5-year survival rates of melanoma patients treated by diet therapy after the manner of Gerson:

a retrospective review.

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Abstract

OBJECTIVE: Compare 5-year melanoma survival rates to rates in medical literature. **DESIGN:** Retrospective. **SETTING:** Hospital in Tijuana, Mexico. **PATIENTS:** White adult patients (N = 153) with superficial spreading and nodular melanoma, aged 25-72 years. **INTERVENTION:** Gerson's diet therapy: lactovegetarian; low sodium, fat and (temporarily) protein; high potassium, fluid, and nutrients (hourly raw vegetable/fruit juices). Metabolism increased by thyroid; calorie supply limited to 2600-3200 calories per day. Coffee enemas as needed for pain and appetite. **MAIN OUTCOME MEASURE:** 5-year survival rates by stage at admission. **RESULTS:** Of 14 patients with stages I and II (localized) melanoma, 100% survived for 5 years, compared with 79% of 15,798 reported by Balch. Of 17 with stage IIIA (regionally metastasized) melanoma, 82% were alive at 5 years, in contrast to 39% of 103 from Fachklinik Hornheide. Of 33 with combined stages IIIA + IIIB (regionally metastasized) melanoma, 70% lived 5 years, compared with 41% of 134 from Fachklinik Hornheide. We propose a new stage division: IVA (distant lymph, skin, and subcutaneous tissue metastases), and IVB (visceral metastases). Of 18 with stage IVA melanoma, 39% were alive at 5 years, compared with only 6% of 194 from the Eastern Cooperative Oncology Group. Survival impact was not assessed for stage IVB. Male and female survival rates were identical for stages I-IIIB, but stage IVA women had a strong survival advantage. **CONCLUSIONS:** The 5-year survival rates reported here are considerably higher than those reported elsewhere. Stage IIIA/B males had exceptionally high survival rates compared with those reported by other centers.

Objective. 5-year survival rates were computed for melanoma patients treated with a nutrition-based cancer therapy developed by Max Bernard Gerson, M.D. These were contrasted with 5-year rates appearing in the melanoma literature. Within the Gerson-treated sample, 5-year rates were compared for males vs females.

Setting. The medical group of Centro Hospitalario Internacional del Pacifico, S.A. (CHIPSA) is consolidated from three previous smaller facilities, Hospital La Gloria, Hospital Jardines la Mesa, and Hospital Del Sol, all in the metropolitan area of Tijuana, Baja California, Mexico. Most patients in this study were hospitalized at one of the four facilities. A few patients were treated by independent physicians.

DESIGN: Retrospective analysis was done on a case series of 153 melanoma patients admitted to the Gerson cancer management program from 1975 through July of 1990. Follow up is ongoing.

Patients. This study reports on 153 adult Caucasian superficial spreading and nodular melanoma patients, 83 (54%) males and 70 (46%) females, ranging in age from 25 to 72 years. 14 (9%) presented with local (stages I and II) disease, 35 (23%) with regional metastases (stage III), and 104 (68%) with distant metastases. Almost all patients were from the U.S., while several came from other English speaking countries.

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Intervention. The diet therapy used in this study is a salt and water management, restricting sodium and supplementing potassium. It provides oral hyperalimentation of nutrients, while forcing fluids, by hourly administration of raw vegetable and fruit juices. Caloric utilization rates are enhanced through thyroid administration, while caloric content of the diet is limited (2,600 - 3,200 cal/day) by a very low fat, lactovegetarian diet. Protein is temporarily restricted. Coffee enemas are administered pro re nata (as frequently as every 4 hours) to improve nutrition, and to relieve pain.

Main Outcome Measured. 5-year survival rates by stage at admission.

Conclusions

Stage-related 5-year survival rates for adult, Caucasian melanoma patients who used Gerson's therapy are considerably higher than rates reported elsewhere in the melanoma literature. Also, in contrast to the experience of other reporting centers, female and male survival rates were equal in regionally metastasized (stage III) melanoma. These outcomes suggest a possible direction for broader clinical investigations.

Results. A 100% 5-year survival rate for stage I and II melanoma patients in the Gerson system (n = 14) compares favorably to the 79% 5-year rate found by Balch in a recent meta-analysis, but due to extremely low early-stage recruitment, the sample is far too small for statistical significance (2 = 2.56, P = 0.109).

An 82% 5-year survival rate was achieved in stage IIIA melanoma patients (any T N1 M0) in the Gerson system (n = 17). Seen in contrast to a 39% 5-year rate published by the American Society for same-stage patients of the Fachklinik Hornheide (n = 103), those in the Gerson system benefited from a 110% greater (.43 difference in means) survival advantage (2 = 9.48 with 1 degree freedom, P = 0.002, Power = 0.887).

Comparison of 5-year survival rates for all T4b, N1, and N2 (stages IIIA + IIIB) patients of the Fachklinik Hornheide (41%, n = 134) with those of CHIPSA (70%, n = 33) reveals a 71% greater (.29 difference in means) survival advantage (2 = 7.62 with 1 degree freedom, P = 0.006, Power = 0.802).

