International Ophthalmology **25:** 147–153, 2004.

Efficacy and safety of 1% rimexolone versus 1% prednisolone acetate in the treatment of anterior uveitis – a randomized triple masked study

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Received 17 July 2001; accepted 29 March 2004

Key words: anterior uveitis, aqueous cells, aqueous flares, prednisolone acetate and rimexolone

Abstract

Purpose: To evaluate the efficacy and safety of 1% rimexolone versus 1% prednisolone acetate ophthalmic suspension in the treatment of anterior uveitis. *Methods:* A randomised triple masked, parallel comparison of rimexolone and prednisolone acetate ophthalmic suspensions was carried out on 78 patients with acute, chronic and recurrent anterior uveitis. Treatment regimen included instillation of one or two drops of drug one hourly through the waking hours during the first week, two hourly in the second week, four times a day in the third week, two times a day for the first 4 days and once a day for the 3 days in the last week. The patient was clinically evaluated on the 3–4th, 7–10th, 14th, 21st and 28th days. The patient was also reviewed on the 30th day. Anterior chamber cells and flare reactions were compared for evaluating the efficacy of the drugs. *Result:* Rimexolone is as effective as prednisolone acetate ophthalmic suspension in the treatment of anterior uveitis. The largest difference found was 0.1 in the flare reaction (statistically insignificant; $p = 0.3$) and 0.2 score units (statistically significant; $p = 0.01$) in the cells. Overall, comparison of the drugs shows no clinical significance in the treatment of anterior uveitis by either drug. Difference in intraocular pressure (IOP) was also statistically insignificant ($p > 0.05$). However, three patients in the prednisolone acetate group and 1 patient from the rimexolone group showed a rise in IOP. *Conclusion:* Rimexolone 1% ophthalmic suspension is as effective as and safer than prednisolone acetate 1% ophthalmic suspension in the treatment of anterior uveitis.

Introduction

Uveitis is an intraocular inflammation affecting the iris, ciliary body, choroid, vitreous body and/or retina. The inflammation can be limited to the anterior or the posterior structures of the eye, or it can affect both simultaneously. It may reoccur or chronically manifest itself over months and in some patients over years. The clinical features of the disease will determine the area and duration of pathophysiological involvement. Anterior uveitis is the most common among all uveitis cases. Out of 1273 new cases in a 3-year period, anterior uveitis accounted for 500 cases (39.28%) [1] in a referral eye centre in India. The anterior uveitis is mostly idiopathic in nature and can be acute, chronic or recurrent. Corticosteroids are effective in the treatment of anterior uveitis. Topical corticosteroids, including dexamethasone, prednisolone, hydrocortisone and fluorometholone are the most frequently used drugs and among them, prednisolone acetate is most preferred. The effects of corticosteroids on target cells, include inhibition of inflammatory mediator production, inhibition of inflammatory/immune cell function, alteration of lymphoid cell trafficking, inhibition of vasodilatation and inhibition of the wound healing process [2]. Topical corticosteroids, though effective as anti-inflammatory agents, are associated with side effects including increase in the intraocular

pressure (IOP) [3–12] and posterior subcapsular cataract formation from prolonged use [13].

Rimexolone, a new topical corticosteroid, has been demonstrated to produce good anti-inflammatory reaction. Foster and co-workers have found rimexolone 1% ophthalmic suspension, safe and effective in the treatment of anterior uveitis in a series of 274 patients [2]. The purpose of this clinical trial was to evaluate the efficacy and safety of rimexolone 1% ophthalmic suspension (Vexol 1%, Alcon Laboratories, Inc., Fort Worth, Texas) compared to 1% prednisolone acetate ophthalmic suspension (Pred Forte 1%, Allergan, Inc., Irvine, California) in patients with anterior uveitis for whom a topical corticosteroid is indicated.

Materials and methods

Between April 26, 1997 and April 22, 1999, a randomized, triple-masked, active controlled, parallel-group study was conducted to evaluate the efficacy and safety of riomexolone 1% ophthalmic suspension compared to Pred Forte (prednisolone acetate 1%). Prior to initiating the study, the clinical investigator received Institutional ethics committee approval. A single investigator enrolled 78 patients in the study, ranging in age from 14 years to 72 years. The patients residing in Chennai and suburban areas were enrolled to ensure seven follow-up visits required during the 1-month study period.

