Evaluation of a modified approach for treating Macular Oedema secondary to Branch Retinal Vein Occlusion with Aflibercept intravitreal injections

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BACKGROUND:

Branch Retinal Vein Occlusion **(BRVO)** is defined as thrombosis within one or more branch retinal veins causing Macular Oedema (MO), which is the most common cause of vision loss in BRVO patients.

The gold-standard treatment currently recommended in the guidelines is intravitreal anti-VEGF therapy with or without laser. The two principle anti-VEGF drugs, having amassed the most clinical research data are Ranibizumab and Aflibercept.

Aflibercept is a chimeric protein, targeting VEGF–A, VEGF–B and placental growth factor (PGF).

Visual improvements have been demonstrated outside of clinical trials by data collected in our department, suggesting fewer intravitreal injections of Aflibercept required to achieve the same results as Ranibizumab. On this basis, **in this current study we selected to use Aflibercept**.

Pro Re Nata (PRN) and Treat and Extend (T&E) protocols are in use in the management of macular oedema secondary to BRVO.

OBJECTIVE:

Anti-VEGFs have improved the management of patients with macular oedema associated with Branch Retinal Vein Occlusion. Although a majority of these patients are responding adequately to the treatment, the choice of an **efficient and viable plan of care** is sometimes problematic. During the first lockdown imposed within the United Kingdom as a result of the COVID-19 pandemic, there was a lack of resources (human or fiscal) that caused delays in the planned treatment of patients. The standard T&E model assumes all hospitals are equipped to deliver Visual Acuity (VA) and Optical Coherence Tomography (OCT) assessments and injections on the same day, as a one-stop service. **The new, modified Treat-and-Extend (mT&E) protocol gives a fixed number of injections, enabling hospitals to better plan treatment doses in advance without a follow up being necessary in every appointment of the patient in the clinic**, which makes it more manageable for two-stop service departments to deliver.

AIM:

The aim of this observational case study was to investigate and assess the treatment outcome of the mT&E protocol for use of anti-VEGF Aflibercept in the management of MO secondary to BRVO.

MATERIAL AND METHODS:

Patients were allocated in the single and only arm of the study and continued unless they did not respond to the fixed treatment and therefore **an appointment was scheduled at months 3, 5, 8, 11 and the final visit at month 13 with patients monitored** via Best Corrected Visual Acuity (BCVA) and Central Retinal Thickness (CRT).

If during visits at months 3,5,8,11:

a) visual acuity decreased more than two lines

b) macular oedema increased more than 20% compared to the last scan or

c) both a and b,

patients were supposed to follow the “rescue” therapy plan which was return to standard T&E treatment.

The study evaluated **30 eyes of 30 patients** enrolled from January 2019 to May 2020. The patients received an initial loading dose of three monthly intravitreal Aflibercept injections, one injection every two months for the next four months and then one injection every three months for the following six months **(injection in months: 0,1,2,4,6,9 and 12). The main outcome measures were BCVA and CRT at 13 months.**

Inclusion criteria:

- Naive patients with BRVO and associated macular oedema with visual acuity <6/12
- Ability to understand the scope of the study and written/verbal consent to participate.

Exclusion criteria were

- Coexisted factors potentially affecting the treatment outcome (epiretinal membrane, uncontrolled diabetes or systemic hypertension).

RESULTS:

All patients (100%) completed the study without having to follow α "rescue" pathway returning to the standard T&E treatment, since no one had significant decrease of visual acuity or increase in macular oedema. No patient had signs of intraretinal/subretinal fluid during the last visit at month 13. Mean CRT from 460,4 μm at presentation was 267,6 μm at the final visit (**diagram 1**). At the final visit the mean increase of BCVA was 0.23 Log MAR units (11.5 letters), (**diagram 2**).

diagram 1

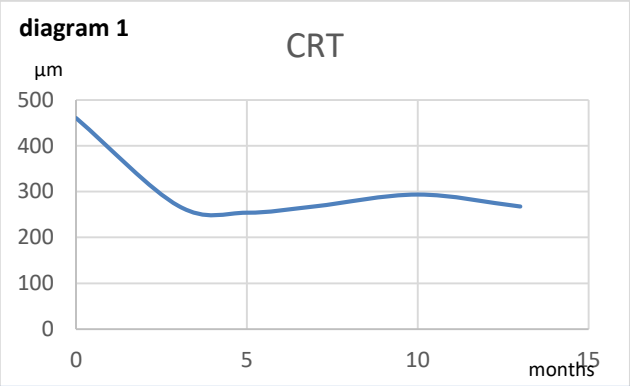
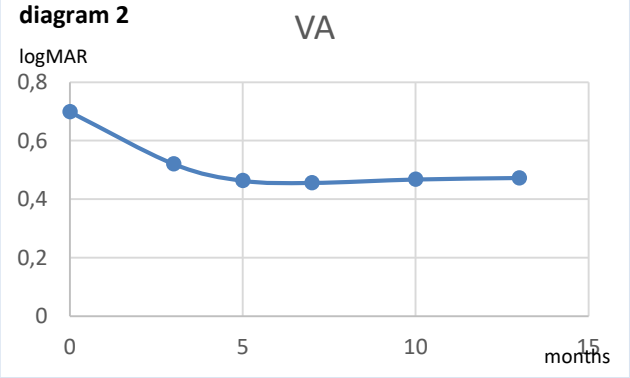


diagram 2



CONCLUSION:

- Most patients with BRVO associated with MO could be treated, whenever necessary, according to the presented mT&E protocol; **fixed gradually extended treatment intravitreal injections without scheduled follow up**.
- All this is achieved whilst still ensuring treatment is proactive, as it is a compromise between the PRN protocol, in which patients can be inadequately treated, and the standard T&E protocol, in which patients can be often over-treated.
- The benefits of VA improvement and elimination of MO could potentially be combined with a longer period of stability during the second year of treatment.
- A relevant study appears to be necessary to conclude on the matter of better disease control in the long term.

References:

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