Cancer Association of South Africa (CANSA)

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Fact Sheet and Position Statement On Insulin Potentiation Therapy

Introduction

Insulin potentiation therapy (IPT) is one of several unproven, dangerous and/or alternative treatments that are promoted by a group of medical practitioners without trustworthy evidence that it works. It is claimed to be effective against cancer, infectious diseases, arthritis, and many other conditions. Several patents have been issued, but patents are based on whether or not something appears to be original. Proof of effectiveness is not required.

[Picture Credit: Insulin Potentiation Therapy]

Insulin potentiation therapy is an experimental alternative cancer treatment using insulin as an adjunct to low-dose chemotherapy. IPT is closely related to Insulin Potentiation Targeted Low Dose (IPTLD). However, IPTLD is used specifically to treat cancer with 10–25% of the traditional dose of chemotherapy drugs. IPT is used to treat a variety of other chronic degenerative diseases in addition to cancer.

Alternative medicine or fringe medicine are practices claimed to have the healing effects of medicine but are disproven, unproven, impossible to prove, or only harmful. Alternative therapies or diagnoses are not part of traditional medicine or science-based healthcare systems. Alternative medicine consists of a wide variety of practices, products, and therapies - ranging from those that are biologically plausible but not well tested, to those with known harmful and toxic effects.

Insulin potentiation therapy involves administering insulin at the same time as chemotherapy drugs, with the idea that lower chemotherapy doses are then needed because insulin lets more of the drug enter cells. However, this has never been proven experimentally. There is no scientific evidence to support Insulin Potentiation Therapy. Insulin Potentiation Therapy is not effective in treating cancer.

Giovannucci, E., Harlan, D.M., Archer, M.C., Bergenstal, R.M., Gapstur, S.M., Habel, L.A. Pollak, M., Regensteiner, J.G. & Yee, D. 2010.
"Epidemiologic evidence suggests that cancer incidence is associated with diabetes as well as certain diabetes risk factors and diabetes treatments. This consensus statement of experts assembled jointly by the American Diabetes Association and the American Cancer Society reviews the state of science

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concerning 1) the association between diabetes and cancerincidence or prognosis, 2) risk factors common to both diabetes and cancer, 3) possible biologic links between diabetes and cancer risk, and 4) whether diabetes treatments influence risk of cancer or cancer prognosis. In addition, key unanswered questions for future research are posed."

Suh, S. & Kim, K.W. 2011. "Diabetes mellitus is a serious and growing health problem worldwide and is associated with severe acute and chronic complications. Moreover, epidemiologic evidence suggests that people with diabetes are at significantly higher risk for many forms of cancer. Several studies indicate an association between diabetes and the risk of liver, pancreas, endometrium, colon/rectum, breast, and bladder cancer. Mortality is also moderately increased in subjects with diabetes. Common risk factors such as age, obesity, physical inactivity and smoking may contribute to increased cancer risk in diabetic patients. Hyperinsulinemia most likely favors cancer in diabetic patients as insulin is a growth factor with pre-eminent metabolic as well as mitogenic effects, and its action in malignant cells is favored by mechanisms acting at both the receptor and post-receptor level. The effect of diabetes treatment drugs, aside from metformin, on cancer is not conclusive. In order to fight the perfect storm of diabetes and cancer, strategies to promote primary prevention and early detection of these conditions are urgently needed."

