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Research Paper

Comparison of RECIST 1.0 and RECIST 1.1 in Patients with Metastatic Cancer: A Pooled Analysis

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Abstract

Background: We conducted this pooled analysis to investigate the impact of RECIST 1.1 on the selection of target lesions and classification of tumor response, in comparison with RECIST 1.0.

Methods: We searched MEDLINE and EMBASE for articles with terms of RECIST 1.0 or RECIST 1.1. We looked into all abstracts and virtual meeting presentations from the conferences of ASCO and ESMO between 2009 and 2013.

Results: There were six articles in the literature comparing the clinical impacts of RECIST 1.0 and RECIST 1.1 in patients with metastatic cancer. A total of 359 patients were recruited from the six trials; 217 with non-small cell lung cancer, 61 with gastric cancer, 58 with colorectal cancer, and 23 with thyroid cancer. The number of target lesions by RECIST 1.1 was significantly lower than that by RECIST 1.0 (P<0.001). Because of new lymph node criteria, fourteen patients (3.1%) had no target lesions when adopting RECIST 1.1. RECIST 1.1 showed high concordance with RECIST 1.0 in the assessment of tumor responses (k = 0.903). Sixteen patients (4.8%) showed disagreement between the two criteria.

Conclusion: This pooled study demonstrated that RECIST 1.1 showed a highly concordant response assessment with RECIST 1.0 in patients with metastatic cancer.

Key words: RECIST 1.0; RECIST 1.1; Target lesion; Tumor response

Introduction

The decision on subsequent cancer treatments usually depends on radiologic changes in the tumor burden, so the accurate assessment of objective therapeutic response is essential for patients receiving anti-cancer treatments. Since the World Health Organization (WHO) issued objective response criteria in 1979, the WHO guidelines have been used as the standard method for evaluating tumor response [1]. Tumor sizes are measured bi-dimensionally by the product of the longest diameter and its longest perpendicular diameter for each tumor, and tumor responses are expressed as percentage changes in the sum of tumor measurements from baseline. Because the methods for selecting and measuring target le-

sions were not clearly described in the WHO guidelines, however, the assessment of tumor response has been poorly reproducible between investigators [2,3]. In clinical practice, measuring with two dimensions and then calculating the sums of their products not only are laborious but also has a potential risk of errors. Theoretically, the simple sum of the maximum diameters of target lesions is more linearly related to cells killed than the sum of the bi-dimensional products [4]. Furthermore, the recent development of new classes of anti-cancer agents and new imaging technologies have necessitated a new methodology for evaluating tumor response [5,6].

In 2000, the Response Evaluation Criteria in Solid Tumors (RECIST) Working Group introduced a new set of tumor response criteria, the RECIST guidelines version 1.0 (RECIST 1.0) [7]. RECIST 1.0 adopted uni-dimensional measurement, instead of the bi-dimensional criterion in the WHO guidelines. Other important features of RECIST 1.0 included definition of minimum size of measurable lesion by computed tomography (CT) and instruction on how many lesions to be evaluated (up to ten, with a maximum of five per organ). RECIST 1.0 had been widely accepted as the standardized method for tumor response assessment, particularly in oncologic trials with primary end point of objective response or time to progression. However, a number of questions and issues were raised, which included the number of target lesions and the size of lymph nodes (LNs) to be measured. Subsequent rapid innovation of new imaging technologies, such as multi-detector computed tomography (MDCT) and positron emission tomography (PET), requested an update of RECIST 1.0 [8].

In 2009, the RECIST Working Group published a revised version of RECIST guidelines (RECIST 1.1) [9], which was based partly on the analyses of the database of about 6,500 patients with more than 18,000 target lesions from 16 clinical trials [10-12]. The most important changes in RECIST 1.1 include reduction in the maximum number of target lesions (up to five in total, with two per organ), new criteria for LN measurement, augmented definition of progressive disease (PD), new criteria for selecting bone lesions and cysts as target lesions, and the inclusion of PET findings for assessing tumor response (Table 1) [9,13-15].

