ISSN: 2474 - 9206

Research Article

Journal of Anesthesia & Pain Medicine

Comparison between Phentolamine and Nitroglycerin for Controlled Hypotension during Functional Endoscopic Sinus Surgery

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Submitted: 20 Dec 2018; **Accepted**: 28 Dec 2018; **Published**: 08 Jan 2019

Abstract

Background: *Intraoperative bleeding is one of the most common complications in Functional endoscopic sinus surgery. Controlled hypotension is a method to minimize surgical blood loss and enhance the operative field visibility. The objective of this study was to compare the efficacy of controlled hypotensive anesthesia with intravenous infusion of phentolamine versus nitroglycerin as regarding intraoperative blood loss and hemodynamic stability.*

Methods: *This current randomized study enrolled 30 patients candidate for Functional endoscopic sinus surgery at Beni-suef university hospital, in 2 equal groups receiving either 0.5 to 10 μg/kg/minute nitroglycerin or 0.1 to 2 mg/minute phentolamine to achieve a mean arterial blood pressure (MAP) of about 50 to 65 mmHg. Mean arterial blood pressure, amount of blood loss and the quality of surgical field using the 0-5 point bleeding scale were recorded.*

Results: *Based on the current study findings, the two drugs produced the desired hypotension on the same time point; there were no significant differences between the study groups regarding the volume of bleeding and operative field visibility.*

Conclusions: *Nitroglycerin and Phentolamine are safe, efficient and might be advisable option for deliberate hypotensive anesthesia throughout Functional endoscopic sinus surgery. Phentolamine can be a good alternative to Nitroglycerin in reduction of MAP during this procedure.*

Keywords: Controlled Hypotension, Functional Endoscopic Sinus Surgery, Phentolamine, Nitroglycerin

Introduction

In acute and chronic sinus pathologies, Functional endoscopic sinus surgery is the primary surgical management when conservative management has failed [1]. Functional Endoscopic Sinus Surgery is associated with severe complications due to poor visibility of surgical field in case of bleeding. Controlled hypotension is one of the best methods to reduce the bleeding from the nasal mucous membranes [2].

Controlled hypotension is a technique to decrease arterial blood pressure in a controllable manner to minimize the intraoperative bleeding and improve the quality of surgical field [3]. In hypotensive anesthesia, arterial blood pressure is reduced by 30-40% below its normal range or mean arterial pressure (MAP) was kept at 65 mmHg [4]. There are numerous physiological and pharmacological methods used for controlled hypotension. The physiological methods include positioning the patient, intermittent positive-pressure ventilation and acute normovolemic hemodilution [5].

There are various pharmacological interventions that can be used, either alone or in combination with each other. The ideal agent to induce controlled hypotension must have a short onset time, simplicity of administration, rapid elimination without the production of toxic metabolites and minimal effects on blood flow to vital organs [6].

Many pharmacological interventions have been used successfully to produce deliberate hypotension, including hypotensive drugs like Alpha blockers, B blockers, calcium channel blockers, vasodilators, or anesthetic drugs like propofol, opioids and inhalational agents [7].

Nitroglycerin is a direct acting peripheral vasodilator and it is frequently used to produce controlled hypotension as it has rapid onset of action [8].

Phentolamine is a reversible nonselective α-adrenergic antagonist of relatively short duration and it can also produce hypotension through its vasodilation effect due to α1 blockade [9].

This study aimed to compare the efficacy of controlled hypotensive anesthesia with phentolamine versus nitroglycerin in patients undergoing Functional Endoscopic Sinus Surgery.

Material and Methods

This single-center randomized study was conducted at Beni-Suef university hospital from January 2018 to October 2018, after obtaining approval from Research Ethical Committee of the institution (The FM-BSU REC). The trial was registered in the Pan African Clinical Trial Registry (registration number: PACTR201712002828410). Written informed consent was obtained from all participants.

Thirty patients of ASA grade I and II, from both sexes, aged between 20-50 years and BMI less than 30 kg/m2 undergoing Functional endoscopic sinus surgery were included in the study. Patients with ischemic heart diseases, heart block, congestive heart failure, valvular heart diseases, cerebrovascular diseases, impaired kidney function, history of chronic liver diseases, uncontrolled hypertension, asthma and chronic obstructive lung diseases, diabetes mellitus, coagulation disorders, pregnancy and history of allergy to any drug or substance abuse were excluded.

