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Review Article

Desoximetasone 0.25% Cream and Ointment - An Updated Review of Its Pharmacological Properties and Therapeutic Efficacy in the Treatment of Steroid Responsive Dermatoses

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ABSTRACT

Topical corticosteroids are commonly used in the field of dermatology. Several topical corticosteroids have been developed over the years, with a focus to develop drugs with high local effect and minimum risk for adverse drug reactions. Desoximetasone cream and ointment 0.25% are high potency (class II), fluorinated topical corticosteroid. Literature search revealed no published review on the clinical evidence with Desoximetasone 0.25% cream and 0.25% ointment after 1992 and very few clinical publications. Hence, we aimed to perform an in-depth updated review of clinical evidence. We performed search across electronic databases like PUBMED, Google Scholar, Cochrane Library and clinical trials registry – www.clinicaltrials.gov. Additionally, a general search at Google search engine was also performed. Desoximetasone or Desoxymethasone were the search terms used. We identified 14 randomized double blind studies with 1095 patients who received desoximetasone 0.25% cream and ointment with average treatment duration of 5.75 weeks in Psoriasis, 4.05 weeks in Eczema and 2 weeks in atopic dermatitis. In these studies, desoximetasone was often been judged superior overall in patients with inflammatory dermatoses compared to several other standard steroid preparations of intermediate potency (e.g. betamethasone valerate 0.1 %, triamcinolone acetonide 0.1 %, fluocinolone acetonide 0.025%) or in a few studies, to some steroids of high potency (e.g. betamethasone dipropionate 0.05 %, fluocinolone acetonide 0.05 %). Desoximetasone was well tolerated in most patients. With the clinical data available till date desoximetasone 0.25% cream and ointment appear to be effective and well tolerated formulations in the treatment of corticosteroid responsive dermatitis.

Key words: Desoximetasone, Steroid responsive dermatoses, Topical corticosteroids

INTRODUCTION

Topical corticosteroids are the most frequently used drugs for the treatment of patients with inflammatory skin diseases. The risks associated with the use of corticosteroids 'parallel' the benefits of therapeutic efficacy, and are related to steroid potency and percutaneous penetration capacity. [1] To understand how a drug's intrinsic activity at the intracellular level is related to drug delivery from vehicle to site of action, it is necessary to review some pharmacologic principles that characterize the corticosteroid family of molecules.

Hydrocortisone, a prototype corticosteroid is made up of 21 carbon atoms constituting the cyclo-pentano-perhydro- phenanthrene nucleus and a 17, 21-dihydroxy (OH)-20-keto (O) side chain

[Figure 1]. This is the basic structure from which all other topical corticosteroid molecules are derived. [2]

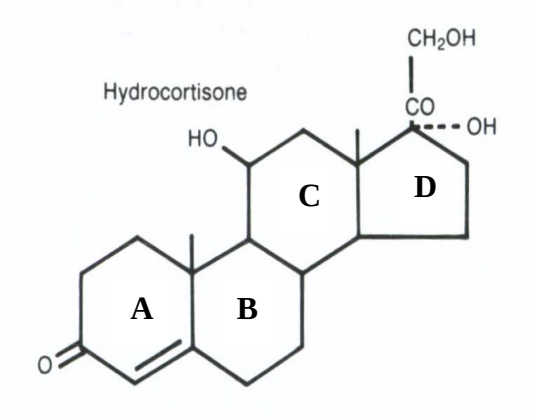

Figure 1: Structure of Hydrocortisone

This side chain is crucial for the glucocorticoid effect. [2] The 4 rings in the structure are designated A to D.

For glucocorticoid activity, the hydroxyl (OH) group at C 11, the double bond at C4, 5 and the ketone moiety on C3 are essential. [2]

Desoximetasone (desoximetasone; 9-fluoro-IIβ21-dihydroxy-I6a-methyl-pregna-I.4-diene-3. 20-dione) is a fluorinated glucocorticoid agent derived from dexamethasone, differing from that drug only by the absence of a hydroxyl group in the C-17 position (Fig. 2), thus increasing its lipophilic properties and topical activity compared with the parent compound. [3,4] Figure 2 represents the Structures and Structure Activity relationships of Desoximetasone and Dexamethasone.

