Original Article

Efficacy and safety of dropless cataract surgery

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Purpose: To evaluate the clinical outcome following intraoperative transzonular intravitreal injection of triamcinolone acetonide and moxifloxacin in patients undergoing phacoemulsification cataract extraction with intraocular lens (IOL) implantation. **Methods:** In this prospective, non-randomized, clinical, interventional study, a total of 200 eyes were enrolled. Patients who voluntarily gave their consent after being informed about dropless cataract surgery along with its pros and cons were included. Those who had glaucoma or were known steroid responders as well as those who were lost to follow-up were excluded. 0.1 ml each of moxifloxacin (500 mg) and triamcinolone acetonide (4 mg) were injected transzonularly following IOL implantation in phacoemulsification cataract surgery with the help of 27G curved cannula. Slit-lamp examination was done to detect cells, visual acuity was noted, and intraocular pressure was measured postoperatively on day 1, 7, 30, 60, and 90. **Results:** Uncorrected visual acuity (UCVA) greater than 6/9 was achieved in 96% of patients at the end of 3 months. The mean IOP was found to be normal in all the cases at every visit. Twenty patients complained of floaters on postoperative day 1 (D1), which decreased to zero after 60 days (D60). None of the patients needed any eye drop during the entire postoperative period. **Conclusion:** The study demonstrates that this procedure is advantageous and safe.

Key words: Dropless, phacoemulsification, transzonular

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Modern phacoemulsification cataract surgery claims to provide the earliest rehabilitation to patients. It is now a walk-in walk-out procedure. The patient can resume normal activities from the very day of surgery. In spite of these advantages, a patient has to put eye drops into the operated eye from time to time for a period of 4 to 6 weeks.[1] That takes away a lot of the sheen out of this unusual procedure. There are also problems of compliance, injury to the corneal epithelial surface, and frequent callbacks.[2] A compliance monitoring study found that cataract surgery patients did not comply with the prescribed number of postoperative drops.[3] Some patients even use improper techniques during application of postoperative drops.[4] Examples of improper methods of drop instillation includes the drop missing the eye, instilling an incorrect number of drops in one dose, and contaminating the bottle tip. The same study also reported that less than half of the patients wait for less than 5 min between instilling different eye drop medications. Noncompliance with topical ophthalmic drops has been reported to be as high as 40%.[5] Noncompliance is likely to increase the risk of infection, and may pose a health safety concern, i.e. not adhering to the prescribed schedule for antibiotic eye drops could increase the risk of bacterial resistance.

It is also known that patients who come for phacoemulsification cataract surgery suffer from dry eye disease of some form.[6-11] In one study, it was reported that 41% patients are symptomatic but there are many more who are asymptomatic in whom the Schirmer's test, fluorescein stain, and tear film breakup time are positive. Postoperative eye drop instillation will add insult to the already compromised corneal surface.[9] The incidence of postoperative dry eye is 9%–11%.[12-14] How many drops are to be instilled, how many times, and in which eye are the frequently repeated questions that an ophthalmologist encounters from the patients during the postoperative period.

Dropless cataract surgery is a new technique practiced by many American cataract surgeons for the last few years.[15-20] Two specially prepared compounds called Tri-Moxi [containing triamcinolone acetonide (3 mg) and moxifloxacin (0.2 mg)] and Tri-Moxi-Vanc [where vancomycin (2 mg) is also added] are used. (Imprimis Pharmaceuticals, San Diego, CA, USA). After IOL implantation, the surgeons inject this mixture trans-zonularly into the vitreous cavity. This eliminates the need for instillation of eye drops postoperatively and patients can lead a life free from any compulsion. There have been many reports of surgeons resorting to this technique, with excellent results and without any significant complication. A literature search revealed that until now, no such study has been done in India regarding this technique. This study is an endeavor to perform this procedure for the first time in India. Since commercially prepared TriMoxi is not available in India, we prepared these two compounds on the

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operation table from fresh bottles of moxifloxacin eye drops (Vigamox eye drop, Alcon) and triamcinolone acetonide (TA).

