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chondria and, in turn, to increase cellular metabolism and demand for coenzymes and the vitamins from which they are derived (thiamine, riboflavin, B12 and C).(27)

In a number of his publications,(16,17) Gerson discussed the anti-tumor effect of calorie restriction *per se*, which had been demonstrated by many authors,(28) but his diet clearly supplied too many calories (2,600-3,200 cal/day; 1,200 cal from the juices alone) to be considered calorie restricted. Gerson referred to the observations of Tannenbaum, (29) that calorie restriction, increased calorie utilization rate, and micronutrient hyperalimentation could favor the tumor bearing host and suppress development of both primary tumors and metastases. Silverstone and Tannenbaum (30) had recently shown the potential utility of thyroid medication in cancer management, a measure which Gerson employed, increasing in his patients the ratio of calorie demand:supply, to emulate the anti-tumor effects of caloric restriction. Contemporary research continues to bolster earlier findings.(31,36)

The literature clearly revealed that high dose thyroid treatment induced far greater than normal nutrient requirements, as well as sobering negative experimental outcomes when those requirements were not met. In the absence of vigorous supplementation with either liver or brewer's yeast, prolonged metabolic hyperstimulation by exogenous thyroid led to wasting and premature death in experimental analogs, even in the presence of the known B-vitamins. Yeast protected against early mortality, created increased appetite, and guarded against weight loss. Liver feeding actually led to thriving weight gain.(32) Approximately 5 years after incorporating high dosages of thyroid and Lugol's solution, Gerson added (in about January of 1952) raw veal liver/carrot juice (17 pg 196) which was prescribed at 24 ounces/day in divided dosages, t.i.d. Each glass contained the pressings from ½ pound of liver and about ¾ pound of carrots. At that time, he discontinued medications which were clearly duplicated by the veal liver/carrot juice, e.g. oral phosphates, brewers yeast, vitamins A and D, and liver with iron capsules.

With one eye on the time frame during which the above medications were used (patients admitted from January of 1942 through December of 1951), and the other on the time frame for veal liver/carrot juice (patients admitted from January of 1952 through April of 1956), it became apparent that (31) (62%) of the positive outcomes reported by Gerson in his *A Cancer Therapy: Results of Fifty Cases*, were treated with the earlier version, while only 19 (38%) were treated with the version presented.

With information from the literature of Gerson's time, and supporting evidence from his own literature, CHIPSA physicians were empowered to revise treatment procedures, taking into account the reported results of both versions of Gerson's cancer management. A decision was made to add to the CHIPSA armamentarium primary dried brewers yeast, oral liver extract, and Coenzyme Q10, a vitamin recently associated with extraordinarily positive outcomes in breast cancer.(33) CoQ10 is a mitochondrial shelf enzyme pivotal to NADH (niacin) metabolism in oxidative phosphorylation. Even though it was unidentified in Gerson's time, it had been amply supplied to his patients in the large daily required quantities of raw veal liver/carrot juice. CoQ10 is only modestly supplied by brewers yeast and liver extracts. The presence of this material in quantity in whole raw veal liver may explain, at least in part, Gerson's strong conviction that the liver/carrot juice greatly improved his patients' responses, and the surprising difference in CHIPSA short term survivals between those who received liver and those who did not.

It has also become apparent that the administration of phosphorus and calcium (essential for phosphorus uptake) along with vitamin D (essential for calcium metabolism) may be more or less required in certain cases to meet the excessive biological demands of thyroid-stimulated metabolism during protein restriction in the early phase of Gerson's treatment. In fact, administration of these materials along with vitamin A, B12, liver and iron capsules, and brewers yeast at levels far above known biological needs was a decade-long epoch in the development of Gerson's cancer management.

From the contemporary viewpoint, the UV irradiated ergosterol (viosterol) used by Gerson as a source of vitamin D to enhance phosphate absorption was probably biologically inactive, its effects being due only to subsequent conversion by the liver and kidneys into active metabolites. Recent advances in understanding of vitamin D mechanisms have led to materials more effective in aiding gut absorption of phosphorus, e.g. 1,25(OH)2D3, a prescription material. This material is a logical choice to replace viosterol in Gerson's protocol.

