Comparison of dexmedetomidine with nitroglycerinefor hypotensive anaesthesia in functional endoscopic sinus surgery

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Abstract

Aim: The aim of the study is to compare Dexmedetomidine with Nitroglycerine for hypotensive anaesthesia for Functional Endoscopic Sinus Surgeries (FESS) with respect to quality of the surgical field, hemodynamics, amount of blood loss, intraoperative opioid requirement, time to first analgesic request and recovery profile.

Methods: After approval by institutional Ethics Committee, 60 patients were randomly allocated by sealed envelope technique into two drug groups: Nitroglycerine (Group N) and Dexmedetomidine (Group D). After induction of anesthesia, Nitroglycerine infusion at 0.5-10 µg/kg/min was started for patients in group N and Dexmedetomidine was given as loading dose of 1 µg/kg over 10 min followed by maintenance infusion rate of 0.2- 0.7 µg/kg/hr for patients in group D. The infusion rates were then titrated to maintain MAP between 50-60 mm of Hg or 30% reduction of baseline MAP, whichever is higher. Parameters observed include heart rate, mean arterial pressure, blood loss (Average Category Scale), emergence time, time to first rescue analgesic and post-operative recovery (Modified Alderete Score).

Results: In our study, statistically significant reduction in heart rate (58/min vs 69/min) was observed in patients in group D, while Systolic, diastolic and mean arterial pressure were comparable. The quality of surgical field as assessed by ACS was better in group D ($p<0.05$, significant). Patients in group D also needed less intraoperative opioid compared to group N (139.33mcg vs 187.67mcg and prolonged time to first rescue analgesic (377.33 sec vs 86 sec). However, emergence time (20.6sec vs 14.0 sec) and recovery profile using time to reach MAS? 9 was better in group N. Patients in group N also had better sedation scores compared to group D (2.2 vs 1.43).

Conclusion: Dexmedetomidine was better compared to Nitroglycerine for hypotensive anaesthesia in Functional Endoscopic Sinus Surgery with respect to quality of surgical field as assessed by average category scale, less intra operative opioid requirement and prolonged time to first rescue analgesic post operatively. However, Nitroglycerine was better with respect to early emergence from anaesthesia and early discharge criteria as assessed by modified Alderete score.

Keywords: Hypotensive anaesthesia, Dexmedetomidine, Nitroglycerine, Recovery profile, Functional Endoscopic Sinus Surgeries (FESS)

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Introduction

Functional Endoscopic Sinus Surgery (FESS) is a widely performed procedure in Otorhinolaryngology. The sinus surgeries have dramatically improved due to illumination provided by endoscopy. However when FESS is performed under General Anaesthesia (GA), excessive bleeding in the operating field can lead to poor vision and thereby cause difficulty in performing surgery. Induced hypotension is one of the techniques, to improve visibility in FESS by reducing intra operative blood loss. Controlled hypotension (also referred to as deliberate or induced hypotension), is defined as a reduction of systolic blood pressure to 80 to 90 mm Hg, a reduction of mean arterial pressure (MAP) to 50 to 60 mm Hg or a 30% reduction of baseline Mean Arterial Pressure (MAP)[1].

Various drugs have been used to induce hypotension for endoscopic surgeries. They include– Nitroglycerine, sodium nitroprusside, inhaled anaesthetic agents, clonidine, magnesium sulphate, beta blockers etc. However these agents have various side effects like tachycardia, tachyphylaxis, delayed recovery, refractory bradycardia, cyanide toxicity and rebound hypertension. Nitroglycerine has been used for a long time to induce hypotension in developing countries in view of its easy titratability, limited interaction with anaesthesia drugs and low cost. However, recently, highly selective alpha 2 adrenergic receptor agonist namely Dexmedetomidine has been introduced as an alternate to existing hypotensive agents and also to reduce analgesic requirement. The central and peripheral sympatholytic action of Dexmedetomidine mediated by alpha 2 adrenergic receptors leads to a dose dependent decrease in arterial blood pressure, heart rate, cardiac output and nor epinephrine release.

The present work attempts to compare the efficacy and safety of Dexmedetomidine with Nitroglycerine in FESS with respect to quality of the surgical field,

hemodynamics, amount of blood loss, intraoperative opioid requirement, time to first analgesic request and recovery profile.