Methods

This was a prospective, non-randomized, non-comparative clinical interventional study. The study period was from February 2018 to September 2018. The study protocol was approved by the institutional ethics committee (IEC) of the Hospital and abides by the tenets of the declaration of Helsinki. All the patients were informed about the pros and cons of the procedure and informed consent was obtained from all participants. Known cases of glaucoma and steroid responders were excluded from the study. The steroid responders were identified by noting any history of previous steroid exposure with subsequent rise in intraocular pressure. Cases that had complications during surgery, such as posterior capsular rupture, vitreous loss, zonular dialysis, and inability to deliver the drug were also excluded.

Standard surgical protocols were used in all cases. Local anesthetic (proparacaine hydrochloride 0.5% drops) was instilled in the conjunctival sac initially at 10 min, and then again 5 min before surgery. A 10% povidone-iodine solution was applied to the skin around the operative site, and a 5% solution was applied to the conjunctival sac 3 min before surgery. Under topical anesthesia, a 2.2-mm limbal temporal incision was made. Phacoemulsification was done using the chopping technique in active fluidics system (Centurion Vision System, Alcon Laboratories). After intraocular lens (IOL) insertion into the bag, the AC was filled with cohesive OVD to expand the ciliary sulcus. A fresh bottle of Vigamox was opened. A 1-ml syringe was used. Its plunger was removed and 4–5 drops of Vigamox were filled into the syringe. In a different syringe, 0.1 ml of Tricort was taken directly from the vial. Subsequently, the two solutions were put into a single syringe and the mixture was ready for injection. The mixture of 0.1 ml each of triamcinolone acetonide (4 mg) (TRICORT, Cadila pharmaceuticals) and moxifloxacin (0.5 mg) (VIGAMOX, Alcon Laboratories) was injected into the anterior vitreous transzonularly with a 27 Gauge bent cannula. A plume of visible triamcinolone suspension with antibiotic was seen within the vitreous. [Fig. 1 and Video 1] A second or third injection was permitted if the surgeon felt the first (or second) injection was inadequate due to leakage. There was immediate rise of intraocular pressure along with shallowing of the anterior chamber (AC) and sometimes with prolapse of iris. Bimanual irrigation and aspiration were done to remove the OVD and reform the AC. No patch was given, and the patient was allowed to go home after checking the vital parameters. All the surgeries were performed by a single surgeon. Follow-up was done on day 1 (D1), day 7 (D7), day 30 (D30), day 60 (D60), and day 90 (D90). On each visit, visual acuity and IOP were measured. Slit-lamp examination was also done to look for cells, flare, and signs of endophthalmitis [Tables 1 and 2].

Results

The primary outcome of this study was to measure the visual acuity after dropless cataract study. The secondary outcomes measured were incidence of steroid-induced glaucoma and number of patients who needed additional eye drops in the postoperative period. There were 128 female (65.3%) and 68 (34.7%) male patients in the study. Mean age of the patients was 63.73 years (SD 3.848). Cataract density showed NS 1 and 1+ in 17 (8.5%), 2 and 2+ in 57 (29.1), 3 and 3+ in 54 (27.6%), and 4 and 4+ in 68 (34.57%) of cases. Out of the 200 cases that were enrolled, 2 cases had posterior capsule rupture and so, the drug was not injected. Another 2 cases were lost to follow-up. We encountered intraoperative complications in 12 cases which comprised of anterior chamber hemorrhage in 1 eye (0.5%), leakage in 8 eyes (4%), pain in 3 eyes (1.5%), and intraoperative IOP rise in 1 eye (0.5%). There was no case of postoperative

