Vital Link
The journal of the Canadian Association of Naturopathic Doctors

Feature Articles

Naturopathic Integrative Oncology

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Fall-Winter 2014

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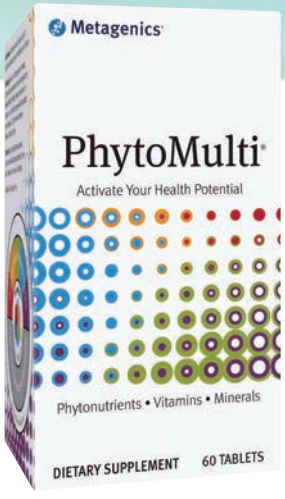

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The *Vital Link* is the professional journal of the Canadian Association of Naturopathic Doctors (CAND). It is published primarily for CAND members and features detailed reviews of specific causal factors: philosophical and research-based papers, clinical practice articles and case reviews, as well as international updates on the profession. The *Vital Link* has an outreach to other health care professions and promotes qualified naturopathic doctors to corporations, insurance companies and the Canadian government.

Forthcoming Themes

Spring 2015 Health-care Changes Through the Ages
Summer 2015 Family Medicine: Health Fusion Edition
Fall 2015 Where You Live Affects Your Health

Submissions
When writing for the *Vital Link*, keep in mind its broad readership and outreach to other professions. Your contribution to the *Vital Link* will benefit the naturopathic profession as a whole and provide you with personal professional exposure. Previously unpublished material is preferred. Please contact the managing editor for submission guidelines.

Circulation
The *Vital Link* is published three times per year and is distributed to over 2400 qualified Canadian NDs and students of CNME-accredited naturopathic programs in Canada and the U.S. The *Vital Link* is also distributed to the CAND's corporate members and in our media kit. The journal is available in print and e-formats, by paid subscription.

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Professional vendors providing NHPD/Health Canada-compliant products or other services to NDs are encouraged to advertise in the *Vital Link*. The CAND's advertising partners enjoy unequalled exposure to qualified Canadian naturopathic doctors.

Naturopathic Notes

Dr. Iva Lloyd, BScH, BCPP, ND

Naturopathic medicine is proving to have a significant impact in the field of cancer care. As our understanding of the causal factors of cancer continues to grow and as both practitioners and patients look for better cancer prevention, more effective and tolerable cancer treatments, ways to improve the prognosis and quality of life for those dealing with cancer, the demand for naturopathic care will continue to increase.

This is an important edition of the *Vital Link*. It looks at the research and the strength of naturopathic treatments in oncology. In his guest editorial, Dr. Dugald Seely, ND, founder and executive director of the Ottawa Integrative Cancer Centre (OICC), outlines the role of naturopathic oncology in an integrative cancer care model. He stresses the importance of staying current with research, working cooperatively with other medical practitioners and the need to continually evaluate patient outcomes.

Dr. Lise Alschuler, ND author of *The Definitive Guide to Cancer, 3rd edition: An Integrative Approach to Prevention, Treatment and Healing*, highlights the research supporting specific lifestyle and diet modifications that have been proven beneficial when undergoing active cancer treatment. In Dr. Alschuler's article **Lifestyle, Diet and Cancer** she explains how diet can be used to assist in recovery from cancer treatment and improve tolerance to radiation and chemotherapy. Likewise, exercise and stress management are linked to improving tolerance and outcomes.

An increasing emphasis is being put on the mental-emotional components of cancer risk and treatment. Dr. Neil McKinney, ND and author of *Naturopathic Oncology, an Encyclopedic Guide for Patients and Physicians*, provides a comprehensive overview of this topic in his article, **The Mental-Emotional Components of Cancer Care**. Dr. McKinney outlines the growing body of research indicating a strong connection between a person's mental state and their risk not only of having, but also surviving cancer. Dr. McKinney also discusses the different therapies that have been shown to be effective in this field.

Essential to naturopathic oncology is the use of safe, effective natural health products (NHPs). We feature an overview, contributed by naturopathic doctors Kimberley Ramberan and Mark Fontes, of the research behind the most common NHPs used in cancer care. Their article, **Natural Health Products Used in Naturopathic Oncology**, covers the clinical application, efficacy, and safety of key nutritional supplements of Astragalus membranaceus, Curcuma longa , EGCG, fish oil, melatonin, modified citrus pectin, medicinal mushrooms, and vitamin D.

Naturopathic oncology is usually associated with the use of intravenous vitamin C and other IV substances. Naturopathic doctor Daniel Lander's article **IV Therapy as an Adjunct to Chemotherapy and Radiation** explores the research and potential of IV therapy in cancer care.

We are also pleased to feature Health Canada's Adverse Reaction Reporting (ARR) Needs Survey authored by Dr. Kevin Bernardo, BHsc (Hon.), ND, Ms. Shawn O'Reilly and Dr. Mano Murty, MD, CCFP, FCFP. The report provides a glimpse of the trends and needs of NDs with respect to ARR, and identifies opportunities to increase the participation of naturopathic doctors in reporting adverse reactions.

We trust that all these articles will provide naturopathic doctors and other medical professionals with a comprehensive overview of the current research in the rapidly expanding fields of naturopathic and integrative oncology. As always, we welcome your feedback.

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Opinions expressed in this article are not necessarily those of the editors, the CAND nor its board of directors.

Adverse Reaction Reporting to Health Canada – A Survey of Naturopathic Doctors

Dr. Kevin Bernardo, BHsc (Hon.), ND, **Ms. Shawn O'Reilly, Dr. Mano Murty,** MD, CCFP, FCFP

PURPOSE

As primary care practitioners, naturopathic doctors (NDs) are well-equipped to obtain the critical details of adverse reactions (ARs) experienced by their patients associated with natural health products (NHPs) and/or other health products (such as drugs), as well as provide objective clinical information which may pertain to the patient's overall condition. The aim of this survey was to understand the current level of awareness and understanding of NDs to Health Canada's AR reporting tools, database and published safety information. It is important that NDs are aware of the process of reporting ARs and the resources and information available to them from Health Canada, including Med Effect and the Canada Vigilance Program.

METHODS

The Canadian Association of Naturopathic Doctors' (CAND) Needs Survey was sent to members in active practice via email on January 12, 2012, with a deadline for response of January 31, 2012. Only members in active practice that received the email invitation had access to the survey. The online survey was created with Survey Monkey (www.surveymonkey.com), a free online survey tool. The survey consisted of 8 multiple-choice questions, and was designed not to be too lengthy or detailed, in order to encourage responses from those surveyed.

RESULTS

Members of the CAND include regulated NDs or those who would qualify for regulation who are currently in active practice as well as inactive members who are not currently practicing, and students at accredited naturopathic medical programs. However, the survey was distributed only to members who are currently in clinical practice. This decision was taken by the CAND, based on the opinion that this cohort would most accurately reflect the NDs who may encounter or report ARs to Health Canada. Student members and inactive members were not surveyed. The total number of CAND active licensed members surveyed was 1,200, and the response rate of this survey was approximately 21% (246 respondents).

Responder Demographics
(Questions 1-3 of survey)

1) Age

The majority of licensed NDs in Canada who responded to the survey are below the age of 40. Approximately 70% of respondents are between the ages of 21-40.

2) Gender

The gender distribution of respondents is approximately 4:1 female to male (n=199 females; n=47 males). Historically, the majority of applicants to schools of naturopathic medicine are female. However, according to the CCNM, the number of male applicants has increased in recent years.

3) Number of years in practice

According to the survey, the majority of respondents have been in clinical practice for less than 10 years (73%). In fact, a large proportion of those surveyed have been in clinical practice for less than 5 years (41%). Twenty-seven percent (27%) of respondents have been in clinical practice for more than 10 years.

Responder Knowledge of Health Canada's Med Effect portal and AR Reporting System
(Questions 4-8 of survey)

4a) Are you consulting and or using new safety information from Health Canada as part of your practice? (i.e., adverse reaction newsletter, Med Effect e-notices).

(Number of responses: Yes: 122; No: 125)

While fifty percent of respondents indicated they were using new safety information the remaining fifty percent indicated they were not consulting and/or using new safety information from Health Canada as part of their clinical practice. A number of reasons were provided by the latter group of respondents, as outlined, below, in B). It should be noted that 18 respondents who indicated that they are not using new safety information from Health Canada did not provide a reason.

4b) If not, why not? *(Number of responses: 107)*

A variety of reasons were highlighted for not using new safety information from Health Canada. It should be noted that 107

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responses were received for this question, but there were 121 total reasons submitted. This is due to the fact that some respondents listed more than one reason for not consulting and/or using Health Canada safety information as part of their practice. The majority of the responses (56%) indicated a lack of awareness of the information resources available from Health Canada. That is, the respondents were not aware of the existence of Health Canada's safety information pertaining to marketed health products. Another 20% of the responses indicated a lack of accessibility to Health Canada resources. Primarily, these respondents expressed difficulty in navigating the Health Canada Web site in order to find the precise information for which they were searching. Some respondents (14%) indicated they are using non-Health Canada resources as their primary source of safety information. In particular, the majority of these respondents indicated that they are referring to their provincial association (e.g., Ontario Association of Naturopathic Doctors – OAND) and/or their national association (CAND) for safety-related information. Monthly newsletters from these associations appear to be the primary communication vehicle from which members are receiving safety-related information. Seven respondents (6%) indicated that they lacked the time to find information from Health Canada and suggested safety information to be sent to them via email. However, in order to avoid large quantities of emails irrelevant to NDs in clinical practice, the respondents suggested that the emails from Health Canada be specific to NDs. Three respondents (2%) indicated that they do not trust information from Health Canada because they believe it to be biased and inaccurate. Two responses were categorized as "Other" (2%); one respondent indicated that they were not in clinical practice and the other respondent indicated that they had not seen an AR in their clinical practice.

5) How would you describe your understanding of adverse reaction reporting with a health product?

According to the survey, 90% of respondents have either a "low" or "medium" level of understanding of AR reporting to Health Canada. There does not appear to be any significant correlation between "low" and/or "medium" levels of understanding of AR reporting and number of years in clinical practice. It should be noted that the qualifiers of "low", "medium" and "high" levels of understanding were not defined within the scope of this question. Responses were based on the individual's perception of each term within the context of the question. In regards to respondents who indicated a "high" level of understanding of AR reporting to Health Canada, there did not appear to be a correlation to number of years in clinical practice (range <1 year – 23 years).

6a) Have you ever reported an AR to Health Canada?
(Number of responses: Yes: 20; No: 228)

6b) If not, why?
(Number of responses: 206)

It should be noted that 206 responses were received for this question, but 232 reasons for not reporting were indicated. This is due to the fact that some of the respondents indicated more than one reason for not reporting ARs to Health Canada. The primary reason was that the respondent had never encountered an AR in their clinical practice (46%). Further delineation of this category shows that most of these respondents did not report because they have not encountered any "severe" ARs. The individual responses clearly indicate that respondents believe that an AR should only be submitted if it is "severe" or "serious" in nature. Based on the survey results, the respondents' perceived definitions of "severe" and "serious" ARs is unknown, as well as how these perceived definitions may differ from the regulatory definitions. This issue is also reflected in the number of responses indicating a lack of awareness and/or knowledge of the AR reporting process (19%). If an ND is unaware of the methods for, or purpose of, AR reporting, they may not submit an AR report if or when it is encountered in their clinical practice. Time constraints (12%) and the perception that the AR reporting process is too complex (8%) were also indicated by respondents. Five respondents indicated that they report any ARs encountered in their clinical practice to the manufacturer or supplier of the product(s) in question. With regards to the "Other" category in the survey question, many of the responses related to misconception(s) of respondents about AR reporting to Health Canada (e.g., Health Canada will remove more NHPs from the market, fear of persecution by the regulator, Health Canada would not take AR reports submitted by an ND seriously). This category represents 12% of the responses.

7) Have you reported an AR to another source, other than Health Canada?
(Number of responses: Manufacturer: 35 Distributor: 12 Both: 24)

As previously mentioned, certain respondents indicated that they did not report ARs to Health Canada since they were reporting elsewhere. These respondents indicated that they reported to manufacturers, distributors and/or manufacturers and distributors.

8) What would make it more likely for you to report an AR to Health Canada?
(Number of responses: 172)

It should be noted that 172 responses were received for this question, but 211 individual factors were indicated by respondents. This is due to the fact that some respondents indicated more than one factor that would make it more likely for them to report. The overwhelming majority (75%) of responses indicate that an easier, clearer reporting process, as well as an increased awareness of the AR reporting process, would make it more likely that NDs would submit ARs to Health Canada. In addition, 12% of responses indicate that respondents would submit an AR report to Health Canada if they encountered ARs that were "serious" or "severe" enough to report. As previously mentioned, it is important to understand how NDs perceive the definitions of "severe" and "serious" ARs, and to relay Health Canada's regulatory definition of a "serious AR." It is also important to increase awareness of what can be reported to Health Canada (e.g., Health Canada accepts all AR reports, regardless if they are serious or not, if there is a suspicion of an association between the product and the AR. The association does not need

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to be certain, only suspected.[1]) An additional 9% of respondents replied they would report if they had more trust in Health Canada. A small proportion (2%; 4 total responses) of respondents indicated that they are using the Med Effect portal and AR reporting forms to submit ARs to Health Canada.

DISCUSSION

The overall response rate to the survey was 21% (246 respondents out of 1,200 NDs surveyed). According to the results of the survey, the vast majority of licensed NDs in active practice in Canada are under the age of 40 and have been in clinical practice for less than 10 years. Typically, this age cohort is quite technologically astute, and so it would be important to capitalize on this asset. Health Canada has worked towards improving its Web site, electronic AR reporting tools, communication via newsletters (CARN) and email feeds (RSS feeds for Med Effect), and presence within the social media environment. This survey highlights that despite these initiatives, there are ongoing barriers that may impact AR reporting by NDs to Health Canada.

One of the primary reasons indicated in the survey for not using Health Canada resources and/or not reporting ARs, is a lack of awareness and understanding of the resources and/or reporting process on the part of NDs in active practice.

While a large portion of the NDs in active practice that were surveyed indicated a lack of awareness as the reason for not reporting ARs to Health Canada, the respondents who are aware of the tools and process for AR reporting cited a lack of accessibility as a major constraint. Approximately 52% of respondents indicated that they would be more likely to report an AR to Health Canada if there was an easier, clearer reporting process available to them. In addition, one of the primary constraints identified was the difficulty in navigating the Health Canada Web site. Some of the respondents indicated the need for "easy navigation of the Web site" and "a direct link to the online reporting form" as necessary components for reporting ARs to Health Canada. Many respondents indicated the need for an "online reporting form" which highlights both a lack of awareness and difficulty finding the AR reporting form on the Health Canada Web site. Other respondents indicated the need for a clearer set of instructions (i.e., a one-page hand out) regarding the location of the reporting form on the Health Canada Web site and steps for filling out the form.

Another major issue identified among the survey respondents is the prevalence of misconceptions associated with AR reporting to Health Canada and the scope of the Canada Vigilance Program. Many of the respondents stated that they are hesitant to report ARs because there is a sense of mistrust towards Health Canada. In particular, some respondents mentioned the following: fear of persecution by Health Canada; decreased access to products that they use in clinical practice; that Health Canada will use AR information to put a "black mark" on NHPs; and the belief that Health Canada would not take an AR report submitted by an ND seriously.

Furthermore, approximately half (46%) of respondents indicated that they had not submitted AR reports to Health Canada because they had not encountered any ARs in their practices. In fact, the majority of these respondents clearly indicated that they had not encountered a "serious/severe AR" in their practice (43% of total respondents). While Health Canada and other regulatory agencies have clear definitions of the terms "serious" and "severe", the respondents in the survey appear to have used the terms interchangeably.

It is important to note some of the limitations of the survey. First, while a 21% response rate is typical for this type of survey according to feedback from the CAND[2], the responses represent only a small percentage of NDs in active practice in Canada. At the time the survey was distributed, NDs were required to maintain membership with either the national association (CAND) or their provincial/territorial association. While many NDs were members of both, there were a number of NDs who were not members of the CAND and would not have been surveyed. However, since the survey was conducted, this requirement has changed and NDs in Canada are now required to have active memberships with both the CAND and their respective provincial/territorial association. Also, the survey did not include students of naturopathic medicine or those who are not currently in active practice, but still in a healthcare setting. Therefore, it is difficult to ascertain if the results are under- or over-represented.

