INTRODUCTION

The World Health Organization guidelines [1] and the Response Evaluation Criteria in Solid Tumors (RECIST) [2,3] are the morphologic criteria commonly used to assess tumor response in clinical practice. However, these...
criteria depending on the size changes based on computed tomography (CT) have limitations in tumors with obscure margins, cystic lesion, or scar tissue. In particular, measuring the longest diameter of lesions on CT is not always possible in gastrointestinal tumors. Because patients treated with targeted agents were not included in the data warehouse [4] when the RECIST version 1.1 was revised [3], there has also been concern regarding the assessment of tumor responses with the RECIST in patients receiving targeted agents [5]. Molecular targeted agents tend to induce necrotic or cystic change, not tumor shrinkage, in solid tumors [6]. Therefore, morphologic response criteria may be not well suited for assessing the efficacy of targeted therapies that stabilize diseases.

$^{18}$F-fluorodeoxyglucose ($^{18}$F-FDG) uptake is enhanced in most malignant tumors which in turn can be measured by positron emission tomography (PET). $^{18}$F-FDG PET has been adopted as a new method for the diagnosis and staging of solid tumors. PET is also increasingly being used to monitor tumor responses to anti-cancer therapies. It can allow the assessment of tumor response even in the absence of anatomical changes [7-9]. There are two sets of criteria using FDG PET to quantify metabolic changes to anti-cancer treatment: the criteria developed by the European Organization for Research and Treatment of Cancer (EORTC) criteria [10] and the Positron Emission Tomography Response Criteria in Solid Tumors (PERCIST) [11]. Tumor response evaluations with the PERCIST and EORTC criteria have shown almost perfect agreement and correlated well with survival [12,13]. The metabolic response criteria may provide clinicians with a more accurate assessment of therapeutic response at an earlier stage of treatment course. However, their usefulness and advantage over the morphologic criteria (RECIST) need to be further investigated.

The assessment of tumor responses between the morphologic criteria and metabolic criteria has shown considerable discrepancies in a series of studies with a small number of patients [14-27]. We performed this pooled study to compare tumor response assessment between the morphologic criteria (RECIST 1.0 and RECIST 1.1) and metabolic criteria (EORTC criteria and PERCIST) in patients with solid tumors.

**METHODS**

**Search strategy**
A computerized systematic search of the electronic databases PubMed, Embase, Scopus, and Google Scholar (up to June 2017) was carried out to find articles with the following terms in their titles, abstracts, or keywords: “RECIST,” “PERCIST,” or “EORTC criteria.” In addition, we checked all the references of identified relevant articles and reviews. We also used the “related articles” feature in PubMed to identify relevant articles.

**Study selection criteria**
Studies comparing tumor responses by using the RECIST and metabolic criteria (EORTC or PERCIST) were considered for inclusion in this pooled study. As the RECIST 1.1 showed a high concordance with the RECIST 1.0 in the assessment of tumor responses [28,29], we included both versions without distinction in the analysis. For a more accurate comparison, however, articles adopting the modified RECIST versions developed for specific types of tumors were excluded. The searched articles were screened again by reviewing the full text, and the original articles that compared tumor responses between the morphologic criteria (RECIST 1.0 or RECIST 1.1) and metabolic criteria (PERCIST or EORTC) were included in the final analysis.

**Tumor response assessment**
The tumor responses according to the RECIST in each study were defined as follows [2,3]: (1) complete response (CR): disappearance of all lesions; (2) partial response (PR): at least a 30% decrease in the sum of diameters of the target lesions and no new lesions; (3) progressive disease (PD): more than a 20% increase in the sum of diameters of the target lesions (and also an absolute increase of at least 5 mm in the RECIST 1.1) or the appearance of new lesions on CT (or PET in the RECIST 1.1); and (4) stable disease (SD): neither sufficient shrinkage to qualify as PR nor sufficient increase to qualify as PD.

The tumor response guidelines for the PERCIST and EORTC criteria are briefly summarized in Table 1.

