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Case Series

Effect of topical nepafenac versus fluorometholone on macular thickness after Nd:YAG capsulotomy

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Abstract

Background: The most common complication following an uncomplicated cataract surgery is Posterior capsular opacification (PCO). Nd:YAG (Neodymium yttrium aluminium garnet) capsulotomy is a safe, non-invasive OPD based procedure to manage an intact PCO. Transient increase in macular thickness have been an observed phenomenon following Nd:YAG capsulotomy. This study aimed to establish standard guidelines for medications to be prescribed after Nd:YAG capsulotomy to mitigate complication of increase in macular thickness & inflammation by analysing the effect of topical Nepafenac versus Fluorometholone.

Materials and Methods: A total of 96 patients diagnosed with PCO in Ophthalmology OPD of TMMC & RC, Moradabad, Uttar Pradesh, were enrolled for Nd:YAG capsulotomy over a period of one year. Optical coherence tomography was done pre and post laser to note macular thickness. Patients were randomised into group A & B and were prescribed topical Nepafenac and Fluorometholone respectively. Follow up was done after an hour, 1 week, 4 weeks, and 12 weeks and the effect of the two drugs on macular thickness was compared. Appropriate statistical tests were applied for data analysis.

Results: Total energy used during capsulotomy was in the range of 12 to 33 mJ in both the groups. The mean macular thickness at baseline was 242.7 ± 18.5 µm pre laser, which significantly increased to 268.9 ± 26.1 µm after 1 hour of treatment showing statistically significant increase compared to baseline. This gradually reduced to 259.1 ± 20.6 µm by week 12 indicating an acute increase in macular thickness after Nd:YAG capsulotomy in both the groups. There were weak to moderate correlations between total energy utilised and changes in Macular thickness. The results indicated that after Nd:YAG capsulotomy, medication is recommended, with both topical NSAIDs and topical steroids being effective options. However, topical NSAIDs may be preferred in cases where the use of steroids poses potential risks.

Conclusion: Both Nepafenac and Fluorometholone eye drops demonstrated comparable effects on acute increase in macular thickness in patients of PCO who were managed with Nd:YAG posterior capsulotomy.

Keywords: Nd:YAG laser, Posterior capsulotomy, Posterior capsule opacity (PCO), Macular thickness, Nepafenac, Fluorometholone.

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1. Introduction

Posterior capsular opacification (PCO) termed as ‘after cataract’, is the most frequently observed late-stage complication after a routine cataract surgery, typically occurring in 20-25% patients.[1] This condition arises from the migration and proliferation of residual lens epithelial cells that may persist within the capsular bag after cataract surgery. PCO detrimentally affects contrast sensitivity, visual acuity and cause glare in most of the patients. PCO patterns can occur as vacuolated Elschnig pearls or form a Soemmerring ring peripherally. Managing PCO involves photodisrupting the posterior capsule opacity with the Neodymium-doped yttrium aluminium garnet (Nd:YAG) capsulotomy which is a standard, non-invasive, effective and safe indicated procedure.[2] Despite the simplicity and quickness of the procedure, certain risks are associated with Nd:YAG capsulotomy including IOL pitting, subluxation, cystoid macular edema, retinal detachment, raised intra ocular pressure etc.[3] Studies have indicated a rise in macular thickness following Nd:YAG capsulotomy. There is ongoing research to establish standard guidelines for post-

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capsulotomy medications to combat the above-mentioned complications.[1]

Cystoid macular edema (CME) occurs due to fluid buildup in the outer plexiform and inner nuclear layers of retina with cyst like cavities containing clear fluid.[4] It occurs in a variety of conditions such as intraocular inflammation but can also manifest after laser treatment.[5,6] On Optical coherence tomography, CME shows thickening of retina with hypo-reflective cystic spaces and foveal depression loss.[7]

Studies have demonstrated that Nd:YAG capsulotomy can cause transient, minimal and acute post-procedural inflammation, primarily in the early hours after the treatment. This inflammation gradually subsides but may persist at a subclinical level.[8] Surgeons recommend topical steroids (e.g., Fluorometholone) and nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., Nepafenac) to prevent inflammation-related complications.[9]

Aim of the research was to analyse the effect of topical Nepafenac 0.1% (NSAIDs) and Fluorometholone 0.1% (Steroid) on Macular thickness after Nd: YAG posterior capsulotomy.

