• Original Article •

A two different chemoprophylaxis approaches after phacoemulsification surgery in one thousand patients in Iraq

Suzan Amana Rattan[1], Najah Kadhum Mohammad[2], Mahir Kadhim Mutashar[3]

[1]Department of surgery, Al-kindy College of Medicine/ University of Baghdad, AL-Nahdha square, Baghdad 10001, Iraq

[2]Department of surgery, Baghdad College of Medicine/ University of Baghdad, Bab aL-Moadham square, Baghdad 10001, Iraq

[3]Eye Specialty Private hospital, Al-Wazyrea, Baghdad 10001, Iraq

Correspondence to: Suzan Amana Rattan. Department of surgery, AL-Kindy College of Medicine, University of Baghdad, Al-Nahdha square, Baghdad 10001, Iraq. suzanophthalmologist @gmail.com

Received: 2019-12-16 Accepted: 2020-07-27

Abstract

• AIM: To evaluate the effectivity of the combination of intracameral moxifloxacin 0.1% with subconjunctival triamcinolone acetonide 4 mg as prophylaxis of infection and inflammation after phacoemulsification in comparison with topical medication treated group.

• METHODS: A total one thousand patients with age range from 38 to 70 years old who scheduled for phacoemulsification were divided into 2 groups of no statistically significant differences in age, preoperative intraocular pressure (IOP) and central macular thickness (CMT), *P*=0.6, 0.9 and 0.8 respectively. The surgeries were done by 2 surgeons each one planned to use one method of prophylaxis at Eye Speciality Private hospital, Baghdad, Iraq. For the 1st group of patients (500) a topical moxifloxacin hydrochloride 0.5% and dexamethasone 0.1% eye drops were prescribed four times a day for 1mo postoperatively. For the 2nd group intracameral (IC) diluted moxifloxacin at 0.1% with subconjunctival (SC) triamcinolone 4mg in 0.4 cc were administered at the conclusion of the surgery. Follow up visits were on the first postoperative day, 1wk, 1mo, and 3mo postoperatively. Anterior chamber (AC) reaction was examined during the 4 visits while IOP was measured during the last 3 and CMT was measured only in the last one.

• RESULTS: The current clinical trial study compared 2 samples with 2 different prophylaxis methods. No endophthalmitis case reported in both group. By a 2-Sample *t*-test, the IC-treated group (group 2) had statistically significant lower AC cells at the 1st day postoperative visit than the other group while there were no statistically significant differences at 1wk, 1 mo and 3mo visits between the 2 groups. There was no statistically significant difference at 3mo visits in IOP and CMT between the two groups. A breakthrough inflammation rate with the topical medication was (9.6%) while in the other group (IC treated) was 4.0%. A significant IOP elevation ≥10 mm Hg at 1mo in 2.4% within the topical medication group which was higher than the rate in the other group (0.8%).

• CONCLUSION: In addition to the safety and effectivity of the combination of intracameral moxifloxacin and subconjunctival triamcinolone in preventing infection and inflammation after cataract surgery. The majority (480) of our included patients didn't require any topical postoperative medication that is cost saving for the patient, helped patients who were unable to administer topical medication, and decreased chance of complication related to patient poor adherence to postoperative medication.

• KEYWORDS: moxifloxacin hydrochloride; triamcinolone acetonide; phacoemulsification

DOI:10.18240/ier.2020.03.04

Citation: Rattan SA, Mohammed NK, Mutashar MK. A two different chemoprophylaxis approaches after phacoemulsification surgery in one thousand patients in Iraq. *Int Eye Res* 2020;1(3):154-159

INTRODUCTION

Post cataract surgery bacterial endophthalmitis is a rare but the most devastating complication with poor visual outcome[1-2]. The incidence of endophthalmitis varies substantially. Within literature the reported incidence rate range from 0.04 to 0.2 % of cases[1-3]. Other causes of significant postoperative vision loss are persistent inflammation and cystoid macular edema (CMT)[4-5]. Many options for prophylaxis were prescribed including topical and subconjunctival antibiotic and povidone iodine preparation that installed on the ocular surface before the surgery.

The preferred pattern of chemoprophylaxis varied world widely. The use of preoperative povidone iodine is universal. Most European surgeons prefer the use of intracameral (IC) antibiotics whereas topical fluoroquinolone that prescribed perioperatively is the most common pattern in the United State (US)[3]. In spite of the fact that the use of IC antibiotics is considered off-label in the US, however, there use is increasing.

