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ORIGINAL RESEARCH PERIOPERATIVE MEDICINE

A comparison between propofol, dexmedetomidine and nitroglycerin as hypotensive agents and their effect on blood loss in functional endoscopic sinus surgery (FESS)

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Abstract

Background & objective: Patients with chronic sinusitis, not responding to medical treatment are managed with functional endoscopic sinus surgery (FESS) by ENT specialists. The surgery demands a bloodless field for its success. Even minimal amount of blood can obscure the surgical field to the operating surgeon. We compared three drugs, propofol, dexmedetomidine, and nitroglycerin as hypotensive agents and their effect on blood loss in FESS.

Methodology: Our study included sixty adult patients scheduled for FESS at Ain Shams University hospitals from September 2018 to September 2019. All patients were ASA I and II and they were distributed into three groups in a random manner, twenty patients in each group. Patients in Group D were administered dexmedetomidine 1 µg/kg as a loading dose over 10 min (in 100 ml normal saline) just after induction, then 0.5 µg/kg/h was infused. Group P patients were administered propofol infusion 8 mg/kg/h. Group N patients were administered nitroglycerin infusion of 2 µg/kg/min. Hemodynamic parameters were recorded every 15 min. We used bleeding score to examine the quality of operating field. We recorded the time to achieve target mean arterial blood pressure. Duration of operation was recorded.

Results: In Groups D and P, our target of mean arterial pressure of 55-65 mmHg was achieved. The hypotensive drugs used in these groups offered good quality of surgical field and shorter duration of surgery. Group D also achieved target blood pressure faster than Group P with significantly lower heart rate in Group D.

Conclusion: Dexmedetomidine and propofol had more favorable effects for attaining the desired blood pressure than nitroglycerin with lower heart rate in dexmedetomidine group. Dexmedetomidine and propofol were associated with less bleeding and shorter duration of surgery in patients undergoing FESS. Also dexmedetomidine was faster in achieving target blood pressure than propofol.

Trial Registry: PACTR202202877370804

Abbreviations: FESS - Functional endoscopic sinus surgery; CSF - Cerebrospinal fluid; GABA - γ-aminobutyric acid' MAP - Mean arterial blood pressure

Key words: Anesthesia; Anesthesia, General; Endoscopy / methods; Humans; Propofol; Dexmedetomidine; Nitroglycerin; Controlled hypotension; FESS.

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1. Introduction

Sinusitis is a medical condition that affects people of both genders and different ages.[1] Endoscopic sinus surgery is a therapy option for chronic sinusitis patients who had failed to respond to medical treatment. Due to the nature of nasal mucosa which is very rich in vascularity, minimal blood can distort the surgical field and impairs surgeon's vision, making the procedure more difficult and time-consuming.[2] Cerebrospinal fluid (CSF) leak, cerebral infection, ocular problems, and bleeding requiring blood transfusion or surgical management are all possible consequences. Controlled hypotension is used to reduce operating field bleeding and potential consequences.[3] Easy administration, quick onset and offset times, quick elimination, little effects on vital organs, and dose dependent effects are all characteristics of an ideal hypotensive drug.[4] Dexmedetomidine is a unique sedative that provides sedation without producing respiratory depression. In addition to its opioid sparing analgesic effect, it also has sympatholytic and anxiolytic effects. It is central α_2-receptor agonist.[5] Dexmedetomidine has a sympatholytic activity. It lowers heart rate, arterial blood pressure, cardiac output, and norepinephrine release.[6] Propofol (2, 6-diisopropylphenol) is a potent intravenous hypnotic which is a γ-aminobutyric acid (GABA) receptor agonist. It has good pharmacokinetic and pharmacodynamic profile, which made propofol one of the most commonly, used intravenous anesthetic for the past three decades.[7] Nitroglycerin, also known as glyceryl trinitrate, is a drug used for heart failure, high blood pressure and to treat and prevent angina. In vivo it converts to nitric oxide which activates guanylyl cyclase enzyme in vascular smooth muscle resulting in vasodilation.[8] Nitroglycerin has been used to induce hypotensive anesthesia as a hypotensive drug. It is a low-cost, simple-to-use, and widely available medication. It works by causing vasodilation, particularly in veins. However, one of the negative effects is reflex tachycardia that can exacerbate bleeding and obscure the tiny surgical field such as in FESS.[9]

The primary outcome was comparing the effects of dexmedetomidine, propofol, nitroglycerin in achieving controlled hypotension. The secondary outcomes were to compare the effect on heart rate, to induce a surgical field free of blood for better exposure, to measure the time needed in every group to obtain the targeted blood pressure and to achieve shorter duration of surgery during FESS.

