Revised RECIST Guideline Version 1.1: What Oncologists Want to Know and What Radiologists Need to Know

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OBJECTIVE. The objectives of this article are to review the new Response Evaluation Criteria in Solid Tumors (RECIST) guideline, version 1.1, highlighting the major changes in the new version compared with the original RECIST guideline (version 1.0), and to present case examples with representative imaging.

CONCLUSION. Familiarity with the revised RECIST is essential in day-to-day oncologic imaging practice to provide up-to-date service to oncologists and their patients. Some of the changes in the revised RECIST affect how radiologists select, measure, and report target lesions.

Objective assessment of the change in tumor burden is important to evaluate tumor response to therapy. The Response Evaluation Criteria in Solid Tumors (RECIST) was introduced in 2000 by an International Working Party to standardize and simplify tumor response criteria [1]. Key features of the original RECIST, version 1.0, included definitions of the minimum size of measurable lesions, instructions about how many lesions to follow, and the use of unidimensional measures for evaluation of overall tumor burden [1]. RECIST has subsequently been widely accepted as a standardized measure of tumor response, particularly in oncologic clinical trials in which the primary endpoints are objective response or time to progression [2]. With rapid technical innovations in imaging techniques including MDCT and PET combined with CT (PET/CT), the limitations of the original RECIST and the need for revision have become clear [2].

In January 2009, a revised RECIST guideline (version 1.1) based on a database consisting of more than 6,500 patients with greater than 18,000 target lesions was presented by the RECIST Working Group [2–5]. Some of the clinical trials at tertiary cancer centers have already started to use the revised guideline, RECIST 1.1, instead of the original RECIST 1.0. Awareness and knowledge of the new criteria are essential for radiologists involved in imaging and response assessment of cancer patients.

In this article, we review the new RECIST guideline, focusing on the major changes in the new version compared with the original RECIST guideline; provide representative cases in which application of the new RECIST guideline influences the response evaluation; and discuss future directions.

Review of the Original RECIST Guideline

The original RECIST guideline, version 1.0, provided definitions for "measurable lesion" and "nonmeasurable lesion" [1]. Measurable lesions must have a longest diameter of ≥ 10 mm on CT with a slice thickness of ≤ 5 mm (or a longest diameter of ≥ 20 mm on nonhelical CT with a slice thickness of > 10 mm) or a longest diameter of ≥ 20 mm on chest radiography [1] (Fig. 1).

Nonmeasurable lesions include other lesions that do not meet the criteria as measurable lesions, such as small lesions with a longest diameter of < 10 mm, skeletal metastases without a soft-tissue component, ascites, pleural effusion, lymphangitic spread of tumor, leptomeningeal disease, inflammatory breast disease, cystic or necrotic lesions, lesions in an irradiated area, and an abdominal mass not confirmed by imaging [1] (Fig. 2).

After identifying measurable and nonmeasurable lesions according to the guideline, target lesions are selected at baseline. Target lesions include all measurable lesions—up to five per organ and 10 total—and are recorded and measured at baseline [1]. Target lesions are selected on the basis of their size (i.e., longest diameter) and suitability for accurate repeated measurements

Keywords: CT, oncologic imaging, response assessment, Response Evaluation Criteria in Solid Tumors, RECIST, RECIST 1.1, tumor measurement

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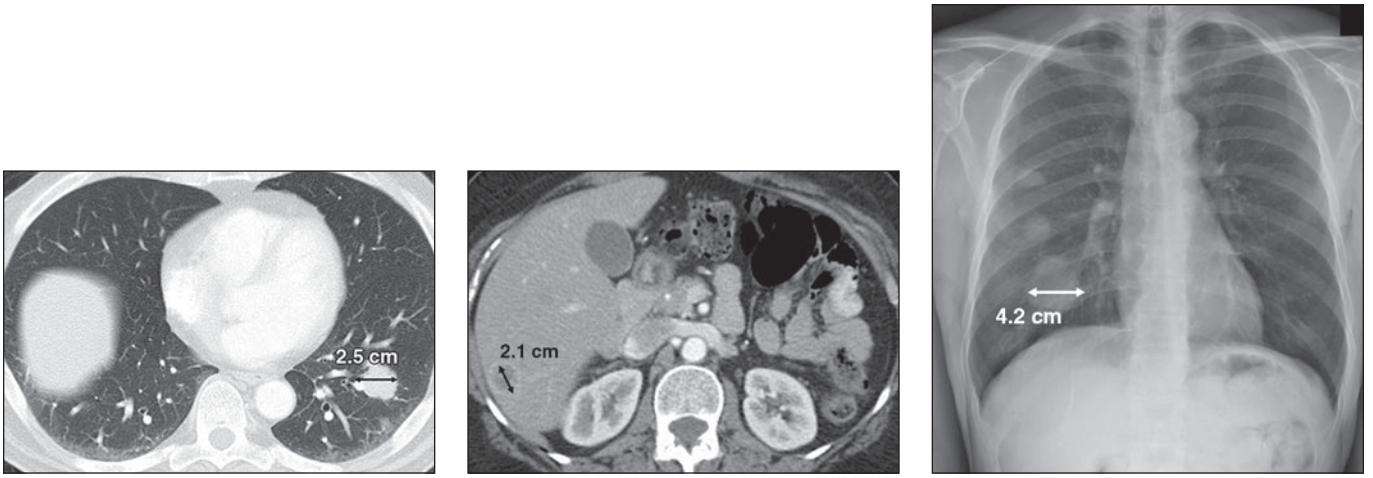


Fig. 1—Measurable lesions according to Response Evaluation Criteria in Solid Tumors (RECIST).
A, CT scan of chest in 64-year-old man with colon cancer. Lobulated nodule in left lower lobe representing metastasis measures 2.5 cm in longest diameter (*arrow*), meeting criteria for measurable lesion on CT (longest diameter ≥ 10 mm).
B, CT scan of abdomen in 75-year-old woman with lung cancer shows metastatic lesion in liver that measures 2.1 cm in longest diameter (*arrow*), meeting criteria for measurable lesion on CT (longest diameter ≥ 10 mm).
C, Frontal chest radiograph in 52-year-old woman shows mass with longest diameter of 4.2 cm (*arrow*) representing lung cancer, which meets criteria for measurable lesion on chest radiography (longest diameter ≥ 20 mm).

[1]. The sum of the longest diameters for all target lesions is recorded and used for objective tumor response assessment [1] (Fig. 3). Nontarget lesions include all other lesions or sites of disease. Measurements of nontarget lesions are not required; however, the presence or absence of each nontarget lesion should be noted at baseline and follow-up examinations [1].

RECIST assigns four categories of response: complete response (CR), partial response (PR), stable disease (SD), and progressive disease (PD) [1]. The criteria of response evaluation of target lesions and nontarget lesions are summarized in Table 1 with a case example in Figure 4. Assessment of overall response is based on the evaluations of target and nontarget lesions at each follow-up time point. The measurements and response assessment are often recorded using tumor measurement tables [6] (Fig. 5).

