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Remifentanil versus Nitroglycerin for Inducing Controlled Hypotension During Primary Open Rhinoplasty: A Randomized Controlled Trial

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Intraoperative Blood Loss.

ABSTRACT
Lowering blood pressure during surgery is a widespread technique aimed at minimizing bleeding and improving visibility for the surgeon, especially when doing facial and aesthetic procedures. The aim of this investigation was to evaluate the efficacy of nitroglycerin and remifentanil on reducing blood pressure during rhino plastic surgery. This study done Al-Shaab teaching hospital in Baghdad, between October 2023 and December 2024. A total of 60 patients were distributed randomly into two groups, first one receiving remifentanil and the other one receiving nitroglycerin to achieve acceptable controlled hypotension, keeping mean arterial pressure within 60 mmHg. Intraoperative hemodynamic variables, including heart rate and systolic and diastolic blood pressures, were continuously monitored. The two groups were further evaluated and compared regarding intraoperative blood loss, duration of surgery, and the quality of the operative field. Both nitroglycerin and remifentanil groups attained similar targets for systolic, diastolic, and mean arterial pressures. Nevertheless, the group receiving remifentanil had a shorter operative time of 135.3 minutes than the one receiving nitroglycerin of 145.3 minutes. The heart rate was very different in both cases, with remifentanil having a better cardiovascular regulation. In addition, there were lower levels of bleeding during operation, improved visualization in the operating field, and increased surgeon satisfaction for remifentanil. The continuous infusion of nitroglycerin and remifentanil effectively achieves hypotension control by achieving the required mean arterial pressure. Remifentanil proves to be better than nitroglycerin because it effectively restricts blood loss and operative time while maintaining hemodynamic stability.

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INTRODUCTION

Aesthetic surgeries, including septorhinoplasty, are very popular procedures around the world. Though bleeding during the procedure is not usually profuse, the presence of any amount of bleeding can seriously impair the operating field. Anatomically, the dense plexus of fine blood vessels in the nose, individual anatomical variations, and the proximity of the operative site to the orbital and intracranial cavities can further hinder surgical vision and increase the complexity of the procedure (Ghodraty et al., 2017). Thus, reduction of bleeding and maintenance of a clear surgical field are important duties for anesthesiologists who take part in microsurgical, aesthetic and reconstructive procedures, because visual control

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makes the process safer and more efficient (Tobias, 2002). Controlled hypotension is one of the best methods of limitation of blood loss during a surgical procedure. This method can be implemented through several different pharmacological methods of lowering blood pressure including administration of volatile anesthetic agents, intravenous anesthetics, beta-adrenergic blockers, and peripheral vasodilators (Simpson, 1992). Other techniques are also used to prevent bleeding during the procedure, such as injection of vasoconstrictors into the tissue (Beikaei et al., 2015). Hypotensive conditions are created by reducing mean arterial pressure (MAP) by 30%, or keeping systolic pressure at 75–90 mmHg and MAP in the range of 50–60 mmHg (Degoute, 2007). The use of moderate hypotensive conditions reduces average bleeding during the procedure by about 40%, reduces the need for blood transfusions by about 45%, and decreases the length of the surgical procedure by 10% (Dongre et al., 2012). Remifentanil is an ultra-short acting opioid drug, which exerts its effects within 5 to 10 minutes with context-sensitive half-life of 3 minutes. It contains ester bonds, which make it vulnerable to nonspecific hydrolysis by esterases in plasma. Usually, it is administered in a form of constant-rate infusion, but can also be administered as a bolus intravenous administration in order to facilitate tracheal intubation. The latter way of administration may result in unwanted laryngeal spasm, muscle rigidity, and bradycardia (Duke & Keech, 2020). People with deficient pseudocholinesterase show no reaction to remifentanil (Flood et al., 2015). Recommended remifentanil regimens comprise an initial bolus of 1.0 μg/kg, a sustaining infusion at 0.25–0.5 μg/kg/min, and a post-surgical analgesic/sedative rate of 0.05–0.3 μg/kg/min (Butterworth et al., 2013). Glyceryl trinitrate, more commonly known as nitroglycerin, falls under the category of organic nitrates and exhibits vasorelaxing effects. It acts primarily on venous capacitance vessels and large coronary arteries in order to facilitate vasodilation and decrease cardiac ventricular wall stress. Increased doses of GTN also act to relax arterial smooth muscles. The pulmonary vasodilation action of GTN corresponds to the same effect produced in systemic arterioles. Medicinally, GTN is commonly used to treat angina pectoris caused by atherosclerosis and coronary artery spasms, being used both sublingually and intravenously. Moreover, GTN is used to control hypertensive crises and ventricular failure. Continuous administration of GTN in a 100 μg/mL diluted form, injected at a rate of 0.5-10 μg/kg/min, can also help induce controlled hypotension (Butterworth et al., 2013). Disadvantages include increased reflex tachycardia, increased incidence of hypertension, inhibition of hypoxic pulmonary vasoconstriction, and accumulation of cyanide at high dosages, leading to metabolic acidosis and arrhythmias (Butterworth et al., 2013). This study attempts to compare the efficiency of using remifentanil and GTN as hypotensive maintenance drugs for the first rhinoplasty procedure. Such evaluation includes their effect on systolic, diastolic and mean arterial pressure, heart rate, degree of bleeding, duration of surgery, operating field visibility, and general satisfaction of surgeons.

