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0.1% Nepafenac reduces pain and increases patient comfort during cataract surgery

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ABSTRACT

Purpose: To evaluates analgesic effectiveness of 0.1% nepafenac during cataract surgery.
Methods: This prospective randomized randomized double-masked, placebo-controlled study comprised 80 eyes of 40 consecutive patients who underwent bilateral cataract surgery and implantation of foldable intraocular lens with topical anesthesia with and without topical nepafenac drops. Each eye of patients was assigned to group 1 and group 2. Topical anesthesia combined with 0.1% nepafenac used three times a day the day before the surgery and once half an hour just before the surgery was group 1, consisting of 40 eyes, and topical anesthesia with using placebo was group 2 consisting of 40 eyes. Patients were asked to score their pain using a visual analog scale (VAS) and verbal pain scale (VPS) immediately following the surgery. When the patient moved or squeeze the eye during surgery, the surgical comfort was evaluated as bad and otherwise, it was evaluated as good.
Results: When the intensity of pain during the surgery was evaluated, the percentage of patients reporting mild or no pain in group 1 was %825 and in group 2 was %45. Mean VAS pain score and mean VPS pain score in group 1 was significantly lower than that in group 2($p = 0.024$, $p < 0.001$). Surgical comfort in group 1 was %825 and in group 2%65($P = 0.075$).
Conclusion: 0.1% nepafenac reduces pain of patients who undergone routine clear corneal phacoemulsification with topical anesthesia and may increase patient comfort during the surgery when used preoperatively.

1. Introduction

Cataract surgery is the most commonly performed surgery in the world. Today duration of the surgery has been quite shorter due to improved technology. Therefore anesthesia in cataract surgery was replaced with mostly local anesthesia by the time. Local anesthesia has many advantages over general anesthesia. It provides a sufficient analgesia and quick recovery [1] Additionally, a wide range of local anesthetic techniques has been developed for cataract surgery such as regional, intracameral, and topical anesthesia [2].

Preferred anesthesia in cataract surgery should provide reduced anxiety and pain of patients and increased patient and the surgeon comfort during the surgery. This situation reduces the possible complications during the surgery. So far many local anesthetic techniques were compared to evaluate analgesic effectiveness in previous studies to find the best technique for cataract surgery [3,4,5]

Topical non-steroidal anti-inflammatory drug (NSAID)s entered the ophthalmology practice in 1970 s when researchers noticed that topical agents were more effective than systemic drugs to penetrate the intraocular tissue [6]. They have many advantages like preventing miosis, cystoid macular edema and reducing postoperative inflammation. In recent studies, NSAIDs were also used to reduce the pain of patient following cataract surgery [7,8]

The main aim of the present study is to assess patients' pain perception during phacoemulsification cataract surgery with intraocular lens(IOL) implantation under topical anesthesia combined with and without nepafenac ophthalmic eye suspension.

2. Materials and methods

This prospective randomized double-masked, placebo-controlled study comprised 40 consecutive patients with bilateral age-related cataract scheduled for phacoemulsification cataract surgery and implantation of foldable IOL. All patients' each eye was operated one week apart. The research was confirmed by Institutional Review Board and was conducted in accordance with the Declaration of Helsinki. All patients gave written informed consent before their participation.

Patients with dementia, major psychiatric disorder or other

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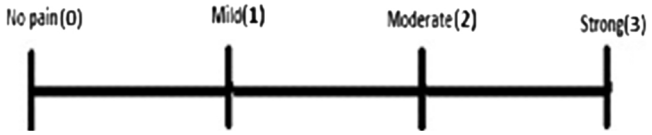

Fig. 1. Verbal Pain Scale.

neurological disease impacting cognitive function and memory and patients who did not sign the informed consent form or were non-compliant were excluded from the study. Group 1 used topical nepafenac with topical anesthesia, consisting of 40 eyes of 40 patients and group 2 used placebo with topical anesthesia, consisting of other eyes of same 40 individuals. Patients one eye' was assigned to group 1 and another eye to group 2 randomly. The eyes in two groups were also randomized equally as being the first or the second operated eye. Where the second eye surgery was reported to be more painful [9]

All patients were operated by the same surgeon (Ogurel T). Prior to the surgery, the pupil was dilated with topical cyclopentolate eye drops. In group 1, nepafenac and in group 2, placebo (sterile saline solution) was used three times a day the day before the surgery and once half an hour just before the surgery. Both agents were supplied in masked vials with trial-specific labels to conceal the identity of the test agent and placed in a tamper-evident box for distribution to subjects.

