



Comparison between Remifentanil and Nitroglycerin in Controlled Hypotension during Rhinoplasty

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Original Article

Abstract

Background: Controlled hypotension has been used to reduce bleeding, it provides satisfactory bloodless (dry) surgical field in all facial plastic surgeries, its achieved when reducing of SBP to 80-90 mmHg, reduction of MABP to 50-65 mmHg or 30% reduction of baseline MAP. Remifentanil is an ultrashort acting opioid with a effect of hypotension and nitroglycerin is a vasodilator with hypotensive technique. Both medication used for controlled hypotension and obtained dry operative field.

Objective: The aim of this study was to evaluate the comparison between Remifentanil to Nitroglycerine in controlled hypotension during rhinoplasty surgery.

Methods: This is a prospective study done in Erbil between January 2016 -July 2016; included sixty patients of ASA I &II underwent elective primary Rhinoplasty operation (open technique), they divided randomly in to two group with 30 patients in each group, namely remifentanil group and NTG group, the operation done by same surgeon and same anesthesiologist All patients were healthy of either sex, aged between (18-45 years), weight 45 -95 kg. The heart rate (HR), mean arterial pressure (MAP), systolic (SBP) and diastolic blood pressure (DBP), infusion rate (IR) and dry operative field were compared between groups.

Result: In this study we compared effect of Remifentanil group to Nitroglycerin (NTG) group, there were no statically significant between R and A group in age, weight, I.V infusion P value 0.44, 0.16, 0.69 respectively also MAP, SBP, DBP non-significant, $P > 0.05$. The Heart rate, duration of hypotension with anesthesia, Duration of surgery was less in Remifentanil group than in NTG group, $p < 0.001$ and in Remifentanil group there was no need for using other hypotensive medication or medications for tachycardia as in A group as R is more hemodynamically stable.

Conclusions: Using remifentanil combined with propofol was interesting in quality of surgical field, reducing blood pressure, reducing time of surgery by decreasing suctioning of surgical site, no need for any other hypotensive agents to reach the target blood pressure. Remifentanil as an ultra-short acting opioid can be used safely for inducing controlled hypotension in combination with propofol.

Keywords: Anesthesia, Rhinoplasty, Controlled hypotension, Remifentanil, Nitroglycerin, Mean Arterial Blood Pressure, Heart Rate.

Received : October, 2023, Published: December, 2023

Citation: Fathulla H S, Shawq B.H, Ahmed H.A. . Comparison between Remifentanil and Nitroglycerin in Controlled Hypotension during Rhinoplasty. JMSP 2023; 9 (4): 121-33

1. INTRODUCTION

Rhinoplasty is one of the most popular facial surgical type done by plastic, ENT, head& neck surgeons (1, 2). During facial aesthetic surgery especially rhinoplasty, hypotension technique is mandatory because it decreases blood loss, the operation time and lastly decreases the major complications, as it makes dry operation field and the surgeon can see the anatomy of nose clearly by controlled hypotension (1). Controlled hypotension has been used to reduce bleeding and decrease need for blood transfusion, in general it provides satisfactory bloodless (dry) surgical field in all facial plastic surgeries (1). Controlled hypotension (C.H) is defined as reduction of systolic blood pressure to 80-90 mmHg, reduction of mean arterial pressure (MAP) to 50-65 mmHg or 30% reduction of baseline MAP (1,2). Another definition of C.H is reduce arterial blood pressure 40-50% below normal range initially and maintaining it at this level during surgical procedure.(2-10). Controlled hypotension achieved by reducing peripheral blood vessels resistance , reduce cardiac output , or by reducing combination of both (1). Many pharmacological agents that can be used alone or in combination with other agents to reduce blood pressure and control it to limit dosage requirement and adverse effect of each agent. The most common medication that had been used are sodium nitroprusside, nitroglycerin, adenosine, prostaglandinE ,B-blockers like esmolol , Ca channel blockers & narcotics like remifentanyl (1-3). The main goal of any hypotensive medication is to achieve the desire level of controlled hypotension without affecting perfusion to vital organs. The ideal medication for controlled hypotension should be ease of administration , fast onset, short half life after discontinuation, nontoxic, maintaining cerebro vascular auto regulation ,not change cardiac performance, has short term effect and be easily titrated (1-4). In rhinoplasty operation bleeding is one of the major problems during surgery which reduce operation field visibility, this may not only prolong operation time but also making discomfort to surgeons and increase complication rate, Epinephrine injection in nasal mucosa, elevation of patient's head and controlled hypotension all can be used to minimize bleeding, make surgical field dry, subsequently decrease complication rate and decrease operation time (5).

