Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 in lung cancer: Comparison with RECIST version 1.0 - A Retrospective Study.

Poster No.: C-1406
Congress: ECR 2016
Type: Scientific Exhibit
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Keywords: Cancer, Audit and standards, CT, Respiratory system, Oncology, Lung
DOI: 10.1594/ecr2016/C-1406

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Aims and objectives

Assessment of the change in tumor burden is an important aspect of the clinical evaluation of cancer therapeutics. Initially, WHO tumor response criteria was considered as standard guideline for tumor response assessment.\(^1\) In 2000, Response Evaluation Criteria in Solid Tumors (RECIST) was introduced by RECIST working group. RECIST guidelines uses unidimensional measurements instead of bidimensional measurements, which was used in WHO tumor response criteria.\(^2\) RECIST criteria defines the minimum size of measurable lesions and provides instructions on how many lesions to follow (up to 10, with a maximum of 5 per organ). Subsequently RECIST criteria was considered as standard guideline for tumor response assessment.\(^3,4\) However number of issues were encountered in using RECIST criteria, which included the total number of lesions to be assessed, the assessment of lymph nodes, and the utility of newer imaging technologies such as multidetector computed tomography (MDCT) and positron emission tomography (PET).\(^5\) In 2009, revised RECIST version 1.1 guidelines were published with reduction in number of target lesions, assessment of lymph node size and clarification of disease progression.

Four major imaging-related changes were included in RECIST 1.1 as comparing to RECIST version 1.0 [Table:1].\(^6\) The number of target lesions to be assessed from a maximum of 10 to a maximum of five and from five per organ to two per organ. Assessment of lymph node size by lesions # 15 mm in the short axis are considered measurable and considered as target lesions in RECIST 1.1. There were no clear guidelines provided for assessing the lymph nodes in RECIST 1.0. Clarification of disease progression and inclusion of FDG PET in assessment of new lesions were also included in RECIST 1.1.

RECIST 1.1 showed almost perfect agreement with RECIST 1.0 in tumor response assessment of patients with solid tumors in western population by clinical trials.\(^7,8,9\) However comparison between RECIST 1.0 and RECIST 1.1 in Indian population was not well studied or documented. This study was conducted to compare the CT measurement and tumor response based on RECIST 1.1 and RECIST 1.0 in patients with lung cancer in Indian population.

Table:1. Difference between RECIST 1.1 and RECIST 1.0.\(^6\)

<table>
<thead>
<tr>
<th>RECIST guidelines</th>
<th>RECIST 1.1</th>
<th>RECIST 1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of target lesions</td>
<td>Up to 2 per organ; up to 5 in total</td>
<td>Up to 5 per organ; up to 10 in total</td>
</tr>
<tr>
<td>Assessment of lymph nodes</td>
<td>Short-axis measurements should be used and recorded; # 15 mm, target lesions; # 10 mm but &lt; 15 mm, nontarget lesions; &lt; 10 mm, Nonpathological.</td>
<td>No clear guideline provided</td>
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<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clarification of disease progression</td>
<td>20% increase in the sum of target lesions and 5-mm absolute increase are required</td>
<td>20% increase in the sum of target lesions (no minimum absolute size increase is required)</td>
</tr>
<tr>
<td>FDG PET scan</td>
<td>Included only in the detection of new lesions.</td>
<td>Not included</td>
</tr>
</tbody>
</table>
Methods and materials

It is a retrospective observational study conducted in the Department of Imageology, Regional Cancer Centre, Trivandrum. The study was approved by Regional Cancer Centre Institutional Review Board (IRB). Lung cancer patients receiving chemotherapy, who have both baseline and follow up CTs taken in our institute between September 2013 to February 2014 (6 months) were included as study subjects.

Forty eligible patients were included in this study. Patients demographic and treatment details are recorded from hospital information system. Tumor measurements and response assessment were performed using RECIST 1.0 and RECIST 1.1 guidelines independently using a measurement tool on PACS workstation (Centricity, GE Healthcare). The variables analyzed are the number of target lesions included, percentage change in follow up CT measurements, sum of largest diameters of target lesions and overall tumor response between RECIST 1.0 and RECIST 1.1.

Data analysis was done by using SPSS.20 statistical software. To measure the mean difference in the number of target lesions included and the sum of largest diameters of target lesions between the two groups the paired Student’s t test is used. The percentage changes in follow-up CT measurements relative to baseline were compared between two groups by using Pearson’s correlation. Concordance of overall tumor responses between the two groups is assessed using the kappa value.
Results

Forty carcinoma lung patients (36 males, 4 females) on chemotherapy with baseline and follow up CT are analyzed. Mean age of patients is 58.52 with the range of 32 to 73. The variables analyzed were number of target lesions, sum of largest diameters of the target lesions, percentage change of target lesions in follow up CT and overall response.

1. Number of target lesions:

The number of target lesions according to RECIST version 1.1 decreased in 23 patients (57.5%), compared with the number according to RECIST version 1.0.

The number of target lesions according to RECIST 1.0 ranged from one to nine (mean - 2.45±1.65), whereas the number of target lesions according to RECIST 1.1 ranged from one to five (mean - 1.55±0.9) [Figure 1].

The number of target lesions using RECIST 1.1 was significantly lower than that using RECIST 1.0 (p < 0.0001, paired Student's t test) with mean difference of 0.9.

2. Sum of largest diameters of the target lesions:

The sum of largest diameters of the target lesions at baseline CT using RECIST 1.1 (mean - 58.40±35.54 mm) was also significantly lower than that using RECIST 1.0 (mean - 71.29±46.39 mm), with mean difference of 12.9 mm (p < 0.0001, paired Student's t test) [Figure 2].

3. Percentage change of target lesions in follow up CT:

The percentage change of target lesions in follow up CT between RECIST 1.1 and RECIST 1.0 in the sum of largest diameters of the target lesions showed a high correlation (r = 0.985 and r² = 0.97, Pearson's correlation) [Figure 3].

4. Overall response:

There was a near perfect agreement in the CT assessment of tumor response between RECIST 1.1 and RECIST 1.0, with a kappa value of 0.954 (P<0.0001). Only one patient with stable disease based on RECIST 1.0 was reclassified as progressive disease by RECIST 1.1.
Fig. 1: No of target lesions

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Fig. 2: Sum of largest dimensions

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Fig. 3: Percentage change in follow up CT

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Conclusion

This study showed significant reduction in number of target lesions according to RECIST 1.1 as comparing with RECIST 1.0. Because of maximum of two target lesions per organ and lymph node criteria (lymph node of # 15 mm in the short axis measurement considered measurable disease) reduced number of target lesions was recorded in 23 of 40 patients. Similarly the sum of largest diameters of target lesions also showed significantly reduced values with mean difference of 12.9 mm.

Percentage change in follow up CT showed perfect correlation between RECIST 1.1 and RECIST 1.0. In thirty nine out of forty patients showed similar overall response rate (24 stable disease, 10 progressive disease and 5 partial response) with kappa correlation of 0.954 (P<0.0001). Only one patient with stable disease based on RECIST 1.0 was reclassified as progressive disease by RECIST 1.1.

Using RECIST 1.1 there was significant reduction in the number of target lesions to be assessed. Inspite of decreased target lesions, RECIST 1.1 showed almost perfect agreement in response assessment as compared with RECIST 1.0 in lung cancer patients in Indian population. This study provides evidence for the accuracy of RECIST version 1.1 and recommends the same for tumor response assessment.
References


