

ASSESSMENT OF TOTAL INTRAVENOUS ANESTHESIA BY PROPOFOL AND INHALATIONAL ANESTHESIA WITH ISOFLURANE FOR CONTROLLED HYPOTENSION IN FUNCTIONAL ENDOSCOPIC SINUS SURGERY

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ABSTRACT

Objective: The study's key objective is to compare the propofol-based total intravenous anesthesia (TIVA) with isoflurane-based inhalational anesthesia for controlled hypotension during functional endoscopic sinus surgery (FESS).

Methods: This study was a prospective randomized and controlled single-blinded clinical study. The study involved 40 patients posted for elective FESS surgery, selected randomly from the ENT department. Anesthesia was induced with Inj. Midazolam 2 mg, Inj. Fentanyl 2 µg/kg, Inj. Propofol 2 mg/kg, Inj. Vecuronium 0.1 mg/kg was ventilated using oxygen, air, and Isoflurane (FiO₂ of 0.5) in patients with isoflurane. Injections of 2 mg of midazolam, 2 µg/kg of fentanyl, 2 mg/kg propofol, and 0.1 mg/kg vecuronium, as well as oxygen and air for ventilation, were used to induce anesthesia (FIO₂ of 0.5) in TIVA group patients. Fromme boezaart scale was used as an evaluation scale for surgical site bleeding.

Results: The average blood loss in the isoflurane group was 134.25±4.65 ml and in the propofol group was 66.95±4.28 ml. The quality of the surgical field in the propofol group is (3.13±0.9), and in the isoflurane group is (3.13±0.8). The results are significant.

Conclusion: Total intravenous anesthesia using propofol provides notable advantages over the traditionally used inhalational anesthetic technique using isoflurane in surgical field conditions and intraoperative blood loss.

Keywords: Isoflurane, Propofol, Surgical field, Functional endoscopic sinus surgery.

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INTRODUCTION

Since Messerklinger and Wigand's lectures in the late 1970s, the fields of rhinology and sinus surgery have grown significantly. Surgeons can carry out intricate treatments with advanced imaging tools, better anatomical knowledge, chronic sinusitis pathophysiology, and other imaging-based techniques with enhanced safety precautions. A skillful surgical method for treating chronic rhino sinusitis is functional endoscopic sinus surgery (FESS). To maintain the natural mucociliary clearance mechanism and realm of the typical anatomical structures, restoration of the paranasal sinuses' aeration and drainage is the goal of FESS [1,2]. This surgery has adverse outcomes such as orbital cellulitis, rhino-oral fistulae, optic nerve lesions, dura mater, and meningitis [2-4]. These complications are often due to surgery performance in inappropriate bleeding [5]. Therefore, it is crucial to retain the surgical field as bloodless to some extent, decrease the likelihood of problems, and increase visibility. This can be accomplished through the use of various techniques and routes, including the administration of intravenous and inhalational anesthetic drugs, alpha- and beta-blockers, alpha agonists, vasodilators, and the use of vasopressors in conjunction with the local anesthetics during the operation, as well as the impact of the reverse Trendelenburg position. Due to the discomfort and the possibility of an incomplete block with topical anesthetic, general anesthesia is chosen over local anesthesia.

Furthermore, controlled hypotension shortens the duration of the procedure and improves the surgical field conditions when FESS is carried out under general anesthesia. In normotensive individuals, controlled hypotension is a drop in systolic blood pressure to 80–90 mm Hg or a decrease in mean arterial pressure (MAP) to 50–65 mm Hg [6-8]. Gardener introduced hypotensive anesthesia into clinical practice in

1946 after Cushing first recommended it in 1917 [9-11]. Griffith and Gilles used solid spinal anesthesia in 1948 to intentionally lower blood pressure [12]. Pentamethonium Ganglion Blockade was used to lower arterial pressure in the 1950s [13]. Halothane was used to create hypotensive anesthesia at the beginning of the 1980s; by the end of the decade, vasodilators and beta-adrenergic blockers were in use [14]. Recently, isoflurane, nitroglycerine, and purine derivatives have all been employed alone to cause hypotension [15].

