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Clinical study for advanced pancreas cancer treated by oncothermia

Is an Integrative Cancer Therapy Concept (ICTC) the answer to improve the present situation in cancer care?

Cancer Treatment Approach at St. George Hospital

Hyperthermia: a treatment possibility for prostate cancer

Regionale Elektrohyperthermie: Ordnungsgemäße Abrechnung und Erstattungsfähigkeit

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Editorial

Dear Reader,

We are presenting you now the sixth issue of our Oncothermia Journal. I am proud to see that publishing a magazine with Oncothermia-related topics has become a tradition and is highly appreciated by our users. To continue traditions is a very important point for our company. Since 1992 we are organizing a yearly Symposium. This year the International Oncothermia-Symposium will be combined with the ICHS (International Clinical Hyperthermia Society) Conference and take place in the Marriott Hotel Budapest. You can find further information about the event in this Journal as well as on the conference website www.ichs-conference.org.

Another significant tradition of Oncotherm is the science. It is the basis of our production, the further development and the idea to provide the best possible devices for the suffering patients. I am very proud that in this year my son Dr. Olivér Szász was accepted as Associate Professor at the St. Istvan University Hungary and will continue to represent the Oncothermia method in the scientific university life.

I hope that you will be satisfied with the contents of this magazine. As always we are presenting some of our users and introduce to you our new customers. Apart from that we are presenting a report about my travel to Korea and Japan, an article about the prostate-treatment with Oncothermia, information on the cancer treatment at the St. Georg Klinik in Bad Aibling, Germany and a text about the Integrative Cancer Therapy Concept and offer you a text about the reimbursement of the treatment in Germany by Dr. Frank Breitkreutz. Another very important issue is an article on pancreas cancer that shows well that especially for this aggressive cancer with a little more than half-year median survival and a rapidly growing incidence-rate the treatment of Oncothermia is a fantastic treatment option with amazing results.

We would be happy if you would like to place your article in our Journal as well! Please feel free to contact us.
Sincerely

Prof. Dr. András Szász

Liebe Leserinnen und Leser,

Wir präsentieren Ihnen nun schon die sechste Ausgabe unseres Oncothermia Journals. Ich bin stolz zu sehen, dass die Veröffentlichung einer Zeitschrift mit Oncothermie-Themen zu einer Tradition geworden ist und wird von unseren Nutzern sehr geschätzt wird. Traditionen sind auch weiterhin ein sehr wichtiger Punkt für unser Unternehmen. Seit 1992 organisieren wir ein jährliches Symposium. Dieses Jahr wird das Internationale Oncothermie-Symposium mit der ICHS (International Clinical Hyperthermie Society) Konferenz kombiniert und findet im Marriott Hotel Budapest statt. Sie können weitere Informationen über die Veranstaltung in diesem Journal sowie auf der Website der Konferenz www.ichs-conference.org finden.

Eine weitere bedeutende Tradition Oncotherms ist die Wissenschaft. Es ist die Basis für unsere Produktion, die Weiterentwicklung und die Idee, die bestmöglichen Geräte für den leidenden Patienten bereit zu stellen. Ich bin sehr stolz darauf, dass in diesem Jahr mein Sohn Dr. Oliver Szász als Associate Professor an der St. Istvan Universität Ungarn wurde angenommen wurde und die Oncothermie Methode im wissenschaftlichen Universitätsleben repräsentieren wird.

Ich hoffe, dass Sie mit dem Inhalt dieses Magazins zufrieden sein werden. Wie immer präsentieren wir einige unserer Anwender und stellen Ihnen unsere neuen Kunden vor. Abgesehen davon finden Sie in diesem Journal einen Bericht über meine Reise nach Korea und Japan, einen Artikel über die Prostata-Behandlung mit Oncothermie, Informationen über die Behandlung von Krebserkrankungen in der St. Georg Klinik in Bad Aibling, Deutschland und einen Text über das Integrativee Krabsbehandlungskonzept. Darüber hinaus bieten wir Ihnen einen Text über die Erstattung der Behandlung in Deutschland von Dr. Frank Breitkreutz an. Ein weiterer sehr wichtiger Punkt ist ein Artikel über Bauchspeicheldrüsenkrebs, der zeigt, dass speziell für diesen aggressiven Krebs mit kurzer Überlebenszeit und einer rasch wachsenden Inzidenz-Rate die Behandlung von Oncothermia eine fantastische Behandlungsoption mit erstaunlichen Ergebnissen ist.

Wir würden uns freuen, wenn auch Sie Ihre Artikel in unserem Journal platzieren! Bitte zögern Sie nicht uns zu kontaktieren.

Mit den besten Grüßen

Prof. Dr. András Szász

As the editorial team we are committed to a firm and coherent editorial line and the highest possible printing standards. But it is mainly you, the author, who makes sure that the Oncothermia Journal is an interesting and diversified magazine. We want to thank every one of you who supports us in exchanging professional views and experiences. To help you and to make it easier for both of us, we prepared the following rules and guidelines for abstract submission.

Als redaktionelles Team vertreten wir eine stringente Linie und versuchen, unserer Publikation den höchst möglichen Standard zu verleihen. Es sind aber hauptsächlich Sie als Autor, der dafür Sorge trägt, dass das Oncothermia Journal zu einem interessanten und abwechslungsreichen Magazin wird. Wir möchten allen danken, die uns im Austausch professioneller Betrachtungen und Erfahrungen unterstützen. Um beiden Seiten die Arbeit zu erleichten, haben wir die folgenden Richtlinien für die Texterstellung entworfen.

1. Aims and Scope

The Oncothermia Journal is an official journal of the Oncotherm Group, devoted to support them, making a collective for using the results and making it common for general use. The Oncothermia Journal has an open-minded character, expecting the complete study-papers, case-reports, reviews, hypotheses, opinions, and all the informative materials which could be helpful for the international Oncotherm community. Advertisement connected to the topic is also welcome.

- *Clinical Studies:* Regional or local or multilocal oncothermia or electro cancer therapy (ECT) treatments, case-reports, practical considerations in complex therapies, clinical trials, physiological effects, Oncothermia in combination with other modalities, and treatment optimization.
- *Biological Studies:* Mechanisms of oncothermia, thermal-or non-temperature dependent effects, response on electric fields, bioelectromagnetic applications for tumors, Oncothermia treatment combination with other modalities, effects on normal and malignant cells and tissues, immunological effects, physiological effects, etc.
- *Techniques of oncothermia*: Technical development, new technical solutions, proposals.
- Hypotheses, suggestions, opinions to improve the oncothermia and electro-cancer-therapy methods, intending the development of the treatments.

Further information about the Journal, including links to the online sample copies and content pages can be found on the website of the journal: www.Oncothermia-Journal.com.

1. Selbstverständnis und Ziele

Das Oncothermia Journal ist das offizielle Magazin der Oncotherm Gruppe und soll diejenigen unterstützen, die ihre Ergebnisse der Allgemeinheit zur Verfügung stellen möchten. Das Oncothermia Journal ist neuen Inhalten gegenüber offen, sollte aber vor allem Studienarbeiten, Fallstudien, Hypothesen, Meinungen und alle weiteren informativen Materialien, die für die internationale Oncotherm-Gemeinschaft hilfreich sein könnten, enthalten. Werbung mit Bezug zum Thema ist ebenfalls willkommen.

- *Klinische Studien*, regionale, lokale oder multilokale Oncothermie oder Electro Cancer Therapy (ECT) Behandlungen, Fallstudien, praktische Erfahrungen in komplexen Behandlungen, klinische Versuche, physiologische Effekte, Oncothermie in Kombination mit anderen Modalitäten und Behandlungsoptimierungen.
- *Biologische Studien.* Mechanismen der Oncothermie, thermale oder temeperaturunabhängige Effekte, Ansprechen auf elektrisches Feld, bioelektromagnetische Anwendugen bei Tumoren, Kombination von Oncothermie und anderen Modalitäten, Effekte auf normale und maligne Zellen und Gewebe, immunologische Effekte, physiologsche Effekte etc.
- *Oncothermie*-Techniken. Technische Entwicklungen, neue technische Lösungen.
- Hypothesen, Meinungen, wie die Oncothermie- und ECT-Methoden verbessert werden können, um die Behandlung zu unterstützen.

2. Submission of Manuscripts

All submissions should be made online at the Oncothermia Journal by email Oncothermia-Journal@oncotherm.org.

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Manuscripts must be written in English, but other languages can be accepted by special reasons, when it has an English abstract.

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Manuscripts may be any length, but must include:

- *Title Page.* Title of the paper, authors and their affiliations, 1-5 keywords. At least one corresponding author should be identified, whose email address has to be provided with full contact details.
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Manuskripte müssen in englischer Sprache vorliegen. Andere Sprachen können in Ausnahmefällen akzeptiert werden, wenn ein englisches Abstract vorliegt.

Texte sollten in einem mit Microsoft Word für Windows (PC) kompatiblen Format eingereicht werden. Tabellen sollten in einem Word-kompatiblen Format eingefügt werden. Alle Graphiken (Illustrationen, Diagramme, Photographien) sollten im jpg Format vorliegen.

Manuskripte können jede Längen haben, müssen aber die folgenden Punkte enthalten:

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- *Abstracts.* Abstracts müssen enthalten: Zielsetzung, Material und Methoden, Ergebnisse, Fazit.
- *Text.* Beliebige Länge.
- *Abbildungen und Tabellen.* Abbildungen und Tabellen sollten im Text erläutert werden (nummeriert). Jede Abbildung / Tabelle muss eine erklärende Bildunterschrift haben. Bilder sollten als jpg verwendet werden (300 dpi).
- *Zitate.* Das Oncothermia Journal verwendet die Vancouver Methode (Autornummer), um Zitate auszuweisen, z.B. [1], [1-3], [1-3]. Die Bibliographie erfolgt numerisch in Reihenfolge der Erwähnung im Text.

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8. Haftung
Die Autoren aller im Oncothermia Journal veröffentlichten Artikel sind in vollem Umfang für ihre Texte verantwortlich. Das Oncothermia Journal übernimmt keinerlei Haftung für die Artikel der Autoren. Der redaktionelle Beirat hat das Recht,, Artikel abzulehnen.

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The Oncothermia Journal has a special peer-review process, represented by the Editorial Board members and specialists, to whom they are connected. To avoid personal conflicts the opinion of Reviewer will not be signed, her/his name will be handled confidentially. Papers which are not connected to the scope of the Journal could be rejected without reviewing.

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Clinical study for advanced pancreas cancer treated by oncothermia

Abstract

Pancreas cancer (PCA) is an aggressive, common malignant tumor. We present two retrospective clinical studies of PCA done in two medical centers (HTT-MED Day-clinic and Peterfy Hospital). Both of the centers made the treatments by oncothermia in combination with the conventional tumor-therapies. We present the data from both centers and make a metaanalysis of the data as well. Results show a remarkable survival benefit for the patients compared to the historical data. The comparison of the studies shows a good correspondence in the data, which strengthens the reliability of the studies, and points out the feasibility of the oncothermia application on PCA.

Keywords: pancreas cancer, clinical-study, hyperthermia, oncothermia, survival-time, comparison.

Introduction, objective

Pancreas cancer [PCA, (topographic ICD: C25)] is a very aggressive tumor, one of the major unsolved health problems of the present, [1].The PCA is one of the most aggressive malignant disease with rapid progression-rate and short survival-time. Despite the massive efforts to find the adequate therapy, relatively low progress could be achieved in survival-rate of the disease.

The prognosis of the disease is extremely poor; only less than a quarter of the patients are operable, and less than a quarter of those survive to 5 years, and its incidence does not decrease in the past five years, [2]. Its gold-standard management is the resection, but most of the patients are unresectable, [3]. The radiation therapy is more palliative than curative, [4], [5]. This is the reason, why the chemotherapy in this disease has an especially important role. The subsequent reviews point out the importance of the adjuvant and neoadjuvat therapies, [6], [7], [8], and the Gemcitabine (Gemzar) + 5-flourouracil + leucovorin combination had shown a remarkable efficacy [9], [10], [11], [12], see Table 1.

Pts.#	RR (%)	1 y surv. (%)	Median surv. (m)	Ref.
16	25			[13]
16	25		5.25	[14]
36	14		4.4	[15]
163			5.4	[16]
164			6.7	[16]
12	25			[17]
16	31		9.6	[18]
54	3.7		7	[19]
34	17		5.7	[20]
26	19.3		8.5	[21]
24	8			[22]
52	31			[23]
44	13		6	[24]
48	9		6	[24]
28	29		8	[25]
24				[26]
24	38	2.5	6	[27]
12	8.3		8.5	[28]
41	11		8.2	[29]
26	19.2		10.3	[30]
27	7.4	22	7	[31]
42	5.7	28	6.5	[32]
29	10		4	[33]
25	8		9.6	[34]
62	25.9		9	[35]
64	29			[36], [37]
13	23			[38], [39]
11	9.1			[40]
19	0			[41]
24	35		9	[42]
23	34.7		9	[43]

38	5	9.3	[44], [45], [46]
24	13	7.5	[47]
14	7	6.1	[48]
42	26	7.1	[49], [50]
40	20		[51]
25	20	6.75	[52]
49	58	11	[53]
43	19	9	[54]
14	14		[55]
21	19	5.5	[56]
16	19	4.7	[57]
15	13	8	[58]
12	25		[59]

Table 1. Clinical studies on effeicacy of Gemzar combination

Hyperthermia (HT), combined with radiotherapy (RT) and chemotherapy (CT), seems to be a promising method for cancer treatment, although many of the underlying molecular mechanisms of this combination treatment are not properly understood yet. Although some widely accepted effects had been recognized:

It has been shown that an increase in temperature can cause vasoconstriction in certain tumors leading to decreased blood perfusion and heat conduction, and also inhibit angiogenesis [60], [61], [62]. At the same time, the elevated temperature causes vasodilation in the healthy tissues, leading to its increased blood perfusion and heat conduction [63]. These effects functioning like an effective heat trap [64], selectively increase the temperature in the tumor [65]. Furthermore it has long been known that hyperthermia can cause softening or melting of the lipid bilayer [66], [67], [68], it can change lipid-protein interactions [69], and it can denature proteins [70]. All of these events can significantly disrupt a tumor cell's capacity to divide. It is shown, that the increased temperatures cause a drastic change in transmembrane currents [71] and structurally alters the transmembrane proteins causing a change in active membrane transport and membrane capacity [72], leading to substantial changes in potassium, calcium, and sodium ion gradients [73], membrane potential [74], cellular function [75], [76], and induce thermal blocks of electrically excitable cells [74], [77]. Hyperthermia changes the pH values by increasing the biochemical reaction rates [78] and therefore also the metabolic rate. The lack of the oxygen for this forced metabolism results hypoxia [79] and the anaerobe metabolism produces lactate [80] and cell destruction by acidosis. Furthermore, the increased metabolism can significantly decrease the cellular ATP stores leading to increased cell destruction [80]. The DNA replication process is also altered by heat. The increased temperatures can slow down or even block DNA replication [81], [82], as well as stimulate the immune system [81], with observed increases in natural killer cell activity [83]. Moreover, the elevated temperature distributes tumor-specific antigens on the surface of various tumor cells [84] and assists in their secretion into the extracellular fluid [85]. It is important to mention for the clinical outcome the improvement in the quality of life due to the significant pain reduction [86], which can be prolonged and enhanced by the electric field using TENS effects [87]. This pain-reduction has special importance at such painful disease like PCA. Additionally, hyperthermia is an ideal combination therapy. It has low toxicity, mild side effects, and has been shown to provide synergies with many of the traditional treatment modalities. It enhances the effect of chemotherapy [88], [89]; and also has pronounced advantages for surgical interventions.

One of the most advanced treatment HT-modalities devoted to oncology is oncothermia (OT), [90], [91]. Due to the limited effectiveness of established therapies, OT could be one of the important future methods to improve the treatment facilities of PCA, [92], [93].

Our objective in this article is to present a retrospective clinical study for PCA. The study concentrates on the effects of the survival time as one of the most important factors to measure the success of a treatment in oncology.

The retrospective data are indications only, the prospective, randomized, controlled study should clarify the situation as according to evidence based medicine. However, we present data from two study-places, showing their similar results, and also present a comparison of the first year survival by oncothermia with two more independent clinics.

Method

The present results are obtained from an open-label, single-arm, retrospective study. The involved patients are being analyzed according to an intention-to-treat (ITT) schedule. Recruiting time was from Apr. 1997 to Aug. 2002, all together 64 months. The primary check of the efficacy of a curative method in such a lethal kind of disease is the survival time. The primary endpoints of the present study therefore were the overall survival oncothermia treatment time (OS) and the survival time from the first oncothermia treatment (oncothermia treatment survival time, OSO). The date of death (or alive) were checked by the Hungarian National Death Register, so the actual and accurate data were collected. The latest check of the deaths was 31. December of 2003.

The evaluation methods were: descriptive biostatistics, log-rank survival tests (Kaplan-Meier plot), and comparison with large studies and databases and/or local historical data. In order to support the reliability of the retrospective data-set, two independent hospitals were involved in the present study. One is the Peterfy Hospital, Budapest (PFY). It is a governmental hospital involved in the regular health-service network. The other one is a private day-clinic (HTT-Med Polyclinics, (HTT)), serving the patients only on private basis. The two trial-places were in tight information-contact, making the treatments with the same practical conditions and guidelines.

Patients were dominantly in late/advanced stages, where the traditional oncotherapies were unsuccessful.

Inclusion criteria were: (1) Inoperable or sub-totally resected or recurrent primary pancreas tumor, (2) progression after surgery and/or chemo-therapy, (3) Karnofsky Performance Score (KPS) > 40%. and the inclusion was irrespective of the localization of the lesion in the pancreas. Most of the patients failed to respond to any of the applied conventional therapies.
Exclusion criteria were only the well-known contraindications of the oncothermia method (metallic implants or replacements in the treated area, missing heat-sense in the treated area, pacemaker or other field-sensitive implants in the patient).

The study had a couple of possible negative biases: (1) the treatment is paid or co-paid by the patients, who do it on a voluntary basis (ITT) in strict control of the oncologist who was responsible for the patient treatment till that time; (2) no randomized control arm exists, the trial is compared to the historical control or to the available literature.

However, the present study had a few possible positive biases as well: (1) patients were treated in their advanced stages, when other treatments had failed and/or were not possible; (2) the involved clinics are not equipped so well as the special institutes/universities; (3) the involved patients had no extra “trial-attention”.

The safety of the method is proven. It has been applied over 15 years in clinical practices. No serious safety problem has been reported about the oncothermia treatments. The devices are approved according to the European Medical Device Directive (CE/MDD) and those are under permanent vigilance system. The treatment dose is personalized, fitted for the actual status of the given patient.

The used device was EHY2000 (OncoTherm), capacitive coupled, working on 13.56 MHz, time-domain (fractal) modulated, with 30-150 W power absorbed by the tumor, keeping the skin surface on 20 oC. (For further details of the method we would like to refer to some of our other papers, [71], [90], [91].) The treatment control was made by the absorbed energy [kJ], which was converted to the equivalent temperature [T]. The equivalent temperature is higher than the actual temperature value, calculated by the assumption that the energy makes only a temperature increase. The reality, that the energy together with the increase of the temperature is basically used for the distortion of the structures, change of the chemical bonds and compensate of the physiological regulations, [94], [95], [96]. The equivalent temperature is in average higher, about 10 oC, than the measurable one in the actual conditions, however it is always the function of the given conditions and mechanisms.

The calculated average equivalent temperature in the tumors was above 43 oC in more than 90% of the treatment time. The targeted area was treated by the properly covering applicator system. OT was performed in two/three sessions per week. Treatment time and power range per session were 60 minutes, and 150 W. The power was gradually and linearly raised up depending on the patient tolerance. The applied average energy was 300 kJ/treatment (250-450). The applied applicators were 3.1 dm^2 and 7.1 dm^2, depending on the tumor volume.

Results

Hospital Peterfy (PFY) (n=26)

The age-distribution of n=26 patients was near to normal (see Figures. 1, 2); no outlier were present. The median age was 64.5 y (37 - 77), the mean-age was 62.5 y (Std.err= 1.99). The gender distribution was 14/12 female/male (53.8/46.2 %). The ratio of the elderly (>68 y) patients were 42.3%.

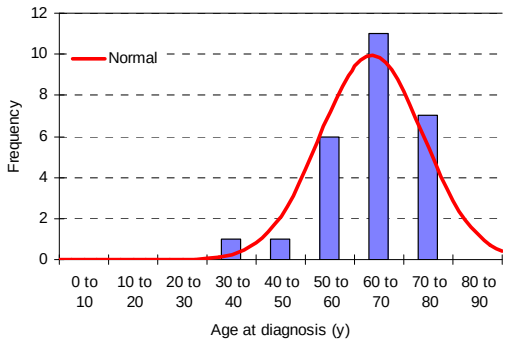


Figure 1. Age-distribution at diagnosis

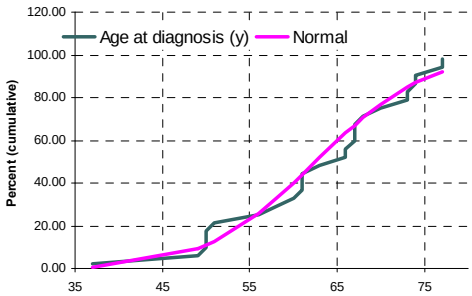


Figure 2. Cumulative age-distribution

Most of the patients (23, 88.5%) had distant metastases. They were heavily pretreated, everybody received at least one chemotherapy and most of them underwent surgery (see Figure 3).

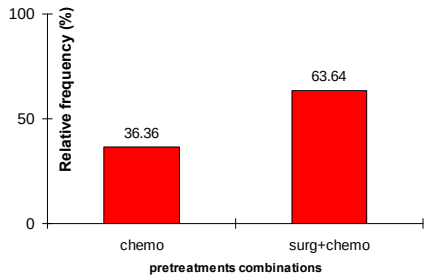


Figure 3. The pretreatment distribution in patient population

The actual staging was made at the first diagnosis: 23, [88.5%] was in advanced [WHO III or IV] stages, and at the first oncothermia treatment 100% was in advanced stages, 19 (73.1%) were in the worst stage.

The median of the elapsed time from the 1st diagnosis to the 1st oncothermia was 4.1m (0.8-75), while its mean was 8.6m (st.err.3.0). The elapsed time ratio to the overall survival was more than 35% (median 37.3%, [5.9-86], mean 44.3 [st.err.4.2]).
The oncothermia treatment was provided 2-3 times a week, the treatment number was in average 9.0 (st.err.0.86) and its median 6 (3-16), (see Figure 4.)

