

Evaluation of Pars Plana Vitrectomy with ILM Peeling in Management of Persistent Nontractional Diabetic Macular Edema

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Abstract

Aim of Study: To assess the improvement of best corrected visual acuity and its correlation with pre-operative variables and change in macular thickness following pars plana vitrectomy and ILM peeling for diffuse non-tractional diabetic macular edema.

Methods: 25 eyes with persistent diabetic macular edema were treated with 23 gauge transconjunctival PPV with ILM peeling. Pre-operative evaluation performed including full medical and ophthalmological history and examination. Central Subfield Macular Thickness (CSMT) and BCVA was evaluated at 6 weeks and 3 months and 6 months post-operatively.

Results: Mean pre-operative BCVA (decimal notation) was 0.1 (SD±0.0674). Mean BCVA was 0.1182 (SD±0.09700), 0.1382 (SD±0.09881), 0.1598 (SD±0.10273) at 6 weeks, 3 months and 6 months post-operative respectively Figs. (27-29). Mean post-operative change in BCVA from base line was 0.0149 (SD±0.08749), 0.0349 (SD±0.08808) and 0.0565 (SD±0.09152) at 6 weeks, 3 months and 6 months post-operative respectively which was statistically significant at 6 months (p -value=0.008).

There was no visual improvement in 8 eyes (32%) and 17 eyes experienced visual improvement (68%) but this was not statistically significant (p -value=1). All non-improved cases were females and this was statistically significant by fisher's exact test (p -value=0.026).

There was anatomical improvement (improvement of central foveal thickness) in 23 eyes (92%) and with no improvement in 2 eyes (8%). Visual and anatomical improvements were correlated in 16 eyes however, visual improvement without anatomical improvement occurred in one eye which wasn't statistically significant.

Conclusion: There was a limited visual improvement which was statistically significant only at 6 months post-operatively and there was no statistically significant correlation between visual improvement and anatomical improvement.

Key Words: ILM peeling – Diabetic macular edema – Best corrected visual acuity – Macular thickness.

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Introduction

MACULAR edema is defined as an abnormal thickening of the macula associated with accumulation of fluid in the extracellular space of the outer plexiform layer and the inner nuclear layer, and occasionally in the intracellular space [1,2]. It contributes to vision loss by altering the functional cell relationship in the retina and promoting an inflammatory reparative response. Macular edema associated with vitreous traction represents a particular tissue reaction due to the mechanical distortion of the retina. However, it is often difficult to differentiate whether edema is linked to the fact that the vitreous is pulling actively on the retina or to the fact that it is simply adherent. Furthermore, in certain circumstances, the changes at the vitreoretinal interface may represent the cause and in some others, the effect of vitreoretinal traction [3]. In 1992 Lewis et al., were the first to report the resolution of macular edema in 80% of cases after vitrectomy for diabetic edema associated with posterior hyaloidal traction [4]. Visual acuity results of vitrectomy for DME, in the absence of traction, are mixed. Some studies suggested positive outcomes; others have shown anatomic but not visual improvement after surgery, while some studies suggested that vitrectomy is not beneficial in eyes with DME without traction [5-7].

Patients and Methods

This was a prospective, nonrandomized interventional study that was performed on 25 eyes of 23 patients with refractory clinically significant diabetic macular oedema. All the patients underwent pars plana vitrectomy with ILM peeling. The patients were selected from the outpatient ophthalmology clinic of Kasr Al-Aini Hospital, Cairo University between March 2013 and August 2014.

The protocol was revised and approved by our Ophthalmology Department ethical committee.

A- Inclusion criteria:

Persistent diffuse DME defined as more than 2 disc diameters in area with central macular thickness (CMT) $300\mu\text{m}$ with history of at least one session of Macular Photocoagulation (MPC) and intravitreal injection of either triamcinolone acetonide or anti-vascular endothelial growth factor (anti-VEGF).

B- Exclusion criteria:

- 1- Lens opacity precluding Optical Coherence Tomography (OCT).
- 2- Massive hard exudates in the fovea.
- 3- Only focal macular edema attributable to focal leaks from microaneurysm.
- 4- History of previous vitreoretinal surgery.
- 5- Evidence of vitreomacular traction on OCT including anteroposterior by posterior hyaloid and tangential traction by taut hyaloid or epiretinal membrane.
- 6- Angiographic evidence of macular ischemia.
- 7- Monocular patient.

