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Padma28 and the effect on MS

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Padma28 and the effect on MS

Experience of Padma 28 in Multiple Sclerosis

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One hundred subjects suffering from a chronic progressive form of multiple sclerosis were randomly divided into two equal groups. Group 1 received Padma 28, two tablets three times a day, and group 2, the control, were treated only symptomatically. Treatment and observation lasted for 1 year. Examinations performed directly prior to the study and in the course of observation included- neurological state, visual and auditory evoked potentials, basic laboratory tests. A positive effect of Padma 28 was observed in 44% of patients with multiple sclerosis in the form of improvement of general condition, increase of muscle strength, decrease or disappearance of disorders affecting sphincters. In 41% of patients with initially an abnormal tracing of visual evoked potentials, an improvement or normalization was achieved. Of patients, who did not receive Padma 28 none felt better, moreover, 40% of them showed a deterioration. Tolerance of the drug was excellent
Keywords: multiple sclerosis; Padma 28; treatment in 100 patients.

INTRODUCTION

Multiple sclerosis is a chronic, often progressive, demyelisation disease that is characterized by gait disturbances, visual and coordination impairment, sensory complaints and genitourinary dysfunction. Numerous studies show that abnormal immunological processes occur in this illness, in the form of humoral and cellular reactions directed to viral cerebral antigens. According to one of these hypotheses, in multiple sclerosis lymphocytes become sensitized to unidentified cerebral viral or miscellaneous antigens. Cytotoxic lymphocytes and activated macrophages are formed, and soluble factors are released (Cendrowski, 1980; Halliday and McDonald, 1977; Kuratowska *et al.,* 1982; 1,owitzsch et al., 1976). Oligodendrocytes and myelin sheaths of the brain become the target of the cytotoxic attack in sclerosis (Cendrowski, 1986). Bach (1982) disclosed that in cerebrospinal fluid and the peripheral blood there is a decrease in suppressory lymphocytes (T,) and an increased index of helper lymphocytes (TH: T,) in the period 2 weeks prior to the attack of the disease, and up to 2 weeks after the attack.

lt is reported in the literature that Padma 28 is likely to exert an effect on immunoregulation by affecting suppressory lymphocytes (Badmajew *et aL,* 1982b; Brzosko *et al.,* 1983). Considering the immunotropic properties of Padma 28 and data that the preparation may induce in humans, synthesis of endogenous interferon (Brzosko *et al.,* 1984), we have attempted to estimate its therapeutic activity in patients suffering from multiple sclerosis. Padma 28 is an herbal mixture of the lamaistic medical science, consisting of 22 ingredients combined in a specific order, according to strict weight ratios and according to the prescription of W. N. Badmajew (Badmajew *et al.,* 1982a). The chemical components of the preparation have been identified using gas chromatography and thin-layer chromatography (Sarnochowiec, 1983). Padma 28 stimulates the

ascorbate system (Wöjcicki *et al.,* 1989) and is able to decrease lipid peroxidation, thus exhibiting antioxidant properties (Samochowiec and Wöjcicki, 1987).

MATERIALS AND METHODS

One hundred subjects suffering from progressive (and proceeding with attacks) multiple sclerosis were randomly divided into two equal groups. Group 1, consisting of 33 women and 17 men, aged 26 to 56 years, mean 38.4 years, received Padma 28, two tablets three times a day (Table 1); Group 2, including 29 women and 21 men, aged 29 to 60 years, mean 40.1 years, was treated only symptomatically, receiving drugs to reduce pain, spasticity and cramps, and to inhibit detrusor contractions. Observation was conducted at the Medical Outpatients Clinic for Multiple Sclerosis. The study and treatment was spread over a period of 1 year for each patient.

Prior to the onset of therapy, in all patients investigations covered the general neurological state, blood morphology with a smear, blood platelets, erythrocyte sedimentation rate, biochemical studies of the blood serum (urea, creatinine, glucose, aminotransferases, alkaline phosphatase), urine analysis. Moreover, before Padma 28 was administered and directly after the end of therapy, visual and auditory evoked potentials were studied in the whole group. Visual evoked Potentials were investigated by applying the stimulation with reversal standard of chequerboard at 2 Hz frequency, by means of a monitor, repeated 200 times, successively exciting the retina of each eye. The per- formed evaluation embraced the amplitude and latency of cortical response originating from the occipital region. The established norm for cortical visual potential P, is 90-1 10 ms.