Because the majority of Gerson-treated stage IV survivors had documentation of only lymphatic, skin, and subcutaneous metastases (no deep internal disease), they were categorized separately from those with visceral metastases. Analysis of stage IV is divided into IVA (metastases limited to skin, lymph, and subcutaneous tissue) and IVB (visceral metastases). In stage IVA (any T, any N, M1-only), Gerson patients achieved a 39% 5-year survival rate (n = 18) which is considerably higher (.33 difference in means) than the 6% 5-year rate (n = 194) of the Eastern Cooperative Oncology Group (2 = 19.3 with 1 degree freedom, P < 0.0001, Power = 0.997). The majority of IVB patients were suffering very advanced disease on admission to the Gerson program.

Survival impact of Gerson's cancer therapy in stage IVB melanoma was not assessed. Male and female survival rates are identical for local and regionally metastasized melanoma. With distant metastases of skin and lymph (stage IVA), women (n = 9) have a strong survival advantange over men (n = 9) at 5 years (Fisher Exact Test, P = 0.049).

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Introduction

This paper summarizes the clinical outcomes of melanoma patients treated with the nutrition-based cancer therapy proposed by Max Gerson, [Ref 1] and contrasts them with rates reported in the literature. To our knowledge, this report is the most thorough retrospective analysis to date to examine the potential survival benefit of this, or any other, well-known alternative method of cancer management.

The genesis of this inquiry occurred during a landmark study by the U.S. Congressional Office of Technology Assessment [Ref 2] to which one of us (G.H.) was an advisor.

In its report, OTA put forward a protocol for best-case reviews based on the premise that, no matter how many patients failed, as few as 10 or 12 cases with objective evidence of tumor response would be enough to propel an investigation by the National Cancer Institute (NCI). Because we had proposed the original best-case review protocol to OTA, we were eager to construct a best-case review.

However, we found OTA's (and later NCI's) protocol to have a serious shortcoming when used retrospectively: its focus on only tumor regression.

Adequate documentation of tumor regression is unlikely to be collected in most alternative medical practices.

Perspective: Positive Outcome

Our efforts to complete a best-case review, however, were not without some rewards. CHIPSA practitioners suggested cases with all different types of cancer which they believed had unusually positive outcomes. Of the 27 cases cataloged, fully 33% were long term melanoma survivors, which underscored the need to do a more complete evaluation of melanoma per se.

We abandoned the best-case review for the more informative retrospective review. In contrast to the best-case review, the retrospective review describes all patients, including non-responders, giving a more adequate impression of the outcomes of treatment.

In the process, we determined that the institutions which originally diagnosed the patients were reliable. We requested histological specimens for the above 27 cases, and forwarded the numbered slides, without clinical histories, to the Armed Forces Institute of Pathology (AFIP). AFIP pathologists' findings agreed with those reported by the original institutions with the exception of one specimen, which had been destroyed by improper handling and storage.

In a related exercise, original diagnostic scans were read by contemporary UCLA physicians whose interpretations were in virtually complete agreement with those of the original readers.

Methods

Over 15 years, from 1975 through July of 1990, 249 patients presented for treatment of melanoma. 53 (21%) are lost to follow-up. Survival outcomes were learned for 196, but 14 were excluded because they did not have verified nodular or superficial spreading melanoma. 29 (19%) of the remaining 182 charts could not be assessed for stage at admission. Therefore, this paper is based on the outcomes of 153 adult melanoma patients treated with Gerson's nutrition-based cancer therapy. All assessable patients were Caucasian. Almost all were hospitalized by physicians of Centro Hospitalario Internacional del Pacifico, S.A. (CHIPSA), Playas de Tijuana, Baja California, Mexico. Several were treated by physicians in private practice. Medical charts supplied by CHIPSA were consolidated from three predecessor facilities, Hospital La Gloria, Hospital Jardines La Mesa, and Hospital Del Sol, all from the Tijuana metropolitan area.

Gerson is credited with the introduction and development of therapeutic sodium restriction [Ref 3] in the context of a high potassium diet, which was first broadly tested in refractory cutaneous tuberculosis (lupus vulgaris). [Ref 4] According to eminent dermatologist Erich Urbach, [Ref 5] the majority of authors of note investigated and approved Gerson's diet therapy for lupus. Emerson [Ref 6] was the first U.S. author to refer to the diet as a metabolic therapy. Gerson's tuberculosis diet became the basis of a number of quite different dietotherapies developed by him for conditions as diverse as pulmonary tuberculosis and cardiorenal insufficiency.

The cancer management employed by CHIPSA was developed empirically by Gerson over the course of thirty years of clinical experimentation. [Ref 7] Gradually, by trial and error, Gerson evolved an integrated set of medical managements which he last published in a 1958 monograph along with fifty cases presented in clinical detail. [Ref 8]

Although Gerson's method was published several times in U.S. [Ref 9] and German [Ref 10] refereed journals, it is not well known by most practitioners and researchers. Therefore, a brief description of the development and nature of the therapy may be useful.

During the 1930s, Gerson's research at the University of Munich was afforded extraordinary laboratory support through funding provided by both the Bavarian and Prussian federal governments. [Ref 11] Gerson focused on the experimental use of diet and medications to improve tissue edema ocurring in a variety of pathologies.

