

## **A Prospective Randomized Trial of Povidone-iodine Prophylactic Cleansing of the Rectum Prior to Transrectal Ultrasound-Guided Prostate Biopsy**

**Introduction and Objectives:** Infectious complications (IC) after transrectal ultrasound-guided prostate biopsy (TRUSBx) include bladder and prostate infections in 3-11% and sepsis in 0.1-5% of patients. This trial investigated the safety and efficacy of Povidone-iodine prophylactic cleansing of the rectum prior to TRUSBx on the rate of IC.

**Materials and Methods:** There were 1069 men invited to participate in this trial, of whom 865 met criteria and were randomized prospectively to undergo TRUSBx with (n=421, "treatment") or without (n=444, "control") rectal cleansing. All patients delivered urine and rectal swab cultures prior to TRUSBx and received a 3 day course of ciprofloxacin prophylaxis. Patients measured their temperature for 48 hours after TRUSBx, delivered a urine culture after 48 hours, and completed a telephone interview after 7 days. The primary endpoint was the rate of IC, a composite endpoint consisting of: 1. fever  $>38.0^{\circ}\text{C}$ , 2. urinary tract infection (UTI), or, 3. sepsis (standardized definition). Chi-square significance testing was performed for differences between groups, and a multivariable analysis was performed to assess risk factors for IC.

**Results:** IC was observed in 11 (2.6%) treated and 20 (4.5%) control patients ( $p=0.15$ ). Sepsis was observed in 1.0% of treated and 1.6% control patients ( $p=0.55$ ). Rectal swab cultures revealed ciprofloxacin resistance in 20% of patients, of whom 3.5% developed IC. On multivariate analysis, resistance to ciprofloxacin in the rectal swab culture ( $p<0.001$ ) and a history of taking ciprofloxacin in the three months preceding TRUSBx ( $p=0.009$ ) predicted IC. No significant adverse effects to rectal cleansing were observed.

**Conclusions:** Rectal cleansing with iodine prior to TRUSBx was safe but the 42% relative risk reduction of infections was not statistically significant. Ciprofloxacin-resistant flora were found frequently, but only a small fraction of these patients developed an infectious complication.