STOP FIGHTING CANCER

From the author of
"Help, My Body Is Killing Me" Solving the Connections of Autoimmune Disease.

& START TREATING the CAUSE

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Section 2

From 2015 Updated Edition

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Fellowship in Integrative Cancer Therapy
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Cancer is…

A SYMPTOM,

An Expression of Dis-ease,

An Outcome,

An End Product,

An Effect,

A Survival Instinct,

An Autoimmune Disorder,

A Compensation

A Warning Sign

A Wake-up CALL

It's time to wake up and change your life!

The Emperor Has NO Clothes

“Truth is generally the best vindication against slander.”

Abraham Lincoln

“Once upon a time there lived a vain Emperor whose only worry in life was to dress in elegant clothes. He changed clothes almost every hour and loved to show them off to his people.

Word of the Emperor's refined habits spread over his kingdom and beyond. Two scoundrels who had heard of the Emperor's vanity decided to take advantage of it. They introduced themselves at the gates of the palace with a scheme in mind.

"We are two very good tailors and after many years of research we have invented an extraordinary method to weave a cloth so light and fine that it looks invisible. As a matter of fact it is invisible to anyone who is too stupid and incompetent to appreciate its quality."

The chief of the guards heard the scoundrel's strange story and sent for the court chamberlain. The chamberlain notified the prime minister, who ran to the Emperor and disclosed the incredible news. The Emperor's curiosity got the better of him and he decided to see the two scoundrels.

"Besides being invisible, your Highness, this cloth will be woven in colors and patterns created especially for you." The emperor gave the two men a bag of gold coins in exchange for their promise to begin working on the fabric immediately.

"Just tell us what you need to get started and we'll give it to you." The two scoundrels asked for a loom, silk, gold thread and then pretended to begin working. The Emperor thought he had spent his money quite well: in addition to getting a new extraordinary suit, he would discover which of his subjects were ignorant and incompetent. A few days later, he called the old and wise prime minister, who was considered by everyone as a man with common sense.

"Go and see how the work is proceeding," the Emperor told him, "and come back to let me know."

The prime minister was welcomed by the two scoundrels.

"We're almost finished, but we need a lot more gold thread. Here, Excellency! Admire the colors, feel the softness!" The old man bent over the loom and tried to see the fabric that was not there. He felt cold sweat on his forehead.

"I can't see anything," he thought. "If I see nothing, that means I'm stupid! Or, worse, incompetent!" If the prime minister admitted that he didn't see anything, he would be discharged from his office.

"What a marvelous fabric, he said then. "I'll certainly tell the Emperor." The two scoundrels rubbed their hands gleefully. They had almost made it. More thread was requested to finish the work.

Finally, the Emperor received the announcement that the two tailors had come to take all the measurements needed to sew his new suit.

"Come in," the Emperor ordered. Even as they bowed, the two scoundrels pretended to be holding large roll of fabric.

"Here it is your Highness, the result of our labour," the scoundrels said. "We have worked night and day but, at last, the most beautiful fabric in the world is ready for you. Look at the colors and feel how fine it is." Of course the Emperor did not see any colors and could not feel any cloth between his fingers. He panicked and felt like fainting. But luckily the throne was right behind him and he sat down. But when he realized that no one could know that he did not see the fabric, he felt better. Nobody could find out he was stupid and incompetent. And the Emperor didn't know that everybody else around him thought and did the very same thing.

The farce continued as the two scoundrels had foreseen it. Once they had taken the measurements, the two began cutting the air with scissors while sewing with their needles an invisible cloth.

"Your Highness, you'll have to take off your clothes to try on your new ones." The two scoundrels draped the new clothes on him and then held up a mirror. The Emperor was embarrassed but since none of his bystanders were, he felt relieved.

"Yes, this is a beautiful suit and it looks very good on me," the Emperor said trying to look comfortable. "You've done a fine job."

"Your Majesty," the prime minister said, "we have a request for you. The people have found out about this extraordinary fabric and they are anxious to see you in your new suit." The Emperor was doubtful showing himself naked to the people, but then he abandoned his fears. After all, no one would know about it except the ignorant and the incompetent.

"All right," he said. "I will grant the people this privilege." He summoned his carriage and the ceremonial parade was formed. A group of dignitaries walked at the very front of the procession and anxiously scrutinized the faces of the people in the street. All the people had gathered in the main square, pushing and shoving to get a better look. An applause welcomed the regal procession. Everyone wanted to know how stupid or incompetent his or her neighbor was but, as the Emperor passed, a strange murmur rose from the crowd.

Everyone said, loud enough for the others to hear: "Look at the Emperor's new clothes. They're beautiful!"

"What a marvelous train!"

"And the colors! The colors of that beautiful fabric! I have never seen anything like it in my life!" They all tried to conceal their disappointment at not being able to see the clothes, and since nobody was willing to admit his own stupidity and incompetence, they all behaved as the two scoundrels had predicted.

A child, however, who had no important job and could only see things as his eyes showed them to him, went up to the carriage.

"The Emperor is naked," he said.

"Fool!" his father reprimanded, running after him. "Don't talk nonsense!" He grabbed his child and took him away. But the boy's remark, which had been heard by the bystanders, was repeated over and over again until everyone cried:

"The boy is right! The Emperor is naked! It's true!"

The Emperor realized that the people were right but could not admit to that. He though it better to continue the procession under the illusion that anyone who couldn't see his clothes was either stupid or incompetent. And he stood stiffly on his carriage, while behind him a page held his imaginary mantle."

Hans Christian Anderson

Publication Bias?

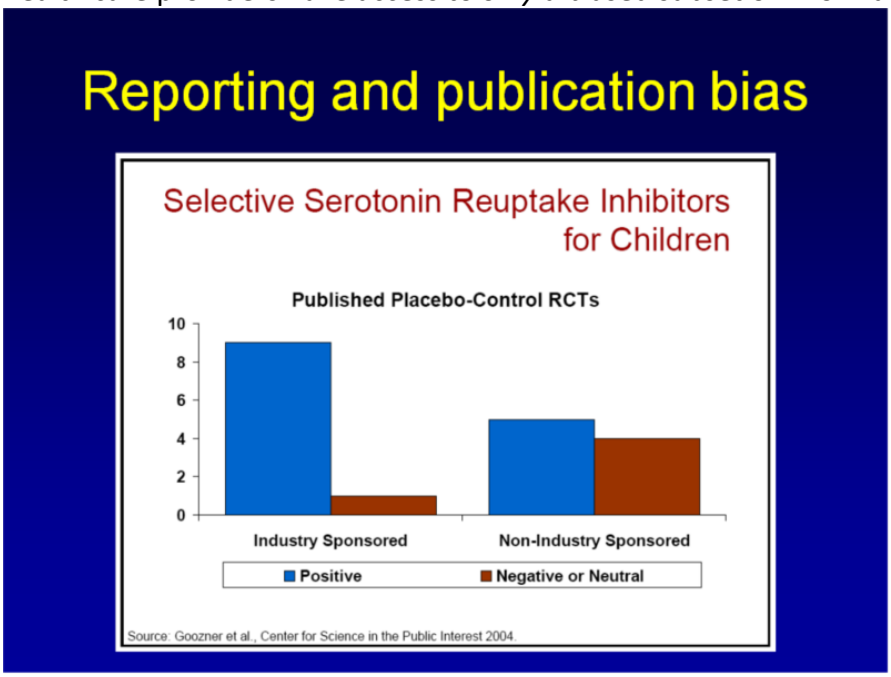
How do you know who and what to trust? Research is supposed to give us hard evidence on what works and medical research is supposed to be the basis of what we call 'evidence-based medicine'. But what happens when the research is biased? Peer-reviewed randomized trials are to provide guidance for how medicine is practiced. Doctors trust in their published results and form protocols based upon proven success. However, trust has been eroded in recent years due to the exposure in several high-profile cases of alleged data suppression, misrepresentation, and manipulation [1–5, 39].