Edema is characterized by salt and water changes that Cope [Ref 12] has defined as tissue damage syndrome: decreased cell K+, increased cell Na+, and increased cell water (cell swelling); changes which are also observed after human death. [Ref 13] Nutritional treatment to provide cells with a high K+, low Na+ environment improved edema and led to enhanced tissue resistance and immunities, and therefore better outcomes. [Ref 14] This rationale can be traced through all of Gerson's subsequent efforts in cancer management. [Ref 8 pp 164,166,184,197]

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The cancer diet is individualized to meet the needs of every patient, but it does have uniform components. For most patients, 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. About half of the melanoma patients included in this study received 24 ounces daily of raw veal liver/carrot juice (each glass contained the pressings of 1⁄2 pound of liver and 3⁄4 pound of carrots). Following numerous disruptions in supplies which began in late 1985, raw veal liver was formally discontinued in 1987 due to repeated instances of bacterial contamination (campylobacter fetus s. fetus). Comparisons of patients from different time frames indicate that those receiving liver juice experienced better survival outcomes overall. [Ref 17]

Gerson restricted calories while simultaneously increasing metabolism in an effort to emulate the anti-tumor effect of calorie restriction per se, first demonstrated by Moreschi and Rous. [Ref 16] Enhanced caloric utilization rates (metabolism) can alter tumor growth whether metabolism is accelerated by iodine medications [Ref 17] (Gerson used thyroid and Lugol's solution), or exercise. [Ref 18] The caloric supply is limited to 2,600 - 3,200 cal/day by the low fat, lactovegetarian diet served in three generous daily meals. Niacin, potassium salts (acetate, gluconate, and monophosphate), and crude liver extract with vitamin B-12 injectable, are given to support accelerated cellular energy production.

In the University of Munich experiments, Gerson found that temporary protein restriction aided edema absorption [Ref 19] 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 recommended for children and elderly patients.

Castor oil, a cathartic with no known clinical side effects, is given every other day for many weeks. Retention enemas medicated with boiled coffee are taken pro re nata, as frequently as every four hours, throughout the day and night, for their observed ability to alleviate pain and to improve nutritional condition. Peter Lechner has observed statistically significant cancer pain relief from coffee enemas in a prospective matched control trial at the University Hospital of Graz, Austria. [Ref 20] Although the mechanism of pain relief is not known, Cope [Ref 7] suggested it may be due to a crude sort of dialysis across the gut wall for tumor breakdown products such as polyamines, toxic bound nitrogen, and ammonia. Lechner [Ref 21] has also observed improved tolerance of aggressive conventional treatments in those patients who are willing to employ Gerson's therapy at the same time. At CHIPSA, the management is prescribed for 18 to 36 months, subject to physician's judgment and patient response.

This study, because of its retrospective nature, makes no attempt to adjust for variables such as mind/body treatments, adjuvant botanical or homeopathic materials (although it is our impression that such treatments were commonly used).

We know of only 2 cases in which non-surgical conventional offerings were employed concurrently with the Gerson treatment: 2 stage IVA patients, both 5-year survivors, added adjuvant biological response modifiers - 1 employed interferon for 6 months, and the other utilized levamisole. Several patients whose disease had escaped surgical management before admission to the Gerson program required one or more additional surgeries during treatment.

Data collection

To begin, we reviewed all records, files and lists at our disposal from Hospitals La Gloria, La Mesa, Del Sol, CHIPSA (Centro Hospitalario Internacional del Pacifico, S.A.) and the Gerson Institute (San Diego). In cases for which original patient phone and address records were no longer valid, we went to stored financial charts in which were found records of collect telephone calls placed by patients to friends and relatives. We used those additional numbers with considerable success to locate living patients and to learn the fate of the deceased. We were also able to extend our search by employing the epidemiological services of Equifax.

For purposes of this evaluation, we have operated under two assumptions regarding deceased patients:

1) the majority probably achieved some measure of compliance with the Gerson treatment, and

2) the cause of death for the majority was probably melanoma.

In 1993, the Gerson Research Organization (GRO) began publishing a free newsletter for current and past patients, who were invited to join a support network. They were encouraged to share with all patients, even if they had not been treated by CHIPSA physicians. Through this route, several independently treated patients were discovered, contacts were established with their physicians, and data were collected.

Levels of documentation

Because ours is a groundbreaking effort among the various alternative forms of cancer management, we feel that explanation of our documentation process is warranted. Two standards of documentation were applied: one for survivors, and one for deceased.

We quite rigorous in the cataloging of charts for survivors. Forty-five survivor charts have been meticulously cataloged to include independent histological verification, previous physicians' notes, surgical summaries and radiological interpretations. In addition, our own physician notes, extended care consultation records, periodic laboratory reports, x-rays and scans, as well as medication purchase records and other evidence of compliance were included. Charts for 5 survivors could not be sufficiently cataloged to assess staging at admission, even though they did contain adequate evidence of the presence of melanoma.

For purposes of this evaluation, we have operated under two assumptions regarding the deceased patients: 1) the majority probably achieved some measure of compliance with the Gerson treatment, and 2) the cause of death for the majority was probably melanoma. Mortality data are being assembled to address these assumptions if possible.

