ORIGINAL ARTICLE

Comparison of The Pre & Post-Operative Corneal Endothelial Cell Count after Phacoemulsification Using Different Irrigating Solutions (Balanced Salt Solution Versus Ringer's Lactate)

MOHAMMAD HASAN BOKHARI[1], MUHAMMAD TAHIR GHAFFAR[2], FAISAL ANWAR[3], MUHAMMAD SHOAIB KHAN[4], SIBGHAT-UL-NOOR[5], NAYAB TARIQ[6]
[1-6]Department of Ophthalmology, Eye Unit 3 Mayo Hospital, Lahore
Correspondence to: Dr. Mohammad Hasan Bokhari, Email mh_bokhari @hotmail.com

ABSTRACT

Objective: The objective of the study was comparison of pre & post-operative corneal endothelial cell count after phacoemulsification using different irrigating solutions (balanced salt solution (BSS) versus ringer's lactate (RL))
Design: It was a quasi-experimental study.
Study Settings: The study was conducted at Department of Ophthalmology Unit III, Institute of Ophthalmology Mayo Hospital/KEMU Lahore from 18/09/2018 to 17/03/2019.
Hypothesis: Ringer's lactate solution causes more corneal endothelial cell damage as compared to the balanced salt solution when used as irrigating solution in patients being treated with phacoemulsification for senile cataract.
Material and Methods: This study involved 270 patients from both the genders divided into two treatment groups, having age between 45-60 years undergoing phacoemulsification. Male to female ratio was 1.08:1. Patients in Group I (n=135) were irrigated with Balanced Salt Solution while group II (n=135) were irrigated with Ringer's Lactate. Outcome variable was pre & post-operative corneal endothelial cell count. Informed written consent was taken from all the patients.
Results: The mean age of the patients was 53.14±4.86 with male and female mean age was 53.45±4.79 and 52.80±4.92 respectively. There was no significant difference in endothelial cell count in both irrigation solution groups after 1st follow up (2574.93±240.84 vs. 2568.13±223.59, P-value=0.810) and after 2nd follow up (2502.70±237.71 vs. 2532.92±221.82, P-value= 0.281).
Conclusion: The results of this prospective study demonstrated that there was no significant difference in endothelial cell count in both the groups at one week and three months postoperatively.
Keywords: Corneal Endothelial Cells, Corneal Edema, Balanced Salt Solution (BSS), Ringer's lactate (RL).

INTRODUCTION

The major cause of blindness worldwide is cataract that is about 33%.[1] Adults of age group 50 and above have a prevalence of cataract of about 47.8%.[2] A survey conducted in Italy showed 18.5% nuclear, 12.9% cortical and 10.8% posterior subcapsular cataracts.[3] Senile or age related is the most common form of cataract. Aging brings changes in lens cortical layers which become cortical cataracts.[4] Women have greater incidence of cortical and nuclear cataracts than men of corresponding ages.[5]

Endothelium of the cornea comprises of a single layer of cells on the posterior (inner) surface of the cornea that has restricted capacity of regeneration after damage. Transparency and normal thickness of the cornea are marked as two most important factors of good visual acuity. They can be sustained by the active fluid pump mechanism and the barrier function of corneal endothelial cells.[6,7] The adult corneal endothelial cell count ranges between 1500-3500 cells/mm^2. The endothelial count can be measured using contact or non-contact specular microscope.[8] Corneal endothelial damage can lead to corneal edema, increase in corneal thickness, corneal striate, bullous keratopathy or corneal decompensation that can result into decreased visual acuity.

Endothelial cell damage can be caused by changed intraocular conditions, such as during phacoemulsification cataract surgery.[9] These conditions can be, power used for phacoemulsification, time for which phacoemulsification power is used and the vacuum power used. During surgery, if the aqueous fluid is replaced with an irrigating solution, it can alter the intraocular environment thus affecting the endurance and performance of endothelial cells. However, the composition of an irrigating solution significantly determines its safety for usage.[10] Primarily irrigation solutions were used for the cataract surgery include plasmalyte solutions, ringer's solution and salt solution. In 1960, enhanced physiological solutions having osmolarity, pH and ionic composition comparable to the aqueous fluid were prepared and named as "Balanced Salt Solution" (BSS).

