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A randomized prospective trial to determine the influence of hirudoid cream on the development of ecchymosis and post-rhinoplasty eye edema

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ABSTRACT:

OBJECTIVE: After rhinoplasty, periorbital edema and ecchymosis have been reduced using a variety of techniques. In this research, we assessed the effectiveness of dexamethasone and iridoid in reducing periorbital edema and ecchymosis.

METHODS: Three groups of sixty primary rhinoplasty patients were randomly selected. From the first postoperative day for five days, Group H got hirudoid cream three times daily (POD). Before surgery, group D got 10 mg of dexamethasone intravenously, whereas group C (the control) did not receive any hirudoid or dexamethasone. Two surgeons who were blind to the drugs given on the 2nd, 5th, and 7th PODs evaluated the degree of edema and the severity of the ecchymosis.

RESULTS: Group D exhibited much less edema than groups H and C on the 2nd POD, but there was no appreciable difference between the three groups regarding the extent or severity of ecchymosis. When compared to group C, group H had much less ecchymosis on the seventh POD. Group H performed better than the other groups in terms of the resolution of edema severity and ecchymosis intensity when the difference between the second and seventh PODs was examined (p-value < 0.001).

CONCLUSION: After rhinoplasty, hirudoid has been demonstrated to be beneficial in decreasing edema and ecchymosis. Early postoperative days saw periorbital edema prevention benefits from dexamethasone treatment, but ecchymosis resolution did not improve.

KEYWORDS: edema, hirudoid, rhinoplasty

INTRODUCTION: Like other surgeries, rhinoplasty, a prominent procedure in cosmetic surgery, causes tissue damage to both soft and bone tissue. Ecchymosis and edema, which are frequent and expected side effects of rhinoplasty, are only two examples of the morbidity that the patient may experience as a consequence of inflammatory reactions to this trauma. The primary cause of this outcome is vascular damage at the location of the osteotomy. Even while these problems cannot entirely be avoided, their scope and severity may be decreased by carefully adhering to surgical protocols. (1,2)

These problems may cause patients' recoveries to take longer while also attracting the attention of the patient, his or her family, and even the doctor. They sometimes cause patients and their visitors to get alarmed as a consequence, which might lower patient satisfaction. More edema, on the other hand, would result in higher adhesion. Post-inflammation hyperpigmentation (PIH), which may even cause or aggravate the black loop around the eye, is also influenced by the presence of ecchymosis (with increased intensity and extent) with permanent discoloration. (3) In clinical trials, a variety of techniques have been used to lessen these side effects. One part per 100,000 adrenaline solution, an ice bag, injectable lipoteichoic acid,

clonidine, herbal therapies like arnica, and topically applied vitamin K are some of the methods used. (4) Given that the aforementioned medicines have drawbacks, such as systemic side effects or administration-related limits, pharmacological agents that are simpler to employ, particularly topically, and that successfully decrease edema and ecchymosis may be utilized regularly in clinical settings. (5)

Although there has been other research conducted outside the realm of surgery, none has shown how hirudoid (also known as heparinoid or HPS) affects edema and ecchymosis after rhinoplasty. Hirudoid has anti-inflammatory, fibrinolytic, and anticlotting capabilities. (6) Mucopolysaccharide polysulfate (MPS), the active component of hirudoid cream, is a semi-synthetic molecule with an average molecular weight of around 9700 Dalton that is produced by sulfating a mixture of glycosaminoglycan derived from mammalian cartilage. It is also known as heparinoid due to its chemical resemblance to heparin. In therapeutic settings, hemorrhoids are utilized as an anticoagulant, fibrinolytic, and anti-inflammatory drug. (7,8) The purpose of this research was to look into how this chemical treated edema and ecchymosis following rhinoplasty.

METHODS: In this research, which used a randomized prospective study design, patients who had rhinoplasty were randomly assigned to one of three groups. Every patient who had rhinoplasty surgery made up the research population. Each patient signed a written permission form. Information on the patients was documented based on the questionnaire that was produced. On days 2, 5, and 7, face pictures were taken, and two observers independently evaluated and graded the amounts of edema and ecchymosis around each subject's eyes. This procedure was done to decrease the possibility of mistakes.

