

# Study of Outcome of High Volume Manual Small Incision Cataract Surgery and Complications in Garhwal Himalayan Region

## Aim of the study

To compare High Volume with Low Volume Cataract Surgery Outcomes in a tertiary eye care hospital in Garhwal Himalayan Region, over a 30-day period, in terms of Quality as gauged in terms of Intra-operative complications and their management and Post-operative complications and their management (on day 1 and day 30).

## Materials and Methods

A prospective, randomized, observational study conducted on 300 eyes of 300 patients at a tertiary hospital, total duration of 4 months was taken for data collection. Patients were divided into 2 groups: A) those coming in the low volume season (summer months) and B) those coming in the high volume season (winter months). Normal standard protocols were followed pre/per/post operatively.

## Results

Intra-operative complications between the two months (settings) by independent t-test the p value was 1.00 which was not statistically significant (mean of complication: August=0.86+1.83; December=0.86 + 1.29). 1 month post-operative complications between the two months (settings) by independent t-test the p value was 0.56 which was not statistically significant (mean of complication: August=0.09 + 0.30; December=0.18 + 0.4).

## Conclusion

Intra-operative, post-operative complications on 1<sup>st</sup> day and at one month follow up, High Volume Cataract Surgery (greater than 40 Manual Small Incision Cataract surgeries) does not affect the quality when compared with Low Volume Cataract Surgery over a 30-days period in a tertiary institute in Central India.

**Keywords:** cataract, manual small incision cataract surgery, phacoemulsification, small incision cataract surgery

## INTRODUCTION

Cataract, a leading cause of global preventable blindness, has prevalence (based on Indian definition) of over 12 million people in India and incidence (based on WHO definition) is around 3.8 million new cases per year.[1,2,3] The current levels of cataract surgery are around 2.7 million cases per year, and this is far below what needs to be done to clear the backlog and also tackle the incidence. The advent of Manual **Manual Small Incision Cataract Surgery** (MSICS) gave improved visual outcome, being cheaper and requiring lesser time.[4-8] Phacoemulsification was too expensive an affair and took more time than **Manual Small Incision Cataract Surgery**. [9-12] This shift was the genesis of the concept of 'high volume with high quality' in cataract surgery. The definition of high volume cataract surgery is variable.[13-15] But more important than the absolute daily volume of cataract surgeries done, is the number of cases operated per hour as increased **Cataract surgery rate** (CSR) caused more complications. A skillful surgeon operating quickly, not only reduces the backlog, but also minimizes surgical handling thereby reducing inflammation and improving outcomes.

## **Aim of the Study**

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## **Materials and Methods**

A prospective, randomized, observational study conducted on 300 eyes of 300 patients at a tertiary hospital Garhwal Region, with a total duration of 4 months was taken for data collection. Patients were divided into 2 groups: A) those coming in the low volume season (summer months) and B) those coming in the high volume season (winter months). Normal standard protocols were followed pre/per/post operatively. Outcomes in these 2 groups were compared in terms of the above mentioned parameters after dividing the complications into sub groups: mild; moderate and severe (based on severity and morbidity).

## **Exclusion Criteria**

- i) Cataract surgery combined with any other procedure / type of surgery in the same sitting.
- ii) All "Guarded Visual Prognosis" cases
- iii) All patients with diabetes or any other systemic disease that would directly affect the surgical outcome.

Independent T test was used for analyzing the data.

## **Results**

Phacoemulsification (*phaco*) is the most common technique used in developed countries. It involves the use of a machine with an ultrasonic handpiece equipped with a titanium or steel tip. The tip vibrates at ultrasonic frequency (40,000 Hz) and the lens material is emulsified. A second fine instrument (sometimes called a "cracker" or "chopper") may be used from a side port to facilitate cracking or chopping of the nucleus into smaller pieces. Fragmentation into smaller pieces makes emulsification easier, as well as the aspiration of cortical material (soft part of the lens around the nucleus). After phacoemulsification of the lens nucleus and cortical material is completed, a dual irrigation-aspiration (I-A) probe or a bimanual I-A system is used to aspirate out the remaining peripheral cortical material.

Manual small incision cataract surgery (MSICS): This technique is an evolution of ECCE where the entire lens is expressed out of the eye through a self-sealing scleral tunnel wound. An appropriately constructed scleral tunnel is watertight and does not require suturing. The "small" in the title refers to the wound being relatively smaller than an ECCE, although it is still markedly larger than a phaco wound.

This study had a total of 300 patients enrolled in the study, 150 each were present in the month of August (low volume month) and December (high volume month).

Of the 150 patients operated in one of the low volume month, intra- operative complication was found in 12(10.43%). Premature entry was seen in 1 case (0.87%). Peripheral **Descemet's Membrane Detachment** occurred in 1 case (0.87%), Capsulorrhexis extension in 6 case (5.22%) and posterior capsular rupture with vitreous loss in 4 cases (3.48%).