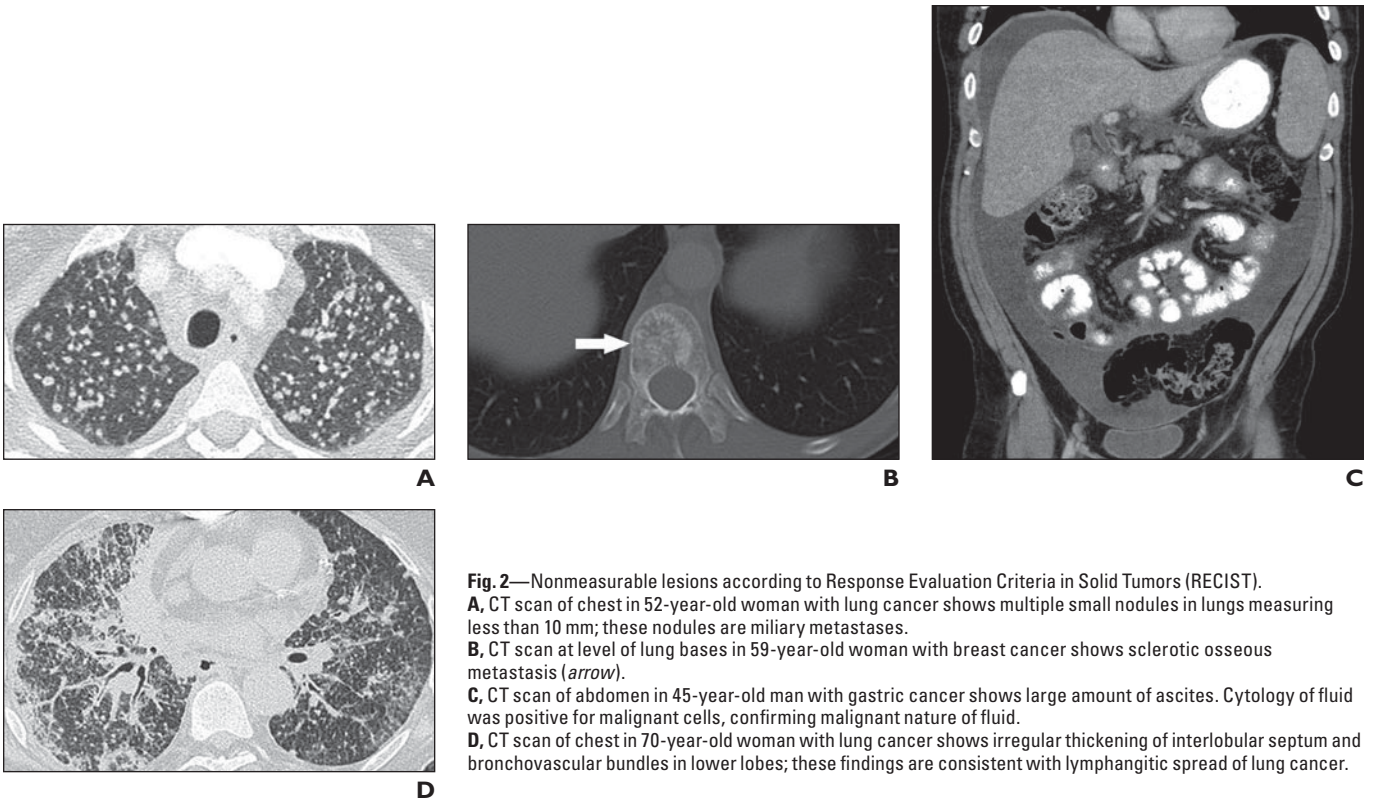


Fig. 2—Nonmeasurable lesions according to Response Evaluation Criteria in Solid Tumors (RECIST).
A, CT scan of chest in 52-year-old woman with lung cancer shows multiple small nodules in lungs measuring less than 10 mm; these nodules are miliary metastases.
B, CT scan at level of lung bases in 59-year-old woman with breast cancer shows sclerotic osseous metastasis (*arrow*).
C, CT scan of abdomen in 45-year-old man with gastric cancer shows large amount of ascites. Cytology of fluid was positive for malignant cells, confirming malignant nature of fluid.
D, CT scan of chest in 70-year-old woman with lung cancer shows irregular thickening of interlobular septum and bronchovascular bundles in lower lobes; these findings are consistent with lymphangitic spread of lung cancer.

TABLE 1: Evaluation of Target and Nontarget Lesions by Response Evaluation Criteria in Solid Tumors (RECIST), Version 1.0

Response Assessment	RECIST Guideline, Version 1.0
Evaluation of target lesions	
CR	Disappearance of all target lesions
PR	≥ 30% decrease in the sum of the longest diameters of target lesions compared with baseline
PD	≥ 20% increase in the sum of the longest diameter of target lesions compared with the smallest-sum longest diameter recorded or the appearance of one or more new lesions
SD	Neither PR or PD
Evaluation of nontarget lesions	
CR	Disappearance of all nontarget lesions and normalization of tumor marker level
Incomplete response, SD	Persistence of one or more nontarget lesions and/or the maintenance of tumor marker level above the normal limits
PD	Appearance of one or more new lesions and/or unequivocal progression of existing nontarget lesions

Note—CR = complete response, PR = partial response, PD = progressive disease, SD = stable disease.

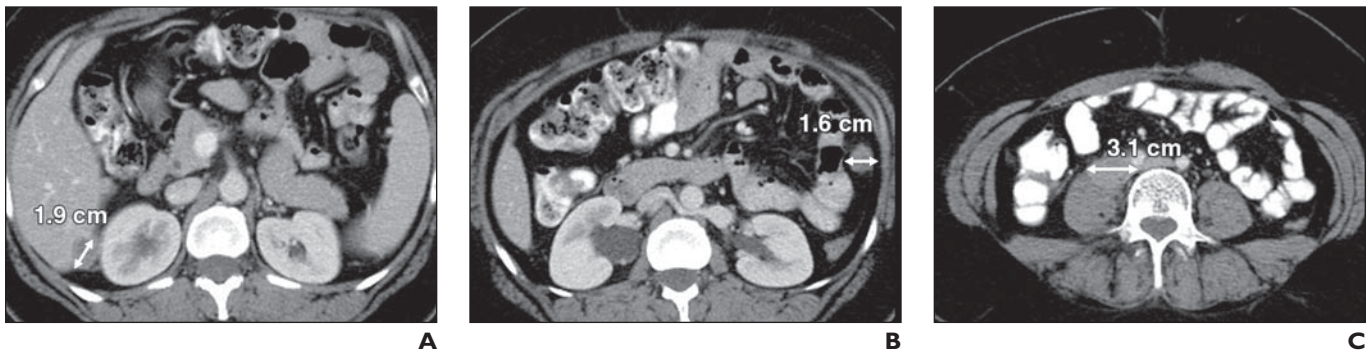


Fig. 3—Target lesions and their measurement.
A–**C,** CT images of abdomen in 49-year-old woman with metastatic ovarian cancer show three measurable lesions (liver lesion, peritoneal implant, and enlarged iliac lymph node) that are selected as target lesions. Measurements of target lesions are 1.9 cm (**A**), 1.6 cm (**B**), and 3.1 cm (**C**), totaling 6.0 cm.

