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Original Research Article

COMPARATIVE EVALUATION OF EFFECT OF SEVOFLURANE VERSUS PROPOFOL FOR INSERTION OF I-GEL AND HAEMODYNAMIC RESPONSES IN ADULT: A RANDOMIZED PROSPECTIVE STUDY

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Abstract

Background: Propofol is a preferred intravenous induction agent for insertion of I-GEL. However, higher doses can cause hypotension, apnoea and collapse of upper airway. Sevoflurane allows a rapid and smooth inhalational induction, quick adjustments, better hemodynamic profile and shorter recovery period. The aim is to evaluate whether sevoflurane is a better induction agent for I-GEL insertion over propofol. **Materials and Methods:** One hundred and ten patients aged 18-65 years of both sexes, ASA grade I & II planned for elective surgery under general anaesthesia were included after obtaining written informed consent and divided into 2 groups. In Group P (n= 55) patients were induced with injection Propofol IV 2mg/kg body weight and Group S (n=55) where 8% sevoflurane with 100% oxygen at rate of 8litres/minute was used for induction. The ease of insertion and presence of adequate jaw relaxation, presence of gag, cough and laryngospasm, number of attempts for I-GEL insertion and hemodynamic parameters during insertion were assessed. **Result:** In the group P the time taken for induction was significantly shorter as compared to group S, however no significant difference was found regarding time taken for insertion of I-GEL among the two groups. Jaw relaxation and I-GEL insertion score were comparable for both groups. Significant increase in heart rate as well as fall in blood pressure was observed in Group P as compared with Group S post I-Gel insertion. **Conclusion:** Sevoflurane can serve as an effective alternative over Propofol as induction agent with better haemodynamic stability for insertion of I-Gel.

INTRODUCTION

The primary responsibility of the anaesthesiologist is to preserve and protect the airway during induction, maintenance and recovery from the state of general anaesthesia. In the event of loss of the airway, prompt re-establishment of airway security should be done before the individuals suffers irreversible injury due to compromised oxygenation. The first supraglottic airway device to be introduced was the Classic Laryngeal Mask Airway (LMA) by Dr Archie Brain.[1] SADs have been well established for the management of patients with normal and difficult airways. I-GEL is a second-generation SAD, developed to overcome the limitations of Proseal LMA. It is a disposable device made up of a thermoplastic elastomer (SEBS-styrene ethylene butadiene styrene) with an anatomically designed, non-inflatable mask, which is soft, gel like and transparent.[2] The advantages of SAD over endotracheal tube are as follows: Increased speed and ease of placement, improved haemodynamic stability at induction as well as during emergence from anaesthesia, minimal increase in intraocular pressure following insertion, reduced anaesthetic requirements for airway tolerance, lower incidence of cough and sore throat during emergence, improved oxygen saturation during emergence.[3] With use of I-

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GEL laryngoscopy is avoided, muscle relaxants may not be needed and haemodynamic changes are minimized during insertion.[4]

Sufficient depth of anaesthesia is required prior to satisfactory insertion of I-GEL as inadequate depth doesn't suppress airway reflexes which results in various complications like gagging, coughing, biting and laryngospasm. Ideal induction agent for I-GEL insertion should produce loss of consciousness, jaw relaxation and absence of upper airway reflexes without cardiovascular or respiratory compromise.

Propofol is a preferred intravenous (IV) induction agent for insertion of SADs due to its proclivity towards subduing oropharyngeal and cough reflex. It is also associated with good recovery.[5] However, higher doses (usually>2.5mg/kg) may be required for adequate jaw relaxation and depth of anaesthesia which may lead to acute hypotension, apnoea and collapse of upper airway.[5-7]

Sevoflurane is a volatile sweet-smelling, non-pungent, non-inflammable highly fluorinated methyl isopropyl ether with minimal respiratory irritant property. It is used as an inhalation anaesthetic agent for induction and maintenance of general anaesthesia while preserving spontaneous ventilation. Sevoflurane allows a rapid and smooth inhalational induction, quick adjustments of anaesthetic depth, rapid elimination, better haemodynamic profile and shorter recovery period. Induction technique using a high inspired concentration of sevoflurane with normal minute ventilation may provide good conditions for the insertion of I-GEL.

