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CLINICAL EVALUATION OF INTRAVENOUS PROPOFOL AND DEXMEDETOMIDINE FOR CONTROLLED HYPOTENSION IN ENT SURGERIES

Dr. Matilda Priyadarshini Lakra[1*], Dr. Raka Rani[2]

[1*]Consultant, Department of Anasesthesiology, Vikas Multi-Speciality Hospital, Bargarh, Odisha, India.
[2] Professor (Retired), Department of Anaesthesiology, BRD Medical College, Gorakhpur, Uttar Pradesh, India.

***Corresponding Author**: Dr. Matilda Priyadarshini Lakra
*Consultant, Department of Anasesthesiology, Vikas Multi-Speciality Hospital, Bargarh, Odisha, India.

ABSTRACT

BACKGROUND

Otorhinolaryngological surgical procedures are prone to copious bleeding. It is essential to achieve a bloodless field during these procedures for better visibility, to minimise the risk of complications, and ensure patient and surgeon comfort. Controlled hypotension required for ENT procedures have been achieved using a variety of medications. This study aims to evaluate the hemodynamic parameters as a reference for evaluating Propofol and Dexmedetomidine for controlled hypotension during ENT procedures.

MATERIAL AND METHODS

This study included 40 patients aged 18 to 65 of either gender and of ASA Grade I or Grade II, and were scheduled to have elective ENT procedures. The patients were randomised into two groups of 20 individuals each and were assigned to receive

- Group P - Propofol 1mg/kg 10 minutes before induction of general anaesthesia followed by infusion at the rate of 2mg/kg/hr.
- Group D - Dexmedetomidine 1µg/kg over 10 minutes before induction of general anaesthesia followed by infusion at the rate of 0.5µg/kg/hr.

Vital signs (heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure), as well as respiratory rate and oxygen saturation (SpO2), were recorded. Intraoperative bleeding in the surgical field was evaluated using an average category scale, pain was measured using a Visual Analogue Scale (VAS), and clinical recovery was assessed using the - CRS (Clinical Recovery Score). The student's unpaired 't' test was utilised in order to conduct the statistical comparison between the two groups. For hemodynamic variables, the student's paired 't' test was used.

RESULTS

There was a significant decrease in pulse rate between pre- and post-operative values for both groups (p value <0.0001). When comparing, pulse rate in Group D was significantly lesser than group P (p value <0.0001). Compared to preoperative values, there was a significant drop in both groups' systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) (p value<0.0001). There was no significant difference in SBP, DBP and MAP between the two groups.

There was no significant difference in intraoperative bleeding between the two groups. Recovery score and post-operative analgesia were better in Group D.

CONCLUSION

While there was no significant difference in hemodynamics and intraoperative bleeding when comparing dexmedetomidine and propofol, dexmedetomidine offers the advantage of better recovery and post-operative analgesia.

KEYWORDS; Controlled Hypotension, Post-Operative Recovery, Analgesia, Dexmedetomidine, Propofol.

INTRODUCTION

During Ear, Nose, and Throat Surgeries, the surgeon works on a very small, anatomically complex area highly susceptible to excessive hemorrhage. It becomes difficult for the anesthesiologist to produce a bloodless field for the surgeon because even a small quantity of bleeding seems significant under the microscopic area. However, it is critical to have a bloodless lot for these procedures for greater visibility and fewer problems, as well as for the comfort of both the patient and the surgeon.[1,2]

When patients experience pain during surgery, it might trigger sympathetic activation, which can increase bleeding in the operative region. Increased usage of volatile agents, opioids, and neuromuscular relaxants is necessary for longer-lasting and deeper planes of anesthesia. Therefore, to prevent needless overuse of anesthetic agents, the sympathetic stimulation must be reduced at several points during the surgical process, such as during laryngoscopy, intubation, the beginning of the incision, and other procedures.

ENT treatments are also linked to a higher rate of emergence anxiety.[3] Due to blood contamination in the airway and surgical packs obstructing the nasal airway, it is advisable to extubate patients while they are conscious following nasal surgery. There have been reports of increased rates of postoperative agitation and restlessness following surgical operations involving the tonsils, thyroid, middle ear, and eyes.[4,5,6] Eckenhoff et al.'s [7] speculated that patients having head and neck surgery might have emergence agitation as a result of a "sense of suffocation" while emerging from anesthesia. Nevertheless, there are currently no corroborating scientific findings. Extubation when awake frequently makes emergence more agitated.[8] Emergency agitation can cause wounds, accidental removal of surgical dressings, intravenous catheter, monitoring probe separation, and-worst of all-self-extubation, which can put the patient in a hypoxic state. To prevent this agitation, a calm emergence from general anesthesia is necessary.[9]

Several drugs have been explored to keep the surgical field bloodless and to give controlled hypotension during ENT procedures. Inhalational agents (isoflurane, desflurane, and sevoflurane), beta blockers (pranolol, esmolol, and most recently, propofol), trimethaphan camsilate, sodium nitroprusside, nitroglycerin, alprostadil (prostaglandin E1), adenosine, and remifentanil, as well as some α2 agonists like clonidine and dexmedetomidine, have all been used. This study aims to assess the effectiveness of propofol and dexmedetomidine infusions in causing controlled hypotension during ENT procedures.