Using an inhalational anesthetic approach, isoflurane has become more common to achieve controlled hypotension. Isoflurane is a volatile and non-flammable anesthetic with a strong smell. It is an enflurane chemical isomer. It has been demonstrated that *in vivo* isoflurane only slightly depresses the heart. Increased heart rate, brought on by the partial preservation of carotid baroreflexes, helps maintain cardiac output. Even if it is not as strong a dilator as nitroglycerine or adenosine, it dilates the coronary arteries significantly when the dosage is increased rapidly. Propofol-based total intravenous anesthesia (TIVA) is a relatively recent technique for this aim. In TIVA, propofol is employed as a medication to induce and maintain anesthesia [3,4]. It has a quick onset of action and lowers blood pressure by vasodilation. The heart rate won't vary significantly following a propofol induction dosage. Propofol may reset or block the baroreceptor reflex, which would lessen the tachycardic response to hypotension. Compared to the traditional isoflurane-based inhalational anesthetic approach, Propofol-based total intravenous anesthesia (TIVA) causes controlled hypotension and better-operating circumstances. The key objective of the present investigation is to compare propofol-based TIVA with isoflurane-based inhalational anesthesia for controlled hypotension during FESS.

METHODS

Study design

The study was a prospective randomized controlled single-blinded clinical study.

Sample size

The study was performed on 40 patients selected for elective FESS surgery and randomly chosen from the ENT department. All of the patients received general anesthesia along with endotracheal intubation.

Sample size calculation

The sample size calculation is done using the following formula, Formula:

$$n = z^2 \times p(1-p) / m^2$$

Where,

n=required sample size

z=confidence level at 95% (standard value of 1.96)

p=estimated prevalence of abdominal and lower limb cases undergoing surgery in the project area = 4% = 0.04

m=marginal of the error at 5% (standard value of 0.05) = 0.05

Using the above-mentioned values in the formula, we calculate, required sample size, $n = \frac{(1.96)^2 \times 0.04(1-0.04)}{(0.05)^2} = 39$ rounded to 40, for the convenience of dividing into two equal groups.

Study place

The study was conducted at GITAM Institute of Medical Sciences and Research, Visakhapatnam during November 2020–March 2022.

Institutional Ethics committee clearance

The study was undertaken after taking patients' Ethical Committee Clearance and informed consent.

Inclusion criteria

The following criteria were included in the study:

- Selected patients for elective FESS surgery.
- Both genders must be between the ages of 20 and 60.
- ASA grade I or II patients.
- Grades I and II airway assessment by Mallampati.

Exclusion criteria

The following criteria were excluded from the study:

- Uncooperative patients.
- Emergency operations.
- Anticipated challenging intubation.
- ASA grade III or higher patients.
- Cardiovascular disease patients.
- Patients take calcium channel blockers, beta-blockers, or two agonists.
- Patients in whom laryngoscopy and intubation proved to be prolonged or difficult.
- Patients with bleeding disorders and on anticoagulation treatment.

After extensive pre-anesthetic evaluation and analysis, patients were chosen. Based on prior research, each group's sample size is calculated to be 20. During the preoperative assessment, all patients received a detailed explanation of the study. All patients who volunteered for the trial gave their informed consent. According to the computerized list created before the start of the study, they were randomly assigned to one of the two groups.

Investigations

Investigations include a complete hemogram, blood sugar levels, renal function tests, ECG, and chest X-ray.

Premedication

The day before surgery, pre-anesthetic counseling was conducted, and all patients underwent examinations. The night before surgery, alprazolam 0.5mg was given orally to all patients. An 18G cannula was used to secure the intravenous line on the day of the procedure. The following premedication was administered 15 min before induction: injections of ondansetron (0.1 mg/kg) and ranitidine (1 mg/kg). A pulse oximeter, non-invasive blood pressure, and ECG monitors were used to monitor the patients. Systolic, diastolic, and mean blood pressure readings were taken before induction. The RL solution intravenous infusion was started.

