

Progress on Therapy of Breast Cancer with Vitamin Q₁₀
and the Regression of Metastases

Knud Lockwood,⁺ Sven Moesgaard,[#] Tatsuo Yamamoto*
and Karl Folkers*

⁺Malmøgade 5, Copenhagen, Denmark

[#]Pharma Nord, Vejle, Denmark

*Institute for Biomedical Research, University of Texas at Austin,
Austin, Texas 78712

Received May 8, 1995

ABSTRACT: Over 35 years, data and knowledge have internationally evolved from biochemical, biomedical and clinical research on vitamin Q₁₀ (coenzyme Q₁₀; CoQ₁₀) and cancer, which led in 1993 to overt complete regression of the tumors in two cases of breast cancer. Continuing this research, three additional breast cancer patients also underwent a conventional protocol of therapy which included a daily oral dosage of 390 mg of vitamin Q₁₀ (Bio-Quinone of Pharma Nord) during the complete trials over 3-5 years. The numerous metastases in the liver of a 44-year-old patient "disappeared," and no signs of metastases were found elsewhere. A 49-year-old patient, on a dosage of 390 mg of vitamin Q₁₀, revealed no signs of tumor in the pleural cavity after six months, and her condition was excellent. A 75-year-old patient with carcinoma in one breast, after lumpectomy and 390 mg of CoQ₁₀, showed no cancer in the tumor bed or metastases. Control blood levels of CoQ₁₀ of 0.83-0.97 and of 0.62 µg/ml increased to 3.34-3.64 and to 3.77 µg/ml, respectively, on therapy with CoQ₁₀ for patients A-MRH and EEL. © 1995 Academic Press, Inc.

INTRODUCTION: A review of the biochemical and biomedical research on vitamin Q₁₀ and cancer has been submitted¹. This review covers 35 years of international research on animals and humans which revealed variable levels of vitamin Q₁₀ in non-tumor and tumor tissues and includes data on vitamin Q₁₀ which are intrinsic to the host defense system as based on increased

survivors of treated mice with tumors. The potential of vitamin Q₁₀ for therapy of human cancer became evident in 1961. The blood levels of CoQ₁₀ in a total of 199 Swedish and American cancer patients revealed variable levels of deficiencies of CoQ₁₀ and with a deficiency of CoQ₁₀ in the cases of both Swedish and American cases of breast cancer being the most statistically significant.^{2,3}

Folkers et al.⁴, 1993, described the survival of ten American patients having diverse cancer for five to fifteen years, and emphasized that six of these patients became free of cancer during therapy with vitamin Q₁₀. These diverse six regressions are impressive.

Lockwood et al.⁵, 1993, described the overt, complete regression of breast cancer in two patients during therapy with vitamin Q₁₀ (Bio-Quinone of Pharma Nord). Such regressions were considered to be a potential new therapy of cancer as based on the fundamental biochemistry of human metabolism, particularly in bioenergetics. Although spontaneous regressions of breast cancer are believed to be possible, this overt complete regression of breast cancer in these two "high-risk" cases was interpreted to have occurred because of the treatment with vitamin Q₁₀. Additional cases of the regression of breast cancer are critically needed, and three additional such cases and regressions are described herein. One of these three additional cases had metastases, which were derived from the intraductal carcinoma in the breast, and which disappeared during the therapy with 390 mg., daily, of vitamin Q₁₀. No signs of metastases were found elsewhere in this patient.

Cancer metastases in the liver can be regarded as a prelude to imminent death. The apparent regression of metastases in the liver of patient A-MRH is of such unique importance that this account is timely.

It is known that as a tumor metabolizes, cells are shed within the efferent circulation and cause independent tumor nodules, or metastases. In humans, circulating tumor cells have been identified in an early stage of breast cancer. It has been estimated that a single circulating tumor cell will become a metastatic nodule on the basis of 1 million:1. Therefore, our recording of the disappearance of liver metastases in even one patient having breast cancer is extraordinarily salient for urgent further research.

