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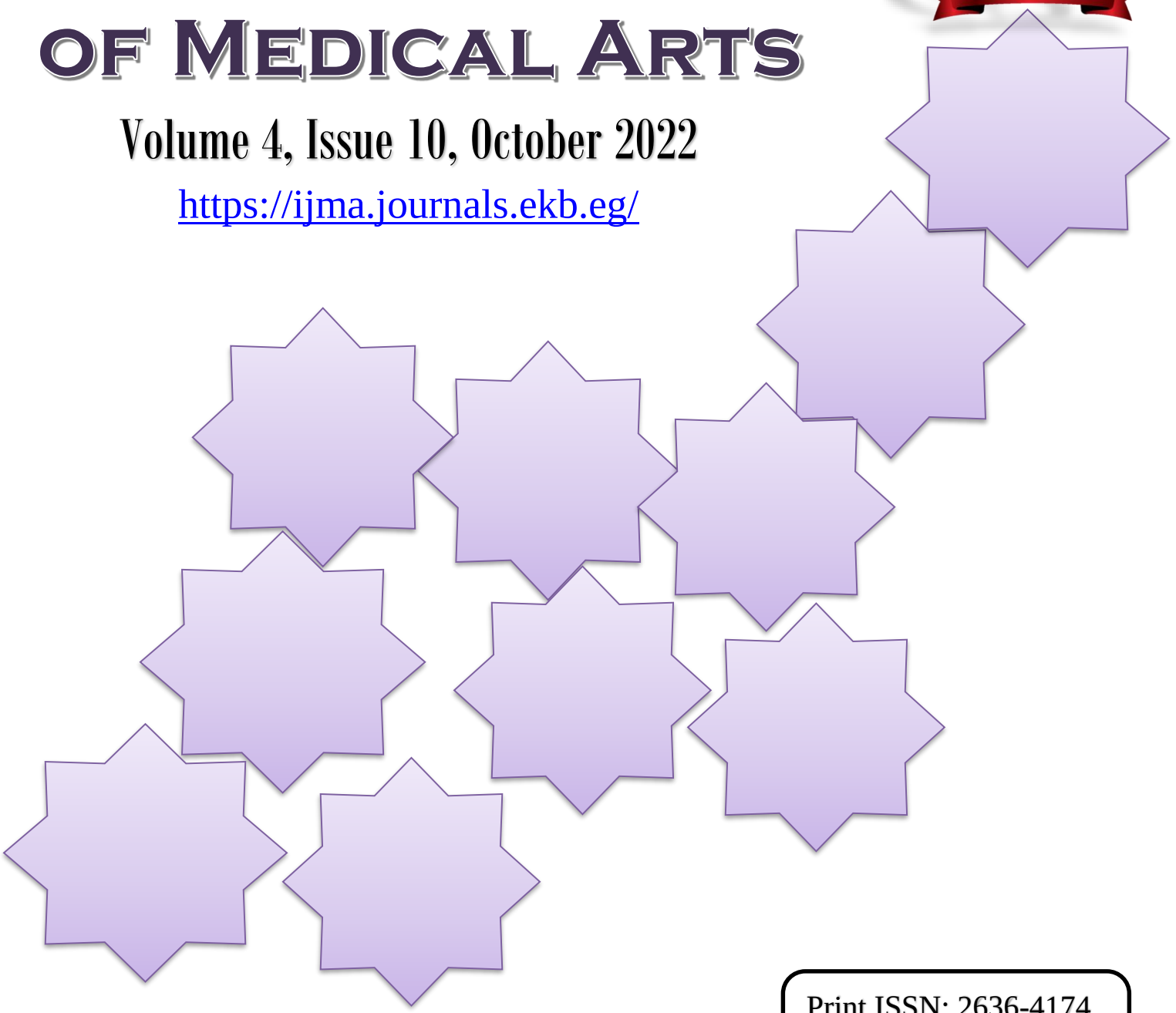

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Original Article

Comparative Study of Oct Angiographic Finding in Diabetic Macular Edema After Intravitreal Triamicinilone Acetonide Injection and Intravitreal Ranibizumab Injection

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ABSTRACT

Background: Diabetic macular edema [DME] is a major factor contributing to the visual deterioration in most developed nations. OCTA helps visualization of diabetic microvascular changes such as microaneurysms, FAZ enlargement, and capillary non-perfusion areas.