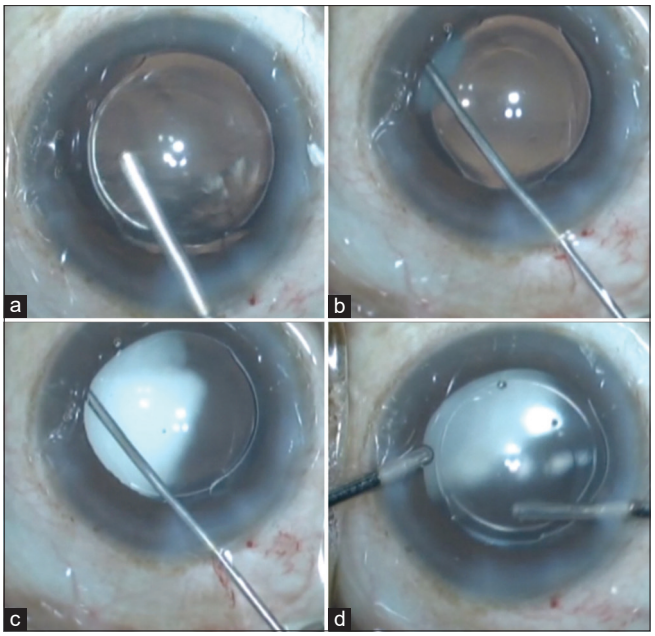

Figure 1: Procedure of dropless cataract surgery. (a) Preparation of bed by injecting cohesive OVD into the cilliary sulcus. (b) Placement of 27 Gauge cannula in the transzonular space, a small amount of mixture is seen. (c) Completion of procedure, a plume of mixture distinctly visible behind the posterior capsule. (d) Bimanual IA to aspirate out the OVD and normalize the IOP

Table 1: Number of patients with cells in anterior chamber postoperatively based on SUN classification

CELLS	OCC	+	++	+++	++++
D1	47	3	10	0	7
D7	3	0	10	0	0
D30	0	0	0	0	0
D60	0	0	0	0	0
D90	0	0	0	0	0

SUN: Standardization Of Uveitis Nomenclature. D1: Postoperative day 1, D7: Postoperative day 7, D30: Postoperative day 30, D60: Postoperative day 60, D90: Postoperative day 90

Table 2: Patients complaining of floaters postoperatively

Postoperative day	Number of patients
D1	20
D7	15
D30	13
D60	0
D90	0

endophthalmitis. Uncorrected visual acuity (UCVA) greater than 6/9 was achieved in 96% of patients at the end of 3 months. Of the seven cases that did not achieve better than 6/9 vision, one had epiretinal membrane and the remaining six had residual refractive error. [Table 3] The best-corrected visual acuity (BCVA) improved to more than 6/9 in all cases but one. The lone case that did not show improvement post refractive correction had an epiretinal membrane. His visual acuity was 6/12 and he was subsequently scheduled for vitreoretinal surgery. Mean IOP was normal in all the cases at all visits. [Table 4] Twenty patients complained of floaters on postoperative day 1 (D1) which decreased to 15 and 13 patients on postoperative day 7 and day 30, respectively. Eventually none of the patients complained of floaters after 60 days post surgery. Of the 196 patients in our study, 13 patients had diabetes mellitus. There was no incidence of cystoid macular edema in these patients. Retinal break or detachment was not noticed in the postoperative period in any of the patients. None of the patients developed zonular weakness or IOL decentration after the surgery and none of them needed any eye drop during the entire postoperative period.

Discussion

Failure to give the injection on the first attempt was an initial hiccup with this procedure. Since the procedure was blind, there was a learning curve associated with this technique. Although we had to repeat the injection thrice in one patient, it was successful in the first attempt in 70% cases. Overall, it was successful in all the cases.

Intraoperative iris prolapse and bleeding were not difficult to manage as phacoemulsification is a closed chamber procedure. The sole case that was complicated by intraoperative bleeding was handled by increasing the IOP to 80 mm of Hg for 3–4 min.

The possibility of immediate postoperative foggy vision, the appearance of floaters, postoperative IOP rise, and infection were concerns that made us apprehensive about the procedure, at the outset. None of the patients complained of hazy vision or had an increase in IOP at any visit. Only 20 of them complained of floaters on day 1 which decreased to 15 and 13 after 7 and 30 days, respectively, and finally, the number came down to 0 after 60 days. We counseled the patients before the surgery about the possibility of immediate postoperative foggy vision and floaters. That could be the reason why none of them complained of hazy vision. Although 20 patients had spoken about floaters on the first postoperative day, they did not complain and were not unhappy.