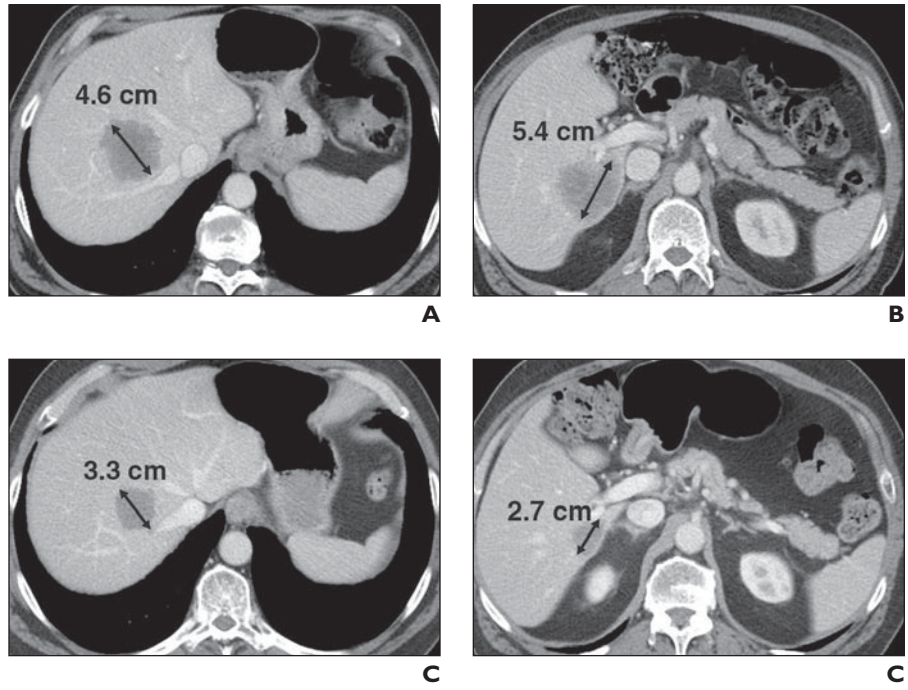
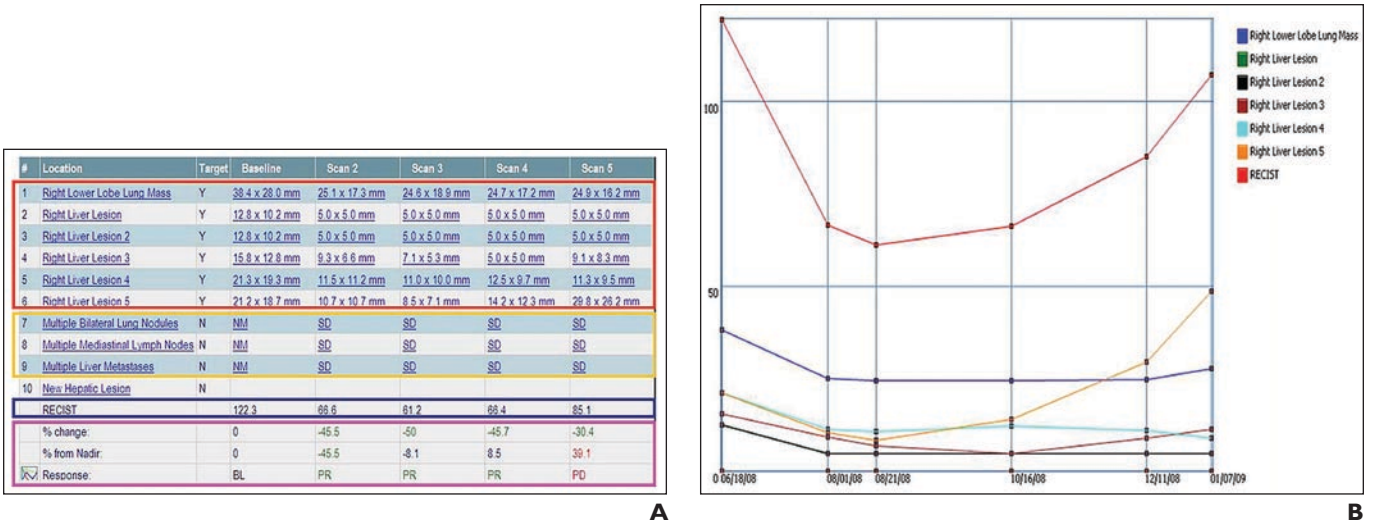


Fig. 4—Response assessment.
A and **B,** Baseline CT scans of abdomen in 68-year-old man with colon cancer show two target lesions (*arrow*) in liver. Measurements according to Response Evaluation Criteria in Solid Tumors (RECIST) are 4.6 cm (**A**) and 5.4 cm (**B**), totaling 10.0 cm.
C and **D,** Follow-up CT scans obtained after initiation of therapy show decrease in size of target lesions (*arrow*). RECIST measurements are 3.3 cm (**C**) and 2.7 cm (**D**), totaling 6.0 cm. Given 40% decrease in sum of measurements of target lesions relative to baseline [(10 cm – 6 cm) / 10 cm × 100], assessment of target lesions by RECIST is partial response.



#	Location	Target	Baseline	Scan 2	Scan 3	Scan 4	Scan 5
1	Right Lower Lobe Lung Mass	Y	38.4 x 28.0 mm	25.1 x 17.3 mm	24.8 x 18.9 mm	24.7 x 17.2 mm	24.9 x 16.2 mm
2	Right Liver Lesion	Y	12.8 x 10.2 mm	5.0 x 5.0 mm	5.0 x 5.0 mm	5.0 x 5.0 mm	5.0 x 5.0 mm
3	Right Liver Lesion 2	Y	12.8 x 10.2 mm	5.0 x 5.0 mm	5.0 x 5.0 mm	5.0 x 5.0 mm	5.0 x 5.0 mm
4	Right Liver Lesion 3	Y	15.8 x 12.8 mm	9.3 x 6.6 mm	7.1 x 5.3 mm	5.0 x 5.0 mm	9.1 x 8.3 mm
5	Right Liver Lesion 4	Y	21.3 x 19.3 mm	11.5 x 11.2 mm	11.0 x 10.0 mm	12.5 x 9.7 mm	11.3 x 9.5 mm
6	Right Liver Lesion 5	Y	21.2 x 18.7 mm	10.7 x 10.7 mm	8.5 x 7.1 mm	14.2 x 12.3 mm	28.8 x 26.2 mm
7	Multiple Bilateral Lung Nodules	N	NM	SD	SD	SD	SD
8	Multiple Mediastinal Lymph Nodes	N	NM	SD	SD	SD	SD
9	Multiple Liver Metastases	N	NM	SD	SD	SD	SD
10	New Hepatic Lesion	N					
	RECIST		122.3	66.6	61.2	66.4	85.1
	% change:		0	-45.5	-50	-45.7	-30.4
	% from Nadir:		0	-45.5	-8.1	8.5	39.1
	Response:		BL	PR	PR	PR	PD

A B

Fig. 5—Screen shots show tumor measurement record of 46-year-old woman with lung cancer.
A, Tumor measurement record lists target lesions with series and image numbers and measurements at baseline and on follow-up CT scans (*red square*). Nontarget lesions (*yellow square*) are also listed. Sum of longest diameters of all target lesions (*blue square*) is recorded. Percent changes compared with baseline and nadir (smallest diameter since baseline, *pink square*) provide response assessment at each follow-up scan.
B, Graph shows chronologic changes of longest diameters of each target lesion and sum of longest diameters of all target lesions (*red line*).