Many retrospective studies confirmed the efficacy of IC cefuroxime for the prophylaxis against endophthalmitis since 2006[6-7]. Moxifloxacin ophthalmic solution (Vigamox 0.5%) was administered in the anterior chamber (AC) as a way to prevent endophthalmitis after cataract surgery, the safety and effectiveness were reported 1st in an animal model at 2005[8].

Many further authors reported their results with IC Vigamox with a different concentration that used for patients after cataract surgery as a prophylaxis of endophthalmitis[9-11].

Regarding the combination therapy, a trans-zonular intravitreal injection of triamcinolone, moxifloxacin, and vancomycin (TMV) has been used as prophylaxis against endophthalmitis and postoperative inflammation[12].

The current study aimed to evaluate the effectivity and safety of a combination of diluted IC moxifloxacin at 0.1% and subconjunctival (SC) triamcinolone acetonide 4 mg/0.4 mL as prophylaxis of endophthalmitis and postoperative inflammation in five hundred phacoemulsification surgeries and compare its results with a same number of patients who treated by topical moxifloxacin hydrochloride (0.5%) and dexamethasone (0.1%) eye drops that prescribed four times a day for 1mo postoperatively.

SUBJECTS AND METHODS

Study Design and Populations The current nonrandomized clinical trial included a total 1000 patients with visually significant cataract scheduled to have phacoemulsification surgery at an Eye Specialty Private hospital in Baghdad/ Iraq during 18mo period from 1st of October 2016 to 1st of February 2018 by 2 surgeons. The study protocol had been approved by the scientific and ethical committee of Al-kindy College of Medicine, University of Baghdad, Iraq. The current two methods of prophylaxis of postoperative endophthalmitis and inflammation were discussed with the patients and informed consent was obtained about the treatment and the enrollment in the current study.

The patients were divided into two equal groups.For 500 patients (group 1) topical moxifloxacin hydrochloride 0.5% (Vigamox, Alcon) and dexamethasone 0.1%(Maxidex, Alcon) eye drops were prescribed four times a day for 1-month postoperatively while for the remaining 500 patients (group 2), IC diluted moxifloxacin 0.1% and SC triamcinolone acetonide 4 mg/0.4 cc was the combination that planned to be used for the prophylaxis.

Inclusion Criteria for Both Groups the patients with visually significant cataract who included in the current study should have no current or previous intraocular inflammation, no history of glaucoma or topical corticosteroid responsiveness. All the included patients had normal preoperative fundus examination and normal preoperative macular OCT. For group 2 any patient who used a topical antibiotic, nonsteroidal anti-inflammatory drug (NSAID) or corticosteroid up to 1wk before the planned day of surgery was excluded. All patients who had these inclusion criteria were included in the current comparison whether phacoemulsification surgery was complicated or not.

The 2 surgeons follow the same protocol for the preoperative evaluation including slit lamp, Goldmann applanation tonometry(AT900, Haag-Streit Diagnostics, Switzerland), dilated fundus examination and macular OCT(Optovue, RTVue-100, Fremont, CA).

The mean age of patients in group 1 was 59.4±9.04y, 300 were female and 200 were male, 160 with type 2 diabetes mellitus (DM) without retinopathy and the preoperative intraocular pressure (IOP) range were from 10 to 25 mm Hg with mean 14.49±3.11 mm Hg.

Group 2 patients had a mean age of 59.7±8.84y, 320 were female and 180 were male, 140 with good controlled diabetes and preoperative IOP mean was 14.47±3.10 mm Hg range was from 9.5-20.6 mm Hg.

Methods One thousand phacoemulsification surgeries were done at the same hospital by 2 surgeons.

For every 500 patients, one method of prophylaxis was used. The patient's demographics, preoperative, intraoperative, and postoperative characteristics were shown in Table 1. All phacoemulsification surgeries were done by infinity vision system (Alcon Laboratories, Inc). The rate of posterior capsular rupture (PCR) was 3% and 2.6% for group1 and 2 respectively.

For group 1 a topical moxifloxacin 0.5% and dexamethasone 0.1 % eye drops were prescribed four times a day started from the 1st postoperative day for the 1-month duration. For group 2 intraoperative IC moxifloxacin (Auromox) and SC triamcinolone (Aurocort) were administered at the conclusion of surgery.

