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Effects of oral clonidine premedication on hemodynamic status in bimaxillary orthognathic surgery: A double-blind randomized clinical trial



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ABSTRACT

Purpose: Controlled hypotension during a surgical procedure is a way to decrease blood pressure and subsequently to improve the field of operation. Clonidine is an antihypertensive agent used for induced hypotension. Correction of maxillomandibular discrepancies may necessitate performing osteotomy on both jaws in many cases. Bimaxillary orthognathic surgery is a procedure that is associated with significant blood loss.

Material and methods: A total of 30 participants who were candidates for double-jaw orthognathic surgery were classified into two groups with equal numbers. In one group, 300 µg oral clonidine premedication was administered 90 min before the operation, and in the other group a placebo with the same condition as in the first group. Mean arterial pressure (MAP) and heart rate at 10 min intervals, operation time, blood loss, and surgeon satisfaction were measured.

Results: A total of 10 men and 5 women with a mean age of 22.9 ± 2.9 years in the study group and 13 men and 2 women with a mean age of 22.1 ± 2.1 years in the control group were evaluated. The MAP was significantly lower in the clonidine group ($P < 0.001$). Intraoperative bleeding was 508.67 ± 46.2 mL in the placebo group and 287.33 ± 72.06 mL in the clonidine group, and the difference was statistically significant ($P < 0.05$). Significant differences were observed in operation time ($P < 0.05$) and surgeon satisfaction ($P < 0.001$).

Conclusion: The authors of this study suggest clonidine premedication in bimaxillary orthognathic surgery. Hemodynamic stability, bleeding control, decrease of operative time, and enhancement of surgical results are advantages of this method.

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1. Introduction

Jaw skeletal discrepancy is an acquired or congenital deformity. Incongruity between the maxilla and the mandible can be due to difference in size or to the positions relative to each other (Beshkar, 2013). In the cases of marked discrepancies, sizable midline deviation, and overgrowth in all three-dimensional planes, double-jaw orthognathic surgery is indicated. Because of satisfactory results of

two-jaw surgery in 1980s, it became a common procedure to correct maxillomandibular discrepancies (Epker et al., 1982; LaBanc et al., 1982). A surgical site with the least bloodshed possible contributes to decreased surgical time, better visualization of the surgical field, and increased quality of the surgery. Induced hypotension is a way to achieve this goal. Decreasing systolic blood pressure to 80–90 mm Hg and mean arterial pressure (MAP) to less than 30% of baseline MAP are used to control hypotension (Degoute, 2007). This method may have some disadvantages, such as impairment of perfusion of vital organs. Control of blood pressure for the first time in the operating room with this method was performed in 1946 (Gardner, 1946). In oral-facial corrective surgery, hypotensive anesthesia was applied in 1976 (Schaberg et al., 1976).

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Many medications have been used for hypotensive anesthesia. Clonidine premedication has been used to control blood pressure, tachycardia, vomiting, and bleeding as well as for postoperative analgesia in many fields of surgery (Lambert et al., 2014; Cardesín et al., 2014; Quintin et al., 1996; Zalunardo et al., 2002; Marchal et al., 2001; Toivonen and Kaukinen, 1990; Ishiyama et al., 2003; Mohseni and Ebnesahidi, 2011; Mikawa et al., 1995).

Clonidine acts as an α_2 -adrenergic agonist (Quintin et al., 1996). It is a sympatholytic medication with a history of more than 40 years in clinical use and plays an important role in anesthesia and pain control (Neil, 2011).

In this study, we evaluate the effects of oral clonidine as a premedication on hemodynamic changes during bimaxillary orthognathic surgery, operative time, and level of surgeon satisfaction in association with a dry surgical field, the amount of fluid administered during operation, blood loss, and severity of bleeding. The primary end-point of this study was to decrease blood pressure. As the blood pressure becomes lower, the blood loss becomes lower and the surgical field will be improved. With that in mind, the primary outcome parameter is MAP.

2. Material and methods

A double-blind randomized clinical trial was carried out. Patients with functional or esthetic problems who were candidates for bimaxillary orthognathic surgery were enrolled in this study. The participants were selected from the admitted patients in the maxillofacial department of Shariati Hospital (Tehran University of Medical Science). The study was approved by the ethics committee of the Tehran University of Medical Science, and informed consent was obtained from all the participants before surgery. All of the participants were in American Society of Anesthesiology (ASA) classification I and II. Exclusion criteria were history of systemic disease, coagulopathy, bleeding disorder, vascular anomaly, and recent anticoagulant therapy.

Patients were divided into two groups by balanced block randomization. The first group was given 300 μ g clonidine orally 90 min before surgery. The second group was given a placebo tablet similar to clonidine at the same time. Both the surgeon and the patient were unaware of drug administration.