While most publicized cases have involved pharmaceutical drug trials, it is scary to reveal that Grandma's medicine received FDA's approval due to a positive outcome in 22 trials yet the 37

that showed negative results were never published [6]. This is like a basketball coach with a record of 3-8 declaring success for a winning season because the losses were never recorded. If we only publish the results of studies that 'prove' our bias, is it really research? These examples highlight the harmful potential impact of biased reporting on patient care, and the violation of ethical responsibilities of researchers and those who fund it.

Biased reporting arises when two main decisions are made based on the significance of the data—whether to publish the trial at all, and if so, what data to report in the publication. Strong evidence for the selective publication of research trials has been available for decades but more recent cohort studies identified major discrepancies—favorable results were often highlighted while unfavorable data were suppressed; definitions of primary outcomes were changed; and methods of statistical analysis were modified without explanation in the journal article. [7-20]. In a new study published in *PLoS Medicine*, Lisa Bero and colleagues revealed that, "a substantial amount of primary outcome data submitted to the FDA was found to be missing from the literature (of new drug trials). One quarter of trials in their sample were unpublished—predominantly those with unfavorable results. Not only were data suppressed for the unpublished trials, but an additional quarter of primary outcomes were omitted from journal articles of published trials. These findings are consistent with two recent reviews of FDA documents and journal articles, one of which was published in *PLoS Medicine* in September 2008."

It's not that anyone is saying that research is falsified; it's just that research that doesn't reveal what the drug company wanted may never get published. How is a doctor to know that the drug prescribed with an attached positive research data really had six other studies that failed? Since the interests of patients are the only thing of importance, it is difficult to justify why health care providers have access to *only* a biased subset of information.



Always look at the bias! What financial interest is there in that prescription drug? The doctor wants you to get better, but the drug company has a consumer for life! Could there be a bias in the pharmaceutical information supplied to the clinic? You decide.

A 2008 study stated that a substantial amount of primary outcome data submitted to the FDA was found to be missing from the literature; this is information that the FDA used to accept a drug yet wouldn't release to clinicians. Twenty-five percent of trials (in their sample studied) were unpublished—predominantly those with unfavorable results. Other recent reviews of FDA documents and journal articles [10,21] reveal similar results, one of which was published in *PLoS Medicine* in September 2008 [21].

One study just openly stated its results as, "Studies with significant or positive results were more likely to be published than those with non-significant or negative results, thereby confirming findings from a previous HTA report. There was convincing evidence that outcome reporting bias exists and has an impact on the pooled summary in systematic reviews. Studies with significant results tended to be published earlier than studies with non-significant results, and empirical evidence suggests that published studies tended to report a greater treatment effect than those from the grey literature."[7] It's difficult to expound upon their statements. Another study wanted to determine whether, "The reporting of outcomes within published randomized trials has previously been shown to be incomplete, biased and inconsistent with study protocols. We sought to determine whether outcome reporting bias would be present in a cohort of government-funded trials subjected to rigorous peer review." Their conclusion stated, "Selective reporting of outcomes frequently occurs in publications of high-quality government-funded trials."

Biased reporting of results of new drug trials is particularly concerning because these journal articles are often the only peer-reviewed source of information on recently approved drugs for health care providers (though I'm sure they receive plenty of 'literature' from drug reps). There are also substantial cost implications if the efficacy is overestimated and the drugs overused, as new molecular entities are among the most expensive pharmaceuticals on the market [22] and profit is necessary.

The FDA and other regulatory agency submissions represent the final description of how the trial was conducted and analyzed prior to journal publication. However, details from these submissions are not publicly available in most countries and rarely viewed by doctors. Although the FDA Web site posts summaries of reviews, their content and availability is variable, and sections are often redacted [9,21,23]. Furthermore, regulatory agency submissions are prepared by companies *after* data analysis and do not represent the full data; these may also be subject to biased reporting. Study protocols (how it was conducted) constitute the most comprehensive description of study design, but access to these are particularly difficult to obtain [25,26]. The SPIRIT initiative (Standard Protocol Items for Randomized Trials) aims to address these deficiencies by producing evidence-based recommendations for key information to include in a trial protocol [27].

Someone once said that one can make statistics say anything one wants. I believe that careful consideration must be taken prior to undertaking any medical care and that goes for alternative care as well. Unfortunately, the trial literature *is* biased, and much remains to be done to establish reliable, comprehensive data/results disclosure processes worldwide, but also to start heeding the calls for increased access to full protocols and regulatory agency submissions [14,23,33,37,38].

I always tell patients that are believers, "pray about your care and make sure you have complete peace in your heart about the path you are going to follow." It is wise to listen to other trusted friends in whom you value their counsel. Try not to make decisions out of fear and do not let anyone pressure you into anything. Even with a cancer diagnosis, you always have more time than you may be pressured into believing to make a conscious and sane decision.

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Medulloblastoma – a childhood brain cancer

Medulloblastomas are the most common brain tumors in children. They usually form deep in the brain between the brainstem and the cerebellum. Although it is thought that medulloblastomas originate from immature or embryonic cells at their earliest stage of development, the exact cell of origin, or "medulloblast" has yet to be identified.

Symptoms are mainly due to secondary increased intracranial pressure due to swelling and a subsequent blockage in the brain and the cerebral spinal fluid. The child develops neurological symptoms, can become listless, nauseous, having episodes of vomiting, and headaches. Soon after, the child may develop a stumbling gait, frequent falls, and diplopia. Other neurological findings are also frequent and facial sensory loss or motor weakness may be present. The tumor is distinctive and usually diagnosed on an MRI.

Treatment nearly always begins with surgery - maximal resection of the tumor. The ‘standard protocol’ includes the addition of radiation but here’s where treatment differences begin to emerge. Some studies reveal radiation alone to be as effective as a combination of radiation with chemotherapy. (37) Other studies attempt to prove better outcomes with chemotherapy added but fail to prove their point as they compare one chemotherapy regimen to another and then conclude that chemotherapy is a wise addition. (5)(6)

Increased intracranial pressure may be controlled with a ventriculoperitoneal shunt that is surgically placed to drain the inflammation.

Their Proof

Here’s a study published in the Journal of Oncology, VOLUME 24, NUMBER 2, SEPTEMBER 1 2006 that was **given to me by an Oncologist to prove the need for continued maintenance chemotherapy** on an 8-year-old girl with Medulloblastoma who has already had chemotherapy and radiation:

Phase III Study of Craniospinal Radiation Therapy Followed by Adjuvant Chemotherapy for Newly Diagnosed Average-Risk Medulloblastoma

Roger J. Packer, Amar Gajjar, Gilbert Vezina, Lucy Rorke-Adams, Peter C. Burger, Patricia L. Robertson, Lisa Bayer, Deborah LaFond, Bernadine R. Donahue, MaryAnne H. Marymont, Karin Muraszko,James Langston, and Richard Sposto

ABSTRACT

Purpose: To determine the event-free survival (EFS) and overall survival of children with average-risk medulloblastoma and treated with reduced-dose craniospinal radiotherapy (CSRT) and one of two postradiotherapy chemotherapies.

