

Study of the Efficacy of Postoperative Topical NSAID for Prevention of Pseudophakic Macular Edema after Phacoemulsification Complicated with Rupture Posterior Capsule and Vitreous Prolapse

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Abstract

Background: Pseudophakic cystoid macular edema (PCME) is an important cause of drop of visual acuity after phacoemulsification especially in complicated cases, studies have focused on the ability of non-steroidal anti-inflammatory drops (NSAIDs) to prevent PCME.

Aim of Study: This study aimed at evaluating the NSAIDs in prevention of PCME in phacoemulsification patients complicated by vitreous loss.

Patients and Methods: This study included 40 eyes of 40 patients complicated with vitreous loss, 20 of them received standard treatment and the other 20 received the standard treatment in addition to NSAIDs, each patient underwent assessment of BCVA and OCT macula scanning at 1st week and 1st month.

Results: This study found that NSAIDs attained better BCVA values when compared to patients who received the standard treatment only, they also recorded lower CMT thickness, however there were no significant difference between the 2 groups when patients with intraretinal cystoid changes were excluded.

Conclusion: At 1 month postoperative, patients who received NSAIDs had significantly better BCVA and did not develop intraretinal cysts.

Key Words: Pseudophakic macular edema — Ocular coherence tomography — Non-steroidal anti-inflammatory eye drops — Phacoemulsification.

Introduction

DESPITE advancements in surgical techniques and technology, cataract surgery may still induce an inflammatory response, which may cause serious adverse events if left untreated, such as increased intraocular pressure and cystoid macular oedema

(CME), leading eventually to decreased visual acuity [1].

As originally described by Gass, pseudophakic CME appears 4 to 12 weeks post-surgery [2].

Indeed, surgery results in a significant release of inflammatory mediators, including arachidonic acid, source of the inflammatory cascade, proinflammatory cytokines, lysozyme or vascular endothelial growth factor (VEGF). This leads to an impairment of the blood-retinal barrier and an increase in vascular permeability [3].

The mechanism of action of non-steroidal anti-inflammatory Drugs (NSAIDs) involves the inhibition of the cyclooxygenase (COX) enzymes, namely COX-1 and COX-2, which are responsible for prostaglandin production [4].

Since prostaglandins mediate inflammatory reactions, the prevention of their formation reduces the inflammatory process [5].

Many risk factors for pseudophakic macular edema have been identified including posterior capsule rupture, uveitis, retinal vein occlusion, retinal detachment repairs, and diabetic retinopathy [6].

The purpose of our study is to compare the use of postoperative both topical steroids and topical Nepafenac 0.1% for 1 month to the use of only postoperative topical steroids, in order to understand if the postoperative administration of this topical NSAID can affect the incidence or the severity of pseudophakic CME occurring after phacoemulsification complicated with rupture posterior capsule and vitreous loss.

Aim of study:

The aim of this study was to assess the efficacy of the postoperative administration of topical non-steroidal anti-inflammatory eye drops in the

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prevention of pseudophakic macular edema in patients with rupture posterior capsule and vitreous prolapse.

Patients and Methods

A prospective randomized case control study that included 40 eyes on which cataract surgery was done and were complicated by rupture posterior capsule, 20 eyes received the usual postoperative treatment and 20 eyes received non-steroidal eye drops for 1 month (Nepafenac 0.1%) 3 times per day. The study was conducted at Ain Shams University Hospital, Cairo, Egypt, in accordance with the ethical standards stated by the Ethical committee of Ain Shams University from March 2022 — April 2023.

The inclusion criteria were: Patients with clinically significant cataract who underwent cataract surgery and was complicated by rupture of posterior capsule and vitreous loss and Age between 20-80 years old. While the exclusion criteria were: Patients with previous ocular surgeries or diseases affecting the macula as diabetic retinopathy, Patients with hypersensitivity to NSAIDs, Other causes of macular edema including systemic and topical prostaglandins, Patients with persistent corneal edema postoperative, Patients with pathological myopia having atrophic maculopathy on fundus examination, Use of intraoperative triamcinolone acetate during anterior vitrectomy and patients who were complicated with postoperative retinal detachment.

Postoperative workup:

All patients underwent phacoemulsification under local anesthesia using the White star Signature phacoemulsification system (Abbott Medical Optics Inc.) and the stop and chop technique was adopted which is the standard phacoemulsification technique at our institution.

