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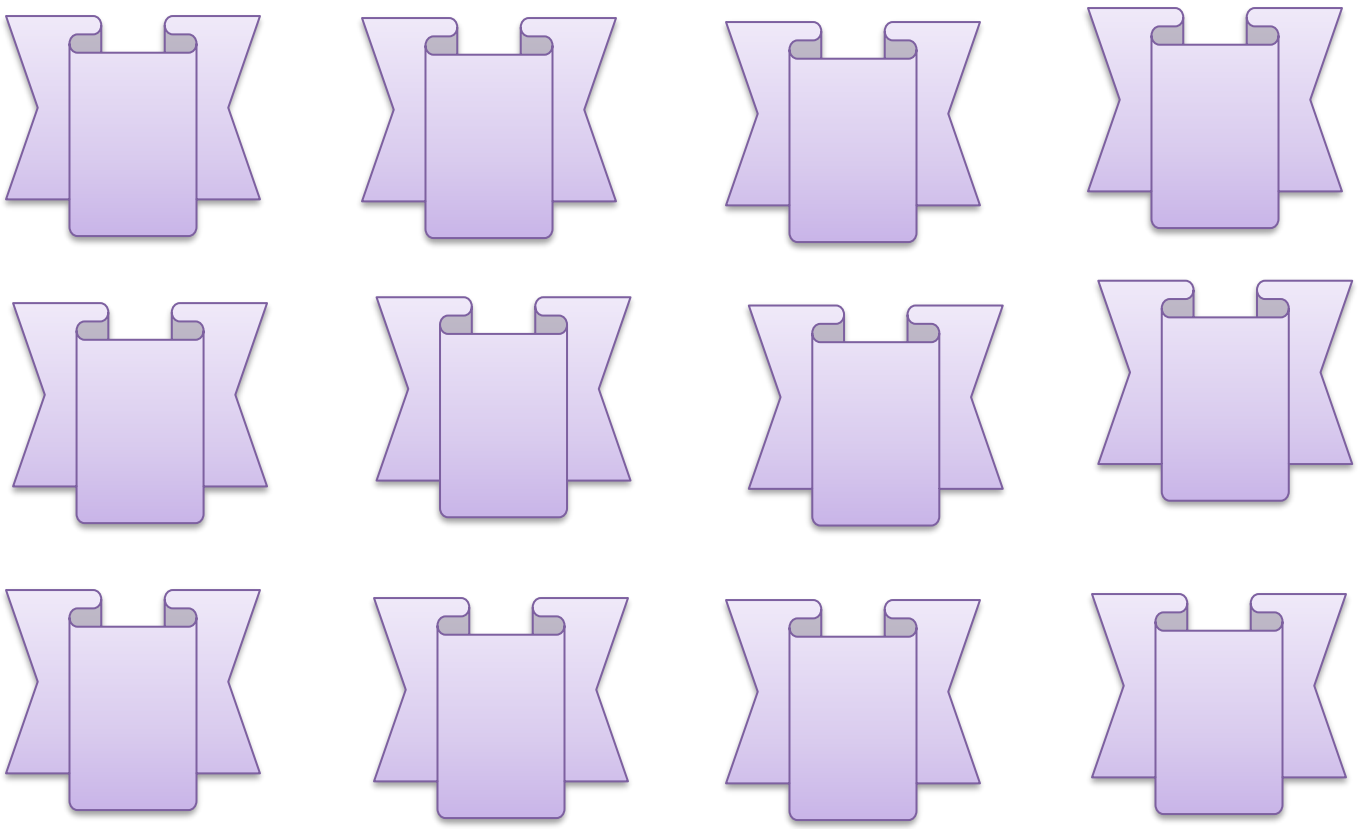

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Original Article

Comparative Study between Optical Coherence Tomography Angiography in Normal People versus Optical Coherence Tomography Angiography in Diabetic Patients with No Clinical Diabetic Retinopathy

Mahmoud Adel El-Manfy *, Al-Sayed Moustafa Elewa, Noureldin Abdelhamid Abdelhalim

Department of Ophthalmology, Faculty of Medicine, Al-Azhar University, Cairo, Egypt

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*Corresponding author

Email: mahmoudelmanfy275@yahoo.com

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ABSTRACT

Background: Diabetic retinopathy [DR] is a prevalent ocular ailment that is a primary contributor to blindness.