**Table 1 –Intra Op Complications and management**

| MSICS Group                     |        |                         |          |                         |
|---------------------------------|--------|-------------------------|----------|-------------------------|
| Intra op Complications          | August | Secondary Interventions | December | Difference              |
|                                 | No %   |                         | No. %    | Secondary interventions |
| Morbidity causing complications |        |                         |          |                         |
| Hyphema                         | 0      | 0                       | 0        | 0                       |
| Iridodialysis                   | 0      | 0                       | 0        | 0                       |
| Total no of complications       | 0      | 0                       | 0        | 0                       |

|                            |     |  |     |  |
|----------------------------|-----|--|-----|--|
| Total patients complicated | 150 |  | 150 |  |
|----------------------------|-----|--|-----|--|

Similarly, of the 150 patients operated in the high volume month (December), intra-operative complication was found in 12 cases (10.43%). Premature entry was seen in 4 cases (3.48%). Descmets Membrane Detachment was present in 1 cases (0.87%), Iris chaffing was present in 3 cases (2.61%), Capsulorrhesis extension was present in 1 case (0.87%), Posterior capsular tear (PCR) with vitreous loss was present in 2 case (1.74%) and zonular dialysis was seen in 1 case (0.87%).

| Table 2: 1st day Post-operative Complications and Management |        |                          |              |                          |                   |              |   |
|--------------------------------------------------------------|--------|--------------------------|--------------|--------------------------|-------------------|--------------|---|
| MSICS GROuP                                                  |        |                          |              |                          |                   |              |   |
| 1st day post-op.                                             | August |                          | December     |                          | Difference        |              |   |
| Complications                                                | No.    | % Secondary Intervention | No.          | % Secondary Intervention |                   |              |   |
| TEMPORARY MORBIDITY CAUSING COMPLICATIONS                    |        |                          |              |                          |                   |              |   |
| Wound gape/leak                                              | 0      | 0                        | 2            | 1.75                     | Sutures at Tunnel | 2            |   |
| Striate Keratopathy                                          | 5      | 4.35                     | Conservative | 8                        | 7.02              | Conservative | 3 |
| Corneal oedema                                               | 10     | 8.70                     | Conservative | 10                       | 8.77              | Conservative | 0 |
| Retained lens/ Cortical Matter                               | 4      | 3.33                     | Conservative | 1                        | 0.88              | Conservative | - |
|                                                              | 48     |                          | 3            |                          |                   |              |   |
| Significant AC cells (>+3)                                   | 0      | 0                        | 17           | 14.91                    | Conservative      | 17           |   |
| Significant AC flare(>+2)                                    | 0      | 0                        | 2            | 1.75                     | Conservative      | 2            |   |
| Shallow AC depth (< ¼; VH grading)                           | 0      | 0                        | 1            | 0.88                     | AC formation      | 1            |   |
| Fibrin membrane/ fibrin strand                               | 1      | 0.87                     | 0            | 0                        | 0                 |              |   |
| Diffuse Hyphaema                                             | 5      | 4.35                     | Conservative | 5                        | 11.90             | Conservative |   |
| Total no. of Complications                                   | 25     | 21.74                    | 46           | 40.35                    |                   |              |   |
| Total No. of Patients                                        | 150    |                          | 150          |                          |                   |              |   |

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| Table 3: 1st day Post-operative Complications and Management |     |       |                        |            |       |
|--------------------------------------------------------------|-----|-------|------------------------|------------|-------|
| MSICS GROuP                                                  |     |       |                        |            |       |
| 1st day post-op. August                                      |     |       | December               | Difference |       |
| Complications                                                | No. | %     | Secondary Intervention | No.        | %     |
| POTENTIAL VISION THREATENING COMPLICATIONS                   |     |       |                        |            |       |
| Vitreous in AC                                               | 1   | 0.87  | AV                     | 0          | 0     |
| Severe Iritis                                                | 1   | 0.87  | Conservative           | 1          | 0.88  |
| IOL drop                                                     | 0   |       |                        | 0          | 0     |
| RD/Vh                                                        | 0   |       |                        | 0          | 0     |
| Total no. of Complications                                   | 2   | 1.74  |                        | 1          | 0.88  |
| Total no. Patients                                           | 115 |       |                        | 114        |       |
| Total Patients with Complications                            | 25  | 21.74 |                        | 43         | 37.72 |