A routine preoperative check-up, hematological and biochemical testing, along with electrocardiograms were performed. The procedure was explained to the patients. The patients were randomly allocated by using closed envelop technique to two groups (15 patients each). Group PHN: Patients received hypotensive anesthesia with phentolamine infusion (Rogitamine, Egypharma) via syringe pump by adding 20 mg (2ml) of Phentolamine to 48 ml of normal saline making it to final concentration of 0.4 mg/ml at the rate of 0.1-2 mg/min according to the patients desired target blood pressure. Group NTG: Patients received hypotensive anesthesia with nitroglycerine infusion via syringe pump by adding 5mg (5ml) of Nitroglycerin (Nitronal, Sunny pharmaceutical) to 45ml of normal saline making it to final concentration of 100µg/ml at the rate of 0.5-10 µg/kg/min according to the patients desired target blood pressure.

On arrival to the operating room, standard monitoring was established (pulse oximetry, electrocardiography, end-tidal carbon dioxide, and noninvasive arterial blood pressure monitoring), and oxygen was delivered via a facemask. Two intravenous cannulas were placed; one (22 gauge) in a vein on the dorsum of the hand that the examined drug was injected in and the other (20 gauge) in the opposite hand.

All patients were received lactated ringer's solution at approximately 3–5 ml/kg/h perioperatively. The patients were premedicated with Midazolam 0.05 mg/kg IV 3 minutes before induction. Anesthesia was induced by injecting 2.5 mg/kg propofol, 2 µg/kg fentanyl & 0.5 mg/kg atracurium. The patients were ventilated via face mask with 100 % oxygen at a rate of 4 L/min and isoflurane 1.2 %. After 3 minutes, the patients were intubated using appropriate sized cuffed oral tube lubricated with lidocaine jelly 2 %.

Maintenance of anesthesia was done using isoflurane 1.2 % in 100 % O2. Muscle relaxation was continued by atracurium 0.1 mg/kg every 20 min. All patients were mechanically ventilated to maintain end-tidal carbon dioxide between 35-40 mmHg. For 5 minutes, no surgical interventions were allowed in the subjects to assess target blood pressure. To provide increase convenience for the surgical team and to reduce the amount of bleeding, all patients were laid in an approximately 30° reverse Trendelenburg position also with administration of a standard dose of lidocaine-adrenaline (1: 100,000 adrenaline + 0.5% lidocaine, 1-2 mL) at the surgical site. Infiltration was administrated to the nasal passages by the surgeon. The MAP was then gradually reduced in both groups to achieve and maintain the target MAP of 50–65 mmHg.

The surgical field was evaluated by the surgeon using the 0-5 point bleeding scale (0: no bleeding, 1: low bleeding-bleeding does not require aspiration, 2: low bleeding-bleeding requires intermittent aspiration, 3: low bleeding-bleeding requires frequent aspiration, 4: moderate bleeding-bleeding becomes serious when aspirator is withdrawn from the surgical field, 5: serious bleeding-requires persistent aspiration, surgical field impossible) during the intra-operative period [4].

Patients who developed severe hypotension (MAP <50 mmHg) were managed by discontinuation of the hypotensive agent and reducing the concentration of isoflurane. If the MAP did not improve, 6 mg Ephedrine was given IV & these patients were excluded from the study. Patient developing bradycardia (<50 bpm) were managed by intravenous atropine and were then excluded from this study.

Infusion of the hypotensive agent was stopped 5 minutes before the anticipated end of surgery. Any residual neuromuscular block was antagonized with neostigmine 0.04 mg/kg and atropine 0.02 mg/kg IV.

The patients were extubated on recovery of adequate tidal volume and sufficient respiratory efforts and transferred to recovery room for observation.

The primary outcome was the achievement of controlled hypotension with MAP of 50-65 mmHg. The secondary outcomes were blood loss, total dose of hypotensive agents and quality of surgical field.

