

Final report Thymu-Skin trial oncology - Wien 1989

The Thymu-Skin preparations have been tested in view to efficacy against the alopecia inducing side effects of cytotoxic substances during additional 7 months (October 1988 - April 1989). In addition to part 1 of the hair study Thymu-Skin hair shampoo and treatment has been used predominantly in patients with carcinoma undergoing a "milder" cytostatic regimen.

For this purpose at the Ludwig Boltzmann Institute for Clinical Oncology in the hospital Krankenhaus der Stadt Wien-Lainz (chairman: Professor Dr. H. Denk, Professor Dr. G. Alth, Doz. Dr. G. Baumgartner) a group of 40 patients has been enrolled into the study with different neoplastic diseases (mammary, ovarian, colon and carcinoma of the bronchi).

37 patients have been treated as outclinic-patients, 3 of them after admission in the hospital. In this study the patients were predominantly female (sex ratio male/female: 34) aged between 33 and 76 years. Depending on the primary disease the following cytotoxic regimen has been applied:

- CMF-regimen (cyclophosphamid + methotrexate + 5-fluorouracil)
- Novantrone (MXO) as a mono or combined therapy with platinol (DDP) or oncovin
- A combination of cyclophosphamid (endoxan, Austrian trade name) + 5-fluorouracil + platinol (DDP)
- Carboplatin monotherapy
- 5-fluorouracil monotherapy

For personal reasons 7 patients with an aggressive cytotoxic treatment (farmorubicin combined therapy) have been admitted to the 2nd part to the study, too.

It should be mentioned that no case developed a total alopecia (WHO stage 3). Despite the limited number of subjects the success rate is about 43% (no hair loss in 3 of 7 patients), which is an obvious better result compared to the evaluation of the first part of the trial.

The investigation period of this 2nd part of the study ranged between 1 and 7 months. Follow-up tests and the patient monitoring have been performed every month; the hair status, possible recent infusion therapy and changes in the treatment have been noticed.

During the time of observation 1 patient died.

Also this report reflexed the reliability of the patients as far as it is verifiable, with a high compliance rate. In no case the study must be discontinued due to incorrect application of the products. Comparing the treatment regimen the control group had been selected out of a group of 753 subjects, all of the undergoing a mild cytostatic treatment. A total control group of 50 subjects has been randomly selected.

Results:

The criteria for evaluating was the WHO classification (alopecia score 0-3):

| | |
|---------|-------------------------------------|
| stage 0 | = no alopecia |
| stage 1 | = minimal hair loss |
| stage 2 | = moderate hair loss, local alpecia |
| stage 3 | = complete reversible hairloss |

There has already been a report about the success rate of Thymu-Skin preparations against aggressive chemotherapy in the 1rst part of the study.

Thirty-three of the 40 patients received a "milder" cytostatic mono and combined therapy (see. summary of the case reports). Only in 2 patients (6%) a hair loss of a mild degree has been observed (WHO degree 1). Thus the success rate in the treatment group was approximately 94% (WHO degree 0). In contrast in the control group a hair loss of 22% (alopecia in 11 of 40 subjects) occurred whereas 4 subjects (8%) developed a moderate hair loss (WHO stage 2). In none of the two groups a case of the complete hair loss (WHO 3) could be observed. By consequent local application of Thymu- Skin products there is a 16 % lower frequency of hair loss when compared to the controls in the thymu skin treated patients.

Summary

The efficacy of the thymu skin preparations in view to a positive adjuvant effect against alopecia inducing side effects of cytotoxic treatment is obvious. Recent data show a positive correlation between the protective effect and the aggressivity of this cytotoxic treatment: the milder chemotherapy, the better are the positive results. Additionally, the local application of the Thymu-Skin products over a complete observation period of 19 months showed no undesired side effects.

Prof. Dr. H. Denck

Dr. med. G.M. Wallner

Table 1 : Summary of Patients' Records

| Number | Study-number | Cytotoxic Treatment | WHO-stage Start of study/ end of study |
|--------|--------------|---------------------|--|
| 1 | 3126 | F/O | 0/0 |
| 2 | 7195 | F/O | 0/1 |
| 3 | 7374 | F/O | 0/0 |
| 4 | 8700 | F/O | 0/2 |
| 5 | 9211 | F/O | 1/2 |
| 6 | 9221 | F/O | 0/0 |
| 7 | 9384 | F/O/C | 0/2 |
| 8 | 4998 | CMF | 0/0 |
| 9 | 5316 | CMF | 0/0 |
| 10 | 6789 | CMF | 0/0 |
| 11 | 7111 | MXO/O | 0/0 |
| 12 | 7158 | CMF | 0/0 |
| 13 | 7265 | CMF | 0/0 |
| 14 | 7362 | 5- Fu | 0/0 |
| 15 | 7489 | Cp | 1/1 |
| 16 | 7733 | CMF | 0/0 |
| 17 | 8219 | CMF | 0/0 |
| 18 | 8398 | MXO/O | 2/2 |
| 19 | 8520 | CMF | 1/1 |
| 20 | 8642 | 5- Fu | 1/1 |
| 21 | 8701 | CMF | 1/1 |
| 22 | 8789 | CMF | 0/0 |
| 23 | 8804 | Cp | 2/2 |
| 24 | 8901 | 5- Fu | 1/1 |
| 25 | 8932 | MXO/DDP | 1/1 |
| 26 | 8949 | CMF | 0/0 |
| 27 | 9004 | CMF | 0/1 |
| 28 | 9167 | MXO | 0/0 |
| 29 | 9217 | 5- Fu | 0/0 |
| 30 | 9252 | CMF | 1/1 |
| 31 | 9279 | CMF | 0/1 |
| 32 | 9295 | CMF | 1/1 |
| 33 | 9326 | CMF | 0/0 |
| 34 | 9334 | CMF | 1/1 |
| 35 | 9402 | CMF | 0/0 |
| 36 | 9407 | CMF | 0/0 |
| 37 | 9411 | DDP | 0/0 |
| 38 | 9429 | CMF | 0/0 |
| 39 | 9485 | C / 5- Fu / DDP | 0/0 |
| 40 | 9552 | 5- Fu | 0/0 |

Abbreviations of cytotoxic drugs

| | | |
|--------------|----------|---|
| F | = | Farmorubicin |
| O | = | Oncovin |
| C | = | Cyclophosphamid |
| M | = | Methotrexate |
| Cp | = | Carboplatin |
| 5- Fu | = | 5- Fluorouracil |
| MXO | = | Mitoxantrone; Novantron |
| DDP | = | Cis- Platin; Platinol |
| CMF | = | Cyclophosphamid + Methotrexate + 5- Fluorouracil |