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A Comparative Study of Vitrectomy with and Without Internal Limiting Membrane Peeling In Diabetic Macular Holes

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Abstract

Context: To clarify if Internal Limiting Membrane (ILM) peeling during Para Plana Vitrectomy (PPV) for diabetic macular hole can improve the visual and anatomical outcome of Diabetic Macular Holes (DMH).

Design: Prospective case-control study.

Participants: 60 eyes of 60 diabetic patients with DMH.

Methods: 30 eyes underwent PPV with ILM peeling (group 1), while PPV only was performed in the other 30 eyes (group 2) with DMH. Closure of the macular hole and visual acuity were assessed and compared at the end of the six postoperative months.

Results: Anatomical closure was achieved in 15 of group 1 eyes, while it was statistically significant higher in group 2 eyes (24 eyes). Eyes which underwent ILM peeling achieved statistically significant more visual gain than eyes with no ILM peeling with 18 and 10 eyes improved two or more Senellen lines in group 2 and group 1, respectively.

Conclusion: visual outcome and anatomical closure of diabetic macular holes were significantly higher in eyes where ILM peeling was performed compared to the other group. Accordingly, bimanual dissection of ILM during PPV may be mandatory to achieve better visual prognosis and anatomical outcome in eyes with diabetic macular holes.

Keywords: Diabetic macular hole; ILM peeling; PDR; PPV with ILM peeling;

Introduction

Macular hole formation has been linked to many causes. Although idiopathic Macular Hole (MH) is the most common, it can also develop in patients with diabetic retinopathy with and without proliferative changes. Macular hole in eyes with diabetic maculopathy can result mainly from either preexisting macular edema or fibro vascular traction [1,2]. Similarly, tangential foveal traction by the posterior vitreous cortex plays the main role in idiopathic macular hole formation [3, 4]. Pars plana vitrectomy combined with gas tamponade has been documented as the gold standard in idiopathic macular hole treatment [4]. Internal Limiting Membrane (ILM) peeling is now a routine step during PPV for treatment of idiopathic macular hole, as it has linked to more surgical success both anatomically and functionally [4]. Studies have described more than 90% anatomical closure of the macular holes when PPV was combined with ILM peeling [5]. Management of MH in PDR has been described; however, few studies about MH treatment associated with PDR were carried out with only few reports have studied the efficacy of ILM peeling in such cases [6].

The aim of the present study is to clarify if ILM peeling during para plana vitrectomy for diabetic macular hole can improve the visual and anatomical outcome of diabetic macular holes.

Methods

The study was performed at Faculty of medicine, Alexandria University hospital, between November 2012 through November 2016, Alexandria, Egypt. The study adhered to the tenets of the Declaration of Helsinki. Institutional Review Board (IRB)/ethics committee approval for human studies has been obtained.

Patients with macular hole as a complication of diabetic retinopathy were eligible for enrollment. Diabetic patients with PDR previously emmetropic with good glycemic control as indicated by hemoglobin A1c level were included in the study. Patients with Hb A1c more than 7%, patients who had other ocular pathologies, such as uveitis, previous trauma, previ¬ous ocular intervention or glaucoma were excluded from the study.

Sixty eyes of 60 patients were enrolled in this case control prospective study. All patients were informed about the design of the study and the procedure involved, and all gave written informed consent. A complete patient's evaluation was performed, which included the patient's age, medical and ocular history. A detailed preoperative ophthalmic evaluation including slit-lamp examination, Intraocular Pressure (IOP) measurement with Goldman applanation tonometry, and dilated fundus examination was performed in addition to documenting macular holes with Spectral Domain Optical Coherence Tomography (SD-OCT) using the Cirrus HD-OCT (Carl Zeiss Meditec, Dublin, CA) and scans were acquired using the Macular Cube 512 x 128, Enhanced HD Raster,

