Original Research Article

Comparision of Induction Dose of Propofol for I Gel Insertion – BIS Guided Versus Clinical Assessment Technique – A Randomised Control Study

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Abstract

Background and Aims: I gel has become one of the popular choice to provide anaesthesia using intravenous propofol as induction agent. This study aims to compare the dose of propofol required for induction and insertion of I gel using Bispectral index monitor as a guide. **Materials and Methods:** A randomised prospective study was conducted in 60 patients of ASA grade I-II of either sex aged 20-50 years who underwent elective surgery under general anaesthesia using I gel device. The patients were randomly divided in to two groups. Group A received BIS guided propofol to achieve target value of 50 and Group B received propofol till loss of eyelash reflex and jaw relaxation. The total dose of propofol and ease of insertion was compared between the groups. The statistical analysis was done using unpaired t test, chi square test and student t test. A p value of <0.05 was considered significant.**Results:** The demographic characteristics were comparable in both groups. The mean induction dose of propofol required in Group A and Group B was 84.66 ± 5.56 mg 97.33 ±10.48 mg respectively which was statistically significant (p <0.000). The ease of insertion and hemodynamic parameters were was comparable in both groups. **Conclusion**: Induction dose of propofol required for I gel insertion by using BIS value as a guide reduces the overall dose without affecting the appropriate conditions required for I gel insertion.

Keywords: BIS, I gel, Induction, clinical method, propofol.

Introduction

The increasing use of day care anaesthesia has led to the greater use of I GEL as an alternative to face mask and tracheal intubation. Since its introduction various intravenous agents and volatile anaesthetic agents have been used for induction of anaesthesia for I GEL insertion. Propofol is most commonly used intravenous induction agent. It produces rapid sedation with favourable recovery profile. However propofol also has disadvantages like pain on injection, cardiovascular and respiratory depression causing hypotension and apnea respectively. Satisfactory insertion of I GEL requires adequate depth of anaesthesia for suppression of airway reflexes and to avoid untoward effects due to airway instrumentation. The recommended dose of propofol required to achieve induction is reported to be 1.5 – 2.5 mg/kg[1,2]. But the recommended dose can vary among the individuals and can lead to untoward effects.

Traditionally most of the anaesthesiologist has been utilizing the clinical responses to assess and maintain adequate depth of anaesthesia, although many advanced techniques like Bispectral monitor and entropy are available. Bispectral index monitor is one of the objective methods to assess the level of sedation. BIS demonstrates the dose response relationship with inhalational and hypnotic intravenous agents such as propofol and midazolam. Bispectral index score (BIS) can be used as a continuous monitor of sedation in adults. It is an useful reflector of great inter- individual variations in pharmacokinetics and pharmacodynamics of induction and sedative drugs[3]. It has been shown that BIS correlated with clinically assessed sedation levels and is useful for differentiating adequate and inadequate sedation. In addition it helps in optmizing the dose of anaesthetic drugs[4].

However fewer studies using BIS monitoring for induction of I GEL insertion are reported in literature. The data available regarding use of BIS guided induction with propofol for I gel insertion is limited. Hence we hypothesized that BIS-guided propofol induction for insertion of I GEL leads to reduction in overall dose of propofol compared to clinical assessment technique of propofol induction. The study was conducted with an aim to compare the dose of propfol along clinical characteristics during induction and insertion of I gel guided by BIS and clinical signs.

Objectives of the study

The main objective of this study was to evaluate whether administration of propofol guided by BIS value compared to administration by clinical assessment technique method for induction and insertion of I gel reduces the overall dose of propofol .

Primary objective

1. To compare BIS guided induction dose of propofol to achieve BIS value of 50-55 in group A and Induction dose of propfol required using clinical method defined as loss of eyelash reflex and jaw relaxation.
2. To compare the ease of I Gel insertion in both groups.

Secondary objective

To compare the hemodynamic parameters – HR and Systolic blood pressure SBP, DBP and MAP.

