

Effect of intravenous labetalol for intranasal surgeries under general anaesthesia

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Abstract

Background: Intranasal surgeries carry high risk and complications. There is increased chance of bleeding during intranasal surgeries. Administration of vasoconstrictive agents, α_2 agonists, labetalol, nitroglycerin, remifentanyl reduce bleeding and produce better visualisation during surgery. **Objectives:** To evaluate the effect of intravenous labetalol during general anaesthesia for patients undergoing intra nasal surgeries. **Methodology:** This was a randomized double blind control study conducted in department of anaesthesiology, Rajah Muthiah Medical College and Hospital between December 2019 and October 2020. Conducted among 60 patients underwent elective intranasal surgeries. They were divided into two groups. Group L received IV Labetalol and Group P received Placebo (Normal saline). Heart rate, systolic and diastolic blood pressure, Mean arterial pressure and bleeding score was recorded. **Results:** The mean duration of surgery was less for the labetalol group than the control group. The heart rate was found to be similar in both the groups over the period. Both systolic, diastolic blood pressure and mean arterial pressure were decreased in Group L than in Group P. Bleeding score was also found to be more in the Group P than Group L. **Conclusion:** Labetalol reduces bleeding at surgical site and provides better visibility of the operative field than placebo. Intravenous labetalol helps to achieve controlled hypotension with minimal side effects.

Key words: Intranasal surgeries, labetalol, bleeding score.

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INTRODUCTION

Intranasal surgeries carry high risks and complications which depend on a lot of factors. First, Owing to the smaller area of surgery and high vascular perfusion of the facial tissue there will be an increased chances of complications especially bleeding¹. The facial tissue especially around the nasal cartilage have high perfusion

leading to increased chance of intra operative bleeding during surgeries. The risk of bleeding from the mucosal surfaces can interfere with visualization of the anatomy and increase the risk of serious complications such as orbital or skull base injury with resultant cerebrospinal fluid leak. In addition, reduction of bleeding could result in greater ease and thoroughness of the sinus surgery owing to better visibility². Providing a clean bloodfree surgical field makes the operation faster, easier and with a better quality leading to a better outcome³. In this regard, several approaches have been used to reduce the bleeding amount although none of them has shown superiority over others. These methods include simple ones like positioning the head higher than the heart surface, administration of vasoconstrictive agents and induced hypotension^{4,5,6}. Controlled hypotension is defined as a reduction of the systolic blood pressure to 80-90 mm Hg, a reduction of mean arterial pressure (MAP) to 50-65 mm Hg or a 30% reduction of baseline MAP. Pharmacological agents used

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for controlled hypotension includes magnesium sulphate, sodium nitroprusside, nicardipine, nitro-glycerin, esmolol, α_2 -agonists, labetalol and high doses of potent inhaled anaesthetics⁸. Labetalol is an antagonist of adrenergic receptors (α_1 , β_1 , β_2) and is used as hypotensive agent³. It is a combined nonselective β -adrenoceptor antagonist and a competitive antagonist of postsynaptic α_1 -adrenoceptors. The effect of Labetalol as intravenous agent has been studied by only few with inconsistent results thus leading to the present study with an aim to assess the effect of intravenous Labetalol in intranasal surgeries under general anaesthesia.

METHODOLOGY

The study was conducted in the department of anaesthesiology, Rajah Muthiah Medical College and Hospital (RMMCH) between December 2019 – October 2020. The study was undertaken after getting approval from the hospital ethical committee for human experiments. The study was conducted on 60 adult patients undergoing elective intranasal surgeries under general anaesthesia. The patients were randomly allocated to one of the two groups, Group L (Labetalol group) and Group P (Placebo group). Patient aged 20 to 60 years, belonging to ASA I and II and undergoing intranasal surgeries under general anaesthesia were included in the study. Patient with systemic illness and on chronic medications, history of allergy to the study drug pregnant mothers, ASA-III, ASA-IV and ASA-V were excluded from the study. Informed written consent was obtained from each of the patient included into the study. As a part of pre anaesthetic preparation NPO was advised since 10 PM the night before surgery. Patients were premedicated with tablet diazepam 5 mg the night before surgery and injection glycopyrrolate 0.2 mg given intramuscular in the pre-operative room 45 minutes prior to surgery. The Patients were allotted to groups by lottery methods and numbering was given to each patients. Two separate 18 G IV lines established. The drug was prepared by the anesthesiologist who was not involved in the study. The study drugs were administered 3min before the induction of general anaesthesia. Patients in both the groups were premedicated with fentanyl 1 mcg/kg IV. Patients were preoxygenated with 100% O₂ for 5 minutes. General anaesthesia was induced with injection thiopentone sodium 5 mg/kg IV and injection Succinylcholine 2mg/kg IV used to facilitate intubation. Appropriate size cuffed ET tube was introduced orally and tube position was confirmed. Anaesthesia was maintained with nitrous oxide in 35% oxygen and 1% Sevoflurane. Injection vecuronium 0.08 mg/kg IV bolus followed by divided doses. At the end of surgery Sevoflurane was cut off, residual neuromuscular blockade was reversed with neostigmine 40 mcg/kg and