Auromox (0.5%): is a sterile clear yellow pale colored preservative free isotonic ophthalmic solution with PH 6.0 to 7.5 and osmolarity 620 -320 mOsm. The sterile Auromox vial contains 1cc moxifloxacin hydrochloride 5.45 mg equivalent to 5mg of moxifloxacin. This product is manufactured by Aurolab an Indian pharmaceutical company. Auromox available in many countries including Iraq.

Each vial enough for 15 different patients by using a sterile needle and 5cc syringe. By the sterile hand's, the surgeon drew the whole 1cc of moxifloxacin 0.5% and diluted with 4 cc of

Table1 Patients demographics, preoperative, intraoperative and postoperative ocular characteristics mean±SD

Data of the patients	T topical prophylaxis group 1 (*n*=500)	IC moxifloxacin + SC T triamcinolone prophylaxis group 2 (*n*=500)	*P*
Age	59.4±9.04	59.7±8.84	0.60
Preop. IOP	14.49±3.11	14.47±3.10	0.90
Preop. CMT	243.15±30.76	242.13±31.92	0.80
3- months IOP	12.49±2.63	12.41±2.38	0.60
3- months CMT	245.9±31.0	246.04±29.0	0.97
1-day AC reaction	0.59±0.19	0.57±0.17	0.03
1- week AC reaction	0.55±0.15	0.54±0.14	0.40
1-month AC reaction	0.21±0.29	0.19±0.27	0.80
Significant IOP elevation at 1mo	12/500 (2.4%)	4/500 (0.8%)	0.04
Breakthrough inflammation at 14-21d	48/500 (9.6%)	20/500 (4%)	0.00
Intraoperative complication			
PCR	15 (3%)	13 (2.6%)	0.70
With vitreous loss	12	10	
Without	3	3	
Endophthalmitis rate	No case 0.0/500	No case 0.0/500	

Preop: Preoperative; IOP: Intraocular pressure; AC: Anterior chamber; PCR: Posterior capsule rupture; IC: Intracameral; SC: Subconjunctival; CMT: Central macular thickness.

balanced salt solution (BSS) to get 5 mg in 5 cc (0.1%) then drew 0.2 cc for every patient.

Routine phacoemulsification surgeries were done, stromal hydration of the main incision by BSS till insured that it was sealed, 200 mg in 0.2 cc of moxifloxacin solution was administered in the anterior chamber through the side port.

Aurocort is a preservative-free triamcinolone acetonide (40 mg/1 cc), with along acting depot preparation of triamcinolone in 1cc vial also the product of Aurolab company and commercially available in our country.

The whole 1cc was drawn and diluted with 3 cc of BSS and SC injection of 4 mg in 0.4 cc of triamcinolone was given (as a final step in the surgery) 6 mm from the limbus usually an inferotemporal site that is easily accessible and the plaque that formed will be not visible within palpebral fissure. Every single vial of Aurocort can give protection against inflammation in 8 different patients. Postoperatively only oral analgesic was prescribed for the patients and no other topical eye drops except for 20 patients who had a breakthrough inflammation at 14-21d postoperatively.

The principal investigators at preoperative and postoperative evaluation were ophthalmologist and optometrist who didn't involve in the study.

Statistical analysis: Minitab 16 software used for data statistical analysis, data were expressed in mean±SD, for each group the preoperative baseline versus the corresponding postoperative data were compared by paired-sample *t*-test, while for the comparison of the 2 independent groups we used two-sample *t*-test and the results considered statistically significant if $P<0.05$.

RESULTS

The current clinical trial study involved 2 groups each with 500 phacoemulsification surgery patients.

For each group, the baseline data that included age, IOP and central macular thickness (within the central 1 mm) were compared with the other group and the results showed that there was no statistically significant differences between the 2 groups, $P=0.6$, 0.9 and 0.8 respectively.

For all patients, the follow-up visits were at 1d, 1wk, 1mo, and 3mo postoperatively. No single endophthalmitis case reported in both groups. IOP was measured for each patient at the last 3 visits by Goldman applanation tonometry to avoid corneal contact at the 1st postoperative visit.

A statistically significant reduction in the mean IOP at 3mo postoperative visit from the baseline data $P=0.000$ (by paired *t*-test) in both groups and the mean reduction at 3mo was 1.99±2.49 mm Hg and 2.07±2.33 for group 1 and 2 respectively.

