

Effect of ophthalmic viscosurgical devices on post cataract intra ocular pressure changes and an assessment of their relative protective effect: a randomized controlled study

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ABSTRACT

Background: Manual small incision cataract surgery (MSICS) has emerged as a popular technique in the ophthalmic practice. Ophthalmic viscosurgical devices (OVDs) are an integral part of the modern ophthalmic practice their role came to prominence with the success of extra capsular cataract extraction (ECCE) and the use of intra ocular lens implants (IOLs). There are few published data about the effect of various OVDs following manual small incision cataract surgery.

Aims and objective: To determine post operative intra ocular pressure (IOP) changes after MSICS technique upon using OVDs; hydroxy propyl methyl cellulose (HPMC) and sodium hyaluronate (NAH) and also to assess the post operative protective effect of these two OVDs on cornea.

Methodology: Sample of 60 senile cataract patients selected from the outpatient department of Ophthalmology and divided into 2 equal groups of 2%HPMC (Group A) and 1%NAH (Group B). MSICS technique was adopted for cataract surgery. Pre and postoperative IOP was assessed using Goldmann applanation tonometer and the cornea was examined under slit lamp Biomicroscope. Data was statistically analyzed using SPSS (statistical package of social sciences) version 16.01. A value of $p < 0.05$ was taken as statistically significant.

Results: In both groups there was statistically significant rise in IOP in the 24 hours Postoperative period and insignificant drop in IOP in the 1 week postoperative period. In 1%NAH group few patients showed corneal complications.

Conclusion: Our study showed significant increase in IOP in the 24 hours postoperative period upon using 2%HPMC and 1%NAH and 2%HPMC proved better protection on the cornea.

Keywords: cataract surgery; hydroxypropyl methyl cellulose; Intraocular pressure; sodium hyaluronate

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INTRODUCTION

Manual small incision cataract surgery (MSICS) has emerged as a popular technique in the last decade and it has been possible to deliver quality surgery to the masses in developing countries.^[1] Manual Small Incision Cataract Surgery (MSICS) is a cataract surgical intervention with the merits of being economical and universally applicable to all grades of cataract. Phacoemulsification is machine-dependent and the costs are often prohibitive in developing countries where large volumes of surgeries have to be performed. Again the learning curve of phacoemulsification is known to be very steep. The economic viability and speed of surgery are twin factors that have made MSICS gain widespread adoption.^[2] Ophthalmic viscosurgical devices (OVDs) or viscoelastic agents are an integral

part of the modern ophthalmic surgery. Although used initially as vitreous substitute, their role came in the forefront of ophthalmology with the success of extra capsular cataract extraction (ECCE) and the use of intra ocular lens implants (IOLs). Sodium hyaluronate (Healon) was the first OVD launched by Pharmacia in 1980. The OVDs are aqueous solution of naturally occurring long-chain polymers such as sodium hyaluronate (NAH), hydroxy propyl methyl cellulose (HPMC) and chondroitin sulphate. They are differentiated from each other by their physical properties of viscosity, elasticity, rigidity, pseudo plasticity and cohesion.^[3] An increase in postoperative intraocular pressure (IOP) is a major postoperative complication within 24 hours after cataract surgery. 1–3 Intraocular pressure spikes of 30 mm Hg or higher in the early period after cataract surgery may be associated with pain, corneal epithelial oedema, and damage of the optic disc, particularly in patients with glaucoma. This has become a concern, since an increasing number of cataract patients are operated in an outpatient setting and discharged shortly after cataract surgery. A main cause for the postoperative IOP increase is that the OVD remains in the eye, which causes a mechanical obstruction of the trabecular meshwork.^[4]

Ocucoat (hydroxypropyl methylcellulose) and Viscoat (sodium chondroitin sulphate–sodium hyaluronate) are dispersive OVDs with low viscosity at zero shear rate. The dispersive nature causes better adherence of the OVD to the corneal endothelium, possibly resulting in better protection of the corneal endothelium against fluid turbulence and lens fragments during phacoemulsification. This has led to frequent use of such dispersive OVD in routine small incision cataract surgery.^[5]

There are many studies available which showed the effect of various OVDs on the changes in the post-operative IOP and also their relative protective effects on cornea post-operative cataract surgery following phacoemulsification technique. There are few studies available in the literature about the effect of various OVDs post operatively following manual small incision cataract surgery technique (MSICS). Accordingly, this study was undertaken to determine and compare pre and post-operative intra ocular pressure changes after manual small incision cataract surgery technique upon using OVDs 2%HPMC and 1% NAH and also to assess the post-operative protective effect of these 2 OVDs on cornea.

