

To Compare the Mean Corneal Endothelial Cell Count Between the Sodium Hyaluronate 1% VS Hydroxy Propyl Methyl Cellulose (HPMC) in Patients Undergoing Phacoemulsification

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ABSTRACT

Objective: To determine mean corneal endothelial cell count between the sodium hyaluronate 1% vs. Hydroxy propyl methyl cellulose (HPMC) in patients undergoing phacoemulsification.

Study Design: Randomized control trial (RCT).

Place and Duration of Study: This study was conducted at the Ophthalmology Department, Jinnah Postgraduate Medical Centre; Karachi from 1st April, 2018 to 30th September, 2018.

Materials and Methods: There were 61 patients having cataract were included in this study. Patients were randomly allocated into two groups. Patients in group 1 were treated with sodium hyaluronate 1% and group 2 was treated with Hydroxy-propyl-methyl-cellulose 2%. All the patients were underwent phacoemulsification. Foldable intraocular lens (IOL) was implanted in all cases. Measurements of the endothelial cell count were made 1 day before the surgery and at the end of 6 weeks. All the data was entered on the pre-designed proforma.

Results: There were 28(45.2%) male and 34(54.8%) female. Reduction in mean endothelial cell count was significantly high in group 2 as compare to group 1 (p=0.0005).

Conclusion: In conclusion, our study suggests that 2% Hydroxypropyl methylcellulose, compared with sodium hyaluronate 1%, is superior in protecting the corneal endothelial cells.

Key Words: Phacoemulsification, Corneal endothelial cell, Hydroxy propyl methyl cellulose, sodium hyaluronate

Citation of article: Kumar N, Chaudhry R, Ali I, Kumar W, Khan QN, Riaz A. To Compare the Mean Corneal Endothelial Cell Count between the Sodium Hyaluronate 1% vs. Hydroxy propyl Methyl cellulose (HPMC) in Patients Undergoing Phacoemulsification. Med Forum 2019;30(11):31-34.

INTRODUCTION

The most recent estimates from World Health Organization (WHO) reveal that 47.8% of global blindness is due to cataract.¹ Phacoemulsification has become the most commonly used procedure in cataract surgery owing to the development of new devices and surgical techniques; However, corneal endothelial damage still represents a serious complication.² Ultrasound energy used during phacoemulsification is known to damage the corneal endothelium and other intraocular structures. Ophthalmic viscosurgical devices (OVD) enlarge and maintain the anterior chamber in cataract surgery.³ Their basic function is to create anterior chamber depth, protect the corneal endothelium and the posterior capsule.⁴

The corneal endothelium is a barrier for metabolic activity that plays an important role in maintaining transparency by utilizing an ATPase pump⁵. The clarity of the cornea is dependent on endothelial cell pump function (Shaw et al. 1978). If the number of cells decreases to below a certain density, corneal edema appears. Adult the mean endothelial cell count [Cells/mm² (SD)] of group Celofal (Methylcellulose) preoperative 2684(338) and 3-months postoperative endothelial cell count 2200(619)⁶. Mean endothelial cell count (cells/mm²) Group B (OVD 1% sodium hyaluronate) preoperative 2786.24, SD 286.57, postoperative 2568.24, SD 378.78⁷. Various types of viscoelastic like cohesive and dispersive in nature are available in the market. All of them claim to provide maximum endothelial cell protection during surgery. But again quality is associated with a high price tag. In a developing country like Pakistan where per capita income is low and health insurance is a rarity, use of these costly viscoelastics becomes a burden both for the patient and for the surgeon. Especially when high volume cataract surgery is performed and resources are limited; its use becomes more and more difficult⁸. The OVD hydroxy-propyl-methyl-cellulose (HPMC) has low zero-shear viscosity

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Received: July, 2019

Accepted: September, 2019

Printed: November, 2019

and dispersive characteristics⁹. Since the introduction of sodium hyaluronate 1% in 1979. Sodium hyaluronate has become the most popular and indispensable viscoelastic substance for use in intraocular surgery. It is also found in the aqueous humor and the vitreous and coats the corneal endothelium¹⁰. To the best of my knowledge very few studies have been done on this important topic in Pakistan. Now a day a large number of patients undergoing for phacoemulsification surgery with different chemical composition ophthalmic viscosurgical device (OVDs) and different cost tag ophthalmic viscosurgical device (OVDs), so this study is designed to provide us the Mean and SD of endothelial cell count of the two groups and thus it may help us in providing information about better and cost effective OVD to system which was finally improvement in phacoemulsification surgery.

