannula and preloaded with 10ml/kg of Ringer Lactate and were briefed about the methods of drugs used for induction. On arrival in the operating room, routine physiological monitoring were applied, including electrocardiogram (ECG), non-invasive blood pressure(NIBP), heart rate (HR), and pulse oximetry(SpO₂) capnography and base line parameters were noted.

The study drug was prepared and administered by an anaesthesiologist who was not a part of the study and the parameters were assessed by another anaesthesiologist who was blinded to the combination used. The Igel was inserted by the blinded anaesthetist who assessed and graded the conditions for Igel insertion and noted any adverse responses (i.e., inadequate jaw relaxation, gagging, coughing, laryngospasm).

All patients were premeditated with inj.Fentanyl 2 microgram/kg and glycopyrolate 4 microgram/kg IV five minutes before surgery. After preoxygenation with 100% oxygen patients in group P received 2ml of iv normal saline(placebo) followed by Propofol 2.5mg/kg for induction at a constant rate titrated to loss of verbal contact with the patient. In group PM patients received intravenous Midazolam 0.04mg/kg as a coinduction agent three minutes before inducing with Propofol 2.5mg/kg.

The adequacy of anesthesia was assessed by loss of response to verbal commands plus loss of eyelash reflex. If inadequate, further bolus of propofol 0.25mg/kg every fifteen seconds was given as required. The pulse rate, systolic and diastolic blood pressures and oxygen saturation were noted after induction in all groups.

Igel was prepared and inserted as per manufacture guidelines. Size 3 and 4 were used for small and medium size adult. If the initial insertion was unsuccessful or took longer than 180 sec, or there was evidence of airway obstruction or desaturation to <93%, the insertion attempt was stopped and the patient's lungs were manually ventilated with 100% oxygen until the saturation exceeded 95% before re-attempting Igel insertion. Not more than three attempts in a patient was attempted.⁽⁶⁾ In view of patient safety, failure to insert Igel in three attempts, and complications like hypotension and desaturation trachea was intubated with endotracheal tube of appropriate size after giving 100% oxygen.

Successful placement was confirmed using Square wave pattern in capnography, bilateral equal air entry and adequate bag refilling and absence of audible leak. Systolic and Diastolic BP, oxygen saturation and pulse rate were recorded post induction and post insertion.

Following Igel insertion anesthesia was maintained by N₂O / O₂ 50:50 and Isoflurane 1-2%. All patients were made to breathe spontaneously using Magill A circuit. The following conditions were assessed during Igel insertion. Primary objectives were the success rate of first insertion attempt, Jaw relaxation (Good-Incomplete-Poor) and Gagging or coughing (None - Mild-Moderate-Severe). Secondary objectives were hemodynamics during induction and insertion, laryngospasm (None-Partial-Total) and the total dose of propofol consumed.

At the end of the surgical procedure all anaesthetic agents were discontinued and 100% oxygen administered. I-gel was removed after the patient had gained consciousness and return of pharyngeal reflexes. After removal of I-gel patients were observed for any laryngo spasm and coughing.

Inclusion Criteria: ASA I and II physical status, patient with airway class I and II of modified Mallampatti score and elective short surgical procedures lasting less than or equal to 60 min.

Exclusion Criteria: Patient posted for emergency surgery, patient with full stomach, with reduced pulmonary compliance, patient with oral and perioral pathology, ischaemic heart disease and pregnancy.

Sample size: Sample size calculation was calculated for the primary objective (Success rate of first insertion attempt) based on our previous study using open source epidemiologic statistics version 3.0. found that 80 patients (40 per group) will be required to have a 95% confidence interval, 80% power of the study.⁽⁷⁾

Statistical analysis: Statistical analysis was done using Statistical Package for Social Sciences (SPSS/version 17) software Data was expressed as mean \pm SD or absolute values. Qualitative analysis was compared with Chi square test and quantitative analysis was compared with student 't' test. $p < 0.05$ was considered statistically significant.