MATERIAL AND METHODS

Individuals hospitalised to Nehru Hospital, B.R.D. Medical College, Gorakhpur, for ENT procedures were the subjects of this research. For every patient, a signed informed consent was obtained. The study enrolled a cohort of forty patients, all of whom were adults between 18 and 65 and classified as ASA Grade I or Grade II. Patients were selected based on their average body weight and height and were enduring elective ENT procedures. The determination of sample size was based on prior research of a comparable nature.[10] The patients had clinical examinations, and pertinent standard investigations were completed for preoperative evaluation with the ethics committee's approval.

Using their admission sequence as a guide, the patients were split into two equal groups of twenty each, based on the medication that would be given before to and during general anaesthesia.

- Group I (P) - Propofol 1mg/kg 10minutes before induction of general anaesthesia followed by infusion at the rate of 2mg/kg/hr.
- GroupII (D) - Dexmedetomidine 1µg/kg over 10 minutes before induction of general anaesthesia followed by infusion at the rate of 0.5µg/kg/hr.

Tab. Alprazolam 0.25 mg and Tab. Ranitidine 150 mg were administered to all patients on the night before their scheduled operations. The baseline cardio-respiratory parameters were measured and an intravenous line was set up in the pre-operative room. Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, and SpO2 were routinely monitored via a multiparameter monitor that was affixed within the operating room.

Patients were administered Inj. Glycopyrrolate, Inj. Midazolam, and Inj. Pentazocine as premedications. Thiopentone was employed as a common inducing drug in both groups, and patients were intubated with Vecuronium. A regulated hypotension was achieved by titrating the infusion rates based on blood pressure. The Mean Arterial Pressure was kept at 65±5 mm Hg to achieve controlled hypotension. The surgeon was blinded to the medication research and used a preset category scale similar to that used by Fromme et al.[11] to measure bleeding during surgery to evaluate the visibility of the surgical site during surgery.

Average category scale for assessment of intra-operative bleeding in surgical field

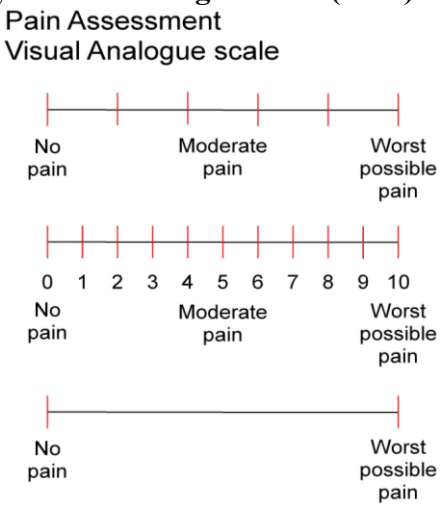
- 0 - No bleeding.
- 1 - Slight bleeding - no suctioning of blood required.
- 2 - Slight bleeding - occasional suctioning required. Surgical field not threatened.
- 3 - Slight-bleeding - frequent suctioning required. Bleeding threatens surgical field a few seconds after suction is removed.
- 4 - Moderate bleeding - frequent suctioning required. Bleeding threatens surgical field directly after suction is removed.
- 5 - Severe bleeding - constant suctioning required Bleeding appears faster than can be removed by suction. Surgical field severely threatened and surgery not possible.

The patients were reversed and given injections of neostigmine and glycopyrrolate after the procedure. Following the procedure, every patient was monitored for eight hours in the recovery area.

The following parameters were observed

- Hemodynamic parameters (Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure)
- Respiratory rate
- Oxygen Saturation (SpO_2)

Pain assessment will be done by Visual Analogue Scale (VAS)



Evaluation of clinical recovery by the – CRS (Clinical Recovery Score).[12]

Category	Points	Criteria
Activity	0 1 2	Unable to sit up Able to sit without assistance Able to stand without assistance
Respiration	0 1 2	Apnea Depressed from preoperative rate Same as or more than the preoperative rate
Circulation	0 1 2	More than 50% decrease below the preoperative systolic blood pressure A 20%-50% decrease below the preoperative systolic blood pressure Less than 20% below the preoperative systolic blood pressure
Consciousness	0 1 2	Unresponsive to verbal stimulation Responsive to verbal stimulation Fully awake
Ambulation	0 1 2	Unable to walk Able to walk with assistance Able to walk without assistance heel to toe along a line 6 ft in length
Color	0 1 2	Cyanotic mucous membranes Pale mucous membranes Normal coloration
Nausea and Vomiting	-2 -1 0	Vomiting Nausea Minimal dizziness
Components of the Clinical Recovery Score		

Total scores may range from -2 to 12.