Aim of the work: This study aims to assess the changes in the macular perfusion of diabetic patients before and after intravitreal triamcinolone acetonide injection compared to intravitreal ranibizumab injection by OCTA.

Patients and methods: This comparative study included 40 eyes having DME scheduled at Al-Azhar university hospital, Damietta. Twenty eyes underwent intravitreal ranibizumab injection [Group I] and Twenty eyes underwent intravitreal triamcinolone acetonide injection [Group II].

Results: This study demonstrated that BCVA and CMT significantly improved in 1st week up to 3 months in both groups. There was no statistically significant difference between the 2 groups as regards BCVA and CMT improvement [P value > 0.05]. As regards SCP [superficial capillary plexus], and DCP [Deep capillary plexus], there was some improvement in the macular perfusion of DCP in the ranibizumab group with no difference in macular perfusion of SCP in both groups and mild worsening of DCP in the triamcinolone group. The difference between the 2 groups was not significant statistically all over follow-up periods [P value > 0.05]. Also, the difference between the baseline macular perfusion and postoperative one in each group was not significant statistically [P value > 0.05].

Conclusion: Our study showed no significant changes in macular perfusion [SCP or DCP] following ranibizumab or triamcinolone injection in DME. In both groups.

Keywords: DME; Ranibizumab; Triamcinolone; OCTA.

INTRODUCTION

Diabetic retinopathy [DR] is a prominent cause of vision loss in working-age populations which has an estimated prevalence of 34.6% for all forms and 6.96% for proliferative DR [PDR] in the diabetic population. About 6.81% of diabetic patients have diabetic macular edema [DME] [1].

Nowadays, macular edema caused by a range of retinal illnesses, including DME, is treated with a series of intravitreal injections of several anti-VEGF drugs. Injections of steroids and macular laser photocoagulation are two more methods of treating DME [2]. Disruption of the blood-retinal barrier and the resulting leaking of microaneurysms lead to retinal edema in DME. Anti-VEGF medicines are the primary treatment for DME because they effectively reduce macular edema and enhance vision; this is because vascular endothelial growth factor [VEGF] is the predominant cause of retinal vascular hyperpermeability. However, cortico-steroids are a viable therapeutic choice for DME patients with anti-VEGF resistance [3].

Despite anti-VEGF medication being the standard of care for DME today, its effect on macular perfusion is still up for debate. For patients with anti-VEGF-agent-resistant macular edema or when anti-VEGF is contraindicated, intravitreal Triamcinolone Acetonide [TA] injection is now considered a second-line therapy option [4, 5].

Non-invasive optical coherence tomography angiography [OCTA] provides high-quality 3D images of the different layers of the retina's vascular system without the use of iodine or contrast dyes. The foveal avascular zone [FAZ] can be scanned with OCTA without the interference of dye leakage or the shadowing of the macular xanthophyll pigment, unlike with FA [6].

OCTA works by comparing the differences between the signals from repeated OCT B-scans taken quickly one after the other of the same part of the retina. allowing imaging of vessels in the retina that are filled with blood and figuring out where there is no flow. Therefore, OCTA allows for an objective and grader-independent evaluation of the retinal perfusion in comparison to FA by providing reproducible and reliable measurements of Vessel Density [VD] and Fractal Dimension [FD] [7].

There isn't much information in the literature about how it works for people with DME. This is because OCTA can be hard to understand in DME because of artifacts caused by intraretinal cystoid spaces, which can move retinal blood vessels and make it hard to tell where there is less blood flow or none at all [8].

So, this study aims to assess the changes in the macular perfusion of diabetic patients before and after intravitreal triamcinolone acetonide injection compared to intravitreal ranibizumab injection by OCTA.