Patients incidentally complicated with rupture posterior capsule and intraoperative vitreous loss and had anterior vitrectomy and implantation of either single piece IOL in the bag, 3 piece IOL in the sulcus or retropupillary verysise underwent full ophthalmological examination including measurement of BCVA in addition to OCT macula study within first week postoperative by utilizing the macula map study, raster and radial line scans, this was done to allow the corneal edema and inflammation to resolve and aid in obtaining clear OCT images. Then the patients were classified into two groups:

Group 1: Received the usual postoperative treatment including topical Moxifloxacin 0.5% (Vigamox@, Novartis, Switzerland) every 2 hours for 2 weeks and topical prednisolone acetate 1% (Optipred@, Jamjoom, Saudi Arabia) every 2 hours tapered gradually for 1 month, in addition to Nepafenac 0.1% (Nevanacil), Novartis, Switzer-

land) 3 times per day for 1 month and Group 2: Received the usual postoperative treatment only.

Both groups were followed-up after one month to measure the postoperative unaided and best corrected visual acuity using the Landoll C acuity chart which was then converted to Log.MAR for statistical analysis and a follow-up OCT macula study.

CME was considered when there was a 10% increase of CMT after surgery or the appearance of intraretinal cysts [7].

Statistical analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric and median, inter-quartile range (IQR) when data found non-parametric. Also qualitative variables were presented as number and percentages. The p-value was considered significant as the following: p-value > 0.05: Non significant (NS), p-value 4:1.05: Significant (S), p-value 4:1.001: Highly significant (HS).

Results

This was a randomized prospective case control study that was conducted on 40 eyes of 40 patients with incidental posterior capsular rupture and vitreous loss during phacoemulsification collected from Ain Shams University from March 2022 to April 2023, 31 of them were females and 9 were males, their age ranging from 27 to 80 years and their demographic data and characteristics are discussed below.

These patients were divided into 2 groups:

Group 1: Received the usual postoperative treatment including topical Moxifloxacin 0.5% (Vigamox01), Novartis, Switzerland) and topical prednisolone acetate 1% (Optipred@, Jamjoom, Saudi Arabia) in addition to Nepafenac 0.1% (Nevanacil), Novartis, Switzerland). Group 2: Received the usual postoperative treatment only.

Optical coherence tomography data and comparison between 2 groups:

In the 1st week postoperative visit, the BCVA was measured for all patients in addition to the OCT macula study and their results are summarized in (Table 1). In this table it is shown that there was no statistically significant difference between group 1 and group 2 regarding the studied parameters at 1st postoperative week.

After 1 month, the BCVA was re-measured and the OCT macula study was repeated with the same study parameters done in the 1st week postoperative visit adding to it the relative change in thickness and their results are shown in (Table 1).

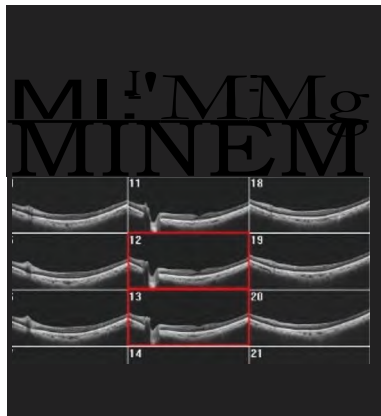
Table (3): Comparison between group 1 and group 2 regarding IOL position, power, estimated surgery time and presence of intraretinal cysts.

		Group 1 (with nevanac)	Group 2 (without)	Test value	P-value	Sig.
		No. = 20	No. = 20			
IOL Position	3p sulcus	12 (60.0%)	14 (70.0%)	0.554*	0.758	NS
	Sp bag	6 (30.0%)	4 (20.0%)			
	Retro verysize	2 (10.0%)	2 (10.0%)			
IOL Power	Mean ± SD	23.21±2.2	203±2.72	3.718•	0.001	HS
	Range	20.5-29	13.5-25			
Estimated surgery time	Mean ± SD	58±8.91	55.81±7.83	0.824•	0.415	NS
	Range	43-75	44-68			
Presence of intraretinal cysts	Yes	0 (0.0%)	4 (20.0%)	4444*	0.035	S
	No	20 (100.0%)	16 (80.0%)			

p>0.05: Non-significant (NS).
 ps0.05: Significant (S).
 s0.001: Highly significant (HS).
 • : Independent t-test.
 *: Chi-square test.