The chemical composition of the "Balanced Salt Solution" (BSS) is superior to the Ringer's Lactate (RL). As compared to the aqueous fluid, the Balanced Salt Solution is only slightly hypotonic holding an alkaline pH. Besides, calcium, lactate and potassium it contains[11]:

- Acetate buffer system
- Magnesium (an essential component for Mg-ATPase endothelial pump)

In a couple of prospective randomized studies on a small sample population it was concluded that a more physiological solution might attest to be a better irrigating solution for intraocular surgeries than the one currently being used, such as Ringer's Lactate.[9,10] These studies have also concluded that corneas having being perfused with less physiological solution show swelling at a more rapid rate and the degenerative changes come into view quicker than those being perfused with more solution.

The rationale of this study was to find the safest intraocular irrigating solution by comparing the difference in

corneal endothelial cell count after the phacoemulsification cataract surgery using BSS and ringer's lactate.

MATERIAL AND METHODS

It was a quasi-experimental study conducted at Department of Ophthalmology Unit III, Institute of Ophthalmology Mayo Hospital/KEMU Lahore from18/09/2018 to 17/03/2019. Sample size of 270 cases (135 in each group) was calculated with 80% power of test, 5% level of significance and by taking expected count of endothelial cell loss in balanced salt solution as 5.5% and in Ringer's Lactate group as 7.8% after phacoemulsification. Patients of both gender groups with ages in the range of 45-60 years suffering from age related senile cataract (Grade - NS +2) and pre-operative corneal endothelial cell count above 1500 cells/mm2, undergoing phacoemulsification were included from outpatient department. Patients who had congenital or secondary cataract (diagnosed on slit lamp examination), previous corneal disease, previous ocular surgery, anterior chamber cells or flare and nystagmus were excluded from the study. Preoperative clinical examination was made that included visual acuity, best corrected visual acuity, intra ocular pressure, indirect ophthalmoscopy, slit lamp examination and specular microscopy for corneal endothelial cell count (using Specular Microscope SP-01 CSO Sandicci Florence-Italy). Then, the patients were assigned to each group randomly. In Patients of group I, phacoemulsification was done by using balanced salt solution while in patients of group II, Ringer's Lactate was used. Pupil was dilated using tropicamide eye drops before surgery. All the surgeries were done under topical anesthesia. Proparacaine eye drops were instilled 5minutes, 3 minutes and 1 minute prior to the surgery. After taking all the aseptic measures patients underwent phacoemulsification with 3.2 mm incision with insertion of a poly methyl acrylate (PMMA) intraocular lens through a 5.5mm self-sealing incision. All the data was noted and recorded on same proforma along with demographic details of the patient. Post operatively, the corneal endothelial cell count will be measured using specular microscope (SP-01 CSO Sandicci Florence-Italy) on first follow up visit after one week and 2nd follow up visit three months after surgery. All surgeries were performed by the same surgical team and endothelial cell count was assessed on the same chart for eliminating biasness and exclusion criteria was used for confounding variables. Numerical variables; age and endothelial cell count have been presented by mean ±SD. For the comparison of endothelial cell count by using BSS and RL between the two groups independent sample t-test was used by taking p≤0.05 as significant. Categorical variable; gender has been presented as percentage and frequency. To address effect modifiers, data has been stratified for gender and age. Post-stratification independent sample t-test has been applied. A p-value of ≤0.05 has been marked as significant.

