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Original Research Article

Comparison of recovery profile of sevoflurane and target controlled infusion of propofol in fibroadenoma surgeries: A randomised controlled trial

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Abstract

Background: Patients undergoing general anaesthesia are exposed to both intravenous and inhalational agents, which can induce various physiological changes. The use of a single agent for anaesthesia, however, has been shown to potentially reduce these changes. This study aimed with the primary objective to compare the recovery profiles of patients undergoing fibroadenoma excision surgery under sevoflurane or target-controlled infusion propofol, as assessed by the Clinical Recovery Score. The secondary objectives was evaluating the ease of Laryngeal Mask Airway (LMA) insertion, monitoring side effects, and assessing the recovery profile using the Post-Anaesthesia Discharge Scoring (PADSS) Score.

Materials and Methods: This prospective randomised study included 90 female patients presenting with fibroadenoma, who were allocated into three groups via computerized randomization. Group P received Inj. Propofol 1% titrated in TCI. Group S received Sevoflurane, titrated to maintain an end-tidal concentration of 2%. Group C received general anaesthesia, where patients were induced with Inj. Propofol at 2 mg/kg, and anaesthetic depth was maintained with Sevoflurane. Depth of anaesthesia was monitored using the Bispectral Index (BIS). Post-procedure, the recovery profile of patients was assessed using the Clinical Recovery Score (CRS) and the Post-Anaesthesia Discharge Scoring (PADSS) scores.

Results: Patients in Group P (Propofol) demonstrated a significantly better recovery, with a Clinical Recovery Score (CRS) of 11.8 ± 0.41 (p-value < 0.0001), compared to Group S (Sevoflurane) at 9.7 ± 0.65 and Group C (Combination) at 10.73 ± 0.52. Additionally, patients in Group P had a better Post-Anaesthesia Discharge Scoring (PADSS) score of 9.8 ± 0.41 (p-value < 0.0001) compared to Group S (8.97 ± 0.41) and Group C (9.63 ± 0.49), when observed 12 hours post-surgery.

Conclusion: Total intravenous anaesthesia with propofol led to superior recovery outcomes, facilitating earlier discharge compared to sevoflurane or a combination of both agents.

Keywords: Propofol, Sevoflurane, Anaesthesia, Fibroadenoma.

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1. Introduction

The concept of single-agent anaesthesia has gained significant attention and acceptance in clinical practice, particularly after the development of Total Intravenous Anaesthesia (TIVA) and Volatile Induction/Maintenance Anaesthesia (VIMA). TIVA involves the use of intravenous agents to achieve and maintain the depth of anaesthesia, whereas VIMA relies solely on inhalational anaesthetics for both induction and maintenance of anaesthesia.[1]

Patients receiving intravenous anaesthetic agents typically experience a range of physiological changes, including loss of consciousness, depressed respiratory drive, reduced muscle tone, cardiovascular depression, diminished cerebral blood flow, and potential alterations in baseline hemodynamics.[1] In contrast, inhalational anaesthetics can induce depressed respiratory function, vasodilation leading to a decrease in systolic blood pressure, unconsciousness, amnesia due to central nervous system depression, and reduced cardiac output and heart rate at higher doses.[1]

TIVA and VIMA are both widely used in short, outpatient procedures, with the former often providing a more controlled anaesthetic experience due to the precise titration of intravenous agents. In conventional general anaesthesia, a combination of both intravenous agents for induction and

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inhalational agents for maintenance is typically employed. However, this dual-agent approach can lead to physiological disruptions due to the differing effects of both agents.[2,3] Additionally, the rapid redistribution of intravenous agents during the induction phase can lead to a lighter plane of anaesthesia before adequate depth is achieved by the inhalational agent, which can be counterproductive and potentially harmful.