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| Table 4: Month Post-Operative Complications and Management |        |      |                        |     |            |
|------------------------------------------------------------|--------|------|------------------------|-----|------------|
| MSICS GROuP                                                |        |      |                        |     |            |
| 1 month Post-operative %                                   | August |      | December               |     | Difference |
| Complications                                              | No.    | %    | Secondary Intervention | No. | %          |
| MINOR COMPLICATIONS                                        |        |      |                        |     |            |
| Persisting DM Detachment (peripheral)                      | 0      | 0    |                        | 0   | 0          |
| Slightly Decentred IOL                                     | 1      | 2.22 | No intervention        | 0   | 0          |
| Total no. of Complications                                 | 1      | 2.22 |                        | 0   | 0          |

|                       |    |    |
|-----------------------|----|----|
| Total No. of Patients | 45 | 52 |
|-----------------------|----|----|

| Table 5: Month Post-Operative Complications and Management |        |                        |          |   |                        |
|------------------------------------------------------------|--------|------------------------|----------|---|------------------------|
| MSICS GROuP                                                |        |                        |          |   |                        |
| 1 month                                                    | August |                        | December |   | Difference             |
| Post-operative %                                           | No.    | Secondary Intervention | No.      | % | Secondary Intervention |
| Complications                                              |        |                        |          |   |                        |
| TEMPORARY MORBIDITY CAUSING COMPLICATIONS                  |        |                        |          |   |                        |
| wound gape/ leakage                                        | 0      | 0                      | 0        | 0 | 0                      |
| Diffuse Hyphaema                                           | 0      | 0                      | 0        | 0 | 0                      |
| Total no. of Complications                                 | 0      | 0                      | 0        | 0 |                        |
| Total No. of Patients                                      | 45     |                        | 52       |   |                        |

| Table 6: 1 Month Post-Operative Complications and Management |          |                        |            |      |                        |
|--------------------------------------------------------------|----------|------------------------|------------|------|------------------------|
| MSICS GROuP                                                  |          |                        |            |      |                        |
| August                                                       | December |                        | Difference |      |                        |
| Post-operative %                                             | No.      | Secondary Intervention | No.        | %    | Secondary Intervention |
| Complications                                                |          |                        |            |      |                        |
| POTENTIALLY VISION THREATENING COMPLICATIONS                 |          |                        |            |      |                        |
| Uveitis                                                      | 0        | 0                      | 0          | 0    | 0                      |
| Vitreous in AC                                               | 0        | 0                      | 0          | 0    | 0                      |
| Corneal decompensation/ bullous keratopathy                  | 0        | 0                      | 0          | 0    | 0                      |
| IOL drop                                                     | 0        | 0                      | 0          | 0    | 0                      |
| RD/CME/Vh                                                    | 0        | 0                      | 0          | 0    | 0                      |
| Late –onset Endophthalmitis                                  | 0        | 0                      | 1          | 1.92 | IV antibiotics         |
| Any other (DM Loss With CO)                                  | 0        | 0                      | 1          | 1.92 | Conservative           |
| Total no. of Complications                                   | 0        | 0                      | 2          | 3.84 |                        |

|                                   |        |        |
|-----------------------------------|--------|--------|
| Total patients                    | 45     | 52     |
| Total Patients with Complications | 1 2.22 | 2 3.84 |

## DISCUSSION

The present study showed total complications at 1 month post-operative period met were 2.22% (1/45) and 3.84% (2/52) in the low and high volume month respectively.

Parikshit Gogate *et. al.* compared, in 200 patients, complications by 4 surgeons equally proficient in both **Manual Small Incision Cataract Surgery** and Phacoemulsification. The table below compares their various findings with that of our study:

Schein *et. al.* and other studies too mentioned little effect of surgical technique and volume of cases.(21-24)

Ruit *et. al.* reported 2.9% surgical complications at 2 months. Also Chaim M. Bell *et. al.* and Jacobs PM mentioned lesser complications with larger number of surgeries in a day while Ninn-Pedersen K *et. al.* mentioned otherwise (*i.e.*, a 2.9-fold greater risk in low-volume surgeons).

In our study in the high volume settings, we had a solitary case of late onset post-operative endophthalmitis.(25-28)

The present study shows a higher percentage of endophthalmitis in our high volume setting as compared to other similar settings in India also.

This may be due to the reason that in the present study the sample size is small compared to other studies which were basically designed to study endophthalmitis incidence.

Also there may be an attrition bias as the records of our hospital show a 0.3%- 0.5% of endophthalmitis rate.

Also this study was done as an 'intention to treat' analysis and therefore the incidence of endophthalmitis cannot be represented by this study which is just comparison of high volume and low volume month complications.

In the present study, the complication rates are either comparable or lower(with the exception of the sole endophthalmitis case in the **manual Small Incision Cataract Surgery** group), than other studies- in both the surgical groups.

Also different studies showed that the various complications did not

have a specific pattern. They also showed that individual complications were independent of the surgical volume difference and seemed to be more dependent on each surgeon's skill and technique. On further analyzing the present study it was seen that outcomes of complications did not have a statistical difference (both Phaco group and Manual Small Incision Cataract Surgery ) by change in volume of surgeries performed as some complications occurred more in low volume setting while others in high volume settings.

## CONCLUSION

As gauged in terms of intra-operative, post-operative complications on 1st day and at one month follow up, High Volume Cataract Surgery (greater than 40 Manual Small Incision Cataract surgeries) does not affect the quality when compared with Low Volume Cataract Surgery over a 30-days period in a tertiary institute in Central India.

## Disclaimer regarding Consent and Ethical Approval:

As per university standard guideline, participant consent and ethical approval have been collected and preserved by the authors

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