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Conflicting Evidence Over Stroke Risk from AMD Drug

Author(s) [Ellen Kurek](#)*Studies find varying results in incidence of strokes from wet age-related macular degeneration treatment.*

Insufficient data has hampered efforts to come to a definitive conclusion about whether intravitreal treatment with anti-vascular endothelial growth factor (VEGF) agents increases the risk of stroke.

However, a recent study based on South Korean registry data provided additional evidence that intravitreal treatment with ranibizumab (Lucentis/Roche) is not associated with a statistically significant difference in the rate of stroke in patients with wet age-related macular degeneration (AMD).

Soon after Genentech introduced Lucentis in 2006, it warned of an increased risk of stroke from the 0.5 mg dose approved by the FDA compared with the 0.3 mg dose, which was also studied. Interim analysis of SAILOR study data showed a 1.2% risk of stroke in the 0.5 mg arm and a 0.3% risk in the 0.3 mg arm ($P = 0.02$). Since then, a [meta-analysis](#) of 5 ranibizumab trials found some evidence of increased risk of cerebrovascular accidents for ranibizumab versus control or for 0.5 mg ranibizumab versus 0.3 mg ranibizumab.

Moreover, [analysis](#) of data on nearly 58,000 Canadian patients with AMD or macular edema treated with ranibizumab or bevacizumab (Avastin/Roche) showed an increase in stroke risk from 10.7 to 18.6 per 1000 patients annually after initiation of treatment with either intravitreal anti-VEGF agent. The increase, which was particularly pronounced for ischemic stroke, exceeded trends due to aging, occurred with each agent, and did not occur in controls who had cataract surgery.

Another [analysis](#) found an increased risk of hospitalization for ischemic stroke in the second month after ranibizumab treatment for wet AMD.

However, other studies did not support these findings. A time series [analysis](#) of Canadian data found that the rapid adoption of anti-VEGF therapy for AMD was not associated with an increased rate of hospital admission for stroke. Moreover, a recently published [analysis](#) of Medicare data showed that the introduction of anti-VEGF agents did not increase the risk of stroke in patients with wet AMD.

A Canadian case-control [study](#) found no increased risk of stroke in wet AMD patients treated with bevacizumab, and a [study](#) of Canadian glaucoma disease patients hospitalized for ischemic stroke found they were no more likely to have received intravitreal bevacizumab or

ranibizumab than controls.

The South Korean study provides additional support for the conclusion that intravitreal ranibizumab does not increase stroke risk in wet AMD patients. This study used national registry data on more than 1 million random subjects to compare a ranibizumab-treated group with 2 matched control groups.

The treated group included 467 wet AMD patients who received intravitreal ranibizumab between 2009 and 2013. The first control group included 2330 randomly selected patients matched to the treated group by sociodemographic factors and comorbidities (hypertension, atrial fibrillation, and Charlson comorbidities index score). Another control group of 2331 patients were matched by sociodemographic factors only. Patients were tracked until 2013, and data were analyzed by using Cox proportional hazard regression.

The South Korean team found that stroke occurred in 6.6% of the ranibizumab-treated group, compared with 7.0% of the controls matched by sociodemographic factors and comorbidities and 6.7% of the controls matched by sociodemographic factors only. These differences were not statistically significant.

Moreover, multi-variable Cox regression indicated that the incidence of stroke was similar for the ranibizumab group and the control groups. For the ranibizumab group compared with the control group matched by sociodemographic factors and comorbidities, the HR was 0.88 (95% CI, 0.60—1.30). For the ranibizumab group compared with the control group matched by sociodemographic factors only, the HR was 0.95 (CI, 0.64–1.41).

As a result, the South Korean team concluded that ranibizumab treatment for wet AMD did not increase the risk of stroke compared with the risk for matched controls.

The study, "[Intravitreal ranibizumab therapy for neovascular age-related macular degeneration and the risk of stroke: a national sample cohort study](#)," was published in the November 2016, issue of *Retina*.

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Conversations Can
Transform Prevention*

**Jaimee Colvin, MSN,
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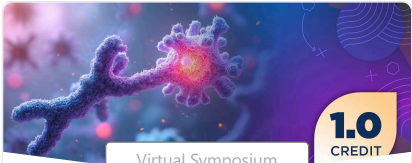
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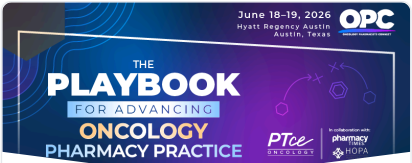
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