

**INDICATIONS, EFFICACY AND OUTCOMES
OF
PARS PLANA VITRECTOMY
IN
DIABETIC RETINOPATHY**

Dissertation submitted to
**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY
CHENNAI, INDIA**



**M.S. DEGREE EXAMINATION
BRANCH – III OPHTHALMOLOGY**

APRIL – 2014

Match Overview

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By: PRAVEEN KUMAR

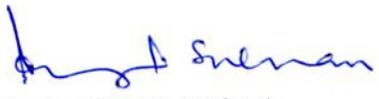
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This is to certify that the dissertation entitled “INDICATIONS, EFFICACY AND OUTCOMES OF PARS PLANA VITRECTOMY IN DIABETIC RETINOPATHY” is a bonafide work done by **Dr.S.PRAVEENKUMAR**, Postgraduate student in M.S. (Ophthalmology) during April 2012 to March 2014, under our direct supervision and guidance, at our Institute, in partial fulfillment for the award of M.S. Degree in Ophthalmology of the Tamilnadu Dr.M.G.R. Medical University, Chennai.

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INDICATIONS, EFFICACY AND OUTCOMES OF PARS PLANA VITRECTOMY IN DIABETIC RETINOPATHY

AIM:

To study the various indications, anatomical results, functional visual outcomes, and safety of pars plana vitrectomy (PPV) in complications of proliferative diabetic retinopathy (PDR).

Materials and Methods:

This was a prospective interventional study performed on patients presenting at the Retina Clinic of a tertiary care eye hospital in Tamil Nadu between April 2012 and June 2013. All eyes undergoing PPV for complications of PDR and having adequate follow up were included. Data collected included indications for PPV, type of surgery performed, intra and post-operative complications, anatomical outcomes and visual results following surgery.

Results:

47 eyes of 46 patients were included in the study. Most common indications for surgery were non-clearing vitreous hemorrhage and tractional retinal detachment (TRD) threatening the macula. Visual acuity improved significantly following surgery across all indications for surgery ($p=0.003$). Visual acuity continued to improve during follow-up period ($p=0.00004$). Rate of visual recovery was slower with eye with TRD as compared to other indications. Retina was attached at last follow up in 89% of eyes. Most common complications encountered were 8% eyes had severe intraoperative bleeding and 17% eyes had iatrogenic retinal break, post-operatively 6% of eyes developed recurrent vitreous hemorrhage and retinal break and one eye developed combined rhegmatogenous and tractional retinal detachment.

Conclusions:

PPV in eyes with visual loss due to complications of PDR can offer significant improvement in visual acuity. However, surgery in these eyes may be associated with vision threatening complications.

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Introduction

INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disease which presents with high blood sugar usually due to inadequate secretion of insulin. The high blood sugar leads to symptoms such as polyuria, polydipsia, and polyphagia.

There are three main types of diabetes mellitus

- Type 1 DM or insulin-dependent DM is due to the failure of the body to produce insulin
- Type II DM or non- insulin-dependent DM (NIDDM) is due to the failure of cells to use the produced insulin
- A third type Gestational diabetes, occurs in pregnant women without previous diagnosis of diabetes

Diabetic retinopathy is a complication of diabetes. It is becoming one of the leading causes of newly-diagnosed legal blindness amongst the working class people (National Diabetes Data group, 1995)¹.

In a study in India, 52% of patients with NIDDM over a 25- year duration were found to suffer from diabetic retinopathy (41.7% from non – proliferative diabetic retinopathy and 10.3% from proliferative diabetic retinopathy) (Mohan et al.)².

The common causes of visual impairment in diabetic retinopathy are macular edema and complications of proliferative diabetic retinopathy. Type 2 DM is commonly associated with diabetic retinopathy with macular edema (Klien et al.)³.

Diabetic maculopathy is the commonest cause of visual impairment in diabetic patients, particularly type 2 diabetes. It is characterized by foveal edema, exudates or ischemia. Diffuse retinal edema is due to extensive capillary leakage, and localized edema due to focal leakage from microaneurysms and dilated capillary segments⁴. Further accumulation of fluid in the fovea leads to cystoid macular edema (CME).

Diabetic macular edema is the result of retinal thickening due to exudation from incompetent retinal capillaries; this can also occur peripheral to the retina which is not vision-threatening. The Early

Treatment Diabetic Retinopathy Study (ETDRS)⁵ coined the term “clinically significant macular edema” (CSME) to refer to:

- retinal thickening occurring at the centre of the macula; or
- retinal thickening and hard exudates occurring within 500 microns of the centre of the macula; or
- retinal thickening greater than or equal to 1 disc area, with any part of which is within 1 disc diameter of the centre of the macula.

Development and progression of diabetic retinopathy can be prevented by strict control of diabetes and other associated risk factors, such as hypertension⁶⁻⁸. In its initial stages, diabetic retinopathy may not require treatment but, in the presence of CSME and proliferative changes, treatment is essential to prevent visual loss and to restore vision. Initial treatment often includes laser photocoagulation (focal, grid or panretinal laser photocoagulation) or the use of intravitreal anti-vascular endothelial growth factor (anti-VEGF) agents or corticosteroids. In some cases, surgical intervention in the form of pars plana vitrectomy (PPV) becomes inevitable.

Diabetic macular edema associated with a taut posterior hyaloid is an important and well-known indication for PPV. Additionally, diffuse diabetic macular edema without posterior vitreous detachment, where the posterior hyaloid is not taut or thickened, can benefit from vitrectomy, with visual improvement in 53% of eyes⁹. Yet another indication is a non-clearing dense vitreous hemorrhage of more than 3 months duration with no prior laser photocoagulation, where the extent of proliferation is extensive and the fellow eye exhibits rapidly – progressive loss of vision, or in the presence of rubeosis with recent vitreous hemorrhage without laser photocoagulation. Early surgical intervention in dense premacular hemorrhage is reported to prevent proliferation¹⁰.

Tractional retinal detachment is due to fibrous transformation and contraction of neovascular tissue which causes macula-threatening traction. Early vitrectomy is indicated in type 1 DM associated with media opacities that prevent laser photocoagulation, and in the presence of rapid progression in the fellow eye. Visual prognosis is poor if macular detachment is of more than 6 months duration¹¹.

Another major indication for PPV in proliferative diabetic retinopathy (PDR) is combined tractional and rhegmatogenous retinal detachment. The rhegmatogenous component is due to fibrovascular proliferation, causing retinal break(s). These breaks commonly occur on old chorioretinal scars and at the base of vitreoretinal adhesions.

In anterior hyaloid proliferation unresponsive to peripheral confluent photocoagulation or in significant recurrent vitreous hemorrhage despite maximal panretinal photocoagulation, early intervention through PPV decreases the risk of peripheral retinal detachment, hypotony and phthisis¹².

PPV in diabetic retinopathy can be associated with a significant risk of complications. Intraoperative complications of vitrectomy include peripheral retinal dialysis, peripheral tears, vitreous or retinal incarceration in the wound, corneal erosions (common in diabetics), filamentary keratitis, bullous keratopathy, damage to the lens by direct touch of instruments, and the solutions used; intraoperative hemorrhage, retinal tears, retinal detachment and posterior breaks can also occur¹³.

Post-operative complications after PPV include residual hemorrhage from surgery, retained blood within vitreous, continued hemorrhage from bleeding sites, retinal traction, bullous retinal detachment, anterior hyaloid proliferation, progression of cataract, corneal decompensation, hypotony, post-operative glaucoma and endophthalmitis^{14,15}.

Recurrence of post-operative vitreous hemorrhage in PDR ranges from 29 – 75%¹⁶. It commonly occurs within 6 months following surgery and is often of unknown cause. Delayed post-operative hemorrhage is due to anterior hyaloid proliferation¹⁷. Other causes include fibrovascularization from the sclerotomy site, recalcitrant fibrovascular proliferation, and neovascularization of the iris and angle¹⁸.

The Diabetic Retinopathy Vitrectomy Study (DRVS), the results of which were published in DRVS report 3 in journal Ophthalmology in 1988, was a prospective, randomized clinical trial that studied the role of vitrectomy in managing eyes with severe PDR. Two outcome measurements in DRVS were percentage of eyes with 10/20 and 10/50 visual acuity, on DRVS-standardized visual acuity charts at 2 and 4 year follow up examination. The DRVS evaluated the benefit of early (1-6

months after onset of vitreous hemorrhage) versus late (at 1 year) vitrectomy for eyes having very severe vitreous hemorrhage and visual loss ($\leq 5/200$). Patients with type 1 diabetes with severe vitreous hemorrhage clearly demonstrated the benefit of early vitrectomy, but no advantage was found in mixed or type 2 patients. The DRVS also showed an advantage for early vitrectomy compared with conventional management in eyes with very severe PDR.

Advances in vitreoretinal surgery, including routine use of endolaser during surgery, have led to modifications of certain recommendations of the DRVS. Patients with preexisting, well-placed, complete panretinal photocoagulation treatment during the phase of vitreous hemorrhage can be under long-term observation. If panretinal photocoagulation has not been performed, early intervention is recommended in patients with vitreous hemorrhage secondary to PDR regardless of type of diabetes^{19, 20}.

It is clear that PPV is an important surgical option when managing patients with PDR. However, further information is needed from centers in India dealing with unique problems faced by Indian diabetic patients, since India is considered to be the “Diabetic Capital of the world”. In the present

investigation on which this dissertation is based, an attempt has been made to document various indications for PPV in patients presenting with diabetic retinopathy (DR) at a tertiary eye care facility in Tamilnadu, India. The anatomical results and functional visual outcomes following PPV in eyes with DR, and putative factors influencing the results obtained, have also been determined. Very importantly, the safety of PPV in eyes with DR has been clarified by documenting intraoperative and postoperative complications, and elucidating factors that possibly contribute to such complications.

Aim of the Study

AIM OF THE STUDY

1. To document the various indications for pars plana vitrectomy in patients presenting with diabetic retinopathy at a tertiary care facility in India
2. To determine the anatomical results and functional visual outcomes following pars plana vitrectomy in eyes with diabetic retinopathy, and to elucidate factors possibly influencing the results obtained
3. To clarify the safety of pars plana vitrectomy in eyes with diabetic retinopathy by documenting intraoperative and post-operative complications, and to elucidate factors possibly contributing to such complications.

Review of Literature

REVIEW OF LITERATURE

Diabetic retinopathy is a leading cause of severe loss of visual acuity in developed countries. When compared to non diabetic populations about 25% of patients with diabetes have sight-threatening retinopathy, with legal blindness (best corrected visual acuity of 20/200 or worse) being 25 times more common (Kahn et al.)²¹.

Fundamentally, diabetes mellitus causes abnormal glucose metabolism which is due to decreased level of insulin or their activity. Increased levels of glucose in blood are said to produce structural and physiologic effect on retinal capillaries which makes them incompetent both functionally and anatomically.

Continuous increase in blood glucose levels in certain tissues sends the excess glucose into the aldose reductase pathway, where sugar is converted into alcohol (eg, glucose into sorbitol, galactose to dulcitol). Increased levels of sorbitol affects the intramural pericytes of retinal capillaries, which eventually leads to the loss of their main function (that is, autoregulation of retinal capillaries)²². This results in weakness and eventual saccular outpouching of retinal capillary walls namely,

microaneurysm formation. These microaneurysms are the earliest detectable signs of retinopathy in DM. It ultimately leads to vascular endothelial damage and hypoxia to the retinal tissues.

In patients with proliferative diabetic retinopathy (PDR), nocturnal intermittent hypoxia/reoxygenation that results from sleep-disordered breathing may be a risk factor for iris and/or angle neovascularization²³.

Neovascularization is commonly seen between the perfused and nonperfused retina, mostly along the blood vessels and at the optic disc. The new vessels, which are fragile and highly permeable, grow along the space in the posterior hyaloid face and surface of the retina. These delicate vessels are damaged easily by traction from the vitreous, and cause vitreous or preretinal hemorrhage. These new blood vessels are usually responsible for the formation of small amount of fibroglial tissue. When the density of the neovascular frond increases, the fibrous tissue formation also increases. Later, these new vessels regress, leaving behind a fibrous tissue adherent to the retina and the posterior hyaloid, which causes retinal edema, retinal heterotropia, tractional retinal detachment and retinal tears as a result of vitreous contraction.

The Early Treatment Diabetic Retinopathy Study (ETDRS), initiated in 1980 divided 3711 patients who presented with severe nonproliferative or early proliferative diabetic retinopathy in both eyes into different groups. Patients were randomly divided into different groups of which 1 had aspirin 650 mg/day or placebo. One eye of the entire patients was subjected randomly to early photocoagulation and the other eye did not receive photocoagulation. Patients were followed-up at every 4 months interval, and photocoagulation was given in eyes that developed high-risk proliferative retinopathy of the control eyes. The study concluded that aspirin had no effect on progression of retinopathy or in vitreous hemorrhage. The risk of development of severe visual loss or eyes requiring vitrectomy, was low in eyes which did not receive photocoagulation (6% at 5 years) and the risk of progression was reduced by early photocoagulation (4% at 5 years). 208 patients underwent vitrectomy during the study period of around 9 years. With regular follow-up and timely (panretinal) photocoagulation the 5-year collective rate of pars plana vitrectomy in ETDRS patients was 5.3%. Use of aspirin did not have any effect on the rate of vitrectomy²⁴.

Vitreous hemorrhage is a serious complication of proliferative diabetic retinopathy, since it provides evidence of the severity of

proliferative retinopathy at stake and precludes laser photocoagulation. However, panretinal photocoagulation remains possible in some cases of moderate vitreous hemorrhage especially using longer wavelengths such as krypton red²⁵; cryotherapy under ophthalmoscopic control may be an alternative to panretinal photocoagulation²⁶. Development of pars plana vitrectomy, however, constitutes the defining breakthrough in the management of severe vitreous hemorrhage. Although pars plana vitrectomy was first reserved for massive, long-standing vitreous hemorrhage, improvements in instrumentation and techniques, as well as observations of the favorable effect of vitrectomy on the progression of proliferative retinopathy have led to an extended array of indications for this procedure.

In addition to severity and duration of visual loss, the main arguments for performing pars plana vitrectomy are bilaterality of lesions, lack of previous panretinal photocoagulation, iris neovascularization, Type 1 diabetes, and severity of fibrovascular proliferation (Mathis A et al.)²⁷.