MATERIALS AND METHODS

Sample size of 60 randomly selected senile cataract patients aged between 45 to 75 years were included in the study. The sample was equally divided into 30 sample of 2% HPMC (group A) and 30 sample of 1% NAH(group B). Senile cataract patients were selected among out patients reported with complaint of decreased visual acuity at Department of Ophthalmology. The study was approved by institution ethics committee. Informed consent was obtained from all patients prior to the commencement of the study. Manual small incision cataract surgery technique was followed for cataract surgery. Exclusion criteria were previous ocular surgery, ocular hypertension (IOP higher than 22 mm Hg), diabetic retinopathy, corneal pathologies, diabetes mellitus, hypertension, ischaemic heart diseases, pupil size <7.5 mm, and primary or secondary glaucoma.

This prospective randomised study comprised 60 consecutive patients with age related cataract scheduled for small incision cataract surgery and implantation of an intraocular lens (IOL). All patients were operated by the same surgeon. Group A is assigned to receive 2% HPMC and group B 1% NAH during surgery. Procedure of MSICS using 2% HPMC and % NAH: preoperative evaluation of the

patient includes measurement of uncorrected visual acuity (UVCA) and best corrected visual acuity (BCVA), cornea and anterior segment examined thoroughly using slit lamp biomicroscope, fundus is evaluated through dilated pupil. Base line IOP was measured preoperatively with Goldmann's applanation tonometer.

Manual small incision cataract surgery (MSICS) procedure was followed using 2% HPMC and 1% NAH: ofloxacin eye drops were installed at 6 hourly intervals in the eye to be operated 1 day prior to surgery. Approximately 1–2 hours prior to surgery phenylephrine 2.5%, tropicamide 0.5%, and cyclopentolate 1% eye drops were instilled for papillary dilatation. Peribulbar anaesthesia was administered using 0.5% bupivacaine and 2% lignocaine mixed with hyaluronidase. Than A side port ab externo incision at 10:30 position was made with a 20 guage microvitrioretinal (MVR) blade for injection of OVD. In group A, 2% HPMC and in group B 1%NAH was used for maintaining the anterior chamber. Capsulorrhesis was performed by a bent tipped 26 G cystitome under 2%HPMC and 1% NAH with group A and group B respectively. A triplaner sclero-corneal tunnel incision of 6mm, starting at mid limbus, 12 o clock position was made with a 15G surgical blade under 2%HPMC in group A and 1% NAH in group B. Hydrodissection and hydrodelineation was performed to achieve free rotation of nucleus. Cortical aspiration was done in both groups with simcoe biway cannula. The rigid, single piece polycast polymethylmethacrylate (PMMA) lense was implanted using Mc Pherson's IOL forceps. In group A, the IOL was inserted using 2%HPMC and in group B under 1%NAH. After IOL implantation OVDs were washed thoroughly. The side port was hydrated at the end of the surgery. Sub-conjunctival injection consisting of 0.5ml gentamycin was administered. Postoperatively patients were prescribed 0.3% ciprofloxacin 4 times in a day for 1 week and dexamethasone eye drops 6 times in a day for 6-8 weeks in tapering dosage.

In both groups IOP was measured using Goldmann's applanation tonometer preoperatively 1 day before surgery and postoperatively at the intervals of 24 hours and 1 week and the cornea was assessed using slit lamp biomicroscope pre and postoperatively. Data was statistically analyzed using SPSS (statistical package of social sciences) version 16.01. Preoperative IOP values were compared with those of 24 hours, and 1 week post-operative period separately for each group using paired *t* tests. A value of $p < 0.05$ was taken as statistically significant.

Table 1: Mean preoperative and post-operative intraocular pressures in both groups

Groups (N=60)	Preoperative IOP(mm Hg)	Post operative IOP (mm Hg)	
		24 hours	1 week
1% NAH(n=30)	13.63	20.43	13.27
2% HPMC(n=30)	12.43	15.67	12.01

Table 2: Mean difference between preoperative and post-operative IOP in both groups

Pre-operative -24 hours post-operative IOP(mm Hg)		Pre-operative -1 week post-operative IOP(mm Hg)	
2% HPMC group	1% NAH group	2% HPMC group	1% NAH group
3.24	6.80	-0.42	-0.36

Table 3: Statistical significance between the preoperative and post-operative IOP in both groups

Groups	24 hours post-operative period		1 week post-operative period	
	P value	Inference	P value	inference
2%HPMC group	0.000232	significant	0.547335	Not Significant
1%NAH group	3.88*10E-11	Significant	0.617071	Not Significant

Table 4: Post operative corneal complications in 2%HPMC and 1%NAH groups

Corneal oedema		Striate keratopathy	
2%HPMC	1%NAH	2%HPMC	1%NAH
0	2	0	9

RESULTS

A total of 60 samples included in the study, among which 30 and 30 were with 2% HPMC and 1% NAH group respectively.

