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Comparison of the Effects of Dexamethasone and Ketorolac on Edema and Ecchymosis after Rhinoplasty

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Abstract

Background: Rhinoplasty is one of the most common plastic surgeries in the world. At the same time, rhinoplasty is considered one of the most precise, delicate and difficult plastic surgeries. Although this surgery is associated with some complications like any other surgery, because it is carried out to change the person's appearance and increase his/her satisfaction and self-confidence, attempts should be made to prevent the occurrence of complications as much as possible because edema and ecchymosis are considered as two consequences of rhinoplasty.

Aim: Considering the severity of edema and ecchymosis after rhinoplasty and limited studies on the effect of non-steroidal compounds, therefore, the present study aims to compare the effect of dexamethasone and ketorolac severity on edema and ecchymosis after rhinoplasty in Loghman-e Hakim Hospital in 2021.

Methods: This was a double-blind clinical trial that aims to compare the effect of dexamethasone and ketorolac on the severity of edema and ecchymosis after rhinoplasty among clients referring to the ENT clinic of Loghman-e Hakim Hospital during the year 2021. The study population included 81 patients applying for primary rhinoplasty were randomly divided into two groups using a randomized block design.

Results: Although the mean edema and ecchymosis severity in the dexamethasone group was lower than the ketorolac group, the results of chi-square and independent t-test showed no significant difference between dexamethasone and ketorolac groups in terms of the severity of edema and ecchymosis. Therefore, both research hypotheses were rejected and the null hypothesis was confirmed.

Conclusion: Despite the difference between the two groups in terms of severity of postoperative edema and ecchymosis, this difference was not statistically significant, which indicates the similar efficacy of the two drugs in reducing edema and ecchymosis after rhinoplasty.

Conflicts of Interest: The Authors declare no conflicts of interest.
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Introduction

Rhinoplasty is considered as one of the most precise, delicate and difficult plastic surgeries (1). Although this surgery is associated with some complications like any other surgery (2), it is carried out to change the person's appearance and enhance his/her satisfaction

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and self-confidence (3). Attempts should be made should to prevent complications as much as possible. Edema and ecchymosis occur as two expected rhinoplasty complications in almost most cases (2, 4). These two phenomena not only cause the dissatisfaction of patients who voluntarily undergo surgery for the aesthetic purposes, but also can be effective on the level of the surgeon satisfaction (5). Postoperative ecchymosis can be mild or severe and even last for weeks to months. This depends on several factors, including the type and method of surgery and the tendency of the patient's body to bruise. Postoperative edema is caused by the increased subcutaneous fluid accumulation and can cause pain and can affect the final surgical outcome (6).

In order to control and prevent edema and ecchymosis after rhinoplasty, different solutions have been proposed (7). Among the practical and effective solutions include applying pressure on the osteotomy site using your fingers during surgery, nasal dressing with mentioned post-operative adhesive, cold compress on the nose and its surroundings, lifting the head while sleeping or lying down, and the type of internal or external osteotomy. According to previous studies, non-steroidal medicinal solutions such as arnica and bromelain) (3, 8) and steroid compounds (9, 10) were mentioned as effective solutions. Glucocorticoids reduce or prevent tissue responses to the inflammatory process without removing the underlying cause. These drugs excrete their anti-inflammatory effect by interrupting the macrophage migration inhibitory (MIF) factor phase and preventing the accumulation of macrophages, thus reducing the dilation and permeability of the inflamed capillaries and the adhesion of white blood cells to the capillary wall, and ultimately prevents the occurrence of edema and migration of white blood cells and downregulate the arachidonic acid derivatives. Attempts to eliminate and reduce this complication are made assuming the effect of steroids in reducing the vascular permeability and preventing vascular leakage of exudate and blood (3). In this regard, dexamethasone is considered as an effective solution considering its strong anti-inflammatory activity and also a half-life of 36-54 hours. Dexamethasone inhibits the early response process, which includes edema, changes in fibrin structure, capillary dilation, lymphocyte migration, and phagocytosis activity (11).

Another drug solution that is suggested in order to control and prevent the rhinoplasty complications is ketorolac administration. Considering its non-steroidal anti-inflammatory and analgesic properties, ketorolac inhibits the enzyme lipoxygenase and cyclooxygenase. Ketorolac, which is used both orally and intravenously, like dexamethasone, reduces pain, edema and bleeding. Since edema and ecchymosis frequently occur after rhinoplasty, and also because there has been limited research on the effect of non-steroidal compounds, therefore, the present study aims to compare the effect of dexamethasone and ketorolac on edema and ecchymosis after rhinoplasty.

