Adherence to oral anticancer drugs in patients with metastatic renal cell cancer

Interim results of the prospective observational multicenter IPSOC study (Investigating Patient Satisfaction with Oral antiCancer Treatment)
Background

- Patient adherence to oral therapy: emerging issue in cancer treatment
- Reports on adherence among patients with cancer:
  - adherence ranges from 16% to 100%,
  - Percentages ~ type of therapy
  - ~ measurement / definition of adherence.
- Determinants:
  - demographic, disease and therapy related factors
  - satisfaction with care activities performed at the initiation of the drug treatment
  - perceived necessity of treatment.

Aim

➢ To investigate the prevalence and severity of non-adherence to oral anti-cancer drugs (OAD)
  ➢ in metastatic renal cell carcinoma (mRCC)
  ➢ by using a combination of self-report and MEMS® data

➢ To identify factors predictive of non-adherence
Methodology

Design:
Prospective observational multicenter trial in 11 Belgian hospitals (8 Dutch speaking hospitals; 3 French speaking; 4 university hospitals, 7 non-academic centers)

Patients:
mRCC patients starting with OADs (Sunitinib, Pazopanib, Everolimus or Sorafenib)

Adherence measurement:
Medication Event Monitoring System (MEMS®, AARDEX Group Ltd, Sion, Switzerland)
Adherence = the percentage of days with at least the prescribed number of doses taken.
Methodology

Other study procedures:

Phone contacts
  at baseline
  at 1, 3, 6 and 12 months of treatment

At each contact moment, patients complete questionnaires on:
  ➢ medication adherence (MMAS and CTSQ)
  ➢ patient satisfaction with treatment (CTSQ)
  ➢ patient satisfaction with treatment education (PS-CaTE)
  ➢ the extent of information desire (EID)
  ➢ quality of life (FACT-G and FKS1)
  ➢ the role of the pharmacist (SWiP)
Preliminary results (May 2012)

Patient characteristics:

- 80 unique mRCC patients
- 12 patients included for a second time
- Total patient-drug combinations = 92
- Median follow-up of patients in our study: 150 days (range 3-465 days)
- 23 ♀, 57 ♂
- Median age at start of study: 64 years (25 – 87 years)
Preliminary results (May 2012)

Patient characteristics:

- 69 patients underwent nephrectomy to treat the primary tumor
- 29 patients used at least one systemic anticancer treatment before entrance in the study

<table>
<thead>
<tr>
<th>Most recent therapy prior to study</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunitinib</td>
<td>14</td>
</tr>
<tr>
<td>Sorafenib</td>
<td>4</td>
</tr>
<tr>
<td>Pazopanib</td>
<td>3</td>
</tr>
<tr>
<td>Temsirolimus</td>
<td>2</td>
</tr>
<tr>
<td>Interferon alfa</td>
<td>1</td>
</tr>
<tr>
<td>Everolimus</td>
<td>3</td>
</tr>
<tr>
<td>Bevacizumab + interferon alfa</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>
Preliminary results (May 2012)

Patient characteristics:

- 51 patients used an oral anticancer drug (OAD) in first line,
  18 patients in second line

<table>
<thead>
<tr>
<th>Therapy started as part of the study</th>
<th>n</th>
</tr>
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<tbody>
<tr>
<td>Sunitinib</td>
<td>36</td>
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<td>Sorafenib</td>
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<tr>
<td>Pazopanib</td>
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<td>Everolimus</td>
<td>16</td>
</tr>
<tr>
<td>Axitinib</td>
<td>1</td>
</tr>
</tbody>
</table>
Preliminary results (May 2012)

Extent of information desire: EID questionnaire

- 6 items, 5-point Likert scale
- Total score between 6 and 30
- Data for the first three months were evaluated

The median EID score was significantly higher at the start of treatment compared to 1 and 3 months after the start of treatment (p<0.05)
Patient Satisfaction with Cancer Treatment Education: PS-CaTE questionnaire

- 16 items, 5-point Likert scale
- 4 sections:
  - Cancer treatment (5 items)
  - Side effects (4 items)
  - Vitamins, herbs and/or complementary therapies (3 items)
  - Resources (4 items)
- Calculated scores: median (1-5)
Preliminary results (May 2012)

