Visual Outcome And Complications of Manual Sutureless Small Incision Cataract Surgery-A Rural Hospital Based Study

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Abstract:

Introduction: According to World Health Organization, an estimated 20 million people are blind from bilateral cataracts and this growing backlog poses one of the greatest public health challenges for 21st century.

Materials And Method: it was a randomized prospective study with a sample size of 200 eyes of 200 patients. It was conducted for 1 year. Patients were explained about the study and those willing to participate in the study were included in the study. After taking the consent of patient all patients were examined.

RESULTS-58.5% cases were male and 41.5% were females. Mean age was 66 years. Mean axial length was 22.64 ± 0.86. Post-operative under corrected visual acuity was 6/18 or better in 81% eyes at 1 week and 92.5% eyes at 4 week respectively and 6/12 or better in 68% of eyes at 12 weeks. Post –operative VA with pin hole was 6/12 or better in 87% eyes at 1 week and 191(95.5%) eyes at 4 week and 97% of eyes at 12-weeks respectively. 92. 46% patients having against the rule astigmatism with mean value of 88.24±7.37. 54% patients achieved BSCVA of 6/6 and 30.5% patients having BSCVA of 6/9.

Summary And Conclusion: Cataract is still the leading cause of avoidable blindness in the developing world. Unless cataract surgery rates were increased, the magnitude of cataract blindness will continue to increase. Early rehabilitation of the patients and no suture-related problems are main advantages of this technique. Manual sutureless small incision cataract surgery(MSICS) is a safe and effective technique for cataract surgery, especially in developing world.

I. Introduction

Cataract is the leading cause of avoidable blindness worldwide, accounting for nearly half (47.8%) of all cases of blindness. According to World Health Organization, an estimated 20 million people are blind from bilateral cataracts and this growing backlog poses one of the greatest public health challenges for 21st century. The cataract surgical rate (CSR) is an important public health metric, which represents the number of cataract operations annually performed per 1 million of population. There was significant variations in the CSR among different countries.

There is clearly a pressing need in the developing world to reduce the backlog of cataract blindness by increasing the CSR over current low rates. Finally, the advanced mature cataracts and brunescent hard cataracts that are so prevalent among poor populations are more challenging to extract with phaco, and the complication rate is higher in most hands except in most skilled and experienced phaco surgeons. Because of these problems associated with phaco in developing world, alternative techniques such as sutureless manual small incision cataract surgery (MSICS) are gaining popularity.

Manual sutureless small incision cataract surgery (SICS) has been proved to be an equally effective and a highly cost- effective alternative to instrumental phaco with a low complication rate. It is generally noticed that the incidence of postoperative astigmatism is more anterior the incision the greater the induced astigmatism. The overall safety profile of MSICS was found to be excellent with intra and postoperative complication rates comparable to phacoemulsification and ECCE. Multiple studies reported the safety and efficacy of MSICS for complicated cases, such as brunescent and white cataract and cataracts associated with phacolytic and phacomorphic glaucoma. Compared to phacoemulsification, MSICS was associated with lower and shorter operative times. Visual outcomes were excellent and comparable to phacoemulsification with upto 6 months follow up.

II. Aims And Objective

1. To determine the surgically induced astigmatism.
2. To determine complications of manual sutureless small incision cataract surgery.
3. To asses final best spectacle corrected visual acuity at 3 months.
III. Materials And Method

**Study Design:** Randomized prospective study conducted in dept. of ophthalmology, Acharya Bhave Rural Hospital (AVBRH), Sawangi, Meghe, Wardha, Maharashtra. Sample size of study was 200 eyes of 200 patients. It was conducted for 1 year.

**Inclusion Criteria:**
1. Immature Senile Cataract.

**Exclusion Criteria:**
1. Posterior segment pathologies
2. Glaucoma, uveitis, trauma, dry eye.
3. Corneal opacity significantly affecting vision.
4. Developmental cataract.
5. Nuclear sclerosis more than grade 4.
6. Primary PCO.
7. Patients with irregular follow-up.

**Pre-operative examination consisted of:**
1. Visual acuity
2. Detailed slit lamp examination to rule out any significant anterior segment pathologies.
3. Type of cataract on the basis of morphology on slit lamp.
4. Applanation tonometry
5. A scan was done by contact method
6. Keratometry was carried out with Topcon auto keratometer of all cases.
7. Fundus examination was done to rule out any posterior segment pathologies.

