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A Clinical Study of Topical Flurbiprofen Eye Drops in Comparision with Placebo in The Treatment of Episcleritis

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Abstract: *Episcleritis is a benign inflammatory affectation of the deep subconjunctival connective tissues including superficial scleral lamellae and frequently affects both eyes; but may not be simultaneous[1]. Topical Flurbiprofen was compared with placebo in the treatment of episcleritis . Sixty patients were included in this study. Rapid spontaneous improvement in symptoms and signs was noted in the majority of cases. There was no significant difference between the cure-rates of patients treated with Flurbiprofen and placebo over a 3-week trial period.*

Keywords: *Episcleritis, Flurbiprofen, Placebo, Scleritis*

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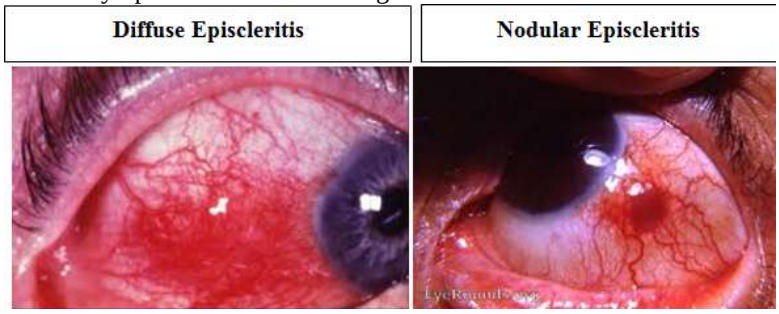
I. Introduction

Episcleritis is generally considered to be a benign condition. Although patients complain of discomfort and of the appearance of their inflamed eye, the problem is recognised as self-limiting. However, it represents one end of the spectrum of ocular inflammatory disease, with necrotising scleral disease at the other. Currently, topical steroids are the mainstay of the treatment of episcleritis; however they are known to give rise to an inflammatory rebound phenomenon as well as to other well documented ocular side-effects such as reactivation of Herpes Simplex Keratitis. Flurbiprofen is one of the few non-steroidal anti-inflammatory drugs which has been found to be effective in the management of scleral inflammatory disease. However, like other drugs in this class, oral administration is complicated by symptoms of heartburn and by gastric or duodenal ulceration. An effective topical anti-inflammatory drug would undoubtedly be useful in the management of scleral as well as episcleral disease. Recently, flurbiprofen has become available in drop form, marketed for use in the prevention of surgically-induced miosis. We assessed its use and compared it with a placebo in the clinical management of episcleritis.

II. Pathogenesis

Dense lymphocytic infiltration of the subconjunctival and episcleral tissues is found[2.]Patients are usually young adults and commonly females[1].An associated local or systemic disorder is present in one third of the patients [2]. A history of Rheumatoid arthritis is commonly obtained [1]. A history of recurrent episodes is common. Clinically, two types of presentations may occur. (i) Simple or diffuse and (ii) nodular episcleritis[1]. Symptoms of episcleritis include redness and mild irritation or discomfort [2]. Ocular examination reveals episcleral injection, which may be nodular sectoral or diffuse. There is no inflammation or edema of the underlying sclera. It is usually temporal [2]. Signs may include engorgement of the large episcleral vessels which run in a radial direction beneath the conjunctiva [1]. In nodular episcleritis a circumscribed nodule of dense leukocytic infiltration which may be as large a lentil, appears usually 2 to 3mm from the limbus. It looks purple but not bright red. It is more symptomatic and takes longer to resolve.



III. Course

It is usually transient lasting several days or some weeks but has a strong tendency to recur. Occasionally the attacks are fleeting, but frequently repeated, (episcleritis periodica fugax). It never ulcerates. The cornea and uveal tract rarely participate in the inflammation. In the worst cases, the disease extends into the deeper parts of sclera to cause scleritis [1].

IV. Differential Diagnosis

Episcleritis must be differentiated from the most dangerous Scleritis and the treatment also greatly differs. Conjunctivitis is ruled out by the lack of palpebral conjunctival injection or discharge [2].
Patients with scleritis commonly complain of severe pain. Presence of scleral edema is the sine qua non her establishing that a patient has scleritis, as agreed by Watson and hazelman.

