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Original Article

STUDY OF MACULAR THICKNESS, MICRO-VASCULAR, AND PERI PAPILLARY NERVE FIBER LAYER THICKNESS CHANGES AFTER UNCOMPLICATED PHACOEMULSIFICATION IN DIABETIC AND NON DIABETIC PATIENTS

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Abstract

Background: *phacoemulsification continues to be one of the most popular surgical procedures for cataract extraction in the ophthalmologic practice. Optical Coherence Tomography (OCT) is a noninvasive and noncontact diagnostic tool with high resolution to assess macular changes.* ***Aim of the study:*** *evaluate changes in macular thickness, micro vascular changes and peri papillary NFL thickness that occur after uncomplicated phacoemulsification surgery in eyes with and without DR in diabetic patients and in a control group.* ***Methods:*** *This study was designed as Prospective, non-randomized study controlled clinical trial. included 100 eyes. Included Diabetic and non-diabetic patients were scheduled for phacoemulsification surgery with intraocular lens (IOL) implantation included divided into four groups: control group, non-diabetic, diabetic with no DR, diabetic with mild -moderate NPDR, diabetic with severe NPDR. The central retinal (foveal) thickness microvascular changes & peripapillary NFL thickness of all patients measured with OCT one week and 1, 3, and 6 months after surgery. A fundus examination with full pupil dilation performed during each scheduled examination.* ***Results:*** *There was non-significant difference in central macular thickness CMT, RNFL after one month there was a significant difference between groups while after 3 & 6 months the difference was highly significant. Regarding visual acuity evaluation there was significant difference between different groups at preoperative and after 1week in the BCVA, also there was moderate significant difference between different groups after 1month, 3months & 6months.* ***Conclusion:*** *cataract phacoemulsification cause increase in CMT, RNFL thickness and SCP values in diabetic with different severities of retinopathy.*

Keywords: *Cataract, phacoemulsification, OCT, Diabetic, Microvascular.*

1. Introduction

When a cataract develops, light cannot enter the eye's retina because of a clouding or opacification of the typically clear lens or the capsule that surrounds it [1]. Early on, the disease process advances gradually without interfering with daily activities. However, with time, particularly during the fourth or fifth decade, the cataract will finally mature and become totally opaque to light, interfering with daily activities [2]. Globally, diabetes is becoming more prevalent, and those who have the condition have a higher risk of developing cataracts than people who do

not [3]. At present, there are two main surgical techniques: phacoemulsification and posterior chamber intraocular lens insertion [4]. In phacoemulsification, a contemporary cataract procedure, the internal lens of the eye is extracted and emulsified using an ultrasonic hand piece. Moving along the longitudinal axis of the phacoemulsification tip, the longitudinal US power employed in the basic phacoemulsification hand piece and tip oscillates. The chattering and repulsion of the fractured lens material away from the aspirating port result from the lens material being sliced as the tip strikes the lens [5]. A common complication following uncomplicated cataract surgery is a Cystoid macular edema (CME) in patients with or without diabetes. It is measured by an alteration in CMT using optical coherence tomography (OCT). The condition is one of the main reasons of poor visual results [6]. Optical coherence tomography (OTT) quantifies the amount of back-reflected light and the echo time delay to create two- or three-dimensional images. This noninvasive, noncontact medical imaging method allows for the quantitative measurement of retinal thickness and volume. OCT is the only noninvasive diagnostic method that can produce images of the vitreous, retinal, and choroidal structure. Its scans have been compared to light microscopy images of histologic sections [7]. The purpose of this study to evaluate changes in macular thickness, micro vascular changes and peri papillary NFL thickness that occur after uncomplicated phacoemulsification surgery in eyes with and without DR in diabetic patients and in a control group.

