

Comparative study of Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in treatment of post-operative uveitis after uncomplicated cataract surgery

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Abstract: Eye is the most important sensory organ and it is prone to many diseases. Development of opacity of lens is called as cataract. Cataract accounts for 81% among all causes of blindness in India. Cataract can be treated by surgery. Post-operative inflammation of eye (aseptic uveitis) is one of the most common complication. It can be controlled by steroid drugs, but they have got other ocular and systemic complications. To avoid this non-steroidal anti-inflammatory drugs are been tried. Based on the literature and clinical study reports we wish to substantiate these findings, we undertook this study to compare Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in the treatment of post-operative uveitis after uncomplicated cataract surgery.

Total 150 patients were taken into the study. They were divided randomly in two groups 75 patients in each group. The study was conducted up to 42nd day of post-operative period. Patients were observed up to 6 weeks. During 1st week, Prednisolone patients responded well than the patients kept on Diclofenac but in later weeks Diclofenac patients yielded better results. No adverse effects were seen in Diclofenac group but in prednisolone group raised intraocular pressure. Cost of prednisolone was more than Diclofenac. So in conclusion Diclofenac 1% eye drops were effective and safer than prednisolone 0.1% eye drops in aseptic uveitis. It could also tried in patients in whom corticosteroids were contraindicated.

Keywords: Aseptic uveitis, Diclofenac sodium. Intra ocular pressure, Prednisolone acetate, Uncomplicated cataract surgery.

I. Introduction

Development of opacity of lens is called cataract. Annual incidence of blindness due to cataract in India is 2 millions [1]. It can be treated by surgery (extra capsular cataract extraction of phoco-emulsification of lens). Post operative inflammation of eye (aseptic uveitis) is one of the most common complications.

Aseptic uveitis can be controlled by steroids and non steroid drugs. Though Steroid drugs are good anti inflammatory drugs, they have ocular complications like steroid induced glaucoma, super infection, flaring of herpes, perforation of corneal ulcers. To avoid these complications, non steroidal anti inflammatory drugs are tried. Wishing to substantiate these findings, we undertook a study to compare Prednisolone acetate 1% eye drops and Diclofenac sodium 0.1% eye drops in the treatment of post operative uveitis (aseptic uveitis) after uncomplicated cataract surgery.

II. Aims and objectives

- To compare the anti inflammatory effect and the outcome of clinical features with Prednisolone 1% eye drops and Diclofenac Sodium 0.1% eye drops in post operative uveitis (aseptic uveitis) after uncomplicated cataract surgery.
- To study the adverse effects of both drugs.
- To compare the cost of both the drugs.

III. Methodology

It was a comparative, prospective randomized study done at Government General Hospital, Vijayawada. The protocol was approved by Institutional Ethics Committee and written consent in local language was taken from patients.

Inclusion criteria.

- Both sexes, male and female
- Age above 45 years
- Patient with senile mature or hyper mature cataract are included.

Exclusion criteria:

- Patients with congenital and traumatic cataract.
- Cataracts associated with seasonal allergic conjunctivitis, rhinitis or iritis
- Patients with diabetes mellitus, hypertension, lichen planus, erythema nodosum.
- Patients with auto-immune diseases like Rheumatoid arthritis, psoriasis, systemic lupus erythematosus
- Patients with ear, nose, throat infections, tuberculosis, HIV and glaucoma.
- History of Hypersensitivity of Diclofenac and Prednisolone.

Total 150 patients were taken into study. They were selected randomly in 2 groups, 75 patients in each group. The first group was given prednisolone and the second group was given Diclofenac. Each ml prednisolone contained 10mg prednisolone acetate and each ml of diclofenac contains 10 mg diclofenac sodium. The patients who underwent extra capsular cataract extraction surgery (ECCE) were taken prednisolone 1% eye drops i.e., 1 drop 4th hourly was given in the respected group from 1st to 7th post operative day in the operated eye. Afterwards 1 drop every 6th hourly from 8th to 42nd post operative days in the respected groups. Each patient in the above mentioned 2 groups were examined in the following way :

1) Slit lamp, 2) Fundoscopic examination 3) vision was checked by Snellen's chart on 42nd post operative day 4) Intra ocular pressure was measured by Schott tonometer on 42nd post operative day 5) observation of adverse effects

On slit lamp examination the various parameters like conjunctival congestion, corneal edema, striate keratopathy, keratic precipitates, Hypopyon, flare and residual lens matter in anterior chamber, pupil shape, posterior synechiae, reaction to light, papillary capture, papillary block, posterior capsular opacification and clarity of vitreous.

