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A prospective randomized trial of Povidone-iodine prophylactic cleansing of the rectum prior to transrectal ultrasound-guided prostate biopsy.

Zeid Abughosh, Zarqa, Jordan, Joseph Margolick, S. Larry Goldenberg, Kouros Afshar, Stephen Taylor, Dirk Lange, Ben Chew, Martin Gleave, Alan So, Martin McLoughlin, William Bowie, Diane Roscoe, Lindsay Machan, Peter Black, Vancouver, Canada*

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, even after antibiotic prophylaxis. This ethics-board approved clinical trial investigated the safety and efficacy of Povidone-iodine prophylactic cleansing of the rectum prior to TRUSBx on the rate of IC.

METHODS: 1069 men were 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°C, 2. urinary tract infection (UTI), or, 3. sepsis (standardized definition). Chi-square (X^2) significance testing was performed for differences between groups, and a multivariate analysis was performed to assess risk factors for IC.

RESULTS: IC was observed in 31 patients (3.5%), including 11 (2.6%) treated and 20 (4.5%) control patients ($p=0.15$). Sepsis was observed in 1.0% of treated and 1.6% of control patients ($p=0.55$). Rectal swab cultures revealed ciprofloxacin resistance in 20% of patients, of whom 3.5% developed IC. Imipenem and piperacillin/tazobactam had the most favorable resistance patterns in the ciprofloxacin resistant organisms (0.1% and 0.7% resistance, respectively). 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 Povidone-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 IC. Patients who have received ciprofloxacin within 3 months of TRUSBx should be considered for alternate prophylaxis or possibly a delay of biopsy beyond 3 months.

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