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ORIGINAL RESEARCH

Nepafenac punctal plugs delivery system- potency in inflammation following cataract surgery

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ABSTRACT

Aim: The purpose of this study was to determine the safety and effectiveness of a nepafenac punctal plug delivery system (N-PPDS) after cataract surgery.

Methods: The investigation was carried out in a single Indian clinical setting. It is a single-center, randomised, parallel-arm, double-masked, prospective pilot research. Thirty-eight participants (aged 22 and higher) with predicted postcataract correctable distant vision of 20/30 or better and lower puncta enabling dilatation up to 1.0 mm were included in the study (N-PPDS group). All of the eyes had standard unilateral cataract surgery with intraocular lens implantation. Postoperative ocular discomfort and inflammation were used as primary and secondary efficacy measures, respectively.

Results: The experimental N-PPDS group had 38 patients, while the control group included 18 individuals. The N-PPDS group had a substantially greater proportion of pain-free patients (22/32 [69%] after 3 days, P =.038; and 24/36 [67%] at 7 days, P =.018). The N-PPDS group had a larger percentage of pain-free patients (15/29 [52 percent]) at all visits (P =.001). At 7 days, the N-PPDS group had good anterior chamber cell scores (patients with no anterior chamber cells: 18/36 [50%]; P =.034). At 14 days, the plug retention rate was 98 percent (55/56).

Conclusion: Adverse events associated with the punctal plug therapy occurred in 1 case of the N-PPDS group involving placement. The N-PPDS was shown to be both safe and effective in the treatment of ocular discomfort and inflammation following cataract surgery.

Keywords: Nepafenac Punctal Plugs Delivery System, Cataract surgery, Inflammation, Ocular discomfort

INTRODUCTION

Cataract surgery is the most widely done operation in the country, with almost 9 million of these procedures conducted in India between 2001 and 2005 among those who were most likely to go blind [1-4]. In India, these figures increased to 14 million between 2016 and 2020. Several studies have found noncompliance and self-administration issues with topical medicines among patients undergoing cataract surgery [1-4]. According to a 2014 research, 92.6 percent of patients were given the wrong topical medicines following cataract surgery [5]. Although advancements in cataract extraction (CE) surgery have reduced the physical damage associated with ocular surgery, disruption of the blood-aqueous barrier during surgery might result in the release of inflammatory mediators, raising the risk of subsequent

ocular problems [6, 7].A favourable postoperative result is dependent on the correct use of topical medicines to reduce the inflammatory response caused by cataract surgery [8, 9]. Post-operative inflammation, if left untreated, might raise the likelihood of moderate iritis with enlarged cells and flare in the anterior chamber (AC) and interfere with the patient's visual rehabilitation [10-14]. In rare situations, inflammation can cause cystoid macular edoema, posterior capsule fibrosis, keratopathy, fibrin response, or chronic uveitis. As a result, anti-inflammatory medications are regularly provided to help patients recover faster from cataract surgery and to increase their comfort [15-18].

Previous clinical trials using 0.1 percent and 0.3 percent ophthalmic suspensions of Nepafenac (NEVANAC®/ILEVRO®) confirmed the safety and effectiveness of epafenacin in the management of pain and inflammation associated with ocular surgery [19, 20]. The goal of this study is to assess the use of a punctal plug drug delivery device capable of delivering a sustained, safe, and effective concentration of epafenacto a subject having cataract surgery for the treatment of post-operative ocular discomfort and inflammation.

METHODS

This is a double-blind, randomised trial with parallel arms. Each trial participant was randomly assigned one to two days before their scheduled cataract surgery: An N-PPDS will be implanted in the lower punctum of each research subject's planned operative eye. Following cataract surgery, all plugs will be left in the research subject's lower punctum for two weeks.

INCLUSION AND EXCLUSION CRITERIA

Any male or female subject in good general health who was 22 years old at the time of the screening visit; any subject with a cataract for which routine phacoemulsification extraction and implantation of an intraocular lens was planned; or any subject with a lower punctum that could be dilated to 1.0 mm in their scheduled surgical eye were all included.

