

Topical steroid alone vs a combination with a posterior segment NSAID after Nd-YAG capsulotomy: Is the posterior segment NSAID really necessary?

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ABSTRACT

Purpose: To compare the effect of topical 1% prednisolone acetate and 0.09% bromfenac versus topical 1% prednisolone acetate alone on macular thickness following Nd: YAG laser capsulotomy. **Materials and Methods:** About 150 eyes with posterior capsule opacification following were included. All patients were treated with Nd: YAG laser posterior capsulotomy. Patients were randomly divided into two groups of 75. Group 1-Patients received: Topical 1% prednisolone acetate and Topical 0.09% bromfenac. Group 2-Patients received: Topical 1% prednisolone acetate alone. Outcome measures by an independent observer were BCVA by Snellen chart, IOP by NCT, and Central Macular Thickness (CMT) by Macular OCT. All patients were examined before the procedure, 1 h after the procedure, at 1 week, and at 6 weeks. **Statistics:** 1. Quantitative variables: Mann-Whitney Test and Wilcoxon ranked sum test. 2. Qualitative variables: Chi-square test. A *P* value of < 0.05 was considered statistically significant. **Results:** Mean IOP increase in both groups is statistically significant at 1 h and later decreases back to nonsignificant levels at 1 week and 6 weeks. No significant change in mean CMT was seen in the duration of 6 weeks neither in Group 1 nor Group 2. **Conclusion:** Prophylactic antiglaucoma medications are not recommended in patients undergoing Nd: YAG laser capsulotomy. No evidence of cystoid macular edema was recorded till the end of 6 weeks follow-up.

Keywords: Nd-YAG capsulotomy, NSAID, post-cataract opacification, steroid

Statement of Justification

The following case study represents a paradigm shift in the management of pseudophakic patients after NdYAG-capsulotomy by assessing the effect of combined topical prednisolone and bromfenac versus topical prednisolone alone on central macular thickness.

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Introduction

Posterior capsule opacification (PCO, secondary cataract, after cataract) caused by the postoperative proliferation of cells in the capsular bag remains the most frequent delayed complication of extracapsular cataract extraction and intraocular lens (IOL) surgery.^[1] These cells migrate to the posterior capsule, where they approach the central visual axis and cause visual-axis obscuration, resulting in a dimness of vision, glare, and other symptoms similar to that of the original cataract.^[2,3] The incidence of PCO is reported to be 20.7% at 2 years and 28.4% at 5 years after cataract surgery.^[4]

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After the pioneering work of Fankhauser *et al.*^[5] and Aron Rosa *et al.*,^[6] posterior capsulotomy has become the standard procedure to reverse the capsular thickening induced diminution of vision. Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy is a relatively noninvasive procedure that is used in the treatment of posterior capsular opacification. Although Nd:YAG laser capsulotomy has been found to be safe and effective, events such as retinal detachment,^[7] macular edema,^[8] and rise in intraocular pressure^[9] tend to occur after ND:YAG laser capsulotomy.

Anti-inflammatory agents have withstood the test of time in the treatment of postoperative macular edema. Even though topical corticosteroids and nonsteroidal anti-inflammatory drugs (NSAIDs) have demonstrated efficacy in prophylaxis and/or treatment of macular edema, NSAID treatment appears to be more effective than topical corticosteroids in re-establishing the blood-aqueous barrier. As compared to corticosteroids, NSAIDs not only stabilize intraocular pressure (IOP) and provide analgesia but also reduce the risk of secondary infections.

Since corticosteroids and NSAIDs both inhibit prostaglandin synthesis by different pathways, an additive-synergistic effect is probable with combined therapy.^[11,12] Studies have confirmed the benefits of combination therapy and it is now widely accepted that a combination of NSAID + steroid is initiated upon documentation of clinical macular edema. There are no randomized prospective trials showing definite response to treatments but a common regimen involves initial steroid used for 1 week with a topical NSAID used for 4 weeks.^[10]

The following prospective randomized comparative study was done to compare the effect of topical 1% prednisolone acetate and 0.09% bromfenac versus topical 1% prednisolone acetate alone on macular thickness following Nd:YAG laser capsulotomy.

Materials and Methods

This prospective randomized comparative triple-blind study was conducted over a period of 2 years from Jan 2016 to Jan 2018. Ethical approval was obtained from the Ethical Clearance Committee, Institutional Review Board (IRB) approval was obtained in Nov 2015.

Inclusion criteria included patients aged group 40–70 years, with a significant PCO, best-corrected visual acuity (BCVA) <6/9.