IV. Results

The following results were noted on 7th, 21st, 42nd post operative days. No of patients responded on 7th, 21st, 42nd post operative day:

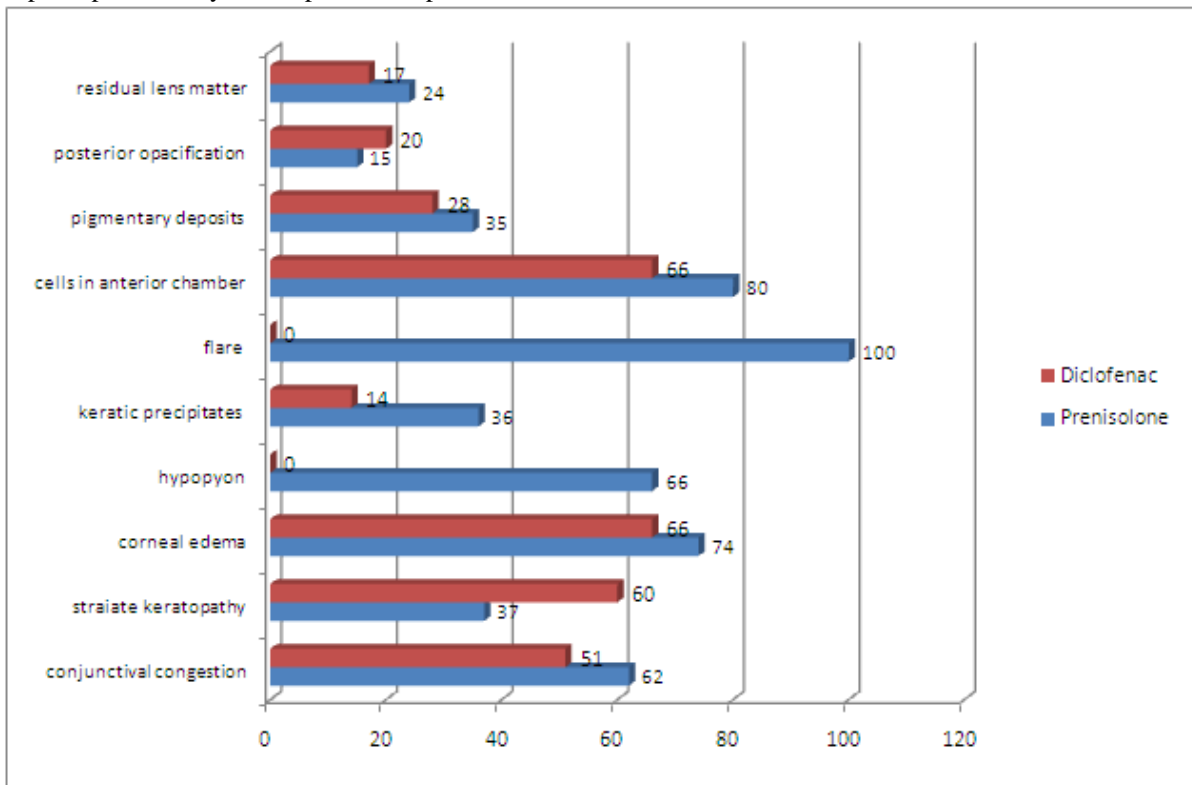
Parameters	Prednisolone acetate No%			Diclofenac sodium No %			p-value
	7 th Day	21 st Day	42 th Day	7 th Day	21 st Day	42 th Day	
Conjunctival congestion	14/23(60.8%)	22/23(95.8%)	23/23(100%)	12/24(50%)	23/24(95.6%)	23/24(95.6%)	>0.05
Striate keratopathy	7/19(36.84%)	13/19(68.4%)	18/19(94.7%)	9/15(60%)	14/15(93.3%)	14/15(93.3%)	>0.05
Corneal edema	22/13(73.3%)	29/30(96.6%)	30/30(100%)	12/18(66.66%)	18/18(100%)	18/18(100%)	>0.05
Hypopyon	2/23	3/3	3/3(100%)	-	-	-	
Keratic precipitates	1/3	2/3	3/3 (100%)	¼(25%)	¼(25%)	4/4(100%)	>0.05
Flare	1/1	1/1	1/1(100%)	-	-	-	>0.05
Cells in anterior chamber	4/5	5/5	5/5	2/3	3/3	3/3	>0.05
Pigmentary deposits	18/17	31/57	51/17	14/52	32/52	48/52	>0.05
Residual lens matter	11/46	29/46	41/46	6/30	20/30	28/30	>0.05

At the end of 42 days there was no change to pupil shape, reaction to light. No posterior synechiae, papillary capture or block in either group. The fundus was normal and vitreous was clear in either group. Results were tabulated; comparison and significance were tested by chi-square test. P value was noted. Results were shown graphically in bar and pie charts.