glycopyrrolate 10mcg/kg and extubation done with 100% oxygen. Intraoperative monitoring was done at 2,4,6,8,10,15,20,25,30,45,60 minutes and every 15 minutes there after till the end of surgery and post extubation with the following parameters Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure. Patients were monitored for any adverse events like bradycardia and hypotension. At the end of the surgery, intraoperative bleeding at surgical site was assessed with a bleeding score as below

Grade 0 – No bleeding – excellent

Grade 1 – Minor bleeding – no suctioning required.

Grade 2 – Minor bleeding – suctioning required.

Grade 3 – Minor bleeding – frequent suctioning required.

Grade 4 – Moderate bleeding – surgical field visible with suctioning only.

Grade 5 – Severe bleeding – very frequent suctioning for surgery to proceed.

At the end of the study, the number were decoded.

Data for all the patients were collected using a pretested, semi-structured proforma by the investigator. The data were then entered into Microsoft excel 360. The above entry into the excel acted as the master chart. The above master chart was then imported into SPSS (Statistical Package for social sciences) version 23. To compare the distribution of categorical variables between the groups, chi square test was applied. To compare the mean values between the groups, unpaired T test was applied. To find out the trend of a variable over timeline, repeated measures ANOVA was applied.

RESULTS

The mean age among those in the group L was 30.03 ± 6.32 years and among those in the group P it was 30.36 ± 6.07 years. Among the study participants belonging to the group L, 56.7% were males and among those in the group P, 50% were males. The mean weight among those in the group L was 58.83 ± 7.01 kgs and among those in the group P it was 59.03 ± 7.18 kgs. Among the study participants belonging to the group L, 86.7% were ASA I and among those in the group P, 76.7% were ASA I. Among the study participants belonging to the group L, 66.7% were diagnosed to have deviated nasal septum to left and among those in the group P, 63.3% were diagnosed to have deviated nasal septum to left (Table 1). All the study participants of both the group had undergone Submucosal resection (SMR) with Functional endoscopic sinus surgery (FESS). Both the groups were similar with respect to characteristics like age, sex, weight, ASA and diagnosis. The mean duration of surgery among those in the group L was 120.33 ± 1.82 minutes and among those in the group

P it was 124.33 ± 7.18 minutes. The mean time taken for surgery in the group P was more than the group L (P value < 0.05) (Fig 1). With respect to heart rate, both the group had similar heart rate in the pre-induction period which then decreased in both the groups. With respect to blood pressure systolic, diastolic and MAP had declined over the period of surgery. The decline of systolic blood pressure with timeline was found to be statistically significant with P value of less than 0.05. When compared between the groups, in both the groups the blood pressure and its decline was statistically distinct with time (P value < 0.05). The decline was more in the Group L than the Group P.

After the 4th min the magnitude of BP was more in the group P than in the group L. The difference was statistically significant after 4th min. Similar pattern was found with respect to MAP (Table 2,3,4). Among the study participants belonging to the group L, 56.7% had minor bleeding without any suctioning requirement and among those in the group P, 40% had minor bleeding without any suctioning requirement. Both the groups were found to be statistically different with respect to nasal bleeding score (P value < 0.05). The score was significantly more in Group P than the group L (Table 5).