In fact, rhinoplasty is one of the most common plastic surgeries around the world. At the same time, rhinoplasty is considered as one of the most precise, delicate and difficult plastic surgeries. Edema and ecchymosis are seen as two expected rhinoplasty complications in most cases. Periorbital edema and ecchymosis is one of the inevitable complications of rhinoplasty, the main cause of which is bleeding in the soft tissue around the nose after lateral osteotomy. Other causes include invasive surgery, tissue reaction and the type and location of osteotomy. According to previous studies, various effective pharmaceutical solutions have been proposed to control edema and ecchymosis after rhinoplasty, which include non-steroidal drugs and steroid compounds. Considering the severity of edema and ecchymosis after

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rhinoplasty and limited studies on the effect of non-steroidal compounds, we decided to conduct a study to compare the effects of dexamethasone and ketorolac on these two inevitable phenomena.

Methods

Study Design

This was an intervention or clinical trial, which is also known as a therapeutic trial. In these studies, the researcher prescribes medicine, diet and any other treatment method for the intervention group and evaluates its efficiency and safety.

Data collection tools and methods

This was as a double-blind clinical trial with the aim of comparing the effect of dexamethasone and ketorolac on the severity of edema and ecchymosis after rhinoplasty among clients referring to the ENT Clinic of Loghman-E- Hakim Hospital during the year 2021. The study population included 81 non-diabetic patients applying for primary rhinoplasty surgery that were randomly divided into dexamethasone and ketorolac groups using a randomized block design. All surgeries were performed with a special method and by an anesthetic process. Clonidine was given to all patients preoperatively. To determine the severity of periorbital edema and ecchymosis, a standard 4-grade scoring scale was used.

Study population

The study population included all rhinoplasty patients with edema and ecchymosis referred to the ENT Clinic of Loghman-e Hakim Hospital.

Sampling method and sample size calculation:

Eligible rhinoplasty patients were selected using non-probable sampling was divided into two intervention groups using random numbers. The minimum total sample number was calculated 60 people (n= 30 per group) using G-POWER (24) ver. 3.1.9.1 software, taking into account 95% confidence interval, 95% test power, and the largest effect size. However, a total of 81 people (n=46 people in the dexamethasone group and n= 35 people in the ketorolac group) was studied.

Method

This was a double-blind clinical trial that aimed to compare the effect of dexamethasone and ketorolac on the severity of edema and ecchymosis after rhinoplasty among clients referred to the ENT Clinic of Loghman-E-Hakim Hospital during the year 2021. Informed consent was obtained from all 81 patients applying for primary rhinoplasty surgery who were randomly divided into two groups at baseline using a randomized block design.

Inclusion criteria included having consent to participate in the study and age range of 18-45 years. Exclusion criteria also included a history of previous rhinoplasty, nasal fracture and rhinoplasty applicants, patients who did not need osteotomy, the presence of severe organ failure including heart failure, kidney failure, severe lung disease such as chronic bronchitis and asthma, drug addiction and abuse, history of sensitivity to non-steroidal anti-inflammatory drugs, history of ulcerative gastrointestinal disease, and diabetes.

All surgeries will be performed using a special method and by an anesthetic process. Clonidine was given to all patients preoperatively. Rhinoplasty was performed using the same procedure with the same general anesthesia. Initially, to induce hemostasis, 1% lidocaine + a 1:1,000 ratio of epinephrine was injected and then external lateral osteotomy was performed. All patients received the same care postoperatively, which included the prescription of oral antibiotics (cephalexin capsules) for five days and acetaminophen for pain relief and ice compresses. Postoperatively, patients were divided into dexamethasone and ketorolac groups. The patients were not charged any money throughout the study. The first group, the drug was administered as a single dose preoperatively and three doses every eight

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hours postoperatively. The drug dose was 8 milligram, which was administrated intravenously. The second group received ketorolac (30 mg) intramuscularly after anesthesia (because the peak effect of ketorolac is seen 2-3 hours after administration, which is approximately equivalent to the surgery duration) and two other 30mg doses were administrated intramuscularly every 8 hours. Omeprazole capsules (20 mg) were prescribed to the patients on an empty stomach while receiving their drugs.

To determine the severity of periorbital edema and ecchymosis, a standard 4-grade scoring scale was used. To determine the presence of ecchymosis, each eyelid was divided into four regions from the internal canthus to the external canthus. The grade of edema and ecchymosis was determined seven days postoperatively using an, at least, 3-megapixel digital camera. Then, two faculty members, who did not know about the patient allocation, and the researcher, investigated the postoperative edema and ecchymosis using the standard five-point-scoring scale ranging from 0 to 4).

Their judgment consistency was investigated in the pilot study. In this grading system, ecchymosis in the upper and lower eyelids was graded as follows: 0: no ecchymosis; 1: spreading towards the internal cantus; 2: spreading towards the pupil; 3: affecting the pupil and 4: spreading towards the external canthus. Also, different edema grades in the upper and lower eyelids were graded as follows: 0: no edema; 1: minimum edema; 2: covering the iris; 3: affecting the pupil and 4: metastatic edema (12).