2. Patients & Methods

This study was designed as Prospective, non-randomized study controlled clinical trial. Prospective, comparative, nonrandomized study included 100 eyes. The study was conducted in Al-Azhar University hospital, from February 2021 to February 2022. The study was approved by the Ethics Committee in the Faculty of Medicine, Al-Azhar University, Assuit Branch. Included diabetic and non-diabetic patients were scheduled for phacoemulsification surgery with intraocular lens (IOL) implantation included in this study and divided into four groups: **1)** control group, non-diabetic patients (25 patients) **2)** diabetic patients with no DR (25 patients) **3)** diabetic patients with mild -moderate NPDR (25 patients) **4)** diabetic patients with severe NPDR (25 patients)

2.1. *Methods*

Systematic: Patients were asked about their previous general medical history. Patients were asked about duration of DM and its control and last HA1C Patients asked about associated diseases as Anemia, HTN and hyperlipidemia. **Ocular:** Patients will be asked about their ocular history regarding medical and surgical ophthalmic history and history of trauma and History of intraocular injection of anti VEGF. All patients had complete ophthalmologic examinations, including the measurement of corrected distance visual acuity (CDVA) in logarithm of the minimum angle of resolution (logMAR), the measurement of intraocular pressure (IOP) with Schiotz contact tonometer, the measurement of axial length (AL) with A scan, a slit lamp bio-microscopy, cataract grading with the Lens Opacities Classification System III, and a dilated fundus evaluation. Immediate preoperative counseling before starting the treatment, the patient counseled about what to expect during the procedure Surgery performed under peribulbar local anesthesia; sterile drape placed over the skin and eyelashes. The central retinal (foveal) thickness, micro vascular changes and peripapillary NFL thickness of all patients measured with OCT one day before surgery. The central retinal (foveal) thickness microvascular changes and peripapillary NFL thickness of all patients measured with OCT one week and 1, 3 and 6 months after surgery. A fundus examination with full pupil dilation performed during each scheduled examination.

2.2. *Statistical analysis*

Data were fed to the computer and analyzed using IBM SPSS software package version 26.0 ***(***IBM Corp**).** Qualitative data were described using number and percent. Independent sample t-test was used to compare quantitative variables between groups. P-value considered stat-istically significant when P < 0.05. As regard using ANOVA between variables with different groups. Using paired T test to comparing parameter change with time in the same group.

3. Results

The demographic data of all included patients are shown in tab. (1). There was non-significant difference (P>0.05) between different groups as regard gender age, site and treatment of diabetes. There was moderate significant difference (P<0.001) between different study groups as regard to duration of diabetes. There was non-significant difference in central macular thickness CMT (P>0.05) between different groups at baseline and after 1 week, however after one month there was a significant difference (P<0.01) between groups while after 3 & 6 months the difference was highly significant (P<0.001) as shown in tab. (2). Regarding visual acuity evaluation there was significant difference (P<0.05) between different groups at preoperative and after 1 week in the BCVA, also there was moderate significant difference (P<0.001) between different groups after 1 month, 3 months & 6 months. However, the difference between the baseline and each postoperative follow up visits was highly significant (P<0.000) in each group as shown in tab. (3). Table (4) shows the comparison between groups regarding Retinal nerve fiber layer thickness "RNFL". There was significant difference (P<0.05) between different groups at preoperative and after 1week, also there was moderate significant difference (P<0.001) between different groups after 1 month & there was highly significant difference (P<0.000) after 3 & 6 months. There was highly significant difference (P<0.05&<0.000) in group 1 & 4 at different follow up periods, also there was moderate significant different (P<0.001) in group 2 & 3 at different follow up periods. The micro vascular changes over the follow up periods in each group are shown in tab. (5). There was significant difference (P<0.05) between different groups at preoperative and after 1 week, also there was moderate significant difference (P<0.001) between different groups after 1 month & there was highly significant difference (P<0.000) after 3 & 6 months. There was highly significant difference (P<0.05& P<0.000) at different follow up periods in group 1 & 4, also there was moderate significant different (P<0.001) in group 2 & 3 at different follow up periods.

Table 1: Demographic data in study groups.