All the patients were nil per os (NPO) to solid and liquid diets from midnight before the day of surgery (approximately 8 h). Both groups received the same drug regimen for general anesthesia: 0.3 mg/kg midazolam, 2.5 μ g/kg fentanyl, 0.5 mg/kg atracurium, 1 mg/kg lidocaine, and 2 mg/kg propofol intravenously were administered. The patients received 3–4 cc/kg/h Ringer solution. All patients underwent the same surgical technique. First the maxilla was moved and fixed in place, and then mandibular osteotomy was performed. All surgeries were performed by the first author. The patients were in reverse Trendelenburg position about 15° and lidocaine 2% with epinephrine 1/80,000 was injected in the upper and lower vestibules 10 min before the incision.

Heart rate and MAP were recorded at the beginning of surgery and every 10 min after nasotracheal intubation during surgery.

The target and acceptable MAP was 60 mm Hg. If an increase in blood pressure occurred, trinitroglycerin (TNG) was used at a dose of 1.5 μ g/kg/min. In the case of bradycardia, 0.6 mg atropine was administered, and in hypotension status during the procedure (MAP <60) intravenous ephedrine 10 mg was used (heart rate <60 beats/min was considered as bradycardia).

The number of surgical gauze pads used was counted by the scrub assistant in the operating room and also by the operator. Gauze pads were used in such a way that they were soaked with serum and blood. To evaluate surgeon satisfaction with the field of surgery, a visual analogue scale (VAS) was used, on which

0 indicated absolute discontent and 10 indicated maximum satisfaction. The surgical time was measured from the first incision to the last suture.

After entering the data obtained from the study into the Microsoft Excel software (Microsoft Corp., Redmond, WA, USA), statistical analysis was carried out. Repeated-measurement analysis of variance, independent t-test, and χ^2 test using SPSS-16 (SPSS Inc., Chicago, IL, USA) were applied for analysis. If the P value was less than 0.05, it was considered significant. Two-sample t-test power analysis with PASS11 software was carried out for MAP, which was the primary end-point and showed 100% power (Fig. 1).

3. Results

A total of 30 patients aged 18–40 years were evaluated during 6 months; 15 patients (10 men and 5 women) were in the clonidine group, with a mean age of 22.9 ± 2.9 years. The rest of patients (13 men and 2 women) were in the control group, with a mean age of 25.1 ± 2.1 years. The mean patient weight in the experimental group was 66.23 ± 10.35 kg and 67.35 ± 10.95 in the control group. Descriptive data are shown in Table 1.

Changes in MAP and heart rate from beginning of surgery until extubation and every 10 min during the operation were evaluated in both groups. The clonidine group showed a greater decrease in MAP in comparison to the control group ($P < 0.001$) (Table 2). Heart rate was decreased in the clonidine group in comparison to the placebo group, but the difference was not statistically significant ($P = 0.07$) (Table 3). The volume and severity of bleeding, number of consumed gauze pads, amounts of fentanyl, atropine, ephedrine, fluid, and TNG intakes, time of operation, and level of surgeon satisfaction were evaluated and are summarized in Table 2. The percentage of patients given atropine and ephedrine are shown in Figs. 2 and 3. Analysis of data revealed significant differences for MAP, blood loss, surgery time, amount of fentanyl and TNG, and fluid intake, and operator satisfaction in favor of the clonidine group.

4. Discussion

Double-jaw ortho-surgery is a common procedure to correct dentofacial deformity. Like other elective surgeries, hemodynamic

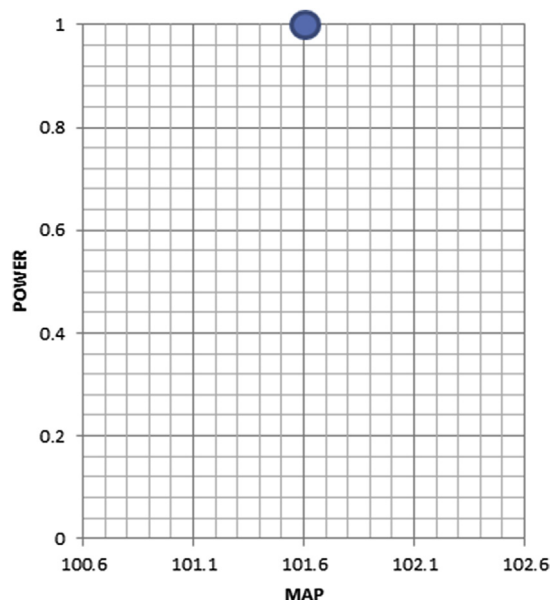


Fig. 1. Results of two-sample t-test for power analysis of mean arterial pressure (MAP).

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