Statistical comparability of both the groups was analysed by Student's unpaired 't' test. Student's paired 't' test was applied for hemodynamic parameters . For all statistical analysis, the value of p <0.05 was considered significant, the value of p <0.01 was considered highly significant and value of p> 0.05 was considered as non-significant.

RESULTS

There was a substantial decrease in pulse rate in both groups compared to their respective preoperative values, which was highly significant (p value <0.0001). A comparison of the two groups revealed that group D exhibited a significantly greater decrease in pulse rate at various time intervals (p value<0.0001).

Comparision of Mean Pulse Rate (per minute) in Both the Groups

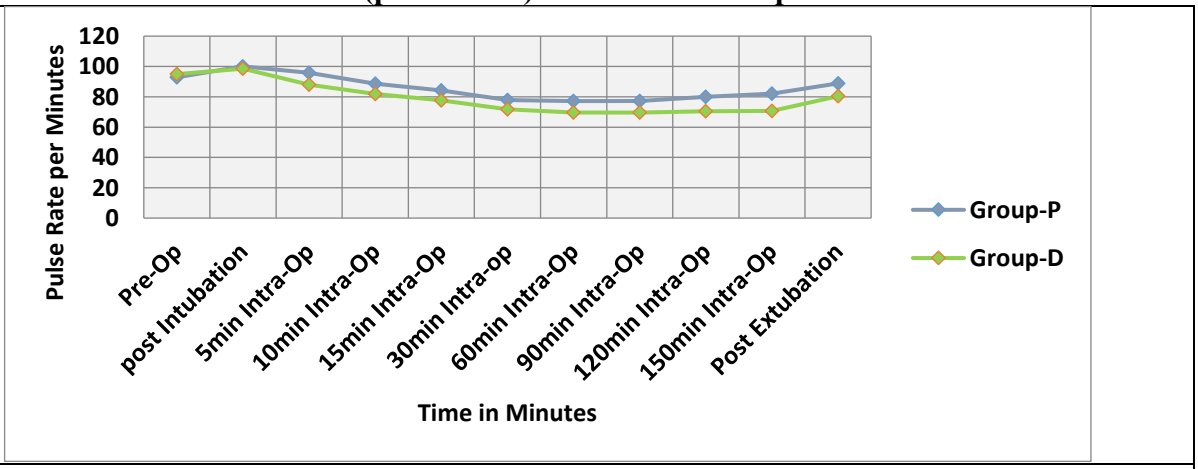


Figure 1: Line diagram showing Mean Pulse Rate between the 2 groups

Compared to their preoperative values, systolic blood pressure decreased significantly in both groups (p value<0.0001). In addition, the difference between the two groups was almost negligible when compared.

Comparision between Systolic Blood Pressure (in mm Hg) in Both the Groups

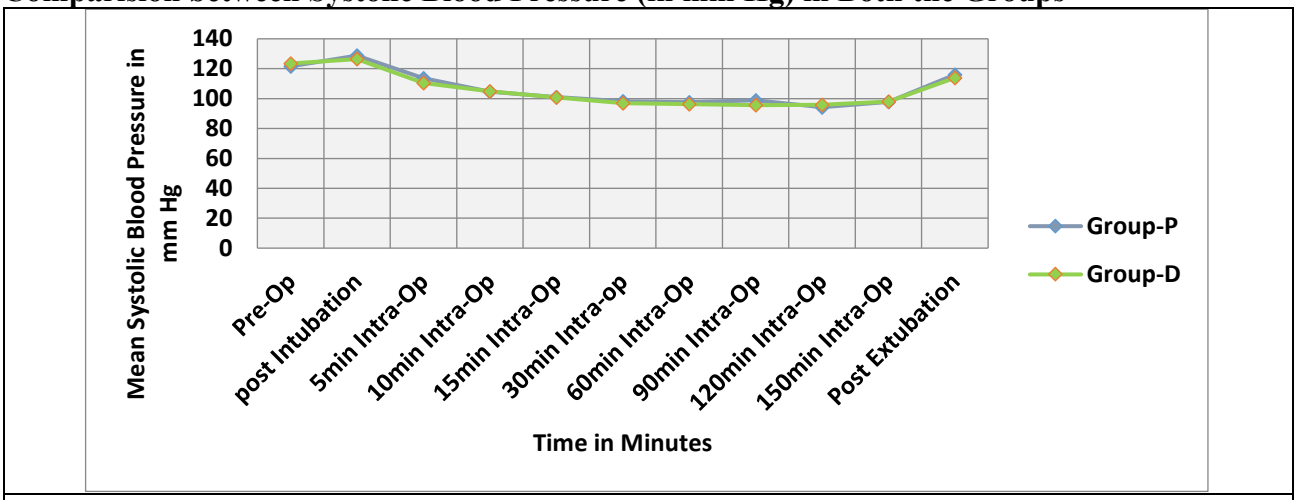


Figure 2: Line diagrams comparing the mean systolic blood pressure in both the groups

Compared to preoperative values, both groups' diastolic blood pressure decreased significantly; however, the decline was not as substantial when the groups were compared.

