

Clinical evaluation of intravenous propofol and dexmedetomidine for controlled hypotension in ENT surgeries.

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Abstract

Introduction: In Ear, Nose and Throat Surgeries the surgery is restricted to very small area with complex anatomy and these areas are prone for profuse bleeding. But it is important to have bloodless field for these surgeries as far as possible for better visibility and lesser complications, it's for the comfort of both the patient and surgeon. Several drugs have been tried to maintain bloodless field and to provide controlled hypotension during ENT surgeries. In this study we intend to compare the efficacy of infusion of Propofol and Dexmedetomidine in providing controlled hypotension in ENT surgeries using the haemodynamic parameters as guideline.

Objectives: The aim of this study was to compare the effects of intravenous Propofol and Dexmedetomidine for controlled hypotension in ENT surgeries.

Material And Methods: A total of 40 patients were included in this study, who were adults of either sex and of the age group 18- 65 years belonging to ASA Grade I or Grade II, of average body weight and height undergoing elective ENT surgeries. The patients were divided into 2 equal groups of 20 each, alternatively by their admission sequence and hence according to the drug to be administered before and during general anaesthesia.

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

Group II (D) - Dexmedetomidine 1µg/kg over 10 minutes before induction of general anaesthesia followed by infusion at the rate of 0.5µg/kg/hr.

The following parameters were observed – Hemodynamic parameters (Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial

Pressure), Average category scale was used for assessment of intra-operative bleeding in surgical field. Statistical comparison of both the groups was analysed by Student's unpaired 't' test. Student's paired 't' test was applied for hemodynamic parameters.

RESULTS: Comparing the Average Category Scale for intraoperative bleeding, there was no significant difference between the 2 groups. However group-D had better score.

Conclusion: So both the groups are comparable with each other but after comparing Average Category Scale for intraoperative bleeding it was concluded that Dexmedetomidine has an upper edge over Propofol, but before recommending Dexmedetomidine for routine ENT surgeries more extensive study is required with a larger population.

Keywords: Controlled Hypotension, ENT surgeries, Dexmedetomidine, Propofol.

Introduction

In Ear, Nose and Throat Surgeries the surgery is restricted to very small area with complex anatomy and these areas are prone for profuse bleeding. Under the microscopic field even minimum amount of bleeding seems to be major one and so it becomes tough on part of anesthesiologist to provide a bloodless field for the surgeon. But it is important to have bloodless field for these surgeries for better visibility and lesser complications, its for the comfort of both the patient and surgeon.^[1,2]

Several drugs have been tried to maintain bloodless field and to provide controlled hypotension during ENT surgeries. Agents that have been used are inhalational agents (isoflurane, desflurane and sevoflurane), sodium nitroprusside, nitroglycerin, trimethaphan camsilate, alprostadil (prostaglandin E1), adenosine, remifentanil, calcium channel antagonist like nicardipine, Beta

blockers- pranolol, esmolol, recently Propofol, and some α_2 agonists like clonidine and dexmedetomidine have been used.

Objectives

In this study we intend to compare the efficacy of infusion of Propofol and Dexmedetomidine in providing controlled hypotension in ENT surgeries, using the haemodynamic parameters as guidelines.

Material And Methods

This study has been conducted on patients admitted for ENT surgeries at *Nehru Hospital, B.R.D. Medical College, Gorakhpur*. An informed written consent was taken from each patient in written form. A total of 40 patients were included in this study, who were adults of either sex and of the age group 18- 65 years belonging to ASA Grade I or Grade II, of average body weight and height undergoing elective ENT surgeries. Sample size was determined by similar studies done in the past.^[3] After taking permission of the ethical committee the patients were examined clinically and relevant routine investigations were done for preoperative assessment.

The patients were divided into 2 equal groups of 20 each, alternatively by their admission sequence and hence according to the drug to be administered before 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 1 μ g/kg over 10 minutes before induction of general anaesthesia followed by infusion at the rate of 0.5 μ g/kg/hr.

