Intractable diabetic macular edema can be treated with vitrectomy and inner border membrane debridement

Yuqing Wang1,Lin Wang2,Zhaode Zhang1,*,Cuiting Huang1,Yanrong Chen1

[1] 1.Department of Ophthalmology, Ningde Affiliated Hospital of Fujian Medical University, Ningde, 352100,China
[2] 2.Department of ophthalmology, Hospital of the First Affiliated Hospital of Harbin Medical University, Harbin, 150000,China

Introduction. Diabetes is the leading cause of old age disability worldwide, with diabetic macular edema (DME) being the primary cause of diminished field of vision. The goal of DME research is to improve anatomical and visual treatment as well as innovation.
Methods. In non-traction DME, the anatomic and visual benefits of planar vitrectomy and inner limiting membrane peeling (ILMP) were studied, as well as the relationship between the completeness of the outer retinal layer and the visual outcome of the spectral domain (SD)-optical coherence tomography (OCT). We examined the medical records of diabetic individuals (n = 42) who had non-tractional DME and were treated with ILMP. During months 1, 3, and 6 after surgery, the completeness of the outer retinal layer was measured, as well as the macular thickness and visual acuity. The student's t-test was used to look for significant differences between groups.
Results. The macroscopic centration of macular density and optometric capacity is greatly improved at month six post-treatment, although there is slight meaningful variation in months 1 and 3 post-operation. Furthermore, those with a fully functional outer limiting membrane had more excellent visual acuity than those who did not.
Conclusions. Parallel vitrectomy combined with ILMP may offer anatomical and visual benefits for patients with non-tractional DME. SD-OCT may help identify patients with potentially improved vision.

Keywords. DME; Elliptical zone; ILMP; Bypass vitrectomy

INTRODUCTION

Diabetes mellitus (DM) is a complicated disease produced by many of pathogenic causes that are not always mutually exclusive. 1 For clinical purposes, diabetes is separated into four types: Type 1 Mellitus is provoked by endogenous pancreatic disruption of pancreatic gland cells, resulting in total insulin insufficiency; Type 2 DM (T2DM) is induced by reduced insulin production and increased insulin resistance; Gestational diabetes; and Other Specific Causes of Diabetes 1 According to published data, 451 million persons aged 18 to 99 years old had diabetes between 1990 and 2016. By 2045, the population was anticipated to reach 693 million. 2

According to multiple studies, patients with T2DM who take insulin show an increase2d risk of macular oedema and diabetic retinopathy (DR) (DR). Although intensive blood pressure control and moderate physical exercise reduced the risk of DR by 20 percent and 31 percent , respectively, vitamin D deficiency elevated the risk of DR by nearly three times. Clinicians must analyze particular therapeutic interactions while picking a treatment. VEGF is able to promote neovascularization and the dissociation of the connections of capillary walls. In proliferative DR, it is thought to be the most significant factor in neovascularization. 5 Diabetic macular edema (DME) represents a major vision-threatening complication of DR, which is in general caused by fluid extravasation from pathologic or damaged microvasculature.
6,7 . 8,9 Optical coherence tomography (OCT) offered evolutionary advances in the recognition of pathophysiological mechanisms behind retinal illness by identifying different structural abnormalities in vivo. 10 OCT can successfully evaluate and detect DME early. Given the global diabetes epidemic, experts and diabetic patients must be informed about the early detection and treatment of DME utilizing OCT. 11 Pars plana vitrectomy (PPV) in combination with ERM peeling is often a useful therapeutic option for chronic DME that are unresponsive to intravitreal injections 12

The goal of this study is to show the anatomical and visual influence of planar vitrectomy and inner limiting membrane peeling (ILMP) in patients with non-tractional DME, and the link of the outer retinal layer integrity to the visual outcome in spectral domain OCT for the relief of visual loss in DME patients.

