

### PUK3 RANITIDINE AND OMEPRAZOLE EFFECT ON SERUM PHOSPHORUS IN HEMODIALYSIS PATIENTS

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**OBJECTIVES:** To evaluate the effect of Ranitidine or Omeprazole in combination with CaCo3 (as a phosphate binder) versus phosphate binders alone on the serum phosphorus level (PO4) in patients performing renal dialysis. **METHODS:** Subjects were at National Institute of Urology and Nephrology (N.I.U.N) and Ain Shams University Specialized Hospital (A.S.U.S.H), Cairo, Egypt. They were classified into three groups. Group I (38 subjects) served as control group in which they received CaCo3 alone. Group II (39 subjects) administered CaCo3 (2 gm-12 gm three times daily) with Ranitidine (150mg twice daily). Group III (31 subjects) received the same dose of CaCo3 with Omeprazole (20 mg once daily). Blood samples were collected monthly for six months during the hemodialysis sessions. **RESULTS:** The obtained data revealed that patients in group II showed marked increase in serum (PO4) level at 4th, 5th and 6th months with significant increase in Calcium-Phosphorus product (CaxP). Significant decrease in serum level of Ca and Alkaline phosphatase (ALP). No significant change in serum PTH level. While in group III, the results show no significant change in serum level of Ca, PO4, PTH, and (CaxP) value with a significant decrease in serum ALP. **CONCLUSIONS:** Ranitidine co-administration with CaCo3 may aggravate hyperphosphatemia. Omeprazole co-administration with CaCo3 may have a beneficial role in minimizing complications in those patients.

### PUK4 THE EFFECT OF PREVENTION USING DRUG THERAPY ON KIDNEY STONE RECURRENCE AFTER MINIMALLY INVASIVE SURGERY IN KAISER PERMANENTE SOUTHERN CALIFORNIA (KPSC)

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**OBJECTIVES:** Surgical intervention (extracorporeal shockwave lithotripsy (ESWL), ureteroscopic lithotripsy (URSL), or staged intervention) is necessary when the likelihood of spontaneous passage of kidney stones is low or complications arise. Secondary prevention can involve drug therapy with allopurinol, thiazides, or potassium citrate, as well as metabolic evaluation to guide drug therapy. Our objective is to evaluate the impact of drug therapy in lowering the risk of kidney stone recurrence. **METHODS:** This retrospective cohort study was conducted in Kaiser Permanente Southern California. Adult patients with a diagnosis of kidney stones and who underwent surgery between July 1, 2006 and June 30, 2008 were selected. Patients were screened for 2.5 years of continuous membership before their surgery [index] date without evidence of previous surgery. Patients were followed until they experienced a recurrence of kidney stones, dis-enrolled from the health plan, death, or the end of study's data period. A Cox proportional hazard model was utilized to estimate the effect of drug therapy on kidney stone recurrence, controlling for other risk factors and the use of metabolic evaluation. **RESULTS:** A total of 2881 patients met inclusion criteria. Only 1159 (40.2%) patients received drug therapy, while 574 (19.9%) patients received metabolic evaluation within 1.5 months of the index date. ESWL was used in 46.6% of patients, URSL in 48.4% of patients, and staged intervention in 5% of patients. 819 (28%) patients had a recurrence (average follow-up: 37.0 months). Drug therapy significantly reduced the rate of recurrence of kidney stone (HR: 0.59, 95% CI = 0.49-0.71, p < .0001) relative to no drug therapy. The significant risk factors for recurrence were the use of ESWL and staged intervention (both vs. URSL), prior use of study drugs or topiramate, and having baseline diarrhea/mal-absorption. **CONCLUSIONS:** Medical prevention using drug therapy had a significant preventive effect on kidney stone recurrence following surgery.

### PUK5 A SYSTEMATIC REVIEW AND META-ANALYSIS OF SOLIFENACIN SUCCINATE VERSUS TROSPIMUM CHLORIDE FOR OVERACTIVE BLADDER

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**OBJECTIVES:** To carry out a systematic review and meta-analysis of solifenacin succinate and trospium chloride, two widely used anticholinergic drugs in the treatment of overactive bladder, in order to provide evidence on which formulary and prescribing decisions can be based upon. **METHODS:** Electronic searches of PubMed, the Cochrane Library, other electronic search engines, as well as manual searches of relevant papers, for randomised controlled trials comparing solifenacin succinate and trospium chloride with one another, with other anticholinergic drugs, or with placebo, from 2003 to October 2011 yielded 260 titles and abstracts from which 8 papers were included in the meta-analysis. Five were trials comparing solifenacin 5mg and 10mg with placebo, while 3 were trials of trospium chloride 20mg (twice a day) immediate release (IR) or 60mg extended release (ER) versus placebo. No direct head to head clinical trials comparing trospium and solifenacin with each other were found. Hence the method of adjusted indirect comparison was used to compare them. **RESULTS:** There was greater improvement from baseline with both solifenacin 5mg and solifenacin 10mg compared to trospium ER in daily micturitions: mean differences (md) (95% CI) -0.89 (-1.14, -0.70) and -1.25 (-1.66, -0.95) respectively, and -0.93 (-1.39, -0.62), and -1.31 (-2.00, -0.85) when compared to trospium IR. Similarly for urinary urgency incontinence: md (95% CI) were -0.78 (-1.43, -0.42) in favour of solifenacin 5mg compared to trospium ER, -0.75 (-1.46, -0.38) in favour of solifenacin 10mg versus trospium ER and -1.55 (-2.17, -1.11) and -1.5 (-2.30, -0.98) comparing solifenacin 5mg and 10mg to trospium IR. There were no statistically significant differences in discontinuations due to adverse

events including both dry mouth and constipation. **CONCLUSIONS:** Solifenacin appears to be more efficacious than trospium (IR and ER) in ameliorating the symptoms associated with overactive bladder syndrome but shows no statistically significant differences in common safety and tolerability issues.