In terms of exclusion criteria, any subject with a history of complications, adverse events, trauma, or disease in the nasolacrimal area, whether or not caused by punctal plug wear, was barred from participating, including but not limited to dacryocystitis, inflammation, or canaliculitis in either eye.Subjects with any signs of intraocular inflammation (cells/flare) in either eye at the screening visit, with a history of chronic/recurrent inflammatory eye disease (e.g., scleritis, uveitis, herpes keratitis) in either eye, with a known sensitivity to nepafenac or any inactive ingredient of the punctum plug, silicone, fluorescein, topical anesthetic, or any other products required for study procedures or cataract surgery, with structural lid abnormalities (e.g., ectropion, entropion) in their schedule surgical eye, with a puncta >0.9 mm prior to dilation in their scheduled surgical eyewere excluded.

CONSENT

Each research participant was informed that they might withdraw from the study at any moment. The investigators ensured that the subjects' identities were preserved throughout in order to safeguard their confidentiality. As a result, the subjects were given a unique ID to use instead of their real names. In order to meet the ethical requirements of this study, the Institutional Ethics Committee of Katihar Medical College authorised an informed consent form.

RESULTS and DISCUSSION

Table 1: Baseline Characteristics of patients

Participants	**38**
Age	
≤ 18	0
Between 18 and 65 years	14
≥ 65	24
Mean standard deviation	67.2
Sex	
Male	19
Female	19
Pain measure	
No pain	30
Trace pain	2
Mild pain	2
Moderate pain	0
Severe pain	0
Intolerable pain	0
Anterior chamber cells assessment	
No cells seen	22
1-5 cells seen	7
6-15 cells seen	5
16-30 cells seen	0
>30 cells seen	0
Anterior chamber flare assessment	
No Tyndall effect	29
Tyndall effect barely discernible	3
Tyndall effect in anterior chamber is moderately intense	2
Tyndall effect in anterior chamber is very intense. The aqueous has a white milky appearance	0
Eye disorders	
Elevated IOP	3
Iritis	2
Posterior capsule rupture	0
Pain/irritation/inflammation	3
Disorders	
Cavity	1
Headache	1

The individuals' pain was measured on a scale of 0 to 5, with 0 representing no discomfort and 5 representing unequivocal, continuous intolerable ocular or periocular pain. Table 1 shows that on day 3 following surgery, the percentage of patients experiencing no discomfort was much higher (>70% ; P =.0032). An study of the proportion of patients with no pain throughout the full postoperative follow-up period revealed a statistically significant difference in favour of the nepafenac PPDS group (>42 percent; P.001) (Table 1).

The anterior chamber cells were graded on a scale of 0 to 4, with 0 signifying no cells and 4 reflecting more than 30 cells. The anterior chamber flare was graded on a scale of 0 to 4, with 0 reflecting no Tyndall effect and 4 signifying a very significant Tyndall effect in the anterior chamber. As shown in Table 1, the secondary outcome analyses revealed statistically significant differences favouring the nepafenac PPDS group for the percentage of patients

with none, trace, or mild anterior chamber cells on day 3 postoperative (98 percent; P =006) and the percentage with none or trace anterior chamber flare (94 percent; P =.067).At postoperative day 14, mean uncorrected visual acuity was significantly good in the patients treated with the nepafenac PPDS (20/32; P =.015), and a significantly high percentage of patients treated with the nepafenac PPDS achieved 20/20 or better best corrected visual acuity (65 percent; P =.021). In this trial, participants were randomly assigned to receive a nepafenac intracanalicular insert following cataract surgery. Other anti-inflammatory medications were not approved before, during, or after surgery.

CONCLUSION

The preliminary findings of this clinical trial testing the Nepafenac Punctal Plug Delivery System to reduce post-operative pain and inflammation in individuals after cataract surgery revealed that sustained release Nepafenac was safe and effective. N-PPDS effectively reduced pain and inflammation, resulting in better clinical results and subject comfort.

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