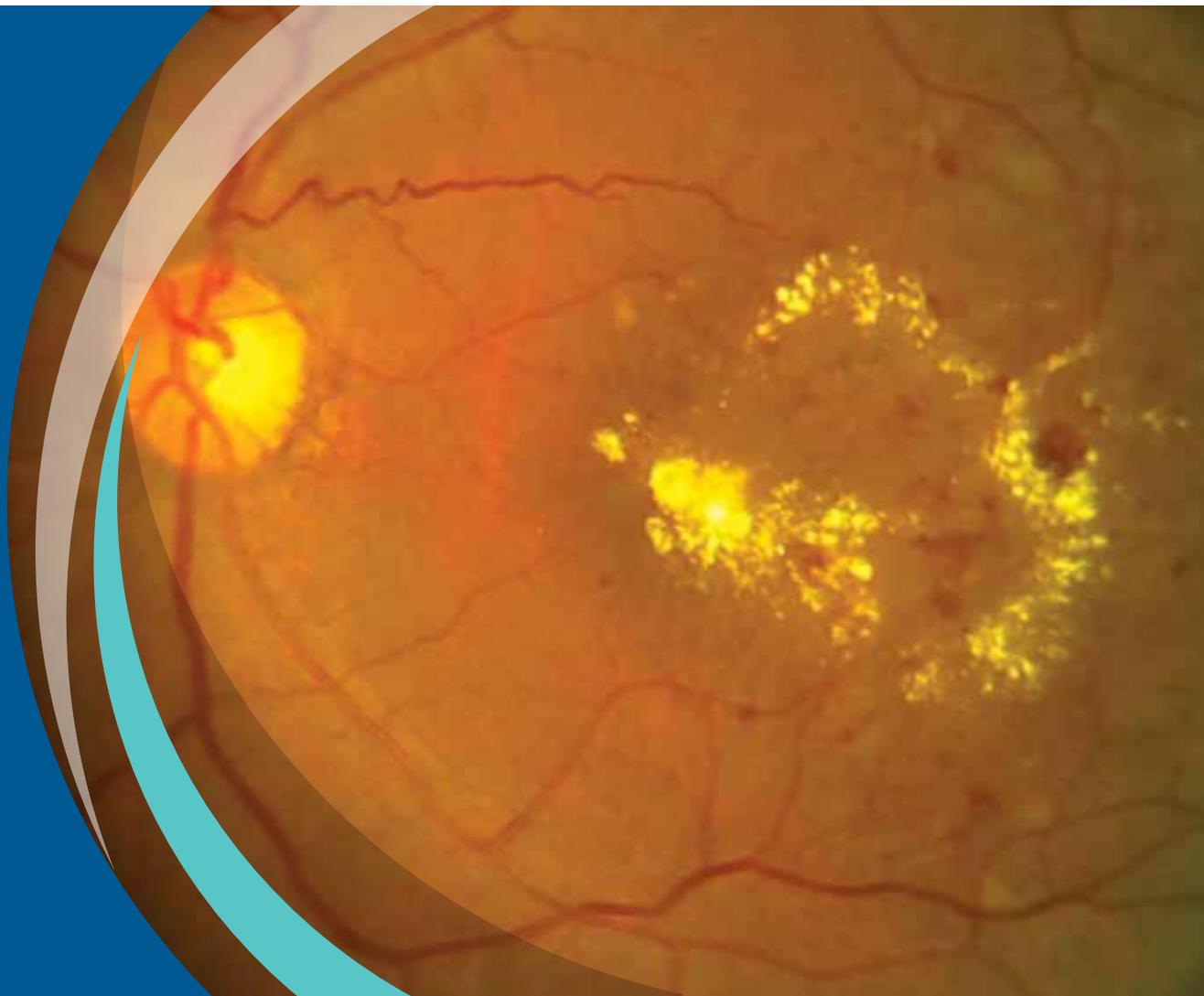




AIOS Guidelines

for Management of DME



AIOS Round Table Meeting

12th January, 2020

AIOS thanks all the Experts



Guidelines Workshop

Guidelines for “Management of DME” were evolved during Round Table Meeting held by AIOS on January 12, 2020

List of Participants

- | | | |
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FOREWORD



Diabetic Macular Edema is frequently encountered clinical condition in day to day practice;

Since the time Anti-VEGF's & OCT came into market, there has been a paradigm shift in the management of various retinal conditions including Diabetic Macular Edema; Thanks to so many randomised controlled trials, Lot of information & data is available on the net ;

But everyone (specially in our country) practices his own way;

The aim of these guidelines is to share with Comprehensive Ophthalmologists & even Retina Colleagues.. what & how majority of Retinal Surgeons in our country approach a patient of Diabetic Macular Edema.