In contrast, single-agent anaesthesia eliminates the need for such transitions, providing a more stable anaesthetic environment by reducing the overall exposure to multiple agents.[4] This approach has been shown to minimize physiological disturbances, making it a promising option, especially in short-duration procedures like fibroadenoma excision. By reducing these variations, single-agent anaesthesia may improve the quality of the patient's hospital stay, resulting in faster recovery and a shortened duration of hospitalization.[5]

Given these considerations, we hypothesized that the use of a single anaesthetic agent for both induction and maintenance would lead to a superior recovery profile compared to conventional general anaesthesia, which uses a combination of intravenous induction agents and inhalational maintenance agents. The primary objective of this study was to compare the recovery profiles of patients undergoing fibroadenoma excision under either sevoflurane or target-controlled infusion propofol, using the Clinical Recovery Score (CRS). Secondary objectives include the assessment of associated side effects, ease of Laryngeal Mask Airway (LMA) insertion, and recovery profiles using the Post-Anaesthesia Discharge Scoring (PADSS) Score.

2. Materials and Methods

This prospective, randomized study was conducted with approval from the institutional ethics committee (IEC-ST0723-539) and registration with the Clinical Trials Registry-India (CTRI/2023/12/060833). Ninety female patients, aged 18-45 years, who were electively scheduled for fibroadenoma excision surgery under general anaesthesia, were enrolled in the study. Inclusion criteria included ASA Class I and II, a BMI less than 24.9, and Mallampati grading I and II, with surgeries expected to last within one hour. Patients who refused participation or were assessed to have a difficult airway were excluded.

A pilot study was initially conducted with five patients per group, measuring the Clinical Recovery Score (CRS), the primary objective of the study. The pilot results showed that patients in Group P (Propofol) had a mean CRS of 9.08, Group S (Sevoflurane) had a mean CRS of 9.9, and Group C (Combination) had a mean CRS of 10.12. These values were used in G*Power analysis for one-way ANOVA to calculate the required sample size, which was determined to be 81 patients. Considering a 10% dropout rate, the final sample size was adjusted to 90, with 30 patients in each group.

Preoperative assessments were performed, and all patients who met the inclusion criteria were included in the study. Informed consent was obtained, and baseline haemodynamic parameters were recorded. Patients were randomly allocated into one of three groups using computerized randomization. In Group P, patients were administered Inj. Propofol 1% via target-controlled infusion (TCI) according to the Schnider formula. Group S patients received Sevoflurane, titrated to maintain an end-tidal concentration of 2%. Group C patients received a routine general anaesthesia protocol, where they were induced with Inj. Propofol at 2 mg/kg and maintained with Sevoflurane.

Patients followed routine preoperative protocols, including fasting as per ASA guidelines. On the night before surgery, they were given T. Alprazolam 0.25mg, T. Ranitidine 150mg, and T. Metoclopramide 10mg, which were repeated on the morning of surgery, two hours before induction.

Upon arrival in the operating room, routine monitors, including non-invasive blood pressure (NIBP), pulse oximetry, ECG, temperature probe, and end-tidal CO2 (etCO2), were attached. A Bispectral Index (BIS) monitor was also used to assess anaesthetic depth. Premedication included Inj. Midazolam 1mg IV, Inj. Ondansetron 4mg IV, and Inj. Glycopyrrolate 0.2mg IV. All patients received Inj. Fentanyl 2 mcg/kg for analgesia and were provided 100% oxygen via a face mask prior to Laryngeal Mask Airway (LMA) insertion.

Anaesthesia was induced according to the group allocation, and BIS values were continuously monitored until they reached a target of 40-50 before LMA insertion. A standardized ProSeal LMA was inserted, with size based on the patient's weight. The time taken for LMA insertion was recorded from when the anaesthesiologist first held the ProSeal LMA until the first appearance of the $EtCO_2$ waveform. The number of attempts for LMA insertion was also noted.

During surgery, anaesthesia maintenance was as follows: Group P received Propofol infusion and O_2: Air via the Circle system, while Groups S and C received Sevoflurane and O_2: Air mixtures. Intraoperative haemodynamic parameters (heart rate, blood pressure, $EtCO_2$) were monitored every 5 minutes until the patient was extubated. The time taken for spontaneous eye opening, extubation, and orientation to time, place, and person was also recorded.