Exclusion criteria included eyes with a subluxated intraocular lens (IOL), raised intraocular pressure (IOP), hypertensive retinopathy, diabetic retinopathy, retinal vein occlusions (CRVO-BRVO), recurrent uveitis, cases with postoperative complications such as endophthalmitis and any intraocular pathology which can affect macular thickness.

About 150 eyes with posterior capsule opacification following uncomplicated phacoemulsification with posterior chamber

intraocular lens implantation surgery were included in the study. All patients underwent a complete ocular examination including BCVA on a Snellen scale, Slit-lamp biomicroscopy, Non-contact tonometry, and Indirect ophthalmoscopy. Biomicroscopic retro illumination technique was used to examine PCO and OCT (Heidelberg Spectralis SD-OCT) was used to evaluate macular thickness.

All patients were treated with Nd:YAG laser posterior capsulotomy. Nd:YAG laser energy was set between 1–4 mJ and laser was focused on the posterior capsule and capsulotomy was performed in cross pattern beginning from the periphery, with capsulotomy size kept 3 mm. The total energy used was recorded. Patients were randomly divided into two groups of 75 each using a table of random numbers.

GROUP 1 - Patients received:

Topical 1% prednisolone acetate QID for 1 week: Day 0 to Day 7

Topical 0.09% bromfenac BID for 6 weeks: Day 0 to Day 42

GROUP 2 - Patients received:

Topical 1% prednisolone acetate QID for 1 week: Day 0 to Day 7

Outcome measures by an independent observer were BCVA by Snellen chart, IOP by NCT and Central Macular Thickness (CMT) by Macular OCT. All patients were examined before the procedure, 1 h after the procedure, at 1 week and at 6 weeks.

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean \pm SD and median. The normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then nonparametric test was used.

Statistical tests were applied as follows:

1. Quantitative variables were compared using Mann-Whitney Test (as the data sets were not normally distributed) between the two groups and Wilcoxon ranked sum test for comparing pre and post.
2. Qualitative variables were compared using Chi-square test.

A *P*-the value of <0.05 was considered statistically significant.

Results

Age

The mean age in group 1 was 58.97 years with age ranging from 54–65 years while mean age in Group 2 was 61.11 years, with age ranging from 57–67 years.

The mean age was not significantly different between the two groups. (*P* = 0.299).

Sex

There were 46 males and 29 female patients in Group 1 while there were 41 male patients and 34 female patients in Group 2.

Sex-wise distribution was not significantly different between the two groups. (*P*-value = 0.408).

IOP: Refer to Tables 1 and 2, Figure 1.

The mean IOP 1 h after the procedure in Group 1 was 13.01 ± 1.55 and in Group 2 was 12.8 ± 1.5 . Therefore no significant difference was found in IOP 1 h after the procedure between the two groups (*P* = 0.30).

The mean IOP at 1 week in Group 1 was 12.31 ± 1.19 and in Group 2 was 12.04 ± 1.28 . No significant difference was found in IOP between the two groups on day 7 (*P*-value = 0.142).

At 6 weeks, the mean IOP in group 1 was 12.35 ± 1.44 and in Group 2 was 12.07 ± 1.14 . There was no significant difference in IOP on day 42 (*P*-value = 0.227).

The mean IOP in Group 1 increases from 12.56 before the procedure to 13.01 1 h after the procedure, which is significant (*P*-value < 0.0001). Then it decreases nonsignificantly to 12.04 at day 7 (*P*-value = 0.06) and 12.07 at day 42 (*P*-value = 0.084).

The mean IOP in Group 2 increases from 12.4 before the procedure to 12.8 1 h after the procedure, which is significant (*P*-value < 0.0001). then it decreases non significantly to 12.04 at day 7 (*P*-value = 0.06) and 12.07 at day 42 (*P*-value = 0.084).

CENTRAL MACULAR THICKNESS (CMT): Refer Table 3, Table 4, Figure 2

The mean CMT in μm 1 h after the procedure in Group 1 was 259.37 ± 18.79 and in Group 2 was 259.21 ± 14.71 . There was no significant difference in CMT after 1 h between the two groups.

The mean CMT at 1 week in Group 1 was 259.57 ± 17.25 and in Group 2 was 259.2 ± 13.32 . There is no significant difference in CMT between the two groups on day 7.

At 6 weeks, the mean CMT in μm in Group 1 was 258.41 ± 17.22 and in Group 2 was 258.57 ± 12.96 . No significant difference was found in the CMT on day 42 in between the two groups.

No significant change in mean CMT from pre-procedure CMT was seen anytime in the duration of 6 weeks neither in Group 1 nor in Group 2.

