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Service (sector) Retina and Vitreous N° CEP

FOCAL EPIRETINAL DELIVERY OF BETA-RADIATION

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Purpose: To determine the feasibility and safety of Neovista focal epiretinal radiotherapy for exudative AMD. Methods: In this AMD pilot study, subfoveal active CNV was treated with custom designed intraocular focal radiation delivery device delivering 15 or 24 Gy. Following institutional review board approval and informed consent, patients underwent ETDRS visual acuity (VA), slit lamp and dilated fundus examinations, OCT and fluorescein angiography. CNV lesion greatest linear dimension (GLD) was required to be < 5400 microns. Patients with other diseases causing visual loss or prior treatment of subfoveal CNV were ineligible. Eligible patients underwent pars plana vitrectomy, insertion of the radiation delivery device into the intravitreal space overlying the CNV followed by focal radiation treatment in the CNV area. Follow-up visits occurred at 1 day, 1 week, 1, 2, 3 and 6 months. Results: 29 eyes of 29 patients (55 to 86 years old) received 15 (8 eyes) or 24 Gy (21 eyes) focal epiretinal radiation to CNV from the Neovista focal radiation devices. The procedure averaged 20 minutes and the treatment time 3,5 to 4 minutes. Follow-up ranged from 1 to 6 months (median 3 months). VA was stable/improved in 100% (48% / 52%) at 1 month, 100% (44% / 56%) at 3 months and 100% (60% / 40%) at 6 months. Compared to baseline, leakage decreased 2% by 1 month, 28% by 3 months and 37% by 6 months. No retinal detachments or endophthalmitis occurred. Conclusions: This small pilot study has shown evidence that the Neovista Focal Brachytherapy device is associated with early positive effects. Further work is indicated for assessing long-term impact on VA of this new technology.