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The Comparison of the Analgesic Effects of Oral Tramadol Tablet and Gelofen Capsule after Photorefractive Keratectomy

Mohammad Naeim Amini Fard[1], Kourosh Shahraki[1]*, Roksana Haghparast[1], Kianoush Shahraki[2], Mohammad Arish[1] and Alireza Maleki[1]

[1]*Department of Ophthalmology, Zahedan University of medical sciences, Iran*

[2]*Department of ophthalmology, Tehran University of medical sciences, Iran*

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***Corresponding author:** Kourosh Shahraki, Eye Research Center, Alzahra Eye Hospital, Zahedan University of medical sciences, Zahedan, Iran, Email: kourosh.shahyar@gmail.com

Abstract

Background: During the first 24 hours after laser treatment, In this study, we compared pain after PRK in the tramadol tablet group and golfing group.

Method: A prospective clinical trial was performed on 100 patients in alzahra (s) hospital in 1391 years. Patients underwent PRK divided in 2 groups of 50 subjected. Study groups were given tramadol 50 Mg tabs twice a day. The observe group was prescribed gelofen (ibuprofen) 400 Mg three times a day. The visual Analogue scale chart was given to all patients and they had been asked to mark the condition for 48 hours after operation.Then data of was analyzed by PASW18 software in T-Test mode.

Results: The average score for pain at the first night in tramadol group was (3.25±1.49) VAS and golfing group was (4.96±1.36) VAS. The average score for pain in the first morning in tramadol group was (2.14±1.35) VAS and golfing group was (4.38±1.56) VAS. Average score for pain in the second night in tramadol group was (1.76±1.21) VAS and gelofen group was (3.98±1.53) VAS. The average score for pain in the second morning in tramadol group was (1.46±0.92) VAS and gelofen group was (3.56±1.47) VAS Average score for pain in third night in tramadol group was (1.12±0.82) VAS and gelofen group was (3.24±1.54) VAS. Average score for pain in third morning in tramadol group was (0.91±0.77) VAS and gelofen groupe was (2.86±1.60) VAS.in the every time there was a significant difference between the tow groups.

Conclusion: It seems that in post PRK patients, pain tolerance in going to be better handled by administration of oral tramadol rather than gelofen.

Keywords: Photorefractive keratectomy; Tramadol; Postoperative pain

Introduction

Refraction is defined as deviation of light rays while crossing the surface between two transparent environments with different densities expressed in terms of Diopter (D). The refractive power of the cornea in its central part is approximately 43 D making up as much as three fourth of the refractive power of the eye. The ideal method of refractive surgery is a simple, useful, and invasive method suitable for most patients [1-3].

Cornea is a transparent and avascular tissue with a bulging external surface and a concaved internal surface whose axial thickness varies from 0.52 to 0.50mm and consists of 5 layers. Epithelium is the most external layer creating the flat refractive surface and acting as a protective layer against micro-organisms. Bowman layer is a thin, cell-less layer proven to be a homogenous area. The cornea owes its resistance to the collagen part of corneal stroma [3,4]. Endothelium and its base membrane (Descemet membrane) play a major role in maintaining the dehydration of cornea and its transparency by pumping Atpase sodium potassium. The main site of impact for Eximer laser is the corneal stroma.

Laser is a means used to change the shape of cornea by removing the tissue from the anterior surface of stroma. Eximer laser was first introduced by [1], while it was first used by Macdonald on human eye in 1991 [1]. This is an ultraviolet ray with a wavelength of 193nm of argon fluoride laser which has the

minimum capacity to pass through corneal tissue with the least possible damage caused to its surrounding tissues resulting in the smoothest extraction surface of all other lasers with greater wavelengths. In a process called ablative photodecomposition, photons with high levels of energy break through the molecular bands of corneal surface tissue in the wavelength of 193nm. Extraction of tissue from cornea commences in a time limit of few nanoseconds to 5-15μs following the Eximer pulse. The most important advantages of using this laser are Optimum irradiance level and optimal repetition rate. What's more, the optical rules have been significantly developed to correct refractive disorders using laser for Atropy. Laser was first approved by FDA in 1995 to correct mild to moderate myopia. Recent advances made in laser sciences include eye tracking systems which make it possible to extract the tissue of cornea accurately during minor eye movements. One of the most important parts of laser beam is to know the functional information concerning tissue extraction conditions. One of the most important item is the correlation between the depth of tissue extraction and Fluence (energy per surface) of the radiated laser beam. The effectiveness of the tissue includes the amount of vaporized tissue per each unit of laser energy pulse whose maximum for the peak of Fluence is approximately 380-600mg/cm2 with an average level of 440mg/cm2 [5-8].

