

Drug may prolong organ life in noncompliant kidney transplant patients

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New research from the University of California, San Diego Department of Medicine, Division of Nephrology, shows that the anti-rejection drug sirolimus (brand name Rapamune) may help prolong the clinical benefit of transplanted kidneys and delay rejection, especially in patients who do not regularly take their prescribed medications (are "non-compliant"). While the transplant field has been highly successful at reducing rejection and graft loss in the first year, post-transplant, reducing risk for graft rejection in the long-term has proved more difficult.

The findings are being presented at the 2008 American Transplant Congress (ATC), in Toronto on Saturday, May 31, 2008, by Cheri Ye, M.D., who was mentored by Robert Steiner, M.D., professor of medicine, and Director of Transplant Nephrology.

"No one is perfect at taking medications," explained Steiner. "But missing doses of immunosuppression, or not taking full doses each day, will bring about gradual rejection of kidney transplants that is almost impossible to detect in its early stages. Long acting drugs like sirolimus may help with this problem."

A team of five UC San Diego investigators reported a careful assessment of immune function at "trough" levels (lowest daily levels) of the three most commonly used immunosuppressive drugs, using an assay (ImmuKnow®/ Cylex) designed specifically to measure the degree of immunosuppression at any given time. Lower "mitogenic response" meant better immunosuppression and more protection from rejection.

On average, the participants, 160 kidney transplant patients, were 6.4 years out from their transplant.

At these trough levels of drug in the blood stream, the assay demonstrated that sirolimus caused a significantly lower level of mitogenic response, and results appeared to be stable in individual patients over time.

"At least half of transplanted kidneys are lost through chronic graft rejection, usually within 10 years. When patients do not have those rejection problems, they can go for 20 to 30 years before kidney rejection or other serious problems. This is an especially important issue now because of our nationwide donor-organ shortage," said coauthor, David Perkins, M.D., Ph.D., professor of medicine & surgery, and Director of Research for Transplantation.

"This study was not commercially funded," added Steiner. "We just wanted to confirm what we suspected from experience in our transplant clinic, where we focus on compliance in many ways to help our patients keep their kidneys functioning well. We showed that when the daily dose is wearing off and another dose is due to be taken, patients taking sirolimus could be more protected against rejection than other commonly used agents."

The assay used is the only commercially available of its kind, and potentially valuable, but researchers emphasized that experience and understanding of it is limited.

"Our ATC abstract is a report of clinical experience, but real progress is often made at the level of basic science. My laboratory is studying this intensively at a basic level in several ways, including looking at the genetics associated with various responses to the assay," said Perkins.

The researchers believe that this new study may help develop tools to monitor patients in the long-term, and also contribute to a protocol for using sirolimus in less compliant patients. Steiner pointed out that, "The best results will occur if we prevent rejection, because once rejection is established the threat to graft survival is much greater, no matter what we do."

Source: University of California - San Diego

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