With the expectation of improving feasibility through a more convenient and accurate assessment of both tumor response and time to progression, investigators have started to adopt RECIST 1.1 in clinical trials. Since being introduced into clinical practice, RECIST 1.1 have shown high concordance with RECIST 1.0 in the assessment of tumor responses for patients with advanced or metastatic non-small cell lung cancer (NSCLC) [16-18], gastric cancer (AGC) [19], colorectal cancer (CRC) [20], and thyroid cancer (TC) [21]. However, each study had a small number of patients with a single type of primary cancer, so it is still necessary to reveal how RECIST 1.1 affects the selection and measurement of target lesions and assessment of tumor responses in patients with metastatic cancer.

We conducted this pooled analysis to investigate the impact of RECIST 1.1 on the selection of target lesions and classification of tumor response, in comparison with RECIST 1.0.

Table 1. Summary of the major changes between RECIST 1.0 and RECIST 1.1 [15]

	RECIST 1.1	RECIST 1.0
Number of target lesions	Up to 2 per organ; up to 5 in total	Up to 5 per organ; up to 10 in total
Minimum size of target lesions	10 mm when slice thickness of CT is ≤5 mm, or 2x slice thickness when it slice thickness is ≥5 mm	10 mm (spiral CT) or 20 mm (non-spiral CT)
Assessment of lymph nodes	Short-axis measurements should be used; ≥15 mm for target ≥10 mm to < 15 mm for non-target < 10 mm for non-pathological Lymph node <10 mm in shot axis is CR	10 mm in long axis for target
CR of lymph nodes	May be used as target lesions (special notes)	Not specified
Bone lesions and cysts	5 mm absolute increase is required	Non-measurable (no specification)
PD of target lesions	Increase of non-target lesions is PD only if the increase is representative of substantial change in tumor burden	No minimum absolute size increase is required
PD of non-target lesions	Included only in the detection of new lesions	Increase in size of one or a few non-target lesions is regarded as PD, even when target lesions are stable or responding.
PET scan		Not included

Abbreviations: RECIST, Response Evaluation Criteria in Solid Tumors; CT, computed tomography; CR, complete response; PD, progressive disease; PET, positron emission tomography

Materials and methods

Searching strategy

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, Issue 5 of 12, May 2014), MEDLINE (from 2009 to May week 4, 2014) and EMBASE (from 2009 to week 20, 2014) for articles that included the following terms in their titles, abstracts, or keywords; 'RECIST 1.0 or RECIST 1.1', 'comparison', 'target lesion' and 'tumor response'. In addition, we surveyed all the references of relevant articles and reviews and used the 'related articles' feature in PubMed to identify the related articles. We also searched all abstracts and virtual meeting presentations from the conferences of the American Society of Clinical Oncology and European Society for Medical Oncology held between 2009 and 2013.

We thoroughly looked into all potentially eligible studies which were indentified via the above searching strategy. Clinical studies comparing the assessment of tumor response using RECIST 1.0 and RECIST 1.1 in patients who were treated with cytotoxic agents or target agents were included in the meta-analysis.

Statistical analyses

A paired Student's t test was used to assess the statistical significance of changes in the number of target lesions between RECIST 1.0 and RECIST 1.1. Chi-square test was used to compare the overall response rates (ORRs) between two groups. P-values less than 0.05 were considered significant. The level of concordance of the best tumor responses between two criteria was assessed using κappa statistics. A kappa value of more than 0.75 was interpreted as showing excellent agreement.

Results

Eligible studies

There were seven articles [16-22] and one abstract [23] in the literature comparing the clinical impacts of RECIST 1.0 and RECIST 1.1 in patients with solid tumors. However, the abstract [23] and one article [22] compared the two criteria mainly focused on the measurement of the LNs, with little information about concordance of tumor responses. Finally, six studies [16-21] that investigated the concordance of tumor responses between RECIST 1.0 and RECIST 1.1 were selected.

