

Vision-Related Quality of Life After Intravitreal Therapy for Diabetic Macular Oedema: A Systematic Review and Current Perspective

Samy El Omda

samy.elomda@uhliverpool.nhs.uk

University Hospitals Liverpool Group <https://orcid.org/0000-0003-1141-2433>

Sara Shahi

Simon Peterson

Omar Masoud

Nihal Kenawy

Royal Liverpool University Hospital

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Abstract

Background/Objectives

: Diabetic macular oedema (DMO) is a leading cause of visual impairment. While intravitreal therapies improve visual acuity, evaluating vision-related quality of life (VRQoL) is essential to comprehensively capture functional outcomes and treatment burden.

Subjects/Methods:

A PRISMA-compliant systematic search of Scopus, Medline(OVID), Web of Science, and PubMed was conducted from inception to July 2025. Included studies assessed pre- and post-treatment VRQoL changes using validated tools. Risk of bias was assessed using the Cochrane tool for randomised trials and the Newcastle-Ottawa scale for non-randomised studies.

Results

The review included 21 manuscripts encompassing 18 unique clinical trials. The majority of studies (89%) utilised the NEI VFQ-25. Anti-VEGF therapies demonstrated clinically meaningful short-term improvements with ranibizumab in multiple trials yielding mean NEI VFQ-25 composite score gains of 5–10 points at 6–12 months. However, these early gains were diminished or no-longer statistically significant over longer time periods in longitudinal extension studies. Intravitreal corticosteroids had limited evidence with heterogeneous outcome measures making it difficult to draw definitive conclusions. A critical evidence gap was identified with no VRQoL data found for newer, extended-dosing anti-VEGF agents (8mg aflibercept, faricimab) and the recently introduced biosimilars.

Conclusions

Intravitreal anti-VEGF agents provide significant short-term improvements in VRQoL for patients with DMO. The attenuation of long-term benefits suggests the cumulative burden of chronic injections may eventually offset functional gains. Incorporating standardised VRQoL measures with predefined clinical significance thresholds into trials and clinical therapy of emerging therapies the recently adopted biosimilars is key to ensure new treatments translate into sustained, patient-centred benefits.

Introduction

Diabetes mellitus is one of the fastest-growing global health challenges and remains a leading cause of visual impairment worldwide(1, 2). One significant complication of diabetes mellitus is the development of diabetic macular oedema (DMO) with subsequent potential visual impairment(3).

A 2021 meta-analysis identified a global prevalence of clinically significant macular oedema (CSMO) among individuals with diabetes as 4.07% (4). A 2013 United Kingdom National Ophthalmology Database study identifying CSMO in 13.9% of eyes in patients with diabetes with 7.4% having centre-involving DMO(5). Furthermore, a 2025 systematic review showed the direct medical costs of treating a patient with DMO for one year ranged between \$6470 to \$6913(6). These costs dramatically increase once indirect costs, such as lost earnings, are factored in with a Spanish study reporting an annual cost of between \$17,807 and \$20,652, and a large US study estimating a net societal benefit of treating DMO to be between \$28.1 billion and \$52.8 billion(6). Intravitreal therapies, including anti-vascular endothelial growth factor (anti-VEGF) agents and corticosteroids, are the cornerstone of DMO management(7). Although visual acuity of affected patients improves with intravitreal therapies, it does not fully capture the patient experience. Vision-related quality of life (VRQoL) provides a more comprehensive measure of treatment impact, incorporating functional vision, and the burden of repeated interventions(8).

This systematic review evaluates the effect of intravitreal therapies in current world-wide clinical practice on VRQoL in patients with DMO. Specifically, we synthesised evidence assessing changes in validated VRQoL measures following treatment, with a focus on magnitude, durability, and clinical relevance of outcomes.

Methods

A systematic search of the literature was conducted in accordance with the guidelines set out in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement(9). The review protocol was registered with the PROSPERO database (CRD420251248208). Scopus, Medline (OVID), Web of Science and Pubmed were all searched from inception to July 2025. The full search strategy can be seen in Appendix 1.

Inclusion and Exclusion criteria:

Included studies assessed changes in VRQoL pre- and post-treatment with an intravitreal therapy for diabetic macular oedema as a primary or secondary outcome. VRQoL had to be assessed by a validated method (e.g. 25 Field National Eye Institute Visual Function Questionnaire (NEI VFQ-25)). Studies were excluded if there were abstract-only, secondary research, protocols, or not in the English language.