The following data were recorded

- Demographic data of the patients. (Age, Sex, BMI)
- MAP, HR, ETCO2 and SPO2 were recorded immediately prior to induction of anesthesia and subsequently every 5 min till the termination of anesthesia.
- Total phentolamine and NTG doses.
- The quality of surgical field was evaluated by surgeon using the 0-5 point bleeding scale.
- The amount of blood loss was determined by collecting the blood and rinsed fluid from the surgical field into the suction bottle by suctioning .The nurse who was not a part of the study made visual assessment of blood soaked gauge pieces that was consumed during surgery.
- The time needed to reach the target blood pressure.
- Duration of surgery and anesthesia.
- In the recovery room, adverse effects such as nausea, vomiting, agitation, bradycardia, coughing, shivering, reflex tachycardia and rebound hypertension were recorded

Sample size estimation

Sample size calculation was done using the comparison of mean arterial blood pressure (MAP) between cases treated with phentolamine and those treated with nitroglycerin for controlled hypotension during functional endoscopic sinus surgery, as it was the primary outcome of our study. As reported in previous publication [5], the mean ± SD of MAP (at 15 min) in nitroglycerin treated group was 75.8 ± 6.7 mmHg. We assumed that phentolamine treatment decreased MAP by at least 10mmHg. Accordingly, we calculated that the minimum proper sample size was 8 patients in each arm to be able to reject the null hypothesis with 80 % power at $\alpha = 0.05$

level using Student's t test. Sample size calculation was done using G*Power software version 3.1.2 for MS Windows, Franz Faul, Kiel University, Germany.

If the power increases to 90%, the sample was 11.

If the power increases to 95%, the sample was 13.

Statistical analysis

Data were statistically described in terms of mean standard deviation (SD), median and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples. For comparing categorical data, Chi-square (2) test was performed. Exact test was used instead when the expected frequency is less than 5.p values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release22for Microsoft Windows.

Results

A total of 30 patients were enrolled in this study (n = 15 in each group). Group (PHN) received Phentolamine infusion at the rate of 0.1mg/min and was titrated in between 0.1-2 mg/min and group (NTG) received Nitroglycerin infusion at the rate of 0.5µg/kg/min and was titrated in between 0.5-10 µg/kg/min. All cases completed the study (Figure 1).

As shown in (Table 1), there were no statistically significant differences between the two study groups in demographic variables of Age, BMI, Sex and ASA. There was no significant difference between both groups regarding the time needed to reach the target Mean arterial blood pressure.

There were no statistically significant differences between the two study groups as regarding Blood loss (Figure 2) and bleeding scale (Figure 3).

There were statistically significant decrease of MAP in NTG group at 5 min ($p<0.05$) but there were no statistically significant differences between the study groups till the end of operation. Basal and intraoperative mean arterial blood pressure during the procedure is shown in (Table 2) and (Figure 4).

Comparison between two groups as regarding HR there were no statistically significant differences between the study groups throughout the operation ($p>0.05$) as shown in (Table 3) and (Figure 5).

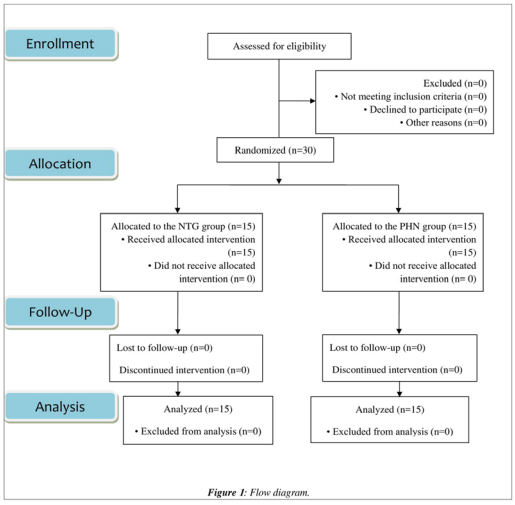

Figure 1: *Flow diagram.*

Table 1: Demographic variables of the two study groups

		(PHN) Group (n=15)	(NTG) Group (n=15)	P value
Age (Year)		34.2 ± 11.3	34.5 ± 9.6	0.93
BMI (Kg/m^2)		26.0 ± 1.8	26.8 ± 1.8	0.57
Sex (No. %)	Male	8 (53.3)	7 (46.7)	0.71
	Female	7 (46.7)	8 (53.3)	
ASA (No. %)	I	14 (93.3)	14 (93.3)	1.00
	II	1 (6.7)	1 (6.7)	

(PHN) group: Phentolamine group, (NTG) group: Nitroglycerin.

Data are represented as mean ± SD (standard deviation) or as numbers and percent.

