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TRANSPLANTATION

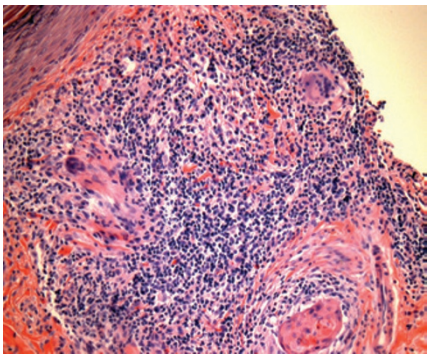
Does switching to a CNI-free regimen reduce cancer risk?

Data from the open-label, randomized, multicenter CONVERT study indicate that conversion from a calcineurin-inhibitor (CNI)-based immunosuppression regimen to a sirolimus-based regimen is associated with a decreased rate of malignancy in renal transplant recipients.

Prolonged use of immunosuppressive agents in transplant recipients, which is necessary to prevent rejection, is also associated with an increased risk of most types of malignancy, particularly nonmelanoma skin carcinomas. Some studies have indicated that skin malignancies are less common in renal transplant recipients on sirolimus-based regimens than among those on CNI-based regimens. Although not the primary focus of the CONVERT study, summary data from the study showed similar findings and led to the performance of a more extensive *post hoc* analysis of the data.

The study analyzed data from 824 renal transplant recipients who had received their renal allografts 6–120 months before randomization. Included patients had to be receiving corticosteroids plus a CNI within 2 weeks after transplantation, plus azathioprine or mycophenolate mofetil for at least 12 weeks before randomization. Patients were randomly assigned to conversion to sirolimus ($n = 551$) or to CNI continuation ($n = 273$).

After 2 years, the overall rate of malignancy was significantly lower in the sirolimus-conversion group than in the CNI-continuation group (2.1 versus 6.0 per 100 person-years of exposure; $P < 0.001$). The differences in malignancy rates persisted after controlling for potentially confounding factors including age and time from transplantation. Nonmelanoma skin carcinomas accounted for most of the malignancies, and rates of these malignancies were lower in the sirolimus-conversion group than in the CNI-continuation group (1.2 versus 4.3 per 100 person-years of exposure; $P < 0.001$). The rates of other cancer types were not significantly different between the two groups.



Histopathology of a squamous-cell carcinoma. Permission obtained from Nature Publishing Group © Neville, J. A. *et al. Nat. Clin. Pract. Oncol.* **4**, 462–469 (2007).

"These findings could serve as the basis for future randomized clinical trials evaluating rates of malignancy in transplant recipients," state the authors.

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Original article Alberú, J. *et al.* Lower malignancy rates in renal allograft recipients converted to sirolimus-based, calcineurin inhibitor-free immunotherapy: 24-month results from the CONVERT trial. *Transplantation* **92**, 303–310 (2011)