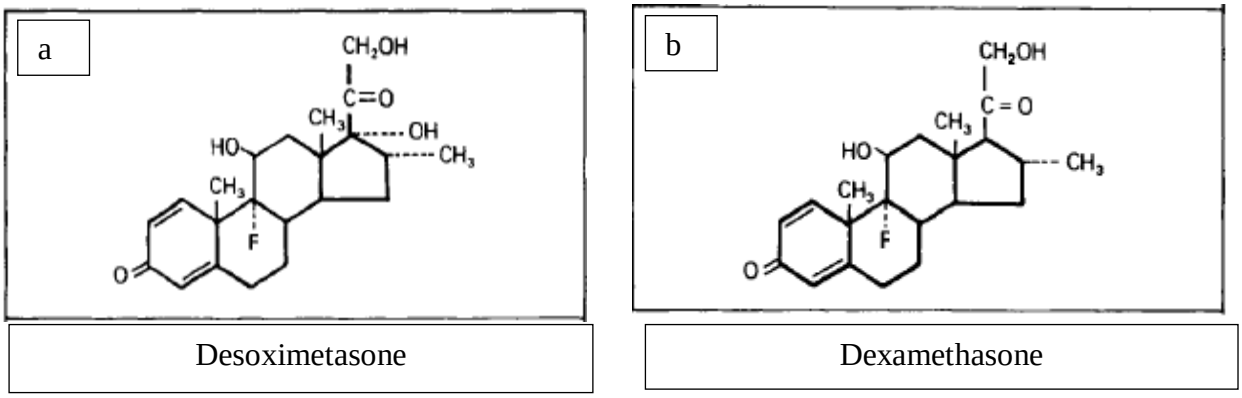

Fig 2: Structural formulas of dexamethasone (a) and desoximetasone (b) with Structure Activity Relationship.

Structure Activity Relationship

1. Fluorination at C9 atom increases potency of the molecule as compared to Hydrocortisone. [1]
2. Double bond at C1–C2 position - Enhanced glucocorticoid activity and decreased rate of metabolism as compared to Hydrocortisone. [5]
3. 16 methyl substitution - Less allergenic potential as compared to compounds with no C16-methyl substitution and hydrocortisone. [6]

Structure Activity Relationship

1. Fluorination at C9 atom increases potency of the molecule as compared to Hydrocortisone. [1]
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3. 16 methyl substitution - Less allergenic potential as compared to compounds with no C16-methyl substitution and hydrocortisone. [6]
4. Absence of a hydroxyl group in the C-17 position - Increases lipophilic properties and topical activity compared with the dexamethasone. [3]

This review focuses on the cream, emollient cream and ointment formulations of 0.25% strength. Desoximetasone 0.25% cream and ointment are placed in high potency category. [7] Desoximetasone emollient cream formulation provides

patients with greater emolliency than standard creams, but also provides an interesting pharmaceutical profile for this drug; in the vasoconstrictor assay, Ishihara found a greater amount of desoximetasone released from the emollient cream formulation than from petrolatum or propylene glycol based ointment vehicles. [8]

Literature search revealed no published review on the clinical evidence with Desoximetasone 0.25% cream and 0.25% ointment after 1992. Hence, we aimed to perform an in-depth updated review of clinical evidence