Comparision of Mean Diastolic Blood Pressure (in mm Hg) in Both the Groups

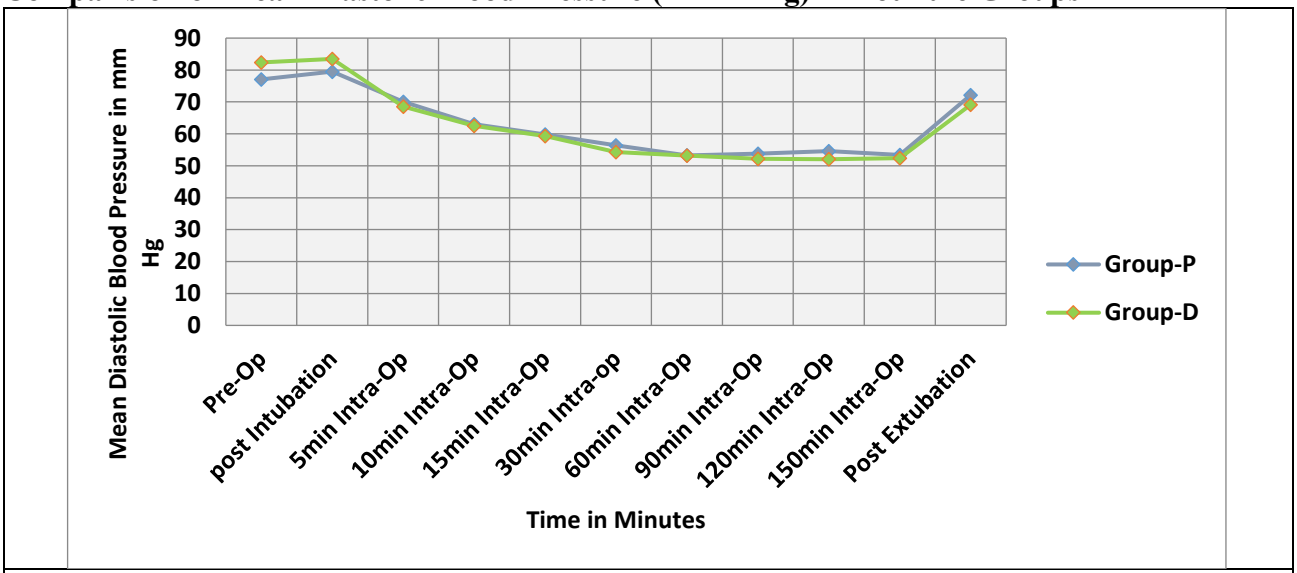


Figure 3: Line diagram comparing mean diastolic pressure of both the groups

In all groups, there was a statistically significant (P<0.0001) drop in mean arterial blood pressure compared to its preoperative value. However, the differences were negligible and equivalent when the two groups were contrasted at various points.

Comparision of Mean Arterial Pressure (in mm Hg) in Both the Groups

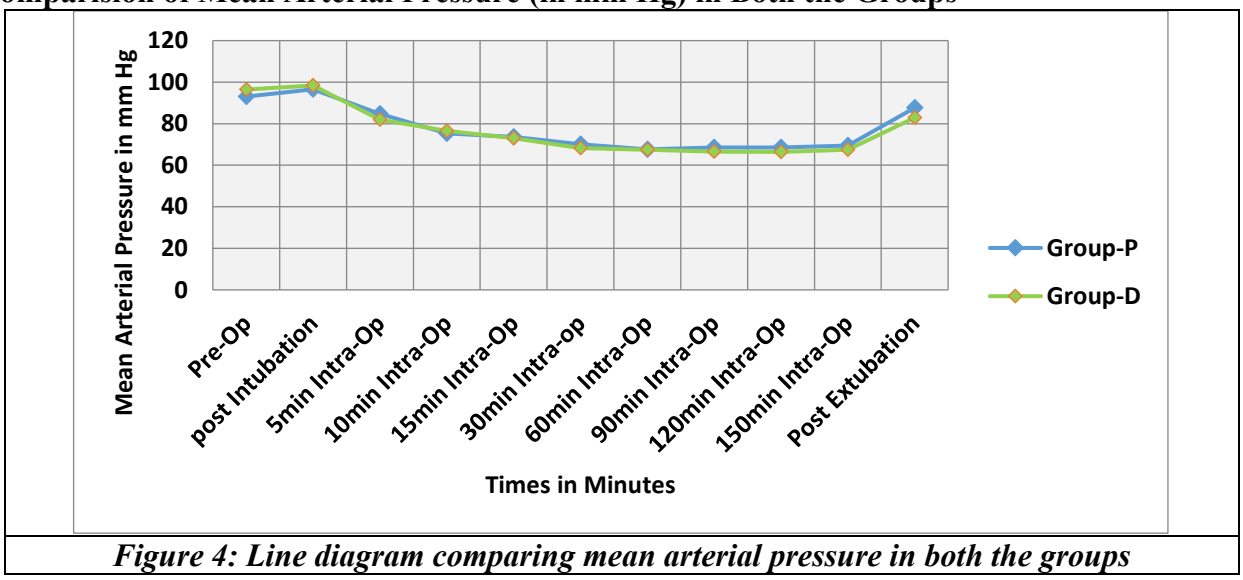


Figure 4: Line diagram comparing mean arterial pressure in both the groups

There was no discernible difference between the two groups when comparing the Average Category Scale for intraoperative bleeding. Nevertheless, group-P achieved a superior score.