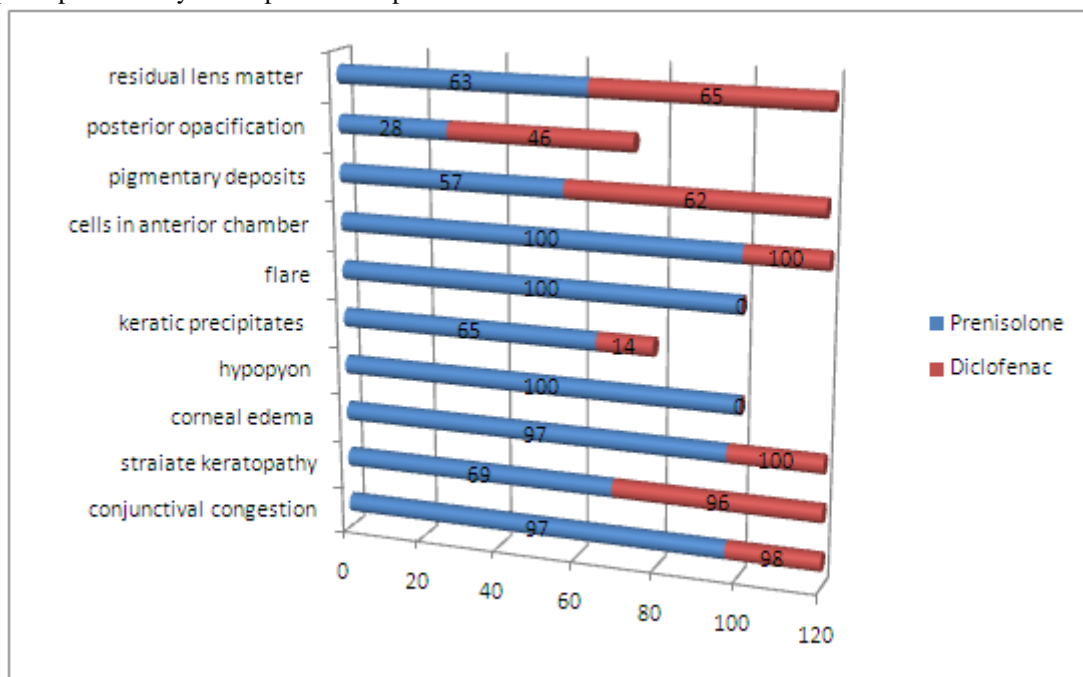
During 1st week prednisolone worked better, but in later weeks Diclofenac 0.1% eye drops were good than prednisolone 0.1% eye drops. But these results were statistically not significant. In steroid group raised intra ocular pressure was seen. No adverse reactions were seen in Diclofenac groups.