4.1 Cardinal features in differentiating of episcleritis from scleritis[(7,1)]

	Conjunctivitis	Episcleritis	Scleritis
Onset	Sudden	Sudden	Gradual
Redness	Bright red	Red	Dusky red or Bluish red
Pain/Irritation	Irritation	Slight, localised	Moderate or Severe, Localised & referred
Photophobia/Lacrimation	No	Ocassionally	Occasional, but present in necrotising scleritis
Vascular changes	Conjunctival vessels	Superficial episcleral vessels	Deep episcleral and occasional vascular patch
Chemosis	No	Occasional	Common in diffuse type
Scleral thickening	No	Rare	Present but definite in scleromalcia
Visual acuity	Normal	Normal	Occasional loss but common in necrotising scleromalacia perforans and posterior scleritis

V. Management

As the condition is self limiting and harmless and frequently symptomless treatement may be unnecessary. If it is felt necessarily to treat the patient either because of symptomatology or because of multiple recurrences,the patient may be treated with topical medication with artificial tear drops or Flurbiprofen eye drops. Topical steroids are never indicated in case of episcleritis because the evidence is abundant that although they may be effective temporarily their use prolongs the natural history of resolution of episcleritis and makes each recurrence more difficult to treat due to rebound phenomenon.

VI. Materials And Methods

This is a comparative study between the placebo and treatment with Flurbiprofen eye drops on patients with episcleritis attending the Ophthalmology OPD, GGH, Guntur. This is a hospital based prospective study to compare the efficacy of Flurbiprofen eye drops in patients with Episcleritis. Sixty patients were included in this study.

4.1 Inclusion Criteria:
Male /female patients between 10 and 50 years with episcleritis.
4.2 Exclusion Criteria:
1) Patients with other ocular diseases.
2) Patients with any associated systemic diseases.
3) One eyed patients
4) Patients with nodular episcleritis, who may definitely need flurbiprofen eye drops.
5) Patients with scleritis.

VII. Methodology

After taking informed consent, the age, sex of the patients were recorded. A detailed history was taken, with particular attention as to whether this was the first or a recurrent episode, the duration of the episode, the patient's past medical history followed by systemic and ocular examination. The severity of their symptoms (pain) & Conjunctival and episcleral injection were each assessed according to intensity and area involved

Examination

Visual acuity was recorded with Snellen's chart, a comprehensive eye examination by Slit lamp, Examination of retina with + 78D or + 90D lens was done, to exclude any other ocular disease. Physician's consultation was taken in all the patients to rule out any systemic disease.

Management Of Episcleritis

We divided the patients in to two groups & started the treatment with placebo for patients of Group I and for the patients of Group II we started Flurbiprofen eye drops. As the disease is self limiting, we wanted to assess the need for treating the episcleritis patients with Flurbiprofen eye drops.The treatment was continued for three weeks in every case even if the inflammation had resolved.

Follow Up

Patients were followed up after the end of first, second and third weeks. The symptoms and signs were noted.

VIII. Observation And Results

60 patients were divided in to two groups & started the treatment with placebo for patients of Group I and for the patients of Group II we started Flurbiprofen eye drops.

Total no of patients	Group I(Placebo)	Group II(Flurbiprofen)
60	30	30

11.1 Age Distribution:

Age of the patients included in the study ranged between 10 and 50 years. Mean age of our study is 28.35 yrs. Majority of the pts falling under the age group of 25-50yrs.

Age	Group I(30)	Group II(30)
10-25 years	9(30%)	8(26.66%)
25-50 years	21(70%)	22(73.33%)

11.2 Gender Distribution:

Out of 60 patients, 54 patients were female and 6 patients were male. Female population was more in this study.