Moderate hypotension was found to be significantly decrease the average blood lose by nearly 40% , reduce the need for transfusion by nearly 45%, and shortened the average operating time by nearly 10% (6).

In general variable drugs have been used to facilitate the induction of controlled hypotension , including vasodilators (NTG , Na nitroprusside), combined alpha and beta adrenergic antagonist (labetalol), or high dose of potent inhalational anesthesia , so no single medication is ideal for controlled hypotension that is mentioned above, because SNP has rapid onset & short duration, it relax both arteriolar and venous smooth muscle. It has disadvantage of reflex tachycardia, rebound hypertension , impairment of hypoxic pulmonary vasoconstriction and lability of cyanide toxicity at high dose which is characterized by metabolic acidosis and cardiac arrhythmia. Other medication like halothane has disadvantage of long post anesthetic recovery period, while esmolol is a relative new B1 selective blocker with rapid onset, half-life around 9 mins but it has disadvantage of possibility of myocardial depression (3, 7,10).

Now a day Remifentanil is a new ultra short acting opioid receptor agonist, it's now used with propofol total intravenous anesthesia (TIVA) compared to other medication as fentanil and alfentanil, it appears to offer superior intraoperative hemodynamic stability & maintain intact cerebral blood flow to mild hypotension, this hypotension effect of remifentanil has not yet been studied for intraoperative controlled hypotension (5, 7, 11). Meanwhile the exact mechanism of hypotension by remifentanil has not been studied (unknown). NTG is another most common medication that is still used for controlled hypotension. Intraoperatively, it is used by infusion. NTG relax vascular smooth muscle with venous dilation predominantly on arterial dilation, its molecules of action is similar to SNP which activates guanylyl cyclase , this enzyme is responsible for the synthesis of guanosine 3-5 monophosphate (GMP), which controls the phosphorylation of several proteins which include smooth muscle relaxation & control intracellular calcium (3). NTG undergoes rapid hydrolysis in the liver and blood by glutathione organic nitrate reductase. It reduces myocardial O₂ demand and increases myocardial O₂ supply by reducing venous return and preload, and by this way, a decrease in ventricular end—diastolic pressure, increased myocardial perfusion , coronary artery vasospasm may be relieved and platelet aggregation may be decreased(3). Meanwhile, opioids biotransformation mainly in the liver and high hepatic extraction ratio cause the clearance to be dependent on liver blood flow. The unique ester structure of remifentanil, which is an ultra-short-acting opioid with a terminal elimination half-life of less than 10 min, makes it susceptible to rapid ester hydrolysis by non-specific esters in blood (RBC) and tissue. The time required for plasma concentration to decline

by 50% after termination of the infusion is approximately 3 minutes, regardless of the duration of the infusion. In our study, we tried to compare the efficacy of remifentanil and NTG as primary drugs for induced and controlled hypotension in rhinoplasty and to compare their effect on the amount of blood loss, duration of surgery, quality of the surgical field, patient's outcome and complications and also to assess the surgeons satisfaction and the use of other emergency drugs (1,11,12)

2. PATIENTS and METHODS

This was a single center non placebo controlled trial included 60 patients of ASA I who underwent elective rhinoplasty operation (open technique), conducted in Erbil city ,during period from January 2016 to July-2016. Patients were randomly assigned in to two groups (R: remifentanil group and A: NTG group). The operations were performed by the same team of surgeon and anesthesiologist.

All patients were healthy of either sex, aged between (18-45) years, weight ranged between 45 - 95kg, primary rhinoplasty, non-smoker, non-alcoholic.