It is of significant importance to measure the size of the pupil before the operation. However, the role of pupil is discussed in post-LASIK operation results and patients' eyesight acceptability. Large pupils result in reduced visual acuity among patients undergoing treatment with laser and those not treated [2,5]. Post- LASIK corneal epithelium failures usually recover within 3 to 4 days using usual treatments. A weaker recovery of epithelium may be observed among those with connective tissue autoimmune diseases or sweet diabetes. The close and accurate examination of patients until the full and accurate reconstruction of corneal epithelium is of significant importance [5,6]. Within the first 24 hours after laser, patients experience various levels of pain (mild to moderate) and they may require to resort to oral narcotics to relieve the pain in many cases. Some studies have highlighted the effect of local non-steroid anti-inflammatory drops in reducing post-LASIK pain. However, these medicines may slow down the process of corneal epithelium reconstruction and cause sterilized opacities on the surface of the cornea and even some cases of corneal tissue melting have been reported following the utilization of diclofenac [9,10].

Various studies have also highlighted the effectiveness of various analgesic local drops including tetracaine in reducing post-LASIK operation pain. However, some studies consider this effectiveness to be far less than what is achieved by using local non-steroid anti-inflammatory drugs. Large quantities and long-term utilization of local analgesic drops may cause severe side effects in cornea, while the appropriate and short-term utilization of them does not seem to cause these damages or delay reconstruction of epithelium. A study conducted by Lichtinger et al. [11], showed that Gabapentin was significantly more effective than placebo in reducing post-PRK pain. To reduce the pain and facilitate reconstruction of epithelium after LASIK, other treatments such as local morphine have recently been studied [10,11].

A research by Zhao et al. [12]. Wang in China studied pain control and inflammation using tramadol after LASEK. In this research, the case group took tramadol pills twice a day in addition to Tobradex and four doses of diclofenac eye drop, while the controls received only Tobradex and four doses of diclofenac a day. The results achieved in that research showed that pain control in the first day of VAS was 0.48±0.67 and 1.70±0.69 ($P<0.001$) which exhibited a statistically significant difference and these values 4 days later were 0.18±0.39 and 0.65±0.55 ($P<0.05$) which exhibited a statistically significant difference. Consequently, tramadol was found to be more effective in controlling pain and inflammation after Lasek.

A research by Clark Js, Bentley E, Smith LJ in America compared the effectiveness of Tramadol with local Nalbuphine in reducing the corneal ulcer pain in dogs. In this research, the dogs were divided into three groups and Dexmedetomidine (5 μ/kg IV) was used to put the dogs to sleep. Then, 4mm of each dog's right eye epithelium was extracted. In Nalbuphine group (5 dogs), local Nalbuphine 1% drop along with placebo were used. In tramadol group (5 dogs), 4mg/kg tramadol along with local saline drop were given every 8 hours, while the placebo group (4 dogs) received placebo and local saline drops every 8 hours. 4 dogs in Nalbuphine group, 1 in tramadol group and 2 in control group required analgesics indicating that tramadol is more useful than Nalbuphine in reducing corneal pain [13,14]

Research method

This is a double-blind clinical trial conducted on 100 patients with refractive disorder who were supposed to undergo PRK. The following inclusion criteria were defined for participants, myopia≤8 diopter, Astigmati≤2 diopter, fixed refraction for at least 6 months, no visual contraindication including Keratoconus, Herpes keratitis, corneal dystrophy and corneal degeneration, cataract, glaucoma, history of any cornea or anterior segmental pathology including scar, lagutalum, dry eye, blepharitis, uveitis, no medical contradictions including diabetes, history of Colloid, autoimmune diseases and cases of immunity failure, pregnancy and breast feeding, no consumption of local or systematic anesthetics within the 2 weeks preceding the study, no consumption of local or systematic non-steroid analgesics within 1 month preceding the research and no consumption of local or systematic steroids. On the other hand, those volunteers who had undergone PRK previously were discarded from the research. The qualified individuals were selected for the research through convenient sampling method using clinical examinations by slit lamp and examination of Pentacum pictures.

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Utilization of rigid lenses was stopped at least 3 weeks prior to the examinations while this period for soft lenses was 1 week prior to the examinations. On the day when the operation was due, all patients filled the questionnaire before undergoing laser.

Then all patients underwent standard PRK using Excimer laser Nidek EC5000 ECXIII (nidek, Gamagori, Japan) under topical anesthesia with 0.5% Tetracaine 3 times every 5 minutes before operation by a surgeon. Laser with a wavelength of 193nm and 100-140mg/cm2 radiant-exposure was used in therapeutic plan. The corrective refractive disorder of the patient was measured using Transitional zone, 7mm and ablation zone, 6mm and given to the device. The epithelial tissue of the cornea was removed using alcohol. The laser was then focused and fixed in the pupil and the patient was asked to look at fixation light. The ray of laser was radiated on cornea in a single stage. After the process of tissue removal with laser was over, a soft bandage contact lens was placed on cornea and one drop of Gentamicin was poured on the eye. In the first group, the patients underwent treatment with 400mg Gelofen three times a day. In the second group, the patients received a single dose of tramadol before operation and one 25mg tramadol tablet every 12 hours for 2 days after the operation.

