



REMARKABLE EFFECT OF TOPICAL BETAMETHASONE VALERATE 0.1% ON PROGRESS OF PSORIASIS DISEASE.

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ABSTRACT... Psoriasis is immuno-inflammatory condition devouring huge negative impact on patient's life as compare to other diseases. Topical regimen is the standard treatment for mild to moderate psoriasis disease. The data of effectiveness of Betamethasone Valerate 0.1% on large number of psoriatic patients were being deficient. **Objectives:** This study evaluates the Topical Betamethasone Valerate 0.1% impact on patient's life in relation to efficacy and safety. **Design:** Interventional experimental study. **Setting:** Study was carried out Basic medical sciences institute (BMSI) alliance with Dermatology Department JPMC, Karachi. **Period:** June 2013 to June 2016. **Methods:** 75 chronic plaque type psoriatic patients prescribed Betamethasone Valerate (0.1%) topically along with placebo for 6 months once daily (one week interval after three week application). The therapeutic effectiveness and safety of studied drug were assessed by means of PASI, DLQI and hsCRP. The results analyzed by using repeated ANOVA. **Results:** Results revealed when comparison of all parameters with base line they were significantly reduced as mean percentage change were 75.001 ± 0.0563 , 72.215 ± 3.17 and 33.692 ± 7.980 for PASI, DLQI and hsCRP respectively at the end of study. Safety profile of therapy showed non-significant outcomes. **Conclusion:** Betamethasone valerate 0.1% is better treatment option in mild to moderate psoriatic patients to improve quality of life and decrease disease severity.

Key words: Betamethasone Valerate 0.1%, hsCRP, Psoriasis Vulgaris, PASI, Quality of Life.

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INTRODUCTION

Psoriasis is an autoimmune disorder associated with several systemic co-morbidities. Hence inflammation is a prime factor for many autoimmune diseases. Therefore primary aim of therapy against psoriasis would be to decrease progression of disease and thus improving both local dermal lesions and also associated systemic co-morbidity. Therefore improvement the study of health related quality of life in psoriatic patients regimen against psoriasis should cover both local skin inflammation and associated systemic spillovers of inflammatory mediators.

Unfortunately there is no ideal remedy for psoriasis that magnificently improving both primary skin lesions and associated co-morbidities. Numerous accessible medications of psoriasis can assist just with controlling skin lesion and associated symptoms.¹ Among all available treatment options

for psoriasis only topical steroids remains gains superiority for management of all stages of psoriasis either as sole or as combinatory regimens.^{2,3}

Therefore nowadays about 80% of psoriatic patients were treated topical steroids efficaciously.⁴ Because Corticosteroids able to reducing the cellular inflammation without adversely affecting.⁵ Correspondingly Corticosteroids would able to inhibit synthesis of local inflammatory mediators and thereby their systemic spill over specially cytokines and prostaglandins (IL-6 and 8, TNF- α , Interferon- γ , leukotrienes). Similarly steroids able to decrease abnormal CD4:CD8 ratio and also decreases the numbers and retard the hyperstimulation of Langerhans cells.^{6,7,8}

The severity of psoriasis disease in clinical trial assess by PASI Scoring which is most commonly used reliable parameter to evaluate the disease

progress. PASI explained the lesion via redness, thickness and scaliness. Most of the researchers used this variable for the assessment of newer drug's effects on the progress of psoriasis disease severity.⁹

Cardiovascular manifestations were most prevalent systemic complication associated with psoriasis.¹⁰ Hence systemic complication in psoriasis mostly due to systemic inflammation and CRP is the imperative predictive marker for both severity of psoriasis and its systemic manifestations.¹¹

MATERIALS AND METHODS

Seventy five psoriatic patients enrolled in this study, 09 patients were lost from follow-ups. Patients were prescribed local application of Betamethasone Valerate 0.1% once time in a day with placebo for six months.

Inclusion Criteria

Were includes both gender of age 25-65 years with PASI scoring of <12 and hsCRP is ≥ 3 .

Exclusion Criteria

Were includes those patients having Steroid and Statin treatment in past one month or history of pregnancy, lactation and others chronic illness. Study period was 180 days and approved by JPMC Ethical Committee. The effectiveness of study drug assessed by Psoriasis Area and Severity Index (PASI). This index explained the treatment effectiveness by change in PASI i.e. 50%, 75% and 90%. Clinically those drug are effective which shows 50% of change as approved by FDA. A PASI score of >12 means disease is severe, 7-12 score is moderate and <7 is mild.¹² C-reactive protein is directly related to inflammation and it rises in psoriasis. Measuring CRP level can be used as a key predictive factor to response the treatment.¹³ Patient's quality of life was estimated by Dermatological Life Quality Index (DLQI) before and end of the therapy.¹⁴

STATICAL ANALYSIS

Statistical analysis was done by using SPPP ver. 16.0 and for clinical effectiveness of studied drug statistical method repeated measure ANOVA was applied. Only p values <0.05 and <0.001 were reflected as statistically significant and highly significant respectively.

RESULTS

Results of demographic data revealed that most of the middle aged patients with positive family history, smoking history and disturbed sleep. Most of them had moderate type lesion and located on upper limb and lower limb as depicted in Table-I. The outcome of all clinical parameters associated with psoriasis as compare to baseline of studied drug showed statistically significant improvement at the end of study such as mean PASI 2.806 ± 0.183 (p value = 0.0001), mean hsCRP 2.65 ± 0.40 (p value = 0.0001) and mean DLQI 5.55 ± 0.53 (p value = 0.001) with significant percentage change most of them reached PASI 50 as depicted in Table-II. Patients showed mild to moderate type of adverse effects like skin manifestations (rash, burning and redness) as showing in Figure-1.