Patients with previous septo-rhinoplasty, difficult cases or abnormal anatomy of nose, operation time more than 3 hours, Hemoglobin level less than 10 g/dL , patient on aspirin or any medication affecting coagulation were excluded.

All patients were admitted on the day of surgery with a fasting period of 6–8 hours. All routine preparations were done by putting an 18-gauge canula in a vein for IV fluid and drug administration, pulse oximetry with 5 leads of ECG attached to the patient's chest, a non-invasive cuff for BP monitoring, a temperature probe, and an ET CO₂ sensor..

Induction of anesthesia was done using the same technique and the same medication for both groups, and exact data were recorded. No premedication given, all patients received propofol 1.5–2.5 mg/kg vecuronium 0.06–0.1 mg/kg with fentanyl 100 mic to facilitate endotracheal intubation (size 7-8 mm cuffed tube), later patient was attached to a mechanical ventilator, a throat wet pack was used, and anesthesia was maintained with isoflurane 1-2 MAC with maintenance of neuromuscular blockage. Vecuronium frequent doses depended on the train of four twitch response (around 20–25 minutes).

The remifentanil group received 1 μkg I.V over 30-60 second and later put on infusion 0.25-0.50 $\mu\text{kg}/\text{min}$ until systolic blood pressure reached 80 mmHg then infusion rate adapted to maintain hypotension in this level, while for A group, NTG infusion started on 0.5-5 $\mu\text{kg}/\text{min}$, NTG infusion stopped around 15 mins before the end of surgery, because it need time to return back to normal baseline BP. Patient position changed to approximately 30 degree head up for surgical team comfort. Nasal mucosa infiltrate with 1:200,000 adrenaline with 2% lidocaine 2-5 cc accordingly to decrease bleeding. I.V fluid crystalloid mostly normal saline 5 ml/kg was administered. Hemodynamic measurements including systolic and diastolic BP, MAP, spo₂, pulse rate were monitored and recorded at every 15 minutes. Blood lose in surgical field was monitored subjectively and visualized by the surgeon until the end of operation. The Average category scales (ACS) for assessment of of intra-operative surgical field bleeding was used to assess the surgical condition, a score of 0 for no bleeding, 1 slight bleeding - no suctioning of blood is required, 2 slight bleeding- suctioning required, 3 moderate bleeding- frequent suctioning required, 4 sever bleeding-constant suctioning required,(bleeding appears faster than can be removed by suction). In all patients after spontaneous breathing returned back throat pack removed and suction of oral cavity done then extubation done and patients sent to recovery room for further monitoring

Statistical analysis: was performed using the statistical package for social sciences (SPSS) version 20. Appropriate statistical tests and procedures were applied accordingly at a level of significance of ≤ 0.05

3. RESULTS

Sixty patients represented the two arms (groups) of the study underwent rihnoplasty by the same surgeon, controlled hypotension applied for all cases. Both groups were not signifciantly different in their age weight and total IV fluid adminstered,, (P. value >0.05). A statistically significant lower mean duration of anesthesia, mean duration of hypotension and mean duration of surgery was found in Remifentanil group compared to NTG group, in all comparisons (P. value <0.05), (**Table 1**).

Regarding the MAP it was not signifciantly different between both groups across the whole monitoring period from the zero minute to the end of monitoring at 120 minutes, however, the

monitoring time for some patients was earlier than others; at 90 minutes the remaining patients were 25 in each group, at 105 minutes the number was 17 and at 120 minutes only 5 patients in each group, in all comparisons, P. value >0.05, (**Table 2**)

Comparison of Heart rate (HR) between the studied groups at different monitoring time revealed significant higher HR in NTG group compared to Remifentanyl where HR was stable and no tachycardia was developed when reaches the target blood pressure in comparison of NTG group once reaches the target blood pressure most of patients complains from tachycardia as show in (**Table 3**).

