A Study on Prescribing Patterns of Monoclonal Antibodies on Cancer Patients in a Teaching Hospital of Central India

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ABSTRACT
The targeted anti cancer therapies include Monoclonal antibodies and Small molecules, for example tyrosine kinase inhibitors. Biologic therapy with Monoclonal Antibodies includes Rituximab, Trastuzumab, Bevacizumab, Alemtuzumab, Cetuximab, Panitumumab etc. The present study was undertaken to evaluate the Monoclonal antibodies drug prescription patterns in cancer hospital and to generate data on the extent of rational/irrational prescribing in this institute. It was a hospital based prospective observational study with follow up during the study period. Feedback from the study would help both the prescriber and institutional authorities to review their prescribing practices and modify if necessary to facilitate better health care delivery. In our study, Out of the 15 subjects, 9 were males (60%) and 6 were females (40%). Majority of the study subjects were in the age group 51-60 years (40%) followed by >60 years age group (26.6%). Out of 15 patients, 3 patients on Bevacizumab, 2 patients on Cetuximab, 5 patients on Nimotuzumab, 4 patients on Rituximab and 1 patients on Trastuzumab therapy. Out of these, 2 patients on Monoclonal antibody monotherapy, 2 patients on Monoclonal antibody along with radiotherapy (RT), 6 patients on Monoclonal antibody along with chemotherapy (CT) and 5 patients on Monoclonal antibody along with chemoradiotherapy (CRT).

Keywords: Monoclonal Antibodies, Bevacizumab, Cetuximab, Nimotuzumab, Rituximab, Trastuzumab.

INTRODUCTION
Cancer is a group of more than 100 different diseases that are characterized by uncontrolled cellular growth, local tissue invasion, and distant metastases.1 According to GLOBOCAN report in 2008, incidence of cancer in India is about 948.9 thousands patients and has a mortality of about 633.5 thousands.2 Cancer treatment may include surgery, radiotherapy and/or systemic medications (chemotherapy, endocrine therapy and/or biologic therapy with targeted agents). Several chemotherapeutic agents used in cancer treatment include doxorubicin, methotrexate, vincristine, cyclophosphamide, etoposide, cisplatin and carboplatin.3 The targeted anti cancer therapies include Monoclonal antibodies and Small molecules, for example tyrosine kinase inhibitors. Biologic therapy with Monoclonal Antibodies includes Rituximab, Trastuzumab, Bevacizumab, Alemtuzumab, Cetuximab, Panitumumab etc.4 The assessment of drug utilisation is important for clinical, educational and economic reasons9. There is enough evidence to demonstrate that prescribing of drugs has shifted from generics to branded and prescribing out of NLEM10,11. The rational prescribing can be assessed with the help of conducting prescription audit on continuous basis. Data about drug usage patterns in India are particularly lacking. Keeping these facts in consideration the present study has been planned to define the pattern of drug use in the cancer hospital.

The present study was undertaken to evaluate the Monoclonal antibodies drug prescription patterns in cancer hospital and to generate data on the extent of rational/irrational prescribing in this institute. Feedback from the study would help both the prescriber and institutional authorities to review their prescribing practices and modify if necessary to facilitate better health care delivery.

MATERIALS AND METHODS
Study area
After getting approval from the institutional ethical committee, the study was jointly conducted in the Department of Pharmacology and Ujjam Ba Cancer Hospital, NSCB medical college, Jabalpur from October 2012 to September 2013 and the first 6 months was the period of data collection.

Inclusion criteria
• Patients of either gender undergoing cancer treatment at Ujjam Ba Cancer Hospital, Jabalpur with Monoclonal Antibodies as part of their treatment regimen.

Exclusion criteria
Patient with following features were excluded:
• Patients who do not give informed consent for participation in the study.
• Patient who are not able to communicate properly.
Study design
It was a hospital based prospective observational study with follow up during the study period.

Data collection
Patient data collection form used to interview the patients was divided into two sections:

- Patient’s Prescription form.
- Patient Proforma.

Patient Proforma includes demographic details and drug and treatment history.