Table 1: IOP trend in group 1

(in mmHg)	Mean±SD	Median	Min-Max	Inter quartile Range	P
IOP D0	12.56±1.63	12	10-17	11-13	
IOP D0 1 h	13.01±1.55	13	10-18	12-14	<.0001
IOP 1 WEEK	12.31±1.19	12	10-16	11.250-13	0.151
IOP 6 WEEKS	12.35±1.44	12	10-16	11-13.750	0.29

Table 2: IOP trend in group 2

(in mmHg)	Mean±SD	Median	Min-Max	Inter quartile Range	P
IOP D0	12.4±1.88	12	10-18	11-13	
IOP D0 1 h	12.8±1.5	13	11-18	12-14	<.0001
IOP D7	12.04±1.28	12	10-16	11-13	0.06
IOP D42	12.07±1.14	12	10-16	11-12.750	0.084

Table 3: CMT trend in group 1

(in mmHg)	Mean±SD	Median	Min-Max	Inter quartile range	P
CMT Do	258.75±17.7	260	200-289	251-270	
CMT D0 1 h	259.37±18.79	259	193-289	250-273	0.315
CMT D7	259.57±17.25	260	198-285	251.250-273	0.055
CMT D42	258.41±17.22	259	201-287	250.500-270	0.195

Table 4: CMT trend in group 2

(in μm)	Mean±SD	Median	Min-Max	Inter quartile range	P
CMT Do	258.73±12.93	258	232-282	252-267.750	
CMT D0 1 h	259.21±14.71	262	223-287	248.250-268.750	0.421
CMT D7	259.2±13.32	259	228-287	253-269.750	0.108
CMT D42	258.57±12.96	258	234-285	250-267.750	0.509

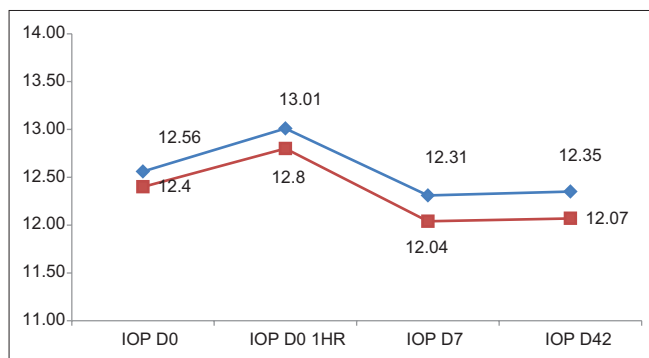


Figure 1: Comparison of IOP trend in group 1 and 2

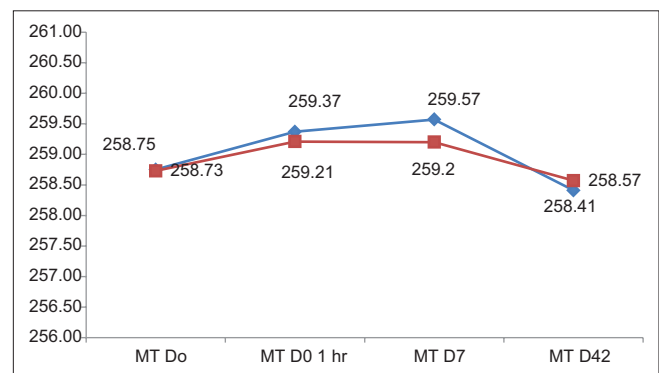


Figure 2: Comparison of CMT trend in group 1 and 2

Discussion

Posterior capsular opacification (PCO) is caused by transdifferentiation of the remaining epithelial cells into the myofibroblasts or proliferation and migration of equatorial lens epithelial cells to the posterior capsule.^[13,14] Nd:YAG laser posterior capsulotomy is the main treatment modality for PCO and has been used during the past 20 years. Nd:YAG laser has a solid pump which emits a 1,064 nm wavelength and is used not only in the treatment of PCO, but also in the opening of peripheral iridotomy, pupillary membrane dissection, and cutting of vitreous bands.^[15]

The most common complication of posterior capsulotomy is increased IOP, which is caused by the release of inflammatory mediators.^[16] Despite the prophylactic treatment, increased IOP was reported in 15% to 30% of patients in several studies.^[17,18] Keates *et al.*^[19] found elevation of IOP in 6% of his patients, whereas Stark *et al.*^[20] reported that the elevation of IOP was 1.0% of patients after Nd:YAG capsulotomy. However, Shani *et al.*^[21] could not find any elevation of IOP and postulated that healthy pseudophakic eyes do not generally show elevation of IOP after Nd: YAG laser capsulotomy. Ari *et al.*^[22] also did not find any persistent rise in IOP.

