

OBJECTIVES: Analyze the nature of the relationship between epoetin dose, hematocrit and mortality and determine if there are any implications for establishing hematocrit targets. **METHODS:** Hematocrit, epoetin dose, and other factors were summarized during a 6-month period for incident ESRD patients in the United States Renal Data System data. Mortality rates are summarized over a 1-year follow-up. A Cox regression model was used to evaluate the association between hematocrit, epoetin dose, and mortality controlling for interaction between hematocrit and epoetin dose. **RESULTS:** Overall unadjusted mortality rate was 251 per thousand patients. Analysis showed hematocrit was inversely associated with epoetin dose. For the same observed hematocrit levels, there were widely varying treatment-related survival outcomes. In general, higher hematocrit level is associated with lower mortality while higher epoetin dose is associated with higher mortality. Compared to patients with an observed study hematocrit of 33 to 36 percent and epoetin dose in the first dose quartile, the highest relative risk of death was observed among patients with hematocrit values < 30 percent and epoetin dose in the fourth dose quartile (RR = 2.14 and 95% Ci = 1.88 to 2.42). **CONCLUSIONS:** Failure to control for epoetin dosage will lead to misinterpretation of the correlation between observed hematocrit and survival. Studies that reported an association between hematocrit levels and survival did not adequately control for epoetin dosage and the validity of the inferred survival benefit from increasing hematocrits is questionable. Previously published claims of a survival benefit related to higher hematocrit level should not be used to justify hematocrit targets until further studies are conducted to determine the causal relationship.

URINARY/KIDNEY DISEASES/DISORDERS

URINARY/KIDNEY DISEASES/DISORDERS—Cost Studies

PUK2

A COST COMPARISON ANALYSIS OF TWO CLINICALLY UROSELECTIVE ALPHA BLOCKERS IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

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OBJECTIVES: In the treatment of benign prostatic hyperplasia (BPH), patient and physician concerns regarding vasodilatory side effects have led to the increased use of uroselective alpha-blockade as first-line therapy over less expensive, generic, non-uroselective agents. This study evaluated the relative economic impact of two currently available uroselective agents, alfuzosin and tamsulosin. **METHODS:** A 1-year decision analysis was undertaken to project the medical costs associated with treating symptomatic BPH patients with alfuzosin vs. tamsulosin. Key inputs included clinical data (efficacy and adverse events [AEs]), dosing, and routine medical care costs. Clinical data were derived from a comprehensive meta-analysis published as part of recently published BPH treatment guidelines, and resource utilization information was obtained from published sources and two nationwide physician surveys. **RESULTS:** Both agents had similar efficacy, however, safety profiles differed. Daily average acquisition costs, after adjusting for average wholesale price for tamsulosin (\$1.99) and alfuzosin (\$1.86) and increased daily average consumption (DACON) (17% of patients required a

double dose of tamsulosin), were \$1.98 vs. \$1.58 per patient per day for tamsulosin and alfuzosin, respectively. This difference based upon price and DACON amounted to \$146.00 per patient per year (PPPY) (tamsulosin = \$722.70, alfuzosin = \$576.70). Costs associated with tamsulosin-related AEs were estimated to be \$4.59 PPPY, whereas, alfuzosin-related AEs were \$2.25 PPPY (\$2.34 PPPY difference). Therefore, in considering the price and DACON differential (\$146.00) together with the differential in costs of treating AEs (\$2.34), alfuzosin saved \$148.34 PPPY, a 20% difference. **CONCLUSIONS:** Alfuzosin provides cost savings over tamsulosin in the treatment of patients with symptomatic BPH. Savings are realized primarily on the basis of total drug acquisition costs, followed by lower costs associated with treating side effects of therapy. Alfuzosin is a less expensive alternative to tamsulosin as a first-line clinically uroselective drug therapy in the management of men with BPH.

PUK3

DITROPAN XL PROVIDES SUPERIOR OUTCOMES AND LOWER COSTS COMPARED TO DETROL LA

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OBJECTIVES: This analysis addresses the cost-effectiveness of the extended release formulation of oxybutynin (Ditropan XL) relative to long-acting tolterodine (Detrol LA) for the treatment of overactive bladder in the US. **METHODS:** A previously validated state-transition model was used to compare the health economic outcomes over the course of one year using efficacy data from OPERA, a 3-month randomized, double-blind trial comparing Ditropan XL 10mg once daily to Detrol LA 4mg once daily, together with data from the literature to project outcomes beyond trial time. Five states were defined based on the severity of symptoms (number of incontinent episodes per week). Severity-specific costs (in 2003 US dollars) of pharmaceuticals, doctor visits, and pad or protection usage for incontinence in the US were used. **RESULTS:** Ditropan XL is expected to lead to superior outcomes and lower overall costs compared to Detrol LA. After one year, 4.6 more patients per 100 treated attain complete continence and an additional 2.4 more will have fewer than 7 incontinent episodes per week. Patients on Ditropan XL have almost 11 additional incontinence free days over the course of the year. Costs are expected to be an average of \$43 lower per patient per year. Ditropan XL maintains its advantage over wide ranges of inputs, and outcomes are similar if analyses are limited to only 3 months, the duration of the OPERA trial. **CONCLUSIONS:** These analyses suggest that Ditropan XL provides better health outcomes and lower costs compared to Detrol LA over a 1-year period.

PUK4

OVERACTIVE BLADDER: AN UNDERESTIMATED AND GROWING DISEASE BURDEN

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OBJECTIVES: The age related prevalence of Overactive Bladder in developed economies is estimated at 17% and is comparable with common diseases including depression, osteoporosis, and COPD. The burden of OAB is likely to grow in the future. The