Evaluation of the anesthetic effect of nasal mucosa with tetracaine 0.5% on hemodynamic changes and postoperative pain of septoplasty: A randomized controlled trial

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Abstract

The nasal septum repair surgery is the dangerous operations that any stimulation of this area causes a large change in the rhythm of the heartbeat and blood pressure. This study aimed to determine the effects of tetracaine 0.5% on changes in heartbeat and heart rhythm, hemodynamic changes during surgery, intraoperative bleeding, and pain after septoplasty surgery. The irregular double-blind clinical trial registry of clinical trials Iran with the code number (IRCT: 201505262625N8) in the first half of 2013 on 86 patients in Kashani hospital of Shahrekord. Having selected and matched the patients were divided into two groups. Case group was dropped tetracaine 0.5% in each of the nasal cavity 15 min before the beginning of the operation. The control group was dropped distilled water 15 min preoperation in each of the nasal cavity. The surgery lasted about 30–60 min. Clinical symptoms were evaluated after anesthetic induction as well as pain using the visual analog scale after the operation, in the recovery room.

The collected data were analyzed using SPSS version software 17 through independent t-test, Chi-square, and repeated measures variance analysis. Postoperative pain intensity in the experimental group compared to the control group was significantly lower than the control group (P < 0.05); however, blood pressure and heart rate during anesthesia, there was no difference between groups (P > 0.05). Based on the findings, intake of tetracaine drop 0.5% has no impact on some hemodynamic changes during septoplasty operation. However, compared with the control group, pain was significantly reduced.

Key words: Blood pressure, pain, pulse rate, septoplasty, tetracaine 0.5%

INTRODUCTION

The nasal septum repair surgery is so-called septoplasty. Septoplasty can be performed with general anesthesia or intravenous sedation or by means of local anesthesia. Operative problems, including heart rate and blood pressure changes are due to the manipulation of area of surgery, since area of surgery has lots of nerve through the autonomic system and submucosal adrenaline and phenylephrine drop are commonly used to reduce bleeding during surgery that it causes changes in heart rate and predisposing patient

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to cardiac arrhythmias and hypertension.[11] The use of appropriate topical anesthesia is high significance in patient satisfaction, reduced bleeding, and safety of surgery.[2]

One of the methods used in septoplasty surgery is local anesthesia without general anesthesia. The advantage of this method is not to require general anesthesia and to reduce bleeding.[3]

Tetracaine is a local anesthetic, which is highly effective and has been commonly used for eye surgery for many years.[4,5] Tetracaine cause to control the passage of sodium through the cell membrane in competition with the calcium perfused on the nerve membrane receptors and to reduce action potential depolarization phase. This impacts started by reversible stabilizing of the nerve cell membranes, and consequently reducing the permeability of this membrane to sodium ions, and stop the conductivity of nerve impulses. Besides, its injections are used for spinal, epidural, peripheral nerve blockage, epineurium, and the lower extremities.[6] Tetracaine dose is 0.1–0.2 mg/kg and the duration time is 90–200 min.[7] Few side effects have been reported for tetracaine with therapeutic doses. However, if the patient has symptoms of poisoning such as seizures, vertigo, tinnitus, tremor or trembling, nervousness or unusual restlessness, vomiting will be occurred.[8] Of the benefits of anesthetic tetracaine can point out to its fast-acting, long-term, having low-risk of methemoglobinemia as well as strong anesthetic properties comparing other local anesthetics.[9] A study suggested the use of this drug in the nasal endoscopic surgery in their study.[10] Surgical repair of the nasal septum (septoplasty) is one of the high-risk surgeries because it is the place where nerve manipulation of the automated system is occurred. Any stimulation of this area causes significant changes in heart rate and blood pressure. Since to have peripheral vision, bleeding is needed to be few during surgery, so vasoconstrictor compounds such as adrenaline and phenylephrine is used. These compounds trigger to increase heart rate and blood pressure due to their high absorption. These factors are the main causes of irregular heartbeat and potential incidence of tachycardia and ventricular fibrillation. One proper solution is the use of anesthetic drops having good mucosal absorption. Which reduces painful nerve stimulation, to prevent high blood pressure and heart rate and reduces post-surgery restlessness of patient in the recovery room? Regarding the cases mentioned in this study, we aimed to assess the effects of tetracaine 0.5% on hemodynamic changes during surgery and postoperative septoplasty pain.