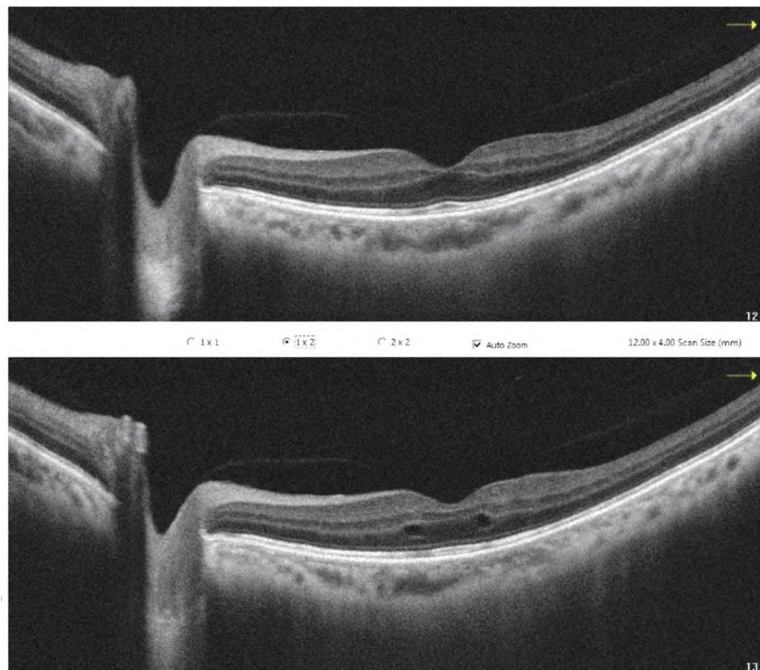
IOL: Intraocular lens.
 3p : Three piece IOL.
 Sp : Single piece IOL.
 Retro very size: Retropupillary a phakicvery size.

Raster



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Fig. (1): OCT raster scans of a patient from group 2 after 1 month showing intraretinal cystoid changes.

The correlation between CMT at 1st week postoperative and the quantitative parameters was also studied but it was found that there was no statistically significant correlation between CMT at 1st week and the patient's gender, type of cataract and presence of PVD.

Correlation between CMT at 1st month and all the quantitative parameters studied was assessed

and showed that the CMT at 1st month is inversely correlated to the patient's age and BCVA (Log. MAR) with a p-value 0.034 and 0.009 respectively (Figs. 5,6), whereas it is directly correlated with the foveal volume at 1st month and the thickness of the outer inferior sector with a p-value 0.00 and 0.039 respectively. (Figs. 7,8).

Table (4): Comparison between group 1 and group 2 regarding the studied parameters at 1st month postoperative.