Comparision between Average Category Scale for Intraoperative Bleeding in Both the Groups

Groups	Total No. of Patients	Mean Average Category Scale
Group-P	20	2±0.48
Group-D	20	3±0.48

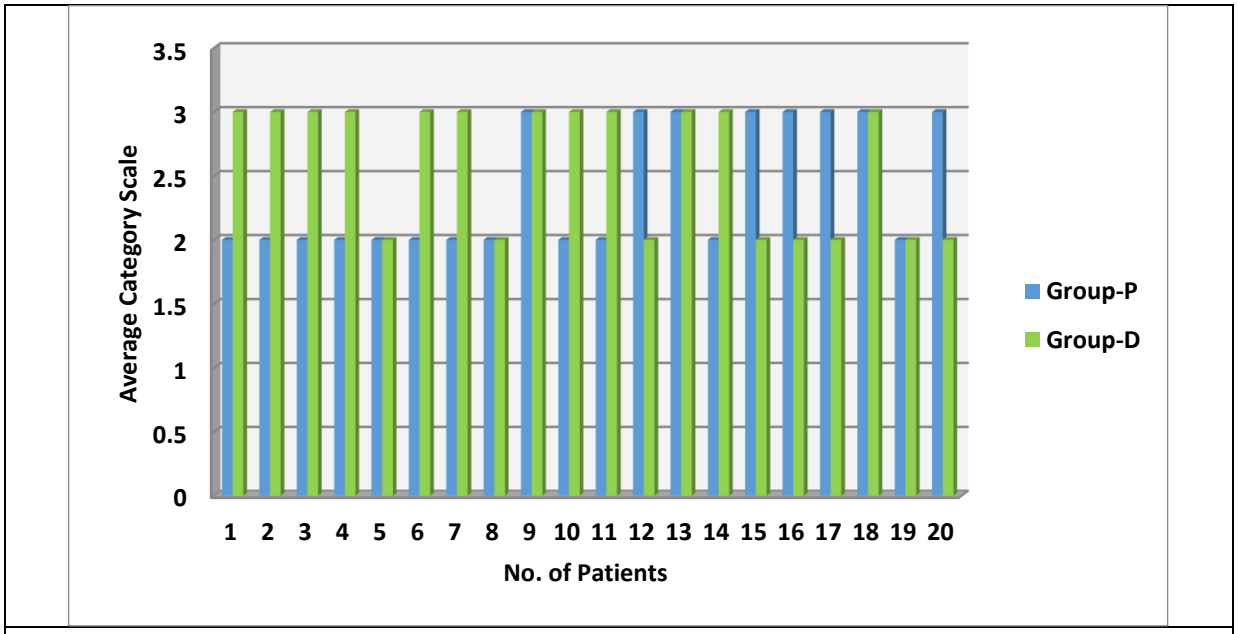


Figure 5: Bar diagram comparing the Average Category Scale between both the groups