Data extraction

3 Authors (SEO, SS, SP) independently reviewed titles and abstracts that met the search criteria. The full texts of the included studies were then reviewed and extracted by SEO. Figure 1 demonstrates a flow chart of the search process as per the PRISMA guidelines.

Risk of Bias

The risk of bias was assessed using the Cochrane risk of Bias tool for randomised control trials (10) and the Newcastle-Ottawa scale for non-randomised studies (Fig. 2).

Results

Study Selection and Characteristics

The search yielded 2630 results, of which 21 manuscripts met the inclusion criteria, representing 18 unique clinical trials after accounting for extension studies and multiple reports from the same cohorts. Reports describing results from multiple studies were separated and marked “a” or “b” to allow for easier comparison of manuscripts covering the same trials. Overall, the evidence comprised several thousand patients with DMO across multiple countries. Most studies (16/18; 89%) used the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) to assess VRQoL, while a minority used alternative validated instruments. A full list of the VRQoL instruments used are seen in Table 1. Overall, the evidence base was largely randomised control trials, with moderate heterogeneity in outcome reporting and follow up duration.

Effects of Anti-VEGF Therapy on VRQoL

Across multiple papers, anti-VEGF therapy was consistently associated with improvements in VRQoL especially in papers with 12 months or less follow up (11–19). Ranibizumab demonstrated clinically meaningful increases in NEI VFQ-25 composite scores at 6–12 months with mean improvements typically ranging from 5–10 points relative to baseline or laser (11, 12, 16, 18). These gains exceeded commonly proposed thresholds for clinically meaningful change and were observed across several functional domains, including near activities, distance vision and driving (12, 18).

Aflibercept showed similar benefits, with improvements in both composite and domain-specific VRQoL outcomes in trials such as VISTA and AQUA (13, 15, 20). However, results were not uniformly consistent across all studies with some trials (e.g. VIVID) reporting non-significant differences despite trends towards improvement (15, 20). Limited data were available for other anti-VEGF agents. Pegaptanib demonstrated modest but significant gains in a single study, whereas bevacizumab showed variable effects, with improvements confined to specific subdomains (e.g. Mental health) rather than overall composite scores (21, 22). Table 2 summarises the main findings of the papers looking at anti-VEGF agents.

Durability of VRQoL Outcomes with anti-VEGF therapy

Longitudinal and extension studies demonstrated attenuation of initial VRQoL improvements over time (17, 23, 24). In the RESTORE extension, early gains observed at 12 months were no longer statistically significant at 36 months (24). Similarly, the patient population followed by Granstrom and Granstrom et al. showed that early VRQoL gains at 12 months were no longer significant at 4 years (14,

23). This pattern suggests that the durability of VRQoL benefit is limited, even when anatomical or visual acuity outcomes are maintained.

Functional Domain-Specific Outcomes of anti-VEGF therapy

Several studies provided granular analyses of VRQoL subdomains(12, 15, 18, 20, 22, 25). Notably, multiple studies showed improvements in near activities, which may be particularly important to certain patient cohorts (12, 15, 18, 20). Bressler et al. looked at the RESTORE, RIDE and RISE cohorts showing an increase in driving subdomain result but no statistical significance calculations were available in the main text(25).

Intravitreal Steroids and Comparative Effectiveness

Evidence for intravitreal corticosteroids was more limited and heterogeneous(26–31). Some studies reported improvements in selected NEI VFQ-25 subdomains following dexamethasone or fluocinolone acetonide(27, 29). Comparative studies and combination studies of Anti-VEGF and corticosteroids showed outcomes broadly similar to those observed with anti-VEGF alone(26, 28, 31). Table 3 summarises the main findings from manuscripts looking at intravitreal steroids or mixed therapies.

Discussion

The current systematic review found that intravitreal therapies, particularly anti-VEGF agents, are associated with meaningful short-term improvements in VRQoL in patients with DMO. However, these benefits are often not sustained over longer follow-up periods. Critically, there is a substantial gap in the evidence base regarding intravitreal steroids, newer intravitreal therapies and anti-VEGF biosimilars.

The majority of trials reporting on anti-VEGF data of 12 months or shorter demonstrated a significant increase in VRQoL during treatment, suggesting a correlation between anti-VEGF pharmacological intervention and improved VRQoL. The decline in VRQoL over time observed across multiple studies may reflect the cumulative burden of frequent injections, logistical challenges and psychological factors associated with chronic treatment. While the injections successfully manage the DMO anatomically, the treatment burden of the ongoing therapy may eventually outweigh the functional visual gains, leading to a return to baseline VRQoL scores (32). One further aspect to be considered is the stagnation of visual acuity seen following a lengthy anti-VEGF intravitreal treatment course. However, it is not clear whether this could also be related to the diminishing VRQoL scores.

