

Study questions safety and effectiveness of common kidney disease drugs

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Drugs commonly prescribed to patients with chronic kidney disease (CKD) may not be as strongly effective as once thought, and may cause unexpected harm to blood vessels, according to a study appearing in an upcoming issue of the *Journal of the American Society of Nephrology* (*JASN*). The findings indicate that additional studies on the drugs, called phosphate binders, are needed.

Higher <u>blood levels</u> of phosphorus that are still within the normal range have been linked with <u>heart problems</u>, kidney disease, and <u>premature</u> <u>death</u>. Because the kidneys get rid of excess phosphorus by excreting it through the urine, patients with CKD often have elevated blood <u>phosphorus levels</u>.

Drugs called phosphate binders can lower blood phosphorus levels, and while they are approved only for patients with <u>kidney failure</u>, they are often prescribed off-label to patients with CKD. Geoffrey Block, MD (Denver Nephrology) and his colleagues evaluated the effects of these drugs (calcium acetate, lanthanum carbonate, sevelamer carbonate) in patients with moderate to advanced CKD and normal or near normal blood phosphorus levels.

The study included 148 patients who were randomized to receive one of the three phosphate binders or a placebo. The investigators examined patients after three, six, and nine months of treatment. The study is the longest placebo-controlled trial of phosphate binders in patients with CKD conducted to date.



Treatment with phosphate binders significantly lowered patients' urinary phosphorus levels, moderately lowered their blood phosphorus levels, and slowed progression of a <u>parathyroid</u> disorder that is a common complication of CKD, while treatment with placebo did not. Despite these positive effects, phosphate binders did not have any effect on the blood levels of a hormone that regulates phosphate excretion in the urine, and the drugs caused calcium build-up in blood vessels, which can lead to heart problems. Heart disease is the leading cause of death in patients with CKD.

These findings call into question the safety and effectiveness of phosphate binders in patients with CKD.

"While we continue to believe that serum, or blood, phosphorus is a key component of the increased cardiovascular risk associated with kidney disease, our results suggest the use of the currently approved phosphate binding drugs does not result in substantial reductions in serum phosphorus and may be associated with harm in this population," said Dr. Block. "Future clinical trials should be conducted in all populations with adequate placebo controls and should address alternative or complementary methods to reduce serum phosphorus," he added.

More information: The article, entitled "A Randomized Trial of Phosphate Binders in Patients with Moderate Chronic Kidney Disease," will appear online on July 19, 2012, <u>doi: 10.1681/ASN.2012030223</u>

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