MATERIALS AND METHOD

Research Design

The study is a theory-building article with an illustrative documentary case study.

The double-blinded, prospective randomized control trial was carried out during the period between October 2023 and December 2024 in Al-Shaab teaching hospital. Baghdad, Iraq. Participants who were adults in the age range of 24 to 36 years and classified as ASA Physical Status I (ASA-I) and had a body mass index (BMI) ranging between 19 to 28 kg/m2 were considered eligible. The patient does not know which drug they receive and the person assessing outcomes, such as bleeding or surgical-field visibility, does not know which treatment the patient received.

All patients having ASA classification of II or higher, falling outside the age range of 24-36 years, or having a BMI less than 19 kg/m2 or higher than 28 kg/m2 are not eligible to be included in this study. More criteria for exclusion included complicated nasal reconstructive surgeries, operation time more than 3 hours, hemoglobin levels less than 10 g/dL, allergies to the drugs being used, or anticoagulant drugs.

The study involved 60 subjects who were scheduled to have non-emergency first-time open nasal rhinoplasty under hypotensive anesthesia.

All surgical interventions were conducted by a single operational surgical team. Participants were allocated at random into two distinct cohorts: the nitroglycerin cohort (Group G) and the remifentanil cohort (Group R). Sedative premedication consisted of midazolam (15–20 μg/kg) combined with fentanyl (1 μg/kg). Anesthetic induction was achieved utilizing propofol (2.0 mg/kg) along with rocuronium (0.6 mg/kg). Maintenance of general anesthesia relied on a combination of oxygen and sevoflurane maintained at 1–2 minimum alveolar concentration (MAC). Following induction, direct laryngoscopy with endotracheal tube insertion, followed by the insertion of a moist pharyngeal pack to protect the airway against aspiration. Patients were positioned in a reverse Trendelenburg orientation with a 30-degree head elevation, and local infiltration of the intranasal tissue was administered using 2% lidocaine compounded with 1:80000 epinephrine. Prior to the initial incision, initial loading doses were delivered via continuous infusion pumps over a 5-minute interval—2.0 μg/kg of nitroglycerin for Group G and 1.0 μg/kg of remifentanil for Group R—targeting an initial 20–25% reduction in mean arterial pressure (MAP). Target MAP values between 50 and 60

mmHg were sustained by titrating syringe-pump formulations containing either 10 mg nitroglycerin in 50 mL normal saline or 5 mg remifentanil in 50 mL normal saline. Maintenance infusion rates ranged from 0.25 to 1.0 μg/kg/min for nitroglycerin and 0.5 to 5.0 μg/kg/min for remifentanil.

Initial cardiovascular metrics—comprising systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and pulse rate (HR)—were established as time zero baseline records. Continuous capnography monitored end-tidal carbon dioxide (EtCO2) levels. Subsequent hemodynamic assessments (SBP, DBP, MAP, and HR) were documented at specific time intervals following induction: 5, 15, 25, 35, 45, 55, 65, 75, and 90 minutes. Intraoperative bleeding was evaluated at regular intervals throughout the perioperative period using a five-grade surgical field assessment scale. Grade 1 represented an almost bloodless, cadaver-like operative field, with suction rarely or minimally required. Grade 2 indicated slight bleeding that necessitated only occasional suctioning. Grade 3 was characterized by more active bleeding, requiring repeated suction. Grade 4 was assigned when blood rapidly obscured the operative area after suction was withdrawn, preventing the surgeon from performing the intended maneuver. Grade 5 represented severe bleeding that could not be adequately controlled. This assessment system was adapted from the grading method described by Peter-John Wormald for endoscopic sinus surgery, and the postoperative evaluations were recorded using a questionnaire completed by the surgeons. When the bleeding score reached grade 4 or 5, tranexamic acid was administered at a dose of 250 mg (10 mg/kg). Following completion of anesthesia and recovery, all participants remained under observation for 30 minutes. In the recovery room, blood pressure measurement in the G-group was performed every 10 minutes, while blood pressure measurement in the R-group patients was carried out twice: after admission to the recovery room and before their discharge. The rationale for these measurements was related to the assumption that GTN can cause more prolonged increase of blood pressure to its baseline value in comparison with patients in the R-group.