In contrast to the data available for anti-VEGF agents, the evidence regarding intravitreal steroids remains sparse and heterogeneous. Although a minority of studies reported improvements in specific VRQoL subdomains following dexamethasone or fluocinolone acetonide implants, small sample sizes and inconsistent use of outcome measures limit definitive comparisons. While corticosteroids require less frequent intravitreal injections, they may introduce alternative burdens such as the management of

raised intra-ocular pressure or the potential need for cataract surgery(33). Consequently, further understanding their effect on VRQoL remains a critical area for future investigation. Although linked to visual acuity, VRQoL is an essential marker of the impact of both pathologies and treatments on a patient's daily activities as well a tool to support regulatory and cost-benefit approvals (34). These objective and subjective findings should be utilised in conjunction as a standard of care to ensure a holistic view of patients' health(35–37). A major finding of this review is the absence of VRQoL data for the second-generation anti-VEGF interventions such as aflibercept 8mg and faricimab, which were designed to help reduce treatment burden through extended dosing intervals. It is yet to be determined whether these regimens would successfully translate into improved VRQoL scores compared to the intravitreal agents discussed in this review. Furthermore, anti-VEGF biosimilars have recently been introduced across multiple countries(38). However, there are no current VRQoL data regarding these biosimilars. While biosimilars offer substantial drug-cost savings and improved healthcare sustainability, it remains unclear if these achieve longer-term economic benefits and do not compromise VRQoL. The psychological and economic impact of remaining on a high-frequency injection schedule, despite the availability of lower-burden alternatives, must be formally evaluated to ultimately allow for a more tailored, individualised treatments for the best patients' benefit.

A significant challenge identified in this review is the lack of standardised reporting for a “clinically significant” change in VRQoL score. The RESTORE trial utilised a 5-point threshold change for a clinically significant result with anti-VEGF therapy; however, as noted in the study's manuscript, this was adopted from previous age-related macular degeneration (AMD) research without specific validation for the DMO population(8, 16). The same point was also highlighted in the RIDE/RISE trials which also highlighted previous AMD research and adopted a 10-point increase for a clinically significant result(8, 19, 39, 40). Bressler et al. recently analysed data from the RIDE/RISE trials and used anchor-based estimates of clinically meaningful improvements (a method that validates subjective questionnaire scores by tethering them to an objective clinical marker such as gains in visual acuity) to suggest an improvement of three to five points on the NEI VFQ-25 composite score as clinically significant in patients with DMO(41).

Several limitations of the current review are acknowledged. First, the lack of trials and reports on third generation anti-VEGF, steroids and biosimilars in current world-wide practice. Second, the review included moderate to high risk of bias in some of the trials and substantial heterogeneity in outcome measures across them. Third, the majority of studies were anti-VEGF-related and affiliated with the pharmaceutical companies manufacturing the study drugs or had authors reporting conflicts of interest, which may introduce bias. Fourth, some of the trials reported improvements in VRQoL but failed to provide a full statistical analysis or p-values. Finally, standard VRQoL instruments focus solely on the patient, failing to capture the wider impact of chronic therapy including caregiver burden. Patients with DMO frequently rely on others for transportation to intravitreal injection appointments(32, 42). This may influence their treatment preferences and adherence, however, there is no literature examining this specifically in people with DMO. The existing literature focuses on intravitreal injections more broadly, which fell outside the scope of our review.

Future research should prioritise the inclusion of VRQoL as a key outcome in clinical trials for novel intravitreal therapies. Additionally, dedicated studies are urgently needed to evaluate currently utilised treatments, such as faricimab, 8mg aflibercept, and biosimilars, using validated VRQoL instruments with clearly defined thresholds for clinical significance. Addressing this evidence gap will be essential to ensure that therapeutic advances translate into meaningful improvements in patient outcomes.

Conclusion

Current evidence on the impact of intravitreal treatments in DMO on VRQoL is largely lagging behind the rapid evolution of the therapeutic armamentarium. Whilst some of the known intravitreal therapies, specifically anti-VEGF, improve VRQoL in the short term, these benefits are not consistently sustained over time. However, there is a critical gap in literature regarding the newer therapies on patient-reported outcomes. Addressing this gap is essential to guide future clinical practice and health policy.

