

THERAPEUTIC
A TOPICAL TAR-STEROID COMBINATION IN
DERMATOLOGICAL MANAGEMENT

(A Clinical-Therapeutic Study in 75 Cases)

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and
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“Some Diseases do not take life, they just ruin it.”

—*Stephen Rothman.*

Dermatological disorders of a chronic prolonged nature, rarely if at all cause death. on the other hand, they may produce complete disability, wreck the social and family life of the unfortunate patient, and act as a psychic trauma, from which he may never recover. In no group of diseases, have the effects of steroids, been more striking and remarkable than in some of the conditions affecting the skin.¹ Since the demonstration of the usefulness of hydrocortisone as a topical agent, several new derivatives of cortisone and hydrocortisone have been investigated and marketed after due experimentation. The recent trend in the development of these derivatives has mainly been towards finding safer compounds. These compounds have brought about some measure of relief from pain, itching and disfiguration to many whose conditions were formerly intractable and for whom no satisfactory method of treatment was previously available. The sustained objective and subjective improvement has been the result mainly of their anti-inflammatory and antibody inhibiting reaction. Clinically, the response may be interpreted as an anti-allergic, anti-pruritic, anti-eczematous and anti-proliferative reaction on the skin.

Tar products are an indispensable part of the dermato-therapeutic armamentarium. They are divided into three classes; wood tars, shale tars (bituminous tars) and coal tars. All these groups have their special indications. The wood tars are less used nowadays than the two other classes. Tars are mixtures of hydro-carbons with different aromatic components, such as toluol, phenol, cresol and guaiacol. Coal tars contain anthracene, shale tars contain sulphur, and wood tars contain acetic acid. Of the shale tars, Ichthammol 3% was investigated by Steward, Goldman and Obermayer. They studied the action of Ichthammol on the skin, both in animals and man. From their experiments, they concluded that there is a distinctly favourable action on the intracellular oedema, but they could not prove an unquestionable action on the vascular dilation. Tumenol ammonium another bituminous oil preparation was strongly recommended by Neisser² (1891). A 5-10% preparation, resembles Ichthammol in many respects, and has been widely and successfully employed in dermatological practice. Its action, however, is claimed to be more anti-pruritic and

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anti-eczematous than that of Ichthammol, Neisser described eczemas and pruritus as special indications and stated that tumenol could also be applied to weeping eczemas. According to him, it did not suppress eczematous infiltrations as tar does, but on the other hand it could be applied earlier in the acute stages; the advantage of tumenol was that unlike coal tar, it did not produce photodermatitis in exposed parts and was generally well tolerated. Polano states that he has obtained very satisfactory results with shake lotions, drying pastes, zinc oils and zinc pastes containing 2–10% tumenol tumenol ammonium in eczema, while a 5% tumenol ammonium shake lotion was useful as an antipruritic.

Hence the antipruritic and anti-eczematous activity of tar derivatives as a local therapeutic agent has long been recognised.^{3, 1, 5, 6} Responses in patients with chronic dermatoses, i. e. psoriasis and lichen chronicus simplex (neurodermatitis circumscripta) to tar creams have been favourable, responses, however, to the same cream in patients with acute inflammatory dermatoses, have not been favourable. Besides, evaluation of ointments containing hydrocortisone have shown that in spite of their effectiveness, they are not satisfactory substitutes for therapy with tar.^{7, 8} Steroids, when inadequate alone, constitutes a valuable adjunct to therapy if it is combined with appropriate anti-bacterial and anti-eczematous agents.⁹