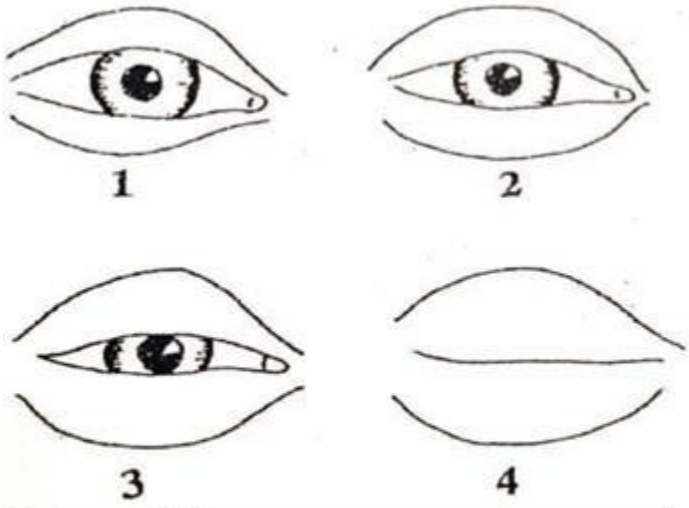
Patients receiving primary septorhinoplasty and osteotomy were evaluated. Being diabetic or hypertensive, having a peptic ulcer, being a patient in a mental health facility, having an allergy to steroids or herudoids, being a woman during menstruation or just before menstruation, and using anticoagulants or antiplatelet medications were the exclusion criteria. The surgical team, which included three surgeons, performed the surgery while the patient was under general anesthesia by injecting one person per 100,000 with an epinephrine solution. The patients also got identical postoperative treatment.

Sixty patients were recruited, split equally among three groups, and ranged in age from 18 to 45. Just before surgery, Group D got one intravenous dosage of 10 mg of dexamethasone. A thin coating of a topical hirudoid cream was applied to Group H's afflicted region 24 hours after surgery, three times per day for three days. Dexamethasone or hirudoid were not administered to Group C, which served as the control group. There was sub-general anesthesia used on all individuals.

All patients received ringer or regular saline at a rate of 2 mL/kg/h throughout the operation, and the MBP was managed between 55 and 65. Patients who had their blood pressure inadequately controlled throughout the surgery were removed. First, one per 100,000 people received injections of 10 mL of the adrenaline solution. After 10-15 minutes, surgery was begun. All patients received regular nasal tampons and intra- and outer-nasal splint care. Records were kept on the length of the procedure, the quantity of intraoperative bleeding, and any intraoperative problems. The beds of the patients were 45 degrees raised for the first 24 hours after surgery. To manage pain, patients were given a 20-minute infusion of 200 mL of normal saline, 25 mg of intramuscular pethidine, and 1 gram of intravenous apostle. Following surgery, patients took oral antibiotics for 5 days. Patients have received acetaminophen codeine every 6 hours and 5 mg oxazepam tablets every 12 hours after surgery. In addition, it was advised to keep your head up for four days while using an ice bag.

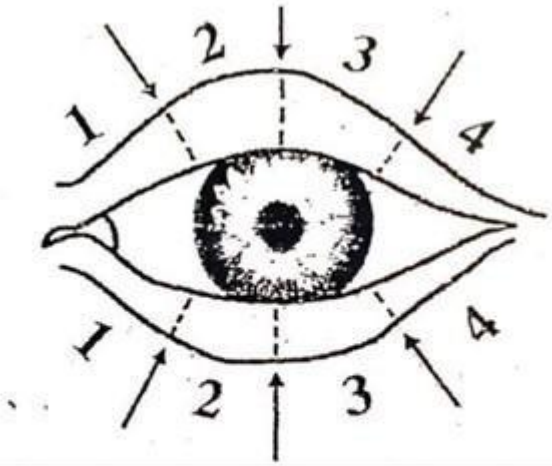
Up until the conclusion of the trial, neither the patients nor the doctors were aware of the treatment's nature or approach. On the 2nd, 5th, and 7th days after surgery, the patients were photographed using a digital camera with a 10-megapixel resolution at a distance of 40 cm. Then, by two observers, the severity and extent of ecchymosis, as well as the degree of edema in each patient, were documented in the questionnaire using a classification scale based on both medical and photographic data (Figures 1 and 2).

The study's statistical evaluation was carried out using SPSS software, version 26. To compare gender between groups, Pearson's Chi-square test was used. The groups were compared against each other using the Tamhane post-hoc and Kruskal-Wallis tests for statistical analysis. The effectiveness of each medicine was evaluated in the control group in a different section of the statistical comparison. The Friedman nonparametric test was used in statistical analysis to compare the variables by three times since they were qualitatively rated according to their nature. Calculated values were deemed statistically significant (p0.05).



Rating	Edema
0	No edema
1	Mild edema (minimal)
2	Moderate edema (extending onto the iris)
3	Severe edema (covering the iris)
4	Eyelid swollen shut

Figure 1: System for grading the severity of eyelid edema.



