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'GRANDFATHERED' DRUG FOR HIGH POTASSIUM HAS NO PROVEN BENEFIT

Ion Exchange Resins Probably Wouldn't Be Approved Today, Review Suggests

Washington, DC (March 9, 2010) — For more than half a century, products containing ion exchange resins have been used in patients with dangerously high levels of potassium. However, there is no convincing evidence that these products are actually effective, according to an article appearing in an upcoming issue of the *Journal of the American Society Nephrology* (JASN). "We suspect that if ion exchange resins were introduced today, they would not be approved," comments Richard H. Sterns, MD (Rochester General Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY).

High potassium levels (hyperkalemia) are a potentially life-threatening problem, commonly occurring in patients with kidney disease. Ion exchange resins, mixed with a cathartic called sorbitol, have long been used to treat hyperkalemia. Millions of doses of this product are prescribed every year in the United States—yet it has never been studied with controlled trials to prove it works. Explains Sterns, "these agents came into widespread use in 1958—four years before drug manufacturers were required to prove the effectiveness of their products before gaining FDA approval. Their approval was essentially 'grandfathered.'"

Last year, the FDA issued a warning against giving ion exchange resins with sorbitol, based on reported cases of potentially fatal bowel injury. Yet pre-mixed preparations of the resin with sorbitol are still marketed and widely used. Sterns asks, "If ion exchange resins were presented to the FDA today, with the data available, would the agency rule them safe and effective?"

The answer, according to Sterns, based on a review of the available data is "probably not." "We found no rigorous scientific evidence that ion exchange resins are effective in ridding the body of excess potassium," says Sterns. "In fact, we found some evidence showing that, on rare occasions, they might be harmful."

"We found no evidence that would meet modern standards for drug approval," Sterns and coauthors conclude. They call for further studies to weigh the harms versus benefits of these products. Meanwhile, they believe that doctors should first try other alternatives

to managing high potassium levels, "before turning to these largely unproven and potentially harmful therapies."

Study co-authors are Maria Rojas, Paul Bernstein, and Sreedevi Chennupati, all of Rochester General Hospital.

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The article, entitled "Ion-Exchange Resins for the Treatment of Hyperkalemia: Are They Safe and Effective?" is available online at <http://jasn.asnjournals.org>, 2009, doi 10.1681/ASN.2010010079.

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