

TREATMENT EFFICACY

"An Assessment of Orthodox Treatments of Cancer"

by Don Benjamin

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Introduction

Throughout the Western world the amount of money spent on research and treatment of cancer is about US\$400 billion. Of this about half (US\$200 billion) is spent in the United States, which works out at about \$1000 per capita of population or about \$200,000 per cancer patient.

In Australia the figure is about \$2 billion or about \$100 per capita or about \$40,000 per cancer patient.

What I plan to show in this article is **firstly** that this cancer industry that costs Australians \$2 billion dollars every year (and the world \$400 billion every year) is based on a treatment – surgery - that doesn't work; that there is no scientifically acceptable evidence that conventional treatment of cancer saves any lives or even produces any significant extension of life except in two situations:

- (1) where a tumour is threatening life by obstructing a vital organ like the colon, or pressing on the brain. Clearly in such cases removal or shrinking of such tumours using surgery or radiotherapy can save a life, but it doesn't follow that this affects the course of the disease. Removing a benign growth can also save a life in such circumstances.
- (2) there is evidence that chemotherapy can have a significant effect on survival when used in some systemic cancers such as some acute childhood leukemias and some lymphomas and possibly a minor effect on some solid tumours. But these together constitute only about 6% of all cancer cases.

Secondly, that there is evidence that some alternative cancer therapies work.

I believe the reason that orthodox therapies don't work and some alternative therapies do work is because the orthodox theory of what cancer is, is wrong and those alternative therapies that do work are based on a more valid theory or paradigm.

I am defining **cancer** as those conditions involving tumours that invade surrounding tissue and tend to metastasise; and malignancies in the blood and lymphatic systems. This therefore excludes most so-called skin cancers apart from melanomas. Strictly speaking it also excludes the carcinoma-in-situ (CIS) since these are not invasive.

Theories of cancer

There are many theories about what cancer is, but most of these fall into two main schools of thought or paradigms. These are as follows:

The current paradigm in orthodox circles is that cancer is a localised disease when first detected. If detected too late it can spread to regional lymph nodes and also possibly to remote sites (metastases), at which stage the cancer has become incurable or inoperable. It can also recur in

another nearby site but is then sometimes referred to as a new primary cancer.

The alternative paradigm sees cancer as a systemic disease caused by the breakdown of many bodily functions including metabolic, endocrine and immune processes. During its later stages tumours appear in one location and later in others. This theory does not rely on the process of spreading or metastasising. In the same way recurrences are not new cancers but fresh symptoms of the same cancer.

One way of testing the two hypotheses or paradigms is to measure the efficacy of the treatments based on the respective theories.

Efficacy of treatment

I am defining an effective treatment as one that alters the course of the disease, as demonstrated either by significantly improved survival or reduced mortality.

Measuring Efficacy

There are four different ways of demonstrating efficacy of a cancer treatment:

1. Anecdotal information - These are accounts of individual cases. Usually there are several different treatments being used at the same time. It is therefore not possible to separate the effects of these different treatments. Not very useful except as a guide for further research. Not acceptable scientifically.
2. Survival Rates - Usually the percentage of patients alive five years after diagnosis is quoted. These are only useful if it can be shown that the rate has improved in a group of patients when compared with a similar group matched with regard to age, gender and stage of tumour at the time of diagnosis who received the same treatment in the past. Very questionable because many factors other than treatment can affect survival figures. For example earlier diagnosis following screening starts the survival clock earlier. A patient can still die at the same time but appear to have lived longer. This is the usual basis for justifying orthodox therapies such as surgery.
3. Tumour response trials - Usually *effective* means a 50% reduction in tumour size. This assumes the tumour is the disease. If this assumption is wrong and the tumour is only a symptom of a systemic disease, the symptom can be destroyed or shrunk without affecting the disease or survival. Wrong conclusions are usually drawn from the results of such trials.
4. Randomised Trials - The basic principle of all randomised trials is that you start with two identical groups, a **study** group and a **control** group. You add one treatment in the study group and compare the results of the two groups. If the survival in the study group is better, or the mortality rate is lower, it is valid to conclude that the treatment that was used or added in the study group caused the improvement. This is the only reliable method of demonstrating that a treatment is effective.

I first investigated the evidence that surgery had affected survival or mortality as shown in randomised trials.

The Efficacy of Surgery

I found that no randomised trial has ever been held to demonstrate the efficacy of surgery^{1,2,3}.

Since proper randomised clinical trials have never been carried out to prove the efficacy of surgical treatment of cancer, what other scientific methods can be used to throw some light on the impact of surgery on cancer?