Rating	Extent of ecchymosis	Color density (Intensity of ecchymosis)
0	No ecchymosis	No color change
1	Up to medial One-third of the eyelid	Yellowish color change
2	Medial half of the eyelid	Light purple
3	Entire eyelid (pass the pupil)	Dark purple
4	Extending to the lateral canthus	Very dark purple
5	Extension of ecchymosis below the malar bone	

Figure 2: A scoring method for the ecchymosis severity and degree around the eye

RESULTS: 60 patients were participating in this trial (Table 1). The last analysis was done on the 18 participants left after two individuals were removed from the research because of hypersensitivity. The first

descriptive research evaluated the degree and extent of edema as well as the intensity of ecchymosis at the initial follow-up, which is the second postoperative day, in all three groups. The results are displayed in Table 2. Despite being statistically significant (p-value < 0.002), the dexamethasone group's mean edema was objectively lower than that of the other two groups.

The hirudoid and dexamethasone groups, as well as the control and dexamethasone groups, were found to vary significantly from one another, but not from the control and hirudoid groups (p>0.9). On the second day after surgery, there was also no appreciable difference between the three groups in terms of the parameters determining the severity and degree of ecchymosis. The third day following surgery was used as a comparison point for all three groups for comparing other research days. Tables 3 and 4 show the results of these analyses.

Table 1: Patient gender and the average age in three groups.

Gender	**Male**		**Female**	
	N	**Mean (S.D)**	**N**	**Mean (S.D)**
Control	3	21.7 (1.5)	17	25.4 (5.8)
Hirudoid	5	28.4 (3)	13	26.8 (7.5)
Dexamethasone	9	24.4 (4.7)	11	26.7 (5.2)
Total	17	25.1 (4.4)	41	26.2 (6.1)

Table 2: The patients' status in the 3 groups on the 2nd day after surgery was assessed in terms of the average edema degree and ecchymosis extent and severity.

Group	**N**	**Ecchymosis Severity (2nd day)**	**Ecchymosis extent (2nd day)**	**Edema Degree (2nd day)**
Control	20	32.43	30.23	34.4
Hirudoid	18	29.92	30.94	35.98
Dexamethasone	20	26.2	27.48	18.95
p-value		>0.4	>0.7	<0.002

Table 3: The patients' status in the 3 groups on the 5th day after surgery was assessed in terms of the average edema degree and ecchymosis extent and severity.

Group	**N**	**Ecchymosis Severity (5th day)**	**Ecchymosis extent (5th day)**	**Edema Degree (5th day)**
Control	20	35.88	31.33	38..40
Hirudoid	18	21.58	25.67	29.17
Dexamethasone	20	30.25	31.13	20.9
p-value		<0.05	>0.4	<0.005

Table 4: The patients' status in the 3 groups on the 7th day after surgery was assessed in terms of the average edema degree and ecchymosis extent and severity.

Group	N	Ecchymosis Severity (7th day)	Ecchymosis extent (7th day)	Edema Degree (7th day)
Control	20	34.88	32.83	37.3
Hirudoid	18	21.11	23.42	26.69
Dexamethasone	20	31.68	31.65	24.23
p-value		<0.05	>0.1	<0.05

Table 5: According to the average degree of edema degree, the severity of ecchymosis extent, and severity in 3 postoperative examinations, patients' situations were divided into three groups.

Group	N	Examinations, Day	Severity of ecchymosis	Extent of ecchymosis	Degree of edema severity
Hirudoid	8	2nd	2.75	2.58	2.61
		5th	1.72	1.94	1.89
		7th	1.53	1.47	1.5
p-value			<0.001	<0.001	<0.001
Control	20	2nd	2.35	2.3	2.3
		5th	2.03	2.05	2.03
		7th	1.63	1.65	1.68
p-value			<0.01	<0.05	<0.05
Dexamethasone	20	2nd	2.18	2.28	2.18
		5th	2.03	2.2	1.95
		7th	1.8	1.53	1.88
p-value			>0.28	<0.005	>0.15

Between the control group and the group that took dexamethasone, the research did not detect a statistically significant difference. On the fifth day after the procedure, the researchers discovered a difference between the three groups in the degree of edema and the severity of ecchymosis.

The degree of ecchymosis varied significantly between the hirudoid and control groups ($p < 0.02$) The other groups did not vary statistically significantly. When compared to the fifth day, similar outcomes were seen on the seventh day.

The three study groups' levels of edema and ecchymosis varied significantly, according to Table 4, with the control and dexamethasone groups exhibiting the biggest variations (p-value<0.01). The degree of ecchymosis differed between the control and hirudoid groups in a statistically significant way (pvalue< 0.05). The results of these analyses showed that there was no statistically significant difference between the different groups' levels of ecchymosis. However, on days 5 and 7, the mean degree for the hirudoid group was lower than the values for the other two groups, which was clinically but not statistically significant.