MATERIALS AND METHODS

This RCT study was carried out at Department of Ophthalmology, Jinnah Postgraduate Medical Centre, and Karachi from 1st April, 2018 to 30th September, 2018 after approval from ethical review board of the hospital. Patients having grade I, II & III cataract. (graded and diagnosed according to LOCS-III classification on slit lamp examination) Both gender (male and Female) Aged between 35 to 70 years. Duration of symptoms 3 months or more. Endothelial cell count > 1500 cell/mm². were recruited in the study through non probability consecutive sampling. An informed consent was taken from all participants. These patients were randomly divided in to two groups by lottery method. The study population was divided in two groups, group 1 received sodium hyaluronate 1% and group 2 was received Hydroxy-propyl-methyl-cellulose 2% patients. All the patients was underwent phacoemulsification by a single surgeon associate professor, more than 10 year experience with same phacoemulsifier (Laureate phacoemulsification system-1002723001X). Foldable intraocular lens (IOL) was implanted in all cases Measurements of the endothelial cell count were made 1 day before the surgery and at the end of 6 weeks. The endothelial cell in the cornea (cells/mm²) was calculated with a non-contact specular microscope (SPOI: CSO, ITALY)

All the data was entered on the pre-designed proforma by the researcher which will include age, gender, duration of symptoms, pre and post phacoemulsification endothelial cell count 1 day before surgery, and at the end of the 6 weeks of surgery. Sample size By taking the mean and SD of corneal endothelial cell count group 1 (SODIUMHYALURONATE) 2568.24+378.78 and in group 2 (hydroxyl propyl methyl cellulose) 2200+_ 619, power

of study equal to 80% , confidence interval equal to 95 % then at least sample of 31 in each group was required. Patients having cataract of grade IV & V. Corneal disease e.g. corneal opacity and corneal dystrophies & degeneration. Uveitis, glaucoma & pseudo exfoliation syndrome. Previous intraocular surgery and diabetes type I. Endothelial cell count below 1500 cell/mm² Aged below 35 & above 70 years were excluded. Complete ophthalmic examination including visual acuity, slit lamp examination and IOP measurement was done. Corneal endothelial cell count for each patient was evaluated using specular microscopy done by the same examiner between 9 and 11 am. An average of three readings taken from central cornea was taken. The data was analyzed by SPSS version 18. Quantitative variable i.e. age, duration of symptoms and pre & post Phacoemulsification endothelial cell count 1 day before surgery and at the end 6 weeks of surgery was presented as mean \pm standard deviation. Frequency of percentages was calculated for gender and grade of cataract. t test was applied to compare the mean endothelial cell count at 6 weeks in both groups. Stratification with respect to age gender and grade of cataract was done. Post stratification t test was applied value ≤ 0.05 was taken as a significant.

RESULTS

There were 61 patients having cataract were included in this study. Independent sample t test Patients were randomly allocated into two groups. Patients in group 1 were treated with sodium hyaluronate 1% and group 2 was treated with Hydroxy-propyl-methyl-cellulose 2%. There were 28(45.2%) male and 34(54.8%) female. Most of cases had grade I cataract 35(56.6%) follow by 20(32.2%) and 7(11.3%) as shown in figure. Pre-phacoemulsification, mean endothelial cell count was not significant between groups while post-phacoemulsification mean endothelial cell count was significantly low group 1 as compare to group 2 (p=0.017).

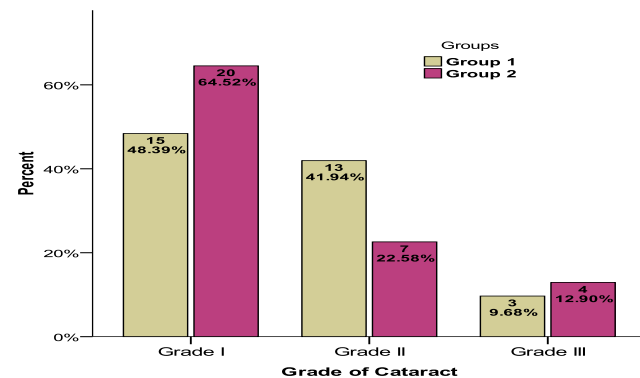


Figure No.1: Grade of Cataract (N=62)