**Statistics**
The overall response rate (ORR) was defined as the percentage of patients with CR or PR (as determined by the
two RECIST versions) and those with complete metabolic response (CMR) or partial metabolic response (PMR) (as determined by the PERCIST or EORTC criteria). The ORRs between the two groups were compared by using the McNemar test and \( p \) values less than 0.05 were considered significant. The level of agreement in tumor responses between the two criteria was estimated using unweighted \( \kappa \) statistics. The agreement was interpreted as poor (\( \kappa < 0 \)), slight (\( \kappa = 0 \) to 0.20), fair (\( \kappa = 0.21 \) to 0.40), moderate (\( \kappa = 0.41 \) to 0.60), substantial (\( \kappa = 0.61 \) to 0.80), and almost perfect (\( \kappa > 0.80 \)) [30].

Ethics

This study did not require approval by an ethics committee because it was a pooled analysis with systematic review of previously published studies. We performed this study according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [31].

RESULTS

Eligible studies

Fig. 1 shows the flowchart of studies. A total of 132 studies were identified according to the search strategy: 110 were excluded after screening the titles and abstracts. The remaining 22 articles comparing tumor responses according to the RECIST and metabolic criteria were potentially relevant. However, eight studies were excluded based on the inclusion criteria: three articles used the modified RECIST and five had no details of response classification [32-36].

Finally, 14 studies with data comparing tumor responses by the RECIST and morphologic criteria (EORTC or PERCIST) were selected [14-27]. Five articles compared the RECIST and EORTC criteria [14,16-19] and six compared the RECIST and PERCIST [22-27]. The remaining

Table 1. Tumor response assessment by two metabolic criteria (EORTC criteria and PERCIST)

|              | EORTC                                      | PERCIST                                    |
|--------------|--------------------------------------------|--------------------------------------------|
| Complete metabolic response (CMR) | Complete resolution of FDG uptake in all lesions | Complete resolution of FDG uptake in all lesions |
| Partial metabolic response (PMR) | \( \geq 25\% \) Reduction in the sum of SUVmax after more than one cycle of treatment | \( \geq 30\% \) Reduction of the SULpeak and an absolute drop of 0.8 SULpeak units |
| Progressive metabolic disease (PMD) | \( \geq 25\% \) Increase in the sum of SUVmax or appearance of new FDG-avid lesions | \( \geq 30\% \) Increase in the SULpeak of the FDG uptake and an absolute increase of 0.8 SULpeak, or appearance of FDG-avid new lesions |
| Stable metabolic disease (SMD) | Not qualify for CMR, PMR, or PMD | Not qualify for CMR, PMR, or PMD |

EORTC, European Organization Research and Treatment of Cancer; PERCIST, Positron Emission Tomography Response Criteria in Solid Tumors; FDG, fluorodeoxyglucose; SUVmax, maximum standardized uptake value; SULpeak, peak lean body mass SUV.

Figure 1. Flowchart of search process. RECIST, Response Evaluation Criteria in Solid Tumors; EORTC, European Organization Research and Treatment of Cancer; PERCIST, Positron Emission Tomography Response Criteria in Solid Tumors.
three studies compared the RECIST and both metabolic criteria [15,20,21].

**Patients’ characteristics**

From the eight studies comparing the RECIST and EORTC criteria [14-21], 216 patients were included; 82 with lung cancer [19-21], 45 with colorectal cancer [14,20], 33 with head and neck cancer [18,20], 17 with malignant melanoma [17], 14 with basal cell carcinoma [15], 12 with stomach cancer [20], seven with desmoplastic small round cell tumors [16], and six with breast cancer [20] (Table 2). Eighty-nine patients (41.2%) were treated with targeted agents and 127 (58.8%) received cytotoxic chemotherapy.

From the nine studies comparing tumor responses by the RECIST and PERCIST, 407 patients were included [15,20-27]: 120 with colorectal cancer [20,23,27], 95 with lung cancer [20-22], 93 with breast cancer [20,25,26], 48 with esophageal cancer [24,25], 14 with basal cell carcinoma [15], 12 with stomach cancer [20], 10 with head and neck cancer [20,25], and 16 with other cancers (Table 3) [25].

