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## Association of macular disease with long-term use of pentosan polysulfate sodium: findings from a US cohort

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## **Abstract**

**Background/aims:** A series at a single clinical centre recently demonstrated an association between the interstitial cystitis drug pentosan polysulfate sodium (PPS) and a vision-threatening pigmentary maculopathy. The aim of this study was to determine if an association exists between PPS use and macular disease in a large national cohort.

**Methods:** A retrospective, matched cohort study using data from a large US medical claims database from 2002 to 2016 was performed. A total of 3012 and 1604 PPS users were compared with 15 060 and 8017 matched controls at 5 and 7 years, respectively. The primary outcome measures included (1) any new diagnosis of a hereditary or secondary pigmentary maculopathy (atypical maculopathy outcome), and (2) any new diagnosis of dry age-related macular degeneration (AMD) or drusen in addition to the aforementioned diagnoses (atypical maculopathy+AMD outcome).

**Results:** At the 5-year and 7-year follow-up, 9 (0.3%) and 10 (0.6%) PPS patients progressed to the atypical maculopathy outcome compared with 32 (0.2%) and 25 (0.3%) control patients, respectively. 103 (3.4%) and 87 (5.4%) PPS patients developed the atypical maculopathy+AMD outcome compared with 440 (2.9%) and 328 (4.1%) control patients at 5 and 7 years, respectively. At 5 years, multivariate analysis showed no significant association (p>0.13). At 7 years, PPS users had significantly increased odds of having the atypical maculopathy+AMD outcome (OR=1.41, 95% CI 1.09 to 1.83, p=0.009).

**Conclusions:** PPS exposure was associated with a new diagnosis of macular disease at the 7-year follow-up in a large national cohort.

Keywords: drugs; macula.

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