2. Methodology

It was a randomized prospective comparative study conducted at Ain Shams University hospitals, from September 2018 to September 2019. Ethical committee approval was obtained (No. FMASU MD 283/2018) and the study was registered with Pan African Clinical Trial Registry, identifier:__PACTR202202877370804. All patients signed a written informed consent form. Sixty adult patients, 18-60 y of age, scheduled for FESS, ASA-I and II, were distributed in a randomly into three groups by a computer-generated random numbers table, each

Table 1: Comparison between the three groups as regards age, gender, weight and ASA score

Parameter		Group P	Group D	Group N	Test value	P- value	Sig.
Age	Mean ± SD	37.15 ± 6.48	37.00 ± 5.11	37.30 ± 7.87	0.010•	0.990	NS
	Range	22 – 47	25 – 45	21 – 49			
Gender	Female	10 (50.0%)	9 (45.0%)	11 (55.0%)	0.400*	0.819	NS
	Male	10 (50.0%)	11 (55.0%)	9 (45.0%)			
Weight (kg)	Mean ± SD	72.40 ± 8.92	73.95 ± 9.30	74.75 ± 8.08	0.370•	0.692	NS
	Range	60 – 88	60 – 89	60 – 89			
ASA	I	11 (55.0%)	8 (40.0%)	11 (55.0%)	1.200*	0.549	NS
	II	9 (45.0%)	12 (60.0%)	9 (45.0%)			

* Chi-square test; • One Way ANOVA test

Table 2: Comparison between the three studied groups regarding MAP

Time of recording		Group P	Group D	Group N	Test value•	P- value	Sig.
Baseline	Mean ± SD	78.05 ± 3.97	77.80 ± 3.85	77.85 ± 3.36	0.025	0.975	NS
	Range	70 – 84	71 – 86	72 – 84			
After induction	Mean ± SD	70.05 ± 3.47	70.85 ± 2.48	70.50 ± 3.87	0.291	0.749	NS
	Range	64 – 76	67 – 77	66 – 79			
After 15 min	Mean ± SD	64.05 ± 1.73	63.40 ± 1.57	79.5 ± 6.91	93.677	0.000	HS
	Range	61 – 67	61 – 67	69 – 89			
After 30 min	Mean ± SD	62.75 ± 1.37	62.40 ± 1.39	82.10 ± 5.18	248.821•	0.000	HS
	Range	60 – 65	60 – 65	70 – 89			
After 45 min	Mean ± SD	61.75 ± 1.12	61.40 ± 0.94	78.50 ± 4.42	264.580•	0.000	HS
	Range	60 – 63	60 – 63	70 – 85			
After 60 min	Mean ± SD	61.60 ± 1.47	61.40 ± 1.47	77.45 ± 4.10	241.379•	0.000	HS
	Range	60 – 65	60 – 65	71 – 86			
After 75 min	Mean ± SD	61.40 ± 1.14	61.00 ± 0.86	78.25 ± 4.27	287.381•	0.000	HS
	Range	60 – 64	60 – 63	71 – 85			
After 90 min	Mean ± SD	61.20 ± 1.11	60.95 ± 0.76	79.20 ± 5.33	217.762•	0.000	HS
	Range	60 – 64	60 – 62	70 – 86			

Post hoc analysis by LSD			
	Group P vs Group D	Group P vs Group N	Group D vs Group N
After 15 min	0.627	0.000	0.000
After 30 min	0.730	0.000	0.000
After 45 min	0.682	0.000	0.000
After 60 min	0.812	0.000	0.000
After 75 min	0.628	0.000	0.000
After 90 min	0.804	0.000	0.000

• One Way ANOVA test

consisting of twenty patients; Group P patients to receive propofol infusion 8 mg/kg/h, Group D received loading dose of dexmedetomidine 1 µg/kg (in 100 ml normal saline) over 10 min after induction followed by maintenance infusion @ 0.5 µg/kg/h via syringe pump, and Group N patients received nitroglycerin infusion @ 2 µg/kg/min.

Patients suffering from heart block, ischemic heart disease, hepatic or renal disorders, hypertension, diabetes, coagulopathy or taking drugs that affect blood coagulation, cerebrovascular insufficiency, peripheral vascular disorders were excluded.