**Comparison of tumor responses between the RECIST and EORTC criteria**

Because the RECIST 1.1 includes PET scans for the detection of new lesions, we reclassified tumor response of two patients with new focal FDG avid marrow lesions as PD [19]. The rate of discordance in tumor responses between the RECIST (RECIST 1.0 and RECIST 1.1) and EORTC criteria varied from 9.7% in non-small cell lung cancer [19] to 80% in colorectal cancer [14] (Table 2). The agreement of tumor response between the two criteria was moderate (κ = 0.447; 95% confidence interval, 0.356 to 0.537) (Table 4). Of 216 patients, 86 (39.8%) showed discordance in the assessment of their tumor responses between the two criteria. The details of the patients showing disagreement are described in Table 2. When adopting the EORTC criteria, tumor response was upgraded in 70 patients and downgraded in 16. The shift in tumor responses was also observed most frequently in patients with SD as determined by the RECIST. Among 68 patients with SD, the tumor response of 56 patients (82.4%) was upgraded to CMR (n = 11) or PMR (n = 85) and that of 12 was downgraded to PMD by adopting the EORTC. Of 37 patients with PR, 31 were reclassified as showing CMR and six as having SMD. There were 24 patients with PD who were upgraded as showing CMR (n = 4), PMR (n = 7), and SMD (n = 13). The estimated ORRs were also significantly different between the two criteria (30.2% by the RECIST vs. 55.0% by the PERCIST, p < 0.0001).

**Comparison of tumor responses between the RECIST and PERCIST**

The rate of disagreement in tumor responses between the RECIST and PERCIST varied from 18.3% [20] to 62.9% [25]. Of 407 patients, 181 (44.5%) showed discordance in the assessment of their tumor responses between the two criteria. The details of the patients showing discordance are summarized in Table 3. The agreement of tumor response between the two criteria was fair (κ = 0.398; 95% confidence interval, 0.323 to 0.456) (Table 5). When adopting the PERCIST, the tumor response was upgraded in 151 patients and downgraded in 30. The shift in tumor responses was also observed most frequently in patients with SD by using the RECIST. Among 120 patients with SD, the tumor response of 96 patients (80%) was upgraded to CMR (n = 11) or PMR (n = 85) and that of 24 was downgraded to PMD by adopting the PERCIST. Of 37 patients with PR, 31 were reclassified as showing CMR and six as having SMD. There were 24 patients with PD who were upgraded as showing CMR (n = 4), PMR (n = 7), and SMD (n = 13). The estimated ORRs were also significantly different between the two criteria (30.2% by the RECIST vs. 55.0% by the PERCIST, p < 0.0001).

**DISCUSSION**

In this pooled study, we investigated the concordance between the metabolic criteria and morphologic criteria for the assessment of tumor responses in patients with solid tumors. There was a considerable discrepancy in the assessment of tumor responses between the morphologic criteria (RECIST) and metabolic criteria (EORTC or PERCIST). When adopting the EORTC criteria or PERCIST instead of the RECIST, the ORR was significantly increased, suggesting significant clinical impact of the metabolic criteria on making therapeutic
In clinical practice, it is not always easy to distinguish necrotic tissue or fibrotic scar from residual tumor on CT scans [37]. In particular, with the increasing use of targeted agents, new evaluation methods are needed to accurately monitor tumor responses. [18F]-FDG PET has become a well-established method for the staging and detection of recurrence in patients with several malig-