Recent findings suggest an important anti-proliferative role in the gut for calcium phosphates,(34) and good absorbability, specifically, of tricalcium phosphate,(35) which may be an additional improvement over materials available to Gerson.

Our discovery, that the 50 cases presented by Gerson (17) in 1958 were treated with two different protocols, was doubly illuminating. First, it illustrated the success of efforts by the American Medical Association to discredit and isolate Gerson. Due to lack of appropriate affiliation and research support, he was forced to rely, with apologies,(17 pg 221) on the antiquated monograph style popular in Germany during the 1930s (the end of the Golden Age of German Medicine), presenting only his best cases even though the situation called for a more modern statistical analysis of all long term follow-up data. Second, read in the context of Gerson's earlier cancer-related publications, *A Cancer Therapy* provided key information for addressing the dilemma of reduced short term melanoma survivals in contemporary practice.

Gerson reflected (17, pp 121-2) on the professional isolation and lack of support he experienced in the USA as a result of the anti-competitive activities of Morris Fishbein's influential American Medical Association. On one occasion, he remarked with chilling candor, "On the one side, the knife of the AMA was at my throat, and on my back I had only terminal cases."(17, pg 406) Gerson's American experience stands out in dark contrast against the brilliant and extraordinary research support which had been afforded him by both the Bavarian and Prussian ministries of health (13) prior to the outbreak of the European conflict. He assessed his predicament bluntly, "In this country, I was not in a position where I could carry out enough experiments to constitute a scientific proof..." The current evidence does nothing to detract from Gerson's legacy. Indeed, retrospective analysis can define current trajectory and predict fruitful directions for the future. The authors are optimistic that the introduction of clinical epidemiology into the CHIPSA medical practice has returned Dr. Gerson's cancer management to an appropriate environment for discovery and growth, i.e. the hands of a medical group engaged in clinical research.

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Stage	TNM	Clark	Breslow	Satellites	Largest Regional Node	In-transit Metastasis	Non-regional skin, subcutaneous and lymph metastasis	Visceral metastasis	n	At 5 years (alive/deceased)
IA	pT1 N0 M0	II	< .75mm						4	4/0
IB	pT2 N0 M0	III	.75mm >1.5mm						7	7/0
II	pT3 N0 M0	IV	1.5>4.0mm						3	3/0
IIIA	pT4a N0 M0	V	>4.0mm						1	0/1
or	pT4b N0 M0	V	>4.0mm	Within 2cm of primary					2	2/0
or	Any pT N1 M0		>4.0mm		<3.0cm				17	14/3
IIIB	Any pT N2 aM0				>3.0cm				10	7/3
or	AnypT N2b M0					>2cm from pT/not beyond region			5	1/4
IVA	AnypT Any NM1						Any		18	7/11
IVB	AnypT Any NM2							Any	86	0/86

Table 1. Staging System used for this report (reprinted by permission of *Alt Ther Health Med*).

pT = primary tumor; N = node; M = metastases
Clark level of invasion: II= in the papillary dermis; III= at the papillary/reticular dermis interface; IV= in the reticular dermis; V= in the subcutaneous tissue