The Aim of the work: To detect early findings of diabetic retinopathy before the appearance of clinical signs by determining retinal layers vasculature affected by diabetes via optical coherence tomography angiography imaging.

Patients and Methods: A comparison analysis included 20 patients with history of diabetes type 2 for 10 years and no diabetic retinopathy was determined by fundus examination versus 20 control persons. To get pictures, we used XR Avanti Optical Coherence Tomography Angiography. With the software's non-flow area tool, which allows for automatic FAZ segmentation, the flow area of the choriocapillaris was assessed in the superficial vascular plexus.

Results: There were statistically significant differences in FAZ area, parafoveal vessel density of SCP, DCP and choriocapillaris flow area between healthy control [group A] and diabetic patients without DR [group B]. The mean FAZ area of the healthy control [group A] was 0.23 ± 0.05 mm^2 compared with 0.34 ± 0.06 mm^2 in the diabetic [group B]. In addition, the mean of the choriocapillaris flow area [mm2] of group A was 2.15 ± 0.09 in compared with 2.07 ± 0.06 in the group B. Finally, we found that among the 40 eyes of 20 patients with DM with no diabetic retinopathy [group B] there were 10 eyes [25%] with microaneurysms by OCTA which weren't detected by fundus examination.

Conclusion: OCTA provides structural and topographic analysis of microvascular abnormalities that occur in diabetic patients before the onset of clinically evident retinopathy by assessment of the FAZ dimensions and vascular density. So, OCTA offers an early biomarker for efficient screening of DR, before the onset of clinically evident complications.

Keywords: Angiography; Optical Coherence Tomography; Diabetic Retinopathy

INTRODUCTION

The World Health Organization [WHO] estimates that over 422 million individuals worldwide have diabetes mellitus [DM], and by 2030, that figure is projected to increase to 552 million [1].

Diabetic retinopathy [DR] is a prevalent ocular ailment that is a primary contributor to blindness. DR is frequent in the first five years of type 1 diabetes, and after 20 years, all individuals with type 2 diabetes have some kind of DR [2]. As a result, a methodology is required to identify individuals who are at high risk of blindness before irreversible retinal abnormalities develop. We need objective and repeatable diagnostics for diabetic retinopathy screening, early diagnosis and therapy assessment. Diabetic retinopathy was once thought to be a kind of vasculopathy. The pathophysiological mechanism involving various levels of intraretinal capillary closure and increasing intraretinal permeability of the vascular system caused by hyperglycemia is osmotic stress, which results in macular edema and ischemia [3].

Recent research [4] suggests that neurodegeneration plays a crucial role in the pathogenesis of DR. Diabetes-related changes to metabolic pathways may encourage retinal neuronal cell degeneration, according to histological examinations of post-mortem samples [5].

According to several studies, neural loss may begin before any obvious symptoms of vascular abnormalities, glial reactivity, ganglion cell body loss and neural apoptosis which all have been found in the early stages of retinopathy in animal studies [6]. The link between blood flow regulation and brain activity that is assumed to be engaged in the pathophysiologic mechanism of DR is known as neurovascular coupling [7].

Eliminating the need for dye injection, optical coherence computed tomography angiography is a non-invasive imaging method that may provide clear, high-resolution images of the retinal microvasculature. It functions by gathering and contrasting decorrelation data at a particular retinal area from successive OCT B-scans [8].

The aim of the study is to detect early findings of diabetic retinopathy before the appearance of clinical signs by determination of retinal layers vasculature that is affected by diabetes via optical coherence tomography angiography imaging.

PATIENTS AND METHODS

A Comparative study was carried out in the ophthalmology department at AL- Hussien and Sayed Galal University Hospitals. The data were collected from the patient assigned according to exclusion and inclusion criteria.