PATIENTS AND METHODS

This prospective comparative study included 40 eyes having DME who were scheduled for either intravitreal ranibizumab or intravitreal triamcinolone Acetonide [TA] injection at Al-Azhar university hospital, Damietta. from April 2022 to November 2022. After approval of the ethics committee at Al-Azhar University, and informed written consent from all patients, we recruited the patients according to the following criteria;

Inclusion criteria: 1] Patients with type II diabetic patients having DME. 2] Pseudophakic patients. 3] IOP of 20 mm Hg or lower.

Exclusion criteria: 1] Refusal to participate in the study. 2] Phakic patients with DME. 3] Previous anti-VEGF or triamcinolone acetonide injection. 4] Proliferative diabetic retinopathy. 5] Previous laser retinal photocoagulation was applied to the macula. 6] Patients with glaucoma. 7] Concomitant ocular diseases [other than DR] affecting the visual acuity [e.g., retinal vein or artery occlusion, uveitis, or another ocular inflammatory disease]. 8] Previous vitrectomy. 9] Patients with uncontrolled DM [high HbA1C].

The patients were randomly divided into two groups, [**Group I]** included 20 eyes that underwent intravitreal ranibizumab injection, and [**Group II]** included 20 eyes that underwent intravitreal triamcinolone acetonide injection 40mg/1ml [Kenacort; Bristol-Myers Squibb, Tokyo, Japan].

Full detailed systemic history including **[**smoking and its duration, previous general medical history, duration of DM and its control, associated diseases such as anemia, hypertension, and hyperlipidemia] and full

detailed ophthalmic history including: **[**medical and surgical ophthalmic history and history of trauma, history of previous intraocular injection of anti-VEGF or surgery]. Complete ophthalmological examinations were done, including the measurement of best corrected visual acuity [BCVA] in decimal visual acuity, intraocular pressure [IOP], slit lamp bio-microscopy, and dilated fundus evaluation using 90 D lens.

Surgical procedure

All cases were done under topical anesthesia. Preparation of the skin, eyelashes, and ocular surface with povidone-iodine solution, draping to isolate eyelashes from the surgical field. A lid speculum was applied followed by the instillation of a 5% povidone-iodine solution. **Group I:** underwent intravitreal injection of 0.3mg/0.05mL of Ranibizumab supratemporal, or inferotemporal for ease of access. **Group II:** underwent intravitreal triamcinolone acetonide injection 2mg/0.05mL. The site of injection was 3-3.5mm from the limbus as all our patients were pseudophakic. Fundus examination to exclude CRA spasm and paracentesis was done. Antibiotic drops were placed then the eye was patched.

Post-operative Evaluation

Evaluation of patients was at 1 week, 1- and 3 months post-operative. At all visits, patients were evaluated for: measurement of best corrected visual acuity [BCVA] in decimal visual acuity, intraocular pressure [IOP] by air puff tonometer, and evaluation of macular perfusion and macular thickness obtained by DRI OCT Triton which used 1050 nm OCT for Posterior segment OCT and optional OCT Angiography imaging.

Statistical analysis: Statistical analysis was performed by a version 26 of SPSS software. Categorical data were presented as numbers and percentages and were compared using the Chi-Square Test. The normality of continuous data was initially checked by the Shapiro-Wilk test. All continuous data were not parametric, so we present it as Interquartile range and median [IQR]. Within-follow up comparison in each group was done using the Friedman Test, and the 2 groups were compared using the Mann-Whitney U-test. Wilcoxon signed-rank test was used to compare preoperative and postoperative outcomes in each study group.

RESULTS

Our study included 40 patients with diabetic macular edema receiving either an anti-VEGF injection [20 patients] or a triamcinolone acetonide injection [20 patients]. The median and IQR age of the patients was 55 [45 – 46] years, with no significant difference between the 2 groups [P value= 0.43]. Forty percent [40%] were male and 60% were female. The percentage of males was higher in the Anti-VEGF group; however, the percentages of females were higher in the triamcinolone group, this difference between the 2 groups was significant statistically [P value < 0.05]. As regards the side of injection, 55% of the patients were injected on the right side and 45% on the left side with no significant difference between the 2 groups [P = 0.88] as shown in table [1].

