

Unconventional therapies for cancer: 6. 714-X



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on Alternative Therapies of the Canadian Breast Cancer
Research Initiative

This article on 714-X completes the series that reviews the evidence for the safety and effectiveness of 6 unconventional therapies commonly used by Canadian cancer patients. The purpose and methodology of the review appear in part 1 (CMAJ 1998;158[7]:897-902). Annotated bibliographies providing more detailed references are available in print from the Canadian Breast Cancer Research Initiative (CBCRI; address appears at end of article). [The annotated bibliography also includes references pertaining to the somatoscope developed by Gaston Naessens, creator of 714-X, and to Naessens' theories of the infective causes of cancer.] The reference lists and the lay summaries of the task force's findings on the 6 therapies (published in 1997) can be found on the CBCRI's Web site (www.breast.cancer.ca). The following article adapts the lay summary on 714-X for clinicians and provides references for the key findings. [Copies of this and other articles in the series can be found on CMAJ's Web site (www.cma.ca/cmaj/series/therapy.htm).]

The product 714-X was developed in Canada by Gaston Naessens, a French-born scientist and researcher who has worked out of a privately financed laboratory in Quebec for more than 30 years. Early in his career Naessens developed the "somatoscope," a specialized microscope that enabled him to examine fresh, unstained human blood at a significantly higher magnification than was possible with an ordinary light microscope.¹ (The later development of the electron microscope, which allows even higher magnification [although not of fresh, unstained blood and tissues], displaced interest in the somatoscope and other similar microscopes that used dark-field microscopy.)

Using his somatoscope to examine fresh blood from healthy individuals and those with various diseases, Naessens reported the presence of "somatids" in the blood of individuals with serious diseases, including cancer. He believed somatids to be living organisms distinct from bacteria and viruses, and he described 2 distinct life cycles for these organisms: a "microcycle" consisting of 3 forms, which he observed in healthy individuals, and a more complex "macrocycle" consisting of 16 forms which he usually observed in individuals with degenerative diseases, including cancer. He reports that at the different stages of the cycle, the form of the somatids may resemble bacteria, yeasts or fungi. He claims to be able to diagnose and monitor disease processes by observing the number and forms of somatids in the blood.

From his own research findings, Naessens developed the theory that the more complex macrocycle of the somatid occurs only when disease processes have damaged the immune system and altered the characteristics of intercellular fluids. He believes that, when stress or some other environmental factor initiates this macrocycle, the somatids start to secrete "toxic" substances and growth hormones (which he calls "trephones"). Naessens states that these substances disrupt normal cell metabolism and incapacitate immune cells, allowing many diseases to progress more rapidly. He believes that they also disrupt cell division and result in the proliferation of cells that are more primitive. Such cells, he reports, derive their energy anaerobically, act as "nitrogen traps" to deplete the rest of the body of nitrogen and may become cancerous over time. In addition, Naessens believes that cancer cells secrete "co-cancerogenic K factor" (CKF) and that this sub-

Education

Éducation

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The Canadian Breast Cancer Research Initiative does not endorse the use of any particular unconventional therapy. It urges patients to evaluate all evidence carefully and to consult their caregiver in order to make thoughtful and fully informed personal decisions.

This article has been peer reviewed.

CMAJ 1998;158:1621-4

THERAPIES EVALUATED IN THIS SERIES

1. Essiac (158[7]:897-902)
2. Green tea (158[8]:1033-5)
3. Iscador (158[9]:1157-9)
4. Hydrazine sulfate (158[10]:1327-30)
5. Vitamins A, C and E (158[11]:1483-8)
6. 714-X



stance further inhibits normal immune mechanisms.²

Naessens' theories about the underlying causes and mechanisms of cancer are clearly not consistent with current scientific opinion. Although a small number of researchers have long believed that certain bacteria, viruses and other organisms such as cell-wall deficient or pleomorphic bacteria play a much more important role in the development of cancer,³⁻⁶ this view is not generally accepted by mainstream scientists.

Although Naessens has developed a number of substances for use in the management of cancer and other conditions, the agent he currently makes available to cancer patients is 714-X. He believes that this agent interferes with the somatidian macrocycle, reverses the metabolic disruption caused by the somatids, permits recovery of the immune system and promotes disease regression. He also claims that it can decrease tumour size, increase appetite and improve an individual's overall sense of well-being.

