Opinion
Volume 7:2, 2022

Journal of Cancer Clinical Trials

ISSN: 2577-0535 Open Access

Significance of Stages in Cancer Trials

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Opinion

Cancer staging is a critical activity for cancer control for both populations and individuals. The dual purpose of staging was recognized by the International Union Against Cancer (UICC) TNM Committee almost 50 years ago when they defined the objectives of cancer staging as to aid the clinician in planning cancer treatment, to give some indication of prognosis, to assist in evaluating the results of treatment, to facilitate the exchange of information between treatment centers and to contribute to continuing investigation of human malignancies. In this issue for the call redesign of the TNM system for breast cancer in order to improve its utility for decision making in individual patients. No one would argue that all of the information necessary for the determination of therapy is contained in the current TNM system. The inclusion in TNM of additional variables proposed by the authors such as hormone receptor status and HER status, while telling us what therapies might appropriately be considered for a patient, still does not allow a determination of what is the best therapy for an individual. The choice of the optimal therapy must also take into account co-morbidities and the patient's attitude toward what constitutes an acceptable level of risk and benefit of treatment. No staging system will ever serve as a substitute for evidenced-based clinical medicine tailored to an individual patient's needs, particularly since the "best" available treatment is a continuously evolving target.

But, a useful staging system should have the ability to assess whether the mortality from cancer is decreasing as therapy improves. The current TNM system has the ability to address changes in cancer incidence and mortality over time, both in nations with substantial resources and those in the developing world. Although extent of disease as measured by TNM does not provide a complete biologic portrait of tumor behavior, it does offer a framework within which the effects of screening and therapy can be distinguished. The inclusion of additional variables as proposed by Veronesi will not allow TNM to be used to evaluate the effectiveness of new therapies. This will remain the primary province of clinical trials in well-defined populations, while evaluation of the uptake of new treatments will continue to require the linkage of cancer registry data with administrative data sets. Veronesi correctly emphasize that breast cancer prognosis is a continuum across tumor size and number of involved lymph nodes, and make a plea for recording exact information on tumor size and extent of nodal involvement, rather than using current stage groupings.

This is a reflection of how individual patient care decisions are made. But, for survival analyses groups must be created, and the authors fail to provide any evidence that they have identified subgroups which are more appropriate than those currently defined by TNM. Clearly, an infinite number of prognostic groups could be created through grouping of individual tumor sizes and numbers of involved nodes, but how does this advance our understanding of breast cancer? The Oxford Overview Analysis has demonstrated that the relative benefits of both chemotherapy and endocrine therapy are consistent across the spectrum of node-negative and node-positive breast cancers. The key clinical question, which cannot be answered by any staging system, is what threshold of benefit justifies therapy [1-5].

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How to cite this article: Gough, Randy. "Significance of Stages in Cancer Trials." J Cancer Clin Trials 7 (2022): 150.

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Received 09 February, 2022, Manuscript No. jcct-22-55319; **Editor assigned:** 09 February, 2022, PreQC No. P-55319; **Reviewed:** 11 February, 2022, QC No. Q-55319; **Revised:** 14 February, 2022, Manuscript No. R-55319; **Published:** 18 February, 2022, DOI: 10.37421/jcct.2022.7.150