Aim

The primary aim of the study is to compare Dexmedetomidine Vs Nitroglycerine for hypotensive anaesthesia for Functional Endoscopic Sinus Surgeries (FESS) with respect to quality of the surgical field. The other parameters include amount of blood loss, hemodynamics, intraoperative opioid requirement, recovery profile, time to first analgesic request.

Materials and Methods

Study design: Prospective, comparative, single blinded study

Study area: Department of Anaesthesiology, SRM Medical College Hospital & Research Centre, Kattankulathur, Chennai.

Study population: 30 subjects in each group of both sexes scheduled for elective surgeries

Inclusion criteria: Patients of age between 20 to 50 years with consent for anaesthesia as well as planned surgery

ASA PS I or II

Elective FESS surgeries in otorhinolaryngology.

Exclusion criteria

1. Patient's refusal
2. Recurrent sinus surgeries
3. Hypertensive patients
4. IHD (Ischemic Heart Disease)
5. Renal /Hepatic/ Cerebral Insufficiency
6. Coagulopathies
7. Patients on drugs influencing coagulation

Methods

Approval from institutional ethical committee and informed consent from the patient abtained. Nasal cavity packed with cotton soaked with adrenaline in the concentration 1:100000 in all patients to minimise the blood loss. In operation theatre standard monitoring was instituted and two i.v cannula were inserted, one for infusion of study drug, other for administration of anaesthetic drugs and intravenous fluids. All the patients were pre-medicated with Inj.Midazolam 0.05mg/kg i.v & Inj.Fentanyl 2mcg/kg i.v 5 min before induction. A 22G radial artery catheter was inserted inradial artery for continuous measurement of IBP and sampling for ABG, patients were randomly assigned by sealed envelope technique to either group D (Dexmedetomidine) or group N (Nitroglycerine).

Anaesthesia for patients in both groups was induced with Inj.propofol 2mg/kg i.v and vecuronium 0.1mg/kg i.v. After ventilating the patient with N_2O/O_2 (nitrous oxide/oxygen) - 50-50% and isoflurane 0.8-1.2% for 3mins, patient were intubated with appropriate size endotracheal tube. Anaesthesia maintained with isoflurane 0.8-1.2%. All patients in both groups were placed in reverse trendlenburg (i.e. 15 degree) position post induction and after securing airway to facilitate venous drainage. After induction of anaesthesia and securing airway, patients received one of the drugs according to their randomisation:

Group D (Dexmedetomidine), patients received a loading dose of 1mcg/kg Dexmedetomidine over 10 minutes followed by continuous infusion at the rate of 0.4-0.8mcg/kg/hr (200 mcg in 50 ml normal saline) titrated to achieve the target blood pressure.

Group N (Nitroglycerine) – patients received no bolus dose but were started on a continuous infusion of 1.5-10mcg/kg/min (25 mg in 50 ml normal saline) titrated to achieve the target Blood Pressure.

Surgery was started once the target blood Pressure achieved. Throughout the surgery the drug dose were titrated to maintain target Mean Arterial Pressure of 50-60 mmHg or 30% reduction in baseline MAP, whichever is higher. The investigator who prepares and titrates the study drug did not participate in data collection. The surgeon and the investigator involved in data collection were blinded to the drug used.

In both groups patient were supplemented with additional dose of fentanyl 0.5 mcg/kg and vecuronium 0.02 mg/kg, if signs of inadequate anaesthesia like elevated mean arterial pressure, somatic response like movement or sweating are noted. If targeted blood pressure was not achieved or heart rate was greater than 100/ min with either of these agents, Esmolol was used to reduce blood pressure (loading dose of 500 mcg/kg/min followed by infusion of 100 mcg/kg/min). The same surgeon performed all procedures to ensure consistency in estimation of surgical field and was blinded to hypotensive agent used. When mean arterial pressure reached desired range and was maintained for about 10 minutes, surgeon estimated quality of surgical field using predefined category scale adopted from Fromme et al.

Infusion of hypotensive agents were stopped 5min prior to anticipated end of surgery and isoflurane was stopped at the end of surgery (Nasal packing) and residual neuromuscular blockade was reversed with neostigmine 50mcg/kg and glycopyrolate 10mcg/kg. After extubation and full recovery, patients were transferred to the post anaesthesia care unit (PACU) for observation.