Mean of Components of Clinical Recovery Score in Both the Groups

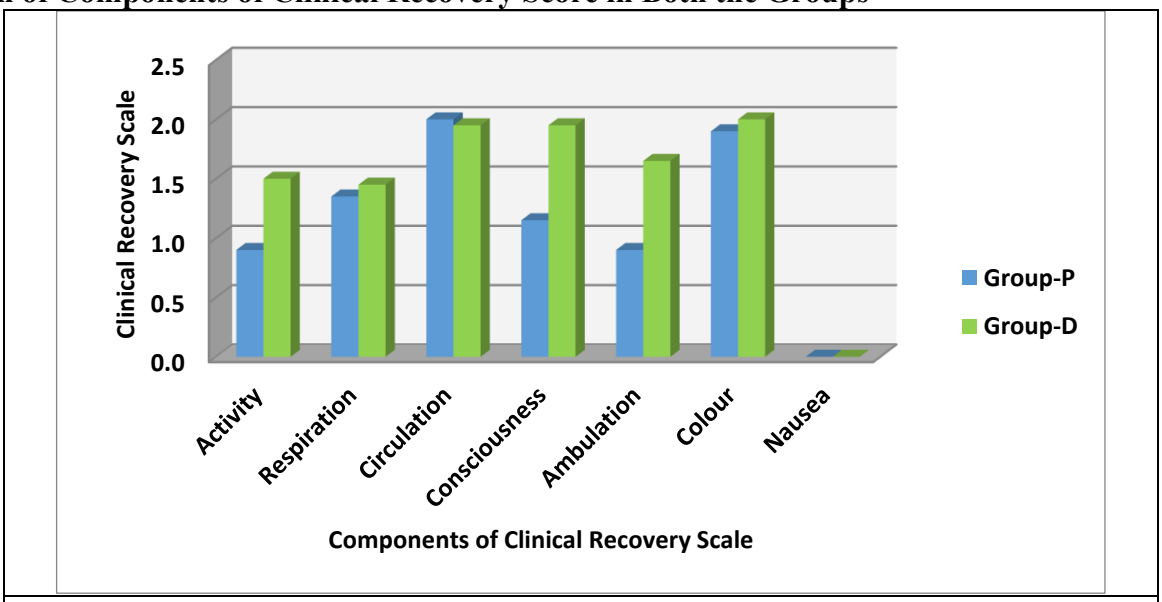


Figure 6: Bar Diagram comparing the components of Clinical Recovery Scale between both the groups

