

Antineoplastons and the Challenges of Research in Integrative Care

The story of the antineoplastons, the compounds that make up the alternative cancer therapy offered by Stanislaw R. Burzynski, is in some ways a tale of natural product drug development gone awry. The antineoplastons were isolated from human urine and demonstrated antitumor activity in early laboratory evaluations, as has been observed with many other chemical compounds isolated from naturally occurring substances. Some of these were isolated from higher plants and have become pillar drugs in the modern oncology arsenal. After the laboratory evaluation, however, the path of antineoplastons diverged from that of most antitumor compounds. Rather than proceed through the conventional pharmaceutical drug development pathway, Burzynski took his compounds directly into the clinic himself. Every new drug needs an advocate who is willing to give it considerable attention in the competitive world of drug development, and Burzynski took his responsibilities very seriously. With negligible outside involvement or collaboration, he rejected the pharmaceutical route and instead proceeded on what has been recognized by many as a controversial course for attempting to validate this approach. The antineoplastons are the mainstay of treatment at the Burzynski clinic. While this clinic is not a multidisciplinary integrative clinic in the sense usually understood in this journal, it does represent one of the alternative medicine treatment modalities that patients under integrative care sometimes choose.

In this issue, we have published a review of the current state of clinical trials on antineoplaston therapy, based on a presentation given by Dr Burzynski at the Center for Mind-Body Medicine's Comprehensive Cancer Care Conference in 2003. Phase II clinical trials, properly registered with the Food and Drug Administration, have been under way at his clinic for several years. Burzynski reports interesting data on brain tumors in this review. Phase II clinical trials are, of course, only preliminary steps in the development of drugs, and many conventional drugs or protocols that have looked promising in phase II development have gone on to obscurity after phase III trials. However, most phase II protocols of conventional drugs that show encouraging results are also published in the scientific literature. We are therefore publishing this summary of progress in clinical trials of the

antineoplastons. We understand that this decision might be criticized by some due to the preliminary nature of the data, due to the apparent lack of collaboration with investigators outside of his institution, such as university or medical center scientists, and due to the fact that the article comes from an alternative medicine center. Clearly, Burzynski's results need to be replicated in other centers and need to be subjected to full-scale randomized trials before the antineoplastons should be considered a fully validated therapy. It is important, nonetheless, that the integrative medicine community be aware of the specific cancers in which Burzynski feels he is making progress toward validation of the antineoplastons, to better assist patients in making decisions about whether they might choose to pursue this alternative cancer treatment.

Dr Mitchell Hammer of American University and Dr Wayne Jonas, now at the Samueli Institute for Information Biology, have contributed a very interesting commentary related to the development and validation of the antineoplastons. Designing a randomized trial on chemical agents such as the antineoplastons is relatively straightforward, and the Mayo Clinic worked with Dr Burzynski in the 1990s to carry out such a trial, which was sponsored by the National Institutes of Health (NIH). Unfortunately, the trial was not completed due to disagreements about management of the study, although partial data were obtained and published. The contribution of Dr Hammer and Dr Jonas represents an analysis of the social issues of managing trials of alternative medicine, specifically the Burzynski trial, and is very pertinent to those embarking on research on the many integrative and alternative therapies that scientists are now beginning to examine.

Hammer and Jonas's contribution is also relevant to larger considerations of the design of trials in integrative cancer care, the topic of a 2-part Point-Counterpoint that begins in this issue. In this first part, our respondents offer their thoughts on whether randomized trials are useful at present for the evaluation of integrative cancer therapy. We have also asked our respondents to consider how to approach the problem of researching the overwhelming number of herbs and supplements that may be suitable for use in integrative care. Dr Adrian Dobs of Johns Hopkins University Medical School, Dr Andrea Cohen of the

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University of Colorado, Dr Suzanne Hess of Wake Forest University School of Medicine, Dr Andrew Vickers of Memorial Sloan-Kettering Cancer Center, and Ms Beverly Burns of the Charlotte Maxwell Complementary Clinic in San Francisco are participants in this first part of a 2-part series. In our next issue, a panel will respond to a different set of questions on the same topic. We hope that opening a discussion on study design and procedures in this forum will result in a greater degree of consensus on what types of trials are suitable and practical in our field and perhaps fewer problems of the type Hammer and Jonas discuss.

Opening this issue is an article from the US Department of Agriculture's Grand Forks Human Nutrition Research Center, reviewing the anticancer mechanisms of food plants in the cruciferous vegetable group—foods widely cited as critical to the healthy diet. Both the glucosinolates (eg, sulphoraphane and indole-3-carbinol) and selenium compounds are important phytochemicals in this food group, and they appear to be responsible for cancer inhibition through an impressively diverse set of mechanisms. Another contribution comes from Dr Mitchell Gaynor, a long-standing contributor to the area of integrative care, who discusses his origins and development in this field. An unusual and intriguing article by Roxanne Struthers and Valerie Eschiti explores the experiences of Native American cancer patients who consider themselves to have been cured of cancer through participation in the traditional healing rituals of their cultures. This study was done using qualitative research methods, appropriate for the initial explorations of human experiences in areas that are difficult

to evaluate through more familiar forms of scientific investigation. The work of Struthers and Eschiti demonstrates just how far we will need to go to truly grasp this important aspect of traditional healing and its relevance to contemporary patients. Finally, Dr Miriam Cotler of the California State University at Northridge shares an intensely personal piece, a reflection on the anguish and frustration of a health professional as she sees her beloved brother through his terminal cancer. We encourage more pieces of this nature with the hope that these experiences shared by those in the health care field will provide greater insight and improvement in patient care.

Our Integrative Tumor Board in this issue concerns a case of metastatic renal cell carcinoma. We are privileged to have medical oncology input from 2 continents. Drs Supriya Gupta and Nicholas Vogelzang of the University of Chicago and Dr Hardev Pandha of the University of London review the case, with some interesting differences in conclusions. Dr Dan Rubin provides a naturopathic perspective on the case. Finally, Ms Penny Block of the Block Center for Integrative Cancer Care provides a psycho-oncology perspective.

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Integrative Cancer Therapies

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