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COMPARATIVE STUDY OF VARIOUS DRUG REGIMENS IN VITILIGO

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100 cases of vitiligo were treated with topical 0.25% fluocinolone acetonide and topical placental extract. To these we added levamisole (Regimen I); systemic betamethasone and levamisole (Regimen II), oral psoralen (Regimen III) and oral psoralen plus oral betamethasone (Regimen IV). Treatment continued for 6-12 months. Results in the regimen II and IV were found be very good. Recurrence with oral steroid was noted. Levamisole showed marked response.

Key Words : Vitiligo, Levamisole, Psoralen, Placental extract, Corticosteroids

Introduction

Vitiligo is an age old cosmetic, acquired depigmentary disorder with patchy loss of normal skin colour, due to the absence of melanin pigment in that area. Its incidence in world population varies from 1-2%.[1]

Inspite of more and more research in this field, still much more is to be known about this disease which has profound psychological effect on the patient and even associatd with social stigmata. To counteract this, various regimens have been evolved, still it requires more research to search out the full proved and most effective therapy. In this study by using various drugs in different combinations, comparative study has been done with an intention of evolving the best one with least side effect and most acceptability.

Materials and methods

100 patients of vitiligo with age ranging from 5-65 years and duration ranging from 20 days to 32 years in all the types and stages were taken in this study. Pregnant women were excluded. Patients were given any of the four regimens under study at random. A patient was considered improving if the lesions started repigmenting or the previously progressive nature has turned into stationary one. 30 patients each were taken in regimen I and regimen III at random and 20 patients each in regimen II and IV similarly. Regimens used were as follows :

Regimen I : Tab. levamisole - 150 mg in adult and 50-100 mg in children orally daily for 2 consecutive days each week, combined with topical 0.25% fluocinolone acetonide cream and Injection placental extract locally once daily in the morning followd by sun exposure.

Regimen II : Regimen I in combination with tab. betamethasone 2 mg orally on alternate day.

Regimen III : Tab. psoralen 20 mg in adults and 10 mg in in children orally with breakfast followed by controlled sun exposure after 2 hours for 15 minutes to 30 minutes daily, alongwith topical 0.25% fluocinolone8 acetonide and topical injection placental extract once a day.

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Regimen IV : Regimen III with tab. betameshasone 2 mg. orally on alternate day. Treatments were given for 6-12 months depending on the clinical response. Necessary precautions were taken to avert the harzards of sun exposures.

Laboratory investigations like complete blood count, LFT, renal function test, blood sugar, urinalysis and examination of the stool were done for each patient. Side ettects were noted.

Results

In our outpatient department

Results were noted in the following way :

0-25%	'Poor resopnse'	-	Erythema or no response;
25-50%	'Moderate response'	-	Follicular pigmentation;
50-75%	'Good response'	-	Half of the patches became pigmented and
75-100%	'Excellent response'	-	Allmost all patches were repigmented or disappeared.

Table I. Results in various types of vitiligo

Type	Reg. I	Reg. II	Reg. III	Reg. IV
Vulgaris				
0-25%	4(19.04%)	1(8.33%)	3(12.50%)	1(12.50%)
25-50%	5(23.80%)	-	6(25.00%)	1(12.50%)
50-75%	6(28.57%)	4(33.37%)	11(45.83%)	2(25.00%)
75-100%	5(23.80%)	7(58.30%)	5(20.83%)	4(50.00%)
Extensive				
0-25%	1(14.28%)	-	-	-
25-50%	1(14.28%)	2(28.57%)	-	1(09.09%)
50-75%	3(42.85%)	4(57.15%)	2(100%)	7(63.64%)
75-100%	1(14.28%)	1(14.28%)	-	3(27.27%)
Acral				
0-25%	1(50.00%)	-	2(33.33%)	3(42.86%)
25.50%	1(50.00%)	2(50.00%)	1(16.67%)	2(28.57%)
70-75%	-	2(50.00%)	1(16.67%)	2(28.57%)
75-100%	-	-	-	-
Mucosal				
0-25%	2(66.67%)	2(50.00%)	4(80.00%)	3(42.86%)
25-50%	1(33.33%)	1(50.00%)	2(20.00%)	2(33.30%)
50-75%	-	-	-	1(16.67%)
75-100%	-	-	-	-
Guttate				
0-25%	-	-	-	-
25-50%	-	-	1(100%)	-
50-75%	-	-	-	-
75-100%	-	-	-	-
Zosteriform				
0-25%	-	-	-	-
25-50%	-	-	1(100%)	-
50-75%	-	-	-	-
75-100%	-	-	-	-
Leukotrichia				
Repigmentation of hair	2(33.33%)	2(50.00%)	2(50.00%)	3(42.85%)
Recurrence	4(13.33%)	6(30.00%)	3(10.00%)	4(20.00%)