Each patient underwent a routine preoperative evaluation, 8 h of fasting and were premedicated with inj. granisetron 1 mg and ranitidine 50 mg IV 30 min before surgery.

The hemodynamic data monitored included SpO_2, five-lead ECG and non-invasive blood pressure.

Anesthesia was induced with propofol 1-2 mg/kg and fentanyl 2 µg/kg IV, followed by endotracheal intubation aided by 0.5 mg/kg atracurium. Maintenance of anesthesia was by 1.2% isoflurane and 0.15 mg/kg atracurium boluses every 30 min. All patients were mechanically ventilated with volume controlled mechanical ventilation with an oxygen/air mixture. End tidal CO_2 was continuously monitored. Radial arterial line was inserted under complete aseptic conditions to monitor mean arterial blood pressure continuously.

We recorded time in min needed to reach target hypotension. Mean arterial blood pressure (MAP) and heart rate (HR) were recorded at baseline, after induction of anesthesia and then at 15, 30, 45, 60, 75, and 90 min. Bleeding score assessment was used to measure total blood loss.

At the end of surgery, the drug infusions and isoflurane were stopped, and neuromuscular blockade reversed. On response to spoken directions, they were extubated.

A fall of MAP $\leq$ 55 mmHg was treated by discontinuation of the hypotensive medication and lowering isoflurane concentration. If not improved,

ephedrine 9 mg IV was given and the patient removed from the study. Patients with bradycardia (< 50 beats/min) were given of atropine 1 mg IV and were excluded from the study.

Bleeding in the operating field was scored as: zero - no bleeding, 1 - slight bleeding, no suctioning of blood required, 2 - slight bleeding,: occasional suctioning needed, 3 - slight bleeding; frequent suctioning of blood needed, 4 - moderate bleeding; frequent suctioning required and 5 - severe bleeding; constant suctioning required as bleeding appears faster than could be suctioned.

Table 3: Comparison between the three groups as regards heart rate

HR		Group P	Group D	Group N	Test value•	P- value	Sig.
Baseline	Mean ± SD	77.20 ± 7.34	75.65 ± 8.26	77.60 ± 8.01	0.342•	0.712	NS
	Range	65 – 88	62 – 89	64 – 96			
After induction	Mean ± SD	77.40 ± 4.92	77.35 ± 7.60	78.10 ± 5.97	0.090•	0.914	NS
	Range	69 – 90	65 – 88	71 – 96			
After 15 min	Mean ± SD	69.15 ± 3.79	60.25 ± 3.43	102.55 ± 5.07	575.459•	0.000	HS
	Range	62 – 75	55 – 67	93 – 110			
After 30 min	Mean ± SD	71.60 ± 2.35	60.45 ± 3.28	102.30 ± 4.27	816.319•	0.000	HS
	Range	67 – 76	56 – 65	95 – 110			
After 45 min	Mean ± SD	69.05 ± 3.99	60.10 ± 2.51	99.40 ± 7.54	322.124•	0.000	HS
	Range	64 – 82	55 – 65	71 – 109			
After 60 min	Mean ± SD	68.90 ± 4.01	60.55 ± 5.16	101.40 ± 3.76	491.864•	0.000	HS
	Range	62 – 76	54 – 72	94 – 108			
After 75 min	Mean ± SD	68.35 ± 4.49	59.20 ± 3.09	101.10 ± 3.82	657.430•	0.000	HS
	Range	62 – 77	53 – 64	95 – 109			
After 90 min	Mean ± SD	68.70 ± 3.85	59.55 ± 3.50	101.65 ± 4.00	681.894•	0.000	HS
	Range	62 – 77	54 – 68	95 – 109			

Post hoc analysis by LSD shows P < 0.001 between Group P and D / N, and between Group D vs. N

• *One Way ANOVA test*

Table 4: Comparison between the three groups as regards bleeding score.