METHODS

The irregular double-blind clinical trial registry of clinical trials Iran with the code number (IRCT201505266625N8) in the first half of 2013 on 86 patients in Kashani hospital of Shahrekord University of medical sciences was performed. Determining the sample size with analysis method accuracy with the formula $n = Z^2α/2σ^2/d^2$ by, respectively, choose to enter the study the patient’s age 15–35 years, candidate for septoplasty and class American Society of Anesthesiologists 1, 2, exclusion criteria were having hypertension, sensitivity to tetracaine, history of addiction to opioids, nonsteroidal anti-inflammatory drugs used >5 days in recent months, body mass index >30 and <5/18, duration of surgery >45 min. The use of any drug except for during anesthesia is required and is not defined.

Patients randomization was by patient file number. Patients were divided into two groups after reviewing the necessary 5 min before induction of anesthesia into the nasal cavities of the intervention group, and the control group received 0.5% tetracaine and distilled water was dropped. Of a general anesthesia were the same for both groups induction of anesthesia (fentanyl 3 μg/kg, thiopental 5 mg/kg, and atracurium 0.5 mg/kg) were used. For maintenance of anesthesia of propofol 5 mg/kg/h was used. Heart rate and blood pressure were recorded every 5 min until the end of anesthesia.

At the end of surgery and anesthesia, patients were transferred to the recovery room and 30 min after the transition to recovery pain scores were determined using visual analog scale (VAS). Patients were matched for age and sex into two groups using t-test and Chi-square test. Data from this study were collected from the checklists software was analyzed by SPSS version 17 (Chicago, IL: SPSS, Inc) with variance analysis, Chi-square tests, t-test were analyzed. Statistical significance was considered as 0.05.

In this study, the expected tetracaine reduced hemodynamic changes and postoperative pain in the intervention group.

Prespecified primary and secondary outcome measures induced by nasal mucosal numb was by tetracaine. This blocking stimulation of sympathetic system cause unchanged of blood pressure and heart rate perioperation and reduced of postoperative pain.

According to interviews, history taking, clinical and laboratory findings, patients were assigned to the interventions of interest representing by the cards labelled A or B encoded by an anesthesia nurse who poured into the nose.

RESULTS

In this study of 86 patients undergoing septoplasty surgery were 34 patients on the basis of exclusion criteria were excluded from the study [Figure 1].

According to the independent t-test, there was no significant difference between the two groups in terms of age. The mean
age of the first group was 18.28 years, and 37.31 years were the second group ($P > 0.05$).

In the first group, 28 patients (5/87%) and 4 patients (12.5%) were female and 25 patients in the second group (3/83%) were male and 5 (16.7%) were female. Using the Chi-square test, there was no significant difference between the two groups in terms of sex ($P > 0.05$).

In this study, based on analysis of variance with repeated changes in systolic blood pressure and heart rate in four steps variables measured in the two groups showed no significant difference ($P > 0.05$) [Tables 1 and 2].

Average pain intensity 30 min after arriving at recovery based on the VAS scale using analysis of variance indicated the intensity of pain after surgery in Group A (cases) compared to the second group (control) was significantly lower were $P < 0.05$ [Table 3].

**DISCUSSION**

The results of our study showed that tetracaine 0.5% is effective in reducing pain in patients who have undergone septoplasty surgery but has no effect on hemodynamic changes.

In a similar study on 200 patients undergoing septoplasty, the results showed significantly lower pain scores in patients treated with tetracaine than in patients treated with cocaine.