The screening of the patients was done with predefined inclusion and exclusion criterian. Those patients who met these criteria were enrolled in this study. This included patients older than 10 years of age, of either sex or any race, willing to make required follow-up visits and being able to follow instructions including avoiding disallowed medication (such as non-steroidal anti-inflammatory drugs), smoking or drinking alcoholic beverages.

The patient screening process began with an explanation of the study details including possible risks and benefits, to each potential subject. Before enrollment, a signed informed consent form was obtained from each subject. Patients were diagnosed as having acute uveitis, recurrent iridocyclitis, or chronic uveitis; there was no further classification of these diagnoses. The acute uveitis group consisted of patients with rapid onset or sudden inflammation of anterior structures of the uveal tract with duration of 2 weeks or less. Recurrent iridocylitis was defined as uveitis that occurred more than once, at intervals of less than 1 week, with quiet periods between episodes. Chronic uveitis was characterized by continuing and persistent uveitis. Anatomic area of inflammation (anterior, intermediate, or diffuse) and duration of disease (less than 3 weeks, 3–6 weeks, and longer than 6 weeks) were also used to further categorize each of the participant's uveitis. All patients underwent tailored laboratory investigations to rule out causes of anterior uveitis. This includes erythrocyte sedimentation rate, antinuclear antibody, rheumatoid factor, Mantoux test, Veneral disease research laboratory test and treponema pallidum haemagglutination test.

The study was designed to assess information in all anterior uveitis patients in whom a topical corticosteroid was appropriate rather than those within a specific diagnostic subgroup. No attempt was made to control the number of patients in each diagnostic subgroup in this study.

Potential study candidates were not enrolled into the study when any of the following exclusion criteria existed: pregnancy, lactation, or use of inadequate birth control methods; patients for whom a topical corticosteroid was contraindicated; uveitis secondary to a local or systemic infectious disease; contact lens wear during the study; concomitant medications that could interfere with therapeutic response; corticosteroid use (topical or systemic) within 24 hours before study entry; partial or total cataract interfering with the fundus examination; hypersensitivity to any component of the study medication; known alcohol or drug abuse; or use of any investigational drug within 30 days before receipt of the study medication Concomitant therapies permitted during the study were the use of topical ocular medication required to control an increase in intraocular pressure (IOP) or mydriatic cycloplegic agents (Homatropine) for photophobia. The prescription of cyclopentolate hydrochloride to prevent synechiae formation was also permitted.

The qualified volunteers underwent slit lamp examination, a dilated fundus examination with indirect ophthalmoscopy including scleral indentation and recording of ocular symptoms (discomfort, photophobia). Anterior chamber evaluation

of uveitis (keratitic precipitates, cells and flares) was measured using slit lamp (Haag-streit 900® BM). The dilated fundus was examined with a binocular indirect ophthalmoscope to evaluate vitreous haze (Using a 20 Diopter aspheric lens), macular oedema, presence of any chorioretinal nodules and retinal neovascularisation. Intraocular pressure (IOP) was recorded by Goldman applanation tonometer, and any reading more than 20 mm of mercury was considered clinically significant.

The patient and investigator were unaware of the treatment. Treatment was administered by another faculty of the institute after randomisation. The volunteers were randomized to use either 1% rimexolone or 1% prednisolone acetate. The patients were instructed to instil drops, hourly in the first week, every 2 hours in the second week, and 4 times a day in the third week and twice a day for first 4 days and once a day for the last 3 days in the 4th week. A follow-up examination took place 36–72 hours after cessation of treatment to check for off-steroid rebound effects.

The patient was advised to continue treatment and follow-up exams during 4 weeks. The treatment was discontinued when a patient experienced a significant worsening in ocular signs or experienced an increase in IOP that the investigator felt was not adequately controlled by topical ocular hypotensives. Patients who took concomitant medications prohibited by the study protocol or did not take the study medication as directed were also discontinued from the study.

