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# A Retrospective Non-Randomized Case Study Analysis of Mitomycin-C Efficacy in Patients Undergoing Combined Phacotrabeculectomy at a Tertiary Care Hospital in Salem, India

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**Abstract:** Glaucoma and cataracts, which are major contributors to worldwide blindness, frequently occur together, requiring phacotrabeculectomy as the primary therapeutic approach. This study conducted a retrospective analysis of cases to evaluate the efficacy of Mitomycin-C (0.2mg/ml for 3 min) in phacotrabeculectomy, which is a combination surgical treatment that involves trabeculectomy and phacoemulsification. The study was conducted over six months, from January 2022 to June 2022, in a tertiary care hospital in Salem. An analysis was conducted on the records of 60 patients who underwent phacotrabeculectomy and met the inclusion criteria. The study included 60 patients, with 28 (47%) being men and 32 (53%) being females; of these, 22 (37%) underwent surgery on their right eye, while 38 (63%) underwent surgery on their left. Most patients belonged to the age bracket of 51-65 years. The grading of cataracts identified many forms, such as Nuclear Sclerosis (NS-1: 3%, NS-1 and PSC: 10%, NS-2: 17%, NS-2 and PSC: 23%, NS-3: 7%, PSC: 13%). The most prevalent type, affecting the majority (27%) of the population, was Senile Immature Cataract (SIMC). The average preoperative intraocular pressure was 22.4 ± 1.52 mmHg, and after the surgery, the pressure reduced dramatically to 13.20 ± 1.42 mmHg. The difficulties associated with blebs are resolved on their own. After the operation, there was an improvement in visual acuity. The average values increased from 0.86 ± 0.15 before the surgery to 0.22 ± 0.26 on day 1, 0.20 ± 0.23 on day 7, 0.19 ± 0.23 on day 14, 0.18 ± 0.19 on day 30, and 0.18 ± 0.19 on day 45. A paired t-test demonstrated a statistically significant difference (p=0.02) in postoperative visual acuity between day 1 and day 45. The study's findings indicate that Mitomycin-C is efficacious in phacotrabeculectomy, resulting in decreased intraocular pressure and enhanced visual acuity, with no notable problems. The findings provide valuable insights into managing concurrent glaucoma and cataracts, presenting a viable strategy in tertiary care settings.

## Introduction

The leading causes of blindness are mainly glaucoma and cataracts. Glaucoma may be defined as a progressive optic neuropathy that results in an irreversible loss of vision. The risk factor that can be modified in glaucoma patients is intra-ocular pressure (IOP). A cataract is a lens opacity or cloudiness which may develop in one or both eyes at any age (Kastner and King, 2020).

Glaucoma and cataracts are two ophthalmic disorders that may co-occur in some patients (Sengupta et al., 2021; Medhi et al., 2023). It is more common among the elderly population. All those patients with glaucoma and

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cataracts together require a combined surgical procedure called phacotrabeculectomy, which combines two separate procedures called trabeculectomy and phacoemulsification (Veldman et al., 1987). Trabeculectomy is a procedure useful for treating glaucoma; Phacoemulsification is a procedure useful for treating cataracts. Phaco-trabeculectomy is widely used for the simultaneous treatment of glaucoma and cataracts (Casson and Salmon, 2001; Kass et al., 2002; Wishart and Austin, 1993).