Breast Cancer, Case Report A-MRH. - A 44-year old woman had a bilateral mastectomy performed in September, 1992, in the right armpit (axilla). There were metastases in 2 out of 12 lymph nodes. No metastases were found in the left axilla. Microscopic examination demonstrated an invasive intraductal carcinoma of the breast on both sides. The tumors were estrogen receptor positive. The patient underwent a series of 10 treatments with cyclofosfamide, methotrexate and 5-fluorouracil. A bilateral breast reconstruction was performed in January, 1994. After this reconstruction, the patient was examined by an echography of the liver, April 8, 1994. This examination revealed numerous metastases in the liver. A fine needle biopsy showed metastases from an intraductal carcinoma of the breast. Treatment was supplemented with tamoxifen, 30 mg. daily. Since the mastectomy, and after the liver metastases, the dose of CoQ₁₀ was increased to 390 mg. daily. Echoscans of the liver were repeated in August, 1994, November, 1994, and March 1, 1995. This last echogram showed that the liver metastases had disappeared. The patient is in excellent condition in April, 1995, and no signs of metastases have been found elsewhere.

Breast Cancer, Case Report, EEL. - A 49-year old woman had a right-sided mastectomy performed in May, 1990. In May, 1991, she developed a recurrence of the tumor on the chest wall. The diagnosis was intraductal carcinoma of the breast. After the removal of the metastases, the patient received X-ray treatment, because the recurrent chest wall tumor could not be removed radically. The X-ray dosage was 66-68 g-ray. In January, 1992, the patient had fluid in the right pleural cavity which contained tumor cells which stemmed from the carcinoma of the breast. In January of 1992 she was started on 90 mg. of CoQ₁₀. In December, 1992, the dose of CoQ₁₀ was increased to 390 mg. Six months later, an X-ray of the chest showed normal conditions, i.e., no fluid in the pleural cavity. The patient's condition was excellent. On March 31, 1995, no signs of recurrence could be found.

Breast Cancer Case Report, SP. - A 75-year old woman allowed a biopsy which revealed a lobular carcinoma of the breast and dispersed intraductal carcinoma, in situ. A right-sided lumpectomy was performed. Microscopy revealed that tumor tissue had been left in the breast after surgery. In January, 1992, the patient had a right-sided mastectomy, because of fear of an eventual spread of the carcinoma to be caused by the non-radical surgery. She was treated with a dosage of 90 mg. per day of Bio-Quinone (Pharma Nord, Denmark) beginning in November, 1991. The mastectomy was in January, 1992. After December, 1992, the dosage of Q₁₀ was increased to 390 mg. daily, and is still in progress, and histology did not reveal any signs of the cancer in the tumor bed. The patient was examined in February, 1995, and was in an excellent clinical condition. No signs of tumor tissue or metastases were observed (Table 1).

DISCUSSION: It is established that vitamin Q₁₀ is indispensable in the bioenergetic functionalities of the mitochondria of human cells. Hanioka et al.⁶ reported that the ratio of T4/T8 lymphocytes of eleven subjects (not with known cancer) increased ($p < 0.01$) in two months on CoQ₁₀. For the same

Table 1. Vitamin Q₁₀ Blood Data

<u>Patient</u>	<u>Date</u>	<u>CoQ₁₀ (μg/ml)</u>	
A-MRH	07/22/92	0.97	control
	12/07/92	0.83	control
	12/05/94*	3.34	on 390 mg. Q ₁₀
	* Two samples	3.64	on 390 mg. Q ₁₀
EEL	07/22/92	0.62	control
	10/04/94	3.77	on 390 mg. Q ₁₀
SP	02/10/92	0.84	on 90 mg. Q ₁₀
	02/15/92	0.73	"
	12/07/92	0.83	"
	03/24/94	1.21	on 390 mg. Q ₁₀
	06/09/94	2.36	"
	09/20/94	1.12	"
	12/05/94	1.96	"

eleven patients, the levels of IgG increased ($p < 0.05$) in six months. Therefore, it is considered that these regressions of breast cancer are based upon the immunological activities of vitamin Q₁₀.

