MEDICOR CANCER CENTRES

DCA (dichloroacetate) Frequently Asked Questions Updated Sept 12, 2012

Medicor Cancer Centres was the first cancer clinic in North America to begin prescribing DCA "off label" to cancer patients (in April 2007) under the full supervision of a medical team. We consulted with the relevant regulatory bodies in Canada and have been following their guidelines and policies. We would like to thank everyone who has expressed an interest in our DCA therapy. We appreciate your feedback and encouragement. We would also like to acknowledge and extend a special thanks to two of our patients who brought DCA to our attention, and motivated us to begin DCA treatments. As of this latest update of FAQ, we have treated over 1100 patients with DCA. This is greater than the sum of all patients in *all* of the human DCA clinical trials that have *ever* been conducted (both cancer and non-cancer) put together! Even though we are not conducting a clinical trial, the experience gained by treating over 1000 patients is extraordinary, and helps us to use DCA more safely and effectively.

Background
In 2007 it was discovered that the drug DCA (dichloroacetate sodium) induced the death of human breast, lung and brain cancer cells that were implanted into rats, while being non-toxic to healthy cells. This research was published in *Cancer Cell, 11, 37–51, January 2007*. DCA has been found to kill cancer cells by a newly discovered mechanism that appears to be common to several types of cancer. DCA works by turning on the natural cell suicide system (called apoptosis) which is suppressed in cancerous cells, thus allowing them to die on their own. DCA does not poison the cells like cytotoxic chemotherapy drugs. DCA also interferes with the cancer cell's use of glucose, starving the cell of energy. At the same time, it does not starve healthy cells in the body of glucose.

DCA research has accelerated in the last 2 years. The latest research shows that DCA also kills many types of cancer cells, and can boost the cancer-killing effects of radiation. The first formal human cancer research using DCA was published in May 2010. It confirmed that DCA is an effective anti-cancer drug for treating glioblastoma patients (*Metabolic Modulation of Glioblastoma with Dichloroacetate, Science Translational Medicine, Vol 2, Issue 31*).

MEDLINE is the largest medical database in the world, and contains information on published DCA research. This database can be searched free of charge for those interested in reading DCA research, or at least the summaries of the DCA publications: http://www.ncbi.nlm.nih.gov/pubmed?term=dichloroacetate%20cancer

Further research to determine how well DCA works against various cancers within the human body is ongoing: http://clinicaltrials.gov/ct2/results?term=dichloroacetate+cancer

What types of cancers does DCA work on?
Several publications demonstrate that DCA works in a variety of cancers. These include human studies / case reports and lab studies (rat and *in vitro*). The cancer types studied so far are: colon, breast, prostate, ovarian, brain (neuroblastoma), brain (glioblastoma), lung (carcinoid), uterus (cervix), uterus (endometrial), lymphoma (non-Hodgkins), and cancer of unknown primary.

Observational DCA Data
For the first time in the world, on Dec 7, 2007 we publicly shared our observational data from the treatment of our first 118 cancer patients with DCA. We updated our data in 2009 from treating over 347 patients. This can be found at: http://www.medicorcancer.com/dca-data.html. Since clinical trial data is now emerging, we are no longer collecting observational data. Instead, we are focusing our efforts on publishing our findings in reputable peer-reviewed medical journals. Our first publication is: "Use of Oral Dichloroacetate for Palliation of Leg Pain Arising

from Metastatic Poorly Differentiated Carcinoma: A Case Report." This can be viewed here: http://www.liebertonline.com/doi/pdfplus/10.1089/jpm.2010.0472

We have papers currently being written on angiosarcoma, malignant fibrous histiocytoma, cervical carcinoma, renal squamous cell carcinoma, T-cell lymphoma, colon adenocarcinoma, glioblastoma, ovarian carcinoma, small cell lung carcinoma, Bartholin's gland carcinoma and pancreatic neuroendocrine carcinoma. We are excited by these results and hope to begin publication of these papers in the next few months.

Is DCA natural?
DCA is a synthetic drug, but it is a very simple compound similar to a chemical combination of salt and vinegar. It works against cancer in a natural way (by triggering natural cell suicide).

