Patients' estimation of overall treatment burden: why not ask the obvious?

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PURPOSE: We investigated the clinical validity of patients' estimation of overall treatment burden. This measure was expected to be responsive to the wide spectrum of reactions on treatment and thus less precise for specific effects.

PATIENTS AND METHODS: After the first chemotherapy within a randomized, double-blind trial of the prophylaxis for delayed emesis (SAKK 90/95), 249 patients documented nausea and vomiting daily for 6 days. Over the whole period, they estimated nausea/vomiting (N/V) burden and overall treatment burden by linear analog-self assessment (LASA) indicators and documented other side effects. RESULTS: At day 6, the two burden indicators were moderately correlated (r = 0.58) in accordance with their different concepts. No, partial, or total control of delayed emesis (days 2 to 6) was reflected in a consistent pattern by both indicators, with a stronger and more significant effect (P < .001) on changes in N/V burden than overall treatment burden. In contrast, toxicity other than N/V, assessed independently by patients and physicians, was mainly associated with overall treatment burden. Patients who indicated at least one other side effect rated their overall burden substantially higher than those with no indication of other toxicity (P < .0001). Physician-rated toxicity had a similar effect (P < .0001). CONCLUSION: A direct patient estimation of overall treatment burden by a LASA indicator may serve as an end point in clinical trials, particularly when treatments with different toxicity profiles are being compared. It is complementary to physicians' ratings of specific toxicities and a major component of patient-rated symptom checklists and quality-of-life measures.