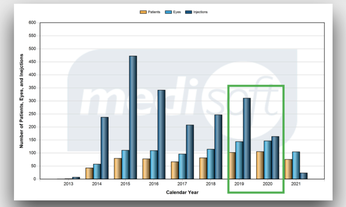
To determine the efficacy of treatment of Ranibizumab over a period of 5 years in patients with DMO at PAH, Harlow

E Dorairaj, A Butt, R Cheema, P Prakash

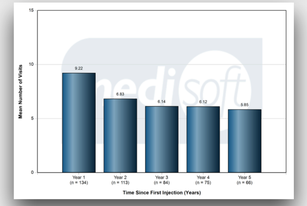
The Princess Alexandra Hospital NHS Trust

Purpose:
To determine the visual acuity (VA) outcomes, injection frequency of Ranibizumab in patients with Diabetic Macular Oedema (DMO) treated in Princess Alexandra Hospital, Harlow. To determine the efficacy and to compare our data with other RCT's

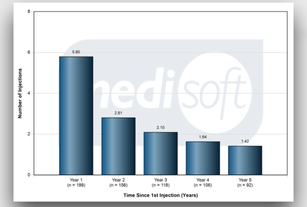
Methods:
This data was collected for patients attending Eye Clinic in Princess Alexandra Hospital from Jan 2014 to Jan 2021. Retrospective systematic review and analysis of patient data was carried by use of Medisoft. 2015 Intra vitreal Ranibizumab injections were performed as per National Institute of Clinical Excellence criteria for DMO, initial loading dose of 3 monthly injections followed by 2 more based on response, at 6 months, Treat & Extend was followed if recurrence or fluid on OCT and after 3 stable visits, injections were on a PRN basis



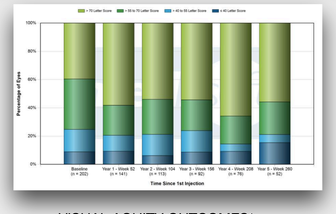
NO OF PATIENTS, EYES, INJECTIONS[1]



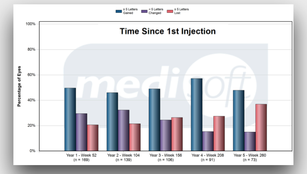
MEAN NUMBER OF VISITS BY YEAR[1]



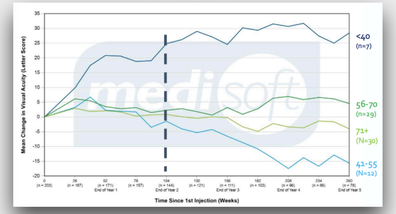
MEDIAN TREATMENT FREQUENCY / YR[1]



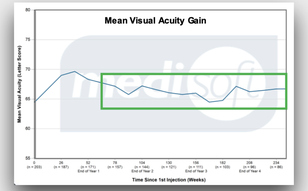
VISUAL AQUITY OUTCOMES[1]



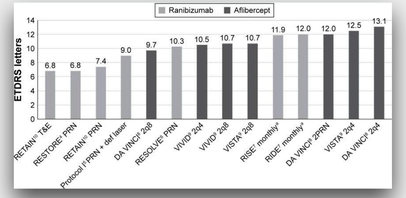
% OF EYES WITH VISION GAIN / LOSS[1]



MEAN CHANGE IN VA GAIN OR LOSS (STRATIFIED BY BASELINE VA)[1]



MEAN VISUAL AQUITY GAIN / YR[1]



COMPARISON WITH OTHER RWE DATA[3]

Results:
Number of Injections over 5 years:
2015 Injections were administered as per NICE guidelines. During COVID, patients were prioritised as per guidelines and only sight threatening conditions were treated during the lockdown, as reflected by the drop in total number of injections in 2020[1].

Median number of visits over 5 years:
The visits were 9.22 (year1), 6.83 (year 2), 6.14 (year 3), 6.12 (year 4) and 5.85 (year 5) respectively[1]. During COVID and due to capacity issues one stop practice was changed to diagnostic hub model. Though the number of visits were higher, there were reduced waiting time in the eye unit and patients only came face to face for assessment or treatment only if indicated after diagnostics and Telephone Consultation.

Median treatment over 5 years:
The median treatment frequency was 6 (year1),2 (year 2), 2 (year 3),1 (year 4) and 0.5 (year 5) respectively. By end of year 1, 84% of eyes (n=171) received an injection, at year 5, 42% of eyes (n=86) were being monitored and maintained with Ranibizumab for DMO[1].

Mean VA changes from baseline: Visual acuity increased by up to +5 letters in year 1, Over 5 years by +2.25 and Stability was noted from year 3. 79% of eyes (n=169) had stable or improved vision in year 1, 63% of eyes (n=73) had stable and or improved vision at year 5. Stability was defined as anyone withVA+/- 5 letters. A loss of up to 45 letters was seen in a few patients due to other factors, which resulted in overall drop of visual acuity. Patients in letters groups 56–70, and 71+ were relatively stable, the biggest gains were seen in the <40 letters group[1].

Conclusion:
Multi-centre database study[2] described characteristics of 3102 eyes (2416) patients treated with Ranibizumab for DMO, the proportion of eyes with VA of 72 letters or better was 25% (baseline) and 33% (1 year) for treatment naïve eyes. In comparison, PAH data[1] showed VA of 72 letters or better was 40% (baseline) and 58% (1 year) of DMO eyes.

In comparison with the 2 year data[2,3,4], with the initial Phase II and III clinical studies indicated that a higher injection frequency in the first year of treatment is associated with better VA outcomes. This can be attributed to the intensity of the initiation treatment, a strict re-treatment algorithm, and close monitoring during the active treatment phase compared to less VA outcomes in RWE as evidenced in our audit[1].

In comparison with other long term real world evidence[2,4,5], the first year outcomes in our unit is comparable to the Vision study but stabilises from year 3 to +2.25 letters over 5 years, however this drop in overall mean visual acuity is attributed to a few patients in whom the visual acuity had dropped significantly due to other factors over the course of 5 years[1].

Ranibizumab treatment option for patients with DMO, has a potential to gain and maintain vision over a long period of time, highlighting the efficacy of current treatment regimen at PAH, Harlow[1]. We need more long term studies with Real World Evidence and Data for comparison.

References:
1 Prakash, Pr. Et al. To determine the efficacy of treatment of Ranibizumab over a period of 5 years in patients with DMO at PAH, Harlow, presented at Royal College of Ophthalmology congress 2021
2 Egan, C. et. All, The United Kingdom Diabetic Retinopathy Electronic Medical Record Users Group, Report 1:baseline characteristics and visual acuity outcomes in eyes treated with intravitreal injections of ranibizumab for diabetic macular oedema, Br J Ophthalmol. 2017 Jan;101(1):75-80. doi: 10.1136/bjophthalmol-2016-309313. Epub 2016 Dec 13.
3. Baseline visual acuity strongly predicts visual acuity gain in patients with diabetic macular edema following anti-vascular endothelial growth factor treatment across trials Clin Ophthalmol. 2016; 10: 1103–1110.
4. Real-World Outcomes in Patients with Diabetic Macular Edema Treated Long Term with Ranibizumab (VISION Study) Clin Ophthalmol. 2020; 14: 4173–4185.
5. Long-term follow-up of antivascular endothelial growth factor treatment for diabetic macular oedema: a four-year real-world study Acta Ophthalmol. 2020 Jun;98(4):360-367. doi: 10.1111/aos.14290.