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Commentary

Brief Note on Response Criteria in Cancer Immunotherapy

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DESCRIPTION

When an immuno-oncology therapy is being tested, a set of published guidelines known as the Immune-related Response Criteria (irRC) is used to determine when tumours in cancer patients respond (improve), stabilise (stabilise), or worsen (advance) during treatment. Cancer immunotherapy comprises medications called immuno-oncology that work with the body's immune system to treat cancer.

The WHO or RECIST Criteria could not account for the time lag in many patients between initial treatment and the immune system's apparent intervention to reduce tumour burden, leading to findings that immuno-oncology drugs would fail in clinical trials using these criteria.

As part of the process of assessing anti-cancer drugs' efficacy in clinical trials, the amount of tumour shrinkage that they can cause is quantified. The first widely accepted fundamental standards for the codification of tumour response evaluation were the WHO Criteria, which were developed by the International Union against Cancer and the World Health Organization in the 1970s. In 1981, these standards were first made public. The WHO standards were amended by the RECIST criteria.

Less lesions were assessed, tumour size was estimated unidimensionally rather than bidimensionally, and the idea of "progression" was changed so that it no longer depended on an isolated growth in a single lesion. The shrinkage threshold employed by RECIST for the concepts of cancer response and development was different.

The WHO defined a partial response as having more than50% tumour shrinking or, in the case of progressive disease, it's 25% more tumour growth. It was a Partial Response contraction of more than 30% and an increase in Progressive Disease of more than 20% for RECIST. Many patients who would have been considered "progressors" under the previous criteria ended up being "responders" or "healthy" under the new standards as a result of both of these adjustments.

The irRC was developed in response to the finding that the desired Complete and Partial Responses, as well as Stable Disease, only occurred after an increase in tumour burden, which the traditional RECIST Criteria would have called "Progressive Disease," in studies of various cancer therapies originating from the immune system, such as cytokines and monoclonal antibodies. In essence, RECIST refused to take into consideration the interval between a dose and an anti-tumor T cell response, which led to the failure of otherwise "effective" medications in clinical trials—that is, drugs that ultimately increased life expectancy.

Evaluation of the tumour burden

The irRC calculates tumour burden by adding "index" lesions and new lesions. Typically, the number of "index" lesions—the biggest identifiable lesions at baseline—will be used to compute the tumour burden, with any additional lesions found at later timepoints being counted as "Progressive Disease." On the other hand, new lesions are merely a change in the irRC's tumour load. The bidirectional lesion calculation that was initially specified in the WHO Criteria was maintained by the irRC.

Evaluation of immune-related reaction

An immune-related Partial Response (irPR) is defined by the irRC as a 50% decrease in tumour burden from baseline, and an immune-related Progressive Disease (irPD) is defined as a 25% increase in tumour burden from the lowest level reported. An immune-related Complete Response (irCR) is the removal of all lesions, measured or unmeasured, and the absence of new lesions. The other cases are considered immune-related Stable Diseases (irSD). Even while the cancer burden may be rising, it is believed that the immune system begins to "kick in" a few months after the initial dose, which causes the tumour burden to fall for many individuals. The 25% criterion provides an explanation for this apparent delay.

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