Recurrent diabetic macular edema (DME) is characterized by the accumulation of plaques of hard exudates in a grossly edematous retina not amenable to the standard modalities of therapy and showing a very poor visual potential. These patients usually have a poorly controlled glycaemic status of long duration with associated co-morbid condition such as systemic hypertension, dyslipidemia and chronic renal failure.

Majority of these eyes would have had severalittings of laser photocoagulation and hence it is necessary to employ alternative treatment modalities.

Initial reports on uncontrolled interventional case series reported an unprecedented efficacy of intravitreal steroids in reducing diabetic macular edema often accompanied by significant improvement in visual acuity. These uncontrolled series were followed by randomized placebo-controlled trials demonstrating the efficacy of Intravitreal Triamcinolone Acetonide (IVTA) compared with standard of care, both short term and long term. The beneficial effect of intravitreal injection of triamcinolone acetonide in most cases lasted for 6-9 months. In the Intravitreal Triamcinolone Acetonide for Clinically Significant Diabetic Macular Edema that persists after laser treatment study (TDMO), the mean number of injections was only 2.4 over 2 years with a total potential for five injections. It has also been reported that repeated intravitreal injection may not be as effective as the initial treatment. The high incidence of adverse effects which include cataract (54%), glaucoma (20-40%) and need for trabeculectomy (6%) demands caution in its use.

The introduction of IVTA has been a major advance in the treatment of refractory diabetic macular edema. The high risk of steroid related adverse effects however leaves room for improvement and innovation in treatment strategies.

Focal/Grid laser photocoagulation after IVTA has been shown to maintain improved vision and may reduce recurrent macular edema.

Patients with diabetic macular edema have been found to have increased levels of vascular endothelial growth factor (VEGF) in the vitreous. Hence intravitreal injection of anti VEGF may have a role in reducing diabetic macular edema. Their efficacy is similar to IVTA, but they do not cause adverse events associated with corticosteroids. On the other hand, frequent injection (every 4-6 weeks) for an extended period may be required, making injection related complications such as infectious endophthalmitis a major drawback.

There are very few studies on the efficacy of combining triamcinolone acetonide and bevacizumab (an anti VEGF antibody). We undertook a pilot study to compare the efficacy of intravitreal monotherapy with Triamcinolone and Bevacizumab versus combination of Bevacizumab and triamcinolone in the management of recalcitrant DME not amenable to laser treatment. We also assessed the Optical coherence tomography (OCT) patterns in recalcitrant DME which showed a favorable response to intravitreal injection of Triamcinolone and Bevacizumab.

We recruited 60 patients who fulfilled all the inclusion criteria from March 2006 – March 2008. The inclusion criteria for enrolment into the study were:

1. Diabetic age ≥ 10 years
2. Good Glycaemic Control (Hb A1C ≤ 7 gm%)
3. Stable Renal Status
4. Controlled serum lipid level
5. H/o prior Focal/Grid laser Photocoagulation (PHC)
3 sittings) ≥ 6 months to time of enrolment into the study.

6. Presence of DME clinically and angiographically OCT showing Central Retinal Thickness (CRT) ≥ 300 μm

7. Absence of significant lens opacity

8. Absence of macular ischemia

9. Absence of Vitreo Macular Traction (VMT) or a taut posterior hyaloid phase in OCT.

Exclusion criteria were poorly controlled diabetes with associated nephropathy and dyslipidemia, significant cataract precluding fundus evaluation or presence of macular ischemia. The patients were randomized to receive one of the three modes of interventions tested in this study.

**Group B:** Received 1.25 mg / 0.05 ml Intravitreal injection of Bevacizumab (IVB).

**Group T:** Received 4 mg / 0.1 ml Triamcinolone acetonide injection intravitreally (IVTA).

**Group BT:** Received both Bevacizumab and Triamcinolone acetonide injections administered intravitreally (IVB + IVTA).

All patients underwent a thorough preoperative evaluation. The best corrected visual acuity was determined after dilated refraction. Slit lamp biomicroscopy of the macula, applanation tonometry and indirect ophthalmoscopic evaluation of the fundus were performed and the findings noted. The degree of cataract was assessed prior to intervention. All patients underwent a fluorescein angiographic evaluation and OCT assessment of central retinal thickness and pattern of edema as part of the baseline evaluation. An informed consent was obtained in all the patients. The intervention was performed under strict aseptic precautions in the operation theatre under topical anesthesia in all the patients. Paracentesis was performed to bring the IOP under control and the eye was kept patched for an hour after the procedure. Postoperatively 3 hours after the procedure applanation tonometry was performed in all patients using the Keeler Pulsair non contact tonometer. The patients were instructed to use topical antibiotic drops qid, topical non steroidal anti inflammatory drops qid and topical dorzolamide drops once at bed time for a period of 7 days postoperatively. Counseling on the appearance of floaters and slight visual blurring were discussed with the patients.

