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Original article

Small-gauge vitrectomy for advanced diabetic eye disease: outcomes and predictive factors for poor postoperative vision

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Abstract

Objective: To evaluate the anatomical and visual outcomes of small-gauge vitrectomy in patients with advance diabetic eye diseases (ADED) and the predictive factors for poor visual outcome.
Materials and methods: A retrospective study was conducted from 2009 to 2014. Data at baseline, 6 months, and 12 months post-surgery were collected along with baseline demographic data, indications of surgery, systemic associations, visual and anatomical outcome, and postoperative complications. Poor visual outcome was defined as visual acuity worse than 6/36.
Results: A total of 158 eyes from 133 patients were recruited. Mean age was 54.01 ± 11.57 years and mean follow-up was 9.9 ± 3.7 months. Indications for vitrectomy were vitreous haemorrhage (VH, 77 eyes [48.7%]), tractional retinal detachment (TRD) with macular involvement (75 eyes [47.5%]), and other causes in 6 eyes (3.8%). There was visual improvement in 59.3% of patients, 23.6% worsened, and 17.1% stabilized at 12 months post-surgery. Patients with VH (75.4%) showed significant

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improvement compared to patients with TRD (48.3%). Successful anatomical outcomes were achieved in VH (98.2%) and TRD (96.7%). However, patients with TRD were found to have a 2.4-fold higher risk of having poor visual outcomes.
Conclusion: Small-gauge vitrectomy for ADED resulted in excellent visual and anatomical outcomes. Eyes with TRD were at a higher risk of developing poor visual outcomes.

Keywords: diabetes mellitus, diabetic retinopathy, tractional retinal detachment, vitrectomy, vitreous haemorrhage

Vitrektomi gauge kecil untuk penyakit mata diabetes terminal: hasil kajian dan faktor ramalan penentu bagi ketajaman penglihatan yang teruk pasca pembedahan

Abstrak

Objektif: Untuk menilai hasil pelekatan retina secara anatomi dan fungsi penglihatan selepas prosedur vitrektomi gauge kecil pada pengidap penyakit mata diabetes terminal (ADED) dan faktor ramalan penentu untuk hasil ketajaman penglihatan yang teruk.
Bahan dan kaedah: Ini adalah kajian retrospektif dari 2009 hingga 2014. Data pada peringkat garis awal, 6 dan 12 bulan selepas prosedur telah dikumpulkan. Ini termasuk data demografi peringkat garis awal, indikasi untuk menjalankan prosedur, penyakit sistemik, ketajaman penglihatan dan pelekatan retina secara anatomi, serta komplikasi pasca prosedur. Ketajaman penglihatan yang buruk ditakrifkan sebagai lebih buruk daripada 6/36.
Hasil: Sebanyak 158 mata dari 133 pesakit telah terlibat dalam kajian ini. Umur min adalah 54.01 ± 11.57 tahun dan purata masa rawatan adalah selama 9.9 ± 3.7 bulan. Indikasi untuk prosedur vitrektomi adalah pendarahan vitreous (VH, 77 mata [48.7%]), pelekangan retina secara traksi (TRD) dengan penglibatan makula (75 mata [47.5%]), dan penyebab lain pada 6 mata (3.8%). Terdapat peningkatan ketajaman penglihatan pada 59.3% pesakit, 23.6% menjadi bertambah buruk, dan 17.1% stabil pada 12 bulan selepas pembedahan. Pesakit dengan VH (75.4%) menunjukkan peningkatan penglihtan yang ketara berbanding dengan pesakit dengan TRD (48.3%). Hasil kejayaan pelekatan retina secara anatomi dicapai dalam pesakit mengalami VH (98.2%) dan TRD (96.7%). Walau bagaimanapun, pesakit dengan TRD didapati mempunyai risiko 2.4 kali lebih tinggi untuk mempunyai

hasil ketajaman penglihatan yang teruk.
Kesimpulan: Vitrektomi gauge kecil untuk ADED menghasilkan ketajaman penglihatan visual dan kelekatan retina secara anatomi yang sangat baik. Mata dengan TRD mempunyai risiko yang lebih tinggi untuk melarat dan menghasilkan ketajaman penglihatan yang teruk.

