“A Comparative Study to Evaluate Visual Outcome in Post-Operative Patients of Manual Small Incision Cataract Surgery and Phacoemulsification”

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Abstract

Aim: A comparative study to evaluate visual outcome in post-operative patients of Manual Small Incision Cataract Surgery and Phacoemulsification. Design: A prospective, comparative hospital based interventional study was conducted on 246 eyes having visually significant senile cataract undergoing cataract extraction surgery by either of two methods viz Manual Small Incision Cataract Surgery or Phacoemulsification at Regional Institute of Ophthalmology, Pt.B.D.Sharma PGIMS, Rohtak. A detailed post-operative examination was carried out on first post-operative day, then follow-up of patients of both the study groups regarding BCVA was carried out in Eye O.P.D. on 7th, 1 month. Results: Although the initial visual recovery on the 1st postoperative day was better in the patients who underwent phacoemulsification, with the uncorrected visual acuity better than or equal to 6/18 in 74% of the patients, whereas the percentage was 58.5 % in the SICS group. Similarly BCVA 6/18 or better on 7th post-operative was 100 % in the Phacoemulsification study group as compared to 87% SICS (p=0.010) group. Initial difference in visual outcome was nearly equalized within 1 month in both the study groups. There was no significant difference between the M-SICS & Phacoemulsification in terms of BCVA at Post-Operative 1 month, Post-Operative Spherical Refraction at 1 Week (p = 0.693) and 1 month (p = 0.640). But there was significant difference between two groups in terms of Cylindrical Refraction at Post-Operative 1 Week) (p<0.001) and at 1 Month (p = <0.001) with the median Post-Operative Cylindrical Refraction higher in M-SICS group at 1 week & 1 Month. The median Post-Operative Cylindrical Refraction difference is all due to the fact that M-SICS had larger surgical incision causing higher surgically induced astigmatism. Conclusions: Phacoemulsification gives better uncorrected visual acuity (UCVA) at post-operative day 1 and better BCVA at 1 week and Post-Operative Cylindrical Refraction at 1 Week and at 1 month. Whereas, BCVA at 1 month is similar in both the study groups MSICS and Phacoemulsification.

Keywords: Manual Small Incision Cataract Surgery, Phacoemulsification, Hydrophobic PCIOL Lenses, Visual outcome, surgical induced astigmatism.

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INTRODUCTION

The word Cataract has been derived from the Greek word ‘katarrakatas’ which means ‘Waterfall’. Cataract can occur due to either formation of opaque lens fibres (Congenital or Developmental Cataract) or due to degenerative process causing opacification of the transparent lens fibres (Acquired Cataract or Secondary Cataract)[1]. Senile cataract is an age related, vision impairing disease characterized by gradual, progressive thickening of the lens. It is one of the world’s leading causes of avoidable blindness [2]. All techniques of cataract extraction are being modified to achieve best uncorrected visual acuity and early rehabilitation [3].

Phacoemulsification and manual small-incision cataract surgery (MSICS) are the most commonly done procedures [4]. In our country, there is a large volume of cataract backlog, mainly among the rural and suburban population. Phacoemulsification is considered the gold-standard procedure for cataract. However, MSICS has emerged as a popular procedure of choice in the surgical treatment of cataracts as it is less expensive and is as effective as phacoemulsification [5]. It may be considered a better procedure for doing mass surgeries [6]. However, MSICS comes with its own set of limitations. Surgically induced astigmatism (SIA) remains a common cause of poor postoperative visual recovery [7]. Site and size of scleral incision are the factors...
which influence the SIA [8]. Larger the incision size more is the astigmatism. However, when the size is kept constant, the main determinant for the amount of SIA is the site of the scleral incision. The purpose of this comparative hospital based study was to assess the visual outcome in the post-operative M-SICS and Phacoemulsification.