		Group 1 (with nevanac)	Group 2 (without)	Test value.	P-value	Sig.
		No. = 20	No. = 20			
CMT	1st wk postop.	244.32±12 (220-272)	239.52±6.94 (220-251)	1.548	0.130	NS
	1st ^m postop.	263.74±15.6 (230-290)	342.46±141.08 (240-678)	-2.480	0.018	S
	Excluding intraretinal cysts cases	263.74±15.60(230-290)	297.70±84.49(240-463.5)	-1.767	0.086	NS
BCVA (LogMar)	1st wk postop.	0.97±0.42 (0.48- 2.08)	0.76±0.24 (0.3-1.3)	1.874	0.069	NS
	1st ^m postop.	0.4±0.13 (0.18-0.6)	0.6±0.26 (0.3-1.3)	-3.116	0.003	S
	Excluding intraretinal cysts cases	0.40±0.13 (0.18- 0.6)	0.55±0.19 (0.3-0.89)	-2.899	0.007	S
Relative change in thickness (%)	Median (IQR)	0.1 (0.08-7.8)	2.11 (0.27-7.93)	0.677	0.498	NS
	Range	0.0-12.7	0.6-175			
	≤10%	16 (80.0%)	17 (85.0%)	0.173	0.677	NS
	>10%	4 (20.0%)	3 (15.0%)			
Foveal volume	1st wk postop.	0.19±0.01 (0.17 -0.21)	0.19±0.01 (0.17-0.2)	1.514	0.138	NS
	1st ^m postop.	0.21±0.01 (0.18-0.23)	0.27±0.11 (0.19-0.53)	-2.480	0.018	S
Inner sup. Sector	1st wk postop.	312.66±11.33 (292-338)	316.12±12.51 (280-336)	-0.917	0.365	NS
	1st ^m postop.	334.56±15.22 (306 -366)	363.07±52.29 (310-516)	-2.341	0.025	S
Inner nasal sector	1st wk postop.	312.65±13.59 (289-343)	314.3±13.58 (277-337)	-0.384	0.703	NS
	1st ^m postop.	333.8±16.42 (312-366)	379.86±78.91 (302-588)	-2.556	0.015	S
Inner inf. Sector	1st wk postop.	307.75±14.47 (278-341)	312.56±12.29 (277-329)	-1.133	0.264	NS
	1st ^m postop.	327.29±17.24 (298-363)	375.3±77.99 (305-569)	-2.688	0.011	S
Inner temporal sector	1st wk postop.	301.17±13.59 (274-326)	303.82±13.38 (263-322)	-0.621	0.538	NS
	1st ^m postop.	321.44±17.07 (291-352)	372.95±91.46 (287-648)	-2.476	0.018	S
Outer sup. Sector	1st wk postop.	283.68±12.59 (257-311)	278.05±9.54 (262-296)	1.592	0.120	NS
	1st ^m postop.	303.1±18.8 (267-339)	315.43±49.58 (272-477)	-1.039	0.305	NS
Outer nasal sector	1st wk postop.	291.45±14.76 (272-327)	291.42±9.87 (275-310)	0.006	0.995	NS
	1st ^m postop.	311.47±21.11 (283-357)	333.68±53.68 (286-505)	-1.721	0.093	NS
Outer inf. Sector	1st wk postop.	273.38±13.96 (248-310)	269.76±9.42 (252-289)	0.959	0.343	NS
	1st ^m postop.	288.1±17.01 (256-328)	308.16±48.67 (265-457)	-1.740	0.090	NS
Outer temporal sector	1st wk postop.	272.91±15.37 (239-303)	267.06±11.09 (242-281)	1.381	0.175	NS
	1st ^m postop.	287.85±18.69 (242-329)	305.76±48.22 (260-459)	-1.549	0.130	NS
Presence of intraretinal cysts	Yes	0 (0.0%)	4 (20.0%)	4.444*	0.035	S
	No	20 (100.0%)	16 (80%)			

p>0.05: Non-significant (NS).
 ps0.05: Significant (S).
 s0.001: Highly significant (HS).
 •: Independent t-test.
 *: Chi-square test.

CMT : Central macular thickness.
 BCVA: Best corrected visual acuity.
 Sup.: Superior.

Inf.: Inferior.
 SD : Standard deviation.
 IQR: Interquartile range.

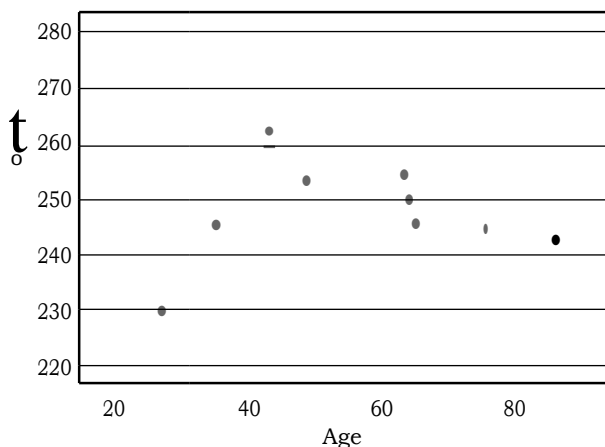


Fig. (2): Correlation between CMT in Itm at 1st week postoperative and age of the studied patients.

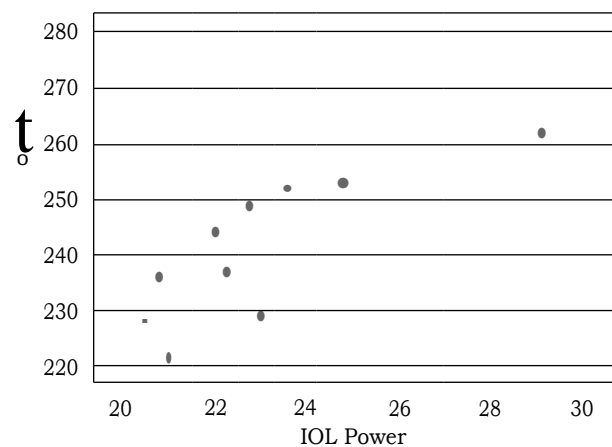


Fig. (3): Correlation between CMT in Itm at 1st week postoperative and IOL power of the studied patients.