RESULTS

The age of the patients was 45-60 years having mean value 53.14±4.86 years. There were 140 (51.9%) male and 130 (48.1%) female patients with a male to female ratio of 1:1.08 as shown in Table 1. The mean age of male was 53.45±4.79 while mean age of female was 52.80±4.92. In Ringer's lactate group the mean age of the patients was 52.91±4.70 (Range 45-60), while in balanced salt solution it was 53.14±4.86 (Range 45-60). In terms of mean age and gender, both the groups had no significant difference (p=0.447, p=.534), respectively, as presented in Table number 2. There was statistically insignificant difference in endothelial cell count in both irrigation solution groups after 1st follow up (2574.93±240.84 vs. 2568.13±223.59, P-value=0.810) and after 2nd follow up (2502.70±237.71 vs. 2532.92±221.82, P-value= 0.281) as given in Table 3.

Table 1: Demographic characteristics

Characteristics	Participants
Age (years)	53.14±4.86
Gender	
• Male	140 (51.9%)
• Female	130 (48.1%)

Table 2: Baseline Characteristics of both the Groups.

Characteristics	Group-I n=135	Group-II N=135	P Value
Age (years)	52.91±4.70	53.36±5.01	0. 447
Gender			
• Male	73 (54.1%)	`67 (49.6%)	0.534
• Female	62 (45.9%)	68 (50.4%)	

Difference was observed statistically insignificant through independent sample t-test and chi-square test.

Table 3: Pre & Post-Operative Endothelial Cell Count between Study Groups.

Characteristics	Group-I n=135	Group-II N=135	P Value
• Pre-operative	2706.07±253.61	2668.55±229.46	0.203*
• 1st visit post-operative(1-Week)	2574.93±240.84	2568.13±223.59	0.810*
• 2nd visit post-operative (3-months)	2502.70±237.71	2532.92±221.82	0.281*

* The difference was observed statistically insignificant with independent sample t-test,

DISCUSSION

In corneal epithelium, endothelium and stroma, dystrophic age related changes occur. Most commonly observed ageing change in cornea is arcus senilis. Owing to non-regeneration of corneal endothelium, its density is reduced with increasing age. However, this loss of endothelial cells is covered to an extent by enlarging of remaining endothelial cells which results in pleomorphism. Corneal deturgecence is maintained by endothelial cells, so further decreased number of endothelial cells count either by progressive guttata or surgical damage, results into corneal thickening leading decreased vision quality and opacity. That is why it imperative to safe endothelial cell loss during phacoemulsification by using appropriate irrigating solution.

Many clinical studies have compared BSS versus BSS plus. This study was confined to compare Ringer's lactate with BSS because of cost effectiveness and widespread use of Ringer's lactate in contrast with BSS plus. Moreover, comparison between BSS and Ringer's lactate was clinically more relevant in the context of minimally traumatic cataract surgeries. Sufficient evidences have already supported BSS plus depicting its ability to cause less corneal alteration, both in experiments [12,15,16] and in clinical trials.[13,17] That is why, BSS plus was not included for comparison in this study, and also because it owes a high cost.

Three months post-operative values exhibited no change in density of endothelial cell between the both groups. The changes in the morphology of the endothelial cells are very sensitive indicators of the endothelial function loss.[15] This is one of the few studies that has evaluated the impact and outcome of irrigating fluids over a span of 3 months postoperatively.[14] Results of this study were matching with results of Lucena et al. (2010) [18] where endothelial cell loss was not significant (BSSL 13.1±2.0% vs. RL 9.2±1.9%, $p<0.05$) and Nayak et al. (2012) [19] 1st week (P=0.582) and at 1 month (P=0.668).

This study has shown the clinical advantages of BSS in early post-operative period and hence the use of BSS seems justified in cataract surgeries. Using appropriate technique and technology, BSS has offered clinical benefits on first post-operative day providing immediate visual rehabilitation. It is believed that the impact of using Ringer's lactate in eyes having low endothelial cell reserve can be significant, therefore, in selective eyes, having lower endothelial cell count, anticipated prolonged duration of surgery and this requiring excessive surgical manipulation should be considered for use of BSS instead of Ringer's lactate during surgery. There is a strong limitation to the present study and that it didn't compare the complications/ side effects of this combination therapy which is an important aspect of management and should be considered in future studies.

CONCLUSION

The results of this prospective study demonstrated that there was no significant difference in endothelial cell count in both the groups at one week and three months postoperatively.

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