Bleeding score	Group P	Group D	Group N	Test value	P-value	Sig.
Median (IQR)	2 (2 − 2)	2 (1 − 2)	4 (4 − 4.5)	43.411≠	0.000	HS
Range	1 – 3	1 – 3	4 – 3			
Post hoc analysis (≠ - Kruakal-Wallis test)						
Group P vs Group D		**Group P vs. Group N**		**Group D vs. Group N**		
0.094 (NS)		0.000 (HS)		0.000 (HS)		

Table 5: Comparative duration of surgery in the groups

Parameter		Group P	Group D	Group N	Test value•	P- value	Sig.
Duration of surgery (min)	Mean ± SD	97.40 ± 4.39	93.30 ± 3.39	110.35 ± 6.46	65.545	< 0.001	HS
	Range	91 – 110	90 – 102	100 – 122			
Post hoc analysis by LSD							
Group P vs Group D		**Group P vs Group N**		**Group D vs Group N**			
0.011(NS)		< 0.001(HS)		< 0.001(HS)			
•: *One Way ANOVA test*							

Table 6: Comparison between groups as regards time needed to achieve hypotension

Time to achieve hypotension (min)	Group P	Group D	Test value	P-value	Sig.
Mean ± SD	13.10 ± 0.85	7.40 ± 0.88	20.777•	0.000	HS
Range	12 – 15	6 – 9			

• *Independent t-test*

Table 7: Comparison between three groups as regards side effects

Side effects	Group P	Group D	Group N	Test value	P-value	Sig.
Hypotension (MAP < 60)	3 (15.0%)	1 (5.0%)	0 (0.0%)	3.750*	0.153	NS
Bradycardia (HR < 50)	0 (0.0%)	2 (10.0%)	0 (0.0%)	4.138*	0.126	NS

* Chi-square test

Time in min needed to reach target blood pressure and duration of surgery were also recorded.

Statistical analysis

The statistical analysis was carried out using the statistical package for social science on a computer (SPSS, version 20; SPSS Inc., Chicago, Illinois, USA). The mean and standard deviation were used to describe quantitative (numerical) variables. The qualitative (categorical) data was described in terms of number of cases and percentages. The error bars show the 95% confidence interval. In quantitative data, the ANOVA test and chi-square tests were employed to compare different times in the same group. $P \leq 0.05$ was considered significant, and $P \leq 0.001$ regarded as highly significant.

3. Results

There was no significant difference among the three groups regarding gender, age, body weight, and ASA status with $P > 0.05$ as shown in Table 1.

No significant difference was found in MAP among the three groups at baseline and after induction. No significant difference was noted between Groups P and D at all times. The difference between P and N groups at 15, 30, 45, 60, 75, 90 min was highly significant with a lower MAP in Group P at all time points. The difference was highly significant between Group D and N at 15, 30, 45, 60, 75, 90 min with lower MAP in Group D at all time points as shown in Table 2.

No significant difference was observed among the three studied groups, regarding the heart rate (HR) variation at the baseline and after induction. While a highly significant difference was noted between Groups P and

D after 15, 30, 45, 60, 75, 90 min, with lower HR in Group D at all these time points of measurement. The differences between Groups P and N at 15, 30, 45, 60, 75, 90 min with lower HR in Group P in all these time points of was highly significant. Whereas, a highly significant difference was noted between Groups D and N at 15, 30, 45, 60, 75, 90 min, with lower HR in Group D at all these time points as shown in Table 3 and Figure 1.

The difference between Groups P and D was not significant regarding bleeding score, while there were significantly higher values for median (IQR) and range for Group N compared to Groups P and D as shown in Table 4 and Figure 2.

The duration of surgery showed significantly higher values for Group N compared to Groups P and D with longer duration of surgery in N group. The difference

between P and D groups was not significant as shown in Table 5.

Regarding time in min needed to achieve targeted hypotension, the difference between P and D groups was significant with faster onset of hypotension in Group D. According to Group N the desired hypotensive effect wasn't achieved at any time of measurement as demonstrated in Table 6.

In propofol group hypotension (MAP <55 mmHg) was recorded in three cases while one case was recorded in dexmedetomidine group. These results were not statistically significant. Ephedrine increments 9 mg were administered to treat these patients. In Group D bradycardia (HR< 50 b/m) was recorded in two cases and was treated with 1 mg atropine. This was statistically insignificant. All patients developed side effects were excluded from the study as shown in Table 7.