The surgical management of coexisting cataract and vitreoretinal disease has been controversial, particularly for eyes with a history of PDR or chronic uveitis. Forster et al., (1993) retrospectively studied the results of combined extracapsular cataract extraction (ECCE), posterior chamber

intraocular lens (PC-IOL) implantation, and pars plana vitrectomy in 20 eyes of 16 patients. The indications for combined vitrectomy included dense, non-clearing vitreous hemorrhage (attributed to PDR) in 10 eyes, age-related macular degeneration in two, and trauma in one. The remaining seven eyes underwent pars plana vitrectomy to remove inflammatory vitreous cells and debris associated with chronic uveitis. In this series of patients, the follow-up ranged from 4 to 32 months (average, 17.4 months). Visual acuity was found to have improved in 19 eyes (95%) to 20/100 or better in 12 eyes (60%); the improvement ranged from 1 to 13 Snellen lines (average, 4.9 lines). The postoperative visual acuity improvement averaged 7.5 Snellen lines for eyes with chronic uveitis, 7.0 lines for those with age-related macular degeneration, and 3.3 lines for those with a history of PDR. The postoperative visual acuity was less than 20/100 in eight eyes (40%); these results were mostly attributed to macular changes associated with the underlying ocular disease. The authors concluded that combined ECCE/PC-IOL implantation and pars plana vitrectomy is a well-tolerated surgical procedure for diabetics, which can provide clear anterior and posterior segment media²⁸.

In another setting, Neely and Scroggs conducted a retrospective study of patients who had repeat vitrectomy for post-operative diabetic

vitreous hemorrhage (PDVH) and who also received peripheral retinal cryotherapy in phakic patients. Final Best corrected visual acuity (BCVA) after repeat vitrectomy with peripheral retinal cryotherapy was compared to BCVA at the time and before in case of PDVH. Anatomic outcomes studied were retinal attachment, vitreous hemorrhage, iris new vessel formation, development of cataract, and anterior hyaloidal neovascularization. Based on their results, they opined that in case of non-clearing PDVH in phakic eyes, peripheral retinal cryotherapy (augmented, if possible with posterior pole endolaser photocoagulation) can be used to supplement previous retinal photocoagulation during repeat vitrectomy, since this technique leads to a more stable retina and better visual outcome in most treated eyes. These authors concluded that transscleral peripheral retinal cryotherapy was frequently feasible to use in situations (such as media opacity) where peripheral retinal endolaser or indirect laser photocoagulation could not be done²⁹.

Yeh et al. sought to study whether cryotherapy of the sclerotomy sites and anterior retina would prevent fibrovascular ingrowth (FVIG) at sclerotomy sites and recurrent vitreous hemorrhage in patients with PDR. Cases were divided into those undergoing anterior peripheral retinal cryotherapy (ARC) in addition to panretinal endolaser treatment, or having

endophotocoagulation, ARC, and cryotherapy on the 3 sclerotomy sites, or panretinal endolaser treatment alone. Ultrasound biomicroscopy of the 3 sclerotomy sites was performed at or later than 2 months, and the findings obtained were differentiated into 4 groups: FVIG, gap, well-healed, and vitreous incarceration. History and management of recurrent severe vitreous hemorrhage were recorded. The occurrence of recurrent postoperative vitreous hemorrhage was strongly correlated with presence of fibrovascular ingrowth. The authors concluded that ARC along with cryotherapy of sclerotomy sites might be useful additional measure for formation of FVIG and prevention of recurrent vitreous hemorrhage in diabetics³⁰.

En bloc perfluorodissection (EBPD), is a surgical technique that helps in removal of posterior hyaloid and epiretinal membrane, it is performed to separate the epiretinal membrane from the adjacent retina by injecting perfluorocarbon liquid between the posterior hyaloid and the retina. Aravelo et al. (2008) described the technique and sought to demonstrate the same during vitrectomy in eyes with tractional retinal detachment in PDR. None of the patients studied developed ocular hypertension or any other inflammation, and all eyes had good anatomical and functional success. In 14 eyes (24.5%), the best corrected visual acuity

(BCVA) remained stable, and in three (5.2%) eyes, BCVA decreased (≥ 2 ETDRS lines). Final BCVA was 6/12 or better in 25%, between 6/18 and 5/60 in 47%, and worse than 5/60 in 28%. One eye developed phthisis bulbi (1.7%), four (7%) eyes had iatrogenic retinal breaks, four eyes had vitreous hemorrhage requiring another surgery, and cataract in 15 (26.3%) eyes. Thus EBPD can be performed during vitrectomy in eyes with tractional retinal detachment in PDR³¹.

Pokroy et al., (2011) retrospectively assessed the safety and effectiveness of preoperative intravitreal bevacizumab before vitrectomy in case of proliferative diabetic retinopathy with tractional retinal detachment. All patients with this condition who had undergone 3-port 20-gauge vitrectomy (primarily performed by one surgeon) over a 5 year period were included. Eyes that had received intravitreal bevacizumab were compared with those that had not. Ninety-nine eyes of ninety patients were included in the study. In all, 34 patients had received intravitreal bevacizumab on an average of 11.5 (range, 3-30) days previtrectomy; while the visual acuity had improved from 20/617 to 20/62 in the eyes that had received bevacizumab, the improvement was from 20/440 to 20/80 in the eyes that had not received bevacizumab. In younger patients (≤ 40 years), time taken for performing the surgery was found to be

significantly shorter and a trend to better visual acuity was noted in the eyes that had received intravitreal bevacizumab, prompting the authors to conclude that pre-operative bevacizumab might be a useful adjunct to vitrectomy for severe proliferative diabetic retinopathy complicated by tractional retinal detachment in young patients with diabetes³².

Zhao et al., performed a meta-analysis of six randomized controlled trials and one comparative study with a view to compare vitrectomy alone (142 eyes, control group) with vitrectomy with intravitreal bevacizumab pretreatment (139 eyes) for severe diabetic retinopathy. The occurrence of intraoperative bleeding and frequency of endodiathermy were found to be less in bevacizumab pretreatment group than in the group which underwent vitrectomy alone; the bevacizumab pretreatment group had markedly less surgical time than the control group. There was a significantly shorter blood reabsorption time, incidence of recurrent vitreous hemorrhage was almost significantly less, and final BCVA was markedly better in the eyes that had received bevacizumab than in those that had not. Other complications, such as final retinal detachment, and resurgery, were not statistically significant between the groups³³.

Sato et al., compared outcomes and procedures done, including the time taken for recovery, in eyes with PDR that had undergone 25-gauge

microincision vitrectomy surgery (87 eyes, 55 patients) with those that had undergone 20-gauge vitrectomy (72 eyes, 53 patients). There were no marked differences between surgical procedures or cases with postoperative complications between those that had undergone 20-gauge or those that had undergone 25-gauge vitrectomy. The anatomical success rate in both the groups was 100%. The BCVA at the end of 6 months after final vitrectomy was much better than the preoperative reading for both types, and was not different between both the groups. Interestingly the average duration of hospital stay was 19.5 days after 20-gauge vitrectomy, which was much longer than the 11.0 days after 25-gauge vitrectomy. The authors concluded that their results indicated that 25-gauge microincision vitrectomy surgery were not different from 20-gauge vitrectomy in eyes with PDR in terms of anatomical and functional outcomes. However, after 25-gauge microincision vitrectomy surgery the recovery period is shorter and less traumatic than 20-gauge vitrectomy³⁴.

Gupta et al. (2012) sought to evaluate anatomical outcome and eyes with visual acuity of ≤ 0.3 log MAR in patients who had undergone 20G PPV over a 17-month period for complications of PDR such as severe vitreous hemorrhage and tractional retinal detachment; Three hundred and forty six eyes of 249 patients with follow-up period of 1.5 years were

analyzed. Flat retina was observed in 95.3% of eyes during final follow-up; 136 eyes out of three hundred and forty six (39.4%) eyes had final visual acuity of 6/12 and 129 (37.3%) had 6/60 by snellen; 50 out of 181 (27.6%) eyes with tractional retinal detachment and 84 eyes out of 165 (50.9%) with non clearing vitreous hemorrhage achieved a final visual acuity of ≤ 0.3 logMAR (Snellen 6/12). Sixty three percent of eyes showed ≥ 0.3 logMAR improvements from pre-operative to last follow-up. Both preoperative visual acuity and final postoperative visual acuity improved every year significantly. The per-operative complication which was encountered frequently was iatrogenic retinal tear in 28.4%, which was a risk factor for the development of post-operative retinal detachment. During the procedure silicone oil was used in 5.2% of patients. Non-clearing post-vitreotomy hemorrhage needed removal in 9.2% of eyes³⁵.

End-stage diabetic eye disease is an important cause of severe visual impairment in the working-age group. Gupta et al. identified patients who had undergone vitrectomy over a three-year period because of diabetes-related complications in South East London. The prevalence of people requiring vitrectomy in that area was two per thousand diabetics. 185 eyes of 158 patients underwent vitrectomy during this period (Fifty one Afro-Caribbeans, seventeen South Asians, seven from other ethnic groups and

eighty three Caucasians). 58 patients presented with type I diabetes (mean duration 23 years) and 100 with type II diabetes (mean duration 16.5 years). 109 eyes with tractional retinal detachment, 68 eyes with non-clearing vitreous hemorrhage, and eight eyes with other causes underwent vitrectomy. Finally, at the end of 12 months 50% of eyes with tractional retinal detachment and non clearing vitreous hemorrhage, and 87% of the eyes with non-clearing vitreous hemorrhage improved by minimum of 3 ETDRS lines. Poor visual success was attributed to (i) duration of diabetes being longer, (ii) patient using insulin, (iii) presence of heart disease, (iv) delay in undergoing surgery, and (v) failure to come for follow-up. Use of intravitreal bevacizumab pre-operatively in eyes undergoing vitrectomy with tractional retinal detachment had some beneficial effect on the maculopathy if present and post -operatively the need for laser photocoagulation was less, but did not have any effect on vitreous hemorrhage that occurred post-operatively. The authors concluded that visual outcomes was significantly better in their study compared with the results from the Diabetic Vitrectomy Study³⁶.

Newer horizons have been achieved in vitreoretinal surgery due to technological up gradation in the instruments used for the surgery. The main aim of modern day vitreoretinal surgery is to achieve the best

possible outcome by the least possible surgical intervention. The advances in surgery include transconjunctival sutureless vitrectomy (23 and 25 G) and the availability of high speed cutters, microcannulas, insertion trocars, xenon light source, wide angle fundus viewing systems such as binocular indirect operating microscope and erect indirect binocular ophthalmic system, pulsed electron avalanche knife, perfluorocarbon liquids, expansile gases, and anti – VEGF adjuncts³⁷.

Transconjunctival sutureless vitrectomy provides earlier visual improvement (as early as 7 days) and less surgically- induced astigmatism about -1.50 Dioptre than conventional vitrectomy³⁸. One study reported that there were fewer complications in 23G transconjunctival sutureless vitrectomy and an improved final visual acuity of 20/70, (from a pre operative visual acuity of 20/150) with a mean follow up of 6.5 months (range 3-9 months), thus providing improved outcome and prognosis³⁹.

Challenges that remain ahead in vitrectomy are to minimize iatrogenic trauma, to make the procedure safe and reproducible and to develop techniques that help avoid surgery (such as chemical induction of a posterior vitreous detachment).

In the present investigation, the various investigations for parsplana vitrectomy in patients presenting with diabetic retinopathy have been documented; the anatomical results and functional outcomes, the intraoperative and post-operative complications, and factors contributing to the results and complications have also been elucidated.

Materials & Methods

MATERIALS AND METHODS

This was a prospective interventional study performed on patients presenting at the Retina Clinic of a tertiary care eye hospital in Tamil Nadu between April 2012 and June 2013. This study was approved by the Institutional Ethics Committee.

Patients were recruited in the study if they (Inclusion Criteria):

1. Provided informed written consent to participate in the study
2. Presented with proliferative diabetic retinopathy and were willing to undergo pars plana vitrectomy to manage complications

Patients were excluded if any one of the following occurred (Exclusion Criteria):

1. Did not provide informed consent
2. Presented with other retinal vascular disorders, epiretinal membrane or macular hole not attributable to diabetes
3. Suffered from pre-existing conditions such as age-related macular degeneration and advanced glaucoma that were deemed capable of adversely affecting visual outcomes

4. Suffered from a medical condition for which pars plana vitrectomy was contraindicated.

Data of patients who had not completed a three month follow-up were excluded from final analysis.

A complete medical and ocular history was taken at the baseline visit, including duration of diabetes, treatment history, control of diabetes and other co-existent morbidities. All the patients underwent a detailed ophthalmic examination which included:

1. Best corrected visual acuity for distance and near vision (Snellen's chart for distance vision and Snellen's chart for near vision)
2. Slit lamp biomicroscopy
3. Fundus examination (+90D lens) and indirect ophthalmoscopy
4. Intraocular pressure measurement (Goldmann's applanation tonometry)
5. Fundus photography
6. Fundus fluorescein angiography
7. Optical coherence tomography (OCT) for detection of macular edema, vitreomacular traction, epiretinal membranes, taut posterior

hyaloids and partial or full thickness macular holes, and for assessment of degree and extent of posterior vitreous detachment.

OCT was performed on the Zeiss® Cirrus HD OCT™ (Zeiss Meditec, Dublin, CA, USA) using a macular cube or Raster scan protocol

8. Ultrasonography B scan was performed to assess the vitreous and retinal status if media opacities precluded a clear view of the fundus.

Eyes were considered for pars plana vitrectomy if any of the following lesions was present:

- a) non-clearing vitreous hemorrhage of more than a month's duration;
- b) vitreous hemorrhage producing severe visual loss (visual acuity less than 5/60) in one-eyed patients;
- c) tractional retinal detachment affecting the fovea or within 0.5 disc dioptries of the fovea;
- d) combined rhegmatogenous and tractional retinal detachment;
- e) thickened and taut posterior hyaloids significantly affecting visual acuity;
- f) vitreomacular traction; and

g) persistent diabetic macular edema unresponsive to laser and intravitreal therapy.

The indication for pars plana vitrectomy was recorded and all cases were operated upon by one of three experienced vitreoretinal surgeons.

Procedure

All patients received an explanation of the procedure and its possible complications, and written informed consent was obtained.

In patients with active neovascularization or fresh vitreous hemorrhage, bevacizumab (2.5mg/0.1ml) was given intravitreally 1 or 2 weeks prior to surgery.