I looked at the results of using six different methods:

1. Graphical method

2. Comparative Studies
3. Epidemiological Studies
4. Long-term follow-up of treated patients
5. Randomised mixed treatment trials
6. Comparison Of Incidence and Mortality

The Graphical Method

This is based on the fact that from birth to death populations die at an increasing mortality rate, the rate doubling about every 8.5 years, a so-called exponential curve. When plotted on special (log-linear) graph paper these curves become straight lines. People with cancer, and other degenerative diseases, have a higher mortality rate for their age, but their mortality still continues to double every 8.5 years. It is as if getting cancer has aged these people by about 15 years. If people are successfully treated for these diseases these sub-populations drop back onto lower (healthier) mortality rate curves. There is no evidence that surgical treatment for any type of cancer produces this mortality lowering effect.

Comparative Surgery Studies

By comparing the survival or mortality of different groups of cancer patients who have undergone different amounts of surgery it is possible to evaluate the efficacy of surgery itself. According to the orthodox rationale for cancer surgery it is important to remove all malignant cells; otherwise the remaining cells will continue to grow and maybe spread. Therefore the more extensive the surgery, the less the likelihood of any malignant cells remaining and the lower the mortality rate should be. If this rationale is wrong, and tumours are only local, late-stage symptoms of a systemic disease, there would be no difference in survival or mortality between groups receiving different amounts of surgery.

Several randomised clinical trials have been carried out to compare the survival of breast cancer patients after different amounts of surgery. No difference in survival was observed between women who had received radical mastectomy, total (simple) mastectomy, quadrantectomy, segmental mastectomy (lumpectomy) and excisional biopsy⁴.

The results of these comparative trials therefore suggest that surgery has no impact on the course of the cancer because it is a systemic disease.

Epidemiological Studies

There are claims that there is some evidence from epidemiological studies that surgery may be effective for invasive cervical tumours. For example, the decline in mortality from cervical cancer that has been observed in many countries throughout the world is attributed to the introduction of PAP smear programs, when it can be assumed that more women were diagnosed early with, and therefore treated for, invasive cervical cancer.

However there are counter claims that this decline began in the late 1930s, over 20 years prior to the introduction of the PAP smear. There is no observed acceleration of this decline after the introduction of the Pap test on a widespread basis⁵.

Long-term Follow-up of Treated Patients

Long-term follow-up of breast cancer patients (30-40 years) by medical researchers has failed to identify any group of patients with evidence of cure. They found that the mortality rate for the longest surviving breast cancer patients was at least twice that of healthy women the same age. They therefore concluded that breast cancer is **incurable**^{6,7}.

Randomised Mixed Treatment Trials

Other evidence that breast cancer is incurable has come from randomised treatment trials over the years where radiotherapy or chemotherapy has been added to surgery. For example James

Devitt when delivering the opening address at the Lancet Conference "The Challenge of Breast Cancer" in April 1994 summarised the situation as follows:

"..Amputating, irradiating or ignoring involved lymph-nodes does not affect survival. Preventing local recurrence after mastectomy by radiotherapy does not affect survival. The reappearance of cancer in the breast after conservative surgery does not worsen survival. Failing to find some breast cancers and finding others later does not prejudice outcome...Perhaps the breast lesion is not the cause of the disease but merely the local expression resulting from a combination of changes in both local organ-tissue and systemic growth-restraining training factors"^{8,9}.

Comparison Of Incidence and Mortality

If, as the above evidence suggests, surgery is ineffective, what is the explanation for the apparent improvement in the percentage five-year survival rates for **all** cancer sites between 1960 and 1975 as claimed by the American Cancer Society?¹⁰

Two possible explanations have been offered:

- (1) These figures are unreliable for reasons of poor methodology.
- (2) Earlier figures with lower survival applied when more aggressive treatments were being used and were reducing survival.

The main example of poor methodology is that related to the increased percentage five-year survival rates. This increase can result from death happening later - This would be real progress. It can also result from making an earlier diagnosis, as has happened in more recent times for most types of cancer - There is no progress here. Death still occurs at the same time but the existence of the cancer has been known for a longer time, leading to an "apparent" increase in survival.

Other factors include comparison between unmatched groups. For reasons such as these epidemiologists have concluded that "survival rates should not be used as a sole or primary measure of progress in cancer control because factors unrelated to the efficacy of treatment play an important role in the determination of those rates and their trends"¹¹.

Whatever the reason, survival figures are unreliable as a measure of the efficacy of surgery as a treatment for cancer.