Preoperative evaluation:

- Full history including medical history (duration of diabetes, controlled or not), other systemic diseases and previous management for DR.
- HbA1C (glycosylated hemoglobin) should be 7%.
- Serum lipids and kidney functions were assessed and patients received statins in cases of hyperlipidemia.
- All eyes were subjected to examination of Best Corrected Visual Acuity (BCVA) using snellen's chart projector at a viewing distance of 3 metres and expressed in Decimal system.
- Slit-lamp examination of anterior segment to exclude corneal abnormalities and significant cataract.
- Intraocular pressure measurement using Goldman applanation tonometry.
- Fundus examination was done using slit lamp biomicroscopy and indirect ophthalmology.
- Pre-interventional fluorescein angiography using Topcon TRC 50IX retinal camera (Topcon Optical Co., Tokyo, Japan).

- Optical Coherence Tomography (OCT) to document macular thickness, configuration of macular oedema and to exclude vitreomacular traction and taut posterior hyaloid using Spectral Domain (SD) OCT (Optovue, Northport loop west Fremont, CA, USA) using the following protocols:
 - *Radial line scans:* 6mm diameter radial lines separated by 30 degrees and centered on the fovea. The line scan comprises 1024 axial scans. Sixteen scans for 16384 total data points averaged to single scan image.
 - *Macular map 5mm (MM5):* Central subfield foveal thickness, defined as the average retinal thickness of 1mm of central scanned area, using macular cube (MM5) in which 5x5mm square grid centered on fixation, the grid spacing is 0.25mm in the inner 3x3mm area and 0.5mm in the outer area. Seventeen horizontal then 17 vertical line scans all centered at fovea.

Surgical technique:

- Fourteen cases were done under General Anesthesia (GA) and 11 cases under peribulbar local anesthesia (lignocaine 1%: Bupivacaine 0.5% 1:1).
- Periocular skin was sterilized with 10% povidone iodine painting and conjunctival sac was sterilized using 5% povidone iodine eye drops.
- Three 23 gauge one step valved trocars was inserted at infero-temporal, supero-temporal and supero-nasal quadrants and infusion cannula was secured in the infero-temporal trocar.
- Phacoemulsification with 3 piece "acrysof" acrylic hydrophilic intra-ocular lens acrysof (Alcon, Aliso Viejo, California, USA) implantation in the bag (10 eyes) or in the ciliary sulcus (4 eyes) was done in all phakic patients irrespective of lens clarity.
- Core vitrectomy was done using Constellation vitrectomy machine (Alcon, Aliso Viejo, California, USA) using high cutting rate 4500 cut per minute (cpm) and 300mmhg linear vacuum.
- Triamcinilone was injected to stain cortical vitreous adherent to retina.
- Posterior hyaloid detachment was induced using vitrectomy probe by activating vacuum of vitrectomy machine starting from optic disc and extending to posterior border of vitreous base.
- ILM blue (Biriliant blue G 0.025%) (DORC International, Zuidland, the Netherlands) dye was injected under air and left for 30 seconds.

- A scratch was made in stained ILM by 23 gauge needle and flap was initiated using disposable 23 gauge diamond dusted sweeper (DORC International, Zuidland, the Netherlands).
- ILM peeling was completed using 23 gauge disposable ILM forceps (DORC International, Zuidland, the Netherlands).
- Vitreous base shaving was done and endo-laser photocoagulation was performed in cases with proliferative diabetic retinopathy.
- Air fluid exchange was done and trocars were removed and sutures were taken in case of leak.

Results

Demographic data analysis:

Twenty five eyes of 23 patients, 2 patients for both eyes, 7 males and 16 females were included. All patients were type 2 diabetes mellitus, 3 patients received oral hypoglycemic drugs and 20 patients received insulin. Mean age was 57.5 years (SD ± 6.87). Eight eyes had proliferative diabetic retinopathy and 17 eyes had non proliferative diabetic retinopathy. Eleven eyes were pseudophakic 6 were cataractous and 8 were nuclear sclerotic. Posterior vitreous detachment was present in 3 eyes. Nineteen eyes received only intravitreal anti-VEGF (Bevacizumab) and 6 eyes received both intravitreal bevacizumab and triamcinolone. The mean number of bevacizumab injections was 3.08 (SD ± 1.41).

1- Visual acuity:

Mean pre-operative BCVA (decimal notation) was 0.1 (SD ± 0.0674). Mean BCVA was 0.1182 (SD ± 0.09700), 0.1382 (SD ± 0.09881), 0.1598 (SD ± 0.10273) at 6 weeks, 3 months and 6 months post-operative respectively. Mean post-operative change in BCVA from base line is shown in table 1 which was statistically significant at 6 months (p -value=0.008). There was positive correlation between change in BCVA at week 6 and final change in BCVA at month 6 that was statistically significant (p -value=0.007) Fig. (1).