Major Imaging-Related Changes in Revised RECIST Guideline

Major changes in RECIST 1.1 related to imaging include the following: first, the number of target lesions; second, assessment of pathologic lymph nodes; third, clarification of disease progression; fourth, clarification of unequivocal progression of nontarget lesions; and, fifth, inclusion of ^{18}F-FDG PET in the detection of new lesions [2].

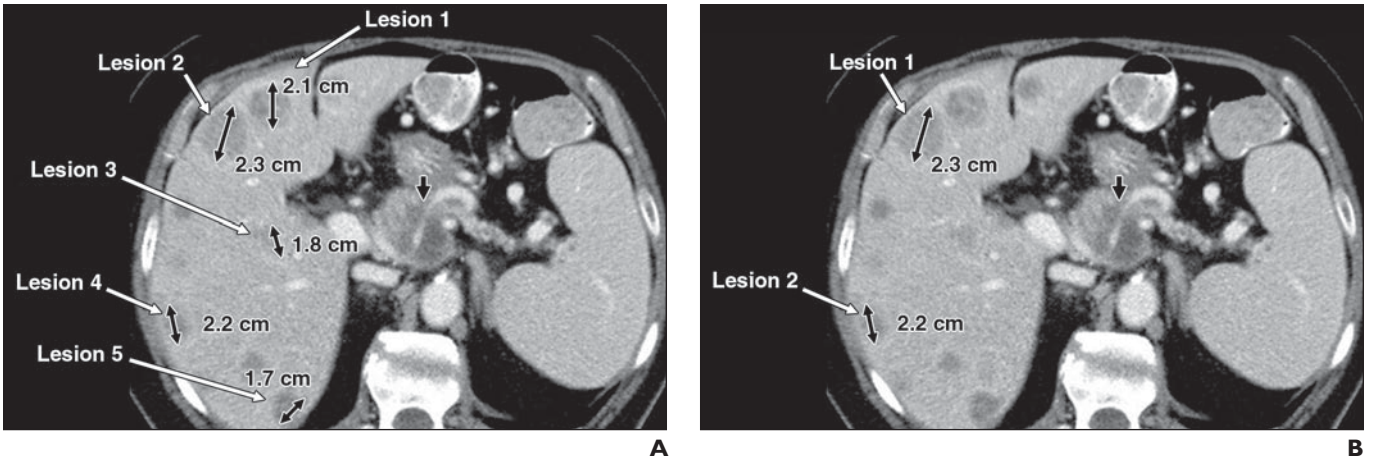
Number of Target Lesions

The number of target lesions to be assessed was reduced from five per organ to two per organ and from a maximum of 10 target lesions total to a maximum of five total [2] (Figs. 6 and 7). The change is based on the analysis of a large prospective database from 16 clinical trials that showed that assessment of five lesions per patient did not influence the overall response rate and only minimally affected progression-free survival [3].

Assessment of Pathologic Lymph Nodes

In RECIST 1.0, there was no clear guideline for lymph node measurement. In RECIST 1.1, detailed instructions about how to measure and assess lymph nodes are provided [2, 5]. Lymph nodes with a short axis of ≥ 15 mm are considered measurable and assessable as target lesions, and the short-axis measurement should be included in the sum of target lesion measurements in the calculation of tumor response as opposed to the longest axis used for measurements of other target lesions. Lymph nodes with a short axis of < 10 mm are defined as "nonpathologic" (Fig. 8A). All other pathologic nodes—that is, those with a short axis of ≥ 10 mm but < 15 mm—should be considered nontarget lesions [2] (Fig. 8B).

Given the changes made in the assessment of pathologic lymph nodes, CR by RECIST 1.1



A B

Fig. 6—Number of target lesions according to revised Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, has been reduced to up to two target lesions per organ.
A, CT scan of abdomen in 72-year-old woman with pancreatic cancer shows dominant pancreatic mass (*single-headed black arrow*) with multiple metastatic lesions in liver. Using RECIST, version 1.0, up to five lesions per organ (*white arrows*) could be selected. Double-headed black arrows show longest diameter of each lesion.
B, Using RECIST, version 1.1, which allows only up to two lesions per organ, only two liver lesions should be selected as target lesions (*white arrows*). Double-headed black arrows show longest diameter of each lesion.

requires, first, the disappearance of all target lesions; and, second, a reduction in the short-axis measurement of all pathologic lymph nodes (whether target or nontarget) to < 10 mm [2]. It is likely that the changes in the lymph node assessment mainly influence the evaluation of patients with epithelial cancers, which tend to metastasize to the lymph nodes.

Clarification of Disease Progression

PD for target lesions according to RECIST 1.1 requires a 5-mm absolute increase of the sum of the longest diameters of the target lesions in addition to a 20% increase in the sum of the target lesions [2] (Fig. 9). The new criterion of a 5-mm absolute change in size is particularly important in the follow-up assessment of patients with small-volume disease after response to therapy because a minimal increase in size due to measurement variability could meet the criterion of 20% increase by RECIST 1.0 without a true increase in tumor burden in these patients (Fig. 10).

Clarification of Unequivocal Progression of Nontarget Lesions

RECIST 1.1 further clarifies when one can assign "unequivocal progression" of nontarget lesions in the response assessment [2]. When measurable disease or a target lesion is present, the overall level of substantial worsening in nontarget disease, which leads to an increase of overall tumor burden even with SD or PR in target disease, is required to assign progression [2]. RECIST 1.1 emphasizes that a modest increase in the size of one or more nontarget lesions is usually not sufficient and that progression solely based on change in nontarget disease in patients with SD or PR of target disease is extremely rare [2].

If no measurable disease is present, which may be the case in some phase III trials that do not require measurable disease as a criterion for study entry, the same general concepts apply as in cases with measurable disease [2]. An increase of tumor burden that would be required to declare PD for measurable disease should be present. Examples include an increase in pleural effusion from trace to large or an increase in lymphangitic disease from localized to widespread [2].

