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Remifentanil Vs Nitroglycerine for Controlled Hypotension during Rhinoplasty

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Abstract: Objective: To evaluate the clinical efficacy of remifentanil infusion in comparison with nitroglycerine regarding controlled hypotension during rhinoplasty. **Background:** Controlled hypotension is a well-known technique used in many operations to reduce blood loss and need for blood transfusion and to provide satisfactory bloodless surgical field. Many Drugs are used to preform controlled hypotension intra-operatively. **Patients and Methods:** A total of 120 adult consented patients of both genders undergoing rhinoplasty aged (20-50) years with ASA I or II, were randomized to receive remifentanil infusion (0.3 – 0.5) µg/Kg/min. (group 1 = 60 patients) or nitroglycerine (1) µg/Kg/ min. (group 2 = 60 patients) intraoperatively with adjusting dose till reaching target MAP around 60 mm Hg. Anesthetic Technique was standard for both groups . Time to onset of induced hypotension and Time to Target MAP were recorded in addition to heart rate during induced hypotension, PaO_2, PCO_2 and pH Together with the total infusion dose of the hypotensive agents in both groups. **Results**: Remifentanil infusion intraoperatively induces adequate hypotension with no statistical significant difference to that induced by nitroglycerine. **Conclusion**: This study confirmed that remifentanil infusion with dose of (0.3 – 0.5) µg/Kg/min. Induced desired controlled hypotension intraoperatively during rhinoplasty with no complications occurred either intra or postoperative with advantage of rapid recovery from anesthesia.

Keywords: Remifentanil, Nitroglycerine, controlled hypotension, Rhinoplasty.

BACKGROUND

Controlled hypotension has been used to reduce bleeding and the need for blood transfusion, and also to provide a satisfactory bloodless surgical field in many operations as in Oro maxillofacial surgery, endoscopic Major orthopedic surgery (as hip or Knee replacement, spinal) cardiovascular, neurosurgery and organ Transplant surgery. Controlled hypotension is defined as a reduction of the systolic blood pressure to (80 – 90) mmHg, a reduction of mean arterial pressure (MAP) to 50 – 65 mmHg or a 30% reduction of baseline MAP. Many pharmacological used for controlled hypotension include those can be used successfully alone or in combination with others to limit dosage requirements and the adverse effects of each agent. The common agents that had been used are inhalational anesthetics, sodium nitroprusside, nitroglycerine, adenosine, prostaglandin E, beta blockers and narcotics (especially remifentanil).

Other agents may be used mainly as adjunctive us ACE inhibitors and α agonists (e.g.: clonidine) . The main goal of any hypotensive drug is to achieve the desired level of controlled hypotension without affecting the perfusion of vital organs. and should have a rapid onset , which is easy to be administered and disappears quickly when administration is discontinued without Toxic metabolites. The new ultra-short acting U-opioid receptor agonist Remifentanil hydrochloride is Known to have a hypotensive effect during a propofol total intravenous anesthesia (TIVA), and this is used effectively for controlled hypotension and providing a clear dry surgical field.

Nitroglycerine is a well- Known direct vasodilator (acting on both venules and arterioles) commonly used to induce controlled hypotension with its high potency and short duration of action but it has some side effects making it is not ideal for many patients. Tachycardia, Venous polling and methemoglobinemia are the common side effects. The purpose of this study was to evaluate the effectiveness of remifentanil to induce controlled hypotension as primary goal and to reduce the disadvantage of traditional methods used to induce controlled hypotension as the secondary goal.

PATIENTS AND METHODS

After approval of the local ethical committee , A total of 120 patients ASA I or II of both genders with age ranging from 20–50 years undergoing rhinoplasty were randomly divided using closed envelope method of randomization into two groups remifentanil group (group I , n=60 patients) or nitroglycerine group (group II, n= 60 patients). Exclusion criteria were, patients with uncontrolled hypertension, severe renal or hepatic disease, anemia, age <20 years and >50 years, patients who refused to participate in this study and patients with severe ischemic heart disease or cardiac failure. All patients were admitted on the day before surgery and fasted for at least 8h before surgery.

All patients received preoperative sedation in the form of midazolam (0.5 mg/Kg) two hours before surgery.

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In all patients, a 20 – gauge catheter was inserted into the left radial artery determination of arterial blood pressure (systolic, mean and diastolic). Heart rate was continually recorded by ECG, also other routines were monitored in the form of pulse oximetry, and end Tidal CO_2 was connected.

Serial arterial blood gas analysis was done to detect any change in pH or in the partial pressure of oxygen (PaO_2) and carbon dioxide ($PaCO_2$) , Samples were taken every 30 min after the induction of general anesthesia until 20 min in the recovery room . An 18 – gauge cannula was inserted into a suitable vein for fluid and drug administration. Ringers solution was administered continuously at a rate of 5 ml/kg/h.

