

Iontophoretic tumor therapy

For this innovative development in the field of the cancer therapy contact to the pharmaceutical industry or to special research institutes and oncological hospitals is sought.

This method resulted from the practice as the life work of a long-standing clinician. It is an unchallenged method, which employs a new tumor destroying medication of selective effect and curing aim void of significant adverse effects. Based on school medicine, the iontophoretic tumor therapy is no procedure of the alternative medicine and no outsider method, but an original scientific development.

The medication developed for the iontophoretic tumor therapy was subject of extensive scientific toxicological examinations executed by a renowned company meeting highest scientific standards, which have proved its non-toxic character. The scientist responsible for the examinations summarized: "From the toxicological view, the planned application in man ought to be considered safe. Also, pharmacological interactions in the sense of adverse effects can hardly be expected at doses administered in man. From my point of view all legal standards governing the manufacture and prescription of drugs are fulfilled."

This medicine is a priori no cytostatic: however, the agent is transformed exclusively at the site of effect (only then and only there!) into a highly potent selective antineoplastic drug due to Iontophoresis effects. Its main active agent is an ionic acridine derivative, transported extra- and intracellular under iontophoretic conditions. The result is a selective admission of the substance to the nuclei of the tumor cells with the subsequent death of these cells. Since Iontophoresis affects exclusively nuclear membranes, only tumor tissues are permeated by the medication, an effect, which fails to appear in healthy tissues. This biological phenomenon constitutes the uniqueness of the iontophoretic tumor therapy. It also explains the selectivity and allows to understand the excellent treatment results. Electrical current intensities and current densities used for the Iontophoresis are in a physiological range at milliamps; they are not traumatic, well tolerated. The technical apparatus needed for the application of the method is comparatively low. As for the complete iontophoretic tumor therapy developed by the inventor/inaugurator, medication and Iontophoresis form a key and lock principle tuned subtly with each other. I.e.: neither the medication can be replaced by another substance nor can the Iontophoresis be replaced by another electrical modality.

So far, the primary application of the antineoplastic tumor Iontophoresis was the organ conserving therapy and relapse prophylaxis of the bladder cancer. Long-standing clinical results and scientific publications are already available so this method is an advanced clinical procedure. Early on, considerations started to transfer this underlying principle to tumors of other organs. It was only in 2003 that a corresponding model was developed.

The iontophoretic modality found now allows to precisely and selectively direct the current to tumors at various locations within the body exerting the selective antineoplastic effect at exactly defined current intensities and current densities. However, detailed treatment concepts for malignancies of the lung and mamma available now could not yet be practically realized. Obviously, no therapeutic success can be guaranteed at this moment. There are, however, good chances that success is to be expected.

This optimism is nurtured by excellent results achieved with the iontophoretic tumor therapy of the bladder and with reproducible animal experiments. The latter were extended inocula-

tion tumors, which regressed without exception completely due to a single antineoplastic Iontophoresis. Follow-up was 2 years until the natural death of the laboratory animals. During this time, animals were at good general conditions with no accounts of a relapse. According to literature, the experimental tumors chosen previously resisted all other forms of therapy. Further support comes from the almost biological order the selective iontophoretic mechanism exhibits in combination with the special medication. Bladder and skin tumors treated with antineoplastic Iontophoresis, the selectivity was regularly faultlessly clinically proven and documented.

It needs to be stressed that the principle of the selective antineoplastic iontophoresis not only applies to proliferative cells of the tumor, but also for its quiescent cells. This not only stops the tumor growth but results a complete tumor remission, as was already shown by the experiments mentioned above.

Evidence for the effectiveness of the iontophoretic tumor therapy at other internal organs, however, can only be secured by specific curative tests. Diligent execution will likely exclude harm of the patients. The 'primum nil nocere' is thus ensured. As in the bladder, when applied to other sites the iontophoretic tumor therapy should be easily manageable, non-toxic and selective. With respect to the toxicological testing of the medication mentioned above, the scheduled dosage will be completely within legal limits and by far below those causing adverse effects or being toxic. From a pharmacological point of view, there are "light years" between therapeutic concentrations and those being toxic. This fact is also underpinned by the fact that the medication kills all cells in cell cultures at the inconceivable concentration of $0.05 \mu\text{g}$ (= 50 billionth of a gram).