After the surgical procedure, once the LMA was removed, all patients were transferred to the recovery room for monitoring. The recovery profile was assessed using the Clinical Recovery Score (CRS) 15 minutes after arriving in the recovery room. This scoring system is similar to the Modified Aldrete Score, with the addition of nausea and vomiting as parameters. Nausea was scored as -1, and vomiting was scored as -2.[6] Twelve hours post-surgery, the

recovery profile was further assessed using the Post-Anaesthesia Discharge Scoring (PADSS) Score.

Data were entered into an MS Excel spreadsheet (2010), and statistical analysis was performed using SPSS software (Version 26). One-way ANOVA was used to compare data between the three groups, with a p-value of < 0.05 considered statistically significant.

3. Results

The study included 90 patients, who were randomly assigned to three groups: Group P, Group S, and Group C, with 30 patients in each group. Throughout the study, there were no exclusions based on any unforeseen circumstances.

3.1. Demographic data

As shown in **Table 1**, when comparing the age, weight, and height of the patients across the groups, a statistical significance was observed in height and weight, but no significant difference was found with respect to age.

3.2. LMA insertion

Table 2 highlights that the duration for Laryngeal Mask Airway (LMA) insertion was significantly shorter in Group P compared to Groups S and C. Additionally, the success rate of LMA insertion on the first attempt was higher in Group P. Out of the total patients, 17 required a second attempt for LMA insertion due to inadequate jaw relaxation, despite adequate anaesthetic depth as confirmed by Bispectral Index (BIS) monitoring. Specifically, 2 patients in Group P, 14 in Group S, and 1 in Group C required a second attempt, with this difference being statistically significant.

3.3. Postoperative recovery and side effects

The time to eye opening, extubation, and full orientation to time, place, and person was significantly shorter in Group P (**Table 3**). Discomfort due to pain from intravenous injection was reported by 8 patients in Group P, though this was not statistically significant. In Group S, 5 patients experienced respiratory irritation and coughing. Furthermore, 21 patients in Group S, 6 in Group P, and 18 in Group C complained of nausea post-surgery. Group S had a notably higher incidence of vomiting compared to the other groups.

3.4. Clinical recovery score (CRS)

Fifteen minutes after being moved to the recovery room, CRS was assessed in all patients. In Group P, all 30 patients scored 10 or higher, with an average score of 11.8. Group C also had all 30 patients scoring 10 or higher, with an average score of 10.7. In contrast, in Group S, only 18 out of 30 patients achieved a score of 10 or higher (**Table 4**).

3.5. Post-anaesthesia discharge scoring system (PADSS)

Twelve hours post-surgery, the PADSS score was evaluated. In Group P, 21 out of 30 patients achieved a score of 10, while the remaining 9 patients scored 9. In Group S, only 2 patients achieved a score of 10, with 25 scoring 9 and 3 scoring 8. In Group C, 19 patients scored 10, and 11 patients scored 9 (**Table 4**).

3.6. Comparison of hemodynamic parameters across groups

The mean arterial pressure (MAP) remained most stable in Group P (Propofol) compared to Group S (Sevoflurane) and Group C (Combined). Post-induction, Group P showed the lowest MAP (80.4 mmHg) but recovered within five minutes, maintaining steady values (85-88 mmHg) throughout surgery. In contrast, Group S exhibited more fluctuations, with a notable dip around the 20-minute mark, while Group C followed a similar but slightly higher trend. Post-extubation, MAP returned to baseline across all groups, with Group S showing a slight drop. These findings suggest that Propofol provided better MAP stability than Sevoflurane (**Table 5**, **Figure 1**).

Heart rate (HR) varied significantly among groups. Group S had the highest post-induction HR spike (98.6 bpm), while Group P maintained better control (88.2 bpm). Intraoperatively, Group P showed stable HR (74-81 bpm), whereas Group S remained elevated (85-92 bpm), possibly due to its vagolytic effects. Group C had the lowest HR values. Post-extubation, HR in Group P briefly increased (90.5 bpm) before stabilizing, while Group S and C showed less fluctuation (**Table 5**, **Figure 2**).