The extended use of a tar-steroid preparation will largely depend on their optimal composition (ointment base, content of steroid or steroidal derivatives and of tar or tar derivatives), the degree to which they are tolerated locally and certain rather more cosmetic aspects, such as odour, colour, etc. Besides the even dispersion of active agents in a vehicle is a desirable attribute of any well prepared combined medication intended for topical application. In 1951 Pflag and Zopf¹⁰ showed that addition of a surfactant to crude coal tar reduced its particle size in the ointment in which it was incorporated. The finished product showed uniformity of size and even dispersion of the coal tar particles. In 1955, Carney and Zopf¹¹ reported a 1% crude coal tar ointment, made with a surfactant, was therapeutically as effective and had the advantage of being relatively non-irritating to the diseased skin, compared to the commonly used 2% to 5% concentration of crude coal tar preparation. Cullen¹² in 1965 demonstrated that crude coal tar is evenly dispersed when added to creams without the use of a surfactant. Crude coal tar was similarly distributed in ointments by use of polysorbate 80, if the surfactant was thoroughly mixed with the crude coal tar prior to its incorporation into the ointment. Hence, the observation that the use of a surfactant (0.5% polysorbate 80) with crude coal tar prior to its addition into ointments, producing even dispersion and uniformity of size was a beneficial and desirable attribute in combined tar-steroid medications.

The synergistic anti-pruritic, anti-inflammatory and anti-eczematous activity of a tar-steroid product, prompted us to clinically evaluate a tar-steroid ointment in some of our dermatological cases. Tarsolon, a product of Hoechst Pharmaceuticals Ltd.—a tumenolammonium prednisolone ointment was used in this study. 1 g. ointment contains prednisolone acetate 2.8 mg. and tumenol ammonium 30 mg. The ointment

base is a special mixture of higher aliphatic hydrocarbons with wool fat and titanium dioxide.

METHOD OF STUDY

Patients included in this study, were provided with the tar-steroid ointment; they were instructed to apply the medicament thinly over a small part of the affected area and watch and report any untoward reactions such as irritation, erythema and the like, before the application was extended on to larger areas. Patients were instructed to stop the use of the ointment if untoward reactions should occur and to report immediately for observation. Where the skin was very dry, or when an intense drying effect was observed, particularly when extensive areas of the body were covered by the application, the ointment was alternated with olive oil applications. Applications of the ointment was advised twice daily depending upon the skin condition. Patients were observed twice or thrice weekly during the initial stage then weekly and later at more widely spaced intervals depending upon the progress. This report is based upon a study of 75 cases.

EFFECT OF THE OINTMENT

The triple effectiveness of the tar-steroid ointment, Tarsolon (anti-pruritic anti-eczematous and anti-inflammatory) were assessed in cases of atopic dermatitis including infantile eczema, psoriasis, lichen simplex chronicus (neurodermatitis circumscripta), contact dermatitis, chronic infectious eczematoid dermatitis, nummular dermatitis, pruritus scroti, seborrhoeic dermatitis, stasis dermatitis and pityriasis rosacea. The ointment was extended for application to a few disseminated and generalised cases of atopic dermatitis, psoriasis and pityriasis rosacea, with a view to observe any untoward reactions following extensive applications of the medicament. The ointment was applied in the sub-acute exudative phase of some of the eczematous processes to note tolerance. Besides, some of the cases being of a chronic nature presenting clinically a residual element of lichenification and hyperpigmentation associated with pruritus, observations were extended to note any keratoplastic effect of tar. The results were assessed by the subsidence of the initial lesions, by the relief of pruritus, disappearance of lichenification and hyperpigmentation. They were considered good if relief was more than 70%, fair if between 40-70% and poor if there was less change or no change.

TABLE I:—SHOWS THE RESULTS OF TREATMENT

This table indicates the disease entities, the number of patients, duration of therapy and the response to the tar-steroid ointment.

Response to therapy with Tar-Steroid Ointment

Diagnosis	No. of Patients	Duration of Therapy			Responses		
		Less than 1 month	2-3 months	4-6 months	Good 70-100 %	Fair 40-70 %	Poor or No Improvement
1. Atopic Dermatitis (including infantile eczema)	14	3	10	1	8	5	1
2. Psoriasis	11	3	6	2	6	3	2
3. Lichen Chronicus Simplex (Neurodermatitis circumscripta)	10	6	4	—	7	3	—
4. Contact Dermatitis	8	3	5	—	4	1	3
5. Chronic Infectious Eczematoid Dermatitis	6	6	—	—	5	1	—
6. Nummular Dermatitis	6	4	2	—	4	2	—
7. Pruritus Scroti	6	3	2	1	3	2	1
8. Seborrhic Dermatitis	5	—	4	1	2	2	1
9. Stasis Dermatitis	4	1	3	—	2	2	—
10. Pityriasis Rosaea	5	5	—	—	5	—	—
TOTAL	75	34	36	5	46	21	8