The most gratifying achievement of this study was that none of the patients had to put any eye drop during the postoperative period. They were promised a drop less postoperative period and we were able to deliver on that promise. The term "breakthrough" is used for those patients who need the addition of eye drops, especially a steroid during the postoperative period. According to Stringham *et al*., the reported incidence of breakthrough in the literature is about 5%.[18]

Based on the review of existing literature, we expected a rise in IOP in at least some of our cases. But surprisingly, there was no such case even after 3 months of follow-up. This finding is similar to a study by Fisher and Potvin. They did not find any statistically significant difference in IOP between two study groups, one of which underwent dropless cataract surgery and the other which underwent cataract surgery followed by postoperative topical antibiotic-steroid eye drop combination administration.[17]

Ocular hypertension following systemic, topical, subtenon, and intravitreal steroid instillation is a known phenomenon in steroid responders. Steroid responders are identified only after the patients are exposed to steroid. It is known to occur in genetically predisposed individuals.[21] Steroids induce the expression of a gene located on chromosome 1 and is known as TIGR or GLCIA.[22-24] In these patients, there is an increase in glycosaminoglycans in response to steroid, which reduces the aqueous outflow and subsequently raises IOP. There is no test available to detect the responders beforehand. In our study, known cases of steroid responders were excluded. A high incidence of ocular hypertension is reported following intravitreal triamcinolone acetonide in the treatment of diffuse discoid macular edema, exudative ARMD, retinal vein occlusion, uveitis, and cystoid macular edema.[25]

In a prospective, clinical, interventional, comparative, and non-randomized study involving 260 patients (293 eyes) who received an intravitreal injection of 20–25 mg of TA, intraocular pressure readings higher than 21, 30, 35, and 40 mmHg were measured in 94 (36.2%), 22 (8.5%), 11 (4.2%), and 4 (1.5%) patients, respectively.

The mean terminal elimination half-life ($t_{1/2}$) of triamcinolone acetonide (TA) is 448.3 ± 136.5 h (18.7 ± 5.7 days).[26] Assuming intraocular concentrations will persist for five half-lives in nonvitrectomized participants, triamcinolone concentrations will be present intraocularly for 93 ± 28 days. Since TA is degradable inside the eye, the initial rise in IOP can be controlled effectively by antiglaucoma medication until the half-life of the drug is over. Only in about 3% of cases and in particular when there is a family history of glaucoma or chronic use of steroid (at least four years), the ocular hypertensive response is found to be irreversible.[17,19,20] The management of such cases is no different from that of primary open-angle glaucoma. If the situation demands urgent removal of intravitreal TA, a simple 25G pars plans vitrectomy can be done to manage complication.[23]

The not so "wow" vision immediately after surgery may be a disappointment to the patient unless he or she is thoroughly counseled before the surgery. Fortunately, we did not face this problem.

Table 3: Postoperative uncorrected visual acuity on days 1, 7, 30, 60, and 90

Postperative UCVA	D1	D7	D30	D60	D90
>6/9	172 (87.75%)	180 (91.8%)	180 (91.8%)	186 (94.9%)	189 (96.4%)
6/12-6/24	15 (7.65%)	11 (5.6%)	16 (8.2%)	10 (5.1%)	7 (3.5%)
<6/24	9 (4.6%)	5 (2.6%)	0	0	0

Table 4: Mean IOP of all postoperative cases

Postoperative day	Number of patients	Mean IOP (mm of Hg)
D7	196	12.96±1.414
D30	196	15.25±1.243
D60	196	14.04±1.064
D90	196	13.6±1.500