Observation and Results

The patients in each group were statistically comparable in distribution of age, weight and sex distribution. I-gel was successfully inserted at first attempt in 33 patients(80%) in group PM and 24 patients(60%) group P and it was statistically significant($p \leq 0.03$). Ten patients (25%) needed second attempt in group P and 7(17%) in group PM while none needed 3rd attempt in group PM. There were no difference in premedication and pre-induction systolic and diastolic blood pressure within groups. In group P the fall in post-induction (114.40 \pm 9.620) and post insertion (110.50 \pm 7.997) systolic BP were more compared to group PM, post induction (112.10 \pm 10.351) post insertion (121.60 \pm 10.985) systolic BP and statistically significant(post induction $p < 0.02$ and post insertion $p < 0.001$). The total dose of propofol

consumed in group P(45.5±8.165) was more compared to group PM(44.65±6.483) (p≤0.002).

Table 1: Demographic profile

	Group P Mean ±SD	Group PM Mean ±SD
Age *	28.85±10.13	27.40±7.49
Weight*	45.15±8.165	44.65±6.483
Male: Female@	20:20	20:20

*By student t-test p>0.05, @ by chi-square test.

Table 2: Number of Insertion attempts of I-Gel

Insertion attempts	Group				Chi-square test
	Propofol		Propofol + Midazolam		
	n	%	n	%	
First	24	60	33	80	X 2 = 4.32 P = 0.03 significant
Second	10	25	7	17	
Third	6	15	-	-	

Table 3: Comparison of Propofol dose with combination of both Propofol and Midazolam for I-Gel insertion

Group	Total propofol mean±SD	Dose in per kg body weight mean±SD	Student t-test
Propofol	128.3±28.5	3±0.35	P < .002 significant
Propofol + Midazolam	104.2±16.2	2.25±0.01	

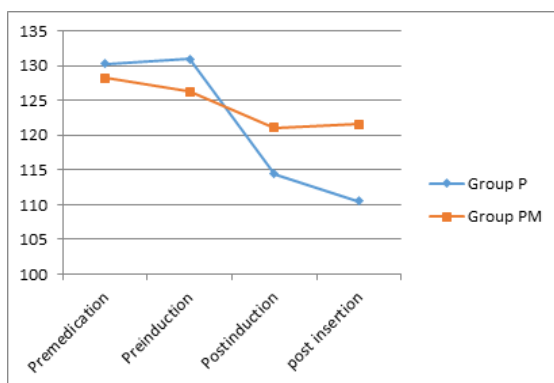


Fig. 1: Comparison of Systolic blood pressure in both the groups

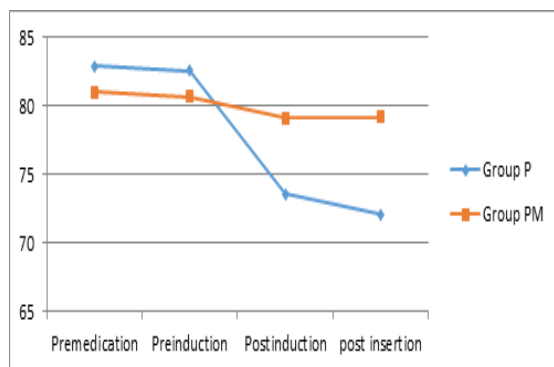


Fig. 2: Comparison of Diastolic blood pressure in both the groups

Discussion

The use of supraglottic airway devices are well established in anaesthetic practice and the incidence of airway trauma is lower with SGAs than with endotracheal tubes; SGAs may facilitate faster recovery and earlier discharge of patients.⁽⁸⁾ The I-gel is a second generation airway device that has been designed to work in perfect unison with the laryngeal anatomy. It has a unique non-inflating cuff which made its insertion easy, rapid and consistently reliable.