Inclusion of FDG PET in the Detection of New Lesions

One of the major changes in RECIST 1.1 is the inclusion of FDG PET in the detection of new lesions that define progression [2]. RECIST 1.1 provides a detailed guideline for using FDG PET to detect new lesions, as summarized in Figure 11. The inclusion of FDG PET, which evaluates glucose metabolism of tumor, adds a new functional aspect of response assessment to RECIST, which has been solely based on morphologic assessment using size measurements (Fig. 12).

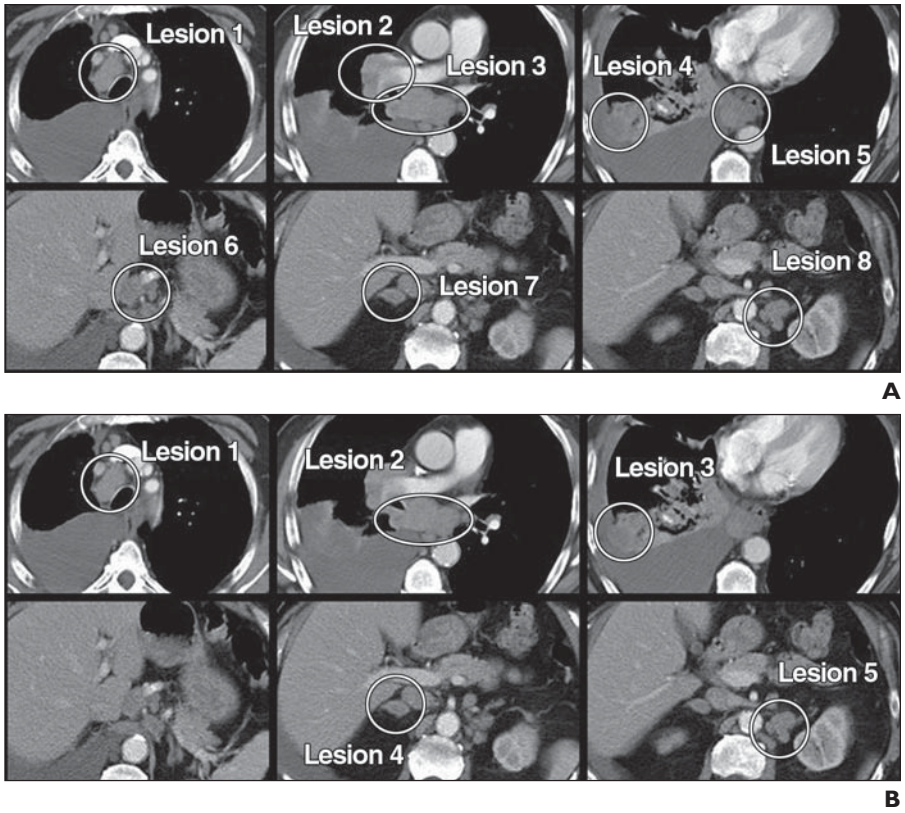


Fig. 7—Number of target lesions according to Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1, has been reduced to up to five total.
A, CT scans of chest in 74-year-old man with advanced non–small cell lung cancer show multiple enlarged thoracic and upper abdominal lymph nodes, lesion in right lower lobe of lung, and bilateral adrenal metastases. Using RECIST 1.0, which allows up to 10 lesions total, all eight lesions (*circles*) could be selected as target lesions. **B,** Using RECIST 1.1, maximum of five lesions (*circles*) total can be selected to adhere to rule of up to two target lesions per organ.

Issues Remaining to Be Solved

Despite the significant revisions made in RECIST 1.1, many issues remain to be solved in the response assessment of tumors in day-to-day practice. Examples of such problems that are discussed in this section include, first, the CT attenuation measurement (known as the Choi criteria [7, 8]) in gastrointestinal stromal tumor (GIST); second, intratumoral hemorrhage in response to treatment; and, third, cavitation of lung lesions.

CT Attenuation in Gastrointestinal Stromal Tumor

In patients with GIST naive to any molecular targeted therapy and initially treated with the tyrosine kinase inhibitor imatinib, CT attenuation has been used as an important tumor response parameter. After treatment with imatinib, the overall tumor CT attenuation decreases dramatically with development of myxoid degeneration, hemorrhage, or necrosis [7, 8] (Fig. 13). This pattern of response is important to recognize particularly in the context of hepatic metastases because apparent "new lesions" may appear in response to therapy. These lesions are initially isodense to the hepatic parenchyma but become hypodense (and therefore visible) in response to therapy and should not be confused with new lesions and misinterpreted for PD. If there is any ambiguity regarding the CT interpretation, FDG PET can help resolve this and confirm that there is no metabolic activity within these masses. Choi response criteria, defined as a 10% decrease in the unidimensional tumor size or a 15% decrease in CT attenuation, have been shown to correlate well with response by FDG PET and to be more predictive of time to progression than response

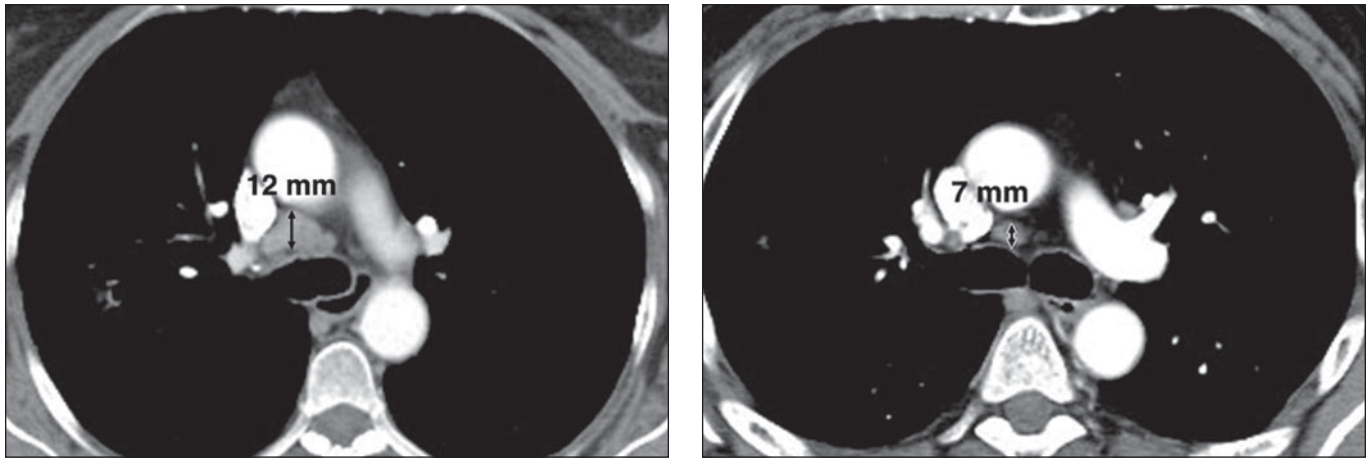


Fig. 8—Assessment of pathologic lymph nodes by Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1.
A, CT scan of patient with lung cancer. Subcarinal lymph node measures 12 mm in short axis (*arrow*) on chest CT, so it should be considered as nontarget lesion according to RECIST 1.1.
B, CT scan of patient with lung cancer. Precarinal lymph node measures 7 mm in short axis (*arrow*). Given that short-axis diameter is less than 10 mm, lymph node is nonpathologic according to RECIST 1.1.