IOP=Intra Ocular Pressure

There was no endophthalmitis in our series of cases. Two hundred eyes is too small a number to comment upon incidence of endophthalmitis. In a study of approximately 2000 eyes, Kishore *et al*. reported four cases (0.25%) of acute-onset postoperative endophthalmitis after uneventful temporal clear corneal topical dropless cataract surgery involving intravitreal triamcinolone-moxifloxacin drug combination (TriMoxi).[27] A similar study by Tyson *et al*. reported no incidence of endophthalmitis in a series of 1541 eyes.[28] Compared to the landmark post-cataract endophthalmitis studies by Aravind Eye Hospital[29] and ESCRS,[30] the number of patients in the dropless cataract surgery studies is small. Nevertheless, the dropless cataract surgery studies have demonstrated that the incidence of post cataract surgery endophthalmitis is similar to that of conventional phacoemulsification surgery where the incidence is 0.04%–0.2%.[27] This raises the question of whether these studies are good enough to prove that dropless cataract surgery is as safe as conventional phacoemulsification surgery. The answer is probably not.

There has been a lot of debate regarding the usefulness of perioperative antibiotics in the prevention of post cataract endophthalmitis.[31] An All India Ophthalmological Society member survey revealed that 90% of them used topical antibiotics both pre and postoperatively, 46% used subconjunctival antibiotic at the end of surgery, and 40% used instillled antibiotic intracamerally.[32] Several studies have found topical moxifloxacin, a fourth generation antibiotic, to be superior in terms of potency. It has the lowest mean inhibitory concentration (MIC) for most bacterial endophthalmitis isolates; thus, it seems to be a better choice as a prophylactic antibiotic.[33-35] Although the concept of instilling intracameral antibiotics is quite old, it is yet to be established as a universal prophylactic measure against post cataract surgery endophthalmitis.[19] The ESCRS study is substantial proof that intracameral injection of cefuroxime is responsible for a five-fold decrease in post cataract endophthalmitis.[30] This study was done across Europe and the results were so astounding that it had to be stopped midway to offer the control group the benefit of the outcome. Intracameral moxifloxacin is used prophylactically in India, Canada, and in many South American countries. A recent study published by Aravind Eye Hospital confirms the efficacy of intracameral moxifloxacin in the prevention of postcataract endophthalmitis.[26]

Injection of moxifloxacin prophylactically into the vitreous cavity is a new concept although it has been used previously as a treatment in bacterial endophthalmitis cases.[20]

We injected 500 mg of moxifloxacin into the vitreous. The intravitreal half-life of moxifloxacin is only 1.7 h as it is cleared, both, via passive diffusion anteriorly as well as by active transport through the retinal pigment epithelium.[36] It is doubtful whether therapeutically effective moxifloxacin would be available after 10 h of the injection. Since no antibiotics or steroids are given topically during the postoperative period in dropless cataract surgery, the eye may be vulnerable to infection after 10 h. This is unlike intracameral antibiotic, which is always backed by topical application of antibiotics for at least 2 weeks.

The American Society of Cataract and Refractive Surgery (ASCRS) and the American Academy of Ophthalmology had alerted its members about two separate outbreaks of acute retinal toxicity after intravitreal injection of triamcinolone-moxifloxacin drug combination.[37] The outbreaks occurred at operating centers following cataract surgeries performed in February 2017. Both centers obtained the drug formulation from the same Dallas compounding pharmacy. The affected patients presented with variable, but frequently severe vision loss as well as OCT abnormalities of the ellipsoid layer of the macula. They referred to this complication as toxic posterior segment syndrome. Thus far, 50 patients have been identified. Fortunately, there has been no such episode in our series of cases. Though Tri-Moxi is available in the American markets, many hospitals prefer to use mixtures compounded by some pharmacy. This is a cheaper option but not devoid of risk, as compounding of medicines needs utmost care and precaution. For our study, we prepared the mixture ourselves, in the operating room itself.

Conclusion

The study demonstrates that this procedure is advantageous and safe. If further randomized controlled studies can prove its usefulness, the technique could be a boon to the working rural population of India for whom putting eye drops during working hours is not only cumbersome but unsafe as well.[2] If they can be freed from this burden, their postoperative period will be more comfortable.

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Conflicts of interest

There are no conflicts of interest.

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