Table No. 1: Comparison of Mean Endothelial Cell Count between Groups

Endothelial Cell Count (cells/min ²)	Group 1 n=31	Group 2 n=31	P-Value
Pre-Phacoemulsification (1 day before)	2652±150.78	2706.58±99.75	0.09
Post-Phacoemulsification (At the end of the 6 weeks of surgery)	2439.84±138.72	2346.91±158.25	0.017
Difference (Pre-Post)	212.16±12.06	359.67±58.50	0.0005

Pre and post reduction in mean endothelial cell was 359.67±58.50 in group 2 and 212.16±12.06 in group 1. Reduction was also significantly high in group 2 as compare to group 1 as shown in table. Stratification analysis was also performed and observed that mean reduction was also high in group 2 as compare to group 1 for different age groups, both gender and grade I cataract while mean reduction was not significant between groups for the grade II and III cataract patients.

DISCUSSION

Cataract is an important public health issue and the leading cause of blindness in Pakistan. Phacoemulsification and intraocular lens implantation is the preferred method to treat cataract, however, the quality of surgery is a problem that needs to be addressed¹¹. PRIOR to the use of viscoelastic materials (VEMs), corneal edema was the most common cause of failed cataract surgery.¹² Postoperative corneal edema or corneal decompensation results from corneal endothelial damage during surgery.^{13,14} The introduction of viscoelastic materials VEMs in the 1970s greatly improved the outcome and safety of anterior segment surgery. Ophthalmic viscosurgical devices (OVDs) facilitate any surgical manoeuvres and decrease the possible damage of the corneal endothelium due to surgical trauma.^{15,16} An OVD is believed to protect the CECs during the phacoemulsification maneuver due to suppression of free radical formation¹⁷ Endothelial cell loss is a primary indicator of corneal injury. Since endothelial cells do not regenerate, adjacent cells expand to fill in the gaps. As a result, endothelial cell density or count decreases and cell size increases in response to injury. Endothelial cell hexagonality and corneal thickness have been shown to increase as a result of corneal stress.^{13,14} The damage of the corneal endothelium can be evaluated by measuring the endothelial cell decrease after surgery.¹⁸ Adult human corneal endothelium is considered a non-replicative tissue and there is a natural decrease in endothelial cell density by age.¹⁹ In our study there were 61 patients who were divided into two groups. Patients in group 1 were treated with sodium hyaluronate 1% and group 2 was treated with Hydroxypropyl-methyl-cellulose 2%. Post-phacoemulsification mean endothelial cell count was significantly low in group 1, treated with sodium hyaluronate 1%, as compare to group 2, treated with Hydroxy-propyl-methyl-cellulose 2% (p=0.017). Stratification analysis was also performed and observed that mean reduction was also high in group 2 as compare to group 1 for different age groups, both gender and grade I cataract. Chaudhuri et al in their prospective study found that 2%

Hydroxypropyl methylcellulose, compared with sodium hyaluronate 1%, is superior in protecting the corneal endothelial cells, has the same effect on central corneal thickness. It compares favorably with sodium hyaluronate 1% and can be used as an effective and cheaper alternative in routine small incision cataract surgery with implant.²⁰ Glasser et al.²¹ and Probst et al.²² found no significant differences in endothelial cell loss after phacoemulsification using two different drugs. These studies found that 2% Hydroxypropyl methylcellulose has a higher likelihood of being retained during surgery and may confer better endothelial cell protection. It is possible that advances in phacoemulsification instrumentation and techniques may have sufficiently improved the safety and efficiency of cataract surgery such that the type of VEM used is of secondary importance. This belief is supported by a recent study by Kiss et al. It revealed similar changes in corneal edema and endothelial cell morphology, whether the VEM used during phacoemulsification was expensive or low-cost.²³ In our study we also found that other factors, such as patient age and degree of nuclear sclerosis, may be important determinants affecting the way the corneal endothelium recovers from surgery. The process of endothelial damage is likely to be multifactorial in nature. Surgical skill and technique are also likely to be important factors in determining surgical outcomes.

CONCLUSION

In conclusion, our study suggests that 2% Hydroxypropyl methylcellulose, compared with sodium hyaluronate 1%, is superior in protecting the corneal endothelial cells. It compares favorably with sodium hyaluronate 1% and can be used as an effective and cheaper alternative in routine small incision cataract surgery with implant.

Author's Contribution:

Concept & Design of Study: Naresh Kumar
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Conflict of Interest: The study has no conflict of interest to declare by any author.

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