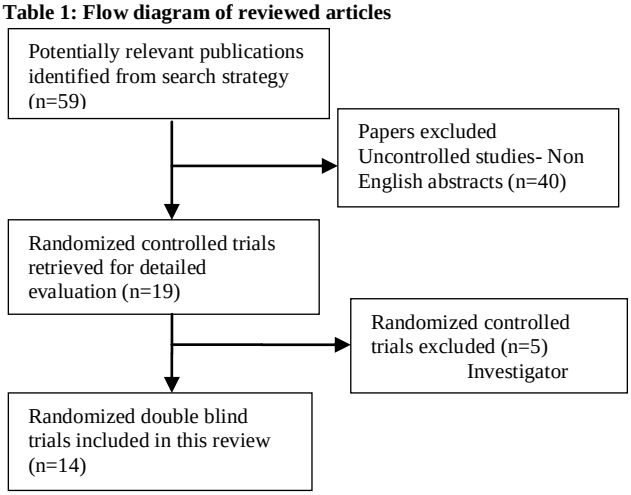
SEARCH METHODOLOGY

We performed search across electronic databases like PUBMED, Google Scholar, and clinical trials registry – www.clinicaltrials.gov. Additionally, a general search at Google search engine was also performed. Desoximetasone or Desoxymethasone were the search terms used. Clinical studies including randomized trials, observational and post-marketing studies in eczema, dermatoses, atopic dermatitis, psoriasis before November 2017 of desoximetasone cream and ointment were included in the review. For non-English literature articles, information available from the abstracts was captured.

RESULTS

After an extensive search, a total of 59 studies were identified of 0.25% Desoximetasone cream, emollient cream and ointment. In these, 19 were RCT's (monotherapy), 40 were uncontrolled studies of 0.25% desoximetasone in patients with inflammatory dermatoses (usually eczema, dermatitis or psoriasis). The uncontrolled (40 studies) were not included as they had Non-English abstracts. 1 RCT which was an investigator blinded study and 4 RCT's which were of Non-English were also not included in this systematic review. Finally, 14 randomized double blind clinical trials were selected (Table 1). In these studies, betamethasone valerate (7 studies) and triamcinolone acetonide (2 studies) and Fluocinolone acetonide (1 study) were the major comparator molecules. Other comparator molecules from 2 studies were betamethasone dipropionate and hydrocortisone butyrate (Table 2).

Table 1: Flow diagram of reviewed articles



For the use in dermatoses and psoriasis, Major findings from the randomized double blind clinical trials are summarized in Table 2. Most of these studies were comparing Desoximetasone 0.25% with Placebo, Betamethasone valerate, 0.1% Triamcinolone acetonide, 0.025% Fluocinolone acetonide and 0.05% Fluocinonide. There were few studies which deserve special mention.

In a between patient, vehicle controlled study which used the commercially available water-in-oil emulsion base of desoximetasone as the control, the active drug was statistically superior ($p < 0.001$) to the placebo after 1 or 2 weeks in 35 patients with atopic dermatitis, or at 1 to 3 weeks in 35 patients with psoriasis. [17]

In a study Ashton et al [21] 0.25% desoximetasone was the most effective treatment, producing the greatest degree of improvement in all clinical parameters. The 0.1% betamethasone produced results similar to 0.25% desoximetasone for 3 clinician assessments and one patient assessment but was less effective overall. Treatment with 0.25% desoximetasone

produced the greatest change in clinical symptoms with progressive improvement being sustained throughout the study period. Betamethasone valerate group generally maintained the initial clinical improvement with little or no further change in score. Treatment with 1% hydrocortisone was the least effective and 0.05% desoximetasone lay midway in effectiveness between 0.25% desoximetasone and 1% hydrocortisone.

Table 2: Summary of randomized double blind clinical trials of desoximetasone 0.25 % cream, emollient cream and ointment