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Materials and Methods

A prospective clinical comparative study entitled 'Comparision of induction dose of propofol for I gel insertion – BIS guided versus clinical assessment technique - A randomised control study' was conducted in ESIC medical college and Hospital Gulbarga, during the period February 2021- July 2021 after obtaining Institutional Ethical committe clearance. CTRI registration was obtained on 18/03/2021 with registration number as CTRI/2021/03/032118. The study included 60 patients of either sex belonging to ASA(American society of Anaesthesiologists) grade I and II aged between 20-50 years undergoing elective surgery under general anaesthesia. The patients with difficult anticipated intubation, ASA grade III-IV, Mallampatti grade 2-3, heavy smokers, morbidly obese patients, patients with significant systemic co-morbid conditions and patients at risk of aspiration were excluded from the study. A written informed consent was obtained from the selected patients. Thorough preanaesthetic evaluation was done one day prior to the surgery. The standard fasting guidelines were followed. On arrival of patient to the operating room, an approproiate intravenous cannula was secured and was connected to the fluid. Before induction all the patients were monitored for non-invasive blood pressure (NIBP), pulse oximeter (SpO2), electrocardiogram (ECG), end tidal carbon-dioxide (ETCO2) and anaesthetic gas monitor (AGM). Group A patients were connected to BIS monitor. BIS sensor was attached to forehead and was connected to BIS monitor to record BIS value. Patients in both group received inj midazolam 0.02mg/kg as premedication before induction. Preoxygenation was done with 100% oxygen for 3 minutes. The drug was injected by the anaesthesiologist who was not involved in the study and the parameters were assessed by other observer who was blinded to the procedure. The I gel insertion was assessed and graded by an anaesthesiologist who was blinded to the procedure.

The study population was randomly divided by using computer generated random numbers in to two groups containing 30 patients in each group. The groups were labelled as Group A and Group B. Group A received BIS guided intravenous propofol 2.5mg/kg (30mg/15sec) to achieve BIS value of 50-55. Group B received intravenous propofol 2.5mg/kg (30 mg/15sec) till loss of eyelash reflex and adequate jaw relaxation. In Group A after injection of the drug, a wait period of 15 seconds was given to obtain a sustained BIS value. In Group B the loss of eyelash reflex and adequate jaw relaxation assessed by clinical methods was considered as the end point of induction. At this point the following parameters were recorded by the observer: Induction dose of propofol to achieve BIS value 50-55 in group A and Induction dose of propfol required to cause loss of eyelash reflex and jaw relaxation in group B.

The size of I-gel chosen was based on patients body weight and manufacturer's recommendations. After induction the observer assessed for the jaw relaxation by giving jaw thrust and if satisfied, the observer proceeded for I gel insertion. At this point BIS scores during insertion and after insertion of I GEL were recorded. The ease of insertion was recorded. The overall conditions for insertion of I GEL was assessed as excellent (18) satisfactory (16-17) and poor (<16) based on the total score obtained by summing up the individual scores of each component. If the observer was not satisfied with the jaw relaxation injection propofol 0.5mg/kg was incrementally added till adequate jaw relaxation was achieved and I gel insertion was attempted successfully. After insertion, I-gel was fixed and correct placement was confirmed by bilateral symmetrical chest expansion on manual ventilation, breath sounds on auscultation, waveform on capnography, no audible leak of the gases, and no gastric insufflations. After successful insertion of I gel, anaesthesia was continued as per the surgical needs decided by the anaesthesiologist.

Calculation of sample size was done on the basis of findings from previous study considering reduction in propofol dose as a main parameter[5]. A difference between the groups of more than 20-25% was considered practically significant. Using $\alpha = 5\%$ and $\beta = 80\%$, the minimum sample size required would be 27. Considering 10% drop out the total sample size was calculated to be 30 in each group. Statistical analysis of demographic data was done using unpaired t test and chi square test. Comparison between the induction dose and hemodynamic parameters were done using Student t test. A p value less than 0.05 was considered statistically significant.

