Incidence of macular edema after phacoemulsification with and without diabetes mellitus: A hospital-based clinical prospective trial in Upper Egypt

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Abstract

Background: Diabetes mellitus, or DM, is a condition that increases the risk of developing cataracts. Cataracts are one of the leading causes of blindness; some studies report that DM patients with cataracts have an increased risk of progression, while other studies report that their progression is merely the natural course of the disease.

Objectives: To estimate incidence of macular edema (ME), in patients with and without diabetes following phacoemulsification operation.

Patients and methods: This study is a prospective cross- sectional observational which enrolled 100 eyes of one hundred subjects, fifty patients suffering diabetes (group 1) and fifty patients suffer no diabetes (group 2) having immature senile cataract . Participants belonged to the ophthalmology department of South Valley University. OCT was done preoperatively and postoperatively by one month.

Results: Mean age of patients with and without diabetes was 66.48 and 66.16 respectively. Males represent 64% of group 1 and , and 80% of group 2 respectively. Both groups showed a considerable rise in the central macular thickness one month postoperatively, but there was no potential variation statistically in central macular thickness between the two groups neither before, nor after the surgery.

Conclusion: There is an increase in central macular thickness as a result of the effects of phacoemulsification on the macula in patients with and without diabetes. OCT is the single most crucial diagnostic and prognostic tool for managing macular oedema. But long-term studies are needed to prove longer effect of uncomplicated phacoemulsification and macular thickness and its visual impact.

Keywords: Macular oedema, Phacoemulsification, Diabetes mellitus, OCT.

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Introduction

Diabetes mellitus (DM) is a prevalent disease affecting 425 million persons worldwide. Diabetes mellitus, or DIABETES, causes many complications in the eyes; among them are cataracts and diabetic retinopathy. These complications often co-exist in diabetic patients (**Kelkar et al., 2018**). Cataracts cloud the vision when they grow in opacity. This can be remedied by removing the cataract with ultrasonic coagulation phacoemulsification. After receiving an intraocular lens implant, many patients choose to have cataract removal surgery. Patients may choose this treatment option if they want better vision than what their current eyes can provide (**Ostri et al., 2011**).

However some studies have shown cataract surgery accelerates the development of diabetic retinopathy (DR) and increases the occurrence of macular edema in diabetic patients (**Jeng et al.,2018 ; Baker et al., 2013**). The risk factors for development of DR and diabetic macular edema (DME) after cataract surgery are still unclear. Macular edema postoperatively in patients with diabetes can be caused by cataract surgery or diabetes but it is difficult to distinguish between both two causes (**Kim et al.,2007**). Macular inflammation is associated with blood-retinal dysfunction and increases the risk of surgery in diabetic patients

Cystoid macular edema (CME) occurs sometimes following cataract surgery. Visual recovery can be delayed, although visual prognosis is good (**Ray and D'Amico,2002**). The phenomenon of pseudophakic edema or Irvin-Gass syndrome was described by Irvin in 1953 (**Rossetti and Autelitano ,2000**) . The current study aims to estimate incidence of ME after phacoemulsification surgery in diabetic and non-diabetic patients

Patients and methods

Ethical Approval: All participants in the current study were informed about the study's‘objective and they had signed an informed consent. This study follows Tenants of Helsinki. The ethical board committee approval of Qena Faculty of Medicine was obtained under IBR Registration number: SVU/Med/ OPH026/1/22/4/381.

Type of the study: Prospective cross-sectional.

Study setting: at Qena University Hospital.

Date and duration of the study: between April 2022 to November 2022.

Study subjects

a. Inclusion criteria:

Patients who underwent cataract surgery with or without diabetes mellitus with cataract density allows OCT imaging.

b. Exclusion criteria:

Children and uncooperative patients, patients complaining very dense cataract precluding visualization of fundus.

c. Sample Size Calculation: 100 patients of both sexes; 50 individuals suffering diabetes (without diabetic macular oedema) and 50 individuals without diabetes suffering senile cataract involved for this study from inpatient wards and outpatient clinic of ophthalmology sector in Qena University hospital.