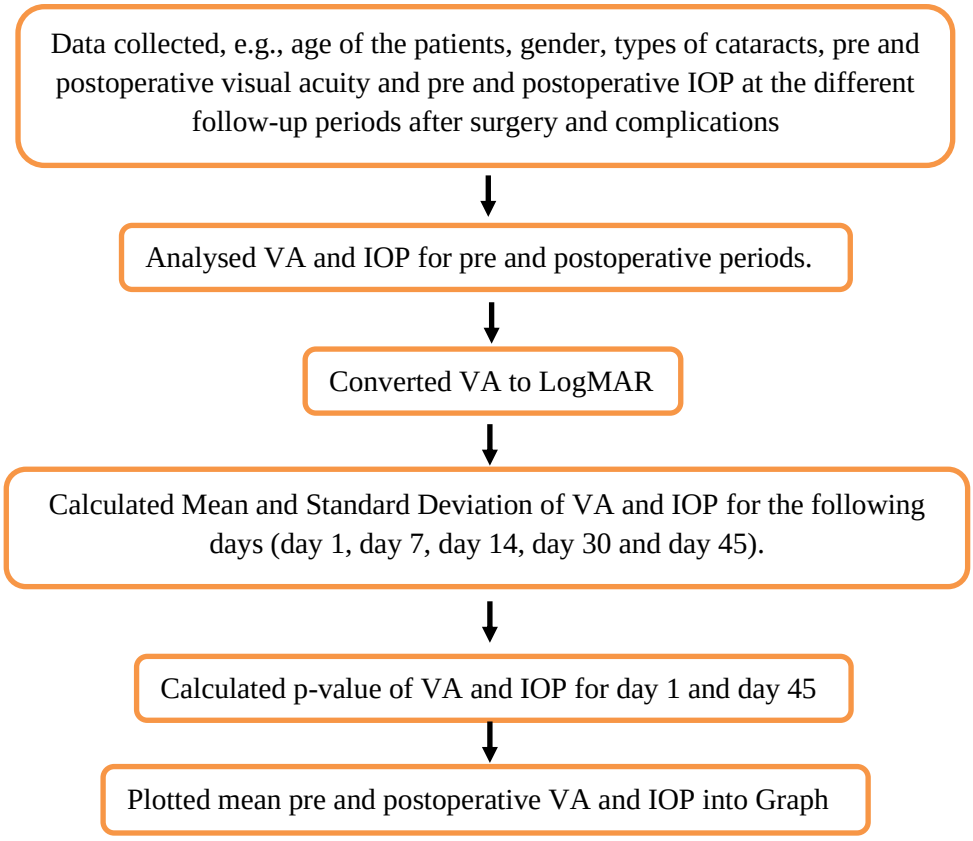


**Figure 1. Flow chart of the methodology.**

In this combined procedure, both glaucoma and cataracts are treated. This procedure saves the patients from two separate surgeries and achieves better postoperative results. It also minimises the cost of surgery. Hence, it has been recommended as an effective procedure for treating those patients with glaucoma and cataracts together (Husain et al., 2012). For the past few years, combining trabeculectomy with phacoemulsification has been a successful therapy for patients (Kastner and King, 2020).

Phacotrabeculectomy has some advantages over trabeculectomy and phacoemulsification:

#First, it reduces the risk of additional intraocular pressure (IOP) because, after trabeculectomy, lens opacity rapidly progresses into a visually significant cataract that requires cataract surgery.

#Second, sequential cataract surgery has a higher risk of trabeculectomy failure, which can be reduced by combining phacotrabeculectomy with cataract surgery (Verges et al., 2005).

Recent studies have shown that when the intra-ocular pressure is reduced after treating glaucoma, it results in a slow progression of the visual field in patients. However, glaucoma surgery has some complications, like hypotony, bleb leak, flat bleb, phlebitis, etc. (Kotrappa et al., 2016). So, as a result, antifibrotic drugs, e.g. mitomycin-c, are used to modify wound healing to improve the success rate of glaucoma filtration procedures (Agarwal et al., 2002).

Mitomycin-C (MMC) is an antibiotic and antimetabolite first isolated from *Streptomyces caespitosus*, which has been demonstrated to inhibit fibroblastic activity. The advantages of its use as an adjunctive to glaucoma filtering surgery are the reduction of corneal complications, a more profound reduction in IOP and the elimination of the need for postoperative administration of drugs (Skuta and Parrish, 1987). Trabeculectomy with MMC is often performed as a primary procedure for glaucoma patients and cataract extraction, as it is considered safe and effective in lowering IOP (Friedman et al., 2002). Thus, antimetabolites such as MMC have been used in filtering surgery to reduce reactive scarring in the subconjunctival region in the postoperative period (Wilkins et al., 2005). However, there is a risk of complications, including hypotony, bleb leak and blebitis in the early postoperative

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period and also many recent studies have shown that MMC was effective in lowering the IOP with a lower rate of postoperative complications (Ben Simon and Glovinsky, 2006; Khandelwal et al., 2019; Sihota et al., 2015). The introduction of MMC as an adjunct to phacotrabeculectomy was a significant advance in improving the procedure's IOP-lowering efficacy (Hyung & Kim, 2001). Hence, this study was designed to evaluate the safety and efficacy of MMC (0.2mg/ml) in combined phacotrabeculectomy.