Methods: Four hundred twenty-one patients between 3 years and 21 years of age with nondisseminated medulloblastoma (MB) were prospectively randomly assigned to treatment with 23.4 Gy of CSRT, 55.8 Gy of posterior fossa RT, **plus one of two adjuvant chemotherapy regimens**: lomustine (CCNU), cisplatin, and vincristine; or cyclophosphamide, cisplatin, and vincristine.

Results: Forty-two of 421 patients enrolled were excluded from analysis. Sixty-six of the remaining 379 patients had incompletely assessable postoperative studies. Five-year EFS and survival for the cohort of 379 patients was 81% +/- 2.1% and 86% +/- 9%, respectively (median follow-up over 5 years). EFS was unaffected by sex, race, age, treatment regimen, brainstem involvement, or excessive anaplasia. EFS was detrimentally affected by neuroradiographic unassessability. Patients with areas of frank dissemination had a 5-year EFS of 36% +/- 15%. Sixty-seven percent of progressions had some component of dissemination. There were seven second malignancies. Infections occurred more frequently on the cyclophosphamide arm and electrolyte abnormalities were more common on the CCNU regimen.

Conclusion: This study discloses an encouraging EFS rate for children with nondisseminated MB treated with reduced-dose craniospinal radiation and chemotherapy. Additional, careful, step-wise reductions in CSRT in adequately staged patients may be possible.

Let's break this down:

1. Starting with the purpose of the study, it states, "Purpose: To determine the event-free survival (EFS) and overall survival (OS) of children with average-risk medulloblastoma and treated with reduced-dose craniospinal radiotherapy (CSRT) and one of two postradiotherapy chemotherapies."
    a. EFS (event-free survival) in research study terms are usually measured in percentage and denote those in the study that survived (as opposed to those that died) that didn't experience a specific event. As stated in page 2 of the study under "Statistical Considerations", "The primary end point for analysis was time to a treatment failure event (EFS) measured from the time of study enrollment." Therefore, data was measured for each patient until an event occurred. An event was defined in the same paragraph as, "the first occurrence of death from any cause, relapse, progressive disease, or development of a second malignancy."
    b. OS (overall survival) simply denotes those in the study group that remain alive at the end of the study as defined, "The secondary end point was time to death from any cause, from which actuarial survival probability was computed."
    c. "Average risk medulloblastoma" refers to the fact that medulloblastoma can be classified into several risk groups and candidates for this study were considered average risk.
    d. "Treated with reduced-dose craniospinal radiotherapy (CSRT) and one of two postradiotherapy chemotherapies." - This sets the parameters of the study as to what is actually being measured and is my greatest concern. Why?
        i. This study is comparing efficacy between two chemotherapy regimens: lomustine (CCNU), cisplatin, and vincristine; or cyclophosphamide, cisplatin, and vincristine.
        ii. It is NOT comparing efficacy between chemotherapy and doing nothing.
        iii. It is NOT comparing efficacy between chemotherapy and doing a natural approach.
        iv. It is NOT comparing efficacy between chemotherapy and doing a specific alternative therapy. The study states exactly what is being compared – two chemotherapy regimens. Therefore ONE regimen will probably show better success than the other regimen. What does this prove? It proves that one regimen showed better success than another in this study.
    e. What one CANNOT extrapolate from this study:
        i. One CANNOT extrapolate that chemotherapy is necessary for this type of cancer.
        ii. One CANNOT extrapolate that chemotherapy is better then doing nothing, doing something else, or even requiring the patient to chant and throw dried rattlesnake venom over their left shoulder.
    f. There is ONLY one piece of information that can be gathered from the data from this study: Comparing chemotherapy regimens, which one worked better?

Remember this because when the authors write their opinion at the conclusion, they extrapolate far more than possible from their own data.

2. Next let's move on to the study's method: "Four hundred twenty-one patients between 3 years and 21 years of age with nondisseminated medulloblastoma (MB) were prospectively randomly assigned to treatment with 23.4 Gy of CSRT, 55.8 Gy of posterior fossa RT, plus one of two adjuvant chemotherapy regimens: lomustine (CCNU), cisplatin, and vincristine; or cyclophosphamide, cisplatin, and vincristine."
    a. First we see that four hundred twenty-one patients were included in this study.
    b. Then we see the inclusions –
        i. Patients were between 3 years and 21 years of age.
        ii. Patients had a nondisseminated (not dispersed, localized) medulloblastoma
        iii. All patients had radiation therapy to their brain
        iv. Patients were randomly divided into two groups that received the two separate chemotherapy cocktails.
    c. What CAN we understand from the method?
        i. This was a fairly large study (as studies go) and all received radiation therapy
        ii. All patients received chemotherapy of one of two types
    d. What we CANNOT extrapolate from understanding the method:
        i. We have no idea the health of any individuals in this study
        ii. We have no idea of the diets, other therapies explored by the parents, family habits, or lifestyle changes made by any individuals in either group.
        iii. We cannot compare anything other than that which is measured. In this case, all that is measured is EFS and OS, by percentage, of those in these two groups.
3. Now is where it gets exciting; let's see the results: "Forty-two of 421 patients enrolled were excluded from analysis. Sixty-six of the remaining 379 patients had incompletely assessable postoperative studies. Five-year EFS and survival for the cohort of 379 patients was 81% plus/minus 2.1% and 86% plus/minus 9%, respectively (median follow-up over 5 years). EFS was unaffected by sex, race, age, treatment regimen, brainstem involvement, or excessive anaplasia. EFS was detrimentally affected by neuroradiographic unassessability. Patients with areas of frank dissemination had a 5-year EFS of 36% plus/minus 15%. Sixty-seven percent of progressions had some component of dissemination. There were seven second malignancies. Infections occurred more frequently on the cyclophosphamide arm and electrolyte abnormalities were more common on the CCNU regimen."
    a. Forty two patients were excluded for reasons disclosed later in the writing which leaves 379 remaining for the study.
    b. The five-year EFS of the two groups was 81% +/- 2.1%, and 86% +/- 9%. From this data one can conclude:
        i. Group number two appears to have had a better EFS rate than group number one.

ii. Given the +/- 2.1%, and +/- 9% error rate pretty much negates the above statement that group number two's success rate was better.

c. From the above data, one CANNOT conclude:
    i. One CANNOT conclude that success or lack thereof in either group compares to any other treatment.
    ii. It is both illogical and impossible to compare success rates of these two groups to any other group utilizing any other therapy or, for that matter, doing nothing. There is NO data in this study that allows such extrapolation.

d. "EFS was unaffected by sex, race, age, treatment regimen, brainstem involvement, or excessive anaplasia. EFS was detrimentally affected by neuroradiographic unassessability." This tells us other factors affecting/not affecting the results.

e. "Patients with areas of frank dissemination had a 5-year EFS of 36% plus/minus 15%. Sixty-seven percent of progressions had some component of dissemination." This tells us that patients with dissemination (widely dispersed in the tissue or other tissues) had a markedly lower 5-year EFS rate. It does NOT tell us if this EFS rate was worse/better in group one or group two.

f. "Sixty-seven percent of progressions had some component of dissemination. There were seven second malignancies. Infections occurred more frequently on the cyclophosphamide arm and electrolyte abnormalities were more common on the CCNU regimen." From this we find:
    i. Sixty-seven percent of progressions (those whose cancer progressed) had some component of dissemination.
        1. This does NOT tell us how many patients in the study had 'progressions' only that some did
        2. This tells us that 67% of those that did had dissemination
    ii. There were seven second malignancies though the study does not define if these were diagnosed as new, distinct tumors or metastatic lesions
    iii. The data also states that other complications were present such as infections and electrolyte abnormalities yet does not fully define this or the numbers that experienced them.