The patients were followed up on day 7, 30 days and 90 days after the procedure. At each visit an assessment of the glycaemic status, control of BP, renal status and serum lipid profile was assessed. Fundus fluorescein angiography (FFA) and OCT were performed at 30 days and 90 days after the procedure. Refraction, tonometry, slit lamp evaluation for cataract and biomicroscopic macular evaluation for degree of macular edema was performed at all visits. Response to therapy was assessed by:

1) Improvement in the best corrected visual acuity

2) Slit lamp biomicroscopy and OCT showing reduction in retinal thickness

**Figure 1(a):** Pre treatment and (b): post treatment fundus photography, Fluorescein angiographic and OCT appearance showing minimal regression in a patient who received intravitreal triamcinolone acetone injection.
3) FFA showing decrease in fluorescein leakage
4) Progression of lenticular changes
5) Presence or absence of post treatment IOP spike and
6) Recurrence

Follow up data in the IVTA group (Figure 1a & b), IVB group and combined group (Figure 2) show regression of macular edema.

We had recruited 60 patients enrolling 20 patients for each mode of intervention. The patients were of the age group ranging from 45-70 years (Mean age 58 years). There were 46 males and 14 females in our study giving a M: F ratio of 2:1. The mean duration of diabetes was 13.5 years (Range: 7 -20 years) and the mean value of glycosylated hemoglobin at baseline was 6.7 (Range 5.9 - 7.5). Associated co-morbid conditions were:

1. Hypertension : 25 (41.67%)
2. Hyperlipidemias : 40 (66.67%)
3. Chronic Renal failure : 3 (5%)
4. Both HT and HL : 30 (50%)
5. No associated disease : 15 (25%)

Fifty percent of the patients had proliferative diabetic retinopathy associated with maculopathy and 50% had background diabetic retinopathy with clinically significant macular edema.

**Group T (IVTA Group)** an improvement in visual acuity was observed in 9/20 eyes (45%) who showed a mean reduction of central retinal thickness in the OCT scans from a baseline mean CRT value of 550 μm ± 26 μm to 285 μm ± 20 μm. This 45 % reduction in central retinal thickness persisted up to 6-9 months after which the recurrence of clinically significant macular edema (CSME) was observed in 15 of the 20 eyes (75%). These eyes underwent focal/grid laser photocoagulation / or repeat IVTA in 4 eyes (20%).

In the remaining 11 patients the mean reduction in central retinal thickness was by 20% of baseline value (from a mean CRT at baseline of 550 μm ± 26 μm to 350 μm ± 20 μm) at 6 months follow up. Although there was no improvement in visual acuity, the vision stabilized at the baseline level. Recurrence of edema was noticed in 9/11 patients (81.81%).

Progression of cataract was noticed in 6 eyes (30%) and 2 patients with significant cataract underwent phacoemulsification with foldable IOL implantation under topical anesthesia.

Intraocular pressure increased to mid twenties in 3 eyes (15%) but could be controlled medically with single antiglaucoma medication (Dorzolamide).

There were no cases of endophthalmitis, vitreous hemorrhage or retinal detachment in this group.

**Table 1: Effectiveness of treatment on Vision**

<table>
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<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
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<th>Mean Diff.</th>
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<tr>
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**BT**: Before Treatment  **AT**: After Treatment

![Figure 3: Efficacy of intervention with respect to vision gain](image-url)

**Figure 3:** Efficacy of intervention with respect to vision gain.

**Table 1:**

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in one patient (5%) which was amenable to medical therapy.

**Group BT (Combined IVTA & IVB):** An improvement in visual acuity was observed in 60% (12/20) eyes. The reduction in the central retinal thickness was maximum in this group and was observed in 64% of eyes. The reduction in retinal thickness peaked at one month post injection and persisted up to 9 months. Recurrences in 15% of eyes were similar to group B showing that an additional injection of TA did not have any effect in preventing recurrences. A higher incidence of elevated intraocular pressure in 22% of cases questioned the efficacy of adding TA, when IVB alone would have sufficed.