Kata kunci: diabetes mellitus, pendarahan vitreous, retinopati diabetes, vitrektomi

Introduction

Diabetic retinopathy (DR) is a chronic, sight-threatening disease of the retinal microvasculature associated with prolonged uncontrolled hyperglycaemia. Prognosis of surgical treatment such as vitrectomy with or without intraocular anti-vascular endothelial growth factor (anti-VEGF) depends mostly on the duration of the disease and structures involved. Overall visual and anatomical outcomes in cases of diabetic vitrectomy have remained fairly stable despite technological advances in surgical instrumentation.[1]

The 20-year-old Diabetic Retinopathy Vitrectomy Study is still the major reference for managing patients with advanced diabetic eye disease (ADED).[2] The indications for diabetic vitrectomy have not changed much since the era of 20-gauge (G) surgery. But the threshold of surgery has reduced with improvement in the safety profile of retinal surgery using small-gauge vitrectomy (23-G and 25-G). Reports on long-term outcomes were mainly from retrospective studies and the majority of these described the traditional sutured 20-G system.[2]

Predictive factors for visual outcome were previously reported to be related to the duration of diabetes, use of insulin, presence of ischaemic heart disease, delay in surgery, and failure to attend clinical appointments.[3] In this study, we aim to evaluate both anatomical and visual outcomes of sutureless small-gauge vitrectomy in ADED cases and the predictive factors for poor visual outcome post-vitrectomy.

Materials and methods

This was a retrospective study of small-gauge vitrectomy for ADED performed between 2009 to 2014 in Hospital Universiti Kebangsaan Malaysia, Kuala Lumpur. Patients' clinical data were obtained from the medical records. Patients' data remained anonymous and subjects were coded accordingly. Indications for vitrectomy were classified based on the predominant factor for poor vision, either non-resolving vitreous haemorrhage (VH) with or without tractional retinal detachment (TRD), TRD involving the macula, and others (epiretinal membrane, vitreomacular traction).

Data collected were as follows: baseline demographic data, visual and anatomical outcomes at 6 and 12 months, predictive factors for poor visual outcomes, and postoperative complications. Patients who defaulted follow-up before 6 months were excluded.

Poor visual outcome was defined as Snellen visual acuity of 6/36 or worse. It was further classified into worsening, better, or stable. Worsening of vision postoperatively was defined as a drop in vision of at least one line compared to the preoperative state. Stable vision was defined as no change in visual acuity, whereas improvement in vision was defined as at least one line of visual improvement on Snellen acuity chart. Anatomical success was defined as flat retina without any intraocular tamponade at the end of the study period. Preoperative and postoperative best-corrected Snellen vision was converted to logarithm (LogMAR) of the minimum angle of resolution units to facilitate statistical comparison. Comorbidities were defined as a history of treated relevant diseases like hypertension, diabetes, and hypercholesterolaemia.

The details of the patients were kept confidential. Statistical analysis was performed using SPSS for Windows, Version 21.0. Demographics were analysed with paired t-test when comparing pre- and postoperative outcomes. Chi-square was used to analyse categorical data. The predictive factors for poor visual outcome were determined using multiple linear regression analysis. *P*-values of < 0.05 were considered statistically significant.

