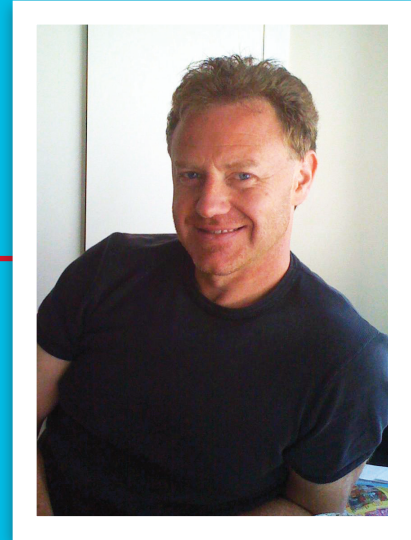


THE SCIENCE BEHIND A CANCER FIGHTING DIET

HEALTH & WELLNESS:

by
Alex Rolland

Founder and Chief
Research Scientist
@ Cancer Treatment
Options and
Management Inc.



There have been
many Exciting
Developments in



CANCER *Research* Treatment & PREVENTION

in the last few years.

The previously uncertain relationship between what we eat and the subsequent development or prevention of cancer has started to be more clearly defined. In the last few years a number of studies have been published that demonstrate the potential of certain nutraceuticals to prevent and treat cancers of all kinds.

As you may recall from my previous articles, a **nutraceutical** is the term used to describe a naturally occurring substance that has a *proven role* in regulating the genes and processes that drive the progression of cancers.

Gene targeted, nutraceutical diets are a key method of addressing cancer treatment. For years we've been helping our clients to experience greater recovery rates, lessened treatment side-effects, and a reduced likelihood of recurrence for many forms of cancer with the aid of individual nutraceutical diets. As such, at CTOAM we get a lot of questions from our clients about general diet and nutraceuticals in particular.

Some of the most common questions we'll hear are:

1. Which nutraceuticals are the best for reducing my cancer?
2. How much should I take and when?

A main source of concern in regards to nutraceutical diets is that there are many contrary opinions and, sadly, a lot of downright misinformation regarding what to take and what that benefits of that supplement actually are. I am sure

you have some experience with the confusion that occurs when you enter a health food store or visit a naturopathic doctor and are told about the many different supplements and vitamins that can help with your cancer. Likewise, it is common for cancer patients to be inundated with confusing and conflicting information when browsing the internet. *This series of articles that I have prepared for you will go a long way to clearing up your confusion and will aid you in identifying the best nutraceuticals for both preventing cancer and for treating it.*

THE SOLID EVIDENCE FOR NUTRACEUTICALS:

As a scientist, I believe that in order for a person to have true confidence that any treatment will benefit them they must first understand why it works and know that the methodology behind the treatment is sound. This knowledge of what works and why also helps us to become more educated consumers in general and therefore makes it easier for us to tell when the science behind a recommended treatment or supplement just isn't sound enough for us to put our faith in it.

On that note, before we dive in to the independent exploration of some of my favorite nutraceuticals, let me share some details with you of how the scientific community determines whether or not a specific substance/nutraceutical truly has significant cancer fighting/suppressing power.

Pre-clinical Studies:

The first step in determining whether a specific nutraceutical has cancer fighting activity happens in the lab and is referred to as pre-clinical evidence. Pre-clinical studies involve two main approaches referred to as *in-vitro* (test tube) and *in-vivo* (in life) studies. With *in-vitro* studies, various types of cancer cell lines are grown in a petri dish and then fed various concentrations of the nutraceutical being studied.

Defined Mechanism Studies:

If a cancer cell line is affected by the nutraceutical, then the next stage of research involves identifying how the nutraceutical affects the specific cancer cell line or, in science jargon: Which cancer causing genes and molecular processes are targeted by the nutraceutical. This process is referred to as the 'defined mechanism phase' and involves looking at the regulation of established cancer causing genes that are known to be involved in the specific cancer being studied.

Once the defined mechanism of the nutraceutical has been established, the research moves on to the *in-vivo* stage. In this stage, mice are either surgically implanted with cancers (I know! Scientists can be so cruel!), or given chemicals that induce cancers. They are then treated with the nutraceutical to see if it has any affect on the animal's cancer. Usually, three different animal models are required (eg, mice, rats, and monkeys) to establish whether a substance is clinically significant for prevention and treatment of a cancer.

Human Clinical Trials:

Once these pre-clinical studies have been conducted, the nutraceutical is tested in humans in a series of studies referred to as **clinical trials** which typically involves 3 phases.

1 In Phase 1 trials, researchers test the nutraceutical in a small group of people to evaluate its safety, determine a safe dosage range, and identify side effects.

2 In Phase 2 trials, the nutraceutical is given to a larger group of people to see if it is effective and to further evaluate its safety.