Breslow = greatest thickness of pT

Veal liver juice

We started testing the impact of the year of admission to Gerson management with the year 1985, which is about when serious difficulties with contamination and interruption of CHIPSA's veal liver supplies began. A Wilcoxon life test hinted at a possible effect (*see Table 2*), which led to a Cox proportional hazards regression. The Cox regression (*see Table 3*) also suggested that date of prescription was likely to be a significant variable if we were able to locate the point of greatest difference. To visualize this, we created a Kaplan-Meier survival plot comparing the survival curves of different time groups (*see Figure 2*). With the Kaplan-Meier plot run out in Harvard Graphics, it became immediately evident that the greatest difference was in the short term survival outcomes of people admitted at stages IIIA, IIIB, and IVA. During the years 1986 - June, 1987 there were multiple outbreaks of campylobacter sepsis which led to interruptions and finally to discontinuance of raw veal liver/carrot juice. We compared patient groups from three distinct timeframes: 1) patients admitted before 1985, who had a safe and continuous liver supply, 2) patients admitted from 1986 - June, 1987, whose liver supplies may have been contaminated or disrupted and 3) patients admitted after July of 1987, after which time it had become clear that there were no safe supplies of raw liver to be found. At 18 months, the survival rate for pre-1985 patients ($n = 19$) was 95%, while for post-July 1987 patients ($n = 16$) it was only 56% (*see Figure 3*). The .39 difference in means is quite significant (Fisher Exact Test, $P = 0.013$). This comparison was also significant with a Wilcoxon life test ($P = 0.032$).

DISCUSSION

Clinical epidemiology provided the CHIPSA medical practice two illuminating findings: the correlation of both surgery and raw veal liver/carrot juice with higher survival rates in stages IIIA, IIIB, and IVA melanoma. With retrospective data analyses in hand, correction of the surgical problem was straightforward and required almost no discussion among the CHIPSA practitioners. Surgical tumor debulking is expected to considerably improve stage IIIA, IIIB, and IVA melanoma 5-year survival rates, and the physicians are eager to share this information with their patients. However, simplicity was not a characteristic of the problem which was created with discontinuation of the liver/carrot juice: a sharp reduction of 18-month survival rate for the same stages. Even though the survival curves eventually evened out and ran closer together at the 5-year

tion or discontinued altogether. These outcomes led to changes in clinical practice.

INTRODUCTION

The late Senator Sam Irvin remarked during the famed Watergate hearings, "The human being is like the lightening bug, in that we tend to carry our illumination behind us." Recently, in his book *The Death of Common Sense*, Philip K. Howard invoked a visionary statement by Alexis de Toqueville, who wrote, "If the lights that guide us ever go out they will fade little by little as if by their own accord." In their absence, we will "lose sight of basic principles" and will be "only able to make a clumsy and unintelligent use of wise procedures no longer understood." While Toqueville foresaw the dismal ineptitude which can result from the decay of a well-organized system, he might have reminded us that, even when lost in uncharted territory, we can regain our bearings by retracing our steps (and those of our predecessors).

It is fortunate that, even while targeted by an illegal, anti-competitive, AMA-led boycott, Max Gerson, MD was able to publish a small body of literature chronicling the development and best-case results of his nutrition-based cancer management. Those publications and a surviving oral tradition have served as the clinical rule book for the medical practice of the Centro Hospitalario Internacional del Pacifico, S.A. (CHIPSA), of Playas de Tijuana, Baja California, Mexico.

Recent dynamically changing circumstances, coupled with surprising retrospective findings, as well as in depth studies of Gerson's publications and the relevant literature of his time, have raised questions, provoked animated debates, and led ultimately to changes in CHIPSA's clinical guidelines and practice. In this paper, we describe our experiences with the hope that they may be instructive to other alternative practitioners who are ready to add a retrospective analytical component to their own practices.

Background

We recently reported (1) stage-related 5-year survival rates for stage I, II, IIIA, IIIB, and IVA patients drawn from a consecutive sample of 153 melanoma patients treated with the nutrition-based cancer therapy proposed by Max Bernard Gerson. (2) To our knowledge, this report was the first published retrospective analysis of survival outcomes for any of the well-known alternative method of cancer management. (3)

For the benefit of this discussion, we will summarize the outcomes as reported in *Alternative Therapies in Health and Medicine* (Sept-Oct, 1995). A 100% 5-year survival rate for stage I and II melanoma patients was seen in the Gerson system ($n = 14$). This was considerably higher than the 79% 5-year rate found by Balch (4) in his 1992 meta-analysis, but the Gerson sample was a third too small for statistical significance ($c2 = 2.56$, $P = 0.109$).