Table 2. Summary of eight studies comparing the RECIST and EORTC criteria

| Study                  | Tumor type                          | No. of pts | Treatment               | Comparison       | Discordant rate, % | Details of discordance |
|------------------------|-------------------------------------|------------|-------------------------|------------------|--------------------|------------------------|
| Monteil et al. (2009)  | Colorectal cancer                   | 25         | Palliative chemotherapy | RECIST 1.0 vs. EORTC | 80 (20/25)         | 3 PR→2 CMR, 1 PMD      |
|                        |                                     |            |                         |                  |                    | 17 SD→5 CMR, 13 PMR, 1 PMD |
| Thacker et al. (2012)  | Basal cell carcinoma                | 14         | Targeted agent (vismodegib) | RECIST 1.0 vs. EORTC | 50 (7/14)           | 2 PR→1 CMR, 1 SMD      |
|                        |                                     |            |                         |                  |                    | 4 SD→4 PMR, 1 PD→1 SMD |
| Magnan et al. (2013)   | Desmoplastic small round cell tumor | 7          | Chemotherapy             | RECIST 1.0 vs. EORTC | 71.4 (5/7)          | 5 SD→5 PMR             |
| Adkin et al. (2014)    | Head & neck cancer                  | 27         | Targeted therapy (cetuximab) | RECIST 1.0 vs. EORTC | 51.9 (14/27)        | 14 SD→9 PMR, 5 PMD     |
| Zukočynski et al. (2014) | Malignant melanoma               | 17         | Targeted therapy (imatinib) | RECIST 1.0 vs. EORTC | 29.4 (5/17)        | 1 PR→1 SMD             |
|                        |                                     |            |                         |                  |                    | 1 SD→1 PMD             |
|                        |                                     |            |                         |                  |                    | 3 PD→1 PMR, 2 SMD      |
|                        |                                     |            |                         |                  |                    | 3 SD→3 PMR             |
| Puranik et al. (2015)  | Non-small cell lung cancer          | 31         | Targeted therapy (gefitinib) | RECIST 1.1 vs. EORTC | 9.7 (3/31)          |                        |
| Aras et al. (2016)     | Colorectal cancer                   | 20         | Chemotherapy             | RECIST 1.1 vs. EORTC | 20 (12/60)         | 4 PR→3 CMR, 1 SMD      |
|                        | Lung cancer                         | 16         |                         |                  |                    | 8 SD→7 PMR, 1 PMD      |
|                        | Stomach cancer                      | 12         |                         |                  |                    |                        |
|                        | Head & neck cancer                  | 6          |                         |                  |                    |                        |
|                        | Breast cancer                       | 6          |                         |                  |                    |                        |
| Shang et al. (2016)    | Non-small cell lung cancer          | 35         | Chemotherapy             | RECIST 1.1 vs. EORTC | 57.1 (20/35)        | 16 SD→12 PMR, 4 PMD    |
|                        |                                     |            |                         |                  |                    | 4 PD→4 SD              |
| Summary                | Lung cancer                         | 82         |                         | RECIST vs. EORTC  | 39.8 (86/216)      | 10 PR→6 CMR, 3 SMD, 1 PMD |
|                        | Colorectal cancer                   | 45         |                         |                  |                    | 68 SD→3 CMR, 53 PMR, 12 PMD |
|                        | Head & neck cancer                  | 33         |                         |                  |                    | 8 PD→1 PMR, 7 SMD      |
|                        | Malignant melanoma                  | 17         |                         |                  |                    |                        |
|                        | Basal cell carcinoma                | 14         |                         |                  |                    |                        |
|                        | Stomach cancer                      | 12         |                         |                  |                    |                        |
|                        | Breast cancer                       | 6          |                         |                  |                    |                        |
|                        | Desmoplastic small round cell tumor | 7          |                         |                  |                    |                        |

RECIST, Response Evaluation Criteria in Solid Tumors; EORTC, European Organization Research and Treatment of Cancer; pts, patients; PR, partial response; CMR, complete metabolic response; PMD, progressive metabolic disease; SD, stable disease; PMR, partial metabolic response; SMD, stable metabolic disease; PD, progressive disease.

