



Original Article

Investigating the Effect of Oral Clonidine on Surgeon Satisfaction from Surgical Field in Septorhinoplasty

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ABSTRACT

Introduction: Haemorrhage during septorhinoplasty surgery is challenging for the surgeons since it can reduce the visibility of the surgical site. Thus, the present study aimed to investigate the effect of oral clonidine on surgeon satisfaction in surgical zone quality in septorhinoplasty.

Methods: This was a double-blind randomized clinical trial on 53 patients undergoing septorhinoplasty at Motahari Hospital in Jahrom. The patients were randomly divided into two groups: Oral clonidine and placebo. Demographic information, weight, level of intraoperative fluid infusion, mean arterial pressure (MAP), heart rate, and intraoperative surgeon satisfaction data were analysed considering the surgeon's satisfaction as the primary endpoint.

Results: Systolic and diastole blood pressure and mean arterial pressure (MAP) were not significantly different between the two groups. Mean heart rate significantly differed between the groups after induction, 1 minute, 5 minutes, 15 minutes, 30 minutes, 60 minutes, and getting out of the recovery room ($P > 0.05$). There was no significant difference between the study groups at different times in terms of the level of surgeon satisfaction ($P < 0.05$).

Conclusion: The findings of current study demonstrated that there was no considerable difference in surgeon satisfaction after septorhinoplasty surgery between the clonidine and control groups. Since limited studies have been conducted on surgeon satisfaction during septorhinoplasty surgery, new contributions might lead to novel clinical procedures with alternative approaches. Integration of clinical knowledge and clinical experience to design evidence-based clinical investigations on surgery site quality is needed.

GRAPHICAL ABSTRACT



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Introduction

Cosmetic plastic surgery has increased in the recent years [1]. According to the reports of the American Society of Plastic Surgeons, cosmetic surgical procedures in the United States have been increased to 98% from 2000 to 2012 [2]. In 2013, Iran was ranked first in the world, while more than 175,000 surgical and non-surgery operations have been carried out in Iran [3]. Septorhinoplasty is one of the most accurate, delicate, and difficult plastic surgeries, but it might be associated with complications, like any other surgery [4-6]. Incessant bleeding at the surgical site is one of the key hurdles in large procedures that can negatively impair the quality of the surgery and the needed time. It can drastically restrict the surgeon's manoeuvring on the target tissue and result in unintended attacks on nearby limbs [7]. Despite several advancements in surgical and anaesthetic procedures, bleeding during septorhinoplasty surgery remains an issue, and even a tiny quantity of blood might impair the surgeon's field of vision, lengthen operation time, or result in incomplete surgery [8]. Sometimes, heavy haemorrhage leads to termination of surgery even in limited field surgery. Common methods used by the surgeons and anaesthesiologists to reduce haemorrhage in this type of surgery include raising the head relative to the body surface, injecting epinephrine at the surgery site, and inducing controlled hypotension [9]. In some cases, clonidine tablets are given to patients on the morning of the operation before surgery [10-13]. Various techniques can reduce haemorrhage, including hemodynamic methods such as controlled hypotension and local vasoconstrictors. Various drugs can be used to induce controlled hypotension [14]. Alpha-2 agonists are anaesthetic adjuvants that reduce the peripheral release of epinephrine and are used as antihypertensive drugs. Clonidine is considered one of these drugs [15], used to treat hypertension, congestive heart failure, sedation, and quitting addiction [16]. Clonidine lowers

arterial blood pressure without lowering postural blood pressure. It also reduces heart rate and general haemorrhage during surgery and reduces stress during surgery [17]. Clonidine was used before surgery of sinus endoscopy and improved the quality of the surgical field [18]. In their study, Sadri et al. showed that the oral premedication of Clonidine could satisfy the surgeon during rhinoplasty surgery [19]. Cosmetic surgeries such as Septorhinoplasty require reducing hemodynamic fluctuations to reduce haemorrhage during the surgery and improve the surgeon's field to perform the surgery, which in turn reduces complications of surgery during and after operation and the decreases patient's recovery time. The present study aimed to investigate the effect of oral clonidine on surgeon satisfaction in surgical field in septorhinoplasty