In staging the deceased, we allowed less stringent documentation to suffice, with the understanding that the negative outcomes were probably due to melanoma. Fifty-seven charts of deceased patients contained independent confirmation of staging by their previous physicians, the standard of evidence required for all survivor charts in this study. In contrast, 44 were staged by relying on the admitting physicians' oral histories and physical examinations. Beyond this, questionnaire responses and correspondence were considered to provide adequate information for 7 patients whose charts could not be located.

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Such lower level documentation (admission oral history and physical exams, and the questionnaire responses) was considered acceptable only for charts of deceased patients whose disease had apparently progressed. If we have erred in this judgment, it was on the side of caution. Because physicians administering the Gerson cancer therapy did not make exhaustive staging efforts on admission for any of their melanoma patients, the possibility certainly exists that deceased patients may have developed undetected distant and internal metastases before admission; in fact, this possibility cannot be ruled out for the survivors. With these criteria, 108 charts of the deceased were assessable for stage at admission.

Statistical Methods

5-year survival rates for each stage were compared to rates previously published by Balch, the American Cancer Society, the Eastern Cooperative Oncology Group, and Fawzy I. Fawzy.

For most comparisons, we used the Chi-square.(2) When comparing small samples, we employed the Fisher Exact Test.

24 charts were missing, presumably destroyed in the La Gloria Hospital fire of 1985 in which approximately 900 charts of all different pathologies were lost. Two cases for which outcomes had been documented (both were noted deceased in a Gerson Institute file index) were identified by initials only, with no gender markers. Survival outcomes are known for 72 females and 81 males. 42 (58%) of the females and 69 (85%) of the males are deceased, a finding consistent with the female survival advantage widely reported in the melanoma literature. 2 deceased males and 1 deceased female (all stage III) lived 5 or more years and are reflected in this report as 5-year survivors.

Statistical Methods

153 charts were assessable for both outcome and stage at admission. 5-year survival rates for each stage were compared to rates previously published by Balch [Ref 22] the American Cancer Society, [Ref 23] the Eastern Cooperative Oncology Group, [Ref 24] and Fawzy I. Fawzy. [Ref 25] For most comparisons, we used the Chi-square (2).

When comparing small samples, we employed the Fisher Exact Test. For the above tests, we employed a computer program, SigmaStat, by Jandel Scientific Software. Programs were created by one of us (S.C.) to generate Kaplan-Meier survival functions. Survival curves were plotted in Harvard graphics. Cox regressions and log-rank tests for homogeneity of survival curves were used for comparison of data.

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Table 1. Staging System used for this report.

Stage	TNM	Clark	Breslow	Satellites	Largest Regional Node	In-transit Metastases	Non-regional skin, subcutaneous and lymph metastases	Visceral Metastases	At 5 years alive / deceased
IA	pT1 N0 M0	II	> .75 mm	-	-	-	-	-	4/0 4
IB	pT2 N0 M0	III	.75 mm > 1.5 mm	-	-	-	-	-	7/0 7
II	pT3 N0 M0	IV	1.5 mm > 4.0 mm	-	-	-	-	-	3/0 3
IIIA	rT4a N0 M0	V	> 4.0 mm	-	-	-	-	-	1/1 2
or	pT4b N0 M0	V	> 4.0 mm	Within 2 cm of primary	-	-	-	-	1/0 1
or	Any pT N1 M0	-	> 4.0 mm	-	3.0 cm	-	-	-	14/3 17
IIIB	Any pT N2a M0	-	-	-	3.0 cm	-	-	-	7/3 10
or	Any pT N2b M0	-	-	-	-	2 cm from pT/ not beyond region	-	-	1/4 5
IVA	Any pT Any N M1	-	-	-	-	-	Any	-	7/11 18
IVB	Any pT Any N M2	-	-	-	-	-	-	Any	0/84 84

rT = recurrent tumor Clark level of invasion: II = in the papillary dermis Breslow = greatest thickness of pT.
pT = primary tumor III = at the papillary/reticular dermis interface.
N = node IV = in the reticular dermis.
M = metastases V = in the subcutaneous tissue.

Note: Stages IA, IB, and II are determined by the Breslow and Clark measures, going by whichever one is worse.

Staging criteria used in this report

Because there exist so many different staging systems for nodular and superficial spreading malignant melanoma, we thought it advisable to provide a breakdown of the staging criteria we used (see Table 1).

We borrowed from current international standards of TNM (tumor, nodes, metastases) for melanoma as published by the American Joint Committee on Cancer [Ref 26] as well as the more precise staging divisions for micrometastases as published by the International Union Against Cancer. [Ref 27] Both of these methods incorporate Clark levels (tissue invasion) and the Breslow index (tumor thickness).

The recent reclassification of melanoma staging emphasizes micrometastases and has, therefore, caused considerable stage migration. Many melanomas which would previously have been categorized stage IIB have moved to stage III. Stage III has been expanded and divided into stages IIIA and IIIB. The net effect of this reclassification, from our point of view, is an amplification of the survival benefit of lifestyle management as represented by the Gerson cancer treatment. In this paper, we have presented our findings with a proposed new division of stage IV into two parts. We believe that our findings support this division.