Six patients were excluded from the study due to use of emergency medication for achievement of the necessary MAP and heart rate values, and they were replaced by other six patients in order to get precise results. Of all GTN patients, one patient received metoprolol 2 mg for decreasing of increased heart rate. Two additional patients received supplementary propofol infusion in a dose of 0.1-0.2 mg/kg/min to reach target MAP. One of the GTN-treated patients demonstrated pronounced hypotension, when MAP became equal to 30 mmHg. At that time, phenylephrine – α1-adrenergic agonist was used until reaching target MAP value. Six patients are excluded from the study due to special medical condition but are replaced by Six other patients. As for remifentanil group, one patient showed marked bradycardia (heart rate less than 40 beats/min) and received atropine, while another one needed additional propofol infusion in a dose of 0.1-0.2 mg/kg/min to reach the target MAP.

Statistics:

All patient data from both groups were recorded in a database program. The data were reviewed for errors and subsequently analyzed with Minitab software, version 17 for Windows. Descriptive statistics for the variables were reported as means and standard deviations. Comparisons of means and assessments of significant differences between the two groups were performed using Student's t-test for all continuous variables, while the chi-square test was applied to categorical variables. Statistical significance was defined as a p-value less than 0.05.

RESULTS AND DISCUSSION

A total of 60 patients undergoing elective primary open rhinoplasty were recruited initially six patients are excluded from this study due to special medical condition and replaced later on by anather six patient for simplicity of comparison. These patients were randomly divided into remifentanil group (R-group) and GTN group (G-group) equally comprising 30 participants in each group. As depicted in Table 1, the baseline variables, which included age and body mass index did not show any significant difference between both the groups. However, a significant difference was found in terms of the duration of the operation and the total volume of intravenous fluids in the R-group.

As far as the systolic blood pressure (SBP) is concerned, there were no significant differences in SBP between the two groups at any point in time (table 2). As far as the diastolic blood pressure (DBP) is concerned, there was no significant difference in DBP between the two groups up to 90 minutes into the operation ($p > 0.05$). Beyond that, at75 and 90 minutes, the R-group showed significantly low DBP than G-group ($p=0.002$ and $p=0.006$).

Regarding mean arterial pressure (MAP), the two groups demonstrated comparable values at nearly all intraoperative time points. as presented in the corresponding table 4.

Table 1: Demographic and Perioperative Characteristics (n=30 in each group)

Variables	Remifentanil (n=30) R group Mean+ s.d	Nitroglycerin (n=30) G group Mean+ s.d	P value
Age (years)	30.6±5.32	31.1±6.47	0.488
BMI (kg/m2)	24.7±4.98	24.2±5.23	0.982
Time of operation	135.3±10.87	145.25±11.36	<0.001
Volume of I. v fluid ml	800±65.3	850±58.3	0.001

Table 2 :Comparison of systolic blood pressure (SBP) between groups.

Time (min)	R-group (mmHg)n=30	G-group (mmHg)n=30	p-value
0	120.5	119.3	0.657
5	111.4	109.6	0.342
15	97.5	97.5	0.956
25	92.3	93.1	0.623
35	90.2	91.5	0.874
45	88.5	89.3	0.911
55	88.6	87.8	0.984
65	87.3	86.2	0.841
75	85.4	85.3	0.789
90	84.5	84.1	0.714

Table 3: Comparison of diastolic pressure (DBP) between groups

Time (min)	R-group (mmHg) n=30	G-group (mmHg)n=30	p-value
0	71.9	71.9	0.754
5	72.4	72.4	0.874
15	63.3	63.3	0.654
25	53.5	53.5	0.637
35	52.8	52.8	0.741
45	43.7	44.3	0.624
55	42.9	43.0	0.987
65	42.2	43.3	0.874
75	39.1	42.3	0.002
90	39.5	41.8	0.006

Table 4: Comparison of mean arterial pressure (MAP) between groups.

Time (min)	R-group (mmHg) n=30	G-group (mmHg) n=30	p-value
0	86.9	88.8	0.537
5	78.4	79.3	0.634
15	60.5	59.9	0.432
25	59.2	58.6	0.587
35	58.7	57.6	0.651
45	58.2	56.9	0.268
55	56.6	55.8	0.365
65	55.5	54.7	0.235
75	54.4	53.3	0.258
90	53.6	54.8	0.361

Table 5: Comparison of heart rate (HR) between groups.