The primary objective of this study is to evaluate whether sevoflurane serves as a better induction agent for I-GEL insertion over commonly used propofol.

MATERIALS AND METHODS

This prospective double blinded randomized study was conducted after approval from the institute ethical committee. One hundred and ten patients aged 18-65 years of both sexes, ASA grade I & II planned for elective surgery under general anaesthesia (GA) were included after obtaining written informed consent and were randomly allocated by a computer software into 2 groups. Patients with, history of uncontrolled hypertension, ischemic & valvular heart disease, cerebrovascular accident, morbid obesity (BMI >40 kg/m2), severe ascites, hiatus hernia & gastro-oesophageal reflux disease, ASA III/IV, mouth opening <2 cm, patients undergoing head and neck surgery, modified mallampatti (MMP) > III were excluded from the study. Non-fasted, pregnant patients, any evidence of oro-pharyngeal growth or obstruction, undergoing head and neck surgery, refusal for participation and failure to place I-GEL even after two attempts were further excluded. The trial was registered with Clinical Trials Registry – India (ICMR-NIMS) with CTRI Reg. no. CTRI/ 2020/02/023544.

- Group P (n= 55) was the control group. Patients were given injection Propofol IV 2mg/kg body weight till onset of induction.
- Group S (n=55) was the intervention group. Patients were given 8% sevoflurane with fresh gas flow of 100% oxygen at rate of 8litres/minute through ventilator circuit using tidal breathing induction technique (TBT) till onset of induction.

On the arrival of the patient in the operating room, pre-procedure checklist was completed. Standard ASA monitors were attached and baseline haemodynamic parameters noted. Subjects of both groups were premedicated with injection Midazolam 1mg IV, injection Glycopyrrolate 0.004 mg/kg IV and injection Fentanyl 2mcg/kg IV. After premedication, anaesthesia was induced as per allocated group of the patient.

In group P, pre-oxygenation was done with 100% oxygen at fresh gas flow rate of 10 litres/minute. All the patients of group P were asked to continue their normal tidal breaths which was to inhale and exhale normally without holding the breaths in between from the facemask. After 3 minutes of preoxygenation, patients were induced with injection propofol 2 mg/kg body weight IV, till loss of verbal response.

In Group S, pre-oxygenation with 100% O2 at the rate of 10 litres/min with a facemask was done using first anaesthesia machine and the second anaesthesia machine was used to deliver 8% Sevoflurane for induction of general anaesthesia. All the patients of group S were asked to continue their normal tidal breaths which was to inhale and exhale normally without holding the breaths in between from the facemask connected to the first anaesthesia machine. After 3 minutes of pre-oxygenation, the facemask was connected to the primed circuit from second anaesthesia machine. The patients were asked to continue normal tidal breathing till onset of induction which was assessed by loss of verbal contact. Two anaesthesia machines were utilized for the study in the group S. First anaesthesia machine was used for delivery of 100% oxygen at rate of 10 litres/ min for 3 minutes to achieve pre-oxygenation in group S. The second anaesthesia machine was primed beforehand with 8% Sevoflurane and 100% oxygen at the rate of 8 litres/min for 30 seconds to avoid loss of time during priming of anaesthesia circuit and was immediately used for inhalational induction in group S. The unprimed anaesthesia machine along with breathing circuit was removed from the site for blinding.

Loss of verbal response was considered as induction of anaesthesia in both groups and induction time was noted. In both the groups, mask ventilation was continued for 1 minute after loss of verbal contact before attempting to assess jaw relaxation and I-GEL insertion. After 1 minute of mask ventilation from onset of induction, first attempt of appropriate size I-GEL insertion according to body weight, was done in both the group. I-GEL was inserted by an experienced individual with proper training of

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handling airway who was called in after induction, in order to maintain blinding.