All patients were operated on under local anesthesia with close monitoring of the patient's medical condition by an anesthesiologist with the titration of 50:50 mixture of 2% lidocaine (combined with 1 in 100000 adrenaline and hyaluronidase) and 0.75% bupivacaine (Neon laboratories ltd, Mumbai, India) as the local anesthetic agent given as a peribulbar injection. The eye was prepared by cleaning the skin and eye lashes with 5% povidone- iodine (Aurodine, Aurolab, Madurai, India) solution, and

instillation of 5% povidone – iodine in the conjunctival cul-de-sac. The eye was draped and all the surgeries were performed. If a visually significant cataract was present or if cataract prevented adequate visualization of the retina, a manual small incision cataract surgery or phacoemulsification was performed, with implantation of a posterior chamber intraocular lens. A standard 3 port 20 gauge pars plana vitrectomy was done using the Alcon Accurus ® vitrectomy system (Alcon Surgical, Texas, USA). Sclerotomies were made, 3.5 mm posterior to the limbus in pseudophakic eyes and 4mm in phakic eyes, using a 19 gauge microvitrectomy blade; a 4mm long infusion cannula was then inserted at the sclerotomy site inferior to the lateral rectus insertion with the infusion closed. The cannula was fixed with a 8-0 vicryl mattress suture and the tip of the cannula was visualized clearly before the infusion was opened. The other 2 sclerotomies were placed 150- 160° apart just superior to the meridian of the horizontal rectus insertions. One port carried the fiberoptic light source and the other was used for the instruments and the vitrector. With the non contact wide angle viewing system binocular indirect operating microscope (BIOM) in place, the eye was manipulated with a bimanual technique with two instruments. Core vitrectomy was done, vitreous hemorrhage was cleared

and a posterior vitreous detachment was induced if not present. The posterior hyaloid was first opened over the attached retina; the opening of the posterior hyaloid was then enlarged until the retina was visualized. If the blood in the subhyaloid obscured the retina, it was removed with the help of a silicone-tip suction needle. All the fibrovascular membranes were removed by horizontal and vertical scissors with the combination of segmentation and delamination technique. Bleeders were cauterized by endocautery. Perfluorocarbon liquids (PFCL) were used to stabilize the retina prior to membrane removal in extensive tractional retinal detachments. Any preexisting retinal breaks or iatrogenic breaks were treated by endolaser photocoagulation all around the break using the Iridex™ 810nm laser with endodelivery system (Iridex corporation, California, USA). If rhegmatogenous retinal detachment was present, the retina was flattened using PFCL or by fluid air exchange. If panretinal photocoagulation was inadequate, it was completed on the table. Patients who needed internal tamponade were treated either with silicone oil or intraocular gases, such as 20% sulfur hexafluoride (SF6) and 16% perfluoropropane(C3F8). In certain cases, pars plana lensectomy was done

during surgery in cases requiring membrane dissection in the vicinity of the vitreous base.

At the end of the procedure, the 2 sclerotomy sites were closed by 8.0 vicryl sutures and a fluid-air exchange or fluid- gas exchange or with silicone oil was done and the third port was also closed. Intraoperative complications, such as iatrogenic breaks, excessive bleeding, inability to completely remove membranes and damage to the lens, were recorded. The patient was advised to maintain proper positioning depending on location of breaks and macular status. All patients were started on a combination of antibiotic and steroid eye drops (Ocepred eye drops, 10mg prednisolone/3mg ofloxacin, Sun Pharma, India) 6 times a day and 0.5% timolol maleate (Timoblu, 0.5% timolol maleate, Lupin pharma, India) twice daily, and follow up examination was done at one week, one month, and three months.

At each review visit, the following examinations were performed:

1. determination of best corrected visual acuity for distance and near vision;
2. slit lamp biomicroscopy;

3. fundus examination (+90D lens) and indirect ophthalmoscopy;
4. intraocular pressure measurement (Goldmann's applanation tonometry);
5. fundus photography; and
6. optical coherence tomography for macular edema.

The main outcome measures evaluated were changes in visual acuity, anatomical results (clearing of vitreous opacities, reattachment of retina and resolution of the macular edema) and changes in macular thickness. Intraoperative complication rates were analyzed and the occurrence of post-operative complications such as secondary glaucoma, development of cataract, retinal detachment and rebleed into vitreous cavity or development of neovascularization of the anterior segment, was also studied.



Figure 1. Alcon Accurus ® vitrectomy system (Alcon Surgicals, Texas, USA).

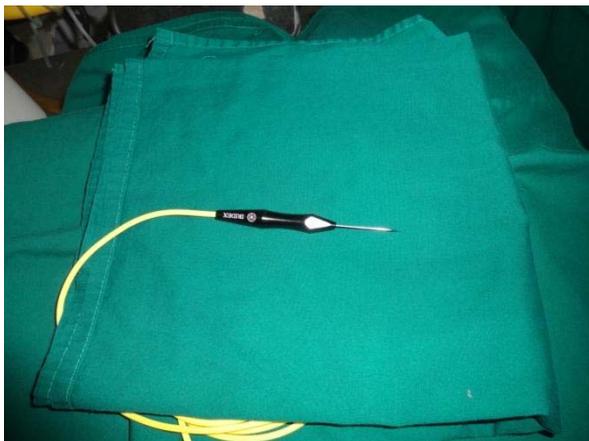


Figure 2. Iridex™ 810nm laser with endodelivery system (Iridex corporation, California, USA).



Figure 3. Oculus® BIOM (Binocular indirect operating microscope) attached to the Zeiss ® Visu 150 Operating microscope.



Figure 4. 20 G Vitrectomy probe (top), 20 G endoilluminator probe (middle), Curved endolaser delivery probe (bottom).

Results

RESULTS

Over a period of 13 months (May 2012 to May 2013), 81 patients underwent pars plana vitrectomy for complications of diabetic retinopathy at Joseph Eye Hospital and were considered for inclusion in the study. Of these, 34 patients were excluded due to one or more exclusion criteria, hence 46 patients (47 eyes) were included in the study

1. Demography of patients

a. Gender distribution of the enrolled patients

Of the 46 patients enrolled in the study, 26 patients were male and 20 were females. (Chart-1)

b. Age characteristics of the enrolled patients

In this study the mean age of the patients was 55.04 ± 9.6 years (range 35 to 80 years), with 16 patients (35 %) in the 41 to 50 year age group, 14 patients (30 %) in the 61 to 70 year age group and 14 patients (26 %) in the 51 to 60 year age group. (Chart-2)

Chart 1. Gender distribution of patients undergoing pars plana vitrectomy for diabetic retinopathy complications

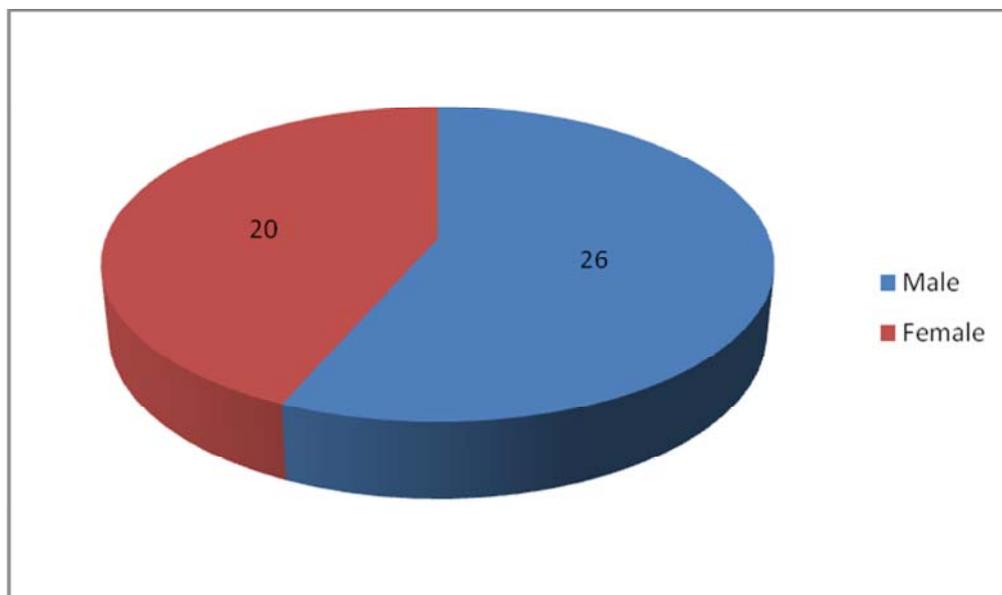
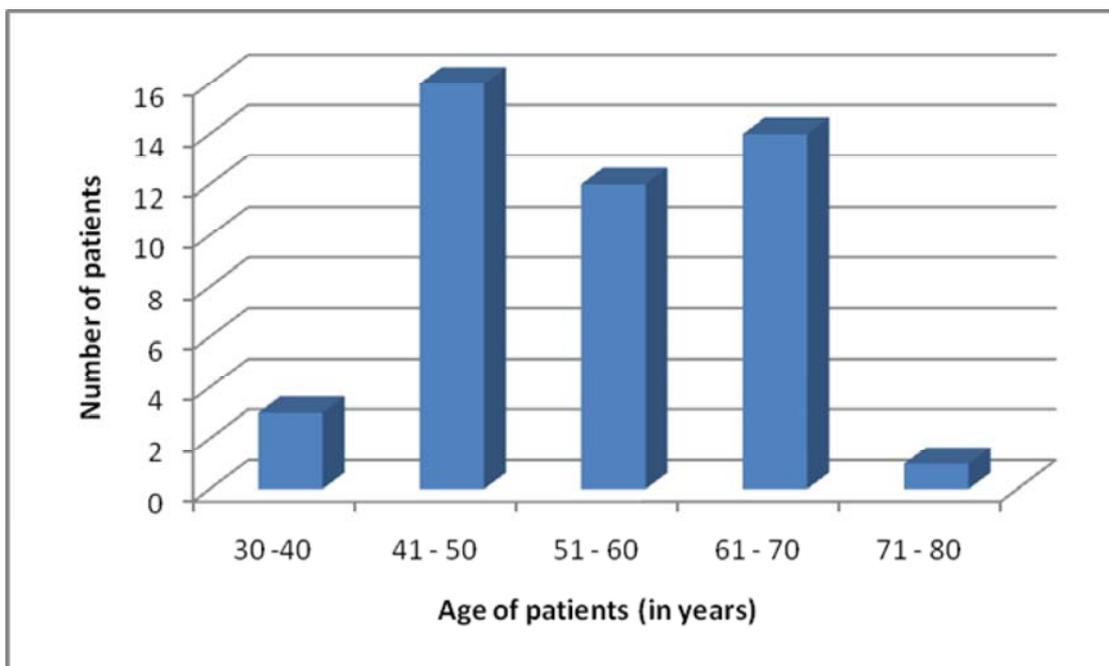


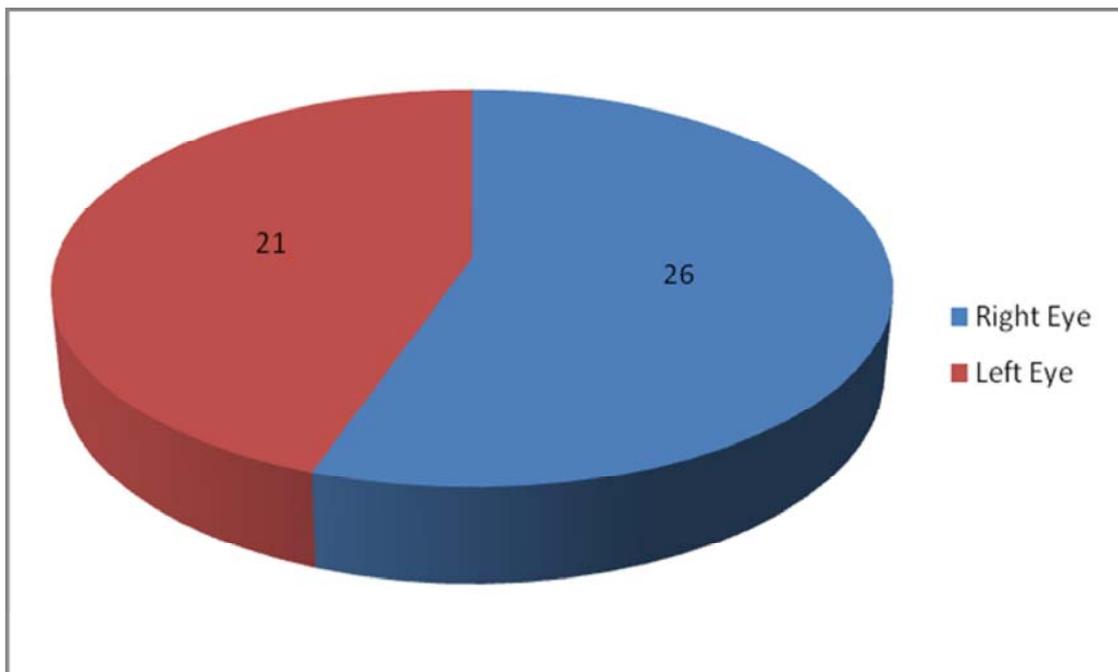
Chart 2. Age distribution of patients undergoing pars plana vitrectomy for diabetic retinopathy complications



c. Laterality of study eyes

Forty seven eyes presented with complications of diabetic retinopathy. Vitrectomy was performed for the right eye in 26 instances (55%) and for the left eye in 21 instances (45%). (Chart-3)

Chart 3. Laterality of study eyes in patients undergoing pars plana vitrectomy for diabetic retinopathy complications



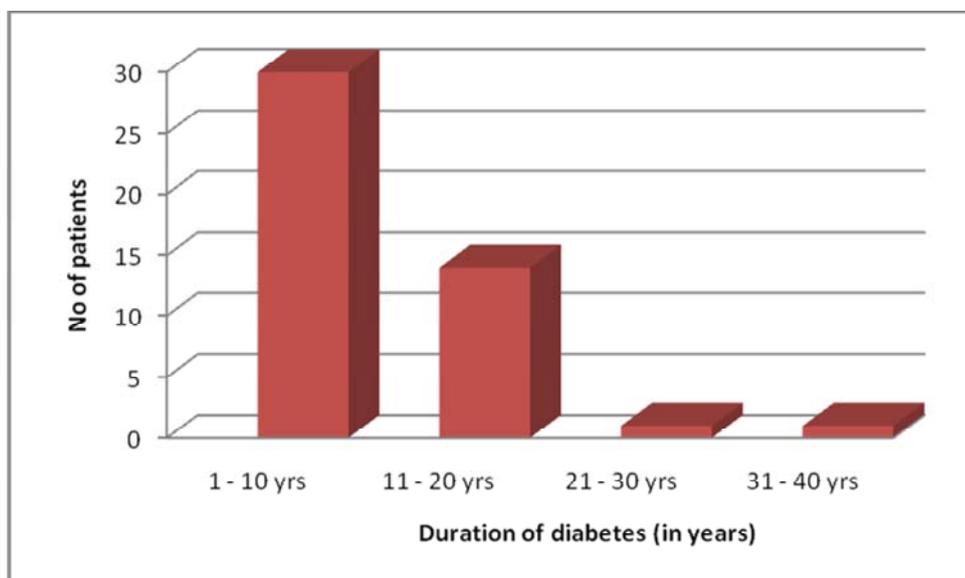
d. Duration of diabetes

In this study, 30 (65 %) of patients had suffered from diabetes mellitus for between 1 to 10 years duration, 14 (30 %) patients in the study had duration of diabetes ranging between 11 to 20 years and one (2 %) patient each had suffered from diabetes for 21 to 30 years and 31 to 40 years, respectively (Table 1; Chart-4). The mean duration of diabetes in patients with vitreous hemorrhage was 11.64 ± 7.40 years, and mean duration in patients with Tractional retinal detachment was 8.81 ± 4.19 years, this difference was not statistically significant ($t' [d.f :42] = 1.57$; $p=0.13$) (unpaired Student's 't' test).