Bispectral index (BIS) monitoring indicated deeper sedation in Group P (BIS ~41) compared to Group S (~48), which maintained a lighter anesthetic plane. Intraoperatively, BIS remained within the target range across groups. Post-extubation, BIS rose sharply in Group P (73.9), indicating faster emergence, whereas Group S had a slower recovery (**Figure 3**).

Table 1: Patient's demographics

	Group P (Mean ± SD)	**Group S (Mean ± SD)**	**Group C (Mean ± SD)**	**p value**
Age	25.07 ± 3.27	25.9 ± 4.5	26.03 ± 5.28	0.67
Height	155.67 ± 3.98	157.3 ± 5.8	152.6 ± 4.67	0.0016
Weight	69.23 ± 8.29	65.7 ± 9.86	73.57 ± 9.91	0.008

Table 2: Ease of LMA insertion among different groups

	Group P (Mean ± SD)	Group S (Mean ± SD)	Group C (Mean ± SD)	p value
Time taken for LMA Insertion (secs)	29.8 .12.16	63.6 .19.13	38.27 .11.63	<0.0001
Number of attempts taken for LMA insertion	1.07 .0.25	1.47 .0.5	1.03 .0.18	<0.0001

Table 3: Observed parameters among different groups

	Group P (Mean ± SD)	Group S (Mean ± SD)	Group C (Mean ± SD)	p value
Time taken for intubation (secs)	29.8 ± 12.16	63.6 ± 19.13	38.27 ± 11.63	<0.0001
Time taken for spontaneous eye opening (min)	8.1 ± 1.8	9.83 ± 2.18	11.77 ± 2.20	<0.0001
Time taken for extubation (min)	10.87 ± 1.75	12.5 ± 1.52	14.47 ± 2.05	<0.0001
Time taken for orientation (min)	13.2 ± 1.64	14.63 ± 1.68	16.67 ± 2.04	<0.0001

Table 4: Recovery parameters among different groups

	Group P (Mean ± SD)	Group S (Mean ± SD)	Group C (Mean ± SD)	p value
Clinical Recovery Score	11.8 ± 0.41	10 ± 0.65	10.73 ± 0.51	<0.0001
PADSS Score	9.8 ± 0.41	8.97 ± 0.41	9.63 ± 0.48	<0.0001

Table 5: Mean MAP, Heart Rate, and BIS values at different time intervals among different groups

Time Interval	MAP P	MAP S	MAP C	HR P	HR S	HR C	BIS P	BIS S	BIS C
Preoperative	90.17	87.90	88.73	83.53	85.83	80.23	91.97	92.23	92.00
Before Induction	83.13	82.00	82.90	88.17	98.57	81.70	92.00	92.27	92.13
After Induction	80.40	82.50	81.00	78.67	92.83	77.30	41.17	48.63	41.67
2 mins post induction	83.07	82.07	82.40	74.63	89.97	74.63	42.40	42.83	42.73
5 mins post induction	86.43	85.43	85.13	79.57	88.53	75.33	42.37	42.70	42.40
5m	86.53	86.30	86.03	78.97	86.33	74.67	41.90	42.37	41.17
10m	87.53	87.17	86.20	78.83	84.90	75.37	42.70	43.07	42.23
15m	86.13	86.53	84.07	80.67	85.57	75.80	42.23	42.50	42.27
20m	87.03	84.57	86.23	77.93	86.53	74.93	42.03	43.03	43.03
25m	87.27	85.07	85.87	78.83	85.03	75.87	42.27	42.57	41.90
30m	87.33	86.13	85.83	81.47	84.93	75.60	42.43	42.27	42.27
35m	87.17	86.70	86.40	81.93	83.97	75.50	41.90	42.23	42.50
40m	87.00	86.67	86.03	80.43	83.30	75.70	42.50	41.90	42.43
45m	87.00	87.17	86.63	80.47	85.53	75.47	42.27	42.50	42.23
50m	88.20	86.07	86.63	79.27	83.27	76.67	43.03	42.43	42.03
55m	85.90	87.57	85.83	81.23	81.97	77.30	42.23	44.20	41.90
1h	87.17	85.63	86.30	80.63	80.90	78.40	43.07	46.93	42.70
Post extubation	87.03	87.33	86.77	90.53	82.03	84.83	73.90	67.60	71.70
5 mins post extubation	87.80	85.57	88.83	84.43	82.70	81.50	78.93	72.43	73.2

