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TO ASSESS THE EFFECTIVENESS OF SHORT BURST APPLICATION OF 0.05% FLUTICASONE CREAM IN PREVENTING DYSCHROMIA DUE TO SUPERFICIAL CUTANEOUS PROCEDURES

Dermatology

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ABSTRACT

Background Topical corticosteroids are known for their anti-inflammatory effect. Post-procedural dyschromia is a very common in skin of colour and people with excessive sun exposure. In our study we assessed the effect of prior application of fluticasone 0.05 % cream in different time period on post procedural dyschromia. **Methods** This was a single-center, open-label, prospective case-control study in which consecutive subjects suffering from small lesion of face (DPN or Milia), belonging to the age group of 18 years and above were recruited. The three equal study Groups-A, -B and -C received 4 hours, 12 hours and no application of fluticasone 0.05% cream prior to procedure. Clinical progression and effect on post procedural dyschromia was assessed in follow-up visit after 1 week and 2 week respectively. **Results** In our study, we could not found any significant effect of prior applicantion of topical corticosteroid cream over post procedural dyschromia. **Conclusion:** Our study suggests that fluticasone 0.05% cream is ineffective in preventing post procedural dyschromia

Summary:

- Post procedural dyschromia is a major complication after removal of smaller leions of face.
- No study was available to address the effect of prior application of topical corticosteroid over the appearance of Post procedural dyschromia
- We have assessed efficacy of short burst application of fluticasone 0.05% cream in preventing post-procedural dyschromia (hyper and hypopigmentation)

KEYWORDS

Postprocedural dyschromia, Fluticasone cream, DPN

INTRODUCTION

Post procedural dyschromia (hyper or hypopigmentation) is alteration in normal skin pigmentation. Post procedural dyschromia is very common after cutaneous procedures.[1] Post inflammatory dyschromia is more common in dark skin people and people with excessive sun exposure.[2,3] Post procedural dyschromia can produce significant psychological and emotional distress and negatively impact a patient's quality of life.

For prevention of post procedural dyschromia no acute preventive measures are available. However, a priming method has been described, in which 2-3 weeks before cosmetic procedure, topical application of hydroquinone, tretinoin, kojic acid is advised, which is costly and time consuming.[4] So there is a requirement of some preventive measure, which may be utilized over a short period of time before the procedure.

Post procedural dyschromia is considered to be due to inflammatory processes[3-5] and topical corticosteroids have established anti-inflammatory property[6-10], so this study has been designed to assess, whether short contact of topical corticosteroid may prevent appearance of post procedural dyschromia in patients of Dermatosis papulosa nigrans(DPN) and Milia.

MATERIALS AND METHOD

A single centre, randomized, open-label, prospective case control study was performed at Out-Patient facility of Department of Dermatology, Venereology & Leprosy of Mahatma Gandhi Memorial Medical College and associated Maharaja Yashwant Rao Hospital, Indore, India; over a period of 12 months, from April 2015 to march 2016. Study protocol was approved by Institutional Ethics Committee prior to initiation of the study. Written informed consent was obtained from all patients for participation in the study, publication of clinical photographs, and the radiofrequency (RFC) procedure.

Patients with multiple skin lesions over face, either DPN or Milia with an age group of 18 years and above were screened for the study. Those with history of keloidal tendency, photosensitivity, active herpes infection were excluded from the study. Subjects with Diabetes mellitus, Addison's disease, Vitamin B_{12} deficiency, pregnant females and lactating mothers were also excluded from the study.

All the participants in the study were subjected to the detailed personal and clinical history recording including past and present medical history, past and concomitant drug history. Participants were randomized with the help of table of random numbers in to three groups containing 30 participants in each group.[11]

Group A, had applied fluticasone 0.05% cream four hour before procedure; while group B had applied fluticasone 0.05% cream 12 hour before procedure. Group C, control group had not applied 0.05% fluticasone cream. Fluticasone cream was applied by the study participants in Group A and Group B with the help of Finger Tip unit (FTU). They were instructed to use 2 FTU over the face. Finger Tip unit (FTU) is the amount of ointment expressed from a tube with a 5 mm diameter nozzle, applied from distal skin crease to the tip of the palmer aspect of the index finger. After 4 hours in group A and after 12 hours in group B, Radiofrequency Cautery was done and patients were followed for post procedural dyschromia after one week and two week. Clinical photographs were taken before the procedure and at the time of one week and two week follow up.

A single brand of fluticasone 0.05% cream was used, which was kindly provided by Glaxosmithkline pharamaceutical Ltd, India; in the form of their market product flutivate cream.

Statistical analysis

All randomized patients who received study medication and completed the study were included for analysis. Analysis was done by Chi-square test.