Data collection: Quality of surgical field: Quality of surgical field was assessed by surgeon using average category scale for assessment of intraoperative surgical field by Fromme. The ideal average category scale value for surgery was 2 & 3. Total blood loss was measured from suction apparatus and weighing cotton pre-operatively and after soakage. Hemodynamics (heart rate, blood pressure, saturation) was recorded intra-operatively every 15 minutes and every 5 minutes after discontinuing hypotensive agents till complete

recovery. Emergence time is defined as interval between discontinuation of anaesthetic agent to eye opening to verbal command. Time to first rescue analgesic was recorded. Postoperative recovery will be evaluated using a modified Aldrete Score (0-10) and time needed to achieve ≥9 was recorded.

Statistical Analysis

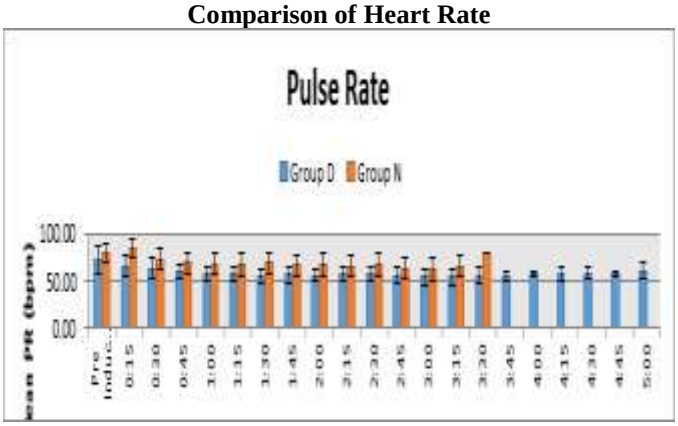
Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test and categorical variables were analyzed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

Results

1. **Age Distribution:** Most of the Group D patients were clustered in the 21-30 years age group (n=15, 50%) with a mean age of 30.83 years. In the Group N patients the clustering was in the same age group as Group D (n=11, 37%) with a mean age of 31.43 years. Age distribution was not statistically significant since $p > 0.05$ as per unpaired t test.
2. **Gender Distribution:** Majority of the Group D patients were males (n=23, 77%). Similarly Group N reflected the same picture of male majority (n=18, 60%). Not statistically significant since $p > 0.05$ as per chi squared test.
3. **Heart Rate Comparison:** In group D, the heart rate intra-operatively was decreased to an average of 58.30 beats per minute between 15 minutes after induction to 2 hours 30 minutes intra-operatively in comparison with group N in whom the heart rate was average of 69.38 beats per minute with a p-value of < 0.02 according to unpaired t-test. The heart rate intra-operatively was meaningfully less in intervention group D compared to intervention group N by 11.08 beats per minute.
4. **Systolic Blood Pressure:** Most of the Dexmedetomidine intervention group patients had mean SBP ranging from 117.13 mm Hg at baseline to 103.67 mm Hg at the end of 5 hours intraoperatively. Similarly the Nitroglycerine intervention group patients had mean SBP ranging from 126.00mm Hg at baseline to 102.00 mm Hg at the end of 3 hours 30 minutes. Systolic blood pressure was not statistically significant since $p > 0.05$ as per unpaired t test.
5. **Diastolic Blood Pressure:** Most of the Dexmedetomidine intervention group patients had mean DBP ranging from 71.77 mm Hg at baseline to 69.67 mm Hg at the end of 5 hours intraoperatively. Similarly the Nitroglycerine intervention group patients had mean DBP ranging from 72.80mm Hg at baseline to 58.00 mm Hg at the end of 3 hours 30 minutes. Diastolic blood pressure was not statistically significant since $p > 0.05$ as per unpaired t test.
6. **Mean Arterial Blood Pressure:** Most of the Dexmedetomidine intervention group patients had mean MAP ranging from 85.87 mm Hg at baseline to 63.33 mm Hg at the end of 5 hours intraoperatively. Similarly the Nitroglycerine intervention group patients had mean MAP ranging from 87.47mm Hg at baseline to 74.00 mm Hg at the end of 3 hours 30 minutes. $P>0.05$
7. **Average Category Scale:** Majority of the patients belonging to intervention group D were in grade II ACS (22, 73.33%) in comparison with patients belonging to intervention group N most of whom were in grade I (11, 36.67%) with a p-value of 0.0009. By conventional criteria the association between the treatment groups and average category scale (ACS) is considered to be statistically significant since $p < 0.05$ as per fishers' exact test.
8. **Blood Loss:** Most of the Group D patients were clustered in the 101-300 ml blood loss group (n=16, 53.33%) with a mean blood loss of 188.50 ml. In the Group N patients the clustering was in the same blood loss group as Group D (n=16, 53.33%) with a mean blood loss of 192.17 ml. By conventional criteria the association between the treatment groups and blood loss is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.
9. **Total Fentanyl Dose:** Most of the Group D patients were clustered in the 101-150 mcg dosage group (n=18, 60%) with a mean fentanyl dosage of 139.33 mcg. In the Group N patients the clustering was in the > 200 mcg dosage group (n=12, 40%) with a mean fentanyl dosage of 187.67 mcg with a p-value of 0.0001. The total fentanyl dosage was meaningfully less in intervention group D compared to intervention group N by a mean 48.33 mcg.
10. **Emergence Time:** Group D patients had emergence time between 11-20 minutes (n=19, 63.33%) with a mean emergence time of 20.67 minutes. In Group N patients had emergence times similar to Group D (n=22, 73.33%) with a mean emergence time of 14 minutes with a p-value of 0.0015. The mean emergence time was meaningfully more in intervention group D compared to intervention group N by 6.67 minutes.
11. **Time to reach Alderete Score≥9:** Most of the Group D, patients required 16-30 minutes (n=17, 56.67%) with a mean time (32.37 sec) to reach ≥9 of Modified Aldrete Score while patients in Group N had mean emergence time of 18.33 minutes with a p-value of 0.0000. The mean time to reach ≥9 of Modified Aldrete Score was meaningfully more in intervention group D compared to intervention group N by 14.03 minutes.

