

WEIGHT LOSS IN CANCER AND THE 2017 COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS – DANGEROUS AND MISLEADING

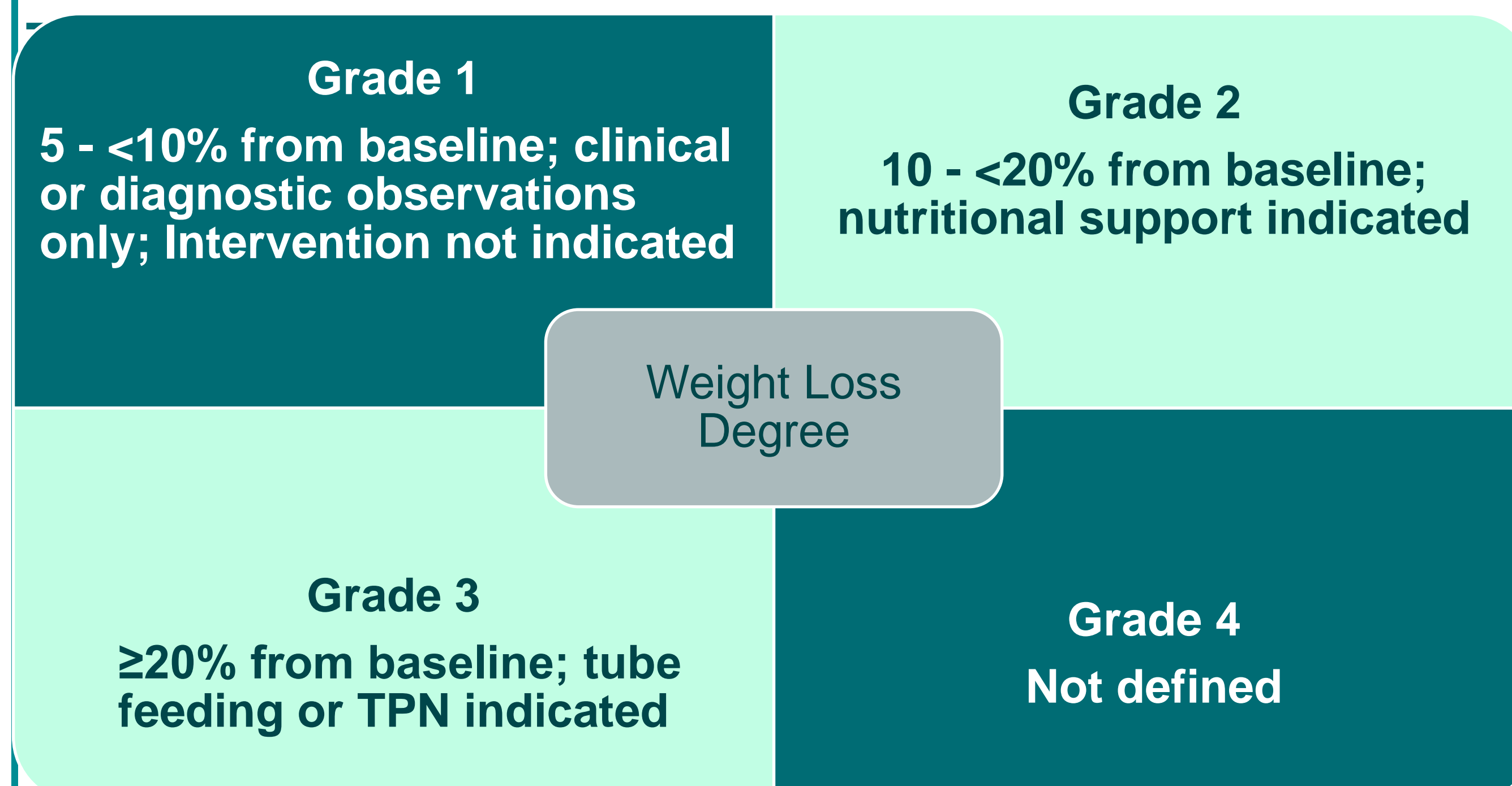


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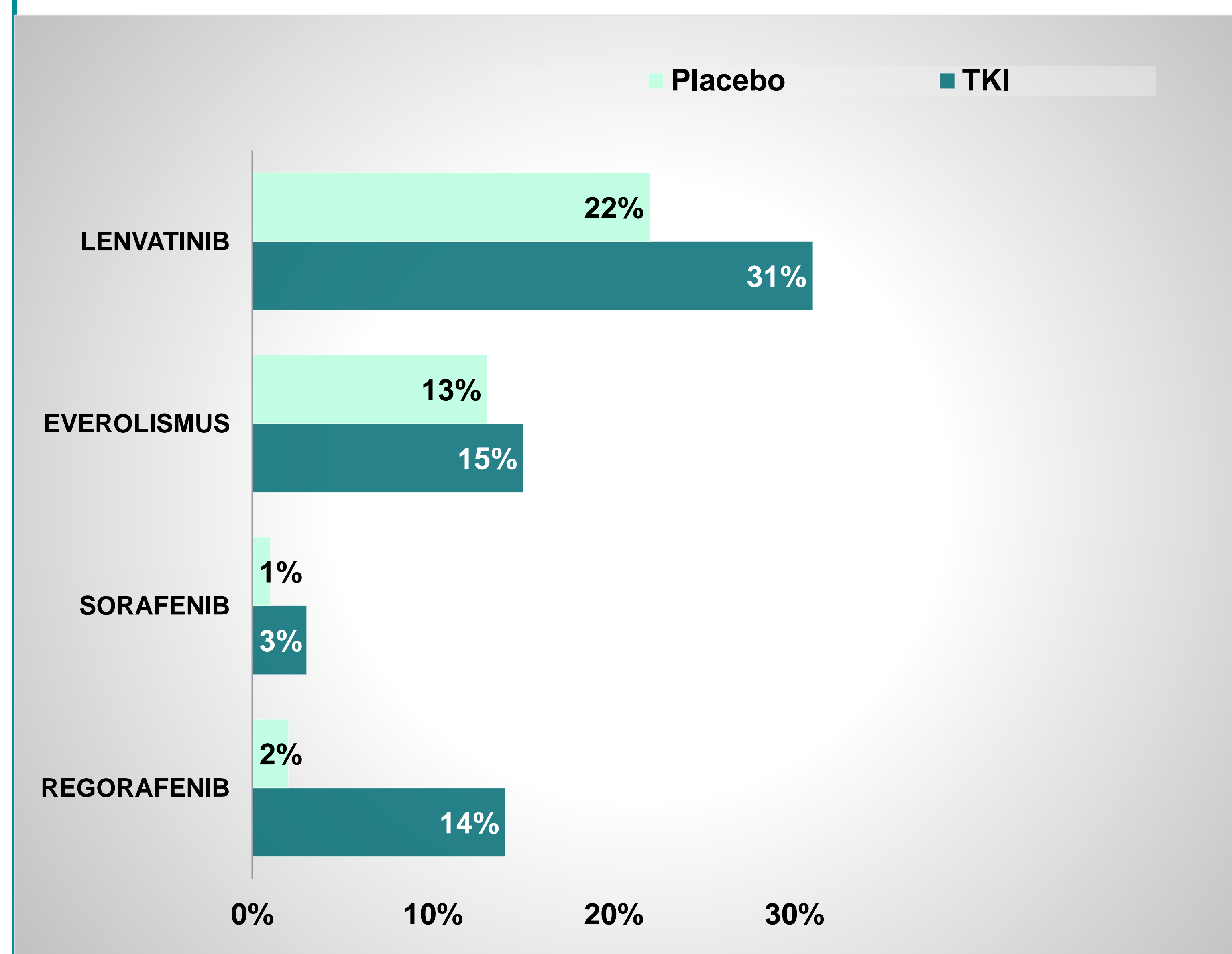
BACKGROUND

- Weight loss (WL) is highly prevalent and associated with shorter cancer survival (independent of primary site, stage, and performance status)
- WL is often ignored in oncology trials and frequently evaluated with a nonspecific classification
- We have identified two dangerous and misleading approaches in the Common Terminology Criteria for Adverse Events (CTCAE) specific to WL
 1. Severity grades and associated clinical descriptions
 2. Lack of longitudinal weight assessments
- Although Tyrosine Kinase Inhibitors (TKI) can improve cancer survival, they are known to paradoxically contribute to WL
- We examined if and how WL was reported within Phase III TKI landmark trials in GI oncology that led to FDA approval



RESULTS

Figure 1: Tyrosine Kinase Inhibitors and Weight Loss In Phase III Randomized Controlled Trials



WL (any grade) was more frequent in the experimental arm of all trials.

- Interventions associated with severity grades do not align with nutrition management guidelines for cancer patients
- Current grading system does not capture WL trajectory, as severity is confined to a single initial assessment
- Pretreatment WL is not considered, although this is common and may be severe even at cancer diagnosis

RESULTS

- WL is often ignored in oncology trials and frequently evaluated with a nonspecific classification
- WL is entirely absent from the Patient Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE) item library even though it is both a symptom (subjective) and a sign (objective) of disease

RECOMMENDATIONS

1. Weight assessment should be routinely integrated into study reports
1. AE assessment should be patient-focused and supported by clinically relevant definitions of each grade level
2. WL should require continuous assessment across all CTCAE grades to capture duration, severity, and trajectory
3. WL should be urgently incorporated into the PRO-CTCAE to define the individual impact
4. Development of a PRO-CTCAE tool specifically tailored to TKI therapies
5. WL reports as an AE should be urgently revised to improve patient safety and data integrity in clinical trials

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