Safety assessment included all patients who used the study medication at least once. Evaluation of safety included adverse events obtained, as solicited complaints from study patients and observation from the study investigator. Adverse events were defined as any changes from baseline (expected or unexpected) in a patient's ophthalmic or medical health that occurred during the course of the study. Serious adverse events were defined as any events that were life threatening or sight threatening, disabling, or caused a prolonged hospitalization.

Primary efficacy variables were ocular signs of flare and cells in the anterior chamber. Slit lamp examination grading was used similar to several other uveitis studies, as we did not have a flare cell meter. Scale for aqueous cells was determined by using the narrowest slit beam (0.5 mm) at 8 mm height of slit beam at maximum luminance: 0 = less than 5 cells; 1 = mild: 5–10 cells; 2 = moderate: 11–20 cells; 3 = marker: 21–50 cells; 4 = severe: more than 50 cells; 5–hypopyon. Similarly, aqueous flare scale was defined using the narrowest slit beam (0.5 mm) at highest luminance: 0 = none to trace; 1 = mild: clearly noticeable, visible; 2 = moderate: without plastic aqueous; 3 = marked: with plastic aqueous; 4 = severe: heavy with fibrin deposits and clots (iris details hazy).

Secondary variables analyzed were keratic precipitates, ciliary flush, photophobia, and discomfort. Ciliary flush was scored as 0 = absent or 1 = present. All other secondary variables were scored on a 0–3 scale in which 0 = absent, 1 = mild, 2 = moderate and 3 = severe.

Primary efficacy analysis was based on the analysis of cells and flare, by using two-tailed 95% confidence intervals on the difference at each visit between rimexolone 1% and prednisolone acetate 1% ophthalmic suspension. A confidence interval was a region defined by the mean differences between treatments, and the width of the confidence interval was a reflection of the standard error of the mean. The interval was calculated so that we could expect the mean differences between treatments to fall within this interval 95% of the cases. When the upper limit of the 95% confidence limits for the difference between treatments was smaller than what was considered to be a clinically significant difference, then we concluded with 95% confidence that the true difference between treatments was not clinically significant and that the treatments are equivalent. The change in IOP was also analyzed using the *t*-test.

Rimexolone 1% was evaluated for safety against prednisolone acetate 1% with respect to adverse events, clinically important increases in IOP, and changes in visual acuity. Adverse events in both the 1% rimexolone group and prednisolone acetate 1% group were tabulated and the frequency of events from each group compared. The tendency of each corticosteroid to raise IOP was compared by measuring the increase in mean IOP relative to baseline between the treatment groups. Additionally, the average of the maximum IOP increase (that is, the largest increase in IOP measurement observed from baseline) was compared, along with the frequency of clinically important spikes in IOP (increases of 5 mm of Hg or greater compared to baseline). The maximum change in

visual acuity for each patient was calculated as the change from baseline to the final visit.

Results

In our study, 78 patients were randomized to one of the two groups (rimexolone 1% or prednisolone acetate 1%) enrolled after screening initial requirements for the study. There were 39 patients each enrolled in rimexolone and prednisolone group. In total 12 patients were taken out of the study: five patients were lost to follow-up (two patients in prednisolone and three in rimexolone), and seven who developed adverse events were excluded to avoid any risk of visual loss. In addition, one patient who noted an adverse event was not taken out of the study as she developed the event due to concomitant medication (homatropine hydrobromide), she continued the study medication as scheduled. Excluding the patients of lost to follow-up and adverse event cases, 66 cases of safety data were obtained for the study analysis. This included data of 34 patients in the rimexolone and 32 patients in the prednisolone group.

Demographic distribution of uveitis in our study showed an average of 42.84 years, which ranged from 14 to 72 years. Between the two groups the average age was 46.2 in rimexolone and 39.28 in prednisolone. There were 24 males (61.5%) and 15 females (38.5%) in rimexolone and 17 males (53.1%) and 15 females (46.9%) in the group of prednisolone. Since the study was conducted in the local community racial data had no variations: all the patients were Asian Indians with brown coloured iris. Including the safety data, we observed 82 eyes that required treatment with topical steroids. Of these, 43 eyes were in rimexolone and 39 eyes in prednisolone acetate groups, respectively. There were 41.2% of acute cases, 20.6% of chronic cases and 38.2% of recurrent cases in the rimexolone group and 81.3% of acute cases, 3.1% of chronic cases and 15.6% of recurrent cases in the prednisolone group (Table 1).