Methods

This was a double-blind randomized clinical trial on 53 patients undergoing septorhinoplasty at Motahari Hospital in Jahrom. The research method was clarified to the patients before they were recruited for the trial, and they volunteered their informed consent. Researchers followed the principles of the Helsinki Declaration and kept patient information secret all through the trial. The researchers covered all project expenditures, and the patients were not charged any additional fees. The ethics committee of Jahrom University of Medical Sciences authorized the current study under the code of ethics IR.JUMS.REC.1400.072. Using the Altman nomogram, the sample size was calculated to be 60 participants in each group, assuming a standard difference of 0.85 and a 95 percent confidence level of power of 80 percent. The samples were then randomly assigned to research groups (30 participants in each group of intervention or placebo) via coin-flipping, with equal chances of being included in either the intervention or control groups. Sampling proceeded until the two groups were in agreement on fundamental criteria (Figure 1).

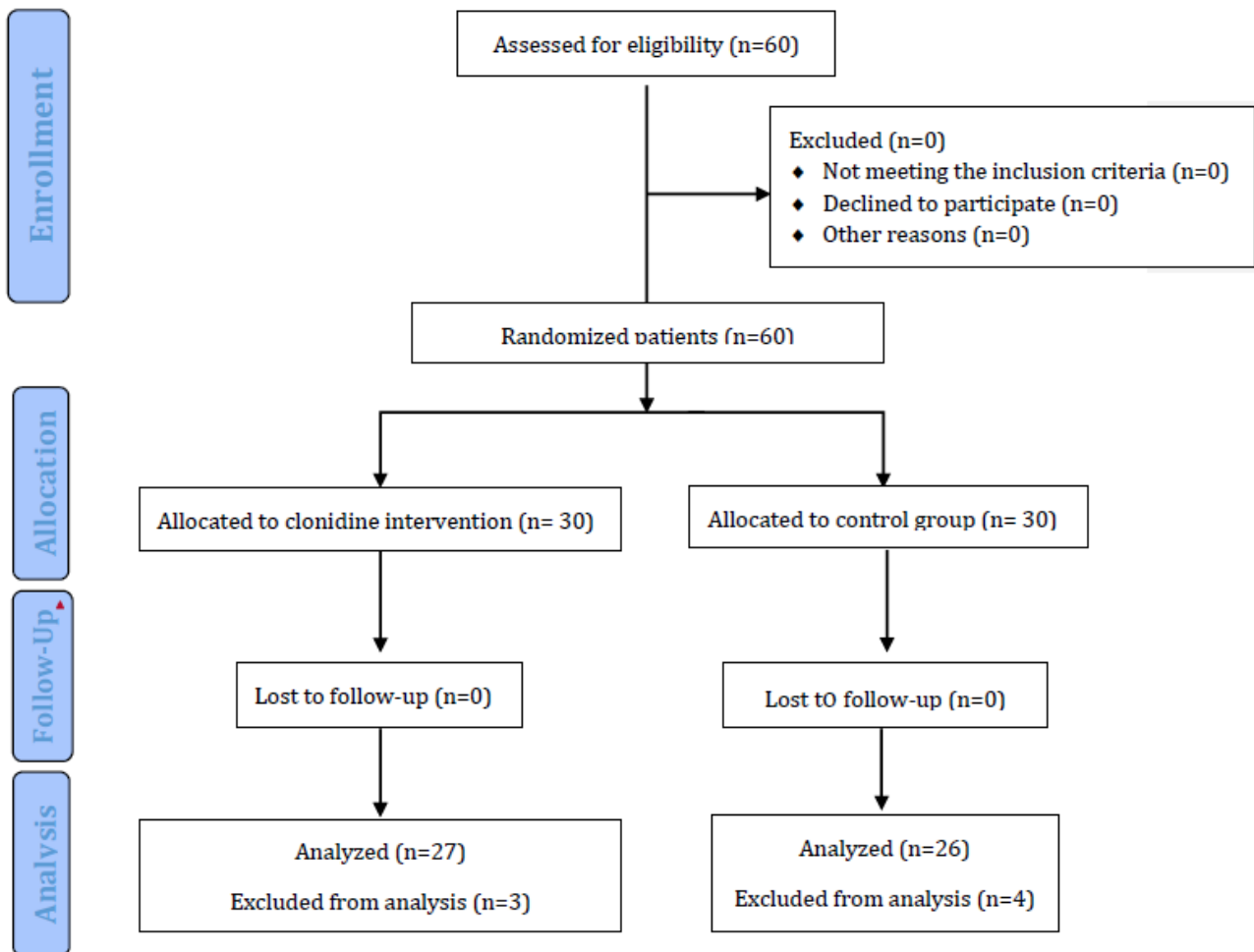


Figure 1: The consort flow diagram of the study

The research inclusion criteria included all subjects over 18 years, haemoglobin above 10, normal PT / PTT / INR, normal hemodynamic, and heart rate above 60 beats per minute. Exclusion criteria included patients with coagulation disorders, coronary artery disease, stroke, venous thrombosis, and allergy to clonidine. The patients were randomly divided into clonidine and placebo groups based on coin-flipping. Group A was treated with oral 0.2 mg of clonidine (Alborz Pharmaceutical Company) and Group B was treated with a placebo. The patient, the operation room nursing staff, and the data analyst were not aware of the type of the drug. Both groups received the drugs orally (with a small amount of water) two hours before induction of anaesthesia. Both groups of patients underwent septorhinoplasty by a single surgeon. Age, gender, weight, level of fluid intake during surgery, systolic and diastole blood pressure, mean arterial pressure (MAP), heart rate, and surgeon satisfaction during surgery were