4. Discussion

Improving surgical outcomes is accomplished by reducing surgical field bleeding and, as a result, reducing complications. (9) Because a blood drop can totally

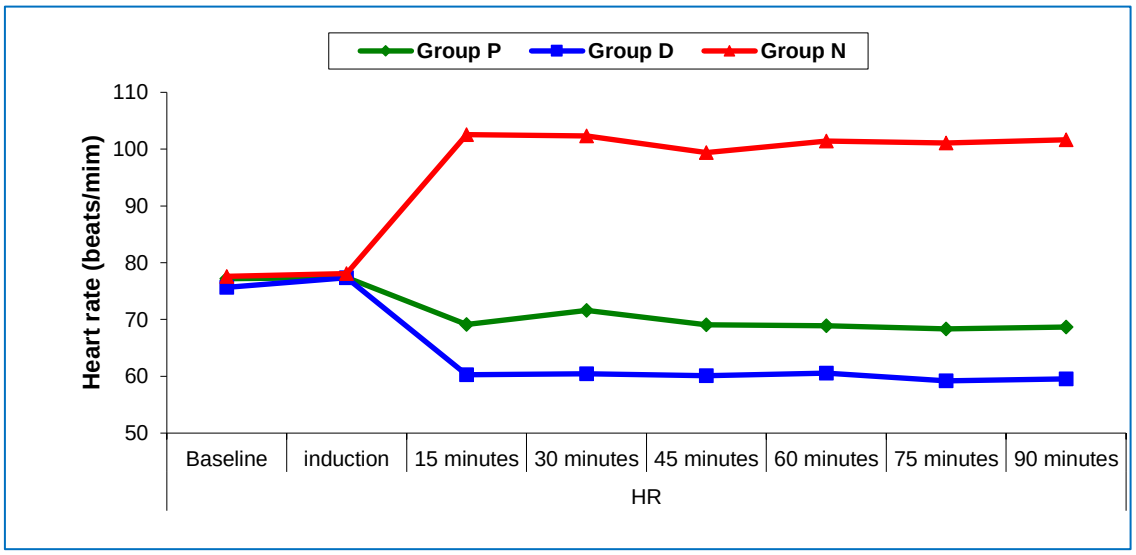

Figure 1: Comparative heart rates in the three groups

interfere with the operating field, bleeding should be kept to a minimum.[10, 11]

In our prospective randomized study dexmedetomidine, propofol and nitroglycerin were used to provide hypotension that causes optimal surgical field during FESS.

We found in our study that both dexmedetomidine and propofol had more favorable effects attaining the desired blood pressure than nitroglycerin with lower heart rate in dexmedetomidine group. Dexmedetomidine and propofol were associated with less bleeding and shorter duration of surgery in patients undergoing FESS, and dexmedetomidine was faster in achieving target blood pressure than propofol.

Regarding mean arterial blood pressure (MAP), the difference was not significant among our three studied groups in baseline measurement and after induction;

between P and D groups at all times of measurement, but a highly significant difference between Groups P and N after 15, 30, 45, 60, 75, 90 min with lower MAP in Group P in all these points of measurement. A highly significant difference was between Groups D and N after 15, 30, 45, 60, 75, 90 min with lower MAP in Group D in all these points of measurement. Similar results also were demonstrated by other studies that compared propofol infusion vs nitroglycerin infusion during FESS surgery and demonstrated a lower MAP in propofol patients compared to nitroglycerin patients.[12, 13, 14] A study, which compared dexmedetomidine, esmolol, nitroglycerine to induce hypotension during FESS, showed that dexmedetomidine and esmolol were better than nitroglycerine regarding hemodynamic stability and operating field.[15]

Mathur et al. in their study, which compared between propofol–fentanyl-based anesthesia and dexmedetomidine–isoflurane during FESS, reported that both groups achieved good hemodynamics.[16]

In contrast to the results of our study Vineela et al. who concluded that nitroglycerin and dexmedetomidine are safe to be used for controlled hypotension in FESS. This may be due to different targeted mean arterial pressure which was 65-75mmHg compared to 55-65 mmHg in our study.[17]

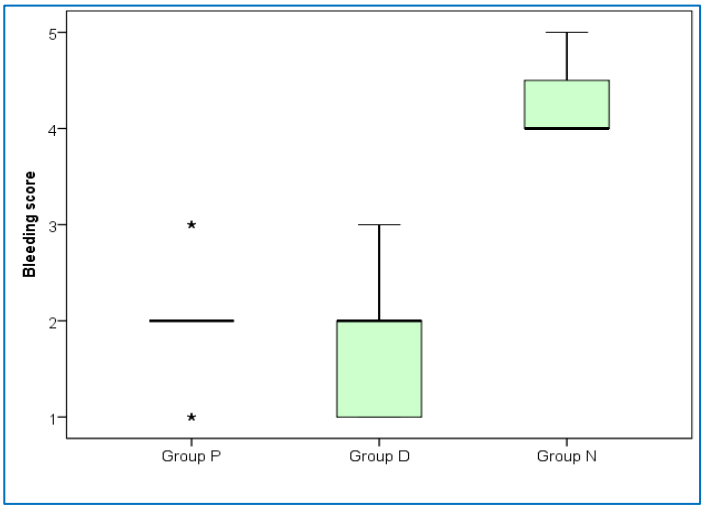

Figure 2: Comparison between the three groups as regards bleeding score

As regards heart rate (HR) a study by Sie´skiewicz et al. reported that lowering the HR to 60 beats /min can achieve a better operative field without lowering MAP to very low levels.[18] Our results showed that the difference among the three groups was not significant in baseline measurement and after inducting anesthesia.