Table-1 Duration of diabetes in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Range in years	No of Patients	Percentage %
1 – 10	30	65
11 – 20	14	30
21 – 30	1	2
31 – 40	1	2

Chart 4. Duration of diabetes in patients undergoing pars plana vitrectomy for complications of diabetic retinopathy



e. Co existing morbidity

In this study of the 46 patients who presented with diabetic retinopathy, 24(52%) also had other associated systemic disease. Twenty (44%) patients presented with hypertension and diabetes, four (8%) patients had ischemic heart disease along with diabetes and 22 (48%) patients presented with only diabetes. (Table-2)

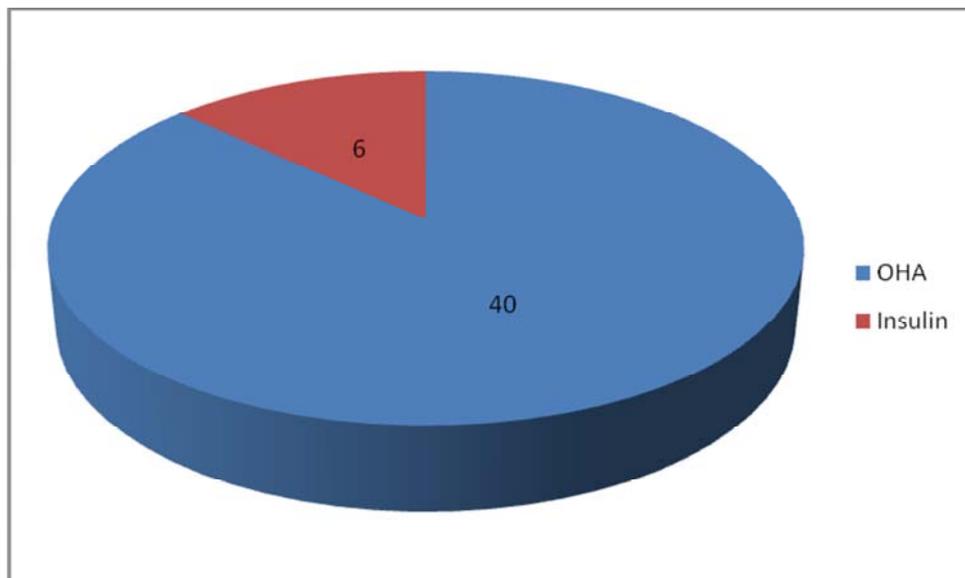
Table - 2 Coexisting morbidity in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Disease	No of Patients	Percentage %
Hypertension	20	44
Ischemic heart disease	4	8
Only Diabetes	22	48

f. Treatment of diabetes

In the study, of the 46 patients who were being treated for diabetes, 40(87%) patients were on oral hypoglycemic agents and 6(13%) patients were on insulin. (Chart-5)

Chart 5. Treatment of Diabetes in patients undergoing pars plana vitrectomy for diabetic retinopathy complications



OHA – oral hypoglycemic agents

2. Indications for Vitrectomy

Of the 47 eyes included in the study 25 (53 %) eyes underwent surgery for vitreous hemorrhage, seven (15%) eyes for tractional retinal detachment, nine (19%) eyes for tractional retinal detachment with vitreous hemorrhage, two (4%) eyes for recalcitrant macular edema, 2 (4%) eyes for dense non- clearing premacular hemorrhage, one (2%) eye for vitreomacular traction and one (2%) eye for vitreomacular traction with vitreous hemorrhage (Table-3; Chart-6).

Table-3 Indications for vitrectomy in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

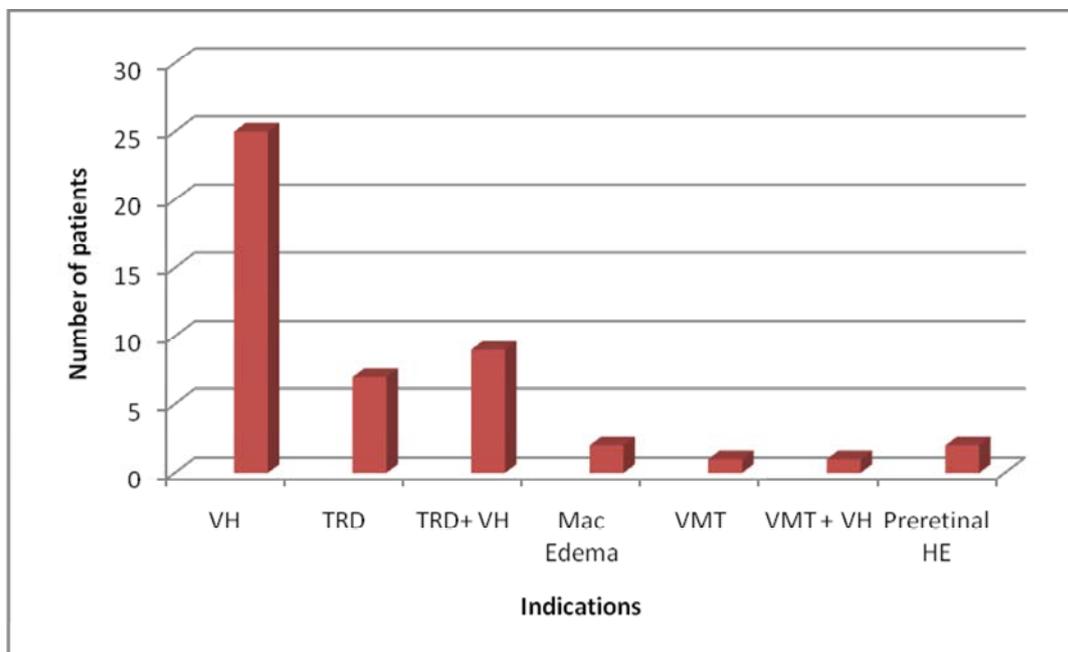
Indications	Number of Eyes
VH	25
TRD	7
TRD + VH	9
Macular edema	2
Premacular hemorrhage	2
VMT	1
VMT + VH	1

VH – Vitreous hemorrhage

TRD – Tractional retinal detachment

VMT – Vitreomacular traction

Chart 6. Indications for pars plana vitrectomy in patients with complications of proliferative diabetic retinopathy



VH- Vitreous hemorrhage

TRD – Tractional retinal detachment

VMT – Vitreomacular traction

3. Pre Operative visual acuity

In this study, mean best corrected visual acuity (BCVA), in decimals, prior to surgery was 0.048 ± 0.01 (~3/60). In patients with vitreous hemorrhage the average BCVA was 0.019 ± 0.01 (~1/60), in case of tractional retinal detachment the average BCVA was 0.070 ± 0.029 (~4/60), in combined tractional retinal detachment with vitreous hemorrhage the BCVA was 0.053 ± 0.03 (~3/60) and in other groups the BCVA was 0.133 ± 0.038 (~6/60). These differences were statistically significant (one way analysis of variance [ANOVA] Fisher 'F' value = 5.1, degree of freedom {d.f} = 46; p= 0.004 (Table-4)

Table-4 Mean pre operative best Corrected Visual Acuity in different groups of patients undergoing pars plana vitrectomy in diabetic retinopathy complications

Patient (eye)group	No of eyes	Mean BCVA (\pm SEM) In Decimals	Approximate Snellens equivalent
VH	25	0.019 ± 0.01	1/60
TRD	7	0.070 ± 0.01	4/60
VH + TRD	9	0.053 ± 0.03	3/60
Others	6	0.133 ± 0.04	6/60
Overall mean	47	0.048 ± 0.01	3/60

VH – Vitreous hemorrhage

TRD – Tractional retinal detachment

BCVA-Best corrected visual acuity

SEM – Standard error of the mean

Fisher 'F' value = 5.1 [d.f=46]; p=0.004

4. Surgery performed

In this study, all 47 eyes of 46 patients underwent standard 20G 3-port pars plana vitrectomy, of which 21 (45%) eyes underwent vitrectomy with membrane peeling, endolaser and silicone oil injection, seven (15%) eyes underwent vitrectomy with membrane peeling and endolaser, six (13%) eyes underwent vitrectomy with endolaser alone, six (13%) eyes underwent vitrectomy with intraocular lens implantation, four (8%) eyes underwent vitrectomy with intraocular lens implantation, membrane peeling and endolaser and three (7%) eyes underwent vitrectomy with membrane peeling, endolaser, silicone oil injection and intraocular lens implantation (Table-5; Chart-7).

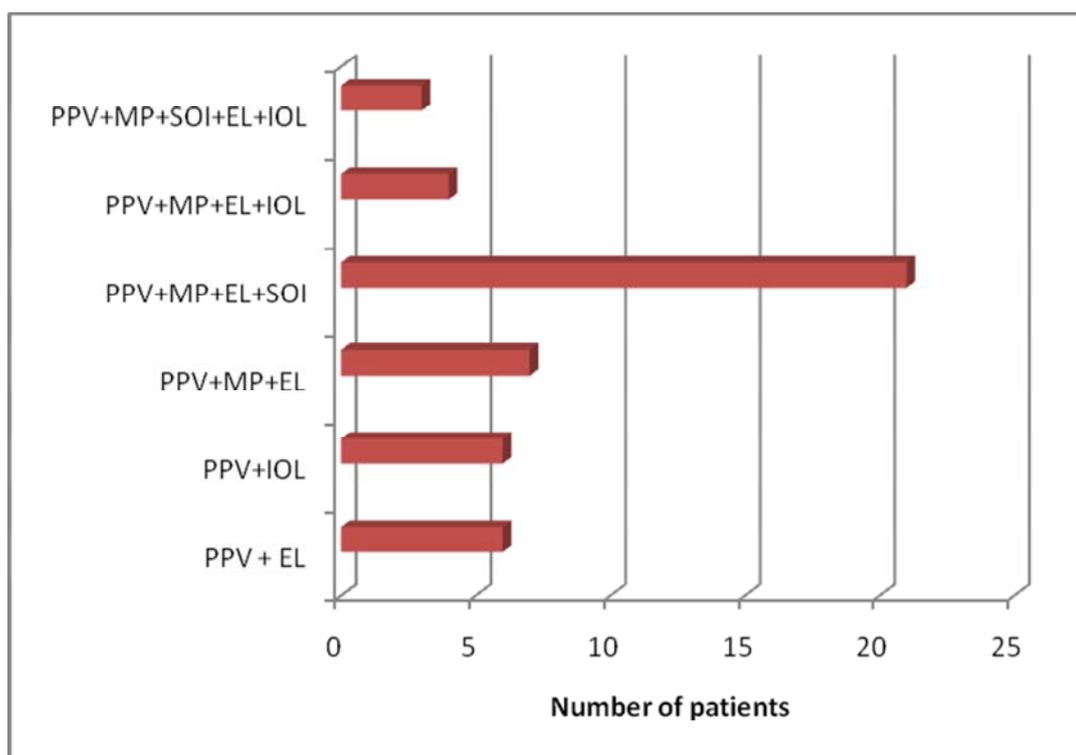
Table -5 Type of surgery performed in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Surgical procedure performed	Number of eyes
PPV +EL	6
PPV + IOL	6
PPV + MP + EL	7
PPV + MP + EL + SOI	21
PPV + MP + EL + IOL	4
PPV +MP + EL + SOI + IOL	3

PPV – Pars plana vitrectomy
MP – Membrane peeling
SOI – Silicone oil

IOL – Intraocular lens
EL – Endolaser

Chart 7. Surgical procedure performed in patients with proliferative diabetic retinopathy



PPV – Pars plana vitrectomy
MP – Membrane peeling
SOI – Silicone oil

IOL – Intraocular lens
EL – Endolaser

5. Intraoperative complications

In this study, of the 47 eyes which underwent vitrectomy, four (8%) eyes had severe intraoperative bleeding and eight (17%) eyes had iatrogenic retinal break (one from vitreous hemorrhage group and seven from tractional retinal detachment group). Of the four (8%) eyes which encountered intraoperative bleeding, one each was from different groups. (Table – 6)

Table-6 Intra operative complications in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Group	Bleeding (no. of patients)	Retinal break (no of patients)
VH	1	1
TRD	1	4
TRD +VH	1	3
Macular edema	1	-

VH – Vitreous hemorrhage TRD – Tractional retinal detachment

6. Post operative complications

Of the 47 eyes which underwent vitrectomy, ten (21%) eyes had significant post operative complications. Three (6%) eyes had recurrent vitreous hemorrhage, three (6%) eyes had retinal break detected post-operatively, two (4%) eyes presented with severe macular edema (500 μ on OCT), one eye developed combined rhegmatogenous and tractional retinal detachment detected post operatively and one eye developed cataract. (Table-7)

Table-7 Postoperative complications in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Group	Retinal break	Recurrent vitreous hemorrhage	Combined RRD + TRD	Macular edema	Cataract
VH	2	2	1	-	-
TRD	1	-	-	-	1
TRD + VH	-	1	-	1	-
VMT	-	-	-	1	-

VH – vitreous hemorrhage TRD – Tractional retinal detachment

VMT- Vitreomacular traction

RRD – Rhegmatogenous retinal detachment

7. Visual acuity and anatomical outcomes

a. Immediate post operative period

In this study of 47 eyes which underwent pars plana vitrectomy, the mean post operative BCVA was ($\sim 6/60$) 0.10 ± 0.02 in decimals (Table-8). Forty-two (89%) eyes out of 47 eyes had a stable retina postoperatively while three (6%) eyes developed retinal detachments (who were not willing for second surgery) and two (4%) eyes had severe macular edema.

b. At 1 month post operative period

Of the 47 eyes, the average BCVA at 1 month post operative period was ($\sim 6/60$) 0.15 ± 0.03 in decimals (Table-8). The retina was well attached in 42(89%) eyes at 1 month follow up whereas two (4%) eyes had macular edema and three (6%) eyes had retinal detachment at 1 month.

c. At 3 months follow up

At 3 months following surgery, of the 47 eyes which underwent pars plana vitrectomy for diabetic retinopathy, 42(89%) eyes had a stable well attached retina while three (6%) eyes had retinal detachment and two (4%) eyes had persistent macular edema at the end of the follow up. The mean best corrected visual acuity at the end of 3 months was ($\sim 6/36$) 0.22 ± 0.21 in decimals (Table-8).

Table-8 Mean post operative visual acuity in patients undergoing pars plana vitrectomy for diabetic retinopathy complications

Post operative visit	Visual acuity range in decimals (\pmSD)	Approximate Snellens equivalent
Immediate	0.10 \pm 0.02	6/60
1 month	0.15 \pm 0.03	6/60
3 month	0.22 \pm 0.21	6/36

8. Comparison of pre operative and post operative visual outcome

In this study of the 47 eyes which underwent pars plana vitrectomy, the mean pre operative visual acuity(decimals) was 0.05 \pm 0.009 (~3/60) while the mean post operative visual acuity immediately post surgery was 0.10 \pm 0.02 (~6/60) which was statistically significant ('t'[d.f :92] = 2.3 ; p= 0.003) (Table-9/Chart-7).