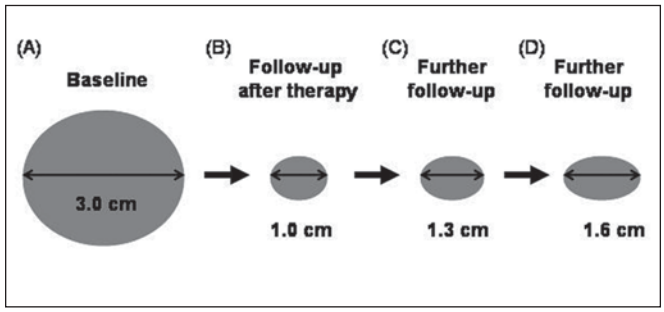


Fig. 9—Clarification of disease progression. Target lesion at baseline (A) has longest diameter of 3.0 cm. On follow-up study after initiation of therapy (B), lesion measures 1.0 cm—showing 67% decrease in size compared with baseline. This finding is consistent with partial response. On further follow-up study (C), lesion has slightly increased in size and measures 1.3 cm. Because 30% increase in size of lesion since smallest diameter (nadir) of 1.0 cm, assessment category according to Response Evaluation Criteria in Solid Tumors (RECIST) 1.0 would be progressive disease and therapy would be terminated. However, using RECIST 1.1, which requires 5-mm absolute increase in size in addition to > 20% increase, assessment would be stable disease and therapy would be continued. If further follow-up showed increase to diameter of 1.6 cm (D), then criteria for progressive disease according to RECIST 1.1 would be met—that is, > 5 mm absolute increase in size in addition to > 20% increase compared with nadir.

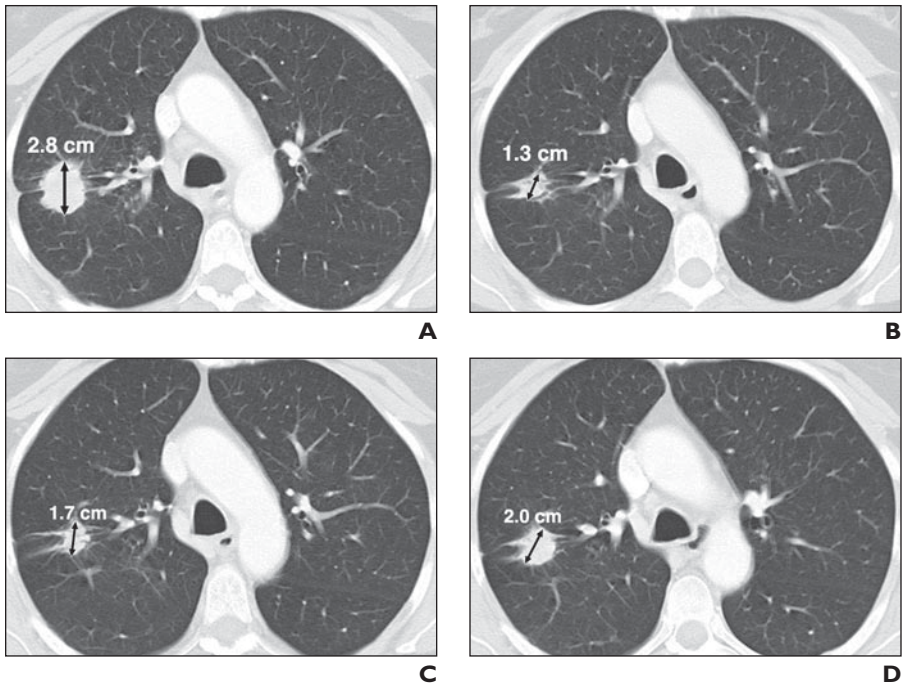


Fig. 10—Clarification of disease progression in 55-year-old woman with non–small cell lung carcinoma treated with epidermal growth factor receptor inhibitor erlotinib.
A, CT scan of chest shows spiculated right lung lesion, which was only target lesion, has longest diameter of 2.8 cm (*arrow*).
B, After one cycle of therapy, lesion measures 1.3 cm (*arrow*), showing 54% decrease in size compared with baseline. This change is consistent with partial response.
C, After initial response, small residual tumor slowly increased in size and measured 1.7 cm (*arrow*) on further follow-up study. Given 30% increase compared with nadir (1.3 cm), assessment using Response Evaluation Criteria in Solid Tumors (RECIST) 1.0 would be progressive disease and therapy would be terminated. However, using RECIST 1.1, assessment is stable disease because absolute increase in size is less than 5 mm.
D, Another follow-up CT scan shows further increase in size of residual tumor with longest diameter of 2.0 cm (*arrow*), which meets criteria for progressive disease by RECIST 1.1 given 54% increase and 6-mm absolute increase in size compared with nadir.

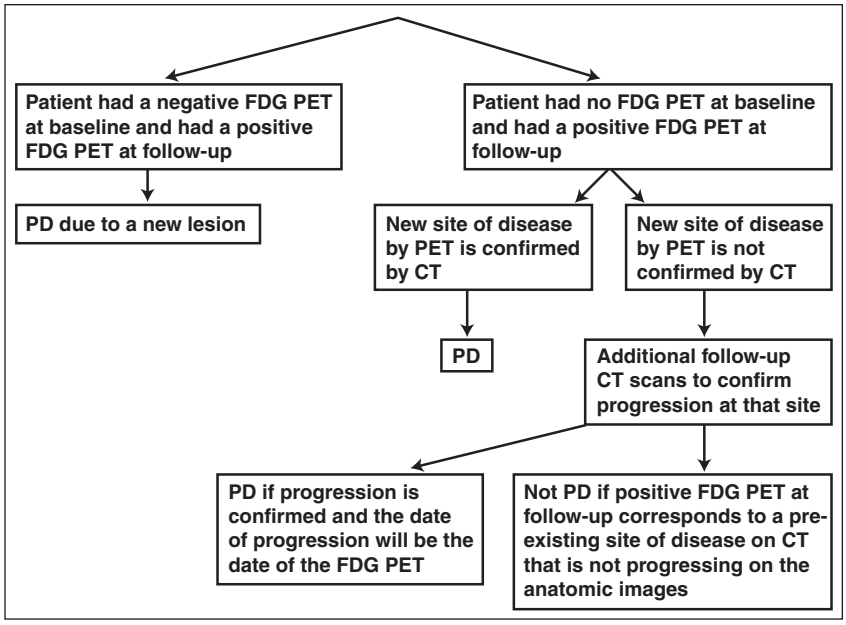


Fig. 11—Summary of guideline for including FDG PET in detection of new lesions according to Response Evaluation Criteria in Solid Tumors, version 1.1. PD = progressive disease.

by RECIST 1.0 [8]. Similar criteria using CT attenuation have been shown to be useful for response assessment in soft-tissue sarcomas other than GIST and in carcinomas [9, 10]. It is important to note that, in patients with GIST after the initial response to imatinib, recurrent disease may show a "nodule-within-a-mass" pattern that cannot be detected as PD using conventional size measurements alone [11].