P-value < 0.05 (Significant)

P-value > 0.05 (Non-significant)

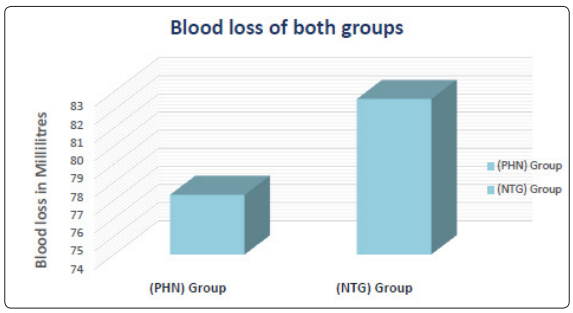

Figure 2: Comparison between group (PHN) and group (NTG) as regarding blood loss

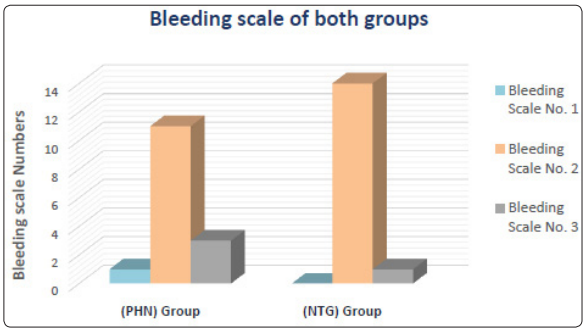

Figure 3: Comparison between group (PHN) and group (NTG) as regarding bleeding scale

Table 2: MAP of the two study groups

Time (min)	MAP of (PHN) Group (n=15)	MAP of (NTG) Group (n=15)	P value
Baseline	98.1 ± 9.6	98.8 ± 5.5	0.80
5	63.4 ± 1.7	61.7 ± 2.2	0.03
10	64.7 ± 3.0	62.7 ± 3.9	0.13
15	61.6 ± 4.3	61.2 ± 4.9	0.78
20	61.8 ± 5.1	60.0 ± 4.0	0.31
25	61.5 ± 8.2	61.3 ± 4.3	0.93
30	62.0 ± 7.8	57.5 ± 4.5	0.06
35	60.0 ± 4.4	57.2 ± 5.1	0.12
40	59.7 ± 4.2	59.1 ± 4.5	0.71
45	56.6 ± 4.2	58.7 ± 5.1	0.24
50	59.7 ± 4.2	59.1 ± 4.5	0.71
60	61.1 ± 3.7	62.1 ± 6.5	0.61
65	64.2 ± 5.5	63.7 ± 6.4	0.83
70	66.0 ± 9.0	63.8 ± 7.3	0.54
75	68.7 ± 7.0	66.8 ± 6.3	0.56
80	72.8 ± 4.0	70.6 ± 9.9	0.53
85	75.1 ± 4.5	71.6 ± 6.0	0.26
90	82.3 ± 5.9	75.4 ± 5.2	0.07

(PHN) group: Phentolamine group, (NTG) group: Nitroglycerin. Data are represented as mean ± SD (standard deviation) or as numbers and percent.

P-value < 0.05 (Significant)
P-value > 0.05 (Non-significant)