Item	G1 "n=25"	G2 "n=25"	G3 "n=25"	G4 "n=25"	p-value
Gender:					
▪ ***Female***	13(52.0%)	8(32.0%)	10(40.0%)	9(36.0%)	P= 0.691n.s
▪ ***Male***	12(48.0%)	17(68.0%)	15(60.0%)	16(64.0%)	
Age "years":					
▪ ***Mean ± SD***	57.38±4.82	61.61±5.14	56.91±4.17	57.83±5.81	P= 0.485n.s
▪ ***(Range)***	(31-65)	(51-68)	(47-64)	(51-67)	
Site:					
▪ ***Left***	5(20.0%)	10(40.0%)	15(60.0%)	16(64.0%)	P= 0.395n.s
▪ ***Right***	20(80.0%)	15(60.0%)	10(40.0%)	9(36.0%)	
Treatment of DM:					
▪ ***Insulin***	---	8(32.0%)	12(48.0%)	13(52.0%)	P= 0.643n.s
▪ ***Oral***		17(68.0%)	13(52.0%)	12(48.0%)	
Duration of DM "months":					**P<0.001****
▪ ***Mean ± SD***	---	105.41±17.35	185.29±39.45	198.95±43.51	
▪ ***(Range)***		(85-134)	(142-245)	(165-259)	

Table 2: Comparison between groups according to central macular thickness CMT in each group.

Item	G1 "n=25"	G2 "n=25"	G3 "n=25"	G4 "n=25"	p-value
Pre- operative:					
▪ ***Mean± SD***	187.75±24.56	185.43±16.42	212.79±40.76	224.23±17.76	P= 0.086n.s
▪ ***(Range)***	(160-225)	(165-210)	(156-265)	(175-270)	
1 week:					
▪ ***Mean± SD***	194.46±25.76	200.78±16.73	227.89±18.76	253.43±21.43	P= 0.437n.s
▪ ***(Range)***	(160-230)	(185-220)	(175-250)	(200-280)	
1 month:					P<0.01*
▪ ***Mean± SD***	207.43±26.75	225.46±28.46	285.76±67.45	305.43±82.46	
▪ ***(Range)***	(175-280)	(195-300)	(195-390)	(205-420)	
3 months:					P<0.001**
▪ ***Mean± SD***	202.25±21.45	235.54±23.55	274.40±59.27	298.65±75.67	
▪ ***(Range)***	(177-260)	(192-265)	(195-370)	(195-410)	
6 months:					P<0.001**
▪ ***Mean± SD***	198.78±25.46	205.76±24.76	270.46±56.22	292.34±71.46	
▪ ***(Range)***	(178 -250)	(189 – 245)	(195 – 320)	(190 – 405)	
P-value	**P<0.03***	**P<0.001****	**P<0.001****	**P<0.001****	

Table 3: Comparison between groups according to BCVA over the periods in each group.

Item	G1 "n=25"	G2"n=25"	G3"n=25"	G4"n=25"	p-value
Pre-operative:					
▪ ***Mean± SD***	0.17±0.03	0.14±0.03	0.14±0.04	0.16±0.03	**P<0.02***
▪ ***(Range)***	(0.125-0.2)	(0.125-0.17)	(0.12-0.16)	(0.12-0.19)	
1 week:					
▪ ***Mean± SD***	0.30±0.10	0.26±0.04	0.23±0.04	0.26±0.05	**P<0.01***
▪ ***(Range)***	(0.2-0.5)	(0.2-0.35)	(0.18-0.27)	(0.19-0.30)	
1 month:					
▪ ***Mean± SD***	0.49±0.15	0.45±0.16	0.31±0.09	0.35±0.06	**P<0.001****
▪ ***(Range)***	(0.25-0.8)	(0.2-0.70)	(0.2-0.4)	(0.21-0.45)	
3 months:					
▪ ***Mean± SD***	0.53±0.10	0.49±0.13	0.37±0.09	0.40±0.07	**P<0.001****
▪ ***(Range)***	(0.32-0.8)	(0.30-0.69)	(0.2-0.5)	(0.2-0.5)	
6 months:					
▪ ***Mean± SD***	0.59±0.13	0.52±0.11	0.39±0.09	0.42±0.07	**P<0.001****
▪ ***(Range)***	(0.4-0.8)	(0.35-0.68)	(0.2-0.5)	(0.2-0.5)	
P-value	**P<0.000*****	**P<0.000*****	**P<0.001****	**P<0.000*****	

Table 4: Comparison between groups regarding Retinal nerve fiber layer thickness "RNFL" over the follow up periods in each group.

