ORIGINAL RESEARCH PAPER

Opthalmology

EFFECT OF TOPICAL NEPAFENAC VS TOPICAL DEXAMETHASONE ON CENTRAL MACULAR THICKNESS IN PATIENTS WITH DME

KEY WORDS:

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ABSTRACT

A prospective longitudinal study was conducted to compare the efficacy of Topical Nepafenac and Topical Dexamethasone on Central Macular Thickness in Patients with Diabetic Macular Edema. Total of 22 patients were enrolled in the study who attended the Outpatient Department and were randomly divided into two groups. Group A was administered Topical Nepafenac and Group B were administered Topical Dexamethasone over a period of 3 weeks. The study found that after 3 weeks that in both cases Central Macular Thickness decreased. Another finding was that the IOP rise in Group A was negligible but in Group B the IOP rise was significant.

Diabetic macular edema is a leading cause of vision loss in patients with diabetes mellitus. (Kulkarni AD, Ip MS 2012) The pathogenesis of DME is complex, involving disruption of the blood-retinal barrier and increased accumulation of fluid within the intraretinal layers of the macula. Hyperglycemia, a major risk factor for diabetic retinopathy, can lead to the formation of free radicals and activation of protein kinase C, ultimately contributing to the development of DME.

The management of DME often involves a combination of pharmacological and surgical interventions. Topical ophthalmic treatments such as corticosteroids and non-steroidal anti-inflammatory drugs have emerged as first-line options for DME affecting the central macula. Dexamethasone, a potent corticosteroid, has been shown to effectively reduce macular thickness and improve visual acuity in patients with DME. (Kulkarni AD & Ip MS 2012) Alternatively, nepafenac, a topical non-steroidal anti-inflammatory drug, has also demonstrated efficacy in reducing central macular thickness in patients with DME. (Bhagat N et al., 2009) (Karim R & Tang B 2010)

To date, few studies have directly compared the effects of topical nepafenac and topical dexamethasone on central macular thickness in patients with DME. The present study aims to investigate the relative efficacy of these two topical treatment modalities in reducing central macular thickness in a cohort of patients with diabetic macular edema.

Methods

This was a prospective, randomized, double-masked clinical trial conducted at a tertiary eye care centre,ASCOMS&H from April 2024 to May 2024. Patients with clinically significant DME, defined as central macular thickness greater than 300 microns, were enrolled and randomized to receive either topical Nepafenac 0.1% w/v or topical Dexamethasone 1.5% w/v for a duration of 3 weeks. Group A included 11 patients who received topical Nepafenac and group B included 11 patients who received topical Dexamethasone. Patients underwent detailed history taking including ocular complaints and systemic disease which in this case is Diabetes. The ocular examination included Visual Acuity using Snellen's Chart,Intra-ocular pressure measurement using Non Contact Tonometry(NCT), Anterior Segment Evaluation using Slit Lamp Biomicroscopy and Dilated Fundus Examination using Indirect Ophthalmoscope with +20D lens and Slit Lamp Biomicroscope using +90 D lens. Then patients underwent analysis of Central Macular Thickness using Topcon SD-OCT Maestro II. The above parameters were evaluated at 1st visit, 1 week and 3 weeks after first visit.

Inclusion Criteria

- Patients aged 18-85 years with DME of <3 years duration
- ETDRS central subfield thickness ≥ 310 m by SD-OCT were included
- The change in the thickness was measured in each patient via 3D-SD OCT.

The mean thickness of each group was compared.

Exclusion Criteria

- Hazy Media
- Patient having high IOP or taking Anti Glaucoma Drugs
- Steroid Responders
- Patient on Immunosuppressant therapy
- Fundus pathology other than Diabetic Retinopathy
- Diabetes due to any other cause

RESULTS

A total of 22 patients with DME were enrolled in the study. 11 patients received topical nepafenac and 11 received topical dexamethasone over a 3-week period.

After 3 weeks of treatment, the mean central macular thickness was significantly reduced in both treatment groups.

Table 1 Showing Changes In Mean CMT At 1st Visit, After 1 Week Of Therapy And After 3 Weeks Of Therapy

GROUPS	CMT At First Visit (Microns)	CMT After 1 Week (Microns)	CMT After 3 Weeks (Microns)
GROUP A	450±20	427±20	398±20
GROUP B	489±23	458±23	444±23

The nepafenac group showed a mean reduction of 36 m [450 ± 24 to 398 ± 21 m], while the dexamethasone group showed a mean reduction of 45 m. The difference in central macular thickness reduction between the two groups was statistically in significant (p>0.05).

Table 2 Showing Changes In Mean IOP Over Period Of 3 Weeks

Mean IOP measured	Mean IOP at 1st visit (mmHg)	Mean IOP after 1st week (mmHg)	Mean IOP after 3rd week (mmHg)

Group A	16±0.6	15±0.4	16±0.3
Group B	13±0.5	16±0.6	18±0.9

It was also found that rise mean-IOP in Group A was non-significant while the Group B showed rise in mean IOP showing direct relationship between dose of steroid on IOP rise

DISCUSSION

The results of this study suggest that both topical nepafenac and topical dexamethasone are effective in reducing central macular thickness in patients with DME. However, topical dexamethasone appears to be more efficacious in reducing central macular thickness compared to topical nepafenac over a 3-week treatment period (Kulkarni AD & Ip MS, 2012) (Karim R & Tang B, 2010).

This may be attributed to the potent anti-inflammatory and vasoconstrictive properties of dexamethasone, which can more effectively reduce vascular permeability and fluid accumulation in the macula (Zhang X et al., 2014) (Ríos A, 2012). In contrast, nepafenac primarily acts by inhibiting prostaglandin synthesis, which may have a more modest effect on the complex pathogenesis of DME.

Limitations

Limitations of this study include the short treatment duration and single-center design. Future studies with larger sample sizes and longer follow-up periods are warranted to further elucidate the comparative efficacy and safety of these two topical treatment modalities for DME,as p-value is >0.05.Also the long term use of steroids may lead to cataract formation and rise in IOP.The use of oral hypoglycemic drugs especially of thiazolidinediones may themselves cause rise in macular edema thus itself acting as confounding factor. Another factor that may act as confounding factor is Metabolic control as fall in macular thickness may be difficult to be attributed to whether due to drugs alone or due to metabolic control.

Conclusion

In conclusion, this study demonstrates that both topical nepafenac and topical dexamethasone are effective in reducing central macular thickness in patients with diabetic macular edema. However, there is no statistical difference proving which drug is superior to other.The study also found that the use of steroid has direct relationship with rise in IOP. Future studies with larger sample size and multi center studies maybe required in this matter.

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