The objectives of the study were:

1. To analyze the differences in the effect of Nepafenac versus Fluorometholone on macular thickness after Nd:YAG posterior capsulotomy.
2. To evaluate the effect of total energy used during Capsulotomy on macular thickness.

2. Materials and Methods

This randomized controlled study was carried out at the Department of Ophthalmology, TMMC&RC, Moradabad, Uttar Pradesh from the year 2022 to 2023. The study enrolled 96 patients diagnosed with posterior capsular opacity who were scheduled to undergo Nd:YAG posterior capsulotomy, provided they met the inclusion criteria. Each patient provided an informed consent prior to the procedure.

2.1. Inclusion criteria

Co-operative patients who fully understood the implication of Nd:YAG procedure after being diagnosed with posterior capsular opacity following an uneventful cataract surgery with posterior chamber intraocular lens implantation at least 6 months earlier, were included in the study.

2.2. Exclusion criteria

1. Patients less than 18 years of age.
2. Refusal to consent.
3. Patients with history of any intra ocular surgery <6 months ago.
4. Patients with history of cataract surgery <6 months ago.
5. Patients with history of ocular trauma within 6 months of presenting.
6. Patients with ocular disorders like corneal opacity, retinal diseases, optic neuropathy, age related macular degeneration, glaucoma and steroid responders.
7. Patients with an active ocular inflammation like uveitis, vasculitis.
8. Pregnant patients.
9. Patients with refraction error greater than -2/+2 diopters.

2.3. Sample size

The sample size was determined to be 96 in total which was divided into two groups of 48 each.

2.4. Randomization

Patients were randomly assigned to Group A and Group B, following the Chit-in-Box method. Group A (n=48) received 0.1% Nepafenac eye drop, administered 6 hourly a day for one week, while Group B (n=48) was prescribed 0.1% Fluorometholone with the same dosage and duration.

2.5. Methodology

After approval from College Research committee and Institutional Ethics committee, patients presenting with complaints of reduced visual acuity 6 months post cataract surgery were identified. On obtaining a detailed ocular and systemic history, slit lamp and dilated fundus examination was carried out. On fulfilling the Inclusion criteria, patients diagnosed with PCO were required to sign a standard informed consent. Carl Zeiss Meditech Cirrus HD-OCT Model-500 was used to evaluate macular thickness pre and post laser. Carl Zeiss Meditech LSL YAG III IP20 was used for Nd:YAG capsulotomy which was carried out by a single operator. Total energy utilized was noted. Patients were randomised into 2 groups using Chit in box method & medications were prescribed accordingly. Group A patients were prescribed 0.1% Nepafenac eye drops for one week, while Group B patients received 0.1% Fluorometholone eye drops for the same duration. Macular thickness was re-measured after an hour of Nd:YAG posterior capsulotomy. Follow up was carried at week one, week four and week twelve to evaluate Macular thickness. Comparison of effect of Nepafenac and Fluorometholone on Macular thickness was done. Appropriate statistical tests were applied.

2.6. Follow up

Each patient was followed up after one hour of procedure, week one, week four and week twelve of Nd:YAG capsulotomy. During these intervals, complete eye examination and macular thickness was carried out.

2.7. Statistical analysis

SPSS version 25.0 was used for performing the data analysis. For quantitative data, the mean and standard deviation were

computed, while frequency and percentages were determined for qualitative data. Further, associations between categorical variables were assessed using the Fisher's Exact and Chi-square tests. The Pearson correlation test was applied to evaluate relationships between study variables. A significance level of 5% ($p \leq 0.05$) was considered statistically significant.