12. **Time to request first Reque Analgesia:** Patients in group D needed rescue analgesic after 240 minutes (n=30, 100%) with a mean time to first rescue analgesic of 377.33 minutes. Patients in Group N needed rescue analgesic in 60 minutes (n=18, 60%) with a mean time to first rescue analgesic of 86.00 minutes with a p-value of 0.0000.
13. **Sedation Score:** Patients belonging to intervention group D, the mean sedation score between 0-30 minutes is 2.20 minutes in comparison with patients belonging to intervention group N in whom the sedation score between 0-30 minutes is 1.56 minutes with a p-value of < 0.0007 according to unpaired t-test. The mean sedation score between 0-30 minutes was meaningfully more in intervention group D compared to intervention group N by 0.64 minute.

Comparison of Heart Rate



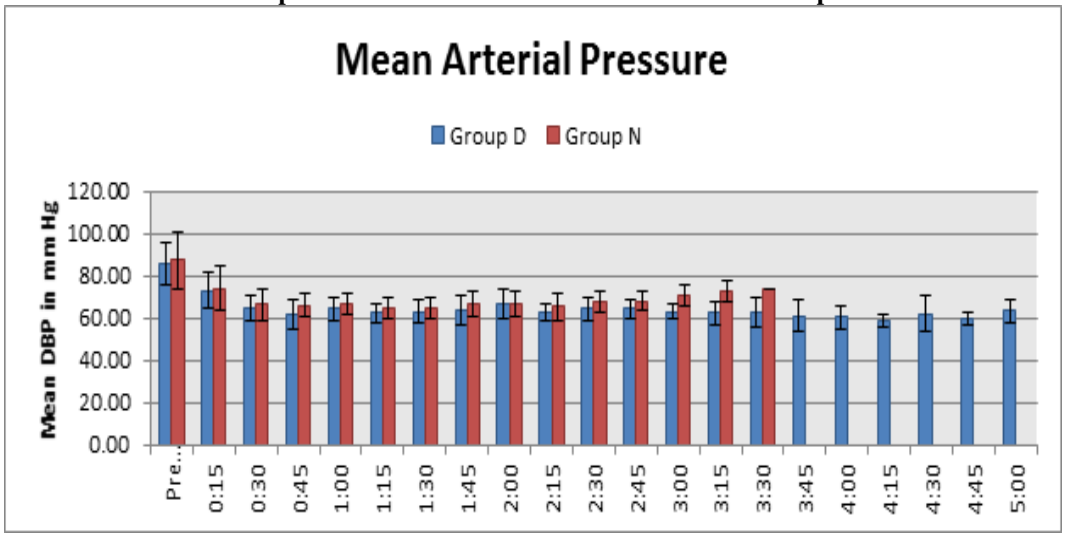
Comparison of Heart Rate

Pulse Rate		**00:00:00 (Pre Induction)**	**00:15**	**00:30**	**00:45**	**01:00**	**01:15**	**01:30**	**01:45**	**02:00**	**02:15**	**02:30**	**02:45**	**03:00**
Group D	N	30	30	30	30	29	29	29	28	26	18	16	15	14
	Mean	72.90	65.47	63.63	59.57	57.59	57.17	55.66	56.89	56.15	56.44	56.75	55.93	54.07
	SD	14.53	11.39	9.88	7.54	6.78	6.69	6.92	9.15	7.17	7.27	7.28	9.08	7.72
Group N	N	30	30	30	30	29	28	27	25	20	13	12	9	5
	Mean	79.37	85.50	73.33	69.07	68.00	67.93	68.96	66.28	66.70	66.00	68.08	63.33	62.80