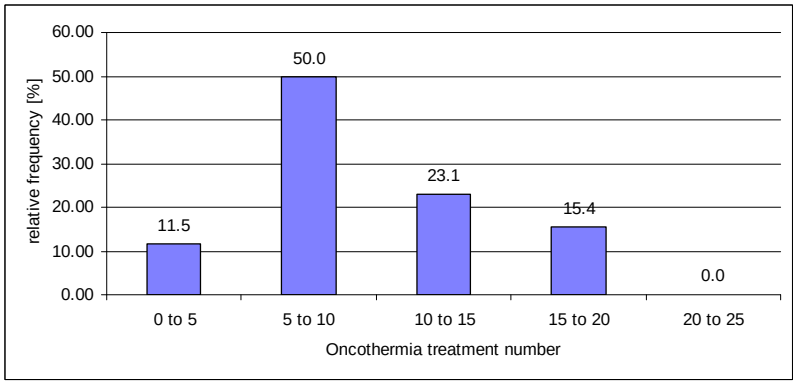
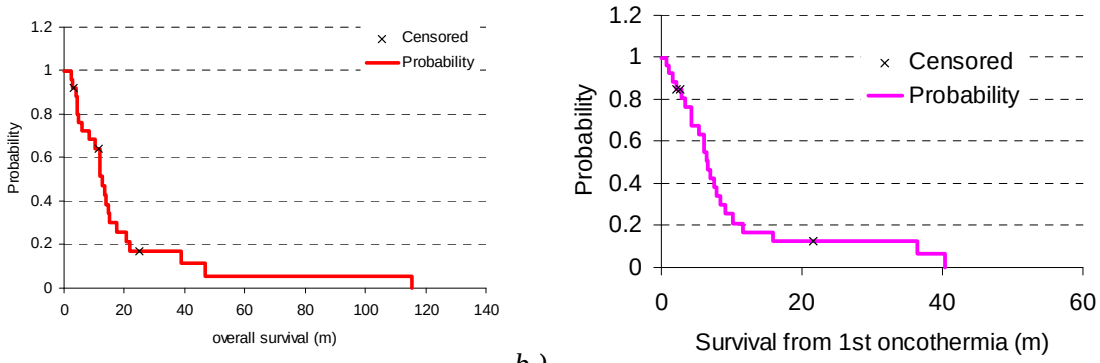


Figure 4. Treatment numberof oncothermia is dominantly in the 5-10 interval

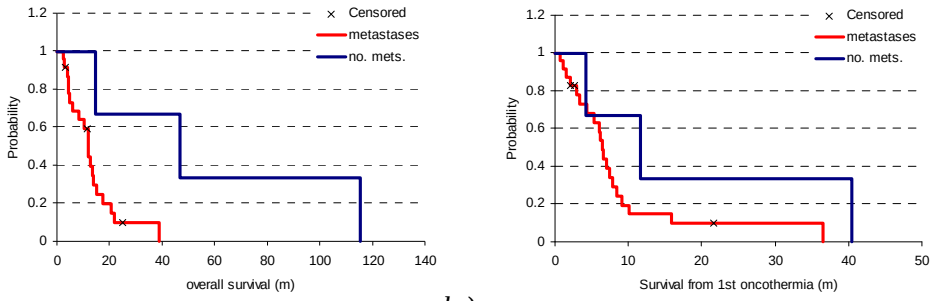
The Kaplan-Meier plots of the overall survival (OS) (median 12.0m, [2.3-115.5]; mean 17.5m, [st.err.4.4]) and the survival from the first oncothermia treatment (OSO) (median 6.32m, [0.7-40.4]; mean 8.9m, [st.err.1.9]) are shown in Figure 5. For elderly patients neither the OS nor the OSO were different (p=0.41 and p=0.61, respectively).



a.) *b.)*

Figure 5. The OS (a) and OSO (b) Kaplan-Meier plots

The survival was significantly different and for patient without or with metastases in their OS, (p=0.039), but was not significant in their OSO (p=0.20), see Figure 6.



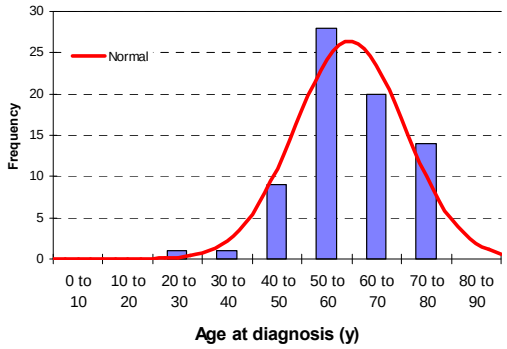
a.) *b.)*

Figure 6. OS (a) and OSO (b) survivals depend on the preliminary surgery

We studied the effect of the experience of the treating medical personnel by the data before and after the median time of the study. No observable effect could be registered: OS (p=0.86) and OSO (p=0.69). The elapsed time to the first oncothermia from the first diagnosis is lower in the late experience, (medians are 5.17 m [0.8-75.1], and 3.27 m [0.9-35.3], in early and late experience period, respectively) but the difference is not significant either (p=0.29).

HTT-MED Polyclinic (HTT) (n=73)

The age-distribution of n=73 patients was near to normal (see Figures. 7., 8.); no outlier were present. The median age was 58 y (24 - 79), the mean-age was 59.1 y (Std.err= 1.3). The gender distribution was 33/40 female/male (45.2/54.8%). The ratio of the elderly (>68 y) patients were 26.0%.



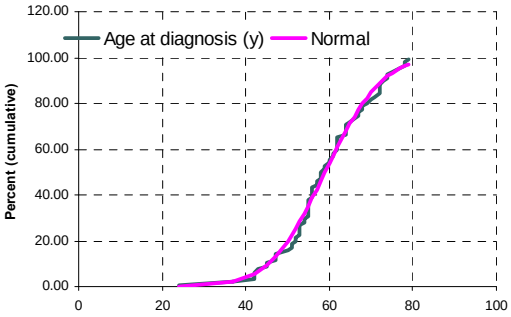
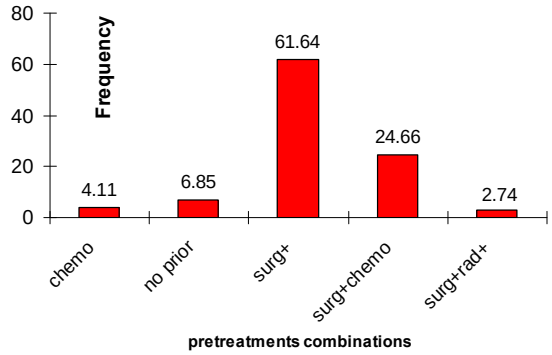


Figure 7. Age distribution of patients in HTT trial *Figure 8. Cumulative age-distribution in HTT*

Most of the patients (54, 74.0%) had distant metastases, (one, two and three metastases were observed for 43 (58.9%), 10 (13.7%) and 1 (1.4%) patients, respectively). They were heavily pretreated, mostly (93.4%) underwent surgery and subsequent radiation and/or chemo-therapies, see Figures. 9, 10).



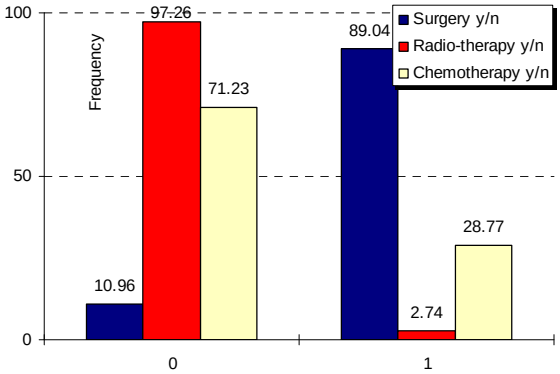


Figure 9. Pretreatment combinations *Figure 10. Pretreatment distribution*

The actual staging was made at the first diagnosis (45, 61..6% was in advanced [WHO III or IV] stages) and at the first oncothermia treatment they were in more advanced status.

The median of the elapsed time from the 1st diagnosis to the 1st oncothermia was 3.3 m (0.3-85.7), while its mean was 6.6 m (st.err.1.3). The median of the elapsed time ratio to the overall survival was 37.1% (5.1-96.0], mean 41.2 [st.err.3.4]).
The oncothermia treatment was provided twice a week, the treatment number was in average 8.0 (st.err.0.6) and its median 6 (3-26), (see Figure 11.). The equivalent temperature in average was 50.7 (sd.err.0.6), median 51 (43-59). (Note, that the equivalent temperature is not the real temperature. It is the calculated value from the actual energy-absorption and the impedance, meaning the actual destruction rate, which is as high, as it would be in a purely temperature oriented case.) The applied treatment time in average was 67.2 min, (st.err.1.8) and its median was 60 (45-120).

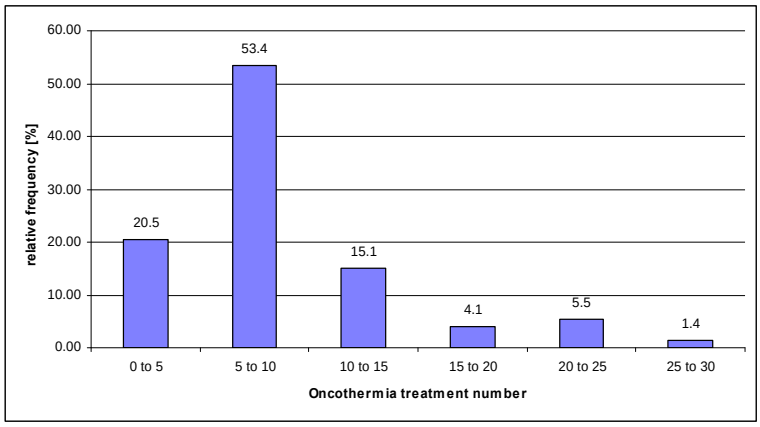
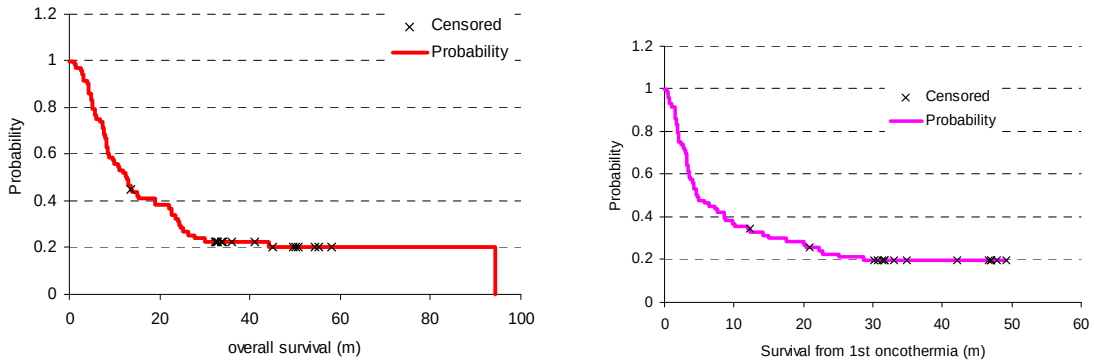


Figure 11. Number of oncothermia treatments

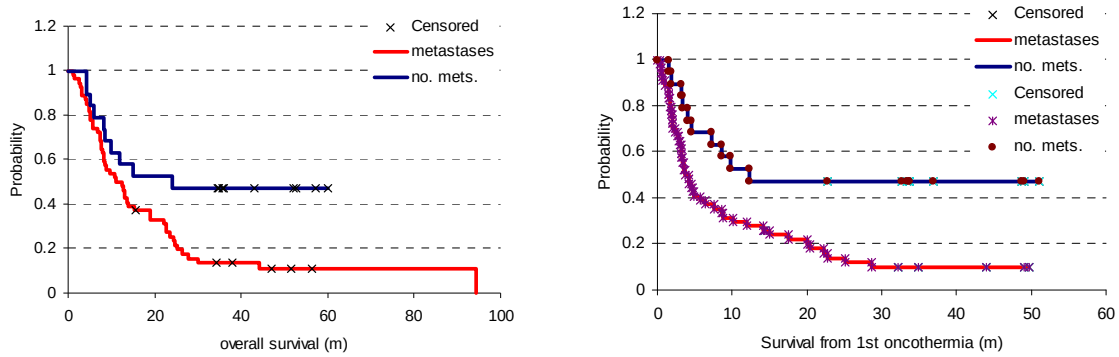
The Kaplan-Meier plots of the overall survival (OS) (median 12.7 m, [1.2-94..5]; mean 19.2 m, [st.err.2.1]) and the survival from the first oncothermia treatment (OSO) (median 4.7 m, [0.3-49.2]; mean 12.6 m, [st.err.1.7]) are shown in Figure 12. For elderly patients neither the OS nor the OSO were different (p~0.23 and p~0.42, respectively).



a.) *b.)*

Figure 12. OS (a) and OSO (b) of HTT-study

The differences between patients without or with metastases in their OS and OSO were significantly different (p=0.016 and p=0.004 for OS and OSO, respectively) see Figure 13.



a.) *b.)*

Figure 13. Dependence of the survival from the number of metastases [a) OS, b) OSO]

The number of treatnemts does not significantly influence the OS (p=0.24) and the OSO (p=0.16) and the follow-up time after the last oncothermia (p=0.23), see Figure 14.

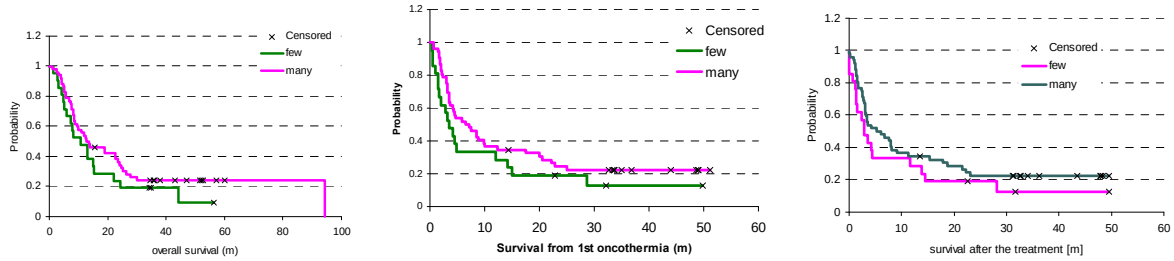


Figure 14. . The typical survival times do no depend significantly on the number of treatments (few = below median, many = above median number of treatments)

Interestingly, the gold-standard, the surgical pretreatment wasn't significantly important for the longer survival either for OS (p=0.84) and OSO (p=0.87) (see Figure 15.). This was probable because the tumor was only partially resected, or the surgery was only for palliation.

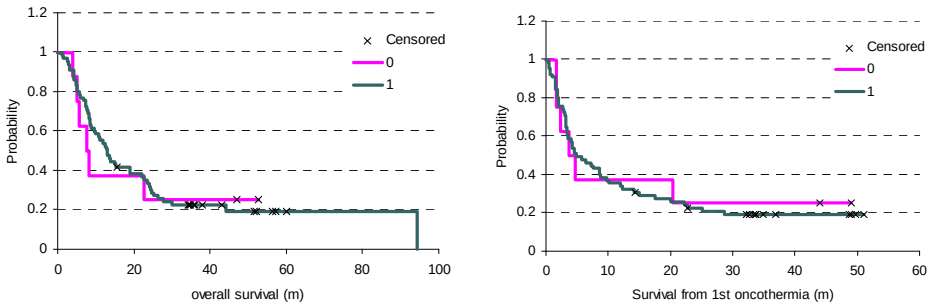


Figure 15. The survivals' dependence on the surgery ((0) – no; (1) – yes

We studied the effect of the experience of the treating medical personnel by the data before and after the median time of the study. There is some difference (not significant) in the OS, OSO and ETO (p=0.15; p=0.077 and p=0.52, respectively), (see Figure 16.).

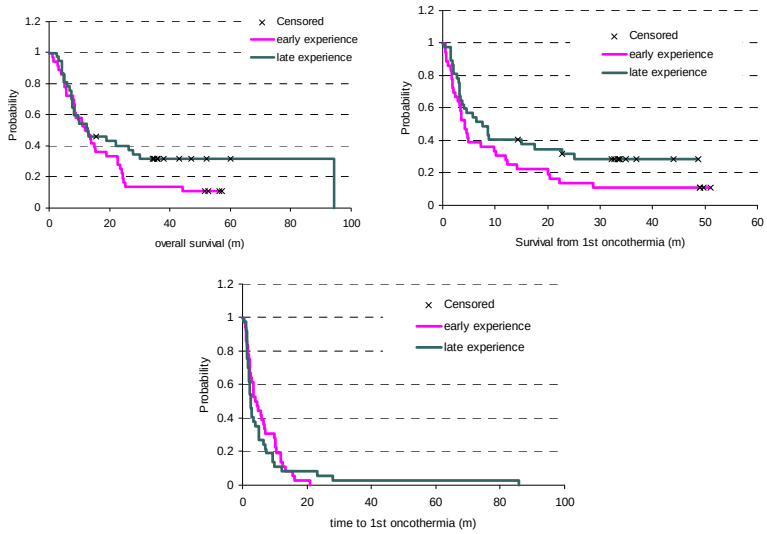
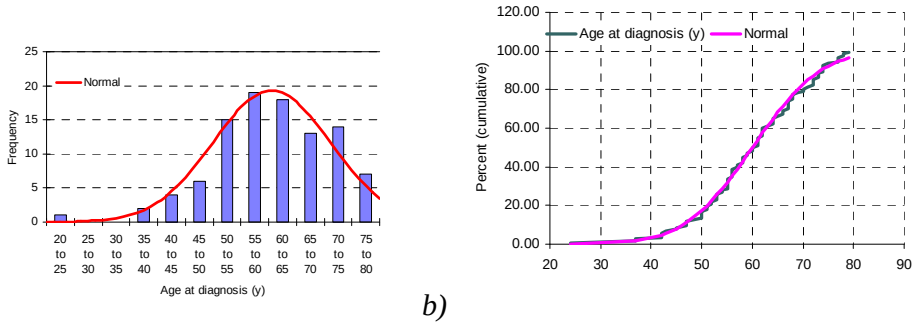


Figure 16. The experience of the treating personnel did not modify the results significantly ("early experience" = the treatment was started earlier than the median time of the study; "late experience" = the treatment was started later than the median time of the study)

Comparative-analysis

The age-distribution of the altogether n=99 patients was near to normal (see Figure 17.); and no outlier were present. The median age was 60 y (24 - 79), the mean-age was 60 y (Std.err= 1.1). In the spectrum of the PTF a shift to the elderly patients was present (see Figure 18.). The gender distribution was 47/52 female/male (47/53 %), and no significant difference could be measured between the places (see Figure 19.). The PFY/HTT patients' ratio is 61/197 (24/76 %).



a) *b)*

Figure 17. Age-distribution of lung tumor patients (n=99). a) distribution by 10 y categories, b) probit cumulative

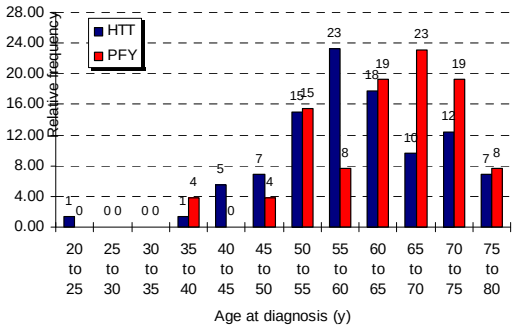


Figure 18. . The age-distribution differences in the given clinics

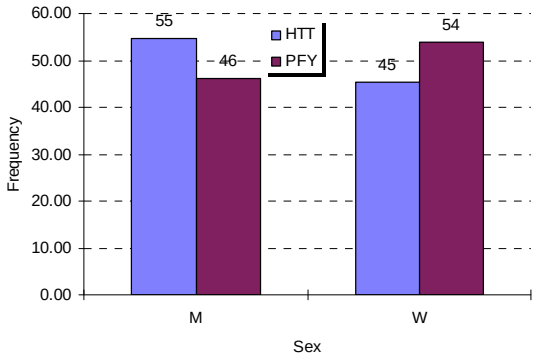


Figure 19. The gender distribution in the given clinics

74% and 88% of the patients had distant metastases in HTT and PFY groups, respectively (see Figure 20). Patients were heavily pretreated (see Figure 21), in PFY the chemo-therapy, in HTT the surgery was the most frequent modality.

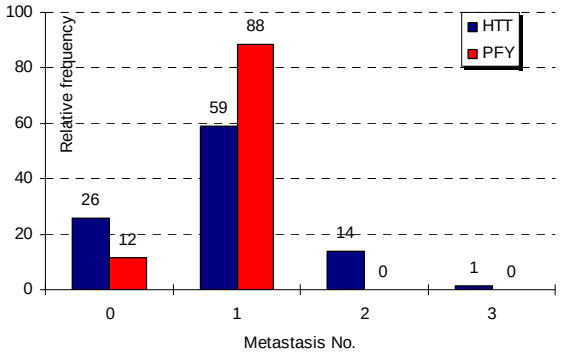


Figure 20. Number of metastases of the patients involved in the study

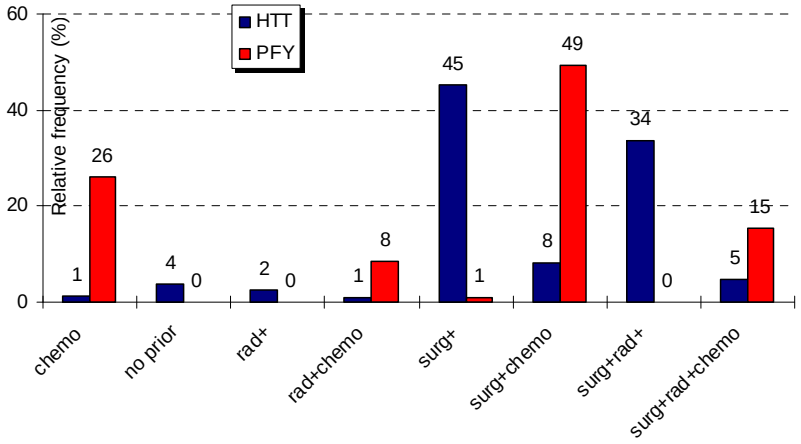


Figure 21. Pretreatment distribution

The elapsed time to 1st oncothermia from the first diagnosis was identical (p=0.69) in the two places, see Figure 22.

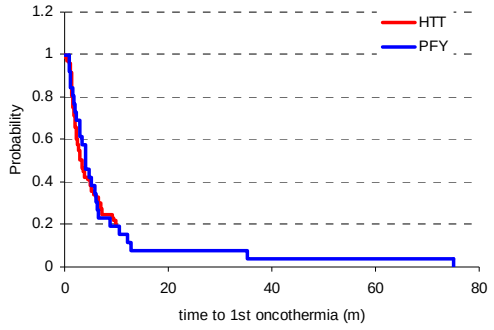


Figure 22. The distribution of the elapsed time to the first oncothermia treatment

The oncothermia treatment was provided twice a week, the treatment number was in average was more in PFY than in HTT procedures, (see Figure 23.).

