

36 mg Bioactive PAC Supplement - **ellura**[®] - for the Prevention of Recurrent Urinary Tract Infections (rUTIs) in Skilled Nursing Facility Residents - An Observational Pilot Study

Bayview Health Care; 301 Rope Ferry Road, Waterford, Connecticut (June – September 2018)
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Introduction: Urinary tract infections (UTIs) are the most prevalent bacterial infection in skilled nursing facilities (SNF), primarily treated with antibiotics. The call for antibiotic stewardship in these facilities stems from the high rates of UTI recurrence, accounting for up to 30% of all infections and 60% of antibiotic prescriptions. Intense antimicrobial use, especially associated with the unnecessary treatment of asymptomatic bacteriuria, has begun to compromise quality care of aging residents, leading to adverse drug reactions and increased rates of antibiotic resistance. In addition, there is a high hospital readmission rate among aging residents with a history of UTIs, contributing to poor quality care and increased healthcare costs. The current situation underscores the need for alternative interventions.

Bayview Health Care (an Athena Health System facility), a 127-bed skilled nursing facility, looked to evaluate the benefits of a urinary tract supplement as a prophylactic alternative to reduce UTI occurrence among residents, and the associated reduction in antibiotic (ABX) utilization. Bayview reported 5.51% of residents with a history of recurrent UTIs (rUTI) over the past year, and a much larger percentage exhibit asymptomatic bacteriuria. Participation in the study was overseen by Bayview's Infection Control Specialist and implemented along with nursing staff.

Objective: The study's primary objective was to examine the benefits of the urinary tract supplement (ellura[®]) in the reduction of culture-proven and symptomatic UTI incidence in participants, as compared with the 6 months preceding the study. (June – September 2018)

Methods: SNF residents that had a documented history of rUTIs (2 UTIs in the previous 6 months or 3 UTIs in the previous 12 months) were included. UTIs were required to be both culture proven and symptomatic. UTI was defined by the McGeer Criteria, which is $\geq 10^5$ (cfu)/mL of ≥ 1 bacterial species in a single urine specimen and signs and symptoms compatible with a UTI. Qualified residents were enrolled to take once daily ellura orally for prevention of rUTI and the associated reduction in antibiotic (ABX) utilization. Two (2) capsules were taken together at approximately the same time daily for sixty (60) days, then one (1) capsule daily for sixty (60) days. Residents were observed taking ellura daily for 120 days. Asymptomatic bacteriuria was not factored as the goal of the study was to evaluate the reduction of culture proven and symptomatic rUTIs.

Intervention: Each ellura capsule contains 36 mg of standardized and bioactive PAC extracted from pure cranberry juice with 100% Anti-Adhesion Activity.

Results: Seven residents were enrolled in the trial; six residents (mean age 78 years, 4 women, and 2 men) completed the study. One male was withdrawn due to non-compliance to PO medications. One male had a suprapubic catheter. One female had an indwelling catheter. The cumulative UTI count in the previous three month period leading up to enrollment was 19, including 8 different bacterium. There were zero (0) culture proven symptomatic UTIs during the 120-day treatment protocol. **ellura was effective in reducing the number of culture proven symptomatic UTIs in all residents (n=6). No residents had adverse events while taking ellura.**

Conclusions: ellura reduced the number of culture proven symptomatic UTIs in this cohort by 100% and the associated antibiotic utilization. Based on this outcome, larger trials are warranted to further define the role of ellura in the prevention of rUTIs in SNF residents.

