Original Article

Ophthalmology

Comparison of the Effect of Ringer's Lactate and Balanced Salt Solution on Postoperative Endothelial Cell Count after Phacoemulcification?

1. Syed Ahmer Hussain 2. Muhammad Imran

1. Assoc. Prof. of Ophthalmology 2. MO & PG Trainee of Ophthalmology,
Nishtar Medical College / Hospital Multan

ABSTRACT

Objective: Objective of this study is to compare the effect of ringer lactate and balanced salt solution on endothelial cell count after Phacoemulcification on larger sample size.

Study Design: Randomized Control Trial Study

Place and Duration of Study: This study was conducted at the Department of Ophthalmology, Nishtar Medical College & Hospital Multan from December 2009 to May 2011.

Materials and Methods: In this study, total 2902 eyes were included. 1453 were included in group A (where RL was used as irrigating fluid) and 1449 were included in group B (where BSS was used as irrigating fluid). The patients were examined on Day 1, and at one and three months. At each follow-up visit, corneal clarity was noted as the presence or absence of Descement's folds and intra-stromal or epithelial edema. Anterior chamber was examined for the signs of inflammation as flare and cells. At three months follow-up, specular microscopy was performed. These examinations were done by the same observer who performs the tests preoperatively.

Results: It was found that mean endothelial loss in total population was 310.471±163.055 with SE 3.036 while in group A it was 321.592±171.620 with SE 4.523. Endothelial cell loss in group B was found to be 299.380±153.292 with standard error 4.034. Percentage decrease in endothelial cell count in group A was 13.40% while in group B it was 12.54%. Difference in percentage loss of endothelial cell count between two groups was 0.86%.

Conclusion: It is found that BSS is better solution for irrigation during intra-operative use during phacoemulsification than ringer lactate.

Key Words:

INTRODUCTION

Cornea is the transparent, dome-shaped window covering the front of the eye. It is a powerful refracting surface, providing +43D of the eye's focusing power i.e. +54D.[1]Refractive ability of the cornea is due to its transparency which is maintained by lamellar arrangement of collagen fibers, relative detergence state of its stroma, avascularity of central cornea, decreased number of keratocytes in the stroma[1, 2].

Endothelium is the most important structure involved in the maintenance of relative detergence state and so clarity of the cornea. Endothelium performs this task by pumping water contents against the concentration gradient i.e. from stroma to anterior chamber. Different factors influence on endothelial cell count, including age, glaucoma, ocular hypertension, Diabetes Mellitus[3,4]. Lenticular opacity causing obstruction to visual pathway is said to be cataract. Cataract is the most common cause of preventable blindness in the world. Treatment of cataract is to remove opaque lens surgically and replace it with Intra-Ocular lens.

Phacoemulcification is the recently used technique for cataract extraction. Different factors influence outcome of Phacoemulcification, such as, cataract status, phaco power, and phaco-effective time, age of the patient at the time of surgery, incision site and viscoelastics used and irrigation fluid used[5]. Different congenital primary endothelial dystrophies also effect on surgical outcomes such as Fuch's dystrophies, congenital hereditary endothelial dystrophies, and posterior polymorphous dystrophy[1, 2].

During cataract surgery, replacing the aqueous with the irrigating solutions can affect the survival and functioning of the endothelial cells. The safety of an irrigating solution, especially when used for extended periods is critically dependent on is composition[6,7].

In the literature, one study states that ringer lactate is less safe than balanced salt solution for corneal endothelial cells but better than BSS for retinal vascular endothelial cells[8].

Similarly, in another study, it has been found that percentage loss of endothelial cell count after 3 months of surgery was 5.5% for balanced salt solution and 7.8% for ringer lactate[9]. In other studies it was found that BSS causes fewer changes in corneal thickness than ringer lactate[10].

One study also debates that reduction of endothelial cells was 13.1±2.7% with balanced salt solution and 9.2±1.9% with ringer lactate[11].

MATERIALS AND METHODS

This study was carried out at the department of Ophthalmology, Nishtar Medical College & Hospital Multan from December 2009 and was completed in May 2011 in a period of one and half year. In this study, total 2902 eyes were included. 1453 were included in group A (where RL was used as irrigating fluid) and 1449 were included in group B (where BSS was used as irrigating fluid).

Sampling technique was non probability, purposive sampling. It was Intervenentional, randomized control trial study**.** Careful sample selection was done, patient were selected between the ages of 40-60 years as nuclear sclerosis is common in this age group. Both male and female were included and nuclear sclerosis scale +2 as per LOCS II(lens opacity classification system II) were included in the study.