Secondly, the nature of some of the questions represents another limitation to the analysis of the data. In order to simplify the survey and create the least amount of burden for respondents, a number of close-ended questions were utilized (e.g., Question 5 involves a self-assessment of the respondents' knowledge of AR reporting to Health Canada: "low, medium, or high", which were not defined).

In conclusion, this survey will assist in establishing the current level of understanding and awareness of AR reporting amongst NDs in active practice in Canada. It also provides information on the proportion of NDs surveyed who are reporting ARs to Health Canada, and reasons why they may not be reporting ARs to Health Canada. Furthermore, this survey highlights some of the misconceptions NDs have towards Health Canada's AR reporting system and, thus, the need for Health Canada to clarify these misconceptions.

To report any adverse reactions you observe in your practice visit www.healthcanada.gc.ca/medeffect.

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1. Health Canada (2011). Adverse Reaction Reporting and Health Product Safety Information Guide for Health Professionals. Accessed October 31, 2012. Available at: http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_fs-if/2011-ar-ei-guide-prof/index-eng.php

2. In-person meeting with Ms. Shawn O'Reilly, Executive Director of the CAND. Toronto, ON (November 14, 2012).

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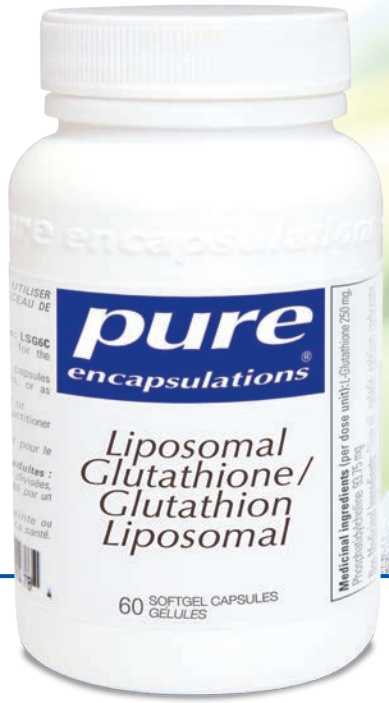

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Editorial: Naturopathic Medicine and Integrative Oncology

Dr. Dugald Seely, ND, FABNO

Naturopathic doctors (NDs) work in a time when chronic disease is the major health issue we face and cancer is taking an increasingly large role. As a profession, we will be dealing with a huge influx of people living with cancer in the context of relative diminishing conventional services. A recent report by Medscape Oncology indicates that in the USA by 2025, oncology services provided by our conventional colleagues will have grown by 28% whereas need for these services will have grown by 42%.[1] These numbers are based on U.S. statistics but equally reflect the situation in Canada.

Factors contributing to growing demand for naturopathic medicine in cancer care include increases in cancer incidence, patient longevity, and recognition of the value NDs offer. Our focus on environmental influences, the mental-emotional sphere, treating root cause, and particularly a whole-person approach to care is a great value to patients and one that is increasingly recognized.

Cancer related mortality is the leading cause of death in Canada responsible for 30% of all deaths annually, superseding the next three main causes of death including heart disease, stroke, and lower respiratory diseases combined.[2] Aging is by far the greatest contributor to diagnosis and our society supports a demographic 'boomer' bubble that is entering their late 60s. With this curve on the horizon it should come as no surprise when cancer incidence begins to spike exponentially. The increasing diagnoses related to aging is compounded by better management of the disease and people living longer with the disease and thus requiring more health care services overall.

Through earlier detection of certain cancers, particularly breast, and some improvements in treatment that extend life, our health care system has shifted towards more long term chronic management of the disease. This approach which includes 'survivorship' care covers a wide spectrum from diagnosis, active treatment, prevention of recurrence, palliation and end-of-life care. The upshot to this change is that we are facing a tsunami of people living with cancer that is just starting to hit our clinical shores. With over half of people living with cancer seeking complementary medicine,[3-6] there is a huge demand for the services that naturopathic doctors can provide. Indeed, within the field of integrative oncology, naturopathic doctors have played a leading role and are perfectly placed to continue this trend. Not only can we offer our patients incredible support and effective care, but we can also speak the language of our conventional colleagues and communicate with them to improve care and reduce anxiety regarding safety and rationale for use. Ultimately if such communication is enhanced NDs could gain recognition as valuable partners and providers of responsible effective care.

We need to support naturopathic clinicians to be actively engaged in caring for our patients in a way that is safe, well informed, and effective. In this context it is a rich and exciting time to be practicing. Our range of therapies and base of evidence has grown substantially. In addition, the profession has leading associations such as the Oncology Association of Naturopathic Physicians (OncANP) and the Society for Integrative Oncology (SIO) who are building on the knowledge base and delivering the training needed to best serve the profession and public.

Integrative oncology

First defined by Dr. Stephen Sagar in 2006, "Integrative oncology combines the discipline of modern science with the wisdom of traditional healing. It is an evolving evidence-based specialty that uses complementary therapies in concert with medical treatment to enhance its efficacy, improve symptom control, alleviate patient distress, and reduce suffering."[7] Additional elements of integrative oncology that reflect the principles of naturopathic medicine include the focus on patient needs, an individualized approach, and the application of whole-person care that deals with much more than just the pathology of disease. NDs are trained to be experts in complementary medicine as well as understanding the language, science and diagnostics of western medicine. Effectively educated, NDs are perfectly placed to help bridge the gap between complementary and conventional care and indeed have something special and unique to offer our patients.

Within the context of providing cancer care, NDs often work with the patient and support them in their utilization of the conventional health care system and its various therapies as well as our own. This is not to say that we should not provide care for patients who wish to only use our therapies, but we should be well informed

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of the strengths and weaknesses of our medicine as well as that of conventional medicine. Through knowledge and experience we can guide our patients in a way that best serves them without judgment and without coercion. We are not here to serve the system and be subservient to our conventional colleagues but rather to offer the patient the best we can in their quest for quality of life and to overcome the disease or simply grapple with it with greater peace and equanimity.

In caring for our patients, we have a responsibility to truly understand what they are going through and being given at the hospital and to understand the effectiveness and limitations of the conventional therapies they are undergoing. One of the major roles we take on is that of an information broker who can help guide our patients in decision making and the knowledge to better understand what they are facing. For example, a recurring question I see is whether my patients should choose to undergo chemotherapy or not and to what degree will this offer real improvement in terms of survival and quality of life. In fact, there are many who do not trust the conventional health care system and see standard medical care as best avoided entirely. Sometimes the best service I can provide is to demystify surgery or chemotherapy and give my patients enough information to get them to understand that this may be their best option and that I will support them in every way I can through the process. On the other hand, sometimes the best I can do is support their choice to not pursue conventional therapy if the benefit is low and they are most interested in quality of life. That said, I believe that providing true alternative care is only possible if the patient is well informed of all options including the limitations of the care I might be able to provide them as well.

Naturopathic oncology

There are so many ways in which we can play a role in caring for people living with cancer that touches on the physical, psychosocial, and existential or perhaps spiritual depending on the patient's and practitioner's orientation. Selecting the right mixture of therapies, information, and support is critical and like any clinical encounter depends very much on each unique situation. Our toolkit is large and includes active listening, nutritional advice, targeted natural therapies, physical medicine, and lifestyle counselling to name a few. For NDs trained and able to use more aggressive therapies the options open further to include a variety of IV therapies, other injectable medicines, hyperthermia, and therapeutic metabolic oriented diets.

People living with cancer pose some of the most challenging cases for our profession. From my perspective no other situation brings forward the need for a truly holistic approach encompassing mind, body and spirit that we so often speak of. Those with stage IV disease often face a fragile imminent mortality and experience an array of physical, mental, emotional and spiritual symptoms that we are asked to help navigate. These patient encounters are humbling and profoundly enriching at the same time. There are definitely times of frustration, self-doubt, and often real sadness in clinic, but the process of caring for these patients overall is one that is deeply educational and rewarding.

At this year's fall retreat and board meeting of the Oncology Association of Naturopathic Physicians, we laid out a definition for naturopathic oncology as the following. "*Naturopathic oncology is the application of the art and science of naturopathic medicine in the field of cancer care and treatment. Furthermore, naturopathic oncology is a vital component of a comprehensive whole-person approach to cancer care that spans from prevention through treatment and into survivorship*."

The goals in naturopathic oncology will of course vary depending on context. In the case of supporting patients during active oncology care at the hospital, the focus is usually on sustaining them through the process and offering symptomatic support and/or prophylactic treatment. In the face of surgery we aim to support the healing process, reduce the negative impact on immune function, provide pain control, reduce adhesions, and speed recovery and tissue repair. When a patient is undergoing chemotherapy, things to look for include: developing neuropathies, mucositis, neutropenia, digestive dysfunction, fatigue, nausea, and potential organ toxicities. With radiation therapy, emphasis may be on reduction of collateral tissue and organ damage like that to the heart; reducing fatigue; and providing support for skin damage.

Along with active treatments at the hospital, oncologists have their own adjunctive medicines that we need to be aware of both in the context of symptomatic support and also with respect to potential interactions. Examples are broad and consist of numerous agents including: immunostimulants (e.g. neupogen and neulasta), steroidal anti-inflammatories (e.g. decadron and dexamethasone), anti-nauseants (e.g. zofran and stemetil), pain killers (e.g. lyrica and morphine), and aids for constipation (e.g. colace and sennokot).

After active care at the hospital, patients are increasingly receiving longer lasting therapies that they may have to take for years and require our understanding. These may be hormonally related as in the case of estrogen receptor positive breast cancers (e.g. tamoxifen and letrozole) or androgen dependent prostate cancer (e.g. Lupron and Zoladex). Other examples include a growing list of non-cytotoxic chemotherapy agents like the monoclonal antibodies and tyrosine kinase inhibitors. These newer drugs target characteristic genetic signatures on certain cancers (e.g. Herceptin for Her2/Neu positive breast cancer, and Gleevec for chronic myeloid leukemia exhibiting the Philadelphia chromosome). These are only a few examples of what we may be faced with and it is important to be aware of them to better guide our patients effectively.

When it comes to our treatments, principle targets for naturopathic oncology include the following broad areas: supporting the immune system, reducing inflammation, enhancing programmed cell death (apoptosis), having specific cancer cell cytotoxicity, supporting a healthy terrain, hindering metastatic and angiogenic processes, influencing epigenetic oncogene expression, and more recently targeting the unique metabolism of cancer. For each of these broad areas, there are a variety of therapies we have at our fingertips. Amongst many other issues, the challenge and art of our

medicine is when to apply these therapies, how many to provide, their affordability for patients, and when to discontinue them. All in all, our therapies, sometimes subtle, sometimes aggressive, have the potential to aid greatly in symptom control and promising evidence supports our approach as hindering cancer progression and metastasis.

The articles in this and other issues of the *Vital Link* will give more life to the therapies and their evidence but I would stress that we have a number of interventions available to us that can and do have a powerful beneficial clinical impact both for symptomatic support and for their active anticancer effects. Some examples of oral natural health products that have varying degrees of evidence include: curcumin, green tea, melatonin, immunogenic mushrooms, astragalus, alpha lipoic acid, fish oils, vitamin D, berberine, quercetin and modified citrus pectin to name but a few. When it comes to intravenous therapies, promising ones include the use of vitamin C, alpha lipoic acid, curcumin, artesunate, glycirrhiza glabra, and Myer's cocktail. Venturing further towards off label use of prescription medications there are potential anticancer applications for dichloroacetate, metformin, aspirin, calcium channel blockers, low dose naltrexone and no doubt many others. How and when to apply these therapies safely requires knowledge, training and experience and an awareness of how the evidence on these therapies constantly evolves.

Application of evidence based medicine in naturopathic oncology

Having many therapies and modalities that can be applied clinically; it is a challenge to know when, what, and how to apply particularly when we may be uncertain to what degree or not our patients are responding. Resources from which we can draw in making our decisions include the experts we've learned from, the evidence in the medical literature, and our own clinical experience.

Cancer research and the evidence base is a rapidly changing landscape and I would suggest we are cautious regarding the certainty with which we interpret the available evidence. Promising therapies have frequently proven to not have much benefit regardless of how compelling the idea behind it was initially. We need to be open to this possibility even when it comes to our *favourite* intervention. What is perceived as true today may well change and it is crucial that we stay current with the literature and what our colleagues are witnessing. In evaluating the evidence we should be careful as well to not overestimate value from single studies and especially so when evidence only comes from preclinical studies. All too often, therapies with a powerful biological rationale that look good in the lab never amount to anything after being applied in humans.

While the limitations to applying an evidence based practice are enormous, we should also be cognizant of the limitations of a faith based practice perhaps even more. Just as we critique our MD colleagues, as NDs we should have an eye to the evidence and not hold on dogmatically to our beliefs. Constant questioning and a skeptical attitude are healthy, especially when it comes to our own beliefs. Just because something has been handed down from expert to student doesn't make it true and we must be ever mindful not to fall into the trap of a belief based approach to care that is more reminiscent of a religion than medical practice. The evidence based approach to medicine while imperfect holds clues and important information to glean when selecting therapies and recommending them to patients particularly as the cost/benefit ratio rises.

RESOURCES FOR CLINICIANS INTERESTED IN CANCER CARE

- OncANP membership – provides access to online chat room, referral listing, webinars, discounted access to annual conferences, committee membership and involvement, process for application and testing to write the exam leading to designation as a Fellow to the American Board of Naturopathic Oncology (FABNO). oncanp.org
- Society for Integrative Oncology (SIO) – conferences, collaboration with others in integrative oncology field for referral and research opportunities. integrativeonc.org
- Naturopathic Associations – CAND, OAND, and others for conference and continuing education seminars in cancer care.
- Seminars given by active and experienced members of the profession.
- Textbooks: numerous excellent resources including those written by Neil McKinney, Lise Alschuler, Sylvan Schreiber, Donald Adams, Elena Ladas and others.
- CTCA residency for additional training – a FABNO recognized residency

Need for adequate training

Just as there is a great need for clinicians who can effectively address cancer; there is an equally large need for good education in naturopathic oncology. As we see increasing demand for naturopathic cancer care so do we see greater educational needs. To strengthen clinicians' ability to address this need, the OncANP is advocating for stronger core cancer education in the colleges' four year curriculum. Fortunately, there are many avenues that a clinician can follow to get additional learning in this area outside of the accredited colleges. Places for additional education include the conferences put on by national (both AANP and CAND) associations as well as provincial and state conferences. The most focused and intensive coverage occurs at the annual conference put on by the Oncology Association of Naturopathic Physicians (OncANP) held in February.

The most accessible and useful resource for NDs interested in learning about cancer care is the OncANP. I encourage anyone who has any exposure to cancer patients to become a member of this group. Beyond the conferences, the OncANP provides rich and

frequent content and support from peers that is unparalleled. There is an email chat group which is collegial, active, and offers multiple clinical pearls and discussion. The group also has a seminar series, tumour boards, case discussion and referral support by website. The OncANP has spearheaded the development of a fellowship program through an educational platform and testing that allows clinicians to up their level of education through applying and writing the exam for the American Board of Naturopathic Oncology to achieve fellow status.

Final thoughts

Naturopathic doctors have so much to offer with respect to mainstream care for people living with cancer with the potential to greatly improve their quality of life, act synergistically with conventional therapy, and extend life. With additional training in cancer care, NDs should feel confident that they can have a dramatic impact on the lives of their patients and change the course of their disease and how they cope with it. Ideally our care is integrated early on when the patient's vitality is strong and we can support them most going forward. At every stage of cancer, NDs have something to offer and we should not be shy in informing our conventional colleagues that we are here and provide excellent professional support to their patients even in the most advanced cases. Our profession needs to be proactively engaged in primary prevention and its research. When it comes to our principles, a proactive preventative approach is perfectly suited to: treating root cause, doctor as teacher, prevention, and enabling the innate healing powers of the body. Cancer in its many guises poses unique and difficult challenges to the clinician. Cancer care is an area that we all need to have some degree of comfort in and is so well suited to the application of naturopathic medicine at its best. I believe we will see our medicine and the application of naturopathic oncology continue to improve and be more widely accepted rapidly in the years to come. We need more clinicians working actively in this area.