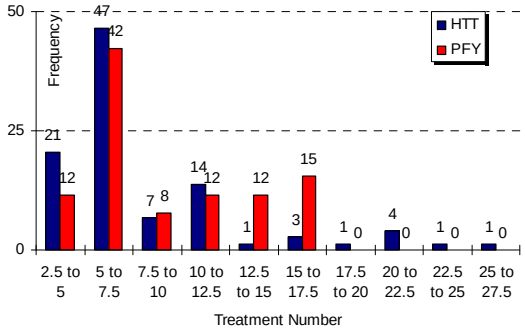
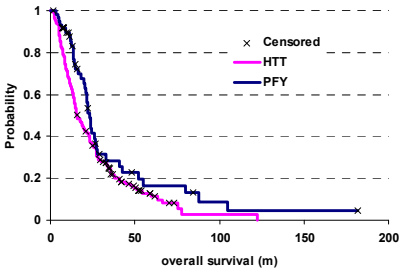


Figure 23. The number of treatments for the patients in the study

The overall survival (OS) and the survival from the first oncothermia treatment (OSO) are shown in Figures 24 and 25. Neither of the measured parameters differed from each other (p=0.38 and p=0.39, respectively).



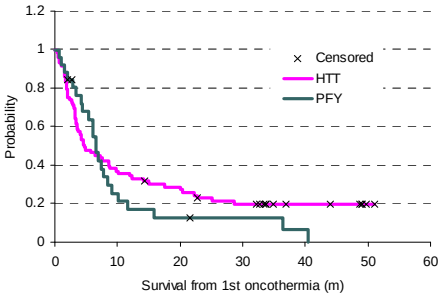


Figure 24. The OS comparison of the studies *Fig. 25. The OSO comparison of the studies. No significant difference could be observed*

Survival after the treatment was not different in the two places (p=0.34, in Figure 26.).

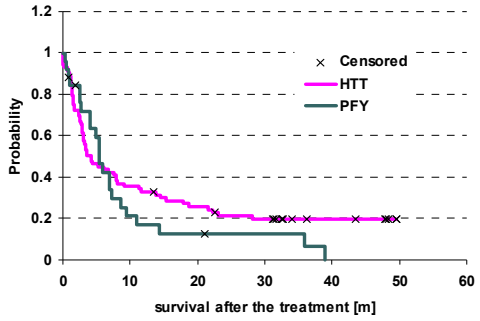


Figure 26. The follow-up-time does not differ in the two studies either

Discussion

Results show the identical survival parameters in the two independent places. The yearly survival rate is also not significantly different (see Figure 27.)

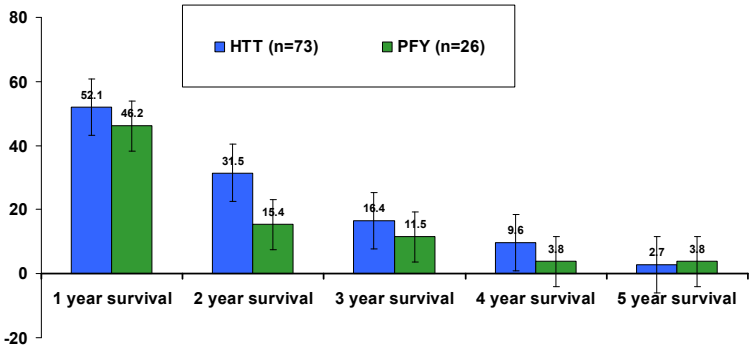


Figure 27. The yearly survivals are well corresponding in the two studies

The results could be well compared to the available SEER [97] and Eurocare-3 [98] data. The comparison of the yearly survival rate is shown in Figure 28. The gain of the first few years is obvious, while the difference gradually vanishes approaching the 5th year. The reason is the difference of the treated patients. When the patient has a long survival, His/Her oncothermia treatment starts only at the end of the available conventional treatments; the patient receives oncothermia only in a small fraction of His/Her survival time, therefore the survival time does mostly not depend on the end-application of oncothermia. While in case of the short survivals a considerable lifetime depends on the oncothermia application.

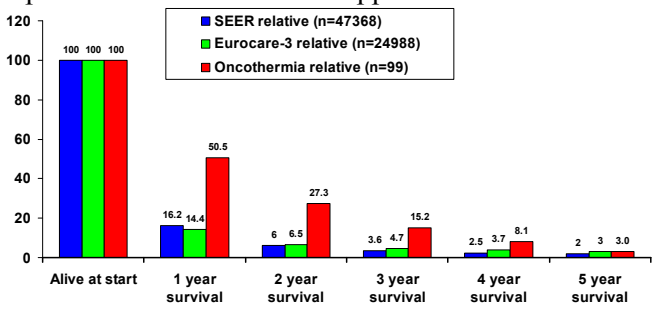


Figure 28. The comparison of the results with SEER and Eurocare-3 data in first five years survival-rate (%).

To prove the results we had compared the most surprising first-year survival with other independent clinical results from two German clinics. The two additional retrospective oncothermia trials were performed by VeraMed Clinic, [99] and Nurnberg Town Hospital [100]. The result is shown on Figure 29. The result convincingly demonstrates the significant difference

between the oncothermia and the general retrospective data.

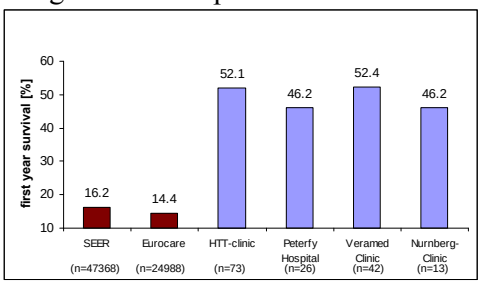


Figure 29. Comparison of the first year survival-rates (%) in various clinics.

For additional check a historical control (n=34) from the St.Borbala Hospital (Tatabanya, Hungary) was given as comparison to the data. The reality of this comparison is the fact that one of the author (AD) had worked at HTT and at St.Borbala Hospital at the same time and so the comparison of his own data is feasible. The median OS of the control was 6.5 m (1-31), and the mean survival was 8.7 m (St.err.1.29), while the compared HTT (n=73), median 12.7 m (1.2-94.5), mean 19.6 (std, err.2.1).
The comparison of the Kaplan-Meier survival curves demonstrates the cogently significant difference (p<10-4), (see Figure 30.).

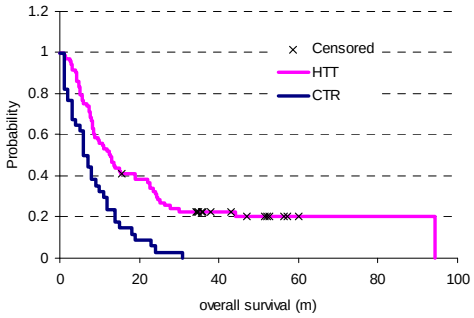


Figure 30. The comparison of the Kaplan-Meier survival curves of the results by HTT and the historical control, collected by the same treating physician in St.Borbala Hospital

Conclusion

Our present paper indicates the feasibility of the oncothermia treatment of PCA. The results are well indicating the benefit of treating PCA by oncothermia:

1. Oncothermia was applied for pancreas tumors, showing a valid treatment potential and safe application.
2. No safety or notable toxicity problem has occurred. The development of an edema or burn, which was a complication of hyperthermia applications in the past, is not the case with oncothermia. The treatment is safe and convenient to use.
3. The survival time, as one of the most important parameters, was increased for the patients making progress by other treatments.
4. The quality of life of the patient was improved by oncothermia according to their subjective reports.

Our present data are only retrospective indications of the efficacy of the oncothermia method. A prospective, randomized, controlled double-arm clinical study is needed for an evidence-based evaluation.

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Is an Integrative Cancer Therapy Concept (ICTC) the answer to improve the present situation in cancer care?

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Introduction

The demand for integrative oncology is on the upswing as both patients and doctors grow impatient with the failed war on cancer, internationally. More and more physicians move away from a one-size-fits-all kind of treatment to an integrated, patient-centered approach as we practice it at St. George Hospital, since more than twenty years.
Cancer is a multibillion Euro market that is growing fast and companies make a lot of money on something that doesn't work that well. Metastases are the major cause of death in cancer. Yet from 1972 to 2004, only 0.5% of the official Multi-Center studies focused primarily on metastasis.

Metastases (the spread of cancer from one spot to another) are a manifestation of treatment failure. The first treatment, after the diagnosis, was not effective enough to keep the cancer under control, so it came back. Today, the survival rate for metastatic cancer is about the same as in the 1970s.

Integrative oncology does not mean standard doses of chemo and radiation plus some vitamins, minerals, trace elements, bioactive substances and acupuncture treatment or neural therapy.
Cancer is a very complex disease and several cancer controlling systems have fallen ill. That is when the cancer establishment tells you to fight cancer and you march out for one of the conventional treatment modalities and attack the cancer with surgery, chemo, and radiation - weapons of mass destruction. But they weaken for instance an already debilitated immune system. The majority of the cancer drugs are not taken up by the cancer cells alone but also by the healthy cells, and organs like liver, nerves, kidney and blood components get damaged in the process. Good cells die along with the bad ones. We know that surgeries can cause metastases in the long run, once chemo and radiation have killed the P53 tumor-suppressor gene. Indeed, cancer usually returns between 6 and 11 years, which is why the statistics measure only 5-year survival rates.

When the initial treatment produces clear cancer markers, the patient is sent home and told to hope for the best. The cancer is declared "gone," yet a very fragile immune system and organs are left without any advice for the patient what to do to get it repaired. Too often the body flounders and the cancer returns – harder to kill than before and easier to metastasize. Therefore, the soil on which cancer could grow has to be turned around, that means we have to treat the causes. Conventional oncology is focused on the cancer and not so much on the carrier of the cancer - the patient.

It is becoming clear that we therefore are losing "the war on cancer", in great parts because the current paradigm is too focused on bombarding cancer cells and cancer tissue rather than healing a depleted body. It is accepted for instance, that cancer is a failure of the immune system. Rudolph Virchow in 1865 said: „Tumors are wounds that do not heal. Every cancer medication should improve wound healing."

Cancer is a very active tissue, it mutates quiet frequently and it is always tough for us to get adjusted to this. That is why we really need to support the immune system. The immune system, under normal conditions, kills daily many cancer cells. A tumor is partly you but not completely you, so we need to include the body's own immune system in the treatment. It is the only system in our body that can differentiate between self and non-self. Even if with conventional therapy, we could kill every single tumor cell but we would not support the immune system, then the cancer would, very likely, come back. The immune system must be supported to become stronger

than it was before the cancer was diagnosed. The intact immune system is potentially the best fighter against metastases. Yet conventional therapy weakens the immune system and almost never repairs or supports it. Most patients are not precisely informed about the immediate and long term toxicity of chemotherapy or radiation therapy. In many cancer patients we observe a shift in the Th1 to Th2 ratio with a Th2 dominance, which is very unfavourable. Such cases need support, which one we will explain later. Cancer patient are prone to infections and silent inflammation, which we should recognize and treat. Another aspect, often overlooked in conventional oncology are the environmental toxins. Cancer is associated with a high intake of such toxins. [1, 2] We have more than 80,000 chemicals in our environment, but only about 15% have been tested for safety. Chemicals damage several systems of the body, including the immune stem. Over time these toxins can damage the DNA, so that a cell turns into a cancer cell. Pesticides, for instance, damage the mitochondria. We find pesticides and heavy metals in almost all our patients. It is clear that if we want that a cancer patient gets well again, then, we have to detoxify them with chelation and other effective modalities. This is for us an integral part of our cancer strategy. We don't consider the job done when the cancer cells are killed; we pay attention to the inner terrain during treatment and, most importantly in terms of preventing cancer's return. **After the initial treatment is over,** we teach our patients how to boost their inner terrain, longterm, **to stabilize remission.**

The therapy itself is quite complex, but basically involves three components: **diet,** aggressive **supplementation** with nutrients and pancreas product (containing naturally occurring enzymes), and **detoxification**. The protocols are individualized and each patient receives a diet designed for his or her specific needs. The diets are quite variable, ranging from a pure vegetarian program to a more lacto-vegetarian diet, which also could include, in selected cases, a small amount of fish and meat. The supplement regimens are also individualized, and powerful. The supplement regimens include a range of vitamins, minerals, trace elements, anti-oxidants and animal glandular products, prescribed according to each patient's particular needs and cancer type. The use of nutritional supplements for cancer patients is vastly misunderstood in conventional oncology. Most of the oncologists I know have little or no idea about it. And since they don’t know the details, they tell patients not to use it, because they contain antioxidants and since radiation and chemotherapy are pro-oxidant, the nutritional supplements could interfere with the activity of these pro-oxidant treatments.

Before trying to answer the question as to the value of nutritional supplements while undergoing conventional cancer treatment, it might be helpful to discuss the similarities and differences between conventional treatment and nutritional supplements. An ideal chemotherapeutic agent would be one that is highly selective in its action by promoting the destruction of cancer cells while not harming, but rather nurturing normal cells. Unfortunately, conventional therapy does not do this. Radiation, chemotherapy, antihormonal treatments, and even the targeted monoclonal antibody treatments generally are harmful to normal cells; hence the adverse side effects observed during their administration. We achieve this selectivity with insulin potentiation and hyperthermia. With this we damage, respectively kill cancer tissue, but don’t harm healthy tissue, especially the immune system. In this phase it is extremely important to support the immune system, so it can do all the repairs necessary. Nutritional supplements have different effects on cancer cells than on normal cells. They are harmful to cancer cells but nurture normal cells. These nutrients do not, we believe, have a direct anti-cancer effect, but instead serve to improve overall metabolic function, balancing the hormones and supporting the immune system. In addition to these supplements, every cancer patient has to take large amounts of proteolytic enzymes (Bromelain, Papain) and pancreas enzymes (Trypsin, Chemotrypsin) in capsule form, which we believe provides an additional anti-cancer effect. During the development of cancer a series of pro-cancer events occur, natural substances can interfere with these processes without harming normal cell. These events are: (1) gene mutation genetic instability; (2) gene expression (switching on and off); (3) abnormal signal transduction; (4) abnormal cell communication; (5) new vessel formation angiogenesis; (6) invasion into tissues; (7) and other organs; (8) immune

suppression and other forms of immune evasion. There is a long list of literature available how these substances can affect several steps of this process. For example, curcumin (derived from turmeric) inhibit; PTK, PKC, NFkB, and PGE2 synthesis which play a role in inflammation and cancer, inhibiting invasive enzymes, while stimulating or supporting the immune system. EPA (from fish oil) inhibits PKC and PGE2 synthesis, stimulates or supports the immune system and inhibits invasive enzymes. Vitamin D3 (1,25 dihydroxy D) has 9 possible anticancer effects, melatonin even 15, vitamin A and boswellia have15. These compounds can be compared with chemotherapy drugs, they are 30 times less potent in vitro and about 21 times less toxic than chemotherapy drugs. Each substance acts during several steps of the malignant process. They act synergistically and are used most effective in combination with hyperthermia and as maintenance when the cancer is gone or under control. In combination with our specific cancer destructing methods like Insulin Potentiated Chemotherapy (IPT) and hyperthermia we have to support the patient to improve his repair mechanisms and his immune system. Another important component of all phases in our integrative cancer therapy concept is **detoxification**.

During our therapy, we found that as patients repair and rebuild their system, large amounts of metabolic wastes and stored toxins are released. As a result, patients routinely develop a variety of symptoms, most commonly described as "flu-like," such as low grade fevers, muscle aches and pains, even rashes. Together with hyperthermia and low dose Insulin Potentiated Chemotherapy we can cause tumor lysis, which is responsible for these symptoms. Therefore, detoxification is during this phase very important. Detoxification is carried out with a variety of different methods; like chelation, alkalinization with Bicarbonate or coffee enemas to clean the bowels and support the liver. Coffee enemas enhance liver function and in turn, the processing and excretion of metabolic wastes. The coffee enemas are done daily, and patients, most commonly, report symptomatic relief. Coffee enemas have been discussed in the orthodox medical literature. The rectal instillation of fluids will stimulate gallbladder contraction and emptying.[21]

The list of such efforts to improve the health in our cancer patients includes teaching our patients

- how to make permanent changes in their diet
- how to make ongoing use of chelation, colonics, coffee enemas and other detoxing tools
- how to get the hormones rebalanced
- how to get heavy metals and root canals out of the mouth

and learning how to coop with emotional and psychological problems, which may be contributing to a depressed immune system.

Cancer does not appear suddenly; there is more to this than normal cells becoming abnormal. There are several severe underlying diseases such as a too high load of heavy metals, imbalance of the hormone system, imbalances or blocked immune system, chronic infections, silent inflammation, etc. etc. The cancer nodule is only a symptom of these many ill making factors. To treat the symptom, that means to take the node out, or radiate it, or throw a chemical on it, is too easy. Treating just the symptom is like shooting the messenger of bad news. Usually, the conventional oncologists do not trust the body's ability to heal it self. It is clear now, that cancer is a biological answer to internal imbalances created by unresolved inner conflicts in conjunction with other factors, such as lifestyle, diet, environmental toxins and infectious agents, psychological and mental conflicts, etc.

Targeted Delivery of Chemo enhanced by hyperthermia

Hyperthermia is a treatment modality in cancer, which is rather old, but still not wide-spread in oncology. Although hyperthermia, by itself, is oncotoxic, meaning that it can destroy cancer cells, it induces also heat shock proteins, which make the cancer recognizable by the immune system. Heat shock proteins are the signals for the natural killer cell to eliminate that cell. So, hyperthermia does not only destroy cancer, it also induces an immune answer to cancer. You see here already the fundamental difference between conventional cancer treatment and our approach. In our system the cancer gets destroyed within the body by hyperthermia and the immune system gets the chance to recognize the cancer and learns how to destroy it. We know that hyperthermia can enhance the activity of chemotherapy and radiotherapy. This is interesting for us, but not what we were looking for. We wanted to have on one side higher effectivety at the tumor site and on the other side less toxicity out of our treatment. Our slogan is to attack the cancer, but support the host. In conventional oncology patients often suffers more from the treatment than from the disease. What we also learned was very simple. It is long know, that insulin, the body's own hormone allows us to target chemotherapy drugs directly to the cancer cells while largely bypassing the healthy cells.

This approach, IPT, was first used for cancer treatment in 1946 and has been a successful cancer treatment used around the world, ever since. Studies at George Washington University, the National Cancer Institute, and M. D. Anderson Hospital and Tumor Institute demonstrated that insulin potentiates (makes more effective) chemotherapy drugs. Otto Warburg, a German Noble Prize winner, taught us that cancer cells differ from normal cells in the aspect that their main fuel is glucose (sugar). This is a clear difference that can be used to our advantage in therapy. When we administer insulin to drop a patient's blood sugar level, cancer cells become ravenous for any sugar (fuel) that they can find left in the bloodstream.

At the therapeutic moment, or “therapeutic window” - that is usually when the blood sugar level drops into the 40s - the cancer cells are screaming for sugar, all doors and windows are open. Now we administer the chemo drugs, and the cancer cells take the drugs also in their effort to get more sugar. It doesn't take long for the drugs to find their way into the cancer cells; a few minutes later the patient's blood sugar level can be brought back up to normal.

A 1981 George Washington University study found that using insulin increased the killing effect of one of the key chemo drugs, methotrexate, by a factor of 10,000.[5,6] The use of insulin to target chemo works so well, that patients need to receive only about 10%-20% of the usual dose. This cancer destruction can be enhanced even further by the synchronical application of local or systemic hyperthermia. Hyperthermia enhances the metabolism of cells in general and an increase in metabolism means a higher demand for sugar. A normal cell can gain 36 mol of ATP from one mol of glucose, a cancer cell can gain only 3 mols since it burns down glucose by anaerobic glycolysis to pyruvate, respectively to lactic acid. So, long term exposure of cancer tissue to heat means metabolic exhaustion and together with the targeted chemo drugs through IPT: **death of the tumor**. The smaller dosage of chemo used by IPT and the additional enhancement by hyperthermia avoids a lot of the known side effects on the bone marrow, immune system and other vital organs. Our patients, typically, do not have severe nausea, or gastro-intestinal symptoms, or hair loss as commonly happens in conventional therapy. Our patients feel better during treatment and report a better quality of life than these patients who undergo conventional treatment.

Hyperthermia in combination with Insulin brings other assets to the table as well. In conventional treatment, only about 20% of the cells are being attacked at any one time. Hyperthermia plus IPT, however, sends cells into a growth phase so they are sensitized and this makes it more likely to kill the cancer cells. Another aspect why we like to combine IPT with hyperthermia is, that this

approach increases the cellular permeability, meaning glucose goes in more easily as does the low-dose chemo and so the cancer cell become more sensitive to heat.

Chemo Isn't the Only Game

Cancer cells tend to become resistant to chemo. It is therefore very helpful if we have something else available that contains something other than chemo. This is where high dose vitamin C can be used. It is used as an adjuvant agent to kill cancer cells. The US National Institutes of Health (NIH) reported in 2005 that high doses of vitamin C given intravenously are able to kill a high proportion of cancer cells. This mechanism of cellular death results from high levels of intracellular hydrogen peroxide which are produced in response to the vitamin C. High dosages of intravenous vitamin C can also help the immune system to control bacterial and fungal infections.

Whereas conventional oncologists don't use, or even tell their patient not to take, the antioxidants because they could interfere with the oxidative action of chemo-drugs, integrative oncologists, like us, use a number of antioxidants. Conventional therapy sees the need for the chemo agents to act for several days to damage as many dividing cells as possible. Our integrative therapy concept does not need this because with IPT and hyperthermia we target the cancer cells when the drugs are administered and kill them together with hyperthermia. This approach of using antioxidants afterwards to get the chemo out quickly is better for the immune and the natural repair mechanisms. In this phase it also very important to supply the patient with enough oxygen. We use ionized oxygen in combination with pulsed magnetic fields. This increases, not only, the oxygen supply to the tissues, but also increases the energy and helps to overcome the fatigue problem that very many cancer patients have. Cancer patient, in general, have no normal oxygen utilization; we can quantitatively measure that. Helpful is in this phase ozone treatment. A certain amount of ozone is mixed inside a bag of blood, the ozone disappears in seconds. There is no ozone in the blood when it reenters the patient because it has already formed into peroxides. We are infusing peroxides. respectively ozonides, that act for several weeks and stimulate the ATP (cellular energy) production as much as 40%; they are antibacterial/- fungal/-viral. Combining oxygen with antioxidants markedly increases also the synthesis of TNF-alpha, which the body produces to interfere with growth of tumors.