OBSERVATIONS AND RESULT

90 patients were recruited for study and they were divided in three Groups A, B and C (control group). Age group obtained in this study was indeed ranged from 25 years to 40 years. There were 59 (65.6%) female and 31(34.4%) male participants in the study.

The participants were randomized in three study groups. The groups were balanced with respect to baseline characteristics. Baseline characteristics of the study participants have been presented in Table 1.

In this study 30 patients participated in group A. there were 10 (33.3%) male and 20 (66.7%) female patients in the group. Dermatosis

papulosa nigra was present in 25 (83.3%) patients and milia were present in 5 (16.7%) patients. In group B, out of 30 patients, 12 (40%) were male and 18 (60%) were female. Dermatosis papulosa nigra was present in 22 (73.3%) patients and milia were present in 8 (26.7%) patients. In group C, out of 30 patients, 9 (30%) were male and 21 (70%) were female. Dermatosis papulosa nigra was present in 22 (73.3%) and milia were present in 8 (26.8%) patients.

Table 1: Baseline characteristics of study population

Characteristics		Group A	Group B	Group C
Total number of patients		30	30	30
Male		10	12	9
Female		20	18	21
Age range		25-40	26-40	25-40
Patients with DPN	Male	8	7	5
	Female	17	15	17
Patients with milia	Male	2	5	4
	Female	3	3	4

On 1st follow-up, in group A, 27 (90%) patient showed dyschromia, 24 (80%) patient presented with hypopigmentation and 3 (10%) patient presented with hyperpigmentation. Only 3 patients presented without any dyschromia. In group B, 26 (86.7%) patients presented with dyschromia. Out of 26 patients, 19 (63.3%) patients presented with hypopigmentation and 7 (36.7%) patients presented with hyperpigmentation. Only 4 patients presented without any dyschromia. In group C, 27 patients presented with dyschromia, out of 27 patients, 20 (66.7%) patients presented with hypopigmentation and 7 (33.3%) patients presented with hyperpigmentation. Only 3 patients presented without any dyschromia. On 2nd follow up, no significant changes were observed in dyschromia in Group A, Group B and Group C (control group). The clinical progression of several participants have been shown in Figure 1.

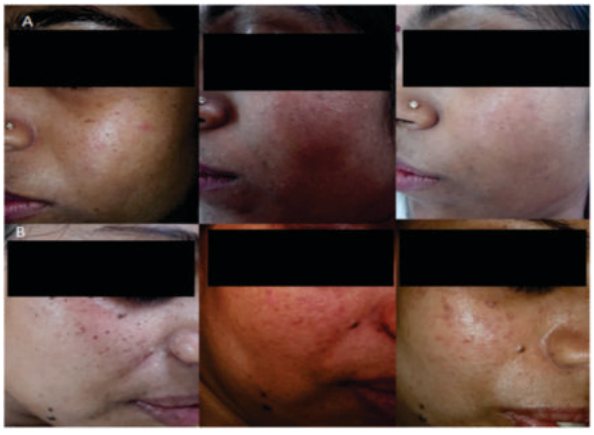

Figure 1: Clinical progression of several participants

Results were analysed by chi-square Test. P value was more than 0.05 (P> 0.05) Table 2. So, no significant co-relation observed between topical application of fluticasone 0.05% cream 4 and 12 hour before procedure and prevention of dyschromia.

Table 2: Analysis by Chi-square Test

Pearson chi-square	Value	Degree of freedom	P value
Pearson Chi-square	0.225	2	0.894
Liklihood ratio	0.219	2	0.896
No. of valid cases	90		

DISCUSSION

In our case control study, we have assessed the effect of fluticasone 0.05% cream in prevention of post procedural dyschromia. Post procedural dyschromia is common after cutaneous procedures, which is considered to be due to inflammatory process.[3,5] Melanocytes can react with normal, increased or decreased melanin production in response to cutaneous inflammation.[2] As inflammatory process underlies the appearance of post procedural dyschromia ; steroids as anti-inflammatory agent should be able to revert it. However our study was unable to demonstrate any preventive capacity of fluticasone 0.05% cream even upon 12 hours of pre procedure application. It seems plausible that a longer duration of pre as well as post procedure application, may be required to demonstrate such an effect. Secondly, the amount of anti-inflammatory effect of fluticasone may be insufficient to attain desired effect. Time of initiation of anti-inflammatory effect of fluticasone 0.05% cream is unknown but owing to its pharmacokinetics, it should be less than the application we had chosen. Because of its case control design we can only predict a probable association. Due to small sample size, we could not performed stratified analysis according to skin type. [12]

CONCLUSION & SUMMARY

Our study suggests that Fluticasone 0.05% cream is ineffective in preventing post procedural dyschromia. A single 4 hour and 12-hour application of this topical steroid was unable induce anti-inflammatory effect, sufficient enough to reduce post procedural dyschromia.

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