The studies of auditory evoked Potentials consisted of applying stimuli through headphones in the form of "clicks" lasting 0. 1 ms, frequency 30 Hz and intensity 60 dB, above the auditory threshold (electroneuronograph, Neuramatic 2080, Disa, Skovlunde, Denmark). These stimuli were used to excite the right and left ear, 2000 times consecutively. Then the bioelectric responses from the brainstem were estimated. Attention was paid to the individual components as responses from respective nuclei of the brainstem. The brainstem auditory evoked responses comprise a series of potentials (1-1V). Wave 1 corresponds to activation of the Vlllth nerve, waves 111111 of the cochlear and olivary nuclei, wave IV corresponds to the nuclei of the lateral lemniscus, wave V to the inferior colliculus. Latencies are often measured from wave 1. The evaluation included the latent excitation (absolute latency) as well as intercomponent latency (relative latency). The elongation of intercomponent latency 1-111 was looked upon as pathological change, thus pathological changes in the pons were accepted as values being 2.25 ms. But the elongation of latency 111-V evidencing a pathological change in the mesencephalon was taken as over 2.05 ms.

In the evaluation of the therapeutic efficacy, attention was focussed on the number of attacks, the dynamic with which the symptoms regressed after a new attack, the delay in the slowly intensifying course of multiple sclerosis as well as a diminution in intensity of certain neurological symptoms according to a numerical scale (Cendrowski, 1986). This numerical scale is used to estimate the intensity of the individual neurological symptoms in points from 0 to 4. In this way there were estimated pyramid symptoms, cerebellum symptoms, disorder of sensation, sphincters and sight.

Characteristic of patients treated with Padma 28

Age	*Menduallary*	*Cerebellospinal*	*Dissemination*	*Total number of patients*
20-30	2	2	1	5
31-40	7	19	-	26
41-50	3	11	-	14
above 50	2	3	-	5
Total number of patients	14	35	1	50

RESULTS

The effect of Padma 28 on multiple sclerosis depending on the course of disease is presented in the table. An objective estimation of the improvement or aggravation in multiple sclerosis is difficult. We were estimating the patients' neurological state according to the numerical scale in several trials.

An improvement was reported in 22 patients, i.e. in 44% (Table 2). In 18 of them a diminution of paresis was observed, to the following degree: in 10 of them moderate paresis changed into light paresis (according to the numerical scale from 3 to 2 points); in 5 of them grave paresis reduced to moderate paresis (according to the numerical scale from 4 to 3 points); in 3 of them tight paresis disappeared (reduction from 2 to 1 point). Apart from this, in 3 patients the disorder of sensation, and in 1 subject the ataxy, disappeared.

An assessment of the health of untreated subjects (control group), with the course of the disease being taken into consideration, is depicted in Table 3. lt is obvious from this Table, that among patients who did not receive Padma 28, none of them felt better, while 20 patients (40%) reported deterioration.

The results of treatment with Padma 28, including the age of patients, are shown in Table 4. lt is seen from this Table, that among the subjects over 50 years of age, no deterioration was observed. In other groups, the deterioration occurred most frequently among patients 41-50 years old.

Before the onset of therapy, visual evoked potentials were found to be normal in 26 patients, while 24 subjects demonstrated an elongated latency of the P, wave from 118 to 150ms. At follow-up examination, after the end of therapy with Padma 28, 8 patients showed an improvement expressed by the shortening of P, wave latency.

Examination of the auditory evoked potentials in 30 patients exhibited an abnormal tracing (60%). In 15 of them the intercomponental latency 1-111 was elongated over 2.25 ms; in 10 persons the elongation of intercomponental latency 111-V was over 2.05 ms and in 5 patients there was an elongation of latency 1-111 and 111-V. At control examination upon the termination of therapy the tracing, from 1 patient had worsened, in others the tracings failed to indicate any significant changes.

No side effects were noted. The tolerance of the drug was excellent. Laboratory tests were unchanged in the course of the trial.

Effect of Padma 28 on the course of disease

Courses of disease	*Improvement*	*Result Nochange*	*Deterioraton*	*Total Number of Patients*
Attacks	15	11	3	29
Progression	7	11	3	21
Total number of patients	22	22	6	50

Course of multiple sclerosis in the control group

Courses of disease	*Improvement*	*Result Nochange*	*Deterioraton*	*Total Number of Patients*
Attacks	-	20	11	31
Progression	-	10	9	19
Total number of patients	-	30	20	50

Results of the treatment with Padma 28 in relation to age

Age	*Improvement*	*Result Nochange*	*Deterioraton*	*Total Number of Patients*
20-30	2	2	1	5
31-40	10	14	2	26
41-50	5	6	3	14
above 50	5	-	-	5
Total number of patients	22	22	6	50

DISCUSSION

None of the therapeutic methods in current use has influenced the natural course of multiple sclerosis. In treatment, 180 or so methods and drugs have hitherto been used, and only a small number have overcome the test of time (Wender, 1990).