A round table meeting of Retina Experts from all across India, under the aegis of AIOS, was held at New Delhi on 12th January 2020 wherein day long discussions were held on various aspects of DME. This booklet describes the consensus reached in this meeting;

Thank AIOS for the opportunity & all the participants for their valuable inputs.

Hope this serves the purpose & is useful , specially to Comprehensive Ophthalmologists.

Dr. Lalit Verma

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Diagnosis of DME :

Initial 90D examination;

OCT – is more sensitive for diagnosis of DME & for also helpful monitoring treatment ;

Any OCT is OK; Although Spectral Domain preferable Time Domain is also OK.

Fundus Fluorescein Angiography is optional except in following situations :

1. Before Planning laser
2. Non-response to pharmacotherapy (OCT Angiography also good enough to assess cause for non response)
3. Cannot explain vision loss (OCT Angiography can also be used to assess macular ischemia)

Classification of DME:

1. Traction/ Non-tractional
2. Centre Involving DME (CI-DME) / Non-centre Involving DME (NCI-DME)

Can treat even CIDME with focal laser if leak > 750 um (FFA needed to plan laser)

Non CI-DME poor vision: FFA/ OCT Angiography

Approach to Management in different situations:

1. CI-DME: Good vision (6/9 or better , near vision N6) near vision recording is also important:
No ocular treatment,
Only Systemic Metabolic Control (Pay attention to Glycemic status, BP, Anemia, Kidney status (Microalbuminuria), Serum Lipid Profile etc.)
Need close follow up as 40% will need injection in 2 years (Protocol V)
If OCT shows severe thickening (>600 um): Monthly review, treat as required
2. Asymptomatic & Poor systemic control: Pay attention to Systemic Metabolic Control
3. Symptomatic & Poor systemic control: Systemic Metabolic Control ;
4. Symptomatic & Good systemic control: Treat (Injections)

Can start injections at the same time as systemic control (can run concurrently)

Even if HbA1C is high, anti-VEGF injections help.

Parameters to be considered before Intravitreal Injection in a patient of CI-DME:

VA, OCT (thickness/ traction), FFA – all 3 in combination (Not in Isolation)

Change Defined as: ≥ 1 Line VA; $\geq 10\%$ change in CRT (on OCT),

Initial treatment

25% patients may need 3 injections in first year, generally 9 injections in 1 year
As per current evidence 15 injections required in 5 years

VA is more important than OCT (both distance & near vision)

In OCT: OCT morphology, 10% change in Central Retinal Thickness (CRT), pay attention to OCT morphology also.

Ideal Post-Injection Follow Up time:

After Intravitreal anti-VEGF Injection: 1st visit within a week desirable (Mandatory when symptomatic) & at 1 month

After Intravitreal Steroid Injection : 1 week, 1 month

Ideal regimen:

Monthly follow up till OCT picture stabilises, then 3 monthly

In event of Recurrence: Repeat FFA & OCT

Definition of Non-response:

If after 4 monthly consecutive visits, VA & OCTs show no improvement : Labelled as Non response (there was some debate whether non-response should be decided after 2 or 3 injections; 2 injections and 3 OCTs or 3 injections and 4 OCTs)

In treatment-naive 3 injections can decide non-response;

In previously treated eyes 2 consecutive injections (3 OCTs) can decide non-response.

In DME : Concept of loading dose does not hold.

Shifting of Intravitreal Injections :

If patient is on Bevacizumab : can consider shifting to one of the other 2 anti VEGF`s (Ranibizumab or Aflibercept),

But if patient is already on Ranibizumab / Aflibercept : Consider shifting to Intravitreal Steroid.