Results

The primary purpose of our study was to assess survival outcomes as measured by 5-year survival rates by stage. These are summarized in Table 2.

TNM	All pT1-3	(Any T) N1	(Any T) N2	(Any T, Any N) M1	(Any T, Any N) M2
n =	14	17	15	18	86
5-year survival	100%	82%	67%	39%	-
Alive at 5 yrs	14	14	8	7	0
Deceased	0	3	7	11	86

Table 2.
5-year survival rates by most clinically important disease (TNM)

Table 2. 5-year survival rates by most clinically important disease (TNM). Two rT4a and oneT4b (early stage III) patients are not reflected in the above table. 249 potential melanoma patients were identified from lists and files of the above mentioned organizations. Survival outcomes were learned for 196 (79%), while 53 (21%) are lost to follow-up. 1 67 cases (85%) were assessable for stage at admission, while 29 cases (15%) were not.

14 cases (8%) were excluded. 3 of these cases did not have malignant melanoma (2 had melanoma in situ, and 1 had a previous history of melanoma). 1 case of pediatric melanoma was excluded due to its unique nature. Also excluded were 10 cases of ocular melanoma (2 surviving, 8 deceased), which has different staging criteria and is not directly comparable to either nodular melanoma or the superficial spreading type. Superficial and nodular melanoma become comparable with the use of Clark levels and the Breslow index. [Ref 21]

After exclusions, a total of 153 patients were included in this review. 45 (29%) lived at least 5 years (41 of whom are alive at this writing), and 108 (71%) are known deceased. Survival rates within the Gerson system are clearly stage-related (see Table 3).

Year	Stage I/II (*n* = 14)	Stage III/IVA (*n* = 53)	Overall
0	100	100	100
1	100	83 ± 5	87 ± 4
2	100	74 ± 6	79 ± 5
3	100	66 ± 7	73 ± 5
4	100	64 ± 7	72 ± 6
5	100	64 ± 7	72 ± 6

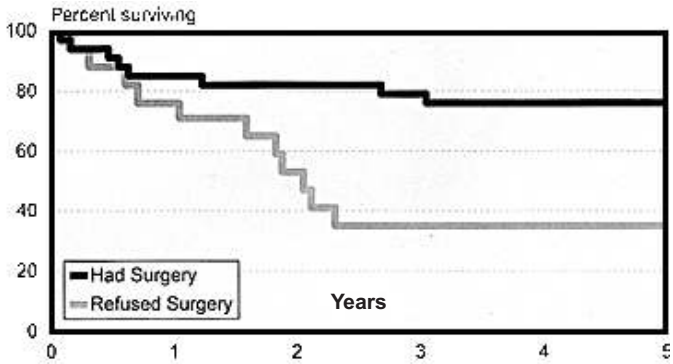
Table 3.
Survival rates by stage

Table 3. Survival rates by stage Note: Stage IVB was not assessed.

A log-rank test for homogeneity of Kaplan-Meier survival curves for early (localized) vs. late (regionally or distantly metastasized) disease (see Figure 1) reveals that the difference is statistically significant (P = 0.007).

Figure 1. Early (localized) vs late (regionally or distantly metastasized melanoma. However, as will be seen nearby, survival rates for males and females do not differ until distant (beyond the primary lymphatic drainage system - stage IV) metastases have presented.

Table 2.
5-year survival rates by most clinically important disease (TNM)



Gerson melanoma patients (stages III / VA)

Stages I and II

14 (9 %) of 153 patients assessable for stage at admission entered the Gerson program with early (stage I or II) melanoma. At admission, 4 patients were stage IA, 7 were IB, and 3 were stage II. None suffered progression of melanoma after admission. All remained free from melanoma for up to 17 years. 13 are alive at this writing. 1 is deceased of other causes.

All of the stage I and II patients reviewed were admitted to the Gerson program prior to May of 1987 and are, therefore, assessable for a 5-year survival rate. 14 (100%) of 14 early stage melanoma patients have remained disease-free for a minimum of 7½ years and a maximum of 17 years. No deaths due to melanoma have occurred in this group (although a 74 year-old, 15-year stage II survivor died of prostate cancer). When contrasted to a meta-analysis of 15,798 stage I and II melanoma patients from reporting centers worldwide in which Charles Balch [Ref 22] found an overall average 5-year survival rate of 79%, the sample size in the Gerson treatment system is too small for statistical significance (2 = 2.56, P = 0.109). The sample would have to be 36% larger, i.e., an additional 5 non-recurrent early stage patients would be required to reach significance. However, seen in the context of this study's unusually positive findings for stages III and IVA, these data hint that aggressive lifestyle intervention (e.g. Gerson's therapy) may hold a potential to reduce the worldwide 5-year mortality rate for early stage, localized melanoma. 21% of the early stage patients in Balch's meta-analysis (more than 3,300) were deceased at 5 years.

It is also of interest that stage I and II melanoma comprised approximately 88% (15,798 of 17,914) of the patients reported by centers worldwide, while physicians offering the Gerson cancer treatment saw only 9% (14 out of 153) at such an early and hopeful stage.