Patients' characteristics

A total of 359 patients with metastatic cancer were recruited from the six trials; 217 with NSCLC [16-18], 61 with GC [19], 58 with CRC [20], and 23 with TC [21]. The characteristics and clinical features of the patients were briefly described in Table 2. However, two trials by Sun *et al.* [16] and Nishino *et al.* [17] had no enough basic information about the enrolled patients.

Most patients (97.2%) had at least one target lesion according to RECIST 1.0. However, 11 patients (3.1%) had no target lesions when RECIST 1.1 was used. The most common metastatic site with measurable target lesions in patients with GC or CRC was the LNs, followed by the liver.

Patients with metastatic NSCLC were all treated with epidermal growth factor tyrosine kinase inhibitors (EGFR-TKI) such as gefitinib and elrotinib. Patients with metastatic GC or CRC received a first-line chemotherapy, most commonly with FOLFOX (5-fluorouracil/leucovorin plus oxaliplatin). Patients with radioactive iodine-refractory TC were treated with sorafenib, an oral, small molecule TKI.

Number of target lesions

The data about the number of target lesions was available in five studies [17-21], except for the trial by Sun *et al*. Especially for the two studies [19,20], we also used the raw data because the studies had been conducted in our institution (Hallym University Medical Center). The number of target lesions according to RECIST 1.1 was significantly lower than that according to RECIST 1.0 ($P < 0.001$, paired Student's *t*-test). The median number of target lesions was 3 (range, 0-10) by RECIST 1.0 and 2 (range, 0-5) by RECIST 1.1, respectively. Among 255 patients from the 5 studies, 157 (61.6%) showed a decrease in the number of target lesions when RECIST 1.1 was used. In 49 patients (21.8%), the decreased total number of target lesions was resulted from the reduced maximum number of target lesion per organ in RECIST 1.1. Twenty-six patients (11.6%) showed a decrease in the number of target lesions due to both the new LN criteria and the reduction of maximum target lesions. The new LN criteria of RECIST 1.1 contributed to the reduction of target lesions in 82 patients (32.2%). Among 359 patients, 14 (3.1%) had no target lesions when adopting RECIST 1.1, because all their target lesions were LNs < 15 mm along the short axis.

Re-categorization of LNs by RECIST 1.1

The data about re-categorization of LNs by RECIST 1.1 that were candidate target lesions based on RECIST 1.0 was only described in the study of metastatic CRC by Jang *et al.* [20]. From 58 patients, a total of 95 LNs were regarded as target lesions according to RECIST 1.0. According to RECIST 1.1, however, only 40% of the LNs were classified as target lesions.