3. Results

Comparison of gender distribution across Group A and Group B (**Figure 1**) showed that the p-value associated with this comparison was 0.68, indicating no statistically significant difference between the two groups with respect to gender distribution.

Comparison of age distribution between the two groups (**Figure 2**) indicated no significant difference statistically.

The change in mean Macular thickness (in µm) in Group A & B (**Figure 3**) during the study period indicated that there is a difference between the two groups 1-hour post-treatment; however, this difference was found out to be not significant statistically. Further, after week 1, week 4 and week 12, the mean Macular thickness in Group-A remained slightly lower but, again the differences between the two groups were not significant statistically, with p-values of 0.37, 0.56, and 0.68, respectively.

The comparison of total energy utilised in Group A and Group B (**Table 1**) showed that both the groups have similar central tendencies, with mean values of 22.96 for Group-A and 23.51 for Group-B, and an identical median value of 24.00. This suggests that there is no significant difference statistically between the two groups.

Table 1: Total energy (in mJ) comparison in Group A and Group B

Statistics		**Group-A**	**Group-B**
Mean		22.96	23.51
95% Confidence Interval for Mean	Lower case	21.96	22.15
	Upper case	23.96	24.88
Median		24.00	24.00
Variance		24.782	22.588
Standard Deviation		4.978	4.753
Minimum		12	13
Maximum		33	33
Range		21	20
Interquartile Range		8	8

Table 1 interpretation: Both the groups had similar central tendencies, with mean values of 22.96 for Group-A and 23.51 for Group-B, and an identical median value of 24.00. This indicates no statistically significant difference between the two groups.

There were weak to moderate correlations between total energy and changes in Macular thickness with some correlations reaching statistical significance in certain follow-up periods in both the groups. In Group A, there was a weak positive correlation found which was not statistically significant at one hour, week one and week four (**Table 2**).

Group B showed statistically significant strong positive correlation after one hour and week one of treatment (**Table 3**). A moderate positive correlation was observed at week four which was also statistically significant. Similarly, after week twelve, there was a moderate positive correlation but it was statistically insignificant. These findings suggests that higher energy levels used during Nd:YAG posterior capsulotomy might influence rise in IOP and macular thickness post-procedure.

Table 2: Correlation of total energy & macular thickness in group-A.

Group-A		
Macular Thickness		**Total Energy**
Pre	Pearson Correlation	0.119
	Significance (P-value)	0.414
After 1 Hour	Pearson Correlation	0.168
	Significance (P-value)	0.249
After Week 1	Pearson Correlation	0.176
	Significance (P-value)	0.226
After Week 4	Pearson Correlation	0.115
	Significance (P-value)	0.432
After Week 12	Pearson Correlation	-0.059
	Significance (P-value)	0.686

Used pearson correlation test**

Table 2 represents the correlation between Macular Thickness and Total Energy in Group A at different follow-up time points: After 1 hour, first week, and fourth week there was weak positive correlation but it was not significant statistically. At twelfth week, there appeared a weak negative correlation between Macular Thickness and Total Energy but, was not significant statistically with Pearson correlation coefficient of -0.059 and p-value of 0.686.

Table 3: Correlation of total energy & macular thickness in group-B

Group-B		
Macular Thickness		**Total Energy**
Pre	Pearson Correlation	0.16
	Significance (P-value)	0.27
After 1 hour	Pearson Correlation	0.50
	Significance (P-value)	**<0.001**
After Week 1	Pearson Correlation	.45
	Significance (P-value)	**<0.001**
After Week 4	Pearson Correlation	0.28
	Significance (P-value)	0.052
After Week 12	Pearson Correlation	0.26
	Significance (P-value)	0.07

Used Pearson Correlation Test**

Table 3 represents the correlation between Macular thickness and Total Energy in Group B at different follow-up time points: At 1 hour and week 1 post-procedure, a strong positive correlation was observed, both of which were statistically significant. After week 4, a moderate positive correlation was observed, approaching statistical significance with Pearson correlation coefficient of 0.28 and p-value of 0.052. At week 12, there appeared a moderate positive correlation, but it was not significant statistically with Pearson correlation coefficient of 0.26 and p-value of 0.07.