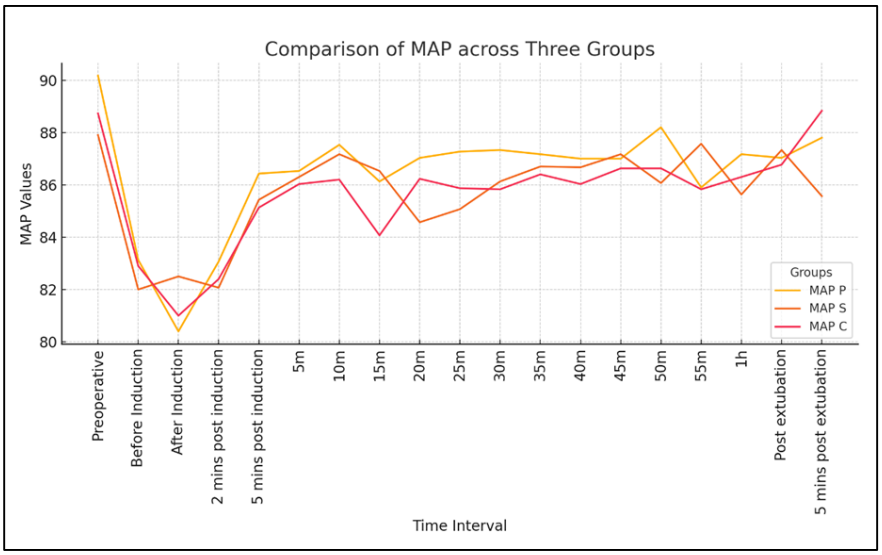

Figure 1: MAP values at different time intervals among different groups

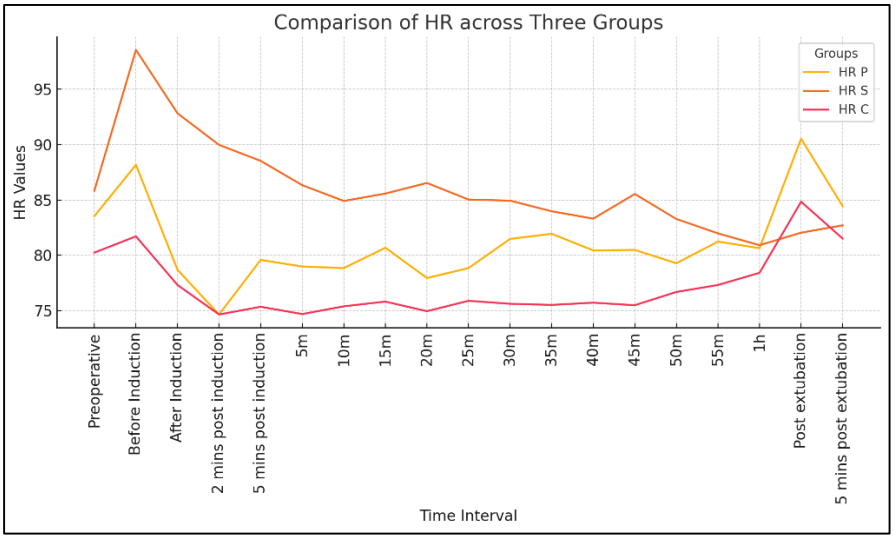

Figure 2: Mean heart rate values at different time intervals among different groups