Paradoxical Increase of Tumor Size in Response to Therapy Due to Hemorrhage or Necrosis

Targeted anticancer therapy using antiangiogenesis agents or tyrosine kinase inhibitors is known to cause a paradoxical increase of tumor size despite response because of hemorrhage or necrosis. This phenomenon is often seen in liver tumors, including hepatocellular carcinoma and liver metastasis from GIST or melanoma [11, 12]. A paradoxical increase in size in the setting of hemorrhage or necrosis in responding tumors should not be mistaken for PD, and MRI can be performed to confirm the presence of these intratumoral changes (Fig. 14). FDG PET can also help confirm metabolic response in these tumor masses despite the apparent increase in size. Radiologists must be aware of this phenomenon to avoid misinterpretation and to prompt appropriate further evaluation by MRI or PET/CT.

Cavitation of Lung Lesions

Cavitation of lung lesions is commonly observed, especially in non–small cell lung cancer treated with antiangiogenic agents such as vascular endothelial growth factor receptor inhibitors [13, 14]. Cavitation of lung lesions provides a challenge to radiologists who try to obtain the appropriate measurement that best represents tumor burden. Rather than simply measuring the longest diameter of a lesion including the area of cavitation, an alternative measurement that excludes the area of cavitation has been proposed [14] (Fig. 15). Response assessment might be improved by incorporating cavitation into tumor measurement; however, further prospective study is needed to validate this hypothesis.

Future Directions: Volume and Functional Assessment

Recent rapid progress in MDCT technology has enabled scanning of large anatomic volumes in a single breath-hold with isotropic voxels and high resolution. Three-dimensional methods for nodule and tumor volume measurement—aiming for more accurate and consistent tumor measurement and better determination of temporal change in a

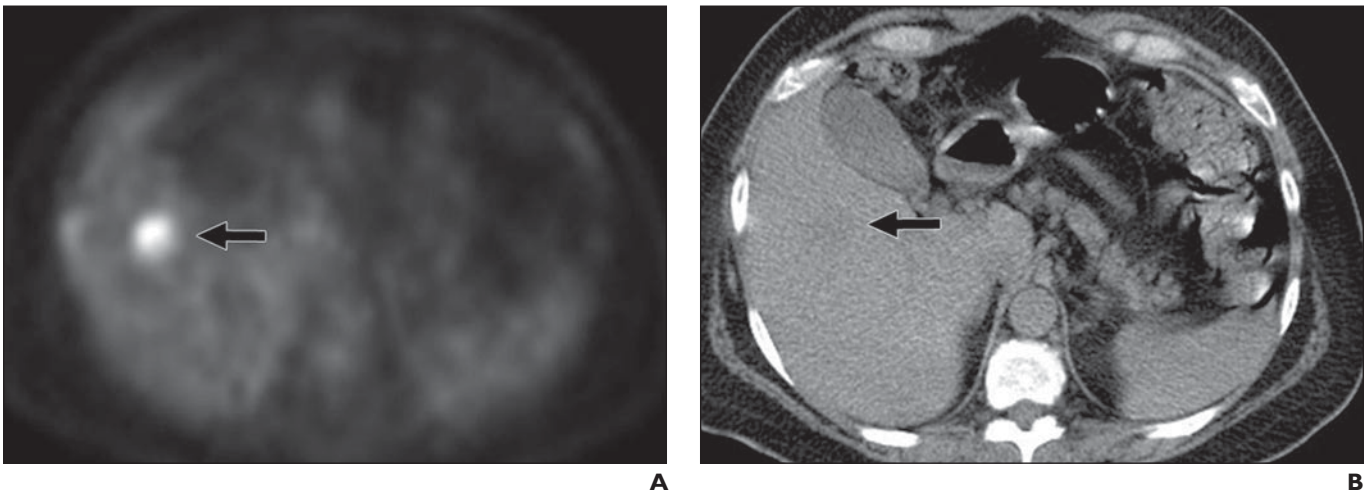


Fig. 12—FDG PET in detection of new lesions in 48-year-old woman with breast cancer who had negative FDG PET/CT findings at baseline.
A and **B,** Follow-up FDG PET/CT images show new FDG-avid liver lesion (*arrows*) representing metastasis. Finding meets criteria for progressive disease using Response Evaluation Criteria in Solid Tumors 1.1 because new lesion has been detected on FDG PET.

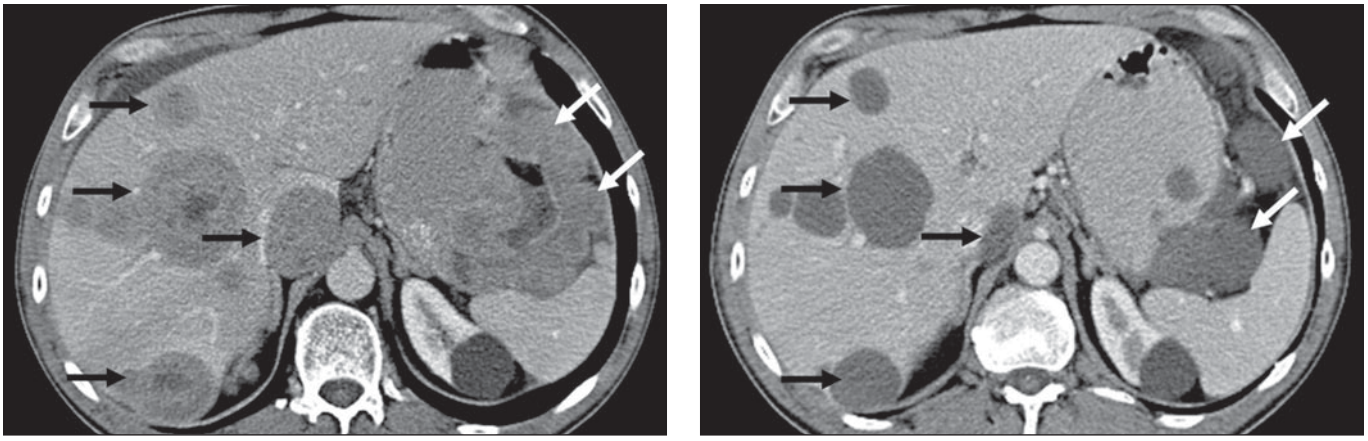


Fig. 13—CT attenuation decrease in gastrointestinal stromal tumor (GIST) treated with tyrosine kinase inhibitor imatinib.
A, CT scan of abdomen in 59-year-old man with gastric GIST shows circumferential mass involving gastric wall (*white arrows*) and multiple liver masses (*black arrows*) representing metastases.
B, Follow-up CT scan of abdomen shows markedly decreased CT attenuation in both gastric and liver lesions (*arrows*). According to Choi criteria, these changes in CT attenuation indicate response to imatinib therapy.