Item	G1 "n=25"	G2"n=25"	G3"n=25"	G4"n=25"	p-value
Pre- operative:					
▪ ***Mean± SD***	84.31±11.41	87.42±8.76	91.24±12.43	95.76±9.76	P= 0.375n.s
▪ ***(Range)***	(75-94)	(76-98)	(79-105)	(82-109)	
1week:					
▪ ***Mean± SD***	95.76±12.45	103.45±10.76	115.23±14.67	124.46±16.12	**P<0.02***
▪ ***(Range)***	(85-125)	(95-115)	(96-138)	(96-154)	
1month:					
▪ ***Mean± SD***	98.37±16.77	110.77±16.79	119.45±19.46	128.46±17.89	**P<0.001****
▪ ***(Range)***	(90-128)	(97-139)	(102-145)	(110-150)	
3 months:					
▪ ***Mean± SD***	101.04±17.14	112.33±16.96	121.24±19.65	130.16±20.25	**P<0.000*****
▪ ***(Range)***	(94-125)	(105-140)	(120-150)	(124-155)	
6 months:					
▪ ***Mean± SD***	102.16±18.26	115.42±17.46	124.56±19.75	134.76±23.25	**P<0.000*****
▪ ***(Range)***	(94-125)	(105-140)	(120-150)	(124-155)	
P-value	**P<0.02***	**P<0.001****	**P<0.001****	**P<0.000*****	

Table 5: Comparison between groups according to micro vascular changes "OCTA" over the follow up periods in each group.

Item	G1 "n=25"	G2"n=25"	G3"n=25"	G4"n=25"	p-value
Pre- operative:					
▪ ***Mean± SD***	45.18±8.40	40.01±6.37	36.57±5.43	37.39±7.45	**P<0.001****
▪ ***(Range)***	(40.35-45.58)	(38.37-42.94)	(34.44-38.70)	(36.65-38.69)	
1week:					
▪ ***Mean± SD***	45.19±8.64	41.81±6.79	38.08±5.47	37.94±7.46	**P<0.001****
▪ ***(Range)***	(41.47-52.53)	(40.87-43.59)	(37.02-39.48)	(40.68-47.74)	
1month:					
▪ ***Mean± SD***	45.37±8.79	43.76±7.08	39.98±6.46	41.94±7.81	**P<0.001****
▪ ***(Range)***	(41.54-50.14)	(42.18-46.20)	(36.95-42.46)	(38.83-46.28)	
3 months:					
▪ ***Mean± SD***	47.06±9.24	44.98±7.46	40.62±7.12	49.14±7.91	**P<0.001****
▪ ***(Range)***	(44.84-51.84)	(41.49-46.79)	(37.02-41.94)	(48.50-52.51)	
6 months:					
Mean± SD	48.85±9.05	48.14±7.88	41.77±18.26	49.65±8.02	**P<0.001****
(Range)	(45.78-50.35)	(45.65-52.51)	(39.64-43.43)	(46.87-51.50)	
P-value	**P<0.001****	**P<0.001****	**P<0.001****	**P<0.000*****	