3 In Phase 3 trials, the nutraceutical is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.

It is important to note that while human clinical trials provide the best evidence for the role of a particular nutraceutical, there are many issues that prevent both effective drugs and nutraceuticals from ever reaching the medical establishment. Furthermore, these studies are prone to misinterpretation and confusion regarding the specific benefits that can be obtained.

The Problem with Clinical Trials:

Most nutraceuticals are sold with limited pre-clinical research with a very small number making it to any human clinical trials. There are, however, a few key nutraceuticals that have made it to the human clinical trial stage and have strong evidence to indicate their application for both prevention and treatment of cancers.

While the issues that confound the various types of human clinical trials can be complex, the following considerations should be included when reviewing human clinical trial data.

Incentive for Testing:

For starters, the estimated cost of testing a new drug or nutraceutical through the first three phases of a clinical trial can be in excess of \$1-2 billion dollars. Since nutraceuticals can not be patented, there is little incentive for their research and development. While various nutraceutical clinical trials have been conducted by universities and public health organizations, most of these trials have shown mixed results and have suffered from poor funding (more on this later). A lack of funding can have numerous consequences on the results obtained from a clinical trial and can undermine the credibility of any positive results.

Lack of Patient Stratification:

One of the most significant issues undermining positive clinical trial results is a lack of patient stratification. Patient stratification refers to the concept of establishing the genes and mechanisms that have resulted in a person's specific form of cancer. A lack of patient stratification almost always leads to varied results for the participants in the trial.

For a clinical trial to produce meaningful results from a specific nutraceutical, the defined mechanism has to be the main focus of the trial. In other words, the trial needs to contain a select group of patients whose specific form of cancer is based on the same genetic alterations and molecular processes that the nutraceutical has been shown (in pre-clinical studies) to target and regulate. However, this is rarely the case.

Most clinical trials consist of a variety of patients with the same type of cancer, but the genetic causes for their cancer are almost never considered. Furthermore, the health of the patients varies greatly, usually consisting of people in various stages of disease progression. The main reason for this is a lack of the funding needed to perform the expensive genetic and molecular testing required for proper patient stratification. The end consequence is varied trial results which undermine any positive benefits to the patients that happen to respond well to the nutraceutical, and generally leads to the end of the trial for that nutraceutical.

This is unfortunate because in most nutraceutical clinical trials a certain group of patients do benefit from the addition of the nutraceutical. The simple explanation for these positive results is that the patients that benefited from the nutraceutical had cancers that were caused and perpetuated by the genes and mechanisms that the nutraceutical targets.

Given that the goal of personalized medicine is to use defined mechanisms to determine the right treatment for each individual patient, the lack of proper patient stratification in clinical trials has resulted in many beneficial drugs never making it to market. It has also led to many medical professionals to confusedly discount the significant benefits that can be had from an individual nutraceutical diet.

Optimal Dosage:

Two additional confounding factors that can lead to varied results from a clinical trial are the issue of nutraceutical bioavailability and a lack of consistency in the clinical trials regarding the amount of the nutraceutical used.

Bioavailability refers to the amount of the nutraceutical that remains in the body at a level that is required for its cancer fighting activity. The big difference between drugs and nutraceuticals is that drugs have been adapted to remain in a specific tissue for a specific amount of time at a required concentration. With nutraceuticals, this can be a real problem. For starters, when most nutraceuticals are taken orally, they get broken down by the body's natural digestive

processes and excreted before they reach the circulatory system and long before they reach the tissue that contains the tumor.

Clinical trials are designed to compare two groups of people: The group getting the nutraceutical (treatment group) and the control group (typically receiving a placebo) to which the treatment group is compared. With this in mind, researchers often focus on high doses of a single nutraceutical at a time. The problem with this is that *it is impossible to achieve cancer fighting levels of a specific nutraceutical when it is taken by itself, orally*. This can easily be overcome by carefully designing trials that use combinations of nutraceuticals that have undergone bioavailability testing in humans and have been shown to increase the bioavailability of the nutraceutical being tested.

Another factor that affects bioavailability is that the enzymes that break down nutraceuticals can significantly vary between people (up to 1000-fold). Finally, people that have undergone many rounds of treatment can have problems absorbing vitamins and supplements due to the negative side-effects of chemotherapy on the digestive organs.

Variations in The Sources of the Nutraceuticals Being Tested:

Finally, one of the biggest problems that has confounded nutraceutical clinical trials is the naturally occurring, and significant, variation in the nutraceutical sources being tested.

The amount of nutraceutical can vary greatly depending on the strain of the plant and the type of plant it is obtained from. Thus, if researchers are not careful to use the same form of nutraceutical from the same distributor and the same harvest of plant product, and test the amount of nutraceutical in that batch, the results from their studies cannot be considered significant or at all reliable.

For example, the Japanese have been cultivating green teas for ceremonial purposes for hundreds of years. It became apparent that people who participated in these ceremonies showed reduced rates of cancer when compared to those that didn't partake.