The ease of insertion and presence of adequate jaw relaxation, presence or absence of gagging, cough and laryngospasm, attenuation of laryngeal reflexes and number of attempts for I-GEL insertion were assessed as part of I-GEL insertion score, as described by Priya et al.[8] [Figure 1] After insertion of I-GEL, haemodynamic parameters were monitored till 5 minutes from baseline (before induction), at induction, at time of I-GEL insertion followed by monitoring of parameters at 1 minute, 2 minute, 3 minute, 4 minute and 5 minute after insertion. failed insertion in both the group was defined as failure to insert the I-GEL after 2 attempts and were given injection Succinylcholine 1.5 mg/kg IV to facilitate endo-tracheal intubation. The study ended after monitoring and recording haemodynamic vitals for 5 minutes from insertion of I-GEL.

General anaesthesia was maintained with a mixture of 1% Sevoflurane and 50% O2. Intermittent injection of vecuronium 0.1 mg/kg body weight IV was given to maintain muscle relaxation as per need during surgery. Injection Paracetamol 15 mg/kg IV was given for analgesia. Injection ondansetron was given IV to reduce incidence of post-operative nausea, vomiting. After completion of surgery, neuromuscular blockade was reversed by injection neostigmine 50 mcg/kg and injection glycopyrrolate 10 mcg/kg IV and extubated.

Proportion of samples having successful I-GEL insertion at first attempt in Propofol group with excellent grading were reported to be 100% and proportion of samples having successful I-GEL insertion at first attempt in Sevoflurane group with excellent grading were found to be 84.7%. Sample size was calculated with the minimum expected difference between two groups of 15%. For statistically significant result with α=0.05 and β=0.80, 55 patients were required in each group [Fleiss, Statistical Methods for Rates and Proportions]. Results are presented as mean ± standard deviation (SD) for continuous variables and frequency with their respective percentages for categorical variables. For categorical data Chi-square test and Fischer Exact test was used. For paired samples Paired Student's test was used. P value less than 0.05 were considered statistically significant. Data was extracted and analysed using SPSS version 27.

RESULTS

A total of 134 patients were selected out of which, 24 were excluded and 110 patients were finally included in the study [Figure 2]. No significant differences among the two groups were noted regarding patient characteristics such as age, sex, height, weight, BMI and ASA status [Table 1]. In the group P the time taken for induction was significantly shorter as compared to group S, however no significant difference was found regarding time taken for insertion of I-GEL among the two groups. the characteristics of I-GEL insertion such as jaw relaxation, ease of I-GEL insertion, and I-GEL insertion score were comparable for both groups and statistically not significant. [Table 2]

Baseline Heart rate, systolic and diastolic blood pressure were comparable in both the groups. At the time of induction and insertion, statistically significant increase in heart rate was observed in Group P as compared with Group S while post I-Gel insertion up to 5 minutes, Group S had shown significantly higher heart rate than in Group P. [Table 3] Systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were comparable at time of induction and I-GEL insertion and no significant difference could be observed. Post I-Gel insertion, however significant degree of fall in SBP, DBP and MAP was observed in Group P in comparison to Group S which had relatively stable parameters. [Table 4, 5] [Figure 3] No significant differences were observed regarding complications such as coughing, gagging or laryngospasm among the groups.

CRITERIA	SCORE		
	3	2	1
Introduction of I-GEL			
Jaw Opening	Full	Partial	Nil
Ease of insertion	Easy	Difficult	Impossible
Response to jaw thrust in terms of motor response	Nil	Partial	Full
Patient response on I-GEL insertion			
Coughing	Nil	Minor	Severe
Gagging	Nil	Minor	Severe
Laryngospasm	Nil	Partial	Complete
Maximum total score:			
	Excellent- 18	Satisfactory- 16 to17	Poor- <16
Attenuation of laryngeal reflexes			
	Grade I (Full)	Grade II (Partial)	Grade III (Poor)
	I-GEL is inserted smoothly	I-GEL insertion is accompanied by gagging or coughing	I-GEL insertion is not possible

