Clinical benefit response in pancreatic cancer trials revisited.

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Abstract

OBJECTIVES:
Clinical benefit response (CBR), based on changes in pain, Karnofsky performance status, and weight, is an established palliative endpoint in trials for advanced gastrointestinal cancer. We investigated whether CBR is associated with survival, and whether CBR reflects a wide-enough range of domains to adequately capture patients' perception.

METHODS:
CBR was prospectively evaluated in an international phase III chemotherapy trial in patients with advanced pancreatic cancer (n = 311) in parallel with patient-reported outcomes (PROs).

RESULTS:
The median time to treatment failure was 3.4 months (range: 0-6). The majority of the CBRs (n = 39) were noted in patients who received chemotherapy for at least 5 months. Patients with CBR (n = 62) had longer survival than non-responders (n = 182) (hazard ratio = 0.69; 95% confidence interval: 0.51-0.94; p = 0.013). CBR was predicted with a sensitivity and specificity of 77-80% by various combinations of 3 mainly physical PROs. A comparison between the duration of CBR (n = 62, median = 8 months, range = 4-31) and clinically meaningful improvements in the PROs (n = 100-116; medians = 9-11 months, range = 4-24) showed similar intervals.

CONCLUSION:
CBR is associated with survival and mainly reflects physical domains. Within phase III chemotherapy trials for advanced gastrointestinal cancer, CBR can be replaced by a PRO evaluation, without losing substantial information but gaining complementary information.

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Comment in
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