All of individuals were subjected to history taking, ophthalmological clinical examination and optical coherence tomography (OCT) (Maestro, Topcon healthcare, Tokyo, Japan) before surgery and after four weeks of cataract extraction to estimate and compare central macular thickness. These findings were considered as the baseline of patients and were used for referencing the subsequent scans using “follow-up” function of the SD-OCT, assuring us that the scans would be performed in the same position. In order to ensure the best scan extent and the same scan of the retinal area, all images were taken as close to the fovea as possible.

Phacoemulsification surgery: All patients were treated with standard phacoemulsification with folding PCIOL was performed. Only patients who performed uncomplicated operation were included. The surgical procedure was similar for all patients. All surgeries had been done by same surgeon.

Post-operative treatment: All patients used moxifloxacin 0.5% and prednisolone acetate 1% eye drops five times a day for 2 weeks and tapered in 2 weeks.

Statistical analysis

Data analysis was done by Statistical Package for Social Sciences (SPSS) Software program (version 25). Categorical data was

recorded as number and percentage and were compared using chi-square test. Numerical variables were reported as means ± standard deviation (SD) and were compared by student t-test. Correlations and regression analysis were performed as indicated. P value < 0.05 was significant.

Results

A total of 100 eyes of 100 cataract patients who expereinced successful posterior chamber IOL implantation and phacoemulsification were included in the current study.

They were divided into 2 groups;

Group 1: Diabetes mellitus group (DM group) consisted of 50 eyes (50 diabetic patients).Thirty –two of them were males (64.0%) , and eighteen of them were females (36.0%) , with a mean age of 66.48 ±7.31),twenty-six are right eyes (52.0%) and twenty –four are left eyes(48.0%).

Group 2: Control group of non-diabetics involved 50 eyes (50 patients without diabetes). Forty of them are males (80.0%) and ten of them are females (20.0%), with a mean age of 66.16±8.25), twenty-six eyes are right eyes (56.0%) and twenty –two are left eyes (44.0%), (**Table.1**) summaries these findings.

Table.1. Clinical and demographic information regarding the participants

Variables		Diabetics	Non-diabetics	Test value	P-value	Sig.
		No. = 50	No. = 50			
Age	Mean ± SD Range	66.48 ± 7.31 50 – 80	66.16 ± 8.25 46 – 79	0.205•	0.838	NS
Sex	Male Female	32 (64.0%) 18 (36.0%)	40 (80.0%) 10 (20.0%)	3.175*	0.075	NS
Eye	OD OS	26 (52.0%) 24 (48.0%)	28 (56.0%) 22 (44.0%)	0.161*	0.688	NS

P-value >0.05: Non-significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS) *:Chi-square test; •: Independent t-test

Group1 (diabetics) had mean macular thickness preoperatively is 271.92 (±33.88) and 280.00 (±36.84) one month postoperatively. While **group 2** (non-diabetics): mean macular thickness preoperatively is 262.72±31.82) and 270.48±26.48) one month postoperatively. While Fifty non-diabetic patients with mean macular thickness preoperatively is 262.72 ±31.82) and 270.48±26.48) one month postoperatively (incidence of Irvin Gass Syndrome in non-diabetic patients). (**Table.2**) summaries these findings. In both groups there were clinical significant differences of the postoperative from the preoperative macular thickness.

Table 2. Comparison of Macular thickness between the two groups

Macular thickness		Diabetics	Non-diabetics	Test value•	P-value	Sig.
		No. = 50	No. = 50			
Pre	Mean ± SD Range	271.92 ± 33.88 216 – 408	262.72 ± 31.82 198 – 342	1.400	0.165	NS
1 month post	Mean ± SD Range	280.00 ± 36.84 222 – 411	270.48 ± 26.48 209 – 340	1.484	0.141	NS

P-value >0.05: Nonsignificant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)

50 diabetic patients with a preoperative mean macular thickness of 271.92 (SD ± 33.88) and 1 month postoperatively ,it increases to 280.00 (SD ± 36.84) (incidence of Irvin-Gas syndrome) in diabetic patients. using paired samples t-test ,the mean increase in macular thickness was 2.509 (p-value=0.015), (**Table.3, Figs.1,2**).