Emotional Baggage

The role of chronic stress in degenerative disease is well documented. People with positive outlook have a better prognosis. The mind-body link is basically biological. Cancer runs in families or patients have a genetic change, but these expressions are not cut in stone. The coding on our DNA acts like an antenna scanning what it finds, and then coding the proteins. The environment, diet - and ones' feelings, the way one responds to stress - can change how the body deals with weaknesses in the DNA. There is no doubt about a connection between the type of cancer and the emotions of a patient. It can be so specific that we for instance find that breast cancer is about a "nest conflict," an emotional trauma related to a loved one living in the home. One other aspect is that cancers are triggered by a traumatic emotional conflict or a severe shock, usually within two years prior to the cancer's diagnosis. But not all patients are willing to go deep into their psyche, usually, they don't like to talk about the traumatic event. They may not even remember the event, as it has been put into their subconscious. But awareness can be very important for healing and our immune system regulators. However, conventional medicine, with its focus on finding one drug/one cure, has difficulties to accept and integrate the concept of emotional stress into their treatment strategy. Conventional oncology is focused toward one magic bullet, but we are not going to defeat cancer looking for the magic bullet.

Most everybody now knows someone who has undergone conventional cancer treatment and they know how difficult it is. The majority of people who die of cancer die after taking mainstream cancer treatments. So many people get pushed into conventional treatment with the sales tactic of fear. That is not right. Everybody should have enough time to find out what is his way. One should keep in mind that one does not have the opportunity to reverse later when one learns more and knows better. Most treatments in conventional therapy are one way strategies. In contrast to our system, that always allows for reverse. Treating the whole human being makes a dramatic turnaround in cancer survival rates, particularly in later stage cancers. So, if we want to survive we have to create this personalized "platform".

What hast to be done

- serious diet changes,
- physical exercise,
- coffee enemas,
- detoxification that lessen the chemicals in the bodies and in environments
- procedures and medical therapies that work together to heal holistically (e.g., IPT, vitamin C, nitrilosides, hyperthermia, ECT, quercetin, curcumin and other natural anticancer drugs, ozone etc.
- digging into the emotional level

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Cancer Treatment Approach at St. George Hospital

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Cancer Treatment Approach at St. George Hospital

We focus upon treating patients individually, and addressing the particular characteristics of their cancers, as well as their ability to detoxify.

This includes stimulating the immune system to help it recognize cancer. We use three non toxic treatment modalities to destruct cancer within the body, so that it can be recognized by the immune system. This is in the first line hyperthermia (heat treatment), electro cancer therapy (ECT) and photodynamic therapy (PDT). With these three treatment modalities we not only have the possibility to reduce the cancer mass gently within the body, but we also change the immunogenicity of the cancer by inducing heat shock proteins, for instance HSP 70, so that the tumor can be recognized and then destructed by the immune system. The phagocytes help to dissolve the dead tumor material and present the immune system the tumor antigens, so that it can start to work and specifically in the future can be recognized by a restored and in particular stimulated immune system. These three treatment modalities can be used, even in advanced cases where conventional medicine had reached its limits. Parallel to this we reduce the blood flow to tumors by inhibiting angiogenesis with different natural drugs.

These, as well as other aspects of our treatment approach are covered more in depth in the following sections.

Hyperthermia an effective treatment to fight cancer Electro-Chemotherapy (ECT) for

cancer Phodynamic therapy (PDT)

IPT - Insulin Potentiation Therapy

Hyperthermia (Heat treatment): a very important modality in cancer therapy

Hyperthermia therapy is a very gentle but nevertheless very effective treatment, and is one of the basic elements of the integrated cancer therapy concept of St. George Hospital. During Hyperthermia therapy, tumorous tissue is heated using different techniques. As a result of this heating:

The cancer cells are damaged

The blood and oxygen supply is reduced, causing an increase of cancer cell killing

The body's own immunological defense mechanisms are activated

Hyperthermia is applied solely or, in combination with radiation, chemotherapy (possibly insulin potentiated) and non toxic biological cancer therapies. Hyperthermia is also used, very successfully, in the aftercare or secondary cancer prevention. Especially metastasis and tumors that are inoperable or resistant to conventional treatments can be influenced favorably by Hyperthermia. There are different forms of Hyperthermia used in the hospital.

Systematic Whole Body Hyperthermia (SWBH)

The Systematic Whole Body Hyperthermia is specifically for all patients with advanced tumors e.g. suffering from cancer of the lung, liver, bones and for patients with malignant lymphomas.

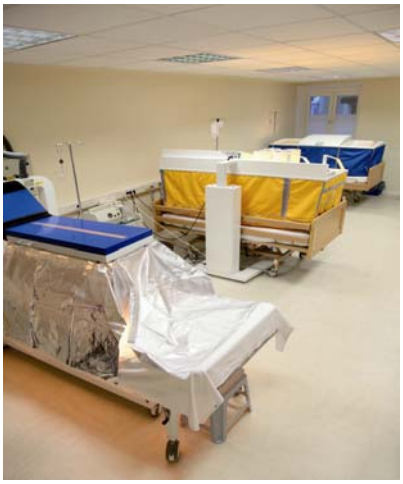

Figure 1. View with the whole body hyperthermia unit of the hospital. We have three units and electively the last five years carried out more than 5000 treatments

Local Regional Hyperthermia

Applied as Superficial Hyperthermia for different types of skin cancer and skin metastasis of other primary tumors.

Applied as Deep Hyperthermia for cancers which are deeply seated for instance in the mediastinum, praesacral area, liver and brain, etc.

Applied as Prostate Hyperthermia

Special form transuretheral hyperthermia (TURF)

Prostate hyperthermia is a special form of hyperthermia; it is applied under local anesthesia. With the help of a catheter, a heat probe is inserted into the urethra and placed in the prostate. The probe does not get hot; it acts on radio wave emitted current. This radio wave passes the normal tissue, easily, but gets caught in the hyperplastic tissue of BPH or the dense tissue of the prostate cancer and then here it is converted into heat. It is a self focusing system; only the diseased tissue gets hot, while the healthy tissue only gets warm and thus will not be damaged by the heat (that means no damage to the urethra, sphincters, etc.). In the diseased tissue we achieve a temperature between 48°-52°C (118.4°-125.6°F) causing benign and malignant tissue to melt. This procedure is controlled by thermal probe of the computer.

Malignant tissue is destroyed within the prostate and replaced by healthy tissue (scar tissue). Patients treated with this method experience a significant improvement in their urination. The prostate will be sterilized from cancer.

Figure 2. View into the local hyperthermia department. We use Oncotherm machine for instance the EHY-1020 and EHY-2000

Figure 3. Oncotherm machine EHY-1020. This machine is used transuretheral prostate hyperthermia

Figure 4. Oncotherm machine EHY-2000. This machine is used for local superficial prostate and deep local-regional hyperthermia

Electro Cancer Tretment (ECT)

Unlike Hyperthermia, this therapy does not use heat, but electrical current or disc is used. To create a standing electrical field either needles are inserted directly into the tumor or discs are placed on top of the tumor tissue. The electrical field changes the pH-value and the natural electrical charge of the tumor tissue. This disturbs the essential life-processes of the tumor cells and causes them to die. This therapy is used at St. George Hospital for the treatment of:

Breast cancer, especially accelerating forms as inflammatory types

Tumors of the ear, nose and throat, especially throat

Gynecological, urological carcinomas (prostate and bladder) and soft tissue tumors (sarcomas).

Skin cancer such as basal cell carcinoma, spinocellular carcinoma and melanoma.

With this technique we have long time experience (more than 20 years) and achieved excellent results.

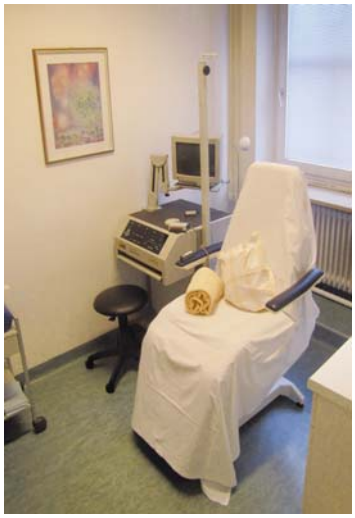

Figure 5. View into the room where ECT is carried out. Electro cancer treatment (ECT) is used especially for superficial cancer, chest wall relapse of breast cancer, skin cancer, etc. ECT works with direct current

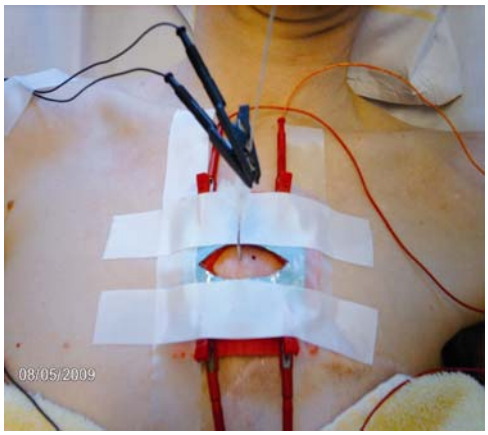

Figure 6. Example of the electrode application

Photodynamic therapy (PDT)

Using special light against cancer – a new treatment modality. Photodynamic Therapy (PDT) is a treatment where a special dye is positioned in or on tissue where it specifically accumulates in the tumor tissue. By using a special light, usually a laser, this area is made fluorescent, thus producing damage to the tumor cell that then results in cell death. These dyes are named Photosensibili**s**ators because it needs a special light before the zytoxic reaction is produced. Herewith, it is possible to create, assuming that they accumulated mainly in the tumor tissue, a locally very effective tumor therapy. This curative approach is aimed at superficial cutaneous and mucosal tumors because they cannot exceed the depth of the light penetration. PDT is more and more used in palliative oncology because it allows for interstitial application of thin light applicators which effectively destroy the tumor in a minimally invasive manner with the least discomfort for the patient.

Currently, PDT is especially used in bronchial, esophageal and bladder cancer and with a vari- ety of skin tumors. Photofrin is authorized for use but it has a relatively slow pharmacogen- esis and a large accumulation in the skin so that the patient has to be protected from intensive light exposure for weeks. This prevents wider use, we do not use it at all.

With the new developed Photo sensitizers and advancements in radiation applicators (new lasers) and light sources the range of indications for PDT has been constantly expanding in the recent years.

In a clinical study, we use a novel dye – natrium salt from Chlorine-e - either topically or sys- temically.

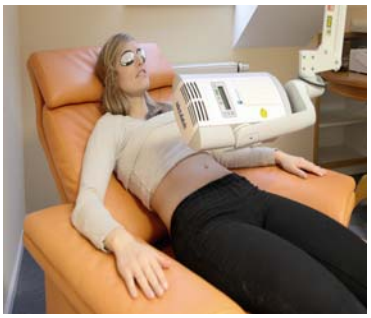

Figure 7. Shows the laser light applied to the tumor site. This technique is indicated for superficial cancer, for instance inflammatory breast cancer

Chlorine-e derivative– a novel, tropically and systemically administrable dye for PDT

This is a derivative of Chlorine-e, a dye that is derived from chlorophyll which has absorption between 660 and 670 nm. With systemic application, it reaches a maximum accumulation in the tumor mass in about three hours. In the healthy tissue we find only a minimal accumula- tion and therefore is the usual protection against intense light exposure not needed. After 24 hours, the dye is also eliminated from the tumor tissue, so that it has to be applied three hours before light exposure. This Chlorine-d derivative is also in a topical version available.

Skin tumors

Due to the easy accessibility of this organ, the dermatological use of PDT is already well ad- vanced. Currently, actinic keratosis and superficial basal cell carcinomas are treated with PDT,

especially when a good cosmetic effect needs to be achieved. As shown in the previous clinical results, the remission rates are comparable with surgical procedures.

M. Bowen only has a 12% recurrence rate when using a topical application of 5-ALA (5-aminolevulinic acid). However, the recurrence rate of squamous cell carcinoma is significantly higher, at 24%, with topical application of 5-ALA. Therefore, we conducted a study on actinic keratosis, basal cell carcinoma and squamous cell carcinoma with topically applied Chlorine-e derivative. This Chlorine-e derivative is a water-soluble substance of sodium salt in Chlorine- e6 in a low molecular polyvinylpyrrolidone solution.

Clinical results in skin tumors treated with topical Chlorine-e derivatives

In the study, 10 patients with histologically confirmed squamous or basal cell carcinoma and actinic keratosis were included. Three hours before laser light exposure, the center of the tumor and the surrounding area was rubbed with a Chlorine-e derivative ointment and covered with an occlusion dressing. After removal of the dressing, the tumor center was exposed to a laser light with a 665 nm wave length for 8 – 10 minutes. The intensity of the laser was J/cm^2.

Treatment Results

	Patient #	CR	PR	NC	PD
Actinic keratosis	7	7			
Basal cell carcinoma	5	4	1 (was operated)		
Squamous cell carcinoma	2	2			

The therapy was well tolerated by all patients, possibly because the irradiation induced pain was intercepted by pre treatment intra- or subcutaneous local anesthesia. In 93% was complete remission achieved. The cosmetic result was good. In phase 1, just after light irradiation, there was occurrence of edema and hyperemia in the light exposure zone.

This lasted about two to four days. Then, in phase 2 within 5-15 days necrosis of the tumor developed. In phase 3, between the 15th and 20th day, the necrosis was shedding and the healing process commenced.

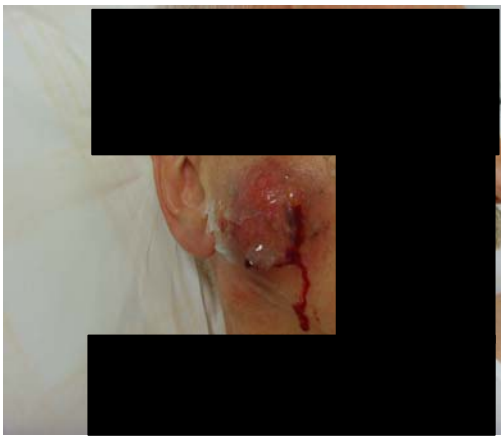

Figure 8. Squamous cell carcinoma remission before PDT

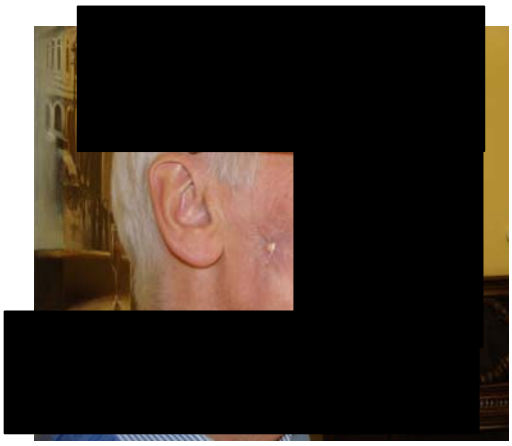

Figure 9. After PDT, complete (CR) with Chlorine-e

Results with localized placed Chlorine-e derivative

Diagnosis	Number of Tumors	Number of Patients	Complete Remission (CR)	Partial
Skin tumors	14	14	91 (%)	3 (%)

A patient, dermatologically treated for years for actinic keratosis, and recurrent basal and squamous cell carcinoma, now again had developed a recurrent squamous cell carcinoma, on the left temple. He was treated with a topical Chlorine-e derivative and, then, irradiated with 665 nm laser light using a total energy of J / cm ², after which he had a complete remission.

Applications of PDT in melanoma

Usually, the melanoma, due to their color intensity, are not accessible by PDT. However, with Chlorine-e derivative in the tumor tissue we were able to use PDT in a limited number of melanoma and achieved good results.

Insulin Potentiation Therapy

Insulin Potentiation Therapy (IPT) is a simple medical procedure that uses the hormone insulin, followed by chemotherapy and glucose to make chemotherapy drugs, in smaller doses, more effective with few to no side effects.

There are no double-blind, placebo controlled studies for IPT, but a lot of experience and positive case reports, world wide. We have almost 10 years of our own experience and so positive that we integrated it into our cancer treatment concept (ICTC). IPT was basically developed as a result of a better understanding of the cancer physiology and how the body works. It was shown that cancer patients can be treated with less toxicity than in conventional medicine.

The Mexican doctor Perez Garcia, MD, was the first who noticed that insulin, when combined with certain medications and nutrients was useful for treating various health problems. He found that, when combined with low dose chemotherapy, insulin was very effective for treating cancer patients.

In order to understand how IPT works, it is important to first explain the cancer cell physiology and compare it to that of normal cells. Cancer cells have six times more insulin receptors on the surface of their membranes than normal cells, and ten times as many IGF-1 factors, or Insulin growth Factor-1 receptors. Insulin stimulates growth and the cell uptake of glucose for energy production. It also transports amino acids and Vitamins into the cells. Cancer has a higher metabolism than normal cells and depends on sugar. It prefers mainly sugar and simple carbohydrates since it doesn't metabolize fats and proteins very well. Cancer cells are sugar robbers.

Because of PET scans, we know that cancer has a higher need for sugar than normal. They show areas of increased metabolic activity in the body. In a PET scan labeled sugar is injected, which then is selectively taken up by cancer because it has an elevated metabolism and a higher use for sugar, this, then, can be detected by the scanners. The labeled sugar molecules go to areas with increased metabolic activity (fig 10), meaning that sugar is picked up much faster by them. When the sugar blood level drops after a certain dose of insulin is given to a

patient, adrenaline and epinephrine is released. The patient feels hot, sweaty and sometimes drowsy, this occurs mainly, when blood sugar is down to 50 mg/dl. We call this the „therapeutic moment“ or „therapeutic window“. The tumor needs more sugar for its energy production supported by the higher concentration of insulin receptors, so it picks up sugar a lot faster, when insulin is given IV during IPT.

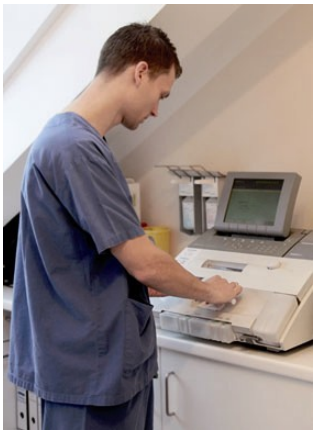

Figure 10. Laboratory monitoring

When adrenaline and insulin occur together in a low blood sugar state, cancer cells and other inflamed cells become much more receptive to whatever substances are introduced to them by IV, including chemotherapy. This means that we can give much lower doses of chemotherapy to the patient, and the therapeutic effects will be greatly enhanced, or potentiated by the insulin. The drugs are selectively absorbed by the cancer cells and the normal cells are mainly protected. Only one to two-tenth of the full chemotherapy dose is needed to obtain effective results, and it can be administered in a much shorter period of time than regular chemotherapy. In order for IPT to be effective, the patient's blood sugar levels must be dropped to 30- 40 mg/dL (the normal range is 65-99 mg/dL). Despite this, the procedure is pretty safe, if necessary, the blood sugar level can quickly be restored to normal by giving an infusion of glucose

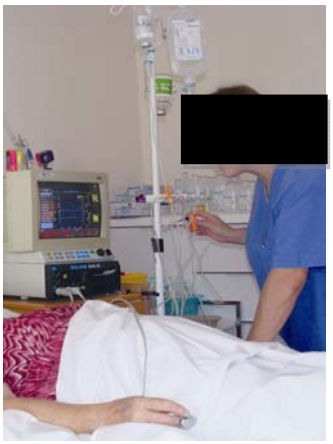

Figure 11. Intensive care of patients receiving IPT

Chemotherapy Sensitivity Testing

Two patients with the same type of cancer can be sensitive to a whole different array of chemotherapeutic agents, so instead of grouping all of our patients together and giving them all the same agents, we do chemotherapy sensitivity tests. These determine the specific

chemotherapy agents that their tumor cells may best respond to. There are two labs we use for this purpose; one is in Hamburg (Metavectum), the other is in Bayreuth (Dr. Pachmann). The Metavectum Institute (Dr. B. Stefan) extracts circulating tumor cells from patients' blood samples and performs a genomic and proteomic analysis. According to the results we can then choose the agents that the cancer cells have the highest response to and preferably use these substances for treatment. The Metavectum lab also provides us with comprehensive information on the genetic makeup of the tested cancers, which helps us to determine, not only, the appropriate therapies for our patients, but we also get more precise information about the biology of the tumor, which is very important for the prognosis. Once we have this information, ideally, we will put together an individualized treatment regimen for the patient. It takes ten days for the results of Metavectum to come back. Another advantage of this test is that only a blood sample is required to do it, rather than tissue from the tumor itself. So, unlike some other types of chemotherapy sensitivity testing where cancer tissue is necessary, it's safe for us to use this test with isolating circulating tumor cells from peripherical blood, especially in those with metastatic disease.

Most doctors, world wide, will not even look at this type of testing, but we find it helpful. Sometimes we are using drugs that I, as an oncologist, wouldn't even think of using to treat these types of cancer. For example, we learned that many cancers have a high production of cyclooxigenase 2 (COX2) which is a mediator causing inflammation and it is also helping cancer to proliferate. By just prescribing a COX2 inhibitor we can interfere with the tumor activity. With this testing we also receive information on which complementary drugs or supplements could be helpful and we find that this works well.

So, we are not only able to figure out the best treatment for our patients through chemotherapy sensitivity testing and the IPT process, but years ago we also developed an integrative cancer therapy concept (ICTC) that also includes hyperthermia, ECT and PDT to make treatments more tolerable and effective for them.

Pretreatment Protocol

In addition to the cancer destructive efforts, which include hyperthermia in combination with IPT, we give our patients obligatory IVs, composed of several nutritional supplements. We administer these prior to chemotherapy, hyperthermia & IPT. These substances make the treatment modalities more effective by increasing the sensitivity of cancer tissue to our treatment. This combination prevents the cancer from repairing itself, after it has been damaged by hyperthermia and chemotherapy. With hyperthermia and IPT we can overcome the multi drug resistance (MDR) most cancers have, especially if they have been treated with several chemotherapy regimens before. Although, our complementary treatment is clearly intended to have its greatest effects at the cancer site, it has additional benefits of boosting the immune system and detoxification at the same time.

One of the substances that we use in the pre-cancer nutritional IV is high dosed Vitamin C. We give patients this vitamin in a high dose to use it as prooxidant (see high dosed Vitamin C in cancer). We also give amino acid both orally and intravenously before they start treatments, we include in the IV amino acids, bicarbonate, procaine but also bioactive substances. Furthermore, we give artemisinin, resveratrol, quercetin, curcumin and a green tea extract known as EGCG. Each one of these substances has a different effect upon the cancer and patients' symptoms. For instance, glutamine boosts neutrophil, macrophage and other immune cell counts and is a source of food for them. Glutamine has additional anti- cancer properties, and protects the Gl tract against the side effects of chemotherapy.

In oncology we very often struggle to overcome the MDR-1 (multi-drug resistance-1) gene in

cancer. This gene stands for a pump in the cancer cell called the Pgp pump, which removes chemotherapy drugs from the cancer cells. Hyperthermia and IPT can inhibit this pump, but also nutrition can influence it.