About the Author

Dugald Seely is a naturopathic doctor and the executive director of the Ottawa Integrative Cancer Centre (OICC). He also serves as the director of research for the Canadian College of Naturopathic Medicine (CCNM). Dr. Seely completed his M.Sc. in cancer research at the University of Toronto and is a Fellow of the American Board of Naturopathic Oncology (FABNO). As a clinician scientist, Dugald has been awarded competitive grant and trainee funding from CIHR, CBCRA, the SickKids Foundation, the Lotte and John Hecht Memorial Foundation, the Ottawa Regional Cancer Foundation, and the Gateway for Cancer Research. Dr. Seely has led numerous research projects and most recently secured funding for the largest integrative naturopathic cancer care clinical trial in North America. In addition to clinical research, Dr. Seely has conducted and supervised dozens of synthesis reviews and meta-analyses with the goal of building on the growing body the evidence that supports integrative oncology. Dr. Seely has published more than 50 Medline indexed peer-reviewed publications and believes strongly in the ability of evidence-based medicine to effect positive change in the health-care system.

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Lifestyle and Dietary Recommendations for Patients with Cancer

Dr. Lise Alschuler, ND, FABNO

The mainstays of conventional cancer treatment, surgery, chemotherapy, and radiation therapy, while preserving and prolonging the lives of many, present toleration challenges and often lack effectiveness in fully reaching desired goals of remission and survival. An integrative naturopathic approach offers additional adjunctive strategies that can improve both toleration and efficacy of conventional cancer treatment and further improve survival statistics. Fundamental to the naturopathic approach are diet, exercise and stress management.

Diet can be used to assist in recovery from surgery and to improve tolerance to radiation and chemotherapy as specific dietary nutrients offer synergistic antineoplastic actions. Exercise is an effective strategy to both improve tolerance and outcome. Finally, the impact of stress on prognosis is significant, pointing to the important role of stress management during any form of cancer treatment.

Diet

Diet has potential to optimize tolerance to conventional cancer therapies. Notably, there is evidence to suggest that patients who undergo conventional treatments without receiving nutritional support have higher complication rates.[1] Diet can be utilized to support optimal weight, specifically to prevent weight loss during treatment; to support bowel regularity; and to reduce localized areas of inflammation and pain such as headaches, arthralgia and mucositis.[2] While the full arsenal of dietary interventions is beyond the scope of this article, several dietary approaches deserve mention.

Dietary Patterns

Plant-based diets have been shown to be very important in cancer treatments. Fruit, vegetables, and certain components of plant foods, such as fiber and polyphenols, have significant research supporting a protective effect against cancer.[3] The impact of a plant-based diet has also been studied in specific cancer patient populations.

In women diagnosed with early-stage breast cancer and treated with chemotherapy, self-report of hot flashes (HFs) after treatment has been associated with approximately 25% to 30% decreased risk for additional breast cancer events, independent of the subsequent type of antiestrogen therapy. The HFs are associated with, in part, lowered levels of circulating estrogen. With this in mind, the protective effect of a whole foods, vegetable-rich diet might be especially relevant to women without HFs – essentially women with potentially higher circulating estradiol levels and hence a worse prognosis.[4] Specifically, changes in dietary patterns to either decrease energy from fat or to increase fiber intake can alter the enterohepatic recirculation of estrogens, leading to lower circulating estrogen concentrations. A low-fat/high-fiber diet can be expected to reduce serum estradiol by an average of 7.5%,[5] an effect of particular importance to women diagnosed with estrogen receptor positive breast cancer. Although this effect is modest, if it persists over years, this would have biological significance. A secondary analysis of the Women's Healthy Eating and Living (WHEL) Randomized Trial[6] was conducted to determine if HF-negative women gained specific benefit from the study diet that consisted of 5 vegetable servings plus 16 oz of vegetable juice, 3 fruit servings, 30 g of fiber, and limited energy intake from fat to 15% to 20% of total caloric intake.[7] Among women who reported no HFs (therefore presumably with higher estradiol levels and at greater risk) at baseline, there was a 31% lower recurrence rate in the group of women following these dietary recommendations than the HF-negative women in the comparison group (no dietary intervention) over 7.3 years of follow-up. Among HF-negative postmenopausal women, the intervention effect was more significant, with a 47% reduction in risk compared with HF-women assigned to the comparison group.

The beneficial effect of fiber specifically has been noted in other trials. For instance, women diagnosed with breast cancer who, within 12 months of their diagnosis, consumed significant fiber (average consumption of 15.5 g/day of insoluble dietary fiber) experience a 49% reduction in the likelihood of having elevated C-reactive protein (CRP) levels (OR, 0.51; 95% CI, 0.27, 0.95) compared to those who consumed an average of 5.4 g/day (P = 0.053).This suggests an anti-inflammatory effect of fiber consumption which, in turn, improves treatment toleration and is associated with improved survival.[8]

A dietary pattern characterized by significant reduction in the consumption of saturated fat, increased consumption of vegetable proteins with accompanying reductions in animal proteins and dairy

products has been shown to significantly increase PSA-doubling time in men with prostate cancer.[9] The slowed PSA doubling-time reflects decreased prostate cancer progression.

Colon cancer development and progression is also influenced by diet. Frequent consumption of red meat, refined carbohydrates, dairy and eggs is associated with an increased risk for developing colorectal cancer compared to infrequent consumption.[10] There is a significant inverse relationship between total fiber intake and risk of colorectal cancer (OR 0.57, 95% confidence interval 0.47-0.68). Vegetable fiber appears to be more protective than either fruit or grain fiber.[11] In patients with diagnosed colon cancer, a dietary pattern that emphasizes plant foods and minimizes animal sources of protein would be expected to exert a beneficial effect on the colon, perhaps influencing progression risk.

Obesity

It is now estimated that 2.4-3.9% of cancer deaths can be attributed to obesity.[12] The role of obesity in the progression and mortality risk of several cancers including breast, prostate and colorectal cancer is increasingly well defined. In an analysis of 70 clinical trials comprising 80,000 patients with early stage breast cancer, the relative risk of dying from breast cancer was increased by 34% in obese (BMI >30) pre-menopausal women (younger than age 55y) with ER+ tumors.[13] Thus, the absolute 10-year breast cancer mortality for pre-menopausal women with ER-positive disease was 21.5% for obese women compared with 16.6% for non-obese women. Post-menopausal obese women with ER-positive disease had a 6% increased risk of dying from breast cancer. There was no association between obesity and breast cancer death in women with ER negative tumors. Genetic analysis of pretreatment tumor biopsies has identified 121 genes with statistically significant changes in expression between obese and non-obese women.[14] Obesity is often characterized by hyperinsulinemia, estrogen signaling, and inflammation – all of which play important roles in obesity-accelerated breast cancer aggressiveness.

Obesity is also associated with unfavorable outcomes for patients with prostate cancer. Higher BMI (consistent with being overweight and obese) is predictive of a greater likelihood of rising PSA after surgery, indicating prostate cancer recurrence.[15] Furthermore, overweight and obese men experience shorter times to biochemical recurrence after surgery than normal weight men.

Obesity is a known risk factor for the development of colorectal cancer as well as its progression. Obesity related dyslipidemias, increased adipokines and elevated insulin and insulin-like growth factor-1 are collectively associated with both increased colorectal cancer incidence and mortality in both men and women.[16] Obesity also decreases the effectiveness of bevacizumab, a mainstay of conventional colorectal cancer treatment. Bevacizumab is the primary targeted therapy used for inhibiting tumor angiogenesis by blocking the VEGF/VEGF receptor pathway. Obesity is associated with increased levels of vascular endothelial growth factor (VEGF), which could lead to resistance to anti-VEGF bevacizumab therapy. In fact, a prospective clinical trial demonstrated that in patients with metastatic colorectal cancer who were treated with bevacizumab, those who were overweight (BMI >25kg/m^2) experienced significantly shorter time to progression (p = 0.01; HR: 4.37).[17]

Insulin Resistance

A significant driver of malignant behavior in cancer cells of all cancer types, is the increased expression of insulin and IGF-1 receptors.[18] As noted previously, insulin and IGF-1 are direct growth factors in many cancer cells.[19] Insulin and IGF-1 stimulate cellular proliferation in malignant cells via the constitutively "turned on" insulin receptor (IR) and IGF-1 receptors (IGF-1R), which culminate in mTOR activation. Activated mTOR drives proliferation, alters mitochondrial metabolism toward anabolism (aerobic glycolysis), and decreases apoptosis.[20] Some cancers rely exclusively on insulin and IGF-1 for their growth, including an estimated 27% of breast cancers. Approximately 8% of these cases have upregulation of the PIK3/Akt pathway.[21] Additionally, IGF-IR is constitutively activated via autophosphorylation in breast cancer cells with predilection for metastasis to the brain. *In vivo* models demonstrate that experimental deactivation of IGF-IR attenuates the invasive and metastatic potential of these breast cancer cells thereby delaying the development of brain metastases and prolonging survival. These preclinical findings are corroborated by the fact that 25% - 40% of patients with Her2+ and the same percentage of those with triple negative breast cancer have significantly increased risk of brain metastasis. This clinical finding correlates with increased IGF-IR signaling in these breast cancer subtypes.[22]

This concept has clinical application in the dietary advice given to patients. A trial followed 87 women with metastatic breast cancer receiving first line liposomal doxorubicin and cyclophosphamide chemotherapy for a median of 15 months.[23] Of the subjects, 87% had ER+ positive disease and 48% were insulin resistant, with insulin resistance defined as >2.5 HOMA-IR score. (Of note, HOMA-IR can be calculated as fasting serum glucose (mg/dL) x fasting plasma insulin (uU/mL)/405 with a value greater than 2.5 indicative of insulin resistance.) Even after adjusting for other prognostic factors such as age, endocrine status of tumor, visceral disease, and body mass index (BMI), patients with advanced breast cancer and insulin resistance had a statistically significant higher risk of disease progression (P = .035). The median progression-free survival was 8 months in women with insulin resistance, compared with 14 months for those who did not have insulin resistance (P = .04).

The role of insulin resistance is implied in colorectal cancer progression by looking at dietary glycemic load. Dietary glycemic load is positively correlated with insulin, IGF-1 and insulin resistance.[24] A prospective, observational study of 1011 patients with stage III colon cancer reported their dietary intake during and for 6 months after conventional treatment.[25] The median follow-up from the time of completion of adjuvant therapy was 7.3 years. Higher dietary glycemic load was associated with statistically significant decreases

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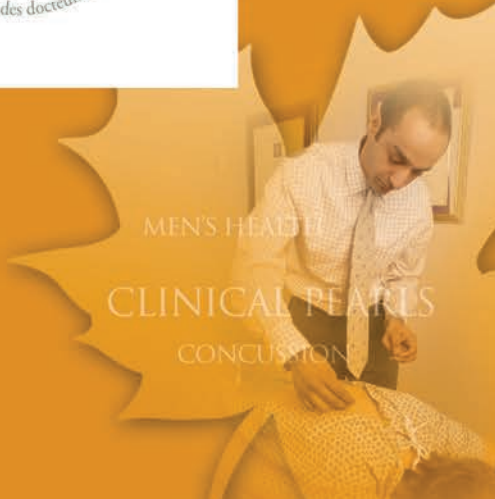


in disease-free, recurrence-free, and overall survival. Specifically, patients with stage III colon cancer who were in the highest quintile of dietary glycemic load experienced an adjusted hazard ratio (HR) for disease recurrence of 1.79 (95% confidence interval [CI] = 1.29 to 2.48), compared with those in the lowest quintile (HR = 1). Increased glycemic load was associated with decreased overall survival. These associations were strongest for overweight patients (BMI > 25; HR 2.26). All of these findings reached statistical significance. These data points support the use of a low glycemic, nutrient dense diet in people diagnosed with colon cancer.

Anti-inflammatory Nutrients

Polyphenols are found in plant foods and spices and possess uniquely potent anti-inflammatory effects. The anti-inflammatory effects of polyphenols are illustrated, for instance in a parallel-designed, placebo-controlled clinical trial of 120 men and women aged 40-74 years that compared the effect of 300 mg of an anthocyanin rich drink isolated from bilberries and black currants to placebo over a three week period.[26] Consumption of the proanthocyanin-containing beverage decreased NF-kappaB-controlled pro-inflammatory chemokines and IFNalpha (an inducer of NF-kappaB activation) by 45% and 40% respectively vs. 20% and 15% in the placebo group (P < 0.050). Another trial assessed the impact of 30 grams of freeze dried vegetables and medicinal herbs mixed into hot water added to the daily diet of five patients with stage I non-small cell lung cancer (NSCLC) in a toxicity study group and 6 patients with stages III and IV NSCLC in a treatment group for up to 24 months.[27] These patients were matched to 13 patients with stages III and IV NSCLC in the control group. The freeze-dried medicinal vegetable soup included soybean, shiitake mushroom, mung bean, red date, scallion, garlic, lentil bean, leek, hawthorn fruit, onion, ginseng, angelica root, licorice, dandelion root, senegal root, ginger, olive, sesame seed, and parsley. All patients were treated with conventional therapies, including radiation, surgery, and/or chemotherapy. Those patients eating the vegetable soup had median survival of 15.5 months compared to a median survival time of 4.5 months in the control group (P<0.01). There was no adverse toxicity in the vegetable/herb group.

There is an emerging body of data which supports specific benefits derived from various flavonoids, members of the polyphenol family of compounds. In a controlled trial, 87 patients, 36 with resected colon cancer and 51 patients after polypectomy, were divided into two groups.[28] One group of 31 patients was treated daily with a flavonoid mixture of 20 mg apigenin and 20 mg epigallocathechin-gallate and compared with a matched control group of 56 patients. Both groups were observed for 3-4 years by surveillance colonoscopy and by questionnaire. Among the 14 patients with resected colon cancer and treated with the flavonoid mixture, there was no cancer recurrence, and one adenoma developed. The cancer recurrence rate of the 15 matched untreated controls was 20% (3 of 15) and adenomas evolved in 4 of those patients (27%). The combined recurrence rate for neoplasia was 7% (1 of 14) in the treated patients and 47% (7 of 15) in the controls (P = 0.027).

In a trial of 26 men with newly diagnosed localized prostate cancer, the subjects were randomized to either 30 mg lycopene or no supplement prior to radical prostatectomy.[29] In the lycopene group, at surgery, 84% had tumors less than 4mL versus 45% in the control group. Additionally, 73% of the lycopene group and only 18% of the control group had clean margins. Prostate intraepithelial neoplasia was present in 67% of the lycopene group compared to 100% of the control group. Finally, PSA decreased by 18% in the lycopene group versus an increase of 14% in the control group.

A pooled analysis of three large prospective trials – the Shanghai Breast Cancer Survival Study (SBCSS), the Life After Cancer Epidemiology (LACE) Study, and the Women's Healthy Eating & Living (WHEL) Study – collectively representing 9514 breast cancer survivors with a mean follow-up 7.4 years, assessed the impact of soy isoflavone.[30] Consumption of over 10 mg isoflavones per day was associated with a 25% reduced risk of recurrence. This inverse association was seen in tamoxifen users, estrogen receptor negative and estrogen receptor positive women.

Polyphenols found in plant foods both down-regulate inflammatory NFkB and up-regulate the transcription factor Nrf2. Nrf2 is normally sequestered in the cytoplasm as an inactive complex with its cytosolic repressor Keap-1. Phytochemicals, specifically polyphenolic flavonoids, activate diverse upstream kinases, which in turn stimulate dissociation of Nrf2 from Keap-1. Once released from Keap-1 repression, Nrf2 translocates to nucleus and binds to promoter region of genes encoding antioxidant and detoxifying enzymes.[31] This effect is synergistic with chemotherapy in so far as intracellular antioxidants are required to preserve the apoptotic cascade initiated by chemotherapy. Additionally, polyphenols directly up-regulate apoptosis the ultimate step in removing aberrant cells. There are many examples of these pro-apoptotic polyphenols such as trans-resveratrol[32] from grapes, peanuts, berries, and red wine. Genistein[33] from soy and curcumin[34] from turmeric, activate apoptosis in cancer cells.

