

Drugs commonly used in kidney transplant patients not as effective as previously thought

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Kidney transplants saves lives and dramatically improve quality of life, but transplant recipients often must take dozens of pills a day to keep their new kidney functioning and prevent complications. Now, three new studies led by researchers at The Ottawa Hospital and the University of Ottawa show that three of these drugs are not nearly as effective as previously thought and may have serious side-effects. The results are expected to change medical practice around the world.

The most recent study, published in *The Lancet Diabetes & Endocrinology* on October 22, 2015, tested a drug called ramipril in [kidney transplant](#) patients with high levels of protein in the urine (which is considered a risk factor for kidney failure). The randomized, double-blinded trial included 212 patients from 14 centres in Canada and New Zealand and was funded by the Canadian Institutes of Health Research (CIHR).

After an average follow up of four years, there was no difference in key markers of kidney health among those who received the drug compared to those who received a placebo. In addition, patients who received ramipril were more likely to experience side-effects such as low blood counts (anemia), which can contribute to transplant failure and death.

"Ramipril lowers blood pressure, and previous research has shown that it reduces the risk of kidney failure in high-risk patients who have not had a transplant," explained Dr. Greg Knoll, co-lead author of the study and a kidney transplant specialist and scientist at The Ottawa Hospital and

the University of Ottawa. "Many people assumed that ramipril would also help high-risk [transplant patients](#), so this drug has been commonly used in these patients despite limited evidence of benefit."

"Our study shows that ramipril provides no significant benefit to high-risk kidney transplant patients," concluded Dr. Dean Fergusson, co-lead author of the study and an epidemiologist and senior scientist at The Ottawa Hospital and the University of Ottawa. "We expect that this will change [medical practice](#) around the world and spare patients from taking unnecessary and potentially harmful medication."

The study comes on the heels of two similar studies also led by Drs. Knoll and Fergusson.

One, published in the *Journal of the American Medical Association* in November 2014, examined a drug called levofloxacin, which had been commonly used to prevent infection with the kidney transplant-related BK virus. The randomized, double-blinded trial included 154 transplant patients from seven Canadian centres and was funded by the CIHR. The results, summarized here, show that levofloxacin does not prevent BK virus infection, and in fact, is associated with a higher risk of developing antibiotic-resistant bacterial infections.

The last study, published in the *British Medical Journal* in November 2014, examined a drug called sirolimus, which suppresses the immune system and prevents transplant rejection. The challenge with many immune-suppressing drugs is that they can also increase the risk of cancer, but sirolimus was thought not to have this pitfall, so it was commonly prescribed to transplant patients with a high risk of cancer. Drs. Knoll and Fergusson conducted a meta-analysis of sirolimus in nearly 6,000 kidney transplant patients who participated in 21 trials around the world. The results, summarized here, show that while sirolimus does indeed lower the risk of cancer, patients who took the

drug were 43% more likely to die overall. This study was funded by Pfizer.

"It's quite astounding that in the last year, we've found that three drugs commonly used in kidney transplant patients either don't work at all, or don't work nearly as well as we thought," said Dr. Knoll. "This shows how essential it is to conduct rigorous research to evaluate [drug](#) treatments."

"Taken together, these studies will save lives, improve quality of life and save the health care system money," said Dr. Fergusson. "They also open the door to research on new treatments that hopefully will provide more benefit to patients."

Jim Ward received a kidney transplant from his brother in 2001 and has participated in research led by Drs. Knoll and Fergusson at The Ottawa Hospital. "While it's disappointing to find these drugs do not work, it's only through research we can discover this information, and eventually prevent and eliminate kidney disease," he said.

More information: *The Lancet Diabetes & Endocrinology*, [www.thelancet.com/journals/lan ... \(15\)00368-X/abstract](http://www.thelancet.com/journals/lan... (15)00368-X/abstract)

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