Study population: As mean FAZ SCP in patients' group 308.19+/-82.12 compared to 230.66+/-90 in control group [9], sample size was calculated using Open Epi software with confidence level 95% and power 80% so the minimum required sample was 20 patients who came to the outpatient clinic and 20 control persons.

Inclusion criteria: Patients with history of diabetes type 2 for 10 years with no diabetic retinopathy as ascertained by fundus examination with a hand-held slit light and + 90 D lens.

Exclusion criteria: Patients with refractive errors [+/- 5 D], previous ocular surgery, significant media opacity or any other ocular pathology like uveitis, glaucoma, retinal disease or any other systemic diseases.

Methods: Every patient underwent complete history taking, comprehensive ophthalmic examination, Snellen equivalent visual acuity measurement, autorefraction by [TOPCON KR8000 Auto-refractor Keratometer, Japan], ideal corrected Snellen equivalent visual acuity recording, IOP measurement by [TOPCON CT-80 Computerized Tonometer, Japan]. After that pupil dilation was done followed by examination of both eyes using a slit lamp and a hand-held + 90 D lens that were done to detect signs of diabetic retinopathy. Besides, blood sample was taken for fasting blood sugar and glycosylated hemoglobin [HbA1C].

Twenty healthy control persons were chosen randomly from relatives who accompanied patients to the outpatient clinics at El-Hussin and Sayed Galal University Hospitals. They were age suited with the patients and did not have a diagnosis of diabetes, any systemic medical condition or any ocular illness.

The equipment we used to take pictures was XR Avanti OCT Angiography [RTVue XR AVANTI, Optovue, and Fremont, CA, USA].

The vascular density within a 6 × 6 mm scanning region centered on the fovea [macular cube], a 3 mm parafoveal circle excluding the FAZ and the fovea was obtained using embedded AngioAnalytics software. The segmentation method of the integrated software was utilized to determine the superficial capillary plexus [Fig. 1] and deep capillary plexus [Fig. 2] in face OCT angiograms. The software's non-flow area tool was utilized to derive the flow area for the choriocapillaris [Fig. 3] in the superficial vascular plexus, hence enabling automatic FAZ segmentation [Fig. 4].

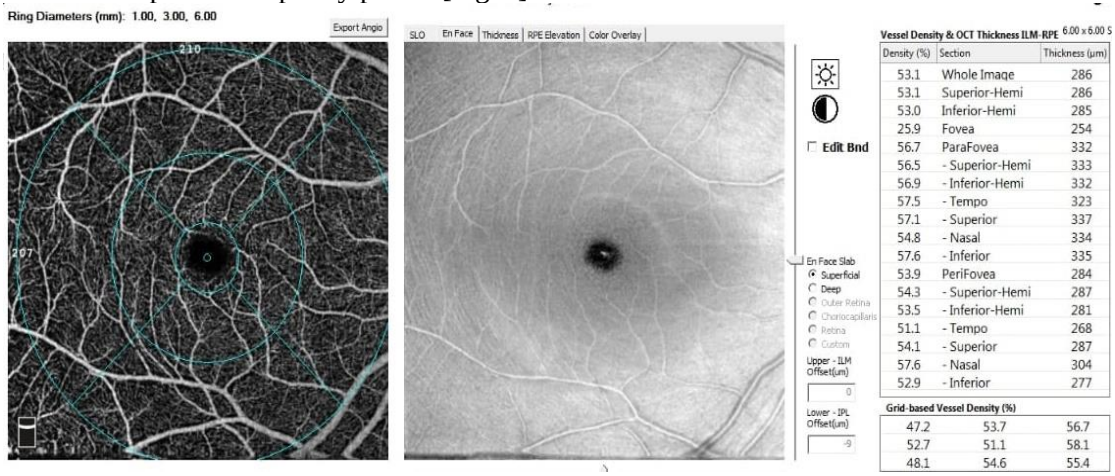

Fig [1]: OCTA imaging in normal Person showing superficial capillary plexus density