There was no visual improvement in 8 eyes (32%) and 17 eyes experienced visual improvement (68%) but this was not statistically significant (p -value=1). All non-improved cases were females and this was statistically significant by fisher's exact test (p -value=0.026).

In group without PVD visual improvement was in 16 eyes and 6 eyes showed no improvement while in group with PVD 1 eye showed improve-

ment and 2 eyes showed no improvement, but this wasn't statistically significant (p -value=0.231).

In PDR group visual improvement was in 4 eyes while 4 eyes showed no improvement. In NPDR group 13 eyes showed improvement while 4 eyes showed no visual improvement but, this wasn't statistically significant (p -value=0.359).

Distribution of visual improvement in relation to lens status is shown in (Table 2). But, this wasn't statistically significant (p -value=0.641).

There was a negative correlation between number of pre-operative anti-VEGF injection and mean change of BCVA at all follow up visit which wasn't statistically significant (p -value=0.262 at 6 month). Also, there was a negative correlation between pre-operative TA injection and mean change of BCVA at all follow-up visit which wasn't statistically significant (p -value=0.104 at 6 month). There was negative correlation between age of the patients and the post-operative mean change of BCVA at all follows-up visit which wasn't statistically significant (p -value=0.248 at 6 month).

2- Central Subfield Macular Thickness (CSMT):

Mean pre-operative CSMT was 536.56 μ (SD ± 134.064). Mean post-operative CSMT was 395.44 μ (SD ± 102.844), 359.16 μ (SD ± 116.005), 321.8 μ (SD ± 111.233) at 6 weeks, 3 months and 6 months respectively. The mean change in CSMT is shown in (Table 3) which was statistically significant (p -value < 0.0001). There was anatomical improvement (improvement of central foveal thickness) in 23 eyes (92%) and with no improvement in 2 eyes (8%).

Complications:

I- Intra-operative complications:

There were 2 posterior iatrogenic breaks in 1 eye during induction of PVD however they didn't interfere with ILM peeling and they were treated by endo-laser photocoagulation and air tamponade and post-operative face down positioning.

II- Post-operative complications:

There was 1 case of persistent epithelial defect that treated by bandage contact lens, excessive lubricants and autologous serum and another case developed hypopyon 4 days post-operatively and it was treated by frequent topical steroid under topical antibiotic cover. Vitreous hemorrhage occurred in 1 eye immediately post-operatively and managed conservatively with complete resolution after 10 days.

Table (1): Mean change in BCVA at different follow-up visits.

	Mean	Standard deviation	p-value
W6 BCVA change	0.0149	0.08749	0.525
M3 BCVA change	0.0349	0.08808	0.084
M6 BCVA change	0.0565	0.09152	0.008

Table (2): Relation between lens status and visual improvement.

	Lens status			Total
	IMSC	NS	Pseudophakic	
<i>Visual improvement:</i>				
No	3	2	3	8
Yes	3	6	8	17
Total	6	8	11	25

Table (3): Mean change in CSMT at different follow-up visits.

	Mean	Standard deviation	p-value
W6 BCVA change	-141.12	122.588	<0.0001
M3 BCVA change	-177.4	127.343	<0.0001
M6 BCVA change	-214.76	124.331	<0.0001

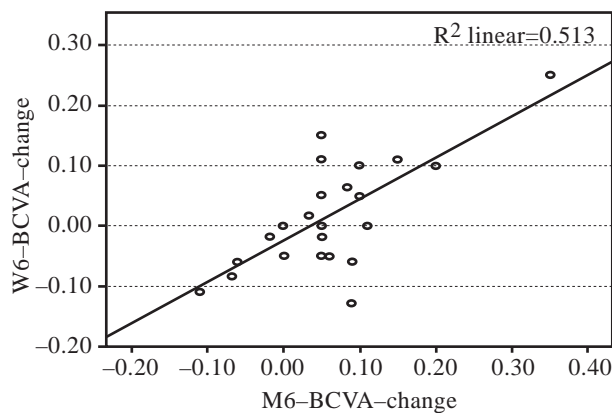


Fig. (1): Scatter plot graph showing relation between mean change in BCVA at week 6 (W6-BCVA-Change) and month 6 (M6-BCVA-Change).

Discussion

In our study 23 (92%) eyes showed marked decrease in mean central macular thickness compared to pre-operative values. This is in accordance to most published studies [8-16]. This anatomical improvement is attributed to surgical removal of the posterior vitreous membrane which causes a hydrostatic pressure gradient and relieves extravascular leakage and edema [17].