Mean IOP changes from preoperative to 24 hours post-operative, and 1 week postoperative period has been summarized in the Table1.

At 24 hours post-operative period the mean IOP was higher compared to preoperative period in both groups and the difference was statistically significant in both groups [Table 2 and 3]. However, the mean difference between preoperative and 1 week post-operative period was decreased in both groups but it was not significant [Table 3].

Among 1%NAH group 2 cases presented with corneal edema and 9 cases with striate keratopathy. None of 2% HPMC group experienced corneal complications [Table 4].

DISCUSSION

In our study we have evaluated the effect of two commonly used OVDs; 2%HPMC and1%NAH on the IOP after small incision cataract surgery and also their protective role on cornea.

Our findings showed that in the 24 hour post-operative period there was significant increase in IOP in both groups but there is insignificant drop in IOP in the 1 week post-operative period in both groups. Our study is in agreement with, Rainer et al,^[5] Lane SS et al,^[6] Dada et al,^[7] Javadadehet et al.^[8]

Rainer et al^[5] reported the small increase of IOP in postoperative period upon using 2%HPMC. Lane SS et al^[6] studied the effect of HPMC, NAH and VISCOAT on post-operative IOP changes and

discovered a statistically significant increase in IOP in 3 groups after 4 hours and 24 hours post-operative period. However 1 week postoperative IOP increase was not statistically significant in 3 groups. Dada et al^[7] studied IOP changes upon using 3 different OVDs namely HPMC, NAH and Hyaluronic acid and found statistically significant increase in IOP in NAH and IAL groups at 6 hours and 24 hours postoperative period and there was no significant increase in IOP in HPMC group.

Javadadehet et al^[8]studied post-operative IOP changes upon using 1%NAH and 2%HPMC and reported that both groups showed rise in IOP in post-operative period and it was statistically significant in 1%NAH group. They also observed that complete removal of OVDs with proper technique and enough washout time was essential to avoid postoperative rise in IOP.

Intraocular pressure of 30 mm Hg or higher in the early post-operative period after cataract surgery may cause pain, corneal oedema, and optic disc damage in patients and these complications are more common in patients with glaucoma. The mechanism of postoperative IOP increase is not yet fully understood. A major reason for the postoperative IOP increase seems to be the amount of the remaining OVD at the end of surgery. It is assumed that the remaining OVD mechanically obstructs the trabecular outflow pathway and hence decreases the outflow facility^[4]. In order to avoid a postoperative IOP increase, thorough removal of OVD is vital. Surgical techniques for the removal of OVDs, especially from behind the IOL, have been described, but a complete prevention of a

postoperative IOP increase could not be achieved with any technique.^[5,9,10,11]

Assuming that the amounts of the remaining 2 OVDs were similar in our study, the difference in postoperative IOP increase between the two OVDs might be explained by differences in their biophysical properties. The clearance of the OVDs through the trabecular meshwork is dependent upon their viscosity and molecular weight. Lower the viscosity and the molecular weight of the OVD, the faster is the clearance rate through the trabecular meshwork which results into low rise in intraocular pressure. The 2%HPMC possess the property of low viscosity and low molecular weight. So in our study the mean increase in IOP in the 24 hours post-operative period in 2%HPMC group (3.24mm hg) is lower compared to 2%NAH group(6.80 mm hg).

In our study 2% HPMC group not experienced corneal complications this is because Hydroxypropyl methylcellulose is dispersive in nature with low viscosity at zero shear rate. The dispersive nature causes better adherence to the corneal endothelium, possibly resulting in better protection of the corneal endothelium against fluid turbulence. This has led to frequent use of this OVD in routine small incision cataract surgery.

Our study in agreement with above studies proved that 2% HPMC is better compare to 1%NAH and our study differed compared to above studies because we used MSCIS Technique which is economical and very useful for developing countries like India and above studies followed phacoemulsification technique which is cost effective, and the OVD used in our procedure is also economical and very safe.

CONCLUSION

From our study we found that 2%HPMC and 1%NAH produced statistically significant increase in IOP in the 24 hour post-operative period, but 1%NAH group showed much higher and very much statistically significant increase in IOP in comparison to 2%HPMC group. Though IOP decreased in both groups during 1 week post operative period but it was almost near to normal preoperative values. Corneal complications were found to be more in the NAH group and no complications occurred in the HPMC group.

Thus in consideration of our findings we conclude that 2%HPMC is more economical and safe for MSICS technique, which is also an economically viable procedure. To support our findings further longitudinal studies with larger sample sizes are required.

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