In the vitreous hemorrhage group the mean pre operative visual acuity (decimals) was 0.02 \pm 0.006 (~1/60) while the mean post operative visual acuity (decimals) immediately post surgery was 0.08 \pm 0.03 (~5/60) ('t' [d.f :48] = 1.9; p= 0.02). At the end of the 1 month postoperative period, the mean visual acuity (decimals) was 0.11 \pm 0.03 (~6/60) which was significantly better than the mean pre-operative value ('t' [d.f : 48]

=2.9; p=0.001). When compared at the end of 3 months the visual acuity (decimals) was 0.18 ± 0.04 (~ 6/36) which was significantly better than the mean pre- operative value (Student's's 't' test) ('t' [d.f :48] = 3.9; p=0.001) (Table-9; Chart-8).

In the tractional retinal detachment group the mean pre operative visual acuity was 0.06 ± 0.02 (~4/60); at the immediate post operative visit the mean visual acuity, (decimals) was 0.09 ± 0.01 (~5/60) 't' [d.f : 30] = 5.3; p=0.06 (approaching statistical significance). At 1 month post- op, the mean visual acuity was 0.17 ± 0.05 (~6/36) which was significantly better than the mean pre-operative value ('t' [d.f :30] =1.9; p=0.04). Similarly, at the end of 3 months follow up, the mean post operative visual acuity was 0.21 ± 0.06 (~6/36) which when compared with the pre operative visual acuity, was statistically significant ('t' [d.f :30] = 2.3; p=0.01) (Table-9; Chart-8).

Table-9 Comparison of pre and postoperative visual acuity

Duration	All eyes		Vitreous hemorrhage		Tractional retinal detachment	
	VA in decimals	Statistical analysis p value	VA in decimals	Statistical analysis p value	VA in decimals	Statistical analysis p value
Pre operative	0.05±0.009		0.02±0.006		0.06±0.02	
Immediate PO	0.10±0.02	0.003*	0.08±0.03	0.02*	0.09±0.01	0.05*
1 month PO	0.15±0.03	0.00004**	0.11±0.03	0.001**	0.17±0.05	0.04**
3 month PO	0.22±0.21	0.00004***	0.18±0.04	0.0001***	0.21±0.06	0.01***

PO – Post operative VA – Visual acuity

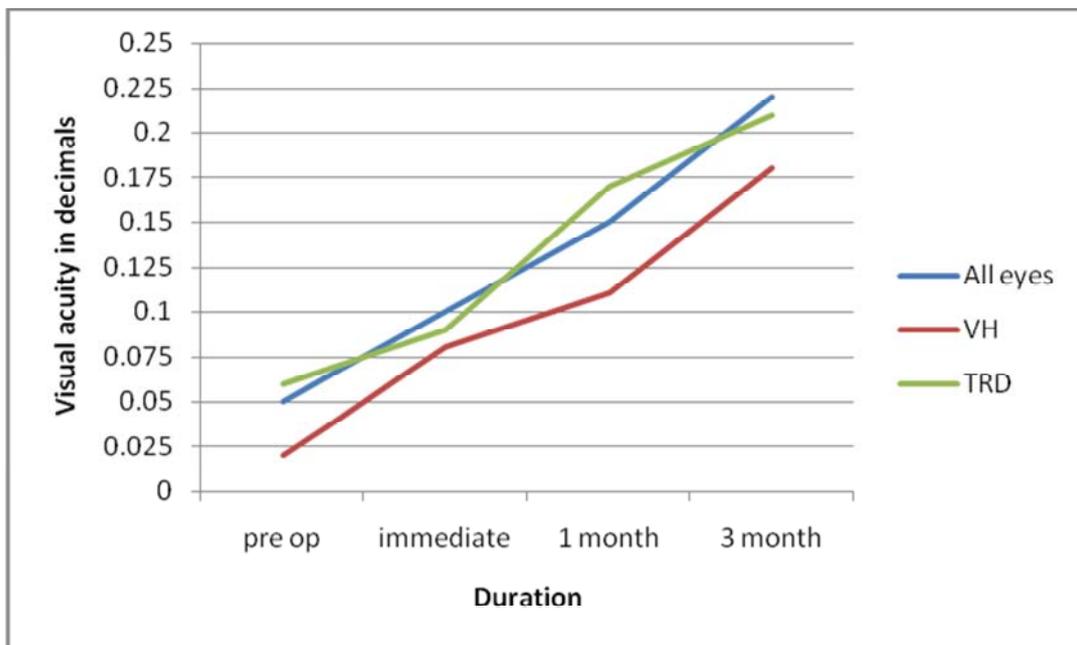
* - Pre operative visual acuity vs immediate post operative VA

** - Pre operative VA vs 1 month post operative VA

*** - Pre operative VA vs 3 month post operative VA

Statistical Analysis – Student’s ‘t’ test

Chart 8. Comparison of improvement in pre and post-operative visual acuity between different groups



VH – Vitreous hemorrhage

TRD – Tractional retinal detachment

9. Improvement in mean visual acuity between groups

In this study, the improvement in visual acuity after surgery was compared between 25(53%) eyes that had vitreous hemorrhage versus 22(47%) eyes without vitreous hemorrhage. Also, improvement in visual acuity was compared between 16(34%) eyes that had tractional retinal detachment and 31(67%) eyes those that did not have tractional retinal detachment. The mean post operative visual acuity (decimals) at 3 months in vitreous hemorrhage group was ($\sim 6/60$) 0.18 ± 0.12 while the mean BCVA (decimals) in the group without vitreous hemorrhage was ($\sim 6/36$) 0.23 ± 0.01 (Table-10; Chart-9). The mean BCVA (decimals) in tractional retinal detachment group was ($\sim 6/36$) 0.21 ± 0.01 and the mean BCVA (decimals) in the group without tractional retinal detachment was ($\sim 6/36$) 0.20 ± 0.12 (Table-11; Chart-10).

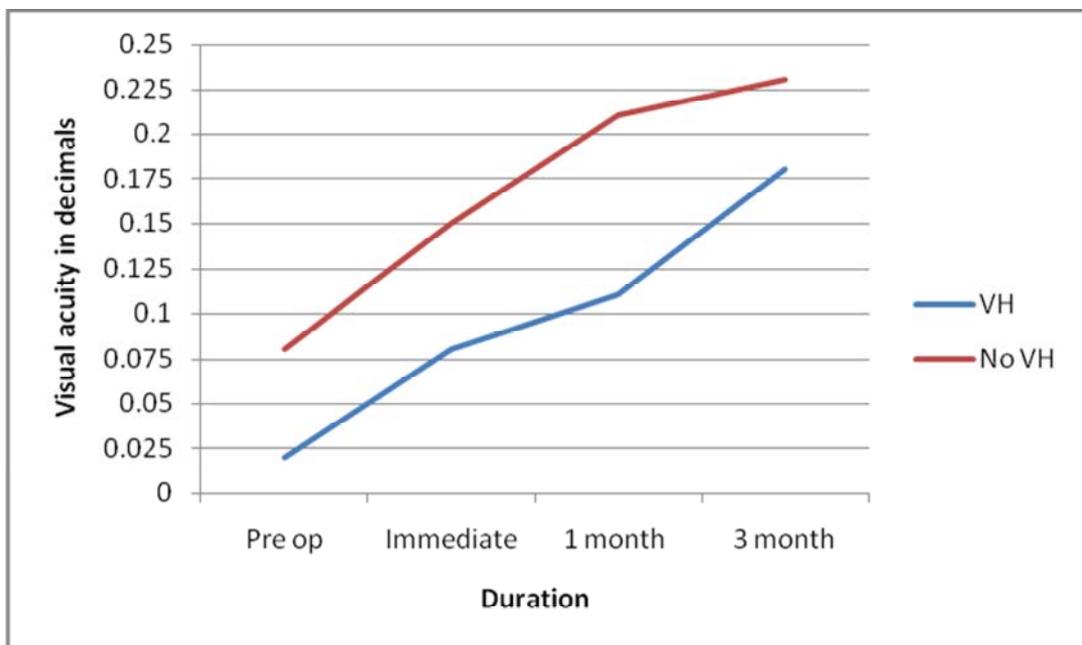
When the mean visual acuity in the vitreous hemorrhage group was compared with that in the group without vitreous hemorrhage immediately after surgery the difference was not statistically significant ($p=0.1$). Similarly no significant differences were noted when compared at the end of 1 month ($p=0.1$) and at the end of 3 months ($p=0.4$) (Table-10).

Similarly when the mean visual acuity in the tractional retinal detachment group was compared with that in the group without tractional retinal detachment, no significant differences were noted immediately post operatively (p=0.8), at the end of one month (p=0.6) and at 3 months (p=0.8) (Table-11).

Table-10 Comparison of mean post operative visual acuity between group with vitreous hemorrhage and group without vitreous hemorrhage at various post-operative visits in patients undergoing pars plana vitrectomy.

Post operative visit	Mean best corrected visual acuity (decimals)		Statistical analysis (Student's 't' test)
	Vitreous hemorrhage n=25	No vitreous hemorrhage n=22	
Immediate	0.08 ± 0.03	0.15 ± 0.11	p= 0.1
1 month	0.11 ± 0.03	0.21 ± 0.001	p= 0.1
3 months	0.18 ± 0.12	0.23 ± 0.01	p= 0.4

Chart 9. Comparison of mean post-operative visual acuity between groups with vitreous hemorrhage and group without vitreous hemorrhage at various intervals



VH- Vitreous hemorrhage

Table-11 Comparison of mean post operative visual acuity between group with tractional retinal detachment and group without tractional retinal detachment at various post operative visits

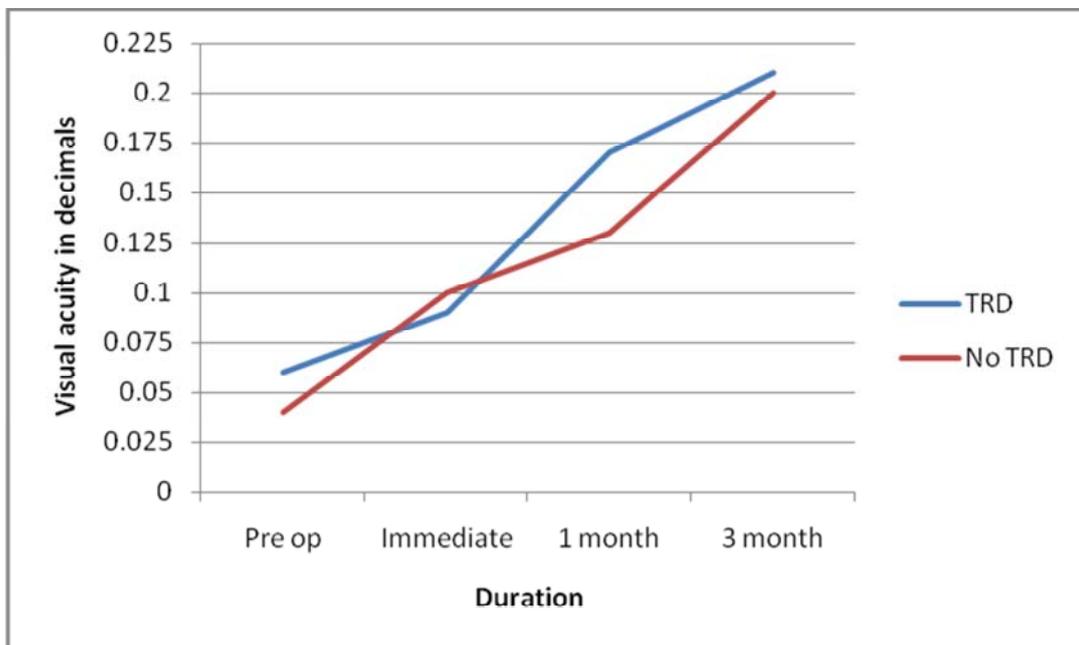
Post operative visit	Mean BCVA (decimals)		Statistical analysis (Student's 't' test)
	TRD group (n=16)	Group without TRD (n=31)	
Immediate	0.09 ± 0.01	0.10 ± 0.01	p= 0.8
1 month	0.17 ± 0.001	0.13 ± 0.03	p= 0.6
3 months	0.21 ± 0.01	0.20 ± 0.12	p= 0.8

VH – Vitreous hemorrhage

TRD – Tractional retinal detachment

BCVA-Best corrected visual acuity

Chart 10. Comparison of mean post-operative visual acuity between groups with and without tractional retinal detachment at various post-operative intervals



TRD – Tractional retinal detachment

10. Comparison of quantum of change in visual acuity

a. In group with Vitreous hemorrhage vs group without vitreous hemorrhage

In this study, 25(53%) eyes underwent pars plana vitrectomy for vitreous hemorrhage and the mean BCVA (decimals) post-operatively was 0.06 ± 0 (immediate post-operative), 0.09 ± 0.08 (1 month post-operative) and 0.17 ± 0.09 (3 months post-operative). Of the 22(47%) eyes which had no vitreous hemorrhage, the mean BCVA (decimals) post operatively, was 0.11 ± 0 (immediate), 0.13 ± 0.02 (1 month post operative), and 0.14 ± 0.09 (3 months post-operative) (Table-12).

The quantum of change in visual acuity did not differ significantly between the two groups (with vitreous hemorrhage versus without vitreous hemorrhage) at immediate post operative period ($p=0.06$), at 1 month ($p=0.2$) and at 3 months post operatively ($p=0.9$) (Table-12).

b. In group with Tractional retinal detachment vs group without tractional retinal detachment

In this study, 16(34%) eyes underwent vitrectomy for tractional retinal detachment (TRD), and the mean post operative BCVA (in decimals) immediate post-operative was 0.07 ± 0 , at 1 month was 0.13 ± 0.05 , and at 3 months was 0.16 ± 0.05 . Of the 31(67%) eyes which had no TRD the mean BCVA (in decimals) was 0.08 ± 0 immediate post-operative, 0.11 ± 0.02 at 1 month post-operative and was 0.17 ± 0.02 at 3

months post-operative, differences were not statistically significant (p=0.9) (Table-13).

Similarly, the quantum of change in visual acuity did not differ significantly between the TRD and no TRD groups at immediate post operative period (p=0.9), at 1 month post-operatively (p=0.6) and at 3 months follow up (Student's 't' test) (p=0.9) (Table-13).