Anesthetic technique:
In all cases, induction was done by 2–2.5 mg/kg propofol followed by 0.15 Cisatracurium to facilitate oro-tracheal intubation by cuffed tubes then the patients were connected to the mechanical ventilator to maintain an end tidal CO_2 ranging from 30–35mmHg and to ensure SpO_2 97% with 100% oxygen . Anesthesia was maintained by Isoflurane with MAC 1.3–2 and with increments of the muscle relaxant (Cisatracurium) every 45 min (0.05mg/kg).

After induction of anesthesia, patients received intraoperative infusion according to their groups either remifentanil (group I) or nitroglycerine (group II).

In group I
Patients received 1 µg/kg remifentanil IV over 30 - 60 seconds , Followed by a continuous infusion of 0.3–0.5 µg/kg/min until systolic blood pressure was brought within 80 mmHg , then infusion rate was adapted to maintain hypotension at this level.

In group II
Patients received nitroglycerine as a continuous IV infusion at a rate of 1 µg/kg/min. until systolic blood pressure was brought within 80 mmHg , Then infusion rate was adapted to maintain hypotension at this level.

Direct visual analysis of the surgical field was performed from starting surgery until the end of the surgery using the six point scale. In all cases, the surgeon infiltrated the submucosal tissue of the nose with 1:200000 epinephrine to minimize blood loss. The surgeon was blinded to the hypotensive agent used, as well as to the monitor recording the hemodynamic variables. After the surgery, patients were recovered and were transferred to the recovery area (PACU) for a continuous monitoring.

The required sample size has been calculated using the G power software version 3.1.7 (University of Dusseldorf , Germany). The primary outcome measures were the time to onset of induced hypotension , time to target hypotension, and heart rate during hypotension. Secondary outcome measures were the PaO2, PaCO2 and pH. It was estimated that a sample of 60 patients in either study group would have a power of 81% (type II error, 0.19) to detect a statistically significant difference between the two study groups for a medium effect size of Cohen's d= 0.5 which is equivalent to difference of 0.5 SD in the outcome measures. This difference was chosen as it could be regarded as a clinically relevant difference to seek in this pilot study. This calculation used a two tailed type I error of 0.05. A two –sided p- value 0.05 was considered statistically significant. Our study is a non–equivalence study. So you are supposed to use usual two- sided tests (table 1).

Table 1. Category scale of intra operative surgical field assessment.

0	No bleeding .
1	Slight bleeding –non suctioning required .
2	Slight bleeding – occasional suctioning required .
3	Slight bleeding – frequent suctioning required .
4	Moderate bleeding – frequent suctioning required . Bleeding threatens the surgical field after suctioning removed .
5	Severe bleeding – constant suctioning required bleeding appear faster than can be removed by suction . Surgical field severly threatened and surgery is not possible.

RESULTS

Demographic data, duration of hypotension, duration of anesthesia and baseline hemodynamic data did not show any statistically significant. Difference among groups (table 2). Infusion rate and the total dose of remifentanil and nitroglycerine are shown in table 3. There were no statistically significant differences between both

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groups regarding PaO2, PaCO2 and pH data (table 4).

Tablet 2.Patients characteristics in both study groups

Variable	Remifentanil group(n=60)	Nitroglycerine group (n = 60)	P –value
Age (years)	30.0 (8.6)	29.0 (10.9)	0.580[a]
Weight (kg)	70.9 (24.5)	68.2 (26.3)	0.555[a]
Gender (m/f)	40/20	46 / 14	0.853[b]
Baseline SBP (mmhg)	114 (19)	115 (22)	0.797[a]
Baseline MAP (mmhg)	84 (9)	82 (12)	o.308[c]
Baseline DBP (mmhg)	69 (18)	65 (19)	0.300[a]
Baseline heartrate (bpm)	73(20)	75(20)	0.569[c]
Duration of anesthesion (min)	79 (32)	82 (22)	0.557[c]

a: Unpaired t test.
b: person chi-squared test.
c: Welch test.

Table 3. Details of the induced hypotension in both study groups .