## Materials and Methods

A retrospective, non-randomized case review was conducted from January 2022 to June 2022 with all the patients who underwent phacotrabeculectomy with MMC in our study site from January 2021 to December 2021. The methodology adopted is shown in Figure 1 as a flow chart. The cases were collected from the medical records department of a tertiary care hospital. This study included patients with uncontrolled IOP and controlled IOP with advanced damage to the optic nerve or visual field. About 60 patients met the inclusion criteria.

### Study procedure

All patients underwent a baseline examination prior to surgical intervention, which included an assessment of best corrected visual acuity (BCVA), biomicroscopy with cataract grading scales using LOCS III (Lens Opacities Classification System III), a dilated evaluation of the fundus with a 78 D lens, and IOP measurement. Following surgical intervention, follow-up appointments were scheduled on day 1, day 7, day 15, day 30, and 45. Except for the LOCS III, all of the above-mentioned examinations conducted at each visit were recorded. Following phacotrabeculectomy, postoperative complaints were noted.

### Surgical procedure

Under the ophthalmologist's guidance, the surgery was performed by administering peribulbar anaesthesia. All patients underwent phacotrabeculectomy using a one-site approach. A superior fornix-based conjunctival flap (1-1.5mm) was dissected. To control episcleral haemorrhage, electrocautery was utilised. Three tiny sponges with MMC (0.2mg/ml) were placed deep into the conjunctival pocket for a broad and diffuse application, and one was also placed under the scleral flap for 2-3 mins. A balanced salt solution was used to rinse the MMC thoroughly. The anterior chamber was then penetrated beneath the scleral flap using a 2.8 mm keratome, and phacoemulsification was done using the direct chop approach. After inserting a foldable acrylic intraocular lens (IOL), the phaco incision is closed with an interrupted 10-0 nylon suture. A piercing punch was used to remove the trabecular meshwork, and peripheral iridectomy was done in each instance. Using 10-0 nylon sutures, the scleral flap was closed. Finally, the conjunctiva was sutured with 10-0 nylon sutures throughout the procedure. Following that, the wound is examined for leakage and bleb development by injecting a balanced salt solution and subconjunctival dexamethasone 2 mg. Prednisolone acetate 1% eye drop was administered to all the patients nearly 8-10 weeks after the surgery was performed. Other eye drops, like ciprofloxacin, have been used four times a day per week. An anticholinergic drop like homatropine 2% can be used three times a day for up to 2-3 weeks (Bowman et al., 2010).

### Data analysis

The data collected were the age of the patients, gender, types of cataracts (nuclear sclerosis, posterior sub-capsular, senile immature cataract), pre and postoperative visual acuity (VA) and pre and postoperative IOP at the different follow-up periods (baseline, postoperative day 1, day 7, day 15, day 30 and day 45) after surgery. All visual acuities were converted to logMAR from Snellen form respectively by using the formula as:

$$\text{LogMAR} = \frac{Snellen\ numerator}{Snellen\ denominator}$$

In the equation mentioned above, the numerator is the top number of fractions, and the denominator is the bottom number of fractions. For e.g., In visual acuity 6/9, 6 is the numerator, and 9 is the denominator. So according to the above equation LogMAR = 0.67.