Table 3. The diabetic group's pre- and post- operative outcomes

Diabetic group		Preoperative	1 month postoperative
		No. = 50	No. = 50
Macular thickness	Mean±SD Range	271.92 ± 33.88 216 – 408	280.00 ± 36.84 222 – 411
Paired t-test		--	2.509
P-value		--	0.015 (S)

NS: Non significant; S: Significant; HS: Highly significant

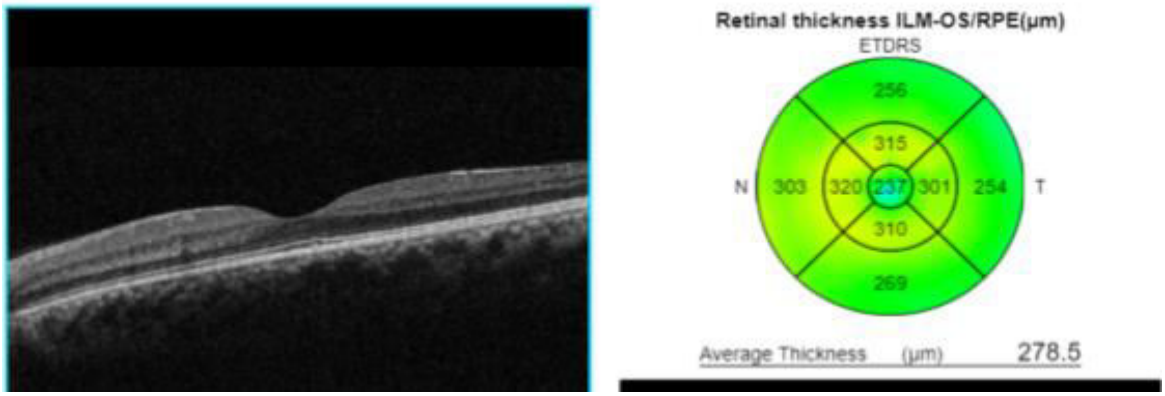

Fig.1. Preoperative oct of a female diabetic patient

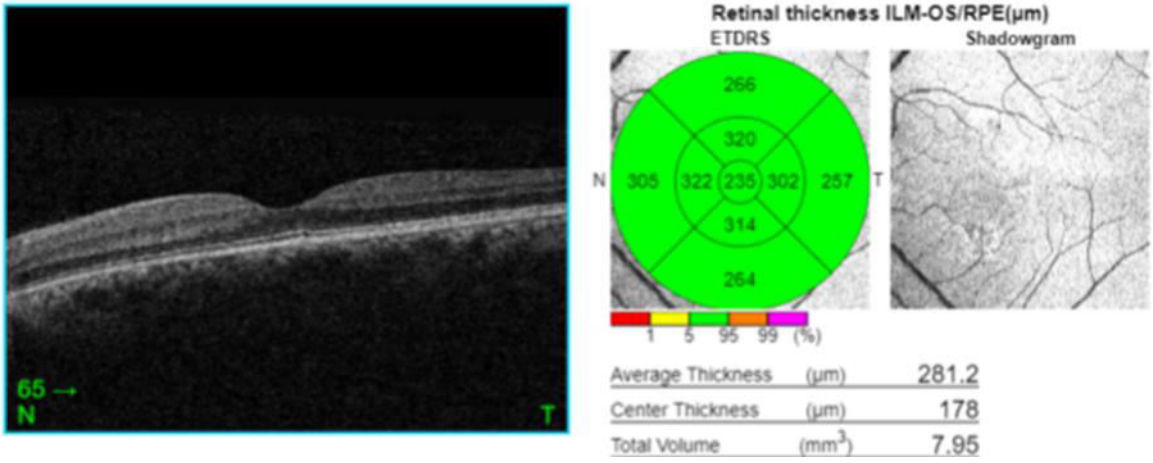

Fig. 2. Post –operative oct of the same patient

50 non - diabetic patients with a mean macular thickness of 262.72 (SD ± 31.82) preoperatively and 270.48 (SD ± 26.48) one month postoperatively (incidence of Irvin-Gass syndrome) in nondiabetic patients. using paired samples t-test ,the mean increase in macular thickness was 2.109(p-value=0.040), (**Table.4, Figs. 3,4**).