Statistical Analysis

Patients' demographic and medical data was completed by clients. This data includes sex, age, examination and treatment results. Also, the patients' data was kept with confidential by the authors and no money was charged from the studied patients. The collected data was analyzed using descriptive statistical methods (frequency, percentage, mean and standard deviation) and mean difference test for independent groups, ANOVA test, chi-square test, and the Spearman coefficient in SPSS ver. 25 software.

Ethical considerations:

Patient medical records were used and no invasive procedure or unnecessary treatment procedure was performed according to the purpose of the present research.

Results

Eighty-one consecutive patients were included in this survey. Majority of our patients (58 patients or 71.6%) were females. Patients were divided into two groups, one receiving dexamethasone and the other ketorolac. More than half of the included cases (46 patients) received dexamethasone, and for the rest of the patients (43.2%) ketorolac was administered.

Table 1 shows the distribution of edema grade among included patients.

Edema grade	Frequency	Percentage
Grade I	15	18.5
Grade II	42	51.8
Grade III	18	22.2
Grade IV	6	7.5

As it is demonstrated in table 1, majority of cases developed grade II of edema after rhinoplasty.

Table 2. the distribution of edema grade regarding the gender

Gender	Edema grade	I	II	III	IV
Female		11	30	12	5
Male		4	12	6	1

Table 2 shows the distribution of edema grade regarding the gender. After conducting Chi-square test, it was revealed that there is no significant association between gender and edema grade.

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Table 3. The frequency and percentage of ecchymosis grade

Ecchymosis grade	Frequency	Percentage
Grade I	5	6.1
Grade II	43	53.1
Grade III	26	32.1
Grade IV	7	8.7

As it is shown in table 3, majority of our cases suffered from grade II ecchymosis.

Table 4. The distribution of gender considering the grade of ecchymosis

Gender	Ecchymosis grade	I	II	III	IV
Female		5	33	16	4
Male		0	10	10	3

Table 4 shows the distribution of gender considering the grade of ecchymosis. Likewise, after conducting Chi-square test, we found no statistically significant correlation between gender and grade of ecchymosis (P-value > 0.05).

To compare the severity of edema and ecchymosis between two groups, T-test was conducted. It was revealed that there is no statistically significant difference between two groups. The severity of edema and ecchymosis does not vary between patients who receive dexamethasone or ketorolac.

Discussion

The aim of the present study was to compare the effect of dexamethasone and ketorolac on the severity of edema and ecchymosis after rhinoplasty among the patients referred to the ENT Clinic of Loghman-E-Hakim Hospital during the year 2020.

Cosmetic surgery is one of the most common surgeries in the world, and related statistics shows its application is increasing. One of the most common cosmetic surgeries is rhinoplasty. With the advancement of cosmetic surgery, many surgeons seek to reduce edema and ecchymosis after surgery. To reduce this problem, different steroid have been used before or after surgery. In theory, the anti-inflammatory properties of glucocorticoids reduce the vascular permeability and thus reduce ecchymosis and edema severity. Dexamethasone is one of the strongest anti-inflammatory steroids, which has a half-life of 36-45 hours, but the use of steroids, especially for a long time, can lead to complications. Due to the wide range of physiological effects of steroids, physicians are always looking for safer methods to reduce the severity of postoperative edema and ecchymosis. Ketorolac is another drug that is proposed in order to control and prevent the unwanted rhinoplasty complications. Ketorolac is a non-steroidal anti-inflammatory drug with analgesic properties, and inhibits both lipoxygenase and cyclooxygenase enzymes.

The present study, which sought to compare the effects of dexamethasone and ketorolac sepaseverityly on severity of edema and ecchymosis after rhinoplasty. The study population included 81 rhinoplasty candidates (58 women and 23 men), and were randomly divided into two dexamethasone (n=46 people) and ketorolac groups (n=35 people).

Before testing the research hypotheses, the relationship between the severity of edema and ecchymosis with gender was investigated using the chi-square test. Results showed gender plays no role in the severity of these two phenomena, and in fact, there is no significant relationship between the severity of edema and ecchymosis and gender, which is consistent with the results of studies by Giakamara et al. (2011), Becker et al. (2011) and Ghazipour & Akbari (2007) who did not report a significant difference between men and women who underwent rhinoplasty in terms of ecchymosis severity. However, Hashemi et al. (2005) reported a significant difference between women and men in terms

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of the edema and ecchymosis severity and stated that the ecchymosis severity was higher in men than women, which is inconsistent with the present study.