Regarding the dose of drug from the time of starting infusion till reach the target blood pressure, lower dose was required in Remifentanyl group compared to NTG group, as shown in (**Table 4**)

Surgical field rating was performed by the surgeon. It had been found that the average category scale (ACS) for assessment of intra-operative surgical field assessment was significantly higher in NTG compared to Remifentanyl group. The number of patients with moderate to severe bleeding in the NTG group was much higher than that in Remifentanyl group, (P. value <0.001), so as, the mean ACS was significantly higher in NTG compared to Remifentanyl group, (P. value < 0.001), (Table 5 and Figure 1)

Table 1. Age, weight, IV fluid infusion, duration of anesthesia, surgery, hypotension.

| Variable | Groups | | | | P. value |
|-------------------------------|---------------|-------|------------------------|-------|----------------|
| | NTG (n=30) | | Remifentanyl (n=30) | | |
| | Mean | S.D | Mean | S.D | |
| Age (year) | 28.2 | 5.9 | 26.7 | 7.4 | 0.44 NS |
| Weight. (kg) | 74.6 | 15.0 | 70.7 | 8.5 | 0.16 NS |
| Total IV fluid (ml) | 658.6 | 204.4 | 634.4 | 202.3 | 0.69 NS |
| Duration of anesthesia (min) | 120.8 | 33.7 | 102.3 | 22.6 | 0.010 S |
| Duration of hypotension (min) | 116.1 | 25.4 | 92.8 | 24.1 | 0.001 S |
| Duration of surgery (min) | 111.8 | 31.1 | 97.2 | 27.5 | 0.040 S |

SD: standard deviation, S: significant, NS: non-significant

Table 2. Comparison of MAP between the studied groups at different monitoring time.

| Monitoring time | Groups | | | | | | P. value* |
|-----------------|--------|------|------|--------------|------|------|-----------|
| | NTG | | | Remifentanil | | | |
| | N | Mean | S.D | N | Mean | S.D | |
| MAP 0 min | 30 | 85.6 | 9.5 | 30 | 88.5 | 14.2 | 0.39 |
| MAP 15 min | 30 | 75.4 | 14.4 | 30 | 74.1 | 14.1 | 0.75 |
| MAP 30 min | 30 | 63.3 | 13.8 | 30 | 66.0 | 11.6 | 0.48 |
| MAP 45 min | 30 | 62.8 | 14.2 | 30 | 62.2 | 9.9 | 0.84 |
| MAP 60 min | 30 | 57.6 | 12.8 | 30 | 61.4 | 12.0 | 0.25 |
| MAP 75 min | 30 | 57.0 | 11.5 | 30 | 62.4 | 12.5 | 0.15 |
| MAP 90 min | 25 | 64.1 | 13.3 | 25 | 63.5 | 11.8 | 0.85 |
| MAP 105 min | 17 | 62.8 | 9.9 | 17 | 66.8 | 12.5 | 0.51 |
| MAP 120 min | 5 | 66.8 | 16.4 | 5 | 70.4 | 18.3 | 0.69 |

SD: standard deviation,
* P. value not significant in all comparison

Table 3. Comparison of Heart rate (HR) between the studied groups at different monitoring time

| Monitoring time | Groups | | | | | | P. value* |
|-----------------|--------|-------|------|--------------|------|------|-----------|
| | NTG | | | Remifentanil | | | |
| | No. | Mean | S.D | No. | Mean | S.D | |
| HR 0 min | 29 | 82.3 | 9.6 | 29 | 87.8 | 13.7 | 0.082 NS |
| HR 15 min | 29 | 91.5 | 14.9 | 29 | 86.7 | 13.1 | 0.18 NS |
| HR 30 min | 29 | 93.5 | 17.4 | 29 | 81.6 | 10.0 | 0.006 S |
| HR 45 min | 29 | 97.9 | 19.4 | 29 | 77.4 | 9.0 | 0.001 S |
| HR 60 min | 29 | 101.0 | 19.9 | 29 | 76.3 | 9.6 | 0.001 S |
| HR 75 min | 29 | 102.6 | 19.0 | 29 | 75.5 | 9.0 | 0.001 S |
| HR 90 min | 24 | 100.3 | 19.7 | 24 | 77.0 | 5.0 | 0.001 S |
| HR 105 min | 16 | 100.4 | 16.3 | 16 | 80.8 | 6.0 | 0.001 S |
| HR 120 min | 7 | 103.7 | 17.0 | 7 | 86.1 | 3.8 | 0.027 S |