If issue of Cost constraints: Consider shifting from Bevacizumab to Triamcinolone Acetonide

If no issue of cost constraints : Can shift from Ranibizumab/ Aflibercept to OZURDEX; Ozudrex preferable because of less possibility of IOP rise, more data available with prospective randomised trials.

Peripheral laser for CNP areas not generally helpful in the management of DME (DAVE Study; though Protocol S showed that those eyes that had PRP required significantly less number injections for DME than those on injections only)

Indications for Focal laser for leaks on FFA:

FFA is a must before contemplating any Laser in DME:

1. As Initial treatment in NCIDME
2. Non-responders in CI-DME (Carefully study FFA)
3. Any lesions amenable to laser even in responders, to reduce number of injections

Guidelines for blood sugar levels before Injection:

1. AIOS Guidelines for Endophthalmitis Prevention in Cataract Surgery:
Recent – in last 1 week; FBS \leq 140 mg/dl; RBS or PPBS \leq 200 mg/dl
2. VRSI guidelines for Injections: no definite level; DM should be controlled

Focal laser can be combined with injections

Anti-VEGF combined with Steroid Injections: Not desirable as initial therapy; Can be given in recal-citrant cases

Monthly/ every visit OCT

Choosing the right anti-VEGF

Bevacizumab in India not same as USA where compounding pharmacies supply sterile single use vials; If using Bevacizumab : Follow VRSI guidelines

Approved Biosimilar of Ranibizumab (RAZUMAB) can be used in place of innovator drug

Co-existing Diseases

- Proliferative Diabetic Retinopathy: Start Panretinal Laser photocoagulation simultaneously with Intravitreal drug therapy of DME management
- DME with Co-existing Cataract: Ideally stabilise DME (with Injection &/or Laser) then proceed with Cataract Surgery; Practically, however, can combine with cataract surgery (either steroid / antiVEGF) if cataract is significant

Cataract surgery should not be done without addressing DME

Cataract without DME does not need injection

- **Co-existing Glaucoma:** look at IOP/ Disc, Steroids to be used with caution(IVTA should preferably be avoided)

If patient on 1 drug for IOP control, OZURDEX can be given

OZURDEX to be administered only by retina specialists (since it is 22G Injection)

- **Recent Stroke/ MI/ Cardiovascular Events:**

1. For First 3 months of CVA : Avoid Intravitreal Anti-VEGF injections ;
2. If very severe DME, can use Intravitreal Steroid Injection if no ocular contraindication (raised IOP/ Glaucoma);
3. If steroid contraindicated and CI-DME requires Injection: use lower dose RBZ (0.3 mg; this dose can be achieved by using only 0.03 ml of the regularly available 0.5 mg vial)
4. Waiting for 2-3 months with attention to metabolic control is not a bad option.

- **Pregnancy:**

Avoid anti-VEGF injections, Also avoid Dorzox, NSAID Drops;

Can use Intravitreal Steroid Injections

- **Nephrotoxicity** of Anti-VEGF is also a concern to be kept in mind (As per recent reports)

Screening of peripheral Retina is desirable before any Intravitreal injection & treat lesions based on discretion of Physician

Plaque of hard exudate in foveal centre, lipid profile normal, start statins (under Physician supervision)

Ischaemic maculopathy - can give anti-VEGF if OCT picture demands

OCT evidence of Vitreomacular Traction/ Epiretinal Membrane: Refer to retina surgeon; can try one injection (based on 3-D OCT)

In absence of traction, vitreous surgery for DME can be the last resort (left to treating surgeon's discretion)

How to manage Chronic DME: VA important

If the patient does have symptomatic center involvement, with relative thickness of the macula and or vision loss, then look at the lens status. If the lens is clear and there is no significant cardiovascular disease or recent event, anti-VEGF is the first choice. If the patient is pseudophakic the 1st line choice can be either anti-VEGF or Ozurdex.

Terms of Use

Aim of these guidelines is to assist the ophthalmic surgeon in minimizing the occurrence of post-operative infection. These, in any case, are not all inclusive and are not a substitute for good surgery and pre/peri/post-operative care.

These guidelines are mere suggestions and cannot be used in court of law to safe-guard against or for any legal proceedings.

AIOS has no financial or any other interest in formulation of these guidelines.



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