Epidemiologists state that a better measure of progress in cancer treatment is to compare the incidence of each type of cancer with the mortality rate over the time interval in question. For, so long as incidence and mortality remain unchanged, or change proportionately, no genuine change in survival can occur. Progress in cancer control requires that the mortality rate decline more rapidly or rise more slowly than the incidence for the particular type of cancer¹¹.

If incidence is compared with mortality over the period from 1950 to 1970 it is found that there have been large changes in incidence and mortality over this time with several types of cancer but none of the mortality rate changes satisfy this requirement. So there are no clear cases where survival could have improved as a result of surgery. The US General Accounting Office has confirmed that claims of increased survival have been overstated¹². This is further evidence that surgery has not had a proven impact on the course of cancer.

The Efficacy of Mammograms and Earlier Surgical Intervention for Breast Cancer

Another example of poor methodology is the group of randomised breast cancer screening trials. It has been claimed that breast cancer screening saves lives, as shown by results of several randomised breast cancer screening trials carried out in the US, UK and Sweden. It is argued that earlier diagnosis following screening enables earlier surgical intervention before the cancer has spread.

I identified a common flaw in the design of these trials. There were at least five factors, other than earlier surgical intervention, that differed between the study and control groups that could have affected the results. I confined my analysis to radiotherapy.

I found that the trial with the earlier surgery in the study group saved the least number of lives; and the trial with the least early surgery saved the most lives. So earlier surgery could not have saved any lives.

Radiotherapy has been shown to reduce survival and increase mortality with breast cancer. It does this by suppressing the immune system and damaging the heart^{13,14}. So I investigated its possible effects in these trials.

I found that all of the apparent saving of lives could be explained either by less radiotherapy being used in the study group; or more radiotherapy being used damaging the heart and causing deaths due to heart or respiratory failure instead of deaths due to breast cancer, thus reducing the deaths from breast cancer. Thus the reduction in deaths from breast cancer was accompanied by an equal increase in deaths from other causes, with no overall benefit.

The observed reduction in the mortality of breast cancer patients following mammograms can therefore be explained by poor methodology, not earlier surgical intervention as claimed¹⁵.

A more recent review of these mammography trials has confirmed my conclusion that mammography has not been shown to save any lives¹⁶.

The Efficacy of the PSA Test and Early Intervention for Prostate Cancer

A recent paper reported on the result of a randomised trial comparing Radical Prostatectomy with Watchful Waiting for prostate cancer. It also contained serious flaws. For example it used an ambiguous definition of "death from prostate cancer" and claimed a 50% reduction in mortality using surgery as compared with watchful waiting. The reduction in overall mortality was not significant¹⁷. An analysis of the deaths from other causes showed that most of the apparent reduction in deaths from prostate cancer can be explained by wrong attribution of deaths from prostate cancer to deaths from other causes in the treated group or deaths from other causes attributed to prostate cancer deaths in the watchful waiting group.

Similarly a paper reporting on results of a randomised trials comparing mortality after PSA screening with an unscreened control group also contained serious flaws. Although its authors claimed a 69% reduction of deaths as a result of screening¹⁸ they arrived at this figure by comparing only 23% of those invited for screening in the Invited group with 93.5% of those in the Uninvited group, a meaningless comparison in randomised trials. In a second analysis they combined part of the Invited group with part of the Uninvited group and compared their mortality with that of a different group made up from combining another part of the Invited group with a part of the Uninvited group, another meaningless comparison. When the whole Invited group was compared with the whole Uninvited group the difference in mortality was not significant.

An even more serious flaw was that they completely ignored the deaths from other causes.

The Efficacy of Radiotherapy

The reason for the damage caused by the radiotherapy mentioned above was that, up until the end of the 1960s, the radiation doses were very high. Later as the damage being caused became apparent the doses were significantly reduced (by factors of more than a hundred). This became possible with more modern technology. However some damage still occurs with the more modern techniques¹⁴.

In recent years randomised trials evaluating conservative breast cancer management (lumpectomy plus radiotherapy) have shown a significant reduction of recurrence of breast cancer. (Recurrence refers to another tumour growing nearby.) This has led to claims that radiotherapy is effective because it reduces recurrence. However these claims are invalid because no effect was observed on overall survival¹⁹. As mentioned before, these false claims

arise from a wrong assumption. When there is no link between reduced recurrence and increased survival this shows that the presence or absence of a tumour is not a reliable indication of the presence or absence of cancer. In other words cancer is a systemic disease unaffected by tumour removal.

From these trials I concluded that radiotherapy is not effective in reducing deaths from breast cancer. I have also found that other randomised trials carried out to evaluate radiotherapy for other forms of cancer, such as colon cancer have produced the same results. Post-operative radiotherapy (PORT) for lung cancer has been found to *increase* the mortality from cancer.

