

Why So Many Kidneys Are Discarded: An Analysis of 36,700 Discards

Discarded and transplanted deceased-donor kidneys overlap considerably in quality, with many potentially transplantable organs being discarded, suggests a study in *Kidney International*.

Using the Scientific Registry of Transplant Recipients, the researchers identified 212,305 deceased-donor kidneys recovered for transplantation between 2000 and 2015. Of these, 36,700 kidneys were discarded: a rate of 36.7%. Reasons for organ discard were analyzed, along with associated donor- and organ-related factors. The quality of transplanted and discarded organs was compared using the Kid-

ney Donor Risk Index and the Kidney Donor Profile Index.

Three-fourths of discarded kidneys were bilateral discards. The most common reason for discard was “biopsy findings” (38.2%); others included inability to locate a recipient (14.6%), “poor organ function,” (9.6%), and “other” (16.3%). Discarded kidneys had a higher median Kidney Donor Risk Index, 1.78 versus 1.12, but there was large overlap in scores between discarded and transplanted kidneys.

Discard was more likely for kidneys from donors who were black, obese, diabetic, or

positive for hepatitis, and from donors with multiple unfavorable characteristics. Unilaterally discarded kidneys—which accounted for 21.5% of all discards—were from donors with the most desirable characteristics. The transplanted partner kidneys from these donors had good outcomes, with 1-year death-censored survival of over 90%.

The likelihood of discard showed considerable geographic variation, with increased odds of discard for organs recovered in the Southeast, Southwest, and part of the Midwest region.

The number of deceased-donor kidneys

that are recovered but subsequently discarded has been rising steadily in the United States. The factors associated with this trend are unclear.

The new analysis confirms the significant overlap between kidneys that are transplanted versus discarded. Although some discards are inevitable, the researchers write, “this overlap suggests that there are opportunities for improving allocation to facilitate increased utilization.” They discuss the issues raised by organs with “no recipient” located and the rising rate of unilateral kidney discards [Mohan S, et al. Factors leading to the discard of deceased donor kidneys in the United States. *Kidney Int* 2018; DOI: <https://doi.org/10.1016/j.kint.2018.02.016>]. ■

VELTASSA® (patiromer) for Oral Suspension

Brief Summary of Prescribing Information. Please see Full Prescribing Information for complete product information.

INDICATION AND USAGE

VELTASSA is indicated for the treatment of hyperkalemia.

Limitation of Use: VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

CONTRAINDICATIONS

VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components [see *Adverse Reactions*].

WARNINGS AND PRECAUTIONS

Worsening of Gastrointestinal Motility Avoid use of VELTASSA in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because VELTASSA may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies.

Hypomagnesemia VELTASSA binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with VELTASSA [see *Adverse Reactions*]. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels on VELTASSA.

ADVERSE REACTIONS

The following adverse reaction is discussed in greater detail elsewhere in the label:

- Hypomagnesemia [see *Warnings and Precautions*]

Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of VELTASSA cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice. In the safety and efficacy clinical trials, 666 adult patients received at least one dose of VELTASSA, including 219 exposed for at least 6 months and 149 exposed for at least one year. Table 1 provides a summary of the most common adverse reactions (occurring in ≥ 2% of patients) in patients treated with VELTASSA in these clinical trials. Most adverse reactions were mild to moderate. Constipation generally resolved during the course of treatment.

Table 1: Adverse Reactions Reported in ≥ 2% of Patients

Adverse Reactions	Patients treated with VELTASSA (N=666)
Constipation	7.2%
Hypomagnesemia	5.3%
Diarrhea	4.8%
Nausea	2.3%
Abdominal discomfort	2.0%
Flatulence	2.0%

During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of VELTASSA were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%). Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated with VELTASSA in clinical trials. Reactions have included edema of the lips.

Laboratory Abnormalities Approximately 4.7% of patients in clinical trials developed hypokalemia with a serum potassium value < 3.5 mEq/L. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL.

DRUG INTERACTIONS

In clinical studies, VELTASSA decreased systemic exposure of some coadministered oral medications. Binding of VELTASSA to other oral medications could cause decreased gastrointestinal absorption and loss of efficacy when taken close to the time VELTASSA is administered. Administer other oral medications at least 3 hours before or 3 hours after VELTASSA.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

VELTASSA is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

Lactation

Risk Summary

VELTASSA is not absorbed systemically by the mother, so breastfeeding is not expected to result in risk to the infant.

Pediatric Use Safety and efficacy in pediatric patients have not been established.

Geriatric Use Of the 666 patients treated with VELTASSA in clinical studies, 59.8% were age 65 and over, and 19.8% were age 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. Patients age 65 and older reported more gastrointestinal adverse reactions than younger patients.

Renal Impairment Of the 666 patients treated with VELTASSA in clinical studies, 93% had chronic kidney disease (CKD). No special dosing adjustments are needed for patients with renal impairment.

OVERDOSAGE

Doses of VELTASSA in excess of 50.4 grams per day have not been tested. Excessive doses of VELTASSA may result in hypokalemia. Restore serum potassium if hypokalemia occurs.

PATIENT COUNSELING INFORMATION

Drug Interactions Advise patients who are taking other oral medication to separate the dosing of VELTASSA by at least 3 hours (before or after) [see *Drug Interactions*].

Dosing Recommendations Inform patients to take VELTASSA as directed with food and adhere to their prescribed diets. Inform patients that VELTASSA should not be heated (e.g., microwaved) or added to heated foods or liquids and should not be taken in its dry form.

Manufactured for:

Relypsa, Inc.
Redwood City, CA 94063
Version 04: November 2016

References: 1. Weir MR, Bakris GL, Bushinsky DA, et al; for OPAL-HK Investigators. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med*. 2015;372(3):211-221. 2. Data on file as of December 2017. Relypsa, Inc.

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NIH Launches National Enrollment for Historic All of Us Research Program

The National Institutes of Health (NIH) has launched national enrollment for its All of Us Research Program. This historic project aims to collect data from more than 1 million volunteers to accelerate research and enable the delivery of precision medicine by considering factors such as individual lifestyles, environment, and biology.

Participants who volunteer for the program will be asked to contribute information about their medical history and lifestyle over time by completing health surveys, sharing electronic health records, and potentially submitting physical measurements and biosamples. Researchers will conduct studies using the data collected to identify patterns that may lead to medical breakthroughs. Enrollees will be asked to provide input throughout their participation and will be provided their individual study results and summarized data from across the program.

Enrollment is open to anyone over the age of 18 who is living in the United States, regardless of health status. In the future, the program hopes to enroll those younger than 18.

The All of Us Research Program's goal of collecting data from more than 1 million volunteers has great potential to spur scientific and medical breakthroughs. The American Society of Nephrology applauds NIH for undertaking this bold initiative and encourages the entire kidney community to participate in the program. It is essential that individuals affected by kidney diseases volunteer to enroll to ensure the nephrology community makes advances in precision medicine to prevent, treat, and cure kidney diseases.

To learn more about enrollment, please visit JoinAllOfUs.org. ■