

Integration of Traditional and Complementary Medicine During Chemotherapy: A Physicians Viewpoint

Interview with Rudy A. Segna, MD, FACOG

By Lisa Colodny, Pharm D., BCNSP

The use of alternative or supplemental medicines is at an all-time high in the United States as well as other countries. It is no surprise, then, that questions about their efficacy, side effects, drug interactions, and place in therapy are among the most frequently encountered by healthcare practitioners of all disciplines and specialties. Recently Chris Foley, MD, coeditor of the *Journal of the American Nutraceutical Association (JANA)* spoke with Rudy Segna, MD, FACOG, in New York about the methodology required to integrate the use of nutraceuticals into a medical practice. Dr. Segna maintains a private oncology practice in New York City, and is an assistant professor, Department of OB/GYN, at the Mount Sinai Medical Center in New York City. The following interview is a result of a conversation between Dr. Foley and Dr. Segna.

Foley: Dr. Segna, what experiences have you had in your practice vis-a-vis patients seeking advice on alternative cancer treatments?

Segna: Patients are innately both curious and suspicious about the medicines commonly prescribed for them by their physicians. As a result, they seek answers to some of their questions via the Internet or publications written both in and outside of the USA. The challenge for the physician is to evaluate the data and incorporate worthwhile therapies into the traditional regimens. For example, in advanced ovarian cancer, most patients may require a radical surgical procedure followed by 6 to 8 cycles of intensive chemotherapy. Many are more frightened by the chemotherapy than the surgery. They research their options before chemotherapy is scheduled to begin and consult with their physicians for final recommendations.

However, these consultations can have both positive and negative implications for the patient. The physician has to evaluate data on alternative products individually. I've certainly seen some [recommendations] that are very inap-

propriate. However, for most patients with educated opinions, evaluation of the pros and cons for the product usually produces a compromise where the physician doesn't lose any ground in terms of the traditional standard chemotherapy treatment, and the patient may gain potential benefit from the supplement.

Foley: Is there a downside to patients doing their own research and seeking advice on a complementary approach to their treatment?

Segna: A delay in conventional treatment while the patient researches alternative therapy could have a negative outcome. Abandoning standard treatment in favor of alternative treatments is never recommended in my practice. More importantly, since these patients are researching drug information from several sources (traditional and alternative), how their questions are addressed by the physician becomes important. Failure to address their concerns or questions appropriately may push patients away from standard medical treatment, and this can be detrimental. More specifically, the attitude of the physician is most important to the atmosphere of teamwork that must exist between physician and patient before successful outcomes may be realized.

Foley: Share with us your personal experiences in the use of nutraceuticals in your gynecology/oncology practice.

Segna: I was recently introduced to a specific dietary supplement, or nutraceutical, that was being used by many of my patients. About six months ago I learned that my patients were seeking advice outside of my office for guidance on the use of nutraceuticals, and I discovered that they were taking a specific supplement to support their bodies' nutritional needs during the treatments I was administering to them. It only made sense to learn more about this issue, evaluate my patients needs, and guide them about nutri-

tional supplementation during their treatment regimens as their physician. The added benefit was that I could monitor how the nutritional supplementation affected the chemotherapy treatments that my patients were undergoing.

Foley: Describe for us the number of patients you placed on the nutraceutical supplement, how long you followed them, and what was the outcome.

Segna: I monitored 8 of my ovarian cancer patients over a 6-month period. Patients were placed on a nutritional supplement (Propax® with NT Factor™) that contains a preset amount of essential trace minerals, antioxidants, essential fatty acids, and vitamins. The formulation also includes phospholipids and creatine, tyrosine, alpha ketoglutarate, and probiotics. Finally, the formulation utilizes a unique delivery system that mimics the way the body utilizes nutrients.

Nutritional supplementation typically started with commencement of the first cycle of chemotherapy. Patients with recurrent disease or those who had numerous cycles of chemotherapy were usually started on the product at the end of a new salvage regimen. Preliminary results for these patients have been positive, especially with improvements in their energy levels and a reduction in the fatigue normally associated with chemotherapy treatments. During the treatment period of these 8 patients, I saw a general improvement in their overall physical well being. All 8 patients experienced fewer side effects associated with their chemotherapy compared to other patients undergoing similar chemotherapy, but not on a nutritional supplement.

Foley: Dr. Segna, please share with us the changes in these 8 patients in terms of their specific chemotherapy treatment and outcome.

Segna: The patients who received nutritional supplementation experienced no episodes of sepsis or infection. Hematologically, they did not require platelet or blood transfusions nor were they administered filgrastin. In addition, there were no admissions for neutropenic fever or other commonly encountered immunosuppressive sequelae. I might point out that the clinical evaluations for Propax® to date have been mainly focused on the fatigue commonly encountered by patients who are receiving different chemotherapy treatment regimens. Fatigue is multifactorial and difficult to objectively treat or assess. Objective parameters (laboratory values, admissions, transfusions, fever, cultures, etc) are usually better indicators of the success or failure of a treatment with a combination of therapies.

All 8 patients treated nutritionally during the full 6 months of chemotherapy treatment responded positively. There were no treatment delays or dose reductions required by the patients for chemotherapy. This is an interesting result, as delays in treatment or dose reductions of therapy are very common in the treatment of this type of cancer, mostly due to myelosuppression. One would expect to see a certain number of patients who after 8 cycles of chemother-

apy might require admission for febrile neutropenia, or the need of transfusion. Looking at 8 consecutive patients where none of the 8 had a negative sequela is quite interesting and quite frankly, I have not experienced this level of results during the past 10 years. One would expect 1 or 2 patients to experience at least one commonly encountered sequela. Studies to better evaluate effectiveness in terms of hematological parameters, admissions into the hospital, total length of treatments, total dose, etc, would definitely be interesting and useful in evaluating the effectiveness of nutritional supplementation.