	SD	10.38	9.74	11.20	11.08	10.85	11.73	11.83	11.98	12.83	11.02	12.16	10.44	11.61
	P value Unpaired t test	0.0525	0.0000	0.0008	0.0003	0.0001	0.0001	0.0000	0.0027	0.0026	0.0132	0.0108	0.0980	0.1754

Comparison of Heart Rate

Pulse Rate		**03:15**	**03:30**	**03:45**	**04:00**	**04:15**	**04:30**	**04:45**	**05:00**
Group D	N	10	9	6	5	4	4	4	3
	Mean	54.10	56.00	55.33	56.80	56.50	58.50	57.50	60.33
	SD	7.78	7.98	4.76	2.39	7.42	5.74	3.00	8.39
Group N	N	5	1	0	0	0	0	0	0
	Mean	65.80	79.00						
	SD	10.45							
	P value Unpaired t test	0.0665							

Comparison of Mean Arterial Pressure In two Groups



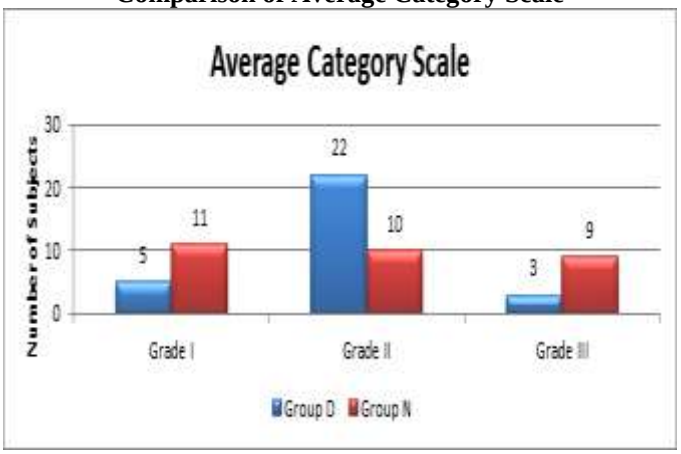
Comparison of Mean Arterial Pressure

Mean Arterial Pressure		**0:00 (Pre Induction)**	**00:15**	**00:30**	**00:45**	**01:00**	**01:15**	**01:30**	**01:45**	**02:00**	**02:15**	**02:30**	**02:45**	**03:00**
Group D	N	30	30	30	30	29	29	29	28	26	18	16	15	14
	Mean	85.87	73.17	64.97	61.90	64.34	62.55	62.97	64.11	66.81	63.00	64.25	64.27	63.14
	SD	10.29	8.67	6.09	6.79	5.75	4.57	5.50	7.08	7.36	3.80	5.39	4.45	3.46
Group N	N	30	30	30	30	29	28	27	25	20	15	13	10	6
	Mean	87.47	74.20	66.27	66.23	66.34	64.57	64.81	66.48	66.95	65.33	67.92	68.10	70.50
	SD	13.29	10.32	7.23	5.92	4.95	5.19	5.13	5.88	5.76	6.35	4.91	4.65	5.05
	P value Unpaired t test	0.6041	0.6762	0.4544	0.1108	0.1613	0.1253	0.1985	0.1888	0.9417	0.2252	0.0658	0.0542	0.1137