aBecause the RECIST 1.1 includes positron emission tomography for the detection of new lesions, two patients with new focal fluorodeoxyglucose avid marrow lesions were reclassified as having PD.
| Study                        | Tumor types                  | No. of pts | Treatment                  | Comparison          | Discordant rate, % | Details of discordance       |
|------------------------------|------------------------------|------------|----------------------------|---------------------|--------------------|------------------------------|
| Thacker et al. (2012) [15]   | Basal cell carcinoma         | 14         | Targeted agent (vismodegib) | RECIST 1.0 vs. PERCIST | 50 (7/14)          | 2 PR→1 CMR, 1 SMD           |
| Aras et al. (2016) [20]      | Colorectal cancer            | 20         | Palliative chemotherapy    | RECIST 1.1 vs. PERCIST | 18.3 (11/60)       | 4 PR→3 CMR, 1 SMD           |
| Shang et al. (2016) [21]     | Non-small cell lung cancer   | 35         | Chemotherapy               | RECIST 1.1 vs. PERCIST | 62.9 (22/35)       | 18 SD→14 PMR, 4 PMD         |
| Ding et al. (2014) [22]      | Non-small cell lung cancer   | 44         | Palliative chemotherapy    | RECIST 1.1 vs. PERCIST | 34.1 (15/44)       | 6 PR→4 CMR, 2 SMD           |
| Skougaard et al. (2014) [23] | Colorectal cancer            | 61         | Palliative chemotherapy    | RECIST 1.0 vs. PERCIST | 54.1 (33/61)       | 1 PR→1 SMD                  |
| Yanagawa et al. (2012) [24]  | Esophageal cancer            | 46         | Neoadjuvant chemotherapy   | RECIST 1.1 vs. PERCIST | 56.5 (26/46)       | 13 PR→13 CMR, 10 PMR        |
| Agrawal et al. (2014) [25]   | Breast cancer, PNET, Head & neck cancer, Sarcoma, NHL, Esophageal cancer, Others | 22, 5, 4, 3, 2, 2, 5 | Metronomic palliative hemotherapy | RECIST 1.1 vs. PERCIST | 20.6 (9/43)      | 8 SD→1 CMR, 1 PMR, 6 PMD, 1 PD→1 CMR |
| Riedl et al. (2017) [26]     | Breast cancer                | 65         | Chemotherapy, targeted therapy, hormonal therapy | RECIST 1.1 vs. PERCIST | 52.3 (34/65)      | 10 PR→10 CMR, 20 SD→6 CMR, 8 PMR, 6 PMD, 4 PD→3 CMR, 1 SMD |
| Bang et al. (2017) [27]      | Colorectal cancer            | 39         | Targeted therapy (regorafenib) | RECIST 1.1 vs. PERCIST | 61.5 (24/39)      | 1 PR→1 SMD, 17 SD→14 PMR, 3 PMD, 6 PD→3 PMR, 3 SMD |
| Summary                      | Colorectal cancer, Lung cancer, Breast cancer, Esophageal cancer, Basal cell carcinoma, Stomach cancer, Head & neck cancer, Others | 120, 95, 93, 48, 14, 12, 10, 16 | | RECIST vs. PERCIST | 44.5 (181/407) | 37 PR→31 CMR, 6 SMD, 120 SD→311 CMR, 6 SMD, 24 PDM, 24 PD→4 CMR, 7 PMR, 13 SMD |

RECIST, Response Evaluation Criteria in Solid Tumors; PERCIST, Positron Emission Tomography Response Criteria in Solid Tumors; pts, patients; PR, partial response; CMR, complete metabolic response; SMD, stable metabolic disease; SD, stable disease; PMR, partial metabolic response; PD, progressive disease; PDM, progressive metabolic disease; PNET, primitive neuroectodermal tumor; NHL, non-Hodgkin's lymphoma.

*Five patients were excluded from the final analysis because their disease was not classifiable according to the RECIST 1.1.
nancies [38]. It is also increasingly used to assess tumor responses to anti-cancer therapies [8-10]. FDG PET responses have correlated more significantly with survival than those assessed by CT [39]. However, the metabolic response criteria have shown differences compared with the morphologic criteria for the assessment of tumor responses.

In our pooled analysis of 216 patients from eight studies [14-21], the agreement of tumor responses between the RECIST and EORTC criteria was moderate (κ = 0.447). Eighty-six patients (39.8%) showed discrepancies in the assessment of tumor responses between the two criteria. Use of the EORTC criteria resulted in upgraded tumor responses in 70 patients and downgraded responses in 16. When adopting the EORTC criteria, the ORR significantly increased from 28.2% to 52.8% (p < 0.0001). The level of concordance of tumor responses between the EORTC criteria and RECIST is 0.447 (unweighted κ, 95% confidence interval, 0.356 to 0.537). The overall response rates were significantly different between the two criteria (28.2% by RECIST vs. 52.8% by EORTC, p < 0.0001).

RECIST, Response Evaluation Criteria in Solid Tumors; EORTC, European Organization Research and Treatment of Cancer; CMR, complete metabolic response; PMR, partial metabolic response; SMD, stable metabolic disease; PMD, progressive metabolic disease; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease.