Figure 1: I-GEL insertion Score assessment

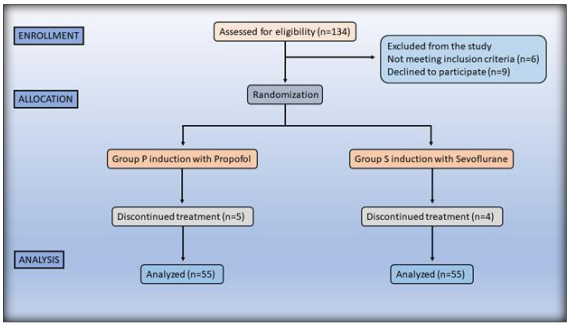

Figure 2: Flowchart of participants through the study

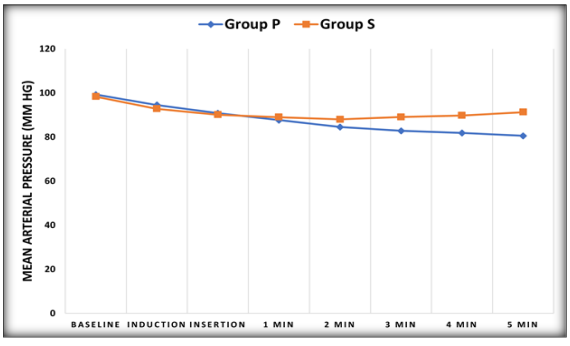

Figure 3: Comparison of Mean Arterial Pressure (MAP)

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Table 1: Patient characteristics.

		GROUP P (n=55)	GROUP S (n=55)	P value
Age (years)		40.75±13.82	39.58±13.19	0.80
Weight (kg)		60.55±5.83	61.02±6.01	0.67
Height (cm)		148.55±9.83	150.55±7.83	0.71
BMI (kg/m2)		31.75±13.82	31.58±13.19	0.89
ASA		31/24	39/16	0.37
Sex	1. Male	32 (58.18%)	29 (52.73%)	0.56
	2. Female	23 (41.82%)	26 (47.27%)	
Size of I-gel	Size 3	40 (72.73%)	39 (70.91%)	0.83
	Size 4	15 (27.27%)	16 (29.09%)	

Table 2: Changes in I-gel insertion parameters

		GROUP P (n=55)	GROUP S (n=55)	P value
Induction time (sec)		37.62±6.29	55.2±4.93	<0.001
Insertion time (sec)		15.2±2.05	15.71±2.41	0.23
Ease of insertion	Easy (Grade 3)	54 (98.18%)	51 (94.55%)	0.31
	Difficult (Grade 2)	1 (1.82%)	3 (5.45%)	
	Impossible (Grade 1)	0	0	
Jaw relaxation	Full (Grade 3)	52 (94.55%)	49 (89.09%)	0.29
	Partial (Grade 2)	3 (5.45%)	6 (10.91%)	
	Nil (Grade 1)	0	0	
I-gel insertion score	Excellent (18)	45 (81.82%)	37 (67.27%)	0.08
	Satisfactory (16-17)	10 (18.18%)	18 (32.73%)	
	Poor (<16)	0	0	

Table 3: Changes in Heart Rate

HEART RATE	GROUP P (n=55)	GROUP S (n=55)	P value
Baseline	80.87±6.90	78.73±6.81	0.10
During induction	87.27±7.91	82.49±6.82	0.001
During insertion	91.11±6.82	88.27±7.25	0.04
1 min	90.6±6.46	90.8±7.27	0.88
2 min	87.85±6.53	94.45±8.16	<0.001
3 min	82.69±6.56	92.95±7.39	<0.001
4 min	82.09±7.5	93.65±6.73	<0.001
5 min	82.53±6.6	89.51±7.13	<0.001

Table 4: Changes in Systolic Blood Pressure (SBP)

SBP	GROUP P (n=55)	GROUP S (n=55)	P value
Baseline	128.05±11.27	131±7.13	0.10
During induction	122.49±11.58	125.05±6.83	0.16
During insertion	117.91±10.58	122.18±7.21	0.15
1 min	113.78±11.56	119.04±7.78	0.006
2 min	110.47±9.57	115.78±6.3	0.001
3 min	108.56±9.32	117.8±8.14	<0.001
4 min	106.84±8.99	120.4±6.98	<0.001
5 min	105.44±10.46	123.2±6.77	<0.001

Table 5: Changes in Diastolic Blood Pressure (DBP)