Figure 12. Out patient infusion room. We have six chairs. The room is operated by 3 RNs and a physician

Conventional Chemotherapy versus IPT

When patients' cancers respond well to conventional therapy, as in cases of leukemia, lymphoma, or testicular cancer, we prefer the conventional approach in combination with local or systemic hyperthermia, to optimize treatment effect. We also support them with orthomolecular medicine, which helps them to go through their conventional treatments and reduces the side effects of those treatments. We can do IPT for these cancers too, but it is often not necessary.

IPT does work in most types of cancer, though we apply it only in such cases where patients wish it, because the insurances do not cover this therapy. Sometimes, insurance companies are very strict and tell their clients not to take IPT, because they would only pay for conventional chemotherapy and, of course, for all the side effects thereof. We regularly observe that patients respond well to IPT, especially when combined with hyperthermia with fewer side effects than if they had done the conventional full-dose chemotherapy. Some patients that stopped conventional care due to side effects had no problems with IPT and achieved the full positive treatment effect we had expected. We always observe that, compared to conventional treatments, patients using our integrative cancer therapy concept (ICTC) have less deterioration of their life quality. Our patients are, generally, very well educated and don't want conventional treatment alone. They prefer a combination like we provide in our integrative cancer therapy concept, i.e. nutrition, orthomolecular medicine, detoxification, hyperthermia, ECT, PDT and psychotherapy. Many of our patients already had conventional therapy, but either the side effects of their conventional treatments were intolerable or they didn't respond to the treatments. Then, they make their own decisions regarding treatment (rather than allowing someone else especially not the insurances to dictate what they should do or not). Usually, we don't have to discuss whether our integrative cancer therapy concept (which includes conventional and complementary therapies) or conventional medicine alone is best for them. They come here because they want to be here. People look for us; we don't look for them. They come to us because they don't want conventional treatment only, they want more.

We have no animosity towards mainstream medicine, but we prefer to do it more effective, better tolerated with better life quality and better prognosis. One day, our conception may become the mainstream type of treatment as more and more people become aware of its benefits.

Treating Hormone Imbalances

It's important for us to treat our patients' hormone imbalances, especially if they have hormonally driven cancers, such as breast, prostate, ovaries, and uterus. To determine hormonal status, we take tests that provide us with the actual hormone levels, and help us determine how to treat them. If women have hormonally driven cancers, it's important that we get their estradiol (and some of their other hormones) into a less proliferative state. Estradiol is one of three types of estrogen that the body produces which contributes to cancer growth. Estriol, or E-3, is a less proliferative hormone than estradiol E-2. E-2 is a great hormone for females to have as girls when they are becoming women, but women in their 50s and 60s need more estriol, not estradiol.

Unfortunately, we live in a society where we are exposed to chemicals and toxins, such as polystyrene, which are mimicking and creating more estradiol in our bodies. We call such substance xenoestrogens. As a result, men are becoming more feminine, gaining weight, developing insulin resistance, and getting bigger breasts. These chemicals stored in the fat tissue are estrogen-aggravating, which perpetuates the problem. Women face similar problems as a result of excess estrogen. Also, estrogens interfere with thyroid function, so the thyroid function becomes disturbed. Most women with breast cancer also have a thyroid dysfunction and need special support. Then the liver, for instance, has difficulty metabolizing all the estrogen resulting in estrogen dominance in the body. This, then, worsens insulin resistance and creates a lot of unnecessary other problems like metabolizing estradiol to 16 OH-estradiol, which might be carcinogenic.
Excess estrogen not only has an effect upon cancer, but upon the immune and nervous systems, as well. We therefore treat imbalances in each one of these systems so that they work together better, as a whole.

The body's hormonal system is based primarily on the thyroid, adrenal gland, and sex hormones. It's important to make sure that all of these hormones are functioning properly, because they affect not only cancer growth but also patients' overall health. We have many patients who have low thyroid and adrenal function, and their sex hormones are also low. So what they need is a hormonal balance. In this context we just replace the missing hormones and also try to balance it by giving liquid glandular formulas. We use these from "Cell Immune®" it contains proteins and peptides, as well as other growth factors and signaling molecules and mesenchyme tissue from the umbilical cord of sheep (the latter is a type of loose, connective embryonic tissue). We further use several other agents for adrenal and thyroid support, as well.

Treating Immune System Imbalances and Infections

We don't just do tests to determine the status of our patients' cancers and hormones; we also look for any other problems that might be impacting their health. Through additional testing, we often find that we need to detoxify them and clean up their immune systems. For instance, in the beginning of our treatment, we measure inflammatory mediators, such as CRP, Procalcitonin, a-TNF, Il-6, NFkB to determine what is causing the inflammation in their bodies and how severe it is. We check the status of their immune system to see, for example, what the T-cells and natural killer (NK) cells are doing. For this we utilize a special function test. With this

information we can actively balance the immune system and make it work against the cancer. When patients have chronic infections that weaken their immune systems it impairs their ability to fight cancer.

The immune system is composed of a variety of different cells that all have specific duties, for instance the T-Helper cells are divided into three different subtypes Th-1, Th-2 and T-regs (so called regulating cells) and the ratios of these should be balanced. That is not always easy, but possible.

In addition, to support the immune system with xenogenic peptide, thymus factor, nutrients, etc. we look for other chronic diseases our patients may have in addition to the cancer, for instance Lyme disease and other infections. In case that it is necessary we will treat these also. Especially Lyme disease is very sensitive to heat treatment and will disappear mostly after one or two whole body hyperthermia treatments in combination with IPT (with antibiotics). By using whole body hyperthermia with IPT in cancer patients with infections, we are thus able to kill two birds with one stone.

Brain Chemistry

The brain, like the immune system, has its own balancing mechanisms, which can be categorized as excitatory inhibitory. The inhibitory mechanisms put the body to sleep, while the excitatory mechanisms keep it functioning during the day. It is not good to have too many excitatory mechanisms without inhibitory ones and vice versa because otherwise people get ill. Our patients often have not enough inhibitory- supporting neurotransmitters such as Serotonin, so their mood is down, nor do they have enough excitatory neurotransmitters, so they have no energy. With a Neurostress test, we can obtain information on our patients' brain chemistry, and then determine which treatment is indicated to correct their neurotransmitter deficiencies. We can treat the body's Serotonin levels, with a combination of 5-hydroxy tryptophan (5-HPT), SAme, zinc, B6, and other vitamins; this helps the patients to maintain a positive mood and good quality of sleep. Serotonin also helps to activate the rest of the brain; it's the gateway to the entire functioning of the brain and its chemistry. Balancing the hormones and immune system also has a positive effect upon brain chemistry.

Figure 13. Laboratory for monitoring our patients

Other Tests and Treatments to Heal and Support

We also give high dose Vitamin C and K-3 IVs, and do detoxification therapy. Vitamin C appears to a cancer cell as a sugar molecule and is quickly taken up by the cancer. Once the Vitamin C connects with an iron molecule in the cell, peroxide is released, which injures the cells internally.

Because cancer cells have low activity of catalase and superoxiddismutase they have a difficult time repairing from such damage. Vitamin K-3 augments the effects of Vitamin C and helps to inhibit cancer growth.

Finally, many of our patients have low Vitamin D levels, so we often prescribe 10,000-15,000 units of Vitamin D per day, along with choleretics and pancreas enzymes to help digest fat, if they have trouble digesting these fats (since Vitamin D is fat-soluble). Some patients have a poor antioxidant status, as a result of not being able to digest fats and proteins (and hence their nutrients), so we add enzymes to their regimens which aid in protein and fat digestion. We also give them antioxidant support in the form of supplements. We find it important to restore everything during the specific cancer treatment. This restoration, usually, cannot be accomplished in a short period of time. Thus, we inform and teach our patients that the treatments have to be followed by an extended period of time, perhaps many months.

Figure 14. Green Tea

In summary, we look at different parameters in our patients, and try to improve those. The healthier the patient as carrier of the cancer is, the more difficult is it for the cancer to grow. With our integrative cancer therapy concept we not only attack the cancer, but support the host.

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Hyperthermia: a treatment possibility for prostate cancer

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Hyperthermia: a treatment possibility for prostate cancer

Introduction

Early detection of prostate cancer (PC), as, in all malignancies, is very important, so that with appropriate therapy the chances of a cure increase. The prostate cancer screening guidelines suggest, next to surgical removal of the prostate (prostatectomy) and the various forms of radiation, to monitor the patient through "Active Surveillance". This controlled and regularly executed observation is especially used in patients with a slow-growing tumor (so-called insignificant prostate cancer). This type of prostate cancer is characterized by minor tumor volume and less aggressive growth. The latest studies on this subject show that the results of the "Active Surveillance" are as good as after invasive procedures, such as surgical removal of the prostate or radiation.

Many men diagnosed with prostate cancer have a rather good chance that they will never require active treatment. The slow growing tumors in these patients, usually, do not compromise their life expectancy. However, since many men, psychologically, cannot tolerate a "wait-and-watch" approach after they have been diagnosed with cancer, there is considerable interest in finding an alternative that has relatively few side effects. For decades now, at St. Georg Hospital, we have had excellent clinical results using urethral thermo therapy (also known as transurethral hyperthermia with radiofrequency waves). We combine this with temporary hormone therapy.

What is transurethral hyperthermia and why is it combined with a temporary hormone therapy?

Hormone therapy alone does not have a survival advantage. An important study published in JAMA by Grace L. Lu-Yao et al. of the Robert Wood Johnson Medical School, New Brunswick, NJ [1] has questioned the efficacy of this widely used form of treatment. In this study, a total of 19,271 mostly elderly men (with a median age of 77) with cancer limited to the prostate (known as T1 and T2 tumors). Men, who received primary hormone treatment, were compared to an equal number of men without treatment, so-called "active surveillance". One surprising result was that hormonally treated patients survived no longer than those who received no active treatment. The ten-year overall survival rates was 30.2% in the treated and 30.3% in the untreated groups, i.e., virtually identical in both groups. More surprising, the prostate-cancer specific survival was actually lower in the hormone-treated group than in the no-treatment controls (80.1% vs. 82.6%).

The patients treated were mostly elderly, over 66 years old (median age 77) with cancer limited to the prostate (known as T1 and T2 tumors). The authors therefore recommend restraint with long-term hormone therapy, also because it is associated with enormous health risks such as increased bone fragility, diabetes, heart disease and impotence. The authors also mentioned: "Maybe the survival time is not the sole goal, quality of life is also of importance"[1]. In this therapy are also economic aspects. In 2008 alone, the United States spent 1.3 billion US Dollars for hormone treatments. The German and European numbers are similarly high.

Prostate cancer, together with bronchial cancer is one of the most common forms of cancer for men. The average age at diagnosis is over 70 years. Given the absence of early symptoms of cancer it was usually only discovered in the early stages by chance, but this has favorably changed in the PSA era, i.e. since 1990.

In a subset of patients with poorly-differentiated PC, there was a slight improvement in PC-specific survival, but this did not carry over into overall survival.

The authors therefore recommended restraint in the use of long-term hormone therapy, also because it is associated with enormous health risks such as increased bone fragility, diabetes, heart disease and impotence[1]. Maybe the survival time is not the sole goal, quality of life is also of importance. This therapy also has important economic aspects. In 2008 alone, the United States spent USD $1.3 billion on such hormonal treatments. European numbers are similarly high.
The recommended therapy for prostate cancer depends on the stage of the disease and the general condition of the patient. With localized, non-metastasized prostate cancer is in most cases „Active Surveillance" the right recommendation. The survival rate, especially in elderly patients with a limited life expectancy, would not improve with a radical prostatectomy even with possible RO-Resection. However, such procedure would reduce life quality with incontinence and impotence.

Little difference in survival times

A large survey of urologists and radiation oncologists in the United States [2] has shown that over 90% of urologists recommended radical surgery and the vast majority of the radiologists radiation therapy. This suggests that there is no "best therapy" and that it may be difficult for the person involved to make a therapy decision. However, since prostate cancer due to its slow growth does not make an immediate treatment decision necessary, should the patient choose the therapy that, after extensive research, promises the best conditions for a good quality of life and few side effects.

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In the largest such study since the introduction of routine PSA testing, Lu-Yao [3] has shown that the results of "Watchful Waiting" with prostate cancer are so good that it is questionable whether invasive measures can still make an improvement.

80% of patients are impotent after radical surgery

The potential impact should also be considered with surgery. For instance, the urinary sphincter may be damaged and the patient will thereby suffer from incontinence. Another serious consequence of operated patients is impotence, which occurs in approximately 80%. Pursuing a "Watchful Waiting" approach leads to only about half of the patients experiencing impotence problems. After a radical prostatectomy every second patient experiences urinary incontinence (49%), but with "wait and see" management occurs this only in one of five men (21%) [4].

Impotence (defined as an erection weakness) is an essential quality-of-life factor that should be considered in their treatment choice, even if there is a significant survival advantage after radical therapeutic measures. However, even with expectant management we can anticipate problems. A bladder emptying disorder may develop during the course of a slow-growing prostate cancer, because the expanding tumor presses on the urethra, decreasing it in size. This urination problem occurs in 44% of the patients, but can be somewhat remedied**.**

Prostatectomy with radiation therapy combined?

If you look at recent studies, it must be clear that because of diligent PSA testing more early-stage tumors are found as compared to older examinations. Only in advanced stages (T3 prostate cancer) does surgery in combination with radiation therapy offer a better survival time, as shown in the Ulmer Multicenter Study [5]. Also, other studies, see figure 1, attest to the fact that only patients in advanced stages where positive margins during operation were found, benefit from additional radiation therapy [6].

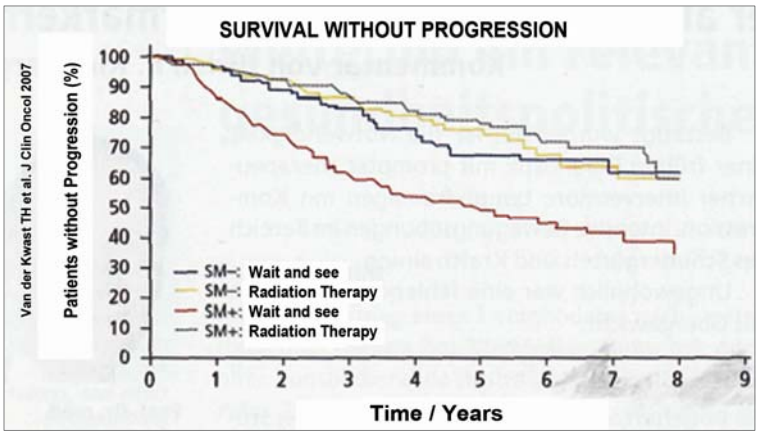

Figure 1. Survival curve of patients in advanced stages with negative and positive section margin (SM). SM negative surgery only and then "wait and see". SM negative plus radiation shows no advantages over wait and see. Patients with positive resection margins profit from an additional radiotherapy and achieve similar results as patients with negative resection margins (SM)

Alternative: Transurethral Thermotherapy with a time-limited complete Androgen blockade

Despite the slow growth and long, sometimes inconspicuous clinical characteristics of prostate cancer, in a few cases can spontaneous proliferation and metastasis arise and subsequently the window of opportunity for a curative treatment is missed. Many patients know this and are understandably afraid of the consequences. So, they justifiably look for alternatives.

Transurethral hyperthermia (i.e., heat therapy guided through the urethra) can be an additional alternative in such cases, especially when it is combined with temporary hormone therapy. Prostate cancer proves to be extremely sensitive to heat. Two treatments of three hours and an average temperature between 48-52º C (118.4-125.6ºF) in the prostate kill most of the localized prostate cancer.
To keep the local area tumor free and to prevent remaining tumor cells from growing at St. George Hospital we combine this method with hormone therapy given for 6-9 months.

Thanks to transurethral thermo therapy no permanent side effects

Transurethral hyperthermia leads to massive tumor cell destruction due to the high temperatures that we achieve in the prostate with a computer controlled radio frequency device (Oncotherm EHY 1020**).** The technology of this device is based on the generation of short waves and an electromagnetic field, where the tumor cell destruction results from both the heat and the electric field (see Figure 2, 3 and 4).

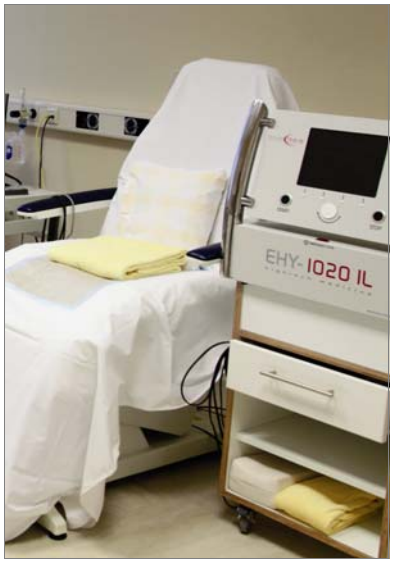

Figure 2. The EHY 1020 from Oncotherm, a radiofrequency machine for transurethral hypothermia of the prostate is in use now at St. George Hospital

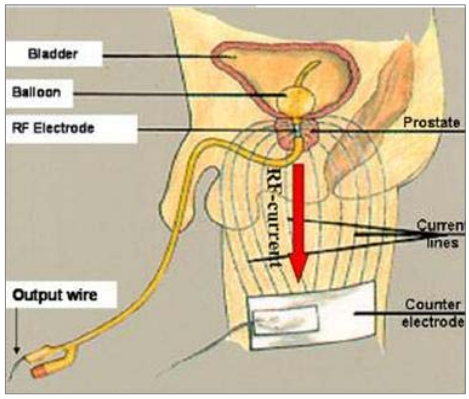

Figure 3. Shows the treatment catheter in the right position in the center of the prostate. The electrode emits radio waves, which penetrate the normal and healthy prostate tissue easily, but is absorbed to a normal and higher extend from cancerous tissue, which then gets selectively heated up to 52º C (125.6º F). Important is the counter electrode around the hips to establish an electromagnetic field

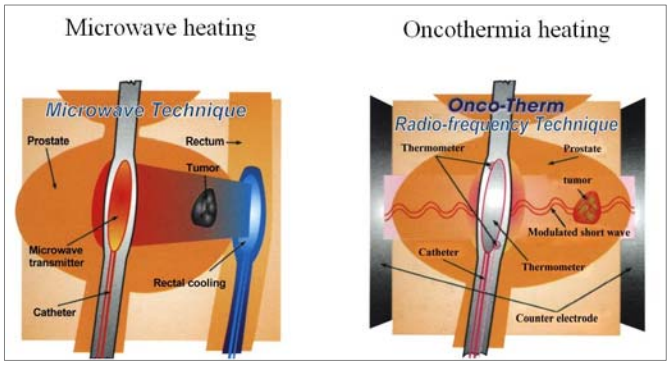

Figure 4. Demonstrates the difference between microwaves, respectively radiowaves (shock waves) for prostate-hyperthermia and radiofrequency. In microwave hyperthermia, the waves radiate with high energy directly into the tissue, but have only a penetration depth of 1-2 cm. Inside the urethra and at the rectal mucosa a sophisticated cooling is used. Radiowaves, asused in the Oncotherm system, go easily through healthy tissue, but caught in the dense cancer tissue they are converted into heat. It is a self processing system. Only, the electrodes get warm and no cooling is used. So, injuries to the urethra and sphincters are not possible

The former, microwave devices often used in urology, are unsuitable for tumor treatment because they are not capable of heating the prostate evenly because of their low penetration and some other unresolved technical problems.

Furthermore, these devices produce too many complications. Radio frequency hyperthermia, also known as oncotherapy, allows specifically for the heating of the cancer tissues, which has different impedance than healthy tissue. Thus, the radio waves are absorbed more by the cancer tissue which becomes very hot and dies off, the so-called apoptosis (programmed cell death). This process also causes increased “heat shock proteins” in the cancer cells. These are special proteins that occur whenever cells come under stress or age. Especially the immune system recognizes, destroys and discards these charged cells. By heat treatment, we generate these heat shock proteins, particularly in the cancer cells. These cells not only die as a result of overheating, but are also increasingly recognized by the body's own immune system which in turn attacks and destroys them. This form of heat treatment not only destroys the prostate tumor, but also induces a specific immune response.

Of course, this also shows the fundamental difference to conventional therapies. First, during an operation is the tumor removed from the body and thus also important information for the immune system. Second, this is a major trauma that provokes inflammation and the release of growth hormones that encourages still present cancer cells to grow. With the, through the urethra guided, heat treatment dies the tumor within the organ and the surrounding healthy tissue is not damaged and remains fully functional. The body's own immune system is stimulated to recognize and battle the tumor. The usual side effects of surgery and radiation do not occur in hyperthermia. Even for these reasons alone, hyperthermia is a real alternative to „watchful waiting“. In other words, for the qualified patient it is still better to conduct an effective method with few side effects than to wait and see if the tumor is growing, even when for this approach studies with larger numbers are still pending. The patient's quality of life is improved by it, especially while potency problems and urinary incontinence do not occur with hyperthermia. Given the fact that so far none of the conventional therapies offer significant survival advantage for prostate cancer patients, it may be difficult to impose a specific invasive procedure with irreversible damage on a patient. Rather, the patient should have a say in what he wants, especially when you take into consideration the possibility of a dramatic impairment life quality.

We combine the, already very effective, transurethral heat therapy with a temporary hormone therapy. Why? Because it has been shown that in most patients already had a transrectal multi-biopsy during which, not only, the malignant cells were washed into the system where they lodged in the lymph nodes or bone marrow, but the biopsy insult also induced local prostate inflammation followed by a healing process during which many mediators are released such as growth hormones (for example EGF, VEGF, COX2, etc).

The biopsy injury to the prostate must heal and for this are inflammatory mediators and growth hormones needed. But precisely these mediators produce in a less vicious tumor a faster and aggressive growth of the tumor and thus feed a general activation. Therefore, we offer our patients, currently, an injury-free diagnosis of prostate cancer, that is to say we replace when needed the biopsy with molecular genetic testing and appropriate imaging techniques. One can also abstain from the traumatizing biopsy because even for a positive diagnosis is usually only a „Watchful Waiting" recommended. So why should a man risk a carry-over of tumor cells, or tumor activation, or even a local infection, if they have no therapeutic consequences.

We start the hormone therapy shortly before and continue up to 6 months after the heat therapy with it. What is their function? Hormone therapy prevents the in the body remaining cancer cells from growing. Also, there remains sufficient time for the hyperthermia induced immunological effects to become active.