The Efficacy of Chemotherapy

When I started investigating chemotherapy I found this had already been done. Ulrich Abel, a biostatistician at the Institute of Epidemiology and Biometry of the University of Heidelberg, Germany carried out a comprehensive analysis of the efficacy of chemotherapy in prolonging survival in advanced epithelial cancer (i.e. solid tumours). He concluded that there was little proof of efficacy²⁰.

In the one case where increased survival was demonstrated with randomised trials, small-cell lung cancer, the gain in survival was measured in weeks or months. The treatment was still questionable because this small extension of life was hard to justify in view of the serious side effects and reduction in quality of life.

Ralph Moss, who has also questioned the efficacy of chemotherapy²¹, found that the assumption that the tumour is the disease had led to wrong conclusions being drawn from the efficacy trials. Where a trial showed that there was more tumour shrinkage in the study group than in the control group the treatment was claimed to be effective, even though there was usually no improvement in survival. As with radiotherapy the term "disease-free survival" was also used to describe a part of the study group who had an improved survival when compared with those in the control group. Such comparisons are invalid. Whenever the entire study group was compared with the control group no improved survival was observed.

Although no randomised trials have been carried out to test the efficacy of chemotherapy with some acute childhood leukaemia's, the increased percentage ten-year survival figures (from less than 10% in the 1950s to about 60% in the 1980s²²) is sufficiently large for these claims of efficacy to be accepted, although some of this apparent improvement is probably due to poor methodology described above. A similar but much smaller increase has been observed over time with some lymphomas.

Thus in most trials evaluating the efficacy of orthodox therapies a wrong assumption has been made about what cancer is; then a false conclusion has been drawn from the results obtained, usually with the help of poor methodology.

Epidemiologists Peto and Easton state that in the many situations where it is not known whether treatment is effective, "many clinicians respond by developing a set of firmly held but unsupported beliefs in the merits of particular regimens. The primary treatment of advanced non-metastatic laryngeal cancer, for example, will usually be by surgery at certain treatment centres and by radiotherapy at others. Whether chemotherapy is given as well and, if so, what form it will take, are also determined more by the idiosyncrasies and outpatient arrangements of the particular treatment centre than by objective evidence of long-term efficacy. Similar examples could be taken from most areas of cancer therapy"²³.

Comparison of Survival After Treatments Based On Different Hypotheses

The best five-year survival statistics have been produced using therapies based on the hypothesis that cancer is a systemic disease, and tumours are only local symptoms. Therefore the cancer patient should be treated using a therapy designed to restore the body's own natural healing mechanisms.

After undergoing such a therapy "terminal" cancer patients showed a 16.6% five-year survival

compared with less than 5% expected with conventional therapies and a 15% fifteen-year survival compared with less than 1%. With pre-terminal patients there was an 85% five-year survival compared with about 50%²⁴.

Similarly a therapy designed to augment the body's own immune system is reported to have produced 50% five-year survival with 11 cases of peritoneal mesothelioma, a malignancy with an expected prognosis of about 12 months²⁵.

A third example is psychotherapy. A randomised study of 86 patients with metastatic breast cancer showed that a 90-minute weekly supportive group therapy session resulted in a doubling of survival from 19 months to 37 months²⁶.

Two other randomized trials of structured psychotherapy have produced similar dramatic improvements in survival^{27,28}.

These are further evidence that cancer is a systemic disease.

Conclusion

It is therefore clear that the claims that surgery, radiotherapy and chemotherapy are effective are invalid for most types of cancer. Yet dozens of trials, including some randomised ones, have been carried out that result in claims that these therapies are effective and save lives.

Can it be that all the scientific papers reporting on these results are scientifically unsound? Is medical science so badly organized that most of the results of their clinical trials are invalid?

To answer this question I quote from an editorial in the British Medical Journal in October 1991 - "Where is the Wisdom...? The poverty of medical evidence"

"...only about 15% of medical interventions are supported by solid scientific evidence... ..This is partly because only 1% of the articles in medical journals are scientifically sound²⁹".

For cancer the figure is about 6%, not 15%.

How is it that the peer review system, that determines which scientific papers are of sufficient quality to warrant publication, lets all these unsound papers through? To answer this question I quote from Tom Jefferson, from the Cochrane Collaboration's Methods Group interviewed by the Guardian (UK) in January this year. He said:

"If peer review were a medicine it would never get a license...We had great difficulty in finding any real hard evidence of the system's effectiveness, which is disappointing, as peer review is the cornerstone of editorial policies worldwide"³⁰.

I therefore I believe I have proved my case.

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