Immunotherapeutical potential of Âyurvedic drugs

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INTRODUCTION

Current research interest has started to realize the immunotherapeutical potential of âyurvedic drugs.

Among the âyurvedic plants which have such an immunotherapeutical potential is for example *Boswelia serrata*. The gum resin exudate of it (Guggul) has been used in the traditional âyurvedic medicine for the treatment of inflammatory diseases. Recently evidence is accumulating that this is due to leukotriene B4 formation, probably by direct action on 5-lipoxygenase[1, 2].

There is also evidence in animal experiments of the immunotherapeutical potential of âyurvedic plants, for instance *Tinospora cordifolia* has been shown to reduce mortality rate in abdomial sepsis induced by caecal ligation in rats as good as in a control group given metronidazol and gentamicin[3].

Finally, the clinical evaluation of âyurvedic herbomineral formulations has started, for example in the treatment of osteoarthritis (4).

Materials and Methods. Case studies are investigated and documented according to European standard medical practice[5]. Clinical trials are set up according to Pocock[6]. Âyurvedic drugs were analyzed for non toxicity prior to treatment.

RESULTS

1. CASE STUDIES

To encourage further research into the vast immunotherapeutical potential of âyurvedic drugs we are currently conducting case studies on the effect of âyurvedic treatments in concurrence to available standard drugs. Profiting from the better medical infrastructure in Germany it is much easier to objectively document positive and negative effects of both treatments.

On a case by case basis we find that the immunotherapeutic effects of âyurvedic drugs can be quite striking, notably in chronic diseases like asthma or in degenerative diseases like the already above mentioned osteoarthritis.

To put this promising preliminary findings on a more solid basis we intend to focus our current attention to one specific plant, *Tinospora cordifolia*. As the effects of a positive stimulation of the patient immunesystem will be more easy noticable in a depressed situation of the immune response we have selected for the next step of our investigation illnesses with a depressed immune response like for example cancer patients, chronic hepatitis and aquired immunodeficiency.

Data from four case studies for *Tinospora cordifolia* given as an adjuvant to chemotherapy in cancer patients are summarized in Table 1.

2. FURTHER TRIALS

As even a small scale clinical trial requires a large recruitment of patients we are now actively seeking clinicians who would like to cooperate in clinical trials of *Tinospora cordifolia*. To reduce interference with a preferred standard therapy to a minimum, initial comparisons will only investigate whether there is an improvement comparing standard therapy to standard therapy + *Tinospora cordifolia* (compare for example with group IV and group II[3]). The necessary supply of the âyurvedic drug is available. A direct co-operation with the Interdisciplinary school of âyurvedic medicine, Ganeshkind, Pune-411007 (India) can also be established.

Please contact Dr. Govind Dandekar at his adress given above if you are either interested in

– conducting clinical trials with *Tinospora cordifolia* (a first study is currently conducted, bottom of Table 1) or

– to get in touch with the interdisciplinary school of âyurvedic medicine in Pune.

DISCUSSION

The immunotherapeutical potential of âyurvedic drugs should be investigated in more detail. On a case by case basis, using the good medical infrastructure in Germany the therapeutic effects of âyurvedic drugs can be well documented and are sometimes quite striking.

What is needed now, are well documented larger clinical trials to convince also sceptics about the efficacy of this drugs, and, equally important, stimulate basic research to understand the principles involved.

Isolation of an active principle, *e.g.* a lipoxygenase inhibitor[1,2] is a helpful first step, but non-trivial synergistic effects of the complete formula and treatment regimen[4] may well be equally important and must not be underestimated.

TINOSPORA CORDIFOLIA IN CLINICAL TRIALS.

Casuistic 1: Patient: W.H., male, 81 years.

This patient was never seriously ill in his life excepting war injuries.

In May 1993 after proper examinations the diagnosis of malign lymphoma of the stomach was confirmed and after operation a chemotherapy was started.

The blood picture (leukocyte count etc.) before he became ill was normal (31.7.92 leukocytes 5760/ml). Immediately before the chemotherapy was started the blood count was normal as well.