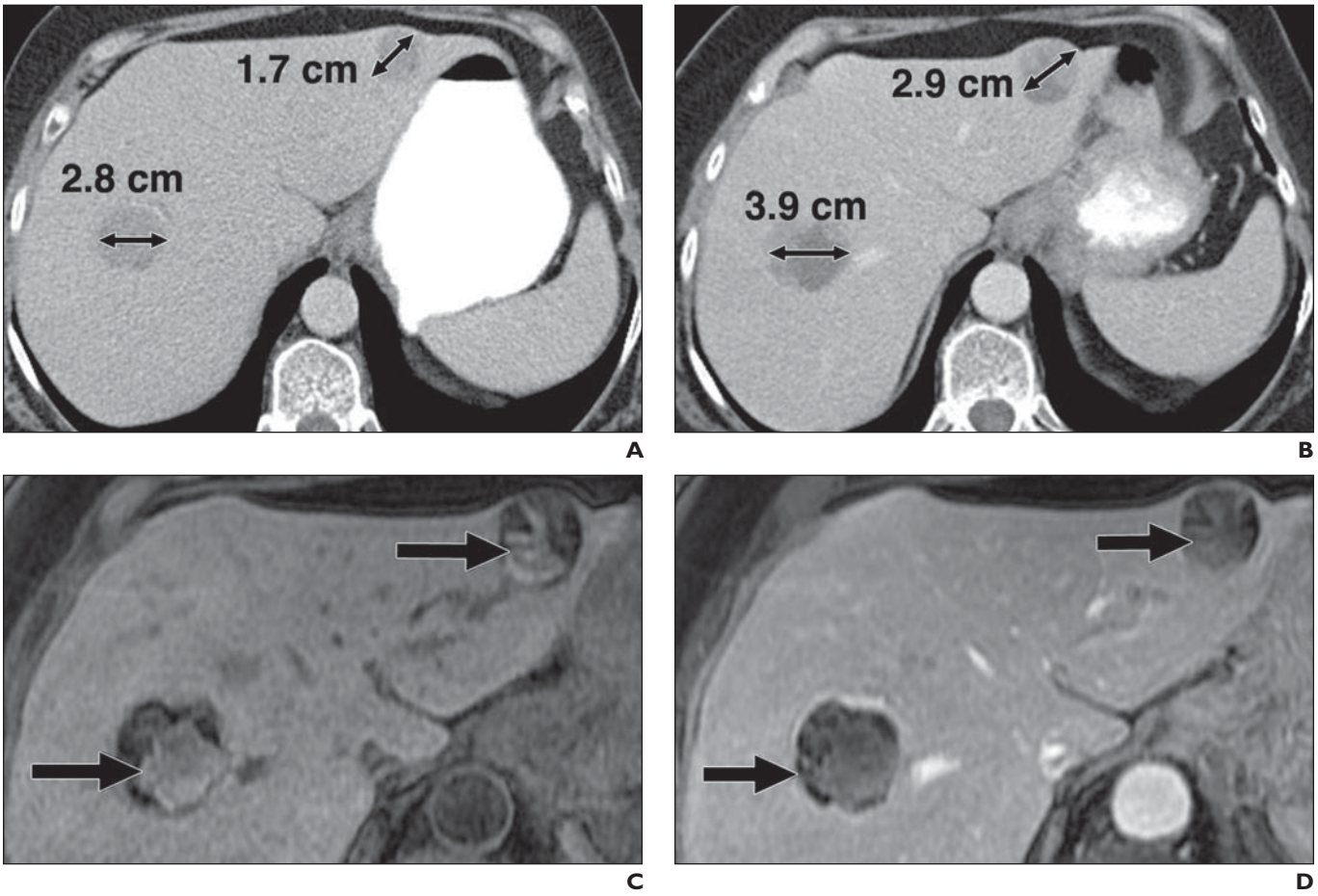


Fig. 14—Paradoxical increase in size of target lesions after targeted therapy in 69-year-old woman with melanoma.
A, Baseline CT scan of abdomen shows two metastatic lesions in liver.
B, Follow-up CT scan obtained after treatment with tyrosine kinase inhibitor, sorafenib, shows increase in size of metastatic liver lesions, measuring 3.9 cm at follow-up compared with 2.8 cm at baseline and 2.9 cm compared with 1.7 cm at baseline. Note heterogeneous CT attenuation within liver lesions.
C and **D,** MR images of abdomen show central high signal intensity of lesions (*arrows*) with surrounding hypointense rim on unenhanced T1-weighted image (**C**) and without enhancement on contrast-enhanced T1-weighted image (**D**).

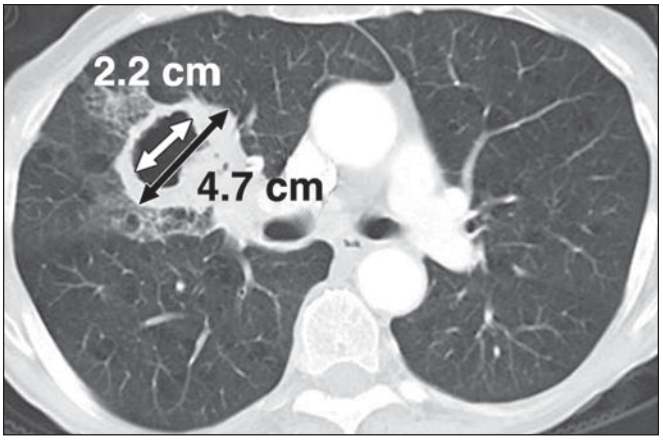


Fig. 15—Cavitation of lung lesions. CT scan of chest in 78-year-old woman with non–small cell lung cancer shows large cavitary lung lesion. Longest diameter of lesion according to Response Evaluation Criteria in Solid Tumors (RECIST) is 4.7 cm (*black arrow*). Modified measurement that has been proposed would incorporate cavitation into calculation by subtracting diameter of cavity (2.2 cm) (*white arrow*) from longest diameter of entire lesion, which would give measurement of 2.5 cm (4.7 – 2.2 cm = 2.5 cm).

shorter interval—have been developed [15]. Advanced functional imaging tools such as PET/CT and dynamic contrast-enhanced MRI have become available in clinical practice and are attracting attention as promising methods for response assessment of tumor. Given this background, the RECIST Working Group addresses the thought that it might be time to move from anatomic unidimensional assessment to volumetric or functional assessment in RECIST 1.1 [2]. However, they concluded that sufficient standardization and widespread availability are needed to recommend assessment method alternatives to conventional size measurement.

Conclusion

Familiarity with the revised RECIST guideline is essential in day-to-day cancer imaging practice to provide adequate up-to-date service to oncologists and their patients. Some of the major changes in the revised RECIST 1.1 affect how radiologists select, measure, and report target lesions. Further standardization is needed for volumetric and functional imaging tools to be considered part of the routine methods of tumor response assessment.

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