I-gel is also indicated in establishing a patent airway during resuscitation of the unconscious adult patient by personnel who are suitably trained and experienced in the use of airway management devices and techniques.⁽⁹⁾ Tanaka, Ishikawa, Teruhiko et al (2005) hypothesize that even after minor surgery, the presence of an endotracheal tube (ETT) impairs the receptors at the vocal cord and diminishes the defensive laryngeal function.⁽¹⁰⁾ Hence supraglottic devices are reliable for day care procedures. The insertion of these devices requires reasonable depth of anesthesia for the relaxation of jaw muscles and suppression of upper airway reflexes such as coughing, gagging.⁽¹¹⁾

Propofol has been used commonly as an induction agent for supraglottic airway device insertion. It provides smooth induction and depression of airway reflexes, allowing easier insertion. In our study, Igel was successfully inserted at first attempt in 33 patients (80%) in group PM and 24 patients (60%) in group P and statistically significant (p ≤ 0.03) as proved by our earlier studies. Yeoh, Tze Yeng, Koo Boon et al (2014), evaluated I-gel insertion in 70 pediatric patients and the overall insertion success rate was 96% with a median insertion time of 25 seconds.⁽¹²⁾

Kannaujia, Srivastava, Uma Saraswat et al (2009) conducted a preliminary study on I-gel with propofol-midazolam and their success rate at first attempt was 90%. There was no statistically significant difference in jaw relaxation and gagging as proved by studies of Kannaujia.⁽¹³⁾ Amr YM, Amin SM compared two regimes of thiopental and propofol for I-gel supraglottic airway device insertion and proved that insertion conditions for Igel are better with propofol.⁽¹⁴⁾ Nakazawa, Hikawa, Y. Maeda(1999) evaluated Laryngeal mask airway insertion using propofol without muscle relaxants, pre-treatment with midazolam or fentanyl concluded that pre-treatment with midazolam 0.05 mg combined with propofol 2.5 mg kg-1 provides safe and satisfactory conditions for LMA insertion.⁽¹⁵⁾ Elwood, Tom Huchcroft, Shirley MacAdams, (1995) proved that midazolam propofol co-induction in the presence does not delay discharge after anaesthesia.⁽¹⁶⁾

The reduction in systolic and diastolic blood pressure post induction and post insertion was greater in group P and statistically significant compared to group PM. As the patients in the group P received higher mean dosage of propofol(3mg/kg), decrease in blood

pressure was noted in our study. Propofol reduces arterial blood pressure due to reduction in sympathetic tone and direct venodilator effect. Gill PS, Shah J, Ogilvy A (2001) concluded that patients given midazolam required significantly less propofol to achieve satisfactory laryngeal mask insertion.⁽¹⁷⁾ Goyagi, T Tanaka, Nishikawa, T(2000) in their study proved that Fentanyl decreases propofol requirement for laryngeal mask airway insertion.⁽¹⁸⁾ Park, Hye Jin Lee, Jeong Rim et al (2007) proved Remifentanyl halves the EC50 of propofol for successful insertion of the laryngeal mask airway and laryngeal tube in pediatric patients.⁽¹⁹⁾ None of our patients had complications such as laryngospasm, and this was correlating with the finding Jaoua, H Djaziri, L.Bousselmi, J(2014) et al that use of the I-gel produce fewer postoperative throat.⁽²⁰⁾

Conclusion

We conclude that I-gel insertion was swifter with better hemodynamic profile, when combination of propofol-midazolam were used for induction and insertion than propofol alone for elective day care surgeries.