In terms of BVCA, in Anti VEGF group, BCVA improved in 1st week – 3 months, from 0.05 [0.05-0.10] [median and IQR] at baseline to 0.1 [0.1 – 0.19] in 1st week, 0.5 [0.4 – 0.6] at 1st month, and 0.6 [0.5 – 0.7] at 3rd month respectively [p<0.001]. In the triamcinolone group, BCVA improved in 1st week – 3 months, from 0.04 [0.03 – 0.05] [median and IQR] at baseline to 0.1 [0.04 – 0.17] in 1st week, 0.5 [0.4 – 0.6] at 1st month, and 0.6 [0.5 – 0.7] at 3rd month respectively [p<0.001]. The degree of BCVA improvement at all follow-up periods was similar in the 2 groups with no statistically significant difference [P value > 0.05] as presented in table [2].

In terms of CMT, in the Anti VEGF group, the median and IQR CMT decreased at 1st week – 3 months, from 0338.5 [326.25 – 384.25] at baseline to 322 [306.5 – 344.25] at 1st week, 285.5 [266 – 310.75] at 1st month, and 260.5 [250.25 – 288.25] at 3rd month respectively [p<0.001]. In the triamcinolone group, it reduced at 1st week – 3 months, from 372.5 [352.25 – 462.25] at baseline to 356 [340 – 403] at 1st week, 278.5 [237 – 345.5] at 1st month, and 276 [233.75 – 330] at 3rd month respectively [p<0.001]. The degree of CMT improvement at all follow-up periods was similar in the 2 groups with no statistically significant difference [P value > 0.05] as shown in table [3].

As regards SCP and DCP, there is some improvement in macular perfusion of DCP in the Ranibizumab group but not of statistical significance with no difference in macular perfusion of SCP in both groups or mild

worsening of DCP in triamcinolone group but not statistically significant. The difference between the 2 groups was not significant statistically at any follow-up periods [P value > 0.05]. Also, the difference between the baseline and any follow-up periods in each group was not significant statistically [P value > 0.05] as presented in tables [4, 5].

As regards the IOP, the 2 groups were not different statistically [P value >0.05]. However, it was increased in the Anti VEGF and Triamcinolone groups from 17 [16.25 – 18] mmHg, and 17 [16 – 18] respectively at the baseline to 18 [17 – 18], and 18 [17 – 24.25] at 1st week postoperative [P value = 0.6, and 0.001 respectively]. This elevation is statistically significant in the Triamcinolone group at all follow-up periods [P value 0.001, 0.03, and 0.04] at 1 week, 1 month, and 3 months respectively as shown in table [6].

Table [1]: Demographic characteristics of both groups

Variables		Total [n = 40]	Anti-VEGF [n = 20]	Triamcinolone [n = 20]	P-value
Age [years] median [IQR]		55 [46 – 64]	53 [45 – 64]	55 [52 – 63]	0.43 [a]
Gender, n [%]	Male	16 [40%]	11[55%]	5 [25%]	0.05 [b]
	Female	24 [60%]	9 [45%]	15 [75%]	
Side, n [%]	Right	22 [55%]	11 [55%]	11 [55%]	0.88 [b]
	Left	18 [45%]	9 [45%]	9[45%]	

a: Friedman Test, b: Wilcoxon Signed Ranks Test.

Table [2]: Comparison of BCVA over follow-up periods between the 2 groups

BCVA [Decimal]	Anti-VEGF [n = 20]	P-value [b]	Triamcinolone [n = 20]	P-value [b]	*P*-value [c] between groups
Baseline	0.05 [0.05 – 0.1]	-	0.04 [0.03 – 0.05]	-	**0.02***
1st week	0.1 [0.1 – 0.19]	**<0.001****	0.1 [0.04 – 0.17]	**<0.001****	0.11
1st month	0.5 [0.4 – 0.6]	**<0.001****	0.5 [0.4 – 0.6]	**<0.001****	0.82
3rd month	0.6 [0.5 – 0.7]	**<0.001****	0.6 [0.5 – 0.7]	**<0.001****	0.32
P-value [a]	**<0.001***		**<0.001***		

a: Friedman Test, b: Wilcoxon Signed Ranks Test, c: Mann-Whitney U test, *: statistically significant at P<0.05.
**: significant at P <0.0125 according to post hoc comparison adjusted by Bonferoni's corrections (p< 0.05/ 4 = 0.0125).

