

# Comparative Effectiveness of Intravenous Vitamin D Agents

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### INTRODUCTION

The topic of comparative effectiveness research (CER) of therapeutic agents has risen to top of the national healthcare debate with the recent passage of healthcare reform. Dialysis electronic health records provide a unique environment for evaluating CER across multiple categories. We undertook an evaluation of two formulations of intravenous (IV) activated vitamin D used for end stage renal disease (ESRD).

#### METHODOLOGY

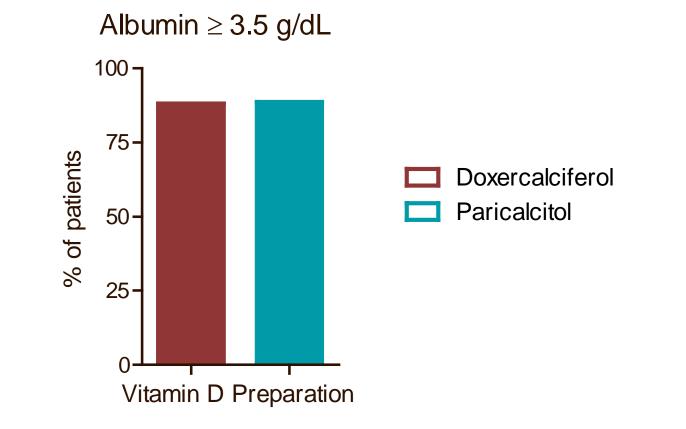
- We analyzed data from a large dialysis organization (LDO) patient database. Patients were included who met the following criteria:
- o received in-center hemodialysis in December 2009
- o over age 18 as of the end of December 2009
- at least one treatment in the month
- o on dialysis for 90 days or more
- at least one of the lab tests each for calcium, phosphorus and parathyroid hormone (PTH) within the last 90 days
- received at least one dose of IV activated vitamin D
- received only one vitamin D formulation during the month
- Patients receiving doxercalciferol were propensity matched at a 1:1 ratio to patients receiving paricalcitol.
- Matching included the following variables: Charlson score, hospitalization, age, race (African American vs. other, Caucasian vs. other), marital status, height, weight (last dry), group within LDO.
- Percent of patients meeting standard mineral and bone disease (MBD) outcomes were determined (using the latest test within 90 days) and compared using a Chi-square.

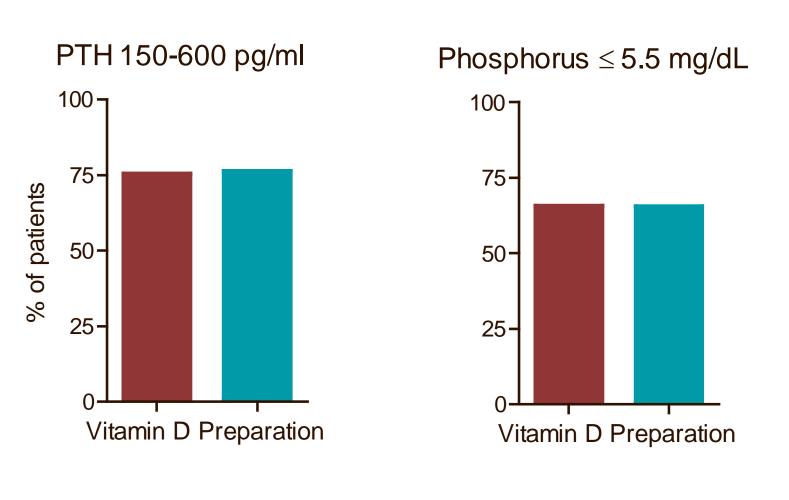
#### RESULTS

Table 1. Patient Demographics

| Mean ± SD                       | Doxercalciferol | Paricalcitol |
|---------------------------------|-----------------|--------------|
| N                               | 9000            | 9000         |
| Age (yr)                        | 60.0±14.7       | 59.8±14.8    |
| % Male                          | 55.5%           | 55.0%        |
| Race and Ethnicity              |                 |              |
| % African<br>American           | 42.6%           | 42.8%        |
| % Hispanic                      | 22.4%           | 20.6%        |
| % Asian,<br>Pacific<br>Islander | 4.0%            | 4.6%         |
| % Native<br>American            | 0.9%            | 1.9%         |
| % Unknown                       | 0.1%            | 0.2%         |
| % Diabetic                      | 72.3%           | 73.7%        |
| Vintage (yr)                    | $4.3 \pm 3.7$   | 4.0±3.5      |
| BMI                             | 28.1±7.3        | 28.0±7.2     |

No statistically significant or clinically meaningful differences remained after propensity match.





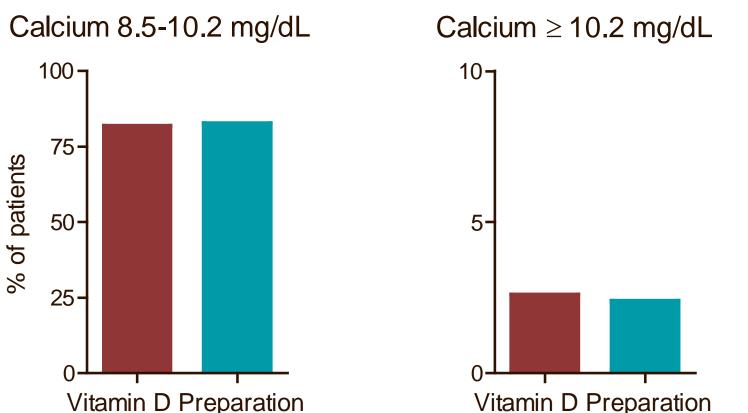


Figure 1. Lab Outcomes by Vitamin D Preparation

## SUMMARY of RESULTS

- In a matched sample of 9,000 patients per group no statistically significant differences were noted between doxercalciferol and paricalcitol with regards to albumin, PTH, calcium, or phosphorus (Figure 1).
- There was no evidence of superiority of either agent on markers of bone and mineral metabolism or nutrition.

#### KEY LEARNINGS

- ✓ Evaluation of the comparative effectiveness of the two predominant vitamin D preparations showed no significant differences with regards to important MBD outcomes.
- ✓ Our findings illustrate how CER can be useful to preserve superior quality outcomes while responsibly stewarding public funds in a changing reimbursement environment.

We express our sincere appreciation to the teammates in our nearly 1600 clinics who work every day not only to take care of patients but also to ensure the extensive data collection on which our work is based. We thank DaVita Clinical Research® for support in preparing this poster. DCR is committed to advancing the knowledge and practice of kidney care.

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