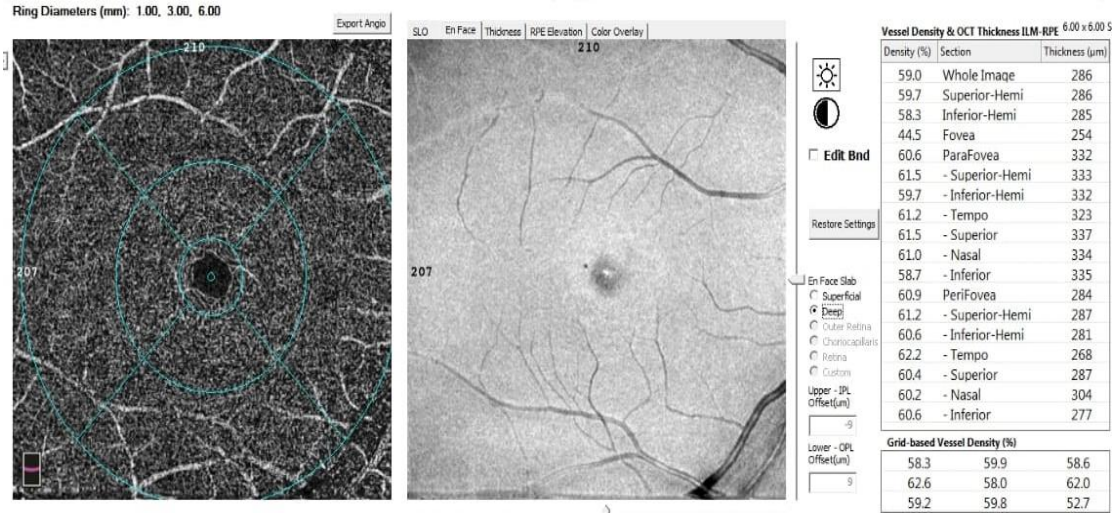

Fig [2]: OCTA imaging in normal Person showing Deep capillary plexus density

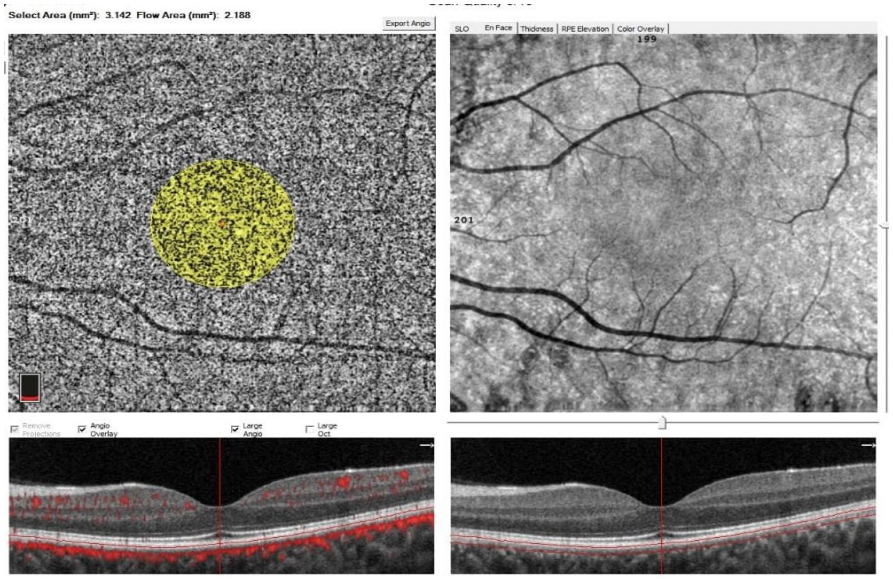

Figure [3]: OCTA imaging in normal Person showing Choriocapillaris flow area

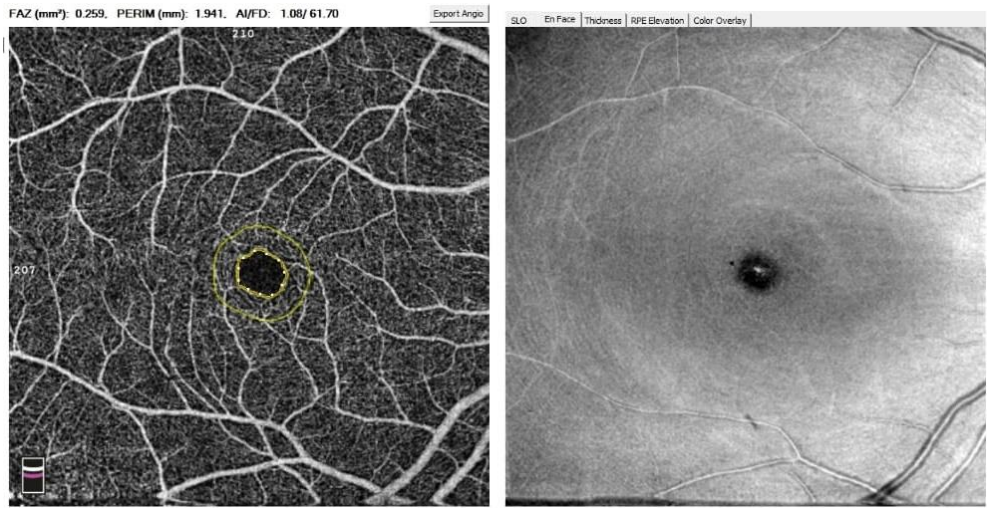

Figure [4]: OCTA imaging in normal Person showing Free Avascular zoon [FAZ]

Ethical consideration: Our protocol was considered official after acceptance by the ethical committee of Al-Azhar University at Cairo under acceptance number 681 on 29th June, 2022. This work was not financially supported by any organization, society or government.

Statistical analysis: The computer was given data, and IBM SPSS software package version 20.0 was used for analysis. [IBM Corp., Armonk, NY] Numbers and percentages were used to describe the qualitative data. The distribution's normality was confirmed using the Kolmogorov-Smirnov test. The terms range [minimum and maximum], mean, standard deviation, median, and interquartile range [IQR] were used to characterize quantitative data. The results were deemed significant at the 5% level. Chi-square test was used for categorical variables, to compare between different groups. Student t-test was used for normally distributed quantitative variables, to compare between two studied groups.

RESULTS

Table [1] demonstrates that there was an age-related statistically significant distinction among the groups under study.

Table [2] shows that the mean duration of DM was 12.6 [±2.09 SD] with range [10-16].