MATERIALS AND METHODS

Clinical Sample Collection

From 2012 to 2014, we analyzed the clinical information and the medical records of patients who had PPV with ILM stripping for DME. Acuity below 20/400 on preoperative sdOCT, anomalies at the vireo-retinal interface, and DME treatment within 3 months of vitrectomy were excluded. Patients with a history of intraoperative or postoperative steroid or anti-staphylococcal injections were excluded. One surgeon performed a typical 25-gauge vitrectomy on all patients. After causing posterior vitreous detachment, indocyanine green was used to remove ILM from three-disc diameter sections centered on the eye socket (ICG). Preoperative and postoperative Heidelberg sdOCT pictures (Heidelberg Engineering, Heidelberg, Germany). We assessed the OCT images to determine the status of the outer limbus (ELM) and ellipsoid zone (EZ).

Surgical method

Both groups received the same postoperative care. All patients had periorbital blockade under anesthesia. All eyes were subjected to central. The posterior vitreous was aspirated from the retina, and any noticeable vitreous streaks were eliminated. The ILM was then peeled off by brilliant blue or indocyanine green dye. Intraoperative pan-retinal photocoagulation or cryotherapy was used for insufficient previous pan-retinal photocoagulation. Topical antibiotics and anti-inflammatories were applied four times daily for one-month post-op.

Result Measures

Gender, age, systolic and diastolic blood pressure, BMI, diabetes characteristics (type, time of evolution, treatment, HbA1c), ophthalmologic abnormalities, and previous treatments were reviewed. Patients were assessed preoperatively and then every 6 to 12 months afterward. Each patient had a thorough ophthalmologic exam, including visual acuity, slit lamp, intraocular pressure, and dilated fundus examinations—statistics using Snellen visual acuity logarithms record complications during and after surgery. Postoperative visible acuity improvement or decline was defined as a change of 0.2 logMAR units. These included suprachoroidal hemorrhage, vitreous hemorrhage, severe IOP hypertension (30 mmHg) or hypotension (6 mmHg), retinal tears, retinal detachment, and uveitis. The exam used an OCT instrument. An expert examiner did it with a dilated pupil. The OCT exam comprised six 6-mm-long radial scans of each eye, spaced 30 。 apart. A retinal map analysis procedure was used to read automatic machine-generated retinal thickness values. Standard retinal thickness was 213 (19) mm. 10 Preoperative OCT was used to assess central macular thickness (mm) and vitreous traction.

Statistical study

Variables with a mean SD and categorical variables with a proportion (%) are written as mean + The

Kolmogorov-Smirnov test compared the continuous variable distribution to the theoretical normal distribution. Unpaired T-tests for consistent data were utilized. When comparing preoperative and postoperative results, paired student t-tests were performed. When reaching group proportions for binary outcomes, the stratified Cochran chi-square test and Fisher's exact test were utilized. To examine the relationship between final BCVA changes and other variables in the study, linear regression was used. The variables linked to P, 0.20 underwent multivariate regression. Statistical significance was set at 0.05. SPSS for Windows 20.0 was used for statistical analysis.

RESULTS

Baseline Characteristics

Figure 1 presents the selection process of patients. This research included 73 eyes from 55 patients with a mean age of 63.05 years (ranging 38.5-78.6 years). There were 38 males and 17 females, 11 eyes (15%) were from type 1 and 62 eyes (85%) were from type 2 DM. 20 eyes had vitreoretinal traction for DME, while 53 had little responsiveness to laser photocoagulation or intravitreal tretinoin injection. The two groups had the same baseline characteristics (Table 1). Table 2 summarizes the baseline ophthalmologic features of the eyes.

Surgical method

Using indocyanine green (65%) and bright blue (50%) in 45 eyes, respectively. Pan retinal photocoagulation was completed in 27 eyes with intraoperative cryotherapy, 6 eyes with Endo laser photocoagulation alone, and 10 eyes with a combination of the two. The two groups had no significant differences in cryotherapy and internal laser photocoagulation treatments.