Curative tests are permitted legally with medication not yet admitted. They can be carried out in individual cases to patients who decline heroic radical operations and chemotherapies, looking for treatment, which appears an alternative and only little stressing. The stress due to 1-3 cycles of the iontophoretic tumor therapy cannot be compared with conventional surgical interventions and usual chemotherapy. In case the iontophoretic tumor therapy has no success, therapies using those conventional methods can be immediately changed to. The delay accepted for use of the iontophoretic tumor therapy can be justified from a physician's standpoint. The risk for patient and doctor is therefore low.

It is the creed of the inaugurator of the iontophoretic tumor therapy, to consider this innovative method not only as an expansion of the existing therapeutic repertoire, but also as a potential method of different therapeutic dimension.

It is the declared aim of this gentle antineoplastic tumor iontophoresis as a curative therapy to do in as many cases as possible for the most frequent cancers without mutilating operations, without conventional chemotherapy and without palliative radiation therapy which shorten the life and reduce the quality of life of patients. This aim is already accomplished for malignancies of the bladder, with the exception of very advanced stages. For other organs, this aim is at hand.

This opens a rewarding field not yet developed for interested oncologists for practical and scientific activity beyond the everyday routine of conventional cancer therapies. At the present stage, the realization of the aim outlined above can no longer be achieved by the inaugurator of the method himself, which is the reason why he tries this way to win a comrade-in-arms to tackle this humanitarian task.

The production of the new (and still not authorized) preparation is protected by patents in the USA and Germany. The protective rights are in the possession of the inventor/inaugurator just like the pleasant and catchy trademark under which the preparation shall be commercialized.

It is intended to entrust the patents including the complete clinical and technical know-how to a qualified enterprise, for exclusive usage, which is ready to tackle the task and challenge also in the humanitarian aspect of this innovation.

You are asked to contact using e-mail in case of serious technical interest disclosing the qualification and profile of the enterprise/institution.

Further information concerning antineoplastic iontophoresis of the bladder carcinoma and selectivity:

Bladder Carcinoma

Iontophoretic tumor therapy of the bladder carcinoma is a fully developed clinical method. Medicine (instillat) is being transported iontophoretically from the bladder lumen into the tumor respectively the bladder wall. Here – under the influence of iontophoresis – it develops its selective antineoplastic effect (=permeability of core membrane only in the tumor cell, and iontophoretic transportation of the medicine into the nucleus entailing cell death).

With this method it is possible to locate and destroy tumors even in deeper tissues of the bladder wall as well as latent and at first diagnosis optically not detectable ubiquitous tumor sprouts in all bladder wall sections and layers. These non-evident tumor sprouts produce most of the time in chronological graduation and multi ocular the so-called relapses that are after all a new manifestation of the tumor. This constellation constitutes the actual prognostic, therapeutic, and prophylactic dilemma of the bladder carcinoma.

Antineoplastic iontophoresis therefore allows genuine relapse prophylaxis in all stages of the illness. Every specialist/urologist knows how important effective relapse prophylaxis is during the treatment of bladder cancer. Real cure can only be achieved through relapse prophylaxis. Conventional cytostatic bladder instillation therapies do not have this ability, at least when it comes to deeper infiltrating areas. They cannot spontaneously penetrate deep enough into the bladder wall, are not selective, and have other serious side effects.

The new method can in many cases avoid mutilating cystectomy, surgery from which - according to American statistics - only 10 – 20 % of patients benefit anyway. In 50% of the operated cases distant metastases occur within two years, in spite of (or because of) intensive pre- and postoperative chemotherapy. Compared to conventional therapy schemes the iontophoretic tumor therapy of bladder cancer is a patient friendly, gentle, and bladder conserving method with an efficiency that in the past could not be imagined. Thus the bladder carcinoma can be considered as classical application area for the iontophoretic tumor therapy.