All the patients received the premedications in the previous night of surgery .i.e. Tab. Ranitidine 150mg and Tab. Alprazolam 0.25mg. In the pre-operative room the baseline cardio-respiratory parameters were

recorded, and an intravenous line was secured. Inside the operation theatre a multipara monitor was attached for regular monitoring of – Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure and SpO₂. Patients were premedicated with Inj. Glycopyrrolate, Inj. Midazolam and Inj. Pentazocine. Thiopentone was used as common inducing agent in both the groups and Patients were intubated by using Vecuronium. Infusion rates were titrated according to BP, and to provide controlled hypotension. For controlled hypotension the Mean Arterial Pressure was maintained between 65±5 mm Hg. Bleeding during the surgery was assessed by the surgeon blinded to the study of drugs, by predefined category scale adopted from that of Fromme *et al.*^[4] - for assessment of intra-operative surgical field.

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.

At the end of the surgery the patients were reversed with Inj. Neostigmine and Inj. Glycopyrrolate. After the surgery, all the patients were observed in the recovery

room for 8 hours. 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.

Observations

Table 1: Comparison of Mean Pulse Rate (Per Min) In Both Groups

Time Interval in Minutes	Mean Pulse Rate per minute		t' value	p' value
	Group-P	Group-D		
Pre-Op	93±12.5	95±11.9	0.277	0.782
Post Intubation	100±9.8	99±13.4	0.531	0.598
5min Intra-Op	96±9.8	88±9.6	2.418	0.020*
10min Intra-Op	89±10.9	82±7.1	2.538	0.015*
15min Intra-Op	84±8.5	78±6.4	2.922	0.005**
30min Intra-Op	78±5.7	72±5.8	3.421	0.001**
60min Intra-Op	77±4.6	70±5.4	4.643	0.00004**
90min Intra-Op	77±4.4	70±6.4	4.364	<0.0001**
120min Intra-Op	80±4.9	70±6.4	5.009	<0.0001**
150min Intra-Op	82±5.0	71±4.3	0.631	0.534
Post Extubation	89±5.9	80±4.1	3.974	0.0003**

p>0.05= Insignificant, p<0.05= Significant (*),
p<0.01= highly Significant (**)

Table 2: Comparison Between Mean Systolic Blood Pressure (In Mm Hg) In Both The Groups

Time Interval in Minutes	Mean Systolic Blood Pressure in mm Hg		t' value	p' value
	Group-P	Group-D		
Pre-Op	122±8.7	124±10.3		
Post Intubation	129±11.2	126±13.0	0.781	0.439
5min Intra-Op	114±6.1	110±8.6	1.690	0.097
10min Intra-Op	105±6.5	105±5.4	0.000	1.000
15min Intra-Op	101±4.3	101±4.6	0.000	1.000
30min Intra-Op	98±3.3	97±4.2	0.837	0.407
60min Intra-Op	98±4.3	96±3.8	1.558	0.127
90min Intra-Op	99±4.3	96±4.2	2.232	0.031*
120min Intra-Op	94±24.8	96±4.3	1.381	0.173*
150min Intra-Op	98±16.6	98±3.7	0.000	1.000
Post Extubation	116±21.8	114±10.1	0.372	0.711

p>0.05= Insignificant, p<0.05= Significant (*),
p<0.01= highly Significant (**)

Table 3: Comparison between Diastolic Blood Pressure (In Mm Hg) In Both Groups

Time Interval in Minutes	Mean Diastolic Blood Pressure in mm Hg		t' value	p' value
	Group-P	Group-D		
Pre-Op	77±5.4	82±9.6		
Post Intubation	80±7.2	83±14.8	0.815	0.420
5min Intra-Op	70±5.0	69±7.3	0.505	0.616
10min Intra-Op	63±3.6	62±5.5	0.680	0.500
15min Intra-Op	60±3.7	59±3.6	0.866	0.391
30min Intra-Op	56±2.1	54±2.9	2.498	0.016*
60min Intra-Op	53±1.9	53±3.1	0.000	1.000
90min Intra-Op	54±2.4	52±2.3	2.601	0.010*
120min Intra-Op	55±2.3	52±2.4	4.036	0.0003**
150min Intra-Op	53±2.9	52±1.4	1.388	0.173
Post Extubation	72±6.3	69±8.0	1.317	0.195

p>0.05= Insignificant, p<0.05= Significant (*),
p<0.01= highly Significant (**)

Table 4: Comparison of Mean Arterial Pressure (In Mm Hg) At Various Time Intervals in Both the Groups