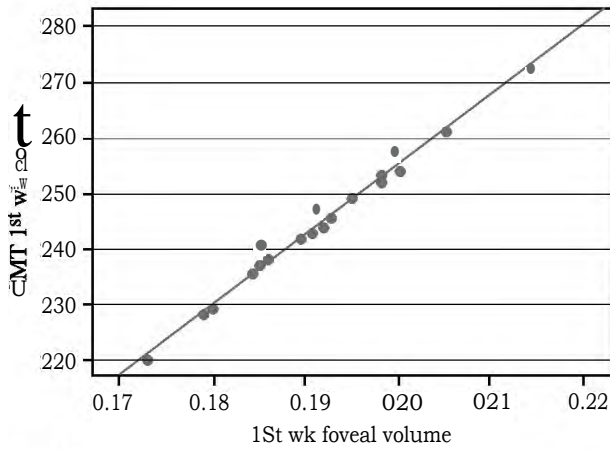


Fig. (4): Correlation between CMT in pm at 1st week postoperative and 1st week foveal volume in mm³ of the studied patients.

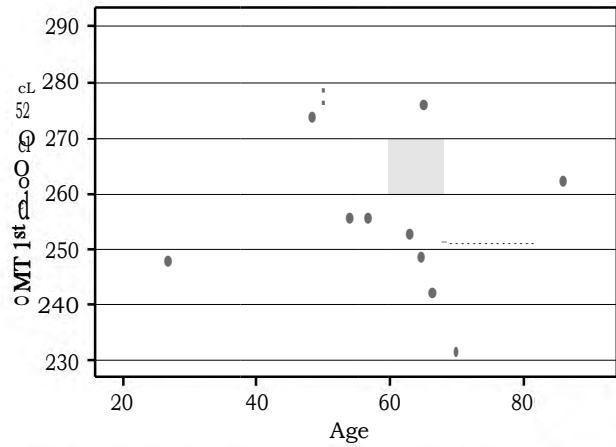


Fig. (5): Correlation between CMT in pm at 1st month postoperative and age of the studied patients.

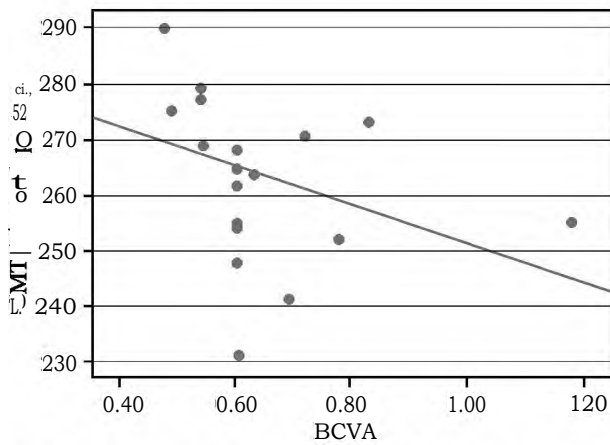


Fig. (6): Correlation between CMT in pm at 1st month postoperative and BCVA (Log.MAR) of the studied patients

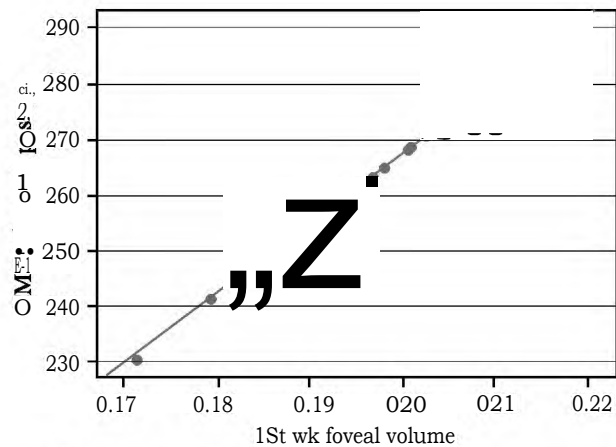


Fig. (7): Correlation between CMT in pm at 1st month postoperative and 1st month foveal volume in mm³ of the studied patients.