Table 2. Summary of the 6 studies comparing RECIST 1.0 and RECIST 1.1

Characteristics	Sun *et al*. [16] NSCLC (n=104)	Nishino *et al*. [17] NSCLC (n=43)	Nishino *et al*. [18] NSCLC (n=70)	Jang *et al*. [19] GC (n=61)	Jang *et al*. [20] CRC (n=58)	Ruan *et al*. [21] TC (n=23)
	no. of pts	no. of pts	no. of pts	no. of pts	no. of pts	no. of pts
Age, years (range)	na	na	median 62 (35-84)	median 58 (26-78)	median 62 (42-79)	mean 54 (33-75)
Gender	na	na				
Male			12 (17.1%)	42 (68.9%)	29 (50%)	14 (60.9%)
Female			58 (82.9%)	19 (31.1%)	29 (50%)	9 (39.1%)
Histology	na	na				
Adenocarcinoma			63 (90%)	61 (100%)	58 (100%)	-
Well/moderately differentiated			na	22 (36.1%)	35 (60.3%)	-
Poorly differentiated			na	39 (63.9%)	23 (39.7%)	-
Non-adneocarcinoma			7 (10%)	0	0	-
Papillary			-	-	-	22 (95.6%)
Follicular			-	-	-	1 (4.4%)
Target lesions by RECIST 1.0	104 (100%)	43 (100%)	69 (98.6%)	61 (100%)	58 (100%)	14 (60.9%)
Lungs	na	na	na	2 (3.2%)	8 (13.8%)	0
Lymph nodes	na	na	na	51 (83.6%)	37 (63.8%)	0
Liver	na	na	na	8 (13.1%)	27 (46.5%)	0
Adrenal glands	na	na	na	0	2 (3.4%)	0
Ovary	na	na	na	0	3 (5.2%)	0
Median target lesions*(range)	na	2 (1-9)	2 (1-10)	3 (1-10)	4 (1-10)	3 (1-6)
No target lesion by RECIST 1.1	0	3 (6.9%)	2 (2.9%)	3 (4.9%)	6 (10.3%)	0
PET	0	6 (4.3%)	10 (14.3%)	0	0	5 (21.7%)
Treatment						
Erlotinib	36 (34.6%)	43 (100%)	63 (90%)	0	0	0
Gefitinib	68 (65.4%)	0	7 (10%)	0	0	0
Capecitabine + cisplatin	0	0	0	21 (34.4%)	0	0
FOLFOX	0	0	0	40 (65.6%)	53 (91.4%)	0
FOLFIRI	0	0	0	0	5 (8.6%)	0
Sorafenib	0	0	0	0	0	23 (100%)

Abbreviations: NSCLC, non-small cell lung cancer; GC, gastric cancer; CRC, colorectal cancer; TC, thyroid cancer; na, not available; no. of pts, number of patients; PET, positron emission tomography; FOLFOX, oxaliplatin plus 5-fluououracil/leucovorin; FOLFIRI, Irinotecan plus 5-fluorouracil/leucovorin.
* according to RECIST 1.0.

Tumor responses

We compared the tumor responses between the two criteria using 332 patients who had at least one target lesion based on RECIST 1.1. The remaining 27 patients were excluded from the comparison because they had no target lesions according to RECIST 1.1 and the tumor responses were uncertain in most of them. The results are presented in Table 3. There was high concordance between RECIST 1.0 and RECIST 1.1 in the assessment of tumor responses. The estimated kappa value was 0.903, with 95% confidence interval of 0.863-0.943. When we compared the ORRs, which were estimated regardless of the primary site and anti-cancer treatment, were not significantly different between the two criteria (42.2% by RECIST 1.1 versus 39.1% by RECIST 1.0, P=0.430).

A total of 16 patients (4.8%) showed disagreement between the two criteria. The details of the patients showing disagreement between RECIST 1.0 and RECIST 1.1 were described according to reference in Table 4. The discrepancies of the two criteria were between PR and SD in 8 patients, SD and PD in 6, and PR and CR in 2. No patients showed disagreement between PR and PD. The most common cause of the discordance was the new LN criteria, which led to the different response classification in 9 (56.3%). Four patients (25.0%) showed disagreement between the two criteria because of the maximum of target lesions (5 in total, with up to 2 lesions per organ) in RECIST 1.1. Two patients with SD according to RECIST 1.0 were reclassified as PD because of the new lesions noted on PET/CT.

Table 3. Comparison of tumor responses by RECIST 1.0 versus RECIST 1.1

Tumor response by RECIST 1.0	Tumor response by RECIST 1.1				Total
	CR	PR	SD	PD	
CR	1	0	0	0	1
PR	2	125	2	0	129
SD	0	12	111	4	127
PD	0	0	3	72	75
Total	3	137	116	76	332

Abbreviations: CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease
The level of concordance of tumor responses between RECISI 1.1 and RECIST 1.0 is 0.903 (95% CI, 0.863-0.943).
The overall response rates were not significantly different between the two criteria (42.2% by RECIST 1.1 versus 39.1% by RECIST 1.0, P=0.430)

