Clinically Localized Prostate Cancer:
AUA/ASTRO/SUO Guideline
Very Low-/Low-Risk Disease

Jeffrey A. Cadeddu, MD
Professor, Department of Urology
UT Southwestern Medical Center
Vice-Chair, AUA/ASTRO/SUO LCaP Guidelines Panel
DISCLOSURES

Jeffrey A. Cadeddu, MD
• Titan Medical Inc: Investment Interest
• Transenterix: Investment Interest
• Levita Magnetics: Consultant or Advisor, Scientific Study or Trial
A comprehensive literature search was performed by the Agency for Healthcare Research and Quality (AHRQ)

- January 1, 2007 through March 7, 2014
- Supplemented in August 2015 and August 2016

This formed the basis for Strong, Moderate, and Conditional Recommendations with additional information provided as Expert Opinion or Clinical Principle.
METHODOLOGY

A • Well conducted RCT’s
• Exceptional observational studies

B • RCT’s and/or observational studies with some weaknesses

C • Observational studies that are inconsistent - difficult to interpret

Faraday 2009
GUIDELINE OVERVIEW

Guideline Statements (Total = 68 Statements)

I. Shared Decision Making (5 Statements)

II. Care Options by Cancer Severity/Risk Group
   I. Very Low-/Low-Risk (9 Statements)
   II. Intermediate-Risk (7 Statements)
   III. High-Risk (6 Statements)

III. Recommended Approaches and Detail Specific Care Options
   I. Active Surveillance (6 Statements)
   II. Prostatectomy (8 Statements)
   III. Radiotherapy (8 Statements)
   IV. Whole Gland Cryosurgery (7 Statements)
   V. HIFU and Focal Therapy (4 Statements)

IV. Outcome Expectations and Management (8 Statements)
RISK STRATIFICATION

The core of the Panel’s risk-grouping is the original low-, intermediate-, and high-risk grouping as proposed by D'Amico et al. We further augmented the D'Amico criteria by subcategorizing the low-risk group into very low- and low-risk based on criteria analogous to that first proposed by Epstein.

<table>
<thead>
<tr>
<th>Prostate Cancer Severity</th>
<th>Amount of Prostate Cancer on Biopsy</th>
<th>PSA (ng/ml); PSAD</th>
<th>Clin Stage (DRE)</th>
<th>Pathology Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low Risk</td>
<td>≤1/3 of cores; ≤50% per core</td>
<td>&lt;10; &lt;0.15</td>
<td>T1-T2a</td>
<td>Gleason score ≤6 (Grade Group 1)</td>
</tr>
<tr>
<td>Low Risk</td>
<td>Any</td>
<td>&lt;10; any psad</td>
<td></td>
<td></td>
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</table>
Staging in Asymptomatic Very Low-/Low-Risk Patients

- Clinicians should not perform abdomino-pelvic CT or routine bone scans (Strong Recommendation; Evidence Level C)
GUIDELINE STATEMENTS

Active Surveillance- Very Low-Risk

• Clinicians should recommend active surveillance as the best available care option (*Strong Recommendation; Evidence Level A*)

Active Surveillance- Low-Risk

• Clinicians should recommend active surveillance as the preferable care option (*Moderate Recommendation; Evidence Level B*)

• Clinicians may offer definitive treatment (i.e. radical prostatectomy or radiotherapy) to select patients who may have a high probability of progression (*Conditional Recommendation; Evidence Level B*)
GUIDELINE STATEMENTS

Definitive Treatment for Low-Risk Prostate Cancer

- Clinicians should not add ADT along with radiotherapy except to reduce prostate size for brachytherapy (*Strong Recommendation; Evidence Level B*)
- Clinicians should inform patients considering cryosurgery that side effects are considerable and survival benefit has not been shown compared to active surveillance (*Conditional Recommendation; Evidence Level C*)
- Clinicians should inform patients who are considering focal therapy or HIFU that these interventions are not standard care options because comparative outcome evidence is lacking (*Expert Opinion/No RCT evidence*)
Additional Statements

• Clinicians should recommend observation or watchful waiting for men with a life expectancy ≤5 years with low-risk localized prostate cancer (Strong Recommendation; Evidence Level B)

• Among most low-risk localized prostate cancer patients, tissue based genomic biomarkers have not shown a clear role in the selection of candidates for active surveillance (Expert Opinion)
<table>
<thead>
<tr>
<th>Evidence Level/ Recommendation Strength</th>
<th>Prostate Cancer Severity/Aggressiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very Low Risk</td>
</tr>
<tr>
<td>A / Strong</td>
<td>Active Surveillance</td>
</tr>
<tr>
<td>B / Moderate</td>
<td>NA</td>
</tr>
<tr>
<td>B / Conditional</td>
<td>NA</td>
</tr>
<tr>
<td>C / Conditional</td>
<td>NA</td>
</tr>
<tr>
<td>No evidence / clinical principle or expert opinion</td>
<td>NA</td>
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