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Research Article

Bleeding Reduction by Acupuncture in Rhinoplasty: A Triple-Blind Randomized Clinical Trial

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ABSTRACT

Background: Bloodless surgical field obtained by controlled hypotension reduces the bleeding, the surgical time and improves outcome of rhinoplasty and other facial plastic surgeries.
Since acupuncture is used for epistaxis, this study was designed to investigate its effectiveness in reducing the bleeding in open rhinoplasty.
Methods: In a triple-blinded randomized clinical trial, 88 patients with ASA I and II physical status, aged between 20 – 48 years, who were candidates of open rhinoplasty were enrolled in the study.
After randomization, 44 patients were assigned to each group of acupuncture or control. They were given identical anesthesia. In addition to the hemodynamic monitoring, blood loss was assessed in all patients and compared between the two groups.
Results: There were statistically significant differences between two groups in terms of the amount of bleeding (P = 0.001) and surgeon satisfaction (P = 0.010). Coagulation indicators were similar in both groups (All P > 0.05). Mean SBP and DBP, average HR and average MAP in both acupuncture and control groups did not show significant differences (All P > 0.05). Adverse events such as bradycardia or hypotension requiring treatment were not seen.
Conclusion: Our findings demonstrated that acupuncture could reduce bleeding during rhinoplasty without side effects.

Introduction

Rhinoplasty as the most common cosmetic surgery in Iran is performed on over 130,000 individuals annually [1]. This procedure is associated with various complications including intraoperative bleeding, edema and ecchymosis which carry risks for patients and complicate the operation for surgeons [2].

Intraoperative bleeding and blood in the surgical field during open rhinoplasty impairs the visibility of the field and may prolong the operation with subsequent negative impact on surgical outcomes [3]. Thus, various methods have been introduced for reduction of intraoperative bleeding, with their own merits and demerits.

As the first solution for reduction of intraoperative bleeding, Cushing introduced deliberate hypotension that could reduce the bleeding in the surgical field in 1917. This approach gained popularity over next decades [4].

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To induce deliberate hypotension, a high dose of intravenous or inhalational anesthetics are often used, which may lead to prolonged recovery and probably other adverse events. Therefore, anesthesiologists had to administer various medications to reduce blood pressure in addition to anesthetics [5].

Nowadays, growing evidence suggest that not only blood pressure but also heart rates of less than 60 beats per minute can reduce blood loss during surgery. Beta blocker agents are mainly used for this purpose [6-7].

Due to the reasons mentioned above, anesthesiologists are always looking for newer methods that can reduce bleeding during rhinoplasty with minimal complications. Tranexamic acid administration [8] and patient positioning [9] have also been suggested as methods of reduction in intraoperative bleeding during rhinoplasty.

Acupuncture as an ancient Chinese medicine has been extensively evaluated in numerous medical conditions and now is accepted as a method in integrative medicine [10]. Acupuncture has been shown to decrease the need for anesthetics, reduce postoperative nausea and vomiting, have a very–short-term effect that reduces BP during endotracheal intubation, and alleviate postoperative pain in plastic surgeries [11-14] but evaluation of its role in management of intraoperative bleeding is almost absent in the studies. A study in dental surgeries has revealed results in favor of effective role of acupuncture in reduction of intraoperative bleeding [15].

In the tradition of acupuncture, stimulation of certain acupuncture points is used for reduction of epistaxis and treatment of nasal congestion. Thus, this study was designed to evaluate application and effectiveness of acupuncture in open rhinoplasty procedures.

Methods

Study Design

This triple-blinded randomized clinical trial study was designed according to the CONSORT guidelines. The approval from ethical committee of Tehran University of Medical Sciences was obtained and the study was submitted in IRCT registry with code of 2013073114238N1. 88 ASA I, II patients aged 20 to 48, who were candidates for primary open rhinoplasty during an 18 consecutive months period, were enrolled in the study. An informed written consent was obtained from all patients. For obtaining the study power of 95% and detecting 20% reduction of intraoperative bleeding in the intervention group, the P value of 0.05 was considered significant.

Exclusion criteria were recent treatment with acupuncture, revision surgery, cardiovascular disease (congestive heart failure, coronary artery disease), cerebrovascular disease, poorly controlled arterial hypertension, history of renal or hepatic insufficiency, history of drug abuse, the presence of a pacemaker, coagulation disorders, neurological disorders, pregnancy and patients taking corticosteroid.