Stage III

25 (53%) of the 5-year survivors entered the Gerson program at stage III. In all, 35 (23%) of the assessable cases were admitted at stage III. The 5-year survival rate for 35 assessable stage III melanoma patients treated with the Gerson diet therapy is 71%, with 10 deceased prior to the 5 year mark, and 25 cancer-free for at least 5 years.

The American Cancer Society (ACS) publishes a 39% 5-year survival rate for stage III melanoma. Other reported 5-year survival rates [Ref 22] range from 27% in Brisbane to 42% at Duke University. Interestingly, no center included in Balch's meta-analysis, [Ref 22] other than Duke University, reported a 5-year survival rate higher than 37%.

The Fachklinik Hornheide, writing in the American Cancer Society's journal, Cancer, [Ref 23] reported a 39% 5-year survival rate (n =103) for patients with stage IIIA (N1-only) melanoma. A comparable group from the Gerson system (n = 17) achieved an 82% 5-year rate. The comparison (.43 difference in means), which reveals a 110% greater survival advantage for patients in the Gerson system, is statistically significant (2 = 9.48 with 1 degree freedom, P = 0.002, power = 0.887).

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The Fachklinik Hornheide also provided a 41% 5-year survival rate for all (n = 134) its stage IIIA (T4b and N1) and stage IIIB (N2 patients). Same-stage patients in the Gerson system (n = 33) achieved a 5-year survival rate of 70%. The difference in means (.29) is statistically significant (2 = 7.62 with 1 degree freedom, P < 0.006, Power = 0.802).

Stage IVA

104 (68%) of the assessable patients were stage IV at admission. All stage IV survivors in the Gerson program were admitted presenting only superficial metastatic disease (limited to skin, subcutaneous and lymph involvement) with no internal metastases. We believe that these patients represent a responsive subgroup within stage IV, and suggest categorizing such patients separately, as stage IVA.

According to Balch (1992), 23% of stage IV patients reported worldwide present first metastases confined to lymph, skin and subcutaneous tissue (any T, any N, M1). He reports that this group has a median survival of 7.2 months, and a 1-year survival rate of 25% worldwide.

18 (17%) of the stage IV patients admitted to the Gerson program were classified M1 (stage IVA). 7 (39%) of 18 are alive at this writing. Their survival range is 5 to 19 years. Therefore, the 5-year survival rate for 18 melanoma patients admitted to the Gerson program at stage IVA is 39%.

The Eastern Cooperative Oncology Group (ECOG) has recently published an outcomes analysis of 635 advanced-stage melanoma patients in which they offered a breakdown of survival by most significant sites. ECOG showed 11 of 194 patients fitting our stage IVA criteria to have lived 5 years, for a 5-year survival rate of 6%. [Ref 24] Contrasted with that, the 5-year survival rate for 7/18 stage IVA melanoma patients in the Gerson system is 39% (550%) greater (.33 difference in mean). This comparison is statistically significant (2 = 19.3 with 1 degree freedom, P < 0.0001, Power = .997).

Stage IVB

The current study makes no attempt to assess the survival impact of Gerson's cancer therapy in stage IVB. Because there were no exclusion criteria at any of the Gerson-treating facilities, we were unable to find a single comparable treatment group moving through any other reporting treatment system. 86 patients (56% of the assessable group) were admitted to the Gerson program at stage IVB, most with gravely advanced disease. All are deceased. 6 of the deceased were not able to start the Gerson treatment. 6 died in the hospital. 1 presented both melanoma and AIDS. 14 patients are known to have had LDH readings 300% or more above normal at admission. The highest recorded was 3,776, or more than 2,400% above normal. Major metastases were distributed as follows: 26% had brain involvement, 30% had liver tumors, 18% had tumors in abdominal viscera other than the liver, 40% had lung disease, 21% had melanoma in bone, and 25% exhibited skin tumors.

Only 1 patient, a female registered nurse originally admitted at stage III, has documented objective radiological evidence of progression to internal (bone) disease (M2, stage IVB) and subsequent complete remission of those lesions. She remains alive and well for 8 years at this writing.

Influence of gender on survival

A female survival advantage has been reported widely in the melanoma literature. While a female survival advantage is seen in the Gerson system (see Table 4),

Table 4. Survival rates by gender Note: Stage IVB was not assessed.

Year	Female (*n* = 39)	Male (*n* = 28)	Overall
0	100	100	100
1	92 ± 4	79 ± 8	87 ± 4
2	87 ± 5	68 ± 9	79 ± 5
3	85 ± 6	57 ± 9	73 ± 5
4	85 ± 6	54 ± 9	72 ± 6
5	85 ± 6	54 ± 9	72 ± 6

Table 4.
Survival rates by gender

Male and female 5-year survival rates are not significantly different until stage IVA (distant metastases to skin, subcutaneous tissue and lymph). Male and female survival rates are substantially the same for patients with stage I and II (completely local disease) as well as stages IIIA and IIIB (regionally metastasized disease).