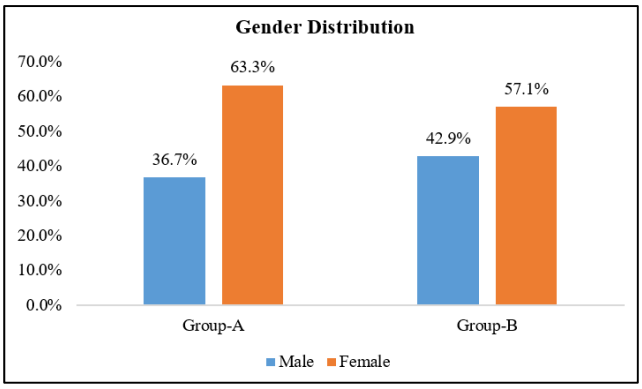

Figure 1: Comparison of gender distribution in Group A and Group B

Figure 1 illustrates a group-wise comparison of gender distribution within the study population. The p-value associated with this comparison was 0.68, indicating no significant difference statistically in the gender distribution between the two groups.

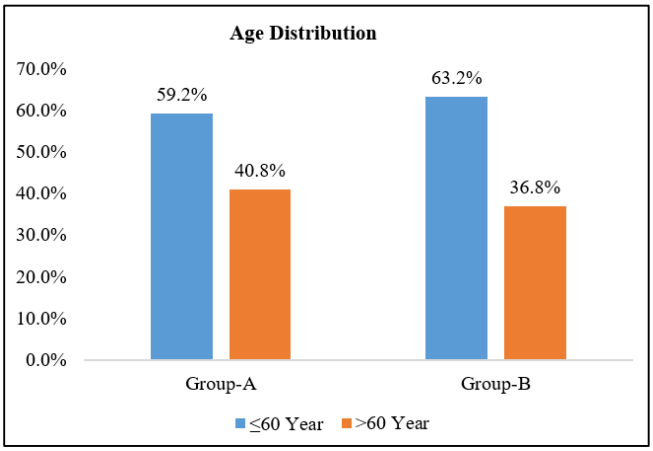

Figure 2: Comparison of age distribution between Group-A and Group-B

Figure 2 illustrates the age distribution comparison between Group A and Group B within the study population, indicating no statistically significant difference in age distribution between the two groups.

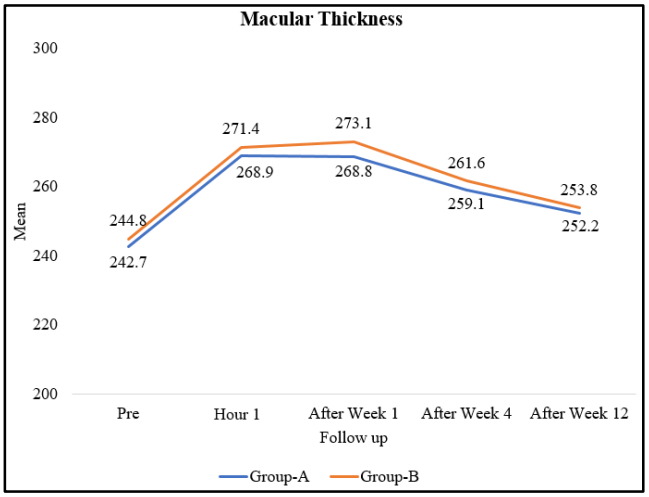

Figure 3: Change in Macular thickness (in µm) during study period in Group A & B

Figure 3 represents the difference between mean macular thickness in Group-A & Group-B on hour 1 post-treatment which is not statistically significant. After week 1, week 4 and week 12, the mean macular thickness in Group-A remains slightly lower than that in Group-B, however, these differences did not reach statistical significance, with p-values of 0.37, 0.56 & 0.68, respectively.