COMMENTS ON THE RESULTS IN THE VARIOUS DISEASE ENTITIES

Atopic Dermatitis:—These cases of constitutional allergy are generally of a recalcitrant type. The cases in this group were selective in nature, the selection being limited to cases which were being treated by other methods, but with limited residual areas which had not completely healed. The areas of dermatitis found to be most resistant were on the usual allergenic sites, i.e. back of neck, cubital and popliteal fossae and dorsum of the hands and feet. Out of 14 cases in this group, 8 cases showed a good response with complete subsidence of lesions, 5 cases responded fairly satisfactorily and one case showed a poor response. Two cases of a generalised form with wide spread lesions, were given extensive applications, one case responded well, and the other case poorly. In spite of large areas being covered by the ointment, no untoward signs of the application were noticed, except for an extreme dryness of the skin, which was remedied by alternate olive oil applications,

In this group, cases suitable for treatment were those patients with restricted, residual lesions or recurrent lesions involving small areas, and the treatment was advantageous in cutting short the time and expense of the disability. The ointment was well tolerated in the sub-acute exudative phase of the disease. In our

opinion, though the ointment was well tolerated, it would evidently not be practicable for generalised and wide spread cases, as it would be much easier and economical to use systemic steroid therapy.

Psoriasis: In the treatment of psoriasis, the regime of "Steroid cream and polythene occlusion" was hailed as a major advance. Unfortunately, it was soon realised that while there was a definite place for this therapy, it was not a panacea for all forms of psoriasis. It seemed that psoriatics were sometimes more intractable after this treatment, the lesions cleared initially, but relapsed very quickly and perhaps became more widespread and resistant to treatment. Hence the general impression seems to be that patients treated successfully with steroid creams and polythene occlusion, followed up by an application of tar would offer an increased chance of prolonged freedom from psoriasis.¹³ On this basis, 11 cases of psoriasis were put under treatment, (Pic. 3, 4, 5 and 6) 6 cases cleared up completely, 5 cases showed a fair response and 2 cases responded poorly. Two cases in the generalised exfoliative phase were treated with extensive applications alternately with olive oil application. They responded well, though 1 patient suffered a further relapse, one month after stopping treatment. The medicament was well tolerated, even in the acute exfoliative phase.

LICHEN CHRONICUS SIMPLEX (NEURODERMATITIS)

These patients presented clinically with circumscribed lichenified lesions mainly over the nape of the neck (Pic. 7), the extensor surface of the hands and the lateral aspect of the legs. The characteristic features of neurodermatitis is a severe pruritus, over an underlying mosaic pattern of lichenification, associated with hyperpigmentation; occasionally a few raised keratotic papules may be seen in the lesions. Of the 10 cases treated, all responded well, with relief of pruritus, subsidence of lichenification and gradual disappearance of hyperpigmentation. The keratoplastic effect of tar was responsible for the rapid subsidence of lichenification. Besides, the psycho-therapeutic element in the treatment of this disorder may have been an added factor, inherently, in the successful treatment,

CONTACT DERMATITIS

One patient presented with mild lichenification on the dorsum of the left hand; he was an artist, and came in contact with water colours. By force of habit, he would point his paint brush on the dorsum of the left hand before painting. He had discontinued this habit 1 month prior to reporting to us; with treatment the residual patch responded well. Another case of contact sensitivity over the watch strap area responded well. Six patients presented with lichenified patches on the dorsum of the feet, in a symmetrical band like fashion due to leather sensitivity, over the slipper-strap areas (chappal). 3 of these cases responded well and 3 cases poorly. The 3 cases which showed a poor response, presented hyperkeratotic lichenified lesions; this type of lichenified or keratinised lesions is always difficult to tackle by other known methods as well, failure may be probably due to difficulty of adequate percuta-

neous penetration of the medicament, so as to reach the deeper areas, associated with the occasional maintenance of indirect contact with the wearing apparel i. e. slippers (chappals).