Results

Demographic

There were 174 cases of small-gauge vitrectomy surgeries performed for diabetic-related complications from January 2009 to December 2014. Only 158 eyes (one eye per patient) were identified based on the inclusion criteria. One hundred thirty eyes completed a minimum follow-up of 6 months and 123 eyes completed

Table 1. Clinical profiles of patients

Clinical profile	***n* = 158**
Gender, *n* (%)	
Male	80 (50.6)
Female	78 (49.4)
Age (years), mean ± SD	54.01 ± 11.57

Clinical profile	***n* = 158**
Ethnicity, *n* (%)	
Malay	89 (56.3)
Chinese	50 (31.6)
Indian	16 (10.1)
Others	3 (1.9)
Distance to HUKM (km), mean ± SD	36.45 ± 65.57
20 km	106 (67.1)
> 20 km	52 (32.9)
Indication of vitrectomy, *n* (%)	
VH	77 (48.7)
TRD	75 (47.5)
Others	6 (3.8)
Ocular factors	
Duration of surgery (min), mean ± SD	126.37 ± 53.26
Duration of symptoms (months), mean ± SD	13.34 ± 12.85
Status of lens prior to surgery, *n* (%)	
Phakic	89 (56.3)
Aphakic	3 (1.9)
Pseudophakic	66 (41.8)
Preoperative visual acuity (LogMAR)	1.48 ± 0.642
Systemic factors	
Duration of DM (years), mean ± SD	13.96 ± 8.05
Complication of DM, *n* (%)	
Stroke	9 (5.7)
Ischaemic heart disease	26 (16.5)
Neuropathy	33 (20.9)
Nephropathy	73 (46.2)
Underlying systemic conditions, *n* (%)	
Hypertension	145 (91.8)
Dyslipidaemia	84 (53.2)

DM: diabetes mellitus; HUKM: Hospital Universiti Kebangsaan Malaysia; SD: standard deviation; TRD: tractional retinal detachment; VH: vitreous haemorrhage

12 months of follow-up. Indication of surgery and clinical profiles of the patients are shown in Table 1.

The mean age was 54.01 ± 11.57 years and slightly more than half of the patients were male, with a male-to-female ratio of 1.03:1. The indications for surgery were divided into non-resolving VH with or without TRD but without macular involvement (n = 77, 48.7%), TRD involving the macula (n = 75, 47.5%), and others, which include epiretinal membrane or vitreomacular traction (n = 6, 3.8%)

The mean duration of diabetes was 13.96 ± 8.05 years and duration of ocular symptoms was 13.34 ± 12.85 months. Slightly more than half the patients were Malay (56.3%), with Chinese and Indian ethnicities comprising the remaining ethnic distribution. Most patients lived within 20 km of the hospital (67.1%). Mean waiting time for surgery was 26.70 ± 47.94 days. Preoperatively, anti-vascular endothelial growth factor (anti-VEGF) was used in 98 patients: ranibizumab (Lucentis®; Novartis Pharma AG, Basel, Switzerland) was used in 92 eyes (62.0%), and bevacizumab (Avastin®; Novartis Pharma AG, Basel, Switzerland) in 6 eyes (6.1%).

The majority of patients had underlying hypertension (92%) and slightly more than half (53.2%) were also diagnosed to have hyperlipidaemia. Cerebrovascular accident was present in only 9 patients (5.7%), ischaemic heart disease in 16.5% of patients, 20.9% had neuropathy, and 46.2% had renal impairment based on the creatinine level. Only 69 patients (43.7%) complied with their systemic medications. Mean glycosylated haemoglobin (HbA1c) was 7.91%, indicating fair glycaemic control.

More than half cases were phakic (56.3%) prior to vitrectomy, 41.8% were pseudophakic, and the remaining were aphakic (1.9%). The majority of patients (76.6%) had visual acuity of 6/60 or worse prior to surgery. Based on the indications for surgery, the majority of patients with non-resolving VH (74%) had vision of counting fingers or worse. Slightly less than half (48%) of TRD patients had vision of counting fingers or worse.