Table-12 Comparison of quantum of change in mean best corrected visual acuity in groups with vitreous hemorrhage and without vitreous hemorrhage

Post operative visits	Mean quantum of change in BCVA		Statistical analysis (Student's 't' test)
	Vitreous hemorrhage group(n=25)	No vitreous hemorrhage group(n=22)	
Immediate	0.06 ± 0.0	0.11 ± 0.0	p= 0.3
1 month	0.09 ± 0.08	0.13 ± 0.02	p= 0.2
3 month	0.17 ± 0.09	0.14 ± 0.09	p= 0.9

BCVA – Best corrected visual acuity

Table-13 Comparison of quantum of change in mean best corrected visual acuity in group with tractional retinal detachment and without tractional retinal detachment

Post operative visits	Mean quantum of change in BCVA		Statistical analysis (Student's 't' test)
	Group with TRD n=16	Group without TRD n=31	
Immediate	0.07 ± 0.0	0.08 ± 0.0	p= 0.9
1 month	0.13 ± 0.05	0.11 ± 0.02	p= 0.6
3 month	0.16 ± 0.05	0.17 ± 0.02	p= 0.9

TRD – Tractional retinal detachment

BCVA- Best corrected visual acuity

11. Comparison of proportion of eyes that had improvement in visual acuity in different sub groups

In the present study, pars plana vitrectomy was done for 25 eyes with vitreous hemorrhage and 22 eyes without vitreous hemorrhage. On the first post-operative day, 19(76%) of eyes in the vitreous hemorrhage group and 11(50%) of eyes in the non-vitreous hemorrhage group showed improved visual acuity, this difference approached statistical significance (χ^2 [d.f = 1]= 3.5; p=0.06). At the end of one month and at the end of three months, 18 eyes in each group (72% of eyes in vitreous hemorrhage group, 82% of eyes in non-vitreous hemorrhage group showed improved visual acuity; this difference was not statistically significant.

In the same study, pars plana vitrectomy was done for 16 eyes with tractional retinal detachment and 31 eyes with no tractional retinal detachment. On the first post operative day, 7(44%) of eyes with tractional retinal detachment and 23(74%) of eye in the no tractional retinal detachment group showed improved visual acuity. This difference was statistically significant (χ^2 [d.f =1]= 4.2; p=0.04). At the end of 1 month and at the end of 3 months, 12(75%) eyes from tractional retinal detachment group and 24(77%) eyes from no tractional retinal detachment group showed improved visual acuity, this difference was not statistically significant.

Table-14 Comparison of numbers of eyes with improved visual acuity in eyes with and without vitreous hemorrhage

Post operative visit	Vitreous hemorrhage		No vitreous hemorrhage		Statistical analysis (chi-square test)
	Improved	Not improved	Improved	Not improved	
Immediate	19	6	11	11	p=0.06
1 month	18	7	17	5	p=0.6
3 month	18	7	18	4	p=0.4

Table-15 Comparison of numbers of eyes with improved visual acuity in eyes with and without Tractional Retinal Detachment

Post operative visit	TRD		NO TRD		Statistical analysis (chi-squared test)
	Improved	Not improved	Improved	Not improved	
Immediate	7	9	23	8	p=0.04
1 month	12	4	23	8	p=0.9
3 month	12	4	24	7	p=0.8

TRD- Tractional retinal detachment

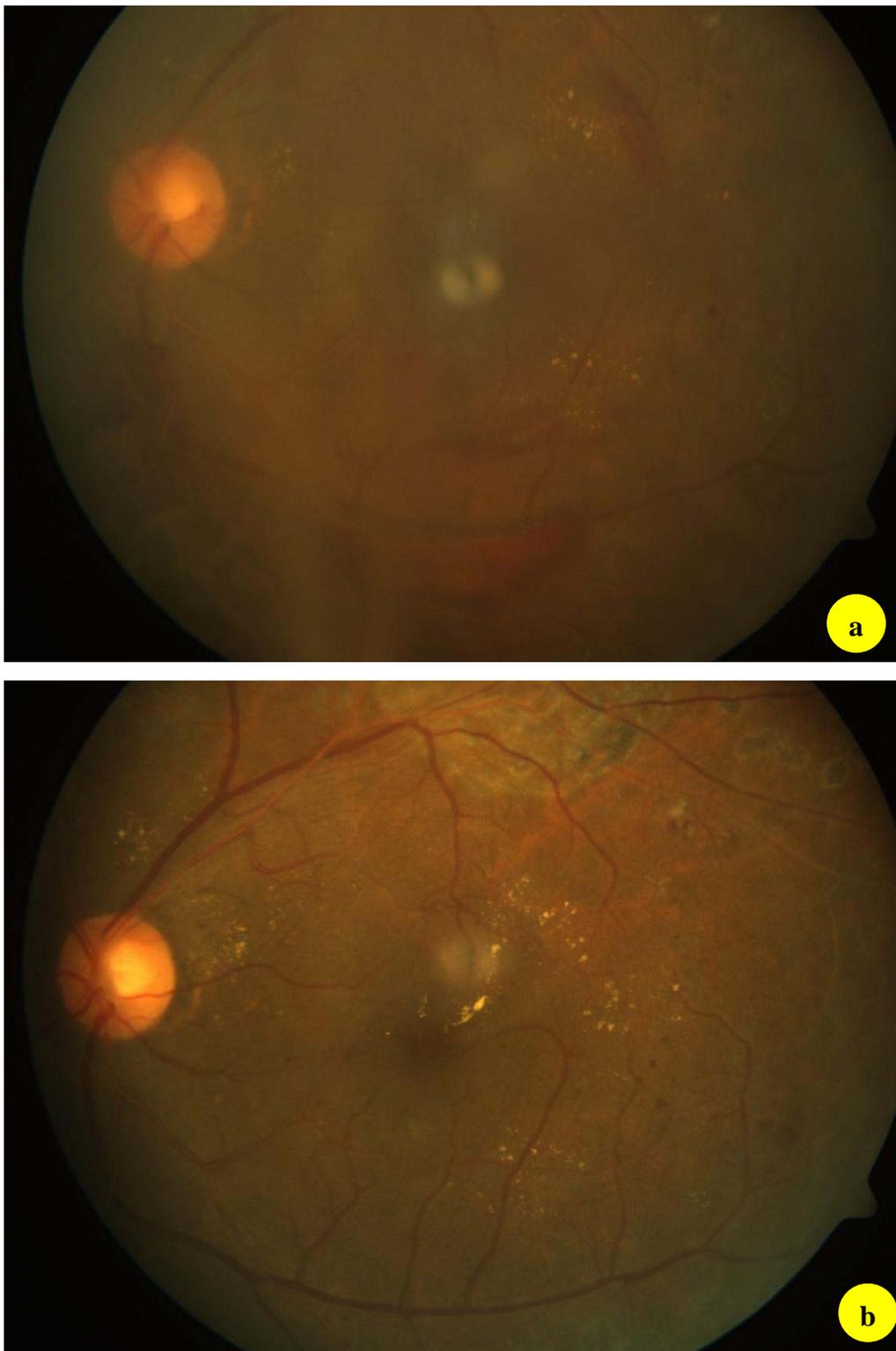


Figure 5. (a) Colour fundus photograph of a study patient showing vitreous haemorrhage. (b) Colour fundus photograph of the same eye as in Fig 5a following pars plana vitrectomy.

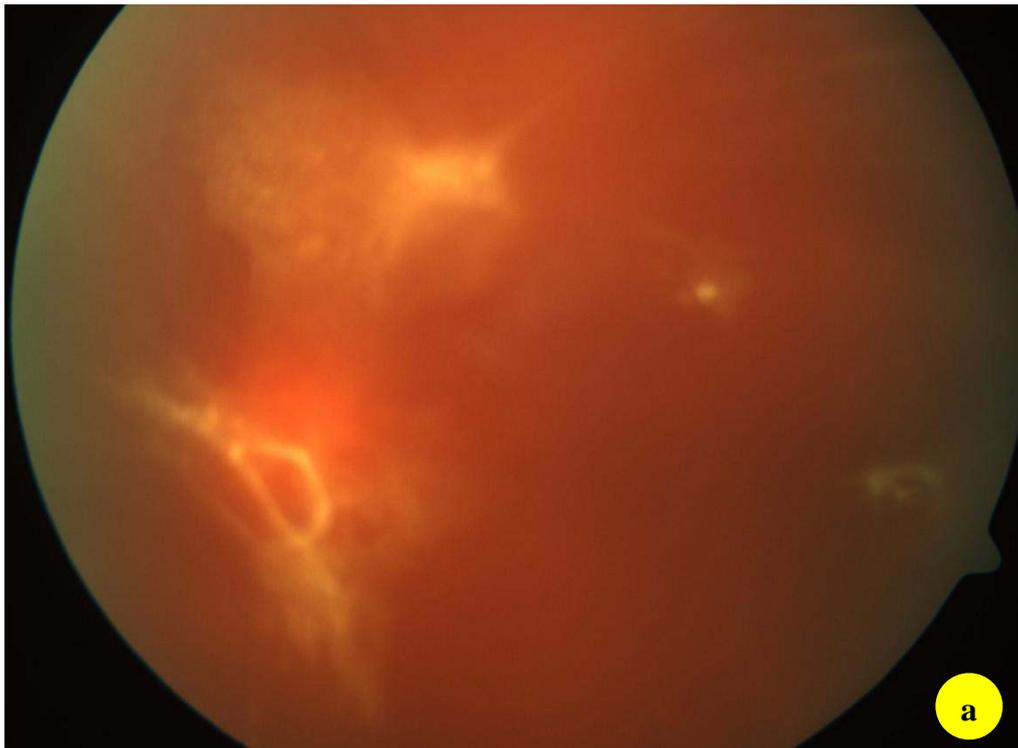


Figure 6. (a) Colour fundus photograph of a study patient showing dense vitreous haemorrhage. (b) Colour fundus photograph of the same eye as in Fig 6a following pars plana vitrectomy with silicone oil.

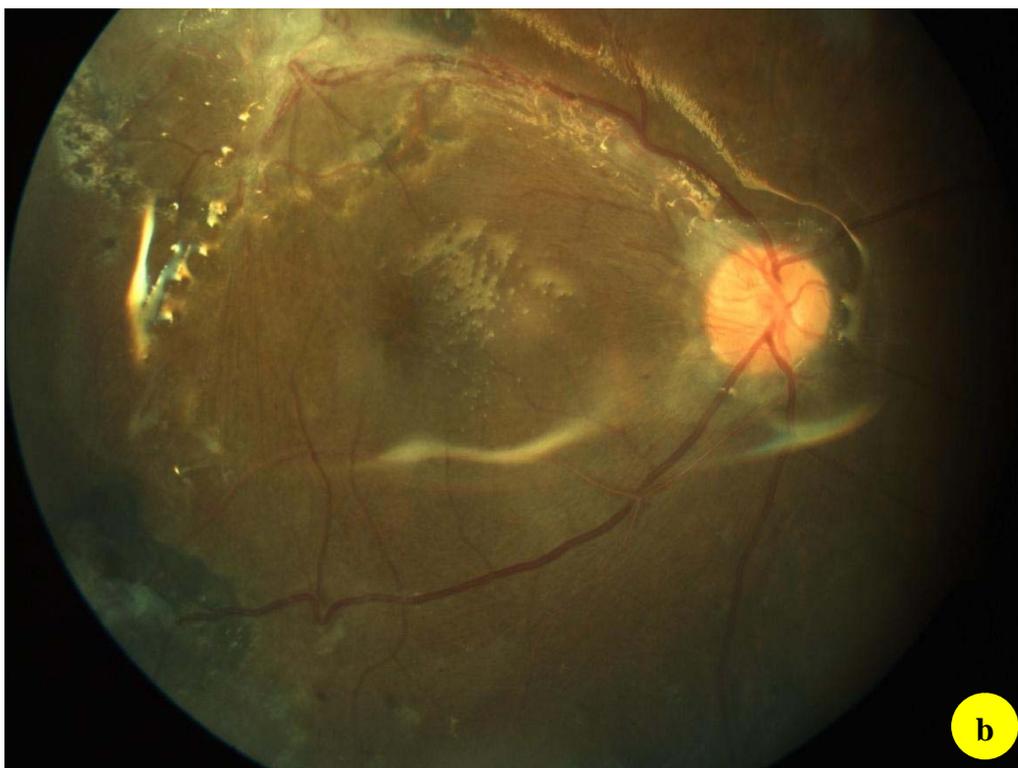
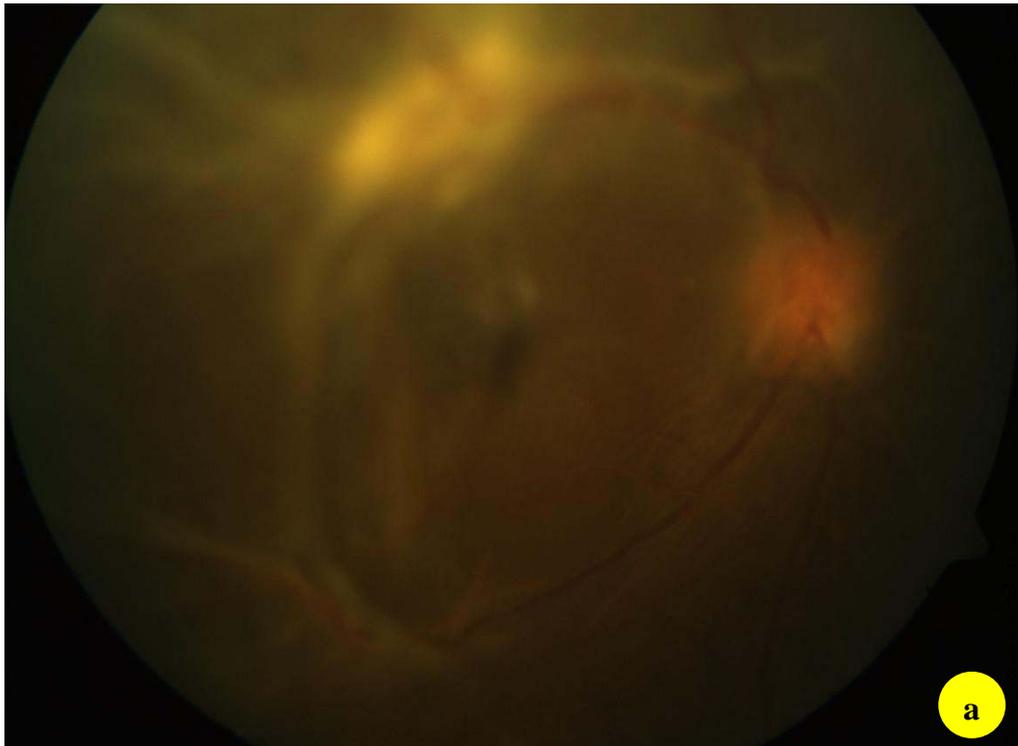


Figure 7. (a) Colour fundus photograph of a study patient showing fibrovascular proliferation with tractional retinal detachment involving the macula. (b) Colour fundus photograph of the same eye as in Fig 7a following pars plana vitrectomy showing stable retina with silicone oil.