4. Conclusions – "This study discloses an encouraging EFS rate for children with nondisseminated MB treated with reduced-dose craniospinal radiation and chemotherapy. Additional, careful, step-wise reductions in CSRT in adequately staged patients may be possible."
    a. "This study discloses an encouraging EFS rate for children with nondisseminated MB treated with reduced-dose craniospinal radiation and chemotherapy." Really? As stated previously by the data itself, this study compares TWO groups of patients receiving two different chemotherapy cocktails. The only conclusion that can possibly be drawn directly from this study is that one chemotherapy cocktail fared better than another. Nothing more can be concluded from data collected!
    b. "Additional, careful, step-wise reductions in CSRT in adequately staged patients

may be possible." This speaks to the fact that this study utilized a reduced (from common) dose of radiation on all subjects. The only way to conclude that, "Additional, careful, step-wise reductions in CSRT in adequately staged patients may be possible," is to compare the success (EFS) of patients on this study to patients on other *identical* studies utilizing a higher dose of radiation which the authors state in the study proper.

i. Authors state in study proper that, "The EFS rate compares favorably with results obtained after treatment with radiotherapy alone, including a contemporary prospective trial which found a 64.8% EFS rate for nondisseminated patients treated with 36 Gy of CSRT and supports the use of chemotherapy for all children with medulloblastoma." However, to compare one study result to another, one must compare apples to apples, identical parameters except the variable being studied. The authors cite this study (an un-identical comparable) in the above quote: "Low-stage medulloblastoma: final analysis of trial comparing standard-dose with reduced-dose neuraxis irradiation." Published in the Journal of Clinical Oncology. 2000 Aug;18(16):3004-11. The problems with this comparison:
    1. The above study's purpose was comparing doses of radiation usage, "To evaluate prospectively the effects on survival, relapse-free survival, and patterns of relapse of reduced-dose (23.4 Gy in 13 fractions) compared with standard-dose (36 Gy in 20 fractions) neuraxis irradiation in patients 3 to 21 years of age with low-stage medulloblastoma, minimal postoperative residual disease, and no evidence of neuraxis disease."
    2. In comparing dosage use of radiation, this study revealed, "At 8 years, the respective EFS proportions were also 67% (SE = 8.8%) and 52% (SE = 11%) (P =.141)."

ii. The above statement from the study proper in quoted point 'i.' also cites this (another un-identical comparable) study: "Results of a randomized study of preradiation chemotherapy versus radiotherapy alone for nonmetastatic medulloblastoma: The International Society of Paediatric Oncology/United Kingdom Children's Cancer study group PNET-3" Published in the Journal of Clinical Oncology 21:1581- 1591, 2003. The problem with this comparison:
    1. Its methods were distinct and different, as stated in its purpose, "to determine whether preradiotherapy (RT) chemotherapy would improve outcome for Chang stage M0–1 medulloblastoma when compared with RT (radiation) alone.
    2. The results of this study revealed that long-term survival of those receiving chemotherapy prior to radiation fared no better than those who did radiation alone, "There was no statistically significant difference in 3-year and 5-year OS between the two arms."

iii. To extrapolate any further data from this study other than that which the study compares (one chemotherapy regimen to another) one must compare studies that utilize identical methods with a variable of comparison.
iv. To extrapolate that this study "proves" the validity of the use of chemotherapy over anything other than the chemotherapy that was used in comparison is overreaching. It is as if one formulated an experiment where one would juice two varieties of oranges; let's say Mandarin and Valencia. The results of the experiment revealed that our population group preferred the juice from the Valencia oranges. What could we conclude?
    1. Could we conclude that our study proves that everyone should drink Valencia juice?
    2. Could we conclude that nothing other than Valencia juice is affective in satisfying the population because 81% of those in our study prefer it?
    3. Could we conclude that the population does not prefer apple juice?
    4. Could we even conclude that Valencia is the superior orange for juicing?

We obviously could NOT conclude any of the above yet that is exactly the logic used in taking a study comparing two types of the same therapy, rating one superior than another, and then stating that it is superior to ALL therapy, even those it has not been compared to.

The logic is fuzzy at best.

More Studies Cast Doubt in Standard Protocols

I know this all seems complicated so let's look at a few more studies. Here's one published in the Journal of Clinical Oncology in 1999 Mar;17(3):832-45. "Metastasis stage, adjuvant treatment, and residual tumor are prognostic factors for medulloblastoma in children: conclusions from the Children's Cancer Group 921 randomized phase III study."
Zeltzer PM, Boyett JM, Finlay JL, Albright AL, Rorke LB, Milstein JM, Allen JC, Stevens KR, Stanley P, Li H, Wisoff JH, Geyer JR, McGuire-Cullen P, Stehbens JA, Shurin SB, Packer RJ.
University of California at Irvine Medical Center, Orange, USA.

The Abstract:
PURPOSE:
"From 1986 to 1992, "eight-drugs-in-one-day" (8-in-1) chemotherapy both before and after radiation therapy (XRT) (54 Gy tumor/36 Gy neuraxis) was compared with vincristine, lomustine (CCNU), and prednisone (VCP) after XRT in children with untreated, high-stage medulloblastoma (MB)." This means that this study compares two groups of patients – those receiving an 8-in-1 chemotherapy cocktail and another group receiving a cocktail of vincristine, lomustine (CCNU), and prednisone (VCP). Both groups received XRT, that is, radiation therapy.

Immediately, from the purpose, one can discern data that can and cannot be gathered from this study regardless of results.

1. It is logical to expect that one of the two groups may have a better outcome then the other.
2. It is logical to then state that patients in similar scenarios as the patients in this study may do better on one protocol than the other based on outcome of this study.
3. It is completely illogical to imply in any way that results of this study can be used to determine the efficacy of any other therapy other than the comparison of the two in the study.

A medulloblastoma study published in Nature, July 2012, states, “Despite recent treatment advances, approximately 40% of children experience tumor recurrence, and 30% will die from their disease. Those who survive often have a significantly reduced quality of life.” (36) This paints a different picture then the 2006 study (six years previous) that an oncologist used to ‘prove’ that her recommended therapy would result in an 81% cure rate. So how can one study give data that 81% are cured and another state that 40% have tumor recurrence, and 30% will die from their disease? It’s easy, just look at what is compared to achieve the numbers. If you want to prove something, simply compare two products that you wish your audience to use and run a study. One will win and you can now convince the masses that it is superior to all - even those it was never compared to.

An article published in the April 2012 issue of Journal of Medical Imaging and Radiation Oncology, stated when measuring Medulloblastoma treatment outcomes at the Prince of Wales Hospital Cancer Centre, “The 5-year PFS (progression-free survival) was 69.7%. The 5-year PFS for patients treated pre and post 1990 was 66.1% and 71.8%, respectively. The 5-year CSS (cancer-specific free survival) for high- and low-risk patients was 61.1% and 78.4%, respectively.”(37) And this was for surgical resection and radiation ONLY!

A study published in March of 2012 on the commonly used chemotherapy agent cisplatin attempted to see why, “cancer cells often develop resistance to cisplatin, which limits therapeutic effectiveness of this otherwise effective genotoxic drug.” They found that what is a common problem in many other cancers, an inhibited estrogen-beta receptor (which is actually an apoptotic receptor), “interfere(s) with cisplatin-induced cytotoxicity in human medulloblastoma cell lines.” (38) This just means that there is a percentage of medulloblastoma patients (and other cancer patients with ERbeta inhibition) that will not respond as desired to cisplatin usage.