Time of operation (min)	R-group n=30	G-group n=30	P-value
0	80.7	79.9	0.354
5	81.2	88.6	<0.001
15	76.5	105.7	<0.001
25	73.8	105.4	<0.001
35	70.3	106.1	<0.001
45	68.6	105.3	<0.001
55	68.3	104.8	<0.001
65	67.3	100.6	<0.001
75	67.2	98.4	<0.001
90	66.9	96.7	<0.001

The given passage is an analysis of the cardiovascular effects of remifentanil compared with GTN for deliberate hypotension anesthesia. Both the drugs successfully achieved targeted reductions in systolic, diastolic and mean arterial blood pressure without any significant difference between the two groups receiving the two treatments. However, remifentanil was more effective in maintaining stable heart rate, and significantly prevented reflex tachycardia ($p<0.001$). These results coincide with those of Degoute et al. (2001) that combined remifentanil with propofol to maintain deliberate hypotension, microvascular reduction in the middle ear and clear surgical visualization during tympanoplasty without the need for any additional vasodilator hypotensive drugs.

Dolman et al. (2000) investigated hypotensive anesthesia during Le Fort I osteotomy and found that deliberate reduction of blood pressure was associated with lower intraoperative blood loss and improved visualization. They also reported that hypotensive anesthesia facilitated smoother and more controlled tissue dissection, although it did not result in a reduction in the overall operative duration. These observations are consistent with the findings of the present investigation concerning the quality of the operative field and the extent of intraoperative hemorrhage, although no quantitative data were available, but the surgeon's satisfaction and verbal feedback suggested that the surgical field was better and bleeding was reduced. These observations appeared to have a positive impact on the overall surgical procedure, facilitating tissue dissection and improving intraoperative conditions. However, these impressions were subjective and were not supported by formal numerical measurements or a standardized assessment too. Nevertheless, our results differed with respect to operative duration, which was significantly shorter among patients who received remifentanil. In another study published in 2013, Tuncel et al. (2013) evaluated the influence of intraoperative bleeding and postoperative edema and ecchymosis in patients undergoing rhinoplasty. The authors of the paper used controlled hypotensive anesthesia in combination with dexamethasone administration. The authors discovered that the triple administration of dexamethasone along with controlled hypotension decreased the number of postoperative complications after osteotomies performed during rhinoplasty operations. Moreover, the application of such technique led to an effective decrease in intraoperative bleeding. Several earlier studies support the results of the current research regarding reduced surgical bleeding in the R-group, even though our approach used only deliberate hypotension without using additional administration of corticosteroids. Koşucu et al. (2014) assessed the influence of remifentanil with induced low blood pressure on the amount of bleeding, periorbital puffiness and discoloration during open rhinoplasty operations. Their results show that remifentanil-induced hypotension can decrease periorbital swelling and discoloration because of lowering mean arterial pressure and reducing hemorrhagic losses during the procedure. At the same time, Tinker and Michenfelder (1976) used sodium nitroprusside, which is a nitrate vasodilator similar to GTN in the current research, and found out that moderate hypotension caused by nitroprusside infusion resulted in extensive vascular relaxation, tachycardia and increased cardiac output due to its direct effect on vascular smooth muscle cells. Moreover, they noticed that under the influence of sodium nitroprusside arteriolar mucosal beds remained unaffected by catecholamines, which is similar to our result about GTN-induced hypotension-induced tachycardia. Finally, Guney et al. (2012) performed a comparison of esmolol and nitroglycerin for hypotension management during nasal surgeries and concluded that there were no differences in baseline systolic, diastolic and mean arterial pressures before hypotension induction.

The present results agree with other research on similar levels of systolic, diastolic, and mean arterial pressures in different treatment arms provided a MAP target was achieved beforehand. In their research, Modir et al. (2018) compared remifentanil with magnesium sulfate and dexmedetomidine in terms of intraoperative hypotensive control, volume of bleeding, and recovery after endoscopic sinus surgery. Similarly, Saber and Rahman tested

remifentanil and nitroglycerin for hypotensive effects during tympanomastoidectomy. Both studies revealed that remifentanil was superior since it created adequate hypotensive effect with little decrease of systemic pressure and pulse rate while providing quick anesthesia awakening (Modir et al., 2018). On the contrary, dexmedetomidine decreased the bleeding; however, it produced more pronounced hypotensive and bradycardic effect (Modir et al., 2018). In our study, remifentanil showed adequate pressure regulation but created a significant bradycardia, along with a great reduction of intraoperative bleeding and improved visualization of the operative field, which is a result that goes beyond the advantages of dexmedetomidine.

CONCLUSION

The results indicate that both remifentanil and nitroglycerin were effective in achieving controlled hypotension during primary open rhinoplasty, according to the anesthetic protocols used. The reported mean arterial pressure (MAP) values were comparable between the two treatment groups, whereas remifentanil use was associated with a lower intraoperative heart rate and a shorter operative duration. Although remifentanil may offer advantages in controlling intraoperative heart rate, its efficacy and safety compared with nitroglycerin cannot be conclusively established based on the currently presented results. Therefore, further analysis of all randomized patients, together with comprehensive reporting of bleeding outcomes, adverse events, and statistical estimates, is required before definitive clinical recommendations can be made.

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