Real world efficacy and safety of Ximluci ranibizumab biosimilar

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Introduction

Ximluci, a biosimilar to ranibizumab, is a recently approved treatment for wet age-related macular degeneration (wet AMD), diabetic macular oedema, proliferative diabetic retinopathy and retinal vein occlusion related macular oedema[1]. While clinical trials have demonstrated its efficacy and safety, real-world data are limited. Biosimilars like Ximluci offer a cost-effective alternative to reference biologics, with comparable efficacy and safety demonstrated in clinical trials[2,3].This study evaluates the real-world efficacy and safety of Ximluci in patients treated at a tertiary eye care centre.

Methods

A retrospective observational review was conducted, analysing data from patients who received Ximluci for wet AMD or other retinal vascular diseases between January 2023 and December 2024. 37 patients received Ximluci between December 2023 and June 2024, with 28 receiving loading a loading dose of 2 injection. The visual acuity (VA), central retinal thickness (CRT), and the incidence of adverse events were recorded before and after the loading dose.

Results

28 patients received an average of 2 injections between December 2023 and June 2024. 54% of these were for proliferative diabetic retinopathy or diabetic macula oedema and 16% for wet age-related macula degeneration or CNV. Patients had visual acuity and OCT parameters taken before and after the 2 injections which showed the following changes. There was a mean improvement in vision of 0.13 logMAR (1 patient was excluded due to a vitreous haemorrhage). There was also a mean improvement in central subfield thickness of 22.9 µm. Adverse events were rare with one case of raised intraocular pressures which required treatment. 13% of these patients were switched to alternate drug treatments.

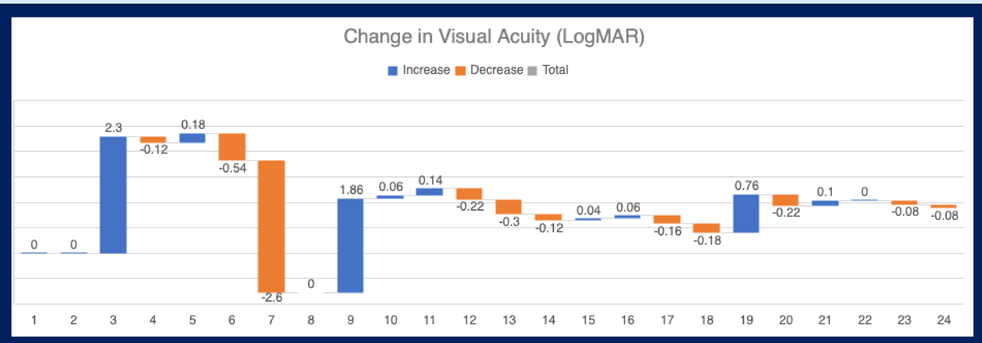


Table 1: Change in visual acuity in LogMAR before and after loading dose of Ximluci. Improvement shown in orange and worsening in blue.

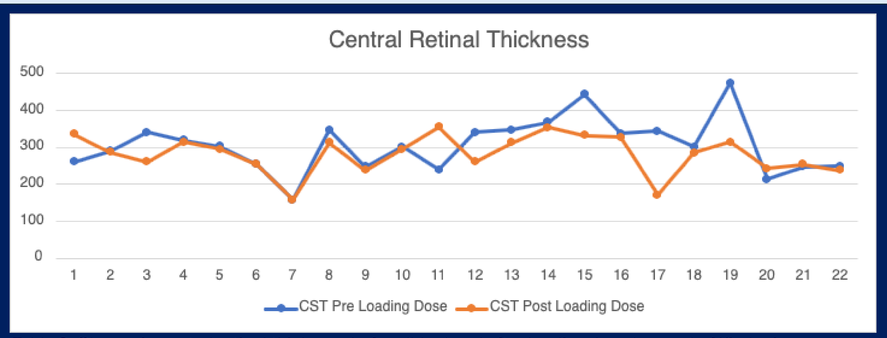


Table 2: Change in central retinal thickness before (blue) and after loading dose (orange) of Ximluci.

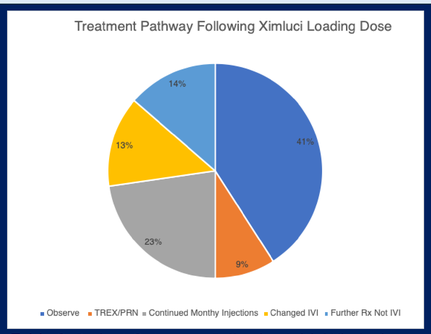


Table 2: Patient Outcomes Following Initial Ximluci Therapy

Discussion

This limited sample of patients demonstrated the real-world use of Ximluci has shown an improvement in patient outcomes in the treatment of retinal vascular diseases. patients experienced a mean improvement in visual acuity of 0.13 logMAR and a reduction in central subfield thickness by 22.9 µm. Adverse events were rare, with only one reported case of raised intraocular pressure. However, 13% of patients required a switch to alternative treatments. Further studies with larger sample sizes and extended follow-up would be warranted to validate the efficacy and safety profile of Ximluci.

References

1. European Medicines Agency. Ximluci: EPAR – Product Information. 2022. Available from: https://www.ema.europa.eu/en/medicines/human/EPAR/ximluci
2. Loewenstein A, Czumbel N, Ernest J, et al. Randomized trial of biosimilar XSB-001 versus reference ranibizumab in patients with neovascular age-related macular degeneration. Ophthalmol Retina. 2023;7(9):753–761. doi:10.1016/j.oret.2023.05.005.
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