References

1. Jeon WJ, Cho SY, Baek SJ, Kim KH. Comparison of the Proseal LMA and intersurgical I-gel during gynecological laparoscopy. *Korean J Anesthesiol*. 2012;63(6):510-4.
2. Roussin A, Montastruc JL, Lapeyre-Mestre M. Pharmacological and clinical evidences on the potential for abuse and dependence of propofol: A review of the literature. *Fundamental and Clinical Pharmacology*. 2007. p. 459-65.
3. Lee TL. Pharmacology of propofol. *Annals of the Academy of Medicine Singapore*. 1991. p. 61-5.
4. Vanlersberghe C, Camu F. Propofol. *Handb Exp Pharmacol*. 2008;182:227-52.
5. Pieri L. Preclinical pharmacology of midazolam. *Br J Clin Pharmacol*. 1983;16(1 S):17S - 27S.
6. Ashay NA, Wasim S, Anil TB. Propofol requirement for insertion of I-gel versus laryngeal mask airway: A comparative dose finding study using Dixon's up-and-down method Abstract Background and Aims: Material and Methods : Results: 2-7.
7. Atef HM, Helmy AM, El-Taher EM, Henidak AM. Comparative study between I-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. *Middle East J Anesthesiol*. 2012;21(4):583-90.
8. Luba K, Cutter TW. Supraglottic Airway Devices in the Ambulatory Setting. *Anesthesiology Clinics*. 2010. p. 295-314.
9. Wetsch W a, Schneider A, Schier R, Spelten O, Hellmich M, Hinkelbein J. In a difficult access scenario, supraglottic airway devices improve success and time to ventilation. *Eur J Emerg Med [Internet]*. 2014;1-3. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/254608110>.
10. Tanaka A, Isono S, Ishikawa T, Nishino T. Laryngeal reflex before and after placement of airway interventions: endotracheal tube and laryngeal mask airway. *Anesthesiology*. 2005;102(1):20-5.
11. Vanlersberghe C, Camu F. Propofol. *Modern Anesthetics: Handbook of Experimental Pharmacology [Internet]*. 2008. p. 227-52. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18175094>.
12. Yeoh TY, Chan KB, Yeo LSH, Liu EHC, Pan TLT. An evaluation of the I-gel supraglottic airway in 70 pediatric patients. *J Anesth [Internet]*. 2014;1-4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25238682>.
13. Kannaujia A, Srivastava U, Saraswat N, Mishra A, Kumar A, Saxena S. A preliminary study of I-gel: a new supraglottic airway device. *Indian J Anaesth*. 2009;53:52-6.
14. Amr YM, Amin SM. Comparison of two regimes of thiopental and propofol for I-gel supraglottic airway device insertion. *Anesth essays Res [Internet]*. 4(1):25-8. Available from: <http://www.pubmedcentral.nih.gov/articlerender>.
15. Nakazawa K, Hikawa Y, Maeda M, Tanaka N, Ishikawa S, Makita K, et al. Laryngeal mask airway insertion using propofol without muscle relaxants: A comparative study of pretreatment with midazolam or fentanyl. *Eur J Anaesthesiol*. 1999;16(8):550-5.
16. Elwood T, Huchcroft S, MacAdams C. Midazolam coinduction does not delay discharge after very brief propofol anaesthesia. *Can J Anaesth*. 1995;42(2):114-8.
17. Gill PS, Shah J, Ogilvy A. Midazolam reduces the dose of propofol required for induction of anaesthesia and laryngeal mask airway insertion. *Eur J Anaesthesiol*. 2001;18(3):166-70.
18. Goyagi T, Tanaka M, Nishikawa T. Fentanyl decreases propofol requirement for laryngeal mask airway insertion. *Acta Anaesthesiol Scand*. 2003;47(6):771-4.
19. Park HJ, Lee JR, Kim CS, Kim SD, Kim HS. Remifentanyl halves the EC50 of propofol for successful insertion of the laryngeal mask airway and laryngeal tube in pediatric patients. *Anesth Analg*. 2007;105(1):57-61.
20. Jaoua H, Djaziri L, Bousselmi J, Belhouane H, Skander R, Ben Maamer A, et al. Evaluation of a new supraglottic airway device in ambulatory surgery: the I-gel. *La Tunisie M Dicale*. 2014;92(4):239-44.