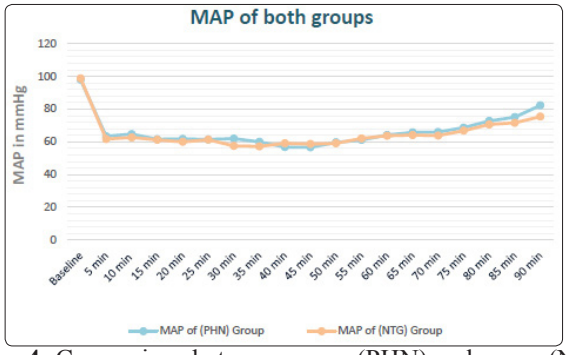

Figure 4: Comparison between group (PHN) and group (NTG) as regarding MAP

Table 3: HR of the two study groups

Time (min)	HR of (PHN) Group (n=15)	HR of (NTG) Group (n=15)	P value
Baseline	82.2 ± 8.4	82.1 ± 7.6	0.98
5	81.1 ± 8.6	80.8 ± 5.8	0.90
10	80.7 ± 9.0	81.4 ± 7.0	0.80
15	79.2 ± 9.0	80.9 ± 7.6	0.57
20	78.1 ± 5.6	79.8 ± 5.7	0.41
25	79.1 ± 6.4	79.2 ± 4.8	0.97
30	80.0 ± 7.0	80.2 ± 6.1	0.93
35	80.1 ± 8.2	82.4 ± 5.7	0.37
40	78.2 ± 9.3	82.0 ± 5.6	0.18
45	79.1 ± 6.5	80.0 ± 5.6	0.69
50	77.5 ± 6.5	79.2 ± 5.7	0.44
55	77.2 ± 5.0	79.6 ± 5.4	0.22
60	77.3 ± 5.6	81.5 ± 6.6	0.07
65	80.2 ± 3.7	82.5 ± 3.9	0.12
70	83.0 ± 3.9	79.9 ± 3.6	0.11
75	82.0 ± 4.1	79.2 ± 4.2	0.16
80	83.5 ± 7.2	80.9 ± 4.7	0.38
85	83.8 ± 7.4	82.1 ± 5.9	0.66
90	84.6 ± 5.0	83.5 ± 7.0	0.76

(PHN) group: Phentolamine group, (NTG) group: Nitroglycerin.

Data are represented as mean ± SD (standard deviation) or as numbers and percent.

P-value < 0.05 (Significant)
P-value > 0.05 (Non-significant)

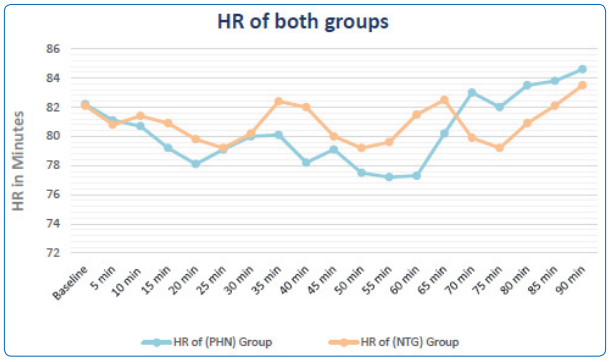

Figure 5: Comparison between group (PHN) and group (NTG) as regarding HR.

Discussion

Excessive bleeding impairs surgical visibility, prolongs the duration of surgery and anesthesia, and increases the risk of complications. Controlled hypotensive anesthesia is an important technique to decrease bleeding during FESS [10].

To our knowledge till the time of conduction of this study, this is the first study to compare Phentolamine and Nitroglycerin for Controlled

Hypotension during Functional Endoscopic Sinus Surgery. This randomized study designed to compare the efficacy of controlled hypotensive anesthesia with intravenous infusion of phentolamine versus nitroglycerine in patients undergoing Functional Endoscopic Sinus Surgery (FESS) as regarding intraoperative blood loss and hemodynamics stability. In present study we found that there was no statistically significant difference between Phentolamine and Nitroglycerin for controlled hypotension.

Ghodraty M et al. compared Labetalol and Nitroglycerine on Inducing Controlled Hypotension and Intraoperative Blood Loss in Rhinoplasty [11]. Results were based on the study findings, systolic ($P < 0.001$), diastolic ($P = 0.002$), and the mean arterial blood pressures ($P < 0.001$) were significantly lower in the nitroglycerine group. Ninety percent of the patients in the labetalol group received isoflurane to achieve the targeted blood pressure defined as controlled hypotension. There was no significant difference between the groups regarding the volume of bleeding ($P=0.75$); however, the surgeons were more satisfied with nitroglycerine than labetalol ($P < 0.001$). According to the results of the study, it can be concluded that TNG, compared to labetalol, and prescribed with the tested dosage, was a more convenient drug to induce controlled hypotension in septorhinoplastic surgery as it caused hypotension more rapidly and provided a better surgical field for the surgeons; a result nearly similar to that of the current study.

In agreement with our results, *Hadavi MR et al* studied 60 ASA I and ASA II patients who were referred for rhinoplasty [12]. Patients were randomly assigned to two groups. Labetalol was given to the first and nitroglycerin to the second group of patients. Blood pressure and the amount of intra-operative bleeding during surgery and surgeon satisfaction were measured. They found that there was a little difference between labetalol and nitroglycerine on the effect of intraoperative blood loss and surgical field quality in rhinoplasty surgery. However the results of nitroglycerin use showed minor improvements in the case of operation field quality and bleeding amount over the labetalol. Regarding these side effects, nitroglycerin may be a better choice to induce hypotension during rhinoplasty. However these data, they suggested confirmation with another study and a bigger sample size.