S: significant, NS: non-significant, min: minutes

Table 4. Comparison of Infusion rate (IR) between the studied groups at different monitoring time

| | Groups | | | | | | P. value* |
|------------|------------|------|------|---------------------|------|-----|-----------|
| | NTG (n=30) | | | Remifentanil (n=30) | | | |
| | No. | Mean | S.D | No. | Mean | S.D | |
| IR 0 min | 29 | 16.9 | 19.6 | 29 | 9.6 | 3.1 | 0.053 NS |
| IR 15 min | 29 | 11.9 | 3.8 | 29 | 9.5 | 3.7 | 0.030 S |
| IR 30 min | 29 | 12.5 | 4.3 | 29 | 9.4 | 4.2 | 0.019 S |
| IR 45 min | 29 | 12.6 | 4.9 | 29 | 9.7 | 4.3 | 0.029 S |
| IR 60 min | 28 | 12.4 | 4.8 | 28 | 9.6 | 4.6 | 0.059 S |
| IR 75 min | 23 | 13.0 | 4.0 | 23 | 9.5 | 4.8 | 0.003 S |
| IR 90 min | 13 | 14.4 | 3.9 | 13 | 9.2 | 3.3 | 0.010 S |
| IR 105 min | 2 | 14.8 | 2.7 | 2 | 8.2 | 2.0 | 0.34 NS |
| IR 120 min | 2 | 14.0 | 3.8 | 2 | 9.0 | 1.4 | 0.010 S |

S: significant, NS: non-significant

Table 5. Comparison of surgical field rating in both studied groups

| Surgical field rating | Study groups | | | | Total | |
|--------------------------------------|--------------|-------|---------------------|-------|-------|-------|
| | NTG (n=30) | | Remifentanil (n=30) | | | |
| | No. | % | No. | % | No. | % |
| No | 0 | 0.0 | 5 | 16.7 | 5 | 8.3 |
| Slight bleeding. no suctioning | 0 | 0.0 | 12 | 40.0 | 12 | 20.0 |
| Slight bleeding, suctioning required | 9 | 30.0 | 12 | 40.0 | 21 | 35.0 |
| Moderate bleeding | 16 | 53.3 | 1 | 3.3 | 17 | 28.3 |
| Severe bleeding | 5 | 16.7 | 0 | 0.0 | 5 | 8.3 |
| Total | 30 | 100.0 | 30 | 100.0 | 60 | 100.0 |