Fasting

A recent and promising approach to improve tolerance of chemotherapy is caloric restriction prior to and during chemotherapy. This approach has gained significant momentum from the research of Valter Longo, PhD. The premise of short term starvation (STS) in an oncology context is twofold. First, when energy is scarce, cells will use energy preferentially for maintenance functions at the price of growth. Furthermore, IGF-1 levels decrease dramatically in response to short-term (36 -120 hours) of starvation. Cells throughout the body respond to IGF-1 as a signal for growth. Thus, fasting results in growth arrest of normal cells. However, most tumor cells have mutations in pTEN, p53, and the PI3K/Akt/mTOR pathway, leading to constitutive upregulation of insulin and IGF-1 initiated proliferation pathway.[35] Thus, in malignant cells, short term starvation and the resultant decrease in IGF-1, does not downregulate the PI3K/Akt/mTOR pathway and therefore does not arrest their growth. This differential effect can be

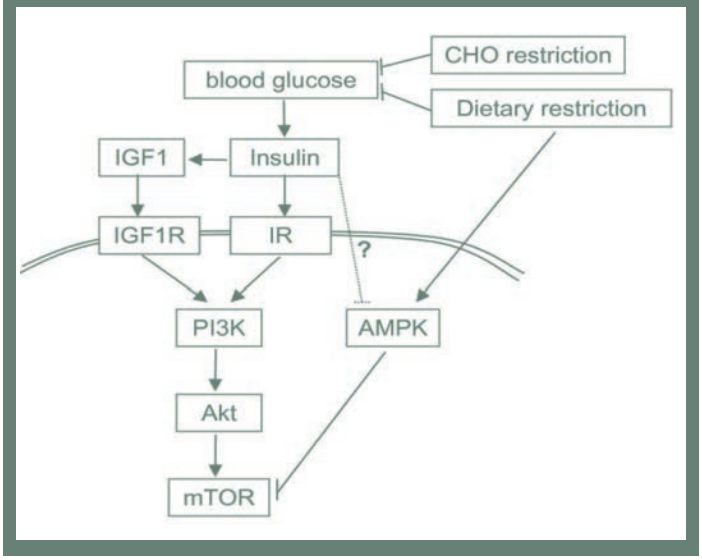
used with chemotherapy to preferentially protect healthy cells that will be in a dormant, non-proliferative state. This state renders these cells somewhat immune to the effects of chemotherapy. Malignant cells continue to proliferate during STS and remain susceptible to chemotherapy.

The effects of STS were demonstrated in case series report of ten patients (7 females and 3 males) with cancer (four with stage IIA breast cancer, two with prostate cancer – stage II and stage IV, one with stage IA ovarian cancer, one with stage IV endometrial cancer, one with stage IV non-small cell cancer of the lung and one with stage IVB esophageal cancer).[36] All patients received chemotherapy and underwent a water-only fast for 48-140 hours pre-chemotherapy and continued for 5-56 hours post chemotherapy. Patients served as their own controls and during fasting cycles they experienced less toxicity even after non-fasted accumulation of toxicity. Patients received an average of 4 cycles of various chemotherapy drugs including docetaxel/cyclophosphamide, docetaxel/carboplatin/±5-FU, carboplatin/paclitaxel, gemcitabine/docetaxel, docetaxel, doxorubicin/cyclophosphamide. Specifically, the chemotherapy received during the water fast resulted in less fatigue, weakness, and gastrointestinal side-effects.

While the benefit and safety of this approach, specifically the impact of fasting on treatment response and survival is still under clinical investigation, it could be considered empirically in patients who experience significant chemotherapy-induced toxicity to a level that is threatening their ability to complete treatment. Of note, preclinical research has indicated that fasting may reduce multidrug resistance in malignant cells,[37] however this needs to be confirmed in human clinical trials. The exact nature of the fasting regimens are under investigation. One fasting protocol under study includes 24, 36, or 48 hour fasts prior to chemotherapy.[38] Another active clinical trial of women with gynecological cancers is studying the impact of modified fasting with daily caloric intake of <400kcal by juices starting 36 to 48 hours before beginning chemotherapy and lasting to 24 hours after ending each chemotherapy.[39]

Although not clinically evaluated, a variation of STS can also be considered between chemotherapy treatments and as a follow-up to conventional treatment. In the absence of active treatment, diet can be used to influence the same constitutively over-active IGF-1 and insulin stimulated PI3K/Akt/mTOR pathway in malignant cells and in individuals with insulin resistance. This proliferation pathway's activity is enhanced in the presence of IGF-1 and insulin, both of which are reduced during caloric and carbohydrate restriction. Furthermore, dietary caloric restriction stimulates AMPk which directly blocks mTOR activation. (see Diagram 1.) The result of down-regulating mTOR is reduced proliferation. Despite the promising theoretical basis for this approach, the clinical data on the impact of caloric and carbohydrate restriction on overall survival and recurrence risk in humans is yet to be determined.

DIAGRAM 1. Dietary restriction and mTOR



Cachexia

Of note, this approach should not be considered for any patient at risk for cachexia, a condition of significant weakness and wasting caused by inflammatory cytokines released by malignant tissue. Certain cancers such as lung cancer, pancreatic cancer and many advanced cancers carry a high risk of cachexia. Protein and essential fatty acid consumption is a clinically validated way to both prevent and delay cachexia.[40] Protein requirements may exceed 80gm/day in people at risk for cachexia. Typically, 0.45 – 0.9g protein/2kg body weight is needed to prevent and manage cachexia. Omega-3 fatty acids, especially eicosapentanoic acid (EPA), at 2gm to 3gm daily is associated with weight gain and improved quality of life. Feeding (increased caloric intake) has not proven to control cachexia.

Exercise

Exercise is a critical component of a lifestyle-based support program during cancer treatment and beyond. Data collected over a median of 23 months post-diagnosis (interquartile range 18–32 months) were pooled in the After Breast Cancer Pooling Project (n = 13,302).[41] The study found that 2.5h (10 MET-hours/week) of moderate intensity physical activity per week was associated with a 27% reduction in all-cause mortality and a 25% reduction in breast cancer mortality compared with women who did not meet the physical activity guidelines (<10 MET-hours/week). In another study, women who engaged in the equivalent of at least two to three hours of brisk walking each week in the year before they were diagnosed with breast cancer were 31% less likely to die of the disease than women who were sedentary before their diagnosis [(HR) = 0.69 (95% CI, 0.45 to 1.06; P = .045)].[42] Women who increased physical activity after diagnosis had a 45% lower risk of death (HR = 0.55; 95% CI, 0.22 to 1.38) when compared with women who were inactive both before and after diagnosis. Conversely, women who decreased physical activity after diagnosis had a four-fold greater risk of death (HR = 3.95; 95% CI, 1.45 to 10.50).

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From a cohort of 184,194 adults without colorectal cancer at baseline in 1992-1993, 2,293 participants were diagnosed with invasive, non-metastatic colorectal cancer up to mid-2007.[43] The mean follow-up time from diagnosis to death or end-of-study was 6.8 years. Participants completed detailed questionnaires that included information concerning recreational physical activity and leisure time spent sitting at baseline, before their cancer diagnosis, and again after their cancer diagnosis. The highest pre-diagnosis recreational physical activity category (8.75 or more MET hours per week which was the equivalent of greater than 150 minutes/week) compared with the lowest category (3.5 MET hours per week) was associated with a 28% lower risk of all-cause mortality. The same comparison for post-diagnosis recreational physical activity resulted in a 42% reduced risk of mortality. Additionally, leisure time spent sitting 6 or more hours per day on the pre-diagnosis survey was associated with a statistically significant 36% higher risk of all-cause mortality. Post-diagnosis sitting time was associated with a statistically significant 62% higher risk of colorectal cancer–specific mortality. These studies support recommendations for recreational physical activity and the avoidance of sedentary time among people diagnosed with cancer – throughout the continuum of care.

Stress Management

A third foundational component of lifestyle-based support of people undergoing cancer treatment is stress management. Elevated and prolonged stress hormones, namely cortisol, epinephrine and norepinephrine are associated with the carcinogenic process and shortened survival. The effects of stress on survival was eloquently demonstrated in a prospective trial of 217 participants with newly diagnosed metastatic renal cell cancer, all with life expectancy of greater than 4 months, with good performance status and no major concurrent diseases.[44] All participants completed depression questionnaires, had salivary cortisol levels assessed, and provided blood sample for genomic analysis at baseline and at 4 months. The following factors were associated with decreased survival time: depression, poor quality of life, and flattened diurnal cortisol slope (with elevation of average cortisol). Genomic analyses identified up-regulation of genes involved in inflammation, immune response, and down-regulation of genes that activate programmed cell death (all $p<.0001$) as well as genes involved in cell trafficking, adhesion, oxygen transport, and hemostasis (all $p<.05$).

Based on rodent models of triple negative breast cancer, social isolation causes a heightened stress response that, in turn, increases expression of genes in adipocytes that increase glucose metabolism, lipid synthesis and leptin secretion. These metabolic changes increase the conversion of mammary carcinoma in situ to invasive carcinoma.

Mammary fat, in particular, has heightened sensitivity to stress hormones over visceral fat, making breast tissue especially vulnerable to stress.[45] While the clinical evidence for the negative effects of stress is still developing, early evidence indicates the benefit of stress management on prognosis in people being treated for cancer. Furthermore, a more robust body of data demonstrates the improvement in quality of life that people diagnosed with cancer experience after active stress management.[46-48]

Mindfulness based stress reduction (MBSR) is a particularly well-researched stress management behavior. A meta-analysis of 10 studies showed a significant improvement in psychological and physical quality of life with the practice of MBSR.[49] MBSR has been shown to reduce depression and fear of recurrence in women diagnosed with breast cancer.[50] MBSR lowers cortisol, reduces IL-6, lowers systolic blood pressure and improves NK cell activity – each one of which is correlated with higher quality of life and with better prognosis.[51]

Conclusions

There is ample evidence to support the inclusion of a lifestyle-based approach in people undergoing treatment for cancer. A plant-based diet that is high in polyphenols and has a low in high glycemic load is the foundation of such an approach. Intermittent or continuous caloric restriction may have unique benefits to the improved toleration of treatment and overall survival. Exercise is a potent strategy to increase overall and cancer-specific survival. Finally, stress management has direct impact on reducing the risk of recurrence and in optimizing the quality of daily living.

About the Author

Lise Alschuler is a naturopathic doctor with board certification in naturopathic oncology and has been practicing since 1994. She received her bachelor's degree from Brown University in medical anthropology and her doctorate of naturopathic medicine from Bastyr University, where she also completed her residency. She maintains a naturopathic oncology practice out of Naturopathic Specialists, based in Scottsdale AZ. Dr. Alschuler works as an independent consultant in the area of practitioner and consumer health education. She is the Executive Director of TAP Integrative, a nonprofit educational resource for integrative practitioners. Dr. Alschuler is the co-author of *The Definitive Guide to Cancer* and *The Definitive Guide to Thriving After Cancer*. She co-created http://www.FiveToThrivePlan.com, and co-hosts a radio show, Five To Thrive Live! on the Cancer Support Network about living more healthfully in the face of cancer. She is the current president of the Oncology Association of Naturopathic Physicians. Learn more at http://www.drlise.net.

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The Mental, Emotional and Spiritual Components of Cancer Care

Dr. Neil McKinney, ND

No matter where in the physical body cancer occurs, it makes a wound on the heart and the mind. Life changes with a diagnosis of any life-threatening disease. An existential challenge arouses primal defenses at all levels of our being.

Traditional Chinese medicine is based on the Taoist philosophy of living in harmony with Nature, including adjusting lifestyle to changing seasons or circumstances. Naturopathic medicine is based on a philosophy of living in harmony with our own nature – respecting our genetic individuality, supporting the natural processes that give us health and life, and helping a person to be true to their own way and being. Naturopathic doctors utilize the forces of nature that support healing of the mind, body and spirit. Each of these realms contributes to a cancer patient's cancer journey and survivorship.

Every patient with cancer filters their experience through their culture, spiritual beliefs, prior learning, imagination, and unique consciousness. They weave a story to evaluate possible future events, and to create meaning out of the disorder. This subjective realm has potent effects on outcomes.[1, 2]

Social roles are impacted with a diagnosis of cancer and cancer treatment related symptoms such as fatigue, hair loss, disfigurement, scarring, adhesions, congestive heart failure, infertility, dental issues and sexual dysfunction. Family ranking, gender-defined roles and household duties may be altered. Financial stress often adds to the burden. There can be worries about reoccurrence, anxiety about becoming a burden to loved ones, and nameless fears. Angst can affect social, spiritual, marital, employment, vocational and cognitive functions. Depression can follow anxiety in many people living with cancer, and also impact people living with them.

Research exploring the mental, emotional and spiritual impact on cancer care is in its infancy. This paper highlights the current findings and is designed to give the reader a sense of how broad this area really is.

> *"…not one single person has ever truly healed from cancer without undergoing a transformation and healing of their inner self."*
>
> Jeremy Geffen, MD
> *The Journey Through Cancer*

Can emotions cause cancer?

It is not fair to blame anyone for having cancer, as so many causal factors are involuntary or hidden. We most certainly do not want anyone to feel they are emotionally or spiritually incompetent. In fact, we want to focus on and explore opportunities to use emotional and spiritual strengths to heal and even cure. Every physician should inquire into and encourage patients to resolve grief, trauma, resentment, and hurt that may influence their ability to make good choices, accept help, adapt to change, comply with treatment or be well.

There is ongoing debate as to specific emotions or personality styles that contribute to cancer. LeShan,[3] Booth[4] and Thomas[5] have described a cancer-prone personality profile where there is a tendency to value and live through others, with most thoughts and activities being outwardly directed. LeShan[3] named this "Type C" behavior, and linked it not only a higher risk of developing cancer, but also a less favorable course of the disease. Patients with this cancer-prone coping style:

- rarely express anger, anxiety, hostility, fear, resentment or sadness
- inwardly experience despair, hopelessness, self-loathing, a loss of goals and dreams and reason to live
- are unassertive, appeasing, yielding and very cooperative
- tend to be overly concerned with meeting the needs of others, and do not put their own needs forward
- suffer fear of rejection, which promotes social isolation
- fear emotional relationships are dangerous and doomed
- feel they can be themselves, or be loved, but never both
- illness may be provoked by the loss of a crucial relationship (brittle object relationship)
- may feel the only way out is death.

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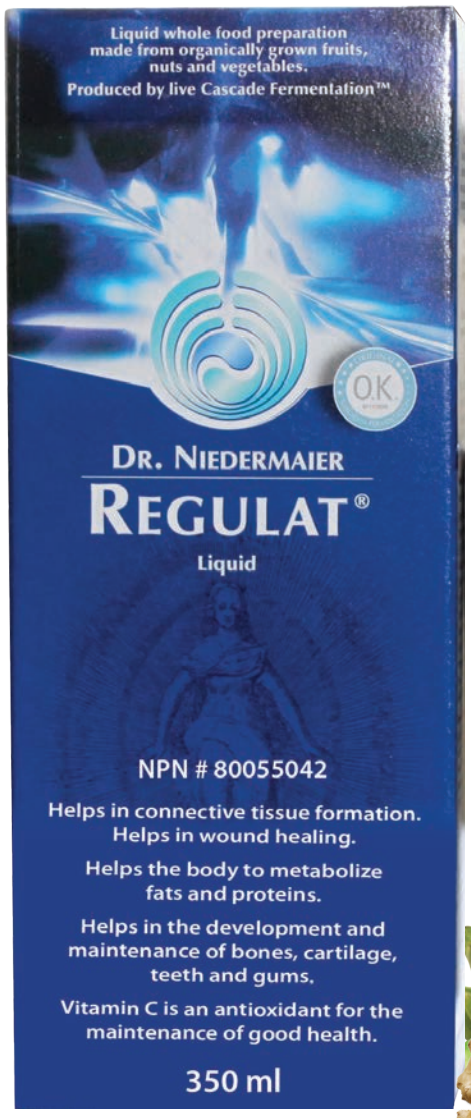

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Much of the research has focused on the emotional impact that a cancer diagnosis has on a person. Both acute and chronic psychological distress is common after a diagnosis of cancer, with mental health issues reaching fourfold that of the general population. Approximately one-third of cancer patients report significant anxiety, depression and adjustment issues arising from these new circumstances.[6] Feelings of loneliness, worthlessness, and fear are common inner conflicts in those diagnosed with cancer. A higher level of self-worth has been associated with an improved self-caring approach and the will to live. Poor outcomes have been associated with feelings of helplessness or hopelessness in response to the cancer diagnosis and perceived consequences of treatment; pro-active and self-directed patients tend to fair better.[7]

Biochemistry and Pathophysiology of Distress

There have been a number of studies that have found correlations between emotional states and specific cancers and that have been able to link the progression of cancer to stress and other psychological factors. For example, depression has been found to increase risk of breast cancer by 42%.[8] In turn, cancer often elevates levels of interleukin 6 (IL-6), triggering cognitive dysfunction and depression. IL-6 has also been linked to an increased risk of metastasis. Another pro-inflammatory cytokine which is elevated in depressed patients is tumor necrosis factor alpha TNFα. TNFα is involved in angiogenesis, immune function and apoptosis.