The current research sought to answer two hypotheses, both of which were analyzed using independent t-test and chi-square. With regard to hypothesis 1, results of descriptive statistics showed that the mean ± standard deviation of edema severity in the dexamethasone and ketorolac groups was 2.10 ± 0.849, and 2.28 ± 0.788, respectively, which was similar to the results of other studies showing the greater effect of dexamethasone on edema after rhinoplasty (Fengzhi, 2003) and (Ghazipour, 2007). Although the edema severity in the ketorolac group was higher than that of the dexamethasone group, and indeed there was a difference between their means, but this difference was not significant because the results of both tests according to independent t and chi-square.

Similarly, Totonchi et al. (2007) compared the effect of arnica and corticosteroid on edema and ecchymosis after rhinoplasty. They showed that in addition to tranexamic acid as a corticosteroid compound, arnica is also one of the drugs effective in reducing the severity of postoperative edema. However, the results of the presents study revealed no difference between these two drugs, which is similar to the result of the Totonchi et al.'s study. Although they found that both arnica and dexamethasone reduced edema severity, they found no statistically significant difference between corticosteroids with arnica in terms of their efficacy in reducing edema severity. Huang et al. (2019) also performed a study on 312 patients and found that dexamethasone significantly reduced the severity of postoperative edema and ecchymosis on days 4 and 7 after rhinoplasty. In the above study, a comparison was made between the dexamethasone and placebo groups. The results of this study are inconsistent with the results of the present study.

With regard to the hypothesis 2, the results of descriptive statistics showed that the mean ±standard deviation of edema was 2.45 ±0.721, and 2.40 ± 0.774 in the dexamethasone and ketorolac groups, respectively, which is similar to the result a study by Gurlek (2006). In fact, there was a difference between their means, but this difference was not significant according to the results of independent t and chi-square tests. In the current study, ketorolac showed a similar result, which is contrary to the results of the study by Kara et al., who found a significant difference between the two groups in terms of the severity of periorbital ecchymosis ($P<0.05$) (20).

Moreover, this result was consistent with the results of the study by Mehdizadeh et al. (2017). Mehdizadeh et al. aimed to compare the effect of dexamethasone and tranexamic acid separately or in combination on edema and ecchymosis after rhinoplasty. Periorbital edema and ecchymosis score were performed by an expert on all groups using a 0-4 scale. The results of the present study showed that the periorbital edema and ecchymosis grading was significantly lower in D, T and DT groups compared to the control group ($p = 0.01$). There was no significant difference between the D, T and DT groups in terms of a reduction in edema and ecchymosis severity. According to these results, tranexamic acid and dexamethasone, separately or in combination, have similar effects in reducing periorbital edema and ecchymosis in open rhinoplasty, and their combined use did not have higher beneficial and significant effects. Also, Erisir et al. (2001) evaluated the effect of steroids on edema and ecchymosis after rhinoplasty surgery in Turkey. They found that steroids were effective in reducing edema and ecchymosis after rhinoplasty compared to

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placebo. However, the effect of dexamethasone disappeared after the first two days, and it did not shorten the recovery period. It was also reported that dexamethasone had no complications, which is consistent with the findings of the current research. Besides, in a double-blind clinical trial in Iran, Jalali et al. (2010) compared the effect of dexamethasone and tranexamic acid in reducing the severity of edema and ecchymosis after rhinoplasty. The results of this research showed no significant difference between the two groups in terms of the occurrence of edema and ecchymosis after closed rhinoplasty with external lateral osteotomy. Tranexamic acid had the same effect as dexamethasone in reducing edema and ecchymosis after rhinoplasty, and the decision to choose one of these two drugs depends on the other related side effects, which is also consistent with the results of the current research. Also, Motamel al-Shariati et al. (2009) evaluated the effect of dexamethasone in reducing edema and ecchymosis in the first week after rhinoplasty in a causal intervention study of multiple time series design. They found a difference between three studied groups in terms of the severity of edema and ecchymosis. That is, the edema severity was lower in the group that received three doses of steroids compared to the other two groups. Also, this effect was statistically significant in terms of ecchymosis severity on day 6. According to these results, dexamethasone is effective in the treatment of periorbital edema and ecchymosis in closed rhinoplasty, which increases patient satisfaction in the short term after surgery. This effect is durable and dependent on the drug dose and time.

Conclusion

Although there was a difference between the two groups in terms of postoperative edema and ecchymosis, this difference was not statistically significant. This finding shows the similar effect of two drugs on reducing edema and ecchymosis after rhinoplasty. Considering the fewer complications of dexamethasone compared to ketorolac, this drug can be used as a suitable alternative to reduce postoperative edema and ecchymosis.

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Conflicts of Interest

The authors declare no conflicts of interest.

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Ethics

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