There are other studies that have shown remarkably favorable outcomes for medulloblastoma patients NOT utilizing chemotherapy. Published in the International Journal of Radiation Oncology and Biological Physiology in February, 2012, twenty-five children with medulloblastoma receiving radiation alone showed a “3-year relapse-free survival and overall survival of 83.5% and 83.2%, respectively.” (39)

Oncologists seemingly ignore studies that call for a novel approach to treating childhood cancers. Published in February, 2012, "Brain Tumors in Children- Current Therapies and Newer Directions" points out the need to discover new therapies given cell biologists discoveries in "major targets like the Epidermal Growth factor Receptor (EGFR), Platelet Derived Growth Factor Receptor (PDGFR), Vascular Endothelial Growth factor (VEGF) and key signaling pathways like the MAPK and PI3K/Akt/mTOR."(40) See my book, "Stop Fighting Cancer and Start Treating the Cause" for a descriptive natural approach to blocking such pathways.

One study published in January 2012 revealed the pathway that Curcumin (the Indian spice AKA turmeric) utilizes to block inflammation and induce apoptosis (programmed cell death necessary to stop cancer). (41) I'm willing to bet that your oncologist didn't refer to this study when he recommended this nutrient.

Even studies that reveal possible causes of cancers seem ignored. An October, 2011 study revealed the astonishing fact repeated by alternative practitioners for decades, "that a large proportion of primary medulloblastomas and medulloblastoma cell lines are infected with HCMV and that COX-2 expression, along with PGE2 levels, in tumors is directly modulated by the virus." (42) That's crazy! Why hasn't the oncological community jumped on this and begun recommending anti-viral nutritional protocol? Is it possible that this study was overlooked because there are no anti-viral drugs worth using? Is it in the least bit contraindicative to bombard an immune system with destructive chemotherapy if you know you will be creating an enormous opportunity for the virus to replicate uninhibited?

Not to get too technical in this book, but there are many other studies that reveal information that make excessive use of chemotherapy contraindicative:

1. A 2011 study (43) proves that a Th2 chemokine (a chemical produced in a hyper Th2 response which is the response the immune system is 'stuck' in if suppressed).
2. An up-regulation of chemicals that increase cell replication necessary in growth and healing but NOT desired in cancer are stimulated by a suppressed immune system. Transcription factor Forkhead box M1 (FoxM1) is one of these 'stimulators of cell division' that a healthy immune system keeps at bay. If your immune system is suppressed – like in aggressive chemotherapy usage, transcription (cell growth and replication) is less uninhibited! This is just one reason that chemo, though it can kill a growth tumor, also causes cancer growth! (44)
3. MicroRNA-21, an oncogene that is up regulated in a variety of cancers increases cancer growth, which is stimulated by a high sugar diet and a suppressed immune response. (44)(45)(46)
4. Other oncogenes (genes that, when up regulated, increase cancer growth) and apoptotic pathways are possibly affected by excessive chemotherapy use (20-32)
5. Other studies showing that novel, natural alternatives to chemotherapy exist. (47)(48)(49)(50) Unfortunately, unless pharmaceutical companies can create patented medications from them, don't expect to hear about them soon.

Many studies openly reveal the inadequacies of current treatment protocols:

1. "The 5-year EFS for patients receiving standard-dose irradiation is suboptimal, and improved techniques and/or therapies are needed to improve ultimate outcome. Chemotherapy may contribute to this improvement." (3)
2. "The addition of chemotherapy to standard radiotherapy improves the rate and length of disease-free survival for those children with MB/PNET who have the most extensive tumors at diagnosis. It remains to be determined which drug or drug combinations are the most effective in MB/PNET, and which patients are most likely to benefit from chemotherapy." (4)
3. "After 3600 cGy of radiation therapy, children <7 years of age at the time of diagnosis have declines in overall intelligence of between 20 and 30 points within three years of the completion of radiation therapy." (5)
4. Later the same study admits, "It is also increasingly clear that long- term survivors of medulloblastoma may have difficulties in organization and attention, and such "executive" function disabilities will greatly impair learning. Most children <7 years of age with medulloblastoma who are treated with surgery and radiation will require special education placement, and a significant number of older children will also need some type of classroom help."
5. Oncologists readily use studies done on patients included under specific criteria and use them to 'prove' the benefits for everyone. In one patient's case the study that the oncologist handed me to 'prove' her position on continued chemotherapy stated, "To be eligible for study entry, patients had to be older than 18 months of age at diagnosis and have a subtotal resection, evidence of metastatic disease, and/or brainstem involvement." (6) Our patient WOULD NOT HAVE BEEN ELIGIBLE FOR THE STUDY!!! She had NO evidence of metastatic disease, was considered to have had a total resection (not subtotal), and NO brainstem involvement. Yet, she is being recommended for the same care BASED on this study!
6. I later checked the citings of the 'proof study' to find that it referenced studies clearly stating that chemo should be recommended in HIGH risk MB (which our patient was NOT), "In the past two decades, chemotherapy has proven to be an increasingly more effective modality in the treatment of medulloblastoma. Current evidence suggests that chemotherapy be included as part of standard treatment for all patients with high-risk medulloblastoma." (12)
7. It even referenced a study that proved, "There was no statistically significant difference in 3-year and 5-year OS between the two arms" (OS = Overall Survival and the two arms being two groups in the study – one with radiation alone and one with chemotherapy plus radiation) (17)
8. "The 2-year results of this study suggest that children with brain tumors treated with CRT are cognitively impaired and that these deficits worsen over time. The younger the child is at the time of treatment, the greater is the likelihood and severity of damage. These children, although not retarded, have a multitude of neurocognitive deficits which detrimentally affects school

performance. New treatment strategies are needed for children with malignant brain tumors." (7)

9. "This study represents the largest series of patients with average-risk MB/PNETs treated with a combination of reduced-dose RT and adjuvant chemotherapy whose intellectual development has been followed prospectively. Intellectual loss was substantial but suggestive of some degree of intellectual preservation compared with effects associated with conventional RT doses. However, this conclusion remains provisional, pending further research." (8)
10. "In the past two decades, chemotherapy has proven to be an increasingly more effective modality in the treatment of medulloblastoma. Current evidence suggests that chemotherapy be included as part of standard treatment for all patients with high-risk medulloblastoma."
11. The German Society of Pediatric Hematology and Oncology (GPOH) conducted a randomized, prospective, multicenter trial (HIT '91) "in order to improve the survival of children with medulloblastoma by using postoperative neoadjuvant chemotherapy before radiation therapy as opposed to maintenance chemotherapy after immediate postoperative radiotherapy." (19)
12. "Reduced-dose craniospinal radiation therapy can be proposed in standard-risk medulloblastoma provided staging and radiation therapy are performed under optimal conditions." (33)

What IS Clear

One thing we DO know as we investigate all the existing data on Medulloblastoma is this: we have a long way to go before we know everything! This is exactly the point. One cannot argue that continued excellence in surgical procedures is the major contributor to greater treatment success and that some chemotherapy and radiation may be necessary in this aggressive cancer. One also cannot rule out both the need for and the efficacy of an alternative, natural approach. For an oncologist to force the parents of a child into their protocol because of the research supporting it is ludicrous. There is NO research that supports the traditional approach of chemo and radiation and then maintenance chemotherapy to be ANY more effective than a natural protocol following radiation. It doesn't exist!

What can we say? Is it wrong to recommend maintenance chemo? No. Is it wrong to make it illegal to try something else? Yes. Chemotherapy can kill as easily as it can save, so let's stop pretending anything else!