Author (Year)	Disease condition	n	Duration (weeks)	Desoximetasone	Comparator	Results	AEs
1. Mitra and Banerjee [9] (1974)	Dermatoses	75	<8	0.25% ointment	B-valerate 0. 12% Triamcinolone acetonide 0.1% ointment	Excellent to good improvement seen in 91.7% of patients with Desoximetasone as against 45.8% with B-valerate and 41.7% with triamcinolone. acetonide. Relatively quicker onset of action with Desoximetasone.	No side effects seen with any of the treatments. No evidence of skin atrophy judged clinically.
2. Mulay and Sood [10] (1974)	Dermatoses	55	2	Not mentioned	B-valerate (no other details)	Desoximetasone had significantly earlier onset of action and greater effect on various signs and symptoms	Both the treatments were well tolerated
3. Nair and Nair [11] (1975)	Psoriasis Other dermatoses	30 45	7+	Not mentioned	B-valerate 0. 12% Triamcinolone acetonide 0.1% (no other details)	Dermatoses Group- No significant difference between the 2 drugs, but in the psoriasis group at the end of the 5th and 6th weeks, 89% of patients given desoximetasone showed complete disappearance of lesions as opposed to 50% with B-valerate and Triamcinolone acetonide 0.1%.	None of the patients developed atrophic changes or showed any significant changes in the laboratory tests.
4. Sehgal[12] (1976)	Bilateral acute dermatitis	50	2	Not mentioned	B-valerate (no other details)	Desoximetasone was somewhat greater than that of betamethasone valerate.	well tolerated with no local side effects
5. Lassus[13] (1977)	Psoriasis	40	3	0.25% cream	Betamethasone dipropionate 0.05% cream	Desoximetasone side responded better in 27.5% of cases as against 10.0% with BDP	No side effects of treatment were observed.
6. Kuokkanen [14] (1977)	Psoriasis	56	2	0.25% ointment	0.05% Fluocinonide ointment	Erythema, scaling and induration on the desoximetasone-treated side showed a significantly better improvement than on the fluocinonide-treated side	Not mentioned in abstract
7. Lundell [15] (1975)	Eczema	50	4	0.25% cream	Fluocinolone acetonide 0.025% cream	Significantly better effect of desoximetasone compared to Fluocinolone-acetonide during the 1st, 3rd and 4th week of treatment	Not mentioned
8. Zacharie[16] (1976)	Psoriasis	30	2	0.25% cream	Hydrocortisone butyrate (0.1%) cream	Significantly better effect of desoximetasone as judged by the observer	Not mentioned

Table 2 to be continued….							
9.Savin[17] (1978)#	Atopic dermatitis	35	2	0.25% Emollient cream	Placebo	Improvement with desoximetasone emollient cream was significantly superior to vehicle.	No significant burning, irritation or other side effects. Both the treatments were well tolerated
	Psoriasis	35	3	0.25% Emollient cream	Placebo	Improvement with desoximetasone emollient cream was significantly superior to vehicle	
	Psoriasis	128	2	0.25% Emollient cream	B-valerate 0. 1%	Desoximetasone clinically and statistically superior than B-valerate	
	Psoriasis	45	24	0.25% Emollient cream	B-valerate 0. 1%	Desoximetasone clinically and statistically superior than B-valerate	
	Atopic dermatitis	83	2	0.25% Emollient cream	B-valerate 0. 1%	Desoximetasone more effective than B-valerate. Difference not statistically significant.	
10..Burnett [18] (1978)	Psoriasis	125	3	0.25% cream	B-valerate	Desoximetasone had significantly earlier onset of action and greater effect on various signs and symptoms	
11. Magnin [19] (1978)	Psoriasis	Not mentioned	Not mentioned	0.25% Ointment	Betamethasone dipropionate 0.05%	Desoximetasone cream to be significantly more active concerning reduction of erythema and overall improvement of lesions.	
12. Henry[4] (1980)	Varicose eczema	57	38 days	0.25% Oily cream	Hydrocortisone 17-butyrate (HB) 0.1% Oily cream base	Desoximetasone produced similar results to comparator.	5% with Deoximetasone, 1.75% with HB, 3.44% with oily cream base.
13. Shah[20] (1980)	Dermatoses	60	2-7 days	0.25% cream	Placebo	68.34 % showed marked improvement or complete disappearance of lesions following treatment with desoximetasone cream 0.05% for 2 to 7 days, compared with 31.67 % given placebo	Excellent patient tolerance.
14. Asthton[21] (1987)	Eczema	96	3	0.25% cream	0.05% Desoximetasone cream 0.1% B-valerate 1% Hydrocortisone	0.25% Desoximetasone was the most effective treatment, producing the greatest degree of improvement in all clinical parameters.	No side-effects were reported in any treatment group

n= Number of patients, AE=Adverse event, B-valerate: Betamethasone valerate, BDP: Betamethasone dipropionate.
 # Studies conducted in the USA and reviewed by Savin