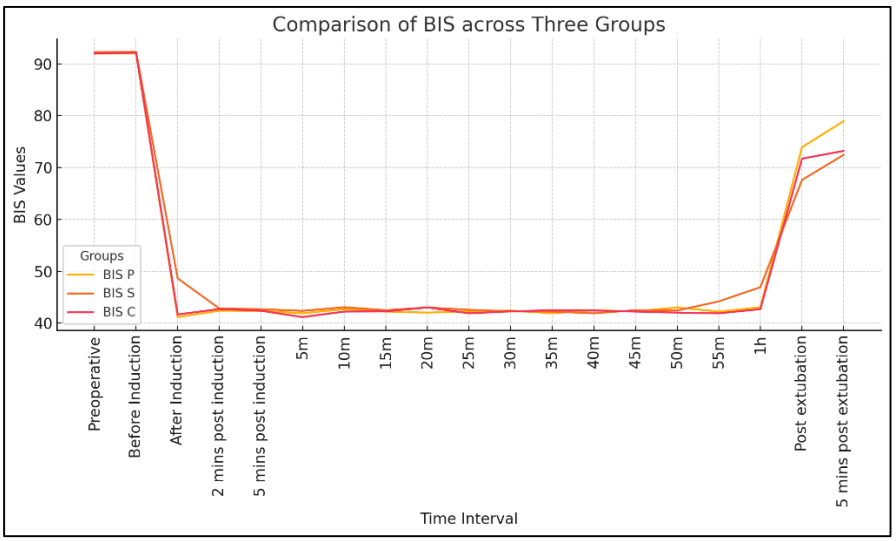

Figure 3: Mean BIS Values at different time intervals among different groups

4. Discussion

Daycare procedures, which include the admission, surgery, and discharge of patients all within the same day, have become a standard practice in many surgical settings. These procedures typically involve the use of intravenous agents for anaesthesia induction and inhalational agents for maintenance throughout the surgery.[7] However, one of the challenges associated with this approach is the rapid redistribution of intravenous agents, which may lead to a lighter depth of anaesthesia before the inhalational agent reaches an adequate level of effect.[8] This can result in an insufficient anaesthetic plane during critical stages such as intubation, potentially causing complications like involuntary movements and awareness during the procedure.

The introduction of single-agent anaesthesia has provided a more seamless approach to managing the anaesthetic plane. By reducing the transition phase between intravenous induction and inhalational maintenance, single-agent anaesthesia ensures a more stable and controlled depth of anaesthesia. This results in improved patient recovery profiles and may mitigate the risks associated with fluctuations in anaesthetic depth, offering significant advantages for patients undergoing procedures that require precise anaesthetic management.

In this study, our primary objective was to compare the efficacy and safety of three different modes of general anaesthesia administration in patients undergoing similar types of surgery. To minimize confounding factors, we standardized variables such as gender, type of surgery, and surgery duration. The fibroadenoma excision surgeries, which are routinely performed as daycare procedures, were ideal for this comparison, as they typically last less than an hour and have a predictable recovery trajectory, allowing for consistent evaluation of anaesthetic outcomes. Additionally, these surgeries are considered low-risk, minimizing the potential for unavoidable surgical complications, which further ensured that the focus could remain on the anaesthetic management.

According to our hospital protocol, although these fibroadenoma excision surgeries are classified as daycare procedures, all patients scheduled for elective surgery must be admitted a day before their procedure and kept under observation until post-operative day one. This precautionary measure allowed for more comprehensive monitoring of the patients' recovery status, ensuring that they were fit for discharge before being sent home. Moreover, we specifically noted the time taken for Laryngeal Mask Airway (LMA) insertion and the number of attempts required for each procedure. These metrics were carefully recorded to observe any potential variations in outcomes that might arise from different anaesthetic techniques.

Initial phase of recovery was primarily assessed from the end of surgery, in the operation theatre, prior to the patient being shifted to the immediate post-operative recovery room. Here, time taken for eye opening, extubation, orientation to time, place and person were noted.

