Urinalysis Results in Healthy Individuals

NCT04055675

July 19, 2019

Introduction:

The urinalysis (UA) is one of the most commonly utilized tests in the emergency department (ED) [1]. In some busy EDs, a UA is routinely ordered by protocol on patients with abdominal pain, and in elderly patients, a UA is often ordered for a variety of chief complaints including dizziness and altered mental status. When these patients, who often do not specifically have symptoms of a urinary tract infection, have a urinalysis demonstrating pyuria or bacteriuria, it may be interpreted as an atypical presentation of a UTI. However, it is possible that these patients do not have urinary tract infections, but have baseline pyuria or bacteriuria. One prior study found that 5% of sexually active healthy women 18-40 have asymptomatic bacteriuria [2], and the rate of asymptomatic bacteriuria increases with age, such that it is present in 8-10% of women from 70-80 years of age [3]. Moreover, one prior article stated that 30-50% of residents of long term nursing facilities have positive urine cultures at any given time [4].

The above statistics come from the results of urine cultures. In the ED, the decision to treat or not treat a patient for a UTI is not made based upon culture results, but upon a urinalysis (microscopic or dipstick). To our knowledge, only one prior study has looked at the frequency of abnormal urinalyses in healthy individuals, and it found that over a third of asymptomatic women had at least 1+ leukocytes in their urine [5]. This is evidence that a substantial number of people who do not have symptomatic UTIs have UAs that could be interpreted as UTIs. If these results could be replicated and expanded to include a wider group of individuals (males, elderly patients, various races, etc.), it would provide valuable information about how we can better interpret and utilize the results of a UA.

Thus, we propose a prospective study to assess the frequency of abnormal UAs in a wide variety of individuals without acute symptoms.

Methods:

This will be a prospective, observational study of subjects over the age of 18.

Any person over the age of 18 who is able to spontaneously provide a urine sample may be included. Exclusion criteria include any acute symptoms, active vaginal bleeding or abnormal discharge, pregnancy, prisoner status, antibiotics within the last 72 hours, or urologic procedure within the last week. Patients will be sampled from volunteers in the community.

All volunteers will sign a written consent, approved by the IRB. The consent form discusses the risks and benefits of our study.

The patient will fill out a brief data collection form to include their age, gender, weight, race, whether or not they reside in a long-term nursing facility, and chronic medical problems,.

Urine will be collected by all subjects by midstream clean-catch technique after receiving standardized verbal and written instructions. In particular, female subjects will be instructed on how to provide a mid-stream sample: void initially in the toilet, then spread the labia to collect a sample. We won't mandate perineal cleansing as that has not been shown to decrease perineal flora contamination [6].

While some EDs use microscopic UAs to evaluate for UTIs, urine dipstick (Mission® Urinalysis Reagent Strips) has been compared to microscopic testing in many prior studies [7,8,9,10,11]. Some show microscopic tests to be a bit more accurate [8,9,10], while others find similar accuracies [7,11]. Overall, urine dipstick is thought to have a very high sensitivity for UTI [12,13,14], and for the simplicity of this study, we will only use urine dipstick results to determine if a patient has a UTI.

Subjects will void into a sterile cup. While wearing gloves, the research assistant will place the dipstick such that all markers are immersed in the urine for 3 seconds. The urine will be analyzed after 2 minutes (as per manufacturer instructions).

The definition of a positive urinalysis is variable in the literature. These studies define a positive UA as having at least 1+ leukocytes or any nitrite [5, 15], while other studies have defined a positive UA as having any leukocyte or nitrite [8, 12]. As a means to not overestimate the rate of positive UAs in asymptomatic individuals, we will define a positive UA as one in which the dipstick shows at least 1+ leukocytes or positive nitrites.

The patient will be informed of the results of their UA, but since all patients in this study will have no acute symptoms, no patients will be treated with antibiotics. If there is an abnormal result (such as hematuria or proteinuria), the patient will be counselled to follow up with a primary care doctor.

The primary outcome for this study is the overall frequency of urine dipsticks that are positive (as defined above) in subjects without symptoms of a UTI. Secondarily, we seek to determine if the frequency of positive UAs varies based on gender, age, chronic medical problems, or living facility. Multivariate linear and logistic regressions will be performed to determine if certain factors are associated with an increased risk of pyuria or urinary nitrites.

In order to protect the privacy of the research subjects and to maintain the confidentiality of the data, all data will be handled only by research staff. No protected health information will be collected except on the consent form, which will be stored separately from the data collection form.

We intend to enroll 200-300 healthy volunteers.

References:

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