Moreover, vitrectomy enhances the intraocular oxygen pressure as it passes from arterial blood in the ciliary processes into the fluid in the vitreous cavity. Vitrectomy also removes substances that enhance vascular permeability such as cytokines [18].

In the current study, mean BCVA improvement was limited at 6 weeks and 3 months post-operatively yet was only statistically significant at 6 months. It was also found that visual improvement at 6 weeks post-operatively was positive predictor of the visual outcome at 6 months (p -value=0.007).

This limited visual improvement could be attributed to chronicity of the edema that persisted after both grid laser and intravitreal injections with mean pre-operative number of intravitreal anti-VEGF injections 3.08 (SD±1.41). Also, the poor pre-operative BCVA=0.1 (SD±0.0674) correlating with poor prognostic factors on OCT such as high pre-operative CSMT (536.56µ SD±134.064), disrupted IS/OS and ELM lines and cystic spaces in OPL with Muller fiber damage.

Visual and anatomical improvement occurred in 16 eyes however, visual improvement without anatomical improvement occurred in one eye and it was due to extraction of a significant cataract. Seven eyes didn't show visual improvement yet they showed anatomical improvement. However, there was one eye that didn't show neither visual nor anatomical improvement.

In our study Phacovitrectomy was performed for all phakic patients irrespective of lens clarity rather than performing vitrectomy alone in cases with clear lens or mild cataract to rule out effect of post-vitrectomy cataract progression on visual acuity. This was supported by Diabetic Retinopathy Clinical Research Network (DRCR net.) study which demonstrated that Eyes remaining phakic at the 6-month visit appeared more likely to have a decrease in visual acuity from the preoperative to the 6-month visit measurement than eyes that were pseudophakic at the preoperative examination, but there was no difference in the change in CSMT comparing phakic and pseudophakic eyes. This association appears to be related to development or progression of lens opacity after surgery rather than being a more favorable effect of vitrectomy on DME in pseudophakic eyes [19]. On the other hand, Rosenblatt et al., reported no statistically significant difference between pseudophakic and phakic eyes in their study which included 26 eyes (16 were phakic and 10 were pseudophakic). However, this was likely due to relatively limited follow-up period and small sample size [20].

In contrast to the anatomical improvement, post ILM peeling visual improvement was controversial among different studies and this is attributed to different inclusion criteria and variations in study design.

In current study there was limited improvement in mean BCVA and 68% of patients showed visual improvement which was in agreement with Stolba et al., Kumar et al., Kumagai et al., and Rosenblatt et al., who reported limited improvement in BCVA and around 50% of cases showed visual improvement. This limited visual improvement could be explained by chronicity of the edema (average duration of ME before surgery was 6 to 18 months) and poor baseline VA (6/60). Moreover, visual acuity and macular thickness showed significant improvement in favor of ILM group at all-time points in the comparative studies by Stolba et al., and Kumar et al., however, in Kumagai et al., the visual outcomes of ILM peeled eyes were better than ILM reserved eyes at 6 months and 1 year postoperatively, but there was no difference in the long-term visual outcomes between the two groups [20,22-24]. Also, a similar result of limited visual improvement was reported by Yanyali et al., and Recchia et al despite they had a small sample size (12 eyes and 10 eyes respectively) [19,21].

However, Bahadir et al., reported a non-significant difference in mean change in BCVA between PPV with ILM peeling and vitrectomy alone although it was significant in both groups. Non superiority of ILM in this study was due to inclusion of patients with thickened posterior hyaloid which was considered by our study as an element of traction which can be relieved by vitrectomy alone and these patients were excluded. Also, small number of eyes in ILM group (17 eyes) compared to vitrectomy group (41 eyes) in this non randomized study may signify selection bias [25].

European Vitreo Retinal Society Macular Edema (EVRS ME) study on 2012 reported more superior results for ILM peeling than our study. This study was a large scale non-randomized study based on 2,603 ME cases with a minimum follow-up of 6 months. 870 cases of diabetic edema superior to 300 microns were included. This study showed excellent results for ILM peeling starting from 3 lines at 3 months to finish at more than 8 lines at 24 months which was 2 to 3 times what was achieved by combined ILM peeling + TA and 3 times what was achieved by intravitreal anti-VEGF. However, comparing our results to this study is difficult because the pre-operative data of the patients in this study regarding the condition of vitreomacular interface, duration of macular edema and previous treatment was lacking as well as the large number of cases (61 cases treated by ILM peeling alone) [26].