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and HD 5 Line Raster protocols. All operations were performed by the same surgeon (AS) under general anesthesia. Dilating drops in the form of phenylephrine 2.5% and tropicamide 1% eye drops were instilled before surgery. After anesthesia and draping, 23 gauge sclerotomy ports were made, after which standard vitrectomy was done. Peeling of posterior hyaloid was assisted by the use of intravitreal preservative free trimicinolone acetate. Following that patients were randomly allocated to one of two groups. In group 1 (n= 30 eyes of 30 patients) air/fluid exchange and temponade by air or non expansile sulfur hexafluoride gas was done without performing ILM peel (the mean operation time was 30 ± 7.4 minutes). In group 2 (n= 30 eyes of 30 patients) following posterior hyaloid peel, ILM was done. To achieve this, ILM was stained with high density Trypan blue stain (Monoblue Naf X, Acradophta, France) and left in the eye for two minutes without pressure. This was followed by removing the ILM bimanually using Tano scraper and ILM peeling forceps.

Immediately after surgery, moxifloxacin 0.5% eye drop was prescribed five times a day for 1 week together with prednisolone acetate 1% eye drop five times a day with a one drop/week taper over five weeks.

Patients were examined on the postoperative days 1, 7, 30, 90 and 180. Postoperative evaluations included patient history regarding any ocular complain, Snellen Visual Acuity (VA), slit-lamp examination, IOP measurement and fundus examinations. Evaluation was based on anatomical closure of the macular hole as indicated by OCT scan at the end of the six postoperative month, as well as, improvement in best corrected visual acuity as indicated by improvement of two Snellen lines or more. Optical Coherent Tomography (OCT) analysis was done by independent observer.

Statistical analysis was performed as the data were fed to the computer and analyzed using IBM SPSS software package version 20.0. Comparisons between groups for categorical variables were assessed using Chi-square test (Fisher or Monte Carlo). F-test (ANOVA) for normally distributed quantitative variables, to compare between more than two groups. Kruskal Wallis test for abnormally distributed quantitative variables, to compare between more than two studied groups, and Post Hoc (Dunn's multiple comparisons test) for pair wise comparisons. Significance of the obtained results was judged at the 5% level.

Results

Patients in group 1 included 17 women and 13 men with mean age 50 ± 7.3 years. Group 2 included 15 women and 15 men with an average age of 53.4 ± 5.2 years. The mean Hb A1c at the end of third postoperative month among group 1 patients was 6 ± 0.20%, while in the other group it was 6 ± 0.23%. There were no significant differences between the groups as regard age, gender and Hb A1c level (P > 0.05).

Anatomical assessment of macular hole closure was done with the aid of Spectral Domain Optical Coherence Tomography (SD-OCT) using the Cirrus HD-OCT (Carl Zeiss Meditec, Dublin, CA) and scans were acquired using the Macular Cube 512 x 128, Enhanced HD Raster, and HD 5 Line Raster protocols. Anatomical closure was achieved in 15 eyes of group 1, while in group 2 it was statistically significant more higher as 24 eyes demonstrated macular hole closure by the end of the sixth postoperative month. (Table 1)

Regarding visual acuity outcome, visual improvement as marked by improvement of two or more Senellen acuity lines by the end of six postoperative month was demonstrated in total of 28 eyes out of 60. Eyes which underwent ILM peeling achieved statistically significant more visual gain than eyes with no ILM peeling with 18 and 10 eyes improved two or more Senellen lines in group 2 and group 1, respectively. Conversely, visual loss of two or more lines was four times common in group 1 eyes than group 2. (Table 1)

All studied eyes left with temponading agent at the conclusion of surgery either air or sulfur hexafluoride gas (SF6). Air as a temponade was used more in group 2 eyes (26 eyes), in four eyes of group 1air was used. The rest of eyes received SF6 as a temponade. (Table 1)