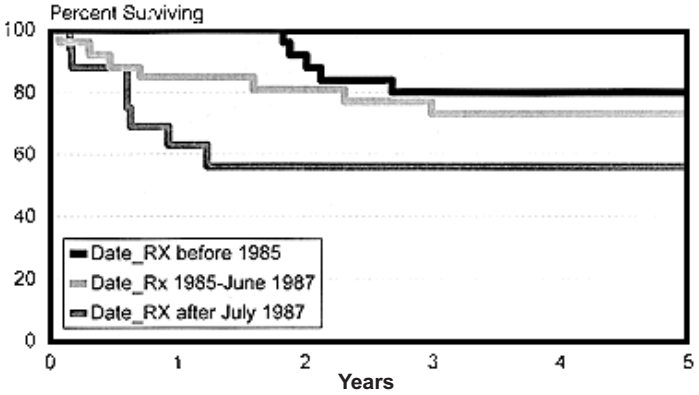
12 females and 2 males were admitted with early (stage I + II) melanoma. This shows an unexplained female recruitment bias (6:1) in early stage patients. This did not occur with any other stages.

Of 35 patients assessed for stage a IIIA + IIIB (all pT4a, pT4b, N1, and N2) 5-year survival rates, 18 (51%) were males and 17 (49%) were females, a distribution very similar to that reported by the Fachklinik Hornheide [Ref 23] which had 49% males and 51% females. Of those who were cancer-free at 5 years or beyond, 12 were male and 13 were female. Of the deceased, 6 were male and 4 were female.

Comparison of the 67% 5-year survival rate for all stage III males in the Gerson system with the 76% rate for females (.09 difference in mean) is not statistically significant (Fisher Exact Test, P = 0.711). 2 of the 12 male 5-year survivors recurred after the 5th year and are deceased. One female 15-year survivor recurred and is deceased. Even at 10-years, the survival rate for females (63%, n = 8), while considerably higher than that for males (50%, n = 12), the difference in means (.13) is not statistically significant (Fisher Exact Test, P = 0.489).

Of 18 patients admitted for treatment of stage IVA melanoma, 9 were women (50%) and 9 were men (50%). This recruitment pattern, half and half, is consistent with the melanoma literature. Of 7 who survived 5 years, 6 (86%) are female, while only 1 (17%) is male. Although the samples are tiny, comparison of the 67% female 5-year survival rate with that of the males (11%) is statistically significant (Fisher Exact Test, P = 0.0498).

Figure 2.
Effect of gender on overall average survival for melanoma stages I-IVA.



When IVA survival and mortality data are included with data for stages I through IIIB, the Kaplan-Meier survival curves for stage I - IVA males vs those of females (see Figure 2) are significantly different (P = 0.004) when log-rank tested for homogeneity over 5 years.

Figure 2. Effect of gender on overall average survival for melanoma stages I-IVA.

Limitations

It has been repeatedly suggested that patients who use alternative cancer treatments may be different from patients who employ conventional treatments. Several differences have been reported by Cassileth, [Ref 28] who found that alternative treatment users tended to be white and better educated than those who used only conventional treatments. It remains to be seen whether these or any other influences yet to be discovered can account for the survival advantage reported here. However, at present, we can cite no convincing evidence that patients treated in the Gerson system differed from the comparison groups according to any meaningful prognostic variables.

This report has not accounted for variables within the Gerson system, i.e. the role and influence of individual components, and various sets of components. Subsequent to the completion of this report, two major variables, complementary use of surgery and the use of raw veal liver/carrot juice, have been significantly associated with improved melanoma survival outcomes. [Ref 15] Studies of the rationales for modifications made by Gerson over the 30-year course of development of his treatment have led to contemporary modifications, [Ref 15] creating still more challenges for thorough analysis.

This study is a retrospective analysis, and therefore lacks the luster of a randomized clinical trial (RCT). However, the authors have made every attempt to verify adherence to therapy (especially by the survivors), to contrast these data with existing data banks, and to clearly present the comparisons here.

Discussion

No clearly defined mechanism has been identified to account for the survival advantage demonstrated above. Gerson believed that oxidizing enzymes supplied by the raw juices of his diet therapy improved host functions sufficiently to disadvantage malignant cells, which he believed produced their energy through fermentative metabolism. This belief was based on the long popular, but now disproven, cancer generalization of Otto Warburg. [Ref 29] The clinical findings of the present study neither validate Gerson's Warburg-based rationale, nor disprove Gerson's idea of host enhancement to challenge malignancy.

Gerson also believed, after Tannenbaum, [Ref 33, 34, 35, 36, 37] 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. In principle, this belief may have withstood the test of time and advances in research. [Ref 38]

A huge general category of micronutrients, phytochemicals, has become the focus of a great deal of basic cancer and chemoprevention research. Clearly, Gerson's treatment provides high, and in some cases extraordinary, doses of many thousands of phytochemicals. However, the literature does not yield practical knowledge of the effects of either individual or combined phytochemicals in human cancers.

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Cope [Ref 32, pp. 700-711] wrote that Gerson's salt-and-water management for cancer was an approach which probably led to correction of tissue damage syndrome, i.e. cellular edema caused by poisoning, starvation, hypoxia or physical trauma. He felt that Gerson's sometimes extraordinary outcomes may have been due, at least in part, to this mechanism.

