Ranibizumab 0.5 mg Treat-and-Extend Regimen for Diabetic Macular Edema (DME): The RETAIN Study

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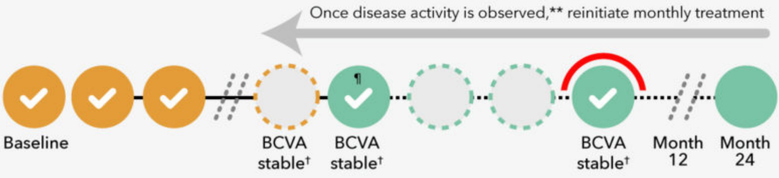
In this study the researchers demonstrated noninferiority of ranibizumab treat-and-extend (T&E) with/without laser to ranibizumab pro re nata (PRN) for best-corrected visual acuity (BCVA) in patients with DME.

This was a single-masked, randomized study with a treat-and-extend regimen.

The primary objective was to demonstrate noninferiority (4-letter margin) of the T&E regimen with/without laser to the PRN regimen with respect to mean average change in BCVA from baseline to Month 1 through Month 12.



Monthly treatment until BCVA stability, ie, at least 3 monthly injections

If BCVA stable, no treatment administered and period to next treatment extended by 2 months

T&E visit: Mandatory treatment including a decision point for potential reinitiation of monthly injections

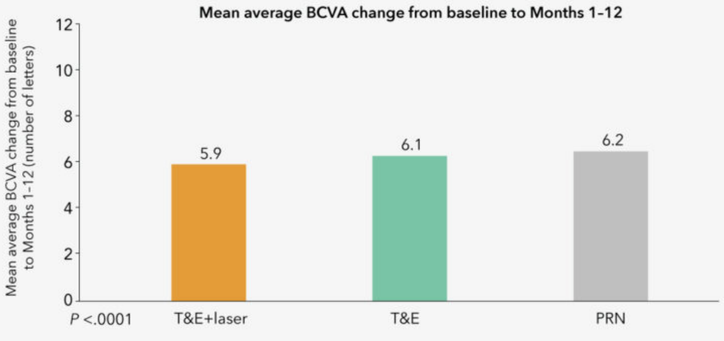
Protocol mandated intermediary visit*

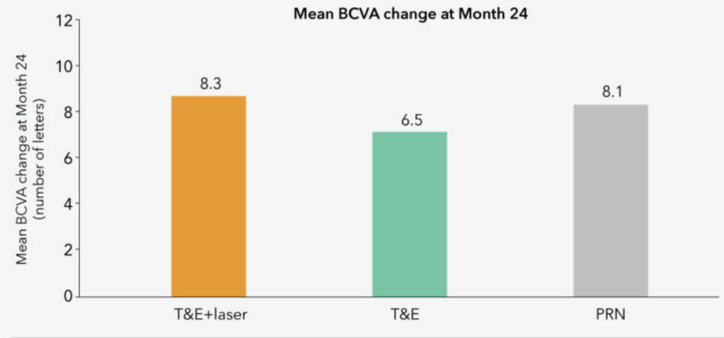
Study design did not permit treatment intervals >3 months

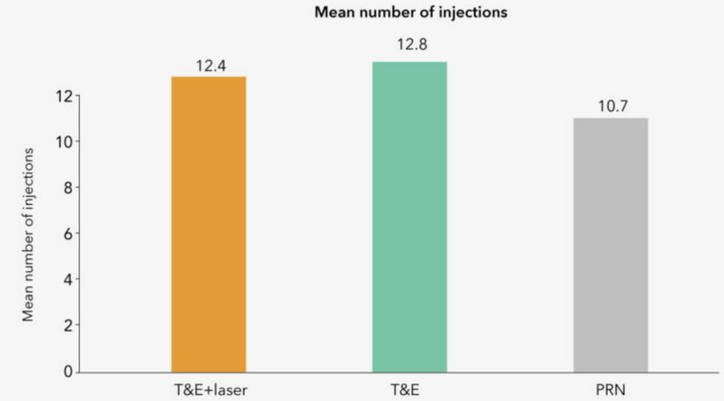
†BCVA stable: No BCVA improvement or deterioration noted for 3 consecutive monthly study visits under treatment.
**Patient's BCVA worsened due to DME disease activity.
¶First T&E visit followed 1 month after the visit at which stabilization was confirmed.
*Scheduled between the T&E visits for masking purposes only, ie, no study treatment was administered and no decision for study treatment was made. For the PRN (control) regimen, each monitoring visit was also a potential treatment visit.

Both T&E regimens were noninferior to PRN based on mean average BCVA change from baseline to Months 1 to 12.

All patients received monthly injections until BCVA stabilization. The investigator decided on retreatment.







The T&E regimens showed a 46% reduction in the number of clinic visits.

Conclusions

T&E is a feasible treatment option for patients with DME, with a potential to reduce treatment burden. Slightly more injections were required versus PRN, likely due to the specifics of the T&E regimen applied here.