Study intervention

Group 1: Inhalational anesthesia

Midazolam, Fentanyl, Propofol, and Vecuronium injections produced anesthesia. Oxygen, air, and isoflurane were used for ventilation (FiO₂ of 0.5). A saline-soaked throat pack was placed in the oropharynx, and an orotracheal tube was inserted. Oxygen, air, isoflurane, and vecuronium were given as needed to maintain life. According to the patient's response, the isoflurane concentration is changed to obtain a mean arterial pressure range of 60–70 mmHg. However, it is decided not to exceed a 2% isoflurane end-tidal concentration.

Group P: TIVA with propofol

Injections of 2 mg of midazolam, 2 µg/kg each of fentanyl, 2 mg/kg propofol, and 0.1 mg/kg vecuronium, as well as oxygen and air for ventilation were used to induce anesthesia (FIO₂ of 0.5). An orotracheal tube was introduced, and the oropharynx was packed with a saline-soaked throat pack. Oxygen, air, and a propofol infusion were used to maintain anesthesia. Following intubation, propofol infusion rate in this group was initiated at 12 mg/kg/hr for 10 min, followed by 10 mg/kg/hr for the following 10 min, and then continued at 8 mg/kg/hr. The infusion rate was changed in response to the patient's response to attain a mean arterial pressure of between 60 and 70 mmHg. The maximal propofol infusion rate was not to be exceeded by 12 mg/kg/h.

All patients received an intravenous infusion of ringer lactate at a rate of 4 ml/kg/h while tilting up 20 degrees. Vecuronium intermittent bolus dosages were used to maintain muscle relaxation, while a nerve stimulator was used for evaluation. To calculate the amount of blood loss, the amount of blood sucked up and collected in the drain was measured. The second anesthetist examined the blood-soaked gauze pieces used during the procedure without being a part of the study. The amount of blood loss increased as a result of this. Ondansetron 4 mg injection was administered after the procedure. Following the endoscopic procedure, the throat pack was removed. Before extubation, the residual neuromuscular blockade was treated with 0.05 mg/kg of neostigmine and 0.01 mg/kg of glycopyrrolate. Patients were monitored for pain scores using visual analog scores, nausea, and vomiting following extubation for every 15 min in the 1st h and every 30 min in the next hour in the post-anesthesia recovery room. The patients were also monitored for pain, nausea, and vomiting.

Outcome measures

The outcome measures that are studied had the following goals.

Major

- Is controlled hypotension more easily attained with TIVA than with inhalational anesthesia?
- Is it simple to achieve regulated hypotension?
- Is the surgically-achieved controlled hypotension maintained?

Minor

- Exists a relationship between the following variables and controlled hypotension that has been achieved?
- Blood loss during surgery.
- Satisfaction of surgeons with the field of intraoperative surgery.

- Surgical procedure's length.
- The Fromme-Boezaart scale for assessing the intraoperative surgical field.

Surgical field grading: Fromme boezaart scale (evaluation scale for surgical site bleeding)

- 0: There is no bleeding.
- Grade 1: Minor bleeding; no blood suctioning is necessary.
- Grade 2: Minor bleeding; sporadic suctioning necessary. The surgical field is not in danger.
- Grade 3: Minor bleeding; frequent blood suctioning is necessary. A few seconds after the suction is stopped, bleeding puts the surgical area in danger.
- Grade 4: Moderate bleeding that necessitates frequent suctioning. The surgical field is immediately in danger of bleeding after the suction is released.
- Grade 5: Extreme bleeding; continuous suctioning is necessary. The bleeding happens more quickly than suction can stop it. Surgery is not possible since the surgical field is seriously jeopardized.

Statistical analysis

Each group's sample size of 20 patients was chosen randomly. Using the independent Sample t-test method, two groups' means are compared. The results evaluated the mean, standard deviations, medians, ranges, percentages, and numbers. Utilizing one-way analysis of variance, the two groups' normally distributed continuous variables were compared (ANOVA). A Master sheet was used to record the data gathered regarding the chosen cases. MS Excel and SPSS 22.0 are used for computer-aided data analysis (Trail version). Frequencies, percentages, ranges, means, standard deviations, student t-tests, and "p-value" were computed using this software. A significant association is proved to exist when $p < 0.05$.