The name "714-X" reflects Naessens' pride in his creation. The numbers "7" and "14" represent the seventh and fourteenth letters in the alphabet (Naessens' initials), and the "X", the 24th letter in the alphabet, represents the year of his birth (1924).

The base of 714-X is a camphor compound that has been chemically combined with extra nitrogen as well as ammonium salts, sodium chloride and ethanol. Camphor is a natural product derived from the shrub *Cinnamomum camphora*. Naessens selected camphor as the base because he believes it has a special affinity for cancer cells. He added nitrogen to satisfy the nitrogen requirements of cancer cells and thus prevent them from depleting the nitrogen in immune cells, which could then recover and fight disease again. He also considers that nitrogen-enriched camphor decreases the secretion of CKF by cancer cells. Naessens included ammonium salts because he believes they improve the circulation of lymph in cancer patients. He also believes that the ammonium salts activate certain kinins that inhibit abnormal cell growth and enhance the healthy functioning of the immune system.

714-X is prepared as a sterile, normal, solution. In Canada, it is available through Health Canada's Emergency Drug Release Programme on compassionate grounds.⁷ The Health Protection Branch has not received the documentation of 714-X's safety and efficacy required to approve it for general therapeutic use. Outside Canada, 714-X is available in Mexico and Western Europe but not in the US, where it is currently under investigation by the Food and Drug Administration. Current information on its availability in Canada can be obtained from the Centre expérimental de recherches biologiques de l'Estrie, Inc. (CERBE), in Rock Forest, Que. (www.cerbe.com/index.html).

714-X is usually administered by injecting it into the lymph nodes in the groin. Because this is an unusual route for drug administration, most health care providers will require special instruction to carry out the procedure safely. CERBE has videos and printed materials describing how to inject 714-X that are available for use by both patients and their caregivers. Intravenous or oral administration is not recommended. Recently, the distributors have advised that 714-X can sometimes be administered nasally using a nebulizer containing a solution of 0.6 mL of 714-X in 1.9 mL of saline. The nasal route has been recommended for patients with lung or oral cancers.

Each treatment cycle consists of a morning injection for 21 days followed by a 3-day rest period. At least 3 treatment cycles are usually recommended, but up to 12 may be suggested for patients with advanced cancer.

Naessens and his colleagues advise that 714-X can be used in conjunction with conventional therapies. However, they believe that it is more likely to be beneficial in patients who have not received chemotherapy or radiotherapy and recommend that it be given as early as possible in the course of the disease. They further advise that vitamin B₁₂, vitamin E supplements and alcohol should be avoided during treatment with 714-X.

Safety

714-X appears to cause few side effects, although local redness, tenderness and swelling at the injection site are common. No published reports were found of infection, local or systemic, associated with the use of 714-X. Animal studies have shown that 714-X is well tolerated, with minimal side effects.^{8,9}

Laboratory and clinical effectiveness

The Task Force on Alternative Therapies found it difficult to locate material pertaining to the history of, and rationale for, the development and use of 714-X. Much of the information was published by special interest groups and is not readily available. [The assistance of the manufacturer's staff who provided sources and copies of some of the background information is gratefully acknowledged.]

There have been very few published animal studies of the safety and effectiveness of 714-X, and those that have been conducted have shown no beneficial effect. A study carried out in 1982, the results of which were presented at a colloquium in Montreal, showed no significant side effects and no beneficial effects in rats with transplanted lymphosarcomas;⁹ however, the duration of treatment was short (less than 3 days), and the route of administration was intraperitoneal rather than intra-lymphatic. In an-



other unpublished study of the effectiveness of 714-X in comparison with conventional chemotherapy treatments in dogs with spontaneous lymphoma, there was no evidence of any improvement in response to the 714-X treatment; however, the investigators encountered several difficulties in the course of the study and could not complete it (Ronald Carter, Associate Professor of Pathology, McMaster University, Hamilton, Ont.: personal communication, 1996). These investigators also examined the use of 714-X in a small number of cows with spontaneous lymphoma, but no effect was noted. Naessens was critical of these studies and claimed that “real” 714-X had not been used.