Table [3] demonstrates that there was a substantial statistical variance in HbA1C and fasting blood glucose levels between the groups under study.

There was statistically insignificant variation in IOP between the groups under investigation [Table 4].

Table [5] demonstrates that, in terms of OCT angiography parameters, there was a substantial statistically significant difference between the examined groups.

Table [6] shows that among the 40 eyes of 20 patients with DM with no diabetic retinopathy [group B] there were 10 eyes [25%] with microaneurysms by OCTA not detected by fundus examination. Using the mean FAZ it was shown that above 0.307, it can predict diabetic retinopathy with an AUC of 0.899, level of sensitivity 77.5%, specificity 90%, PPV 88.6%, NPV 80% and accuracy 83.8%.

Using the mean superficial plexus para-foveal density it was shown that below 51.05, it can predict diabetic retinopathy with an AUC of 0.923, level of sensitivity 92.5%, specificity 77.5%, PPV 80.4%, NPV 91.2% and accuracy 85%.

Using the mean deep plexus parafoveal density it was shown that below 55, it can predict diabetic retinopathy with an AUC of 0.942, level of sensitivity 97.5%, specificity 72.5%, PPV 78%, NPV 96.7% and accuracy 85%. Using the mean flow area in the choriocapillaris it was shown that below 2.1105, it can predict diabetic retinopathy with an AUC of 0.773, level of sensitivity 72.5%, specificity 85%, PPV 82.9%, NPV 75.6% and accuracy 78.8%.

