Assessment of UK standard of care intravitreal aflibercept treatment effectiveness in diabetic macular edema patients: DRAKO 12-month outcomes

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INTRODUCTION

- DRAKO (NCT02850263) is a prospective, observational, 2-year study evaluating the effectiveness of intravitreal aflibercept (IVT-AFL) injection in diabetic macular oedema (DMO) patients in routine clinical practice
- Study eye results for the anti-vascular endothelial growth factor therapy treatment-naïve patient cohort at Month 12 (M12) are described

METHODS

Patients

- Male and female patients with DMO from 35 National Health Service centres were enrolled from July 2016 to April 2018
- Patients had not previously received any of the following: Intravitreal dexamethasone or fluocinolone acetonide; pan-retinal photocoagulation in the previous 8 weeks; or macular laser photocoagulation in the previous 4 months

Objectives

- **Primary:** To evaluate the change from baseline (BL) in best-corrected visual acuity (BCVA) with refraction and central subfield thickness (CST) at M12
- **Secondary:** To evaluate the change from BL at M12 for Diabetic retinopathy (DR), haemoglobin A1c (HbA_{1c}) and macular volume (MV), and stratify BCVA and CST by BL measures

Clinical Care and Assessments

- Patients were treated as per each study site's local standard protocol
- Primary assessments measured: BCVA and CST
- Secondary assessments measured: DR, HbA_{1c} and MV
- National Eye Institute Visual Function Questionnaire 25-item version (NEI VFQ-25)

Statistical Analysis

- Patients with BCVA or CST data at BL and M12 within a +/- 1-month window, who received at least one IVT-AFL injection were included in the analysis
- Summary statistics were calculated for all quantitative variables and 95% confidence intervals (CI) were calculated for the primary endpoints

RESULTS

Patient Population

- A total of 507 treatment-naïve patients were enrolled in the study (safety population), 388 patients met the defined requirements and were included in this analysis

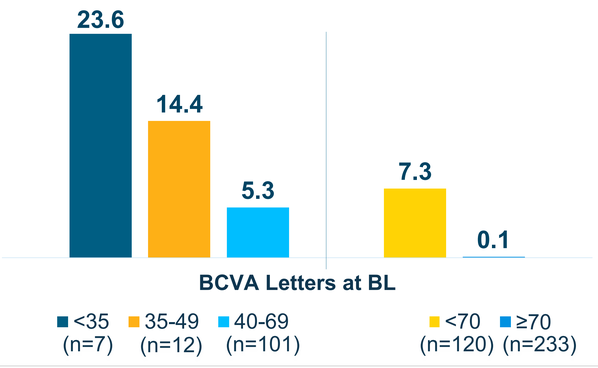
Functional and Anatomic Outcomes

- 65.3% of patients had BL BCVA ≥70 letters (mean 78.1)
- Improvements were observed for both BCVA and CST (**Table 1**)
- Patients with BL BCVA <70 letters (mean 58.7) experienced mean (standard deviation [SD]) letter gain of 7.3 (12.9) (**Figure 1**)

TABLE 1:
BCVA and CST outcomes observed at M12

		Mean (SD)	95% CI	n
BCVA (Letters)	BL	71.4 (12.0)	-	375
	M12	73.6 (13.9)	-	362
	Change from BL	**2.5 (12.2)**	1.3, 3.8	353
CST (µm)	BL	448.7 (88.7)	-	388
	M12	329.8 (92.3)	-	386
	Change from BL	**–119.1 (116.4)**	–130.7, –107.4	386

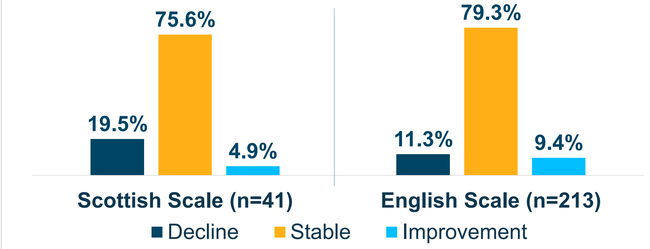
FIGURE 1:
Change from BL in BCVA, stratified by BL BCVA measures