Exclusion criteria for this study was; Previous corneal pathology (dystrophic or degenerative such as Fuchs' endothelial dystrophy or advanced trachoma)**,**history of intra ocular surgery**,** history of ocular trauma **,**corneal opacities**,** history of corneal ulcers**,** glaucoma or ocular hypertension**,** pseudo exfoliation syndrome (PEX)**,** pigment dispersion syndrome**,** eyes with a history of anterior Uveitis**,** diabetes mellitus**,** anterior chamber depth (ACD) less than 2.5 mm**,** density of endothelial cells less than 1500 cells per mm^2**,** history of contact lens usage**,** Intra-operative complications (posterior capsule rupture with or without vitreous loss)**,** postoperative Uveitis**,** postoperative surgical wound leakage**,** Intra operative endothelial touch**,** Intra-operative iris incarceration**,** post operative glaucoma**,** per operative corneal burns.

Operational Definitions:

- **Endothelial cell count**; number of cells present in central one millimeter of cornea.
- **Specular microscope**; Instrument used to calculate corneal endothelial cells/mm^2.
- **Relative Detergence Sate**; The state of relative dehydration.
- **Endothelial Decompensation**; Loss of endothelium that is not repairable.

Data Collection:

Informed consent was obtained from all selected patients before they were enrolled in the study from OPD. All study issues were addressed before local ethical society and study proceeded after recommendation. All cases were diagnosed after proper slit-lamp examination to evaluate nuclear sclerosis and fundus evaluation (if possible) was done to rule out retinal pathology to assure patient's visual prognosis. All cases were divided into two groups i.e. Group A (for Ringer Lactate) and Group B (for BSS) by draw method. One patient selected a group and his correspondent fulfilling same criteria was included in other group. This was done to minimize confounder effect.

Preoperative Specular microscopy was performed with a non-contact specular microscope (Topcon, Japan) to analyze the central corneal endothelium. The endothelial cell density (ECD) was measured in the central $1mm^2$ cornea. Prior to surgery, the patients were randomized into two groups using simple draws system. Group A received BSS and Group B received RL as an irrigating solution during surgery. The fluids were stored in a cold room at $25C^o$ and were brought inside the operation theater immediately prior to the surgery after covering in a sterilized wrap to minimize effect of heat on cornea and making the study double blind.

A single experienced surgeon performed all surgeries under local anesthesia using a standardized surgical technique that was 'divide and conquer'' technique. In all cases two incisions one of 2.75mm(main) and second of 1.5mm(side port) were made in the clear cornea 90 degrees apart, using dual beveled knives (Alcon Laboratories). Methylcellulose was injected in the anterior chamber to maintain its depth. A 26G cystotome was used for capsularrhexis. The parameters used during different stages of surgery were; a power of 30-50%, microburst with burst width of 5-30milliseconds, a vacuum of 150-300mmHg, and an aspiration flow rate of 25-30cc/min.

Constant anterior chamber depth was maintained by injecting methylcellulose. The bottle height was raised to a maximum of 100cm to maintain constant flow rate. Bimanual irrigation/aspiration was performed to remove cortex and to remove residual Methylcellulose at the end of surgery. Intraocular lens were implanted in the capsular bag.

The following intra-operative observations were made to standardize all surgeries to overcome any BIAS of surgical technique: amount of fluid used from commencement of surgery to the end of residual Methylcellulose removal after IOL implantation was mean 60ml, surgical clock time from commencement of surgery to the end of nucleus removal was mean 4.23min, effective Phaco-time (average ultrasound (u/s) power x average u/s time/100) was mean 21 sec, occurrence of excessive iris manipulation was avoided, descemet's detachment, incision burns, and posterior capsule rupture did not occur.

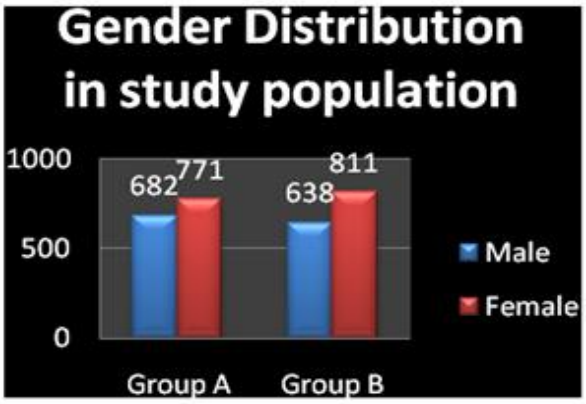
Postoperatively, the patients were examined on Day 1, and at one and three months. At each follow-up visit, corneal clarity was noted as the presence or absence of Descement's folds and intra-stromal or epithelial edema. Anterior chamber was examined for the signs of inflammation as flare and cells. At three months follow-up, specular microscopy was performed. These examinations were done by the same observer who performed the tests preoperatively.