Gandorfer et al., also reported marked visual improvement and VA improved by at least 2 lines in 11 eyes and 1 eye remained stationary. However, this study recruited 10 patients with an attached thickened and glistening posterior hyaloid face which was found intra-operatively to be totally adherent to the macula. This finding was considered as tractional element and these patients were excluded from our study [27].

On the other hand, Patel et al., reported no improvement in VA or perifoveal cone function despite the improvement in foveal thickness and macular volume 12 months after surgery. There was no significant difference in outcome parameters between the no peeling group and the ILM peeling group. The non-improvement in this study can be explained by chronic nature of the edema with the average duration of macular edema before surgery was 15 months and average number of number of previous laser treatment was 3 and also the relatively good mean pre-operative VA 20/50 (range, 20/32 to 20/125) which wasn't associated with significantly high mean macular thickness that was 400µm (range, 256-509µm) [28].

Shah et al., and Thomas et al., showed deterioration of BCVA in patient treated by PPV + ILM peeling which was performed by using ICG dye to enhance ILM visualization at concentration of 0.5% which was reported to be toxic to retina [29, 30].

However, our study is the first study to report using brilliant blue G (BBG) 0.025% in ILM peeling in DME. Because, in contrast to the good biocompatibility of BBG, Indocyanine Green (ICG) has revealed toxic effects in some studies which underline the narrow safety margin of this dye. Postoperative visual field defects and less favorable functional outcome have been described in the literature [31,32].

In our study we find a correlation between gender and final visual improvement with all males had visual improvement (p -value=0.026). This correlation wasn't demonstrated in other studies and needs further investigation.

Conclusion:

PPV with ILM peeling was successful in reducing central foveal thickness and this effect was maintained during the follow-up. There was a limited visual success which was statistically significant only at 6 months post-operatively and there was no correlation between visual success and anatomical success. Males were more respon-

sive to surgery than females and all males showed visual improvement. There were no serious complications that affect the final visual outcome. Further studies need to be performed with larger sample size and compared with other treatment modality to determine the effectiveness of surgery in management of macular edema.

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الملخص العربي

ارتشاح ماقولة العين السكرى سبب رئيسى لانعدام الرؤية عند مرضى السكر ويسبب تدهور مستمر فى حدة الابصار مع العلم بأن نصف المرضى يفقدون على الأقل سطرين خلال عامين. ويمكن تصنيفه شكليا الى بؤرى ومنتشر وسببيا بناء على العلاقة بين سطح الشبكية والجسم الزجاجى الى شدى وغير شدى. وبالرغم من اقرار دور ازالة الجسم الزجاجى وازالة الاغشية المتكونة على سطح الشبكية مع أو بدون ازالة الغشاء الداخلى المحد للشبكية فى علاج حالات ارتشاح ماقولة العين السكرى الناتج عن شد الجسم الزجاجى الا أن دورها فى علاج الارتشاح الغير ناتج عن شد الجسم الزجاجى لا يزال محل خلاف بين الدراسات حيث أن بعضها يبين تحسن فى سمك ماقولة العين ولكن بدون تحسن حدة الابصار وبعضها يبين تحسن فى سمك ماقولة العين وتحسن حدة الابصار. وقد قمنا بعمل دراسة لسلسلة من الحالات التدخلية لازالة الجسم الزجاجى مع ازالة الغشاء الداخلى المحد للشبكية فى علاج الارتشاح السكرى الغير ناتج عن شد الجسم الزجاجى المستمر بعد العلاج الضوئى بالليزر وحقق الجسم الزجاجى بالكورتيزون أو بالأجسام المضادة ضد عامل نمو الأوعية الدموية. وقد قمنا بعمل ازالة عدسة العين مع الجسم الزجاجى بغض النظر عن شفافية العدسة. وقد استخدمنا صبغة brilliant blue G (BBG) بتركيز ٠.٠٢٥٪ للمساعدة فى توضيح الغشاء الداخلى المحد للشبكية. وقد كان هذا الاجراء الجراحى ناجح فى الحد من سمك ماقولة العين مع استمرار هذا التأثير خلال المتابعة. وكان هناك نجاح بصرى محدود الذى كان ذو دلالة إحصائية فقط بعد ٦ أشهر من العملية وليس هناك علاقة بين النجاح البصرى والنجاح التشريحي. وقد كان الذكور أكثر استجابة للعملية الجراحية من الإناث. ولم تكن هناك مضاعفات خطيرة تؤثر على حدة الابصار النهائية.