Table [1]: Patient personal and clinical characteristics among study groups

	Group A [n = 20] [Control Group]		Group B [n = 20] [Diabetic Group]		Test of Sig.	p
Age [years]						
Range	43 – 60		49 – 60		t= 2.259	0.030
Mean ± SD	51.05 ± 4.32		53.7 ± 2.98			
Sex	No.	%	No.	%		
Female	8	40.0	11	55.0	χ^2= 0.902	0.342
Male	12	60.0	9	45.0		

Table [2]: Duration of DM in group B

	Group B [n = 20] [Diabetic Group]
Duration of DM	
Range	10 – 16
Mean ± SD	12.6 ± 2.09

Table [3]: Comparing the examined instances based on laboratory findings

		Group A [n = 20] [Control Group]	Group B [n = 20] [Diabetic Group]	Test of Sig.	p
FBG	Range	75 – 105	105 – 346	t= 8.133	**<0.001***
	Mean ± SD	88.35 ± 9.96	198.6 ± 59.8		
HbA1C	Range	5.6 – 6.5	6.6 – 9	t= 10.658	**<0.001***
	Mean ± SD	6.04 ± 0.29	7.61 ± 0.59		

Table [4]: Comparison between studied cases according to IOP

IOP	Group A [n = 40] [Control Group]	Group B [n = 40] [Diabetic Group]	Test of Sig.	p
Range.	11 – 18	11 – 17	t= 1.376	0.173
Mean ± SD.	14.13 ± 1.83	13.55 ± 1.91		

Table [5]: Comparison between studied cases according to OCT Angiography parameters

		Group A [n = 40] [Control Group]	Group B [n = 40] [Diabetic Group]	Test of Sig.	p
Free Avascular Zone-FAZ [mm2]	Range	0.147 – 0.357	0.199 – 0.489	t= 8.171	<0.001*
	Mean ± SD	0.23 ± 0.05	0.34 ± 0.06		
Superficial plexus Parafoveal Density %	Range	49.1 – 58.2	44.6 – 54.7	t= 9.513	<0.001*
	Mean ± SD	54.1 ± 2.43	48.77 ± 2.58		
Deep plexus Parafoveal Density %	Range	54.2 – 60.6	49.7 – 57.2	t= 9.173	<0.001*
	Mean ± SD	57.5 ± 1.43	53.45 ± 2.21		
Flow area – choriocapillaris [mm2]	Range	1.933 – 2.306	1.945 – 2.202	t= 4.382	<0.001*
	Mean ± SD	2.15 ± 0.09	2.07 ± 0.06		

Table [6]: Prevalence of Microaneurysm in group B

		Group B [n = 40] [Diabetic Group]
Microaneurysm	No	30	75.0
	Yes	10	25.0

Table [7]: Roc curve analysis for the use of OCT Angiography to predict diabetic retinopathy [n = 80]

	AUC	p value	95% C.I L.L	95% C.I U.L	Cut off#	Sensitivity	Specificity	PPV	NPV	Accuracy
FAZ	0.899	<0.001*	0.833	0.966	**0.307**	77.5	90.0	88.6	80.0	83.8
SCP – density %	0.923	<0.001*	0.867	0.978	**51.05**	92.5	77.5	80.4	91.2	85.0
DCP - density %	0.942	<0.001*	0.897	0.986	**55.0**	97.5	72.5	78.0	96.7	85.0
Flow area – choriocapillaris	0.773	<0.001*	0.665	0.881	**2.1105**	72.5	85.0	82.9	75.6	78.8

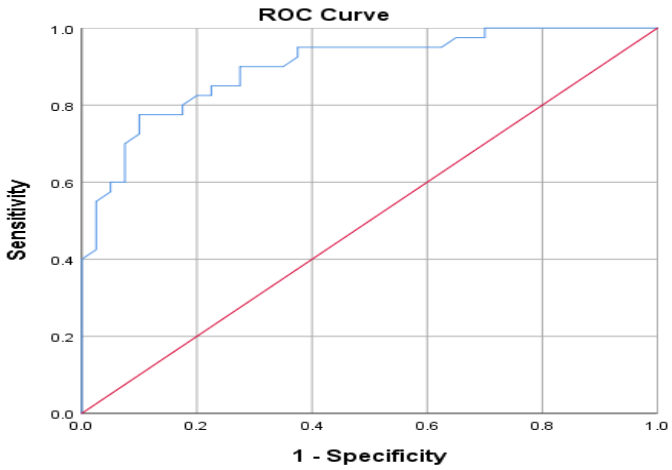

Fig [5]: Roc curve analysis for the use of FAZ to predict Diabetic Retinopathy.