Data analysis
Data was spread in Microsoft Excel 2007 and analysis was done. Data was further analysed using the software SPSS 19 for windows for the following:

1. Age & Sex distribution of ADRs
Patients were divided into following age groups:

- Group 1 - 0 – 20 years of age
- Group 2 - 21 – 30 years of age
- Group 3 - 31 – 40 years of age
- Group 4 - 41 – 50 years
- Group 5 - 51 – 60 years
- Group 6 - ≥ 60 years of age

Patients in each age group were further segregated as Males & Females.

2. Drug utilization pattern
Patients receiving anticancer monoclonal antibodies (mAbs) were subdivided into patients receiving Monoclonal antibodies monotherapy, Monoclonal antibodies in combination with radiotherapy, Monoclonal antibodies in combination with chemotherapy and Monoclonal antibodies in combination with chemoradiotherapy. Patients receiving monoclonal antibodies monotherapy were grouped into patients receiving individual monoclonal antibodies. Patients receiving monoclonal antibodies polytherapy were further subdivided on the basis of individual combination.

Demographic data
Table 2 shows the age-wise distribution of the subjects in the study. Majority of the study subjects were in the age group 51-60 years (40%) followed by >60 years age group (26.6%) and 41-50 years age group (13.3%).

Table 2 shows the gender-wise distribution of the subjects in the study. Out of the 15 subjects, 9 were males (60%) and 6 were females (40%). The Male: Female ratio in this study was 1.5:1.
Figure 4: Drug utilization pattern monoclonal antibody combinations

Table 2: Age wise distribution

<table>
<thead>
<tr>
<th>Age</th>
<th>No. of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 20</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>21 - 30</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>31 - 40</td>
<td>1</td>
<td>6.7</td>
</tr>
<tr>
<td>41 - 50</td>
<td>2</td>
<td>13.3</td>
</tr>
<tr>
<td>51 - 60</td>
<td>6</td>
<td>40.0</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>4</td>
<td>26.6</td>
</tr>
<tr>
<td>TOTAL</td>
<td>15</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Table 3: gender wise distribution

<table>
<thead>
<tr>
<th>Gender</th>
<th>No. of patients</th>
<th>Percentage</th>
<th>Male:female ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>9</td>
<td>60</td>
<td>1.5</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
<td>40</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>100</td>
<td>1.5:1</td>
</tr>
</tbody>
</table>

Table 4: Drug utilization pattern

<table>
<thead>
<tr>
<th>Monoclonal Antibody (mAb)</th>
<th>mAb alone</th>
<th>mAb with RT</th>
<th>mAb with CT</th>
<th>mAb with CRT</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Nimotuzumab</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Rituximab</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

This table shows that out of 15 patients, 3 patients on Bevacizumab, 2 patients on Cetuximab, 5 patients on Nimotuzumab, 4 patients on Rituximab and 1 patient on Trastuzumab therapy. Out of these, 2 patients on Monoclonal antibody monotherapy, 2 patients on Monoclonal antibody along with radiotherapy (RT), 6 patients on Monoclonal antibody along with chemotherapy (CT) and 5 patients on Monoclonal antibody along with chemoradiotherapy (CRT).

DISCUSSION AND CONCLUSION

Rational prescription of drugs is essential for better patient care. The first step in any intervention programme to improve drug utilization is to assess the extent of existing problem in prescribing. The objective of our study was to evaluate the drug prescription patterns among patients admitted to the cancer hospital of a tertiary care hospital.

The demographic results of patients admitted to the cancer hospital revealed male preponderance and the majority of the patients were in the age group 51-60 years.

In our study Nimotuzumab and Rituximab were more prescribed than other monoclonal antibodies. Majority of the patient were in the group of monoclonal antibody along with chemotherapy.

Overall, scope for improving rational use of monoclonal antibodies exists. The present study on monoclonal antibody prescribing patterns in cancer hospital can provide a framework for continuous prescription audit in cancer hospital. Longitudinal surveillance of monoclonal antibodies use in cancer hospital can be carried out to create a database to compare the future trends in utilization of monoclonal antibodies.

This will help in rationalizing prescribing practices based on the feedback from this study and practices between institutions, regions and countries can be compared.

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REFERENCES


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