In a study Ashton et al [21] 0.25% desoximetasone was the most effective treatment, producing the greatest degree of improvement in all clinical parameters. The 0.1% betamethasone produced results similar to 0.25% desoximetasone for 3 clinician assessments and one patient assessment but was less effective overall. Treatment with 0.25% desoximetasone produced the greatest change in clinical

symptoms with progressive improvement being sustained throughout the study period. Betamethasone valerate group generally maintained the initial clinical improvement with little or no further change in score. Treatment with 1% hydrocortisone was the least effective and 0.05% desoximetasone lay midway in effectiveness between 0.25% desoximetasone and 1% hydrocortisone.

B. K. H. Nair, and C. H. K. Nair conducted a clinical study on 75 patients in a randomized double-blind fashion, in 3 parallel treatment series with 0.12% betamethasone valerate, 0.1% triamcinolone acetonide and 0.25% desoximetasone with dermatoses and psoriasis. In the dermatoses group, there was no significant difference between the 3 drugs, but in the psoriasis group at the end of the fifth and sixth weeks, 89% of patients given desoximetasone showed complete disappearance of lesions as compared to 50% in the other 2 series. [11]

Mitra and Banerjee evaluated the efficacy and safety of 0.25% Desoximetasone compared to 0.12% betamethasone valerate, 0.1% triamcinolone. It was a double blind, randomized study in 3 parallel groups (Table 2). With Desoximetasone, complete relief of itching was seen within an average period of 3.04 weeks as against 3.79 and 3.17 weeks with Betamethasone valerate and Triamcinolone acetonide. Relatively quicker onset of action with Desoximetasone is further evidenced by 75% or more reduction in itching severity at the end of first week of treatment in 30.4% patients treated with this drug against 4% and 8% of patients treated with Betamethasone valerate and Triamcinolone acetonide respectively. [9]

Besides, betamethasone valerate, triamcinolone acetonide, hydrocortisone, desoximetasone was compared with betamethasone dipropionate. This study showed desoximetasone cream to be significantly more active concerning reduction of erythema and overall improvement of lesions as compared to betamethasone valerate. The difference was most evident 4 days after treatment started, the desoximetasone side being regarded as responded better in 27.5% of the cases. The difference was not statistically significant. Desoximetasone had a rapid effect on psoriatic lesions than betamethasone dipropionate 0.05%. [13]

In all published trials Desoximetasone has been well tolerated in most patients. In isolated instances in these trials reactions such as ulcers, redness or pruritus have occurred [4] but similar adverse effects have also been reported with placebo treatment. [4] Less than 1% of the patients in controlled clinical trials reported an adverse reaction. [8]

DISCUSSION

We have aimed to perform an in-depth review of clinical evidence of Desoximetasone 0.25% cream and ointment formulation. The rationale was that literature search revealed no published review on the clinical evidence with Desoximetasone 0.25% cream and 0.25% ointment after 1992 and very few clinical publications.

The safety and efficacy of Desoximetasone cream and ointment 0.25% has been established in steroid responsive dermatoses like eczema, atopic dermatitis, psoriasis. We have included randomized clinical trials in over 1095 patients.

