

GENTAMICIN-HYDROCORTISONE CREAM IN SOME INFLAMMATORY DERMATOSES

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Summary

75 patients suffering from acute, sub-acute and chronic inflammatory dermatoses were treated with a new antibiotic and corticosteroid combination Genticyn HC Topical Cream. 71 (94.6%) of 75 cases responded favourably to treatment; 45 (60%) of them obtained complete cure, 20 (26.6%) had marked improvement and 6 had slight improvement. Most of the cases where active or potential bacterial infection was the primary cause or secondary aggravator, Genticyn HC Cream was found to be dramatically effective. The response was slow in cases of chronic lichenified conditions. Genticyn HC Topical Cream was found to be on the whole a very effective, non-sensitizing and cosmetically acceptable preparation.

A wide range of topical preparations containing broad spectrum antibiotics and corticosteroids is available today. These are fairly effective in the management of inflammatory conditions associated with bacterial infections that are commonly seen in dermatological practice. The problems, however, posed by their continued use are development of resistant organisms and enhanced percutaneous absorption of steroids. Besides, contact sensitization is being increasingly reported with antibiotics like neomycin¹⁻⁷ and framycetin^{8,6,7}. In view of this it would be natural to look for some superior and safer substitute for topical use.

Gentamicin

Gentamicin is a new unique spectrum antibiotic of the aminoglycoside group. The drug made available all over the world consists of three components,

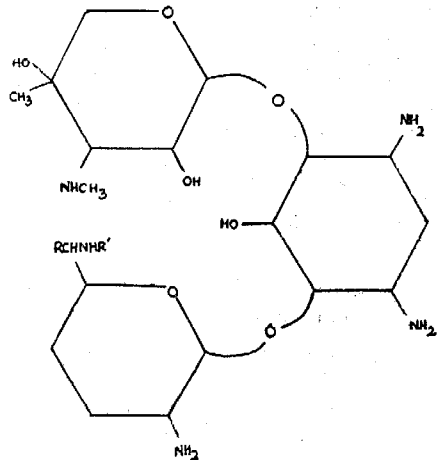
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Received for publication on 23-1-1976

gentamicin C₁, C₂ and C_{1A}. The gross structure of gentamicins is shown below.

Gross structure of the Gentamicin C Components



GENTAMICIN C₁ R = R' = CH₃

GENTAMICIN C₂ R = CH₃, R' = H

GENTAMICIN C_{1A} R = R' = H

It has claimed to possess an exceptionally wide spectrum of activity against

Gram -ve and Gram +ve bacteria. It is of special value against problem pathogens such as resistant Staphylococci, Proteus and Pseudomonas. Gentamicin has already been proved to be an effective antibiotic for topical use in pyodermas in a number of clinical trials^{8,12}. The investigators have also shown that gentamicin is practically a non-resistant and non-sensitizing antibiotic in dermatological practice^{9,12}. However, the drug has never been tried clinically before in combination with a corticosteroid. In view of this, we undertook a clinical study of one such preparation (Genticin HC Topical Cream) with a view to assessing its efficacy and reliability in the management of infective dermatoses and secondarily infected allergic dermatoses.

Material and Methods

The drug under trial was Genticyn HC Topical Cream containing gentamicin sulphate B.P. = 0.1% w/w gentamicin base (1000 units/g) and hydrocortisone acetate I.P. 1.0% w/w. A total of 75 patients were selected from the Dermatology Out-Patient Department of the Medical College and Hospital, Calcutta for this clinical study. The patients belonged to the age groups between 2 and 60 years and were both male and females (Table 1).

TABLE 1
Incidence of age and sex

Age Group in years	Male	Female
1-10	6	2
11-20	4	8
21-30	18	12
31-40	4	8
41-50	4	3
51-60	2	4

Patients selected for the study were examined clinically before initiation of therapy and the findings were recorded in a comprehensive proforma in each case. They belonged to different disease groups as indicated in Table 2.

