AUA/SUNA White Paper on the Incidence, Prevention and Treatment of Complications Related to Prostate Needle Biopsy

Purpose of White Paper

• Critical review of the literature
  – Censored April 2012
  – www.auanet.org

• Etiology, Incidence, Risk Factors, Prevention, and Management of Most Common Complications
  – Infection
  – Bleeding
  – Urinary Retention

• Reprocessing of equipment related to prostate biopsy

• Summary statements
Indications for prostate biopsy

• The indications for prostate biopsy are not within the scope of this document
  – Prostate biopsy indications may be reviewed within the AUA PSA Best Practice Statement

  – As with all procedures, patients must receive extensive counseling and informed consent regarding the risks and benefits of this procedure
Introduction

• Prostate cancer is the most common, non skin related malignancy with an estimated 241,740 cases in 2012 (Siegel 2012)
  – Second leading cause of cancer related death with an estimated 28,170 deaths expected in 2012

• TRUS guided prostate biopsy has replaced original techniques of digitally guided or transperineal biopsy (Terris 2002)

• The most common complications related to TRUS guided prostate biopsy include infection, bleeding, and urinary retention (Berger 2004)
  – Complications range from mild and self limited to severe and life threatening
Infection / Sepsis

- Infection related complications include bacteriuria, UTI, febrile UTI, bacteremia, and sepsis
  - Epididymitis, prostatitis

- Infectious complications range from 0.1 – 7% depending on antimicrobial regimen used (Liss 2011)

- Transient asymptomatic bacteriuria occurs in approximately 5% of men who receive antimicrobial prophylaxis
  - Symptomatic UTI occurs in 2-3% (Zani 2011)
Infection / Sepsis

• Increasing number of men require hospitalization as a result of infectious complications (Loeb 2011)
  – Risk of hospitalization ranges from 0.6 – 4.1%
    • Increased over past ten years (Nam 2010, Loeb 2011)

• Increasing rate of quinolone resistance amongst men hospitalized for infectious complications
  – Community and nosocomial acquired
    • 22% of men found with quinolone resistance on rectal swab prior to prostate biopsy (Liss 2011)
Origin of quinolone resistance

• Antimicrobial utilization
  – Increased, inappropriate, or repetitive prescribing
  – Ability of bacteria to mutate and develop resistance
    • Chromosomal mutation, changes in membrane permeability, development of efflux pumps, and perhaps by more than one of these factors in a stepwise fashion

• Use of fluoroquinolones in livestock and veterinary practice (Bearden 2001)

• Lack of an evidence based, standardized regimen for peri-procedural antimicrobial prophylaxis
Infection / Sepsis

• Risk factors
  – Exposure to antimicrobials within 6 months of biopsy (*3-4 fold risk*) *(Shigehara 2008, Mosharafa 2011)*
    • Three weeks of quinolone use to decrease PSA has a three fold risk of sepsis with biopsy *(Akduman et al 2011)*
  – Hospital employment (family members)
  – Recent international travel (*2.7 fold risk*) *(Patel et al 2011)*
  – Prior prostate biopsy

• No association between the number of prostate cores and infectious complications *(Berger 2004)*
Prevention of Infection / Sepsis

• Enema use
  – No standard exists on the topical preparation of the rectum prior to biopsy
    • Antimicrobials and enema appear to be better than antimicrobials alone (Otrock 2004, Carey 2001)
      – Rate of fever following biopsy same in each group
      – Rate of hospitalization not studied

• Antimicrobial preparation
  – Randomized, placebo controlled trials have confirmed that antimicrobial use is indicated
    • Single dose is as effective as three day dosing (Aron 2000)
  – Subsequent studies have shown that single dose and one day regimens are equivalent (Sabbagh 2004, Shigemura 2005)
Adapted from AUA Best Practice Policy Statement on Urologic Surgery Antimicrobial Prophylaxis (Updated February 2012)

<table>
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<tr>
<th>Procedure</th>
<th>Organisms</th>
<th>Prophylaxis</th>
<th>Antimicrobial of Choice</th>
<th>Alternative Antimicrobials</th>
<th>Duration Of Therapy</th>
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</thead>
<tbody>
<tr>
<td>Transrectal Prostate biopsy</td>
<td>Intestine</td>
<td>All</td>
<td>Fluoroquinoline 1st/2nd/3rd generation cephalosporin</td>
<td>Aminoglycoside (Aztreonam) + Metronidazole or clindamycin</td>
<td>≤24 hours</td>
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Prevention of Infection / Sepsis

• All antimicrobials should be administered IM or IV except fluoroquinolones or TMP/SMZ (AUA Best Practices 2012)

• If risk factors exist for infectious complications the use of alternative regimens should be considered

• Risks outweigh the benefit for routine endocarditis prophylaxis
  – AHA suggests high risk patients receive enterococcus prophylaxis (Dajani 1990)
    • Previous endocarditis, prosthetic valve

• Routine use of pre-biopsy rectal swab remains unclear
Treatment of Infection/Sepsis