**At all follow-up visit i.e. at (1 week, 4 weeks & 12 weeks)**
1. Visual acuity
2. Detailed slit lamp examination for any post-op surgical complication.
3. Keratometer was done for type and amount of astigmatism
4. Auto refractometry was done.
5. Fundus examination was done.

At last follow up along with above all, refraction was given and axis of astigmatism along with best spectacle visual acuity was recorded. Any complications found during surgery or on follow up visits were also recorded. All reading were taken by single observer to obtain consistent results. Astigmatism was recorded in dioptres. Astigmatism was graded and classified according to Holmström’s Gradation As,

- No astigmatism, when it was < 0.25 D
- Non-significant, when it was >= 0.25D but <1.0D
- Significant, when it was >= 1.0D but <2.0D
- High, when it was >= 2.0D

**The axes of astigmatism were divided into three classes:**
- “With the rule “ (minus cylindrer at 180 degree ±15 degree)
- “Against the rule” (minus cylinder at 90 d ±15d) and
- “oblique” (minus cylinder at 16d – 74d & 106d – 164 d)

All the surgeries were performed in operation theatre of Acharya Vinoba Bhave Rural Hospital by Extracapsular cataract extraction with posterior chamber intraocular lens implantation by manual sutureless small incision cataract surgery.

**Preoperative**- consent taken.
- Xylocaine Sensitivity Testing was done.
- Inj. TT0.5 ml I.M. was given to every patient.
- Anaesthesia used (local anaesthesia)- Xylocaine 2% with adrenaline 1:100000 (peribulbar block)
Steps of surgery:
1. The eye and peri-ocular skin was properly disinfected by painting with povidone iodine solution. Draping was done. Universal speculum was applied.
2. After conjunctival section, gentle cautery was done to stop any bleed. Frown incision was given at a distance of 2 mm from limbus, with a 15 number blade.
3. The external width of the incision was made of 6-8mm according to the expected size of nucleus.
4. Sclero-corneal incision was made with a crescent knife and entry into the anterior chamber with a 3.2 mm keratome.
5. The internal opening of the incision was wider, so as to facilitate the nucleus delivery. Before entering into the AC, a side port was made at the limbus, at right angle to the plane of approach with the 1.2 mm lance tip.
6. Anterior chamber was filled with visco-elastic substance by injecting it through side port.
7. Anterior capsulotomy was done with help of a self – made cystitome and capsulorhexis forcep.
8. Hydrodissection and hydrodelination was performed in almost all cases and nucleus was delivered either by hydro-expression or by visco-expression.
9. Cortical matter was aspirated with Simcoe’s cannula and a rigid single-piece poly methyl methacrylate (PMMA) IOL was implanted within the bag or in the ciliary sulcus.
10. Visco – elastic material was removed.
11. Scleral wound was then checked for its self sealing character and conjunctiva approximated by closing with gentle cautery.
12. Subconjunctival Inj. Gentamycin and Dexamethasone was given.
13. Chlopamphenicol eyeointment was applied.
14. Pad & bandage was done.

IV. Observations And Results-
Out of 200 cases, 117(58.5%) cases were male and 83(41.5%) were females with mean age of 66 years. Age and gender wise distribution is

<table>
<thead>
<tr>
<th>Age groups (years)</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-59</td>
<td>11(5.5%)</td>
<td>9 (4.5%)</td>
<td>20 (10%)</td>
</tr>
<tr>
<td>60-69</td>
<td>56(28%)</td>
<td>55(27.5%)</td>
<td>111(55.5%)</td>
</tr>
<tr>
<td>70-79</td>
<td>41(20.5%)</td>
<td>18(9%)</td>
<td>59(29.5%)</td>
</tr>
<tr>
<td>80-89</td>
<td>9 (4.5%)</td>
<td>1(0.5%)</td>
<td>10(5%)</td>
</tr>
<tr>
<td>Total</td>
<td>117(58.5%)</td>
<td>89(41.5%)</td>
<td>200(100%)</td>
</tr>
</tbody>
</table>

Table 2 – 105 patients whose RE was operated and 95 patients LE was operated.