Results

Table 1: Demographic characters

	Group A	Group B	P VALUE
Age (yrs)	36±7.16 9	41±1.52	0.966 (ns)
Weight (kg)	52.86±5.29	53.46±4.15	0.627 (ns)
Gender (M/F)	14/16	14/16	1.000(ns)

Age and weight are presented as mean ± standard deviation ; Yrs – years; kg – kilogram; M/F – male/female; ns – not significant

Table 2: Total induction dose of propofol and ease of I gel insertion

	Group A	Group B	P VALUE
Dose of propofol	84.66±5.56	97.33±10.48	0.000*
Ease of insertion Excellent Satisfactory	\ 93.3% (n=28) 6.7% (n=2)	 96.7% (n=29) 3.3% (n=1)	1.000 (ns)

Data is presented as mean ±standard deviation and numbers and percentages; * - highly significant; ns – not significant; n – number of patients

The demographic characteristic features like age, weight and gender were comparable in both groups as depicted in table 1. The mean dose of propofol requirement in both groups and grading of ease of insertion of I gel is depicted in table 2. The mean dose of propofol required in Group A and in Group B was 84.66 ± 5.56 mg 97.33 ±10.48 mg respectively which was statistically significant with p value of 0.0006. In group A the ease of insertion of I gel was graded as excellent in 93.3% and in group B it was 96.7%. The hemodynamic parameters were comparable in both groups.

Discussion

Supraglottic devices(SGD) like laryngeal mask airway(LMA) classic, LMA proseal, LMA supreme and I gel have been recently used to provide anaesthesia for various surgeries. I gel is made up of soft gel like thermoplastic elastomer that makes up the non-inflatable cuff. I gel insertion is relatively easy and faster compared to other supraglottic devices. Therefore I gel is popularly used for management of airway in elective and emergency situations. It is extensively used to provide general anaesthesia for various surgeries in the operation room theatre. It provides good conditions for controlled ventilation similar to that of endotracheal tube[6]. Insertion of I gel requires adequate sedation and depth of anaesthesia. This is achieved by various intravenous agents like propofol, thiopentone and ketamine. In recent days inhalational agent like sevoflurane has become a popular choice for insertion of I gel[7,8].The most commonly used induction agent is propofol because of its rapid action, better suppression of airway reflexes and rapid recovery profile. Propofol allows smooth induction and smooth

insertion of I gel and other supraglottic airway devices. The dose of propofol for insertion of I gel varies from 2.0-3.42 mg/kg[9].

However at higher doses propofol can cause profound hemodynamic instability leading to bradycardia and hypotension[10].Higher bolus dose of Propofol is also associated with excitatory patient movements. There has been a greater variability in the propofol dose needed for loss of consciousness compared with thiopentone[11]. This suggests that propofol should be slowly titrated to effect in order to avoid overdosage and increased side-effects. Most of the anaesthesiologists use clinical assessment technique i.e loss of eyelash reflex as an end point of induction for I gel insertion. Although the clinical methods are known to allow usage of minimal drug for its effect, it cannot rule out any overdosage. Clinical assessment methods may be subjective and deeper levels of sedation may not be accurately evaluated. BIS is an electroencephalographic monitoring used in recent era to assess and titrate the dose of various sedative and anesthetic drugs. BIS is a dimensionless number ranging from 0-100 wherein 100 represent the fully awake state and 0 represents the complete electrical silence or absence of brain activity. BIS values between 40 to 60 represent adequate general anesthesia for a surgery, values less than 40 represent a deep hypnotic state. BIS is an objective method of evaluating the adequate level of sedation individually to achieve desired level of sedation and thereby it can prevent untoward side effects like hemodynamic instability and overdosage. BIS has been considered as one of the standard device to monitor depth of anaesthesia[12]. Few studies have studied the depth of sedation using bispectral index[13,14] and accordingly the use of the BIS-monitor facilitates the individual titration of propofol to a desired hypnotic level and thereby might reduce the dose of the drug and also the extent of unintended side-effects such as arterial hypotension. Therefore we hypothesized that BIS guided induction with propofol for I gel insertion compared to clinical assessment technique induction with propofol can reduce the total dose of propofol. Our study also intended to compare the characteristics of ease of insertion for I gel in both groups.