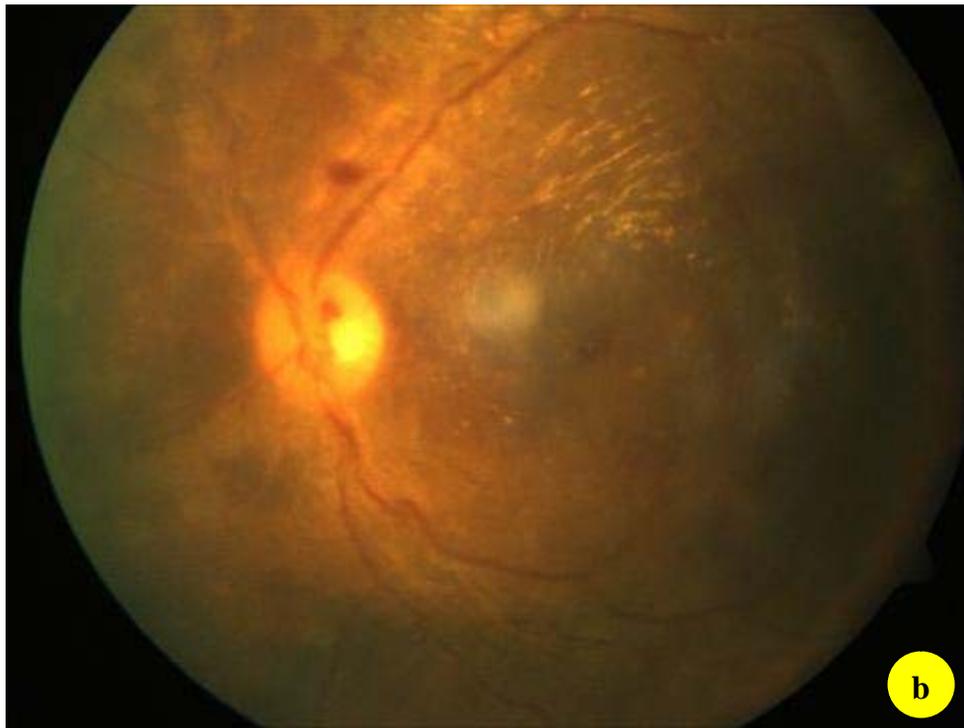
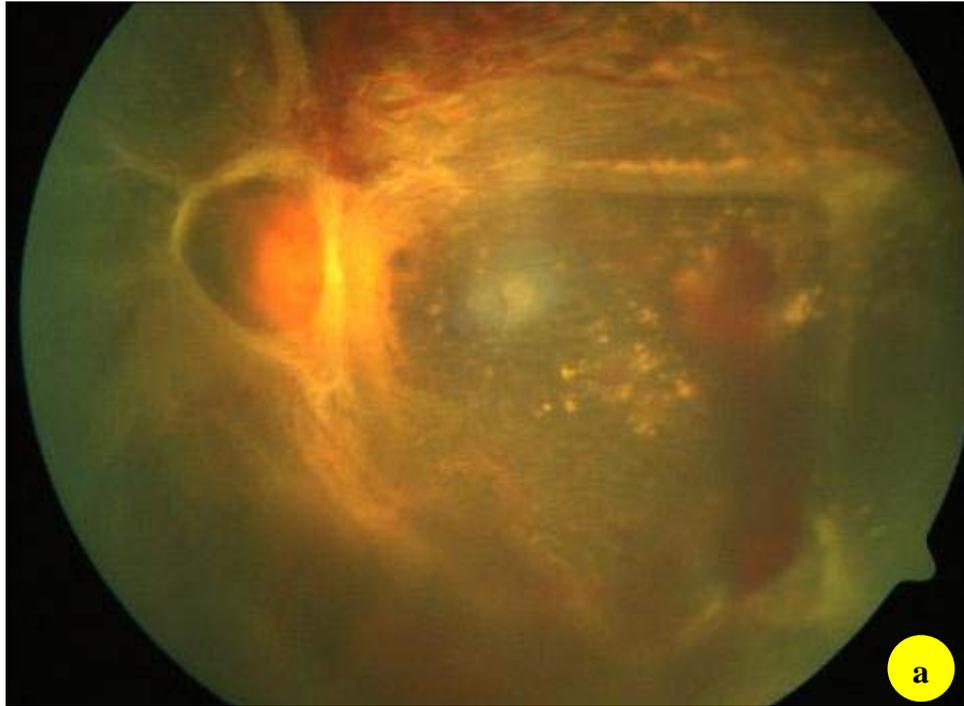


Figure 8. (a) Colour fundus photograph of a study patient showing tractional retinal detachment with vitreous haemorrhage. (b) Colour fundus photograph of the same eye as in Fig 8a following pars plana vitrectomy showing well attached retina with areas of laser photocoagulation.

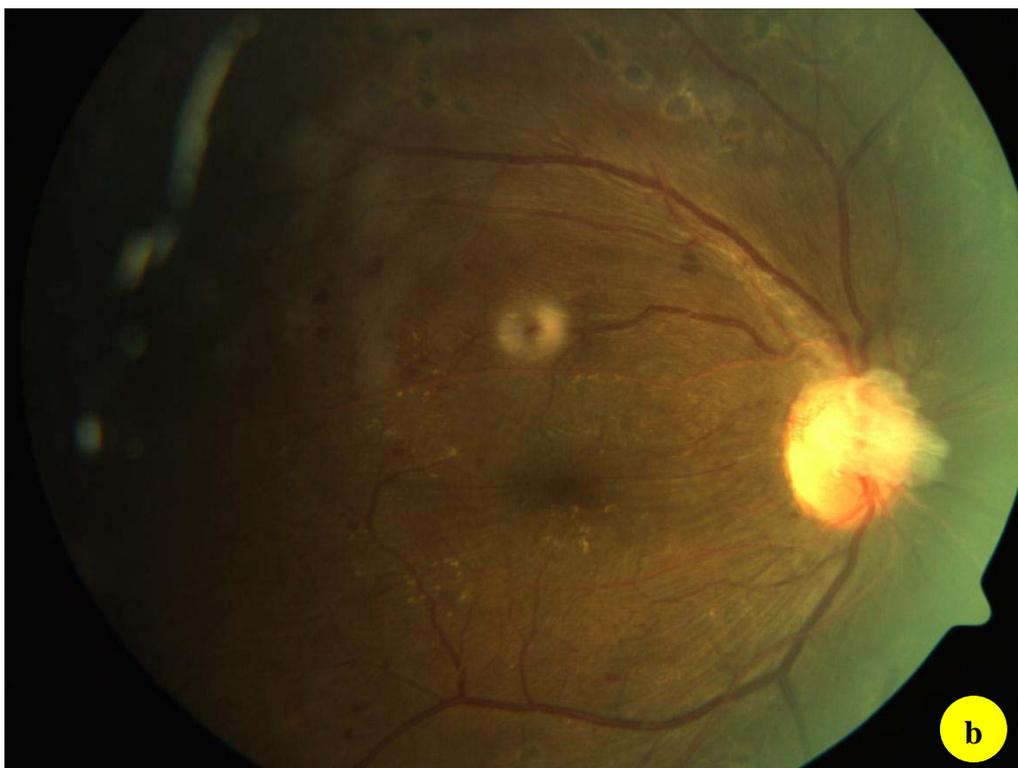


Figure 9. (a) Colour fundus photograph of a study patient showing fibrovascular proliferation and dense premacular haemorrhage. (b) Colour fundus photograph of the same eye as in Fig 9a following pars plana vitrectomy showing stable retina with areas of laser photocoagulation.

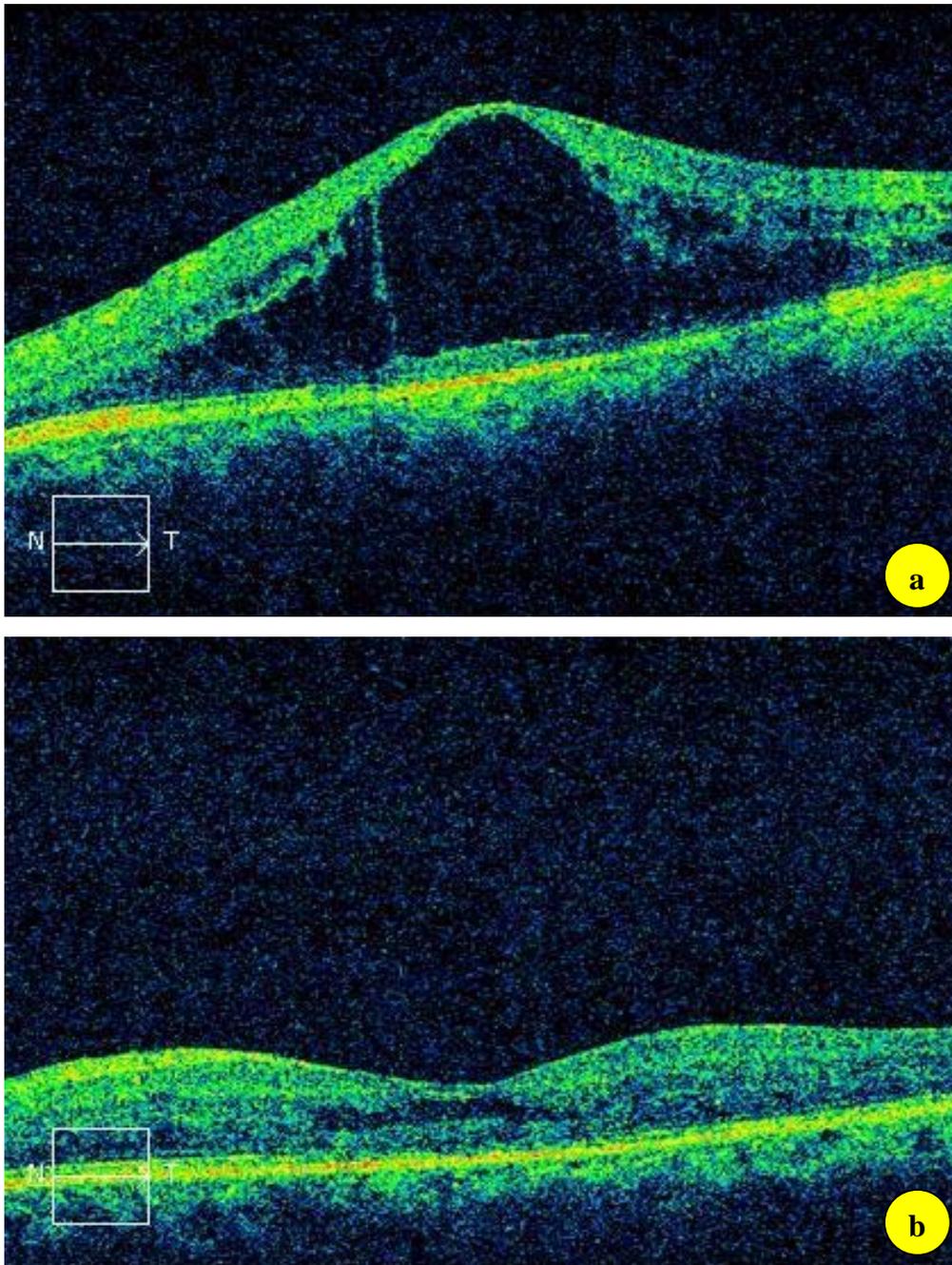


Figure 10. (a) Optical coherence tomography picture of a study eye showing recalcitrant macular edema. (b) Optical coherence tomography of the same eye as in Fig 10 a following pars plana vitrectomy showing reduction in macular edema.

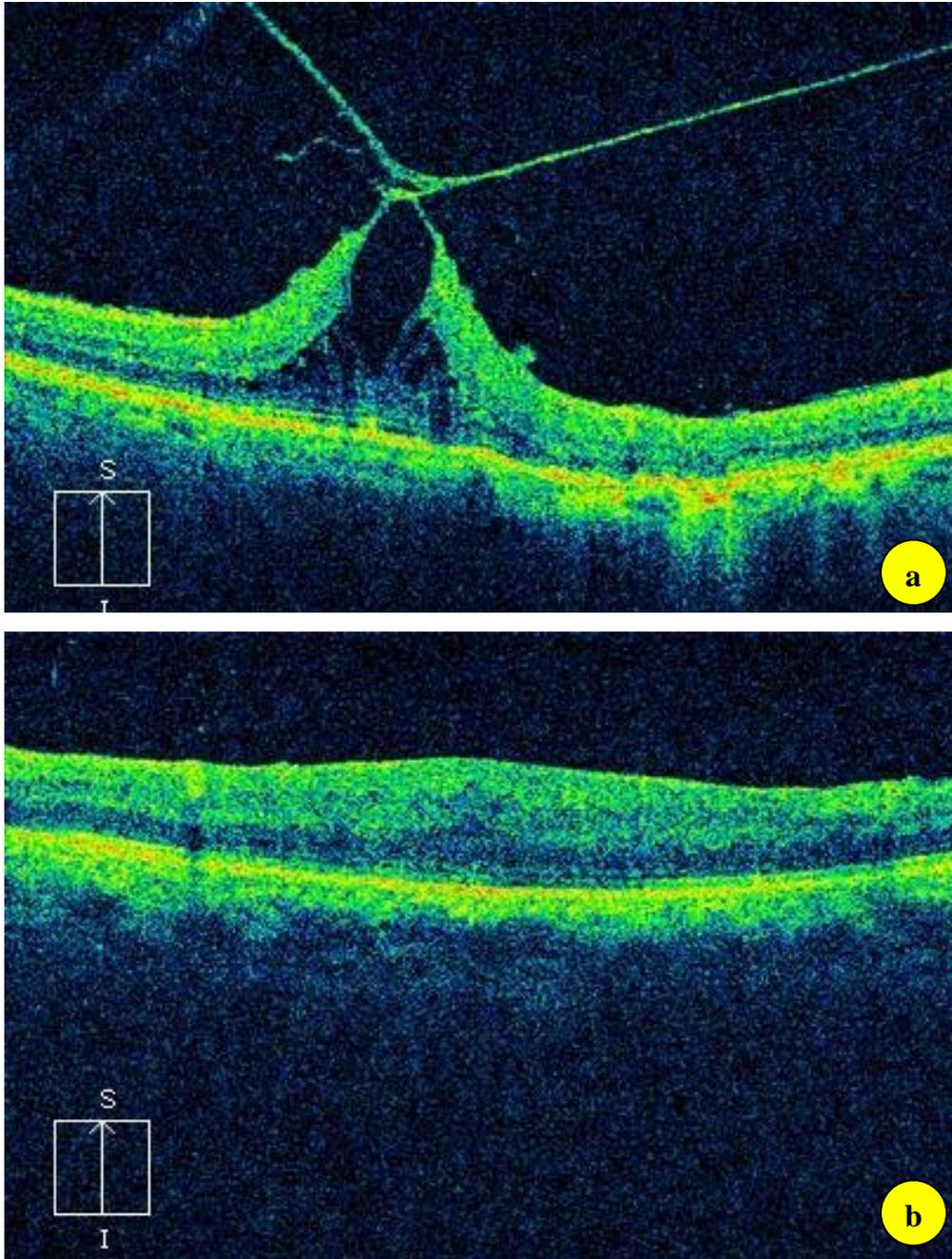


Figure 11. (a) Optical coherence tomography picture of a study eye showing vitreomacular traction. (b) Optical coherence tomography of the same eye as in Fig 11 a following pars plana vitrectomy showing reduction in macular edema.

Discussion

DISCUSSION

Pars plana vitrectomy (PPV) in proliferative diabetic retinopathy (PDR) can be effective in clearing media opacities (such as blood) and relieving traction from fibrovascular tissue in the retina. However, PPV in eyes with PDR can be associated with severe and vision-threatening complications, and the final outcome, in terms of anatomical and visual forms depend on several factors. Hence, it is important to determine the visual prognosis associated with PPV for various indications in PDR so that an optimum course of treatment can be chosen.