The stress hormone adrenaline (epinephrine) stimulates tumorigenesis. Adrenaline activates phosphorylation of kinases involved in growth signal transduction from the cell surface receptors to the nucleus. This stress hormone increases protein kinase A (PKA), which regulates sugar and fat metabolism, and BAD apoptosis regulator protein. As a result, cancer cells get more food and cannot die. Adrenaline also blunts the desired induction of apoptotic cell death by chemo and radiation therapies. Learning to relax is turning out to be a *bona fide* cancer therapy.[9, 10]

Cancer incidence, progression and mortality is linked to circadian rest/activity cycle disruption. Having a lifestyle that is out-of-sync with the circadian rhythm is associated with disturbances with the pineal gland hormone melatonin and the adrenal gland stress hormone cortisol, which in turn increases a person's risk in the following ways:

- Unmitigated stress flattens the daily diurnal peaks of the adrenal stress hormone cortisol
- Cortisol alters melatonin rhythm
- Melatonin deficit from shift-work, and melatonin antagonists increase cancer risk
- Melatonin improves survival twofold[11]

The hypothalamic pituitary adrenal (HPA) axis modulates glucocorticoid signalling. The adrenergic system can affect cancer biology by promoting tumor growth, invasion, angiogenesis, and ultimately increasing metastatic potential. Sympathetic nervous system (SNS) pathway mediates downstream effects through modulation of adrenergic signalling. Adrenergic signalling enhances glucocorticoid receptor (GR) stability and binding to DNA. In turn glucocorticoids increase the expression and affinity of beta-2 adrenergic receptors and prevent their down-regulation. Activation of the glucocorticoid receptor in estrogen-receptor (ER)-negative breast cancer cells has been shown to promote cancer cell survival and growth.

A strong adaptive immune response in patients with ovarian cancer has been linked to improved survival, but it is known to be impaired by active immune-suppression within their malignant tumors. Compared to those with benign ovarian neoplasms, epithelial ovarian cancer patients showed marked elevations in unstimulated and tumor-stimulated type-2 responses such as ascites and tumor infiltration by lymphocytes. Depressed and anxious mood were both associated with significantly altered cytokines IFN gamma and IL-4. This signifies greater impairment of adaptive immunity in peripheral blood and in the tumor microenvironment among ovarian cancer patients compared to those with benign tumors.[12] A common immune-suppressant elaborated by tumours is transitional growth factor beta-1 also called transforming growth factor or TGF. This keeps immune cells in repair mode, which supports tumour growth, and prevents them from going into attack mode against the cancer.

A person's support network has been found to be strongly correlated with survival. Those patients who lack a significant social support network are particularly vulnerable when cancer occurs. Patients who report a poor level of social well-being and support show higher pre-surgical levels of the angiogenesis cytokine VEGF. From a biochemical perspective, Norepinephrine has been found to be reduced in those who have a good social support and it has also been linked to angiogenesis.[13]

Greater forgiveness significantly correlated with better immune function, as indicated by higher CD4 cell percentages.[14]

Talk Therapy as an Effective Cancer Therapy

The rational and scientific evaluation of psychosocial interventions in cancer is in its infancy. Clearly measures which will be useful will have to have potent psychogenicity, the ability to stimulate lasting and major change in the thoughts, moods, habits and lifestyle of these cases. Ideally, the response to the threat of cancer is a realization of a need for significant change, a willingness to act, an application to self-help strategies, and achievement of quality experiences in the new modes of being.

Shock seems to be the most common reaction when a patient hears the word "cancer" from their doctor. Shocked patients may feel a range of emotions from relief to grief reactions, including denial, anger, bargaining, depression and helplessness.

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It is normal for cancer or any life-threatening disease to provoke fear of death, loss of control, pain, weakness, medicalization of one's life, social ostracism, financial loss, and so on. It is important to address these concerns, give stress-busting techniques to relieve anxiety, clarify a person's self-image and give hope. A medical oncologist once remarked that he was apparently unique among his medical colleagues in that he could say the word "hope" without putting "false" in front of it. He found hope is fantastic healing force to harness into a program, describing it as allowing one's internal pharmacy in synch with prescribed therapies.[15] A patient does not have to accept pain, abandonment, suffering or giving up being productive only because the future is uncertain. Hope is just having faith in good outcomes, and what people accept as a good outcome is usually just that they will have some dignity, some control, and be able to handle what will be.

Cancer can be a doorway to change – either out of this world or into a new lifestyle. It is natural to be wary of change. We do not always welcome the effort and losses involved in making a change. Still, it is human nature to try to see meaning, to find the lesson, to grasp that silver lining in the dark cloud. A reminder of our mortality can bring profound meaning back into the lives of patients and their families.

Lawrence LeShan was a psychologist working at the prestigious Revici cancer hospital in New York. Most of his patients there were terminal cancer cases, so he witnessed a lot of death and grief. Distraught at the relentless toll of cancer, despite his diligent care, after several years he suffered a breakdown. He took a mental health sabbatical, which resulted in completely reframing his approach He assumed that it is quite rational for patients with cancer to have anxiety and depression. They were therefore not neurotic or crazy, so he reasoned that he had no need for psychotherapies oriented to those mental illnesses. Rather than looking for psychological defects and trying to fix them, he advocated restoration of emotional and creative expression. He found people with cancer had often lost a main emotional focus in their lives, and had lost hope of finding any satisfactory substitute. He asserted that patients with cancer need to learn how to live fully - as he puts it, "love, laugh, play, learn, sing praises and exercise". He had remarkable success by helping them design a re-vitalized life providing meaning, authenticity, enthusiasm, zest and fulfillment. He has documented durable cures of "terminal" cases with this positive, existential psychology.[13] LeShan made each patient feel the great joy in being true to their own way and being.

Carl O. Simenton is another pioneer in psycho-oncology who has demonstrated clinical efficacy.[16] Circa 1969-1977, he demonstrated he could double survival time of *terminal* cases, meaning those expected to die within six months. In fact 40% were still alive at two years. Foundations of his approach are the following:

- accept responsibility, participate in your own recovery
- forego benefits and secondary gains of illness
- relaxation, visualization, inner guide
- overcoming resentment
- coping with fears of recurrence, death, pain
- goal setting
- family support system
- physical exercise

He and others have shown there is real survival value in positive affirmations, meditation, creative visualization, peer support, professional psychological facilitation, and therapy.

Louise Hay is a layperson who has popularized Simenton's approach of positive affirmations.[17] Drawing from her own recovery from cancer, she believes that positive language is powerful, and if attached to feelings of success and recovery, it can be healing. It is very easy to do, as she has demonstrated in many self-help books.

Guided imagery or self-directed visualization has also been found to be beneficial when faced with a terminal illness or major life change. If a person can imagine a bunch of worries, they are already skilled at imagery. Refocusing from fear and dread to clear goals and action steps is not just wishful thinking, it is strategic and wise.

Gabor Maté, MD, a prominent contemporary Canadian author and lecturer, has an extensive background in treating addictions, mental illness, and in palliative care. These intense experiences have given him insights into the connection between emotional and psychological stress and health. In several published works he gives importance to childhood exposure to abuse, neglect, trauma or violence as destabilizing forces on personality development. He believes that the patient who cannot say no to what they do not want is at higher risk of morbidity and mortality across the disease spectrum. His position is that if we do not know our own needs and identity, we cannot discern when to say no, to avoid being exploited or hurt. This has implications for obtaining informed consent to therapies. He has determined that we do not have to consciously perceive stress and emotionality for it to hurt us physically. He postulates that the physical body will say no, by introducing disease, when mental or emotional afflictions prevent us from being self-protective.[18]

> *"Ultimately, medicine's job is not to relieve suffering or eliminate it. Medicine's job is to relieve unnecessary suffering and to help shift our relationship to necessary suffering."*
>
> Ted Kaptchuk, OMD

Pain and suffering are highly subjective experiences, with strong inputs from the cerebral cortex. How noxious a signal is depends on how threatening we find it, cultural contexts, and many other perceptions and beliefs. Pain may be more easily borne by a patient who feels hopeful in facing a challenge, compared to another whose thoughts dwell on what is lost and what is threatened by their

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disease. Hope is not something to avoid arousing, it is essential, for the physical therapeutic value as well as for psychological well-being There is an opportunity for growth in every challenge, and it is quite necessary to look at all emotions and problems, and take the time to live through some processing. People who come to embrace and feel good about their cancer therapy tend to have far less side-effects than those who fear it and have morbid expectations. Anxiety and depression set a patient up for a poorer response and more harm from chemotherapy, such as anticipatory nausea.[19]

Distress is common among cancer patients, especially those undergoing chemotherapy. Skill in stress management is associated with lower levels of anxiety and depression and better overall mental quality of life.[20] Common de-stressing techniques include 'mind-body' techniques such as yogic belly breathing, skin temperature biofeedback, autogenic progressive relaxation, compassionate heart-focused meditation, journalling, music and art.

Cognitive Behavioural Therapy (CBT)

Cognitive behavioural therapies (CBT) are a very useful, efficacious and practical non-drug intervention in many medical conditions. Integrative oncology practitioners refer to trained grief counsellors at hospice, and to psychotherapists for hypnotherapy or CBT. A successful cognitive therapy for clinical anxiety is Time-Line Therapy. Patients are rapidly guided to revisit and reframe past experiences, but with their present maturity and dispassion. It is primarily a mental exercise, without lengthy retelling of the story, or emotive discharges. The patient, however, often releases the emotions of the event by putting it into a much larger perspective of their life, and even their gestation time and the influences of their parents or ancestors.

Cognitive-behavioral therapy is an evidence-based treatment readily adapted to address realistic concerns related to having cancer, such as worries about disease progression, disability, and death, targeting skills for relaxation, coping with cancer worries, and activity pacing. Adults with incurable malignancies and elevated anxiety who received at least five of the required six CBT sessions significantly decreased their anxiety.[21]

Dr. David Burns, MD has contributed a book[22] and work-book on mood therapy,[23] which address cognitive distortions behind pessimism. The beneficial effects of CBT appeared to be sustained for cancer patients experiencing depression.[24] Good psychotherapy opens up a person to new expression of their physical, psychological and spiritual selves. Patients who truly become engaged with their own healing take responsibility for their lifestyle, emotions, and spirit. They change the things they can, and accept what they cannot.

Hot flushes and night sweats (HFNS) affect 65-85% of women after breast cancer treatment. They are distressing, causing sleep problems and decreased quality of life. Hormone replacement therapy in the form of estrogen is often either undesirable or contraindicated. A 90 min group CBT session a week for 6 weeks, including psycho-education, paced breathing, and cognitive and behavioural strategies has been found to be safe and effective treatment for women who have problematic HFNS with additional benefits to mood, sleep, and quality of life. The treatment could be incorporated into breast cancer survivorship programmes and delivered by trained breast cancer nurses.[25]

Persistent insomnia is a common complaint in cancer survivors, but is seldom satisfactorily addressed. A protocol-driven cognitive behavior therapy (CBT) for insomnia was printed in a manual and delivered by oncology nurses to patients who had completed active therapy for breast, prostate, colorectal, or gynecological cancer. Five small group CBT weekly sessions was associated with mean reductions in wakefulness of 55 minutes per night compared with no change in treatment as usual controls. These outcomes were sustained six months after treatment. Standardized relative effect sizes were large for complaints of difficulty initiating sleep, waking from sleep during the night, and for sleep efficiency (percentage of time in bed spent asleep). CBT was associated with moderate to large effect sizes for five of seven QOL outcomes, including significant reduction in daytime fatigue.[26]

Breast cancer survivors (BCS) benefited from an "uncertainty management intervention" consisting of a scripted CD and a guide booklet, supplemented by four scripted, 20-minute weekly training calls conducted by nurses. BCSs who received the intervention reported reductions in uncertainty and significant improvements in behavioral and cognitive coping strategies to manage uncertainty, self-efficacy, and sexual dysfunction. Materials tested in CD and guide booklet format could be translated into online format for survivors to access as issues arise during increasingly lengthy survivorship periods. Materials could be downloaded to a variety of electronic devices, fitting with the information-delivery needs and management styles of younger BCSs.[27]

Mindfulness

Mindfulness is emerging as a key coping strategy. Mindfulness is a secular approach to meditation, and being aware of one's physical as well as subjective states of being. Mindfulness-Based Stress Reduction (MBSR) typically involves yoga, meditation and non-judgemental awareness of the present. The first to advance this approach as clinically efficacious was the clinical psychologist Jon Kabat-Zinn of the University of Massachusetts, who carries on his work there at the Center for Mindfulness in Medicine, Health Care and Society.

In breast cancer populations MBSR has been associated with positive experiences such as calmness, connection, awareness, acceptance, and confidence. Patients report coping better with stress, anxiety and panic; being less judgemental of themselves and others; improved communication and personal relationships, taking more time and making more space for themselves.[28] An eight-week group based MBSR intervention for women with breast cancer had clinically meaningful, statistically significant effects on depression and anxiety after 12 months' follow-up, and medium-to-large effect sizes.[29]

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A brief mindfulness-based intervention was effective for improving sexual functioning in women with gynecological cancer. Thirty-one survivors of endometrial or cervical cancer (mean age 54.0, range 31-64) who self-reported significant and distressing sexual desire and/or sexual arousal concerns were assigned either to three, 90-minute mindfulness-based cognitive behavior therapy sessions or two months of wait-list control prior to entering the treatment arm. There were no significant effects of the wait-list condition on any measure. Treatment led to significant improvements in all domains of sexual response, and a trend towards significance for reducing sexual distress.[30]

Support groups

Patients can easily become conflicted between the principles of social self-sacrifice versus the drive to seek care. Many have been raised with an aversion to selfish acts, and find it hard to navigate the boundary between being genuinely needy on account of illness, and being demanding or self-centered. It seems it helps to know that others are feeling the same things. Empathy, emotional contact and respect from peers can improve a person's self-understanding, self-acceptance and self-approval. With the will to live, to fight for life, comes restoration of emotional outlets, and inner growth, even in the face of physical catastrophe. This sets the stage for healing of anxiety, despair and disappointment. To quote Gottard Booth, "Illness is a reminder of the purpose of life."[4]

A weekly support group and self-hypnosis for pain was associated with doubling of life-span in advanced stage IV breast cancer, ovarian cancer and melanoma.[31]

Family members are often the most important source of social support for cancer patients. Long-term health-related quality of life (HRQL) study demonstrated that anger control had a positive relationship with perceived partner support. Habitual inhibition of anger showed a negative correlation with partner support. Analyses by gender revealed some clear differences. For the male patients, the wife's high level of anger expression was significantly positively related to patient mental HRQL, whereas for the female patients, their husband's anger expression was negatively correlated with the patient's mental HRQL. The anger expression styles of patients and their partners clearly modify the family atmosphere, and together are important determinants of the long-term quality of life of the cancer patients. Interventions for couples facing cancer should include a focus on mutually acceptable ways of dealing with anger and thereby support dyadic coping with cancer.[32]

Psychotherapy can be beneficial for advanced cancer patients near the end of their lives. Although psychosocial care has been regarded as central to palliative and supportive care, there have been few empirically tested approaches to individual intervention. A brief manual summarizes a new psychotherapy referred to as "Managing Cancer and Living Meaningfully" (CALM). Three to six CALM sessions based on the manual were associated with profound and unique patient-identified benefits and no patient-identified risks or concerns. A qualitative study suggested that the CALM intervention provided substantial benefits for patients with advanced cancer prior to the end of life. Five interrelated benefits of the intervention regarded by participants as unique in their cancer journey were:

- a safe place to process the experience of advanced cancer;
- permission to talk about death and dying;
- assistance in managing the illness and navigating the healthcare system;
- resolution of relational strain; and
- an opportunity to 'be seen as a whole person' within the healthcare system.[33]

Expressive therapies

The old term "placebo response" is now being called a "meaning response". People heal when they find meaning in their life. When they express their inner selves, they can remember love, speak their truth, and move into a still and sacred place where they co-create a reality where they are kind to themselves and all others. Expressive therapies such as journalling, music or art help modulate neuro-endocrine-immune parameters.

