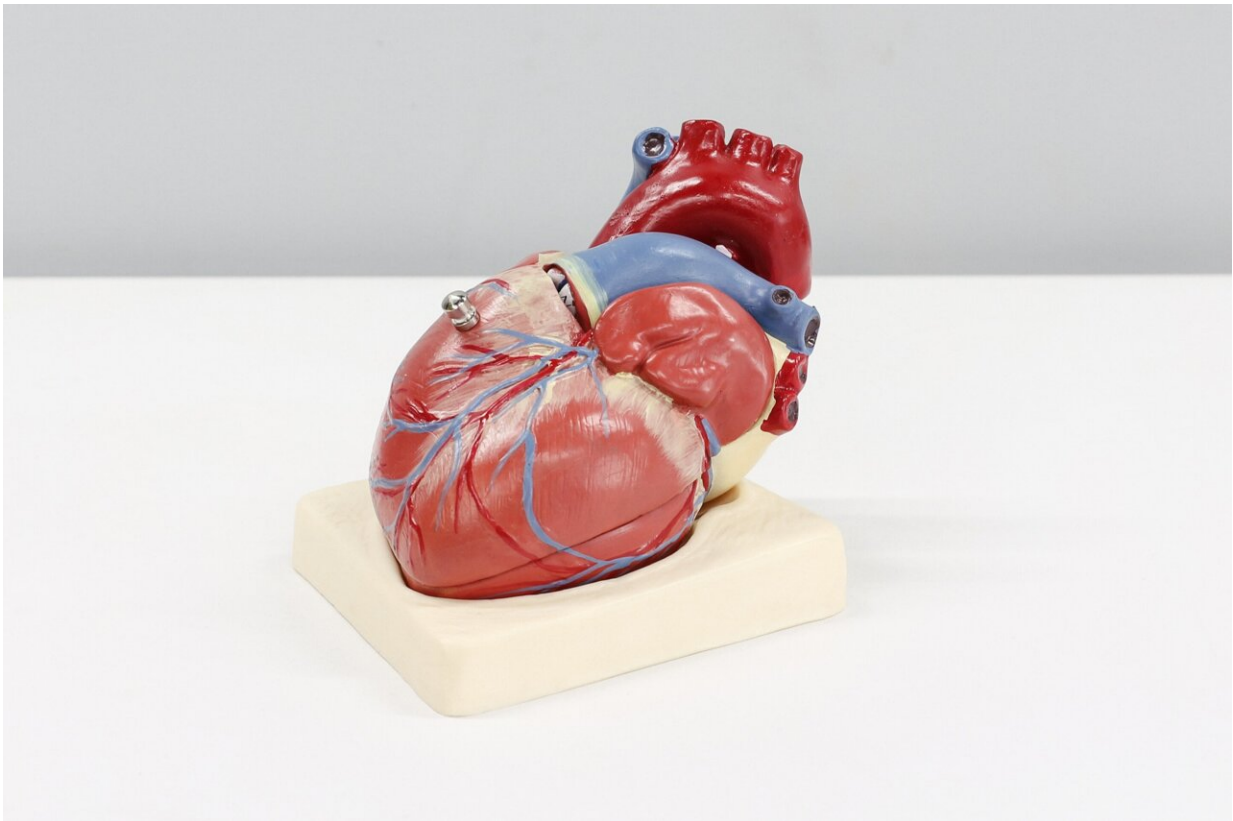


Potassium medication patiromer helps patients stay on optimal heart failure therapy

April 4 2022



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Patients taking renin-angiotensin-aldosterone system inhibitor (RAASi) medications for heart failure had significantly lower blood potassium levels when taking patiromer—a drug that helps to prevent the body

from absorbing too much potassium—compared with a placebo, in a study presented at the American College of Cardiology's 71st Annual Scientific Session.

The results suggest patiromer, which binds to [potassium](#) in exchange for calcium to help the body excrete it along with waste, could be used to help control excess potassium buildup in the blood (hyperkalemia), which is a regular side effect of RAASi therapy. Hyperkalemia can cause symptoms such as [muscle weakness](#), numbness, chest pain, [heart palpitations](#) and nausea. Even though most [patients](#) with high potassium levels experience no symptoms, hyperkalemia is one of the main reasons for discontinuing RAASi medications or lowering the dosage used, leaving patients at increased cardiovascular risk.