- All 3 groups were similar with respect to age, sex, diabetic age, HbA1C, pre treatment vision, and baseline central retinal thickness on OCT and hence they are comparable

- There was a mean increase of 1.6, 1.6 & 1.7 in the pre treatment and post treatment visual scores in the IVTA, IVB and the combined group which was statistically significant by the paired “t” test (p=0.005 in IVTA group, p=0.001 in the IVB group & p=0.000 in the combined group) (Table 1, Figure 3)

- There was no statistically significant difference between the increase in visual scores in the 3 groups by ANOVA test and hence all three modalities are equally effective with respect to visual gain

### Effectiveness of Treatment on Central Retinal Thickness

There was a mean decrease in CRT of 167 μm, 201 μm and 208 μm in the IVTA, IVB and the combined group which was statistically significant by the paired “t” test (p=0.005 in IVTA group, p=0.001 in the IVB group & p=0.000 in the combined group) (Table 2)

- There was no statistically significant difference in the decrease of central retinal thickness in the 3 groups by the ANOVA test (p=0.110) & hence all 3 interventions were equally effective. Analysis of the complications showed that the incidence of cataract formation was highest in the IVTA & Combined Groups (30%). Elevated intraocular pressures were observed in 15% of patients in the IVTA Group and in 25% in the

<table>
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<th>OCT GRADING</th>
<th>Pre injection CRT (Mean)</th>
<th>Post-injection CRT (Mean)</th>
<th>Pre-injection vision (Mean)</th>
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<td>Cystoid edema</td>
<td>422 μm</td>
<td>315 μm</td>
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<td>Subfoveal serous RD</td>
<td>418 μm</td>
<td>256 μm</td>
<td>CF 2m</td>
<td>6/36</td>
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<td>Plaques of H/E</td>
<td>325 μm</td>
<td>250 μm</td>
<td>CF 1m</td>
<td>CF1m</td>
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<tr>
<td>Combination</td>
<td>550 μm</td>
<td>350 μm</td>
<td>CF 2m</td>
<td>4/60</td>
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Although most studies have shown a beneficial effect the intravitreal triamcinolone acetonide injection. beneficial effects when compared to the transient effect of a focal / grid laser photocoagulation gave longer lasting. Eye Institute) sponsored trial have conclusively shown that efficacy of IVTA over laser and / or grid laser photocoagulation have demonstrated the. Several studies in eyes with persistent DME despite focal and long term. The role of steroids is mediated through

1) Suppression of VEGF
2) Stabilizing the leakage from retinal vessels
3) Suppression of the release of endothelial cell activators
4) Possibly its anti-inflammatory action.

Initially uncontrolled interventional case series reported an unprecedented efficacy of intravitreal steroids (usually triamcinolone acetonide) in reducing diabetic macular edema accompanied by significant improvement in visual acuity7,8,9,10. These uncontrolled series were followed by randomized placebo controlled trials demonstrating the efficacy of IVTA compared with standards care both short and long term.

Several studies in eyes with persistent DME despite focal and / or grid laser photocoagulation have demonstrated the efficacy of IVTA over laser11,12. However the NEI (National Eye Institute) sponsored trial have conclusively shown that a focal / grid laser photocoagulation gave longer lasting beneficial effects when compared to the transient effect of intravitreal triamcinolone acetonide injection.

Although most studies have shown a beneficial effect the optional dosage of IVTA is still somewhat confusing. Audren F et al13 conducted a randomized prospective trial comparing the efficacy of 2 mg Vs 4 mg of Triamcinolone acetonide in the management of diffuse diabetic macular edema. This results showed that there was no dose dependent difference in the response to intervention. However Lam DS et al14 and Spandau UH et al15 demonstrated close dependency in the response to intravitreal injection of triamcinolone acetonide.

The beneficial effect of an intravitreal injection of triamcinolone acetonide in most cases lasts for 6 months–9 months and repeated injection may not be as efficacious as the initial treatment.

The high incidence of steroid related adverse effects such as

(1) Necessity for cataract extraction in 54% of phakic treated eyes
(2) Steroid related evaluation of IOP in 44 % of treated eyes necessitates the use of caution.