Comparing the data of rimexolone and prednisolone patients, we found that clinically as well as statistically there was no significant difference in the treatment of anterior uveitis. Both 1% rimexolone and 1% prednisolone acetate ophthalmic suspensions reduced cells, equally and effectively ($p > 0.05$). Both these drugs decreased cells more than 1 score units from the baseline. The scoring range of cells was a range of 0–5 score units. On this scale a clinically significant difference was a difference between treatments of more than 20% of scale range or one score unit. The largest difference observed treatment was 0.2 score units, and situated within the confidence interval. The study showed 1% rimexolone to be as effective as prednisolone on all days except on the 21st day, when 1% prednisolone acetate showed results superior to rimexolone (statistically significantly ($p = 0.01$)). However, there was no significant difference in

Table 1. Demographic data for patients included in the efficacy analysis

Factors	Rimexolone 1% ($N = 34$)	Prednisolone acetate 1% ($N = 32$)
Age		
Mean	46.20	39.28
Minimum	16	14
Maximum	72	63
Sex (%)		
Male	24 (61.5%)	17 (53.1%)
Female	15 (38.5%)	15 (46.9%)
Race		
Asian	100%	100%
Iris color		
Brown	100%	100%
Diagnosis		
Acute	41.2%	81.3%
Chronic	20.6%	3.1%
Recurrent	38.2%	15.6%
Eye involved		
Right	9 (26.5%)	15 (46.9%)
Left	16 (47.1%)	10 (31.2%)
Both 1	9 (26.5%)	7 (21.9%)
Area of inflammation (%)		
Anterior	100%	100%
Duration		
<3 weeks	23 (53.5%)	29 (74.3%)
3–6 weeks	6 (13.9%)	9 (23.1%)
>6 weeks	14 (32.5%)	1 (2.6%)

Table 2. Comparative ocular signs while using the test drugs

Clinical signs	Baseline	3–4 days	7th day	14th day	21st day	28th day	32 hour
Flare (*0–4*)							
Rimexolone	1.6744	1.1163	0.9767	0.5581	0.4884	0.2093	0.0732
Prednisolone	1.8718	1.3077	0.9487	0.6923	0.3846	0.1282	0.1795
Mean difference	−1.1974	−0.1914	0.0280	−0.1342	0.1038	0.0811	−0.1063
Upper 95% confidence limit	0.185[a]	0.043[a]	0.233[a]	0.089[a]	0.323[a]	0.276[a]	0.088[a]
p-value	0.307	0.108	0.353	0.235	0.350	0.410	0.279
Cells (*0–5*)							
Rimexolone	1.8140	1.1628	0.7907	0.4651	0.2791	0.1395	0.0976
Prednisolone	1.7949	1.0769	0.7179	0.4615	0.0769	0.1282	0.1538
Mean difference	0.0191	0.0859	0.0727	0.0036	0.2021	0.0113	−0.0563
Upper 95% confidence limit	0.434[b]	0.438[b]	0.398[b]	0.272[b]	0.365[b]	0.195[b]	0.126[b]
p-value	0.927	0.628	0.657	0.979	0.016	0.903	0.540

[a] Upper 95% confidence limits less than 10% of range (0.4 units for flare).
[b] Upper 95% confidence limits less than 10% of range (0.5 units for cells).

response to the treatment in both groups on the 28th day (difference = 0.01) (Table 2) (Figure 1).

One percent of rimexolone and one percent of prednisolone acetate were also equally effective in reducing aqueous flare (Figure 2). The *p*-value was always >0.05 in all the visits. The largest difference was 0.1 score units, but was statistically insignificant ($p = 0.3$) (Table 2). The upper 95% confidence limit for the difference between treatments was less than 10% in all times in cells (0.5) and in flares (0.4).