A landmark trial was conducted in the year 1976, known as Diabetic Retinopathy Vitrectomy Study²⁰ (DRVS), in which two randomized trials were done to determine whether (i) early vitrectomy was preferable to delayed vitrectomy in eyes with severe vitreous hemorrhage due to PDR and (ii) early vitrectomy is preferable in eyes with PDR without vitreous hemorrhage. The study concluded that early vitrectomy is recommended for eyes with severe vision loss from non-clearing vitreous hemorrhage of at least one month duration in patients with type 1 DM, or in one-eyed patients regardless of the type of diabetes. Early vitrectomy may also be recommended for eyes with advanced active PDR, particularly when there is presence of extensive neovascularization.

In recent years, advances in vitreo retinal surgery and the development of endolaser have changed some of the recommendations of the DRVS. Several advances in surgery, including transconjunctival sutureless vitrectomy (23 and 25 G) and the availability of high speed cutters, microcannulas, insertion trocars, xenon light source, wide angle fundus viewing systems (e.g; binocular indirect operating microscope and erect indirect binocular ophthalmic system), pulsed electron avalanche knife, perflurocarbon liquids, expansile gases, and anti – VEGF adjuncts. Transconjunctival sutureless vitrectomy provides earlier visual improvement (as early as seven days) and less surgically-induced astigmatism (about -1.50 Dioptre) than conventional vitrectomy. These advances have led to improved results, in turn leading to PPV being performed more and more often in PDR with associated visual complications.

The current study was a prospective interventional study done to document the various indications for PPV in patients presenting with PDR, to determine the anatomical results and functional visual outcomes following vitrectomy in eyes with diabetic retinopathy, to elucidate factors possibly influencing the results obtained, and to study the safety of PPV in eyes with diabetic retinopathy by documenting intraoperative and post-

operative complications, and to elucidate the factors responsible for such complications.

With reference to **demographic characteristics** in this study, the patients who underwent PPV for treatment of complications due to diabetic retinopathy were almost equally matched for gender and laterality of the eye (Chart 1&2) undergoing PPV. The mean age of the patients in the study who underwent vitrectomy was 55 years, while 65% of the patients enrolled in the study had suffered from diabetes for around 10 years. In this study, 52% of the patient had other associated (co-morbid) systemic diseases along with diabetes (Table-2). Most of the patients who underwent vitrectomy had type II diabetes (85%), but the duration of evolution of the disease was similar in patients with type I and type II diabetes (7 and 9 years).

Ferreira et al.⁴⁰ (2011) in their study on vitrectomy in diabetic retinopathy reported on 84 eyes that underwent surgery. The mean age of the patients who underwent vitrectomy was 58 years (similar to that of the patients in the present study); the mean duration of diabetes up to the time of vitrectomy was 21 years for type I diabetes and 18 years for type II diabetes. Most of the patients who underwent vitrectomy had type II diabetes (n=61), which is similar to the pattern noted in the present study.

With reference to **indications for vitrectomy** Thompson et al.⁴³ (1986) in their study of vitrectomy in diabetic retinopathy, found that 35% of their patients had vitreous hemorrhage, 36% had tractional retinal detachment (TRD), 17% had combined tractional and rhegmatogenous retinal detachment and 12% had fibrovascular proliferation as indications for vitrectomy due to complications of diabetic retinopathy. Tony Ho et al.⁴¹ (1992), in their study, found that the most common indications for vitrectomy in diabetic retinopathy were severe non-clearing vitreous hemorrhage, tractional retinal detachment involving macula, combined rhegmatogenous and tractional detachment, progressive fibrovascular proliferation and dense premacular hemorrhage. Helbig H et al.⁴² (2007), in their study, reported that the typical indications for vitrectomy were vitreous hemorrhage, TRD, combined rhegmatogenous and tractional retinal detachment and tractive macular edema.

In the current study the most common indication for PPV was found to be vitreous hemorrhage (53%), followed by TRD (34%); 4% of eyes had recalcitrant macular edema and another 4% had non-clearing premacular hemorrhage (Table-3; Chart-6).

Coming to the **surgical procedure** used, Qamar et al.⁴⁵ (2003), performed PPV for patients with TRD without retinal break; all the

patients (84 eyes) underwent PPV with membrane peeling with endolaser. These authors concluded that TRD without retinal breaks can be treated by PPV without internal tamponade. In another study, Castellarin et al.⁴⁶ (2003) concluded that PPV with silicone oil infusion is useful in severely affected eye with PDR even in the presence of rubeosis iridis and neovascular glaucoma, and also in cases of previously failed vitrectomy. In yet another study, Canan et al.⁴⁷ (2003) observed that the combined operation of PPV, phacoemulsification, and intraocular lens implantation was safe and effective for patients with PDR; visual outcome and complications depended on underlying posterior segment pathology and were not related to the combined procedure technique. Interestingly Teresio Avitabile et al.⁴⁴ (2011) compared PPV with pan retinal photocoagulation for severe PDR. In their study, one group of patients underwent PPV with membrane peeling with internal limiting membrane peeling while the other group underwent laser photocoagulation. These investigators concluded that surgery can be deferred in eyes with TRD not involving the macula until progression threatens the vascular centre.

In the current study all 47 eyes underwent a standard 20G three port PPV of which 45% underwent vitrectomy with membrane peeling with silicone oil injection while another 48% underwent vitrectomy without

silicone oil injection; the remaining 7% underwent a combined procedure of pars plana vitrectomy with phacoemulsification alone (Table-5; chart-7). Use of silicone oil tamponade in the current study did not depend on the indications for vitrectomy but on complications encountered in the particular case.

As with any surgery **surgical complications** may be encountered when performing PPV. West et al.⁴⁹ (2000), in their study, found that it was not uncommon for fibrovascular ingrowths at the sclerotomy sites to be responsible for recurrent vitreous hemorrhage in eyes that had undergone PPV. In another study, Kamura et al.⁴⁸ (2013) observed that 29% of patients undergoing vitrectomy for fibrovascular membrane proliferation developed iatrogenic breaks during membrane dissection, while oral dialysis was another intraoperative complication. Post-operatively, 4% of patients had recurrent vitreous hemorrhage, recurrent retinal detachment and sclerotomy site fibrovascular proliferation.

In the present study the most common intraoperative complication, encountered during vitrectomy in eyes with TRD was iatrogenic retinal breaks, which occurred in 17% of 47 eyes, followed by intraoperative bleeding (Table-6). Post-operatively, about 6% of patients in this study presented with recurrent vitreous hemorrhage and retinal break and 4% had

severe macular edema > 500 μ on OCT. In the present series, the complication of fibrovascular ingrowth causing recurrent vitreous hemorrhage was not noted in any of the operated eyes, possibly due to the short period of follow-up in many of the cases.

Surgical outcomes of PPV for diabetic retinopathy complications may be varied. Machemer et al.⁵¹ (1981) in their study on vitrectomy for diabetic retinopathy, found that visual improvement occurred in 59% of the eyes in which the retina was stable, while in 25% of patients there was retinal detachment, which resulted in visual improvement in only 46% of eyes; the total success rate was 51%. The main causes for bad prognosis were rubeosis of the iris and posterior retinal detachment with 42% of all eyes exhibiting some degree of rubeosis of iris. Most of the preoperative eyes (71%) which had rubeosis presented postoperatively also with rubeosis⁵¹. In another study, Karel et al.⁵⁰ (1994) observed that 57% of patients had a good anatomical success, and functional success with visual acuity 0.01 and better in 32%. Functional failures were due to retinal redetachment in 43%, secondary glaucoma in 9%, and retinal ischemia in 13%; the functional success rate decreased with follow-up from 67% after six months to 50% by 60 months⁵⁰. In yet another study, Qamar et al.⁴⁵ (2003) observed successful retinal reattachment in 92% of operated eyes,

in those patients, the retina was stable and attached till the end of the one-year follow-up. Improvement in best corrected visual acuity was seen in 75%; mean improvement in best corrected visual acuity was 2.00+1.24 lines at baseline to 1.24+1.22 ($P<0.05$) at the end of the follow-up⁴⁵.

In the present study 89% of eyes were found to have stable, well attached retinas postoperatively, while 6% of patients had retinal detachment and 4% had persistent macular edema at the end of the follow up period. These results are comparable to those of other studies, suggesting that PPV is a useful and successful surgical technique in PDR. Moreover visual acuity improved significantly after surgery ($p=0.00004$). This improvement was seen across all indications for vitrectomy including non clearing vitreous hemorrhage ($p=0.0001$) and tractional retinal detachment ($p=0.01$) (Table-9; Chart-8). Eyes with tractional retinal detachment tended to gain visual acuity at a slower pace with improvement evident only after one month after surgery. Use of silicon oil tamponade did not affect visual outcomes.

The present study had some limitations:

- (i) All the patients in this study underwent a standard 20G pars plana vitrectomy performed by multiple surgeons; more recent advances like microincision vitrectomy surgery (MIVS) were not performed.
- (ii) Only a small sample size could be studied due to the limited time duration of the study.
- (iii) In the current study, the follow-up period was only 3 months, which is shorter than that reported in other studies.

Summary

SUMMARY

The study entitled 'Indications efficacy and outcome of pars plana vitrectomy in diabetic retinopathy', was performed at the Retina clinic, Joseph Eye Hospital, Tiruchirapalli, during the period from May 2012 to June 2013.

Each patient undergoing pars plana vitrectomy for diabetic retinopathy who did not have any exclusion criterion and who provided informed consent was enrolled. All the patients first underwent a detailed clinical examination (baseline), which included determination of best corrected visual acuity (BCVA) for distance using Snellens chart, intraocular pressure (IOP) measured by applanation tonometry, slit lamp examination, fundus examination using + 90D lens (after dilatation), fundus photography and measurement of macular edema, screening for vitreomacular traction by optical coherence tomography (OCT), ultrasound B scan, and fundus fluorescein angiography.

All the patients enrolled in the study underwent a standard 20 G pars plana vitrectomy for the complications of proliferative diabetic retinopathy. The intraoperative and post-operative complications were

documented and these patients were followed up at immediate, 1 month and 3 months post-operatively.

During the follow-up period, eyes were subjected to visual acuity measurement, fundus examination, IOP measurement, fundus photography and optical coherence tomography.

Forty seven eyes of 46 patients (26 males, 20 females) were enrolled in the study. The mean age of the patients was 55.04 ± 9.6 years; most of the patients in the study were in the age group of 41 to 50 years of age. In this study, 65% of patients who suffered from complications of diabetic retinopathy had suffered from diabetes for less than 10 years; 52% of patients (who all had diabetes) also suffered from other coexisting diseases; 87% of the patients were on oral hypoglycemic agents as a treatment for diabetes.

Of the 47 eyes that underwent vitrectomy, 53% of eyes had vitreous hemorrhage and 34% had tractional retinal detachment as a complication of proliferative diabetic retinopathy (PDR). In patients with vitreous hemorrhage the average BCVA was 0.019 ± 0.01 ($\sim 1/60$), in case of tractional retinal detachment the average BCVA was 0.070 ± 0.029 ($\sim 4/60$).

In this study, the most common surgical procedure performed was pars plana vitrectomy with membrane peeling along with endolaser and silicon oil injection (45%), 28% of the eyes had intraocular implantation along with vitrectomy. Intra-operatively 17% of the eyes, which were mostly from the tractional retinal detachment group, developed iatrogenic retinal break. Twenty-one percent of the eyes in this study had significant complications post-operatively which included recurrent vitreous hemorrhage and combined rhegmatogenous and tractional retinal detachment.

Post-operatively, of the 47 eyes which underwent vitrectomy, 42 (89%) eyes had a stable well- attached retina; with the mean best corrected visual acuity at the end of 3 months being ($\sim 6/36$) 0.22 ± 0.21 in decimals. In the vitreous hemorrhage group, the mean BCVA (decimals) was 0.02 ± 0.006 ($\sim 1/60$), while 3 months after the surgery, the mean BCVA (decimals) was 0.18 ± 0.04 ($\sim 6/36$); this improvement was statistically significant ('t' [d.f :48] = 3.9; p=0.001). Similarly in the tractional retinal detachment group the mean pre operative BCVA was 0.06 ± 0.02 ($\sim 4/60$), and at the end of 3 months follow- up, the mean post-operative BCVA was 0.21 ± 0.06 ($\sim 6/36$); this difference was statistically significant ('t' [d.f :30] = 2.3; p=0.01).

The mean post-operative BCVA (decimals) at 3 months in the vitreous hemorrhage group was ($\sim 6/60$) 0.18 ± 0.12 which was comparable with the mean BCVA (decimals) in the group without vitreous hemorrhage ($\sim 6/36$) 0.23 ± 0.01 ($p=0.4$). Similarly, the mean BCVA (decimals) in the tractional retinal detachment group was ($\sim 6/36$) 0.21 ± 0.01 , which did not differ significantly from the mean BCVA (decimals) in the group without tractional retinal detachment, which was ($\sim 6/36$) 0.20 ± 0.12 .

Comparing the proportion of eyes that showed improvement in visual acuity, on the first post-operative day, there was no difference between eyes with and without vitreous hemorrhage ($p= 0.06$); however, eyes without tractional retinal detachment (TRD) were more likely to have improved visual acuity than eyes without TRD ($p=0.04$), but these differences were seen only on the first post-operative day, and were not sustained at 1 month and 3 month follow up.

Conclusion

CONCLUSIONS

- Vitreous hemorrhage and tractional retinal detachment are the most common indications for pars plana vitrectomy in diabetic retinopathy.
- Patients with vitreous hemorrhage tend to present with significant worsening of visual acuity than other complications of proliferative diabetic retinopathy.
- Pars plana vitrectomy in proliferative diabetic retinopathy results in a significant improvement of visual acuity.
- Visual acuity improvement is seen across all indications of vitrectomy.
- Visual acuity improvement is sustained over a short-term follow up.
- Visual acuity in eyes with tractional retinal detachment tends to improve more gradually when compared to eyes with vitreous hemorrhage.
- Vitrectomy in proliferative diabetic retinopathy may be associated with significant vision-threatening complications

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Proforma

PROFORMA

Indications Efficacy and outcomes of pars plana vitrectomy in diabetic retinopathy

Institute of Ophthalmology
Joseph Eye Hospital
Tiruchirappalli.

Patient number : M.R. Number :

Date :

Name : Age :

Sex :

Address :

Telephone number :

Diagnosis :

Personal history :

DM & Duration :

HT

CRF

CAD

Others

Treatment history :

Allergies :

Indication for vitrectomy:

Surgery details

Type :

Tamponade :

Endolaser :

Intraoperative complications :

Post-operative complications :

Ocular examination

Parameters	Baseline	Immediate POD	1 month	3 months
Date:				
BCVA:				
Distance				
Near				
IOP:				
OCT:				
Retina status:				

Master Chart