Gender	Male	Female
Group I(30)	3(10%)	27(90%)
Group II(30)	3(10%)	27(90%)

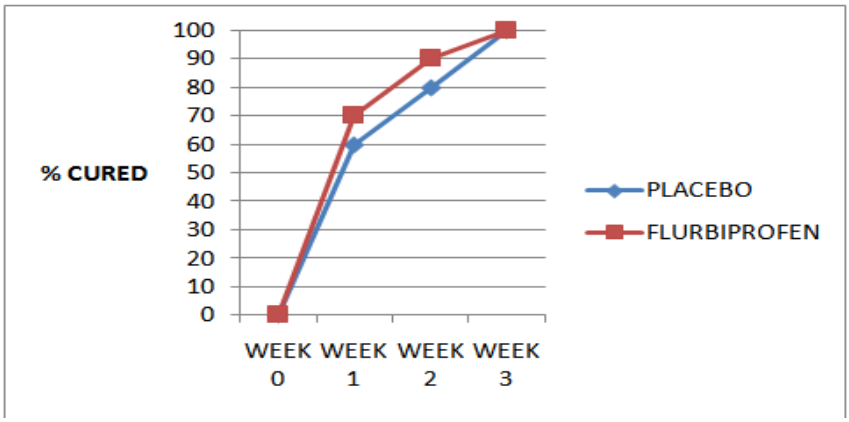
11.3 Improvement in Symptoms & Signs:

	Symptoms		Signs	
	Decrease in irritation	Decrease in Redness	Decrease in Episcleral congestion	No improvement
Group I(30)	27(90%)	28(93.33%)	29(96.66%)	1(3.33%)
Group II(30)	29(96.66%)	27(90%)	29(96.66%)	1(3.33%)

11.4 Complications:

	Complications	
	Nodular Episcleritis	Scleritis
Group I(30)	0	0
Group II(30)	1(3.33%)	0

12.1 Symptoms: % Cured



There was no significant difference between the cure rates of patients treated with Flurbiprofen & Placebo.

IX. Summary

60 patients were divided in to two groups & started the treatment with placebo for patients of Group I and for the patients of Group II we started Flurbiprofen eye drops. Age of the patients included in the study ranged between 10 and 50 years. Mean age of our study is 28.35 yrs. Majority of the pts falling under the age group of 25-50yrs. Out of 60 patients, 54 patients were females and 6 patients were males. Female population was more in this study. There was no significant difference between the cure rates of patients treated with Flurbiprofen & Placebo. Ocular complications occurred in 3.33% of patients. No patient with episcleritis has a decrease in visual acuity.

X. Discussion

This study confirms that in the majority of patients, resolution of symptoms and signs occurs rapidly, even with placebo. However, the duration of the inflammation prior to many cases presenting to OPD and the persistence of an inflammatory reaction even after three further weeks' treatment suggests that in some cases, episcleritis may not be self-limiting. Clearly, the nature of the inflammatory process is very variable. Flurbiprofen sodium is a phenylalkanoic acid (2-(2-fluoro-4-biphenyl)-propionic acid. CI5 H 13 F03.) which possesses anti-inflammatory, analgesic and antipyretic activity. It is thought to act by inhibition of prostaglandin synthetase. Although flurbiprofen is known to be effective in scleritis and episcleritis when administered orally, it does not appear to be a useful topical agent in the treatment of episcleritis. Carbon-14 studies have shown the penetration of flurbiprofen into the cornea, sclera and aqueous to be good, being comparable to that of dipivefrin. The problem therefore is unlikely to be poor bioavailability. As a prostaglandin synthetase inhibitor, flurbiprofen may be more useful in preventing the onset of inflammation than in settling it once initiated. However this does not explain the difference between the effectiveness of oral and topical preparations.

This study confirms episcleritis to be a condition which is usually benign and self-limiting. However, the course of the inflammatory process can be variable and progression to Nodular scleritis was observed in one patient of 60 patients.

XI. Conclusions

Episceritis is a self limiting disease better not to subject the patient to any treatment. But the patients who cannot tolerate can be given any placebo or Flurbiprofen eyedrops. They must be followed up weekly and note any development of complications like nodular episcleritis and scleritis. Then they must be treated.All the patients must be thoroughly investigated for any systemic associations which must be treated appropriately by a physician.

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