URINARY KIDNEY DISORDERS – Clinical Outcomes Studies

INCIDENCE AND COST OF ADVERSE EVENTS (AES) IN PATIENTS WITH RENAL CELLMACROUROINARY CARCINOMA (RCC) TREATED WITH ANGIOGENESIS INHIBITORS (AIS)

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OBJECTIVES: The incidence of AES and the costs associated with the management of those AES have not been widely studied in patients with RCC receiving bevacizumab, sorafenib, or sunitinib. This study evaluates these outcomes using a large claims database. METHODS: Patients with ≥ 2 RCC claims (ICD-9 189.0, 198.0) were identified in a large US commercial insurance claims database from 1/02 through 12/08. Patients were observed and analyzed during the time of their first AI treatment with bevacizumab, sorafenib, or sunitinib. AEs were defined as diagnoses that were treatment-emergent (i.e., diagnoses not present in the 6 months prior to initiation of AI treatment). The incidence rate (IR) and mean cost per visit for each AE were calculated in the outpatient, inpatient, and ER settings. Cost data represented actual payments made by insurers. RESULTS: The inclusion criteria identified 269 bevacizumab, 375 sorafenib, and 472 sunitinib patients. The three most frequent AEs experienced by patients in each treatment group were identified based on the overall IR. The setting-specific IRs and costs per visit for these AEs are: bevacizumab: outpatient = 20.3/1,542,16,12,659; inpatient = 3.0/36,220,1,53,142,848; ER = 1.3/5,643,707,24,1,503,158,176; sorafenib: outpatient = 9.0/25,334,3,028,581,3,224; inpatient = 0.5/5,286,1.2/4,182,0.7/2,280,236; ER = 0.3/368,0.7/447,0.4/125,3,654,177; sunitinib: outpatient = 13.3/2,739,3,028,412,57,224; inpatient = 0.8/449,0.5/595,0.4/167,2,060; ER = 0.3/59,0.7/44,0.3/10,643; respectively. For outpatient treatment, there was a trend for IRs for each of the AEs to be the highest for sunitinib. CONCLUSIONS: Bevacizumab, sorafenib, and sunitinib were associated with frequent AEs, in particular abdominal pain, anemia, and hypertension, respectively; sorafenib; outpatient = 24.5/15,292,19,2/226,11,2/828; inpatient = 1.1/25,0.5/210,0.4/205; 1,558,2,578.6/104,1,618; ER = 0/0,3.2/182; 10.3/249 for lung diseases, hypertension, and abdominal pain, respectively; sunitinib: outpatient = 31.0/11,207,2.4/74,3.7/53; inpatient = 3.7/53,118; 1,530,3,643; ER = 2.7/137,277; respectively. An addi-

tional 69.3 kidney grafts per 100 SLK transplants performed when compared with LTA. CONCLUSIONS: An addi-
tional 69.3 kidney grafts per 100 SLK transplants are required to achieve a 6.1 month improvement in survival for SLK transplant recipients.

EFFECT OF ATYPICAL ANTIADVERSE EVENTS (AES) IN PATIENTS WITH RENAL CELLMACROUROINARY CARCINOMA (RCC) TREATED WITH ANGIOGENESIS INHIBITORS (AIS)

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OBJECTIVES: Chronic Kidney Disease (CKD) is a significant health care problem in the United States; iron deficiency anemia can greatly impact resource utilization. We compared patient and health characteristics and health care utilization of members with stage 3 CKD with anemia versus without anemia in a regional integrated health care system. METHODS: Patients 18 and older were identified with a calculated GFR < 60 ml/min/1.73m2 using the MDRD equation or ICD-9 codes. The study results indicate that Glomerular filtration rates and a sample with an estimated Glomerular Filtration Rate (eGFR) ≤60/ml/min/1.73m2 was included in the study. The eGFR was calculated using the 6-variable MDRD equation. Demographics and laboratory records such as Blood Pressure, cholesterol, glucose, albumin, serum creatinine and Vitamin D levels were recorded. RESULTS: An eGFR ≤60/ml/min/1.73m2 was observed in 413 (5.6%) of 7,344 NHANES participants; of which 71.16% were Non-Hispanic Whites, 10.89% were African-Americans and 11.3% were Mexican-Americans. Lower prevalence of Non-Hispanic Americans and African-Americans was observed in higher stages of CKD. Vitamin D deficiency was noticeable in African-Americans and Mexican-Americans compared to Non-Hispanic Whites at 15.28/100 (95% CI: 12.82–19.74), 17.17/100 (95% CI: 14.87–19.47) and 23.8/100 (95% CI: 20.86–26.8) respectively. Serum Creatinine levels were recorded in 1,717/100 (95% CI: 1,278–2,147), 3.351mg/dl (95% CI: 1,166–3,136) and 3.135mg/dl (95% CI: 3,033–4,046) for Mexican-Americans, African-Americans and Non-Hispanic Whites respectively. CONCLUSIONS: Higher prevalence of African-Americans and Mexican-