Table 1: Baseline characteristics among the study participants

Variables	Group L (n=30)	Group P (n=30)	P value
Age	30.03 (06.32)	30.36 (06.07)	0.836*
Sex - M/F	17.00(56.70)/ 13.00(43.30)	15.00 (50.00)/ 15.00(50.00)	0.605*
Weight	58.83 (07.01)	59.03 (07.18)	0.913*
ASA status - I/II	26.00 (86.70)/ 04.00(13.30)	23.00 (76.70)/ 07.00(23.30)	0.317*
DNS - Left/ Right	20.00(66.70)/ 10.00(33.30)	19.00(63.30)/ 11.00(36.70)	0.787*

*not significant

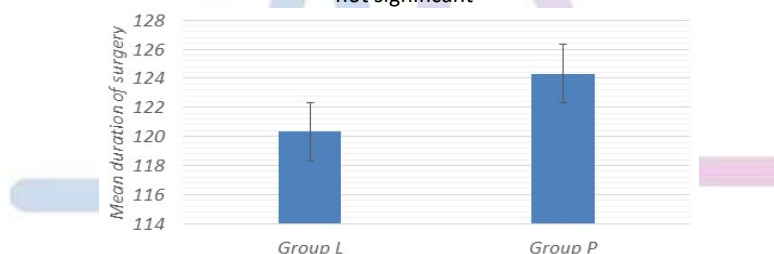


Figure 1: Bar chart showing mean duration of surgery between the groups

T value – 2.616 d.f – 58 P value - 0.017

Table 2: HEART RATE (min)

Time interval	Group L		Group P		Student's t test	
	Mean	SD	Mean	SD	t test	p value
Pre induction	85.20	08.24	88.70	12.59	1.27	0.208
2 min	83.93	10.77	87.73	11.87	1.29	0.199
4 min	80.73	09.37	89.30	08.67	3.67	0.001*
6 min	75.26	10.75	83.30	10.12	2.98	0.004*
8 min	73.50	08.82	79.36	09.45	2.48	0.016*
10 min	72.16	09.05	78.56	10.44	1.74	0.017*
15 min	71.46	07.42	73.46	08.86	0.94	0.347
20 min	71.33	05.84	75.03	09.67	1.79	0.078
25 min	71.40	05.52	74.16	10.42	1.28	0.204
30 min	70.60	05.99	74.33	09.18	1.86	0.067
45 min	70.43	06.04	73.43	08.37	1.59	0.117
60 min	67.96	07.12	69.66	06.69	0.95	0.345
75 min	69.33	07.01	71.93	07.56	1.38	0.173
90 min	67.43	12.60	70.33	12.98	0.87	0.384
105 min	70.83	06.94	72.60	07.35	0.95	0.343
120 min	73.23	06.15	74.20	06.48	0.59	0.556

F value – 1.34 P value – 0.227

Table 3: Systolic Blood Pressure (Mmhg)

Time interval	Group L		Group P		Student's t test	
	Mean	SD	Mean	SD	T	P value
Pre induction	138.54	06.65	140.30	09.56	1.58	0.368
2 min	136.58	13.87	136.20	11.02	1.35	0.273
4 min	118.01	15.14	133.36	10.29	4.59	0.001
6 min	113.90	10.01	135.56	12.68	7.34	0.001
8 min	110.83	08.65	135.83	13.56	8.51	0.001
10 min	109.00	07.84	132.86	13.98	8.15	0.001
15 min	111.93	08.05	130.73	11.84	7.18	0.001
20 min	111.33	08.77	130.93	10.49	7.84	0.001
25 min	112.50	07.42	130.10	12.57	7.39	0.001
30 min	112.96	06.63	130.10	10.94	7.33	0.001
45 min	113.63	09.44	132.76	09.92	5.82	0.001
60 min	111.63	09.14	132.76	09.92	8.57	0.001
75 min	115.06	13.34	131.40	11.95	4.99	0.001
90 min	114.86	08.85	130.83	10.48	6.37	0.001
105 min	116.11	07.83	131.60	09.82	6.75	0.001
120 min	115.90	08.66	130.26	09.83	6.01	0.001

F value – 2.502 P value – 0.016

Table 4: MEAN ARTERIAL BLOOD PRESSURE (mmHg)