Anatomic outcomes

The mean CMT was ameliorated from 528.7 119. 1 mm at baseline to 307.1 109.9 mm at 1 year and 285.3 123.4 mm at the final visit (Fig 1). The mean change in the non-traction group was 230.7 mm (range, 40 to 510 mm) (P = 0.742).

Observations

The mean logMAR BCVA was ameliorated from 0.78 0.38 and 0.75 0.35 to 0.58 0.32 (P< 0.001) and 0.45 0.27 (P< 0.001). The mean improvement in visual acuity was 0.23 logMAR (2.3 rows) for the no-traction group and 0.26 logMAR (2.6 rows) for the traction group at 3 years. The improvement in BCVA from baseline remained significant in both groups, but not as significant as at 3 years (Fig 2). The final post-operative BVCAand visual change showed litter difference between the two groups. The no-traction group improved by 55% and the with-traction group by 56% at 3 years, but 2 patients in the no-traction group and 1 patient in the with-traction group lost more than 2 rows of visual acuity . Moreover, 95.6% patients with no traction and 87.5% patients with traction showed maintained or even improved visual acuity at the final visit (Table 3).

Consequences and postoperative therapy

After surgery, two eyes developed congenital peripheral retinal tears that required cryotherapy and scleral buckling. There were no additional severe intraoperative issues. Postoperative hematogenous retinal detachment subjected. After surgery, 25 eyes (16 in the no-traction whereas 9 in the traction group) acquired cataracts. They all subjected to cataract operation at least a year later. At the end of the study, 19 eyes (15 in the no-traction group and 4 in the traction group) were still aphakic (P = 0.471, chi-square test). 18 eyes (14 [26%] without traction and 4 [20%] with traction) developed IOP hypertension needing medication. After 77 months, one of them underwent non-penetrating deep sclerectomy due to persistently high IOP despite maximal treatment. However, 15 eyes received intravitreal corticosteroid injections (9 concurrent with cataract surgery and 6 for persistent DME) and 7 received anti-VEGF injections (4 for worsening PDR and 3 concurrent with cataract surgery). Fig 3 shows the adjuvant therapy proportion in both groups. Neither research group had endophthalmitis.

Changes in best-corrected visual acuity

The connection between final BCVA alterations and clinical variables was studied using univariate and multivariate regression (Fig 4). It was found that preoperative macular thickness, diastolic blood pressure, and preoperative BCVA were all linked with postoperative BCVA change (R2 = 0.10, P = 0.027). This study's multivariate regression analysis revealed that preoperative BCVA was the only predictor of postoperative BCVA change (P = 0.002), while macular thickness change and systolic and diastolic blood pressure were not.

DISCUSSION

DR is a major microvascular consequence of DM and a leading contributor to vision loss in working-age people. 13. DR has considerable influences on patients, as well as on healthcare and economics (WHO, 2021). 14

Managing blood sugar in diabetes, glycemic control is still paramount. Trials on type 1 and type 2 DM indicated that strict glycemic management decreases the risk of retinopathy and retards the development of DR (UKPDS). [9, 10] Other researchers have found the same. 6, 17 However, this treatment has a number of side effects, such as reduction in visual field, night vision issues, and macular or suprachoroidal effusions that may lead to exudative retinal detachment. 18 NPDR anti-VEGF treatment Intravitreal anti-VEGF therapy for NPDR is new. VEGF may participate in the development of NPDR and PDR. 6 Anti-VEGF This is a newer treatment for NPDR. Clinical evidence links VEGF to NPDR and PDR development. Retrospective studies show that anti-VEGF therapy can enhance DRSS and retard PDR development. 21 Intravitreal anti-VEGF injections are becoming more common in NPDR without DME. At 100 weeks, the PANORAMA research indicated that intravitreal aflibercept reduced the probability of vision loss-related incidents by 77% and 83%, respectively, compared to a sham group. 22 During the second year of the DRCR.net W protocol, the incidence of vision-threatening issues was 16.3% for the aflibercept group and 43.5 percent for the sham group. 23 For example, DME, retinal vascular occlusions, macular degeneration, and inherited retinal dystrophies can all be tracked using OCT biomarkers.24 Because HRF co-localization is connected to drusen formation in the center, it may be a prediction of neovascular advancement. HRF is a crucial feature of with reliable predictive value for