Among topical medication group there were 12/500 patients (2.4%) developed ≥ 10 mm Hg elevation documented at a 1mo visit with 2 patients required topical IOP lowering agent while only four patients (0.8%) developed clinically significant IOP ≥10 mm Hg within group 2 documented at 1-month visit and the highest one was 26 mm Hg for them we didn't add any IOP lowering medication and there IOP was near the baseline level at 3-months visit. Therefore, SC triamcinolone treated group had a statistically significant lower chance of developing ≥10 mm Hg elevation of IOP than topical dexamethasone-treated group $P=0.04$.

The AC reaction was estimated by slit lamp and the grading

was done according to the Standardization of Uveitis Nomenclature (SUN) Working Group [13].

The mean AC cells were found to be less in group 2 (P=0.03) at the 1st postoperative day visit. For the remaining visits: no difference between both groups, it was at Grade 0.5+ to 1+ in a 1-week visit while at 1mo visit it was less than 5 cells (Grade 0.5+) and 3mo postoperatively the AC was almost clear (Grade 0).

A breakthrough inflammation was noticed at 14-21d postoperatively in 48/500 patients (20 of them had DM and 5 had PCR) in group 1 for them, the frequency of topical dexamethasone 0.1% was increased and a topical Ketorolac tromethamine 0.5% eye drops were prescribed 3 times a day for 2wk. This breakthrough inflammation rate was not related to diabetes as Chi-Square test showed P=0.13 while it was related to PCR as P=0.002.

In the 2nd group, 20/500 patients (4%) developed a breakthrough inflammation. All patients with inflammation had uncomplicated surgeries and 4 of them were diabetic. Again the breakthrough inflammation was not related to diabetes (P=0.4) by Chi-Square test. In this group of patients, the condition resolved by topical Ketorolac tromethamine 0.5% eye drops four times a day and tropicamide1% eye drops 3 times a day were administered for 2wk. When comparing the inflammation rate the 2nd group had a statistically significant lower chance to develop breakthrough inflammation than 1st group (P=0.00).

There is no statistically significant difference between the baseline central macular thickness and the 3mo postoperative data for both groups (P=0.09 and 0.21 respectively). And there is no statistically or the clinically significant difference between 3 months central macular thickness data for both groups (P=0.97).

DISCUSSION

As major concerns to ophthalmic surgeons after cataract surgery are bacterial endophthalmitis, inflammation, and CME; many different chemoprophylactic agents had been evaluated.

The current prospective study evaluated the use of Intracameral commercial available in Iraq preservative free moxifloxacin hydrochloride vial 0.5% (Auromox) in the concentration of 0.2 mg in 0.2 cc that was administered through the side port at conclusion of cataract surgery and was followed by the subconjunctival administration of a preservative-free triamcinolone 4 mg in 0.4 cc for the prophylaxis against infection, inflammation and cystoid macular edema in 500 cataract surgeries and compared its affectivity with other group of patients for them topical medications were used as a different chemoprophylactic method.

IC moxifloxacin and SC triamcinolone acetonide in their current concentration were shown to be effective as no endophthalmitis case was reported and as safe as no toxic reaction noticed. Provided that the reported minimum inhibitory concentration(MIC_{90}) value for moxifloxacin was 0.10 to 32 Mg/mL[14-16], the concentration that used in the current study was 200 Mg in 0.2 cc so the anterior chamber concentration of moxifloxacin was 12.5 (more than 10) times the MIC $_{90}$ of susceptible bacteria. For the concentration-dependent antibiotics like moxifloxacin were microbiological cure had been documented for the cases in which the inhibitory quotient (peak drug concentration/MIC_{90}) at that site exceeds 10[17].

Aravind *et al*[18]used the moxifloxacin hydrochloride vial (Auromox) 0.5% in 314638 eyes and reported 3.5 fold reduction in endophthalmitis rate the concentration that used 0.5 mg in 0.1cc where no mixing or dilution required but the safety and affectivity were also provided by our concentration of Auromox as long as the surgeon performed the dilution at the time of the operation so contamination or error in dilution or concentration didn't occur and the single vial of Auromox 0.5% was used for fifteen different patients.