V. Figures

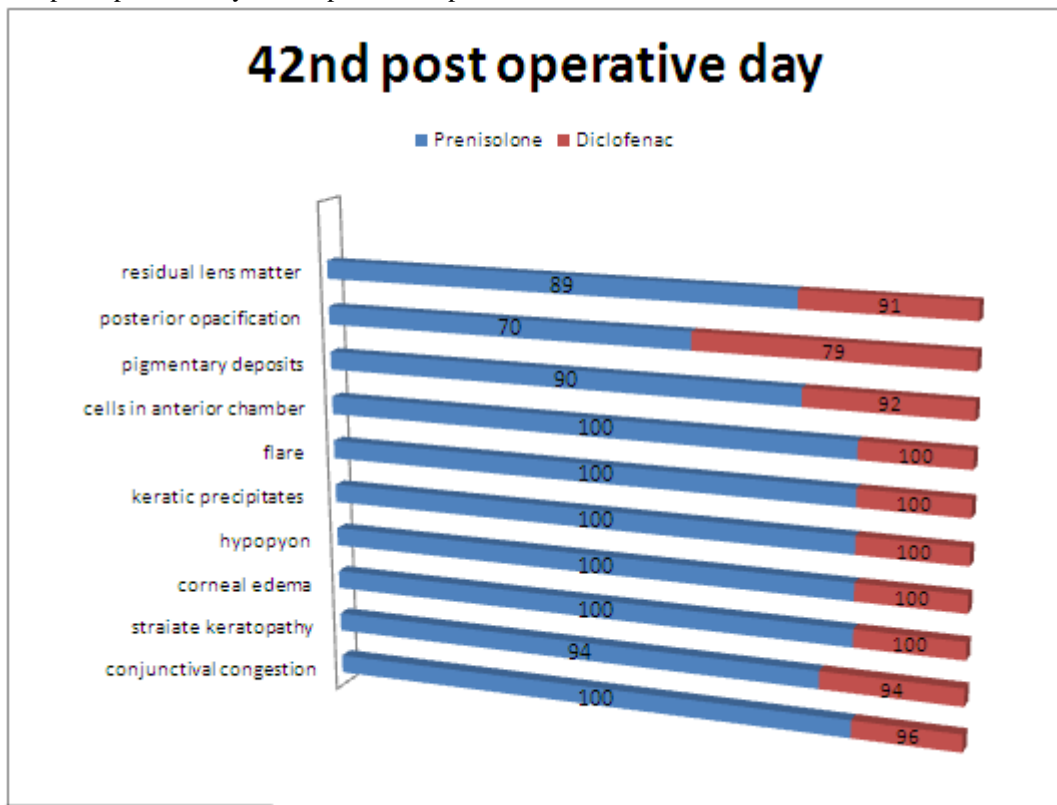
7th post operative day: No. of patients responded:



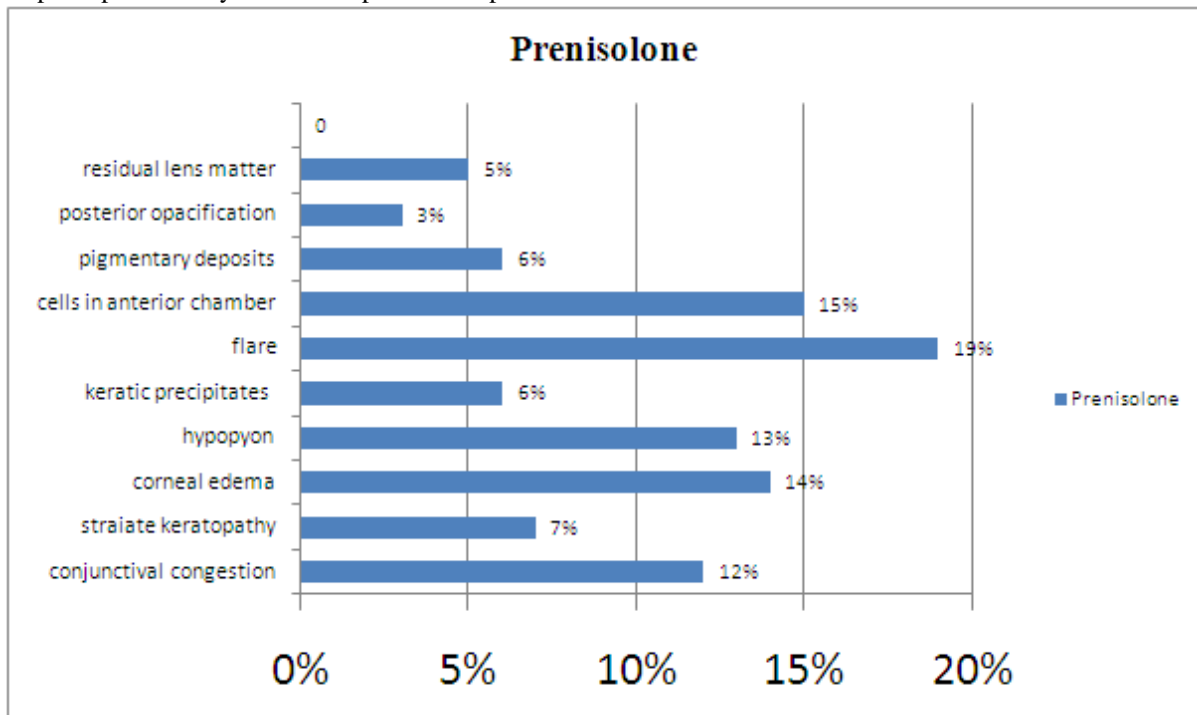
21st post operative day: No. of patients responded:

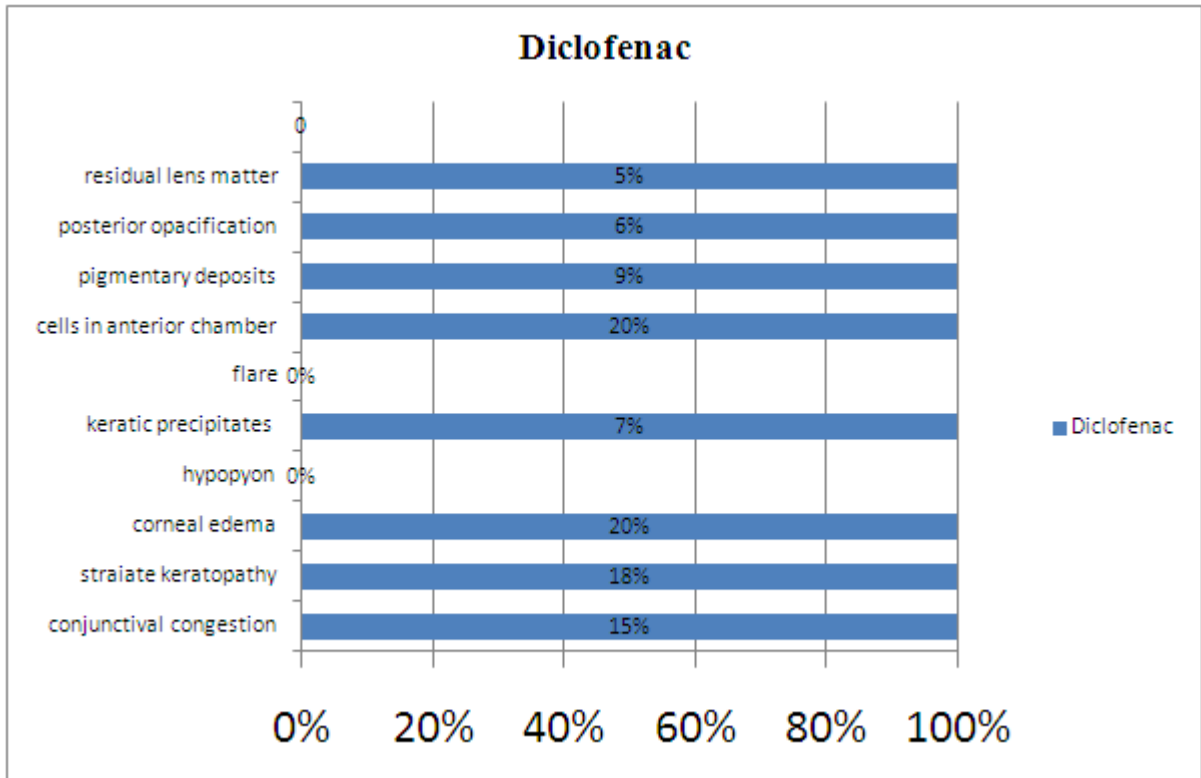


42nd post operative day: No of patients responded :