In addition, it was demonstrated that adrenaline solution with a local anesthetic tetracaine is effective and safe for patients undergoing septoplasty.\[12\]

In contrast of results of our study, in the study by Grant and Johnston pain and discomfort were reported by some patients during or after surgery receiving local anesthetic tetracaine.\[12,13\]

In the study by Drivas, to compare the effects of cocaine solution 4% compared with tetracaine 2% with adrenaline, local anesthetics for patients undergoing septoplasty surgery showed significantly less pain in the tetracaine group than cocaine group.\[14\] In the study by Bourolias, the effect of lidocaine spray with a tetracaine solution in 48 patients undergoing laryngoscopy was examined, and it was shown that mean pain score was significantly lower in the tetracaine group than that of lidocaine. Furthermore, no side effects were reported for the use of lidocaine or tetracaine in both groups.\[15\]

In the current study, the patients had shown no complications regarding the use of tetracaine 0.5%. In a similar survey, pain score in tetracaine group was reported less than normal saline in patients undergoing septoplasty surgery. Besides, in this study, no adverse effects were reported for tetracaine group.\[16\]

In the study by Ezra, tetracaine 0.5% was mentioned as a safe and effective local anesthetic in many cases, such as cataract surgery.\[17\]

In the current study, the use of tetracaine 0.5% was not effective on the blood pressure and pulse rate and changes of these hemodynamic variables were reported similar in both groups.

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**Table 1: The average heart rate between the two groups**

| Average systolic blood pressure | Intervention group (mmHg) | Control group (mmHg) | $P$  |
|--------------------------------|---------------------------|----------------------|------|
| Before anesthesia              | 134±14                    | 120±24               | >0.05|
| 10 min after anesthesia        | 132±20                    | 122±25               | >0.05|
| 15 min after anesthesia        | 120±32                    | 125±22               | >0.05|
| 20 min after anesthesia        | 114±34                    | 124±20               | >0.05|

**Table 2: Average heart rate between the two groups**

| Average heart rate | Intervention group | Control group | $P$  |
|--------------------|--------------------|---------------|------|
| Before anesthesia | 92±6               | 84±4          | >0.05|
| 10 min after anesthesia | 87±5              | 89±6          | >0.05|
| 15 min after anesthesia | 85±7              | 86±9          | >0.05|
| 20 min after anesthesia | 86±2              | 94±4          | >0.05|

**Table 3: Mean pain intensity between the two groups after surgery**

| The mean pain score on a scale from VAS | Intervention group | Control group | $P$  |
|----------------------------------------|--------------------|---------------|------|
| 2.35±0.68                              | 3.53±1.1           | <0.05         |      |

**Figure 1:** The entry and exit of patients
In a similar study by Kobayashi, it was seen in patients undergoing prostate surgery, there were significant differences between the two groups, tetracaine 0.5% with or without phenyl ephedrine 0.25% given to the beginning time of induction at the maximum level of the sensory blockade and blood pressure.[18]

In another study, hemodynamic changes and anesthetic effects of bupivacaine and tetracaine in 200 patients aged 40 to 75 years were studied and the results showed that blood pressure and heart rate decreased significantly in both groups, but the difference between the two groups was in study after spinal anesthesia for cesarean section with general anesthesia with lidocaine by Madineh et al. concluded that pain after surgery with spinal anesthesia with lidocaine under general anesthesia not significant.[19]

In study after spinal anesthesia for cesarean section with general anesthesia with lidocaine by Nishiyama et al. concluded that pain after surgery with spinal anesthesia with lidocaine under general anesthesia. [20]

The weak points of the current study were a low number of samples and low age range.

**CONCLUSIONS**

According to results of the study, local anesthetic by tetracaine drop can be a safe and effective way in reducing pain after septoplasty surgery. Thus, it is recommended to use this drop to reduce pain in the septoplasty surgery.

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**Conflicts of interest**

There are no conflicts of interest.

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