Declarations

Conflicts of Interest Disclosures: SEO, SS, SP, OM, NK - No conflicts of interest to declare.

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Author Contributions:

SEO,SS,NK – Concept and design.

SEO, SS, SP – Acquisition of data.

SEO, SS, SP, OM, NK – Drafting, critical revisions and finalisation of Manuscript.

NK - Supervision

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Tables

Tables 1 to 3 are available in the supplementary files section.

Figures

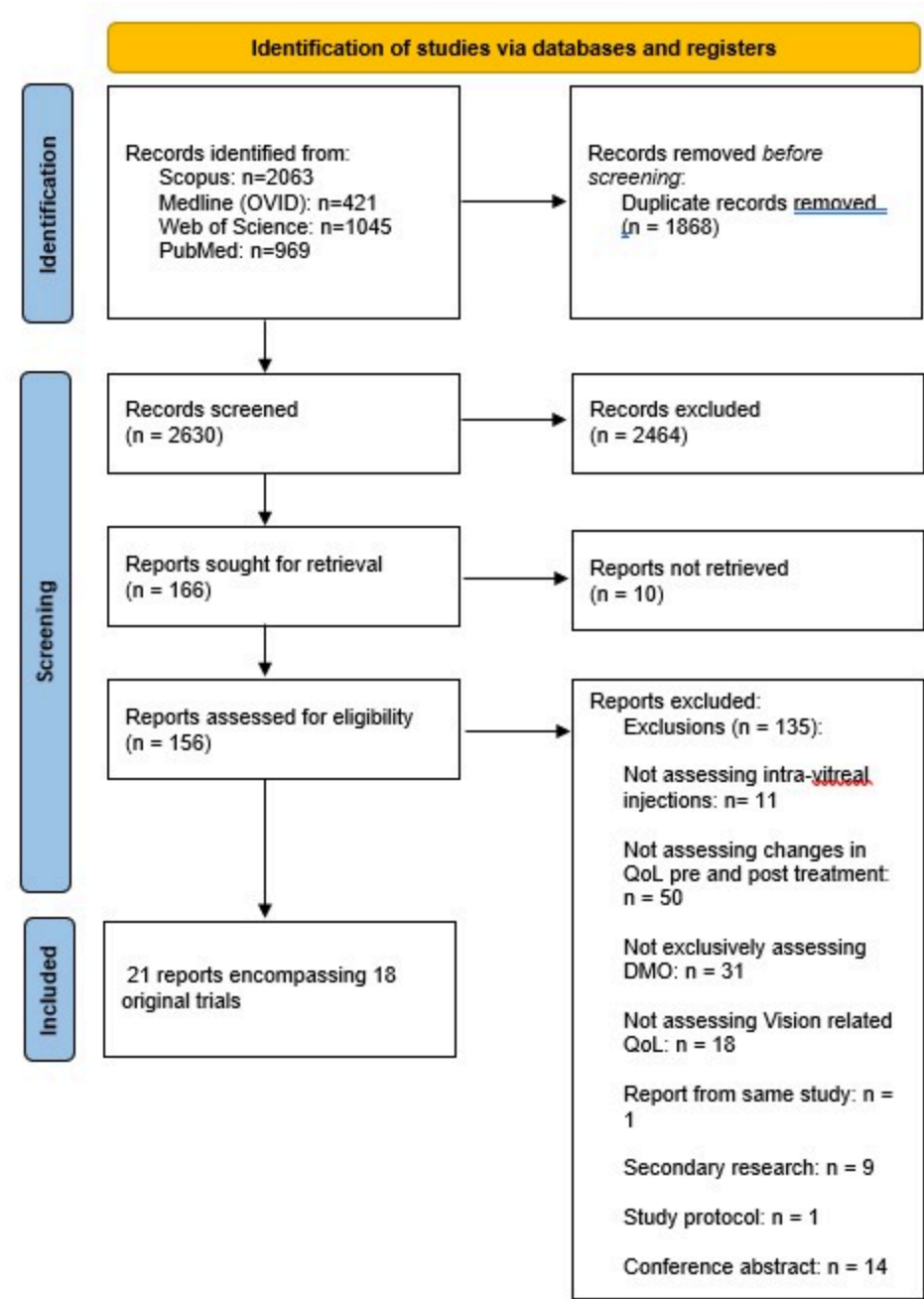


Figure 1

Flow diagram of the literature search process used as per the PRISMA statement guidelines 2020. 2464 records excluded were due to the title and abstract not being relevant to the research question. The 10 reports not retrieved were due to the full-paper article not being accessible.