Table 4. The non-diabetic group's pre- and post- operative outcomes

Non-diabetic group		Preoperative	1 month postoperative
		No. = 50	No. = 50
Macular thickness	Mean ± SD Range	262.72 ± 31.82 198 – 342	270.48 ± 26.48 209 – 340
Paired t-test		--	2.109
P-value		--	0.040 (S)

NS: Nonsignificant; S: Significant; HS: Highly significant

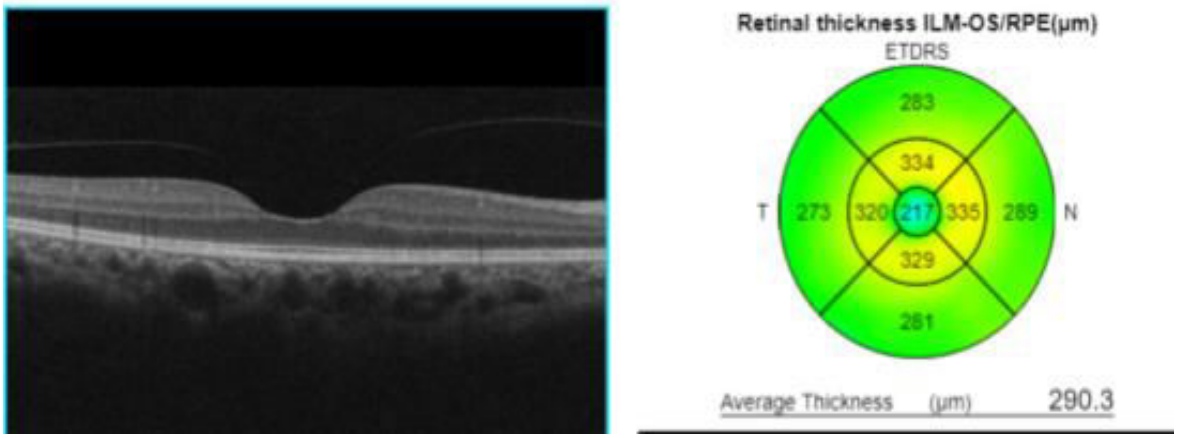

Fig.3. Preoperative oct of a non – diabetic female patient

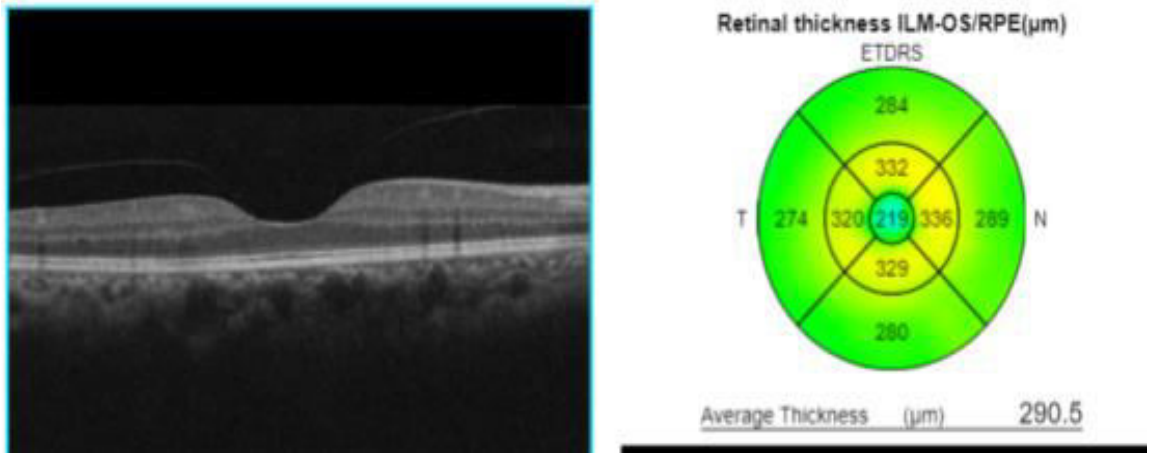

Fig.4. Post – operative oct of the same patient

Discussion

Phacoemulsification cataract procedure is a surgery that has become the most common intraocular operation that often improves outcomes of the vision. However, in a lot of cases experience eye inflammation, exacerbation of pre-existing retinal diseases as diabetic macular edema can occur according to **Romero-Aroca et al., 2006** or progression of new illness such as Irvine-Gass syndrome. This inflammatory response results due to the release of prostaglandins (PG) **(kim et al.,2010 ; Dams et al.,2013)**.