Many individuals with cancer and other serious diseases such as AIDS have provided testimonials of the effectiveness of 714-X, describing how it helped them survive longer or improved their quality of life.¹⁰⁻¹² Many of these individuals felt so strongly about the benefits of 714-X that they assumed considerable personal cost and inconvenience to support Naessens in defending his practices against a variety of charges brought against him in Quebec.¹³

Although testimonials are interesting, they do not constitute reliable evidence of effectiveness. No reports of case series or clinical trials using 714-X were found. A “best case series” (complete data collection and follow-up on a limited number of cases considered by proponents to be their most convincing examples of success) was considered but not completed. Naessens and his colleagues report that they have tried to document the long-term experience of individuals who have received 714-X, but they have encountered difficulty obtaining the necessary data from patients and their caregivers.

Constituents of 714-X

A few animal studies using extracts of the shrub *C. camphora*, which is the natural source of camphor, have demonstrated some evidence of biological activity of potential value in the treatment of cancer. These include improvement of some measures of immune function,¹⁴ enhancement of enzymatic break down of carcinogens¹⁵ and increased susceptibility of cancer cells to radiation.¹⁶ However, research into the effects of camphor remains at an early stage, although the substance has been used as a folk medicine in centuries past. Taken internally, camphor may have serious toxic effects.¹⁷

Conclusion

714-X is being increasingly used, particularly in patients with breast and prostate cancer. Its formulation and administration are based on unconventional views about

the nature of cancer that have not been substantiated by mainstream researchers. Side effects appear to be minimal, but evidence of its effectiveness is limited.

This article reports some of the work carried out by the Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative (CBCRI). The CBCRI is the main funder of breast cancer research in Canada and was established in 1993 as a consortium of the Canadian Cancer Society (CCS), the National Cancer Institute of Canada (NCIC) — which also serves as the administrative home of the CBCRI — and the federal government (through the participation of the Medical Research Council of Canada and the National Health Research and Development Programme). In addition to the author, a number of other CBCRI staff worked on the project, including Dr. Carmen Tamayo (research associate), Ms. Rebecca McDonald and Ms. Jess Merber. Others contributed to the reviews of specific agents. The task force was chaired by Ms. Donna Cappon. Dr. Kaegi was the Director of Medical Affairs and Cancer Control for the CCS and the NCIC and staff partner with the task force.

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Peer-reviewed journals dealing with unconventional therapies:
Alternative Therapies in Health and Medicine
The Journal of Alternative and Complementary Medicine

General reference books and journals

Alternative medicine: expanding medical horizons: a report to the National Institute of Health on Alternative Medical Systems and Practices in the United States. Publ no NIH 94-066. Washington: National Institutes of Health; 1994.

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Lessons learned

The Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative (CBCRI) found the exercise of obtaining and evaluating the available literature on the 6 selected unconventional therapies frustrating but instructive. The information was very difficult to locate, and the quality of data was such that definitive conclusions could not be drawn about the safety or effectiveness of any of the therapies reviewed. Some indication of biological activity consistent with a potential value in the treatment of cancer was found for all of the therapies, but conclusive evidence that this activity did or did not translate into a clinical benefit was lacking. Both proponents and opponents tended to depend on results from inadequately designed studies to support their positions. Resolution of the conflicting views will have to await further research. The task force hopes that the annotated bibliographies of the literature reviewed will facilitate the work of investigators in this emerging field of research.

Next steps

After reviewing the literature and preparing the bibliographies, the CBCRI sponsored a workshop in Vancouver in October 1996 that explored the applicability of existing and innovative research methodologies to the evaluation of unconventional therapies. The value of randomized controlled trials was affirmed, but it was also recognized that the nature of some unconventional therapies precluded use of this study design and that modifications or other methods might be required. Ethical issues as well as approaches to ensuring collaboration in research projects by both conventional and unconventional health care providers as well as individuals with research expertise were discussed. The CBCRI approved a recommendation that it set aside some funds for a special research competition related to unconventional therapies. Since then, it has reviewed grant proposals for specific projects, using a peer-review process comparable to that used for its other breast cancer research projects. It announced the successful investigators and their projects on Mar. 27, 1998.

The public demand for reliable information about unconventional therapies continues to grow. High-quality research is needed to address outstanding questions, and tools are required to help physicians and patients communicate openly about these therapies. Meeting these needs effectively and efficiently will require the cooperation of organizations concerned with many different diseases and of provincial and federal government agencies. The CBCRI and the Canadian Cancer Society are pleased to have contributed to this effort.