**MATERIAL & METHODS**

In our prospective, comparative, hospital based study conducted on patients undergoing cataract extraction surgery by M-SICS & Phacoemulsification method at Regional Institute of Ophthalmology, Pt.B.D.Sharma Post Graduate Institute of Medical Sciences, Rohtak. In this study 246 consecutive patients scheduled for intraocular cataract surgery were randomly divided into two groups of 123 patients each in M-SICS group and Phacoemulsification group. All the patients in both the groups were above the age of 40 years with visually significant age related uncomplicated cataract without any systemic and other ocular comorbidity problems. Both the procedures were carried out by same surgeon and only hydrophobic type of posterior chamber intraocular lenses was implanted in each patient. All patients were given peribulbar regional anesthesia of 6ml of injection 2% lignocaine & 4ml of injection 0.05% bupivacaine mixed with 1500 IU hyluronidase. The patients were examined in detailed especially in terms of visual outcome on day 1, 7th, and 1month post operatively in two different groups of patient.

**RESULTS**

In this study, mean age in phacoemulsification group was 63.01 in comparison to 62.52 in M-SICS group and there was no significant statistical difference was found between two groups in terms of age (p=0.654). With respect to gender distribution, phacoemulsification group had 64 (52.0%) males, and 59 (48.0%) females as compared to M-SICS group, where there were 60 (48.8%) males, and 63 (51.2%) females with (p=0.610) suggesting no significant statistical difference.

There was a significant statically difference between two groups with regards to Nuclear Sclerosis Grade (X^2 = 43.552, p < 0.001). Phacoemulsification had the larger proportion of Nuclear Sclerosis Grade NS4 as in comparison to SICS group which had the larger proportion of mature nuclei.

Significant difference was noticed between two groups when distribution of Vision Category at Post-Operative Day-1 was compared, (X^2 = 6.564, p = 0.010), participants in the group Phacoemulsification (74%) had larger proportion of Vision Category of 6/18 or Better (Due to surgical incision size, surgical induced astigmatism, corneal edema due to more manipulation during surgery).

At Post-Operative Day-7, best corrected visual acuity (BCVA) was measured and compared, wherein, statistical significant difference was found between two groups in terms of distribution of Vision Category, Phacoemulsification group had 100% patients with Vision Category of 6/18 or Better while SICS had 87.0% patients with p value <0.001.

**Table-4: Association between Group and Vision Category (Post-Operative Day-1) (n = 246)**

| Vision Category (Post-Operative Day-1) | Group        | Total | Chi-Squared Test |
|---------------------------------------|--------------|-------|-----------------|
|                                      | Phacoemulsification | M-SICS | Total           | X^2 | PValue |
| 6/18 or Better                        | 91 (74.0%)    | 72 (58.5%) | 163 (66.3%)   | 6.564 | 0.010  |
| Worse than 6/18                       | 32 (26.0%)    | 51 (41.5%) | 83 (33.7%)    |       |        |
| Total                                 | 123 (100.0%)  | 123 (100.0%) | 246 (100.0%) |       |        |

**Table-5: Association between Group and Vision Category (Post-Operative Day-7) (n = 246)**

| Vision Category (Post-Operative Day 7) | Group       | Total     | Fisher’s Exact Test |
|---------------------------------------|-------------|-----------|---------------------|
|                                      | Phacoemulsification | M-SICS | Total     | N^2 | PValue |
| 6/18 or Better                        | 123 (100.0%) | 107 (87.0%) | 230 (93.5%) | 17.113 | <0.001 |
| Worse than 6/18                       | 0 (0.0%)    | 16 (13.0%) | 16 (6.5%)    |       |        |
| Total                                 | 123 (100.0%) | 123 (100.0%) | 246 (100.0%) |       |        |
However, the initial difference between the two groups equalized after 1 month as no significant difference was noticed between these groups when BCVA was compared ($X^2 = -, p = -$). Almost all the participants in both the groups had visual outcome of 6/18 or Better after one month time.

Table-6: Association between Group and Vision Category (1 Month Post-Operative) (n = 246)

| Vision Category (1 Month Post-Operative) | Group       | Chi-Squared Test |
|----------------------------------------|-------------|-----------------|
|                                        | Phacoemulsification | M-SICS | Total   | X^2 | P Value |
| 6/18 or Better                         | 123 (100.0%)   | 123 (100.0%)   | 246 (100.0%) | -- | --      |
| Total                                  | 123 (100.0%)   | 123 (100.0%)   | 246 (100.0%) | -- | --      |

Post-Operative Refraction in terms of Spherical Correction at 7 days and 1 month was not normally distributed in the 2 subgroups. Thus, non-parametric tests (Wilcoxon Test) were used to make group comparisons. No significant difference between the groups was there at 7 days and 1 month with $p = 0.693$ and $p=0.640$ respectively. As spherical correction is dependent on pre operative Biometry and IOL power calculation.