Table [3]: Comparison of CMT over follow-up periods and between the 2 groups

CMT [mm]	Anti-VEGF [n = 20]	P-value [b]	Triamcinolone [n = 20]	P-value [b]	*P*-value [c] between groups
Baseline	338.5 [326.25 – 384.25]	-	372.5 [352.25 -462.25]	-	**0.04***
1st week	322 [306.5 – 344.25]	**<0.001****	356 [340 – 403]	**<0.001****	**0.01***
1st month	285.5 [266 – 310.75]	**<0.001****	278.5 [237 – 345.5]	**<0.001****	0.52
3rd month	260.5 [250.25 – 288.25]	**<0.001****	276 [233.75 – 330]	**<0.001****	0.82
P-value [a]	**<0.001***		**<0.001***		

a: Friedman Test, b: Wilcoxon Signed Ranks Test, c: Mann-Whitney U test, *: statistically significant at P<0.05.
**: significant at P <0.0125 according to post hoc comparison adjusted by Bonferoni's corrections (p< 0.05/ 4 = 0.0125).

Table [4]: Comparison of SCP over follow-up periods and between the 2 groups

SCP	Anti-VEGF [n = 20]	P-value [b]	Triamcinolone [n = 20]	P-value [b]	*P*-value [c] between groups
Baseline	46.7 [43 – 48.9]	-	45.5 [43.2– 47.6]	-	0.82
1st week	46.4 [44.1 – 46.9]	0.42	45.2 [43.2 – 46.9]	0.12	0.6
1st month	45.4 [43.8 – 47.3]	0.69	44.8 [43.5 – 48.6]	0.83	0.23
3rd month	45.3 [44.2 – 47.8]	0.83	45.5 [43.8 – 48.9]	0.38	0.72
P-value [a]	0.9		0.2		

a: Friedman Test, b: Wilcoxon Signed Ranks Test, c: Mann-Whitney U test, *: statistically significant at P<0.05.
**: Significant at P <0.0125 according to post hoc comparison adjusted by Bonferoni's corrections (p< 0.05/ 4 = 0.0125).

Table [5]: Comparison of DCP over follow-up periods and between the 2 groups

DCP	Anti-VEGF [n = 20]	P-value [b]	Triamcinolone (n = 20 patients)	P-value [b]	P-value [c] between groups
Baseline	45.3 [37.5 – 53]	-	48.1 [42.7 – 50.6]	-	0.86
1st week	44.4 [40.4 – 52.9]	0.11	47.5 [43.8 – 49.9.6]	0.41	0.86
1st month	47.1 [42.8 – 53.6]	0.12	47.9 [43.7 – 49.9]	0.32	0.48
3rd month	48.6 [44.05 – 52.9]	0.13	47.5[45.9 – 50.9]	0.92	0.73
P-value [a]	0.51		0.72		

a: Friedman Test, b: Wilcoxon Signed Ranks Test, c: Mann-Whitney U test, *: statistically significant at P<0.05.
**: Significant at P <0.0125 according to post hoc comparison adjusted by Bonferoni's corrections (p< 0.05/ 4 = 0.0125).

Table [6]: Comparison of IOP over follow-up periods and between the 2 groups

IOP [mmHg]	Anti-VEGF [n = 20 patients]	P-value [b]	Triamcinolone [n = 20 patients]	P-value [b]	P-value [c] between groups
Baseline	17 [16.25 – 18]	-	17 [16 – 18]	-	0.7
1st week	18 [17 – 18]	0.63	18 [17 – 24.25]	**<0.001****	0.21
1st month	17.5 [17 – 18]	1	17 [16 – 21.25]	**<0.03***	0.92
3rd month	17.5 [17 – 18]	0.11	17 [16 – 19.75]	**<0.04***	0.92
P-value [a]	0.72		**<0.001****		

a: Friedman Test, b: Wilcoxon Signed Ranks Test, c: Mann-Whitney U test, *: statistically significant at P<0.05.
**: Significant at P <0.0125 according to post hoc comparison adjusted by Bonferoni's corrections (p< 0.05/ 4 = 0.0125).