Comparison of Mean Arterial Pressure

Mean Arterial Pressure		**03:15**	**03:30**	**03:45**	**04:00**	**04:15**	**04:30**	**04:45**	**05:00**
Group D	N	9	8	6	5	4	4	4	3
	Mean	62.44	62.38	61.00	60.40	58.75	62.25	59.75	63.33
	SD	5.50	6.93	7.32	5.22	3.10	8.62	2.87	5.77
Group N	N	5	1	0	0	0	0	0	0
	Mean	72.60	74.00						
	SD	5.03							
	P value	0.1166							

Comparison of Average Category Scale



Comparison of Average Category Scale (Fishers Exact Test)

Average Category Scale	Group D	%	Group N	%
Grade I	5	16.67	11	36.67
Grade II	22	73.33	10	33.33
Grade III	3	10.00	9	30.00
Total	30	100	30	100
P value			0.0009	

Comparison of Blood Loss

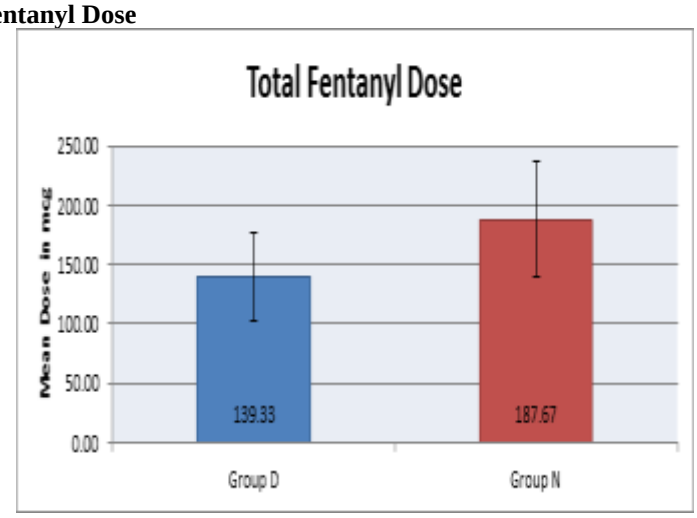
Comparison of Blood Loss

Blood Loss	Group D	%	Group N	%
≤ 100 ml	10	33.33	11	36.67
101-300 ml	16	53.33	16	53.33
301-500 ml	3	10.00	2	6.67
> 500 ml	1	3.33	1	3.33
Total	30	100	30	100

Comparison of Blood Loss (unpaired t test)

Blood Loss	Group D	Group N
N	30	30
Mean	188.50	192.17
SD	144.60	129.92
P value		0.9181

Comparison of Total Fentanyl Dose



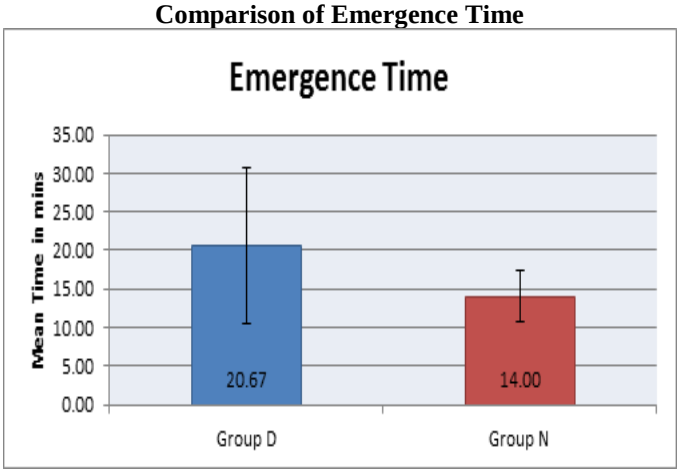
Comparison of Total Fentanyl Dose

Total Fentanyl Dose	Group D	%	Group N	%
≤ 100 mcg	5	16.67	2	6.67
101-150 mcg	18	60.00	6	20.00
151-200 mcg	6	20.00	10	33.33
> 200 mcg	1	3.33	12	40.00
Total	30	100	30	100

Comparison of Total Fentanyl Dose (Unpaired t test)

Total Fentanyl Dose	Group D	Group N
N	30	30
Mean	139.33	187.67
SD	36.67	48.61
P value		0.0001