Table-7: Comparison of the 2 Subgroups of the Variable Group in Terms of Post-Operative Refraction (Spherical) (1 Week) (n = 246)

| Post-Operative Refraction (Spherical) (1 Week) | Group       | Wilcoxon Test |
|-----------------------------------------------|-------------|---------------|
| Mean (SD)                                     | Phacoemulsification | M-SICS | $W$ | p value |
| -0.64 (0.63)                                 | -0.71 (0.64) | 7782.000 | 0.693 |
| Median (IQR)                                  | -0.75 (0.5)  | -0.75 (0.5)   | 7782.000 | 0.693 |
| Range                                         | -1.75 - 2.5  | -2.5 - 2.5    |

Table-8: Comparison of the 2 Subgroups of the Variable Group in Terms of Post-Operative Refraction (Spherical) (1 Month) (n = 246)

| Post-Operative Refraction (Spherical) (1 Month) | Group       | Wilcoxon Test |
|-----------------------------------------------|-------------|---------------|
| Mean (SD)                                     | Phacoemulsification | M-SICS | $W$ | p value |
| -0.62 (0.63)                                 | -0.70 (0.63) | 7621.000 | 0.640 |
| Median (IQR)                                  | -0.5 (0.5)   | -0.75 (0.5)   | 7621.000 | 0.640 |
| Range                                         | -1.75 - 2.5  | -2.5 - 2.5    |

The variable Post-Operative Refraction in terms of Cylindrical correction was compared at 7 days and a significant difference between 2 groups with $p <0.001$, with the mean Post-Operative Refraction (Cylindrical) at 1 Week being highest in the Group M-SICS group (-0.80D) as compared to Phacoemulsification (-0.41D) due to surgically induced astigmatism in M-SICS.
Table-9: Comparison of the 2 Subgroups of the Variable Group in Terms of Post-Operative Refraction (Cylindrical) (1 Week) (n = 246)

| Post-Operative Refraction (Cylindrical) (1 Week) | Group     | Wilcoxon Test |
|-------------------------------------------------|-----------|---------------|
|                                                 | Phacoemulsification | M-SICS | W | p value |
| Mean (SD)                                        | -0.41 (0.27)       | -0.80 (0.46) |               |
| Median (IQR)                                     | -0.5 (0.25)        | -0.75 (0.5)  | 11514.000     | <0.001 |
| Range                                           | -1 - 0             | -2.5 - 0     |               |

Significant difference persisted between 2 groups in terms of Post-Operative cylindrical correction at 1 month with p <0.001 and median Post-Operative Cylindrical correction was still higher in M-SICS group but there was a decrease in mean cylindrical correction in individual group at 1 month as compared with that of 7 days.

Table-10: Comparison of the 2 Subgroups of the Variable Group in Terms of Post-Operative Refraction (Cylindrical) (1 Month) (n = 246)

| Post-Operative Refraction (Cylindrical) (1 Month) | Group     | Wilcoxon Test |
|--------------------------------------------------|-----------|---------------|
|                                                 | Phacoemulsification | M-SICS | W | p value |
| Mean (SD)                                        | -0.42 (0.27)       | -0.79 (0.44) |               |
| Median (IQR)                                     | -0.5 (0.25)        | -0.75 (0.5)  | 11415.000     | <0.001 |
| Range                                           | -1 - 0             | -2 - 0       |               |

**DISCUSSION**

This prospective study was conducted to evaluate the impact of cataract surgery on the visual outcome of individuals who underwent two different M-SICS and Phacoemulsification techniques. There was no significant difference between the groups in terms of Age (Years) Mean age was 63 in the two study groups[9-11], which is consistent with reports of other studies like that of Sharma D et.al and Kanski JJ et al. where the mean age of patients was slightly higher than 60 years.[12],[13] In this study there was not much significant difference between the various groups in terms of distribution of gender (mean women (n= 61) and men (n=62) in both groups) which is constant with the results observed in the previous studies like Javed U et al. [11] There was a significant difference between the various groups in terms of distribution of Nuclear Sclerosis Grade (X^2 = 43.552, p = <0.001). Phacoemulsification group had the larger proportion of participants participants had Nuclear Sclerosis Grade: NS4 in comparison to SICS group where larger proportion of participants (35 patients i.e. 28.5%) had mature nuclei. The SICS group had higher proportion of patients with mature nuclei grade as illustrated by Hesham A et al. [14].