CHRONIC INFECTIOUS ECZEMATOID DERMATITIS

The cases included in this condition were of a localised eczematous dermatitis, usually occurring secondary to a pyogenic inflammatory dermatitis. (Pic. 8) The wide spread and generalised allergic reactions were controlled with appropriate therapy and the localised lesions were then treated by the application. Of the 6 cases, 5 cases completely healed and 1 case showed a fair response. Treatment was satisfactory in the sub-acute exudative phase of the disease.

OTHER SKIN ENTITIES

Six patients of Nummular Dermatitis presenting with lesions on the upper and lower extremities (Pic. 9 and 10) were initially treated systemically with antibiotics to control the infection and responded well to the topical application. Two patients showed a subsequent recurrence over the previous involved areas and on retreatment responded satisfactorily.

Patients presenting with pruritus scroti were found to fall in the essential pruritus or neurodermatitis group. In these, any source of irritation was sufficient to set off prolonged paroxysms of itching. Of the six patients under treatment, 3 cases showed good response, 2 cases a fair, and 1 case a poor response. The psychogenic factor in this disorder, may have had some influence on the results of this group.

Seborrhoeic dermatitis, basically a constitutional diathesis, affecting the skin, with an often in born physiological trait can usually be controlled but not "cured". Of the 5 cases, 2 cases showed a good result 2 fair and 1 case a poor result. The ointment applied over the intertriginous zones showed rapid subsidence of the inflammatory changes.

Four cases of Stasis dermatitis presented with venous incompetency, cyanotic erythema on the inner lower leg and pruritus. With adequate measures to combat the stasis, and local application of the ointment, good response was observed in 2 cases, and relief of pruritus and reduction of the superficial inflammation in the 2 other cases.

Five cases of Pityriasis Rosaea; a benign and self limiting disorder associated with pruritus, responded well with relief of pruritus and subsidence of lesions. The rash being disseminated over the trunk (Pic. 11) and extremities, larger areas of the skin were covered by the application, the purpose was to see if any untoward reactions were elicited when extensive areas of the skin were covered by the medicament. No such reactions were observed; besides the application produced relief from pruritus.

REACTIONS

The ointment was applied over localised areas of skin disease and extensively over the body in cases of disseminated atopic dermatitis, psoriasis and pityriasis rosae.

No untoward reactions were observed. It was found suitable in the subacute exudative phase of some of the skin diseases. Dryness of the skin following application of the ointment, was remedied by alternate olive oil applications. No photosensitivity was observed in any of our cases.

DISCUSSION

The question often raised is whether a combined corticosteroid tar ointment has advantages compared to pure corticosteroid or pure tar preparations. Wulf¹⁴ is of the opinion that the question can be answered in the affirmative for certain indications. These include primarily types of eczemas in which the keratoplastic tar effect ensures more rapid and prolonged cure. This statement being made with some assurance on the basis of clinical experience. On the other hand, he states that combined preparations cannot displace the pure corticosteroids or tar preparations entirely.

In his study of 110 cases treated with Tumeson* (combination of prednisolone and tumenol ammonium) he found that the ointment was well tolerated and had a potent anti-pruritic action. The results when compared with those produced by pure corticosteroid ointments, showed similar therapeutic responses. Tumeson being superior in subacute and chronic superficial eczemas, because of the keratoplastic action of Tumenol ammonium, it was inferior as regards facial application, owing to whitish grey discoloration of the skin (titanium dioxide effect) and the tarry odour. Patients with dry skin complained that the Tumeson base was insufficiently fatty. No photosensitivity was observed.

Comparisons with pure tar or tar derivatives showed that in clinical practice Tumeson was more acceptable and also more rapidly acting. In hyperkeratotic and infiltrated eczemas, pure tar presentations were superior. Special indications for Tumeson being superficial subacute and chronic eczemas of all types in which the corticosteroid action and the keratoplastic tar effect supplement each other to a great advantage. The author concludes that corticosteroid ointment combinations with tar or tar derivatives have clearly defined dermatological indications both on the basis of theoretical considerations and of clinical experience.