Time Interval in Minutes	Mean Arterial Pressure in mm Hg		t' value	p' value
	Group-P	Group-D		
Pre-Op	93±5.9	96±9.0		
Post Intubation	97±7.4	98±13.9	0.284	0.778
5min Intra-Op	85±3.7	82±7.3	1.639	0.109
10min Intra-Op	75±2.6	77±4.6	1.692	0.098
15min Intra-Op	74±3.2	73±3.1	1.003	0.321
30min Intra-Op	70±1.6	68±2.4	3.100	0.003**
60min Intra-Op	68±2.1	68±1.9	0.000	1.000
90min Intra-Op	69±2.1	67±1.9	3.158	0.003**
120min Intra-Op	69±2.1	66±2.5	4.109	0.0002**
150min Intra-Op	70±2.6	67±1.8	4.242	0.0001**
Post Extubation	88±7.5	83±7.6	2.094	0.043*

p>0.05= Insignificant, p<0.05= Significant (*), p<0.01= highly Significant (**)

Table 5: Comparison Between Average Category Scale For Intraoperative Bleeding In Both The Groups

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

Discussion

From this study we concluded that Group-D had better control of heart rate, blood pressure as compared to Group-P. Table 1.shows comparison of Mean Pulse Rate between both the groups at given time intervals. The pulse rate was decreased and controlled in both the groups but the decrease in Group-D was more significant at 5min and 10min intraoperatively, where as it was found highly significant with p value <0.0001 at 30min, 60min, 90min,120min, 150min intra-operatively and in post-extubation period.

In a comparative study between Esmolol and Dexmedetomidine in FESS surgery, done by *Tarek shams et al.*, in March 2014 it was observed that there was significant decrease in heart rate after induction and intraoperative infusion with Dexmedetomidine. In our study we used Dexmedetomidine and we found there was more decrease in heart rate compared to Propofol with no evident bradycardia.^[8]

In another study by *Uddalak Chattopadhyay, et al.*, Comparison between propofol and dexmedetomidine on depth of anesthesia, it was observed that the two groups were also comparable with respect to their baseline HR. Post intubation rise in HR was noted. Subsequently, HR was decreased in both the groups. Post intubation rise was less in Dexmedetomidine group. Subsequent HR was also less in Dexmedetomidine group compared to Propofol group.^[5] Similarly in our study also we observed that HR was decreased in both the groups but there was more decrease in HR in Group-D compared to Group-P.

Table 2. shows comparison between mean systolic blood pressure in both the groups at different time intervals. There was decrease in mean systolic blood pressure in both the groups, but it was more in Group-

D. These readings when compared between both the groups were comparable and insignificant except at 90min which was found to be significant with p value of <0.031.

Table 3. shows comparison of mean diastolic blood pressure in both the groups at different time intervals. It was observed that there is decrease in mean diastolic blood pressure in both the groups but more decrease was seen in Group-D. This decrease was significant at 30 min, 90min and highly significant at 120min intraoperatively.

Table 4 shows comparison of mean arterial pressure in both the groups at various time interval. There was reduction in mean arterial pressure in both the groups with more in group D, which was comparable and not significant statistically except at 30min, 90min,120min and 150min intraoperatively which was found to be highly significant with p value of <0.0001 and significant in post-extubation period.

Naik S Sarika, et al. in 2011 in a retrospective analysis of 213 patients who underwent endoscopic sinus surgery or septoplasty were included. Group A included patients who underwent surgery under local anaesthesia, Group B under Propofol general anaesthesia and Group C under Halothane general anaesthesia. Postoperative complication was minimal with both local and general anaesthesia group but Propofol maintained mean arterial pressure at 60-70mmHg. They concluded that Propofol can be used for induction as well as maintenance of general anaesthesia in endoscopic sinus surgery for extensive nasal polyposis as maintains mean arterial pressure of 60-70mm Hg and provides hypotensive anaesthesia.^[7]

We compared Propofol and Dexmedetomidine in our study groups and in both the groups there was satisfactory controlled hypotension but

Dexmedetomidine was better than Propofol for providing hypotensive anaesthesia as seen in our observations.

