Hormonal therapy for localized prostate cancer in Japan. The outcome of J-CaP database.

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Background

• The J-CaP database was established in 2001 when the Japan Study Group of Prostate Cancer (J-CaP Study Group) started a study to gather information on hormone therapy administered to Japanese patients and to analyze the outcomes of treatment. A prostate cancer registry managed by the Japanese Urological Association revealed that 45% of patients diagnosed with localized prostate cancer in 2000 in Japan were treated with hormonal therapy. The J-CaP database is the largest cohort of over 20,000 prostate cancer patients treated with hormonal therapy.
Objectives

• To estimate overall survival and cause-specific survival of Japanese patients with localized (or locally advanced) prostate cancer treated with hormonal therapy, using information in the J-CaP database.

• To compare overall survival as a primary endpoint of randomized clinical trials performed in Western countries with the outcome of patients in the J-CaP database selected using the inclusion criteria in the randomized trials.
Methods

• Overall survival and cause-specific survival of patients in the J-CaP database were estimated by the Kaplan-Meier method.

• Overall survival of patients in the J-CaP database was compared with the outcomes of five randomized clinical trials identified from a PubMed search, based on selection of J-CaP patients using the same inclusion and exclusion criteria as those in the protocol of the trials.
Results

- 19,275 patients were treated by hormonal therapy in J-CaP database.

- 9,127 patients were stratified by D’Amico risk classification into low risk (1,728, 19%), intermediate risk (1,981, 22%) and high risk (5,418, 59%) cases.
Overall survival of J-CaP database stratified by D’Amico risk classification

Years after PADT

- Low risk (N=1728)
- Intermediate risk (N=1981)
- High risk (N=5418)
Cause specific survival of J-CaP database stratified by D’Amico risk classification
<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>No. of Pts.</th>
<th>Intervention</th>
<th>Inclusion criteria</th>
<th>endpoint</th>
<th>Results in RCT (95%CI)</th>
<th>Results from J-CaP database</th>
<th>Number of Pts. in J-CaP database</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>603</td>
<td>Radiation + CAB</td>
<td>T3,T4 N0,Nx M0 or T2 PSA&gt;40 or T2 PSA&gt;20, Gleason&gt;=8, Age &lt;80</td>
<td>7yr OS</td>
<td>74(70-78) 90(86-93)</td>
<td>74.7 89.0</td>
<td>2778 2778</td>
</tr>
<tr>
<td>2)</td>
<td>987</td>
<td>Radiation + Short ADT</td>
<td>T1b,c T2a,b N0Nx M0 PSA &lt;20</td>
<td>10yr OS</td>
<td>62 Low 67 Inter 61 High 53</td>
<td>74.6 75.1 71.1 75.8</td>
<td>6211 1613 1812 1852</td>
</tr>
<tr>
<td>3)</td>
<td>349</td>
<td>Radical Prostatectomy</td>
<td>T1,2 N0M0 PSA &lt;50</td>
<td>8yr OS</td>
<td>82.1(77.6-85.7) 87.9(81.5-92.2) 77.4(70.5-82.4)</td>
<td>77.7 91.7 76.8</td>
<td>7687 384 7303</td>
</tr>
<tr>
<td>4)</td>
<td>102</td>
<td>Radiation + ADT</td>
<td>T1,2 N0M0 PSA 10 to 40 or Gleason 7 to 10</td>
<td>8yr OS</td>
<td>74(64-82)</td>
<td>75.1</td>
<td>5520</td>
</tr>
<tr>
<td>5)</td>
<td>87</td>
<td>Radical Prostatectomy</td>
<td>T1,2 N0M0, Gleason 8-10</td>
<td>3yr DFS</td>
<td>33.3(28-84) 56.2 19.2</td>
<td>72.0 79.2 69.5</td>
<td>673 170 503</td>
</tr>
</tbody>
</table>

Ref.: Reference, Pts.: Patients, CAB: Combined Androgen Blockade, ADT: Androgen Deprivation Therapy, OS: Overall survival, CSS: Cause-specific survival, DFS: Disease free survival, RCT: Randomized clinical trial, CI: Confidence interval
Discussion

- The prostate cancer registry managed by the Japanese Urological Association revealed that 45% of patients diagnosed with localized prostate cancer in 2000 in Japan were treated with hormonal therapy.
- In an observational study in Japan, the overall survival of patients treated with hormonal therapy (CAB) was similar to the expected survival from vital statistics in Japan.
- It is difficult to make a direct comparison of the survival of patients with localized prostate cancer treated with hormonal therapy in Japan with that of patients treated by radical prostatectomy or radiation therapy in Western countries.
- The generalizability of results from RCTs should be considered. Comparison of survival data from RCTs with results from an outcome study should be interpreted carefully.
- In general, outcomes from RCTs were better than those from outcome studies.
- In the present study, the estimated survival in the present outcome study in Japan was not inferior to the results of RCTs in Western countries.
Conclusion

• Following selection of patients in the J-CaP database based on similar criteria to those used in RCTs of radical treatment in Western countries, Japanese patients with localized (or locally advanced) prostate cancer who were treated with hormonal therapy had similar outcomes to those in the RCTs.
References