The rate of macular thinning following the surgery was variable among eyes in both groups as demonstrated by OCT scans. Macular thinning took place in 43 of studied eyes, 25 of group 2 eyes showed macular thinning on OCT, while 18 eyes in group 1 showed this thinning. Retinal detachment was not a common complication during the period of study. Only two eyes suffered such complication among all studied sample and was among group 1 eyes. (Table 1)

Table 1: Comparison between the two studied groups according to different parameters

	Group1 (without ILM peel) (n=30)	Group 2 (with ILM peel) (n=30)	P
Anatomical closure	15 (50%)	24 (80%)	0.015*
Visual outcome			
Improved by 2 lines or more	10 (33.3%)	18 (60%)	0.021*
No improvement	8 (26.7%)	9 (30%)	
Worsened by 2 lines or more	12 (40%)	3 (10%)	
Type of used temponade			
Gas (SF6)	26 (86.6%)	4 (13.3%)	<0.001*
Air	4 (13.3%)	26(86.6%)	
Type of complications			
Postoperative retinal thinning on OCT	18 (60%)	25 (83.3%)	0.192
Postoperative retinal detachment	2 (6.6%)	0 (0%)	

p: p value for Chi square test for comparing between the studied groups

*: Statistically significant at p ≤ 0.05

Discussion

Proliferative diabetic retinopathy (PDR) frequently associated with retinal traction which could lead to macular hole formation, however, it is not a common complication [7]. Macular hole associated with a proliferative membrane in eyes with PDR has been reported [8]. The mechanism of macular hole formation in diabetic patients with macular edema and without proliferative membrane may be attributed to intraretinal exudation combined with increased vitreomacular attachments and traction [1]. Images obtained with the aid of OCT prior to the surgery revealed multiple intraretinal cysts and interstitial space around the hole, representing preexisting diabetic macular edema, which could cause a macular hole in combination with tangential traction by the adherent posterior vitreous cortex or epiretinal membrane, with and without obvious fibrovascular tissue. Management of diabetic macular hole may be challenging. Although successful anatomical closure can be achieved, the visual prognosis is usually not satisfactory [1, 9]. Poor visual outcome may be linked to macular edema or macular ischemia or the persistence of traction.

In the present study pars plana vitrectomy combined with bimanual dissection of ILM has lead to much better visual outcome and more anatomical closure rate of diabetic macular holes than eyes where ILM peeling were not performed. Para plana vitrectomy combined with ILM peel was documented as effective solution for treatment of diffuse diabetic macular edema without subsequent epiretinal membrane formation [10]. Accordingly, ILM peeling is a routine step to achieve better results in vitrectomy for diabetic macular edema [11]. That is why better anatomical and visual outcome in the present study may be attributed to the role of ILM peeling in reducing tangential traction associated with the taut posterior hyaloids and thus promoting macular hole closure, in addition, it promotes the reduction of preexisting diabetic macular edema.

In eyes with PDR even if vitreomacular separation has developed, adhesions exist between the hyaloid and the hole edge as reported by Kakehashi et al [12]. In their study of posterior retinal breaks in PDR, they found that no posterior vitreous detachment and operculum in the MH area. They also suggested that diabetic hole formation is an interplay between premacular fibrosis induced tangential traction along with longstanding macular edema. This observation has been suggested in other studies [1, 7]. Although ILM peeling, nowadays, is considered as essential step in PPV for treating idiopathic MH, its role remains controversial in diabetic macular hole closure. However, several studies reported successful MH closure after ILM peeling in PDR [1.6].

The current study has its limitation. While visual prognosis was one of the studied parameters, non visual improvement may be linked to other factors than successful macular hole closure. These factors can include and not limited to preoperative visual acuity, degree of macular edema, presence or absence of macular ischemia, duration of macular hole and height of macular detachment.

In conclusion, visual outcome and anatomical closure of diabetic macular holes were significantly higher in eyes where ILM peeling was performed compared to the other group. Accordingly, bimanual dissection of ILM during PPV may be mandatory to achieve better visual prognosis and anatomical outcome in eyes with diabetic macular holes.

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