DISCUSSION

In severe cases, diabetic macular edoema might lead to total blindness. Those of working age and the elderly may bear a disproportionate share of the societal costs in various regions of the world [10]. Even though anti-VEGF medication is the current gold standard for treating DME, its retinal perfusion effect is still up for debate. There is rising evidence for the use of anti-VEGF medication in PDR, and some trials have indicated that it can slow down or even improve macular non-perfusion. However, anti-VEGF medication may aggravate non-perfusion, leading to a decrease in vision [4].

In our study, the demographic characteristics of both groups showed that the median and IQR age of the patients was 55 [45 – 46] years. Forty percent [40%] of the included patients were male, and 60% were female. The percentage of males was higher in the anti-VEGF group; however, the percentages of females were higher in the triamcinolone group. As regards the side of injection, 55% of the patients were injected on the right side, and 45% were injected on the left side.

In terms of BVCA in our study, Anti VEGF group showed improvement in 1st week up to 3 months, from 0.05 [0.05-0.10] [median and IQR] at baseline to 0.1 [0.1 – 0.19] at 1st week, 0.5 [0.4 – 0.6] at 1st month, and 0.6 [0.5 – 0.7] at 3rd month respectively [p<0.001]. While in the triamcinolone group, BCVA improved in 1st week – 3 months, from 0.04 [0.03 – 0.05] [median and IQR] at baseline to 0.1 [0.04 – 0.17] in 1st week, 0.5 [0.4 – 0.6] at 1st month, and 0.6 [0.5 – 0.7] at 3rd month respectively [p<0.001]. The degree of BCVA improvement at all follow-up periods was similar in the 2 groups with no significant difference [P value > 0.05]. This is in line with the results of **Shimizu *et al.*** [12] and **Ozkaya *et al.*** [13].

This also agrees with **Karst *et al.*** [14] who included twenty-five eyes in the study and 10 patients received ranibizumab while 15 patients received triamcinolone. Similarly, **Ahmed *et al.*** [15] reported that in the ranibizumab group there was a BCVA improvement at 3rd and 6th months [p =0.001]. However, in triamcinolone group there was improvements at 1st, 3rd, and 6th months.

In agreement with our results **Hong *et al.*** [11] studied Sixty-four eyes receiving triamcinolone and demonstrated that at each subsequent follow-up assessment revealed a statistically significant improvement in BCVA.

In our study in terms of CMT, in the Anti VEGF group, the median and IQR CMT decreased at 1st week – 3 months, from 0338.5

[326.25 – 384.25] at baseline to 322 [306.5 – 344.25] at 1st week, 285.5 [266 – 310.75] at 1st month, and 260.5 [250.25 – 288.25] at 3rd month respectively [p<0.001]. In the triamcinolone group, it reduced at 1st week – 3 months, from 372.5 [352.25 – 462.25] at baseline to 356 [340 – 403] at 1st week, 278.5 [237 – 345.5] at 1st month, and 276 [233.75 – 330] at 3rd month respectively [p<0.001]. This goes with **Mastropasqua *et al.*** [16] who conducted a totally of 25 eyes of type 2 diabetes with DME treated with 3 monthly ranibizumab injections where the CMT decreased at from 460.3±125.2 µm at the baseline to 342.1± 65.8 µm at 1st month and 322.8±55.6 at 3rd months [p<0.001].

Sorour *et al.* [17] also, reported that the change in CMT was significant statistically following anti-VEGF injection [ranibizumab or aflibercept] in all patients especially the DME subgroup.

In agreement with our results **Hong *et al.*** [11] demonstrated that the mean CMT was decreased from 412.75 µm at the baseline to 299.48 µm at 1st month, and 306.61 µm at 2nd month.