Welsh et al⁶ in their study of 367 cases have demonstrated a three way (anti-pruritic, anti-eczematic and anti-inflammatory) effectiveness of a tar-steroid cream in certain selected dermatoses. They conclude that the tar-steroid combination is more effective than either the alcoholic extract of crude coal tar in cream form or hydrocortisone alone.

Our clinical impressions and experience in the use of a tar-steroid ointment seems to concur with these workers. Of the 75 patients topically treated, 46 cases showed a good response, 21 cases a fair response and 8 cases failed to respond. The medication was well tolerated in the sub-acute exudative phase of the eczematous process. Besides, the corticosteroid action and the keratoplastic tar effect supplementing each other was found to be advantageous in the chronic lichenified lesions. However, in

* Tarsolon is marketed in Germany as Tumeson.

patients, where the presenting lesions were hyperkeratotic and infiltrated, poor responses were elicited, failure being probably due to difficulty of adequate percutaneous, penetration of the medicament.

Regarding the treatment of psoriasis, Alexander (1965)¹³ treated a series of patients who had relapsed when local steroid treatment was stopped and found that of 32 patients treated with steroid creams and polythene followed immediately by a dithranol or tar application, only two again relapsed. On the other hand, of 10 patients treated only with steroids under polythene for the relapse, one cleared, two improved slightly and seven relapsed again within two weeks. She suggested that prolonged freedom from psoriasis may be achieved in those who respond to corticosteroid applications and occlusion by following this treatment with local tar or dithranol preparations. On this basis, we put 11 psoriatics on local treatment, 9 of them responded well, 2 cases poorly, 1 case of exfoliative psoriasis relapsed after 1 month of cessation of treatment.

Lastly, though steroids constitute a valuable adjunct to therapy, if these are combined with appropriate antibacterial and anti-eczematous agents, a note of caution may be sounded here. Recently there has been a tendency to "omnibus" combination of drugs in a local remedy. This trend should be deprecated. It should be left to the clinician to choose the combination according to the individual requirements. Increasing the number of drugs in a local application, arithmetically increases the chances of development of sensitization particularly when the remedy is aimed at treatment of sensitization phenomena like an eczematous process. This remark should also cover the use of various bases with new synthetic chemicals.¹⁵

CONCLUSION

1. The triple anti-pruritic, anti-eczematous anti-inflammatory effect of a tar-steroid ointment (Tarsolon) was assessed in a clinico-therapeutic trial in 75 cases.
2. In cases of residual or localised eczematous dermatitis, like atopic dermatitis, contact dermatitis, chronic infectious eczematoid dermatitis and nummular dermatitis, topical applications were well tolerated in the subacute exudative phase of the disease.
3. In cases of Lichen Simplex Chronicus (neurodermatitis circumscripta) and pruritus seroti, the cortico-steroid action and the keratoplastic tar effect synergistically proved beneficial.
4. Patients of psoriasis, the tar-steroid combination applied produced prolonged periods of freedom from symptoms. Although the number of cases of psoriasis in this study is too small for statistical evaluation, our results are in agreement with those of Alexander.
5. Seborrhoeic lesions, particularly of an intertriginous nature were rapidly controlled and in cases of Stasis dermatitis the superficial inflammation and pruritus were suppressed by the medicament.

6. In hyperkeratotic and infiltrated lesions, the response was poor probably due to difficulty of adequate per cutaneous penetration of the ointment, so as to reach the deeper areas.

7. Extensive applications over the body in disseminated atopic dermatitis, psoriasis and pityriasis rosacea did not produce any untoward reactions, except for dryness of the skin which was remedied by alternate olive oil applications. No photo-sensitivity was encountered in any of our cases.

8. Of cosmetic consideration was the whitish gray discoloration of the skin (titanium dioxide effect) and the tarry odour of Tarsolon. The use of a surfactant in ointments containing tar producing even dispersion and uniformity of the size of the particles was a desirable attribute for any well prepared medication.

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