Is DCA safe?
DCA has been used in humans to treat a rare disease called "congenital lactic acidosis", and found to have some mild to moderate side effects. Our experience so far suggests that DCA is safe to use in cancer patients under close medical supervision. Some animal studies show that DCA can itself cause liver cancer. These studies used doses which are much higher than what would be prescribed for cancer treatment. Also, no human study has every demonstrated liver tumour formation as a result of DCA therapy. We have observed that DCA can have 2 main categories of side effects.

Neurological:

Nerve injury in the hands and feet ("peripheral neuropathy"). Neuropathy typically takes several weeks to months to develop, and is reversible if it is caught early. In the existing literature, neuropathy from DCA has always been shown to be reversible. We use vitamin B1 (benfotiamine or thiamine), acetyl L-carnitine and R alpha lipoic acid to prevent and reduce the severity of peripheral neuropathy. These medicines can be given orally or intravenously depending on the degree of neuropathy. Published data clearly demonstrates all of these medicines can help chemo and/or diabetic neuropathy, and our own extensive experience confirms that these supplements are effective for DCA neuropathy as well.

Sedation, confusion, hallucinations, memory problems, mood changes, hand tremors. These side effects are temporary and appear to be dose-dependent and age-dependent. This finding is consistent with existing human research on DCA that we have reviewed. We use benfotiamine (a type of vitamin B1), acetyl L-carnitine and R alpha lipoic acid to prevent/reduce these side effects. If you are a Medicor patient, you will receive our latest dosing guidelines for these supplements. Due to potential interference with other ongoing treatments like radiation or chemotherapy, certain supplements may not be recommended, or may have to be skipped during part of the radiation or chemo treatment. Medicor patient will receive detailed information specific to their treatment plan.

Gastrointestinal:

Heartburn, nausea, vomiting, indigestion. These side effects may occur with DCA, and we prescribe a "proton pump inhibitor" antacid medication (e.g. pantoprazole) as needed to treat them.

Other Side Effects:
Some patients experience pain at the sites of their tumour(s) within the first few days of starting DCA. This may be an indicator of the effectiveness of DCA. About 1-2% of patients have mild liver toxicity (increase in liver enzymes noted without symptoms). We have not observed any drop in blood cell counts due to bone marrow toxicity, or any other significant organ toxicity. Note that leukemia patients may see a drop in their high white blood cell count, indicating destruction of the cancerous white cells.

Most side effects reported so far have been mild or moderate. Patients experiencing moderate side effects are usually taken off DCA as a precaution. Most side effects typically resolve within days after stopping DCA. Neuropathy can take weeks or months to resolve, and is reversible.

I see DCA for sale online from various merchants. Is it of good quality and safe?
DCA is a prescription drug in Canada, USA and through most of Europe. It cannot legally be sold as a medication unless it is under a doctor's prescription. Lab grade DCA is sold legally online from various chemical

manufacturers and is not suitable or approved for human consumption. Various online merchants have attempted to bypass FDA and Health Canada regulation by selling DCA capsules online to anyone without a prescription. This is not permitted by law in North America. Buyers should be aware that these companies are not regulated and may be selling fake DCA. We have no knowledge of whether the product being sold is DCA, or what the purity is. One online merchant has already been convicted of fraud and is serving a jail term for selling fake DCA to cancer patients: http://www.financialfraudlaw.com/lawblog/counterfeit-cancer-drugs-canada-go-jail/1378

If these merchants are selling DCA illegally, we wonder what other illegal activity they are engaged in (e.g. selling fake, "home-made" or impure DCA). This is the extent of our knowledge on DCA internet sales. *Please do not ask Medicor staff for advice on use of DCA purchased online!* We are not able to answer questions about unknown products.

TLS (Tumour Lysis Syndrome)
This is a condition in which a large number of tumour cells are rapidly killed, causing a sudden release of the contents of the dead cells into the bloodstream. It can result in abnormal heart rhythms, salt imbalance in the blood and kidney failure. A detailed reference article can be found here: http://www.emedicine.com/MED/topic2327.htm TLS occurs most commonly in patients with a large mass of tumour cells in the body who receive chemotherapy, especially with lymphomas or acute leukemia. We have not had a single case of TLS in our patients treated with DCA alone. Since DCA can enhance the effect of chemotherapy in certain cases, it may be more likely to occur if DCA is combined with chemotherapy (especially without medical supervision). We have noticed that intravenous DCA can work more quickly than oral DCA in some cases, so there is theoretically more risk of TLS. Still, we have not observed any cases of TLS with iv DCA so far after 1 year of use.