Patient Satisfaction with Cancer Treatment Education:
PS-CaTE questionnaire

- Overall satisfaction with information:
  median score of 4 (range 2-5) at 1 and 3 months of treatment.
- Subscale analyses:
  satisfaction with information on vitamins, herbs and/or complementary therapies: median score of 3,5 (range 2-5) at 1 and 3 months of treatment
Preliminary results (May 2012)

Quality of life:
Functional Assessment of Cancer Therapy – General scale (FACT-G)

- 27 items, 5-point Likert scale
- Total score between 0 and 108
- 4 sections:
  - Physical well-being (PWB) (7 items): 0-28
  - Social/Family well-being (SWB) (7 items): 0-28
  - Emotional well-being (EWB) (6 items): 0-24
  - Functional well-being (FWB) (7 items): 0-28
Preliminary results (May 2012)

Functional Assessment of Cancer Therapy – General scale (FACT-G)

- The median FACT-G score was significantly higher at start of treatment compared to 1 and 3 months of treatment (p<0.05)
Preliminary results (May 2012)

Functional Assessment of Cancer Therapy – General scale (FACT-G)

- Subanalyses: differences mainly at the Physical and the Functional domains
- Median PWB and FWB scores: significantly higher at start of treatment compared to 1 and 3 months of treatment (p<0,05)
Preliminary results (May 2012)

Cancer Treatment Satisfaction: CTSQ Questionnaire

- 16 items, 5-point Likert scale
- 3 sections:
  - Expectations of Therapy (ET) (5 items)
  - Feelings about Side Effects (FSE) (4 items)
  - Satisfaction with Therapy (SWT) (7 items)
- Score per section between 0 and 100
Preliminary results (May 2012)

Cancer Treatment Satisfaction: CTSQ Questionnaire

- There were no significant differences in median CTSQ scores at 1 and 3 months of treatment
Preliminary results 05/12

Cancer Treatment Satisfaction: CTSQ Questionnaire

- Subanalyses:
  - Median score for ‘Satisfaction with Therapy’ higher at month 3 compared to month 1 (p<0.05)
  - Median score for ‘Feelings about side effects’ decreased significantly between month 1 and 3 (p<0.05)

**Box plots:**
- Satisfaction with Therapy (SWT)
- Feelings about Side Effects (FSE)
Adherence

MMAS = Morisky Medication Adherence Scale

- 4 items, yes or no
- Total score between 0 and 4
- 87% of the patients claimed to be fully adherent to their treatment (MMAS = 4)
- 10 patients indicated to have missed at least one dose

CTSQ extra questions

- Reported reasons for missing a dose were ‘forgetting’ (38% of cases) and ‘side effects’ (31% of cases)
Adherence

Results MEMS bottles

- Number of patients: 77
- Follow-up duration: median 150 days (3 - 465 days)
- Average adherence: 97.95%
Adherence: 100%

Adherence: 99.58%

Dosing Date
Dosing Time
0 50 100 150 200
03:00 06:00 09:00 12:00 15:00 18:00 21:00 24:00 03:00
Votrient QD Votrient QD
04/02/2011 09/22/2011
START END
Discussion

What do our data mean? Significance?

✓ Very high adherence rates (almost 98%!)

✓ Do adherence rates stay high towards the end of treatment?

✓ Can lower adherence be linked with inferior outcomes of treatment?

✓ What is ‘lower adherence’?
Discussion

Strengths of the study:

- Prospective study
- Multi-centre
- Combination of different methods (questionnaires; MEMS data)
Discussion

Potential bias?

✓ Participating centres:

✓ Participating patients:

✓ Additional research: interviews with patients from different treatment centres (participating and non-participating centres)
Discussion

Recommendations from the IPSOC study:

- Adherence data are essential to correctly interpret data from clinical trials; this should be a strict requirement.

- It is possible to obtain high adherence rates; care pathways should be developed that facilitate these high adherence rates.

- Remuneration and reimbursement policies should facilitate these care pathways.

- Multidisciplinary teams: quid composition? Role of the pharmacist?
Contact

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