recorded. Extremely bloody field (interference with surgeon work), reasonably bloody field, comparatively clear field and absolutely clear field were used to evaluate surgeon comfort during surgery. The data were analysed with the SPSS, version 21, and both descriptive (mean and standard deviation) and inferential statistical tests (t-test, Fisher, and Mann-Whitney) were run at a significance level of $P < 0.05$.

Results and Discussions

Sixty patients with the American Society of Anaesthesiologists (ASA I) who had septorhinoplasty were assessed. They ranged in age from 18 to 44 years old (in two groups of 30). Finally, the data from 27 clonidine patients and 26 control patients were analysed. There were 21 female patients in the clonidine group (77.8%) and 23 female patients in the control group (88.5%). The study groups were similar in terms of age, weight, gender, and the amount of fluids infused throughout the procedure ($P > 0.05$). The

clonidine group had substantially higher mean systolic blood pressure than the control group 60 minutes after induction ($P = 0.04$). However, there was no significant change in mean systolic and diastolic blood pressure between the two groups at different periods ($P > 0.05$). The trend of mean systolic and diastolic

blood pressure in the clonidine and control groups indicated a significant difference from before induction to recovery mode ($P 0.001$). From induction to 120 minutes after induction, mean systolic and diastolic blood pressure fell, but then rose (Figure 2 and 3).

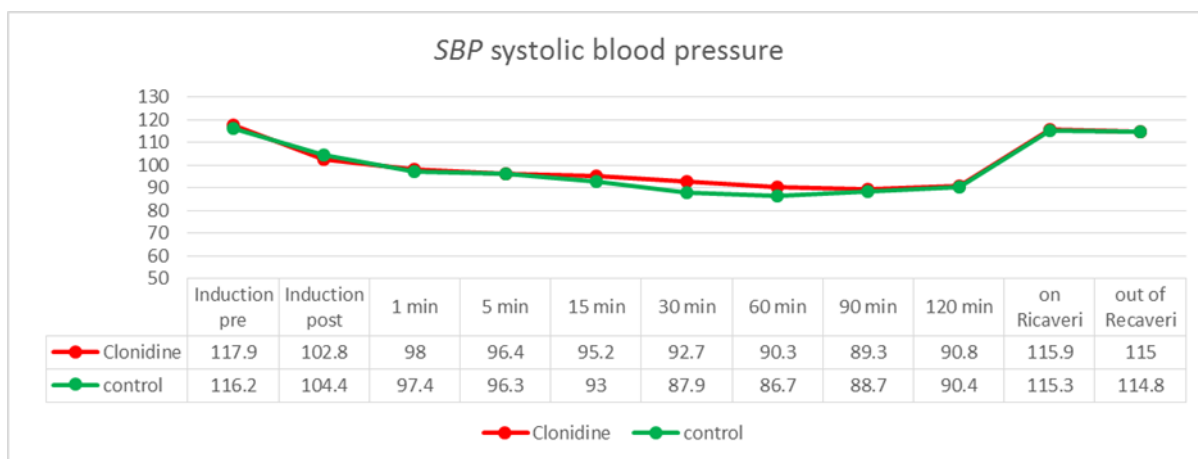


Figure 2: Comparison of SBP variables between clonidine and control groups at different times