To ascertain if the difference in the degree of ecchymosis between the groups is clinically and statistically significant and advantageous for patients, more research on patients would be helpful. According to the research, to prove this, a more thorough examination of each unique instance and a measurement of the ecchymosis would be required. The Friedman nonparametric test was statistically employed in the research to assess the effectiveness of each drug in the control group. According to the test's findings, both the hirudoid group and the control group had less severe edema overall.

Table 5 shows that between days 1 and 5, dexamethasone had a substantial impact on lowering the degree of ecchymosis but not on the other two variables. In contrast, hirudoid had a significant impact on all three variables. According to research findings, patients may not benefit from utilizing dexamethasone. The fact that the severity of edema and ecchymosis was reduced in the hirudoid group and the control group but not in the dexamethasone-treated group supports this theory. Dexamethasone may not be required or helpful in lowering the severity of these problems during rhinoplasty, according to this evidence. Edema severity and the amount and degree of ecchymosis naturally decrease if no further medicine is used. At each of the three follow-up periods in the trial, the two medications' comparative effectiveness with the control group was shown in Figures 3-5. These comparisons were made while taking into consideration the statistical findings provided in the tables.

DISCUSSIONS: The findings of this research demonstrated a strong relationship between periorbital ecchymosis severity and extent, as well as the intake of hirudoid, in patients having primary rhinoplasty. In this trial, only two patients had contact dermatitis, which was identified as a result of irritation and itching, and there were no major side effects associated with the use of hirudoid. The research additionally showed that preoperative dexamethasone reduced patient edema severity to a pretty excellent and statistically significant degree. (9,10,11)

Even though the patients taking hirudoid initially had edema of a comparable degree to the control group after hirudoid treatment began, the rate of edema drastically dropped and, by day 7, was more in line with dexamethasone. It should be highlighted that although dexamethasone has a direct correlation with day 1 in terms of edema reduction and prevention, the progressive clearance rate of edema in the dexamethasone group from days 2 to 7 did not vary substantially from that of the control group.

Furthermore, statistical results showed that although the area of ecchymosis significantly decreased in dexamethasone-treated people, the degree of ecchymosis did not alter significantly between days 2 and 7. This is not clinically significant since both the control group and the hirudoid group saw a substantial decrease in the ecchymosis extent and severity from days 2 to 7, as seen in Table 5. The hirudoid group had a significantly higher incidence of severity and degree of ecchymosis compared to the dexamethasone and control groups.

The study's findings cannot be attributed to observer mistakes. The research took precautions to make sure that several observers assessed the degree of ecchymosis and that they were unaware of the patient group while doing so using patient face photographs. The findings of this study are also in agreement with those of other researchers who discovered that patients who received methylprednisolone before surgery had a reduced incidence of pre-orbital edema and ecchymosis than the control group. This shows that the study's conclusions are trustworthy and consistent with earlier studies. (11,12)

Patients who had just taken one dose of dexamethasone before surgery saw comparable results in the first two days. (13,14,15)

In the present research, individuals who received a single dosage of dexamethasone had just milder edema on the second postoperative day, but there was no improvement in postoperative ecchymosis. Dexamethasone injection was shown to not influence the intensity or extent of ecchymosis surrounding the

eye, and instead, it only altered the pace at which the amount of the ecchymosis was removed, which was a less significant effect than hirudoid. (16,17)

This is in contrast to other researchers' findings, which indicated that dexamethasone injection reduced the pace of recovery of the extent and severity of ecchymosis. (18,19) Dexamethasone, according to another research on arnica, was useful in lowering post-rhinoplasty edema but ineffective in reducing ecchymosis. But according to our research, hirudoid cream may effectively reduce edema as well as the intensity and scope of ecchymosis surrounding the eye. (20)

Our study's findings showed that using hirudoid cream to lower edema rates, ecchymosis severity, and ecchymosis extent following rhinoplasty surgery was a straightforward and low-impact strategy. This method may have positive physical, psychological, social, economic, and patient satisfaction impacts. Although initially avoiding peripheral edema, preoperative dexamethasone injection had little impact on lowering the degree and extent of ecchymosis following rhinoplasty. In light of the aforementioned, it makes sense and improves patient satisfaction to use a topical hirudoid cream post-rhinoplasty to minimize swelling and ecchymosis around the eyes.

CONCLUSIONS: The study's findings suggest that these two therapies, intravenous (IV) dexamethasone injection given before the procedure and topical hirudoid cream application following the procedure, may help reduce some complications that can arise after a rhinoplasty, such as edema (swelling) and ecchymosis (bruising) around the eyes. Additionally, the research finds that this mix of treatments could have a beneficial therapeutic impact, which suggests that it might assist enhance the procedure's final result. The research concludes that using these treatments could increase patients' satisfaction with their outcomes. Overall, the research indicates that combining these two treatments may be a useful strategy for enhancing results and elevating patient satisfaction in rhinoplasty surgeries.

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