RESULTS

The demographic data of all 40 patients are represented in Table 1. Most of the patients were females, and the average age group was between 40 and 43 years. Table 2 shows the surgical diagnosis data. The mean arterial pressure values were comparable between the groups before the induction of anesthesia (isoflurane group - 83.12±5.53 mmHg and propofol group -83.52±5.57 mmHg). During anesthesia maintenance, mean arterial pressure was statistically significantly lower in Propofol patients (69.57±5.44 mmHg) 30 min after induction compared to patients in the isoflurane group (70.76±5.01 mmhg). After 60 min of anesthesia, mean arterial pressure was comparable in the two groups and significantly lower in the propofol group (65.92±4.38 mmhg) compared to the isoflurane group (68.41±4.81 mmhg). p-value is 0.0017 showing that there is a statistically significant difference between the two groups (Table 3). The heart rate values were comparable between the groups before the induction of anesthesia (isoflurane group: 87.65±8.17 bpm and propofol group: 85.52±11.84 bpm). During anesthesia maintenance, heart rate was not statistically significant in Propofol patients (85.21±7.16 bpm) 15 min after induction compared to patients in the isoflurane group (82.35±8.22 bpm). At 30 and

60 min of anesthesia, the heart rate was comparable in the two groups, the propofol group (83.85±6.25 bpm) and the isoflurane group (78.5±8.49 bpm). p-value is 0.14 (Table 4). Our study's mean systolic blood pressure at different time intervals is not statistically significant. The baseline levels in the propofol group are (116.35±8.37mmhg), and the isoflurane group is (118.71±8.54 mmHg). 30 min after anesthesia, the mean systolic blood pressure in the propofol group is (106.71±6.54 mmhg) and isoflurane group is (105.23±6.84 mmHg). After that, the systolic blood pressure was maintained at around (105.31±6.09 mmHg) in the propofol group and (104.67±10.68 mmHg) in the isoflurane group. p-value is 0.28 (Table 5). The mean diastolic

Table 2: Surgical diagnosis

Surgical diagnosis	Propofol (n=20)	Isoflurane (n=20)
Allergic polyposis=AP	2	2
B/L Ethmoidal polyposis=BEP	2	1
B/L Frontal sinusitis=BFS	1	1
B/L maxillary sinusitis=BMS	1	0
L Atticoantral polyp=LP	1	2
L dacryocystitis=LD	2	2
L Maxillary sinusitis=LM	1	2
Pansinusitis=PA	1	1
R Antrochoanal polyp=RA	2	3
R Dacryocystitis=RD	1	1
R Ethmoidal polyp=RE	2	2
R Frontal and maxillary sinusitis=RF	1	1
R frontal fungal sinusitis=RFF	2	2
R Maxillary sinusitis=RMS	1	1
Total	20	20

Table 3: Mean blood pressure (mmHg)

Time	Isoflurane	Propofol
0 min	83.12±5.53	83.52±5.57
15 min	75.23±7.97	71.89±5.71
30 min	70.76±5.01	69.57±5.44
1 h	68.41±4.81	65.92±4.38
2 h	65.74±4.39	62.71±5.28
>3 h	65.11±4.78	61.34±5.29

p-value is 0.0017 (Highly significant)

Table 4: Mean heart rate (beats/min)

Time	Isoflurane	Propofol
0 min	89.1±8.3	85.9±9.1
15 min	84.1±8.5	80.4±10.1
30 min	85.6±8.4	78.3±9.1
1 h	85.6±6.5	83.1±9
2 h	81.3±10.1	80.8±10.1
>3 h	80±6.4	85.6±9.7

p-value is 0.14 (Insignificant)

Table 5: Mean SBP and Mean DBP

Time	SBP		DBP	
	Isoflurane	Propofol	Isoflurane	Propofol
0 min	118.9±6.7	120.7±8.5	73.4±6.2	79.7±10.1
15 min	103.2±4.7	102.8±5.2	70.9±5.3	69.4±4.1
30 min	93.4±3.6	96.6±3.5	61.7±2.3	60.6±3.7
1 h	86.3±2.7	86.6±3.1	60±2.2	60.1±3.5
2 h	86.4±3.1	85.4±3.8	60.8±3.2	59.1±3.3
>3 h	85.7±3.2	84.2±2.9	60.7±5.1	61.1±1.7

p-value is 0.28 (Insignificant) p-value is 0.93 (Insignificant)

SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 1: Demographic data of the study

Parameters	Propofol (n=20)	isoflurane (n=20)
Age (years)		
Range	22-55	24-49
Mean±SD	43.6±7.8	40.0±8.3
Sex		
Male	7	9
Female	13	11
Body weight (Kg)		
Range	47-98	53-107
Mean±SD	68.8±13.4	73.5±13.6
Height (Cm)		
Range	130-180	144-184
Mean±SD	162.1±13.2	165.5±11.3

blood pressure at different intervals after induction of anesthesia was measured. The baseline measurements in the propofol group are (79.35±13.69 mmhg) and the isoflurane group is (80.65±9.11 mmhg). Thirty minutes after anesthesia, the mean diastolic blood pressure in the propofol group is (74.26±13.67 mmhg) and isoflurane group is (73.25±10.16 mmhg). After that, the diastolic blood pressure was maintained at around (72.45±9.93 mmhg) in the propofol group and (71.23±13.99 mmhg) in the isoflurane group. p-value is 0.93. The two groups' measured values are not statistically significant (Table 5). Table 6 shows that SpO₂ levels in the propofol group are (98.35±1.59) and the isoflurane group is (98.15±1.13) at baseline. After that, SpO₂ levels in the propofol group are (98.2±1.19), and in the isoflurane group are (97.21±1.36). p-value-0.71, showing that there exists no statistically significant relationship between the two groups. Our study's amount of intraoperative blood loss was comparable between the two groups. The average blood loss in the isoflurane group was 134.25±4.65 ml and in the propofol group was 66.95±4.28 ml. p-value is 0.0018 showing a statistically significant difference between the two groups (Table 7). The quality of the surgical field in the propofol group is (3.13±0.9), and the isoflurane group is (3.13±0.8), with p-value is 0.02 showing a statistically significant difference. Most of the patients in either group belonged to Grades 2, 3, and 4, which indicates a highly acceptable surgical field as far as the surgeon was concerned (Table 8). In our study, the incidence of side effects was compared between the two groups. We found four patients (20%) complained of pain and three patients (15%) in group propofol. In the isoflurane group, six patients (30%) complained of pain, and nine patients (45%) had no side effects. The Chi-square test value is 1.52 p-value that is 0.89, which indicates a statistically significant difference between the two groups with a higher incidence of adverse effects in the isoflurane group (Table 9). The duration of surgery is represented in Table 10.

DISCUSSION

To achieve controlled hypotension for many surgical procedures, including FESS, isoflurane-based anesthetic approaches have become quite popular. The method is easy, economical, and practicable wherever in India, where general anesthesia is administered using a relatively current anesthetic machine. However, it is always important to research new methods and medications to get better outcomes and conditions for treatments like FESS. TIVA with propofol and remifentanyl, primarily in western countries, is one such approach that is rapidly gaining favor for controlled hypotension. In our country, remifentanyl is not easily accessible. Remifentanyl's infrequent use could be attributed to its high price in India. Therefore, this study aims to assess TIVA using propofol to see if it can improve operating circumstances and hemodynamic stability compared to the traditional isoflurane-based anesthetic approach. In our investigation, heart rate readings before, during, and after anesthetic induction were comparable between the two groups.

The heart rates in the two groups propofol groups (83.85±6.25 bpm) and the isoflurane group (78.5±8.49 bpm) showed insignificance (p-value = 0.14) at 30 and 60 min of anesthesia, and there was a decreasing trend regardless of the type of anesthesia used in TIVA group. These findings were in line with earlier findings by Tirelli *et al.* [16] and Manisha *et al.* [17]. Therefore, in our investigation, there was no statistically significant change in heart rate recorded at different time intervals between propofol and isoflurane groups. Due to the concurrent administration of fentanyl, the absence of tachycardia suggests that both groups had appropriate levels of analgesia and anesthesia. The mean SpO₂ levels at various time intervals are not statistically significant before, during, or after induction of anesthesia, according to Tirelli *et al.* [16]. SpO₂ values in the propofol group were (99.31±0.75) and in the isoflurane group were (98.68±0.96) 30 min after anesthetic was administered, and p-value was 0.76. The results of the studies mentioned above are consistent with the results of our research, which showed that the SpO₂ levels in the propofol group were (98.2±1.19) and those in the isoflurane group were (97.21±1.36). p-value for this study is 0.71, indicating no statistically significant