Analysis of secondary variable like keratic precipitates, ciliary flush, photophobia and discomfort show no specific clinical and statistical difference in treatment between the two drugs.

IOP data at all visits showed that there was not much statistical difference in IOP rise between these two drugs. The largest difference found was 0.2 units, which is statistically insignificant ($p = 0.6$) (Table 3). However, clinically we found that out of 43 eyes of 34 patients, one eye (2.3%) showed an increase of IOP in the rimexolone group and out of 39 eyes of 32 patients, 3 eyes (7.7%) showed increase of IOP in the prednisolone acetate group. Even if statistically there is no raise in IOP, clinical evidence shows important spikes in IOP (increase of 5 mm of Hg or greater compared to baseline), which occurred more frequently in patients treated with prednisolone acetate 1% than with rimexolone 1% ophthalmic suspension. Our study showed that 1% rimexolone is less likely to raise increase IOP when compared to 1% prednisolone acetate ophthalmic suspension.

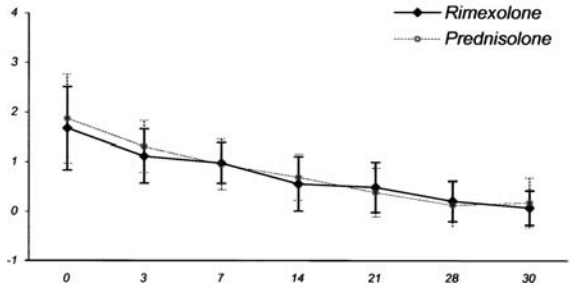

Figure 1. Cell response on instillation of test drugs.

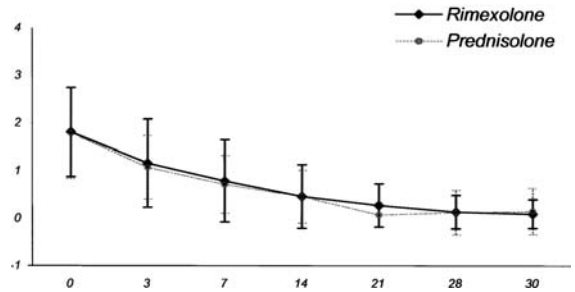

Figure 2. Flare response on instillation of test drugs.

Visual acuity was measured at study day 0 (baseline) and each subsequent visit. The maximum change in visual acuity for each patient was calculated as the change from baseline to the final visit. No clinically significant differences in visual acuity were observed between treatment groups.

During the course of the study 7 patients (2 in rimexolone and 5 in prednisolone acetate) were noted to have undesirable events that needed additional medications. These patients were taken out of the study and their data was not considered for analysis. One of the two patients in the rimexolone group experienced worsening of clinical signs, although non-compliance was attributed to the adverse event in that patient. One patient among five in the prednisolone group developed herpetic keratitis, which is a known side effect of topical corticosteroids, whereas the rest of them were noted to have severe fibrinous reaction that needed increase in frequency of topical steroids and addition of oral steroids. One patient subsequently developed features of panuveitis and skin changes suggestive of Vogt-Koyanagi Harada (VKH) syndrome and was taken out of the study. Non-compliance was attributed to the adverse events in two patients in the prednisolone group.

Discussion

Non-infectious inflammation of the anterior segment of the eye including uveitis, iridocyclitis and iritis, is known to respond to treatment with topical corticosteroids and non-steroidal anti-inflammatory agents [13, 14]. Well controlled, double masked trials that confirm the efficacy of topical steroids justify wide spread usage [13–15]. Although effective as anti-inflammatory agents, the most commonly prescribed corticosteroids are associated with undesirable side effects that include an increase in IOP. As reported by Liebowitz and associates (H. Liebowitz et al. Unpublished data, 1995), analysing several common topical ocular corticosteroids in corticosteroid responsive individuals suggests that 1% rimexolone has less tendency to increase IOP in these patients in comparison to other commonly used topical steroids like prednisolone acetate 1% and dexamethasone sodium phosphate 0.1% [2]. They also demonstrated that rimexolone 1% ophthalmic suspension is equivalent to fluoromethalone 0.1% in IOP elevating potential. Both rimexolone and fluoromethalone lack a hydroxyl group in the 21st position and both molecularly exhibit a reduced tendency to increase IOP [2].

