TITLE: Single Dose Amikacin for Uncomplicated Cystitis in the ED: A Feasibility Study

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INTRODUCTION: Acquiring an antibiotic prescription and taking pills according to a prescribed schedule is a challenge for some patients discharged from the ED with uncomplicated cystitis. If cystitis could be safely and effectively treated with a single dose of an antibiotic administered in the ED, this would be of potential benefit to such patients.

BACKGROUND AND SIGNIFICANCE: Though evidence suggests safety and efficacy in other settings, there are no ED-based studies evaluating the use of aminoglycosides in single dose for uncomplicated cystitis.

STUDY OBJECTIVES: This study aims to answer the following research question: For emergency department patients with uncomplicated cystitis, will a single dose of IM or IV amikacin result in resolution of symptoms in 3 days?

HYPOTHESIS: A single dose of IM or IV amikacin will result symptom resolution in >80% of emergency department patients with uncomplicated cystitis.

STUDY DESIGN:

Subjects: Emergency department patients with uncomplicated cystitis

Eligibility Criteria: The inclusion criteria are female patients ≥14 with uncomplicated UTI, a primary urinary complaint, and nitrite-positive urine. Exclusion criteria are pregnancy; abnormal genitourinary tract; recent urinary tract instrumentation; immunosuppression; CrCl < 25 mL/min; evidence of pyelonephritis or sepsis; any antibiotic treatment within 30 days; not available for phone followup in 3, 7, and 30 days; requires admission to the hospital; and abnormal mental status.

Design: The study is a prospective open-label cohort study that seeks to enroll 75 ED patients diagnosed with uncomplicated cystitis. Enrolled patients will be treated with a single dose of amikacin. The primary endpoint is clinical cure at 3 days. We chose a non-comparative design as our treatment strategy is literature- and guideline- supported; our goal is demonstrate that it is feasible to execute this approach out of the emergency department. Urine culture is not recommended in the in the initial management of patients with uncomplicated UTI treated in emergency or primary care settings.[3]

Data Collection Procedures: Patients will be enrolled as a convenience sample by the research team. The investigators will determine eligibility, approach the ED clinical team, then approach and consent the patient.

If consented, patient will be treated with amikacin 15 mg/kg IV or IM, based on actual body weight; for patients >120% of IBW, we will use AdjBW (IBW + 0.4(ABW-IBW)) rounded to nearest 50 mg. Patients who already have an IV will receive the medication IV, otherwise the dose will be given IM.

The study measurements at enrollment are age, PMH, meds, allergies, symptoms, and symptom duration as well as urinalysis results, amikacin dose and route. Telephone follow-up at 3, 7, and 30 days will include the following data points: symptom resolution: (complete resolution / mostly better / a little better / same / worse); any new symptoms; any provider visits since index visit (if any visits, describe).

Sample Size: This is a pilot/feasibility non-comparative study, we determined a sample size of 50 subjects empirically then added 25 for consideration of patients lost to follow-up.

Data Analysis: This is an observational study. The data will be summarized by the use of descriptive statistics, using percentages for all categorical variables and using means with standard deviations or medians with lower and upper ranges for all continuous variables. Bivariate analyses (t-test or chi-square test) will be used for comparison pre and post intervention. Levels of significance will be tested at $P<0.05$ and/or 95% Confidence Interval. Analyses will be conducted using SPSS (version 27.0).

Expected Outcomes: Our hope is that the study will demonstrate that it is feasible to treat ED patients with uncomplicated cystitis with amikacin, and that >80% of patients treated with amikacin will have resolution of symptoms in 3 days.

Adverse Event Reporting: Adverse events will be explicitly interrogated by patient interview at 3, 7, and 30 days. Any serious adverse events will be reported to the IRB within 24 hours.

REFERENCES

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