Of course, this observation has lead to many studies that have used green teas on a variety of cancers, all producing unreliable and mixed results. When I reviewed many of these studies, I was astounded to find that little consideration was given to the actual amount of EGCG in

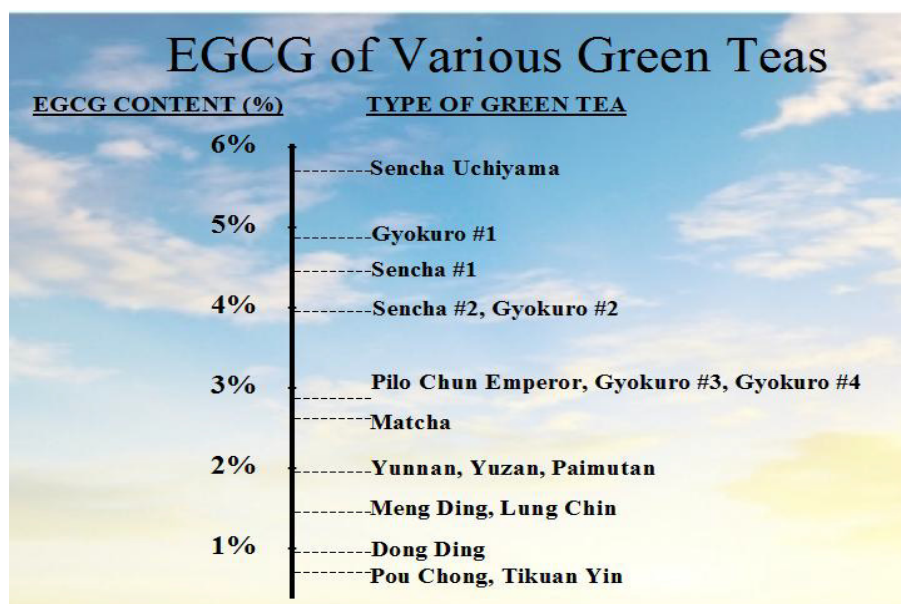
the teas or supplements being tested. (The active cancer fighting nutraceutical in green tea is referred to as EGCG.) In fact, the source of the green tea used in each study (including whether it was administered in supplement form or in raw, tea leaf, form) was typically not discussed. The following diagram should provide an explanation for how this can affect a clinical trial as it shows the variation between various strains of green tea used in the studies.

FIGURE 1:

Variations in the levels of EGCG found in different strains of green tea. The percentage of EGCG is based on the dry leaf weight of the green tea.

As you can see, there is a huge variation in the amount of cancer fighting EGCG found in different strains of green tea. Furthermore, the amount of EGCG released increases with the length of time the tea is steeped. With this in mind, drinking

FIGURE 1





6 cups of Sencha-Uchiyama steeped for 10 mins results in an equivalent amount of EGCG (~1.35mg) as drinking **69** cups of Pou Chong or Tikuan Yin green tea steeped for 2 mins!

It is also important for you to note that, at this time, supplements and vitamins are not required to be tested to prove the percentage of active ingredient claimed to be in the product is actually in each capsule you're taking. Therefore, the amount of a given nutraceutical in a supplement or vitamin can vary greatly between brands and depending on what it was extracted from.

At CTOAM we use only specific distributors of nutraceuticals for our patients because those companies perform (and post the results of) testing on all their raw materials to ensure the maintenance

of proper concentrations of their product across each batch.

As such we recommend that you make sure the brand or type of nutraceutical you use is the same as the one used in the clinical trial or that you can obtain independent data showing proof of the concentration in that batch. One company that does random volunteer testing is www.consumerlab.com. We recommend you review their site for product results before you purchase any nutraceutical supplement.

Considerations when Assessing Evidence for a Nutraceutical:

In summary, here are the questions to ask yourself, and ensure

that you have solid answers to, in order to feel confident that you're taking the right nutraceutical for you and that it will do what it says it will.

1 Is the evidence for the benefits of this nutraceutical based on pre-clinical or human clinical trial studies?

2 Was a defined mechanism for the nutraceutical established?

3 Has the defined mechanism of the nutraceutical been shown to be involved with your specific form of cancer?

4 Did the researchers address the bioavailability issues?

5 Did the trial use nutraceuticals that were tested to ensure consistency of concentration?

6 If human clinical trial studies have been conducted, how similar to your disease and case were the patients that benefited from the treatment?

Look for the next in this series of articles when we will share with you the most current research on a specific nutraceutical that you can easily access and which has been shown to have significant benefits to cancer prevention and treatment.

And please call or email us with any questions or to have us prepare a full nutraceutical diet for you for cancer prevention and for enhanced treatment outcome.

We can be reached at www.ctoam.com; contact@ctoam.com or 778-999-5463.