### PUK6 MEDICATION ADHERENCE IN HEMODIALYSIS PATIENTS TREATED WITH PHOSPHATE BINDERS

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**OBJECTIVES:** The purpose of this study was to 1) determine medication adherence in hemodialysis patients initiated on either calcium acetate or sevelamar, and 2) determine the association between adherence to phosphate binder therapy and age in hemodialysis patients. **METHODS:** Using records from incident hemodialysis patients in the Centers for Medicare and Medicaid Services End-Stage Renal Disease database linked with Medicare Part D data, we compiled information on patients treated with phosphate binders (1/2007 - 6/2009). We included patients that were treated with either calcium or sevelamar. Prescription refill records in the 6-month post-index period were assessed and two measures of adherence; proportions of days covered (PDC) and total gap were computed. A PDC of  $\geq 80\%$  was considered adherent. **RESULTS:** A total of 7299 patients that did not switch therapy and survived at least six months from the index phosphate binder date were included in this analysis. Compared to calcium patients, sevelamar patients had a significantly higher mean PDC, a significantly lower mean total gap, were significantly more likely to be adherent; and were significantly less likely to have gaps in medication possession during the first 6 months of pharmacotherapy (P < 0.05). After adjustment for multiple factors, older patients (age  $\geq 75$  at dialysis initiation) had a significantly higher mean PDC, a significantly lower mean total gap, were significantly more likely to be adherent; and were significantly less likely to have gaps in medication possession during the follow up period than did younger patients (age < 75) (P < 0.05). **CONCLUSIONS:** Overall about one-third of the patients included in this study were adherent at 6 months of initiation of phosphate binder therapy (PDC  $\geq 80\%$ ). Patients treated with sevelamar were more adherent than those treated with calcium, and they had fewer gaps in medication possession. Older patients were more adherent than younger patients.

### PUK7 SAFETY OF ERYTHROPOIESIS-STIMULATING AGENTS IN PEDIATRIC PATIENTS WITH END STAGE RENAL DISEASE

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**OBJECTIVES:** Erythropoiesis-stimulating agents (ESA) are used in patients who develop anemia secondary to end-stage renal disease (ESRD). Increase in incidence of thrombosis and death in adult ESRD patients resulted in a warning by the FDA to adjust ESA doses to maintain target hemoglobin of < 12 g/dL. Children with ESRD also develop anemia that ESAs are used to treat. The objective of this study was to determine cardiovascular outcomes associated with ESA use in pediatric ESRD patients. **METHODS:** This is a retrospective study using the USRDS database from 2004-2008. Children 0-19 years old with a diagnosis of anemia (hemoglobin < 5% for age and sex) were included. Patients with evidence of ESA administration prior to dialysis were excluded. Patients were classified as having received ESA or no-ESA. Cardiovascular events (ischemic heart disease, stroke and embolism) were identified using ICD-9 codes. Logistic regression with cardiovascular event as the dependent variable was undertaken. Covariates included diabetes, hypertension and hypercholesterolemia. **RESULTS:** Of 2,138,876 patients, 3,226 met the inclusion criteria, 1,302 with ESA and 1,924 without. The mean age at time of anemia diagnosis was 14.8 years and 14.06 years in the ESA and no-ESA groups, respectively. A cardiovascular event occurred in 277 patients in the ESA group versus 37 patients in the no-ESA group. In the regression model, odds ratios for cardiovascular event were 6.71 (95% CI 4.62-9.73) for ESA therapy and 4.27 (95% CI 3.17-5.76) for patients with hypertension. **CONCLUSIONS:** ESA therapy in pediatric ESRD patients appears to increase risk of a cardiovascular event in pediatric ESRD patients. Further study should be undertaken to confirm these results.

### PUK8 NOCTURIA AND THE RISK OF FALLS, FRACTURES, AND SLEEP DISTURBANCE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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**OBJECTIVES:** To assess the strength of association between nocturia and falls, fractures, and sleep disturbance in the published literature. **METHODS:** A meta-analysis was conducted based on a search of PubMed and EMBASE from inception to October 2011. Studies were included if they reported risk of falls, fractures, or magnitude of sleep disturbance in relation to nocturia status and were in the English language. Data was collected using a standardized data collection instrument. The pooled odds ratio (OR) was calculated using a random-effects model. A qualitative synthesis was conducted in regards to the impact nocturia has on sleep. **RESULTS:** A total of 9 citations examining falls and fractures with respect to nocturia were identified. One was a duplicate, 3 were review articles, and 1 study only focused on qualitative outcomes. The pooled adjusted OR for falls was 1.40 (95% confidence interval (CI), 1.161-1.688). The OR for fractures was 1.23 (95% CI, 1.04-1.45). Forty-four studies examined the relationship between nocturia and sleep. Eleven studies were excluded due to the effect modification that sleep disorders have on nocturia. Other reasons for exclusion included 11 articles due to irrelevant