TABLE 2
Disease Group

Disease groups	No. of cases
Microbic eczema	34
Seborrhoeic dermatitis	10
Chronic folliculitis	9
Infected contact dermatitis	9
Infantile eczema	3
Contact dermatitis	3
Pompholyx	3
Eczematous drug rash	2
Lichen striatus	1
Lichen simplex	1

Patients having associated diseases or complications or gross infection with lymphadenopathy, constitutional symptoms and leucocytosis necessitating oral antibiotic or steroid therapy were not included in this study. During the period of trial the patients were not given any other systemic or topical drugs. Bacteriological culture was performed in 52 cases suffering from microbic eczema, infected contact dermatitis and chronic folliculitis. Material was collected aseptically from intact pustules if present and was sent for bacteriological investigation.

All patients were supplied with tubes of Genticyn HC Topical Cream and were advised to apply this 2-3 times daily over the affected areas. They were followed up for a total period of 3 weeks. The response was noted after 24 hours, 72 hours, 1 week, 2 weeks and 3 weeks and was expressed as follows :

- +++ (complete cure) = complete healing within 5 — 9 days.
- ++ (marked improvement) = healing within 10 — 14 days.
- + (fair improvement) = healing within 15 — 21 days.
- ± (no improvement) = no improvement within 3 weeks.
- (deterioration) = Aggravation of the symptoms and/or further deterioration of the disease condition.

Observations

The organisms isolated in culture in 52 cases are shown in Table 3.

Mixed infection with *Staphylococcus pyogenes* and *Streptococcus haemolyticus* comprised the largest number of cases (23) including 17 of microbic eczema and 5 of secondarily infected contact dermatitis. *Staphylococcus pyogenes* alone was found to be the offending bacteria in 19 cases, 9 of microbic eczema, 6 of chronic folliculitis and 4 of secondarily infected contact dermatitis. *Streptococcus haemolyticus* was isolated in 8 cases of which 6 were of microbic eczema and 2 of chronic folliculitis. *Pseudomonas pyocyanea* was isolated in 2 cases of microbic eczema. None of the

patients showed infection with *Proteus* or any other group of bacteria. The therapeutic response in various disease group to Genticyn HC Cream therapy is shown in Table 4.

The results revealed that Genticyn HC Cream was remarkably effective in cases of microbic eczema, infected contact dermatitis, eczematous drug rash, pompholyx and infantile eczema; most of whom obtained complete cure within 2-3 weeks. Good improvement was noticed in cases of seborrhoeic dermatitis and the remaining cases of microbic eczema, infected contact dermatitis and infantile eczema.

Though 5 out of 9 cases of folliculitis showed favourable results, complete

TABLE 3
Results of Bacteriological Culture Examination

Organisms isolated	Name of disease		
	Chronic folliculitis	Microbic eczema	Infected contact dermatitis
<i>Staphylococcus pyogenes</i>	6	9	4
<i>Streptococcus haemolyticus</i>	2	6	0
<i>Pseudomonas pyocyanea</i>	0	2	0
<i>Proteus</i>	0	0	0
Mixed			
<i>Staphylococcus pyogenes</i>			
<i>Streptococcus haemolyticus</i>	1	17	5

TABLE 4
Therapeutic Response in Various Disease Groups

Disease Group	Total no. of cases	Complete cure (+++)	Marked Improvement (++)	Fair Improvement (+)	No Improvement (+)	Deterioration (-)
Microbic Eczema	34	29	3	2	0	0
Seborrhoeic Dermatitis	10	0	9	1	0	0
Chronic Folliculitis	9	2	3	1	1	2
Infected Contact Dermatitis	9	8	1	0	0	0
Infantile Eczema	3	2	1	0	0	0
Contact Dermatitis	3	2	1	0	0	0
Pompholyx	3	2	0	1	0	0
Eczematous Drug Rash	2	2	0	0	0	0
Lichen Striatus	1	0	0	0	1	0
Lichen Simplex	1	0	0	1	0	0
Total	75	45	20	6	2	2

cure was seen only in 2 cases. Of the remaining 4 cases, 2 did not reveal any notable beneficial effect while the other 2 showed clinical deterioration necessitating withdrawal of the drug and substitution with oral antibiotic therapy. The preparation was not found to be appreciably effective in chronic lichenified conditions like lichen striatus and lichen simplex. No sensitization reaction of any sort could be noticed in any of the cases in the present series with Genticyn HC Cream. Its vehicle containing a water miscible emulsifying cream base was found to be highly acceptable cosmetically.