A highly significantly lower HR was noted in Group D compared to Group P, in Group P compared to Group N at all points of measurement. Both Group D and Group N showed a highly significantly lower HR at all points.

Same results were reported in study which compared between dexmedetomidine, esmolol and nitroglycerine. A significantly lower heart rate was in dexmedetomidine group throughout the procedure.

Some researchers proved that with dexmedetomidine significantly lowers heart rate than propofol, and that it results in a better hemodynamic profile as regards heart rate and blood pressure than nitroglycerin and magnesium sulfate.[15,19,20,21] On the other hand, Esmail et al. reported that propofol reduced heart rate more than dexmedetomidine. This may be due to higher doses of propofol used in this study 50-150 μg/kg/min.[22]

The results showed significantly higher values for bleeding scores for Group N compared to the other two studied groups and the difference between Groups P and D groups was not significant. Same results were obtained by an earlier study.[13, 17, 22] Other studies reported that dexmedetomidine caused less bleeding and so a better operating field in tympanoplasty and septoplasty.[23, 24]

In contrast to our results, some authors reported that the bleeding was higher in propofol group. This may be due to use of a lower maintenance dose of propofol or higher maintenance doses of dexmedetomidine as used by us. [25, 26]

In contrast to our results, a study showed that the difference was not significant in bleeding among nitroglycerin group, dexmedetomidine group and magnesium sulphate group. This may be due to usage of higher maintenance doses of nitroglycerin 10 μg/kg/min compared to 2 μg/kg/min used in our study.[27]

As regards duration of surgery the results showed significantly higher values for group N compared to the other two studied groups, but the difference between Group P and D was not significant, which is concurrent to an earlier study.[28]

Targeted MAP was achieved faster in dexmedetomidine group than the propofol group, and in Group N the desired hypotensive effect wasn't achieved at any time of measurement. The same result was noted by Rajashree et al.[29]

In Group P hypotension (MAP < 55 mmHg) was recorded in three cases while one case was recorded in dexmedetomidine group. These results were not statistically significant. Ephedrine 10 mg IV was used to treat these patients. In Group D bradycardia (HR ≤ 50 beats/min) was recorded in two cases. They were treated with 1 mg atropine IV. This was statistically insignificant.

An earlier study which compared between dexmedetomidine and nitroglycerin in posterior spine fixation reported that one patient had hypotension and two patients had bradycardia in dexmedetomidine group while there was no hypotension or bradycardia in nitroglycerine group. [28] In contrast to our results Godbole et al**.** compared between dexmedetomidine and propofol in patients undergoing ENT surgeries, didn't report any complications. [27]

5. Conclusion

Both dexmedetomidine and propofol had more favorable effects attaining the desired blood pressure than nitroglycerin with lower heart rate in dexmedetomidine group. Dexmedetomidine and propofol were associated with less bleeding and shorter duration of surgery in patients undergoing FESS. Also dexmedetomidine was faster in achieving target blood pressure than propofol.

6. Limitations to our study:

We didn't achieve the target blood pressure in Group N by the dose of nitroglycerine used in our study.

7. Future scope:

Dexmedetomidine and propofol are effective as single agents to achieve hypotension in FESS while nitroglycerin as a single agent is not effective and may be more effective by adding a beta receptor blocking agent with it.

8. Ethics approval and consent to participate:

This study was approved by the research ethics committee at the faculty of medicine, Ain Shams University (FMASU MD 283/2018) and registered retrospectively with Pan African Clinical Trial Registry, identifier:_PACTR202202877370804. Written informed consent was obtained from all patients.

9. Availability of data

The numerical data of the current study are available from the corresponding author on reasonable request.

10. Competing interests

The authors declare that there were no conflicts of interest.

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12. Authors contribution

All authors participated in the trial and contributed intellectually to the manuscript. The final manuscript has been read and approved by all of the authors.

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