In order to avoid the adverse effect associated with intravitreal therapy, particularly infectious endophthalmitis, the use of periocular steroids in the management of diabetic macular edema has been studied. The results of these trials have been contradictory to each other showing either a beneficial effect or no appreciable effect of the intervention on DME.

Investigators continue to report their experience with intravitreal injections of Bevacizumab, a humanized monoclonal IgG antibody directed against all five VEGF isoforms, in the setting of primary therapy. In a study of 51 patients, Haritoglou et al5 observed that at 6 weeks after a single Bevacizumab injection, patients with DME resistant to other therapies had increased visual acuity as well as decreased central retinal thickness by OCT relative to pre-injection baseline, though the effect on visual acuity was not sustained at 12 weeks. The Pan – American Collaborative Retina Study Group studied intravitreal Bevacizumab as a primary treatment for DME in 78 eyes of 64 patients and found, at six months, over 96 % of eyes had either stable or improved visual acuity or reduction in the mean central retinal thickness by OCT. A phase II DCRC.net study of 109 patients compared two does of Bevacizumab to focal laser photocoagulation and demonstrated its efficacy in decreasing DME in some eyes. To date, no phase III trials have been reported that demonstrate a clear benefit for Bevacizumab in the treatment of DME.

While Ranizumab, an affinity – matured humanized monoclonal antibody fragment directed against all VEGF isoforms, is currently in clinical trials for DME, its off label use in DME patients is limited likely as a result of its increased cost and less wide spread availability worldwide, as compared to Bevacizumab. Clinical trials in DME
patients are limited as a result of its increased cost and less widespread availability worldwide, as compared to Bevacizumab. Clinical trials in DME patients are ongoing. Two pilot studies of 10 patients each, suggested that it was well tolerated and may have some efficacy in promoting improvement in visual acuity and reduction in central retinal thickness by OCT. The READ – 2 (Ranibizumab for edema of the macula in diabetics) studies, a phase II trial comparing the relative efficacy of Intravitreal Ranibizumab, macular laser photocoagulation, and the combination of both treatments among patients with DME, who have not received prior laser is currently ongoing. Six months outcomes suggests a greater improvement in visual acuity for patients undergoing intravitreal Ranibizumab alone as compared to laser or combination treatments.

A report on 101 consecutive eyes with DDME treated with intravitreal Bevacizumab, resulted in both anatomic and functional improvement. Interestingly, the reduction of retinal thickness and improvement of best corrected visual acuity (BCVA) were detected within the first 4 weeks after the injection in most of the patients. In addition, both doses (1.25 mg and 2.5 mg) were associated with improvement of BCVA and a greater reduction in central macular thickness, and no difference between the two were found. Ocular tolerance of the 2 different doses of IVB was demonstrated, and no serious systemic adverse events were noticed during the study.

There are several studies in the literature on the intravitreal administration of antibodies against VEGF for DDME. However, none of them deal with anti-VEGF as a primary treatment. Haritoglou et al reported that intravitreal Ranibizumab has the potential to maintain or improve BCVA and reduce retinal thickness in patients with DDME not responding to previous treatments such as photocoagulation, intravitreal injection of triamcinolone, or vitrectomy. Their follow-up period was too short (6 weeks) to provide specific treatment recommendations. Kumar and Sinha reported results of 20 eyes with DDME treated with IVB dose of 1.25 mg that had not responded to previous photocoagulation. Their follow-up period was 6 months. They concluded that IVB resulted in a significant decrease in macular thickness and improvement in visual acuity at 3 months, but the effect was somewhat blunted, though still statistically significant at the end of 6 months. The current study compares favorably with these reports, and confirms their findings with longer follow-up and a larger no of patients. Furthermore, at the 6 month follow-up time point we noticed a small worsening of vision as described by Kumar and Sinha. When we analyzed our data comparing eyes that had 1 or 2 injections against those eyes that had 3 or more injections, there was a significant drop in BVCA at 6 months in the “1 or 2 injections” group, and not in the “3 or more injections” group. This suggests the need for repeat injection (63.4%) needed at least a second injection at a mean of 15.7 ± 11.9 weeks (range: 4 to 64 weeks).