monitoring the progression of disease and treatment responsiveness in most prevalent macular diseases. 24 It is also possible that the vitreous body, posterior hyaloid, and ILM all contribute to DME etiology25-27. PPV had good results in non-tractional DME eyes before intravitreal therapy was introduced in various case studies. 28-30 ERM is more common in DME eyes. 31,32 A recent study found that even when no ERM is seen on OCT, all watches with DME demonstrate ERM formation under microscopy observation and immunohistochemistry. 12 PPV is now a primary therapy option for eyes with DME and no ERM. 33 A shorter interval between DME diagnosis and PPV was necessary for the improved visual result. 33 Our study revealed that both central macular thickness and visual acuity were significantly improved preoperatively. Patients with an intact outer limiting membrane and ellipsoidal area showed greater preoperative and postoperative visual acuity than those with an uneven outer retinal layer. Patients' macular thickness and visual acuity improved significantly from baseline, as expected. In DME, planar vitrectomy with ILMP is helpful functionally and physically. The outer limiting membrane configuration is an excellent prognostic biomarker. Thus, if the external limiting membrane is intact, we recommend early vitrectomy in DME patients.

LIMITATION

Major weaknesses of the present study are the small number of eye samples and the relatively short follow-up period; these preliminary results warrant further investigation, as well as the fact that we cannot exclude the development of macular atrophy, where ILM stripping leads to a continuous loss of visual acuity in the following years.

COCLUSION

Overall, as the prevalence of diabetes cases rises and more people are predisposed to DR-induced vision loss, there is a need to develop more effective, affordable, and accessible treatments that will be attenuating the progression of DR and DME Vitrectomy is safe and effective in restoring macular thickness in both the traction and non-traction DME groups.

AVAILAILITY OF DATA AND MATERIALS

Data are available on request from the corresponding author.

CONFLICT OF INTERESTS

The authors declare that they have no competing interests.

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Corresponding Author:

Zhang Zhao-De

Ningde Hospital Affiliated to Ningde Normal University, Hunan 352100, China

E-mail: Zhangzhaode1973@163.com

Table 1~2 Comparisons of SAS and SDS scores among AD patients

SAS				
Group	Baseline	3 months	6 months	12 months
Control	24.00 ± 3.44	24.69 ± 5.11	26.25 ± 4.33	28.82 ± 6.63
Intervention	25.54 ± 6.93	28.54 ± 7.25	22. 11 ± 3.62	20.67 ± 3.97
P value	0.959	0.189	0.087	0.043
SDS				
Group	Baseline	3 months	6 months	12 months
Control	25. 15 ± 4.71	27.62 ± 7.09	29.75 ± 7.44	33.09 ± 8.84
Intervention	29.00 ± 8.37	31.00 ± 9.30	29.22 ± 7.05	27.89 ± 4.68
P value	0.164	0.38	0.972	0.047

Table 3 Comparisons of adverse event incidences among AD patients

Group	Cases	Falls	Lost	Misinhalation and misues	Intense	Abuse	Total incidene
Control	50	7	1	3	9	2	22
Intervention	50	3	0	1	4	1	9
P value	/	0.092	1	0.405	0.086	0.311	0.001

Figure legends

Fig 1. Comparisons of QOL-AD scores among AD patients

Fig 2. Comparisons of ADL scores among AD patients

Fig 3. Comparisons of BCS score among nursing staff

Fig 4. Comparisons of SCL-90 score among nursing staff