Table 4. Summary of the patients showing disagreement between RECIST 1.0 and RECIST 1.1

Reference	Tumor type	Tumor response		No. of patients	Causes of disagreement
		RECIST 1.0	RECIST 1.1		
Sun *et al*. [16]	NSCLC	PR	CR	2	LNs < 10 mm
		SD	PR	3	Equivocal LNs
		SD	PD	1	A definitely increased LN
Nishino *et al*. [17]	NSCLC	SD	PD	2	New lesions on PET
		PD	SD	1	A single LN < 10mm
Nishino *et al*. [18]	NSCLC	SD	PR	1	Decreased number of target lesion
Jang *et al*. [19]	GC	PR	SD	1	Four LNs < 15 mm
		SD	PR	1	Up to 2 target lesion per organ
		SD	PD	1	Up to 2 target lesion per organ
Jang *et al*. [20]	CRC	PR	SD	1	Two LNs < 15 mm
		PD	SD	1	Up to 2 target lesion per organ
		PD	SD	1	An absolute size increase of at least 5 mm
Ruan *et al*. [21]	TC	SD	PR	1	Not described

Discussion

Since RECIST 1.1 was presented in 2009 [9], the impact of RECIST 1.1 has been compared with RECIST 1.0 in patients with metastatic NSCLC [16-18], AGC [19], CRC [20], and TC [21]. However, each study had a small number of patients with a single type of primary cancer. In this pooled study, we investigated the impact of RECIST 1.1 on the selection of target lesions and assessment of the best tumor responses. RECIST 1.1 significantly decreased the number of target lesions to be measured in patients with metastatic cancer. However, there was an excellent agreement in the assessment of tumor responses between RECIST 1.0 and RECIST 1.1.

As expected, RECIST 1.1 affected the number of target lesions. The maximum number of target lesions to be assessed in RECIST 1.1 is reduced from 10 to 5 in total, and from 5 to 2 per organ. While the total of 10 target lesions in RECIST 1.0 was arbitrarily selected, RECIST 1.1 defined a total of 5 lesions through the patients' data analysis [10] and statistical simulating studies [11,14]. Out of 255 patient from 5 studies in which the number of target lesions were described [17-21], 157 (61.6%) showed a decrease in the number of target lesions when RECIST 1.1 was adopted. In 49 patients (21.8%), the criteria of two lesions per organ contributed to the decreased number of target lesions. According to RECIST 1.1, lytic or mixed lytic-blastic bone lesions with an identifiable soft tissue component may be used as target lesions. In this pooled analysis with 359 patients, however, only one with TC newly had a bone target lesion when adopting RECIST 1.1.

RECIST 1.1 recommends the measurement of LN along its short axis, regarding LNs of at least 15 mm as target lesions. LN with at least 10 mm but less than 15 mm in its short axis, even though it may be pathological, is considered non-target lesion, and LN with a short axis of less than 10 mm is regarded as normal. These changes in the LN evaluation criteria also had a considerable impact on the number of target lesions. In this meta-analysis, the new LN criteria of RECIST 1.1 led to the reduction of target lesions in 82 patients (32.2%), including 26 (11.6%) in whom the decrease was attributable to both the new LN criteria and the reduction of maximum target lesions.