The results of this retrospective study demonstrated the efficacy of 1.25 mg or 2.5 mg of IVB as primary treatment of DDME, as 49.5% of eyes showed anatomical and functional improvement. In addition, our results suggest a reduced risk of visual acuity loss in eyes with DDME treated with IVB (82.2% of eyes). We found that the anatomical and visual benefit of the intravitreal Bevacizumab appears and reaches its maximum value during the first month and maintains itself over 12 months. Nevertheless, we did not find statistically significant differences between the 2 doses of Bevacizumab evaluated.

A phase 1 study (the READ-1 Study, Ranibizumab for Edema of the macula in Diabetes, sponsored by the Juvenile Diabetes Research Foundation) of 20 patients with DME treated with repeated intravitreal injections 0.5 mg of ranibizumab, showed evidence of biological activity of ranibizumab in DME as well as safety and tolerability (Nguyen, et al. 2006). In the Phase 1 study, patients were given intravitreal ranibizumab at baseline and at months 1, 2, 4, and 6. Results showed that at month 7, one month after the final administration of ranibizumab and the primary endpoint of the study, the median reduction of the excess foveal thickness was 97%, and there was a median improvement of 10 letters.

There have been no adverse events that were believed to be related to the study drug; in particular, intraocular inflammation was not observed.

The READ-2 Study is a Phase 2 randomized, multicenter clinical trial sponsored by the Juvenile Diabetes Research Foundation. The study enrolled 126 patients from 14 clinical centers throughout the United States.

Each study subject in the trail was randomized 1:1:1: to 1 of 3 treatment groups.

Group 1 (ranibizumab only)
Group 2 (laser only)
Group 3 (ranibizumab and laser)
The patients were followed every 12 weeks until month 24 (secondary time endpoint). At any study visit, if there was an increase of a specified amount of retinal thickness on OCT that meet re-treatment criteria, the patients had the opportunity to receive a ranibizumab injection of ranibizumab injection plus laser 7 days later.

The re-treatment criteria for patients in all 3 randomized groups are an absolute retinal thickness in OCT central subfield of 250 μm (at time of study visit).

**Combination Therapy**

As diverse mechanism and patterns of DME are recognized, clinicians are using multimodel therapies to approach DME. In theory, targeting various pathologic mechanisms of DME with combination therapies may have a more lasting effect on reversing and maintaining a clinical benefit to patients.

Focal Laser Photocoagulation is being combined primarily with Ocular Steroid therapy (either IVTA or PST-TA) or anti VEGF agents. This strategy seeks to take advantage of the more immediate effects of pharmacologic agents while employing laser therapy for long term stabilization. Anti VEGF agents have been used to salvage eyes refractory to steroid therapy, in eyes experiencing steroid related side effects, and more recently in combination with IVTA therapy with positive results. Pharmacological agents also used at the time of vitrectomy surgery help to prevent recurrent DME.

The present study also has tried to compare the efficacy of monotherapy with combined modalities of treatment (Table 5).

Thus the result of this study show that:

1. IVTA has an excellent transient effect of causing resolution. Recurrences in 75% elevated IOP in 17% of cases point to the fact that IVTA should be advised with caution and the patients monitored regularly after intervention.

2. IVB is as efficacious or more so with respect to visual gain (45% Vs 55%) and resolution of CSME (45% Vs 59%). The incidence of elevated IOP in only 5% and recurrence in 15% point to the fact that IVB may be a better option to IVTA

3. Combining IVB with IVTA, did not have the expected effect of doubling the resolution and visual recovery. A higher incidence of glaucoma in 22 % makes this combination unsafe. The incidence of recurrence was same as in IVB group.

These results comprehensively prove that there is no added benefit of combining IVB and IVTA.

4. Greater degree of diffuse edema and presence of subfoveal serous RD are indicators of a favorable response to IVTA and IVB.

5. The prediction of poor visual prognosis included poor preoperative vision, HbA1C > 7 during the study period, plaques of hard exudates under fovea and presence of large cystoid spaces under fovea.

Our results compared favourably with those of Soheilian et al² and Ahmadieh et al⁶. who also demonstrated that there was no added beneficial effect of combining IVTA & antiVEGF therapy (Table 6).

Maximum reduction of central retinal thickness and maximum visual gain were obtained in eyes with greater degree of diffuse DME and in the presence of subfoveal serous RD. These eyes responded best to IVTA or IVB

**References**


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**Table 6: Comparison with Similar Studies**

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<tr>
<th>Author</th>
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