Table II. Response of the different regimens in the progressive variety

Response of regimens	R-I	Therapeutic R-II	regimens R-III	R-IV
Progress arrested	11 (64.70%)	8(72.72%)	6(60.00%)	10 (76.92%)
Progress not arrested	6(35.29%)	3(27.27%)	4(40.00%)	3 (23.08%)

incidence of vitiligo was 3.36% of all diseases with a slight female preponderance (M:F =1:1.3) ; 27% of the vitiligo patients belonged to 21-30 years age group. Results of the therapy with different refgimens in defferent form of vitiligo are shown in the Table I and Table II.

In vitiligo vulgaris, good to excellent response (i.e. cosmetically acceptable response) was found in 52.38% of patients in regimen-I, 91.70% of patients in regime-II, 66.6% in regimen-III and 75% in regimen IV.

In extensive type good to excellent response was found in 57.13% patients in regimen-I and 71.43% patients in regimen II,100% in regimen III and 90.91% in regimen IV.

In acral and mucosal vitiligo poor to moderate response was observed with regimen I and II and poor to good response with regimen III and IV.

Progress of the disease was arrested in 64.7% patients in regimen I, 72.72% patients in regimen II, 60% patients in regimen - III and 76.92% patients in regimen-IV.

In progressive vitiligo regimen II and IV showed better resopnse in comparison to regimen I and III.

Recurrence rate was 13.33% in regimen-I, 30% in regimen-II, 10% in regimen-II and 20% in regimen-IV.

In acral and mucosal varieties of vitiligo complete repigmentation was not observed with any regimen. Since the response to all the regimens was little slow, there was no indication of improvement in the first 2 months.

No side effect was noted in regimen I, mild gastric disturbance was noted in regimen II, photosensitivity, pain abdomen and hyperpigmentation were found in regimne III and IV. Acneform lesions were observed in steroid containing regimens.

Comments

In this study it has been observed that regimen II and IV gave better results out of the four regimens. Levamisole in the regimen II is an immunostimulant and immunomodulant drug.[2] Levamisole restores depressed T cell functions.[2] In patients under treatment with levamisole, appearance of the kerationcytes lymphocytes and mastocytes were observed.[3] Adjuvent drugs like steroid have helped reasonably in the increase of efficacy of this regimen, (Regimen II). Racz (1976) has also suggested the combined use of steroid and levamisole in vitiligo.[4] In vitiligo vulgaris levamisole and steroid containing regimen worked better than any other. In extensive type psoralen and steroid worked better than

the levamisole alone or in combination with steroid but the 100% good response shown by regimen III requires further investigation as the result in this study was dependent on only 2 patients, where from no definite conclusion can be drawn.

Psoralen has also shown reasonable effect but at the same time it has produced side effects like pain in the abdomen, photosensitivity etc in some patients. Systemic steroid when added, showed increase in the efficacy, but the recurrence is also high. Pasricha et al using similar regimens have obtained more than good result in 83.33% in regimen I, 68% in regimen II, 65% in regimen III and 76.47% in regimen IV.[5] This present study showed lower results in regimen I but much higher in regimen II and IV in comparison to that of Pasricha. Vitiligo vulgaris being the commnest type, regimen II was found to have more significance in general. Here the use of levamisole is encouraging not only from the success point of view, but if this regimen is used, then the side effects like pain in the abdomen, cataract, and very high chance of sunburn of the tropical climatic condition in psoralen therapy can be averted. Secondly if levamisole can restore the altered immune function then it may be more helpful in the treatment from the aetiopathogenetic point of view. This combination of levamisole is also cost effective. But in extensive type psoralen was found to be better than levamisole. In general acral and mucosal type showed very little success with all the regimens in view of achieving good or excellent response. Progressive type of vitiligo needs special mention, here steroid containing regimens were shown to be much better than regimens without it. So, in the treatment of this type steroid is an important component, but the more chance of recurrence is there. Regarding other types no definite conclusion can be made as the number of patients were few.

In the treatment of vitiligo the combination therapy is almost always the choice; in that case the regimen II has been found by this study is more convenient in general than the other from the success point of view as well as the side effects.

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