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We Still Need Common Criteria for the Assessment of Nausea and Vomiting

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IN 1984, Pater and Willan [1] reviewed methodological difficulties in clinical trials presented at the first, separate, anti-emetic session of the annual meeting of the American Society of Clinical Oncology (ASCO). In another contemporary review, Morrow asserted that there may be as many scales for assessing nausea/vomiting as there are investigative groups studying the phenomenon [2]. Many of the methodological pitfalls pointed out in the aforementioned reviews are purged in modern trials, but several uncertainties still exist.

Assessment of anti-emetic efficacy includes registration of the number of emetic episodes, the duration of emesis (defined as the time elapsed between the beginning of the treatment with the emetogenic drug and the last episode of vomiting), the duration of nausea and the severity of nausea, assessed on a graded scale or a visual analogue scale [3]. Though the need for common assessment criteria has been obvious for several years [4], a recent review demonstrated that differences in anti-emetic assessment still exist [5]. One of the major end-points in anti-emetic trials is the proportion of patients who obtain a complete response (CR). The different definitions of CR constitute a significant problem. In studies investigating the efficiacy of serotonin antagonists, CR has been defined as no emetic episodes, including any degree of nausea (ondansetron studies) or as patients with no emetic episodes and no or only mild nausea (granisetron studies) or as no emetic episodes and no nausea (tropisetron studies) [5]. Adding to the confusion is the fact that some studies define an emetic episode as a vomit or a retch, others as a vomit or one to five retches, whereas in some studies retches are not assessed at all.

It is generally accepted that nausea and vomiting, although related, are distinct phenomena [6], and as such they should be assessed separately. This is supported by a recent trial [7] in which the Common Toxicity Criteria (graded nausea and vomiting separately) was found more valid than the WHO scoring system (considering nausea as an adverse event that preceeds vomiting) in scoring patients' nausea and vomiting induced by chemotherapy.

It is still debated how nausea and vomiting should be assessed, and by whom. In this issue, a paper by Olver and colleagues (pp.. . .) focuses on patient and observer assessment in anti-emetic trials. In three randomised, double-blind trials, the assessments of nausea, vomiting and tolerability carried out by the patients were compared with assessments carried out by nurses. The assessment of subjective efficacy parameters, such as duration and severity of nausea, was only compared in one of the three studies. A poor correlation between patients' and nurses' assessments was seen. This is in concordance with most investigators, who consider nausea a subjective sensation for which patient self-assessment must be the primary measurement tool [2, 3, 5, 8]. Comparing patients' and nurses' assessments of objective parameters, such as the number of vomiting episodes, Olver and colleagues found no significant difference in a parallel study, whereas patients in two cross-over trials recorded more vomiting episodes than the nurses. In the parallel study, nurses recorded observations every hour, but in the crossover studies nurses recorded the data at the completion of each 8-h shift. The authors, therefore, suggest that their findings could be due to differences in the timing and frequency of data collection. Though it requires a great deal of time and dedication for the staff involved, an objective observer assessment is still considered the standard method for estimating the number of emetic episodes [9]. Furthermore, the use of a specially-trained nurse observer is preferable to the ordinary staff nurse as differences could be due, not only to timing and frequency of data collection, but also to being dependant on the quality of the data collected.

The study by Olver and colleagues (pp.1223–1227) strongly emphasises the need for common criteria for the assessment of nausea and vomiting in anti-emetic trials. Until such criteria are available, it is mandatory that a detailed description of the methodology used is presented in published papers, thereby enabling the reader to make a careful evaluation of the studies.

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1. Pater JL, Willan AR. Methodologic issues in trials of antiemetics. *J Clin Oncol* 1984, 2, 484–487.
2. Morrow GR. The assessment of nausea and vomiting: past problems, current issues, and suggestions for future research. *Cancer* 1984, 53(suppl.), 2267–2278.
3. Tonato M, Roila F, De Favero A. Methodology of antiemetic trials: a review. *Ann Oncol* 1991, 2, 107–114.
4. Grunberg SM. Making chemotherapy easier. *N Engl J Med* 1990. 322, 846–848.
5. Aapro MS. Methodological issues in antiemetic studies. *Invest New Drugs* 1993, 11, 243–253.
6. Italian Group for Antiemetic Research. On the relationship between nausea and vomiting in patients undergoing chemotherapy. *Support Care Cancer* 1994, 2, 171–176.
7. Franklin HR, Simonetti GPC, Dubbelman AC, *et al.* Toxicity grading systems. A comparison between the WHO scoring system and the Common Toxicity Criteria when used for nausea and vomiting. *Ann Oncol* 1994, 5, 113–117.
8. Kaye SB. How should nausea be assessed in patients receiving chemotherapy? *Cancer Treat Rev* 1991, 18, 85–93.
9. Gralla RJ, Clark RA, Kris MG, Tyson LB. Methodology in antiemetic trials. *Eur J Cancer* 1991, 27(suppl.), S5–S8.