Art therapy may connect the subconscious to the outer world and reveal the inner journey. Art forms such as music, dance, drawing, painting, or any chosen medium allows some individuals to bring forward emotions and express experiences, advancing them towards resolution and integration.[34]

Spirituality

Spirituality is a dimension of life given great importance by some of our cancer patients, who seek spiritual support as a dimension of their cancer care. Because it is a life-and-death struggle to overcome cancer, for many it is seen as a spiritual process. Treating this "ghost in the machine" is not an area of expertise of most medical practitioners.

A diagnosis of a life-threatening disease can create a sense of hopelessness. Stress is lessened by reasserting personal control, taking action, rather than feeling helpless. Mortality is a fact, but how to live out a life is definitely not pre-determined.

The keys to recovery from afflictions of mind and soul have been associated with:

- the proper perception and expression of anger
- the ability to forgive
- reaching out for social support
- practicing an attitude of gratitude
- changing "I have to…" to "I get to…!"
- cultivating laughter, joy and hope.[14, 32]

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(1) Horneber et al. (2010) Mistletoe therapy in oncology (Review). Cochrane Library Issue 4.

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Before his death, Rabbi Zusya said "In the coming world, they will not ask me: 'Why were you not Moses?' They will ask me: 'Why were you not Zusya?"[35] People all have a chance to let their little light shine, every day. It appears to be a healthy practice to be content with being who and what you are. The spiritual positivist outlook is that joy, gratitude and love are healing to the spirit, whatever the circumstances of the physical body may be.

A terminal diagnosis means a person has time to prepare for their death. Resolution of conflicts and the giving and receiving of forgiveness can be seen as possible gifts.

Larry Dossey, MD has written extensively on the non-locality of consciousness and has taken on the controversial subject of prayer and faith as sources of healing. He has assembled the available evidence for personal values and beliefs as determinants of outcomes. Religious communities provide fellowship and a forum for spiritual practices and prayer, which may reduce loneliness, isolation, abandonment and many other negative experiences that impact enjoyment of life.

> *"…praying more prayers of gratitude and fewer prayers of supplication…is the proper response on realizing that the world, at heart, is more glorious, benevolent, and friendlier than we have recently supposed."*
>
> Larry Dossey, MD

Religious faith, prayers, rituals and spiritual practices are coping mechanisms that have been positively associated with better outcomes. People who believe in a higher power, and particularly those who practice their faith or religion actively, have measurably lower rates of complications, less need for medications, and tend to survive longer with more quality of life. People of faith tend to feel peace, assurance, meaning and well-being, which allows them to embrace life. Faith in an afterlife or spiritual survival does correlate with an increased fighting spirit seen in cancer survivors. They fear death less, yet fight to survive more.[36]

Many patients find religion to be an effective coping mechanism, offering them strength, comfort and hope. A study emphasized the need for including a 'religious time-out' before and after surgery and offering religious leaders/groups to ensure quality care and patient satisfaction.[37]

The Cochrane Reviews have analyzed multiple studies on intercessory prayer that treatment teams had added to health interventions; however, the reviewers could draw no conclusions about the efficacy of prayer because the studies showed either positive or no effects and used different endpoints and methodologies. An RCT had an external group offering remote Christian intercessory prayer to cancer patients. The intervention group showed significantly greater improvements over time for the primary endpoint of spiritual well-being, emotional well-being, and functional well-being.[38]

Wholistic care may come around again to the old therapy of contact with a green, natural environment. A study of integrated medicine showed benefit to cancer patients from a program of walks in the forest, growing a vegetable garden, yoga, meditation, and support group therapy. Sessions were conducted once a week for 12 weeks. There were significant differences in functional well-being and spiritual well-being. This program improved quality of life, reduced cancer-associated fatigue and increased natural killer cell activity.[39]

Reiki means "spiritual blessing". Reiki is the laying on of hands in a traditional manner, clothes on. Some pilot studies show reiki was helpful in improving well-being, relaxation, pain relief, sleep quality and reducing anxiety[40] and fatigue in cancer patients.[41]

Healing touch, therapeutic touch and reiki are 'energy therapies' which have been found to be helpful in symptom and distress reduction by integrative oncology nurses. Healing touch and therapeutic touch are now common in nursing practice, and reiki is now being used in hospices as well as clinics. These modern reinterpretations of ancient healing practices have been shown to provide relief of pain, anxiety, including bringing increased peace and comfort at the end of life. Also improvements were seen in sleep onset and duration. There were improved biophysical markers such as reduced blood pressure, improved heart rate, decreased cortisol, and increased natural killer cells.[42] As well as being calming, they can at times be transformative experiences, and evoke deep emotional processing. Body work practitioners have an expression that 'issues are in the tissues' to describe the connection between touch and the release of emotions, memories, revelations and insights.

Mind-body healing gets results

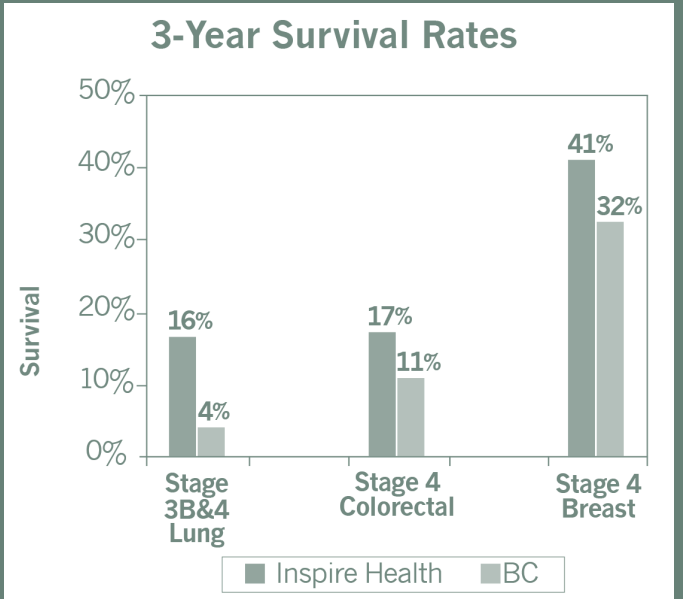
A comprehensive clinical integrative cancer treatment program combining conventional treatments with nutrition and supplementation, fitness and mind-spirit instruction as offered at the Block Center for Integrative Cancer Treatment.

Five-year survival for a consecutive case series of advanced metastatic breast cancer was 27% for the Center versus 17% for comparison patients. Despite a higher proportion of younger and relapsed patients, survival of metastatic breast cancer patients at the Center was approximately double that of comparison populations and possibly even higher compared to trials published during this period. Explanations for the advantage relative to conventional treatment alone may include the nutritional, nutraceutical, exercise and psychosocial interventions, individually or in combination.[43] A previous study incorporating similar nutritional, supplementation and mind-spirit interventions also demonstrated clinical efficacy in prostate cancer.[44]

The Urban Zen Initiative in New York City incorporated yoga therapy, holistic nursing techniques, and a "healing environment" into routine inpatient oncology care. It produced a decrease in use of anti-emetic, anxiolytic and hypnotic medications, resulting in substantial cost savings in the care of oncology patients.[45]

A CD called *Remembered Wellness* by Theresa Clarke, MD, is a very useful set of guided relaxation and visualization exercises. Dr. Clarke was Medical Director at Inspire Health clinic in Vancouver, BC, which provides stress management, mind-body healing and vegetarian diet training for patients with chronic illnesses. Inspire Health has now demonstrated these most basic wholistic interventions go beyond profound effects on quality of life for cancer patients, and actually impact overall survival, as pictured in Figure 1. On the basis of this achievement they received several millions of taxpayer's dollars to open five more clinics in British Columbia, and many millions more for further research.

FIGURE 1. Inspire Health Survival Rates Vs. BC Cancer Agency Standard of Care



Conclusion

Addressing the mental, emotional and spiritual dimension of the cancer experience have been found to greatly influence outcomes in people with cancer. Once thought of as strictly part of the palliative care process to improve quality-of-life, mind-body therapies are now emerging as essential and active therapies with significant impact on tolerance to cancer therapies and to overall cancer survival rates.

Experienced practitioners recognize that each patient brings their own set of values and beliefs to the cause of their cancer and to the ways of healing from cancer, or any disease. Some of these values and beliefs are worth nurturing, and some may benefit from intervention. Limiting beliefs from both patients and practitioners are toxins which are obstacles to cure, as surely as are heavy metals or poisonous chemicals. Assisting patients in creating a positive state of being may require elements of hope and even faith. The future will always remain a mystery, but fortunately present actions change the probabilities of what may occur.

Physicians are not usually psychotherapists, nor should they try to be ministers or gurus, but naturopathic physicians can create integrative programs and lead multidisciplinary teams dedicated to support healing at all these levels.

> *"If you don't believe in miracles, perhaps you've forgotten you are one."*
>
> Dr. Blossom Bitting, ND

About the Author

Dr. McKinney graduated in Biosciences from Simon Fraser University and moved into biophysical (radiation) cancer research. Next he studied kinesiology at the University of Waterloo and graduated as a Doctor of Naturopathic Medicine from National College of Naturopathic Medicine in 1985. He concurrently trained 3 years in TCM at the Oregon College of Oriental Medicine. He founded the BC Naturopathic Association and the Boucher Institute of Naturopathic Medicine, with many contributions to regulation, education and advancement of the profession. He is a professor and author in Naturopathic Oncology. He practices with a focus on integrative oncology in Victoria, BC.

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The Use of IV Vitamin C as an Adjunct to Chemotherapy and Radiation Therapy

Dr. Daniel Lander, ND, FABNO

Vitamin C, also known as ascorbic acid, is a water-soluble vitamin. Unlike most animals, humans cannot produce their own vitamin C and must obtain it from their diet. Within the body, vitamin C functions as a cofactor in numerous vital enzymatic reactions. Vitamin C is required for the synthesis of collagen, carnitine, and catecholamines to name but a few. It also functions as an important antioxidant, protecting cells from oxidative stress. Clinically, vitamin C can be administered both orally and intravenously.

Ewan Cameron and Linus Pauling were the first to report that high doses of vitamin C given both intravenously and orally were effective in the treatment of cancer.[1] Follow-up randomized double-blind placebo-controlled clinical trials sponsored by the U.S. National Cancer Institute showed no survival advantage when similar doses of vitamin C were given orally. This led the mainstream medical community to largely dismiss the use of vitamin C as a potential cancer treatment in the 1980s. However, we now know that the route of administration greatly affects the bioavailability of vitamin C. Tissue and plasma concentrations are tightly controlled in response to oral intake, but this can be bypassed by intravenous administration resulting in significantly higher concentrations.[2] As a result researchers have continued to investigate the role of intravenous vitamin C (IVC) in cancer treatment and it is a commonly used therapy among complementary medicine providers for the treatment of numerous conditions including cancer.[3]

Despite its widespread use, clinical research investigating the effects of IVC in patients with cancer is lacking. This is especially apparent regarding its use in combination with other standard cancer therapies. This article will review the existing research examining the safety and efficacy of IVC administered in conjunction with chemotherapy and radiation therapy.

Mechanisms of Action

While several mechanisms have been proposed, the exact mode of action explaining vitamin C's antineoplastic effects remains uncertain. Cameron and Pauling had originally hypothesized that the formation of new collagen resists the malignant infiltration of cancer cells.[4] Later Chen et al. demonstrated both *in vitro* and *in vivo* (mice) that high concentrations of vitamin C have direct cytotoxic effects on cancer cells, but not normal cells.[5-7] However, they did not find a similar effect with low concentrations. High concentrations of vitamin C appear to be selectively cytotoxic to cancer cell lines through the generation of extracellular hydrogen peroxide. However, neither the selective toxicity nor the mechanism of peroxide-mediated cytotoxicity is fully understood. Most recently Ma et al. revealed that high concentrations of vitamin C caused oxidative DNA damage and adenosine triphosphate (ATP) depletion within ovarian cancer cells. This triggered the activation of the ataxia telangiectasia mutated (ATM)/adenosine monophosphate-activated protein kinase pathway (AMPK) and the inhibition of mammalian target of rapamycin (mTOR), leading to cell death.[8]

In addition to extracellular hydrogen peroxide formation, intracellular mechanisms have also been proposed to explain vitamin C's activity. High intracellular vitamin C concentrations may inhibit hypoxia-inducible factor 1-alpha (HIF1-a) activation.[9] The overexpression of HIF1-a has been shown to promote tumor progression through a number of mechanisms, including the development of resistance to chemotherapy and radiation therapy. This may provide some theoretical basis specifically for the combined use of IVC with standard cancer therapies.

IVC combined with chemotherapy

Although human data is limited, the safety of IVC, including in those with advanced disease, has been confirmed in clinical trials.[10, 11] Additionally, when it is combined with chemotherapy, IVC also appears to be well tolerated.

Several phase I/II clinical trials have specifically studied the use of IVC administered concurrently with arsenic trioxide-based chemotherapy in patients with refractory multiple myeloma to improve the tolerability of this therapy, as detailed in the review by Fritz et al.[12] Although these studies all used a lower dose of vitamin C (1 g) and a clear benefit has been difficult to assess due to the lack of control groups, the addition of vitamin C to the chemotherapeutic regimens was well tolerated and did not appear to cause any increase in adverse effects.

Two more recent observational studies looked at the concurrent use of IVC and chemotherapy and reported improvements in quality of life and the mitigation of chemotherapy-induced adverse effects.

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Vollbracht et al. retrospectively studied a group of 125 women with early stage breast cancer undergoing standard therapy.[13] Fifty-three of these women were given 7.5 g of IVC once a week in addition to their standard therapy. These included various combinations of epirubicin, cyclophosphamide, methotrexate, fluorouracil and/or radiation therapy. It should be noted, however, that IVC was not administered on the same day as any chemotherapy or radiation therapy in this study. No side effects directly attributed to the IVC were reported. Moreover, patients in the IVC group reported significantly less nausea, loss of appetite, fatigue, depression, sleep disturbance, dizziness, and bleeding disorders and to have higher performance status scores during and after their standard therapy.

Takahashi et al. prospectively followed 60 patients diagnosed with advanced cancers who received high-dose IVC.[14] The dose was gradually escalated to achieve serum vitamin C concentrations between 350 and 400 mg/dL. Thirty-four of these patients were also undergoing standard treatment with chemotherapy. Similarly to the Vollbract et al. study, significant improvements were seen in fatigue, insomnia, pain, and constipation, as well as in overall quality of life scores as compared to baseline. However, in this study several adverse effects possibly attributable to the IVC were reported, including: headache (n=5), nausea (n=5), irritation at the site of injection (n=2), painful urination (n=1), dry mouth (n=1), and pain (n=1) at the tumor site. Nevertheless these were all considered mild (grade 1) events.