4. Discussion

Posterior capsular opacification, a potential complication occurring following a cataract surgery, can arise due to variety of factors such as surgical trauma, the type of intraocular lens implanted, and certain cytokines stimulating

proliferation of residual lens epithelial cells within the capsule.[10,11]

Nd:YAG posterior capsulotomy is a pivotal intervention for managing PCO. However, despite its efficacy as treatment, this procedure may show potential repercussions, including fluctuations in IOP and alterations in macular thickness, which can significantly impact visual outcomes. Incidence rates of CME following Nd:YAG capsulotomy approximates between 0.7 to 4.9%, which is believed to be triggered by increased permeability of perifoveal capillary induced by inflammatory mediators like prostaglandins subsequent to laser capsulotomy.[12,13] Reports claim that the amount of energy applied during the procedure of Nd:YAG posterior capsulotomy cause a rise in IOP and result in macular edema as a result of which macular thickness increases. There are no specific guidelines laid out regarding prevention or treatment of these complications. The efficacy of topical NSAIDs versus topical steroids in managing postoperative inflammation remains debatable, lacking a consensus within the ophthalmic community. Given this context, our study was conducted with the objective of comparing the effects of topical Nepafenac eye drop versus Fluorometholone eye drop on Macular thickness after Nd:YAG posterior capsulotomy in patients treated for Posterior capsular opacification.

Nepafenac, a potent NSAID, and Fluorometholone, a corticosteroid renowned for its anti-inflammatory properties, are frequently administered postoperatively to mitigate inflammation and reduce the risk of complications. Understanding the nuanced effects of these medications on macular thickness is paramount for optimizing patient care strategies, tailoring treatment regimens, and minimizing adverse outcomes. By meticulously examining the comparative impacts of Nepafenac and Fluorometholone in the context of Nd:YAG posterior capsulotomy, this research aims to provide clinicians with valuable evidence-based insights to inform their therapeutic decisions and ultimately enhance the visual prognosis and quality of life for individuals undergoing this procedure.

A total of 96 cases were recruited consisting of 48 cases in each group (A and B). After applying chit in box method, patients allotted in Group A were administered Topical Nepafenac 0.1% for a week and Group B were prescribed Topical Fluorometholone 0.1% for a week. Patients were followed up for 3 months after undergoing Nd:YAG posterior capsulotomy.

The gender distribution between the two treatment groups did not show any significant disparity, indicating that any observed differences in outcomes were unlikely to be influenced by gender (**Figure 1**). In the study, Group-A included 18 males (36.7%) and 31 females (63.3%), while in Group B, there were 21 males (42.9%) and 28 females (57.1%). The study findings reported that more than 50% of the cases were females in each group. Similar to our study, S Centinkaya et al observed no significant difference in the distribution of gender.[14]

The age distribution in this study showed no significant difference between Group A and Group B. The average age of participants in both groups were 59.69±10.5 and 57.55±10.3 respectively (**Figure 2**). This helped us deduce that age was not a confounding factor in the analysis. Additionally, the distribution of treated eyes was comparable between the groups, further ensuring the comparability of the study groups.

The energy required for posterior capsulotomy fell within the range of 12 to 33 mJ with a mean value of 22.96 mJ in Group A and 23.51 mJ in Group B during the study period (**Table 1**). While assessing the relation between Macular Thickness and Total Energy in Group A, a weak positive correlation was found which was statistically insignificant after one hour, week one and week four. In Group B it was observed that after one hour and week one of treatment, there was a statistically significant strong positive correlation between macular thickness and total energy. At week four, there was a statistically significant moderate positive correlation. At week twelve, there was a statistically insignificant moderate positive correlation.