Time interval	Group L		Group P		Student's t test	
	Mean	SD	Mean	SD	T	P value
Pre induction	96.90	09.40	98.70	09.35	0.74	0.460
2 min	96.50	09.82	94.31	09.97	0.07	0.939
4 min	90.20	11.39	92.60	12.82	0.76	0.447
6 min	87.13	08.16	88.20	08.07	0.51	0.613
8 min	81.86	06.71	87.96	10.91	2.67	0.012
10 min	82.50	06.56	86.66	09.36	1.99	0.045
15 min	82.73	08.46	88.10	08.71	2.41	0.019
20 min	84.56	08.21	90.96	08.53	2.96	0.004
25 min	84.46	06.82	89.93	08.71	2.71	0.009
30 min	85.10	06.86	90.23	09.20	2.45	0.017
45 min	86.60	08.24	92.70	11.62	2.49	0.015
60 min	84.80	08.29	92.70	11.62	3.03	0.004
75 min	83.36	07.32	90.43	09.90	3.14	0.003
90 min	86.76	07.42	93.71	09.56	3.13	0.003
105 min	86.46	07.44	92.23	09.85	2.55	0.013
120 min	87.73	07.63	93.46	08.72	2.71	0.009

F value – 4.956 P value – 0.001

Table 5: NASAL BLEEDING

Nasal bleeding score	Group L		Group P		Chi-square test	
	N	%	N	%	X ²	P value
No bleeding	03	10.0	00	00.0	8.52	0.03
Minor bleeding no suctioning required	17	56.7	12	40.0		
Minor bleeding, suctioning required	10	33.3	14	46.7		
Moderate bleeding, surgical field visible with suction only	00	00.0	04	13.3		

DISCUSSION

The mean duration of surgery among those in the group L was 120.33 ± 1.82 minutes and among those in the group P it was 124.33 ± 7.18 minutes. Both the group were found to be statistically distinct with respect to mean duration of surgery (P value <0.05). The mean time taken for surgery in the group P was more than the group L. Sajedi *et al.*

reported a similar duration of surgery while using a labetalol infusion. They reported the mean duration to be 125.77 ± 44.8 minutes which was comparable to the present study⁹. The heart rate trend between the groups were statistically similar over the entire period with P value of more than 0.05. Similar results to the present study was obtained by El-shmaa NS *et al.* were they reported that

labetalol infusion produced less tachycardia during the surgery¹⁰. Goldberg ME *et al.* also reported that labetalol's property of inducing hypotension was not associated with increase in heart rate¹¹. When compared between the groups, in both the groups the systolic and diastolic blood pressure and its decline was statistically distinct with time (P value <0.05). The decline was more in the Group L than the Group P. After the 4th min the magnitude of systolic and diastolic BP was more in the group P than in the group L. The difference was statistically significant after 4th min. Similar pattern of blood pressure changes was also obtained by yeasmeen *et al.*¹² Said AM *et al.* conducted Randomised Controlled Trial (RCT) among 104 patients, to evaluate the pre-operative and intra operative changes in the blood pressure following the administration of labetalol and they concluded that labetalol infusion, significantly lowered intraoperative blood pressure than the pre-operative blood pressure¹³. The above finding was in accordance with that of the present study. Among the study participants belonging to group L, 56.7% of the patients had minor bleeding without any suctioning requirement (Grade I), 33% of the patients had minor bleeding with suctioning requirement (Grade II) and none of the patients had moderate bleeding (Grade IV). In the group P 40% of the patients had minor bleeding without any suctioning requirement (Grade I), 46.7% of the patients had minor bleeding with suctioning requirement (Grade II), 13.3% of the patients had moderate bleeding (Grade IV). Both the groups were found to be statistically different with respect to nasal bleeding score (P value <0.05). The nasal bleeding score was more in Group P which shows that bleeding was significantly more in group P. Study by El-Shmaa NS *et al.* reported that labetalol produced increased visualization of surgical site by decreasing bleeding at the site. They also reported that labetalol created ideal surgical condition at a low mean arterial pressure¹⁰. Yeasmeen *et al.* reported that labetalol was associated with increased visualization of surgical field⁽¹²⁾. The above finding was similar to the findings of the present study.

CONCLUSION

From the study we could conclude that intravenous labetalol during general anaesthesia in intranasal surgeries reduce bleeding at surgical site and provides better visibility of the operative field than placebo. Intravenous labetalol helps to achieve controlled hypotension with minimal side effects.

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