Comparison of Emergence Time



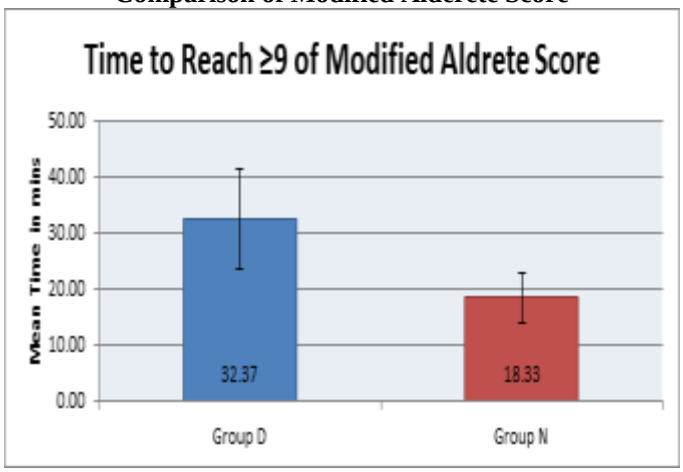
Comparison of Emergence Time

Emergence Time	Group D	%	Group N	%
≤ 10 mins	3	10.00	7	23.33
11-20 mins	19	63.33	22	73.33
21-30 mins	4	13.33	1	3.33
> 30 mins	4	13.33	0	0.00
Total	30	100	30	100

Comparison of Emergence Time (Unpaired t test)

Emergence Time	Group D	Group N
N	30	30
Mean	20.67	14.00
SD	10.06	3.36
P value		0.0015

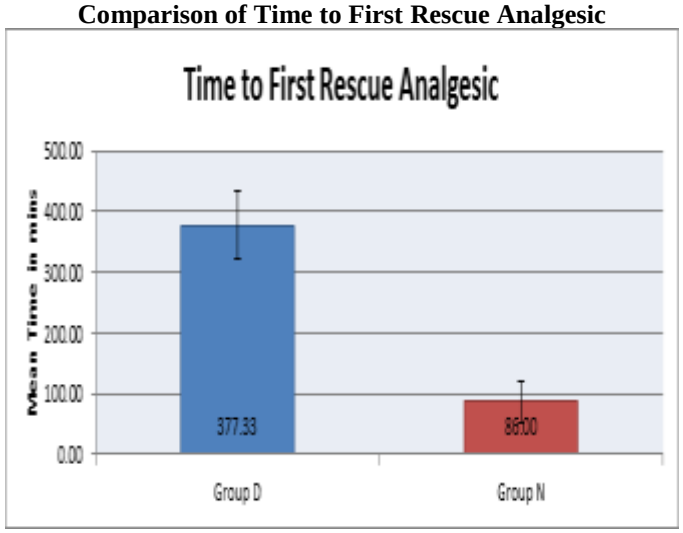
Comparison of Modified Alderete Score



Comparison of Modified Alderete Score (Unpaired t test)

Time to Reach ≥9 of Modified Aldrete Score	Group D	Group N
N	30	30
Mean	32.37	18.33
SD	8.88	4.57
P value		0.0000

Comparison of Time to First Rescue Analgesic



Comparison of Time to First Rescue Analgesic(Unpaired t test)

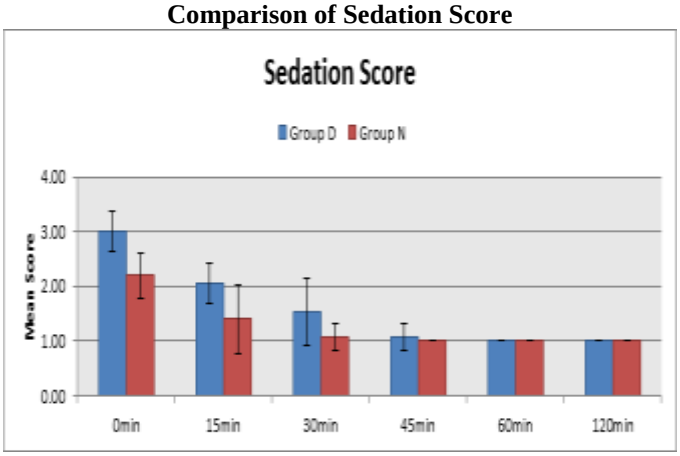
Time to First Rescue Analgesic	Group D	%	Group N	%
≤ 60 mins	0	0.00	18	60.00
61-120 mins	0	0.00	11	36.67
121-180 mins	0	0.00	1	3.33
181-240 mins	0	0.00	0	0.00
> 240 mins	30	100.00	0	0.00