In our study, total patients included were 150, which were divided into two groups of 75 each, Group 1 receiving topical steroid for 1 week with bromfenac for 6 weeks and Group 2 receiving topical steroid alone for a week. No prophylactic antiglaucoma medications were given in both groups. IOP increased one hour after the procedure and came back to baseline values at 1 week. This immediate rise of IOP after Nd:YAG laser capsulotomy can be result of reduced facility for aqueous humor outflow. This reduction occurs due to capsular debris, acute inflammatory cells, liquid vitreous and shock-wave damage to the trabecular meshwork. Unal^[23] in his study concluded that brinzolamide 1% and apraclonidine 0.5% given prophylactically before Nd:YAG laser capsulotomy was effective in preventing IOP spikes after laser. But, as in our study, IOP rise after 1 hour of Nd:YAG capsulotomy was in the range of 0.5 mm to 2 mm. This was statistically significant but not clinically significant, hence prophylactic antiglaucoma medications are not recommended in patients undergoing Nd:YAG laser capsulotomy.

One of the serious complications of Nd:YAG laser capsulotomy is that it can lead to cystoid macular edema. Raza^[24] reported cystoid macular edema in 3% of 550 patients treated with Nd: YAG laser capsulotomy for pseudophakic and aphakic posterior capsule opacification. Steinert *et al.*^[7] studied 897 patients after Nd:YAG laser posterior capsulotomies for the complications of cystoid macular edema. After Nd:YAG capsulotomy, 11 patients developed cystoid macular edema. Bukelman^[25] did Nd:YAG laser Capsulotomy on 65 patients. None of these patients developed macular edema. Wróblewska-Czajka^[26] measured central macular thickness after Nd:YAG laser capsulotomy in 55 patients and reported no significant change in CMT at any time point within 6 months of study.

Shorstein^[27] in a study concluded that adding NSAID to prednisolone is more effective for prophylaxis of macular

edema and increased macular thickness than prednisolone alone post-cataract surgery. Endo *et al.*^[28] in his study found bromfenac was more effective in preventing increased macular thickness than steroids in post-cataract surgery patients. There are no studies so far comparing steroid and NSAID for prophylaxis of macular edema post-Nd:YAG laser capsulotomy. But, in our study comparison of the two groups one receiving topical prednisolone and bromfenac combination and other receiving prednisolone alone, did not reveal any difference before the procedure, at 1 week or 6 weeks after the procedure suggesting that there is no significant role of adding bromfenac to prednisolone for prevention of macular edema till 6 weeks in post Nd:YAG laser capsulotomy patients after uncomplicated phacoemulsification.

Ari *et al.*^[22] evaluated how different energy levels of Nd:YAG laser capsulotomy affect macular thickness. They divided patients into two groups based on the energy levels used in Nd:YAG laser. No prophylactic medications were given, unlike our study. They found that both groups had increased macular thickness compared to preoperative levels; macular thickness measurements of the patients treated with high energy levels were significantly higher compared to low energy levels. Karahan^[29] in his study found increased macular thickness one week after Nd:YAG laser capsulotomy which decreased to baseline values after 4 weeks.

In our study, total cumulative energy levels and capsulotomy size were similar in both groups. The central macular thickness does not change in the first hour after Nd:YAG laser capsulotomy. Treatment is started in both groups after the procedure with one group receiving steroid and NSAID combination and others receiving steroids alone. There was no cystoid macular edema and no significant change in CMT was recorded till the end of 6 weeks follow-up.

The advantages of our study are multifold. Especially in a developing country like India where compliance and follow-up are a serious battle, decreasing the number of medications to the least necessary ones will help improve compliance by cutting financial costs and help patients adhere to their medications. However, as the total number of cases included in our study is less and the follow-up period is short, the long term effect of Nd:YAG laser capsulotomy on macular thickness would require a large scale and long term retrospective studies.

What Was Known

The most common complication of posterior capsulotomy is increased IOP, which is caused by the release of inflammatory mediators. Despite the prophylactic treatment, increased IOP was reported in 15% to 30% of patients in several studies.

One of the serious complications of Nd: YAG laser capsulotomy is that it can lead to cystoid macular edema.

What This Paper Adds

IOP increased 1 h after the procedure and came back to baseline values at 1 week. IOP rise after 1 h of Nd: YAG capsulotomy was in the range of 0.5 mm to 2 mm This was statistically significant but not clinically significant, hence prophylactic antiglaucoma medications are not recommended in patients undergoing Nd: YAG laser capsulotomy.

There was no cystoid macular edema and no significant change in CMT anytime during the study till 6 weeks duration of follow-up. There is no significant role of adding bromfenac to prednisolone for the prevention of macular edema till 6 weeks in post Nd: YAG laser capsulotomy patients.

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Conflicts of interest

There are no conflicts of interest.

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