Patients were randomly assigned to either groups of acupuncture or control by a computer-generated random number (Figure 1).

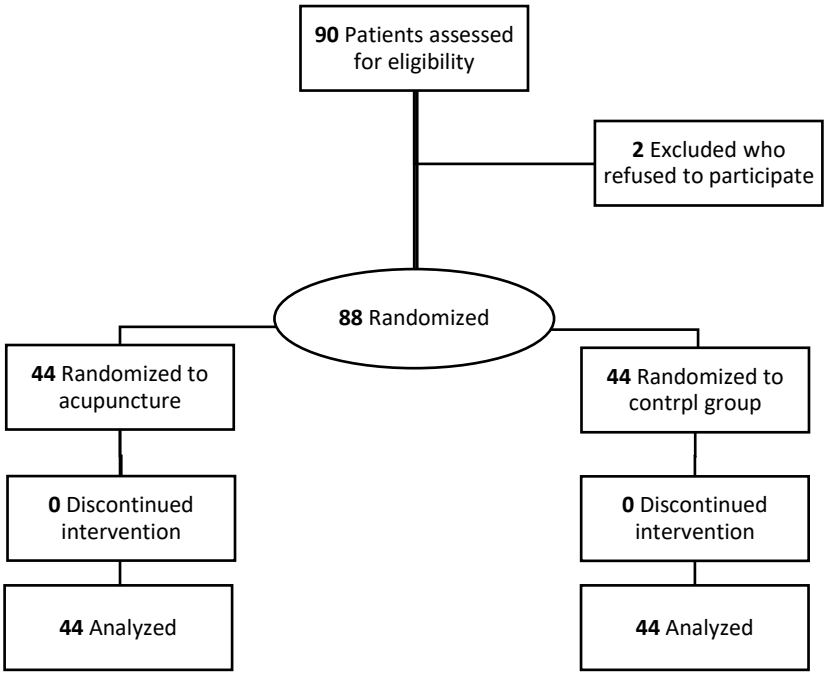

Figure 1- Consort Diagram of study

Anesthesia and Surgery Technique

After preoxygenation, all patients were premedicated by midazolam 0.02 mg/kg and 2 µg /kg of fentanyl. Anesthesia was induced by 2mg/kg of propofol and 0.6mg/kg of atracurium.

After 3-4 minutes, patients were intubated and anesthesia was maintained similarly in both the groups by mixture of 50% nitrous oxide and oxygen along with isoflurane 1%. An end-tidal carbon dioxide concentration of 35-45 mmHg was maintained. Muscle relaxation was maintained by atracurium 0.1mg/kg every 30 minutes. Monitoring included noninvasive arterial pressure (NIBP), electrocardiogram, pulse oximetry and capnography. Controlled hypotension was attained by the infusion of propofol 50-75 mcg/kg/min and remifentanil 0.05-0.5µg/ kg/min in both the groups in the same manner with the aim of mean arterial pressure (MAP) of 65-70 mm/Hg. If the patient developed higher MAP of 70 mm/Hg, dose of anesthetics and analgesics was increased up to maximum allowable amount. Ephedrine had been considered as rescue agent if MAP was less than 50 mmHg, and atropine had been considered if heart rate was less than 60/min. At the end of surgery and before extubation, the muscle relaxation was reversed with neostigmine (0.04 mg/kg) and atropine (0.02 mg/kg). Postoperative recovery was assessed using a modified Aldrete score. This anesthesia method is routinely used in rhinoplasty. All patients were placed in 30-degree head up supine position during the procedure. The technique of surgery was open rhinoplasty in both the groups and performed by the same group of surgeons. For all patients, 10 mL of a mixture of 2% lidocaine and 1 in 200,000-epinephrine solution was infiltrated in the nose 15 min before surgical incision. Intraoperative blood fluid was managed by normal saline 4-5ml/kg/hr.

Intervention

Prior to the surgery, acupuncture points of LI-4, LI-11, LIV-3, SP-1, ST-45 and BL-67 were detected by an anesthesiologist, who is a member of acupuncture society with more than 5 years of experience, who was not interested in the study, with the help of FDA approved PR 0900 TENS, device (acuhealth, PTY, Australia) for better finding points.