Desoximetasone has been studied in relatively large numbers of patients. Most with either psoriasis, eczema or dermatitis. In short-term (usually less than 1 month) open trials, about 75 to 100 % of such patients showed improvement during treatment. [3]

Desoximetasone is a high potent fluorinated corticosteroid for topical use which has often been judged superior overall in patients with inflammatory dermatoses to several other steroid preparations of intermediate potency (e.g. betamethasone valerate 0.1 %, triamcinolone acetonide 0.1 %, fluocinolone acetonide 0.025%) or in a few studies, to some steroids of high potency (e.g.

betamethasone dipropionate 0.05 %. fluocinolone acetonide 0.2 %, fluocinonide 0.05 %). [3]

Studies on the extent of systemic absorption in man during repeated application to diseased skin have not been done. Following occlusive application of 0.27 % desoximetasone radio labeled ointment to the depilitated backs of rats absorption occurred fairly rapidly, radioactivity being detectable in the blood within 1 hour and in the urine after 4 hours. Maximum blood levels occurred at 24 hours. [22]

In a study using a 48-hour occlusion period the drug was deposited primarily in the stratum corneum and the extent of drug penetration was increased in psoriasis and eczema as compared with normal skin. Following 24-hour occlusion of 8g of radio labelled desoximetasone 0.25 % (as the commercial preparation) on a 400cm^2 area of back skin, a mean of 6.5g (81 %) of the preparation remained on the dressing or on the skin surface of 5 healthy subjects. Urinary and faecal radioactivity over the next 10 days corresponded to an absorption of about 5 %. [3]

The tolerance rate during longer-term (up to 20 months) administration has been cited as 97.5 % in the literature. [3] Systemic absorption, as evidenced by indications of adrenal suppression have been demonstrated following application of relatively large amounts of desoximetasone for several days or months. A single case of florid Cushingoid manifestations has been reported in a woman with chronic psoriasis who had continuously used desoximetasone over a 5-year period, most recently in very excessive amounts of up to 30g of the 0.25 % preparation daily. Four months after stopping topical steroid treatment her Cushingoid features had noticeably decreased and her adrenal function appeared to be normal, but her psoriasis had worsened. [23]

Dermatologists' knowledge of topical corticosteroids potency and products they would choose in cases of suspected steroid or vehicle allergenicity was evaluated by 105 dermatologists in USA. Dermatologists most commonly selected desoximetasone (19%) as the product they would prescribe to patient with suspected allergy to a steroid molecule or vehicle, followed by fluocinolone, hydrocortisone butyrate, mometasone, triamcinolone and hydrocortisone. Desoximetasone is halogenated C_{16} molecule categorized in terms of allergenicity as group C corticosteroid that rarely causes product allergy. [24]

Both C16-methyl substitution and halogenation seem to stabilize corticosteroid molecules and thus influence their sensitization potential. C16-methyl substitution, because of steric hindrance, has been considered to protect them against C21 hydrolysis, probably resulting in less rapid conversion into aldehydes. Recent studies have indicated that C16-methyl substitution does not prevent hydrolysis, but avoids the formation of stable cyclic adducts with arginine that leads to sensitization. [6]

CONCLUSION

The safety and efficacy of Desoximetasone cream 0.25% has been established in steroid responsive dermatoses like eczema, atopic dermatitis, psoriasis in randomized clinical trials in over 1095 patients.

Desoximetasone was found to be superior over comparator drugs in patient with psoriasis which is a difficult to treat disease and which might be expected to amplify any small differences in the effectiveness of steroid preparations.

In controlled trials in patients with inflammatory dermatoses, the rapidity of onset of action of desoximetasone (marked symptomatic improvement often within 2 or 3 days) has been noted by several authors.

Desoximetasone effectiveness and safety in the treatment of a wide range of steroid responsive dermatoses in comparison with ultra-high potency and medium potency topical corticosteroids like Clobetasol propionate and mometasone

furoate in randomized controlled trials are warranted.

Desoximetasone 0.25% cream and ointment appear to be effective and well tolerated molecule in the treatment of corticosteroid responsive dermatitis.

Limitations

Although we did extensive search of literature, there is likely chance of missing on non-English literature not covered under the databases searched. Most of the non-English articles were available as abstracts only.

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