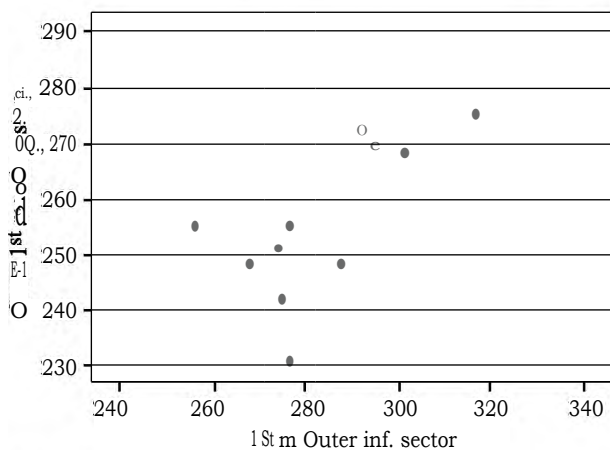


Fig. (8): Correlation between CMT in pm at 1st month postoperative and 1st month outer inferior sector thickness in pm of the studied patients.

Discussion

Nepafenac is a neutral prodrug with superior permeability characteristics compared with oth-

er available topical NSAIDs. Ke et al. [8] topical nepafenac penetrated to the posterior segment, where it decreased PGE2 concentrations, indicating stabilization of the blood—retina barrier [9]. This study was conducted to evaluate such action in prevention of CME.

In this case control study we used the OCT macula with the raster, radial scan and retina map to evaluate the patients who were incidentally complicated during phacoemulsification with posterior rupture and vitreous loss and in the study we compared the use of nepafenac in addition to the usual treatment to using the usual treatment only, in terms of improving BCVA and CMT after 1 month.

The present study also elaborated the significant higher CMT, foveal volume and parafoveal sectors' thickness in group 2 than group 1 after 1 month. Also CMT was directly correlated with the foveal volume both at 1st week and 1st month postoperative as well as the significant higher incidence of intraretinal cystoid changes among group 2 patients after 1 month. However, there were no significant

difference in the number of patients with relative change in CMT more than 10% between the 2 groups and there were no significant change in the CMT at 1st month between the 2 groups after exclusion of patients who developed intraretinal cysts.

The lack of a standard definition for CME might contribute to the lack of consensus regarding the efficacy of nepafenac in preventing PCME. The results of Wolf et al. [10] showed a reduction in visually significant CME in patients treated with nepafenac and prednisolone compared with patients treated with prednisolone alone (0% and 2%, respectively; $p=0.0354$), supporting the addition of topical ocular nepafenac therapy to standard postoperative steroid agents but this study did not only include uneventful cases but they also did not specify in their methodology their OCT standard for diagnosis of CME, instead they only mentioned that if cystic changes were evident in the OCT at 1 month postoperative, the patient was started on a regimen of nonsteroidal anti-inflammatory and steroid drops.

This also applies to the results from the clinical trial by Singh et al. [11] that showed a significantly larger percentage of patients with moderate to severe non-proliferative diabetic retinopathy with no pre-existing macular edema treated with the vehicle developed CME (16.7%) compared with those treated with nepafenac (3.2%) ($p<0.001$) at 90 days postoperative, patients also instilled prednisolone acetate ophthalmic suspension (Omnipred™; Alcon Research Ltd) into the study eye four times daily for 2 weeks postoperative or longer if considered necessary to treat anterior segment inflammation. But in this trial, macular edema was defined as an increase of 30% or more in central subfield macular thickness relative to the presurgical baseline measurement.

In the same study, they also evaluated the patients at day 30 (8.7% developed CME in the vehicle treated group versus 2.4% in the nepafenac treated group, $p=0.029$).

Whereas in a systematic review by Han et al. [12], they concluded that there is still no high quality evidence to whether prophylactic topical NSAIDs in routine phacoemulsification cases actually reduces the risk of developing PCMO compared to existing postoperative regimens.