Total	30	100	30	100

Comparison of Time to First Rescue Analgesic

Time to First Rescue Analgesic	Group D	Group N
N	30	30
Mean	377.33	86.00
SD	56.38	34.10
P value		0.0000

Comparison of Sedation Score



Comparison of Sedation Score (Unpaired t test)

Sedation Score		0min	15min	30min	45min	60min	120min
Group D	N	30	30	30	30	30	30
	Mean	3.00	2.07	1.53	1.07	1.00	1.00
	SD	0.37	0.37	0.63	0.25	0.00	0.00
Group N	N	30	30	30	30	30	30
	Mean	2.20	1.40	1.07	1.00	1.00	1.00
	SD	0.41	0.62	0.25	0.00	0.00	0.00
	P value	0.0000	0.0000	0.0006	0.1608	>0.9999	>0.9999

Discussion

There was no difference among groups with respect to epidemiological data like age, gender distribution in our study.

In our study, mean heart rate of patients in group D is 58/min between 15min after induction to 2hr 30min intraoperatively in comparison to group N in whom mean heart rate was 69/min which is statistically significant with P value <0.02. The significant reduction in heart rate in group D was due to its central sympatholytic effect. Similar results have been obtained using Dexmedetomidine by various other authors.[16,19,20,21,24]

The mean blood loss in patient in group D was lower when compared to group N patients (188.5ml Vs 192 ml) though not statistically significant. This was in contrast in study done by Vineela CH et al[9] where there was significant reduction in blood loss in patients on Dexmedetomidine. This could be due to the fact that in our study average duration of surgery was 135mins compared to 90mins in their study. Prolonged duration of surgery would have contributed to increased blood loss in our study

Patient in group D needed less fentanyl compared to group N (139mcg Vs 188 mcg) in our study. This was due to opioid sparring effect of α_2 agonist activity. Similar results were obtained by Tarek sham[10] where total intraoperative fentanyl dose was lower in Dexmedetomidine group compared to that of esmolol group. This is because nitroglycerine and esm Patients in group N had shorter emergence time from anaesthesia when compared to group D (14mins Vs 21mins). This is because of sedative nature of Dexmedetomidine due to its α_2 agonist activity. Our results are comparable to study done by Abdullah Aydin Ozcan et al[12] comparing Dexmedetomidine with remifentanil in FESS, where patients with remifentanil recovered faster from anaesthesia compared to Dexmedetomidine.

In our study patients in group N attained MAS of ≥ 9 within 18 mins compared to 32 mins in patient with group D. This implies that patient in group N had a shorter duration of stay and early discharge from

recovery room compared to group D. This is due to the fact that nitroglycerine doesn't have sedative effect like that of Dexmedetomidine.

In our study the time to first rescue analgesic is 86 min in group N compared to 377 min in Dexmedetomidine. This finding is statistically significant with $p<0.05$. This is despite the fact that group N received more fentanyl intraoperatively compared to group D. This indicates Dexmedetomidine not only has opioid sparing effects but also provides inherent analgesic due to α_2 agonist action. This effect lasts several hours post operatively even after discontinuing Dexmedetomidine.

Patient in group D had significantly higher sedation score compared to group N. This is due to the central action of Dexmedetomidine on locus ceruleus producing sedation. Tarek Sham et al[10] had similar findings with higher sedation score in patients with Dexmedetomidine group due to inherent sedation in Dexmedetomidine group. Olol has no opioid sparing effect.

In our study there was a significant difference between both the treatment groups with respect to average category scale. Most of the patient in group D had grade I/grade II in average category scale compared to group N. This was statistically significant as shown by P value of 0.0009. Significant difference in ACS in spite of similar MAP can be explained by consistent and sustained hypotension induced by Dexmedetomidine. The low mean heart rate in group D could have contributed to a better ACS.

Conclusion

Dexmedetomidine was better compared to Nitroglycerine for hypotensive anaesthesia in Functional Endoscopic Sinus Surgery with respect to quality of surgical field as assessed by average category scale, less intra operative opioid requirement and prolonged time to first rescue analgesic post operatively. However Nitroglycerine was better with respect to early emergence from anaesthesia and early discharge criteria as assessed by modified Alderete score.

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