Pandey, A., Forte, V., Abdallah, M., Alickai, A., Mahmud, S., Asad, S. & McFarlane, S.I. 2011.
"Although diabetes has been known to increase the risk of cancer for over a century, it was not until recently when this area gained momentum and generated a lot of interest. That is in- part because of the rising global diabetes epidemic and the wide spread use of insulin analogues, metformin and other anti-diabetic agents, providing hypothesis generating data on the cancer risk in the diabetic population. Type 2 diabetes is associated with increased risk of breast, colon, pancreatic and other types of cancer, while type 1 diabetes is associated with increase in stomach, pancreatic, endometrial and cervical cancer. Mechanisms postulated for increased cancer risk in diabetes include hyperglycemia, hyperinsulinemia with stimulation of IGF-1 axis, obesity that serves as a common soil hypothesis for both cancer and diabetes as well as other factors such as increased cytokine production. More recently some antidiabetic agents have been thought to increase cancer risk such as insulin glargine, while metformin appears to lower cancer risk. In this review, we present the evidence for the link between diabetes and cancer highlighting the general mechanisms proposed for such a link as well as specific hypotheses for individual cancer. We will also discuss the role of insulin, metformin and other antidiabetic agents in cancer risk."

Vigneri, R., Goldfine, I.D. & Frittitta, L. 2016.
"Insulin is a major regulator of cell metabolism but, in addition, is also a growth factor. Insulin effects in target cells are mediated by the insulin receptor (IR), a transmembrane protein with enzymatic (tyrosine kinase) activity. The insulin receptor, however, is represented by a heterogeneous family of proteins, including two different IR isoforms and also hybrid receptors resulting from the IR hemireceptor combination with a hemireceptor of the cognate IGF-1 receptor. These different receptors may bind insulin and its analogs with different affinity and produce different biologic effects. Since many years, it is known that many cancer cells require insulin for optimal in vitro growth. Recent data indicate that: (1) insulin stimulates growth mainly via its own receptor and not the IGF-1 receptor; (2) in many cancer cells, the IR is overexpressed and the A isoform, which has a predominant mitogenic effect, is more represented than the B isoform. These characteristics provide a selective growth advantage to malignant cells when exposed to insulin. For this reason, all conditions of hyperinsulinemia, both endogenous (prediabetes, metabolic syndrome, obesity, type 2 diabetes before pancreas exhaustion and polycystic ovary syndrome) and exogenous (type 1 diabetes) will increase the risk of cancer. Cancer-related mortality is also increased in patients exposed to

hyperinsulinemia but other factors, related to the different diseases, may also contribute. The complexity of the diseases associated with hyperinsulinemia and their therapies does not allow a precise evaluation of the cancer-promoting effect of hyperinsulinemia, but its detrimental effect on cancer incidence and mortality is well documented."

Damyanov, C., Gerasimova, D., Masley, I. & Gavrilov, V. 2012.
Purpose. To evaluate the results and quality of life of patients with resistant of castration-resistant tumors previously treated with Insulin-potentiation therapy (IPT) combined with hormone therapy.
Materials and methods. Sixteen patients with metastasis prostate tumors after bilateral castration, androgenic blockade, and progression of the disease were observed during the study. The patients were divided into two groups: group A consisting of 8 patients treated with low-dose chemotherapy Epirubicin, Vinblastine, and Cyclophosphamide combined with LHRH agonist and group B consisting of another 8 patients treated with low-dose chemotherapy Docetaxel combined with LHRH agonist.
Results. The overall (groups A and B) results concerning PSA after the sixth IPT show partial effect in 8 out of 16 (50%) patients, stabilization in 4 out of 16 (25%), and progression in 4 out of 16 (25%). The median survival for all treated patients is 11,7 months (range 3–30 months). During the treatment no significant side effects were observed, and no lethal cases occurred.
Conclusion. In spite of the small number of the treated patients with castration-resistant prostate tumors, the preliminary results are promising and this gives us hope and expectations for future serious multicenter research over the possibilities for routine implementation of IPTLD.