Variable	Remifentunil group (n=60)	Nitroglycerine group (n=60)	P –Value
Time to onset of induced hypotension(s)	36 (21)	55 (15)	$< 0.0001^a$
Time to target blood pressure (s)	68 (15)	109 (52)	$< 0.0001^a$
Duration of induced hypotension (min)	47 (13)	48 (19)	0.948[a]
SBP during induced hypotension (mmhg)	81 (10)	80 (10)	0.585[b]
MAP during induced hypotension (mmhg)	57 (6)	56(4)	0.174[b]
DBP during induced hypotension (mmhg)	48 (6)	48 (6)	0.864[b]
Heart rate during induced hypotension (bpm)	67 (25)	90(25)	$< 0.0001^b$
Total does rate of hypotension agent (mg /kg / min)	1.6 (0.6)	5.4 (2.8)	$< 0.0001^a$
Infusion rate of hypotension agent (mg / kg / min)	0.31 (0.13)	0.98 (0.61)	$< 0.0001^a$

a: Welch test
b: Unpaired t test.

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Table 4 .change in arterial blood gas Variable in both study groups.

ABG variable	Time	Remifentunil group (n=60)	Nitroglycerine group (n=60)	P –Value
PaO_2	Baseline	93 (4)	92 (5)	0.171^b
	20 min	187(33)	166 (40)	0.001^a
	40 min	173(31)	180(28)	0.187^a
	At PACU	141 (27)	123 (26)	$< 0.0002^a$
$PaCO_2$	Baseline	36 (2)	37 (2)	0.130^a
	20 min	32 (2)	41(3)	$< 0.0001^b$
	40 min	34 (3)	40(3)	$< 0.0001^b$
	At PACU	40(3)	43(3)	$< 0.0001^a$
pH	Baseline	7.37 (0.16)	7.39 (0.20)	0.552^b
	20 min	7.41(0.10)	7.31 (0.06)	$< 0.0001^b$
	40 min	7.36(0.27)	7.29 (0.09)	0.045^b
	At PACU	7.34(0.26)	7.29 (0.09)	0.142^b

a: Welch test.
b: Unpaired t test.

Measurements of systolic, diastolic and mean arterial pressure during the period of hypotension showed no significant differences between both groups. Heart rate during the periods of hypotension was significantly lower in group (1) (remifentanil group) compared to group (2) (Nitroglycerine group) ($p< 0.05$).

Time to reach target systolic blood arterial blood pressure of 80 mmHg was significantly more in remifentanil group than in nitroglycerine group ($p < 0.05$) (table 3). There were no postoperative complications in any group and all patients were discharged in the same day of operation (after 8h of operation end).

DISCUSSION

In the present study, controlled hypotension is a well-established technique to decrease blood loss and improve surgical visibility during rhinoplasty and also many other operations. Many techniques have been successfully used in healthy patients. In this study, we traced the advantage of using remifentanil to induce controlled hypotension rather than the traditional use of nitroglycerine. The remifentanil group showed statistically significant decrease time to reach target systolic arterial blood pressure (86) after (36) versus nitroglycerine group (109 ±55) after (55 ±15). These results were also reported by other studies such as Philip (Philip, B. K. *et al.*, 1997) who used remifentanil to induce hypotension in total intravenous anesthesia and also Schuttler, *et al.*, 1997, who used remifentanil in comparison with alfentanil in patients undergoing major abdominal surgery. Nitroglycerine also provided controlled hypotension in the second group of patients in this study with advantages of short duration of action, potency and short time to reach the target hypotension, and this result was also reported by Boezzart and his colleagues, who also used nitroglycerine for inducing controlled hypotension for functional endoscopic sinus surgery in comparison with esmolol and reported that nitroglycerine is a very effective drug in inducing controlled hypotension . In the current study, we reported disadvantages of nitroglycerine as reflux tachycardia which is not suitable in patients with ischemic heart diseases, arrhythmia and venous polling. These disadvantage were also reported by pin and his colleagues. (Pinaud, M. *et al.*, 1989)

Who used nitroglycerine to induce hypotension in patients undergoing craniotomies. Nitroglycerine also involved in inducing light but significant hypercupnia and acidosis .as previously shown in this study. And this was also reported by Tinker and Michenfelder (Tinker, J. H. *et al.*, 1976) who did a full study on nitroglycerine in 1976. Nitroglycerine is a direct vasodilator acting directly on the vascular smooth muscle, causing. generalized vasodilatation and increase cardiac output , so increasing the blood flow to the mucous members and to the capillaries, these may lead to increasing bleeding during surgery. This disadvantages of nitroglycerine was not reported in used nitroglycerine to induce hypotension in patients undergoing anterior maxillary osteotomy who revealed disadvantages of nitroglycerine in the adsorption by plastic tubes tachycardia, venous polling and the need for invasive blood pressure measurements.

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CONCLUSION AND RECOMMENDATIONS

The present study showed that remifentanil infusion was interesting in providing controlled hypotension as well as dry surgical field in patients undergoing rhinoplasty with no need for additional use of a potent hypotensive agent Further studies on large scale are recommended to confirm these results.

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