RESULTS

The study population was selected from department of Ophthalmology, Nishtar Medical College & Hospital Multan. A total number of 2902 eyes were included in the study. These were divided into two groups i.e. group A and group B. 1453 were included in group A in which Ringer lactate was used as irrigating fluid and 1449 eyes were included in Group B in which BSS was used as irrigating fluid during surgery

Table No.1: Distribution of patients (N=2902)

Group	Number of eyes included
A(n_1)	1453
B(n_2)	1449
Total (N) = $n_1 + n_2$	2902



Group A = 1453 Group B = 1449

Figure No.1: Gender distribution in study population

Table 2: Pre-Operative Mean Endothelial Cell Count (Cells/Mm^2)

	Group A	Group B
Male (n=1320)	2396.38±380.419	2385.77±389.860
Female (n=1582)	2402.80±397.932	2388.37±386.256
Total (n=2902)	2399.79±389.690	2387.22±387.715

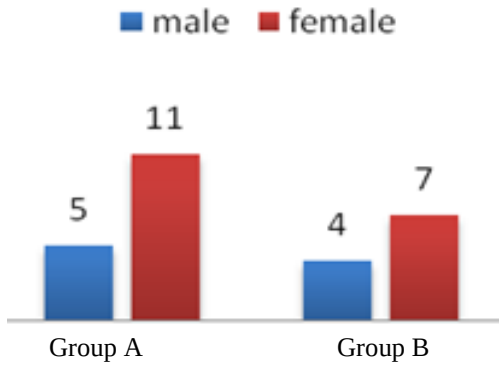


Figure No.2: Number of patients lost

Table No.3: Post- Operative Endothelial Cell Count (cells/mm^2)

	Group A (N=1437)	**Group B** (N=1438)
Male	2078.28±371.910	2083.33±372.006
Female	2074.33±390.695	2093.07±368.751
Total	**2076.19±381.833**	**2088.77±372.006**

It was found that mean endothelial loss in total population was 310.471±163.055 with standard error 3.036 while in group A it was 321.592±171.620 with standard error 4.523. Endothelial cell loss in group B was found to be 299.380±153.292 with standard error 4.034.Percentage decrease in endothelial cell count in group A was 13.40% while in group B it was 12.54%. Difference in percentage loss of endothelial cell count between two groups was 0.86%.

DISCUSSION

These days' ringer lactate and balanced salt are being used as irrigation fluids during Phacoemulsification. Balanced salt solution has Osmolarity of 302mmol/l and PH of 7.2 that is more isotonic to human aqueous in the anterior chamber[12]. Moreover, it also contains sodium citrate and sodium acetate which makes it safer than ringer lactate.

In this study we compared these two fluids and found that endothelial loss was 0.86% less in population where balanced salt solution was used as irrigating fluid. So, our study projects that balanced salt solution is better irrigating fluid than ringer lactate in terms of percentage loss of endothelial cell count.

In this study, sample size was quite large and was difficult to handle. Initially we thought that we would lose quite a few of the patients but a friendly doctor patient relationship and periodic reminders to the patients ensured a very good number of patients till the final follow up. In this study, total loss of sample size was just 27 Patients.

Possible bias in this study may arise if we consider unequal distribution of genders in individual group. But outcome of this study may not be affected due to this bias as gender distribution was almost same in both groups. However, this can be overcome by considering that gender distribution should be same in a group during selection.

There is one factor of cost of fluids used during surgery which is practically considerable. In Pakistan Balanced Salt Solution cost almost 10 times more than Ringer Lactate. This factor can be overcome if we use Balanced Electrolyte Solution which has same composition as that of Balanced Salt Solution and its cost is almost half to that of Balanced Salt Solution. We think whenever there is question of safety of vision; we should choose better fluid for human eyes, whatever it costs.

In one study carried out in India, it was found that difference in percentage loss of endothelial cell count was 2.2% and balanced salt solution was found as better irrigating fluid during surgery but in that study sample size was small[9]. In our study, we got a large sample size and our study also shows BSS as better irrigating fluid but difference in percentage loss of endothelial cell count was just 0.86%.

In another study, it was found that ringer lactate is better irrigating fluid and difference in percentage loss of endothelial cell count was 3.9%[10], while our statistics shows BSS as better irrigating fluid than ringer lactate.

CONCLUSION

It is found that BSS is better solution for irrigation during intra-operative use during phacoemulsification than ringer lactate. No doubt, difference in percentage loss of endothelial cell count was not as significant but when we are dealing with human eyes we should choose better solution.

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Address for Corresponding Author:
Dr. Syed Ahmer Hussain
Assoc. Prof. of Ophthalmology,
Nishtar Medical College / Hospital, Multan