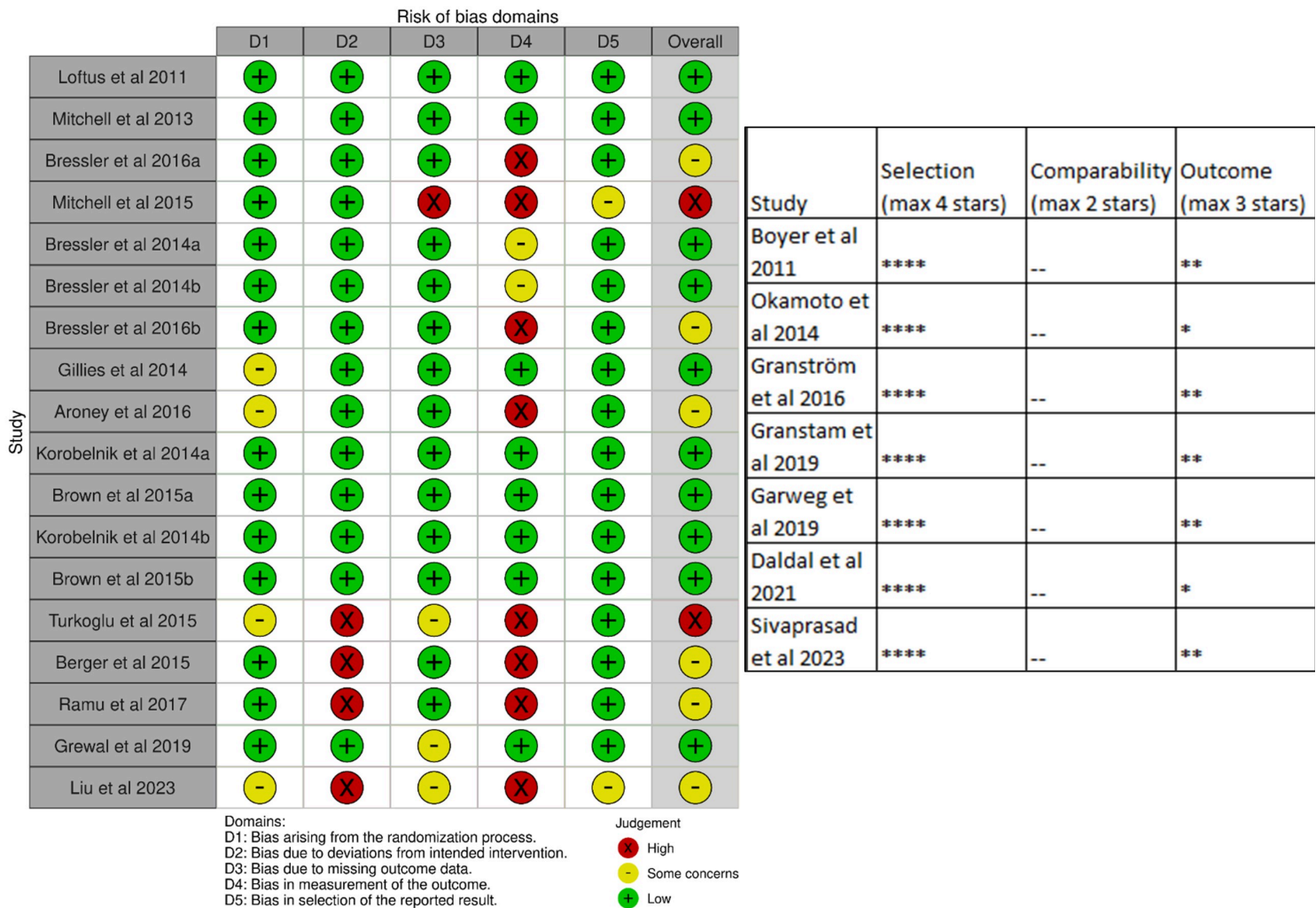


Figure 2

Risk of Bias of reports included in this systematic review. Randomised control trials were assessed using the Cochrane Risk of Bias tool (Left) while non-randomised studies were assessed using the Newcastle-Ottawa scale (Right).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix1.docx](#)
- [Table1DMOVRQoL.xlsx](#)
- [Table2DMOVRQoL.xlsx](#)

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