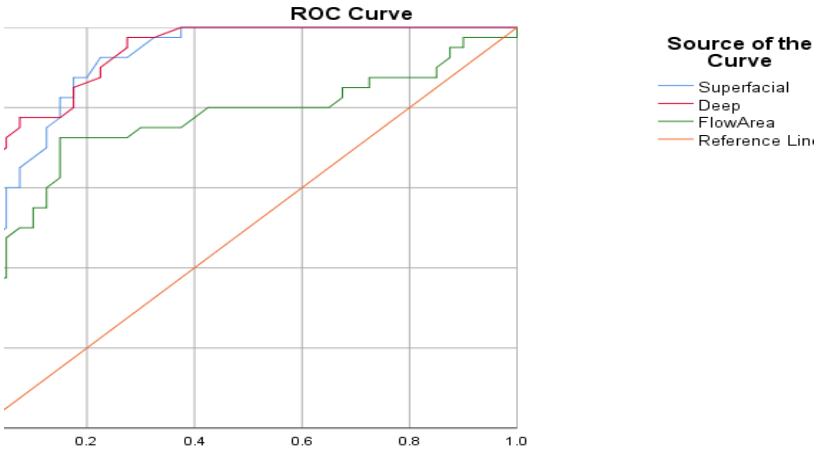

Fig [6]: Roc curve analysis for the use of OCT Angiography to predict Diabetic Retinopathy

DISCUSSION

The major microvascular abnormalities associated with diabetic retinal disease [DR], including microaneurysms, neovascularization, intraretinal microvascular abnormalities, retinal nonperfusion areas, expanded irregular fovea avascular zone [FAZ] and venous tortuosity and loops were all precisely localized by OCTA [10].

We showed in our study that, in terms of OCT angiography parameters, there was a substantial statistically significant variance among the groups under investigation.

First, we discovered that the diabetic with no DR group had a significant increase in FAZ area [P <0.001], with the mean FAZ area of the healthy group being 0.23±0.05 mm^2 and that of the diabetes with no DR group being 0.34±0.11 mm^2.

Eltohamy [11] conducted a study involving 50 participants split into two categories: group A, consisting of twenty-five diabetic patients without clinical manifestation of DR, and group B consisting of twenty-five healthy control participants. The study found that the mean FAZ area of the healthy control group was 0.27±0.08 mm2, while the diabetic with no DR group's mean was 0.32±0.11 mm^2.

In our investigation, we discovered that the diabetic without DR group had a mean superficial plexus parafoveal density [%] of 48.77 ± 2.58, whereas the healthy control group had a mean of 54.1 ± 2.43, and mean of deep plexus parafoveal density [%] of the healthy control group was 57.5 ± 1.43 compared with 53.45 ± 2.21 in the diabetic without DR group so there was a statistically significant decrease in SCP % and DCP % with diabetic without DR group.

Concur with us the study by **Cao *et al.*** [12] involved the examination of 60 eyes from patients with type 2 diabetes and 60 normal eyes from control subjects. In the 4.5 x 4.5-mm whole ONH scan, the Type 2 diabetes group had

a vessel density of [46.51 ± 2.23%], while the control group had a vessel density of [50.97 ± 1.45%]. Within the optic disc, vessel density was [48.98 ± 4.86%] in the group with type 2 diabetes and [51.46 ± 4.48%] in the control group. The type 2 diabetes and control groups had vessel densities of [48.77 ± 3.00%] and [53.12 ± 1.83%] in the whole peripapillary region, respectively.

In our study we found that the mean of the choriocapillaris flow area [mm^2] of the healthy control group was 2.15 ± 0.09 in compared with 2.07 ± 0.06 in the diabetic without DR group, so there was a statistically significant decreased in choriocapillaris flow area with diabetic without DR group [P <0.001]. Concur with us in 84 eyes of 84 individuals [44 with Type 2 diabetes. and 40 as controls], **Li *et al.*** [13]'s study indicated that the mean choriocapillaris flow area [mm^2] in the normal control group was 2.05 ± 0.11 mm^2, whereas the diabetic with no DR group was 1.94 ± 0.28 mm^2.