DCA and Renal Failure
DCA is not toxic to the kidneys. DCA can safely be used in patients with moderately severe renal failure based on our experience.

DCA and Heart Failure
DCA is safe to use in patients with heart failure. DCA improves the pumping efficiency of the heart without increasing oxygen demand. As a result, it can improve heart failure or angina.

DCA and Heart Rhythm Disturbance
DCA shortens the QT interval which is an electrical measurement of the heart determined by ECG. Combination with drugs that prolong the QT interval is therefore unlikely to cause abnormal heart rhythms. Rather, DCA may prevent abnormal heart rhythms.

DCA and Liver Failure / Jaundice
DCA is metabolized by the liver, so dose adjustment is needed for patients with liver failure. Also a difference cycles may be needed. Intravenous DCA is likely safer than oral DCA for patients in liver failure.

DCA and Diabetes
Diabetics may notice a slight improvement in blood glucose control. Diabetes medications generally do not have to be changed, but blood glucose monitoring will determine if adjustment is required.

DCA-Drug Interactions
We have observed that drugs that can cause confusion or hallucinations have a potential to interact with DCA. This may include cannabinoids, benzodiazepines and other CNS drugs, especially if they are already causing some neurological side effects. Patients on stable doses of opiate pain medications or benzodiazepines who are not having side effects from these drugs rarely have such issues.

DCA and Caffeine
We have received a large number of inquiries about caffeine following some anecdotal reports of enhanced DCA effect with excessive tea/caffeine intake. After conducting a limited review of our DCA patients, we have noted that a few patients with high tea/caffeine consumption (> 10 cups per day) have shown no response to DCA. Also

many patients who have shown an excellent response to DCA do not take tea/coffee or caffeine or take it in minimal amounts.

There are a number of potential harmful effects of consuming high doses of caffeine including increased likelihood of seizures in brain tumour patients, abnormal heart rhythms, anxiety, and insomnia. Even though there is new data to show that intravenous high dose caffeine can enhance chemotherapy, the potential for caffeine to enhance DCA therapy is unverified. We are presently recommending against the use of high dose caffeine, unless it is done with medical supervision. Patients should use moderation with consumption of caffeinated drinks and check with their own doctor, naturopath or dietician for specific advice.

DCA and Chemotherapy
For the first time in North America, Medicor and AccuTheranostics www.act-inc.net (previously known as ORT) began conducting ChemoFit tests with DCA and chemo combined (2008). Eligible patients were able to have a sample of their own tumor analyzed to see if combinations of DCA and chemo were effective, and if they worked better than chemo or DCA alone. The accuracy of the ChemoFit test ranges from 85-95%.

We have already had some exciting results showing that DCA can, in some cases, dramatically enhance the cancer-killing effects of chemo, rarely to the point of cure (estimated 0.5% chance of cure). However, there is a possibility that DCA can interfere with chemo as well. This is similar to single agent chemo being better than combination chemo for some patients. Published lab research now confirms our findings.

If you are a patient who is thinking of combining DCA and chemotherapy, we recommend you contact Dr. Bradford or Dr. Thakur at AccuTheranostics www.act-inc.net for information.

The best time for a ChemoFit test to be done is at the time of cancer surgery. If you have already had surgery, but you have an accessible tumour, it can be biopsied by your surgeon for the ChemoFit test. Malignant ascites fluid samples and malignant pleural effusion samples can now be tested with ChemoFit, eliminating the need for a biopsy in some patients. If you are not able to have the ChemoFit test, a treatment plan can be developed to safely combine DCA with most chemotherapy drugs with minimal risk of interference (depending on the chemotherapy schedule).

What is the status of DCA clinical trials?
The first phase 2 clinical trial of DCA in glioblastoma was completed but was not published as a trial, possibly because the DCA doses were too high and resulted in a large number of patients dropping out (our opinion, actual reason not disclosed by the authors). See http://www.medicorcancer.com/news.html for detailed commentary on this trial.