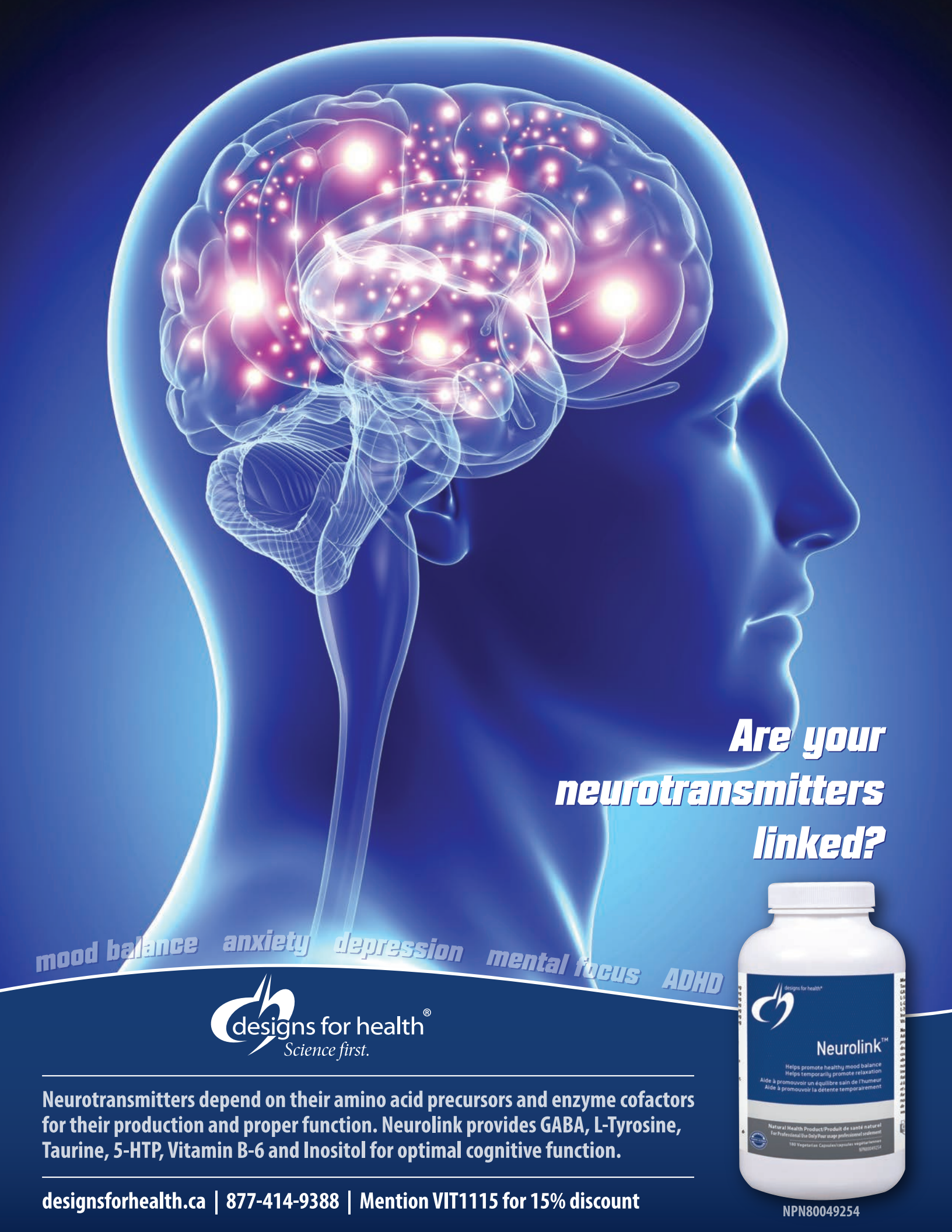
Whenever adverse effects of treatment are mitigated one must ask the question whether the desired effects of the treatment may also be inhibited. While vitamin C does not appear to affect cytochrome p450 drug metabolism,[15] most chemotherapeutics and radiation therapy exert their antineoplastic effects primarily through oxidative mechanisms. Thus concern has been raised with the concurrent use of any antioxidant with these agents.[16] However, the vast majority of preclinical evidence has shown that there is no decrease in efficacy when chemotherapeutic agents are administered in combination with vitamin C. In fact, *in vitro* and *in vivo* studies have repeatedly demonstrated that vitamin C has additive therapeutic effects with various chemotherapeutic agents including: bleomycin, cisplatin, cyclophosphamide, doxorubicin, etoposide, fluorouracil, gemcitabine, paclitaxel, and vincristine as outlined in the review by Wilson et al.[17] Nonetheless, there is also *in vitro* evidence that high concentrations of vitamin C may interfere with the cytotoxic effects of cisplatin, doxorubicin, methotrexate, vincristine, and DTIC,[18, 19] as well as the targeted agents imatinib and bortezomib.[20, 21] However, the results of one of these studies[19] have been called into question[22] as it used dehydroascorbic acid, an oxidized form of vitamin C, instead of ascorbic acid, the form of vitamin C that is used clinically. As mentioned above, while we know vitamin C is an important antioxidant in the body, it appears to also act as a pro-oxidant when present in higher concentrations, such as those attained with high-dose IVC therapy. This ability of high concentrations of vitamin C to specifically cause oxidative stress within cancer cells may help explain its ability to decrease the toxicity of chemotherapy while also increasing the effectiveness of these agents.

Regardless, there is also a growing amount of research to suggest that many antioxidants do not in fact interfere with the cytotoxicity of chemotherapy. Of note, a randomized clinical trial demonstrated that high doses of oral vitamin C, E and beta-carotene (all well-known antioxidants) did not reduce the therapeutic effects of paclitaxel and carboplatin chemotherapy.[23] In this study 136 patients with advanced non-small cell lung cancer were randomized to receive either chemotherapy alone or chemotherapy in combination with daily high oral doses of these antioxidants. There were no statistical differences in chemotherapy response rates or median or overall survival times between groups and in fact there was a trend towards improved response rates and survival times in the antioxidant arm. Toxicity profiles were also similar in both groups.

Data from clinical trials examining the effects of IVC on chemotherapy outcomes is scarce; only three small pilot studies to date have specifically looked at the effects of concurrent IVC with standard cancer care on the progression of disease. Interest in this area is increasing and all three of these studies were conducted in the last three years. Two of them examined the effect of IVC in combination with gemcitabine in patients with advanced pancreatic cancer. Monti et al. administered IVC to nine participants with newly diagnosed metastatic pancreatic cancer along with gemcitabine chemotherapy and the tyrosine kinase inhibitor erlotinib.[24] The IVC was administered in a dose-escalation design from 50 to 100 g three times per week for eight weeks. IVC was well tolerated by all participants and all serious adverse effects during the trial were attributed to progression of disease or treatment with gemcitabine or erlotinib therapy. Although progression-free survival and overall survival times were comparable to those previously reported for gemcitabine with erlotinib therapy alone, the authors suggest several reasons why their findings may have underestimated the full effect of the IVC and they recommend a larger randomized phase II follow-up study.

In a similar phase I trial Welsh et al. treated nine participants with metastatic pancreatic cancer using a combination of IVC and gemcitabine chemotherapy.[25] The dose of IVC was increased until a serum vitamin C concentration of 350 mg/dL was achieved (50 to 125 g per infusion). This dose was administered twice a week for at least four weeks until progression of disease was seen. Again, IVC was deemed a safe addition as the toxicities reported were actually less severe compared to other published trials of gemcitabine chemotherapy. Transient, mild symptoms possibly attributable to IVC included nausea (n=6), diarrhea (n=4), and dry mouth (n=4). While the authors are careful to point out that their small study was not powered to determine therapeutic efficacy, their results are striking when compared to previously published data with gemcitabine therapy alone. They reported a progression-free survival of 26 weeks and an overall survival of 12 months with the combination of gemcitabine and IVC. This is quite remarkable when compared to a progression-free survival of nine weeks and an overall survival of six months previously reported with gemcitabine therapy alone.

Most recently another clinical trial demonstrated that IVC in combination with paclitaxel and carboplatin may improve time to relapse and survival in patients with advanced ovarian cancer.[8]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Ma et al. randomized 25 participants with newly diagnosed stage III or IV ovarian cancer into two groups, to receive either standard chemotherapy with paclitaxel and carboplatin alone (n=12) or in combination with IVC (n=13). The dose was adjusted to achieve serum vitamin C concentrations between 350 and 400 mg/dL and was administered twice a week for 12 months. Participants were followed for five years. The authors reported no increase in grade 3 or 4 toxicities with the addition of IVC and furthermore grade 1 and 2 toxicities were decreased in the IVC arm. Although it did not reach statistical significance due to the small number of participants, the overall survival trended toward improvement with the addition of the IVC as did the median time to progression/relapse which was 8.75 months longer than in the standard chemotherapy group.

IVC combined with radiation therapy

Relatively few studies have focused on the effects of vitamin C on cancer cells alongside radiation therapy. The preclinical data reported, as with chemotherapy, has been conflicting though mostly positive. Koch and Biaglow demonstrated *in vivo* that a greater inhibition in growth of Erlich ascites tumor cells could be achieved using only half the dose of radiation when it was administered in the presence of vitamin C.[26] Similar findings were reported in brain cancer cell lines treated with radiation and the radiosensitizing agent fluorouracil when vitamin C was added.[27] However, a reduction in cell death from radiation has also been observed in myeloid leukemia cells treated with vitamin C.[28]

Clinical studies in this area are lacking. The only human research looking at the combination of radiation therapy and IVC is the observational study by Vollbracht et al. described above.[13]

Conclusion

Large randomized clinical trials examining the use of IVC in conjunction with standard cancer therapies are lacking, especially with radiation therapy, making it difficult to definitively assess the safety and the efficacy of this combination of therapies. However, based on the preliminary information available, IVC appears to be safe with certain chemotherapeutic agents and is unlikely to increase the toxicity, and may even decrease some of the adverse effects associated with these therapies. In addition to the potential for IVC to have synergistic effects with various chemotherapeutics, it may also contribute to improved outcomes by allowing patients to tolerate higher, and potentially more effective, doses of chemotherapy. Unfortunately clinical trials to date have been too small to provide statistically meaningful data on the efficacy of IVC in improving outcomes of standard chemotherapy regimens and larger studies are needed to confirm this plausible hypothesis.

In the meantime IVC continues to be a popular therapy provided by complementary medicine practitioners in the treatment of cancer. It has been suggested that administering natural health products five half-lives away from chemotherapy would help minimize the risk of direct interactions since this is the time required for a substance to be eliminated from the body.[29] The half-life of vitamin C itself is quite short; approximately two hours in patients with advanced cancer.[11] However, many chemotherapeutics have much longer half-lives and depending on the frequency of dosing may restrict the concurrent use of IVC. While this dosing schedule would help to avoid potential adverse interactions it would also prevent the benefit of potential chemosensitizing effects of IVC. Nevertheless, until we have more information this appears to be the safest strategy for patients. Because of the lack of clinical trials looking at the effects of IVC and radiation, and the fact that radiation therapy is generally administered five days per week, IVC would be difficult to schedule in such a way to prevent interactions and should therefore be delayed until after radiation therapy is complete.

Perhaps most importantly, this review should highlight the need for continued research into this emerging therapy. The first three clinical studies looking at the concurrent use of high-dose IVC and chemotherapy have only been published in the last three years and all have called for follow-up studies. There are five clinical trials using a combination of IVC and chemotherapy currently recruiting participants listed on the ClinicalTrials.gov website.[30] Naturopathic doctors who treat patients with cancer will need to stay abreast of the newly developing research into IVC as it evolves over the coming years.

About the Author

As a fellow of the American Board of Naturopathic Oncology (FABNO), **Daniel Lander** is one of only a handful of naturopathic doctors in Canada who are board certified in naturopathic oncology. His clinical training included a residency at the Cancer Treatment Centers of America. He is currently an associate professor at the Canadian College of Naturopathic Medicine teaching oncology and clinical nutrition, as well as supervising fourth-year interns in the Adjunctive Cancer Care Shift at the Robert Schad Naturopathic Clinic. He also maintains a small private practice in Toronto where he focuses in integrative oncology, supporting patients with cancer during and after their conventional care.

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Natural Health Products Commonly Used in Cancer Management

Dr. Mark Fontes, ND, **Dr. Kimberley Ramberan,** ND

Naturopathic oncology is the application of the art and science of naturopathic medicine in the field of cancer care and treatment.[1] Given the complexity of cancer and the potential limitations of treatment, it is understood that no single therapy is sufficient to treat a patient with cancer.[2] The evolving practice of naturopathic oncology should be incorporated into the integrative model of patient-centered cancer care.

The goals of naturopathic oncology are to improve overall survival, minimize the side effects of chemotherapy and radiation therapy safely and effectively, and improve quality of life for patients living with cancer. Naturopathic oncology is a vital component of a comprehensive, whole-person approach to cancer care that spans from prevention through treatment and into survivorship.[1]

In order to achieve these goals, naturopathic oncology focuses on specific dietary interventions, lifestyle changes, exercise recommendations, nutritional supplementation and addressing the mental-emotional impact of the process.

This article focuses on the clinical application, efficacy, and safety of key nutritional and botanical supplements that have been found to be effective in the treatment and management of patients living with cancer. This paper will discuss *Astragalus membranaceus* (astragalus), *Curcuma longa* (turmeric), EGCG, fish oil, melatonin, modified citrus pectin, medicinal mushrooms, and vitamin D.

Astragalus (*Astragalus membranaceus*)

The dried root of the herb *Astragalus membranaceus* (astragalus) is a widely used agent in herbal medicine. The use of astragalus in cancer care came about due to its historical reputation as an immune-modulating agent. Studies have identified that the immune-modulating effects are mostly from the polysaccharide (astragalan) component of the dried root.[3] Although human trials are currently limited, *in vivo* and *in vitro* studies are showing promising results that correlate with clinical findings; in particular, improvements in increasing white blood cell counts.

Astragalus has been found to produce profound immunological effects by stimulating macrophage and NK cell activity.[4] Human studies have demonstrated that when given with chemotherapy, Astragalus improves overall survival, and stabilizes or improves Karnofsky performance status (a quality of life assessment).[5] It also has been shown to protect white blood cells counts during chemotherapy with cyclophosphamide, platinum agents, and other myelosuppressive chemotherapies.[6]

Dosage: 2000 mg qd cc.

Safety: Avoid in acute infections and use with caution with immunosuppressive medications and in patients with autoimmune disease.[4]

Turmeric (*Curcuma longa*)

Curcumin is a polyphenolic derivative extracted from turmeric (*Curcuma longa*) root. It has been used traditionally for centuries in medicine for a variety of ailments, and in particular inflammatory conditions.[7] Curcumin has been shown to exhibit a variety of pharmacological effects in cancer cells by inhibiting enzymes generating reactive oxygen species and inflammatory lipids (e.g., COX, LOX), pro-inflammatory transcription factors (e.g., NF-κβ, STAT3) and kinases (e.g., PKC, EGFR tyrosine kinase). Through these mechanisms, curcumin may provide a direct anti-cancer effect and substantially alleviate the side effects associated with chemotherapy and radiation therapy.[8] Curcumin has been widely studied as an adjunctive treatment with several cancers including colorectal, hepatocellular, kidney, gastric, lung, ovarian and hematological malignancies.[8] For a list of additional studies on curcumin refer to Table 1.

A significant problem to curcumin's therapeutic effect is its poor oral bioavailability. Several studies have looked at different formulations in order to improve absorption and utilization of curcumin. Further research is required in order to ascertain which type of curcumin preparation is the most appropriate to use in cancer care.

Overall safety of curcumin in combination with chemotherapy and radiation therapy has been studied. A randomized controlled trial of 30 breast cancer patients undergoing radiation therapy took 2 grams of curcumin three times per day. At the end of treatment, the group treated with curcumin had fewer side effects, including less severe radiation dermatitis.[9] Curcumin has been demonstrated to be safe in patients receiving various chemotherapy agents including gemcitabine, erlotinib, doxorubicin, 5-FU, paclitaxel, cisplatin, oxaliplatin, and docetaxel.[7,10]

Dosage: 2,000 mg to 6,000 mg *Curcuma longa* qd cc.

Safety: Evidence from *in vitro* and *in vivo* studies suggests curcumin

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may interact with drugs that are substrates of P-glycoprotein or cytochrome P450 enzymes[11]. Curcumin should only be used under the supervision of a practitioner trained in naturopathic oncology by patients receiving chemotherapy, as there are some chemotherapeutics with which curcumin is contraindicated.

TABLE 1. Selected Research Studies on Turmeric

Study	Cancer or cell type	Results
Yin 2014. In vivo.[12]	Ovarian cancer	Induces apoptosis in dose-dependent manner.
Carroll 2011. Phase II trial.[13]	Colorectal cancer	Prevents colorectal neoplasia.
Dhillon 2008. Phase II trial.[14]	Pancreatic cancer	Reductions in inflammatory markers.

Epigallocatechin-3-gallate *(EGCG)*

EGCG is the major polyphenol with pharmacological activity found in green tea (*Camellia sinensis*) leaf.[15] Studies have demonstrated anti-carcinogenic and anti-mutagenic activities, which suggest that it can reduce tumour progression, and provide preventative effects.

The cancer preventative effects of EGCG are supported by results from epidemiological, *in vitro*, animal and clinical studies. Multiple studies have demonstrated that treatment with EGCG inhibits tumour incidence in different organ sites such as skin (UV radiation and chemically induced), lung, liver, breast, prostate, stomach, mammary gland and colon based on preclinical, observational, and clinical trial data.[16] EGCG functions as a powerful anti-oxidant and can suppress inflammatory processes that lead to transformation, hyper-proliferation, and the initiation of carcinogenesis.[17]

In vitro, EGCG has shown to cause growth inhibition, apoptosis and cell cycle arrest in various human cancer cell lines including leukemia, melanoma, breast cancer, lung cancer, and colorectal cancer.[15] The ability of EGCG to inhibit angiogenesis, initiate apoptosis in cancer cells and suppress oncogenic transcription factors has also been proven by research.[18] EGCG promotes cytotoxic T-cell activities in a tumour microenvironment, thereby improving the immune status in a patient undergoing treatment.[19] For a list of additional studies on EGCG refer to Table 2.