4. Discussion

Patients with diabetes have cataracts more frequently and at an earlier age than people without the illness. Phacoemulsification surgery greatly improves visual acuity and allows surgeons to recognize diabetic retinopathy early [8]. On the other hand, macular edema is far more common in diabetic people, and some data suggests that cataract surgery can accelerate the progression of diabetic retinopathy (DR). Research has demonstrated that diabetic patients can effectively avoid postoperative macular edema by using anti-VEGF medication [9]. Still unknown, nevertheless, are the causes of the increased risk of diabetic macular edema (DME) and DR following cataract surgery. Optical coherence tomography angiography (OCTA) is a new noninvasive vascular imaging technique that was developed recently. The continuous OCT scan and blood flow signals are obtained using a unique method that improves the visualization and quantification of the retinal vessels in the various layers and non-perfused portions of the macula and nerve [10]. OCTA has been used in diabetic patients to detect microvascular changes early on, even prior to the onset of clinical symptoms. Show the alterations in microvascular changes, macular thickness, and periphery NFL thickness that occur after simple phacoemulsification surgery in the eyes of diabetic patients and a control group with and without DR [11]. In current study, there was no statistical difference found concerning age or gender distribution between diabetics and control group. These results were in agreement with Mahmoud M. Madeeh [12]. who found that there were no differences in age and sex. Eriksson et al. [13]. showed that the majority were men without significant difference between both groups. Our study demonstrated that diabetic patients with NPDR showed a significant increase in CMT values at postoperative 1, 3 and 6 months. This agrees with Srinivasan et al. [3] who reported that, at one month and six months after surgery, diabetic patients with mild to moderate NPDR did not have altered visual results, suggesting that the alterations in CMT values in these patients remained subclinical. In diabetic individuals without DR, no statistically significant rise in CMT values was seen at postoperative three and six months. The results of Yassin et al. [14] showed that in diabetic patients without DR, uncomplicated phacoemulsification surgery had minimal impact on the underlying pathophysiology of retinopathy. Conversely,

in diabetic patients with mild to moderate NPDR, the incidence of subclinical macular thickening following uncomplicated phacoemulsification was higher than in diabetic patients without DR. In our study all groups showed a significant increase in CMT after one week and one month, then gradual reduction after 1 month postoperatively. However, the increase in CMT was more in diabetic groups after one month, and increasing even more in diabetic patients with severe NPDR group than other groups with a statistically significant difference (P<0.000). These results are in agreement with Bannale et al. [15] who reported that patients with mild NPDR who had diabetes saw a greater improvement in their blood-aqueous barrier following phacoemulsification surgery. After cataract surgery, diabetic patients may develop clinical macular edema or after subclinical retinal swelling. Basic phacoemulsification surgery's impact on the development of DR is still a matter of debate. Age, insulin therapy, and inadequate blood glucose control are among risk factors that could impact how quickly DR progresses after surgery [16]. However, Oh et al. [17] demonstrated that these factors do not affect the progression of retinopathy. A part of the pathogenesis of postoperative CME in people with and without diabetes is intraocular inflammation induced by prostaglandin production [18]. Also, our finding was supported by Liu et al [16].
study which assesses the effect of simple phacoemulsification on changes in BCVA and CMT values in individuals with diabetes without DR and in patients with mild to moderate NPDR. They found in both groups, a significant increase in CMT values were found after 1 month, 3 months and 6 months postoperatively. CMT values in diabetic patients with NPDR showed a statistically significant increase after postoperative 1 month compared with diabetic patients without DR. In diabetic patients with mild to moderate NPDR had a higher incidence of subclinical macular thickening after uncomplicated phacoemulsification than diabetic patients without DR. Oh et al. [17] showed that diabetic patients may be susceptible to developing postoperative subclinical retinal swelling or clinical ME after cataract surgery. In contrast, Wang & Cheng [19] reported that there was no difference in preoperative CMT between the diabetic and control groups. A significant increase in thickness in each group was observed after 4 weeks postoperative in both groups. But there were no significant differences in mean CMT between the groups preoperatively and after 1 week, 2 weeks, and 4 weeks postoperatively. Eriksson et al. [13] found that between the preoperative measures and the 6-week follow-up, CMT considerably increased in both the diabetics and the controls. There was, however, no significant difference between the two groups. In current study, regarding best corrected visual acuity (BCVA), statistically significant difference between diabetic groups II, III, IV and control group in preoperative period was reported. Also, this study shows statistically significant difference between groups after one week, one month and after six months postoperatively. Our finding was supported by Liu et al. [16] who assessed the impact of uncomplicated phacoemulsification on the changes of CMT values and BCVA in both diabetic patients without DR and diabetic patients with mild to moderate NPDR. They found that uncomplicated phacoemulsification significantly improved BCVA after postoperative 1 month and 6 months in both diabetic patients without DR and diabetic patients with mild to moderate NPDR in spite of increased CMT indicating that CMT changes after surgery remained subclinical in diabetic patients with NPDR. In study by Tsilimbaris et al. [20] reported that although none of the patients had clinical CME, all had a considerable improvement in visual acuity following cataract surgery, despite these retinal changes. But, a month after surgery, BCVA signi-