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Ten More Studies

Study #1: Gerson Melanoma Study

This may be the most impressive and successful studies in cancer research. The study was conducted by the University of CA, San Diego and the Gerson Research Organization, title, "5-Year Survival Rates of Melanoma Patients treated by diet and therapy after the manner of Gerson."
CONCLUSIONS: The 5-year survival rates reported here are considerably higher than those reported elsewhere. Stage IIIA/B males had exceptionally high survival rates compared with those reported by other centers.
RESULTS SUMMARIZED: Of 14 patients with stages I and II (localized) melanoma, 100% survived for 5 years, compared with 79%. Of 17 with stage IIIA (regionally metastasized) melanoma, 82% were alive at 5 years, in contrast to 39%. Of 33 with combined stages IIIA + IIIB (regionally metastasized) melanoma, 70% lived 5 years, compared with 41% of 134. Of 18 with stage IVA melanoma, 39% were alive at 5 years, compared with only 6%. Survival impact was not assessed for stage IVB.
http://chipsa.com/download/GRO5yrgs.pdf

Study #2: Gonzalez Pancreatic Pilot Study

This pilot study most likely has the world's best results for any study ever conducted on pancreatic cancer.
RESULTS: As of 12 January 1999, of 11 patients entered into the study, 9 (81%) survived one year, 5 (45%) survived two years, and at this time, 4 have survived three years. Two patients are alive and doing well: one at three years and the other at four years.
CONCLUSION: These results are far above the 25% survival at one year and 10% survival at two years for all stages of pancreatic adenocarcinoma reported in the National Cancer Data Base from 1995.
http://www.dr-gonzalez.com/pilot_study_abstract.htm

Study #3: Spontaneous Remission Study

Researchers at the University of Victoria in British Columbia did a careful follow up on 200 persons who underwent a "spontaneous regression of cancer". They found that 87% of those persons had switched diets, usually to a vegetarian diet!!!
http://www.ocra-oregon.org/foodsthatfightcancer.pdf

Study # 4: Macrobiotics and Cancer

1-year survival rate among patients with pancreatic cancer was significantly higher among those who modified their diet than among those who did not (17 months versus 6 months). The

one-year survival rate was 54.2 percent in the macrobiotic patients versus 10.0 percent in the controls. All comparisons were statistically significant. For patients with metastatic prostate cancer, a case control study demonstrated that those who ate macrobiotically lived longer (177 months compared to 91 months) and enjoyed an improved quality of life.

http://www.kushiinstitute.org/html/research.html#two

Study #5: Chemotherapy Study

Want more information on chemotherapy specific to different types of cancer? This was a mega-study done by the Department of Radiation Oncology, Northern Sydney Cancer Centre.... RESULTS: The overall contribution of curative and adjuvant cytotoxic chemotherapy to 5-year survival in adults was estimated to be 2.3% in Australia and 2.1% in the USA. CONCLUSION: As the 5-year relative survival rate for cancer in Australia is now over 60%, it is clear that cytotoxic chemotherapy only makes a minor contribution to cancer survival. To justify the continued funding and availability of drugs used in cytotoxic chemotherapy, a rigorous evaluation of the cost-effectiveness and impact on quality of life is urgently required. - Full study attached.
http://fiocco59.altervista.org/ALLEGATI/MORGAN.PDF

Study #6: IPT Uruguay Study on Breast Cancer

Is this the future of chemotherapy? In 2003, the first clinical trial for cancer treatment with IPT was published in Uruguay. It showed improved clinical outcome for patients with advanced breast cancer. Also, in a another study In 2009, a Bulgarian three-year study showed that IPT improved patients' quality of life. The researchers stated that they "sincerely believe that the method presents a compelling opportunity for solving the problem with chemotherapy's toxicity, for improving treatment effectiveness and quality of life." Note - IPT is NOT yet approved by the FDA. Attached is the Uruguay study.
http://linchitzipt.com/files/uruguay2004.pdf

Study #7: Small Cell Lung Cancer (Vitamins)

Study by Jaakkola – RESULTS: From the time of diagnosis, at 6 months, the survival of the SEER (Conventional) group was 50% and the Nutrient group almost 95%; at 12 months, 20% of the SEER group and 85% of the Nutrient group was still alive; at 24 months, survival for the SEER group was only 10%, while 55% of the Nutrient group was still alive; at 30 months, only about 1% of the SEER group was still alive while 40% of the Nutrient group was still living, and ***finally at 6 years or 72 months, all of the SEER group had passed on, while 44% (8 of 18 patients) of the Nutrient group was still alive.***
http://www.townsendletter.com/Oct2011/intoncol1011.html

Study #8: Vitamin C Study; Linus Pauling two-time Nobel Prize winner

"100 terminal cancer patients - After 10 days of intravenous Vitamin C therapy, each patient was given 10 grams of vitamin C orally each day indefinitely. RESULTS: The mean survival time for the ascorbate group (Vitamin C) was 4.2 TIME MORE than the control subjects (more than 210 days compared to 50 days for the controls). An analysis of the survival-time curves indicated that deaths occurred for about 90% of the ascorbate-treated patients at one-third the rate for the controls and that the other 10% had a much greater survival time, averaging more than 20 times the controls. CONCLUSION: Cameron and Pauling concluded that high doses of vitamin C should be given to all cancer patients." The full study is on page 62 of the PDF. http://www.breastcancerchoices.org/files/Schachter_PDF_File_from_ICIM_Journal.pdf

Study #9: Root Canal and Breast Cancer

"Dr. Thomas Rau, who runs the Paracelsus Clinic (cancer clinic since 1958) in Switzerland recently checked the records of the last 150 breast cancer patients treated in his clinic. He found that 147 of them (98%) had one or more root canal teeth on the same meridian as the original breast cancer tumor." Attached is an article with more information on the subject: http://naturaldentistry.us/wp-content/uploads/2009/05/cnd-breast-cancer-and-root-canals-ad.pdf

Study #10: Weekly Support Group increase life 18 months longer on advanced breast cancer patients

A study of women with advanced breast cancer, conducted at Stanford University, found that those who attended weekly support groups lived an average of 18 months longer than those who didn't.
http://consumer.healthday.com/encyclopedia/article.asp?AID=644944

Some other studies that are being conducted:

The Effect of Vitamin D & Celebrex® on Breast Cancer Biomarkers

Breast Cancer Prevention Using Synergistic Prostaglandin Inhibitors (The Vitamin D/Celecoxib Study) (NCT01425476)

Summary

Some studies have suggested that inflammation in the body may increase breast cancer risk. Vitamin D helps the body absorb and maintain the right amount of calcium in the blood. It also helps control cell growth and reduce inflammation. Celecoxib (Celebrex®) is a drug that reduces inflammation by

inhibiting an enzyme called COX-2. The purpose of this study is to determine if vitamin D alone or in combination with Celebrex decreases levels of certain biological markers (biomarkers) thought to be related to breast cell changes and breast cancer risk.

Effect of Tumeric on Breast Tissue in Obese, High-Risk Women

Nanoemulsion Curcumin for Obesity, Inflammation and Breast Cancer Prevention - a Pilot Trial (NCT01975363)

Summary

Laboratory studies suggest that tumeric (curcumin) may have anti-cancer effects. This may be because tumeric can reduce inflammation, which has been linked to cancer growth. Researchers think that tumeric may reduce inflammation in fat tissue and breast tissue, which may decrease breast cancer risk. This pilot study is looking at the effect that tumeric has on the breast tissue of obese women who are at high risk for breast cancer.