Similar results to our study Auffarath and Bhargava et al. reported a much lesser energy use (12.7 and 22.8 mJ respectively).[15,16] Ari et al. reported mean energy levels of 58±18 mJ and 117±36 mJ across their two study groups.[17] In contrast, Channell and Beckman observed a higher average energy usage of 250.7 mJ in seven out of thirty-three laser capsulotomy procedures.[18] Additionally, a study by Richter et al. suggested that using total energy of less than 200 mJ for Nd:YAG laser procedure is relatively safer.[19] This inconsistency in the amount of energy utilised could possibly be due to the variation in density and grading of PCO which were treated accordingly.

With respect to the observations on macular thickness in our study, the mean thickness at baseline was 242.7 ± 18.5 μm, which significantly increased to 268.9 ± 26.1 μm after one hour post-treatment. This parameter showed statistically significant difference compared to baseline, indicating increase in macular thickness after initiating laser treatment. There was a subsequent reduction in macular thickness to 268.8 ± 22.5 μm by week one, followed by a gradual reduction to 252.2 ± 19.1 μm by week four and eventually to 259.1 ± 20.6 μm by week twelve. This pattern (**Figure 3**) suggested an acute increase in macular thickness immediately after treatment, followed by a gradual reduction over time which could possibly be due to the total energy applied during capsulotomy. Overall, these results indicate that macular thickness exhibit acute changes immediately following treatment, which gradually resolved over the course of follow-up period.

In relation to our findings, a prospective study by Ucgul Atilgan et al. investigated 75 eyes of patients with PCO, categorizing them into three groups based on post-capsulotomy medication. Group 1 included a total of 25 patients who were prescribed nepafenac 0.1% for one week, Group 2 comprised of 25 patients who were prescribed fluorometholone 0.1% for the same duration, while Group 3 included 25 patients who were not given any medication. The study reported a significant rise in macular thickness at the end of one month follow-up. However, when comparing mean values, no significant differences were observed across evaluations. The only notable finding was that macular thickness at one month was significantly higher than at day one and week one. The study concluded that both drugs had comparable effects on macular thickness.[9]

However, a study by Miyake et al. concluded, Nepafenac is more effective in preventing deterioration of the blood-aqueous barrier and CME in patients who received the medication over a five-week period.[20] Additionally, a study by Jinagal et al. demonstrated that macular thickness in the untreated group initially increased during the first two weeks but returned to normal values by the first month without requiring treatment.[21]

Our study shows that complications like increase in macular thickness were minimal indicating no severe side effects after laser capsulotomy. This could possibly be because of controlled use of energy during capsulotomy procedure. The results implied that post Nd:YAG laser capsulotomy, medication is advisable, with either topical NSAIDs or topical steroids being viable options. The use of topical NSAIDs alone may be favoured, especially in scenarios where steroid usage could pose risks, such as in steroid responders, recurrent keratitis cases including herpetic keratitis, and in situations where there can be increased likelihood of CME, such as in diabetics.[22]

5. Limitation

A restraint found during this research was the difficulty in obtaining a good signal strength OCT based macular thickness in patients with dense PCO. This resulted in higher energy utilization and thereby increase in macular inflammation which could possibly be avoided if similar grade of PCO is opted for research purpose to offer an unbiased result. Additionally, studies with a larger sample size and extended follow-up periods may be warranted to validate these findings and assess long-term safety and efficacy of the two classes of drugs.

6. Conclusion

Based on the observations provided in the statistical analysis it can be concluded that both Nepafenac and Fluorometholone eye drops demonstrated comparable effect of improvement on increased macular thickness and brought it to baseline normal level after Nd:YAG posterior capsulotomy. These findings support the potential utility of both treatments in clinical ophthalmology for managing complication of increase in macular thickness that may occur after Nd:YAG capsulotomy. Owing to the comparable effects of the two drugs, the use of topical NSAIDs alone may be favoured, especially in scenarios where steroid usage could pose risks, such as in steroid responders or in conditions where steroid usage is contraindicated.

7. Source of Funding

None.

8. Conflicts of Interest

None.

9. Ethical Number

Ethical No.: TMU/IEC/2021-22/29.

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