In our study patients in both groups were administered 2.5mg/kg of propofol for induction. The dose of drug and BIS value was chosen in accordance to previous studies where in the dose was considered to be effective for I gel insertion[15,16]. Since opioids may reduce the effective concentration of propofol required for the I gel insertion, our study did not include opioids in premedication.

The results of our study showed that the dose of propofol required to achieve the target BIS value of 50-60 in Group A was significantly lower when compared to Group B. In group B the mean dose of propofol required to achieve loss of eyelash reflex and jaw relaxation was 97.33±10.48 mg whereas in group A the dose of propofol to achieve target BIS value was 84.66 ± 5.56 mg. In accordance to our study, Ercan et al.,[17] also found a significant reduction in the dose of propofol requirement using BIS value as guide. The authors compared the dose requirement of propofol in three groups wherein Group II and Group III received BIS guided 2mg/kg of propofol . The authors observed that the dose of propofol were 147.4±12.1mg, 95.8 ± 10.2mg and 84.3±11.4mg in group I , Group II and Group III respectively. They concluded that there was 36% and 43% reduction in dose of propofol in group II and group III respectively as compared to group I which was statistically significant. Further the authors concluded that BIS guided induction can reduce the dose of propofol by maintaining adequate depth of anaesthesia with stable hemodynamic parameters. Similarly in a study by Quesada et al.,[18] the authors compared the sedation between propofol and remifentanil for ultasound guided bronchoscopy using BIS and clinical scale . The authors reported the mean dose of propofol in BIS group and non BIS group to be 5.6 mg/kg and 6.8mg/kg respectively which was statistically significant (p = 0.001). The authors concluded that use of BIS can effectively control the depth of anaesthesia along with significant reduction in the dose of the drug. In an another study the BIS guided propofol infusion was used to achieve target value of 50 till the loss of palpebral reflex and endotracheal intubation. The authors reported that the mean consumption of propofol was 1.14 - 1.86mg/kg which was significantly low compared to the recommended doses of induction as per the literature[19]. Various studies in past have been conducted to evaluate the dose of propofol requirement by using BIS and have quoted a significant reduction in the dose of propofol. However the studies used target plasma concentration to calculate the total dose of propofol[20-23].

Despite these various studies, there have been many contrasting results regarding the use of BIS value as a guide for induction for propfol. In contrast to our study Rusch et al.,[24] reported no significant difference in the BIS guided manual administration of 2mg/kg propofol for induction of general anaesthesia compared to non BIS group. This might be attributed to the lesser dose of the drug compared to our study where in we used 2.5mg/kg of propofol. Similarly in an another study the mean dose of propfol used for induction was 1.85 and 1.79 mg/kg in group A and group B respectively. The authors concluded that there is no significant difference in the induction dose of propofol when administered either by clinical assessment method or by BIS guided method[25].

In our study the induction dose for insertion of I GEL were significantly reduced when compared to clinical assessment method. Although there was significant reduction in the dose of propofol the adequacy of jaw relaxation was comparable in both groups. The ease of insertion of I gel was graded as excellent, satisfactory and poor. In BIS guided induction 28 (93.3%) patients and in clinical assessment method 29 (96.7%) patients had excellent conditions for I gel insertion. None of the patients were graded as poor condition for I gel insertion. The hemodynamic parameters were comparable in both groups.

Conclusion

In conclusion the induction dose of propofol required for I gel insertion by using BIS value as a guide reduces the overall dose without affecting the appropriate conditions required for I gel insertion.

Limitations of our study include the quoted references , wherein the induction dose of propofol have been studied for sedation and intubation using BIS value as a guide. However our study aimed at comparing the total induction dose required for I gel insertion using BIS value and clinical method. Since the data available regarding the comparison of induction dose of propfol for I gel insertion by BIS guided method and clinical method are scarce, we recommend further studies in this aspect.

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