Background History of Insulin Potentiation Therapy (IPT)
Insulin potentiation therapy (IPT) is based on the notion that intravenous insulin increases the effect of medications so that lower doses can be used. Its promoters suggest that somehow the insulin 'opens the pores' of cells throughout the body so that certain drugs enter more easily. It is used mainly for treating cancer. The leading proponent is Stephen Ayre, M.D., of Burr Ridge, Illinois, who coined the treatment's name in 1986. In 2003, his Web site stated:

The treatment ... features an innovative low-dose chemotherapy protocol called Insulin Potentiation Therapy (IPT) that uses 75-90% less chemotherapy than the traditional treatment to destroy cancer cells. This low dose treatment causes little to none of the negative side effects such as loss of appetite, nausea, hair loss and fatigue.

[Picture Credit: Dr Donato Perez Garcia]

IPT was developed in Mexico City in 1932 by Dr Donato Perez Garcia, Sr. and was used by him for decades to treat a wide variety of cancers, including cancers of the breast, lung and prostate. His son, Donato Perez Garcia Bellon, M.D., and his grandson, Donato Perez Garcia, Jr., M.D, followed Dr Garcia in this work. Collaborating with these two physicians over several years, Dr Ayre studied and researched IPT, resulting in their publication of articles on the therapy in medical journals.

It is claimed that cancer cells have 20 times more insulin sensitive receptors than normal healthy cells. By introducing insulin into the body before the chemotherapy drugs, the insulin highlights the cancer cells due to their higher insulin receptor content, and selectively enhances their absorption of the

chemotherapy. Less chemotherapy is needed to kill the cancer cells, with less dose related side effects. Glucose is given to counter insulin's other effect of lowering blood sugar.

IPT is performed by injecting insulin into the patient's vein. After the blood sugar falls, the practitioners rapidly inject chemotherapy drugs in doses that are below the amounts that have been proven effective. Immediately thereafter, a strong sugar solution is injected to arouse the patient. In some cases, several chemotherapy agents are mixed together even though one or more may not have been validated in full doses for the patient's tumour. This procedure is typically performed in medical offices where resuscitation equipment and training are minimal to non-existent.

The practitioners who perform this are 'trained' in two-day courses and 'licensed' to perform IPT. In 2003, about 100 were listed in the directory on IPTO.org and one practitioner's Web site quoted a cost of US$15,500 to US$17,500 for 3 to 4 weeks of 'intensive' IPT therapy plus US$2,000 to US$3,000 per week additional for up to 4 weeks of 'home maintenance therapy'. About half of the 69 listed doctors who practiced in the United States also offered chelation therapy, which is equally disreputable.

Proponents claim that IPT is free of side effects, however, a rapidly falling blood sugar level can produce coma, shock, stroke, and even death, and it is also known of at least one case where the patient got side effects from the chemotherapy. In 2003, Ayre's Web site further stated:

Steven G. Ayre, M.D., has spent twenty-seven years single-handedly researching, publishing, and speaking at meetings on the science of Insulin Potentiation Therapy. He began practicing IPT in the United States in 1997, after he had become convinced, due to his lengthy study, that this therapy was a much improved way of using chemotherapy. In September of 2000, Dr Ayre and his colleagues made a presentation before the Cancer Advisory Panel of the National Center for Cancer Complementary and Alternative Medicine at the National Institutes of Health in Bethesda, Maryland. This meeting has led to a collaborative effort with cancer researchers at the Comprehensive Cancer Center at the University of Wisconsin, Madison, to design and perform clinical trials on IPT. The funding is provided by the National Cancer Institute. Because of the perceived patient need, and because all drugs used in the therapy are already FDA approved, IPT treatments are now being made available to persons here in the USA. Good patient reimbursement by health insurers is the rule.

This statement is very misleading. Ayre's 'researching' and 'lengthy study' did not include any appropriate study to test whether IPT worked. Nor has the clinical trial to which the passage refers been carried out. To maintain FDA approval for a clinical study it is necessary to have approval from an Institutional Review Board. The 'review board' that approved the study was composed of dubious practitioners (most of whom promote chelation therapy) and was ordered to shut down in January 2001 after the FDA concluded that it was run improperly. In retrospect, it appears that the board and the proposed study were part of a scheme to make patients think they were part of a legitimate study.