In a study conducted by K. R. Watson et al., the effects of Total Intravenous Anaesthesia (TIVA) using Propofol for induction and maintenance via target-controlled infusion were compared to Sevoflurane Induction with the Circle system, using 8% Sevoflurane for induction and 3.5% Sevoflurane for maintenance, along with 67% nitrous oxide and 33% oxygen.[4] Their findings showed that emergence time and early recovery characteristics were unaffected by the anaesthesia techniques, with no significant differences in time to eye opening or extubation.[4] However, our findings contrast with these results. We observed that the time to eye opening was significantly shorter in Group P (8.1 ± 1.8) compared to Group S (9.83 ± 2.18) and Group C (11.77 ± 2.20). Similarly, the extubation time was also shorter in Group P (10.87 ± 1.75) than Group S (12.5 ± 1.52) and Group C (14.47 ± 2.05). Additionally, the duration of orientation was quicker in Group P (13.2 ± 1.64) compared to Group S (14.63 ± 1.68) and Group C (16.67 ± 2.04).

While many studies have suggested that Sevoflurane-based anaesthesia results in a rapid emergence and recovery, our findings are in line with research by M.M.R.F. Struys et al., who observed better recovery in Propofol-based anaesthesia when used with bispectral index (BIS) monitoring.[9] Similarly, A. Yli-Hankala et al. found that BIS monitoring significantly improved immediate recovery in patients undergoing Propofol-based anaesthesia.[10]

Studies by R. Lohia et al. and J. Tang et al. have also indicated that patients administered Propofol-based anaesthesia show better recovery profiles and higher satisfaction levels than those receiving Sevoflurane.[11,12] In our study, we observed that patients in Group P had superior primary recovery with a higher Clinical Recovery Score (11.8 ± 0.41) compared to Group S (10 ± 0.65) and Group C (10.73 ± 0.51). Furthermore, secondary recovery, assessed 12 hours post-surgery using the Post Anaesthesia Discharge Scoring System (PADSS), revealed a better recovery profile in Group P (9.8 ± 0.41) compared to Group S (8.97 ± 0.41) and Group C (9.63 ± 0.48).

J. K. Moore et al. reported a higher incidence of coughing in 11 patients in the Propofol group, compared to 9 patients in the Sevoflurane group. They also noted incidences of breath holding in 2 patients and laryngospasm in 4 patients in the Sevoflurane group.[13] However, in contrast, our study observed a higher incidence of respiratory irritation and coughing in the Sevoflurane group (Group S) compared to the Propofol group (Group P). This discrepancy may arise from various factors, including differences in patient demographics, anaesthetic protocols, and the methods used for monitoring anaesthetic depth.

One key distinction between our study and others, such as those by Watson et al.[4] and Moore et al.,[13] is the use of BIS monitoring, which enabled more precise titration of anaesthetic depth in our study.[10] This more refined monitoring may explain the variations in our results compared to studies that relied on conventional clinical parameters for managing anaesthesia depth. BIS monitoring ensures optimal control over the anaesthetic plane, likely contributing to the improved recovery outcomes observed in our study.

In addition, studies by Matsuura H et al. and Erbatur ME et al. have demonstrated a reduced incidence of post-operative nausea and vomiting in patients receiving Propofol compared to those administered Sevoflurane.[14,15] Our findings align with these studies, as we observed a significantly lower rate of nausea and vomiting in Group P, further supporting the advantage of Propofol in minimizing these common post-operative complications.

This study contributes to the growing body of evidence supporting the use of tailored anaesthesia techniques in improving surgical outcomes and patient satisfaction in day care settings, with potential implications for enhancing patient safety and recovery post-procedure. One limitation of this study was the inability to implement appropriate blinding due to the stark differences in the administration of anaesthesia across the different groups. Additionally, the failure to calculate the cost of each anaesthetic technique and evaluate its cost-effectiveness may have limited the broader implications of this study's findings.

5. Conclusion

A better recovery profile as indicated by higher clinical recovery score, and post-anaesthesia discharge scoring system, was observed in patients administered a target-controlled infusion of propofol compared to those receiving sevoflurane-only or a mixture of both agents in conventional general anaesthesia. BIS monitoring facilitated faster recovery in patients receiving propofol, making it a suitable choice for induction and maintenance of anaesthesia in short day-care procedures. This approach enhances recovery and reduces hospital stay duration.

6. Source of Funding

None.

7. Conflict of Interest

None.

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