

Many Unaware of Their Chronic Kidney Disease

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DENVER – Of people with at least six clinical markers of chronic kidney disease, 12% were aware of their diagnosis, results from a large analysis showed.

Of the common markers of chronic kidney disease (CKD), only elevated albuminuria was associated with greater individual awareness of chronic kidney disease.

The findings underscore the impor-

tance of good communication when common markers of chronic kidney disease arise, Dr. Delphine S. Tuot said in an interview during a poster session at the meeting.

“Even individuals with six manifestations of CKD – that means they’re hypertensive, they have acidosis, anemia, hyperkalemia, hyperphosphatemia, and albuminuria – are unaware that their kidneys are implicated in these conditions and that they have kidney disease,” said Dr. Tuot of the division of nephrology at the University of California, San Francisco. “I found that astounding.”

She and her associates from the Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team evaluated data from 1,725 nonpregnant adults with chronic kidney disease who participated in the National Health and Nutrition Examination Survey, 1999-2008, and who had seen a health care provider within the previous year. Awareness of chronic disease was defined as answering “yes” to the following question: “Have you ever been told by a doctor or other health care provider that you

have weak or failing kidneys?”

The researchers created a clinical markers index score (CMIS), which ranged from 0 to 7 and consisted of equally weighted binary indicators of abnormal values for clinical markers. Those included albuminuria (a urine albumin to creatinine ratio of greater than 17 mg/g in women and greater than 25 mg/g in men); hyperkalemia (a serum potassium level of greater than 5.0 mEq/L); hyperphosphatemia (a serum phosphate level of greater than 4.5 mEq/L); anemia (a hemoglobin level of less than 12.5 g/dL in women and less than 13.5 g/dL in men); acidosis (a serum bicarbonate level of less than 22 mEq/L); hypertension (greater than 140/90 mm Hg without albuminuria or greater than 130/80 mm Hg with albuminuria); and an elevated blood urea nitrogen level (15 mmol/L or greater).

Next, Dr. Tuot and her associates used multivariable logistic regression to estimate the odds and percentages of awareness of CKD based on respondents’

CMIS, adjusted for demographic characteristics and diabetes, weighted to the U.S. population.

Of respondents with at least six clinical markers of CKD, 12% were aware of their disease, Dr. Tuot reported, compared with 11% who had four to five markers, 10% who had two to three markers, and 6% who had up to one marker.

Of the markers in the CMIS, only albuminuria was significantly associated with greater individual awareness of CKD (odds ratio, 3.4).

“Chronic kidney disease is important,” Dr. Tuot said. “Its presence and consequences

need to be relayed to patients. Have that early conversation and assure patients that just because they have kidney disease does not mean they will need dialysis.”

Dr. Tuot acknowledged certain limitations of the study, including its cross-sectional design and the fact that NHANES lacks specific information about physicians or other health care providers who provided care to the respondents. ■

Even patients who had six manifestations of CKD were unaware – ‘I found that astounding.’

DR. TUOT



VITALS

Major Finding: Of individuals with at least six clinical markers of chronic kidney disease, 12% were aware of their disease, as were 11% with four to five markers, 10% with two to three markers, and 6% with one marker.

Data Source: An analysis of 1,725 nonpregnant adults in the National Health and Nutrition Examination Survey, 1999-2008, who had chronic kidney disease and had seen a health care provider in the previous year.

Disclosures: The project was supported under a cooperative agreement from the Centers for Disease Control and Prevention through the Association of American Medical Colleges. Dr. Tuot said she was supported by the American Kidney Fund Clinical Scientist in Nephrology grant.

observed in an additional 22 patients 12 to 17 years of age who were treated with DULERA in another clinical trial. The safety and efficacy of DULERA have not been established in children less than 12 years of age.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. This effect was observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for “catch up” growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including DULERA, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, each patient should be titrated to his/her lowest effective dose [see *Dosage and Administration* (2.2)].

8.5 Geriatric Use

A total of 77 patients 65 years of age and older (of which 11 were 75 years and older) have been treated with DULERA in 3 clinical trials up to 52 weeks in duration. Similar efficacy and safety results were observed in an additional 28 patients 65 years of age and older who were treated with DULERA in another clinical trial. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. As with other products containing beta₂-agonists, special caution should be observed when using DULERA in geriatric patients who have concomitant cardiovascular disease that could be adversely affected by beta₂-agonists. Based on available data for DULERA or its active components, no adjustment of dosage of DULERA in geriatric patients is warranted.

8.6 Hepatic Impairment

Concentrations of mometasone furoate appear to increase with severity of hepatic impairment [see *Clinical Pharmacology* (12.3)].

10 OVERDOSAGE

10.1 Signs and Symptoms

DULERA: DULERA contains both mometasone furoate and formoterol fumarate; therefore, the risks associated with overdosage for the individual components described below apply to DULERA.

Mometasone Furoate: Chronic overdosage may result in signs/symptoms of hypercorticism [see *Warnings and Precautions* (5.7)]. Single oral doses up to 8000 mcg of mometasone furoate have been studied on human volunteers with no adverse reactions reported.

Formoterol Fumarate: The expected signs and symptoms with overdosage of formoterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the following signs and symptoms: angina, hypertension or hypotension, tachycardia, with rates up to 200 beats/min., arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardiac arrest and even death may be associated with an overdose of formoterol.

The minimum acute lethal inhalation dose of formoterol fumarate in rats is 156 mg/kg (approximately 63,000 times the MRHD on a mcg/m² basis). The median lethal oral doses in Chinese hamsters, rats, and mice provide even higher multiples of the MRHD.

10.2 Treatment

DULERA: Treatment of overdosage consists of discontinuation of DULERA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of DULERA. Cardiac monitoring is recommended in cases of overdosage.

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