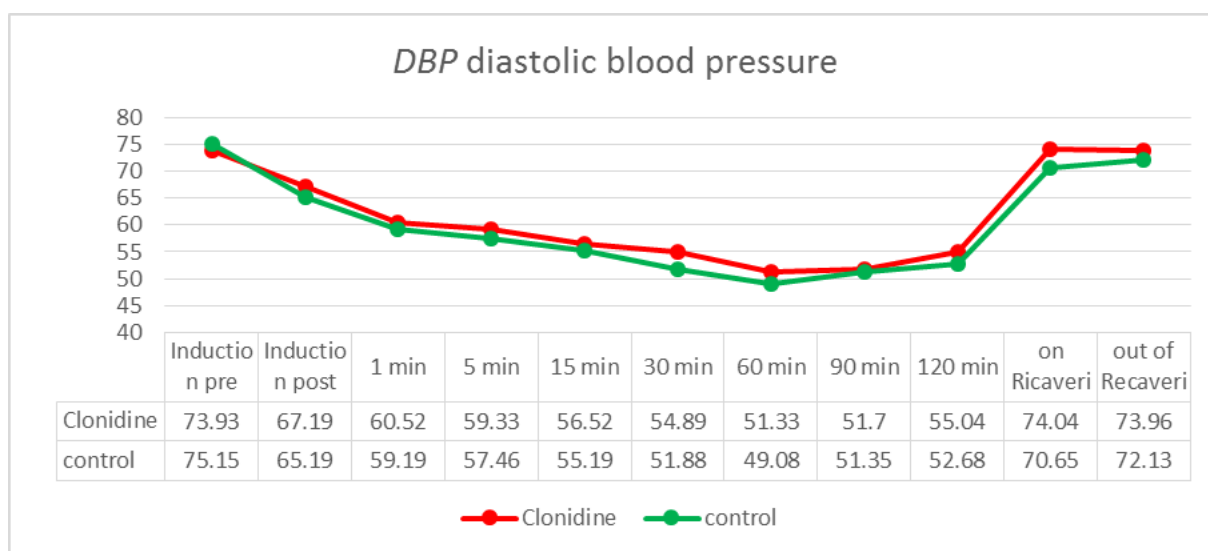


Figure 3: Comparison of DBP variables between clonidine and control groups at different times

At 60 minutes after induction, the mean MAP was considerably higher than the control group ($P = 0.02$). However, no significant change in mean MAP was seen between the two groups in any of the periods investigated ($P > 0.05$). The mean trend of MAP in the clonidine and control groups

differed significantly from before the induction to get out of recovery mode ($P < 0.001$). From the time before injection to 90 minutes after injection, the mean MAP fell, but then rose (Figure 4).