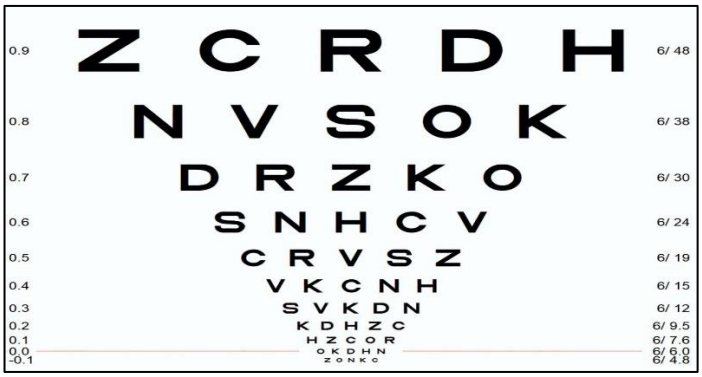


**Figure 2. LogMAR acuity is mentioned on the left side, and Snellen acuity on right side**

Microsoft Excel 2013 was used to calculate the percentages and generate tables and graphs. The statistical analysis was done by using the student's t-test. The p-value is significant at $p \leq 0.05$, highly significant at $p \leq 0.01$ and very highly significant at $p \leq 0.001$.

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## Results and discussion

Case records of 60 patients who underwent phaco trabeculectomy were recruited from the medical records department. The study consists of 28 (47%) males, 32 (53%) females. The surgery included 22 (37%) right eye and 38 (63%) left eye. More than 50% of the patients belong to the age group of 51-65 years.

Patients were categorized based on different types of cataracts using the cataract grading scale. In this study, 3% of the patients were affected with Nuclear Sclerosis-1 (NS-1), 10% with NS-1 and Posterior Subcapsular (PSC), 17% with Nuclear Sclerosis (NS-2), 23% with NS-2 and PSC, 7% with NS-3, and 13% with PSC. The majority of the population (27%) was affected by Senile Immature Cataract (SIMC), as shown in Table 1.

**Table 1. Phacotrabeculectomy based on types of nuclear grading cataracts.**

| Sl. No. | Types of cataracts with nucleus grading | Male | Female | Total no. of patients | Percentage |
|---|---|---|---|---|---|
| 1 | NS -1 | 0 | 2 | 2 | 3% |
| 2 | NS-1, PSC | 2 | 4 | 6 | 10% |
| 3 | NS-2 | 4 | 6 | 10 | 17% |
| 4 | NS-2, PSC | 6 | 8 | 14 | 23% |
| 5 | NS-3 | 4 | 0 | 4 | 7% |
| 6 | PSC | 4 | 4 | 8 | 13% |
| 7 | SIMC | 8 | 8 | 16 | 27% |
| | TOTAL | 28 | 32 | 60 | 100% |

Visual acuity was analysed for the study subjects before and after surgery. Mean visual acuity before the surgery was 0.86 ± 0.15 and after the surgery was progressively improved as follows; 0.22 ± 0.26 on day 1, 0.20 ± 0.23 on day 7, 0.19 ± 0.23 on day 14, 0.18 ± 0.19 on day 30, and 0.18 ± 0.19 on day 45 as shown in figure 3. A paired t-test was used to determine the difference between the mean of postoperative visual acuity on day 1 and day 45.

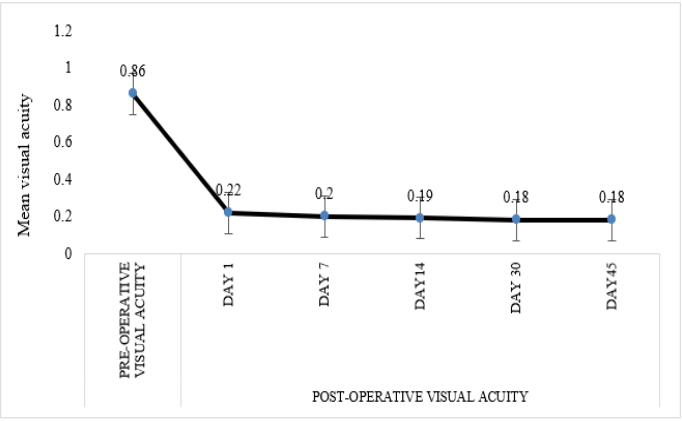



**Figure 3. Mean based on pre and postoperative visual acuity.**

The p-value was found to be significant (0.02), as shown in Table 2.