In our study, the degree of BCVA and CMT improvement at all follow-up periods were similar in the 2 groups with no statistically significant difference [P value > 0.05]. This agree with the study by **Elman *et al.*** [18] which showed that CMT was wqual in both the ranibizumab and triamcinolone groups at the baseline and 3rd month, but BCVA was much better in the ranibizumab group after one year [p = 0.015].

As regards IOP, it was increased in the ranibizumab group from 17 [16.25 – 18] mmHg at the baseline to 18 [17 – 18] mmHg at 1st week postoperative [P value = 0.6] while in the triamcinolone group it was 17 [16 – 18] mmHg at the baseline to 18 [17 – 24.25] at 1st week postoperative [P value 0.001]**.** There was statistically significant IOP elevation is in the triamcinolone group all over follow-up periods [P value 0.001, 0.03, and 0.04] at 1 week, 1 month, and 3 months respectively. Also, there were 5 cases [2**5**% of patients] that showed IOP ranged from [24-29] in 1st week. In all eyes, intraocular pressure could be normalized by topical anti-glaucomatous medication which returned near normal IOP by the end of the follow-up period. This goes with **Ciardella *et al.*** [19] who studied 30 eyes that underwent intravitreal triamcinolone injection for DME and reported that during the study period, IOP was higher than 21 mm Hg in 40%. Similarly, **Ahmad *et al.*** [20] studied 40 eyes with DME 20 eyes were treated with intravitreal triamcinolone injection and showed that there was a temporary increase in IOP [26–34 mmHg] was observed in 4 [20%] eyes, which was managed with anti-glaucoma drugs. This is in line with **Hong *et al.*** [11] who reported that the IOP did not rise significantly, except for 11 patients, in which the IOP was elevated more than 21 mmHg; which was controlled with topical anti-glaucomatous.

In our study as regards SCP and DCP, there was some improvement in macular perfusion of DCP in the ranibizumab group but not of statistical significance with no difference in macular perfusion of SCP in both groups and mild worsening of DCP in triamcinolone group but not statistically significant.

Similarly, **Falavarjani *et al.*** [21] used OCTA to measure the macular perfusion change after intravitreal injection of anti-VEGF, the study did not show a significant change in the parafoveal, foveal, and vessel density.

This is also supported by **Couturier *et al.*** [22] which assessed 10 eyes with DME. After 3 months of treatment with ranibizumab or aflibercept, the superficial capillary density went down from 39.5 % to 36.6 %, and the deep capillary density went down from 44.7 % to 42.5 % in This, however, was not statistically significant, perhaps because there were so few patients in the study.

In agreement with **Mirshahi *et al***. [23] who used OCTA to assess changes in the blood flow to the macula after a single injection of bevacizumab for DME. Before and after the injection, they measured the VD of the retina, the FAZ area, and the VD of the subfoveal choriocapillaris. Aside from a slight recovery in choriocapillaris VD, there were no major changes found after the injection. On the contrary, **Mastropasqua *et al.*** [16] conducted a total of 25 eyes. The SCP did not modify significantly during the follow-up from baseline [39.8±4.4], at 30 days [40.7±6.2], and at 90 days [42.1±3.4] with [p= 0.077] which goes with our results but showed a statistically significant increase in foveal DCPD at 30 d after therapy [P<0.001]. Also, **Golshani *et al.*** [24] who used OCT and OCTA to assess DME patients who switched from ranibizumab or

bevacizumab to aflibercept, found that there was no difference between the two groups [SWAP-TWO Study]. Patients got aflibercept injections every month until an OCT showed that there was no fluid. After that, they got a fixed dose every two months for a year.

In contrast to our study, **Elnahry *et al*.** [3] did a prospective investigation of the impact of bevacizumab on the macular perfusion by optical coherence tomography angiography [IMPACT Study] found that vessel density [VD] decreased by 8%.

In conclusion, this study revealed that no macular perfusion changes [SCP or DCP] following ranibizumab or triamcinolone injection in DME. Also, there were significant BCVA and CMT improvements, with no difference between the two groups.

Conflict of Interest and Financial Disclosure: None

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