After disinfection he stimulated the mentioned points in the intervened groups directly on the skin, by the sterile disposable titanium 27-gauged 3mm-long HUNAQLV CHINA acupuncture needles, while in the control group the same needles were held at same points by the help of adhesive tape. After 30 minutes, the needles were removed in all patients.

Blinding

The acupuncture points and needles were covered by drapes in both groups for 30 minutes, in order to make other members of the team blind to the group assignment of patients. Another anesthesiologist, who was blinded to the treatment group allocation, collected the data during the operations.

Outcomes and Measures

Intraoperative blood loss was assessed by the sum of blood volume in the suction apparatus and weight difference before and after operation of weighed used sterile gauzes during operation. All surgical gauzes were weighed by a digital sarterius, TE 153 mode weight scale with accuracy of 0.01 gr. Each 1.05-gram increase in the weight of stained gauzes was considered as 1ml of bleeding. In addition to the mentioned method of bleeding assessment, the amount of bleeding was rated according to following 6 points scale for evaluation of surgeon's satisfaction based on surgical field visibility during surgery developed by Fromme and Boezaart et al (Table 1). Hematocrit and hemoglobin levels and coagulation parameters were assessed preoperatively and 6hours post operatively. Recorded hemodynamic parameters were Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR) every 5minutes, from prior to induction of anesthesia until the end of surgery. Postoperative hemodynamic parameters and Richmond score also were recorded for each patient.

Table 1- Surgical field visibility grading system

Grade	Assessment
0	No bleeding, cadaveric conditions
1	Slight bleeding, no suctioning required
2	Slight bleeding, occasional suctioning required
3	Slight bleeding, frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed
4	Moderate bleeding, frequent suctioning required, and bleeding threatens surgical field directly after suction is removed
5	Severe bleeding, constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible

Statistical Analysis

Data analysis was performed using SPSS version 16 (SPSS Inc., Chicago, Illinois, USA), by Independent-Samples t-Test, Chi Square Test, Mann-Whitney U test, Kolmogorov-Smirnov Test, Repeated Measures ANOVA, and Bonferroni Pairwise Comparisons Test. P value ≤ 0.05 was considered significant.

Results

Finally, 88 patients (44 in acupuncture group and 44 in control group) between the ages of 20 and 48 years were analyzed in this study. Demographic parameters showed no significant differences between the two study groups (all P>0.05) (Table 2).

The acupuncture group presented significantly less suctioned blood volume and lowered difference in weighting of blood gauzes pre- and post-operatively compared to control group (Table 3).

Suctioned blood volume in the acupuncture group and the control group were 41.48 ± 34.33 mL vs. 63.98± 14.01 mL, respectively (P = 0.001). Weighting blood gauze differences in the acupuncture group and the control group were 9.95± 3.54 mL vs. 13.45 ± 4.6 mL (P= 0.001).

The surgeon was more satisfied about the surgical field quality in acupuncture (2.09 ± 0.29) than the control group (2.41 ± 0.49) (P= 0.010). Richmond score was better in acupuncture group (0.39 ± 0.61) than control group (1.14 ± 0.65) (P= 0.0001).

The patients in acupuncture group had shorter mean surgery time (226.2 ± 15.12 minutes) than those in the control group (239.3 ± 14.11 minutes) without significant difference (P= 0.423) (Table 3).

In addition, there were no significant differences in heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) between the two groups at any measured time point (before, during, and after the operation) (all P> 0.05).

Hematocrit and hemoglobin levels and coagulation parameters such as PT, PTT, INR and platelet count showed no significant difference between two groups (all P> 0.05).

Adverse events such as bradycardia, resistant hypotension or hypertension requiring treatment were not seen in patients in either group.