These prior clinical regressions of breast cancer in two patients were necessarily obtained during the conventional treatment of breast cancer by the procedures of mastectomy, x-ray treatment, and the appropriate anti-cancer drugs. Nevertheless, the apparent complete regression of breast cancer in the two - "high-risk"- cases have expedited this continuing biomedical and clinical research on vitamin Q₁₀ and cancer. Accordingly, three additional cases, for a total of five cases, of breast cancer have therapeutically responded to a daily oral dosage of 390 mg. of vitamin Q₁₀.

Lockwood et al.⁵ had previously observed that a dose level of 90 mg. of CoQ₁₀ in breast cases for ca. 8 months was ineffective, since only 6 of the 32 breast cases showed even a hint of possible clinical regression on CoQ₁₀. This observation is supported by the record on patient SP, who showed blood levels of CoQ₁₀ on a dosage of 90 mg, which were not statistically different from the mean level of CoQ₁₀ in the blood of subjects without overt cancer. Of additional significance for patient SP, her blood levels of CoQ₁₀ in four determinations over nine months on 390 mg. of CoQ₁₀, revealed that only two of these four

determinations showed a level well above the maximum level of people without cancer, and that the other two of these four levels were within the range for people without cancer. In other words, the compliance of patient SP over nine months appeared to have been low to minimal, but, nevertheless, this patient maintained an absence of recurring tumor tissue.

Folkers, et al.⁷ measured the levels of CoQ₁₀ in the blood of two groups of subjects (N = 234 and N = 215) without overt cancer. These data revealed that the incidence of low blood CoQ₁₀ levels was higher (p<0.005) in cancer patients than in approximately age-matched control subjects. None of the 38 matched control subjects had blood levels of CoQ₁₀ below 0.45 µg/ml, but 6/22 (27%) of the cancer patients had levels below 0.45 µg/ml. The blood level of CoQ₁₀ in an individual cancer patient may be very low compared to control, and may be in the mid-range of normal controls. Regardless of the blood level of CoQ₁₀ of a cancer patient, the existence of the cancer is a basis for therapy with CoQ₁₀ to achieve elevated blood levels of 2-3 µg/ml, and even higher levels. A minimum but effective oral dose level of CoQ₁₀ daily appears to be between 90 and 390 mg. for the average patient with breast cancer.

Although in the past, the ethical treatment of breast cancer was based upon mastectomy, x-ray treatment, and anti-cancer drugs, this overall treatment rarely, if ever, caused highly significant regressions of the primary tumor and metastases in the liver.

The regressions of the primary tumor and metastases in these five cases of breast cancer are biochemically understood to be based upon the immunological activity of vitamin Q₁₀. For the treatment of at least some newly diagnosed cases of breast cancer, initial daily therapy with 390 mg. of CoQ₁₀ is plausible before x-ray treatment, mastectomy and anti-cancer drugs. However, concomitant treatment with x-ray and the drugs is not excluded, if it is found in future trials that x-ray treatment and drugs provide minimal benefit, without or with side-effects, and without significant regression.

REFERENCES

1. Folkers, K., "Biochemical and Biomedical Research on Vitamin Q₁₀ and Regression of Cancer." Submitted to Biochem. Biophys. Acta, February, 1995.

2. Folkers, K., Nylander, M., Morita, M., Mellstedt, H., and Osterberg, A. Submitted to Int. J. Vit. Nut. Res., 1995.
3. Folkers, K., Brown, R., Hanioka, T., Williams, M., Quillin, P., and Iafelice, R. Submitted to Int. J. Vit. Nut. Res., 1995.
4. Folkers, K., Brown, R., Judy, W., and Morita, M. (1993) Biochem. and Biophys. Res. Comm., 192:1, pp. 241-245.
5. Lockwood, K., Moesgaard, S., and Folkers, K., (1994) Biochem. Biophys. Res. Comm. 199:3, pp. 1504-1508.
6. Hanioka, T., Mcree, J., Xia, L., Shizukuishi, S., and Folkers, K. (1993) Jour. of Dental Health, 43:5, pp. 667-672.
7. Folkers, K., Ellis, J., Yang, O., Tamagawa, H., Nara, Y., Nara, K., Ye, C., and Shen, Z. (1991) Vitamins and Cancer Prevention, Chapter 8, pp. 103-110.