P. value < 0.001, significant

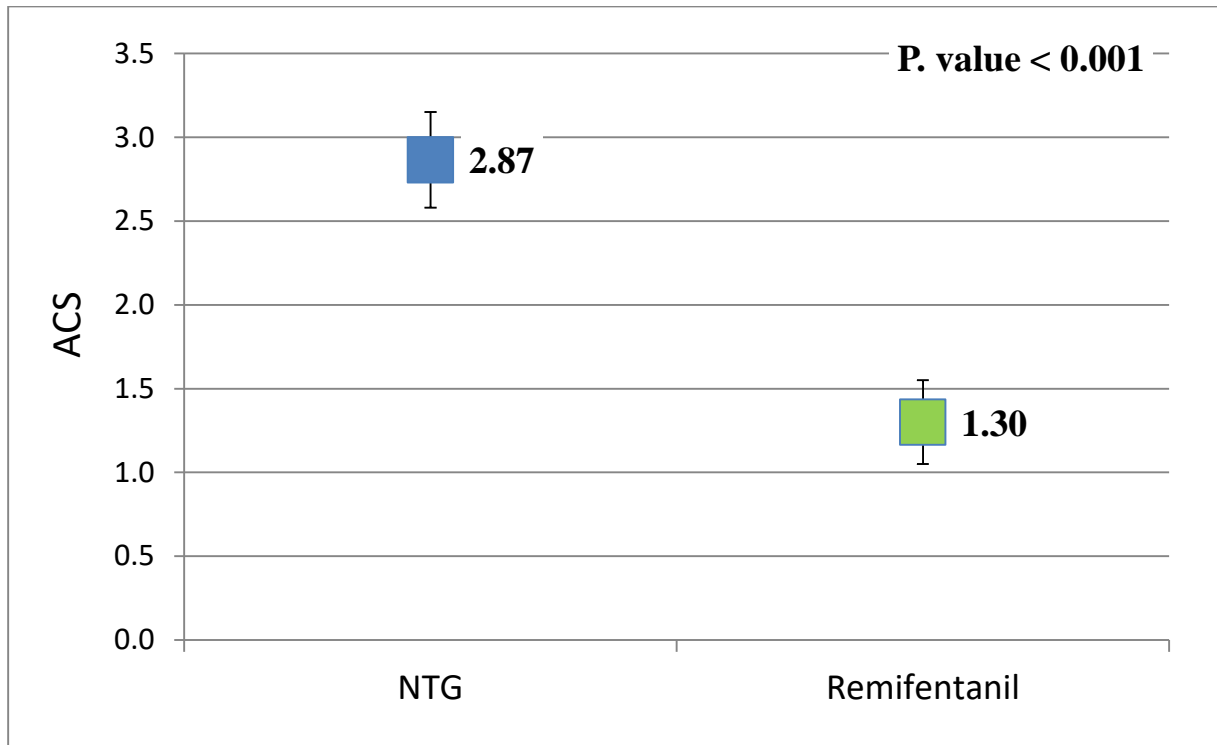


Figure 1. Comparison of mean average category scale for assessment of surgical field

4. DISCUSSION

In our study we compare the effect of NTG versus the ultra-short acting Remifentanil for controlling hypotension under general anaesthesia. NTG are frequently used for C.H during surgical procedures, NTG cause vasodilation and reflex tachycardia, increase in cardiac blood flow. In comparison to remifentanil, NTG has negative effect which is reflex tachycardia (rebound hypertension) and changing in organ perfusion along with history of over dose are reported to be lower (2). In our study two groups were almost matched for their demographic characteristics were enrolled. Duration of surgery was significantly shorter in Remifentanil group ($P= 0.04$). Both groups caused hypotension but the duration needed for hypotension in Remifentanil group was less ($P= 0.001$) this may be due to less oozing in surgical site and less frequent suctioning was required. Previous studies showed that when Remifentanil compared to SNP and NTG, the surgical duration was shorter when controlled hypotension technique. It is used probably because of better visibility of surgical field & less time need for suctioning (5).

Surgical field blood flow is influenced by arterial and venous pressure as well as regional capillary circulation, during nasal surgery capillary flow influenced the operation field visibility and this reduced by providing hypotension & using local vasoconstrictor with head elevation in rhinoplasty (1,2,5). NTG induces hypotension principally by dilation venous vessels, reduce both venous return and cardiac output, while arterial dilation occur in higher dose (5,7,11). Both NTG and Remifentanil produce hypotension as required for rhinoplasty and MAP remains more or less in similar range in both groups during procedure. C.H with non-significant P. value, the insignificant difference in MAP between both groups in our study was similar to that documented in other studies (5,7,12). Remifentanil is known to have hypotensive side effect during propofol TIVA with effect of consistent and sustained controlled hypotensive with decreasing blood flow which provide dry surgical field and no need for additional use of potent hypotensive agents. Remifentanil is as effective as esmolol and NTG in reaching target SABP of 80 mmHg and C.H ensure good operative condition (1, 5). The effect of NTG that cause more (oozing) is due to direct action of NGT on smooth muscle with consequent more oozing at the surgical site and reflex tachycardia which may also be a contributing factor (5, 12). The aim of controlled hypotension is to reduce blood pressure mainly while providing the best operation condition and not affect any organs (5, 10).