Gogate et al. [15] published a meta-analysis in 2015 where phacoemulsification and SICS were compared in terms of safety, efficacy, and expenses. This review analysed, 11 comparative studies documenting 76,838 eyes that had undergone cataract surgery. UCVA of 6/18 and 6/18 BCVA were comparable between techniques (P = 0.373 and P = 0.567, respectively). BCVA of 6/9 was comparable between techniques (P = 0.685). UCVA of 6/60 and 6/60 BCVA aided and unaided vision were comparable (P = 0.126 and P = 0.317, respectively). There was no statistical difference in: Endothelial cell loss during surgery (P = 0.298), intraoperative (P = 0.964) complications and postoperative complications (P = 0.362). The phacoemulsification group had statistically significantly less astigmatism (P = 0.005) and more eyes with UCVA of 6/9 (P = 0.040). The average time for SICS was lower than phacoemulsification and cost <½ of phacoemulsification.

Gamal Mostafa Abo El Maaty et al. [16] in 2014, & Ruit S et al. [17] compared the surgically induced astigmatism, financial cost, intraoperative difficulties and complications and postoperative complications and visual outcome of manual sutureless small incision cataract surgery (SICS), planned extracapsular cataract extraction and phacoemulsification. These studies were in consistence with our study wherein there was a significant difference between various 2 groups in terms of distribution of Vision Category (Post-Operative 1 and 7 Days (p = 0.010 & p less than 0.001 respectively). Participants in the Group: Phacoemulsification had the better proportion of Vision Category (Post-Operative Day-7) 6/18 or better on 7th post-operative day as...
compared to SICS group due the difference in the size of the incision and induced astigmatism.

Indra T. Mahayana et al. [18] also suggested in their study independently that there was no statistical difference in visual outcome between both groups (p=0.10) after 1 month and 6 months respectively. V Ramalakshmi et al. [19] in their study showed that visual outcome was comparable in phacoemulsification and MSICS groups. Both are equally safe and effective in skilled hands to acquire better visual outcome. As per our study there was no significant difference between both the groups in terms of distribution of Vision Category at Post-Operative 1 month with p = 0.000, Post-Operative Spherical correction at 1 Week with p=0.693 and 1 month with p = 0.640. Almost all the participants in both the groups had visual outcome of 6/18 or Better after one month time. However, there was a significant difference between the 2 groups in terms of Post-Operative Cylindrical correction at 1 Week (p =0.001) & 1 Month (p<0.001) with the median Post-Operative Cylindrical correction at 1 Week being highest in the M-SICS Group because of the larger size of the surgical incision and thereafter surgically induced astigmatism esp. more after 7 day than 1 month.

CONCLUSION

Participants in the Phacoemulsification group had the better proportion of Vision Category at 1st and 7th Post-Operative Day with 6/18 or better as compared to SICS group which is justified by the difference in the size of incision, surgically induced astigmatism as well as more manipulation of anterior chamber during surgery causing corneal edema following surgery.

There was no significant difference between the M-SICS & Phaco in terms of BCVA at Post-Operative 1 month, Post-Operative Spherical correction at 1 Week (p = 0.693) & 1 month (p = 0.640).

Due to the fact that M-SICS had larger surgical incision which resulted in higher surgically induced astigmatism at post-operative 7th Day and 1month, there was significant difference between the M-SICS & Phaco in terms of Post-Operative Cylindrical Refraction at 1 Week (p = <0.001) & 1 Month (p = <0.001) with the median Post-Operative Cylindrical Refraction higher in M-SICS group at 1 week & 1 Month.

Hence, Phacoemulsification gives better uncorrected visual acuity (UCVA) at post-operative day 1 and better BCVA at 1week and Post-Operative Cylindrical Refraction at 1 Week and at 1 month. Whereas, BCVA at 1 month is similar in both the study groups MSICS and Phacoemulsification.

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