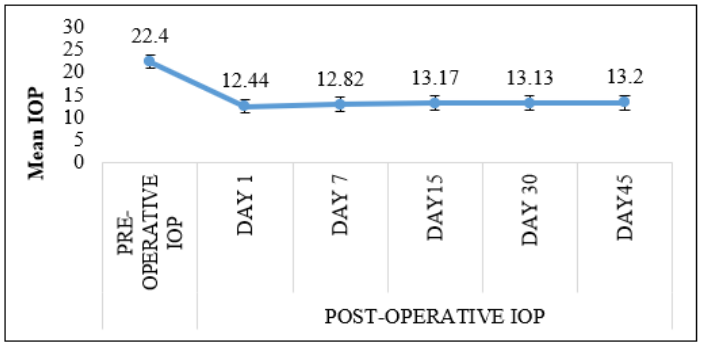
**Table 2. Phacotrabeculectomy based on pre and postoperative visual acuity.**

| Preoperative visual acuity | Postoperative visual acuity (Mean ±SD) | | | | |
|---|---|---|---|---|---|
| 0.86±0.15 | Day 1 | Day 7 | Day 14 | Day 30 | Day 45 |
| | 0.22± 0.26* | 0.20± 0.23 | 0.19± 0.23 | 0.18± 0.19 | 0.18±0.19* |
| P VALUE | 0.02* | | | | |
| Significant at p≤0.05*, highly significant at p≤0.01**, very highly significant at p≤0.001*** | | | | | |

IOP was analysed for the study subject's both before and after surgery. The normal IOP range for a patient is 10-20 mmHg (Khaw et al., 2004). The mean IOP before surgery was 22.4 ± 1.52 mmHg. And after surgery was 12.44 ± 2.51 mmHg on day 1, 12.82 ± 1.92 mmHg on day 7, 13.17 ± 1.41 mmHg on day 14, and 13.13±1.09 mmHg on day 30 and 13.20±1.42 mmHg on day 45 as shown in figure 4.

**Table 3. Phacotrabeculectomy based on pre and post - operative IOP.**

| Preoperative IOP (mmHg) | Postoperative IOP (mmHg) (Mean ± SD) | | | | |
|---|---|---|---|---|---|
| 22.4±1.52 | Day 1 | Day 7 | Day 15 | Day 30 | Day 45 |
| | 12.44±2.51*** | 12.82 ±1.92 | 13.17 ±1.41 | 13.13 ±1.09 | 13.20±1.42*** |
| P VALUE | <0.001*** | | | | |




Significant at p≤0.05*, highly significant at p≤0.01**, very highly significant at p≤0.001***

**Figure 4. Mean based on pre and postoperative IOP.**

A paired t-test was used to determine the difference between the mean of postoperative IOP of day 1 and day 45. The p value was found to be very highly significant (0.001), as shown in Table 3.

After phacotrabeculectomy the patient's eyes were analysed for bleb formation, on day 1 and day 7 patients had hypotony (HY), bleb leak (BL), blebitis (BLS), flat bleb (FB) and choroidal effusion (CF), which eventually improved on day 15, 30 and 45, as shown in Figure 5.

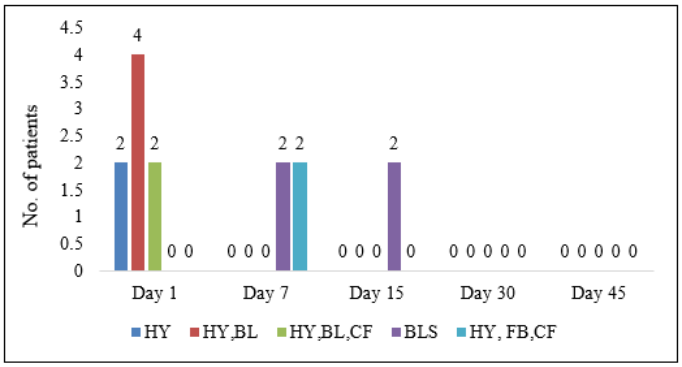



**Figure 5. Postoperative complications of bleb.**

Anterior segment examination was conducted after phacotrabeculectomy, on day 1, day 7 and day 15 patients had hyphema (HYP), sub-conjunctival haemorrhage (SCH), shallow anterior chamber (Sh.AC), anterior chamber reaction (AC.REAC) and corneal oedema (C.OE), which eventually improved on day 30 and day 45, as shown in Table 4.