Using the standard pain questionnaire, the patients recorded their post-operation pain level on the first night after operation and then every morning and night for two days following the operation. The operation was carried out by a surgeon while medical suggestions and the answering and information collection methods were explained by the researcher.

Other medical orders used routinely for both eyes after completion of laser and patient discharge from the hospital were:

a. Chloramphenicol drop (1 drop every 4 hours for 1 week)

b. Betamethasone drop (1 drop every 4 hours for 2 weeks)

c. FML drop since the third week (1 drop every 8 hours for 4 weeks and 1 drop every 12 hours for 4 weeks and 1 drop every day for 8 weeks)

d. Artificial tear drops without preservatives (1 drop every 4 hours for 4 weeks)

3.2. Data analysis method

If the mean of patients' response numbers in the standard questionnaire were less than 3, the pain control procedure would be considered successful. The resulting information was then analyzed using PASW18 software with the aid of T-test.

Results

As many as 100 patients undergoing PRK took part in this project. Using the randomized numbers table, they were divided into 2 groups (each composed of 50 patients) where the first group underwent treatment using Gelofen and the second group underwent treatment using tramadol. Having conducted PRK, three participants in the second group were excluded due to drug abuse. The average age of patients in Gelofen group was 24.80±4.59 years, while this average in tramadol group was 27.80±5.97 years. Both groups were similar in terms of age. 46% of the patients in the first group were male and 54% were female, while this ration in the second group was 42.6% to 57.4%. The average pain acuity using tramadol and Gelofen in various times is presented in the following Table 1 and Figure 1.

Table 1: The results of T-test used to study the pain acuity in terms of the type of medicine and days following the operation.

Average pain acuity	Gelofen (VAS)	Tramadol (VAS)	Test	P-value
In the first night	4.96s±1.36	3.25±1.49	Independent Samples Test	< 0.001
First day after surgery	4.38±1.56	2.14±1.35	Independent Samples Test	< 0.001
2nd night after surgery	3.98±1.53	1.76±1.21	Independent Samples Test	< 0.001
2nd day after surgery	3.56±1.47	1.46±0.92	Independent Samples Test	< 0.001
3rd night after surgery	3.24±1.54	1.12±0.82	Independent Samples Test	< 0.001
3rd day after surgery	2.86±1.60	0.91±0.77	Independent Samples Test	< 0.001

Discussion

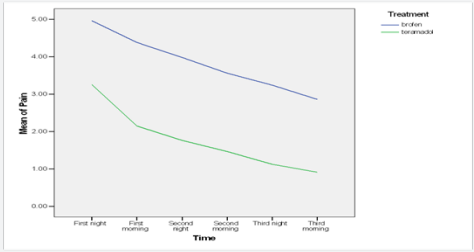

Figure 1: The results of T-test to study the pain acuity in terms of the type of medicine and days following the operation.

PRK using excimer laser beam helps correct the refractive faults of the eyes. Considering the shorter time required for PRK compared to LASEK, the possibility of conducting it on thin corneas, no need for microkeratome and no side effects associated with flap formation, PRK is more preferable than LASEK in myopia, mild to moderate hyperopia and astigmatism. However, PRK is usually followed by more pain and agony and a longer period of drug consumption and rehabilitation time compared to LASEK. The fact that many adherents of LASEK operation prefer not to do PRK merely for its post-operation pain [15-18].

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The general goal of this research is to study post-PRK pain levels in the group undergoing treatment with tramadol and the other group undergoing treatment with Gelofen. The average age of the patients studied was 25 years old nearly close to the average age of those applying for PRK in the society as the patients are usually young people candidated for this operation due to refractive faults and inability or unwillingness to use glasses or contact lenses.

In the present research, the average pain acuity while using oral tramadol was less than the average pain acuity while using oral Gelofen. The statistically significant difference observed there was in line with the results achieved in our research. In all times studied where VAS degree was recorded, tramadol was more effective than Gelofen in reducing post-PRK pain and a statistically significant difference was observed between these various levels of pain reduction. With the exception of the first night following the operation, the slopes of the charts of these reduction were nearly constant and approximately close to one another.

Final Conclusion

Oral tramadol is more useful than Gelofen in reducing post-PRK pain. This difference is statistically significant and its utilization is justified by this research.

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