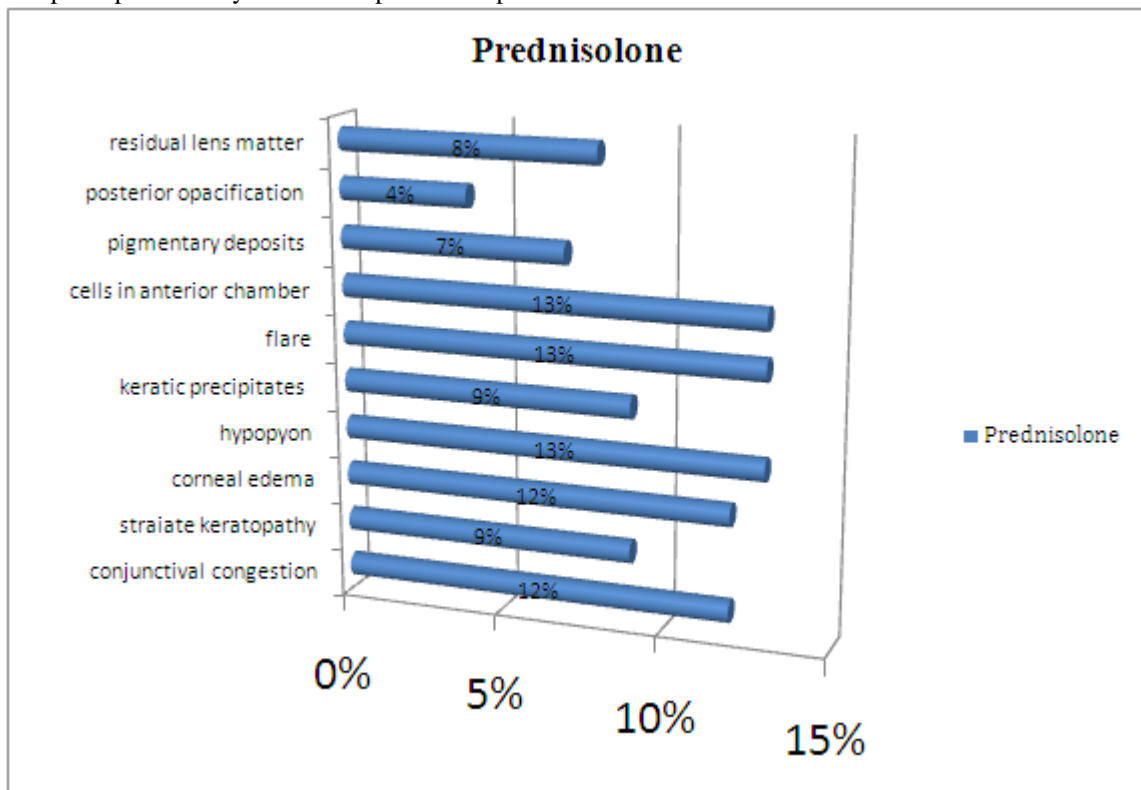


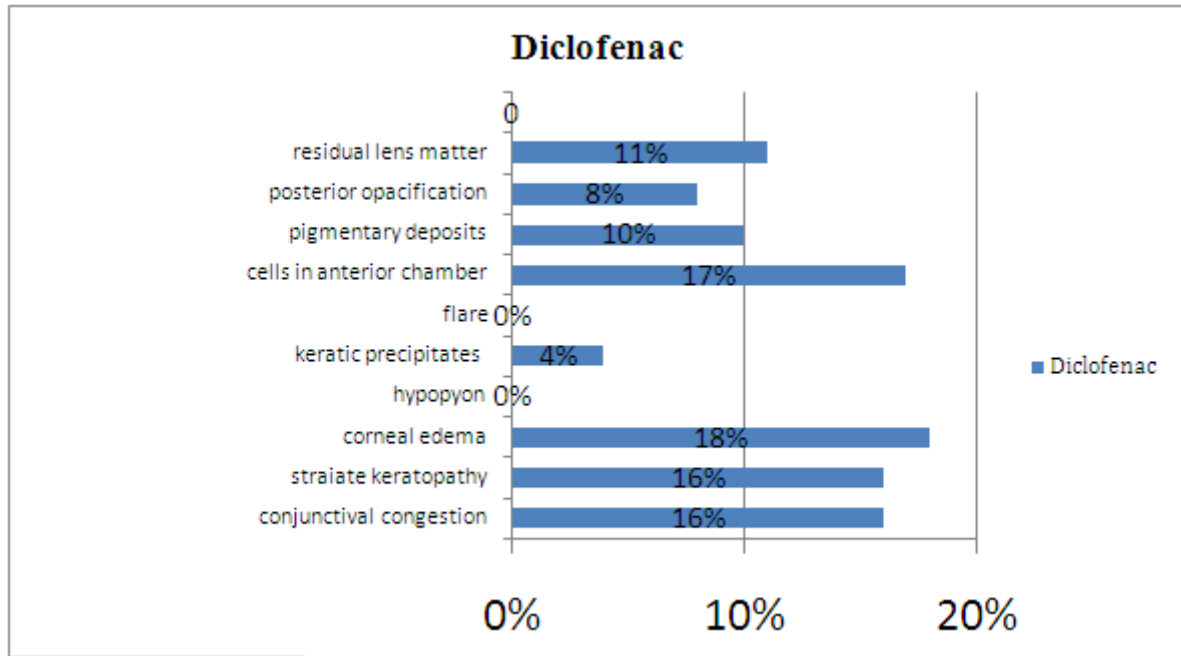
7th post operative day: Percent of patients responded :