Dexmedetomidine versus Nitroglycerin for Controlled Hypotensive Anesthesia in Functional Endoscopic Sinus Surgery was studied by *Darshna DP et al*. Group D (n=20) Patients who received loading dose of Dexmedetomidine 1 microgram/ kilogram (µg/kg) over a period of 10 min before induction of anesthesia and followed by maintenance infusion in the dose of 0.4-0.8 µg/kg/h after intubation *via* syringe infusion pump. Group N (n=20): Patients who received Inj [13]. Nitroglycerin 5-10 µg/kg/min after intubation *via* continuous infusion. Patients were monitored for hemodynamic parameters, arterial oxygen saturation and end tidal CO_2 at fifteen minute time interval. Average category scale score was used to assess the Quality of surgical field. Total amount of blood loss was noted. There was statistically significant increase in mean pulse rate in the Nitroglycerine group as compared to the Dexmedetomidine group. Mean arterial pressure was successfully reduced to the target value in both the groups. There was no difference in amount of blood loss between the two groups.

Vineela Ch et al. found that both nitroglycerine and dexmedetomidine can be used safely for controlled hypotension in functional endoscopic sinus surgeries to achieve a target mean arterial pressure around 65-75mm of Hg. But the average blood loss is less with dexmedetomidine when compared with nitroglycerin [5].

After comparison between nitroprusside and nitroglycerine for hypotensive anesthesia in ear, nose, and throat surgeries, *Mishra A et al* reported that the use of sodium nitroprusside gives the desired results in a significantly, shorter time as compared to nitroglycerin. Reflex tachycardia was the main side effect of the nitroglycerin group. Rebound hypertension was the associated side effect of the sodium nitroprusside group [15].

However, *Tobias MA* compared nitroprusside and nitroglycerin to produce induced hypotension during coronary artery surgery and found that both drugs significantly, decreased arterial pressure without affecting the HR or cardiac output [15].

Min Yu et al. compared the clinical effects of prophylactic injections and continuous infusion of phentolamine, during the pheochromocytoma surgery on 29 adult patients at American Society of Anesthesiologists physician status II to III were treated with phenoxybenzamine for > 2 weeks before the surgery [16]. Group C (n = 11) of continuous infusion, 0.08% phentolamine was intravenously infused at the rate of 1–6 µg/kg/min according to the blood pressure (BP). In the group P (n = 13) of prophylactic injection, phentolamine was intravenously injected during anesthesia induction and at 2 min before skin incision, with the dose of 5 mg at each time. When compared with patients who administered continuous phentolamine infusion, the patients who received prophylactic phentolamine injections had significantly lower MAP at T 2 (131 ± 24 mm Hg vs 159 ± 29 mm Hg) ($P = 0.018$), less use of urapidil (20.4 ± 5.8 mg vs 45.8 ± 7.8 mg) ($P < 0.001$), and less total dosage of phentolamine (20 mg vs 28.4 ± 3.5 mg) ($P < 0.001$).

Wesley D. McMillian et al. concluded that continuous infusion of phentolamine was used in a patient with pheochromocytoma to control perioperative hypertensive episodes during surgical adrenalectomy [17]. The case report was received intermittent bolus injections of phentolamine and a continuou i.v. infusion of esmolol for control of blood pressure and heart rate, and hemodynamic monitoring; despite those measures, cardiovascular instability persisted during the immediate postoperative period. The day after the abortive surgery attempt, a continuous infusion of phentolamine mesylate (1 mg/hr, adjusted hourly to achieve the blood pressure target) was initiated. Four days after initiation of continuous phentolamine infusion, the patient was deemed to be hemodynamically stable, and the surgery was successfully performed.

S. Dianrong et al. Studied Eighty-four women with pre-eclampsia. 43 cases signed to treatment with magnesium sulfate (group 1), and 41 cases with phentolamine (group 2) [18]. The results showed that mean diastolic blood pressure decreased significantly 30 min after administration of phentolamine, but did not decrease significantly until 2 h after $MgSO_4$. This study showed administration of phentolamine shortened the average course of treatment significantly, and provided appropriate time for terminating pregnancy.

Limitations

The sample size was small and for more accuracy, study need to be conducted with larger sample size. Further studies are recommended to evaluate the efficacy of Phentolamine versus other hypotensive

drugs for patients undergoing different types of surgeries.

Conclusion

Our study concluded that Nitroglycerin and Phentolamine are safe, efficient and might be advisable option for deliberate hypotensive anesthesia throughout Functional endoscopic sinus surgery. Phentolamine can be a good alternative to Nitroglycerin in reduction of MAP during this procedure.

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