The anesthetic (%0,5 proparacaine, Alcaine) was administered by one of two nurses both having been trained in and experienced with the technique. Two drops of topical anesthetic were applied 5 min before surgery. In both groups, two side-port and a main temporal incision was performed in all eyes. Following injection of viscoelastic in both group continuous curvilinear capsulorhexis, hydrodissection, phacoemulsification of the nucleus and cortex aspiration were performed. Foldable acrylic IOL was implanted by hydoimplantation technique into the capsular bag and all corneal incisions were hydrated. Posterior capsule rupture did not occur in any eyes. Immediately after surgery, patients were informed for the verbal pain scale(VPS) [Fig. 1] and visual analog scale (VAS) [Fig. 2]. Patients were asked to rate their pain with thr VPS from 0 to 10 that 0 = no pain/no distress and 10 = agonizing pain/unbearable distress. For the VAS, patients were asked to mark their level of pain. The surgeon, the patient and the data collectors are both blind to the drops used to the patients. Only the resident physician knows the groups.

Surgical complication, duration of surgery (min) and patient comfort (poor/good) were evaluated separately for each patient.

The statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) program. The chi-square test was used for intergroup comparisons of nominal data and the Student's *t*-test was used to compare numerical parameters. In all analyses, p value less than 0.05 was considered statistically significant.

3. Results

Eighty eyes of 40 consecutive patients 17 men [42.5%] and 23 women [57.5%]) were enrolled in the study. The mean age of the man and women was 66.4 ± 8.2 and 64.9 ± 5.3 years. The difference between the two groups was not statistically significant in terms of age and gender ($p = 0.310$ and $p = 0.210$). Table 1 shows the demographic data of two study groups.

Table 1
Comparison of the demographic characteristics of patients with VAS(Visual Analog Scale) Score, surgery duration and patient comfort.

	Female(23)	Male(17)	P value.
Age	64,38 ± 5,94	65,15 ± 5,82	0,714
VAS Score	3,15 ± 2,47	2,76 ± 2,19	0,436
Surgery Duration (min)	702 ± 1,07	7,00 ± 1,32	0,110
Patient Comfort	18(%39)	27(%80)	0,018

The number of patients who stated that they did not feel any pain during the surgery were 15 (37.5%) in group1 and 5(12.5%) in group 2(Table 2). Mean VAS pain score was 2.15 ± 1.23 in group 1 and 4.15 ± 1.13 in group 2. Mean VPS and VAS pain score in group 1 were significantly lower than in the group 2 ($p < 0.001$, $p = 0.024$). The patients' intraoperative pain levels evaluated by VPS and VAS are shown in Tables 2 and 3. There was no statistically significant difference when first and second eyes were compared ($p > 0.05$) (Table 3). Total surgery duration was 696 ± 122 in group 1, 707 ± 109 in group 2. No statistically significant association was found between mean surgery duration and age or gender ($p > 0.05$). Patient comfort was %825 in group 1 and %65 in group 2.Patient comfort was higher in group 1, female patients and first eye.

No eyes experienced intraoperative or postoperative complications.

4. Discussion

Today duration of cataract surgery has been shortened following the development of phacoemulsification. Although uncomplicated cataract surgery often takes no longer than 10 min and the degree of pain was decreased during the surgical steps, it still requires analgesia. However, even though topical anesthesia became a popular technique [10], it does not provide an adequate analgesia as efficacious as other local anesthetic techniques such as peribulbar, intracameral, and topical anesthesia [11,12]

Pain in ocular surgery occurs due to surgical manipulation which activates phospholipase and cyclooxygenase (COX) enzymes resulting in prostaglandin production. So this causes peroperative miosis and postoperative inflammation and cystoid macular edema [6]. Therefore, NSAIDs have been used to prevent or reduce these cataract surgery complications.

NSAIDs are potent inhibitors of COX enzymes and reduce the production of prostaglandins. They have been used in ophthalmic disorders systemically. Kessel et al. evaluated prevention of postoperative inflammation and macular edema by steroid and nonsteroidal anti-inflammatory eye drops and found that topical NSAIDs are more effective in controlling postoperative inflammation and more effective than topical steroids in preventing pseudophakic cystoid macular edema after cataract surgery[13]. Rajpal et al. reported that NSAIDs effectively treated pain and inflammation following cataract surgery in their studies[14].In another study Zanetti et al. compared NSAIDs with placebo for maintaining intraoperative mydriasis and described that

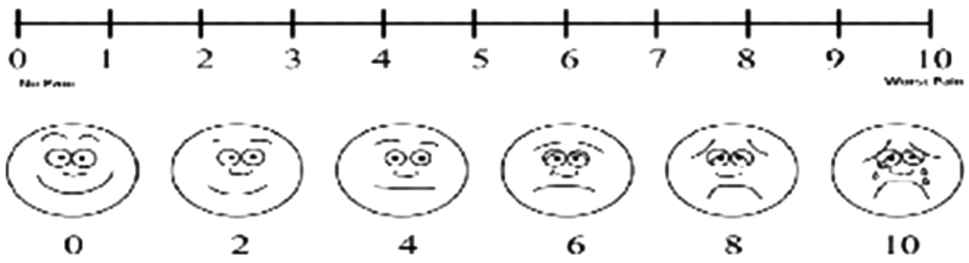

Fig. 2. Visual Analog Scale.