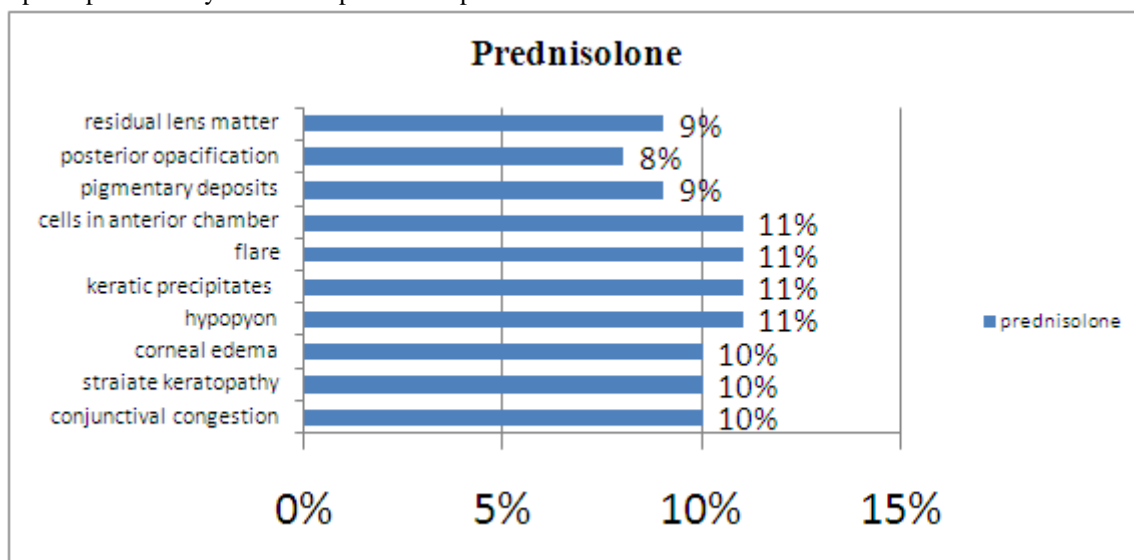


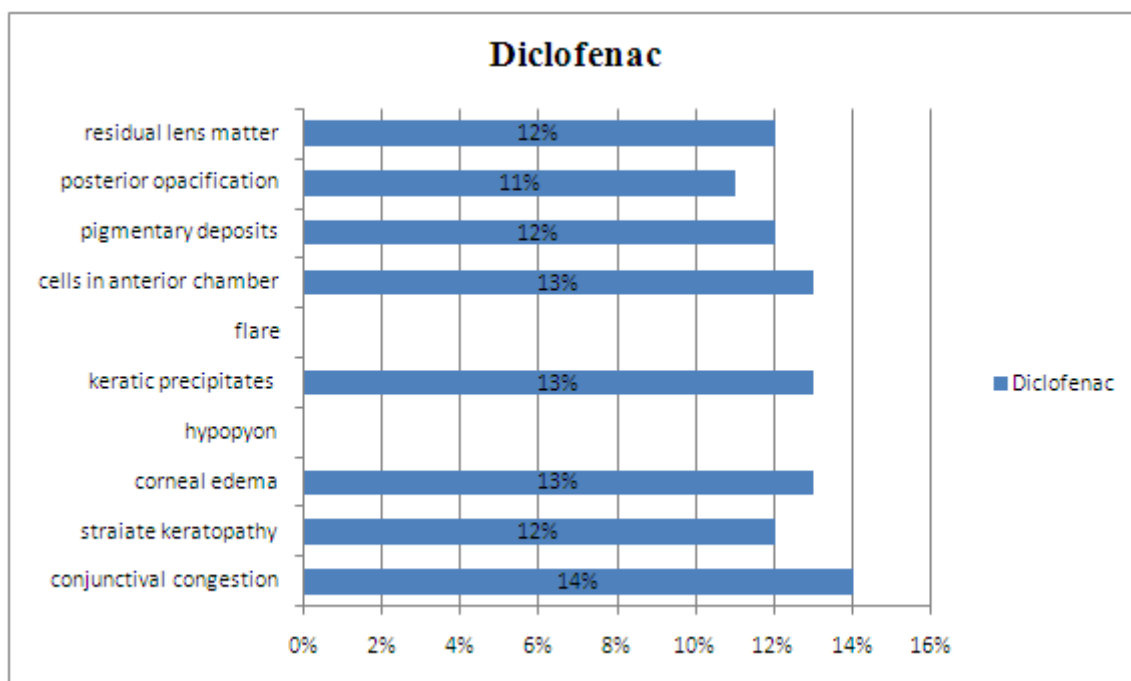
21st post operative day: Percent of patients responded:





42nd post operative day Percent of patients responded :





VI. Discussion

In our study during 1st week Prednisolone eye drops yielded better results than Diclofenac sodium. But in later weeks Diclofenac did better than Prednisolone. But the results were not statistically significant. So, both have got the anti inflammatory effect. Similar results were observed by Brennan KM, Brown RM, Roberts CW [2].