Secondary Assessment Outcomes

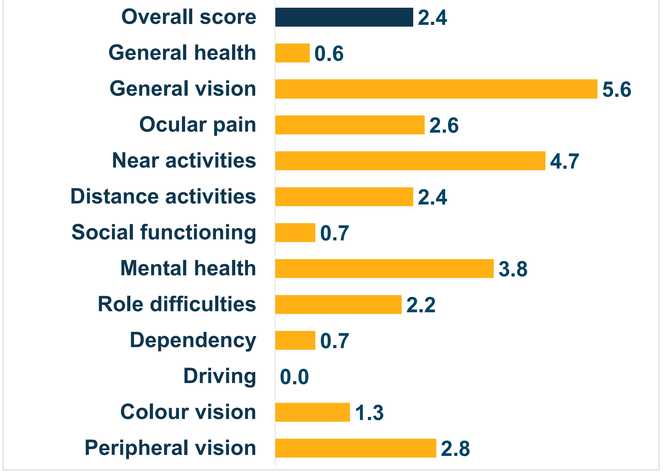
- Dependent on study site preference, either the Scottish DR grading scheme (Scottish) or National Screening Committee classification (English) was utilised to measure DR
- The DR grade for 44.7% Scottish and 37.9% English patients was ≤R1 (background retinopathy), and the majority of patients (>75%) had no change in their DR severity level score at M12 (**Figure 2**)

FIGURE 2:
Change from BL in DR at M12, applying either Scottish or English Scale based on site preference. Data presented is percentage of patients.



- A trend towards improvement in patient quality of life across most NEI VFQ-25 categories was also observed (**Figure 3**). The mean overall score at BL was 80, with a 2.4 gain at M12
- An improvement in MV and HbA_{1c} from BL was observed at M12 (**Table 2**)

FIGURE 3:
Change from BL in NEI VFQ-25 outcomes



Safety Assessment

- The safety profile of IVT-AFL was consistent with previous studies

TABLE 2:
Change from BL in MV and HbA_{1c} outcomes

		Mean (SD)	n
MV (mm^3)	BL	9.6	256
	M12	8.8	226
	Change from BL	**–0.8**	200
HbA_{1c} (mmol/mol)	BL	66.1	194
	M12	65.7	139
	Change from BL	**–2.9**	98

CONCLUSIONS

- **DRAKO M12 results indicated that standard of care IVT-AFL was effective for the treatment of DMO in this representative UK population, maintaining or improving patient outcomes and quality of life following the first year of treatment**
- **These results indicate the effectiveness of DR screening in the UK, with almost two-thirds of treatment-naïve patients presenting with high BL vision (≥70 BCVA letters)**

Disclosures

James Talks participated in advisory boards for Bayer and Novartis; received travel support from Bayer; and received research grants from Bayer, Novartis and Roche; **Simon P Kelly** received travel grants from Bayer, research support from Bayer and Novartis Pharma AG, and participated in advisory boards for Novartis Pharma AG and Polyphotopics; **Sobha Sivaprasad** received consultancy fees from Bayer, Allergan, Novartis Pharma AG, Roche, Boehringer Ingelheim, Optos and Heidelberg Engineering; **Faruque Ghanchi** has been a consultant and speaker for Novartis, Bayer, Allergan, Alimera and Roche; and has received travel grants from Bayer and Novartis; **Ajay Kotagiri** received travel support from Novartis, Bayer, and Allergan, and speaker fees from Allergan and Bayer; **Peter Scanlon** attended advisory boards for Pfizer, Allergan, Boehringer, Roche and Bayer, and his department has received educational, research, and audit grants from Allergan, Boehringer Ingelheim, Novartis, and Bayer; **Moneeb Saddiq** is an employee of O4 Research; **Jackie Napier** is an employee of Bayer Plc.

Acknowledgements

This study was funded by Bayer Plc. Medical writing support was provided by Andrea Parke of O4 Research and editorial assistance by ApotheCom, and was funded by Bayer Plc. The DRAKO Study Team on behalf of Bayer Plc. would like to thank the patients and investigators who have participated in the DRAKO study.

Presented at The Royal College of Ophthalmologists (RCOphth) Meeting, Liverpool, UK, 24–27 May 2021