As regards the BCVA, the present study demonstrated the better BCVA in group 1 patients compared to group 2 at 1st month postoperative even after exclusion of patients who developed intraretinal cysts. This came in contradiction to what was found by Tzelikis et al. [13] where they found that the BCVA was comparable and there was no intraindividual significant difference between the eyes which received nepafenac 0.3% once daily for 5 weeks postoperative and those which received prednisolone 0.1% only with gradual tapering at both 5

and 12 weeks postoperatively in the same patient, but these patients were low risk, uneventful cases.

Mathys and Cohen [14], also found that the increase in OCT-measured macular thickness after phacoemulsification is small and has no clinical effect on visual acuity, but their study was also on low risk cases only and BCVA was measured 2 months postoperative. Meanwhile, the trial done by Singh et al. [15], on at risk patients (Diabetics), found that patients in the nepafenac group maintained better visual acuity and a larger percentage of patients in the vehicle treatment group experienced a decrease of >5 letters in BCVA from day seven to day 90 (11.5% as compared with 5.6% of patients receiving nepafenac).

In the present study, the CMT at 1st week and at 1st month was inversely correlated with patient's age, this was also reported by Ylinen et al. [15], where they found that young patient age and poor glycemic control were risk factors for postoperative central retinal thickness increase in diabetic patients who underwent uneventful cataract surgery. Whereas a database study showed statistically significant findings of older age in the patients who developed cystoid macular edema but this included patients at risk (complicated cases and diabetics) as well as low risk patients [6].

The present study also demonstrated a direct correlation between CMT at 1st month and IOL power, however in a study by Henderson et al. [16], they found no statistically significant difference in the axial length between the patients who developed CME and the patients who did not. This was also reported by Ylinen et al. [15], in their study on diabetic patients who underwent cataract surgery.

Therefore, the present study was a prospective case control having patients treated with prednisolone and moxifloxacin as controls, it demonstrated the efficacy of nepafenac 0.1% three times daily as regard the better BCVA at 1st month which was the primary outcome and as regard CMT which was the secondary outcome, patients received nepafenac had a lower CMT at 1st month, however, there were no statistically significant difference between the 2 groups after exclusion of patients who developed intraretinal cystoid changes.

Study limitations:

On the other side, the present study had its limitations represented in the small number of patients, its short term follow up period (only 1 month) and lack of preoperative OCT data.

Conclusion:

After complicated cataract surgery, there was a significant effect in patients who received nepafenac prophylactically in terms of BCVA and prevention of intraretinal cystoid changes at 1 month postoperative.

Although CMT was statistically found to be higher in patients who received the standard treatment only, there was no significant difference between the 2 groups regarding CMT after excluding patients who developed intraretinal cystoid changes. Further studies are recommended to assess the efficacy of nepafenac in complicated cataract cases in the long term, on larger scale of patients with pre-operative OCT assessment for the patients.

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دراسة فعالية مضادات الالتهاب غير الستيرويدية الموضعية بعد الجراحة للوقاية من الوذمة البقعية الكاذبة بعد عملية إزالة المياه البيضاء بالفاكو المصحوبة بتمزق الكبسولة الخلفية و تدلى الجسم الزجاجى

كانت هذه دراسة مراقبة حالة مستقبلية تهدف إلى تحديد فعالية النيبافيناك ٠,١ ٪ الذى يعطى ٣ مرات يومياً لمدة شهر واحد بعد العملية الجراحية فى الوقاية من الوذمة البقعية الكاذبة فى المرضى الذين خضعوا لعملية ازالة المياه البيضاء بالفاكو وكانت مصحوبه بتمزق الكبسولة الخلفية وفقدان الجسم الزجاجى.

شملت الدراسة ٤٠ عيناً لـ ٤٠ مريضاً، تم إعطاء ٢٠ منهم العلاج القياسى من الموكسيفلوكساسين وقطرات العين الستيرويدية، بينما تم إعطاء ٢٠ آخرين النيبافيناك بالإضافة إلى العلاج القياسى. تم تقييم حدة الإبصار المصححة وسمك البقعة المركزية لكل مريض فى الأسبوع الأول والشهر الأول بعد العملية الجراحية.

وجدت الدراسة الحالية أن المرضى الذين تم علاجهم بالنيبافيناك كان لديهم حدة إبصار مصححة أفضل إحصائياً بعد شهر واحد من العملية، ووجدت أيضاً أن النيبافيناك كان فعالاً فى الوقاية من التغيرات الكيسية داخل الشبكية.