Table 2- The Comparison of Demographic Variable of the Study Groups

Variable	Acupuncture (n=44)	Control (n=44)	P value
Sex (male/female)	12/32	17/27	0.38
Average Age* (year)	30.52±6	29.80±6.1	0.57

*Mean ± SD

Table 3- Comparison of the Main Results Between the Groups (n=88)

Variable	Acupuncture (n=44) (Mean±SD)	Control (n=44) (Mean±SD)	P value
Duration of Surgery (h)	226.2±15.12	239.3±14.11	0.423
Surgeon's Satisfaction about Surgical Field*	2.09±0.29	2.41±0.49	0.010
Suctioned Blood Volume (ml)	41.48±34.33	63.98±14.01	0.001
Differences in Weighting of Blood Gauze (gr)	9.95±3.54	13.45±4.6	0.001
PT	11.78±0.54	11.64±0.52	0.286
PTT	30.11±2.77	30.20±2.48	0.939
INR	1.032±0.087	1.018±0.032	0.439
PLT	277431±45296	285045±52085	0.467
Richmond Score (Index)	0.39±0.61	1.14±0.85	0.0001

* Fromme and Boezaart Score

Discussion

In this study, acupuncture was used for reduction of intraoperative and postoperative bleeding in rhinoplasty for the first time. Richmond index and satisfaction levels were improved with acupuncture compared to control group. The average blood loss volume in the case group was significantly less than the control group. Average SBP, DBP, MAP, and HR did not show a significant difference between case and control groups in three time-points.

Based on the theory of traditional Chinese medicine, acupuncture stimulation in certain areas and at specific depth of the skin may have distinct therapeutic effects. For instance, stimulation of certain points may reduce blood flow to the head and neck, lower congestion in these areas and even decrease bleeding in a patient with epistaxis. The safety of acupuncture has been confirmed in several studies and except for mild and minor side effects in very few cases, no major complications has been reported consequent to acupuncture [10].

Application of acupuncture in plastic surgeries and rhinoplasty has showed numerous advantages. Larson et al [11] evaluated acupuncture on 122 plastic surgery patients. Acupuncture led to significantly lower scores of nauseas postoperatively. Hospital stay duration and analgesics consumption were also lower with

acupuncture. White et al [13] showed that nausea, vomiting and patients' satisfaction were significantly improved with acupuncture in plastic surgery patients. In a study by Pohodenko et al [12], acupuncture was associated with 62% full alleviation of postoperative pain and 38% partial improvement of pain. Lao et al [16] also showed that acupuncture was superior to placebo in prevention of postoperative pain in dental surgeries. Majority of available studies have been in favor of beneficial effects of acupuncture in nausea, vomiting and postoperative pain but a single study was found to have evaluated the impact of acupuncture on bleeding in surgical interventions. Gil et al [15] evaluated 22 patients undergoing dental surgery. It was observed that bleeding volume was 25 ml in acupuncture group while it was 35 ml in the control group (p=0.04). This finding is consistent with our results that acupuncture can significantly reduce intraoperative bleeding in rhinoplasty surgeries.

These findings place acupuncture in a position comparable to other therapeutic agents for reduction of intraoperative bleeding during rhinoplasty. Clonidine as a candidate for this purpose has been evaluated in a study. In that study it was demonstrated that clonidine could significantly decrease intraoperative blood loss compared to controls. Surgeons' satisfaction was significantly in clonidine receivers compared to non-clonidine receivers [17]. Another suggestion for management of intraoperative bleeding has been beta blocker agents. Rahimzadeh et al [6] have evaluated the impact of metoprolol in nasal surgeries. They revealed that patients receiving two doses of metoprolol had slight intraoperative bleeding. In addition, metoprolol improved quality of field for surgeons and decreased agitation of patients in the recovery phase. Tranexamic acid is another potential agent in reduction of intraoperative bleeding in rhinoplasty which has been evaluated in several studies. A systematic review and meta-analysis on these studies has concluded that tranexamic acid is significantly efficacious in reduction of intraoperative blood loss in rhinoplasty patients while its impact on postoperative ecchymosis and edema is not clear, by far [8]. In recent years, several articles have suggested that body positioning can impact intraoperative blood loss in rhinoplasty. Reverse trendelenburg is known to lower intraoperative blood loss in comparison to supine position. This position also enhances the quality of working space for surgeons [9].

The main limitation in our study was lack of administration of other agents for reduction in bleeding. Comparison of these agents in future studies with acupuncture can reveal more comprehensive results. Higher sample size in future studies also enhance the study strength.

Conclusion

In this study, acupuncture was used for the first time as an innovative method for reduction of bleeding in rhinoplasty. Our findings showed that acupuncture as a safe modality could be effective for reducing intraoperative bleeding in rhinoplasty and postoperative period without any side effects.

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