Table 6: Mean SpO₂ distribution

Time	Isoflurane	Propofol
0 min	98.35±1.59	98.15±1.13
15 min	99.3±0.97	99.15±1.30
30 min	98.2±1.19	97.21±1.36
1 h	98.3±1.17	98.05±1.39
2 h	99.35±0.93	99.02±1.19
>3 h	99.45±0.88	99±1.21

p-value is 0.017 (Significant)

Table 7: Intraoperative blood loss (ml)

Group	Mean±SD
Isoflurane	134.25±4.65
Propofol	66.95±4.28

p-value is 0.0018 (Highly significant)

Table 8: Surgical field grading

Score	Propofol	Isoflurane
2-Good	5 (25%)	4 (20%)
3-Satisfactory	7 (35%)	9 (45%)
4-Highly satisfactory	8 (40%)	7 (35%)
Total	20 (100%)	20 (100%)
Mean±SD	3.13±0.9	3.13±0.8

p-value is 0.02 (Significant)

Table 9: Postoperative pain, nausea, and vomiting

Side effects	Propofol	Isoflurane
No	11 (55%)	9 (45%)
Pain	4 (20%)	6 (30%)
Nausea	3 (15%)	2 (10%)
Vomiting	2 (10%)	3 (15%)
Total	20 (100%)	20 (100%)

Chi-square test value is 1.52, and the P value is 0.89 insignificant means of relation

Table 10: Duration of surgery (min)

Group	Mean±S.D
Isoflurane	147.4±8.09
Propofol	123.55±11.09

p-value is 0.0069 (Highly significant)

relationship between the two groups. In terms of MAP, there was a statistically significant difference between the propofol and isoflurane groups when mean arterial pressure values were examined; these results were compared with the study by Abdullah *et al.* [18]. Similar to our findings, Valtonen *et al.* [19] compared the effects of propofol infusion with isoflurane to induce hypotension during middle ear surgery. They discovered a statistically significant decrease in mean arterial pressure in the propofol group (69.34±2.31 mmhg) compared to the isoflurane group (79.76±0.86 mmhg). Propofol provided for brisk control over blood pressure, maintaining moderate hypotension, resulting in a drier surgical field with more minor bleeding. Our study's amount of intraoperative blood loss was comparable between the two groups. The average blood loss in the isoflurane group was 134.25±4.65 ml and in the propofol group was 66.95±4.28 ml.

p-value is 0.0018 showing a statistically significant difference between the two groups. In our investigation, there was a statistically significant difference between the propofol group and the isoflurane group in the surgical field as measured by the Fromme-Boezart scale. Most of the patients in both groups were in Grades 2, 3, and 4, which suggest

a highly acceptable surgical field in the surgeon's eyes. These findings were in line with Tandon *et al.* [20]. According to the results of our study, the average operation time was statistically significantly lower in the TIVA group, which is another proof of better surgical conditions under general anesthesia with propofol. In line with our findings, Aujla *et al.* [21] conducted a study to evaluate the quality of the operating field for patients undergoing functional endoscopic sinus surgeries using TIVA with propofol versus inhalational anesthesia with isoflurane. They discovered that the incidence of intraoperative complications was higher in group isoflurane (nine cases) compared to group propofol (two cases), with p-value of 0.05. These outcomes match those of our investigation.

CONCLUSION

Controlled hypotension achieved was more efficient in the propofol group compared to isoflurane group. Total intravenous anesthesia using propofol provides notable advantages over the traditionally used inhalational anesthetic technique using isoflurane in surgical field conditions and intraoperative blood loss.

AUTHORS' CONTRIBUTIONS

The first author of the study, P.V.S. Lavanya, contributed to conceptual design, investigations and wrote the first draft of the manuscript; the second author, M.V. Ganesh, collected the literature, corrected the manuscript, and managed the statistics. The third author of the study K. Lavanya managed data collection and data analysis.

CONFLICTS OF INTEREST

The authors declared, "No conflicts of interest."

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Nil.

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