Several DCA clinical trials are presently ongoing. These can be reviewed at:
http://clinicaltrials.gov/ct2/results?term=dichloroacetate+cancer
Even though we have seen clear evidence of DCA's effectiveness in several types of cancer, Medicor physicians believe that it is necessary for formal clinical trials to be conducted. DCA is different from other drugs that undergo clinical trials because it is not a "new" drug. It has already been used for decades in humans, and has a relatively safe profile. This means that the trials may take less time, but may still take years. Many cancer patients cannot wait this length of time. We are hopeful that information obtained from our experiences with DCA will supplement clinical trials, and help patients and the medical community.

There is a publication that says DCA increases the growth of colon cancer. Is that correct?
There is a publication which reports that DCA enhances the survival of colon cancer cells. This paper is flawed because the researchers looked at the effects of DCA on cancer cells with a complete absence of oxygen (anoxia). While hypoxia (low oxygen) may be common in tumours, anoxia (complete lack of oxygen) is not a normal situation. In very rapidly growing tumours, there will be areas of anoxia, however colon cancer generally does not behave that way. In summary, we believe our clinical findings from treating actual patients are more meaningful than this lab study done under artificial conditions. DCA (both oral and intravenous) can be an effective treatment for colon cancer based on our extensive clinical experience. DCA can cause symptom improvement, tumour shrinkage, tumour stability, or reduction in the colon cancer blood marker CEA.

Do I Qualify for DCA Treatment?
Patients with a documented diagnosis of cancer (any type) under the following categories qualify for treatment:

a. failed conventional, scientifically proven treatments
b. told by their doctor that there is no safe or effective treatment for their cancer
c. waiting to start conventional treatment, and would like to do something in the interim
d. treated for cancer, and would like to prevent recurrence (where no proven recurrence prevention is available)
e. receiving therapy which has a poor chance of success and would like to strengthen their treatment
f. reviewed conventional therapies with the oncologist (or other specialist) and declined them voluntarily after fully understanding the risks and benefits

How is DCA administered?
DCA is currently available in 4 formulations: cream, oral liquid, oral capsules, intravenous. Oral DCA can be taken at home, DCA i.v. can be administered at the Medicor office or at the office of a naturopathic doctor who is certified to administer iv medications.

What is the duration of treatment?
In order to determine if DCA is effective in treating your cancer, we recommend at least 6 to 8 weeks of treatment. For slow growing cancers, longer treatment is needed, perhaps 3 - 6 months. If your cancer responds to the drug, therapy may continue indefinitely. If you experience significant side effects, treatment will be stopped and may be restarted later.

Is DCA available?
Yes. We obtain certified pharmaceutical grade DCA for our patients from a reputable GMP certified multi-national chemical company. We never obtain DCA made in China or India despite the lower price, and claims of GMP / pharmaceutical quality. We have clearance from the relevant Federal and Provincial regulatory bodies to obtain and dispense DCA. It is compounded into capsules for us by a licensed pharmacist, and dispensed from a local pharmacy to our patients. DCA can only be dispensed to patients who come under the care of our medical team.

I don't live near Toronto, can I still be treated?
Yes, you can come to our clinic to be evaluated, and begin treatment. After that, you may return home to continue treatment under supervision by your naturopathic doctor, family doctor or oncologist. If you are unable to travel, please call or email us to discuss your options. Telemedicine consultation and ongoing care are available.

How do I become a Medicor patient?
Please obtain your pathology report confirming the diagnosis of cancer type (if applicable), your latest CT scan or MRI (if applicable), and your latest blood test report. If you do not have a pathology report (e.g. if you did not have a biopsy), we require some documentation confirming the diagnosis of cancer.

You can call us at (416) 227-0037 or email us at info@medicorcancer.com to make an appointment to discuss your individual case. We will do our best to respond to your request promptly. A valid Health Card from any province (except Quebec) is required for a free consultation. Patients from Quebec must pre-pay for consultation since the Minstere de la Sante does not properly pay Ontario doctors for insured services. Insured patients are only required to pay for the medication, as it is not covered by Ontario Drug Benefits.

Please note that the Ontario College of Pharmacists requires the use of pharmaceutical grade DCA. Therefore, we are presently treating patients using our own verified source of compounded pharmaceutical grade DCA capsules. ***Regrettably, we cannot take responsibility for treatment of patients wishing to bring their own DCA. In this case, we can only provide consultation services to assist you or your physician(s).***