RETROSPECTIVE DATABASE EVALUATION OF PATIENT CHARACTERISTICS AND HEALTH CARE UTILIZATION OF MEMBERS WITH STAGE 3 CHRONIC KIDNEY DISEASE WITH ANEMIA

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OBJECTIVES: Anemia is prevalent and commonly treated in the elderly population. Understanding the relationship between late stage CKD and prevalent anemia is critical. To compare racial variations in risk factors associated with incidence and severity of chronic kidney disease (eGFR) in the incidence of chronic kidney disease in the US population.

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OBJECTIVES: To compare racial variations in risk factors associated with incidence of Chronic Kidney Disease (CKD) in a sample population (age >11 years) and look for possible early indicators. METHODS: A retrospective study was conducted using the NHANES 2003-2004 database comprising of a nationally representative sample containing nutritional and health records. Patients were screened using the MDRD equation or ICD-9 codes. Mean age was 73.3 and 71.5 years (p < 0.001) for with anemia and without anemia groups, respectively. 58% and 27% of anemia patients had comorbid hypertension and diabetes, respectively, versus 50% and 19% in the without anemia group. Per patient visit to nephrology, inpatient, and ED were as follows: 0.32, 4.33, and 0.13 for anemia, 0.19, 1.74, and 0.28 for without anemia (p < 0.001). Average health care costs during the post-index period was 59% higher (p < 0.001) for renal patients versus patients without anemia. 8% of anemia patients progressed to stage 4 anemia patients. RESULTS: The study results indicate that treatment of anemia improves quality of life and reduces hospitalizations. CONCLUSIONS: Anemia is prevalent and commonly treated in the elderly population. Understanding the relationship between late stage CKD and prevalent anemia is critical.

EVALUATION OF SIMULTANEOUS LIVER KIDNEY TRANSPLANTATION VERSUS LIVER TRANSPLANTATION ALONE FOR END-STAGE LIVER DISEASE PATIENTS WITH IMPAIRED FUNCTION – A COMPARATIVE EFFECTIVENESS ANALYSIS

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OBJECTIVES: Simultaneous liver kidney (SLK) transplant improves the survival of liver transplant candidates with renal insufficiency. The indication for SLK transplant remains controversial due to potential renal recovery after liver transplant alone (LTA). This study aims to (1) investigate the difference in survival between SLK and LTA recipients and (2) estimate the additional number of kidney grafts utilized for SLK transplant. METHODS: The Markov decision model was constructed to simulate a hypothetical cohort of liver transplant candidates with impaired renal function to receive either (1) LTA or (2) SLK transplant strategy. Transplant candidates in each strategy were categorized into 4 groups, based on the Model for End-Stage Liver Disease (MELD) score. LTA recipients without recovering renal function within three months post-transplant were subsequently placed on the kidney transplant waiting list. Liver re-transplant and kidney re-transplant were considered in the model for acute and chronic graft failure post-transplant. The simulation period was 10 years. Microsimulations were conducted to estimate survival by averaging outcomes from 10,000 trials for each transplant strategy. The values and ranges of parameters in the model were obtained from the United Network for Organ Sharing (UNOS) and the Scientific Registry of Transplant Recipients (SRTR) data and published literature. RESULTS: The model demonstrated that the overall survival at 11 years was 73.4% for SLK and 77.4% for LTA recipients, respectively. Of the 10,000 trials, 4,181 isolated kidney transplants were performed when using the LTA strategy. The SLK transplant recipient survival was 6.1 months longer than LTA recipient survival. However, this SLK survival benefit occurred at the expense of an additional 69.3 kidney grafts per 100 SLK transplants performed when compared with LTA. CONCLUSIONS: An additional 69.3 kidney grafts per 100 SLK transplants are required to achieve a 6.1 month improvement in survival for SLK transplant recipients.