Pre-prostate biopsy prophylaxis lacks efficacy in interim analysis

By Zvi Gregory Winnubst, MD, PhD

Infection rate in patients receiving povidone-iodine similar to that of controls

Vienna, Austria—Decontamination of the rectum with povidone-iodine prior to transrectal ultrasound (TRUS)-guided prostate biopsy does not yet appear to be efficacious in reducing infection rates, according to an interim report on the first 500 patients of an expected 1,044 patients in an ongoing study being conducted at the Vancouver Prostate Centre, Vancouver, BC.

It is estimated that one million prostate biopsies are done every year in North America. About 3% to 11% of patients develop infectious complications, out of which 0.1% to 5% have sepsis, researchers say.

"We would like to reduce these infections with a simple and cheap antiseptic solution," said first author Zeid Musa AbuGhosh, MD, assistant professor of urology at Hashemite University, Zarqa, Jordan. "We tested the efficacy and safety of povidone-iodine in reducing the rate of postoperative biopsy infections."

Study endpoints were fever, urinary tract infection, and sepsis, said Dr. AbuGhosh, who presented the findings at the European Association of Urology annual congress in Vienna, Austria. All of the patients provided a urine sample, and a swab culture of the rectal mucosa was taken before the biopsy. The patients were randomized to a treatment group to receive rectal cleaning with povidone-iodine or to a control group receiving digital rectal examination of the rectum without using povidone-iodine prior to biopsy.

After the biopsy, patients went home and measured their temperature for 48 hours, at which time they also supplied material for urine culture. Interviews were conducted at 1 week post-biopsy, looking for fever or other symptoms of infection as well as other complications of the biopsy.

Treatment yields no difference

Infectious complications developed in 19 of 500 patients overall (3.8%), including eight of 258 treated patients (3.1%) and 11 of 242 controls (4.5%). There was no statistical difference between the two groups (p > 0.05). There was no significant adverse reaction to the povidone-iodine used.

The sepsis rate was 0.6%, or one of 258 treated patients (0.4%) and two of 242 of controls (0.8%). Again, there was no statistical difference between the two groups.

Rectal swab cultures yielded ciprofloxacin (Cipro, Proquin XR)-resistant bacteria in 21% of cases, out of which 88.5% were Escherichia coli. All three patients with sepsis had ciprofloxacin-resistant E. coli in the rectal swab and post-biopsy urine.

"A lot of patients have Cipro-resistant bacteria in their rectum, but they do not develop an infection," said senior author Peter C. Black, MD, assistant professor of urologic sciences at the University of...
British Columbia, Vancouver. “However, virtually all infections are caused by Cipro-resistant bacteria. We have determined which antibiotics would be appropriate for empiric treatment of patients with post-biopsy infection. The resistant bacteria were especially sensitive to imipenem (100%), ticarcillin/clavulanate (99%), and piperacillin/tazobactam (97%).”

Fewer events than expected

Session moderator Florian M.E. Wagenlehner, MD, PhD, asked Dr. AbuGhosh why his team did not find any difference between the two groups.

“We did not have enough events,” Dr. AbuGhosh replied. “We expected the events to be 10%, and we found them to be only 3.8%. This number of events is less than expected. A larger sample is needed to get statistical power. So we are going to continue the trial until a total of 1,044 patients [is recruited] and see whether there is efficacy for this intervention.”

The reason could be the exclusion criteria used in the study. Patients receiving ciprofloxacin or another antibiotic and patients with a history of UTI within the past 3 months were excluded from these first 500 patients. This could have reduced a group of patients at high risk for infection.

“Now we are including those patients, so we are expecting more resistance and more events at the end of this study,” Dr. AbuGhosh said.

An audience member noted that at the outset of the study, the authors aimed for an absolute rate of 5% or 50% reduction in infectious complications, but the absolute reduction was only 1.4% (51% relative risk reduction). He asked whether this meant the authors will have to repower their study.

“We are still continuing with the same study and we are expecting more events in the next 500 patients after loosening our exclusion criteria to include patients at higher risk for infection. A repowering of the study would require too many patients to be feasible,” Dr. AbuGhosh said.

“We are also continuing because we would like to know what rectal mucosa bacteria are present in our population.”

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**UT Table: Effect of povidone-iodine prophylaxis prior to prostate biopsy**

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<th>Treated group</th>
<th>Untreated group</th>
<th>p-value</th>
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<td>4.5%</td>
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<tr>
<td>Sepsis rate</td>
<td>0.4%</td>
<td>0.8%</td>
<td>&gt;.05</td>
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Source: Prostate Biopsy Antiseptic Clinical Trial, Vancouver, Canada; Zeid Musa, MO

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