Mayo Clinic researchers have found that azathioprine, a drug commonly used to treat autoimmune disease, may increase the risk of myeloid neoplasms. Myeloid neoplasms include a spectrum of potentially life-
threatening bone marrow disorders, such as myelodysplastic syndromes and acute myeloid leukemia. The results are published in *JAMA Oncology*.

Researchers analyzed more than 40,000 patient cases with 27 common autoimmune diseases, such as Lupus, rheumatoid arthritis, among others, that were seen over a decade at Mayo Clinic. They identified 86 patients with therapy-related myeloid neoplasm. Detailed data on each patient's drug exposures, duration and disease characteristics were collected and compared to autoimmune patients without bone marrow disorders of myelodysplastic syndromes or acute myeloid leukemia. The results concluded that only azathioprine was statistically significantly associated with an increased risk of therapy-related myeloid neoplasm. However, other agents used showed a similar trend that was not statistically significant.

"Similar associations were already documented in case reports and case series, but have never been evaluated in a broad spectrum of autoimmune diseases in that many patients and in context of individual medications," says Raoul Tibes, M.D., Ph.D., senior author of the study and former director of the Acute and Chronic Leukemia Program at Mayo Clinic's Arizona campus. "Interestingly, there was no association with length of time on therapy and resulting myeloid neoplasm."

"This study, along with our current knowledge of therapy-related myeloid neoplasm, suggests that individualized drug selection and monitoring during treatment could be possible," says Natalie Ertz-Archambault, M.D., co-author of the study. "Future genomic profiling studies may help to identify patients at risk for myeloid neoplasms when exposed to azathioprine or other drugs," adds Dr. Tibes.

The researchers emphasize that, while the results of the study are intriguing, they should not change or replace the clinical judgments,
monitoring and current standard treatments at this stage for patients with an autoimmune disease.

Despite its large size, the researchers note this study's limitations. It was a retrospective study. Many different autoimmune diseases were analyzed, which can each affect the results. Only myelodysplastic syndromes and acute myeloid leukemia were assessed. And no definitive causal association was made between taking a particular drug and myelodysplastic syndromes or acute myeloid leukemia. Further, the number of patients with autoimmune disease developing myelodysplastic syndromes or acute myeloid leukemia is still low overall, and no prediction for individual patients can be concluded from the study.

The researchers plan to perform molecular investigations into the genetic susceptibility for therapy-related myeloid neoplasm as the next phase of the study.

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