In our study, duration of hypotension was lower in Remifentanil group than NTG groups which is considered to be significant as it doesn't cause prolonged hypotension and not affecting other organs (5). The most common medication used for controlled hypotension is esmolol, NTG, SNP and remifentanil (3). All mentioned medication has advantages of hypotension with possible side effect; NTG causes reflex tachycardia, more oozing at surgical site, tachyphylaxis & rebound hypertension, also risk of cyanide toxicity with using SNP. Esmolol considered safer and more effective than NTG, despite of myocardial failure risk at higher dose more than 500 mg/kg/min. (2, 3). The main advantages of remifentanil is short acting, ability to ensure a satisfactory operation field, hemodynamic stability & safe anaesthesia by limiting surgical stress & pain, another advantage when used with propofol TIVA it causes less humoral disturbance & more stable controlled hypotension than NTG (1, 3, 7). Use of Remifentanil to induce controlled hypotension rather than traditional use of NTG has advantage of rapid action of decreasing heart rate and blood pressure has been mentioned by hyphilip et al and schuttler et al. (1, 5). Lessard et

al. suggested that different technique for inducing hypotension may have different effect on vascular beds of facial structures, perhaps SNP selectively dilate these vascular beds, the adverse effect of SNP on platelet function and bleeding time may also compromise haemostasis during surgery. (5,7) The hypotensive mechanism of action of NTG is by peripheral vasodilatation as they act directly on vascular smooth muscle, on the other hand, the hypotensive effect of Esmolol is due to decrease cardiac output that exceeds the reduction in both blood pressure and heart rates, in 2001 Degoute et al used Remifentanil for the first time for controlling hypotension during tympanoplasty in comparison to Esmolol and SNP medication, they found that hypotensive effect of Remifentanil was similar to Esmolol and SNP groups (1, 4, 5). However, direct comparison of blood lose among studies is relatively difficult because the differences in the duration of surgeries, surgical techniques and other facilities among different institutions in addition to the timing of controlled hypotension(3). In 1985 Guggiari et al used NTG for 1st time to produce induced hypotension in aneurismal brain surgery and proved that it can be used as an agent for hypotension (6). Willium blau et al. have suggested that it is difficult to measure & compare the blood lose after operation due to large volume of irrigation of fluid used also in our study we faced the same problem to calculate blood loss accurately (1, 2). Chritian degout et al found esmolol to be comparable with SNP, Remifentanil creating dry operation field also Nabil fahmy used NTG for controlled hypotension during total hip replacement surgery & creating a dry field was achieved (2.6). In our study the surgeon' s assessment of surgical field in Remifentanil group compared to NTG group there was a significant surgical field dryness in Remifentanil group. If inhalation anaesthesia gases are used to decrease blood pressure, a large inspired concentration is required to provide good surgical anaesthesia and hypotension but it can cause more bleeding because of peripheral vasodilator effects (2). Degoute et al. combined remifcentanil with propofol infusion in a dose of 0.25-0.5 micro\kg\min (4). Following 1 micro mcg\kg bolus in tympanoplasty surgery and they measure middle ear blood flow with larger Doppler flow meter and fonned a significant decrease and a consequent good surgical area (7). In other previous studies, in 2012 which were conducted by Srivastava et al. the mean blood loss was significantly less in Esmolol group compared to NTG group because of probability of lowering intra operative heart rate with subsequent decrease in the amount of blood loss (4, 5).

5. CONCLUSIONS

Using remifentanil combined with propofol was interesting in quality of surgical field, reducing blood pressure, reducing time of surgery by decreasing suctioning of surgical site, no need for any other hypotensive agents to reach the target blood pressure. Remifentanil as an ultra-short acting opioid can be used safely for inducing controlled hypotension in combination with propofol. Hence we recommend using remifentanil in controlled hypotension in rhinoplasty as it is safe and has several advantages like its short action effect that make it to have a significant role in nasal surgery. For patients undergoing rhinoplasty it is better to use remifentanil than traditional use of NTG to obtain controlled hypotension with hemodynamically stable results and rapid diminish of its effect after stopping medication.

Ethical Clearance:

Ethical issues were taken from the research ethics committee. Informed consent was obtained from each participant. Data collection was in accordance with the World Medical Association (WMA) declaration of Helsinki for the Ethical Principles for Medical Research Involving Human Subjects, 2013 and all information and privacy of participants were kept confidentially.

Conflict of interest: Authors declared none

Funding: None, self-funded by the authors

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