Our current concentration of IC moxifloxacin was similar to that used by Arshinoff *et al*[19] who reported a single endophthalmitis case in 3430 when used diluted a self-preserved commercially available moxifloxacin eye drop in concentration 100 mcg in 0.1 cc while no endophthalmitis case reported in 4601 when the authors used 0.2-0.4 cc and regarded this concentration to be safer than 500 mcg in 0.1 cc because the last is more dilute. Regard the effect of our combination (IC moxifloxacin with SC triamcinolone) on postoperative inflammation at 1st postoperative day visit, the mean AC reaction was significantly lower than the topical medication prescribed group, this result agreed with Arbisser *et al*[11] , while no difference within the remaining postoperative visits between both groups.

The breakthrough inflammation rate within the IC moxifloxacin and SC triamcinolone treated group was 4 % that was lower than the rate in our topical medication treated group (9.6%). The rate of inflammation was not significantly different in diabetic patients from nondiabetic in both groups, as good controlled diabetes without retinopathy not significantly alter the postoperative inflammatory behavior[20-21].

The inflammation rate in ICand SC treated group (4%) is less than that reported by TMV that was 9.2% at 14-21d[12]. The difference may be related to the criteria of included patients, different concentration of triamcinolone that had been used and the different approach for administration. Also, this inflammation rate is less than the reported rate with the other potent topical corticosteroid that prescribed postoperatively by the most surgeon to reduce post-cataract surgery inflammation[22].

Our results showed that both approaches the topical and subconjunctival triamcinolone in the current concentration were effective in controlling postoperative inflammation but the subconjunctival approach had the lowest rate of breakthrough inflammation and higher control of AC reaction than potent topical corticosteroid.

At 3mo the AC almost clear in all patients and no single case of breakthrough inflammation at a 3mo visit. IOP changes in the current study showed a statistically significant reduction of the mean IOP at a 3mo postoperative visit from the baseline P=0.000 in both groups.

In the IC and SC treated group, a 0.8% (4/500) of the patients showed the elevation of IOP of ≥ 10 mm Hg at the 1month post-operative visit.This rate of IOP elevation was comparable to that reported by transzonular triamcinolone acetonide 3 mg in 0.2 cc approach (0.9%) by Tyson *et al*[12] but less than our reported rate (2.4%) within the topical steroid-treated group. Our results regard IOP elevation rate with topical dexamethasone 0.1% eye drops agreed with that reported with another topical steroid including difluprednate 0.05% (2.8 % with IOP change ≥ 10 mm Hg)[23] and prednisolone 1% (2.4% with IOP≥ 10 mm Hg)[24] that were prescribed after cataract surgery to prevent postoperative inflammation.

The current study provided that the subconjunctival approach of triamcinolone 4mg in 0.4 cc had less risk of IOP elevation than other approaches. The visible subconjunctival white plaque was almost disappeared by an 8wk postoperative visit.

There was no postoperative toxic reaction (TASS) that was rare but reported in a small number of the patient who received Intracameral vancomycin as prophylaxis against endophthalmitis after uneventful cataract surgery[25].

Macular thickness change after uncomplicated cataract surgery was evaluated by OCT with heterogeneous results some reported increase[26] in retinal thickness while a decrease was reported by others [27].

The current study evaluated the central 1mm macular thickness by OCT and showed no clinical or statistically significant changes at 3mo postoperatively from baseline data in both approaches with the mean difference was 2.99±1.9 mm and 3.75±1.66 mm respectively for group 1 and 2. Our result agreed with Pardianto *et al*[28] who reported an insignificant increase in CMT P=0.068 as measured 2mo postoperatively and compared with preoperative data.

Variation in results of the previous report of macular thickness post cataract surgeries may relate to difference in postoperative treatment regimen that prescribed or difference in OCT devices that used for macular thickness evaluation also a possible cause was the patients who included in this study were those with normal macular appearance by slit lamp and with normal baseline macular OCT and any patient with suspicious or abnormal OCT were excluded from our study. Our result was the same for non-diabetic patients and diabetic patients with no maculopathy.

The current study cannot precisely reflect the endophthalmitis rate after cataract surgery because of the small number of patients who included in each group. To get a prospective study with a large number of patients operated at the same center, at the same standard conditions by the same surgeon we require a longer period of time that would delay our study. Our future work will be with a larger sample and also to show the effectivity of such combination in the pediatric population.

ACKNOWLEDGEMENTS

Conflicts of Interest: Rattan SA, None; **Mohammed NK,** None; **Mutashar MK,** None.

Peer Review File: Available at: http://ier.ijo.cn/gjykier/ch/reader/download_attache_file.aspx?seq_id=20210325152900001&flag=1&journal_id=gjykier&year_id=2020&issue=3

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