Identification of treatment intent from the actual time-to-treatment distribution in prostate cancer patients

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PROBLEM
- Conservative management aims to reduce over-treatment of patients with prostate cancer.
- At time of diagnosis a decision must be made: conservative management or immediate treatment.
- It is an important task of clinical research to inform this decision.
- Observational research could provide such research.
- Unfortunately, the decision is rarely captured in observational data.
- It might be feasible to infer what the decision might have been by checking whether or not there was immediate treatment.
- However, there is no obvious or generally accepted cut-off.
- A data driven approach might help distinguish between patients with the two choice.

OBJECTIVE
- To empirically identify the two distinct populations immediate from the data, and to determine the optimal cut-off.
- Parameters of the optimal fitted models are in line with expectations:
  - 49-76 days for the putative “immediate” group
  - 295-1057 days for the “deferred” group,
  - a proportion with a dominant “immediate” group in the claims versus a 50/50 distribution in the ambulatory setting.

METHODS

Data
1. IQVIA Ambulatory EMR (EHR)
2. IQVIA Hospital Charge Data Master (charge data)
3. IQVIA Oncology EMR (EHR)
4. IQVIA Open Claims (unadjudicated claims)
5. IQVIA PharMetrics Plus (adjudicated claims)

Schematic Study Design

Inclusion criteria:
- >18 years old
- Male
- No history of PCa or PCa-related condition one year prior
- Prostate biopsy +/- 30 days of the first PCa diagnosis
- No ADT or other hormone therapies one year prior

RESULTS

• 912,769 newly diagnosed prostate cancer patients across a network of claims and EMR data were included in the study (Table 1)
• A bimodal two-parameter Weibull distribution fitted the data better than a unimodal one (Figure 2)
• The distribution of the two populations shows substantial overlap across the participating databases (Figure 2)

Table 1. Median days (IQR) Time to treatment initiation and follow-up period in the participating databases

<table>
<thead>
<tr>
<th>Database</th>
<th>N</th>
<th>Time to Treatment initiation</th>
<th>Follow-up time</th>
</tr>
</thead>
<tbody>
<tr>
<td>IQVIA Ambulatory EMR</td>
<td>7079</td>
<td>31 (30, 33)</td>
<td>860 (565, 1032)</td>
</tr>
<tr>
<td>IQVIA Hospital CDM</td>
<td>7476</td>
<td>73 (71, 75)</td>
<td>753 (277, 775)</td>
</tr>
<tr>
<td>IQVIA Oncology EMR</td>
<td>219</td>
<td>14 (10, 18)</td>
<td>391 (295, 457)</td>
</tr>
<tr>
<td>IQVIA Open Claims</td>
<td>602266</td>
<td>55 (50, 55)</td>
<td>1899 (1880, 1904)</td>
</tr>
<tr>
<td>IQVIA PharMetrics Plus</td>
<td>200017</td>
<td>61 (60, 63)</td>
<td>950 (944, 955)</td>
</tr>
</tbody>
</table>

Table 2. EM estimated parameters for the TTT distribution

<table>
<thead>
<tr>
<th>Database</th>
<th>Component 1</th>
<th>Component 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Shape</td>
</tr>
<tr>
<td>PharMetrics Plus</td>
<td>4.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Open Claims</td>
<td>0.9</td>
<td>1.3</td>
</tr>
<tr>
<td>Ambulatory EMR</td>
<td>1125</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Figure 1. Fitted unimodal (green) and bimodal (blue) Weibull distributions to the observed data red.

Figure 2. Empirical depiction of the two patient populations. Green and blue density plots represent the two distinct putative patient populations.

- Prostate cancer patients seem to be composed of two populations with different time to treatment characteristics, as expected from the treatment guidelines.
- The parameters of the optimal fitted models are in line with expectations:
  - 49-76 days for the putative “immediate” group
  - 295-1057 days for the “deferred” group,
  - a proportion with a dominant “immediate” group in the claims versus a 50/50 distribution in the ambulatory setting.

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