CLINICAL EVALUATION OF CLOFAZIMINE IN VITILIGO

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Summary

In a purely clinical unbiased study, fifty patients with multifocal extensive vitiligo were given oral clofazimine therapy for six months and another fifty patients were kept as controls. All the patients were exposed to sunrays for thirty minutes daily. Significantly more patients in the treated group developed pigmentation of the patches compared to the control group. But the pigment disappeared soon after stopping the treatment. It may be tried in extensive multifocal vitiligo cases only where known therapeutic agents are not effective.

Clofazimine is an iminophenazine dye with antibacterial activity against various mycobacteria. The principal disadvantage of this antileprotic agent is the drug induced pigmentation. This side effect of clofazimine is considered useful for the therapy of vitiligo. The objective of this trial was to evaluate the efficacy of clofazimine as a therapeutic agent in extensive multifocal vitiligo.

Material and Methods

This study was carried out from 1971 to 1978 and includes 100 cases of vitiligo vulgaris patients (Multifocal) with extensive or diffuse depigmented lesions. The area of depigmentation in each case was more than 10% of body. I also included the cases which were not suitable to treat with psoralen therapy or which did not respond to psoralen therapy. Patients were between the age groups of 20 to 60 years. Sex distribution was equal.

All these patients received two days treatment with piperdeazine citrate and one tablet of multivitamin. Fifty patients were given clofazimine therapy, 100 mg capsule three times a day for ten days, then one capsule twice a day for ten days and then one capsule daily for six months. The remaining fifty patients were kept as controls and received piperazine citrate for 2 days and later multivitamins only. Patients of both the groups were exposed to natural sunrays for half an hour preferably between 11 a.m. to 1 noon and pigmentary changes were noted. Laboratory investigations were not carried out.

Patients in both the groups came regularly for check up at an interval of three to four weeks and all the patients were further followed for one year even after stoppage of therapy.

Results

After six months, in the therapy group, five patients showed complete pigmentation of depigmented areas, fifteen showed more than 50% cure,

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twenty patients showed some pigmentary changes while ten patients did not develop any pigment in depigmented lesions. In the control group, none of the patients showed complete pigmentation after six months, three patients developed more than 50% pigment in depigmented areas, twelve patients showed some pigment formation while thirty five patients did not develop any pigment. Ten patients in the therapy group who did not show any pigmentation in the depigmented areas, developed new depigmented patches and also areas of depigmentation continued to increase during the therapy and after stoppage of therapy. The remaining forty patients who showed varying degrees of pigmentation in depigmented areas during the therapy showed disappearace of the pigment after stoppage of clofazimine therapy. The repigmentation in vitiligenous areas appeared either from the periphery of the depigmented patch or in punctate areas within the depigmented patch, confined to the hair follicles, during the clofazimine therapy. The response to clofazimine therapy was not related to the duration of the disease, age and sex of the patients.

Four patients developed mild degree of nausea and vomiting but the therapy was continued and the patients were able to take the drug with milk without any nausea and vomiting. Two patients got diarrhoea when the therapy was started but the diarrhoea stopped after ten days when the dose of the drug was reduced to two capsules per day. Three patients complained of mild itching after three months of therapy but the patient could continue to take drug. Thirty five patients developed dryness of skin after six months of therapy and twenty patients showed ichthyotic changes of the skin, more marked on the extremities. Thirty patients complained of burning sensations on the face which was more on exposure to sunrays. None of the patients developed jaundice, renal edema, anemia or alopecia.

Discussion

Bor[1] studied clofazimine in the treatment of vitiligo in eight cases and found considerable pigmentation in all the eight. Punshi[2] found excellent results in twenty one out of thirty cases. In both these studies there was no selection of cases and both these were without any control group. Both workers also included patients with localised vitiligo. Pharmacological action of the drug is not selective on the depigmentend patches but generalised and patients with localised vitiligo may not accept the therapy because of the generalised pigmentation and dryness of the skin with ichthyotic changes. Besides after stoppage of therapy pigment starts disappearing from depigmented lesions in a significant number of patients. These factors were not considered at all in the reports of Bor[1] and Punshi[2]. Effect of this drug is more marked when the patients exposed to sunrays. Bor[1] observed diminution of discomfort by the patients in depigmented skin exposed to the sun while in this series about 60% of the patients on clofazimine therapy complained of burning sensation more on the exposed areas of the skin. This may be because of differences in climate and environmental factors as plenty of sunrays are avilable throughout the year in India.

Clofazimine if used freely may create a problem of acquired drug resistance for leprosy patients after a few years and a good antileprotic agent may not remain effective in leprosy which is a more important problem for our country.

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