Safety of Testosterone Therapy in Patients on Active Surveillance for Prostate Cancer

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INTRODUCTION

• Testosterone (T) therapy (TTH) has a contraindication on product labeling for use in men with prostate cancer.

• Over the past decade, with promotion of the saturation model, men who have been treated for prostate cancer, especially men with low-risk disease (clinically and pathologically) are being increasingly offered TTH.
A small number of reports have presented data on the use of TTH in men on active surveillance (AS) for prostate cancer. We present here our data on TTH use in this population.

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>F/U (m)</th>
<th>Mean initial TT (ng/dL)</th>
<th>Mean duration TTh</th>
<th>Path</th>
<th>Mean PSA at dx (ng/mL)</th>
<th>Last PSA (ng/mL)</th>
<th>Path upgrade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morgentaler 2011</td>
<td>13</td>
<td>Min 12</td>
<td>238</td>
<td>37 m</td>
<td>12 G6 1 G7</td>
<td>5.5 ± 6.4</td>
<td>3.6 ± 2.6</td>
<td>2</td>
</tr>
<tr>
<td>Kacker 2015</td>
<td>28</td>
<td>Mean 38.9</td>
<td>328</td>
<td>22 G6 6 G7</td>
<td></td>
<td>3.29</td>
<td>4.31</td>
<td>3</td>
</tr>
<tr>
<td>Ory 2016</td>
<td>8</td>
<td>Median 27</td>
<td>150</td>
<td>33 m</td>
<td>8 G6</td>
<td>3.9</td>
<td>5.2</td>
<td>0</td>
</tr>
</tbody>
</table>
METHODS

• We prospectively kept data on AS patients on TTH
• Men on AS for CaP
• Criteria for AS: low volume cancer, Gleason sum ≤7, PSA ≤10
• Had two early morning total T levels
• Were symptomatic or had abnormal bone densitometry
• Had at least 6 months follow-up
• FU labs: total T, PSA levels every 3m in year one
RESULTS

• 24 patients met all inclusion criteria
• Mean age = 64.5±8.5 years
• 22/24 (83%) = Gleason 6 cancer, 2/24 (17%) = Gleason 7.
• Mean # cores positive = 1.2±0.5
• Mean core % positive =12±12%
RESULTS

• 7 patients were using TTH before PCA diagnosis

• Mean duration in the AS program pre-TTH = 17.6±20 months.

• Mean duration of FU while on TTH = 29±28 months

• Testosterone therapy was administered as follows:
  - 17 (71%) transdermal
  - 3 (13%) clomiphene citrate
  - 2 (8%) intramuscular
  - 2 (8%) subcutaneous pellets
## RESULTS

<table>
<thead>
<tr>
<th></th>
<th>Total Testosterone (ng/dL)</th>
<th>PSA (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>234 ± 102</td>
<td>3.79 ± 2.65</td>
</tr>
<tr>
<td><strong>Treatment</strong></td>
<td>573 ± 228</td>
<td>4.23 ± 2.42</td>
</tr>
<tr>
<td><strong>p Value</strong></td>
<td>&lt;0.001</td>
<td>0.55</td>
</tr>
</tbody>
</table>
RESULTS

• 8 (33%) had ≥1 point increase in PSA level

• One patient stopped due to anxiety

• 2 patients were upstaged (G6 to G7) while on TTH and proceeded to RALP
  - 10.2 and 37.1 months after TTH commencement
  - 0.11 and 1.56 point increases in PSA
  - PSA levels of 7.53 and 3.72
262 patients included, a median follow-up of 29 months
  – 43 (16%) patients ultimately received active treatment.
• The 2 and 5-year probabilities of remaining on active surveillance were 91% and 75%, respectively.
TAKE HOME MESSAGE

• Testosterone therapy in patients on active surveillance for prostate cancer appears safe in a monitored treatment program.

• The conversion-to-intervention rate appears to be no higher than expected in the AS population not treated with TTH.