Within the study period, 86% of patients underwent 23-G vitrectomy and the remaining 14% underwent the 25-G system. Mean duration of surgery was 126.37 ± 53.26 minutes. Almost half the cases (49%) did not receive any endotamponade at the end of the surgery, 24% had silicone oil, and 27% had gas endotamponade. The majority of surgeries (130 eyes, 82.3%) were performed under local anaesthesia and the remaining were done under general anaesthesia. Intraoperative bleeding was the commonest intraoperative complication (58 eyes, 36.7%) followed by iatrogenic break (44 eyes, 27.8%), and 1 eye (0.6%) had suprachoroidal haemorrhage. Forty-seven patients (29.7%) had reoperation for removal of silicon oil (29 eyes,18.4%), cataract surgery (16 eyes, 10.1%), VH and re-detachment (6 eyes, 3.8%) respectively, and other surgeries (3 eyes, 1.9%).

Visual changes

Generally, vision improved in three-quarters of eyes at 6 months postoperatively. Sub-analysis based on indications revealed that patients with VH tended to do slightly better than patients with TRD, with 79% of patients with VH attaining vision of 6/60 or better, whereas 70% of patients in the TRD group had no change in visual acuity. Looking at improved visual acuity level, 29% of patients treated for VH attained 6/12 or better compared to only 14.5% of the TRD patients at 6 months post-surgery. At 12 months the difference became more apparent, with 33% of patients with VH attaining 6/12 or better while only 8.3% of patients with TRD achieving the same result post-surgery.

Generally, surgery for diabetic-related complications benefited the majority of the patients included in our study. Postoperatively, vision improved in 59.4% of patients and was stable in 17%. Vision worsened in slightly less than a quarter of eyes (23.4%), with most patients losing only 1 or 2 lines of Snellen visual acuity.

Among eyes with VH, more than half the patients (68.3%) attained either better or stable vision 12 months post-surgery. Vision worsened for the remaining 31.7% of patients and only 3.4% of patients lost more than 4 lines of vision. In eyes with TRD, 84.9% had either improvement or stable vision at 12 months postoperatively and vision worsened in 14.1%, as shown in Figure 1. The patients who had worsening of vision lost a maximum of two lines.

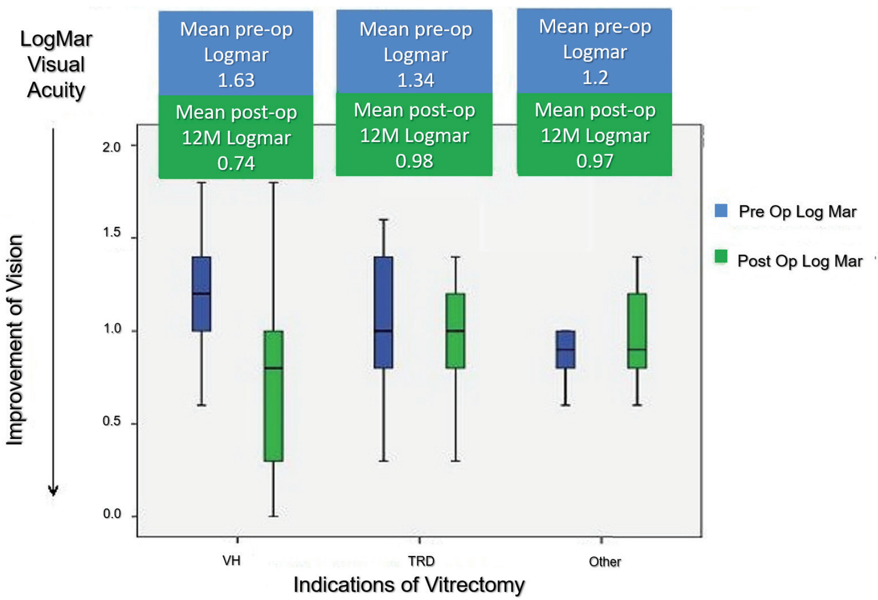

Fig. 1. Box plot describing visual acuity in LogMar before and after surgery for various surgical indications.