Diclofenac sodium 0.1% eye drops was effective, safe and did not raise the intra ocular pressure. Similar results were seen by Strelow SM, Shenwood MB, Bron Cat to LJ[3]

Diclofenac Sodium eye drops decreases the inflammation after cataract surgery, This is similar to the study of Onakoya A.O., Majekonduu AA, Adecate[4]

Topical Diclofenac sodium effectively decreases the post surgical inflammation. This is consistent with Matsuo K, Hojou H, Honbou M and Manjoo S.Reddy, M.S. Suneetha N. M.S.Reji[5,6]

VII. Conclusion:

Post operative uveitis (aseptic uveitis) is a common problem after uncomplicated cataract surgery. Routinely steroids are used to control it. But they possess many adverse effects and contra indications. So other anti inflammatory drugs which belongs to non steroidal anti inflammatory drugs are tried.

The present study compared the efficacy of prednisolone acetate 1% eye drops with Diclofenac Sodium 0.1% eye drops in the treatment of Aceptic Uveitus.

Total 150 patients were taken for study. They were allotted randomly in 2 groups i.e. prednisolone group and Diclofenac group, 75 patients in each group.

The study was conducted up to 42nd post operative day. They were particularly observed on 7th, 21st and 42nd days and full eye examination was done using various instruments. Both the drugs suppressed the post operative inflammation. But in the steroids group, raised intra ocular pressure was seen. During the 1st week prednisolone 1% eye drops yielded better results, but in later weeks Diclofenac Sodium 0.1% eye drops yielded good results than prednisolone 1% eye drops. But there results were statistically not significant.

In steroid group raised intra ocular pressure was seen. No adverse effect in Diclofenac group was noted.

Cost of the prednisolone acetate 1% eye drops (Rs 2) was more than Diclofenac Sodium (Rs 1.50).

Though statistically not significant, on the whole Diclofenac Sodium 0.1% eye drops was effective, safer, than prednisolone 1% eye drops will no adverse effects in controlling aseptic uveitis. Cost was also less. It could also be tried in patients in whom corticosteroids were contraindicated.

Acknowledgments

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References

- [1]. Park's Text Book of Preventive and social Medicine 18th Edition Page:320.
- [2]. Brennan KM, Brown RM, Roberts CW. A comparison of non steroidal anti inflammatory 1993 Apr 18(1) 8-11.
- [3]. Stelow S.A., Sherwood MD, Bron Cato LJ, Napier A. The effect of diclofenac sodium ophthalmic solution on intra ocular pressure following cataract extractus. *Ophthalmi surg* 1992 March, 23(3) : 170-175
- [4]. Onakoya A.O., Majekonduu AA, Adecate. Clinical trial of Diclofenac Sodium eye drops on Nigerions. *Niger post graduate medical journal* 2004 December, 11(4): 265 – 268.
- [5]. Matsuo K, Hojou H, Honbou M, Clinical efficacy of Diclofenac sodium on post surgical inflammation after intra ocular lens implantation. *Journal of cataract refract surgery* 1995 May, 21(3) : 309-12.
- [6]. Manjoo S.Reddy, M.S. Suneetha N. M.S.Reji – Topical Diclofenac Sodium for treatment of post operative inflammation in SWcataract surgery. *Indian Journal of Ophthalmolgy* 2000, 48: 223-36.
- [7]. Shimazaki J, Fujishima H, Yagi Y –Effects of Diclofenac eye drops on corneal epithelium and function after small incision cataract surgery : *J.Ophthalmology* 1996 Jan, 103(1) : 50-57.
- [8]. Ronon S, Rozenman Y, Zylbermann R – Treatment of ocular inflammation with Diclofenac sodium. Double blind trial following cataract surgery. *Ann. Ophthalmal*, 1985 Sep, 17(9) : 577 – 8.