DBP	GROUP P (n=55)	GROUP S (n=55)	P value
Baseline	81.33±9.53	84.55±13.03	0.14
During induction	79.11±8.98	76.84±5.6	0.11
During insertion	76.09±9.00	74.56±5.75	0.29
1 min	73.09±8.23	73.73±6.71	0.66
2 min	70.16±7.92	73.69±6.90	0.01
3 min	68.47±8.18	74.31±5.79	<0.001
4 min	67.64±8.14	74.31±5.15	<0.001
5 min	66.35±6.43	75.36±5.83	<0.001

DISCUSSION

Propofol is a preferred intravenous induction agent for insertion of SAD. Sevoflurane is a suitable inhalational induction agent of anaesthesia and insertion of the I-Gel while preserving spontaneous ventilation. In this study, the conditions for I-GEL insertion obtained with 8% Sevoflurane using normal tidal breathing induction technique was compared with intravenous Propofol as induction agent. Characteristics of I-GEL insertion and fluctuations in haemodynamic parameters were recorded.

Several agents had been tried to facilitate insertion of I-Gel. One of the most popular agents, intravenous Propofol either by bolus dose, intermittent dose or infusion had been studied by various authors for insertion of I-Gel and other Supraglottic airway device. Other alternative agents used were intravenous thiopentone and inhalational agents like

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Halothane, Sevoflurane with orwithout nitrous oxide. The intravenous induction agent Thiopentone, with its failure to suppress the residual intact airway reflexes at dose of 6mg/kg, 5mg/kg and 4 mg/kg was not a suitable choice for I-Gel insertion.

The advantages of Propofol for I-Gel insertion were the rapidity of induction, adequate jaw relaxation and suppression of protective airway reflexes.[9-12] However, Propofol is by no means an ideal agent as it is associated with several adverse effects like pain on injection, hypersensitivity, movements, apnoea and hypotension.[5-7] Inhalation agent Sevoflurane appeared to be a promising alternative to Propofol for I-GEL insertion because of its pleasant, smooth, rapid induction along with haemodynamic stability. Previous studies compared sevoflurane with Propofol and found better haemodynamic stability with almost similar conditions for SAD insertion with Sevoflurane.[9-14]

Use of Lignocaine as adjuvant with propofol before induction has added effect, that lignocaine itself acts via suppression of laryngeal reflexes, rather than a direct general anaesthetic effect. Lignocaine at higher dose may actually increase anaesthetic depth, as it had been shown to potentiate the effect of nitrous oxide in reducing the minimum alveolar concentration of halothane. In our study group P (Propofol), we used intravenous Propofol 2 mg/kg as an induction agent without lignocaine to exclude additional effect of lignocaine on airway reflexes or minimum alveolar concentration of inhalational agent.

In our study mean induction time in group P was significantly lower than in group S. It indicates that induction with Propofol was faster than normal tidal breath induction with 8% Sevoflurane. Similar results have been observed in previous studies which concurs with reported findings.[8,9,14] The mean time taken for insertion of I-GEL in both groups was comparable. Insertion of I-Gel was attempted 1 min after the loss of verbal contact in both the groups and this waiting interval of 60 seconds wasn't included in calculating insertion time unlike many previous studies. This was done in order to wait for the lag time that occurs in equilibration of alveolar concentration with the brain concentration of Sevoflurane. Previous studies have also reported no significant differences regarding time taken for insertion of SAD among propofol and sevoflurane.[8,10,12] The time taken for insertion of I-GEL was shorter than the previous studies probably due to our choice of using higher dose of Propofol and high inspired concentration of Sevoflurane.

I-Gel insertion characteristics in both the groups were compared based on six criteria (jaw opening, ease of insertion, patient movement, coughing, gagging and laryngospasm), each scored on a scale from 1 to 3. Total score of 18 was considered excellent. Score 16-17 was considered satisfactory and score below 16 was considered to be poor. There was no significant difference regarding jaw relaxation, ease of insertion, I-GEL insertion score or complications such as coughing, gagging and laryngospasm.