To be precise, with this method we not only destroy the malignant tumor cells in the prostate, but we also trigger an active specific immune response. Due to the temporary hormone therapy, we achieve a growth hormone inhibition of cancer cells outside of the prostate. The treatment itself is well tolerated, without complications and pain free. It takes place on outpatient basis and does not require hospitalization. In 1998, we have treated 123 patients (see Table 1) according to this protocol (two, three hours long, hyperthermia treatments through the urethra with six months of hormone therapy) and followed them for 10 years. Patients entered the study with a mean age of 71. Prostate cancer was confirmed in all patients by biopsy and metastases were excluded by environmental studies. All patients were in full remission six months after initiation of the therapy and had normal PSA values, after which the hormone therapy was discontinued. In 85% of the patients, this good treatment outcome remained over the entire observation period of 10 years. The therapy was repeated in 15% of the patients, because, at one time or another, they showed PSA recurrence. During the 10 year observation period, 16 patients out of this group died from other diseases, but not from prostate cancer. Two patients were treated with TURP surgery for urination problems. There were no tumor cells in the prostate tissue that was removed, although more than 5 or 7 years before prostate cancer was confirmed by biopsy.

	Days					
Transuretheral hyperthermia 3 hours at 48º-52º C	1 P-Hy	2	3 P-Hy	4	5	
Triple therapy with hormones*	For 6 months					
Hormone Balancing After Care	**Months after treatment**					
	1 ½	3	6	12	18	24
Check ups PSA Control	X	X	X	X	X	X
PCA_3 test	X			X		X

*GMRH-beock Anti-androgen 5-α – reductase inhibition

Table 1. Treatment protocol for prostate cancer limited to the prostate (T_1-T_2). No hospitalization necessary; out patient procedure

Comparative study planned by the usual methods

In summary, it can be said, that even if the guidelines suggest something else, currently there is no best therapy for localized prostate cancer. For that reason, physicians refrain from immediately operating or irradiating each prostate carcinoma, because these invasive therapeutic measures are associated with significant side effects and marked reduction in quality of life. Alternatively, it is proposed to use the „Active Surveillance" method since prostate cancer usually has a long clinical course. However, there are a few cases where it spontaneously proliferates and metastasizes and then an appropriate therapy can be missed. Many patients are aware of this problem and are therefore in search of other treatment options. A side-effect free alternative could be hyperthermia in combination with temporary hormone therapy. We achieved good results with this therapeutic approach as exhibited in our 10-year study during which 85% of the patients showed complete remission and only 15% had a PSA recurrence.

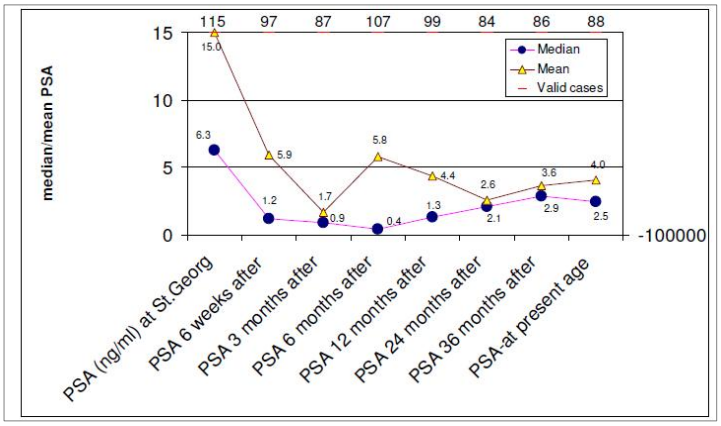

Figure 5. The course of PSA after the transurethral hyperthermia

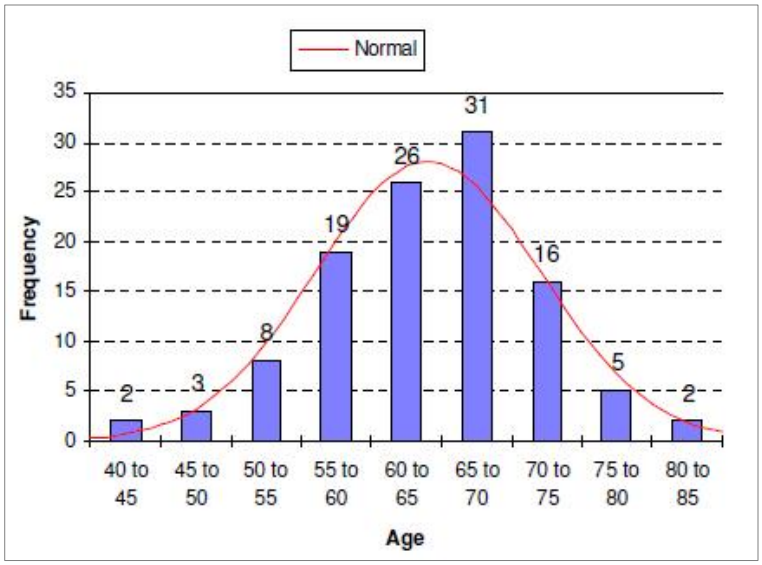

Figure 6. Age distribution of our patients treated by transurethral radiofrequency hyperthermia (TURF)

It is intended, in another controlled, prospective study, to compare hyperthermia in conjunction with temporary hormone therapy with other common forms of treatment in order to finally shed some light on comprehensive long-term results. If „Active Surveillance" with its known risks is permitted, then hyperthermia with temporary hormone treatment should also find its place among

the standard therapies, because no substantial, lasting adverse effects are incurred. To the contrary, it increases quality of life and life expectancy.

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Regionale Elektrohyperthermie: Ordnungsgemäße Abrechnung und Erstattungsfähigkeit

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Regionale Elektrohyperthermie: Ordnungsgemäße Abrechnung und Erstattungsfähigkeit

(Erwiderung auf *Heyll*, Versicherungsmedizin 64 (2012), 70ff.)

Hyperthermische Verfahren werden in der Zivilgerichtsbarkeit mittlerweile bei den verschiedensten Tumoridentitäten als medizinisch notwendige Heilbehandlung eingestuft, deren Kosten von den privaten Krankenversicherungen zu erstatten sind. Auch die gesetzlichen Krankenversicherungen werden - trotz expliziter Bewertung der Hyperthermie als in der vertragsärztlichen Versorgung nicht anerkannter Behandlungsmethode - in lebensbedrohlichen Situationen mehr und mehr dazu verurteilt, hyperthermische Behandlungen als Sachleistung zu gewähren.

Mit zunehmender Einstandspflicht von Sozialversicherungsträgern und privaten Versicherungsgesellschaften sind auch die Abrechnungsmodalitäten stärker in den Blickpunkt gerückt. Wurden die Rechnungen vor einigen Jahren noch fast ausschließlich von den Patienten selbst beglichen, die weder Anlass noch entsprechende Kenntnisse hatten, um die jeweiligen Gebührenziffern in Frage zu stellen, beschäftigen sich nun auch findige (und mit dem Gebührenrecht vertraute) Rechtsabteilungen mit den Behandlungskosten - stets den Schutz der Versichertengemeinschaft vor übermäßiger Kostenbelastung vor Augen.

Die neueste Strategie zur Kostenvermeidung ist die Einordnung elektrohyperthermischer Verfahren in den Abschnitt E - „Physikalisch-medizinische Leistungen“ - des Gebührenverzeichnisses der Gebührenordnung für Ärzte (nachstehend: GOÄ). Soweit ersichtlich wurde dieser Ansatz erstmals im Juni 2012 von einem beratenden Arzt der Deutschen Krankenversicherungs AG veröffentlicht [1]. Die Zusammenfassung der Originalpublikation liest sich wie folgt:

„…Die Anwendung der Elektrohyperthermie zu Lasten der gesetzlichen Krankenkassen ist grundsätzlich ausgeschlossen.

Da der Nachweis der medizinischen Notwendigkeit nicht zu erbringen ist, besteht auch kein Anspruch auf Kostenerstattung gegenüber privaten Krankenversicherungen Nach den gesetzlichen Bestimmungen der GOÄ ist im Regelfall keine Abrechnung als Hyperthermiebehandlung möglich. Vielmehr ist eine Position aus dem Kapitel Elektrotherapie zu wählen.“

Diese Kernaussagen des Artikels bedürfen in wesentlichen Punkten der Richtigstellung, womit auch der Aufbau dieses Beitrages wiedergegeben ist: Weder ist die Leistungserbringung zu Lasten der gesetzlichen Krankenkassen ausgeschlossen (1) noch lässt sich ein Anspruchsausschluss gegenüber privaten Krankenversicherungen herleiten (2). Wenig überzeugend ist auch der Versuch, auf elektrotherapeutische Abrechnungsziffern zurückzugreifen (hierzu unter 3.)

1. Zur Leistungspflicht der GKV

Zunächst bleibt festzuhalten, dass der oft behauptete kategorische Ausschluss der Leistungspflicht für hyperthermische Verfahren schlichtweg nicht existiert. Nach der Gesetzessystematik des Sozialversicherungsrechts kann er auch überhaupt nicht existieren:

Der Leistungsumfang der gesetzlichen Krankenversicherung bestimmt sich bekanntlich nach den §§ 27 Abs. 1 Satz 1, § 2 Abs. 1 Satz 3 des Fünften Sozialgesetzbuches (nachfolgend: SGB V), wobei Qualität und Wirksamkeit der Krankenbehandlung dem „allgemein anerkannten Stand der medizinischen Erkenntnisse“ zu entsprechen haben. Die Feststellung, ob eine ambulante vertragsärztliche Behandlung dem geforderten Versorgungsstandard entspricht, obliegt dem Gemeinsamen Bundesausschuss (nachstehend: GBA). Behandlungsmethoden dürfen nämlich in der vertragsärztlichen Versorgung nur dann zu Lasten der Krankenkassen abgerechnet werden, wenn der GBA eine positive Empfehlung abgegeben hat über die Anerkennung des diagnostischen und therapeutischen Nutzens der neuen Methode sowie deren medizinische Notwendigkeit und Wirtschaftlichkeit.

Es ist daher allein der Einschluss bestimmter Behandlungsmethoden in den Leistungskatalog der GKV möglich, wobei dieser „Einschluss“ darauf beruht, dass die jeweilige Untersuchungs- und Behandlungsmethode in den Kreis des „allgemein anerkannten Standes der medizinischen Erkenntnisse“ aufgenommen wird: Allein eine positive Bewertung des GBA, namentlich die Empfehlung einer Aufnahme in die vertragsärztliche Versorgung, vermag den Umfang der von den Krankenkassen geschuldeten Leistungen zu beeinflussen. Eine negative bzw. (überhaupt) nicht vorgenommene Bewertung kann bereits aufgrund der Gesetzessystematik eine Leistung nicht „ausschließen“, da nicht oder negativ bewertete Behandlungsmethoden bereits per se „ausgeschlossen“ (genauer: nicht eingeschlossen) sind. Denklogisch ist daher eine Statusveränderung hinsichtlich der Leistungsverpflichtung der GKV nicht – wie im Falle der Hyperthermie - durch eine negative GBA-Bewertung möglich.

Damit in diesem kategorischen System die Einzelfallgerechtigkeit nicht auf der Strecke bleibt, hat das BVerfG bekanntlich seine „Nikolaus“-Rechtsprechung postuliert, die mittlerweile Gesetzeswirklichkeit geworden ist: Gem. § 2 Abs. 1a SGB V haben Versicherte mit einer lebensbedrohlichen oder regelmäßig tödlichen Erkrankung, für die eine allgemein anerkannte, dem medizinischen Standard entsprechende Leistung nicht (mehr) zur Verfügung steht, auch Anspruch auf Leistungen jenseits des „allgemein anerkannten Standes der medizinischen Erkenntnisse“, sofern eine nicht ganz entfernt liegende Aussicht auf eine spürbare positive Einwirkung auf den Krankheitsverlauf besteht.

Soweit nun auch heute noch ein kategorischer Leistungsausschluss vertreten wird, beruht dies in der Regel schlichtweg auf fehlender Kenntnis der aktuellen Rechtsprechung bzw. auf einem Fehlverständnis der damaligen Bewertung hyperthermischer Verfahren durch den Gemeinsamen Bundesausschuss: Richtig ist, dass der GBA im Jahr 2005 hyperthermische Verfahren den „nicht anerkannten Untersuchungs- und Behandlungsmethoden“ zugeordnet hat [2]: Im Rahmen einer umfangreichen Methodenbewertung hieß es, dass der Stellenwert der Hyperthermie in der Onkologie im Vergleich zu Standardtherapien wie Operation, Strahlen-, Chemo- und Hormontherapie noch nicht eindeutig belegt werden könne. Zwar sei die Forschung bei einigen Indikationen schon weit fortgeschritten, angesichts der Vielzahl der onkologischen Indikationen, der verschiedenen hyperthermischen Behandlungsformen, der hierdurch bedingten fehlenden Standardisierung und mangels Studien der höchsten Evidenzkriterien könne eine Einführung in die vertragsärztliche Versorgung allerdings (noch) nicht empfohlen werden.

Wie dargestellt, ist diese (negative) Bewertung jedoch in keiner Weise geeignet, hyperthermische Verfahren per se aus dem Leistungskatalog auszuschließen. Denn der GBA hat seinerzeit lediglich eine Bewertung des - sich ständig wandelnden - allgemeinen Standes der medizinischen Erkenntnisse abgegeben und statuiert, dass hyperthermischeVerfahren – vor allem auch aus vorbenannten wissenschaftssystematischen Gründen – noch nicht zu den allgemein anerkannten Behandlungsmethoden zählen. Zwar wurde insoweit teilweise vertreten, dass eine Anwendung der „Nikolaus“-Grundsätze nicht mehr möglich sei, sofern der GBA eine

negative Bewertung abgegeben hat. Das Bundesverfassungsgericht hat diesen Versuchen jedoch bereits nach kurzer Zeit eine Absage erteilt. So heißt es in dem entscheidenden Beschluss - speziell für die Hyperthermie - wörtlich [3]:

„(...) Es ist nicht ausgeschlossen, die im Beschluss des BVerfG (2005-12-06, 1 BvR 347/98 – Nikolaus) aufgestellten Grundsätze auch in einem Fall anzuwenden, in welchem eine neue Behandlungsmethode bereits ausdrücklich vom Gemeinsamen Bundesausschuss ausgeschlossen wurde (…)“

Im Übrigen ist mittlerweile auch durch den Gesetzeswortlaut klargestellt, dass GBA-Bewertungen jedweder Art keinen Einfluss auf die im Einzelfall bestehende Leistungspflicht nach den Nikolaus-Grundsätzen haben können. Denn es heißt in § 2 Abs. 1a SGB V ausdrücklich: „Versicherte (…) können auch eine von Absatz 1 Satz 3 abweichende Leistung beanspruchen (…)“. Mit dieser Verweisung sind Leistungen außerhalb des „allgemein anerkannten Standes der medizinischen Erkenntnisse“ gemeint, mithin Leistungen außerhalb der GBA-Bewertungen.

Vorstehenden Ausführungen entsprechend mehren sich mit der immer belastbareren Datenlage auch die sozialgerichtlichen Entscheidungen, mit denen gesetzliche Krankenkassen zur Gewährung hyperthermischer Verfahren - gerade auch in Form der „Elektrohyperthermie“ - als Sachleistung verurteilt werden. Allein der Unterzeichner hat im vergangenen Kalenderjahr eine zweistellige Anzahl an Entscheidungen erstritten; diverse andere Urteile sind in den einschlägigen Datenbanken abrufbar. Einem Teil der Begehren wird auch im Widerspruchsverfahren abgeholfen oder es wird auf sonstige Weise außergerichtlich reguliert. Da eine umfassende Darstellung der aktuellen Rechtsprechung den Rahmen dieses Beitrages sprengte, sollen an dieser Stelle nur kurz drei Entscheidungen skizziert werden, die aufgrund ihrer Praxisnähe besonders erwähnenswert sind [4].

a. Sächsisches Landessozialgericht: Kein „Onkologenstandard“

Die Erstattung wird oftmals mit der Argumentation abgelehnt, die Behandlung sei nicht von einem entsprechenden Facharzt (etwa für Hämatologie und Internistische Onkologie) durchgeführt worden, sondern „nur“ von einem Facharzt für Allgemeinmedizin.

Das Sächsische Landessozialgericht hat kürzlich die BARMER GEK in einem Eilverfahren zur vorläufigen Gewährung von ambulanten Hyperthermie-Behandlungen verpflichtet [5] und hierbei in wünschenswerter Deutlichkeit klargestellt, dass diese Argumentation wenig überzeugt: Da die Hyperthermie (noch) nicht in die reguläre vertragsärztliche Versorgung einbezogen ist, gibt es auch keine Bestimmungen, welche die Durchführung von besonderen Qualifikationen abhängig machen. Sehr wohl kann daher auch hinsichtlich einer „nur“ durch einen Facharzt für Allgemeinmedizin durchgeführten Hyperthermie ein Anspruch gegenüber der GKV bestehen.

Sachverhalt:

Bei der Patientin wurde ein Mammakarzinom diagnostiziert. Sie unterzog sich einer Chemotherapie, einer Radiotherapie und einer Hormontherapie, was jedoch ein Auftreten von Lymphknoten- und Knochenmetastasen nicht verhindern konnte. Parallel zu nunmehr wechselnden konventionellen Therapien wurde die Patientin hyperthermisch behandelt, und zwar sowohl im Wege der regionalen Tiefenhyperthermie als auch mittels Ganzkörper-Hyperthemie.

Die BARMER GEK verweigerte sich der Kostenübernahme im Hinblick auf die fehlende Anerkennung hyperthermischer Verfahren durch den Gemeinsamen Bundesausschuss. Nachdem das Sozialgericht Leipzig zunächst den Erlass einer einstweiligen Anordnung zurückgewiesen hatte, hob das Sächsische Landessozialgericht auf die eingelegte Beschwerde den erstinstanzlichen Beschluss auf. Die Krankenkasse wurde zur vorläufigen Gewährung der begehrten (regionalen) Hyperthermie verpflichtet.

Das Gericht entschied anhand einer Folgenabwägung: Auf Seiten der Patientin lag angesichts der fortgeschrittenen Metastasierung eine akute Bedrohung des höchsten Rechtsgutes überhaupt vor - des menschlichen Lebens. Weiter sei - nicht zuletzt angesichts der Stellungnahmen der Interdisziplinären Arbeitsgruppe Hyperthermie der Deutschen Krebsgesellschaft - mit einer zumindest spürbar positiven Auswirkung auf den Krankheitsverlauf der Patientin zu rechnen. Insoweit wiederum sei (trotz der erheblichen Dokumentationsmängel seitens der durchführende Hausärztin) zugunsten der Antragstellerin zu entscheiden.

b. Sozialgericht Köln:

Erstattung der regionalen (Elektro-)Hyperthermie beim CCC

Eine bereits besprochene Entscheidung des Sozialgerichts Köln zur Gewährung hyperthermischer Behandlungen ist aufgrund ihrer ausgesprochen pragmatischen Anforderungen an die Erfolgsaussicht der begehrten Elektrohyperthermie besonders veröffentlichenswert [6]:

Sachverhalt:

Bei dem Patienten wurde ein choloangiozelluläres Karzinom diagnostiziert. Aufgrund der Lage des Tumors sowie seiner Histologie war eine operative Entfernung nicht möglich. Trotz mehrfacher Chemotherapie konnte eine Progression nicht aufgehalten werden; auch kam es im Laufe der zytostatischen Therapie zum Auftreten von Metastasen. Der Patient entschloss sich daher (nicht zuletzt im Hinblick auf die ausgeprägten Unverträglichkeiten) zu einem Abbruch der Chemotherapie und zu einer hyperthermischen Behandlung in Form der regionalen Tiefenhyperthermie.

Die AOK Rheinland/Hamburg lehnte die beantragte Kostenübernahme zunächst mit der Begründung ab, dass es sich bei der Hyperthermie um ein neuartiges Therapieverfahren handele. Auch unter Berücksichtigung der höchstrichterlichen Rechtsprechung käme eine Leistung nicht in Betracht; vielmehr sei eine weitere Chemotherapie durchzuführen. Der hierauf erhobene Antrag auf den Erlass einer einstweiligen Anordnung wurde vom zuständigen Sozialgericht Köln kurzfristig zugunsten des Patienten entschieden: Das Gericht verpflichtete die AOK zur vorläufigen Gewährung von 20 ambulanten Behandlungen.

Tragende Erwägungen des gerichtlichen Beschlusses:

Das Gericht folgte im Wesentlichen der Argumentation des vom Verfasser vertretenen Antragstellers: Die Erkrankung war im Streitfall nur noch lebensverlängernd behandelbar. Als Palliativtherapie wiederum stand allein die Chemotherapie zur Verfügung, für welche jedoch aussagekräftige Studien fehlten. Auch ein Standardprotokoll für die palliative Chemotherapie des CCC existierte nicht; vielmehr basierten alle Therapieversuche auf Vorgaben, welche seinerzeit für das Pankreaskarzinom erstellt worden sind.

Umgekehrt ergab sich aus der wesentlichen Verbesserung der Lebensqualität des Patienten und der vorhandenen Studienlage zumindest die Aussicht auf eine spürbar positive Einwirkung auf den Krankheitsverlauf, so dass unter Berücksichtigung der höchstrichterlichen Rechtsprechung die AOK Rheinland/Hamburg zur vorläufigen Leistungsübernahme zu verpflichten war. Angenehm realistisch lesen sich die Ausführungen zum Fehlen einer Standardtherapie und den an die begehrte Elektrohyperthermie zu stellenden Erfolgsaussichten:

„…der frühere Behandler, der Onkologe Dr. (...), hat ausgeführt, dass hier die Chemotherapie nur im Wege eines Off-Label-Use durchgeführt werden könne und dass das CCC im Allgemeinen als wenig chemotherapieempfindlich gelte.

Die Ehefrau des AS hat der Vorsitzenden telefonisch berichtet, dem AS sei es unter der alleinigen Chemotherapie sehr schlecht gegangen. Seitdem diese mit der Hyperthermie verbunden worden sei, könne der AS wieder gelegentlich aufstehen und frische Luft schnappen. Es gehe im deutlich besser als unter der alleinigen Chemotherapie. (...)“

Da die AOK auf Rechtsmittel verzichtete, ist die Entscheidung rechtskräftig.

c. Sozialgericht Osnabrück:

Erstattung der regionalen Elektrohyperthermie beim Glioblastom Sachverhalt:

Bei dem Patienten wurde ein bösartiger Hirntumor diagnostiziert, der zunächst chemo- und radiotherapeutisch behandelt wurde. Gleichwohl kam es zu einer Tumorprogression, aufgrund derer sich der Patient zu einer begleitenden hyperthermischen Behandlung in Form der regionalen Tiefenhyperthermie entschloss.

Die DAK lehnte die Kostenübernahme mit der Begründung ab, der Gemeinsame Bundesausschuss habe hyperthermische Behandlungen verbindlich aus dem Leistungskatalog der gesetzlichen Krankenversicherungen ausgeschlossen, so dass ihr, der DAK, keine andere Entscheidungsmöglichkeit bliebe.