However, the 100% recurrence-free survival of localized melanoma patients can be seen more favorably in the light of an 82% 5-year survival rate in stage IIIA melanoma patients (any T4a, T4b, or N1) in the Gerson system ($n = 17$). Stage IIIA Gerson patients experienced a 110% greater (.43 difference in means) survival advantage ($c2 = 9.48$ with 1 degree freedom, $P = 0.002$, Power = 0.887) than did same-stage patients of the Fachklinik Hornheide ($n = 103$) whose 39% 5 year survival rate is published by the American Cancer Society.(5)

All T4b, N1, and N2 patients (stages IIIA + IIIB) within the Gerson system ($n = 33$) achieved 70% 5-year survival in contrast to same-stage patients of Fachklinik Hornheide ($n = 134$), whose 5 year survival rate was 41%. The 0.29 difference in means is statistically significant ($c2 = 7.62$ with 1 degree freedom, $P = 0.006$, Power = 0.802).

Stage IVA (any T, any N, M1-only) Gerson patients ($n = 18$) experienced a 39% 5 year survival rate. The Eastern Cooperative Oncology Group (6) reported a 6% 5-year survival rate in same-stage patients ($n = 194$). The .33 difference in means is significant ($c2 = 19.3$ with 1 degree freedom, $P < 0.0001$, Power = 0.997). Survival impact of Gerson's cancer therapy in internally metastasized stage IVB melanoma (any T, any N, M2) was not assessed.

METHODS

Over 15 years, from 1975 through July of 1990, 53 self-selecting adult Caucasian melanoma patients assessable for stages IIIA, IIIB, and IVA at admission were treated with Gerson's nutrition-based cancer therapy. Of the 53 cases, almost all were hospitalized by physicians at CHIPSA, while several were treated by physicians in private practice. Medical charts supplied by CHIPSA were consolidated from three earlier facilities, Hospital La Gloria, Hospital Jardines La Mesa, and Hospital Del Sol, all from the Tijuana metropolitan area. All patients were treated with the nutrition-based cancer management described by Gerson.

In the early part of this century, Gerson was responsible for the introduction of therapeutic sodium restriction (7) into the literature. He developed a salt and water management for cellular edema in refractory cutaneous tuberculosis (*lupus vulgaris*) (8) which was broadly tested and approved by the majority of authors (9) for its curative capabilities. Clarence Emerson (10) of Nebraska's Lincoln General Hospital was the first American author to refer to it as a "metabolic" therapy.

Over the fifty year course of his medical career, Gerson developed a number of unique nutrition-based therapies for management of edemas occurring in various pathologies, (8,11,12) taking into account the widely varying requirements of patients suffering from different diseases. His efforts attracted federal funding for advanced clinical research at the University of Munich.(13) His cancer therapy, which was developed empirically over the course of thirty years of clinical experimentation, (14) was published in several distinct versions. (2,15-17)

The nutritional core of all versions of Gerson's cancer management has remained essentially the same since its first publication in 1945. It is restricted in salt, fat and (temporarily) protein. It supplies very high quantities of many nutrients and phytochemicals, while at the same time forcing fluids, through thirteen hourly feedings of raw fruit and vegetable juices daily. It emphasizes intake of solid foods, mostly vegetables, in addition to the juices.

While at the University of Munich, Gerson concluded that temporary protein restriction aided edema absorption (12) and favored improvement in his patients. In Gerson's cancer diet, protein repletion with nonfat cultured dairy products occurs after at least 6 weeks in most cases. Shorter periods of protein restriction are observed with children and elderly patients.

From the outset, Gerson's medications were clearly aimed at ATP production and enhanced carbohydrate, fat, and protein metabolism, reflecting his clinical application of emerging knowledge regarding oxidative phosphorylation (18) and its special nutrient requirements. Niacin, brewer's yeast, dicalcium phosphate with irradi-