In 1994 statistics was compiled (Positive List) about 43 cases of different stages of bladder carcinoma having been treated by iontophoretic tumor therapy. Treatment was finished in all patients in 1993. Follow-up varied between one and five years. At the checkups all patients were bladder healthy, free of relapses and in good general condition.

20 patients, having been treated with antineoplastic iontophoresis, could be followed up till the end of 2003. They were free of relapses and in good general condition. The unusually long period of follow-ups was 10 years!

Selectivity

During iontophoretic tumor therapy of the bladder carcinoma the whole bladder lies within the sphere of influence of iontophoresis and medicine. If the method were not selective, heavy cytotoxic effects – likewise in the predominantly healthy parts of the bladder - would occur. Within the 103 cases treated this way this has never been observed, although some of them underwent several iontophoretic treatment cycles.

The new method's selectivity can especially easily be proven with skin tumors. Photo-documentation of patients suffering from basal cell carcinoma in the face, who had been treated with antineoplastic iontophoresis verify selectivity in a particularly impressive way: The destroyed tumor can sharply be demarcated from the surrounding healthy tissue.

FAQ

The iontophoretic tumor therapy (ITT) is an innovative oncological method. This form of therapy did not find broad clinical application yet. The selective and tumor destroying medicine which has been developed for this method has not been licensed until today and cannot be found on the market so far. Licensing, sale of patent to the pharmaceutical industry, or to a special research institute has not been realized yet.

These facts raise questions as to the reasons. Subsequently we try to answer upcoming questions in note form.

1.

The ITT has been developed at the clinic of a public hospital by its inaugurator as a “lone fighter” in his every day professional life without financial borrowings and without support of a research institute or media. The beginnings of his invention trace back to his years of study. The development includes fundamental research, animal experiment, the entire clinical and technical know how, the conception and production of the medicine as well as the formulation of the meticulous concept of therapy, and its successive clinical application during the years. Parallel to this, patent applications were running for the production of the medicine. Likewise, lectures were given and papers published.

2.

On the apex of the development of the ITT, the inaugurator finished his professional activity for reasons of age. This was at a time where intensive practical application and promulgation of the method should have been started. At the same time, association was made with a company in form of a concession agreement, which aimed at the readiness for marketing of medicine and method.

3.

The inaugurator was forced to terminate the concession agreement due to serious violation of the agreement. The licensee had tried to appropriate patents and trademark of the inaugurator through own registration, and, although still being in a sound contractual relationship, to strike his own path behind the inaugurator's back. Following this, the licensee sued the inaugurator for damages, the lawsuit being delayed for five years, and finally lost by the licensee / plaintiff at both instances. During this time – for understandable reasons - it was not possible to socialize with other companies. Furthermore, the lawsuit concentrated all energy and paralysed any other activities.

4.

After the end of the lawsuit, contact to the pharmaceutical industry was sought. Reasons for rejections were manifold and can be summarized as follows: It is difficult to break new ground. ITT demands courage, revision of opinions, investment, and commitment. It goes beyond the scope of present conventional therapies. There is a conflict of interest concerning sales that figure billions when it comes to problematical and to a large extent ineffective chemotherapeutics. The oncological opinion leaders hold the corridors of power at universities, institutions, and organizations. It is a worldwide and powerful establishment with diverse and parallel operating pressure groups (Frederic Vester). A scientist not belonging to this circle and a practitioner without lobby has little chance here. Ways of research that do not match trend and system are not being taken up and are ignored. In this context, we refer to the extensive and widely known critical literature.

5.

The inaugurator of the ITT – for humanitarian reasons – is not willing to accept the given facts described in point 4 and wants to try again to give interested circles an understanding of his method especially as he managed in 2003 to transfer the selective antineoplastic principle with a new iontophoretic concept to some other organs. Evidence of his idea, however, can only be supplied by medical tests whose risks and exposures lie far below those of conventional therapies and which are not comparable to any chemotherapy or heroic surgery. The problem-free clinical application for the bladder carcinoma is already granted at this stage.