Nachdem der Patient die Mittel für die weitere Hyperthermiebehandlung auch nicht weiter aus eigenem Vermögen aufbringen konnte, wurde der Erlass einer einstweiligen Anordnung beantragt. Das zuständige Sozialgericht Osnabrück entschied innerhalb weniger Tage im Sinne des Antragstellers und verpflichtete die DAK zur Übernahme von vorläufig weiteren 20 hyperthermischen Behandlungen [7] Nachdem diese vollständig durchgeführt wurden und sich die Krankenkasse weiterhin weigerte, die Behandlungskosten zu übernehmen, wurde vom Gericht ein weiterer Eilantrag positiv beschieden.

Tragende Erwägungen des gerichtlichen Beschlusses:

Das Gericht stellte im Wesentlichen Folgendes klar: Zwar wird der Leistungskatalog der gesetzlichen Krankenversicherung in der Tat durch den Gemeinsamen Bundesausschuss geregelt und nicht durch die einzelne Krankenkasse. Jedoch endet zumindest bei lebensbedrohenden Krankheiten die Prüfungspflicht der Krankenkasse gerade nicht an dieser Stelle. Es ist dann im Hinblick auf die sog. „Nikolaus“-Entscheidung des BVerfG eine Entscheidung unter verfassungsrechtlichen Gesichtspunkten zu treffen. Diese wird in Palliativsituationen regelmäßig zugunsten des Antragstellers ausfallen, sofern zumindest eine spürbar positive Einwirkung auf den Krankheitsverlauf zu erwarten ist.

2. Zur Leistungspflicht privater Krankenversicherungen

In ihrer Pauschalität ebenfalls nur bedingt nachvollziehbar ist ferner die Ansicht, für elektrohyperthermische Verfahren sei der „der Nachweis der medizinischen Notwendigkeit nicht zu erbringen“, weshalb auch kein Erstattungsanspruch gegenüber privaten Krankenversicherungen bestehe.

Zwar wird in der Tat von privaten Versicherungsgesellschaften die Erstattung zunehmend mit dem Hinweis darauf abgelehnt, dass es sich bei der Elektrohyperthermie nicht um einen Bestandteil der schulmedizinischen Leitlinien handele. Diese Argumentation übersieht jedoch, dass eine Orientierung an den Leitlinien der evidenzbasierten Medizin lediglich ein erster Anhaltspunkt für die medizinische Notwendigkeit der durchgeführten Behandlungsmaßnahme ist. Keinesfalls ist die medizinische Notwendigkeit nur bei Methoden der Schulmedizin zu bejahen [8].

Wird - wie so oft - mit der Hyperthermie eine lebensbedrohende Erkrankung therapiert, ist von der medizinischen Notwendigkeit der Behandlung bereits dann auszugehen, wenn sie als wahrscheinlich geeignet angesehen werden kann, auf eine Verhinderung der Verschlimmerung der Erkrankung oder zumindest auf ihre Verlangsamung hinzuwirken [9]. Es ist in diesem Fall nicht erforderlich, dass der Behandlungserfolg näher liegt als sein Ausbleiben; vielmehr reicht es aus, wenn die Behandlung mit nicht nur ganz geringer Erfolgsaussicht das Erreichen des Behandlungsziels als möglich erscheinen lässt [10].

Dieser liberalisierte Beurteilungsmaßstab bei Vorliegen einer inkurablen Erkrankung wird von den Leistungsabteilungen der Versicherungen ebenso gern unterschlagen wie die einschlägige Rechtsprechung zur medizinischen Notwendigkeit hyperthermischer Verfahren. So hat etwa das Landgericht Köln ausgeführt:

„… Aufgrund der Beweisaufnahme steht zur Überzeugung des Gerichts fest, dass es sich in Höhe des zugesprochenen Betrages um Kosten für medizinisch notwendige Behandlungen handelte.

Die Kammer folgt insoweit den Ausführungen des Sachverständigen Prof. Dr. (...) Dieser hat (...) die medizinische Notwendigkeit der immunologischen Krebstherapie (...) bejaht.

Dazu führt er aus, dass die immunologische Krebstherapie Gegenstand seriöser immunologisch-wissenschaftlicher Forschung sei und auch der mögliche Beitrag der Hyperthermie im Rahmen der Krebstherapie gut begründet sei...“

(LG Köln vom 15. Dezember 2010, 23 O 187/09, juris-Rz. 20 ff.)

Der Leitsatz des Urteils des Landgerichts Berlin vom 13. Oktober 1998 (7O 265/97) liest sich wie folgt:

„Bei metastasierendem Prostatakrebs ist die Behandlung mit Hormonen, Mistel, Thymus, Reflexzonenmassage, Sauerstofftherapie und Hyperthermie medizinisch notwendige Heilbehandlung.“

In zweierlei Hinsicht erwähnenswert ist in diesem Zusammenhang auch eine vom Verfasser im April dieses Jahres erwirkte Entscheidung des Landgerichts Frankfurt (Oder) [11] mit welcher einer privaten Krankenversicherung im Wege dereinstweiligen Verfügung aufgegeben wurde, bis auf Weiteres vorläufig die Kosten für eine 2 x wöchentlich durchgeführte Elektrohyperthermie zu übernehmen:

- Zum Einen betraf der Streitfall die immer häufiger vorkommende Situation, dass die

Kostenübernahme deshalb abgelehnt wurde, weil sich die Patientin nicht zusätzlich einer Zytostatikatherapie unterzog, sondern die Hyperthermie „nur“ zusammen mit Infusionen von Vitaminen, Mineralstoffen sowie von Mistel- und Thymuspräparaten durchführte.

- Zum Anderen nahm das Gericht im Streitfall eine vorläufige Befriedigung der Patientin in Form einer so genannten Leistungsverfügung vor, was eine absolute Ausnahme im privaten Krankenversicherungsrecht darstellt. An derartige Befriedigungsverfügungen gegenüber privaten Krankenversicherungen - es handelt sich soweit ersichtlich um die erste Leistungsverfügung hyperthermische Verfahren betreffend - stellt die deutsche Rechtsprechung strenge Anforderungen. Sie fordert insbesondere die Aussicht, dass die private Krankenversicherung die Heilbehandlungskosten „mit hoher Wahrscheinlichkeit wird erstatten müssen…“ [12]. Gleichwohl nahm das Landgericht Frankfurt in diesem Zusammenhang weder Anstoß daran, dass es sich „nur“ um eine Elektrohyperthermie handelte noch daran, dass diese als Monotherapie - ohne zusätzliche Zytostatikabehandlung - durchgeführt wurde.

Abschließend bleibt festzuhalten, dass die medizinische Notwendigkeit keineswegs von einer allgemeinen wissenschaftlichen Akzeptanz auf Grundlage der evidenzbasierten Medizin und unter Berücksichtigung strenger statistischer Vorgaben abhängig gemacht werden kann. Vor allem bei lebensbedrohlichen Erkrankungen genügt für den Erstattungsanspruch die nicht nur ganz geringe Erfolgsaussicht, den Krankheitsverlauf zumindest zu verlangsamen. Diese kann nach der Rechtsprechung - natürlich abhängig vom Einzelfall - ohne Weiteres auch bei elektrohyperthermischen Verfahren gegeben sein.

3. Zu den korrekten Abrechnungsziffern

Skurrile Blüten treibt in der Praxis vor allem die dritte These des besprochenen Beitrages, eine „Abrechnung als Hyperthermiebehandlung“ sei bei elektrohyperthermischen Verfahren nicht möglich; vielmehr wäre „eine Position aus dem Kapitel Elektrotherapie zu wählen“. Es muss an dieser Stelle nicht vertieft werden, dass diese Auffassung sehr schnell dazu geführt hat, dass viele Krankenkassen mittlerweile die beantragte Kostenerstattung vornehmen - allerdings lediglich nach Maßgabe der GOÄ-Ziffer 548 (in Höhe von 3,88 EUR pro Sitzung) und natürlich nur im Wege einer „Kulanzentscheidung“.

Der Verfasser betreut bereits diverse gerichtliche Verfahren, welche die Frage der korrekten Abrechnungsziffern betreffen, so dass demnächst mit den ersten Urteilen zur Liquidation elektrohyperthermischer Verfahren zu rechnen ist.

Auch ohne einschlägige Rechtsprechung fällt jedoch ins Auge, dass die Einordnung elektrohyperthermischer Verfahren in die Gebührenziffern der Elektrotherapie zwar nicht einer gewissen Kreativität entbehrt, jedoch tragende Rechtsgrundsätze verletzt (a.) und auf widersprüchlichen Annahmen beruht (hierzu unter b.) Korrekt wäre eine Abrechnung über die Analogziffer 5854, auf deren Voraussetzungen abschließend in der gebotenen Kürze eingegangen wird (c.)

a. zur Dogmatik: Nichtleistung und Schlechtleistung

Die abrechnungstechnische „Herabstufung“ in den Abschnitt E des Gebührenverzeichnisses ist zunächst mit der Systematik des Gebührenrechts in keiner Weise in Einklang zu bringen.

Die Elektrohyperthermie, so heißt es in der besprochenen Arbeit, sei aufgrund mangelnder Energiestärke nicht zu einer therapeutisch relevanten Überwärmung des Gewebes in der Lage. Deshalb sei die Leistungsbeschreibung der Ziffer 5854 (Tiefen-Hyperthermie) „nur unzureichend erfüllt“, weshalb wiederum allein eine Abrechnung als Verfahren der Elektrotherapie in Betracht käme.

Eine derartige Argumentation widerspricht nicht nur den gebührenrechtlichen Vorgaben der GOÄ, sondern auch der medizin- und zivilrechtlichen Dogmatik im Allgemeinen. Sie verwechselt nämlich die Ausführung der Leistung mit dem Leistungsgegenstand an sich:

Es ist bereits dem gesunden Menschenverstand ohne Weiteres einsichtig, dass der Charakter einer versprochenen Leistung sich nicht allein dadurch verändern kann, dass diese Leistung nicht so erbracht wird, wie sie vertraglich geschuldet ist. So wird beispielsweise ein Kaufvertrag über einen Neuwagen nicht deshalb zum Gebrauchtwagenkauf, weil der Verkäufer nicht den versprochenen fabrikneuen Pkw liefert, sondern ein vorbenutztes Exemplar. Vielmehr bleibt es bei einem Kaufvertrag über einen Neuwagen, der lediglich mangelhaft erfüllt wurde, was wiederum gewährleistungsrechtliche Konsequenzen hat.

Besonders stark ist dieser Grundsatz im ärztlichen Vertragsrecht verankert, welches strikt zwischen einer Schlechterfüllung und einer Nichterfüllung trennt. Schlechterfüllung und Nichterfüllung wiederum können nur in absoluten Ausnahmefällen gleichgesetzt werden [13]. Zwar hat eine mangelhafte Ausführung der versprochenen ärztlichen Leistung, die so genannte Schlechterfüllung, unter Umständen durchaus haftungsrechtliche Konsequenzen, ebenso, wie sie auch den Erstattungsanspruch des Patienten gegenüber seiner Krankenkasse tangieren kann. Keinesfalls ist sie jedoch in der Lage, das Wesen der geschuldeten Leistung ändern, etwa dergestalt, dass beispielsweise ein Krankenhausaufnahmevertrag sich mangels unzureichender stationärer ärztlicher Leistungen während des Tages in einen reinen Beherbergungsvertrag wandelt und die geschuldeten Leistungen sich sodann auf Übernachtung und Verköstigung beschränken.

Bezogen auf die hier relevante gebührenrechtliche Fragestellung bedeutet dies: Eine Elektrohyperthermie mit dem Ziel einer therapeutisch relevanten Überwärmung bestimmter Körperregionen bleibt in abrechnungsrechtlicher Hinsicht auch dann eine (Tiefen-) Hyperthermie, wenn im Einzelfall tatsächlich eine klinisch relevante Erwärmung nicht erreicht werden sollte. In diesem Fall handelte es sich lediglich um eine mangelhaft durchgeführte, unter Umständen auch um eine medizinisch nicht notwendige Hyperthermie-Behandlung. Der Charakter als Hyperthermie-Behandlung bleibt jedoch erhalten, so dass die Leistung auch als solche abgerechnet werden kann - nämlich in Höhe einer (analogen) Bewertung nach Ziffer 5854 (hierzu sogleich unter c).

Denn der gegenüber dem Patienten bestehende Vergütungsanspruch entsteht allein durch das Tätigwerden an sich und wird weder dem Grunde nach noch in seiner Höhe durch eine etwaige Mangelhaftigkeit der Behandlung beeinflusst. Vielmehr entfällt der Honoraranspruch nur bei besonders groben (in der Regel bei vorsätzlichen und strafbaren) Pflichtverletzungen [14]. Keinen Einfluss auf das Bestehen und die Höhe des Honoraranspruches hat auch die Verweigerung der Kostenübernahme durch die jeweilige Krankenversicherung des Patienten [15].

Die Frage der hinreichenden Gewebserwärmung kann daher mit anderen Worten bereits denklogisch allein eine Frage der medizinischen Notwendigkeit der durchgeführten Elektrohyperthermie sein [16], die wiederum allein das Rechtsverhältnis zwischen dem (gegenüber dem Arzt voll zahlungspflichtigen) Patienten und seiner Krankenversicherung betrifft, von welcher er Kostenerstattung begehrt.

b. Widersprüchlichkeit der Abrechnung als Elektrotherapie

Eine „Herabstufung“ elektrohyperthermischer Verfahren auf Abrechnungsziffern aus dem Abschnitt E der GOÄ kann auch aus anderen Gründen nicht überzeugen, wie in der gebotenen Kürze ausgeführt werden kann:

Seit Inkrafttreten der vierten Änderungsverordnung zur GOÄ am 01. Januar 1996 ist die Abrechnung von Leistungen aus dem Abschnitt E (Physikalisch-Medizinische Leistungen) nur noch Ärzten mit der Gebietsbezeichnung „Facharzt für Physikalische und Rehabilitive Medizin“ bzw. mit der Zusatzbezeichnung „Physikalische Therapie“ erlaubt. Dies hat beispielsweise in Krankenhäusern dazu geführt, dass Leistungen der Elektrotherapie selbst dann nicht abgerechnet werden können, wenn der sie durchführende „ständige ärztliche Vertreter“ Inhaber der Gebiets- oder Zusatzbezeichnung ist, der Wahlarzt selbst aber diese Bezeichnung nicht erworben hat [17].

Da es sich bei der Elektrohyperthermie nicht um eine originäre Elektrotherapie handelt, kommt auch insoweit lediglich eine Analogbewertung, etwa nach Ziffer 548 (Kurzwellen-/Mikrowellenbehandlung), in Betracht. Eine Analogbewertung hat sich jedoch in die innere Ordnung des weitgehend nach Fachgebieten gegliederten Bewertungssystems der GOÄ einzufügen [18], was im Falle einer Eingliederung in Abschnitt E (Physikalisch-medizinische Leistungen) gerade nicht gegeben ist.

c. Analogabrechnung entsprechend Ziffer 5854

Richtigerweise ist die Elektrohyperthermie im Wege einer direkten bzw. analogen Anwendung der Gebührenziffer 5854 abzurechnen (Tiefen-Hyperthermie, je Fraktion).

Hierbei kann eine direkte Anwendung nach dem eindeutigen Wortlaut der Verordnung nur dann vorgenommen werden, wenn zeitgleich eine Strahlenbehandlung oder eine regionäre intravenöse bzw. intraarteirelle Chemotherapie durchgeführt wird. Fehlt es an einer solchen parallelen Radio-/Zytostatikatherapie, ist die Behandlung im Wege einer Analogberechnung zu liquidieren (A 5854, Tiefen-Hyperthermie, je Fraktion).

Die Möglichkeit einer Analogbewertung ist in § 6 Abs. 2 GOÄ geregelt. Nach dieser Vorschrift kann eine selbständige ärztliche Leistung, die nicht in das Gebührenverzeichnis aufgenommen ist, entsprechend einer nach Art, Kosten- und Zeitaufwand gleichwertigen Leistung berechnet werden.

Diese Voraussetzungen liegen bei der ohne parallele Chemo-/Strahlentherapie durchgeführten Elektrohyperthermie vor: Es handelt sich um eine selbständige Leistung, die nicht in das Gebührenverzeichnis aufgenommen ist (aa.) und die nach Art sowie nach Kosten- und Zeitaufwand im Wesentlichen der Ziffer 5854 entspricht (hierzu unter bb.)

aa. Nichtaufnahme in das Gebührenverzeichnis

Soweit eine Elektrohyperthermie als Monotherapie bzw. „nur“ zusammen mit immunmodulierenden Infusionen durchgeführt wird, fehlt es an einer Aufnahme dieser konkreten Leistung in das Gebührenverzeichnis [19]. Vorsorglich sei darauf hingewiesen, dass der Grund, warum eine ärztliche Leistung nicht in das Gebührenverzeichnis aufgenommen wurde, für deren analoge Berechnungsfähigkeit keine Rolle spielt. Entscheidend ist allein, dass die Leistung im Gebührenverzeichnis nicht enthalten ist. Deshalb kommen für eine analoge Anwendung insbesondere auch solche Leistungen in Betracht, die seit längerem bekannt sind, von deren Aufnahme der Verordnungsgeber aber - etwa wegen ihrer umstrittenen Bedeutung - bewusst

abgesehen hat. Insbesondere steht daher eine analoge Abrechnung gem. § 6 Abs. 2 grundsätzlich auch für ärztliche Leistungen außerhalb des schulmedizinischen Spektrums offen, soweit diese - wie in der Regel - im Gebührenverzeichnis nicht berücksichtigt sind [20].

bb. Gleichwertigkeit der Leistung

§ 6 Abs. 2 GOÄ verlangt weiter die Gleichartigkeit der analog berechneten Ziffer nach ihrem Kosten- und Zeitaufwand sowie nach ihrer Art.

Ein im wesentlichen gleichartiger Kosten- und Zeitaufwand der ohne parallele Chemo-/Strahlentherapie durchgeführten Elektrohyperthermie wird sich mit guten Argumenten begründen lassen, zumal die parallele Strahlenbehandlung bzw. Chemotherapie gesondert berechnet werden kann. Somit unterscheidet sich die Monohyperthermie in Gestalt einer Elektrohyperthermie nur durch die in der Regel niedrigeren Anschaffungskosten des Gerätes und durch die Behandlungsplanung. Hierbei wiederum hat der Gesetzgeber durch die Abrechnungsziffern 5840 und 5851 zu erkennen gegeben, dass er die Behandlungsplanung lediglich bei einer Ganzkörperstrahlenbehandlung vor Knochenmarkstransplantation bzw. bei der Brachytherapie für gebührenrelevant hält. Die reine Behandlungsdauer als solche wird im Wesentlichen identisch sein. Daher kann jedenfalls von einem insoweit gleichartigen Kosten- und Zeitaufwand ausgegangen werden, dass er einer Analogbewertung nicht im Wege steht.

Wie so oft ist es auch hier die Gleichwertigkeit nach der Art der Leistung, die der Analogfindung Grenzen setzt. Die Rechtsprechung stellt insoweit auf die äußeren und auf die inneren Leistungsmerkmale ab, wobei äußere Leistungsmerkmale vor allem die Organbezogenheit und die Behandlungstechnik sind, wohingegen als artbezogenes inneres Leistungsmerkmal in erster Linie der leistungsspezifische Schwierigkeitsgrad heranzuziehen ist.

Gemessen an diesen Grundsätzen ergibt sich Folgendes:
Die äußeren Leistungsmerkmale dürften gleichwertig sein, da die Zielregionen und die Behandlungstechnik als solche, die Überwärmung einer bestimmten Körperregion, sich hinsichtlich des (gebührenrechtlich allein relevanten) Aufwandes des Behandlers nur unwesentlich voneinander unterscheiden.

Fraglich ist jedoch, ob auch die inneren Leistungsmerkmale vergleichbar sind und hierbei insbesondere, ob nicht bei der Elektrohyperthermie womöglich ein derart verminderter Schwierigkeitsgrad im Vergleich zur originären Leistung der Ziffer 5854 vorliegt, dass ihr Wesen nicht mehr erfasst wird. Auch dieses wird man jedoch mit guten Gründen verneinen können: Zwar wird hierzu seitens der Krankenversicherungen regelmäßig darauf verwiesen, dass bei der „wissenschaftlichen“ Hyperthermie eine umfangreiche Behandlungsplanung vonnöten sei, Messsonden in den Körper des Patienten einzuführen wären und dass überdies im Behandlungsverlauf eine Überwachung zu erfolgen habe.

Dem kann jedoch entgegengehalten werden, dass eine besondere Schwierigkeit bei der Ausführung primär bei der Frage nach dem angemessenen Steigerungssatz eine Rolle spielt, die Frage nach der Analogbewertung jedoch nur bedingt beeinflussen kann. Auch kann es naturgemäß nicht darauf ankommen, dass die analog zu bewertende Leistung bestimmte Teile der Leistungsbeschreibung der herangezogenen Ziffer erfüllt. Denn die Voraussetzung einer Analogabrechnung ist ja gerade das Finden einer gleichwertigen, nicht aber gleichartigen Leistung. Im Übrigen wird eine Überwachung der Patienten auch bei der Elektrohyperthermie vorgenommen.

In der Gesamtbetrachtung liegen daher für die Elektrohyperthermie die Voraussetzungen einer Analogabrechnung nach Ziffer 5854 vor, wobei Rechtsprechung zu diesem Thema noch aussteht. In diesem Zusammenhang ist auch zu beachten, dass das Gebührenverzeichnis der GOÄ angesichts des fortschreitenden medizinischen Fortschritts selbst hinsichtlich etablierter Verfahren kaum jemals auch nur annähernd vollständig sein kann, so dass die Leistungserbringer auf eine Analogbewertung nach § 6 Abs. 2 GOÄ zwingend angewiesen sind, um wirtschaftlich therapieren zu können. Erst Recht gilt dies bei der Anwendung neuer Untersuchungs- und Behandlungsmethoden.

4. Ausblick und Zusammenfassung

Die Auffassung, elektrohyperthermische Verfahren seien weder zu Lasten der gesetzlichen noch zu Lasten der privaten Krankenversicherungen abrechenbar, ist zumindest in derartiger Pauschalität unzutreffend. Dies ergibt bereits eine kurze Recherche der einschlägigen Rechtsprechung. Richtig ist, dass es sich bei elektrohyperthermischen Verfahren um eine neue Behandlungsmethode handelt, so dass sich die Leistungspflicht privater und gesetzlicher Krankenversicherungen – stark vereinfacht – auf die Therapie inkurabler Erkrankungen beschränken wird, für welche Standardverfahren nur noch bedingt zur Verfügung stehen. Wenngleich die Rechtsprechung in diesem Bereich lediglich geringe Anforderungen an die Erfolgsaussichten der durchgeführten Therapie stellt, muss im Einzelfall wenigstens die nicht ganz fern liegende Aussicht bestehen, zumindest die Progression zu verlangsamen.