Comparision of Mean CRS in Both Groups

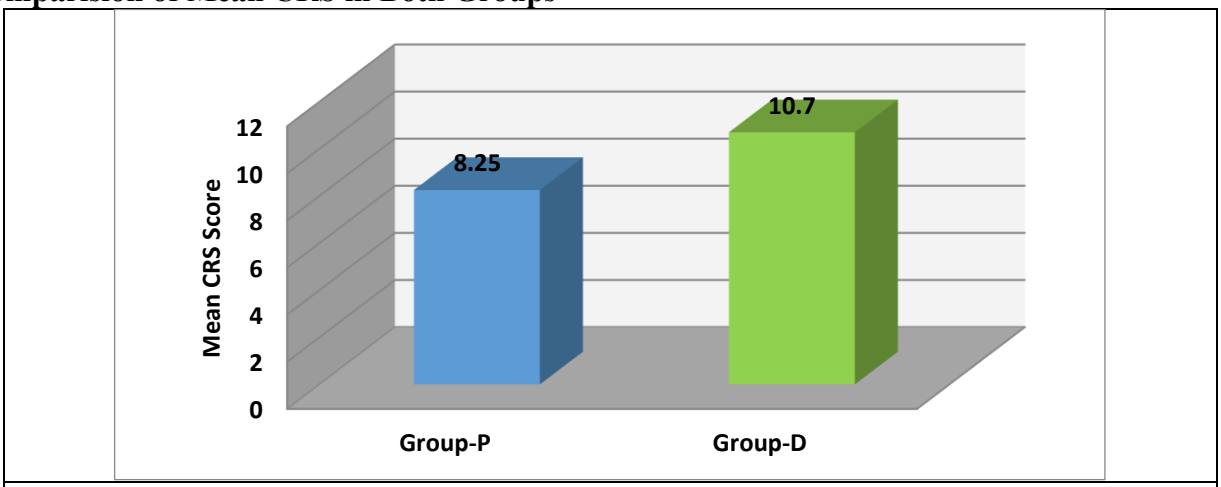


Figure 7- Bar Diagram comparing the mean CRS of both the groups

Comparision of Mean Visual Analogue Score in Both the Groups

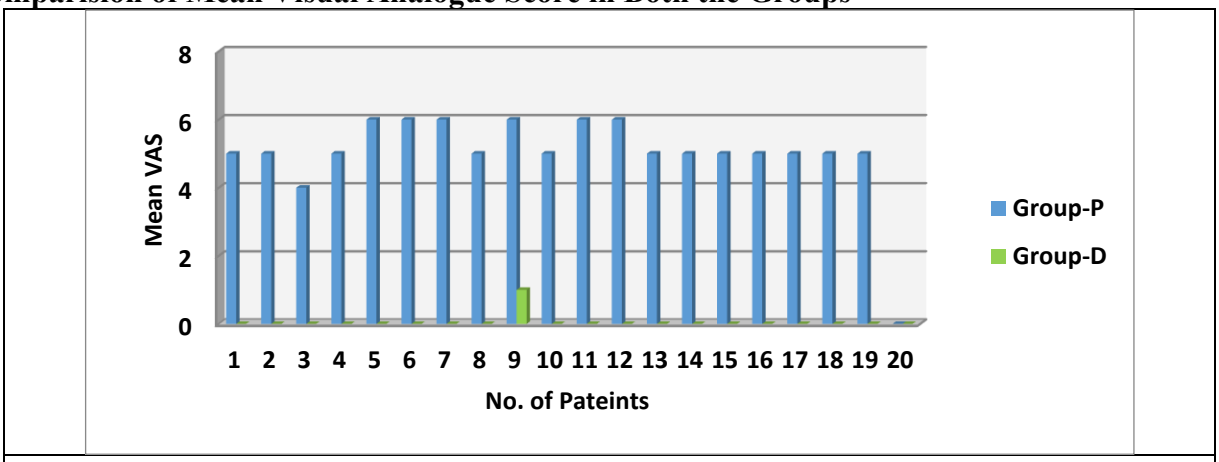


Figure 8: Bar Diagram comparing the mean VAS of both the groups

DISCUSSION

This investigation led us to conclude that, compared to Group-P, Group-D had superior control over heart rate, blood pressure, post-anesthesia recovery, and post-operative analgesia. Figure 1 compares the mean pulse rate between both groups at specific periods. The pulse rate was reduced and managed in both groups. Still, the reduction in Group-D was more significant at 5min and 10min intraoperatively, whereas it was highly significant with p-value <0.0001 during 30min, 60min, 90min, 120min, and 150min intraoperatively and in the post-extubation phase.

Tarek Shams et al. reported in March 2014 that there was a substantial drop in heart rate following induction and intraoperative infusion with Dexmedetomidine in a comparison trial between Esmolol and Dexmedetomidine in FESS surgery. In our investigation, we administered Dexmedetomidine and saw a greater reduction in heart rate compared to Propofol, without any apparent occurrence of bradycardia.[10]

Comparison of propofol and dexmedetomidine on depth of anaesthesia, another study by *Uddalak Chattopadhyay*, et al. (2014) found that the two groups were similar in terms of their baseline HR as well. An increase in heart rate was seen after intubation. Consequently, there was a drop in HR in both groups. In the Dexmedetomidine group, the post-intubation increase was lower. Compared to the Propofol group, the Dexmedetomidine group saw a lower subsequent HR.[13] Similarly, in our study, we found that HR was reduced in both groups, however HR was reduced more in Group-D than in Group-P.

Figure 2 compares average systolic blood pressure between the two groups at various periods. There was a drop in mean systolic blood pressure in both groups, although it was higher in Group D. Except for the 90-min reading, which was determined to be significant with a $p < 0.031$, these values were comparable and insignificant when compared between the two groups.

Figure 3 presents a comparison of the average diastolic blood pressure between the two groups at various time periods. Both groups' mean diastolic blood pressure was found to be decreasing, with Group-D showing a greater reduction than the other. The reduction was statistically significant at 30 min, 90 min, and highly significant at 120 min throughout the surgery.

Figure 4 displays a comparison of the average arterial pressure between both groups at different time intervals. With the exception of the 30 min, 90 minute, 120 min, and 150 min intraoperative periods, which were shown to be highly significant with a $p < 0.0001$ and significant in the post-extubation period, there was a statistically significant drop in mean arterial pressure in both groups.

In 2011, *Naik S Sarika* et al. conducted a retrospective examination of 213 individuals who underwent endoscopic sinus surgery or septoplasty. Patients in Group A received local anaesthesia for their operation, whereas patients in Group B had general anaesthesia with propofol, and patients in Group C received general anaesthesia with halothane. Propofol kept mean arterial pressure between 60 and 70 mmHg, however postoperative complications were negligible for both the local and general anaesthesia groups. They found that Propofol, which maintains a mean arterial pressure of 60-70mm Hg and offers hypotensive anaesthesia, can be utilised for both induction and maintenance of general anaesthesia in endoscopic sinus surgery for severe nasal polyposis.[14] We examined Propofol and Dexmedetomidine in our research groups, and while both provided excellent regulated hypotension, Dexmedetomidine was superior to Propofol in terms of delivering hypotensive anaesthesia, as evidenced by our findings.

Abdullah Aydin Ozcan et al. (2012) conducted a comparative study of Dexmedetomidine versus Remifentanil for controlled hypotension in functional endoscopic sinus surgery. Both dexmedetomidine and remifentanil were shown to offer appropriate, safe, and controlled hypotensive anaesthesia.[15] In another study, *Uddalak Chattopadhyay* et al. (2014) found that when comparing propofol and dexmedetomidine on depth of anaesthesia, the two groups were equivalent in terms of their baseline MAP. A increase in MAP was seen after intubation. Following this, MAP dropped in both groups. The group receiving dexmedetomidine saw a lower rise in postintubation rates. In comparison to the Propofol group, the Dexmedetomidine group had lower subsequent MAP.[13] Comparably, in our investigation, the mean arterial pressure decreased in both groups, with Group-D

seeing a more substantial decrease than Group-P. The findings of our investigation were comparable to those of this study.

Dexmedetomidine and propofol target-controlled infusion were shown to be more effective for sedation during fiberoptic nasotracheal intubation, according to *C. J. Tsai* et al. (2010). Compared to the Propofol group, it was shown that the Dexmedetomidine group's heart rate response to intubation altered considerably. The hemodynamic condition can be more steadily maintained by dexmedetomidine.[16] Comparable results were observed in this study and ours regarding Dexmedetomidine and Propofol; however, Dexmedetomidine significantly reduced blood pressure and heart rate elevation without inducing bradycardia during surgery and the postoperative period.