Although it has been suggested [Ref 33] that any benefits conferred by Gerson's cancer therapy may be due in greatest part to its psychosocial impact, this question has never been investigated. It is reasonable that observers assume a mind/body effect, due to the treatment's obvious self-help components, and the CHIPSA medical team's active encouragement of family involvement, even during the patient's hospitalization. Provisions have been made for inexpensive room and board for all companions, often with the patient in a private room, resulting in a very high level of family and support-community involvement.

Fortunately, Fawzy, et al, [Ref 25] recently provided findings demonstrating the positive impact of psychiatric intervention on the 6-year disease-free survival rate of stage I melanoma patients in his treatment system. In his study, 13 of 34 stage 1 controls had melanoma recurrences (10 had died at the time of his report), while only 7 of 34 test patients had recurrences (3 had died). Therefore, the 6-year disease-free survival rate for Fawzy's controls was 62%, while for his test patients it was 79%, a rate similar to the one cited by Balch (above). Comparison with the 100% 6-year disease-free survival of 14 early stage (localized) melanoma patients in the Gerson treatment system shows a 27% greater survival benefit (0.21 difference in mean). However, due to the small sample size for Gerson patients, a log-rank test for continuity of survival curves (see Figure 3) over the entire study time is below statistical significance, finding only 93% confidence ($P = 0.07$).

Still, especially when seen in the light of stage IIIA, IIIB and IVA melanoma patients in the Gerson system, the complete absence of recurrence in the Gerson patients supports the possibility of a potent physiological effect from Gerson's therapy, in addition to its probable beneficial psychosocial effect.

During the peer review of this paper, a question arose regarding the potential difference between those patients we were able to locate and assess vs. those who remained lost to follow-up. How might lost-to-follow-up patients affected the rates?

To address this issue, we compared the current findings with those tabulated [Ref 41] in September of 1993, at the beginning of our retrospective. After updating its staging system to match the current report, we found that the 1993 analysis included 44 patients in stages I - IVA assessable for 5-year survival. The 5-year rates were as follows: Stages I + II = 100% (n = 12); Stages IIIA + IIIB = 68% (n = 25); Stage IVA = 57% (n = 7). The entire group's average 5-year survival rate was 75%.

14 patients who had been lost to follow-up in 1993 were located and assessed during the last two years. Adding those 14 cases, bringing the number of assessable patients to 58, the rates remain substantially the same (with the exception of IVA where the initial sample size was quite small).

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The 5-year survival rates including those 14 cases are: Stages I + II = 100% (n = 14); Stages IIIA + IIIB = 67% (n = 30); Stage IVA = 36% (n = 14). The enlarged group's average 5-year survival rate was 67%.

An additional 9 patients who were admitted after August of 1988 but before August of 1990 became assessable for 5-year survival. With inclusion of those cases, bringing the number of patients to 67, the rates remain very similar: Stages I + II = 100% (n = 14); Stages IIIA + IIIB = 71% (n = 35); Stage IVA = 39% (n = 18). With recently recruited patients, the group's average 5-year survival rate is 69%.

There are no statistically significant differences among the average rates (2 = 0.786, power = 0.109). We believe that the continuity of findings at various stages of the investigation suggests that the current rates are probably fairly reliable, and that discovery or recruitment of additional patients will probably not alter the average survival rate significantly, barring the recruitment of substantially greater numbers of stage I and II patients.

We were unable to assess a potential survival benefit for stage IVB melanoma patients in this treatment system. While the Gerson treatment provides many clinical benefits to those internally metastasized stage IVB melanoma patients who are able to practice it, these benefits must be measured with validated "quality of life" instruments. Such measurements can only be accomplished through prospective data collection, which is currently ongoing and will be the subject of future reports. Exact date and cause of death data are being pursued by application to the National Center for Health Statistics for use of the National Death Index. We will report findings as they become available.

Clearly, the search for meaningful biological response modifiers, vaccines, and other means of host stimulation may be paramount for the management of advanced, internally metastasized melanoma. In fact, any means of relatively safe tumor debulking must be given serious consideration.

This retrospective is our first effort at assessment of the outcomes of cancer patients moving through the Gerson treatment system as represented by the 20-year old medical team of the Centro Hospitalario Internacional del Pacifico, S.A. (CHIPSA), of Playas de Tijuana, Mexico. It will be the first of many such studies.

The longest surviving melanoma patient in this study has been disease-free for 20 years. 4 patients who were alive and disease free at 5 years (reported alive in this assessment) have died. 3 stage III patients died of recurrent melanoma after the fifth year (1 of them after 16 years). 1 stage IB patient died after 15 years, of prostate cancer, at age 74. 41 patients are alive and free from disease.

While retrospective reviews cannot account for many influences, they clearly can and should be used to describe aggregate outcomes which can stand on their own for purposes of comparison with other groups and treatment systems, and to further the discussion regarding appropriate methods of cancer management. We encourage those involved with other alternative and complementary methods of cancer management to pursue this route.

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This paper is dedicated to the memory of Dr. Arturo Ortuño and Dr. Freeman Widener Cope.

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