Mean axial length was 22.64 ±0.86

<table>
<thead>
<tr>
<th>Axial length</th>
<th>No. Of patients</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;=21.99 mm</td>
<td>35</td>
<td>17.5</td>
</tr>
<tr>
<td>22.24mm</td>
<td>154</td>
<td>77.0</td>
</tr>
<tr>
<td>&gt;=24.01 mm</td>
<td>11</td>
<td>5.5</td>
</tr>
<tr>
<td>Total</td>
<td>200</td>
<td>100</td>
</tr>
</tbody>
</table>

1\textsuperscript{st} follow-up 4 weeks post-op. 2\textsuperscript{nd} follow up 4 weeks post-op. Last follow-up 12 weeks post-op. Post-operative under corrected visual acuity was 6/18 or better in 162(81%) eyes at 1 week and 185(92.5%) eyes at 4 week respectively and 6/12 or better in 136(68%) of eyes at 12 weeks.

Graph1 : Distribution of patients according to unaided visual acuity.
1st follow up 4 weeks post op. 2nd follow up 4 weeks post op. Last follow up 12 weeks post op. Post-operative VA with pin hole was 6/12 or better in 174(87%) eyes at 1 week and 191(95.5%) eyes at 4 week and 194(97%) of eyes at 12-weeks respectively.

Table 5: Distribution of patients according to visual acuity with pin hole.

<table>
<thead>
<tr>
<th>No. Of eyes examined</th>
<th>&gt;6/9</th>
<th>6/12</th>
<th>6/18</th>
<th>6/24-6/60</th>
<th>&gt;6/60 &lt;HM</th>
<th>&gt;HM-PL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st follow up</td>
<td>200</td>
<td>81</td>
<td>93</td>
<td>26</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2nd follow up</td>
<td>200</td>
<td>116</td>
<td>75</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3rd follow up</td>
<td>200</td>
<td>161</td>
<td>33</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Graph 2: Distribution of patients according to visual acuity with pin hole.

1st follow up 4 weeks post op. 2nd follow up 4 weeks post op. Last follow up 12 weeks post op.
Table 6 shows descriptive statistics for k1 and k2.
Pre-op K1 was 45.31±1.69 and K2 was 44.64±1.63
On 1st follow up K1 was 45.54±1.82 and K2 was 44.73±1.77
On 2nd follow up K1 was 45.54±1.82 and K2 was 44.73±1.78
Last follow up K1 was 45.53±1.81 and K2 was 44.80±1.77

<table>
<thead>
<tr>
<th></th>
<th>K1</th>
<th>K2</th>
<th>Z-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>45.31±1.69</td>
<td>44.64±1.63</td>
<td>8.172</td>
<td>0.0005</td>
</tr>
<tr>
<td>1st follow up</td>
<td>45.54±1.83</td>
<td>44.73±1.77</td>
<td>6.444</td>
<td>0.0005</td>
</tr>
<tr>
<td>2nd follow up</td>
<td>45.54±1.82</td>
<td>44.73±1.78</td>
<td>6.539</td>
<td>0.0005</td>
</tr>
<tr>
<td>Last follow up</td>
<td>45.53±1.81</td>
<td>44.80±1.77</td>
<td>6.279</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

Graph 3: Descriptive statistics for K1 (Horizontal corneal curvature) and K2 (Vertical corneal curvature)

In our study, the average astigmatic dioptric difference was 1.05 preoperatively, 1.67 on first follow up and 1.65 on second follow up which was reduced to 1.052 on last follow up suggesting that the difference was statistically significant (P<0.0001)

Table 7: Distribution of patients according to Astigmatism in Diopters

<table>
<thead>
<tr>
<th></th>
<th>Non significant (0.25D to &lt;1D)</th>
<th>Significant (1D to &lt;2D)</th>
<th>High (≥ 2 D)</th>
<th>Z-Value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>108 (54%)</td>
<td>64 (32%)</td>
<td>28 (14%)</td>
<td>1.73</td>
<td>P&lt;0.0001 Significant</td>
</tr>
<tr>
<td>1st follow up</td>
<td>40 (20%)</td>
<td>86 (43%)</td>
<td>74 (37%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd follow up</td>
<td>40 (20%)</td>
<td>89 (44.5%)</td>
<td>71 (35.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last follow up</td>
<td>50 (50%)</td>
<td>83 (41.5%)</td>
<td>67 (33.5%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Graph 4: Distribution of patients according to Astigmatism in Diopters

1st follow-up 4 weeks post op. 2nd follow up 4 weeks post op. Last follow up 12 weeks post op.
There were 92 (46%) patients having against the rule astigmatism with mean value of 88.24±7.37, 20(10%) patients having with the rule astigmatism with mean of 180±0.00 and 88 (44%) patients found to have oblique astigmatism.