"On the basis of these results, unless accessibility or affordability of medications is an issue, there's no good reason not to use potassium binders to optimize [heart failure medical therapy](#)," said Javed Butler, MD, MPH, MBA, president of Baylor, Scott & White Research Institute in Dallas, distinguished professor of medicine at the University of Mississippi and the study's lead author. "For cases where hyperkalemia is the dominant reason for not giving guideline-directed RAASi therapy, I think what we are achieving with patiromer is an enablement strategy to allow patients to get appropriate RAASi therapy while simultaneously lowering the risk of hyperkalemia."

Heart failure is a condition in which the [heart muscle](#) does not pump blood effectively at normal pressures in the [heart](#). RAASi therapy, which helps regulate the abnormal biological processes seen in heart failure, offers significant survival benefits for patients who have heart failure with reduced ejection fraction (HFrEF), the type of heart failure in which the heart doesn't squeeze as strongly as it should, when used according to medical guidelines. However, Butler said, current guidelines recommend stopping RAASi therapy when blood potassium

levels exceed 6 mmol/L, and lowering doses and closely following patients if levels are between 5–6 mmol/L. In practice, clinicians stop or lower these medications about 40%–50% of the time even in patients with potassium levels below 6 mmol/L.

By stopping or reducing RAASi therapy due to hyperkalemia, Butler said many patients miss out on the long-term survival benefits of RAASi therapy to avoid hyperkalemia related risks in the short term.

"We took a very comprehensive look at all levels of hyperkalemia and all levels of RAASi therapy and proved that you really don't have to compromise—you can get good therapy and also lower patients' risk of hyperkalemia," said Butler, who led the study while in a previous role at the University of Mississippi Medical Center.

The trial initially screened 1,642 patients with HFrEF and either a history of hyperkalemia or current hyperkalemia related to RAASi use at 389 medical centers in 21 countries. For the first part of the study, 1,195 patients meeting the [eligibility criteria](#) entered a run-in phase for optimization of RAASi therapy and patiromer treatment for up to 12 weeks. Of those, 1,038 patients completed the run-in phase and 878 patients who had achieved optimized RAASi therapy were randomized to continue taking patiromer or switch to a placebo (patiromer withdrawal). Researchers followed the patients for a median of 27 weeks.

Although neither the study participants nor their treating clinicians knew whether they were taking patiromer or a placebo, their clinicians did know patients' potassium levels over time and were able to adjust RAASi doses accordingly. As a result, many of the treating clinicians lowered the RAASi dosage for patients in the placebo arm. However, even though they were receiving more and higher doses of RAASi medications, the patients who continued taking patiromer still had lower

levels of blood potassium, on average, compared to those taking a placebo, meeting the study's primary endpoint. They also had a lower rate of clinically meaningful hyperkalemia episodes.

"These two things usually go in the opposite direction," Butler said. "You usually have better RAASi therapy and hyperkalemia, or you avoid hyperkalemia but don't optimize RAASi [therapy](#). We took a look to see whether you can win on both."

The study also showed a favorable safety profile for patiromer, with comparable rates of adverse events in both study groups.

Butler said that the trial held a brief pause to redesign the goals in response to the COVID-19 pandemic. The trial was initially designed to assess how the use of patiromer affected morbidity and mortality outcomes, but researchers changed the primary endpoint to blood potassium levels and pre-specified hierarchical endpoints assessing hyperkalemia episodes and RAASi use to better protect patient safety amid the complexities of conducting a clinical trial in high-risk patients during the pandemic.

Common examples of RAASi medications include angiotensin-converting enzyme (ACE) inhibitors, [angiotensin receptor blockers](#) (ARBs), angiotensin receptor-neprilysin inhibitors (ARNi) and mineralocorticoid receptor antagonists (MRAs). Another widely used heart failure medication, beta-blockers, may also cause [hyperkalemia](#).

More information: Javed Butler et al, Patiromer For The Management Of Hyperkalemia In Subjects Receiving Renin-angiotensin-aldosterone System Inhibitor Medications For Heart Failure With Reduced Ejection Fraction: Results From The DIAMOND Trial, American College of Cardiology 71st Annual Scientific Session, April 3, 2022

Provided by American College of Cardiology

Citation: Potassium medication patiromer helps patients stay on optimal heart failure therapy (2022, April 4) retrieved 18 July 2023 from <https://medicalxpress.com/news/2022-04-potassium-medication-patiromer-patients-optimal.html>

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