In our study we found that among the 40 eyes of 20 patients with DM with no diabetic retinopathy [group B] there were 10 eyes [25%] with microaneurysms by OCTA not detected by fundus examination.

Based on a clinical examination, **Thompson *et al.*** [14] assessed the vasculature of diabetic eyes that were reported to be free of diabetic retinopathy. On the OCTA picture, 8 [40%] of the 20 participants had non-clinically evident microaneurysms or capillary dropout.

According to this study, the mean FAZ may predict diabetes with an AUC of 0.899, sensitivity of 77.5%, specificity of 90%, PPV of 88.6%, NPV of 80%, and accuracy of 83.8% when it is over 0.307.

In the superficial layer, **Afarid *et al.*** [15] discovered that FAZ with a cutoff value of 0.599 demonstrated 66% sensitivity and 71% specificity for distinguishing a diabetic eye from a healthy one [AUC of 0.685]. According to **Decker *et al.*** [16], receiver operating characteristic analysis demonstrated that the FAZ was much better than other OCTA parameters, with the greatest overall AUC on OCTA [0.905] for differentiating between referable DR. According to **Barraso *et al.*** [17], ROC was built to determine the AUC for every OCTA parameter among individuals with diabetes who did not have diabetic retinopathy, patients with diabetes who did, and patients with DM who did have diabetic retinopathy [both non-proliferative and proliferative]. The AUC for the FAZ area was 0.52, 0.47, and 0.48 for the control, no DR, and DR groups. For these subgroups, the suggested FAZ area cutoff criteria are 0.36, 0.41, and 0.11, respectively.

In this study we illustrated that the mean superficial parafoveal capillary density showed that below 51.05, it can predict diabetic retinopathy with an AUC of 0.923, level of sensitivity 92.5%, specificity 77.5%, PPV 80.4%, NPV 91.2% and accuracy 85%. According to **Yang *et al.*** [18], ROC curve analysis demonstrated that the superficial parafoveal capillary density had a strong capacity to predict DR, with sensitivity and specificity of 93.1% and 76.4%, respectively, and areas under the ROC curves [AUCs] of 0.8353. According to **Sun *et al.*** [19], there is a significant degree of predictive power for superficial parafoveal capillary density in diabetic retinopathy. The AUCs for this parameter show 0.913, sensitivity of 95.1%, and specificity of 72.4%.

In this work, we showed that the mean deep parafoveal capillary density, below 55, may predict the development of diabetic retinopathy with an accuracy of 85%, an AUC of 0.942, a level of sensitivity of 97.5%, specificity of 72.5%, PPV of 78%, and NPV of 96.7%. Yang et al [18], found that ROC curve analysis showed that the deep parafoveal capillary density had good ability to predict DR, with areas under the ROC curves [AUCs] of 0.8608, with sensitivity 95%, specificity 71%.

In this study we found that using the mean flow area of the choriocapillaris it was shown that below 2.1105, it can predict diabetic retinopathy with an AUC of 0.773, level of sensitivity 72.5%, specificity 85%, PPV 82.9%, NPV 75.6% and accuracy 78.8%. Xu et al [20], found that flow area of the choriocapillaris can effectively distinguish DR participants from non-DR participants with an accuracy of 80% and an AUC of 0.84.

Limitations: The limitations of the current study were the relatively small sample size, being a cross-sectional study and the lack of long-term follow-up of the reported changes over time. Future longitudinal studies including larger sample sizes are recommended to more precisely quantify the early microvascular changes in diabetic patients and establish reliable biomarkers to monitor disease status. Associating microvascular

changes together with structural FAZ quantitative parameters could be valuable biomarkers to accurately identify disease staging and guide and monitor treatment strategies.

Conclusion: OCTA provides structural and topographic analysis of microvascular abnormalities that occur in diabetic patients before the onset of clinically evident retinopathy by assessment of the FAZ dimensions and vascular density. So, OCTA offers an early biomarker for efficient screening of DR, before the onset of clinically evident complications.

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