In a study done by Abdullah Aydin Ozcan, et al. 2012 in a comparative study between Dexmedetomidine versus Remifentanyl for controlled hypotension in functional endoscopic sinus surgery. It was concluded that both dexmedetomidine and remifentanyl provided adequate, safe, controlled hypotensive anaesthesia.^[8]

In another study by Uddalak Chattopadhyay, et al.,(2014), Comparing between propofol and dexmedetomidine on depth of anaesthesia, it was observed that the two groups were also comparable with respect to their baseline MAP. Postintubation rise in MAP was noted. Subsequently, MAP decreased in both the groups. Postintubation rise was less in Dexmedetomidine group. Subsequent MAP was less in Dexmedetomidine group compared to Propofol group.^[5] Similarly in our study both the groups showed decrease in Mean Arterial Pressure, but there was more decrease in Group-D compared to Group-P. Our results were similar to this study.

In a study done by C.J. Tsai, et al.(2010) they compared the effectiveness of Dexmedetomidine versus Propofol target- controlled infusion for sedation during fibreoptic naso-tracheal intubation. It was observed that the Dexmedetomidine group experienced fewer changes in heart rate response to intubation than the Propofol group. Dexmedetomidine allows more stable haemodynamic status.^[6] This study was comparable to our study as we too found similar results with Dexmedetomidine and Propofol, where Dexmedetomidine provided more decrease in heart rate without causing bradycardia and less rise in blood pressure during the surgery and postoperative period.

Figure.5 shows the comparison between Average Category Scale score for Intraoperative bleeding in both the groups. Group-P and Group-D has mean average category score as 3 ± 0.48 and 2 ± 0.48 respectively. Though the group D patient having lesser bleeding than group P but on statistical evaluation it was found that the difference in both the groups was insignificant ($p < 0.0001$).

Naik Sarika, Naik Sudhir in 2011 in their study- "Hypotensive Anaesthesia using Propofol in extensive nasal polyposis", concluded that Propofol can be used for induction as well as maintenance of general anaesthesia in endoscopic sinus surgery for extensive nasal polyposis as it significantly reduces blood loss and thereby increases visualization.^[7] We used Dexmedetomidine for providing hypotensive anaesthesia in one of the groups and Propofol in the other and we found better results with Dexmedetomidine.

In a study done by Durmus et al. in 2007 concluded that Dexmedetomidine decreased bleeding, postoperative analgesic requirements and intraoperative anaesthetic requirements and was associated with more stable haemodynamic responses to anaesthesia.^[9] We observed in our study that there was satisfactory reduction in bleeding in Group-P and Group-D but the score was better in Group-D.

Blackwell KE, et al. in 1993, studied the average estimated blood loss in the propofol group was 101 mL compared with an average estimated blood loss of 251 mL in the isoflurane group, hence propofol infusion may have the advantage of decreased bleeding compared with conventional inhalation agents.^[10] This study was comparable to our study as in our study also Group-D had better intraoperative bleeding control compared to Group-P but the difference was not

statistically significant. Comparing the Systolic, Diastolic, and Mean Arterial blood pressure between the two groups we found that there was not much difference between the 2 groups but there was less rise in mean blood pressure in Group-D compared to Group-P.

Hence we can summarize from this study that Group-D had better control of heart rate, blood pressure with lesser bleeding intraoperatively. So we can conclude that Dexmedetomidine can be used as an alternative to Propofol for ENT surgeries.

Results

- There was significant reduction in pulse rate in both the groups when compared to their respective preoperative value which was highly significant in both groups (p value < 0.0001). When both the groups were compared, it was found that decrease in pulse rate at different time intervals was highly significant in group-D (p value < 0.0001)
- There was significant decrease in systolic blood pressure in both the groups (p value < 0.0001) in comparison to their preoperative value. And when both the groups were compared, the difference was mostly insignificant.
- There was highly significant reduction in the diastolic blood pressure of both the groups when compared to preoperative values but when both the groups were compared with each other the decrease was not very significant.
- The decrease of mean arterial blood pressure in comparison to its preoperative value was found to be statistically highly significant ($P < 0.0001$) in both the groups. Where as when both the groups were compared with each other at different time intervals, the difference were comparable and insignificant

- Comparing the Average Category Scale for intraoperative bleeding, there was no significant difference between the 2 groups. However group-P had better score.
- Recovery score was better in group-D
- Post-operative analgesia was better in group-D.

Conclusion

Both the groups are comparable with each other but after minute observation of Hemodynamic parameters, Average Category Scale, it was concluded that Dexmedetomidine has an upper edge over Propofol, but before recommending Dexmedetomidine for routine ENT surgeries more extensive study is required with a larger population.

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