For successful insertion of I-Gel jaw relaxation is very crucial. Priya et al. reported relatively lesser jaw relaxation with use of sevoflurane as compared to propofol.[8] In this study however, majority of the patients in both groups had complete jaw relaxation and I-GEL was easily inserted. The data was comparable with no significant inclination towards any particular group. None of the patients had shown failure or impossible I-GEL insertion. Prior studies too didn't find any significant difference regarding coughing, gagging or laryngospasm with either propofol or sevoflurane, which supports our observations.[8,15] These findings could be explained by the waiting for 1 min before I-GEL insertion. This led to equilibration of alveolar concentration and brain concentration of Sevoflurane and adequate plasma concentration of propofol to provide deep anaesthesia with suppression of airway reflexes and hence good jaw opening was attained with easy insertion. Chavan et al similarly reported documented excellent SAD insertion conditions with both propofol and sevoflurane.[9]

After induction of anaesthesia, a significant increase in heart rate was seen in group S as compared to group P. There was a constant rise seen in heart rate in the sevoflurane groups after insertion of I-Gel, which did not reach the baseline value even at 5th minute. The observations are is in accordance with pharmacological effect of Propofol which inhibits the baroreceptor reflexes and decreases the heart rate while Sevoflurane which has no effect on the baroreceptor reflex and produces a reflex increase in heart rate in response to falling blood pressure. The results were comparable with a preceding study which also stated that there was first non-significant rise in heart rate up to few minutes followed by return of baseline heart rate in Propofol group. In the same study, there was constant and statistically significant rise in heart rate with Sevoflurane.[9]

There was a significant decrease observed in SBP, DBP and MAP in Propofol group when compared to Sevoflurane group. In both the groups there had been reduction of SBP, DBP and MAP as compared to the baseline levels. Although The decrease was hemodynamically more profound in group P. these findings could be explained by the fact that propofol causes more pronounced hemodynamic changes compared to sevoflurane anaesthesia induction probably due to its inhibitory effect on myocardial contractility and vasodilation. Previously available data supports the findings. It has been previously recorded greater fall MAP with Propofol group than Sevoflurane group because of substantial decrease in SBP as well as DBP.[8,9,16]

We observed that the time taken for induction of general anaesthesia using intravenous injection of Propofol was faster than inhalational induction with Sevoflurane tidal breathing technique. Time taken for insertion of I-Gel using inhalational induction agent (8% Sevoflurane) was comparable to intravenous

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induction agent (2mg/kg body weight Propofol) in adults. Jaw relaxation and ease of insertion of I-Gel were comparable in both the groups. Overall insertion characteristics score of I-Gel insertion was comparable in both the groups. There was a high success rate for I-Gel insertion during first attempt in both the induction techniques. Complications like coughing and gagging were not observed in both the groups. Incidence of Laryngospasm was reported more with Sevoflurane and motor response to jaw thrust was observed more with Propofol, however, incidences of complication remained statistically not significant in both the groups.

In order to keep the uniformity and for the second observer to be invited for insertion of I-Gel, we waited for one minute after the loss of verbal response in both the groups. This will definitely help in equilibrating alveolar and brain concentrations of Sevoflurane. However, this might decrease the concentration of Propofol in the brain as it rapidly starts redistributing to the peripheral tissues, hence, further studies should be done to eliminate this issue. Further studies should be done to compare vital capacity breathing technique using Sevoflurane with Propofol for I-Gel insertion. Further studies should be done using Propofol with Lignocaine to elevate pain during intravenous injection and compare with other concentrations of Sevoflurane for induction and insertion characteristics of I-Gel.

Limitations: In spite of taking all precautions to make the study a double blind, the smell of Sevoflurane, couldn't be masked and the person inserting the I-Gel could have known about the induction agent. Hence, further studies should be conducted with better blinding methods. Patients of extremes of age were excluded from the study, hence further studies should be conducted in patients with extreme ages for induction and insertion characteristics of I-Gel.

CONCLUSION

The study attempted to compare the insertion characteristics of I-GEL with intravenous Propofol and inhalational agent Sevoflurane in adult patients undergoing general anaesthesia. Induction of general anaesthesia using intravenous Propofol was faster than inhalational induction with Sevoflurane. However, time taken for insertion of I-GEL, jaw relaxation and ease of insertion were similar in both groups. Also, there was significant fall in SBP, DBP and MAP with use of Propofol. Therefore, Sevoflurane can serve as an effective alternative over commonly used Propofol as induction agent with better haemodynamic stability for insertion of I-Gel in adults undergoing general anaesthesia.

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