**Graph 5: Astigmatism according to AXIS -**

Out of 200 patients, 108(54%) patients achieved BSCVA of 6/6 and 61 (30.5%) patients having BSCVA of 6/9 with no patients having BSCVA<6/18.

**Graph 6: Distribution of patients according to Best Spectacle Corrected Visual Acuity (BSCVA)**

In our study 23(11.5%) patients developed Striate Keratopathy, 20(10%) developed corneal oedema, 11(5.5%) patients had increased IOT, 4 (2%) with Desmet’s Stripping and 2 (1%) with wound leak. Also we found 6 (3%) patients with post op anterior segment inflammation and 3 (1.5%) patients with intra operative hyphema.
Graph 7: Distribution of patients according to complications-

<table>
<thead>
<tr>
<th>Complication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>SK</td>
<td>23</td>
</tr>
<tr>
<td>Corneal Edema</td>
<td>20</td>
</tr>
<tr>
<td>Increased IOT</td>
<td>11</td>
</tr>
<tr>
<td>ASI</td>
<td>6</td>
</tr>
<tr>
<td>DS</td>
<td>4</td>
</tr>
<tr>
<td>Hyphema</td>
<td>3</td>
</tr>
<tr>
<td>WL</td>
<td>2</td>
</tr>
</tbody>
</table>

V. Discussion

In this study, we tried to assess the safety, efficacy in terms of visual recovery and induced astigmatism in eyes undergoing cataract surgery by the technique of manual sutureless small incision cataract surgery. Phacoemulsification is the universally accepted and most widely practiced technique of cataract surgery in developed countries; however, it cannot be widely adopted in developing world because of the financial and technological constraints. In this regard, manual sutureless small incision cataract surgery technique turns out to be a safe, effective, and cost-effective alternative.

Post operative CVA with pin hole was 6/12 or better in 174(87%) eyes at 1 week and 191(95.5%) eyes at 4 week and 194(97%) of eyes at 12-weeks respectively which is higher than other studies. Out of 200 patients, 108(54%) patients achieved BSCVA of 6/6 and 61(30.5%) patients having BSCVA of 6/9 with no patients having BSCVA less than 6/18. The average astigmatic dioptic difference was 1.05 pre-operatively, 1.67 on first follow up and 1.65 on second follow up which was reduced to 1.50 on last follow-up. This values greater than previous study conducted by Huang and Tsang (0.69D), Bartove et al (0.54D), Zvia, Burgansky et al (0.16 ±0.98D) and Muralikrishnan et al (1.33D- vector analysis method).

Therefore hyphema did not result insignificant adverse effect and was mostly spontaneously resolved in due course of time. Anterior segment inflammation was controlled by subconjunctival injection of Wymisolone + Mydricane+ Gentamycin for 2 days and then patients were discharged.

Summary And Conclusion-

Cataract is still the leading cause of avoidable blindness in the developing world. Unless cataract surgery rates were increased, the magnitude of cataract blindness will continue to increase. The current situation mandates high-volume, high-quality cataract surgery delivered at minimal costs to the underprivileged sections of the community.

Manual sutureless small incision cataract surgery retains most of the advantages offered by phaco at a minimum cost and hence leads itself to high-volume cataract surgery. Manual small incision cataract surgery is a safe and effective technique of ECCE that can be confidently adopted. Though, surgically induced astigmatism is the main complication of this technique but it is comparable with phaco and much lower than conventionally ECCE. Almost all grades of nuclear sclerosis and all sizes of cataractous lens can be dealt with this technique. Early rehabilitation of the patients and no suture-related problems are main advantages of this technique. We advocate more widespread adaptation of this technique to reduce the global backlog of cataract blindness and encourage randomized comparative trials with long term follow-up to firmly establish manual sutureless small incision cataract surgery as a safe and effective technique for cataract surgery, especially in developing world.
References