Discussion

Active infection and the chances of secondary infection are great hindrances to treatment of inflammatory dermatoses in a tropical country like India. As such, treatment of eczematous lesions, in particular, is seldom practised with topical corticosteroids alone. Though the incidence of contact sensitivity to topical antibiotic and chemotherapeutic agents is not so common in this country as compared to Western countries, yet the physician tries to avoid potent sensitizers. However, the problem of antibiotic resistant bacteria is universal and this is particularly problematic in the treatment of open cutaneous infections by a host of resistant bacterial population. The non-sensitizing broad spectrum antibiotic gentamicin, proved to be effective against a wide range of Gram +ve and Gram -ve bacteria, therefore, was a welcome introduction. In the presence of active infection as the primary cause or a secondary complication in an eczematous condition, it is often difficult to balance and choose the combination of antibiotic and the corticosteroid. In a preparation containing a highly potent corticosteroid and an antibiotic like neomycin and/or bacitracin there remains the chance of reduction of the inflammation rapidly to a level favourable for the proliferation of the bacteria

resulting in aggravation of the infective process. On the other hand the condition is likely to be worsened further if the incorporated antibiotic is a potent sensitizer.

Preparation used in this study containing the highly potent non-sensitizing antibiotic gentamicin with an effective but mild anti-inflammatory agent hydrocortisone acetate was found to be a highly dependable combination under such circumstances.

The most striking results were observed in cases with evidence of active pyogenic infection, viz. microbic eczema, secondarily infected contact dermatitis and infected pompholyx. These cases showed a remarkable improvement within 24 hours and almost complete clearance within the next 3 - 4 days in most of the cases. This result could solely be attributed to the high and prompt antibacterial activity of gentamicin.

In seborrhoeic dermatitis, infective factor is a major cause of the aggravation of the disease and as such the antibacterial activity of Genticin fortified by mild anti-inflammatory effect of hydrocortisone resulted in gradual resolution of the disease.

Chronic folliculitis of the legs as seen in male population working in jute and other industries is notorious for its relapsing nature and resistance to treatment. Though remarkable improvement was found in 5 out of 9 cases, the response was not as striking as in other infective conditions. Deterioration in 2 of the cases could be ascribed to constant exposure to infection at work, the spread of infection, antibiotic resistance or contact sensitivity. Clinically though there was no evidence of contact sensitivity to the topical preparation since abstention from work was not practicable and there was noticeable lymphadenitis the authors were compelled to institute oral antibiotic therapy.

The major improvement noticed in all the cases of contact dermatitis and eczematous drug rash could be accounted for by the withdrawal of the causative factor, prevention of secondary infection and anti-inflammatory action by the non-sensitizing topical cream. Similarly in pompholyx and infantile eczema the dramatic control could be attributed to the antibacterial activity of gentamicin as in most of the cases seen in this country, infection is the major perpetuating factor. In this connection it may be stressed that hydrocortisone is a safe and adequately effective topical steroid for infants and children. The limitation of the preparation in controlling cases of lichen striatus and lichen simplex was due probably to the chronic lichenified nature of these diseases in which action of corticosteroid is more important than that of an antibiotic. As such it was felt that for a more successful result and quick resolution a potent corticosteroid like the fluorinated ones would probably achieve better result at least within the specified period of 3 weeks of topical therapy.

Acknowledgment

The authors are grateful to Dr. B. K. Chakraborty, Principal-cum-Superintendent, Medical College and Hospital, Calcutta for his kind permission to conduct the study and to M/s. Indian Schering Limited, Bombay for supply of Genticyn HC Topical Cr.am and the assistance to carry out the clinical trial.

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