There are insufficient biochemical reports on the impacts of cataract procedure on retina. In a lot of cases, phacoemulsification surgery does not alter retina‘s macroscopic funduscopic appearance. However, it was confirmed that the cataract operation results in an inflammatory process in posterior segment of the eye according to **Xu et al., 2011; Liu et al., 2004 .** Another study showed that the lens fragments disrupts the inner blood-retinal partition (**Liu et al., 2004).**

These consequences of inflammation of phacoemulsification operation may be related to subclinical macular variations reported in uncomplicated cataract operation, or to the pathological events as Irvine-Gass syndrome. This in turn resulted in a widespread use of topical steroids and NSAIDs in postoperative period of the surgery as such drugs could reduce the incidence of Irvine-Gass syndrome. In accordance with standard medical practice, all our patients were prescribed these anti-inflammatory drugs to reduce the inflammatory damage caused by the operation. Currently, researchers cannot study the influence of phacoemulsification on the retinal morphology in the patients not receiving topical NSAIDs

and steroids, as this could unacceptably raise the risk of progressing the Irvine-Gass syndrome. Since phacoemulsification surgery is an inflammatory process of eye, we examined the probability that it could lead to increased macular thickness with simple phacoemulsification cataract surgery. In this case-control research, SD-OCT was used to assess macular changes before and one month after cataract extraction using OCT scans of 100 eyes undergoing phacoemulsification. Many studies as **Cagini,2009; Giansanti et al.,2013** assessed effect of phacoemulsification cataract surgery on macular thinness. In another study by **Gede Pardianto et al. (2013),** there is potential increase statistically in the macular thickness after Uncomplicated phacoemulsification and rise in the macular volume . In a research by **Cagini et al., 2009 ,** Macular thickness was measured in 62 eyes before operation and at three, six , twelve , twenty , and twenty- eight weeks post operation using OCT tool. During follow-up, they found a meaningful increase statistically in the macular volume at twelve weeks post-surgery. Clinically significant macular edema was present in both eyes, and there was no relationship between the macular alterations and the best corrected visual acuity (BCVA) or the ultrasonic power time.

Foveal thickness was examined in 110 eyes by follow-up OCT at one day, one week, one , three , and six months. After the first week of operation, a significant rise in macular thickness was noted with a mean of 208.4 ± 27.6 μm ($p<0.001$) by **Giansanti et al., 2013**.

All previous researches on central macular thickness found that there is a considerable increase in central macular thickness after surgery, which is consistent with our results, which found a profound increase statistically in the central macular thickness one month after surgery. Additionally, no statistical considerable variation found in the central macular thickness between the Diabetic group and the group of non-diabetics, neither before nor after surgery. Yet, **Katsimpris et al., (2012)** found that central foveal thickness increases in patients suffering diabetes with no retinopathy after cataract operation on OCT evaluation compared to eyes of healthy controls . It is still unclear how cataract surgery causes retinal and choroidal inflammation. Prostaglandins in the aqueous humor are known to be released as a result of the surgical trauma, which disrupts the blood-aqueous barrier **(Miyake and Ibaraki ,2002)** .In order to reach the retina, such inflammatory mediators permeate to the vitreous cavity. There, they cause a tear in the inner blood–retinal barrier, which triggers an additional cascade of inflammatory mediator secretion and increases the permeability of the perifoveal capillaries and Inflammation following cataract surgery has also been shown to disrupt the outer blood–retinal barrier **(Miyake et al., 2011).** Limitation of this study is the short-term observation so long-term studies and needed and to study the potential later complications of such macular alteration and the effects of these alteration of visual acuity later one.

Conclusion

There is a rise in central macular thickness as a result of the effects of phacoemulsification on the macula in both diabetics and non-diabetics patients. OCT is the single most crucial diagnostic and prognostic tool for managing macular oedema. But long-term studies are needed to prove longer effect of uncomplicated phacoemulsification and macular thickness and its visual effect.

Disclosure

The authors have no conflict of interest in this project.

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