• Urine and blood (if fever) cultures taken
  – Resuscitation if sepsis

• Initial antimicrobial coverage must include E. Coli
  – Avoid empiric treatment with fluorquinolones (90% resistance), piperacillin (72% resistance), TMP/SMZ 44% resistance), and gentamicin (22% resistance)
    • Consider 2nd and 3rd generation cephalosporins (Feliciano 2008, Zaytoun 2011)

• Local antibiogram review is necessary
Bleeding

- Significant bleeding occurs in 1-4% of patients following prostate biopsy
  - Difficult to determine what is significant and most events not perceived as a problem
    - Hematuria (23-84%)
    - Rectal bleeding (17-45%)
    - Hematospermia (12-93%)

- No clear cut risk factors
  - Possibly size of prostate (Raaijmakers et al 2002)
  - Extended core protocols are not associated with increased risk of bleeding (Zaytoun et al, 2011, Chiang et al, 2007)
Anti-coagulation and prostate biopsy

• Literature is limited, mixed and inconclusive
  – Meta-analyses of aspirin use during biopsy shows severe bleeding risk not increased but minor bleeding was increased
    • Dosage not included
  – Warfarin and clopidogrel data limited

• Panel concluded that due to elective nature of prostate biopsy these medications should be discontinued prior to biopsy to allow platelet or coagulative function to return
Treatment of rectal bleeding

• Severe bleeding initially managed with bed-rest, volume resuscitation and transfusion if necessary

• Persistent severe bleeding
  – Digital compression / rectal tamponade
  – Colonoscopy with injection of epinephrine
  – Angiography with embolization
  – Transrectal exploration and suture ligation (Gonen 2004, Pacios 2007)
Urinary retention following biopsy

• Urinary retention occurs in 0.2 – 1.1% of men following prostate biopsy

• Men at risk for urinary retention
  – Larger prostate volume (Zaytoun et al 2011)
  – High IPSS (Raaijmakers et al 2002)

• Alpha blocker therapy prior to prostate biopsy may prevent urinary retention in high risk patients (Challacombe et al, 2011)
Mortality following prostate biopsy

• Overall majority of published series list no or very few deaths (Simsir et al, 2010, Roberts et al, 2002)
  – Unreliable due to inability to track patients when they leave the medical center
  – Small sample size

• Population based cohort studies
  – Ontario, Canada 30 day mortality 0.09% (n=75,190 men) (Nam et al, 2010)
    • No control group comparison
  – SEER sample found mortality to be 0.31% (Loeb 2011)
    • 30-day mortality among those biopsied was lower than comparable control population
      – Healthier than age matched counterparts
    • Hospitalized patients had much higher mortality than healthy controls not undergoing biopsy
Reprocessing of equipment

• Spaulding system for reprocessing medical devices defines any device entering sterile tissue a *critical item*
  – Prostate biopsy needle guide

• FDA and CDC recommend cleaning and then heat sterilizing all reusable prostate biopsy needle guides
  – Data supporting high level disinfection (HLD) of needle guides
    • HLD resulted in complete inactivation of *Pseudomonas* organisms in the internal lumen of the needle guide (Rutala et al 2007)

• Lack of comparative effectiveness data between HLD and sterilization so panel concluded *both* are acceptable practices
Reprocessing of equipment

- Rectal transducers and reusable prostate biopsy guns are *semi-critical*, heat sensitive

- FDA recommends all rectal transducer parts be disassembled and cleaned between uses
  - All heat sensitive parts (transducer) should undergo HLD
    - FDA recommends sterile water to rinse germicide from transducer (tap water contraindicated)
    - Transducer thoroughly dried before next use
  - Avoid alcohol on the transducer
Reprocessing of equipment

• Single use needles and needle guides should be disposed after use

• Ultrasound gel bottles
  – Single packets should be consider to avoid cross contamination between patients
    • Residual bacteria in the lubricant (Hutchinson et al 2004)

• According to the CDC, infection control rounds/audits should be conducted annually to ensure compliance with reprocessing standards and policies
  – Staff training and staff competency
Summary Statements

• There appears to be an increasing number of patients requiring hospitalization for infection related complications following prostate biopsy

• The presence of fluoroquinolone-resistant bacteria in the fecal reservoir is becoming more prevalent
  – Increased, inappropriate, or repetitive prescribing
  – Ability of bacteria to mutate and develop resistance
  – Veterinary practices
Summary Statements

• AUA Best Practice Statement on prophylaxis for prostate biopsy
  – Fluoroquinolones or 1st-, 2nd-, or 3rd-generation cephalosporins are antimicrobials of choice
    – Single-dose regimens appear to be as effective as those spanning 1- or 3-days.
      • Rectal swab use prior to prostate biopsy remains unclear
Summary Statements

• Steam sterilization is the preferred method for reprocessing reusable, heat-stable medical devices, including prostate biopsy needle guides
  — High-level disinfection is an acceptable alternative

• Rectal transducers and reusable prostate biopsy guns are semi-critical, heat sensitive
  — HLD alone acceptable