Demographic Data	
Age:	46.52 ± 7.84
Gender:	
Male:	57 (86.37)
Female:	9 (13.64)
Family History:	36 (54.50)
History of Smoking:	42 (63.64)
Sleep Disturbed:	66 (100)
Mild-PASI:	1 (1.51)
Moderate PASI:	65 (98.49)
Disease Duration (Months):	5.65 ± 2.18
Location of Lesions	
Head:	34 (51.51)
Upper Limb:	63 (95.45)
Lower Limb & Groin:	62 (93.93)
Trunk:	56 (84.84)
Nails:	0 (0)

Table-I: Demographic Data

Adverse Events in Patients

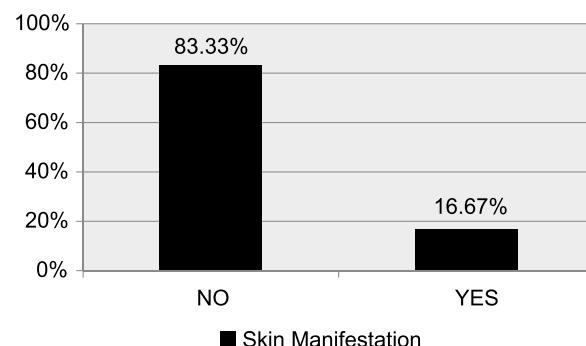


Figure .1

Outcome Variables	Baseline	Three Months Follow-up	Six Months Follow-up	P-value
Psoriasis Area and Severity Index (PASI) (Percentage Change)	11.277±0.729	3.910 ± 0.272 (65.176±0.424)	2.806 ± 0.183 (75.001±0.0563)	0.0001 (0.0001)
hsCRP (Percentage Change)	4.00 ± 0.31	3.37 ± 0.41 (15.767±5.67)	2.65 ± 0.40 (33.692±7.980)	0.0001 (0.0001)
Dermatological Life Quality Index (DLQI) (Percentage Change)	20.2 ± 1.16	-	5.55 ± 0.53 (72.215±3.17)	0.0001 (0.0001)

Table-II: Comparison of Outcome Variables (Psoriasis Area and Severity Index, hsC-Reactive Protein, Dermatological Life Quality Index) among Patients at Baseline and Follow-ups

DISCUSSION

Betamethasone is a powerful anti-inflammatory and immuno-modulatory agent.¹⁵ Apart from that it also had anti proliferating effect that would worthwhile for condition they had duel hperproliferative and immunological consequences.¹⁶ In this study we found the commonest site of lesions were upper limb and lower limb with the history of itching, smoking and positive family history. Most of the patients reached PASI 50 at the end of the study and one patient at PASI 75.¹⁷ Hence Psoriasis is associated with immune induced inflammation so steroids would valuable treatment option for this condition. Psoriasis produced negative psychological and social effect on life and health of patients. So DLQI is used for measurement in term of patient's quality of life but also effectiveness of drugs on health of patients.^{18,19} This study showed favorable effects on progress of disease and health related quality of life as assessed by PASI (p value = 0.0001) and DLQI (p value = 0.001). PASI was decreased to 2.806 ± 0.183 at end of study from 11.277±0.729. Similarly DLQI was reduced to 5.55 ± 0.53 from 20.2 ± 1.16. These findings were in line with study conducted by Kragballe K and Van de Kerkhof (2006), as they reported that Betamethasone showed marked improvement of psoriatic lesions.²⁰

Similarly Thawornchaisit and Harncharoen revealed that topically applied Betanmethasone had favorable effects on psoriatic patient in term of magnificently improving the PASI score in plaque type psoriatic patient.^{21,22}

Beside of improving primary parameters of Psoriasis (PASI, DLQI) in our study additional benefit of Topical Betamethasone was magnificently reduces the

hsCRP levels (p=0.0001). As hsCRP is an important predictable marker for systemic inflammation. Hence Betamethasone would able to reducing the chances of systemic consequences of Psoriasis. These findings were in agreement with the study conducted by Philippine Dermatological Society. They evaluated and compared the effects of Topical Betamethasone with Placebo and Atorvastatin (40mg) in psoriatic patients. They concluded that Topical Betamethasone as effective as Atorvastatin in reducing the hsCRP levels.²³

In our study Topical Betamethasone usage showed better tolerability as patients did not manifest any severe adverse effect apart from those only 16.67% patient revealed minor skin manifestations. These findings were in line with study conducted by Afifi et al. (2005). As they showed that among all available topical therapeutic options for psoriasis, topical steroids were safe and effective option.²⁴

This study supported that topical steroids would be best option for mild to moderate psoriasis with better tolerability as in line with Ahmad et al. (2013).²⁵ As per guideline for psoriasis recommended by USA Topical Betamethasone effective as first line treatment option of all stages of psoriasis either as sole or combinatory therapy.²⁶

CONCLUSION

This study result showed that Topical Betamethasone Valerate 0.1% amends the immune function and hampers the inflammatory process of disease to reduce its progress and enhanced quality of life in chronic plaque type psoriatic patients

CONFLICT OF INTEREST

No Conflict of interest

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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Farah Asad	Wrote the paper, Data collection and data analyzed, Substantial contributions to the conception or design of the work and interpretation of Data for the work.	
2	Fatima Rizvi	Drafting the work or revising it critically for important Intellectual content.	
3	Arfa Azhar	Review the literature.	