Reducing the Risk of Breast Cancer with Omega-3 Fatty Acids and Weight Loss

Randomized Pilot Trial of Omega-3 Fatty Acids or Placebo in Peri- or Post-Menopausal Women at High Risk for Breast Cancer Undergoing a Weight Loss Intervention (NCT02101970)

Summary

Studies have found that women who are overweight are at increased risk for developing breast cancer. This may be because obesity is linked to chronic inflammation in breast tissue, which has been shown to increase breast cancer risk. Omega-3 fatty acids cannot be made by the body and must be obtained from food or supplements. Studies suggest that omega-3 fatty acids have the ability to resolve chronic inflammation. This study is investigating whether adding a high dose of omega-3 fatty acids to a weight loss program reduces inflammation in the breast in women who are at high risk for developing breast cancer.

Exercise Programs in Healthy, High-Risk Young Women

Exercise Programs in Healthy Young Women at Increased Risk of Developing Breast Cancer (NCT00892515)

Summary

Studies suggest that exercise may decrease a woman's risk of developing breast cancer. It is not yet known whether certain types of exercise are more likely to reduce risk than others, or whether low-intensity exercise and high-intensity exercise have the same effects. The goal of this trial is to compare the effects of a low-intensity and high-intensity exercise program on hormone levels, breast density, and body composition in healthy women between the ages of 18 and 35 who are at increased risk of developing breast cancer.

Cognitive-Behavioral Therapy for Insomnia After Treatment

Cognitive-Behavioral Therapy for Chronic Insomnia After Breast Cancer Treatment (NCT00672217)

Summary

Many cancer patients experience persistent difficulty falling asleep or staying asleep. Studies have shown that psychological and behavioral factors play an important role in insomnia. Cognitive behavioral therapy (CBT) is an effective treatment for insomnia that provides an alternative to sleeping pills. The CBT approach aims to change the thoughts and actions that interfere with the ability to get restful sleep. The goal of this study is to examine the effects of CBT on women who experience long-term difficulty with sleeping after cancer treatment. Participants must have completed radiation or chemotherapy within three years of beginning this study.

Comparing Therapies for Depression Related to Breast Cancer

Interpersonal Therapy for Depression in Breast Cancer (NCT01191580)

Summary

Depression can negatively affect a cancer patient's adherence to treatment, survival, symptom management, psychosocial functioning, and quality of life. The goal of this trial is to compare the effectiveness of three different types of therapy (Interpersonal Psychotherapy, Problem-Solving Therapy, and Brief Supportive Psychotherapy) in improving depressive symptoms, psychosocial functioning, and quality of life among patients with breast cancer who have been diagnosed with Major Depressive Disorder.

Exercise During Treatment for DCIS and Early-Stage Disease

Prescriptive Exercise Intervention During Active Treatment for Early Stage Breast Cancer Patients: A Breast Cancer Rehabilitation & Exercise Laboratory (NCT01157130)

Summary

Studies suggest that exercise may reduce the risk of a breast cancer recurrence as well as improve quality of life. Precisely how exercise reduces recurrence risk is not fully understood. However, scientists think that exercise during breast cancer treatment may affect proteins and hormones, such as insulin and estrogen, that are related to cancer growth. The goal of this trial is to determine the effect that exercise instruction has on exercise levels, biological measures, and psychosocial factors. To be eligible, participants must have been recently diagnosed with DCIS or early-stage breast cancer and not yet begun treatment. In addition, participants must be planning to receive treatment that includes chemotherapy and/or radiation.

Counseling for Breast Cancer Patients Age 70 and Over

Pilot of a Geriatric Group Psychoeducational Intervention for Elderly Patients With Cancer (NCT00984321)

Summary

Many women seek counseling after a breast cancer diagnosis. This counseling program was developed to meet the specific needs of older cancer patients, who often find themselves facing problems related to both cancer and aging. The goal of this trial is to see whether a counseling program can help reduce depression, anxiety, and feelings of loneliness and isolation as well as improve the quality of life of older women with breast cancer. To be eligible, participants must be receiving treatment at Memorial Sloan-Kettering Cancer Center.

Acupuncture For Treating Post-mastectomy Pain, Nausea and Anxiety

A Pilot Randomized Controlled Trial to Assess the Impact of Acupuncture on Post-mastectomy Pain, Nausea, Anxiety and Ability to Cope. (NCT02122796)

Summary

Some of the most common side effects that occur after a mastectomy are pain, nausea, and anxiety. Acupuncture involves inserting thin, sterile needles at certain points in the body. Studies have found that acupuncture can help relieve fatigue, hot flashes, nausea, vomiting, and pain. This study is looking at whether acupuncture is better than the standard of care for reducing pain, nausea and anxiety after a mastectomy. To be eligible, patients must be scheduled to have a mastectomy to treat stage I-III breast cancer.

Yoga During Radiation Therapy

Biobehavioral Effects of Yoga for Women With Breast Cancer Undergoing Radiotherapy (NCT01202851)

Summary

Researchers believe that mind-body interventions can be beneficial to women undergoing breast cancer treatment. Yoga is a mind-body intervention that has been shown to reduce fatigue as well as improve quality of sleep, physical vitality, and overall quality of life in women being treated for breast cancer. This study will compare the effectiveness of a yoga program with a stretching/relaxation program for improving the physical and emotional well-being of women with DCIS or Stage I-III breast cancer who are undergoing radiation treatment after surgery. The study will also include a group of women who will not take part in either the yoga or stretching/relaxation program. To be eligible, participants must be planning to receive radiation therapy following breast surgery. In addition, participants must not have practiced yoga in the year prior to breast cancer diagnosis.
This is a Phase III trial

Massage to Reduce Anxiety Before Breast Cancer Surgery

Utility of Preoperative Massage in Breast Surgery Patients (NCT01667328)

Summary

It is not uncommon for patients to report feeling anxious prior to their breast cancer surgery. Studies have demonstrated that massage can offer some health benefits for people with cancer. Massage has also been found to be help reduce anxiety. This study is investigating whether breast cancer patients who receive massage therapy by a licensed massage therapist before surgery have lower anxiety levels than those who do not receive massage therapy.

Swedish Massage Therapy to Reduce Cancer-Related Fatigue in Breast Cancer Survivors

Efficacy of Swedish Massage Therapy on Cancer-related Fatigue in Cancer (NCT01926678)

Summary

Many cancer survivors experience cancer-related fatigue. Studies suggest that individuals whose immune system is continually activated may experience more fatigue. Decreasing this immune system activation may help to reduce symptoms of cancer-related fatigue. Swedish Massage Therapy is a type of massage that may help reduce immune system activation. This study is comparing the effect that Swedish Massage Therapy, light touch therapy, and and being put on a wait list for massage therapy have on the immune system of breast cancer survivors who are experiencing cancer-related fatigue.
This is a Phase II trial

Acupressure for Persistent Cancer Related Fatigue

Acupressure for Persistent Cancer Related Fatigue (NCT01281904)

Summary

Persistent Cancer-Related fatigue (PCRF), a state of being tired or weary, is one of the most common and distressing symptoms breast cancer survivors may experience. There currently are few treatment options for PCRF. Acupressure is a technique derived from acupuncture, a component of Traditional Chinese Medicine. In acupressure, physical pressure is applied to acupuncture points by the hand or elbow or with a special device. Pilot studies suggest that self-administered acupressure may be a promising treatment for PCRF. The goal of this study is to determine the benefit of acupressure for treating PCRF in breast cancer survivors who have completed cancer treatments. (Individuals on anti-estrogen therapy, such as tamoxifen or an aromatase inhibitor, can also participate.) To be eligible, participants must have a complaint of persistent, moderate to severe fatigue despite standard treatment.
This is a Phase II-III trial

Acupuncture to Reduce Chemotherapy Related Side Effects in Early-Stage Breast Cancer

The Efficacy of Acupuncture in Treating Chemotherapy Side Effects in Breast Cancer Patients (NCT01996410)

Summary

Acupuncture is a treatment that involves inserting sterile, hair-thin needles into specific points on the skin. Studies have found that acupuncture can help relieve fatigue, hot flashes, nausea, vomiting, and pain. Researchers believe this is because acupuncture stimulates the nervous system. This study is investigating whether acupuncture can reduce symptoms associated with chemotherapy, such as nausea, vomiting, fatigue, anxiety, anorexia, pain, disturbed sleep, shortness of breath, dry mouth, depression, and peripheral neuropathy. To be eligible, a patient must be planning to receive chemotherapy to treat stage I - III breast cancer.

