Abstract

Background: Multiple new therapies are now approved for patients (pts) with advanced RCC. As these agents enter widespread use, their perceived toxicities may differ from those reported in the literature and impact treatment and clinical outcomes. Patient reporting of toxicities may more accurately identify side effects most relevant to pts.

Methods: In an effort to collect patient-reported side effects from RCC pts treated with novel therapies, an on-line survey was developed. RCC pts were recruited through the Kidney Cancer Association.

Results: 177 pts completed the survey and 146 (84%) received medication for RCC. Most common geographical regions were Midwest (20.0%), Northeast (17.4%), South/Southeast (16.7%), West (11.6%), and outside the U.S. (9.7%). 68 pts (47.2%) were treated at teaching hospitals; 55 pts (38.5%) in private oncology offices; and 21 pts (14.6%) at community hospitals. First-line treatments included sunitinib (Su) (52.1%, n=73); sorafenib (So) (51.3%, n=72); high dose IL-2 (14.3%, n=20); clinical trial (12.9%, n=18); bevacizumab (Bev) (5%, n=7); interferon (4.3%, n=6) and temsirolimus (Tem) (3.6%, n=5). The most common side effects reported for Su were fatigue (32.9%, n=56), altered taste (9.0%, n=63) and diarrhea (9.3%, n=57). Su; hand foot syndrome (9.5%, n=20) and fatigue (9.5%, n=19); Bev; fatigue (83.3%, n=10) and altered taste (83.3%, n=10); Tem; fatigue, altered taste and rash (100%, n=4). Pts reported the most difficult side effects from Su were diarrhea and fatigue (29%, n=18); So; hand foot syndrome (72.7%, n=16); Bev; fatigue (42.0%, n=3); Tem; rash (90%, n=4). Side effects necessitating changes to the schedule, dose, or stopping Rx in 82% (n=18) of Su pts and in 49% (n=28) of So pts, OAC was affected very/extremely for 56.0% of pts (n=73).

Conclusions: These results suggest that the patient-reported impact of molecularly targeted agent side effects may be more significant than suggested by phase III clinical trials. These results also identify specific side effects which improved symptom management strategies and enhanced patient education can be directed. Better side effect management may increase treatment duration and improve clinical outcomes.

Introduction

• Quality of life and patient reported side effect information is not well characterized in the large Phase III and expanded access protocols of newly FDA approved kidney cancer agents.
• Those studies typically involve investigator reported adverse events of patients treated at large academic medical centers rather than community practices.
• Prescribing patterns may vary based on geographical location or practice setting.
• Side effects often negatively impact quality of life which is of major importance to patients with metastatic disease.
• With recent FDA approval of targeted agents, clinicians may not be well prepared to manage side effects.

Patient Reported Toxicities from Molecularly Targeted Therapies in Renal Cell Carcinoma (RCC)

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Results

Demographics

Geographical Distribution

Practice Setting

First Treatment Offered

First Therapy Received

Side effects necessitating dose modification or discontinuation

Medication

<table>
<thead>
<tr>
<th></th>
<th>Any Grade</th>
<th>Grade 3-4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunbifib (n=1237)</td>
<td>51%</td>
<td>0%</td>
</tr>
<tr>
<td>Sunitinib (n=55)</td>
<td>55%</td>
<td>0%</td>
</tr>
<tr>
<td>Sorafenib (n=45)</td>
<td>61%</td>
<td>11%</td>
</tr>
<tr>
<td>Bevacizumab (n=7)</td>
<td>46%</td>
<td>3%</td>
</tr>
<tr>
<td>Temsirolimus (n=9)</td>
<td>52%</td>
<td>11%</td>
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</tbody>
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Most Common Side Effects

Most Difficult Side Effects

Reported AEs from Pivotal Phase III Trials

Impact of Side Effects on Quality of Life

Methods

An online survey was developed for metastatic kidney cancer patients, exploring first line and current treatment; side effects and management; and quality of life. The survey was reviewed by several kidney experts for completeness and accuracy. RCC patients were recruited through the Kidney Cancer Association’s e-newsletter and patient forum. Results were tabulated using descriptive statistics.

Discussion

• Results indicate that targeted agents have significant side effects which negatively impact quality of life.
• Better side effect management strategies are critical to maintaining the quality of life in balance with improved clinical outcomes.
• Improved side effect management may also improve duration of therapy and patient compliance and therefore potentially improve clinical outcomes.
• 40-60% of RCC patients receiving sunitinib, sorafenib and temsirolimus feel their side effects were worse than expected.

Future Implications

• Our survey identified several patient reported side effects which significantly altered quality of life and may be useful in directing interventional studies for management of specific side effects.
• Improved patient education with respect to expected side effects and management strategies is needed.

References