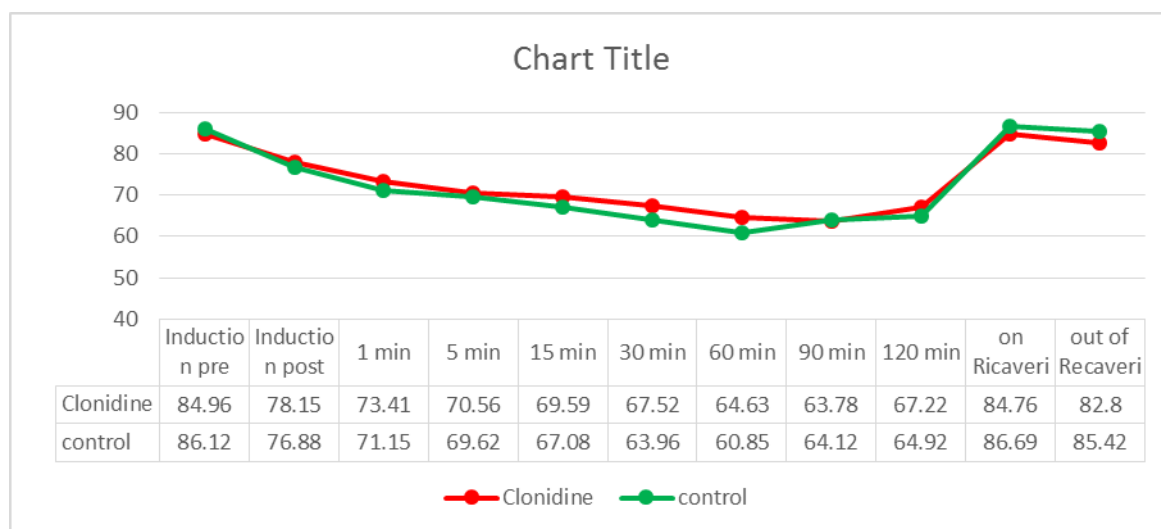


Figure 4: Comparison of MAP variables between clonidine and control groups at different times

A significant difference in mean heart rate was detected between the two groups in all timelines; after induction, minute 1, minute 5, minute 15, minute 30, minute 60, and getting out of the recovery room ($P < 0.05$). The clonidine group had a lower mean heart rate after induction, minute 1,

minute 5, minute 15, minute 30, minutes 60, and getting out of recovery mode than the control group. The Mann-Whitney test revealed that there was no significant difference between the two groups in terms of surgeon satisfaction at the various times evaluated ($P > 0.05$) (Table 1).

Table 1: Comparison of surgeon satisfaction between the clonidine and control groups at different times

Variable	Time	Group				P-value	Test
		Clonidine		Control			
		Mean	SD	Mean	SD		
Surgeon Satisfaction	15 min	3.32	0.84	2.90	1.09	0.22	Mann-Whitney
	30 min	3.46	0.81	3.42	0.81	0.87	Mann-Whitney
	45 min	3.67	0.62	3.38	0.75	0.13	Mann-Whitney
	60 min	3.70	0.54	3.73	0.53	0.82	Mann-Whitney
	90 min	3.52	0.70	3.81	0.49	0.08	Mann-Whitney
	120 min	3.72	0.46	3.92	0.27	0.06	Mann-Whitney

Controlled hypotension during surgery can help reduce surgical site bleeding and improve the surgeon's field of vision [20-21]. Clonidine is one of the medications used for this purpose. Clonidine, an imidazole molecule, is an antihypertensive drug that appears to work by activating central alpha-2 adrenergic receptors, reducing sympathetic flow [22-24]. Other research in this area has found that clonidine has a beneficial influence on surgeon satisfaction with the surgical field, hence the findings of previous studies contradict those of the current study. According to the findings of a study done by Zangouei *et al.* (2019), surgeon satisfaction with the surgery field was higher in the clonidine group than that in the promethazine and

morphine groups [25]. Sadri *et al.* showed that the oral premedication of Clonidine could satisfy the surgeon during rhinoplasty surgery [19].

According to the findings of research by Nadri *et al.* (2014), pre-medication with clonidine improves surgeon satisfaction during tympanoplasty surgery [26]. According to Mohseni *et al.* (2012), the surgeon in the clonidine group was happier with the surgical field compared with the placebo group [27]. The satisfaction of surgeons with the surgical field was not substantially different between the clonidine and tranexamic acid groups, according to the findings of a study done by Ghorbani *et al.* (2018) [28]. During FESS surgery, Puthenveetil *et al.* [2013] discovered that an oral prodrug

containing 300 mg of clonidine gave a superior surgical field to 50 mg oral metoprolol [29]. Wawrzyniak reported that pre-medication with clonidine before FESS could result in a shorter surgical time and a better surgical field [18]. Mohammadi *et al.*, reported that clonidine oral premedication can improve surgeon satisfaction during surgery [30]. The findings of this study revealed that taking 2 mg of oral clonidine before surgery did not improve surgeon satisfaction during septorhinoplasty surgery. Future research should be undertaken with bigger sample size and compare different medication groups.

Conclusion

The findings of this study demonstrated that there was no significant difference in surgeon satisfaction during septorhinoplasty surgery between the clonidine and control groups. Because there have been few studies on surgeon satisfaction during septorhinoplasty surgery, new clinical methods with various approaches, as well as the integration of clinical knowledge and clinical experience to generalize the results of evidence-based clinical studies on patient treatment, can be of great use.

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Authors' contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

Conflict of Interest

There are no conflicts of interest in this study.

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