**Table 4. Anterior segment examination after phaco-trabeculectomy**

| A.S examination | Day 1 | Day 7 | Day 15 | Day 30 | Day 45 |
|---|---|---|---|---|---|
| HYP | 2 | 0 | 0 | 0 | 0 |
| SCH, HYP | 12 | 0 | 0 | 0 | 0 |
| SCH, HYP, Sh.AC | 4 | 0 | 0 | 0 | 0 |
| SCH, HYP, Sh.AC, C.OE | 2 | 0 | 0 | 0 | 0 |
| SCH | 0 | 10 | 0 | 0 | 0 |
| Sh.AC, AC.REAC | 0 | 2 | 2 | 0 | 0 |
| SCH, C.OE | 0 | 2 | 2 | 0 | 0 |
| NORMAL | 0 | 0 | 56 | 60 | 60 |

A retrospective study was conducted at a tertiary care hospital for a period of 6 months. 60 patients were selected based on inclusion and exclusion criteria. In this study minimum concentration of MMC (0.2 mg/dl) had been used to evaluate the efficacy of phacotrabeculectomy.

In this study, patients who went on phacotrabeculectomy surgery were followed up for 45 days. There was a significant decrease in the visual acuity when comparing preoperative values (0.86±0.15), with postoperative results (0.18±0.19). The p-value for VA was found to be significant (0.02). The above results were found to be similar to the study done by E Graf et al. (Graf et al., 2019).

After 45-days, IOP was found to be reduced in all patients who underwent phacotrabeculectomy. At the same time, comparing preoperative values (22.4 ± 1.52 mmHg) with postoperative results (13.20 ± 1.42 mmHg). The p value for IOP was found to be very highly significant (0.001). The above results were found to be quite similar to the study done by El Sayed et al. (El Sayed et al., 2019).

In this study, postoperative complications following phacotrabeculectomy surgery with MMC were addressed. These issues included hypotony, bleb, hyphema, and shallow Anterior Chamber, which were the most frequent postoperative complications found in phacotrabeculectomy. The complications were self-limiting. And this finding correlates with the other studies (Chen et al., 2015).

## Conclusion

This retrospective study carefully assessed Mitomycin-C's effectiveness in phacotrabeculectomy, a crucial intervention for glaucoma-cataract patients. The contrast of these worldwide causes of blindness emphasizes the need to improve treatment. Phacotrabeculectomy, a combination of trabeculectomy and phacoemulsification, became the only treatment for difficult situations. The six-month research at a Salem tertiary care hospital recruited and examined 60 individuals based on strict inclusion and exclusion criteria. Uncontrolled and controlled intraocular pressure and progressive optic nerve injury were evaluated. Preoperative intraocular pressure averaged 22.4 ± 1.52 mmHg, significantly decreasing to 13.20 ± 1.42 mmHg postoperatively. Self-limiting bleb problems were an accidental observation that showed the treatment's resiliency. Importantly, Mitomycin-C, which targets postoperative scarring, reduces morbidity and reduced failure risks. Most of the research population was 51–65 years old, reflecting the frequency of various ocular diseases in this demographic. The most common cataract subtype was Senile Immature Cataract (SIMC). The postoperative visual acuity study showed substantial

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improvement, with a significant advance from 0.86 ± 0.15 to 0.18 ± 0.19 on day 45. The statistical robustness was confirmed by a paired t-test with a p-value of 0.02. Hence, Mitomycin-C's effectiveness in phacotrabeculectomy, as shown by lower intraocular pressure, few significant problems, and better visual acuity, makes it a therapeutically useful adjuvant to glaucoma and cataract therapy. These findings advance ocular therapies and suggest improved therapeutic outcomes in tertiary care.

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## Conflict of Interest

The authors declare no known conflict of interest for this article.

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