Early detection of the tumor response is of great value to avoid unnecessary toxicity and cost of ineffective treatments. Anatomical responses based on the size of the tumor may lag weeks or months behind metabolic response [40]. PET can detect metabolic changes after chemotherapy even when there are no or minimal morphological changes [7], which may explain the reason why tumor responses were upgraded by using the metabolic criteria in many patients who showed SD by using the RECIST in this study. In clinical practice, patients showing disease progression (PD or PMD) after anti-cancer treatment usually need a change in therapeutic approach. If the metabolic criteria had been used instead of the RECIST in this pooled study, it would have changed the treatment course in approximately 10% of the patients. This finding indicates that the clinical impact of the metabolic response criteria on making therapeutic decisions is significant.

The current pooled study has several inherent limitations. First, this study included heterogeneous patients with different types of tumors and different kinds of therapeutic agents. In addition, because of the limited number of studies, we could not compare two criteria in the subgroup with the same cancers. It is necessary to verify these results in studies with larger homogeneous patients’ cohort. Second, we included two versions of the RECIST without distinction in the analysis. Although the RECIST 1.1 has shown almost perfect agreement with the RECIST 1.0 in the assessment of tumor responses, a potential difference between the two versions might affect the results. Finally, this study could not evaluate the prognostic value of the metabolic criteria. Although the PERCIST and EORTC criteria were associated with prognosis in several studies, survival data were not enough to compare the prognostic value.

### Table 4. Comparison of tumor responses according to the RECIST and EORTC criteria

| Tumor response by the RECIST | Tumor response by the EORTC | Total |
|-----------------------------|-----------------------------|-------|
|                            | CMR | PMR | SMD | PMD |       |
| CR                          | 5   | 0   | 0   | 0   | 5     |
| PR                          | 6   | 46  | 3   | 1   | 56    |
| SD                          | 3   | 53  | 25  | 12  | 93    |
| PD                          | 0   | 1   | 7   | 54  | 62    |
| Total                       | 14  | 100 | 35  | 67  | 216   |

The level of concordance of tumor responses between the EORTC criteria and RECIST is 0.447 (unweighted κ, 95% confidence interval, 0.356 to 0.537). The overall response rates were significantly different between the two criteria (28.2% by RECIST vs. 52.8% by EORTC, p < 0.0001).
In conclusion, this pooled study demonstrates that concordance in the assessment of tumor responses between the morphologic criteria (RECIST) and metabolic criteria (EORTC or PERCIST) is not excellent. When adopting the metabolic criteria instead of the RECIST, the ORR was significantly increased. The prognostic value of the metabolic criteria needs to be investigated in larger studies with homogeneous patient cohorts.

**Conflict of interest**

No potential conflict of interest relevant to this article was reported.

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**KEY MESSAGE**

1. The assessment of tumor responses between the morphologic criteria and metabolic criteria has shown considerable discrepancies in studies with a small sample size.
2. The agreement of tumor responses was moderate between the morphologic (Response Evaluation Criteria in Solid Tumors [RECIST]) and metabolic criteria (European Organization for Research and Treatment of Cancer or Positron Emission Tomography Response Criteria in Solid Tumors).
3. When adopting the metabolic criteria instead of the RECIST, the overall response rate was significantly increased.

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**Table 5. Comparison of tumor responses according to the RECIST and PERCIST**

| Tumor response by RECIST | Tumor response by PERCIST | Total |
|--------------------------|---------------------------|-------|
| CR                       | CMR                       | 8     |
| PR                       | PMR                       | 31    |
| SD                       | SMD                       | 11    |
| PD                       | PMD                       | 4     |
| Total                    |                           | 54    |

The level of concordance of tumor responses between the RECIST and PERCIST 1.0 is 0.389 (unweighted κ, with 95% confidence interval, 0.323 to 0.456). The overall response rates were significantly different between two criteria (30.2% by RECIST vs. 55.0% by PERCIST, p < 0.0001). RECIST, Response Evaluation Criteria in Solid Tumors; PERCIST, Positron Emission Tomography Response Criteria in Solid Tumors; CMR, complete metabolic response; PMR, partial metabolic response; SMD, stable metabolic disease; PMD, progressive metabolic disease; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease.
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