Several observations suggest that an immunological process is involved in the pathogenesis of multiple sclerosis (Ross Russei and Woles 1985). Although the CNS is normally immunologically projected by the blood-brain barrier, this structure is easily damaged, allowing CNS invasion by systemic immune cells form which the Ig-secreting cells in the brain of patients with multiple sclerosis are derived. Because of the very incomplete understanding of the immunological basis of multiple sclerosis it is not yet certain whether stimulatory or suppressive immunological treatment should be given. Existing trials suggest that immunological treatment can reduce the rate of disability and frequency of relapse even in severely affected patients (Cendrowski, 1980; Halliday and McDonald, 1977; Lowitzsch *et al.,* 1976). Padma 28 is an immunoregulatory drug (Brzosko *et al.,* 1982) improving the function of T suppressor lymphocyte (T,) and thus the function of the immune system. Although this drug has no lymphopoietic activity like thymic hormones, it seems to influence differentiation and maturation of T, lymphocyte lineage. Taking into account the immunoregulatory properties of Padma 28 application of this drug in patients suffering from multiple sclerosis seems to be fully justified.

Padma 28 was administered to 50 patients affected by multiple sclerosis. They included 29 persons, in whom multiple sclerosis proceeded with attacks, and 21 subjects who had a slowly progressing course of the disease. In the first group improvement was recorded in 52% of patients, deterioration occurred in 10% while in 38% the condition remained unchanged. In a similar control group containing 31 persons with attacks of multiple sclerosis, who were not treated with Padma 28, not a single patient experienced improvement, deterioration appeared in about 35%, and in 65% of subjects the course of multiple sclerosis was unaltered. Twenty-one patients with slowly progressing multiple sclerosis were given Padma 28. Seven of them (33%) revealed improvement, in 3 persons (14%) the state worsened, and in 11 subjects (52%) no changes were observed in the course of treatment. In the group of 19 persons with slowly progressing multiple sclerosis, who were not receiving Padma 28, not a single case of improvement was detected, in 9 patients (47%) deterioration took place, and in 10 subjects there was no alteration. It is worth mentioning that in only 3 patients taking Padma 28, attacks of disease occurred and in 4 patients the attack had appeared after the termination of therapy. Thus, it seems to be obvious that Padma 28 exerts a positive effect on the course of multiple sclerosis. In patients treated with this drug, there was improvement as in many as 44% of subjects. Among the 50 control patients with multiple sclerosis, who were not treated with Padma 28, there was no improvement in any of the cases.

Since no publication on the activity of Padma 28 has been available, the results of our studies may be compared exclusively with other immunomodulating agents, such as levamisole or thymopentin (Bolla *et al.,* 1984; Wender, 1990). However, while applying Padma 28 no complications were observed. Also all the biochemical tests done before, during the course and after Padma 28 administration, demonstrated that the drug is harmless; no single ease involving internal organ complications was revealed.

In all patients with multiple sclerosis treated with Padma 28, our studies dealt with visual and auditory evoked potentials. The visual evoked potentials play an important diagnostic part in detecting lesions of the visual pathway. They were abnormal, before beginning therapy with Padma 28, in 24 patients. Final examination displayed improvement in 8 subjects, while in 2 persons full normalization of the tracing was noted. As

reported by the authors (Lowitzsch *et al.,* 1976; Rossini *et al.,* 1979), during the disease remission period a reduction in previously elongated latencies can be observed. There is a relationship between worsening of the tracings and intensity of the existing or newly forming plaques.

Studies of auditory evoked potentials permit us, to a certain degree, to reach a conclusion as to the state of the structures in the area of the pons and the mesencephalon. In the first study, 60% of patients had an abnormal tracing. Control examination after finishing Padma 28 administration failed to disclose any differences as compared with the initial examination. This observation seems to be consistent with results obtained by other authors (Cendrowski, 1980), who emphasize that in patients with initially abnormal recordings of the auditory evoked potentials, no more pronounced changes were observed during the disease exacerbation or remission.

The results of our studies may be subjective to an extent in that it is known that multiple sclerosis is characterized by irregular periods of disease activity (relapses) lasting from a few days to several weeks, interspersed by intervals of spontaneous remission which may last for a long time.

In conclusion a profitable influence of Padma 28 was observed in 44% of patients with multiple sclerosis in the shape of a reduction of the pyramid symptoms, diminution of the cerebellum symptoms, decrease or disappearance of disorder of sphincters; there was no aggravation of the patients' state during treatment with Padma 28; among patients with abnormal initial visual evoked potentials, in 41% an improvement or normalization of the tracing was obtained, prolonged application of Padma 28 caused no undesirable symptoms- tolerance of the drug was excellent. We therefore believe that Padma 28 may be useful in slowing or arresting the symptoms of chronic multiple sclerosis.

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