

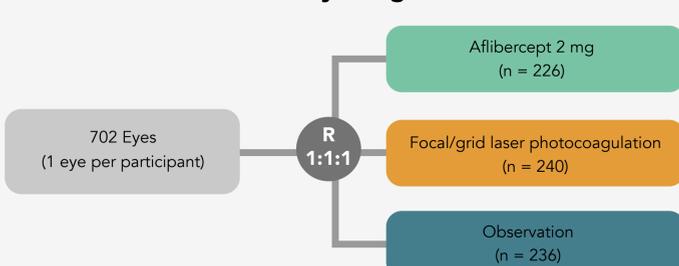
Effect of Initial Management With Aflibercept vs Laser Photocoagulation vs Observation on Vision Loss Among Patients With Diabetic Macular Edema Involving the Center of the Macula and Good Visual Acuity: A Randomized Clinical Trial

Baker CW, Glassman AR, Beaulieu WT, et al. JAMA. 2019;321(19):1880-1894.
doi: 10.1001/jama.2019.5790

Intravitreal injections of anti-vascular endothelial growth factor agents are effective for treating diabetic macular edema (DME) involving the center of the macula (center-involved DME [CI-DME]) with visual acuity impairment (20/32 or worse). The best approach to treating patients with CI-DME and good visual acuity (20/25 or better) is unknown. The aim of this study was to compare vision loss at 2 years among eyes initially managed with aflibercept, laser photocoagulation, or observation.

This was a randomized clinical trial of patients with eyes having CI-DME and good visual acuity.

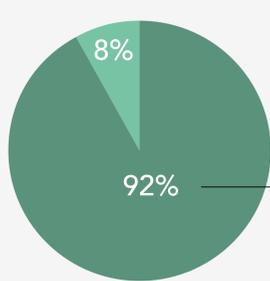
Study design



The primary outcome was at least a 5-letter visual acuity decrease from baseline at 2 years. Antiplatelet Trialists' Collaboration adverse events (defined as myocardial infarction, stroke, or vascular or unknown death) were reported.

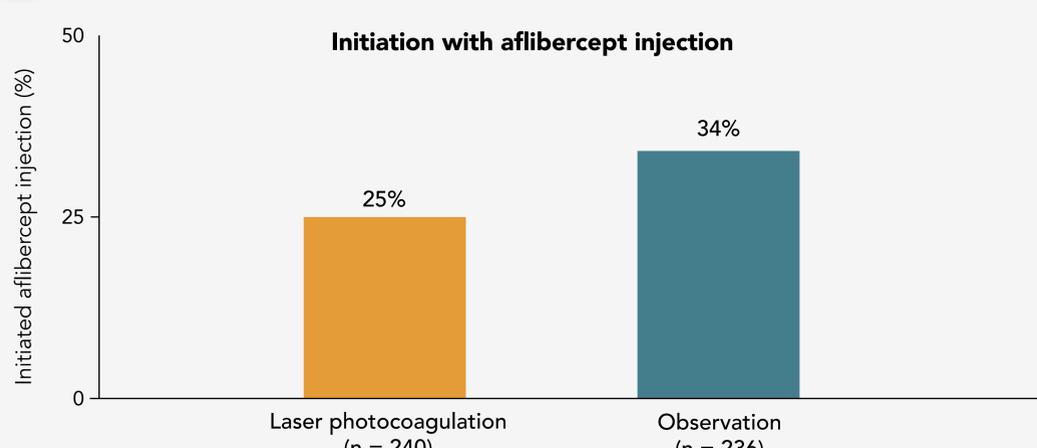
R = Randomization.

Excluding deaths, the 2-year completion rate was high.



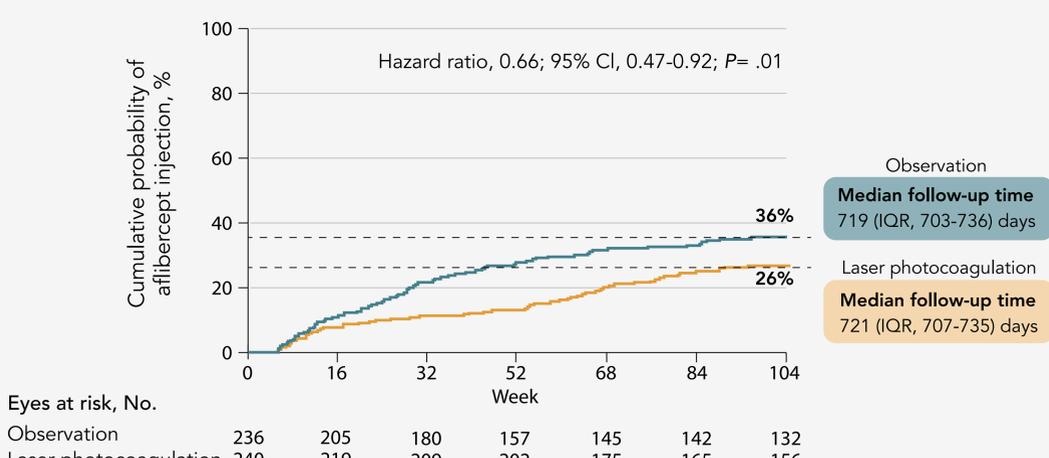
2-year completion rate (excluding deaths)
Visit completion at 2 years was prespecified as completion of any study visit from 92 to 116 weeks.

Eyes in the laser photocoagulation and observation groups with decreased visual acuity from baseline received aflibercept during 2 years of follow-up.