Table 2. Univariate analysis for poor visual outcome

Patient factors	Poor visual outcome		12 M
	Yes	**No**	***p*-value**
Ocular factors			
Duration of symptoms (months)	11.57 ± 9.25	12.52 ± 12.51	0.478
Status of lens prior to surgery			
Phakic	44 (63.8)	25 (36.2)	0.550
Pseudophakic	35 (67.3)	17 (32.7)	
Aphakic	2 (100.0)	0 (0)	
Preoperative IOP (mmHg)	14.91 ± 4.04	15.31 ± 4.79	0.370
Preoperative visual acuity (LogMAR)	1.15 ± 0.32	1.03 ± 0.38	0.186
Systemic factors			
Duration of DM	13.96 ± 7.85	14.4 ± 9.43	0.060
Complications of DM			
Stroke	4 (57.1)	3 (42.9)	0.928
Ischaemic heart disease	11 (57.9)	8 (42.1)	0.426
Neuropathy	19 (73.0)	7 (27.0)	0.946
Nephropathy	37 (68.5)	17 (31.5)	0.581
Underlying systemic conditions			
Hypertension	70 (62.5)	42 (37.5)	0.030
Dyslipidaemia	42 (63.6)	24 (36.4)	0.540
Surgical factors			
Duration of surgery (mins)	127.39 ± 61.42	108.79 ± 32.87	< 0.001
Gauge			0.646
23-G	70 (66.7)	35 (33.3)	
25-G	11 (61.1)	7 (38.9)	
Heavy liquid	23 (82.1)	5 (17.9)	0.039
Silicone oil	28 (82.4)	6 (17.6)	0.017
Reoperation	36 (81.8)	8 (18.2)	0.005

DM: diabetes mellitus; IOP: intraocular pressure

Table 3. Multiple logistic analysis for prognostic factor for poor visual outcome at one year

Factors	**Odds ratio (95% CI)**	***P*-value**
Heavy liquid	0.501 (0.161 to 1.559)	0.233
Silicone oil	0.924 (0.246 to 3.468)	0.906
TRD *vs* VH	2.421 (1.056 to 5.552)	0.037
Duration of surgery	0.993 (0.982 to 1.004)	0.185

TRD: tractional retinal detachment; VH: vitreous haemorrhage

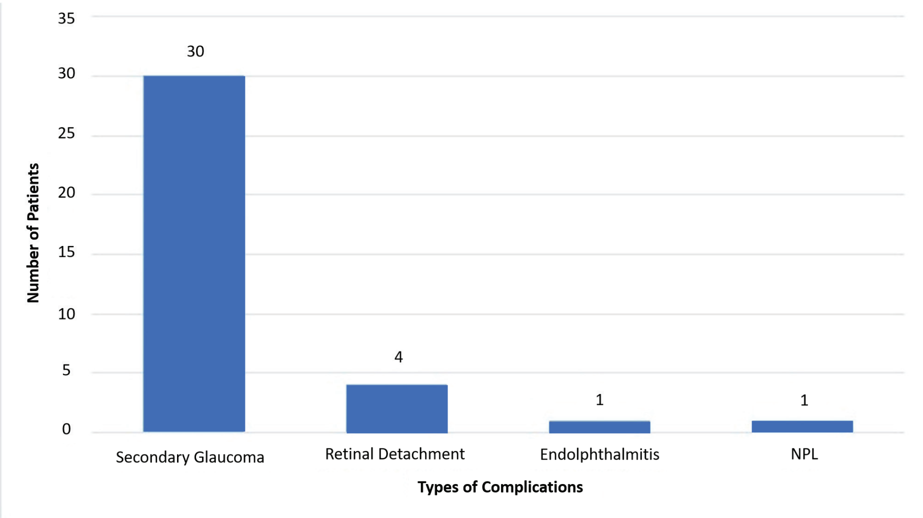

Fig. 2. Bar chart depicting the number of patients developing complications following small-gauge vitrectomy.