Since dose intensity can differ from site to site of different cancer presentations, and the emergence of chemotherapy resistance also impacts the potential treatment plan, nutraceutical agents may have a role in the inhibition of resistance by promoting better overall health.

Foley: Do you plan to pursue a more detailed study and evaluation of nutraceuticals in a controlled study?

Segna: I am currently developing a proposal to study the effectiveness of nutraceutical supplementation in patients receiving adjuvant chemotherapy for advanced ovarian cancer, and it will be submitted for consideration to Mount Sinai's Investigational Review Board. This small niche of patients are in a similar situation and receive nearly identical chemotherapy medications, making them an easy-to-study cohort.

Foley: In your opinion, is it safe to use nutraceutical supplements during chemotherapy?

Segna: I have not read any published data from clinical studies indicating that this type of nutraceutical therapy is unsafe or not in the best interest of the patient. In reference to the use of the specific nutraceutical product Propax® that we looked at in our practice, it appears to be safe. I understand that in other clinical trials involving the product there have been reports of gastrointestinal upset and diarrhea, but this disappears in most cases when the dosage is first reduced, then gradually increased to the original dosage. We had Propax® analyzed by several third and fourth party pharmacists. There's nothing in it that could be construed to be detrimental to the patient's welfare. In my opinion, nutraceutical products that reduce fatigue and address other "quality of life issues" that impact patients during chemotherapy should be considered an option available to oncologists when they are treating their patients.

Foley: Developing criteria to measure the effectiveness of a specific nutraceutical for use in oncology patients is not an easy task. Can you address this issue?

Segna: The treatment groups would have to be divided into specific disease groups. The existence of numerous covariables within the groups would probably make unbiased, blinded studies impossible. Ideally, the groups would be broken down into other disease sites or treatment groups

to best assess the effect or lack of effect for any agent. Ideally, inclusion of radiation patients into the study would also provide interesting results.

Foley: Can you address the status of nutraceutical coverage by insurance programs?

Segna: Results from the use of nutraceuticals during chemotherapy treatment may prove interesting to managed care organizations or other third party insurers. When cost containment or reduction can be demonstrated [with the use of nutraceuticals to decrease sequelae-associated costs of chemotherapy], 3rd party payers may consider making it available to their oncology patients. In the long term, it probably would save them significantly more money than it would cost them to purchase the nutraceutical product. For example, Propax® costs approximately \$135 for a month's supply. One treatment-week of erythropoietin costs about \$2100. However, I must caution that it is too soon to report definitively that Propax® directly decreases the need for other adjunct treatments. With this product and others

like it, the medical profession will still require investigation with large scale controlled studies in homogenous groups receiving similar treatments before specific conclusions can be drawn. As more studies are completed, they can be peer-reviewed and evaluated.

Foley: It seems to me that as an oncologist, you were favorably impressed with the use of a nutraceutical supplement during the treatment of your patients with traditional chemotherapy agents. Do you have a closing remark to share with other physicians?

Segna: Complementary therapies should serve to support the standard of care regimens cancer patients are receiving. If the product used has no significant untoward effects, and can possibly improve the patient's experience with cytotoxic agents, I would strongly consider adding a nutraceutical to their regimen.

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University of the Sciences in Philadelphia Establishes Complementary and Alternative Medicines Institute

In an effort to make herbal and other complementary medicines safer and more effective for Americans, University of the Sciences in Philadelphia is applying its scientific and clinical resources to a new venture, the Complementary and Alternative Medicines Institute.

Funded in part by the Bayer Corporation, the Institute's research will focus on analyses of herbs, bioassays, in vitro and in vivo studies, and clinical evaluations of supplements and other herbal preparations. Staffed by University of the Sciences in Philadelphia faculty, the Institute will provide science-based research expertise in pharmacognosy, clinical pharmacy, pharmaceutical sciences, physical and analytical chemistry, biological chemistry, molecular biology, and genetics.

"There is a need for solid scientific testing, as well as testing of safety and efficacy of these medications in a clinical setting," explained Ara Der Marderosian, PhD, Scientific Director of the Complementary and Alternative Medicines Institute. Der Marderosian is a pharmacognosist known internationally for his research on ginseng.

The US lags behind Western Europe in the standardization of herbal therapies, and with supplementation use growing, it is important that manufacturers and the medical community gain a stronger understanding of purity and efficacy for many of the herbal preparations.

"Herbal remedies may vary in safety and efficacy," said Der Marderosian. "A product might come from a different manufacturer or from a different batch of herbs. It may have been harvested in a different season or stored under different conditions. Because of this lack of standardization, medical practitioners have been reluctant to prescribe herbal remedies for their patients."

Philip P. Gerbino, President of University of the Sciences in Philadelphia, explains, "The establishment of this Institute is a continuation of our original mission. When we were founded in 1821 as the Philadelphia College of Pharmacy, a primary goal was to raise the quality and purity of drugs in the marketplace."

"We think that this will go a long way to ensure that Americans who choose herbal preparations will get the safest, most effective medications available," said Der Marderosian.