EGCG is currently being researched *in vivo* for its synergistic effects with chemotherapy.[20] The combination of EGCG and doxorubicin has been shown to facilitate anti-tumour effects in hepatocellular carcinoma and metastatic prostate cancer.[21,22]

Dosage: 1000-1500mg qd cc of 95% polyphenol extract.[23]

Safety: May cause nausea and GI upset if not taken with food.[24] *In vitro* and *in vivo* evidence suggests EGCG may interact with drugs that are substrates of cytochrome P450 enzymes.[25] EGCG should only be used under the supervision of a practitioner trained in naturopathic oncology by patients receiving chemotherapy, as there are some chemotherapeutics where it is contraindicated.

TABLE 2. Selected Research Studies on EGCG

Study	Cancer or cell type	Results
D'Arena 2013. Clinical trial.[26]	Chronic lymphocytic leukemia	EGCG controlled lymphocytosis and prevented disease progression.
Seely 2005. Meta-analysis.[27]	Breast cancer	Five or more cups of green tea daily demonstrates a trend towards prevention of breast cancer.

Fish Oil (Omega-3 Fatty Acids)

Dietary fish oil has been shown to have beneficial effects in several chronic degenerative and inflammatory diseases such as cardiovascular disease, diabetes and cancer. These beneficial effects appear to be due to the high content of the omega-3 polyunsaturated fatty acids, docosahexanoic acid (DHA) and eicosapentanoic acid (EPA). Neither can be synthesized by mammals and must be obtained from dietary sources.

Researchers have established the capability of omega-3 fatty acids to influence cancer cell proliferation and differentiation, while reducing inflammation and chemotherapy related side effects. DHA in particular has been shown to improve tumour cell cytotoxicity and to inhibit angiogenesis and metastasis. The majority of current literature supports the use of omega-3 fatty acids for the prevention and treatment of breast cancer, colorectal cancer and prostate cancer.[28]

Human studies have demonstrated that at doses over two grams of combined EPA and DHA per day, fish oil can prevent loss of muscle mass and decrease overall weight loss.[29] In non-small cell lung cancer patients who were supplemented with EPA and DHA, CRP and IL-6 levels decreased over the course of two months, supporting the anti-inflammatory mechanism of action of fish oil.[30] Other trials have demonstrated similar findings,[31] including the ability of fish oil supplementation to reduce cachexia and improve albumin levels.[32] These findings are significant as inflammation is a critical component of tumour progression, in that it fosters proliferation, survival and migration of cancer cells.[33] For a list of additional studies on fish oil refer to Table 3.

Dosage: 2,000 + mg combined EPA and DHA qd cc.

Safety and drug interactions: Omega-3 fatty acids are thought to have anticoagulant effects and impair bleeding time. However, studies have shown they do not affect platelet function after surgery.[34] Some patients may experience belching, nausea and diarrhea, although studies show these adverse effects are reported with low incidence.[32]

TABLE 3. Selected Research Studies on Fish Oil

Study	Cancer or cell type	Results
Kim 2009. Case-control study.[35]	Breast cancer	High consumption of fatty fish is associated with a reduced risk of breast cancer, especially postmenopausal breast cancer.
Hutchins-Wiese 2014. RCT.[36]	Postmenopausal breast cancer survivors	At 4g of EPA and DHA per day for 3 months, reduces bone resorption associated with aromatase inhibitor use.
Singh 2014. Review.[37]	Hepatocellular carcinoma	May be associated with reduced risk of hepatocellular carcinoma
Yeh 2013. RCT.[38]	Head and neck cancer	Improved body weight and serum albumin levels in patients with cachexia.

Melatonin

Melatonin is a pleiotropic hormone that was initially believed to be synthesized solely in the pineal gland, however, it has been recently recognized that it has multiple actions and is produced in a variety of tissues, including locally in the GI tract.[39] Melatonin is a natural oncostatic agent that has been researched for its diverse and profound effects in a cancer care setting, including: inflammation, apoptosis, angiogenesis, immune stimulation, reduction in treatment related side-effects, and improvements in tolerance to chemotherapy and radiation therapy. Additionally, melatonin has evidence to suggest it improves overall survival and progression free survival in patients with cancer.[40]

Melatonin has been studied in conjunction with radiation therapy and a variety of chemotherapeutic agents, including anthracylines, anti-estrogens and antiaromatases,[41] etoposide, cisplatin, gemcitabine, oxalipatin, and 5-Fluorouracil.[40] Melatonin may improve treatment response and decrease side effects including thrombocytopenia, neurotoxicity and fatigue.[42, 43]

Melatonin has been shown to significantly modulate the effects of chemotherapy by enhancing its therapeutic effect and reducing its toxicity. This effect is believed to be due in part to melatonin's antioxidant effect and prevention of chemo-induced lymphocytic damage.[44] Lissoni *et al.* assessed the 5-year survival results in 100 metastatic non-small cell lung cancer patients undergoing cisplatin and etoposide, with or without melatonin (20mg qd hs). Overall tumour regression rate and 5-year survival results were higher in patients concomitantly treated with melatonin.[45]

In a systematic review and meta-analysis of randomized trials, melatonin was assessed in conjunction with chemotherapy, radiotherapy, supportive care and in a palliative care setting. 1-year survival, complete response (CR), partial response (PR), stable disease (SD) and chemotherapy-associated toxicities were all assessed. Pooled relative risk for 1-year mortality was 0.63. Improved effect was found for CR, PR, and SD. Melatonin also significantly reduced asthenia, leukopenia, nausea and vomiting, hypotension and thrombocytopenia.[43] For a list of additional studies on melatonin refer to Table 4.

Dosage: 20mg qd hs.

Safety: Melatonin may cause drowsiness, altered sleep patterns and vivid dreams, although these side effects are reported with a low incidence.[45]

TABLE 4. Selected Research Studies on Melatonin

Study	Cancer or cell type	Results
Schernhammer 2012. Clinical trial.[46]	Breast cancer	Melatonin was well-tolerated without any grade 3/4 toxicity.
Lissoni 2007. RCT.[47]	Advanced solid cancers (non-small cell lung cancer, colorectal cancer, gastric cancer)	2-year study survival rate was significantly higher in patients concomitantly treated with melatonin (20mg qd orally).
Persson 2005. RCT.[48]	Advanced gastrointestinal cancer	Melatonin provided a weight stabilizing effect.
Yan 2002. Prospective study.[49]	Hepatocellular carcinoma	Melatonin protected liver function and improved the effect of transcatheter arterial chemoembolization.

Modified Citrus Pectin (MCP)

MCP is a complex polysaccharide that is the water soluble component of plant fiber derived from citrus fruit and modified by means of high pH and temperature treatment.[50] It is used in naturopathic oncology in order to decrease risk of metastasis and induce cancer cell apoptosis.

A significant mechanism of action of MCP is antagonizing the binding protein, Galectin-3 (Gal-3). Gal-3 is a carbohydrate-binding

protein that is involved in many physiological and pathological processes, such as cell growth and differentiation, cell-cell and cell-extracellular matrix adhesions, metastasis, and regulation of apoptosis.[51] Gal-3 has also been shown to enhance tumour cell sensitivity to chemotherapy through the regulation of apoptotic responses to cytotoxic drugs.[52] Gal-3 is expressed in a variety of cancers, including bladder,[53] breast,[54] colorectal,[55] and thyroid[56] cancers. By inhibiting Gal-3, MCP is able to exhibit beneficial anti-adhesive properties and increases apoptotic responses of tumour cells to chemotherapy.

Dosage: The typical adult dosage for the powder is 5g tid, mixed with water or juice. For capsules, the suggested dose is 800mg tid cc.

Safety: May cause mild abdominal cramps and diarrhea, which resolve after stopping MCP.[57]

Medicinal Mushrooms

Mushrooms have an established history of use in traditional Chinese medicine especially in the treatment of cancer, which has led to investigative research into their anti-tumour properties.

Currently there are over 700 published studies demonstrating anti-cancer (cytotoxic and immune enhancing) properties of medicinal mushrooms with large scale clinical trials of *Trametes versicolor* and *Lentinus edodes*, and on a smaller scale, *Grifola frondosa*, *Ganoderma lucidum* and *Agaricus brasiliensis*.[58] Mushrooms contain a diverse variety of compounds with physiological activity. Most clinical trials have studied the polysaccharide portions of the mushrooms (beta-glucans, proteoglycans, and related compounds).[59] Polysaccharides are long-chain polymers of glucose found in the cell walls of fungi. They are minimally orally available in the raw biomass form. It is important to note that hot water extraction is a necessary processing step in making these polysaccharides bioavailable. The level of anti-cancer activity appears to be related to the degree of branching of the polysaccharides and their solubility in water.[58]

Mushrooms have been most thoroughly studied in gastrointestinal cancers (esophageal, gastric, colorectal), hepatocellular carcinomas and breast cancer. However, it is clear that mushrooms have additional benefits through their biological activity in improving immunological parameters, such as white blood cell counts and platelets, in patients with cancer undergoing chemotherapy and/or radiotherapy.

Agaricus has immunological effects on the complement and innate immune systems, which could potentially lead to pro-apoptotic and anti-angiogenic effects.[60] *Coriolus* contains two polysaccharides, Polysaccharide peptide (PSP) and Polysaccharide-K (PSK), that improve overall survival rates in patients with multiple cancers, including gastric, colorectal, and breast carcinomas.[61] *Grifolia* stimulates the function of various immune cells and may improve overall quality of life, reduce tumour burden and act synergistically with chemotherapy, especially in patients with hepatocellular, breast and lung cancer.[62] *Ganoderma* may reduce tumour burden and stimulate immunity in various cancer types.[63] For a list of additional studies on medicinal mushrooms refer to Table 5.

Dosage: Therapeutic dose varies depending on which species of mushroom is used. 3-6 grams qd in divided doses is generally recommended.

Safety: Caution with patients diagnosed with an autoimmune condition, and/or using immunosuppressive medications.[58]

TABLE 5. Selected Research Studies on Medicinal Mushrooms

Study	Cancer or cell type	Results
Tanaka 2012. RCT.[64] Mushroom: *Coriolus*	Gastric cancer	In patients with early tumour recurrence, overall survival was significantly better in the PSK group. In patients with lymph node metastasis, median overall survival was better in the PSK group compared with the control group.
Shibata 2011. RCT.[65] Mushroom: *Coriolus*	Metastatic colorectal cancer	PSK + FOLFOX chemotherapy resulted in lower frequencies of adverse effects (nausea, peripheral neuropathy, neutropenia).
Oka 2010. RCT.[66] Mushroom: *Ganoderma*	Colorectal adenomas	Inhibits development of precancerous colorectal adenomas vs. control.
Kodama 2003. Human trial.[67] Mushroom: *Maitake*	Colorectal adenomas	D-Fraction modestly increased CD4+ and CD8+ cell numbers, and significantly increased NK cell numbers after administration

Vitamin D

Vitamin D, a sterol nutrient, is unique in that it can be obtained either from the diet or endogenous synthesis. Vitamin D undergoes hydroxylation reactions mostly in the liver, to form 25-hydroxyvitamin D (25(OH)D), and then in the kidney where 25(OH)D is converted to 1,25-dihydroxyvitamin D ($1,25(OH)_2D$).[68] The most commonly measured vitamin D metabolite is serum 25(OH)D due to its longer half-life and higher serum levels compared with the $1,25(OH)_2D$ metabolite. Studies have demonstrated that low 25(OH)D levels are associated with an increase in all-cause mortality, cardiovascular mortality, and cancer-related mortality (particularly in patients with a history of cancer).[69] It has been projected that raising serum 25(OH)D levels to 100-150nmol/L would prevent approximately 58,000 new cases of breast cancer and 49,000 new cases of colorectal cancer each year in North America.[70] This is significant because 32% of Canadians are estimated to have vitamin D levels below 50 nmol/L.[71]

	Serum 25(OH)D
Deficient	< 25nmol/L
Insufficient	25-75nmol/L
Optimal	75-250nmol/L

The anti-cancer effects of vitamin D result from its role as a nuclear transcription factor that regulates cell growth, differentiation, apoptosis and a wide range of cellular mechanisms central to the development of cancer. 25(OH)D levels have been found to be associated with a reduction in occurrence of aggressive prostate cancer,[72] breast cancer,[73] lymphoma[74] and colorectal cancer.[75] Improved survival has also been reported for early stage non-small cell lung cancer patients,[76,77] likely due in part to the effect of vitamin D on anti-inflammatory processes in the lung.[78] Preliminary data has demonstrated an anti-proliferative effect of vitamin D on hepatocellular carcinoma cell lines.[79] Evidence is currently limited and inconclusive for esophageal cancer, gastric cancer, and pancreatic cancer. Although studies have focused on the ability of vitamin D to prevent cancer, studies suggest that the effects of vitamin D may be more significant for cancer mortality than for incidence.[80] For a list of additional studies on vitamin D, refer to Table 6.

Further study is required to ascertain the precise benefit regarding vitamin D supplementation in cancer. In particular, the dose and serum levels required to impact outcomes like incidence, prognosis, quality of life and immunological parameters in patients with cancer.

Dosage: 1,000 + IU qd cc depending on 25(OH)D serum levels.

Safety: Close monitoring of vitamin D levels advised in patients with kidney disease, high blood calcium levels, liver disease, or other diseases associated with impaired calcium metabolism. Although rare, case studies of acute toxicity resulting in hypercalcemia have been reported.[81] Discontinue vitamin D immediately until levels return to normal range and symptoms resolve.

TABLE 6. Selected Research Studies on Vitamin D

Study	Cancer or cell type	Results
Maalmi 2014. Meta-analysis.[82]	Colorectal and breast cancer	Higher 25(OH)D levels (>75nmol/L) associated with significantly reduced mortality.
Mohr 2014. Meta-analysis.[83]	Breast cancer	Higher 25(OH)D levels associated with lower mortality. Target levels should be at least 80nmol/L.
Zeicher 2014. Retrospective.[83]	HER2+ non-meta static breast cancer	Improved disease free survival.
Li 2014. Meta-analysis.[84]	Colorectal cancer, breast cancer, lymphoma.	Improved overall survival in patients with higher circulating 25(OH)D levels at or near the time of diagnosis.

Conclusion

The art and science of naturopathic oncology strives to use the best of current available evidence and clinical experience to provide safe, comprehensive and efficacious strategies for patients living with cancer. Studies have demonstrated that over 80% of patients diagnosed with cancer report using vitamin or mineral supplementation.[85] It is imperative that these recommendations are made by a licensed naturopathic doctor in order to provide proper patient care and avoid any interactions with conventional treatment. An integrative patient-centered approach involves the incorporation of naturopathic medicine modalities with conventional therapies. As healthcare professionals providing patient centered healthcare, naturopathic doctors and medical doctors working together will provide patients with the best care and outcome. The field of naturopathic oncology continues to evolve in its awareness among the medical community, research groups and among patients seeking integrative care. Clinical evidence and studies demonstrate that naturopathic treatments can provide significant and profound improvements in quality of life, treatment tolerance and overall prognosis for patients living with cancer.

About the Authors

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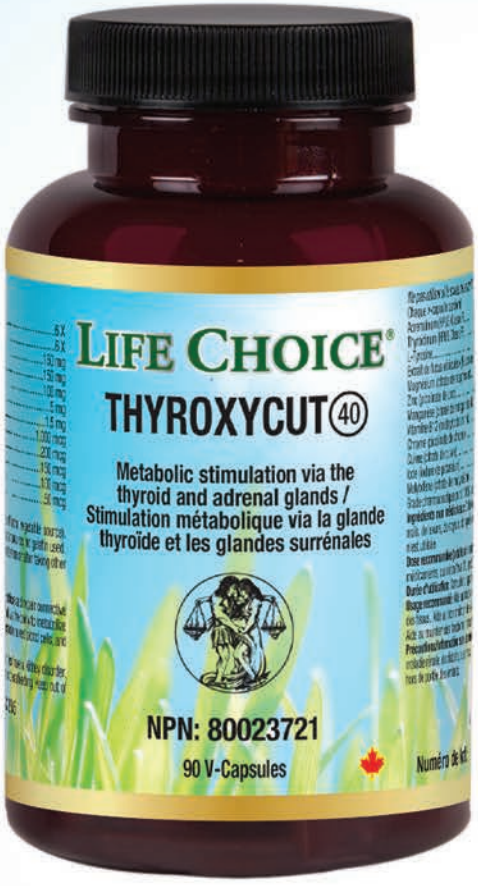

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