Predictive factors for poor vision

Using univariate analysis for poor visual outcomes, duration of surgery was one of the predictors for poor vision (Table 2). Other significant predictors for poor outcomes were the use of heavy liquid, silicone oil, and the need for repeated surgery. However, after multivariate analysis, the only significant factor for poor vision was indication of surgery (Table 3). Patients with TRD had an odds ratio of 2.4 (95% CI: 1.056 to 5.552) of having poor vision compared to patients with VH.

Long-term complications at 12 months postoperative included secondary glaucoma in 30 eyes (24.3%), retinal detachment in 4 eyes (0.03%), endophthalmitis in 1 eye, and neovascular glaucoma in 1 eye that was completely blind with no light perception (Fig. 2). More than 90% of eyes had flat retina at 12 months.

Discussion

Surgery outcomes in diabetic eyes are known to be unpredictable. Various factors contribute to anatomical and functional recovery.[1] Apart from predisposing ocular conditions, underlying medical problems are also pivotal for ocular adaptation and retinal recovery.[2]

The most common indications for surgery in diabetic eye diseases are non-resolving VH and TRD.[3,4] The benefits of vitrectomy in ADED have been described in previous studies mainly using the old cutter system.[5] Despite the significant benefits of surgery among these patients, considerable complications have also been reported.[6] Patient counselling with regards to surgical outcomes may range from saving the eyesight (either to improve or stabilize vision) to delaying blindness. Vitrectomy has helped to deregister 25% of blind patients.[3] Surgical outcomes between populations may also vary due to several factors; outcomes may not always be comparable, especially when patient demographics vary considerably.[1,7] Patients with primary indication of combined tractional and rhegmatogenous retinal detachment (TRD + RRD) appear to have the worse visual prognosis, whereas patients with VH appear to have the best visual prognosis.[8,9]

Most studies reported the visual outcome in a collective manner regardless of the indication of surgery for ADED. Traditionally, ADED studies tend to define a poor visual outcome as 6/60 or worse.[8,9] Considering the improvement in surgical instruments (smaller gauge system), we wished to analyse and report on better levels of visual outcome. Therefore, we defined poor vision as 6/36 or better for the purpose of our analysis.

Small-gauge vitrectomy has been reported to reduce surgical time, reduced patient discomfort, and result in more rapid visual recovery.[6] Evaluation of different sizes of the vitreous cutter in our study failed to exhibit significant association with poor vision or anatomical outcomes post-vitrectomy. A previous report compared the two sizes of small gauge cutter, which were also found to be insignificant.[6] Intraoperative difficulties remained one of the challenges among ADED cases. TRD obviously represents worse preoperative retinal condition, worse perfusion levels, and a more complex surgical scenario. Even then, more than half our patients had improvement of vision post-surgery. TRD patients appeared to have twice the risk for poor vision compared to those with non-resolving VH.

The intraoperative technique using the small-gauge system in ADED during the study period was still at the exploratory stage in our institution (transition from 20-G to small-gauge system). Scissors were still largely utilised during membrane dissection and delamination. Hence, surgical time in our study was more or less the same as those reported for the 20-G system.[2] Only later were "non-scissor" delamination and segmentation used more frequently, potentially reducing surgical time for such cases. The chandelier system, bimanual technique, and non-scissor membrane delamination and segmentation were among the latest surgical manoeuvres popularised by the new system, which slowly gained popularity among retinal surgeons. The known challenges during surgery are thick adhered membrane with underlying retinal detachment, broad attachment of the membrane, thin atrophic retina in long-standing cases, and absence of posterior vitreous detachment (PVD). Yorston *et al.* described the majority of their patients (85%) not having complete PVD and 74% of them still having posterior hyaloid attachment involving the posterior pole and vascular arcades.[2] Unfortunately, due to the retrospective nature of our study, subjective description of intraoperative findings was considered to be highly inaccurate. Hence, we were not able to describe the detail of intraoperative findings in our series.

Using the old vitrectomy system, at least 27% of patients had posterior retinal break, whereas 17% reported to have entry site break.[10] An almost similar incidence was reported in our study (entry site break and posterior tear). We did not analyse in detail the location of tears due to the variability of documentation.