Figure 5 compares the Average Category Scale score for Intraoperative haemorrhage in both groups. The mean average category score for Group-P is 2±0.48, whereas for Group-D it is 3±0.48. Statistical analysis revealed no significant difference between the two groups ($p<0.0001$).

Propofol can be used for both induction and maintenance of general anesthesia in endoscopic sinus surgery for extensive nasal polyposis because it significantly reduces blood loss and increases visualization, according to *Naik Sarika and Naik Sudhir's* 2011 study, "Hypotensive Anaesthesia using Propofol in extensive nasal polyposis. "The user's text is. In this study, we administered Dexmedetomidine to induce hypotensive anaesthesia in one group, while Propofol was employed in the other group. This findings indicate that Dexmedetomidine yielded better results compared to Propofol.

According to Durmus et al., (2007) dexmedetomidine was linked to more stable hemodynamic responses to anesthesia and reduced bleeding, the need for postoperative analgesics, and intraoperative anesthetics.[17] Our investigation found that both Group-P and Group-D had adequate reductions in bleeding, although Group-P had a higher result.

Propofol infusion may offer the benefit of less bleeding when compared to traditional breathing agents, as the study by *Blackwell KE* et al. (1993) found that the average estimated blood loss in the propofol group was 101 mL. In contrast, the average estimated blood loss in the isoflurane group was 251 mL.[18] This study was similar to ours because, while the difference was not statistically significant, Group-P in our study likewise had superior intraoperative bleeding control than Group-D.

Figure 6 and Figure 7 display the average values of the clinical recovery score components and compare the mean scores of CRS in both groups. The Clinical Recovery Score was adequate in all groups, however, it was shown to be significantly higher in group-D compared to group-P.

The effectiveness of intraoperative dexmedetomidine infusion on emerging agitation and the quality of recovery following nose surgery was studied in 2013 by *Kim S. Y*. et al. The administration of dexmedetomidine during surgery resulted in a smooth and steady recovery concerning blood circulation. Furthermore, it enhanced the postoperative recuperation quality following nose surgery.[19] In our study, the Clinical Recovery Score showed a high significance level in Group-D, with a p-value < 0.0001, compared to Group-P.

Figure 8 compares the Mean Visual Analogue score in both groups during the post-operative period. After a statistical analysis, the VAS score in Group-D (0.05±0.21) was significantly lower than in Group-P (5.00±1.26).

In 1998, *Boccara G*. et al. compared the levels of postoperative pain and the amount of analgesics needed in patients who received either Propofol or Isoflurane to maintain anaesthesia. 40 women classified as ASA I and II, who are undergoing cosmetic abdominoplasty. The patient's analgesia satisfaction score, ranging from 0 (zero) to 4 (excellent), was acquired at discharge. The study found that patients who were administered Propofol experienced higher levels of pain and had greater opioid needs during the initial 6-hour period following surgery, in comparison to individuals who received Isoflurane.[20] The outcome was similar to our research findings about the heightened need for opioids in Group-P.

Research conducted by *Jeffrey F*. et al. in 2009 examined the analgesic need of Dexmedetomidine and Propofol following heart surgery. Administering dexmedetomidine following heart surgery led to

reduced opioid consumption compared to those receiving propofol.[21] This is analogous to our investigation.

In 2004, *Turan A*., et al. evaluated Propofol and Dexmedetomidine in supervised anaesthesia management of patients undergoing septoplasty and endoscopic sinus surgery. A total of 40 patients were allocated into two groups using a random assignment method. Dexmedetomidine can be used in controlled anaesthesia treatment as an alternative to propofol, and they discovered that while the sedationit produced was more profound, the analgesia it produced was superior during the postoperative period.[22] Our investigation yielded comparable findings.

Our investigation led us to conclude that, while there was no obvious bradycardia in any group, both groups' pulse rates increased initially after intubation and then decreased. However, Group-D's pulse rate decreased more than Group-P's.

Systolic, diastolic, and mean arterial blood pressure readings were compared between the two groups; the results showed no variation between the groups, however, group D saw a lower rise in mean blood pressure than group P.

The analysis revealed that there was minimal disparity in the average category scale for intraoperative bleeding between the two groups.

When we examined the clinical recovery scores of the two groups, we found that Group-D had a more substantial and improved recovery than Group-P.

By comparing the two groups' visual analogue score for post-operative analgesia, we could determine that Group-D had superior post-operative analgesia than Group-P.

Therefore, compared to Group-P, we may conclude from this study that Group-D had superior control over heart rate, blood pressure, post-anesthesia recovery, and post-operative analgesia. For ENT procedures, we may thus conclude that dexmedetomidine is a viable substitute for propofol.

CONCLUSION

Although both groups are similar, a close look at Hemodynamic parameters, the Average Category Scale, the Clinical Recovery Score, and the Visual Analogue Scale showed that Dexmedetomidine is better than Propofol. However, more research with a larger population is needed before Dexmedetomidine can be recommended for routine ENT surgeries.

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