Eyes in the laser photocoagulation group had a 10% less absolute likelihood of receiving aflibercept injections compared with eyes in the observation group.

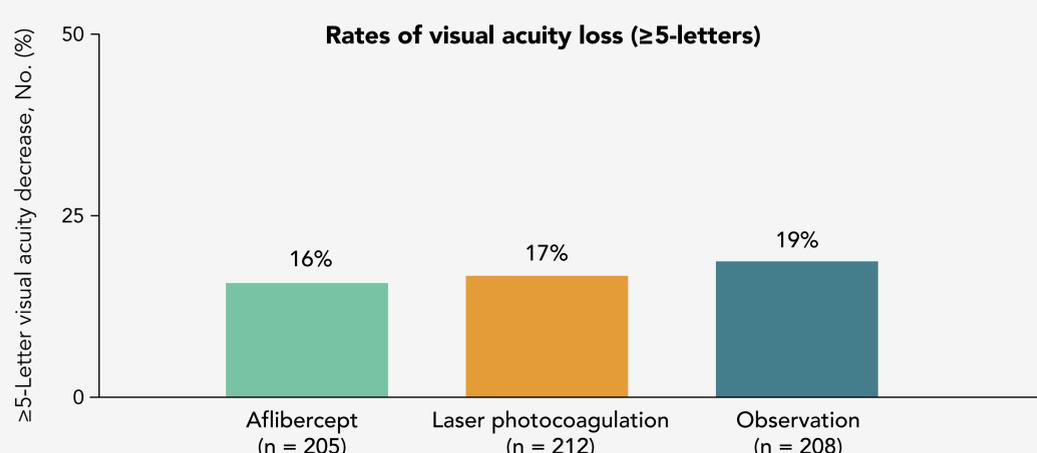
Time to first aflibercept injection



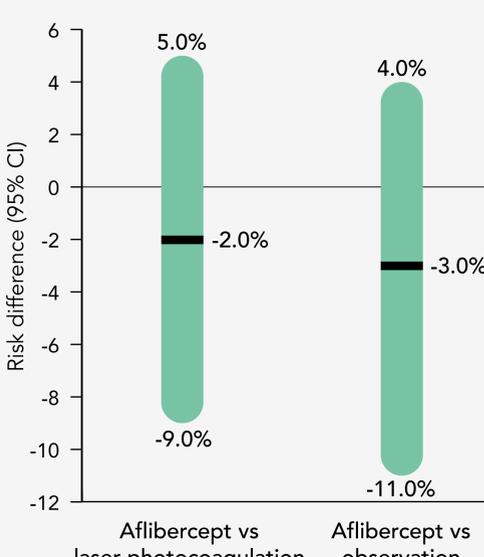
Eyes at risk, No.						
Observation	236	205	180	157	145	142
Laser photocoagulation	240	219	209	202	175	165

Post hoc analysis of prespecified within-group outcomes. Hazard ratio and P value are from Cox proportional hazards regression with robust variance estimation and adjustment for recent or planned diabetic macular edema treatment in the nonstudy eye. IQR = Interquartile range.

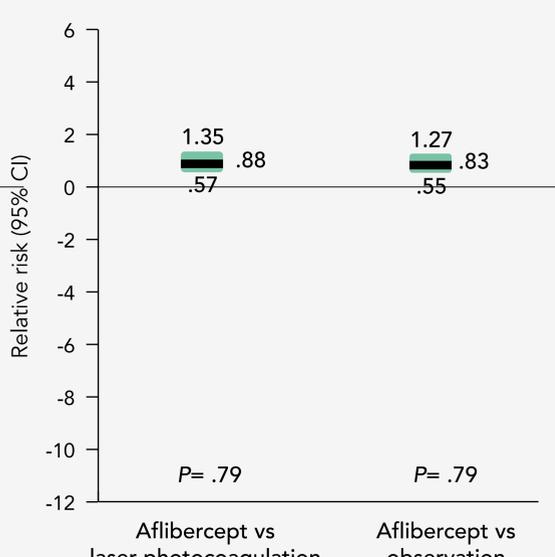
Rates of visual acuity loss of 5 or more ETDRS letters at 2 years were not significantly different among eyes initially managed with intravitreal aflibercept, laser photocoagulation, or observation.



Risk difference (95% CI)

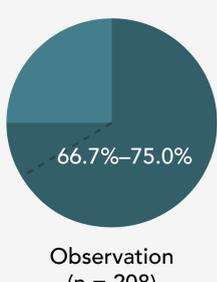
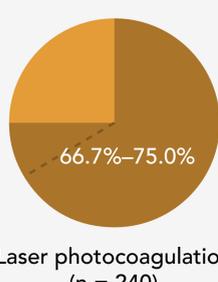


Relative risk (95% CI)



CI = Confidence interval; ETDRS = Early Treatment Diabetic Retinopathy Study.

Approximately two-thirds to three-fourths of the eyes in the observation and laser photocoagulation groups never received aflibercept.



Each aflibercept injection has an average Medicare cost of \$1850, and all intravitreal injections carry a small risk of endophthalmitis (<0.1%). Thus, reducing anti-VEGF treatment in these eyes while maintaining good vision has clinical and economic advantages for patients and public health.

Conclusions

Among eyes with CI-DME and good visual acuity, there was no significant difference in vision loss at 2 years whether eyes were initially managed with aflibercept or with laser photocoagulation or observation and given aflibercept only if visual acuity worsened. Observation without treatment unless visual acuity worsens may be a reasonable strategy for CI-DME.