The chemotherapy was started in July 1993. After the first cycle the leukocyte count fell down to 1600/ml. After a second cycle it was at 760/ml (we had not given *Tinospora cordifolia* (T.C.) tablets as we did not want to interfere with the standard therapy with the hospital). We started then with the T.C. therapy in September 1993 (250 mg/3 times a day). Even though the chemotherapy cycles were continued, the fall in leukocyte count was much less marked:

Blood examination	leukocyte count
18.10.93	3230
25.10.93	3920
05.11.93	7280
19.11.93	3850
30.11.93	5480
06.12.93	4770

This improvement was so remarkable that the doctor in the special clinic wanted to know more about the therapy with T.C.

It seems that T.C. may be able to reduce the side effects of chemotherapy in cancer.

Casuistic 2: Patient: L.C., female, 51 years.

Case history: Cancer of the breast known since July 1989; Chemotherapy.

Even though the standard chemotherapy was continued in April 1992 further metastases were found in the thorax. The patient came to us for supplementary therapy in July 1992.

As the chemotherapy was continued we treated her with T.C. extract in the usual dosis (250 mg/3 times a day). The chemotherapeutic agents were changed several times as they did not show the desired effects. There were intervals in our therapy with T.C. as the patient was not able to come regularly for control examinations. In these intervals the side effects of the chemotherapy were pronounced (Nausea, vomiting, no appetite) and the leukocyte counts were low. The effect of T.C. treatment was much better in the first year then in the following years. It seems that the the longtime effect of T.C. is dependent on how far the immunesystem is already damaged (*e.g.* by intensive chemotherapy).

The patient died with lung metastasis on 08.03.94.

Casuistic 3: Patient: B.M., female, 48 years.

1992: Breast cancer; therapy: exstirpation and radiation therapy. No chemotherapy, no evidence of tumor recurrence uptil now.

We treated this patient because suddenly liver enzymes went up in February 1994.

Liver enzyme status in March 1993 was normal.

03.02.94 enzyme status GOT 37.0; GPT 134.0; gGT 32.0. Bilirubin was normal. The patient felt fatigued. The tests for hepatitis A and B were negative. The tumor markers for breast cancer were normal.

We treated the patient with T.C. (250 mg/3 times a day) over many weeks.

The blood examination on 04.07.94 showed GOT 26, GPT 79, gGT 13. Subjectively the feeling of fatigue was much less. We continued the therapy with T.C.

Blood examination on 05.10.94: GOT 11, GPT 15, gGT 7. The patient now expressed that she was able to do her work without feeling tired and never felt so well since the operation in 1992.

The exact cause of the hapatopathy is not knwon. It is remarkable that even though the malignity of the cancer was high (medullary, solid, undifferentiated carcinoma D_3, pT_3, PN_2, M_0) she has shown no recurrence until now.

Casuistic 4: Patient: L.H., female, 50 years.

Diagnosis: *Mamma neoplasma* left (T2, N1, MX). Therapy: *Ablatio mammæ* left with lymphonodectomy in the axilla - chemotherapy. Histology: Invasive ductale carcinoma (G3).

The patient came to us for treatment in August 1992. The chemotherapy was continued under the therapy with T.C. The patient remained free of symptoms. The side effects of chemotherapy were minimal. The blood counts remained normal.

It is difficult to assess in this patient the effect of T.C. as the *status quo* may be a natural process. Subjectively the patient felt much better, but one could also argue that this is a *placebo* effect.

We have included this patient to show the difficulty of assessing the effect of a drug that modifies the immunesystem.

CLINICAL TRIAL OF T.C. IN HIV PATIENTS

It seems that T.C. has also some effect in cases of human immunodeficiency virus infection (preliminary trial done in cooperation with other clinicians in India). Patients treated with T.C. seem to show a longer interval before the manifestation of AIDS. Unfortunately the blood counts were done only sporadically as the patients were financially unable to pay for the blood examinations. The impression of the doctors treating these patients was that T.C. treatment has a beneficial effect in HIV-infection. Further studies in this direction are going on.

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