Aerobic Exercise for Women with Metastatic Breast Cancer

Phase II Trial of Aerobic Training in Metastatic Breast Cancer (NCT01725633)

Summary

Breast cancer treatments can have an affect on quality of life and fitness. Aerobic exercise may help to improve quality of life and fitness. The purpose of this study is to determine the safety and feasibility of a supervised aerobic training program for women with metastatic breast cancer who are being treated with hormone therapy, chemotherapy, and/or radiation. To be eligible, participants must be receiving breast cancer treatment at Duke University Medical Center (DUMC), Durham Regional Hospital, or Duke Raleigh.
This is a Phase I trial

Acupuncture To Treat Chemotherapy-Induced Neuropathy

Acupuncture to Prevent Chemotherapy Dose Reduction Due to Chemotherapy-induced Peripheral Neuropathy in Breast and Colorectal Cancer Patients (NCT01881932)

Summary

Peripheral neuropathy is a common side effect of chemotherapy. It usually includes pain, tingling, and numbness in the fingers and toes. This may cause a patient to receive a lower dose or a change of medication. Acupuncture, a technique used in traditional Chinese medicine, is commonly used to treat pain. Previous studies suggest that acupuncture could be effective in controlling neuropathy. This study will determine the effectiveness of using acupuncture to manage the pain, tingling and numbness caused by chemotherapy and if this treatment can help prevent reducing the dose of chemotherapy. To

be eligible, participants must be receiving chemotherapy that includes a taxane or oxaliplatin and be experiencing symptoms of neuropathy.

Electroacupuncture to Reduce Nerve Pain Caused by Taxol®

Randomized Sham Controlled Trial of Weekly Electro-acupuncture for the Prevention of Taxane Induced Myalgias and Neuropathy (NCT01163682)

Summary

The chemotherapy drug paclitaxel (Taxol®) is a widely used effective breast cancer treatment. However, one of its common side effects is nerve and muscle pain. Acupuncture is a technique used in traditional Chinese medicine that involves the insertion of hair-thin needles into various points in the skin. Electroacupuncture is a form of acupuncture in which pairs of acupuncture needles are attached to a device that generates electrical pulses between them. Studies have shown that it can help to relieve pain. This trial is investigating whether giving electroacupuncture during paclitaxel treatment can help to prevent or decrease nerve pain. To be eligible, participants must be planning to receive weekly paclitaxel for 12 weeks after surgery for early-stage breast cancer and must never have received acupuncture treatment.
This is a Phase I trial

Black Cohosh Before Surgery for Ductal Carcinoma in Situ

A Pilot Pre-operative Window Trial of Black Cohosh in Women With Ductal Carcinoma in Situ (NCT01628536)

Summary

Black cohosh is an herb that is sold as a dietary supplement to treat hot flashes and other menopausal symptoms. Researchers are investigating whether it could also play a role in breast cancer treatment. This pilot study is investigating whether black cohosh can reduce the overall size and aggressiveness of DCIS when it is given prior to surgery.

Coenzyme Q10 to Reduce Heart Damage from Adriamycin

Phase I Randomized, Placebo-Controlled, Cross-Over, Dose-Finding Pharmacokinetic Study of CoQ10 During One Cycle of Doxorubicin Treatment for Breast Cancer (NCT00976131)

Summary

Many women with breast cancer receive a chemotherapy regimen that includes the drug doxorubicin (Adriamycin®). However, women given doxorubicin may also experience some damage to their heart muscle. Coenzyme Q10 is a vitamin-like substance that helps cells convert the sugars in our food into energy that muscles can use. Researchers believe that Coenzyme Q10 may help to protect against heart damage during doxorubicin treatment. The goal of this trial is to study the safety and effectiveness of

Coenzyme Q10 when taken during treatment with doxorubicin. To be eligible for this trial, participants must be scheduled to receive at least four cycles of doxorubicin.
This is a Phase I trial

Effect of Omega-3 Fatty Acids Given Before Surgery on Breast Cancer Cells

A Randomized, Placebo-Controlled Phase II Clinical Trial of Omega-3 PUFA Dietary Supplementation in Patients With Stage I-III Breast Carcinoma (NCT01869764)

Summary

Omega-3 fatty acids are essential nutrients for good health. They are not made by the body, and are obtained only through foods or supplements. Laboratory studies suggest omega-3 fatty acids can slow the growth of cancer cells. This study is comparing the effect of omega-3 fatty acids to the effect of a placebo on breast cancer cells. To be eligible, participants must be planning to have breast cancer surgery (lumpectomy or mastectomy) at least 7 days from the start of the study.
This is a Phase II trial

Broccoli Sprout Extract For Treating ER+ Breast Cancer

A Pilot Study of Broccoli Sprout Extract in Patients With Invasive Breast Cancer (NCT01753908)

Summary

Broccoli is a member of the brassicales family. Studies have found that plants and flowers that are part of this family contain chemicals, called isothiocyanates, that may prevent or slow the growth of certain cancers. This study is comparing broccoli sprout extract to a placebo in order to see whether broccoli sprout extract alters biological markers associated with cancer cell growth when it is given to postmenopausal women with early-stage ER+ breast cancer for two weeks prior to the start of their cancer treatment.

Vitamin D Before Surgery for Breast Cancer

Vitamin D and Breast Cancer in Obesity: Therapeutic Trials (NCT01472445)

Summary

Vitamin D is an essential nutrient for bone health, calcium absorption, and immune function. Researchers believe that vitamin D may have an effect on breast cancer cells, and that this effect may be even greater in women with breast cancer who are obese. This study will investigate whether giving vitamin D prior to surgery can change the tumor's gene expression pattern from high-risk to low-risk. The researchers will also investigate whether these pattern changes occur in the same ways in obese and non-obese women. To be eligible, participants must be planning to have surgery for breast cancer but have not yet had any treatment.

Green Tea for Newly-Diagnosed DCIS

A Pilot Study of Chemo-prevention of Green Tea in Women With Ductal Carcinoma in Situ (DCIS) (NCT01060345)

Summary

Studies have shown that women with ductal carcinoma in situ (DCIS) have inflammation in the breast tissue surrounding their DCIS. This finding supports the idea that there is a link between inflammation and cancer. Researchers are studying green tea because both laboratory and epidemiology studies suggest that green tea may have anti-cancer and anti-inflammatory effects. The purpose of this study is to find molecular signs (biomarkers) that will help researchers better understand the role of green tea as an anti-cancer and anti-inflammation agent in women with newly-diagnosed ductal carcinoma in situ (DCIS).

Remarks

Regardless of what you choose about healthcare, I pray that you make wise, rational decisions based on facts (though often hidden) and not fear. You need to take responsibility and not hand it over to any practitioner, conventional or alternative. Get advice from many, weigh it all against their biases, and pray for peace about your decisions.

Kevin Conners, Pastoral Medical Association, Fellowship in Integrative Cancer Therapy and Fellowship in Anti-Aging, Regenerative and Functional Medicine, both through the American Academy of Anti-Aging Medicine.

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