From the RECIST data warehouse, 90.5% of LNs were regarded as target lesion according to the new LN criteria of RECIST 1.1 [13]. In the study of patients with GC by Jang *et al*., however, among 95 LNs considered to be target lesions by RECIST 1.0, only 38 (40 %) were defined as target lesions based on RECIST 1.1 [20]. These results are in agreement with those of the study conducted by Fuse *at al.* in patients with metastatic GC. Out of 172 LNs regarded as target lesions by RECIST 1.0, only 66 (38%) were defined as target lesions based on RECIST 1.1 [22]. Piatek *et al*. found the similar results in patients with prostate cancer. Among 158 LNs regarded as target lesions by RECIST 1.0, only 66 (41.8%) satisfied the LN criteria of RECIST 1.1 [23]. Therefore, the new LN criteria of RECIST 1.1 may alter the eligibility of patients for clinical trials in which the ORR or time to progression is a primary endpoint. In the study by Fuse *et al.* the proportion of patients with target lesions was significantly decreased from 67% to 53% by adopting RECIST 1.1 [22]. In this meta-analysis, 14 patients (3.1%) no longer had target lesions when adopting RECIST 1.1, because all their target lesions were LNs < 15 mm along the short axis. If studies using RECIST 1.1 had been planned, these patients would have been excluded from clinical trials. RECIST 1.1 with more stringent LN measurement rules, however, may categorize more patients as CR than RECIST 1.0. In the study by Sun *et al*., two NSCLC patients with PR according to RECIST 1.0 were re-categorized as CR because LNs with short axes of < 10 mm were considered normal based on RECIST 1.1 [16].

This pooled study demonstrates that there is high concordance between RECIST 1.0 and RECIST 1.1 in the assessment of tumor responses. When comparing the tumor response assessment in 332 patients who had at least one target lesion based on RECIST 1.1, the level of agreement in tumor responses between the two criteria was very high, with a kappa value of 0.903. The ORRs estimated regardless of the primary site and anti-cancer treatment were not significantly different between the two criteria (42.2% by RECIST 1.1 versus 39.1% by RECIST 1.0, P=0.430). The disagreement between the two RECIST versions was observed in 16 patients (4.8%). The most common cause of the discordance was the new LN criteria (9 patients), followed by the maximum of target lesions in RECIST 1.1 (6 patients). As patients who achieve PR or SD practically stay on the same treatment, patients showing discordance between PR and SD would have no significant clinical impact of RECIST 1.1. In this study, only six patients (1.8%) displayed disagreement between SD and PD. Therefore, the clinical impact of RECIST 1.1 on changing therapeutic decisions seemed to be minimal.

Several limitations of this pooled analysis should be noted. First, PET was not routinely performed in all 6 studies. PET scans have an important role in the assessment of tumor response using RECIST 1.1. New lesions detected on PET scans change the tumor response from PR or SD according to RECIST 1.0 to PD according to RECIST 1.1. Therefore, the incorporation of PET may have a significant influence on the assessment of tumor responses based on RECIST 1.1. In this pooled analysis, only 21 patients (5.8%) underwent PET. Two patients had new lesions on PET scans, which changed the tumor response from SD to PD. One patient with NSCLC did not undergo baseline PET, and a new lesion was detected on PET scans during therapy. The new lesion was confirmed by the follow-up CT. If the studies had performed PET more frequently, the newly detected lesions could have led to a lower concordance rate for tumor responses between the two RECIST versions. Second, the comparison of tumor responses between the two criteria was conducted only in patients with at least one target lesion according to RECIST 1.1. According to RECIST 1.0, the increase in size of one or a few non-target lesions was regarded as PD, even though target lesions are stable or responding. Based on RECIST 1.1, however, patients with PR or SD based on target lesion response are categorized as PD, only if the increase of non-target lesions is representative of substantial change in tumor burden. Therefore, if the comparison had included patients with non-target lesion, the new criteria of non-target lesion would have affected the concordance between RECIST 1.0 and RECIST 1.1. Third, this pooled analysis only contains patients with four types of primary tumors (NSCLC, GC, CRC, and TC). This means that the results may be insufficient to be generalized for patients with other primary cancer.

In conclusion, this pooled study demonstrates that RECIST 1.1 provides a highly concordant response assessment with RECIST 1.0 in patients with metastatic cancer. Because of the more stringent LN criteria, however, RECIST 1.1 may adversely affect the patients' eligibility for clinical trials.

Conflict of Interest

Authors do not have any conflict of interest.

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