In diesem – und nur in diesem - Zusammenhang wiederum spielt eine Rolle, ob und inwieweit im Wege der Elektrohyperthermie eine klinisch relevante Erwärmung der jeweiligen Körperregion gelingt.

Obwohl diese Frage für einen Großteil der Tumoridentitäten noch nicht definitiv beantwortet ist, lässt sich die gebührenrechtliche Herabstufung als Maßnahmen der Elektrotherapie in keinerlei Hinsicht begründen. Vielmehr ist die eigens für die Tiefen- Hyperthermie geschaffene Abrechnungsziffer 5854 (analog) heranzuziehen, und zwar auch bei solchen elektrohyperthermischen Behandlungen, die nicht im Zusammenhang mit einer Chemo- oder Strahlentherapie erfolgen.

Die Zukunft liegt in der Aufarbeitung der einzelnen Fallkonstellationen:

In juristischer Hinsicht bleibt zu klären, welche Anforderungen an die Aussicht auf eine „spürbar positive Einwirkung auf den Krankheitsverlauf“ (bei GKV-Patienten) bzw. an die „nicht nur ganz geringe“ Aussicht auf eine Verlangsamung des Krankheitsverlaufes (bei PKV-Patienten) zu stellen sind. Einige Gerichte lassen hier erfreulicherweise bereits den individuellen Therapieverlauf genügen, teilweise ergänzt um eine (schlüssige) befürwortende Stellungnahme des Behandlers (sog. interne Evidenz). Andere Spruchkörper fordern möglichst valide klinische Daten für die konkret in Rede stehende Erkrankung und lehnen jede Übertragung von Ergebnissen betreffend andere Tumoridentitäten kategorisch ab.

In tatsächlich-medizinischer Hinsicht bleiben Art und Ausmaß der klinisch relevanten Erwärmung durch elektrohyperthermische Verfahren zu klären, und zwar so „gerichtsfest“ wie möglich. Denn hiervon wird zu einem großen Teil die medizinische Notwendigkeit bestimmt – und damit die Leistungspflicht der Versicherungen.

References

[1] Heyll, Die regionale Elektrohyperthermie - technische Grundlagen, klinische Resultate und versicherungsmedizinische Aspekte, in: Versicherungsmedizin 64 (2012), 70ff.

[2] Beschlussbegründung des Gemeinsamen Bundesausschusses zur Änderung der Anlage B „Nicht anerkannte Untersuchungs- und Behandlungsmethoden“ der BUB Richtlinie vom 18. Januar 2005, abrufbar über die Internetseiten des Instituts.

[3] BVerfG vom 29. November 2007, 1 BvR 2496/07, juris, Tenor zu 3.

[4] Es handelt sich um eine kleine Auswahl vom Verfasser erstrittener, bislang noch nicht publizierter Entscheidungen. Diverse andere (stattgebende) Judikate zur Elektrohyperthermie finden sich in den einschlägigen Datenbanken, vgl. nur Thüringer Landessozialgericht vom 25. August 2010, L 6 KR 290/10 B ER - „Oncothermie“.

[5] Sächsisches Landessozialgericht vom 24. Oktober 2011, L 1 KR 75/11 B ER, nicht publiziert.

[6] Sozialgericht Köln vom 24. November 2011, S 26 KR 833/11, nicht publiziert.

[7] Sozialgericht Osnabrück vom 02. August 2011 und vom 09. Januar 2012, S 3 KR 264/11 ER, nicht publiziert.

[8] OLG Köln vom 14. Januar 2004, 5 U 211/01.

[9] BGHZ 133, 208, 215.

[10] Statt aller: BGHZ 133, 208, 215; BGHZ 164, 122, 127; LG Köln vom 06. Dezember 2011, 23 O 275/11; umfangreiche Nachweise auch bei Dierks/Finn in: Handbuch des Pharmarechts, § 7 Rn. 194 ff

[11] LG Frankfurt (Oder) vom 13. April 2012, 14 O 113/12, nicht publiziert.

[12] Vgl. nur OLG Koblenz vom 07. August 2008, 10 W 486/08, juris Rz. 08.

[13] Statt aller: Mennemeyer/Hugemann in: Wenzel, Der Arzthaftungsprozess, 01. Auflage 2012, S. 225 ff. mit ausführlichen weiteren Nachweisen.

[14] BGH VersR 1996, 233, 234; umfangreiche Nachweise hierzu bei Korn: in Laufs/Kern, Handbuch des Arztrechts 04. Auflage 2010, S. 837 ff.

[15] Der Arzt hat indes im Rahmen seiner Pflicht zur wirtschaftlichen Aufklärung - soweit dies für ihn erkennbar ist - darauf hinzuweisen, dass die Kostenübernahme zweifelhaft sein könnte und der Patient sich insoweit rückversichern sollte - BGH NJW 1983, 2630.

[16] Die medizinische Notwendigkeit ist gem. § 1 Abs. 2 der Musterbedingungen der Krankenkassen Voraussetzung der Leistungspflicht privat versicherter Patienten. Bei gesetzlich versicherten Patienten wird in rechtstechnischer Hinsicht nicht auf die sog. medizinische Notwendigkeit abgestellt, sondern auf die „nicht ganz entfernt liegende Aussicht auf eine spürbare positive Einwirkung auf den Krankheitsverlauf“ i. S. v. § 2 Abs. 1a SGB V.

[17] Hoffmann/Kleinken, Gebührenordnung für Ärzte, Bd. 2, 03. Auflage 2012, C II Rn. 1a ff.

[18] Lang/Schäfer/Stiel/Vogt, GOÄ-Kommentar, 02. Auflage 2002, § 6 Rn. 6.

[19] Nur am Rande sei erwähnt, dass der hier besprochene Beitrag auch insoweit widersprüchlich ist. Es heißt auf Seite 73: „...Tatsächlich ist (...) eine Analogabrechnung nur bei Leistungen möglich, die in das Gebührenverzeichnis nicht aufgenommen sind. Da die Hyperthermie in der GOÄ enthalten ist, entfällt die Möglichkeit einer Analogabrechnung“. Sollte dieses tatsächlich auch für monotherapeutische Elektrohyperthermien gelten (woran angesichts des eindeutigen Gesetzeswortlautes mit guten Gründen gezweifelt werden darf), stellt sich das nachstehend erörterte Problem der Analogbewertung in der Tat nicht. In diesem Fall wäre die Elektrohyperthermie in direkter Anwendung der Ziffer 5854 zu liquidieren.

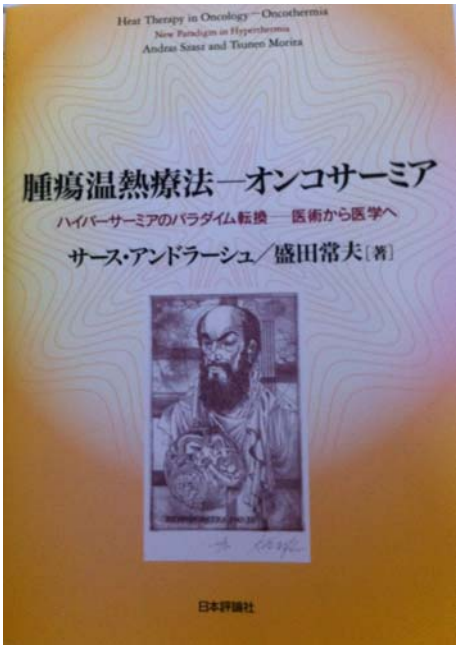
[20] So heißt es wörtlich in der neuesten Auflage des von den Leistungsabteilungen der privaten Krankenversicherungen standardmäßig verwendeten GOÄ-Kommentars Lang/Schäfer/Stiel/Vogt, § 6 Rn. 3.

Report about 2012 Yonsei Oncothermia Symposium, in Seoul, Korea

It was a memorable moment for Oncothermia. On June 1st, Prof. Dr. Szász presented a special lecture at "2012 Yonsei Oncothermia Symposium" in Seoul, Korea. The symposium was organized by Yonsei University College of Medicine, Department of Oncology, which is one of the most prestigious institutes in Korea. Dr. Chang Geol Lee (Chairperson, Radiation Oncology) started the opining with the remark "This symposium celebrates the installation of our Oncothermia device. Younsei University and adjunct Severance Hospital have a long experience in Hyperthermia cancer treatment. Oncothermia adds a new page for our history." At the symposium, nine prominent professors and doctors did presentations about Oncothermia and Hyperthermia treatment. More than 80 people, many of them specialists in the oncological field, gathered in the auditorium and actively exchanged ideas.

Prof. Dr. Szász at the Yonsei Oncothermia Symposium

Another memorable ceremony was held at the Hungarian embassy in Tokyo on June 5th. The newly published book "Heat Therapy in Oncology- Oncothermia- New Paradigm in Hyperthermia" was presented by the co-author Prof. Dr. Szász and Mr. Tsuneo Morita (President of Tateyama Europe R&D).



Ambassador Mr. Istvan Szerdahely introduced Prof. Dr. Szász by comparing him to Prof. Dr. Albert Szent-Gyorgyi, the Hungarian Novel Laureate scientist who discovered Vitamin C, saying

“Prof. Szasz may be the next Hungarian Nobel Laureate scientist.” One of the invited guests, Kenichi Kobayashi, the world-famous orchestra conductor, performed with an impromptu piano performance celebrating the publication. Invited guests were inspired by the lecture of Prof. Szasz, enchanted short classic concert and enjoyed Hungarian cuisine.

Prof. Dr. Szász in the Hungarian Embassy in Tokyo

June 2012
Seoul, South Korea

Impressions from the Korean Oncothermia Symposium

XXXI. Conference of the International Clinical Hyperthermia Society

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The templates of your abstracts, its submission time and the available hotel reservations will be announced on our websites: www.hyperthermia-ichs.org and www.ichs-conference.org.

You can register or send enquiries and questions via email to Ms. Janina Leckler (leckler@oncotherm.de).

XXXI.
Conference of the International Clinical Hyperthermia Society (ICHS)
In: Budapest, Hungary
On: October 12th-14th 2012

Organisation

Oncotherm GmbH
Ms. Janina Leckler
Belgische Allee 9
53842 Troisdorf
Germany

Phone: 0049 2241 31992 0
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Hyperthermia—How to break through?

XXXI. Conference of the International Clinical Hyperthermia Society

Jointly with the 2nd

International Oncothermia Symposium

www.hyperthermia-ichs.org
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On behalf of the International Clinical Hyperthermia Society we cordially invite you to our XXXI. ICHS Conference

At the last ICHS annual meeting in Tbilisi, Georgia in September 2011 Prof. Dr. András Szász was elected as new president of the ICHS. He will take over responsibilities for the society and will host next year's conference. The event will take part in Budapest, Hungary and will it held together with the 2nd International Oncothermia-Symposium. We will inform you about the progress of the organizing and information about talks regularly. Please send us your abstracts for talks and posters as soon as possible! We are looking forward to all speakers and participants! Company sponsorships for students and young researchers are possible. For detailed information please contact Ms. Janina Leckler (leckler@oncotherm.de) or consult with our web-sites (www.hyperthermia-ichs.org, www.ichs-conference.org), where all the detailed info will be actualized.

Prof. Dr. Szász is the new elected president of the ICHS

Dear colleagues,
dear members of ICHS,
dear Oncothermia-users,

Hyperthermia started to be an integrative part of the oncotherapies. Our Society is one of the oldest in this field. Since its establishment ICHS has represented the best traditions of the oncological hyperthermia, uniting the best national and international efforts to reach the wide acceptance of this complementary therapy. Like in most other areas of professional activities, international communication is getting more and more important in the medical field. Let us exchange our experiences, get to know new approaches of hyperthermia in oncology, let us seriously and openly discuss new ideas. Our Society has preferred the direct debates, has protected the explicit and frank opinions for medical approaches for building up a better, safer and successful oncology treatment. Our main concern is to help the suffering patients with a longer survival accompanied with high quality of life. I invite you to our conference to continue our traditions and strengthen hyperthermia as a stable weapon in the war against cancer!

Yours:

Prof. Dr. Szasz Andras
ICHS President

Date

October 12th-14th 2012

Place

Hotel Marriott, Budapest, Hungary

Organisation

Oncotherm GmbH
Ms. Janina Leckler
Belgische Allee 9
53842 Troisdorf
Germany
Phone: 0049 2241 31992 0
Fax: 0049 2241 31992 11
E-Mail: leckler@oncotherm.de

International Clinical Hyperthermia Society (ICHS)

Dear ICHS member,

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The ICHS membership is free of charge. If you would like to become a member we need you to complete the form and fill out all fields.

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Thank you very much.

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October 12th-14th, 2012
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After receipt, the Organizing Committee will send an invoice for the payment and further organizing information.

The registration fee will be refunded minus a 40,00 EUR handling fee for cancellations received in writing before August 31st, 2012. For registrations cancelled after August 31st, 2012 no refunds are possible.

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XXXI. ICHS Conference

2nd International Oncothermia-Symposium

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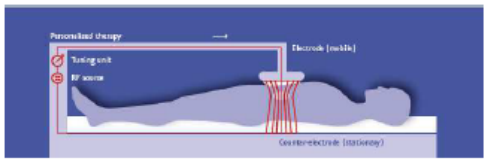

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Klinik im LEBEN

Fachbehandlungszentrum
für Biologische
Krebstherapie,
Naturheilverfahren,
Homöopathie,
spezielle Schmerztherapie

Greiz, Germany

Die Klinik im LEBEN ist eine staatlich konzessionierte und zertifizierte Fachklinik mit dem Schwerpunkt „Naturgemäße Biologische Krebstherapie". Das grundlegende auf allen Ebenen angewandte Behandlungskonzept wird in den Stufen *„Ergänzende Diagnostik, Ursachen beseitigen, Mängel ersetzen, Abwehr stärken, Harmonisieren und* ***Zum LEBEN zurück***" gegliedert

Liebe und eine positive Grundhaltung, die Belebung von Lebenskraft und Lebensfreude, das Wiederfinden von persönlichen Energiequellen und innerer Harmonie besitzen höchste Bedeutung für eine gesunde Lebensqualität. Zurück zu finden zu dieser inneren Ebene, zur eigenen Mitte und zum gegenwärtigen Augenblick bedeutet, sich selbst zu erfahren und Ziele ganz neu zu erkennen . Für das LEBEN zu leben durch mehr Achtung und Beachtung von Körper, Geist und Seele, dafür steht die KLINIK im LEBEN in Greiz.

„Warum ich?" Diese Frage entsteht nach der Diagnose Krebs meistens als erstes im Kopf, danach folgen Leere, ein schwarzes Loch. Im ersten Moment scheint eine glückliche Zukunft undenkbar, aber es ist allgemein bekannt, dass Lebenswille und positive Gedanken den Gesundungsprozess sehr stark fördern können. Die wichtigste Aufgabe für den Patienten ist es jetzt, die Krankheit anzunehmen, sie zu akzeptieren. Denn erst dann können sich Hoffnung, Zuversicht und der Glaube an Heilung verwirklichen. Mit ihrer Naturgemäßen Biologischen Krebsmedizin will die KLINIK im LEBEN den Patienten aktiv unterstützen.

Anders als die Schulmedizin, die Krebs mit Operationen, Bestrahlungen und Chemotherapie nur im körperlichen Bereich für den Moment behandelt, werden in der Naturgemäßen Biologischen Krebstherapie sämtliche Körperebenen diagnostisch und therapeutisch mit einbezogen. Gemeinsam mit dem Patienten wird der für ihn optimale und für den Körper schonendste Weg zur Besserung und Heilung gefunden. Dabei wird sich für ihn Zeit genommen, um das Zusammenspiel der einzelnen Behandlungsmethoden detailgenau zu erläutern.
In der KLINIK im LEBEN wird der Patient als Mensch behandelt – seine Ängste ernst genommen, seine Würde erhalten und er wird fachgerecht und liebevoll auf dem Weg der Gesundung begleitet. Lebensfreude, innere Harmonie und positives Denken für die Zukunft sind die Werte, die ihm hier vermittelt werden, um den Krankheitsverlauf selbstständig positiv zu beeinflussen. „Glück heißt, jeden Moment eines Tages zu genießen" – auch mit der Krankheit Krebs.

Klinik im LEBEN
Biologische Medizin

Ipertermia Italia
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Villa Salaria

Ipertermia Italia
Dott. Carlo Pastore
Rome, Italy

The Ipertermia Italia portal was born from the need to create a more direct and less impersonal doctor-patient-family interaction and from the wish to make the general public aware of the existence of an effective method in the fight against cancer: hyperthermia.

A tumor disease strikes the whole family as a raging storm, becoming not only the disease for the individual, but also affectig the patient's entire social universe.

Loss, fear and a lack of information make it more difficult for the family to face the illness of a loved one in the best possible way.

It is in this context that the actions of Ipertermia Italia developed in order to reduce the distance between the patients and their families, providing expertise, professionalism and comfort.

Dr. Carlo Pastore is working as Head of Operational Integrated chemo-hyperthermia in the clinic Villa Salaria in Rome. He tries to pass his knowledge and opinion on to other colleagues and to all other interested persons through the internet and by publishing articles and ideas. Dr. Pastore wrote the book „Perspectives for clinical oncology in general practice" and published numerous articles in international journals on oncology.

He is a medical surgeon and a specialist in medical oncology. He graduated in medicine with honors from the University of Rome „La Sapienza". He got is specialization in oncology in 2005 and obtained at the First School of Medical Oncology of the University of Rome „La Sapienza" Policlinico Umberto I.

Dr. Pastore enhanced hyperthermia in Clinical Oncology by graduating in 2006 at the Second University of Rome "Tor Vergata".

He was oncology consultant for the Sofia Medical Center (Sweden) until 2010 and for the CMH-Centro Médico Hilu presso Nueva Andalucía in Marbella (Spain) until 2011 and exercised at the Policlinico Umberto I of Rome Operations Unit of Medical Oncology until 2009. Now he is concentrating on his work at the Department of Oncology and Hyperthermia in the Villa Salaria Clinic.

Ipertermia Italia

Deutsche Gesellschaft für Hyperthermie e. V. – Vereinsnachrichten –

Verehrte Kolleginnen und Kollegen,
liebe Mitglieder unserer Gesellschaft
und alle an der Hyperthermie Interessierten,

im letzten Heft (Ausgabe 2/2012) konnten Sie lesen, dass sich Herr Prof. Dr. med. Holger Wehner nach zehnjähriger erfolgreicher Funktion als Präsident der *Deutschen Gesellschaft für Hyperthermie* nun wieder auf seine klinische Tätigkeit konzentrieren will. Das ist durchaus verständlich, wird aber von allen Mitgliedern unserer Gesellschaft bedauert, denn die DGHT und Prof. Wehner waren eine Einheit. Ohne ihn hätte die Gesellschaft nicht den gegenwärtigen Stellenwert, dafür danken wir ihm.

Andererseits ist ein Wechsel an der Spitze auch eine Chance für neue Entwicklungen, und Prof. Wehner bleibt nun als Mitglied des wissenschaftlichen Beirates in der Leitung der Gesellschaft präsent.

Die weiteren Mitglieder des bisherigen Vorstandes stellten sich wieder zur Wahl und wurden von der Mitgliederversammlung am 12. Februar 2012 in Frankfurt bestätigt: Dr. Hüseyin Sahinbas (Vizepräsident), Dr. Wilfried Stücker (Schatzmeister), Dr. Stephan Wey (Sekretär), Dr. Wulf-Peter Brockmann (Koordinator für Rechtsfragen).

Mein Ziel ist es, Kontroversen innerhalb der Hyperthermieanwender zu reduzieren, insbesondere die langjährigen Konflikte zwischen Universitätshyperthermie an wenigen Zentren (gegenwärtig etwa 15) und der Versorgungs-Hyperthermie zur Versorgung tausender Tumorpatienten, der sich vorwiegend unsere Mitglieder widmen (über 200 Geräte für die lokale HT, und fast 300 Geräte für die Ganzkörperhyperthermie im deutschsprachigen Raum!). Der weitere Stellenwert der Hyperthermie bei Nichttumorerkrankungen wird nur innerhalb der DGHT e. V. gebührend definiert. Erste Gespräche mit dem Vorsitzenden der IAH (*Interdisziplinäre Arbeitsgemeinschaft Hyperthermie der Deutschen Krebsgesellschaft*), Prof. Issels, sind diesbezüglich bereits erfolgt.

In der erweiterten Vorstandssitzung am 27. April 2012 in München haben wir festgestellt, dass die DGHT sich Forderungen zur Qualitätssicherung unbedingt stellen muss. Ohne exakte standardisierte Falldokumentationen ist keine Anerkennung der Hyperthermieapplikationen zu erwarten. Hier ist die IAH einen Schritt weiter und hat somit auch bei der Kostenerstattung die Nase vorn, so werden beispielsweise Hyperthermien innerhalb verschiedener Studien von den Krankenkassen erstattet, unabhängig davon, dass Ergebnisse erst in Jahren vorliegen werden. Auf die berühmten prospektiven randomisierten Phase-III-Studien können wir nicht warten – sie sind in der Versorgungsforschung zwar wünschenswert, aber nicht umsetzbar. Deshalb wollen wir den zusätzlichen Weg der Falldokumentationen gehen.

Weitere Ziele der DGHT sind die Erhöhung der Mitgliederzahl (jeder Anwender sollte Mitglied werden!) und verstärkte Präsenz der DGHT in der wissenschaftlichen und allgemeinen Öffentlichkeit. Das wissenschaftliche Interesse an der Hyperthermie ist gleichbleibend hoch: So war das vom Präsidenten der DGHT geleitete hochkarätige 1. Frankfurter Expertenmeeting zur Hyperthermie am 9. Mai 2012 komplett ausgebucht. Ein positives Signal: Die Tagung wurde von der medac GmbH, also einer Pharmafirma, gesponsert, die offensichtlich das Potential unserer Methode erkannt hat.

Mit kollegialer Empfehlung verbleibe ich,

Ihr

Prof. Dr. med. Harald Leo Sommer,
Präsident der DGHT e.V.

Veranstaltungen 2012

Datum	Ort	Veranstaltung	Kontakt
28.–31.08.2012	Kyoto, Japan	Veranstaltung 11th International Congress of Hyperthermic Oncology and 29th Japanese Congress of Thermal Medicine (ICHO & JCTM 2012)	DGHT-Geschäftsstelle Mühlenweg 144, 26384 Wilhelmshaven Tel.: 04421-20 944 80 E-Mail: info@dght-ev.de, www.dght-ev.de Informationen zum Kölner Hyperthermie-Symposium: www.hyperthermie-kongress.de
14.09.2012	Köln	Mitgliederversammlung der DGHT e. V.	
14.–15.09.2012	Köln	III. Hyperthermie Symposium Köln	
12.–14.10.2012	Budapest	ICHS-Meeting	

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