ficantly improved in both the diabetic and control groups. Eriksson et al. [13] showed that six months following cataract surgery, the visual prognosis in diabetic eyes with mild to moderate retinopathy is comparable to that of the control group. But after six weeks, there was a noticeable difference from the control group: eyes with DR had lower VA and more macular changes on both fluorescein angiography and OCT. Kim et al. [21] found Retinal thickening and BCVA have a positive relationship. Some data, however, indicate that there is only a minor relationship between VA and central retinal thickness in DME patients, suggesting that VA may be primarily dependent on direct photoreceptor injury or disruption of the retinal architecture. Nunes et al. [22] provides robust evidence on the effect of uncomplicated phacoemulsification on CMT values in both diabetic patients without DR and diabetic patients with NPDR. Overall, there was a statistically significant increase in CMT values in diabetic patients with mild to moderate NPDR compared with diabetic patients without DR at postoperative 1month. Such an increase in CMT was still higher in diabetic patients with mild to moderate NPDR at postoperative 3 and 6 months. Diabetes patients without DR and diabetic patients with mild to moderate NPDR both had significantly improved BCVA at postoperative 1 month and 6 months. An angiographic examination can identify postoperative subclinical central macular thickening, which is frequently seen without causing vision impairment [23]. One of the main factors contributing to the development of macular thickness is the release of prostaglandins after surgery [5]. CMT values in diabetic patients with NPDR showed a statistically significant increase at postoperative 1 month compared with diabetic patients without DR. The findings suggest that simple phacoemulsification has some impact on the pathogenesis of retinopathy. In present study found that uncomplicated phacoemulsification significantly improved BCVA at postoperative 1 month and 6 months in both diabetic patients without DR and diabetic patients with mild to moderate NPDR. There was a significant increase in CMT values in diabetic patients with NPDR and a nearly significant increase (P= 0.054) in diabetic patients without DR at postoperative 1 month. After cataract surgery in diabetic individuals, it is crucial to differentiate between pseudophakic CME and diabetic macular edema. This is particularly relevant in the early postoperative phase, as research indicates that pseudophakic CME due to Irvine-Gass syndrome tends to regress, whereas diabetes causes it to progress [15]. In current study, compared Retinal nerve fiber layer thickness “RNFL” over the follow up periods in each group. There was significant difference (P<0.05) between different groups at preoperative and after 1week, also there was moderate significant difference (P<0.001) between different groups after 1month & there was highly significant different (P<0.000) after 3 & 6 months in agreement with our study; Perente et al. [24]. compared the retinal thickness values before cataract surgery with the thickness at 1 day, 1 week, 1 month, 3 months and 6 months after surgery, he found that the mean retinal thickness increased with every measurement. The greatest increase in retinal thickness was after 1 month from the surgery (P< 0.05) followed by gradual decrease after 3 and 6 months from the surgery, after 6 months from the surgery, the macular thickness was still significantly greater than that was before the operation (P< 0.05). In current study, compared micro vascular changes “OCTA” over the periods in each group. There was significant difference (P<0.05) between different groups at preoperative and after 1 week, also there was moderate significant difference (P< 0.001) between different groups after 1month & there was highly significant different (P<0.000) after 3 & 6 months In agreement with our study; Giansanti

et al. measured SCP by OCTA and at 1, 6, 15, 30, 60, 90, and 360 days after surgery and found that SCP increased significantly from day 30 after surgery in diabetic patients, reaching its maximum thickness at day 60, but it was measured only on day 360 in healthy subjects [25].

5. Recommendations

From our study we recommend that uncomplicated phacoemulsification does not affect progression of diabetic retinopathy in short term, so we need long term evaluation of diabetic patients after phacoemulsification to know more about progression of diabetic retinopathy.

By overall view to our results, we found that OCT-A might be helpful in detection of the early diabetic changes, thus reducing related complications as it detects patients how need further investigations &close follow up.

6. Conclusion

cataract phacoemulsification cause increase in CMT, RNFL thickness and SCP values in diabetic patients with different severities of retinopathy.

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