Associated medical conditions play a vital role in the general well-being of diabetic patients. We found that at least 20% of our patients had some form of neuropathy at the point of vitrectomy. Potential under-reporting among our patients was not surprising, as the question of neuropathy was only documented at the time of presentation and was not routinely asked on every visit. A prospective study by Yorston *et al.* in 2008 reported that at least one-third of their patients also had some form of neuropathy.[4] Interestingly, only half their patients were reported to have underlying hypertension, whereas most of our patients in the study (90%) had hypertension. Furthermore, more than half suffered from hyperlipidaemia and renal impairment. Concurrently, only half our patients admitted to compliance to systemic treatment.

Patients in our series did not show significant association between lens status or usage of antiglaucoma medications with poor visual outcome post-vitrectomy. We also did not find any significant relationship between the duration of diabetes and poor visual outcomes. Most of the patients in our series had other diabetic-related complications, such as diabetic nephropathy requiring haemodialysis and foot ulcer. However, none of the diabetic complications were found to be significantly related to the surgical outcome. There was also no significant association with the presence of hypertension, ischaemic heart disease, and dyslipidaemia. The findings were comparable to the study reported by Gupta *et al.*[3]

Endotamponade in vitrectomy is used to promote retinal reattachment.[11] In this study, although univariate analysis showed a significant association between the use of tamponade and visual outcome post-vitrectomy, multivariate analysis did not support the differences. Yorston *et al.* reported that in 174 vitrectomies, air was used in 7.5%, sulfur hexafluoride (SF6) in 24.1%, octafluoropropane (C3F8) in 10.3%, and silicone oil in 6.9%.[4] Our study found a tendency to use silicone oil more than gas. The possible reasons for the higher usage of silicone oil in our population is likely due to the more severe form of retinal changes or that surgery was performed in a precious eye requiring immediate visual recovery. It was not uncommon for patients in our study to present late with involvement of the fellow eye.[12] Such cases require early visual rehabilitation.

The use of preoperative anti-VEGF also did not show significant relationship with poor vision after surgery in our patients. The majority of our patients had intravitreal anti-VEGF prior to the surgery. During the period of this study, more ranibizumab than bevacizumab was used in our centre. Before the availability of anti-VEGF, the incidence of recurrent VH post-vitrectomy could be as high as 80%.[14] Our rate of postoperative VH was only 10%. Not only the use of anti-VEGF, but also probably better surgical technique with the use of the small-gauge cutter may have improved the overall rate of postoperative bleeding.

Only one of our patients developed rubeosis iridis and, subsequently, neovascular glaucoma. Other studies have reported the incidence to be as high as 15%.[13] We believe this could be largely attributed to the use of anti-VEGF prior to surgery in our study. At the same time, the small-gauge system potentially causes less postoperative inflammation.[14]

Almost one-fifth of our vitrectomised eyes developed glaucoma at any point postoperatively for various reasons. The majority of cases were managed conservatively with antiglaucoma medications, while a very small percentage resulted in surgical intervention. Similarly, other studies have reported an average of 15–20% of patients developing glaucoma after uncomplicated vitrectomy,[15] and rates were higher in eyes that had undergone cataract extraction (15.0%) compared to phakic eyes (1.4%).[16]

The main limitation of this study is its retrospective design, which is susceptible to bias and relying largely on the accuracy of data entry in the case notes. Despite the limitation of retrospective design, our sample size was large enough to report the findings in our population to show non-inferiority of small-gauge vitrectomy compared to the traditional 20-G system in terms of success in surgical attachment. The demographic findings suggested that we are still dealing with severe forms of ADED (based on the acuity and the need to use silicone oil as endotamponade). The distinguishing features among our population are the higher prevalence of concurrent medical problems such as hypertension and hyperlipidaemia. Even then, the risk of poor visual outcome was not related to the underlying medical problem but rather to the severity of the ocular disease itself.

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