

Substitution of brand name with generic drug proves safe for transplant recipients

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A new study published in the *American Journal of Transplantation* reveals that substitution of a brand name immunosuppressive drug with a generic (manufactured by Sandoz) for preventing rejection of transplanted organs appears to be safe for transplant recipients.

Tacrolimus is an immunosuppressive drug that is used to prevent rejection of transplanted organs following [organ transplantation](#). In August 2009, another pharmaceutical company received approval from the FDA for a generic tacrolimus product.

In the first formal study of its kind, Raman Venkataramanan, PhD, of the University of Pittsburgh, School of Pharmacy and School of Medicine, and researchers analyzed database information regarding tacrolimus concentrations and indices of liver and kidney function before and after generic substitution in 48 liver and 55 [kidney transplant recipients](#).

Substitution of brand name tacrolimus product with the generic formulation resulted in an average reduction of 15.9% and 11.9% in concentration/dose ratio in clinically stable liver and [kidney transplant patients](#), respectively. The substitution was safe, as no changes occurred in liver or [kidney function](#) and no acute rejection episodes occurred during the follow-up time period.

An accompanying editorial by G.B. Klintmalm of Baylor University Medical Center, while offering a different viewpoint, also calls upon the

FDA to change the requirements for approval of these drugs in order for the transplant community to trust and rely on generic [immunosuppressive drugs](#) for the treatment of transplant recipients.

Klintmalm notes that "in order to safely save healthcare dollars, it is urgent that the FDA step up to the plate to implement changes in its approval process for generics of critical-dose drugs."

"Our findings suggest that transplant patients currently taking the brand name tacrolimus formulation may be safely switched to the generic product," Venkataramanan concludes. "However, on an individual basis, since some patients had significant changes in tacrolimus blood levels, increased monitoring of tacrolimus blood levels is necessary following the substitution to assure adequate drug concentrations. Long-term use of generic product will lead to cost savings."

Provided by Wiley

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