• Multivariable regression analysis was conducted on the PROs to account for any non-disease related confounding factors that may have affected the outcome measures.

METHODS

Study Design and Data Source

Data were obtained from the Adelphi Prostate Cancer Disease Specific Programme, an independent cross-sectional survey of 137 urologists and oncologists and their patients (1,330).

The survey was conducted between February and May 2014 in the United States (US).

Study Population

- Physicians were selected from publicly available lists of healthcare professionals, and approached by field-based interviewers regarding participation in this study; those who met the following criteria were included:
  - Personally responsible for prescribing decisions for patients with prostate cancer:
  - Medically qualified as a physician between 1978-2010:
  - Seeing a minimum of five prostate cancer patients per week.

- The patient eligibility criteria were:
  - Male.
  - Prostate cancer (PC).
  - ≥18 years of age at the diagnosis of PC:
  - Not currently enrolled in any clinical trial.
  - Currently receiving ongoing treatment for PC.

- Participating physicians were instructed to report data for the next nine consulting patients meeting the general eligibility criteria and for at least one additional patient currently receiving ablation.
- Data were captured using a detailed Patient Record Form (PRF) for each of the 10 patients (Figure 1).

Figure 1. Data collection process

PHYSICIANS

Patient perspective

Patient record forms (PRF) completed by physicians

Self-completion (PC) questionnaires completed by patients

* on a voluntary basis

Patient perspective

Real world clinical practice

<table>
<thead>
<tr>
<th>Patient's health status</th>
<th>Patient's quality of life</th>
<th>Patient's functional status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health-related QoL</td>
<td>Physical well-being</td>
<td>Emotional well-being</td>
</tr>
</tbody>
</table>

| Patients seen prospectively were asked to record information on their health-related QoL using the EQ-5D and FACT-P instruments which were part of the Patient Self-Completion (PSC) questionnaire.

- However, completion of the PSC was not a compulsory exercise for patients.

- In cases of informed consent was collected from the patient before completion of the form, at no stage did the physician see or influence PSC responses.

- The PSSP methodology has been outlined previously.

Study Variables

- The following information was extracted from the PRFs:
  - Patients’ demographic characteristics, current stage, symptomatology, experience of skeletal related events (bone radiation, fracture, bone surgery and spinal cord compression), comorbidities, CRPC status, treatment history, ECOG performance status (PS) score.

- PRO information was extracted from the PSQs: FACT-P and EQ-5D.

Patient Stratification

Patients were categorized into two groups for analysis:
- HSPC: comprising of patients who were not deemed by a physician to have CRPC and who were receiving androgen deprivation therapy (ADT) (enzalutamide and abiraterone excluded) or who have received ADT in the past and are now on supportive care.
- CRPC: patients with CRPC according to physician report.

Statistical Analysis

- The number of patients seen (Figure 2).
- The percentage of patients experiencing any of the individual symptoms.

- The correlation coefficient (r) was calculated for the EQ-5D and FACT-P scores.

- Spearman’s Rho statistic was used to assess correlations between ECOG status and EQ-5D or FACT-P measures.

- Multivariable regression analysis was conducted on the PROs to account for any non-disease related confounding factors that may have affected the outcome measures.

- The diagnosis of PC, using the FACT-P instrument was undertaken using the FACT Prostate Cancer Advanced Symptom Index (FAPSI-8).

CONCLUSIONS

- CRPC patients were generally at a later disease stage, had more comorbidities and a greater number of symptoms than HSPC patients.

- The development and subsequent progression of prostate cancer to CRPC represents a significant additional burden for patients, as indicated by the significant HSPC vs. CRPC difference captured by EQ-5D.

- Patients with CRPC also suffer from a worse quality of life in respect of their most important symptoms, as demonstrated by the FAPSI-8 symptom-targeted instrument. Such patients also have significantly lower EQ in terms of their physical and emotional well-being.

- Multiple domains specifically physical and emotional may contribute to the deterioration of quality of life during disease progression, and disease progression of PC to CRPC may have significant benefits in terms of quality of life and overall health.

STRENGTHS & WEAKNESSES

- One of the key strengths of this study is that no tests or investigations were undertaken as part of the research, therefore it can be assumed that these data are reflective of real world practice.

- One possible limitation of this work is that data were physician and patient self-reported, as such no measures were clinically verified.

- The purpose of this research was hypotheses generating. As such, it was not specifically powered to look for differences in the quality of life between HSPC and CRPC patients for FACT-P or its individual sub-domains.

ACKNOWLEDGEMENTS

- This study was supported by Millennium Pharmaceutical Inc. (Cambridge, MA, USA).

REFERENCES