A number of factors are likely to contribute to rimexolone 1% ophthalmic suspension's potent anti-inflammatory activity and its decreased tendency to increase IOP. Such factors include intrinsic glucocorticoid activity, intraocular penetration, biological half life within the eye, and selectivity which is different from other steroids [2].

Foster et al. [2] found clinically significant increases in IOP occurring more frequently in patients treated with prednisolone acetate 1% than in patients treated with rimexolone 1% ophthalmic suspension. Our clinical trials also demonstrated that rimexolone 1% ophthalmic suspension is less likely to cause an increase in intraocular pressure in comparison to prednisolone acetate 1% (Table 3), though the numbers were not statistically significant. Clinically only 2.3% of eyes in 1% rimexolone showed increase in IOP as compared to 7.7%% in 1% prednisolone acetate.

Although 1% rimexolone ophthalmic suspension exhibits a modest rate of ocular penetration, it is as highly potent as anti-inflammatory agent as prednisolone acetate 1% [2] as shown in our study. Moreover rimexolone 1% was also shown to be safe and well tolerated by the patients in our study.

Table 3. IOP during the course of the study

IOP	Baseline	3–4 days	7th day	14th day	21st day	28th day	32 hour
Rimexolone	13.0735	12.8382	13.1912	13.0441	13.1912	13.2794	12.6094
Prednisolone	13.2813	13.4375	13.2813	12.8438	13.7969	13.7656	13.2969
Mean difference	−0.2077	−0.5993	−0.0901	0.2064	−0.6057	−0.4862	−0.6875
p-value	0.662	0.188	0.857	0.698	0.220	0.304	0.151

The study design indicated that the patient should be put on hourly topical steroids at the onset. However, seven patients (two of rimexolone and five of prednisolone acetate) showed severe anterior chamber reaction within 3–14 days, resulting in poor vision, and they were exited from the study. One of them responded to topical prednisolone acetate with increased frequency of instillation. Additional oral steroids were needed in three patients. One patient required periocular steroid in addition to topical (15 minutes frequency) and oral prednisolone. We feel a subset of acute anterior uveitis exists, where hourly topical steroids either 1% prednisolone acetate or 1% rimexolone is not adequate enough and needs increased frequency of instillation (every 15 minutes). Systemic steroids may be required in a very small subset of anterior uveitis. One patient needed immunosuppresives (patient diagnosed to have VKH) in addition to topical and oral prednisolone. One patient, who had anterior uveitis to start with, developed acute herpetic keratouveitis 3 days later and was removed from the study. One patient had allergy to homatropine and when switched to cyclopentolate the patient showed resolution of allergic manifestations. Uveitis subsequently responded to the test drug. This uveitis clinical study also demonstrated that rimexolone 1% was as safe as prednisolone acetate 1% with respect to adverse events, though the number of adverse events was higher in the prednisolone acetate group than in the rimexolone group.

Our study indicated efficacy of 1% rimexolone as equivalent to that of 1% prednisolone acetate in the treatment of idiopathic anterior uveitis. There is no difference in the potential among these drugs. Increase in IOP could not be judged among these drugs. Although this study did not show statistically significant differences between rimexolone 1% and prednisolone acetate 1%, with respect to the propensity to raise IOP, clinically important spikes in IOP (increases of 5 mm of Hg or greater compared to baseline) occurred more frequently in patients treated with prednisolone acetate 1% than with rimexolone 1% ophthalmic suspension. Additionally, the cumulative percent increase in IOP over time showed that patients treated with rimexolone 1% had a slightly lower percent increase in IOP. These results support rimexolone 1% use as a safeguard and as an effective treatment of anterior uveitis.

Acknowledgements

We are thankful for Alcon Laboratories Inc., Fort Worth, Texas 76134, USA, for providing the drug and financial support. We are much obliged for the timely and professional assistance on statistical analysis in this study by Mr. B. Sukumar, MSc M.Phil.

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