IPT is often described as an 'off label' use of insulin, with a claim that this is 'allowed'. This description is not quite accurate. The FDA only regulates the sale of products that cross state lines, and approves labelling of drug products for particular uses. Violation of those uses can result in seizure of products and stoppage of further sales. However, under some circumstances a physician can take a drug licensed for one use and use it for another or may use dosages higher than those on the label. This concept is not a wide open door to illicit use; nor can it be used to justify non-approved 'research' that lacks a rational basis.

Registered physicians are expected to conform to a standard of care and do what is clinically acceptable and safe. IPT does not fit this description. No major medical school, hospital, or other institution has embarked on a clinical trial, largely because the 'therapy' is dangerous, potentially lethal if too much insulin is administered, and does not a have a sound biological basis.

Insulin Potentiaton Therapy (IPT) Practitioners in South Africa

There are currently several medical practitioners as well as at least one clinic in South Africa that is listed on the internet for Insulin Potentiation Therapy (IPT).

CANSA's Position on Insulin Potentiation Therapy (IPT)

The Cancer Association of South Africa (CANSA) warns individuals diagnosed, or living, with cancer about false promises that are made about Insulin Potentiation Therapy (IPT). There are periodic campaigns to present IPT as a breakthrough in cancer therapy. Some desperate cancer patients have grasped at this treatment, especially when conventional treatment has failed to arrest the growth of their cancers – without evidence that IPT worked for them.

CANSA advises patients to discuss Insulin Potentiation Therapy (IPT) with their treating physician/Oncologist prior to consulting any practitioner who offers this therapy.

Further Reading

Individuals interested in additional information regarding Insulin Potentiation Therapy (IPT), can consult the following sources:

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- Dr. Ayre. Contemporary Medicine Website.
- Duffield, C. My IPT story. (A 5-part series of articles.) IPTQ.org Website.
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- Insulin potentiation therapy. BlueCross of California medical policy #DRUG00034.
- Insulin-induced enhancement of antitumoral response to methotrexate in breast cancer patients. Cancer Chemotherapy and Pharmacology 53:220-224.
- Local physician to present findings on innovative cancer treatment to the Cancer Advisory Panel at the National Institutes of health. Contemporary Medicine Website.
- Mathieu, M.C. and others. Insulin receptor expression and clinical outcome in node-negative breast cancer. Proceedings of the Association of American Physicians 109:565-57.

- Minutes of the Third Meeting of the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM).
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- Onco. IPTQ.org Website.
- Papa, V. and others. Insulin-like growth factor-I receptors are overexpressed and predict a low risk in human breast cancer. Cancer Research 53:3736-3740, 1993.
- Therapy costs. Integrated Medical Specialists Website.

Medical Disclaimer

This Fact Sheet and Position Statement is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet and Position Statement. So far as permissible by law, the Cancer Association of South Africa (CANSA) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet and Position Statement.

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Sources and References Consulted or Utilised

Damyanov, C., Gerasimova, D., Masley, I. & Gavrilov, V. 2012. Low-dose chemotherapy with insulin (insulin potentiation therapy) in combination with hormone therapy for treatment of castration-resistant Prostate Cancer. *ISRN Urol*. 2012; 2012: 140182.

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Insulin Potentiation Therapy
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Memorial Sloan Kettering Cancer Center
https://www.mskcc.org/cancer-care/integrative-medicine/herbs/insulin-potentiation-therapy

Pandey, A., Forte, V., Abdallah, M., Alickai, A., Mahmud, S., Asad, S. & McFarlane, S.I. 2011. Diabetes mellitus and the risk of cancer. *Minerva Endocrinol*. Minerva Endocrinol. 2011 Sep;36(3):187-209.

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Wikipedia
https://en.wikipedia.org/wiki/Alternative_medicine
https://en.wikipedia.org/wiki/Insulin_potentiation_therapy