Evaluation of the Duration of Use with Oral Chemotherapies at a Community Cancer Center

Robert Mancini, PharmD, BCOP
Clinical Oncology Pharmacist
PGY2 Residency Program Director
St. Luke’s Mountain States Tumor Institute, Boise, ID

*Adapted from presentation created by Dr. Sarah Hogue, PGY2 Resident 2014-2015
Disclosures

IRB: Exempt Status

Co-Investigators:
- Joseph Ineck, PharmD, CPE
- Sarah Hogue, PharmD

Disclosure:
- Dr. Mancini received speaker’s honoraria from Millenium/Takeda & Pfizer Pharmaceuticals.
Institution

Mountain States Tumor Institute
  ◦ Community Cancer Center
  ◦ Part of St. Luke’s Health System

Locations
  ◦ Main clinic located in Boise, Idaho
  ◦ Five satellite clinics

Oral Chemotherapy Service
  ◦ Initiated in 2008
  ◦ Recipient of ASHP and ACCC Awards
Background

3 oral chemotherapy agents approved in 2014\textsuperscript{1}
4 oral chemotherapy agents approved in 2015\textsuperscript{2}
Increasing trend in use of oral chemotherapy agents

NCCN has an Oral Chemotherapy task force\textsuperscript{3}
- Oncologists, nurses, pharmacists, payor representatives

Background

Patients prefer oral chemotherapy to IV
  ◦ Convenience
  ◦ Fewer office visits
  ◦ Gives them control over their care

Perceptions with oral chemotherapies
  ◦ Easier to use
  ◦ Better tolerated
  ◦ Safer than IV

Background

Adherence is a known issue with oral medications

- Remains true for oral chemotherapy
- Hard to measure
- Few published reports
- Patients in clinical trials typically have better compliance than the general population

Objective

Evaluate the duration of use of oral chemotherapies filled exclusively through the MSTI Oral Chemotherapy Service compared to primary literature
Methods

Retrospective chart review

Analyse Oral Chemotherapy Prescriptions → Determine if filled exclusively at MSTI → Classify use as on-label or off-label → Evaluate duration of use

Outcome
- Median duration of use for on-label indications
Methods

Review period: Jan 2010 → Dec 2013
- Prescriptions filled by pharmacy-managed Oral Chemotherapy program
- Adult patients (Age ≥ 18 years)

Assess Oral Chemotherapies
- Top 5 medications filled in 2014
  - Capecitabine, temozolomide, lenalidomide, abiraterone, enzalutamide
- Only FDA approved indications
  - Duration of use compared to trials in the package insert
Methods

Statistical Analysis

◦ Continuous data – Wilcoxon Signed-Rank Test for a Single Sample
  ◦ Non-parametric test
  ◦ Compares data set to hypothesized median
◦ Nominal Data – Chi-squared Test
Results

1105 prescriptions

- 355 off-label use
- 142 mail order
- 95 never filled
- 57 PA only
- 45 free drug
- 43 other

Included in final analysis ➔ 368
# Results – Capecitabine

<table>
<thead>
<tr>
<th>FDA Indication</th>
<th>Reported Median Duration of Use</th>
<th>MSTI Median Duration of Use</th>
<th># of pts</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic Colorectal Cancer</td>
<td>147 days(^1) 4.3 months(^2)</td>
<td>126 days 4.2 months</td>
<td>54</td>
<td>0.206</td>
</tr>
<tr>
<td>Metastatic Breast Cancer</td>
<td>3.8 months(^3) 12.3 weeks(^4)</td>
<td>4.9 months 21 weeks</td>
<td>71</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duke’s Colon Cancer</td>
<td>8 cycles(^5)</td>
<td>5 cycles</td>
<td>29</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

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# Results – Temozolomide

<table>
<thead>
<tr>
<th>FDA Indication</th>
<th>Reported Median Duration of Use</th>
<th>MSTI Median Duration of Use</th>
<th># of pts</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glioblastoma (w/radiation)</td>
<td>85% completed&lt;sup&gt;1&lt;/sup&gt;</td>
<td>80.4% completed</td>
<td>46</td>
<td>0.41</td>
</tr>
<tr>
<td>Glioblastoma (maintenance)</td>
<td>3 cycles&lt;sup&gt;1&lt;/sup&gt;</td>
<td>6 cycles</td>
<td>26</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Anaplastic Astrocytoma</td>
<td>5 cycles&lt;sup&gt;2&lt;/sup&gt;</td>
<td>6 cycles</td>
<td>1</td>
<td>**</td>
</tr>
</tbody>
</table>

** insufficient values to run statistical test

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## Results – Lenalidomide

<table>
<thead>
<tr>
<th>FDA Indication</th>
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<th>MSTI Median Duration of Use</th>
<th># of pts</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple Myeloma</td>
<td>10.1 months(^1)</td>
<td>4.67 months</td>
<td>45</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Myelodysplastic Syndrome</td>
<td>32.9 weeks(^2)</td>
<td>12 weeks</td>
<td>8</td>
<td>0.194</td>
</tr>
<tr>
<td>Mantle Cell Lymphoma</td>
<td>95 days(^3)</td>
<td>28 days</td>
<td>2</td>
<td>**</td>
</tr>
</tbody>
</table>

**insufficient values to run statistical test**

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## Results – Abiraterone and Enzalutamide

<table>
<thead>
<tr>
<th>Chemotherapy Agent</th>
<th>FDA Indication</th>
<th>Reported Median Duration of Use</th>
<th>MSTI Median Duration of Use</th>
<th># of pts</th>
<th>p-value</th>
</tr>
</thead>
</table>
| Enzalutamide       | mCRPC          | 16.6 months\(^1\)  
8.3 months\(^2\) | 3 months                     | 20                   | <0.001  | <0.001  |
| Abiraterone        | mCRPC          | 15 cycles\(^3\)  
8 cycles\(^4\) | 6 cycles                     | 65                   | <0.001  | 0.03    |

mCRPC: metastatic castrate resistant prostate cancer

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Discussion

Potential Confounders

- Did not match patients to inclusion/exclusion criteria of trials
  - Did not distinguish between pre and post transplant treatment in Multiple Myeloma
  - Did not distinguish between pre & post chemotherapy for prostate cancer treatments
- Looked at top filled prescriptions in 2014 but analysis period was 2010-2013
## Conclusion

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<tr>
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<th>Duration of Use</th>
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<tbody>
<tr>
<td>Capecitabine</td>
<td>Metastatic Colorectal Cancer</td>
<td>Similar</td>
</tr>
<tr>
<td></td>
<td>Metastatic Breast Cancer</td>
<td>Longer</td>
</tr>
<tr>
<td></td>
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<td>Shorter</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>Glioblastoma (w/radiation)</td>
<td>Similar</td>
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<td></td>
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<tr>
<td>Lenalidomide</td>
<td>Multiple Myeloma</td>
<td>Shorter</td>
</tr>
<tr>
<td>Enzalutamide</td>
<td>mCRPC</td>
<td>Shorter</td>
</tr>
<tr>
<td>Abiraterone</td>
<td>mCRPC</td>
<td>Shorter</td>
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mCRPC: metastatic castrate resistant prostate cancer
Future Directions

- Perform a non-inferiority analysis
- Update data with more patient information
- Publish results in a peer reviewed oncology journal
Questions
Robert Mancini, PharmD, BCOP
mancinir@slhs.org