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## Use of azathioprine and the risk of cancer in inflammatory bowel disease.

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## **Abstract**

Increased risks of lymphoma and skin cancer associated with thiopurine use among patients with inflammatory bowel disease have been shown, but data on the overall cancer risk are limited. We conducted a historical cohort study of 45,986 patients with inflammatory bowel disease (of whom, 5,197 (11%) used azathioprine) in Denmark from 1997 to 2008. We linked registry data on filled drug prescriptions, cancer diagnoses, and covariates and compared rates of overall incident cancer and cancer subgroups between users and nonusers of azathioprine, adjusting for propensity scores. During a median 7.9 (interquartile range: 3.5-12.0) person-years of follow-up, 2,596 incident cases of cancer were detected. Azathioprine use was associated with an increased risk of overall cancer (rate ratio = 1.41, 95% confidence interval: 1.15, 1.74), whereas former use of azathioprine (rate ratio = 1.02, 95% confidence interval: 0.83, 1.25) or increasing cumulative received doses (increase in rate ratio per 365 additional defined daily doses = 1.06, 95% confidence interval: 0.89, 1.27) were not. In subgroup analyses, azathioprine use was associated with increased risk of lymphoid tissue cancer (rate ratio = 2.40, 95% confidence interval: 1.13, 5.11) and urinary tract cancer (rate ratio = 2.84, 95% confidence interval: 1.24, 6.51). In conclusion, azathioprine use was associated with an increased risk of overall cancer in patients with inflammatory bowel disease, although these data cannot establish causality.

KEYWORDS: immunosuppressive agents; inflammatory bowel diseases; neoplasms; pharmacoepidemiology; registries

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