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Original Research Article

Efficacy and Safety of 15% Lactic Acid Peel Versus 30% Mandelic Acid Peel Versus 10% Trichloroacetic Acid in Periorbital Hypermelanosis

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Abstract:

Background: Periorbital hypermelanosis (POH), also known as periocular hyper pigmentation, dark circles is multifactorial disease that presents as macules, round or semicircular, pigmented with a homogeneous brown or dark brown color in the bilateral periocular region. Chemical peelsare the preferred mode of treatment by many patients because of their safety, tolerability and easyin application.

Aim: To compare and study the efficacy and safety of 15% lactic acid peel versus 30% mandelic acid peel versus 10% trichloro acetic acid (TCA) peel in periorbital hypermelanosis.

Methods: Clinically diagnosed patients of POH were randomly divided into 3 groups i.e. A, B and C. Group A was applied 30% mandelic acid in periorbital region every 15 days. Group B wasapplied 15% lactic acid in periorbital region every 15 days. Total 5 such sittings were performed on each patient in all the three groups. Patients were assessed every 15 days till 5 visits. **Result:** Among group A, 11 (35.48%) patients at the final visit showed excellent results. Among group B, 9 (29.03%) patients at the final visit showed excellent results.

(29.05%) patients at the final visit showed excellent results. Amon showed excellent results.

Conclusion: The efficacy of treatment with all three agents at the final visit showed that Group A showed excellent efficacy compared to Group B and Group C with a statistically significant difference (p < 0.05).

Keywords: Periorbital hypermelanosis, mandelic acid, lactic acid, Trichloro acetic acid, periorbital hyperpigmentation, chemical peeling.

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Introduction

Periorbital hypermelanosis (POH), is also known as periocular hyperpigmentation, infraorbital darkening, periorbital melanosis, dark circles, infraorbital discoloration is a common conditionseen in dermatology practice. [1-4]. It is an ill-defined term and it presents as bilaterally symmetrical, uniform brown or dark brown discoloration around both eyes. [1,2] Women are more concerned about the disease as it impairs their quality of life. It is rare in males, and the percentages of dark circles is more in females due to hormonal factors. [5]

Periorbital hypermelanosis is multifactorial disease with contributions from genetics, constitutional makeup [6], deposition of melanin in dermis, secondary to allergic or atopic contact dermatitis, post inflammatory hyperpigmentation, stress, anemia, faulty habits, periorbital edema, superficial location of vasculature, and shadowing due to laxity of skin, etc.[7] The disease usually starts in puberty or early adulthood at the age of 16 to 25 years. Certain ethnic groups experience more incidence of periorbital hyperpigmentation and there isincreased incidence of family history. [7]

There are various types of treatment modalities Incidence available like dietary supplements, peeling, topical therapy and lasers. Chemical peeling is a simple, safe, non-invasive or minimally invasive and effective procedure with minimal complications for the treatment of periorbital hypermelanosis [8].

Chemical peeling is a procedure in which there is controlled skin damage to the layers of skin, which promotes proliferation of new tissues and causes rejuvenation of tissues. It can be classified into three types based on the histologic depth of injury into superficial, medium and deep peel.

The α -hydroxy acids (AHA) are one of them and low strength Lactic acid (LA) has theproperties of an AHA as well as moisturizing effect which makes it the safest peel forperiorbital region and it can be used in the strength of 30% to 50% face. LA belongs to theAHA group and facilitate progressive weakening of cohesion of the intercellular material ofthe stratum corneum, resulting in regular exfoliation of its outermost layers of the skin.[9] Very few studies and clinical drug trials have demonstrated the efficacy of mandelic acid, inthe treatment of periorbital hypermelanosis. [9]

Thus, the present study was conducted to study the efficacy of mandelic acid peel and compareit with lactic acid peel and Trichloroacetic acid in Indian patients.

Materials and Methods

The present prospective interventional study undertaken to compare the efficacy of 15% lactic acid, 30% mandelic acid, 10% Trichloroacetic acid in the treatment of periorbital hypermelanosis at Department of Dermatology, venereology and leprosy of MGM Medical College and Hospital, Aurangabad with the study duration of 2 years.

Sample size estimation:

Calculated by using the formula

$$n = \frac{\{z1\sqrt{[2P(1-P] + z2\sqrt{P1(1-P1) + P2(1-P2)}]}\}^2}{(P1-P2)^2}$$

P1- Probability of outcome in TEST intervention P1-0.57,

P2- Probability of outcome in CONTROL intervention P2-0.92P- Arithmetic average of P1 and P2 P-0.745

Z1- z value associated with set value of alpha (one sided) Z1-1.6449Z2- z value associated with set value of beta Z2-1.6449

n- minimum sample size N=32

d- Absolute precision (should be fraction of (P1-P2) d-0.025

Hence a sample size of total 93 patients with 31 in each group were included followinginclusion and exclusion criteria.

Inclusion Criteria

- 1. Clinically diagnosed case of periorbital hypermelanosis
- 2. Age had completed 18 years of age.
- 3. Belonging to either sex, males or females.
- 4. Patient must have given written consent before any treatment is commenced
- 5. Patients willing to undergo treatment and come for follow up.

Exclusion Criteria

- 1. Pregnant women & women who intend to become pregnant.
- 2. Active infection or open wound in treatment

area.

- 3. Allergy to chemical peels constituent.
- 4. Insufficient sun protection.

Ethical Consideration

The study was approved by the Ethical Committee of the MedicalCollege.

Study Design

93 Patients were randomly divided into 3 groups of 31 each.

Group A: The selected 31 patients were treated with 30% mandelic acid inperiorbital regionevery 15 days

Group B: The selected 31 patients were treated with 15% lactic acid inperiorbital regionevery 15 days

Group C: The selected 31 patients were treated with 10% TCA in periorbital region every 15days

Requirements for the study design

- 1. 15% lactic acid
- 2. 30% mandelic acid
- 3. 10% TCA

Methodology

Patients for the study were selected from those who attending skin and VD clinic at MGM Medical college and hospital, Aurangabad. Written consent of the patient was obtained. Demographic history name, age, sex, address, contact number, marital status, occupation was noted. Disease history - duration of illness, onset and progress of illness, associated symptoms, site, type and number of lesions was taken along with family history& menstrual history. Chemical peeling is performed every 2 weeks for a series of five sittings. Each patient is recommended to use adequate cover over face during day time to avoid sun exposure. Patient were assessed for safety and efficacy every 2 week. Patient were asked to follow up throughout the course of treatment for any adverse drug reactions.

Steps for performing a chemical peel procedure [11]

- 1. Regarding superficial peeling, the patient is asked to wash their face with soapand waterto remove dust and dirt.
- 2. The hair is pulled back with a headband or hat.
- 3. The patient lies with his head raised 45 $^{\circ}$ and his eyes closed.
- 4. Using a 2 "x 2" gauze, the leather is cleaned with alcohol and then degreased with acetone or a pre-peeling cleaner.
- 5. The inner corner of the eye should be protected with a thin layer of petroleumjelly.

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- 6. The exfoliating agent of the desired concentration is then applied with a brush or acotton tipped applicator or gauze.
- 7. Soft strokes are applied to the edges to blend in with the surrounding skin and avoid dividing lines.
- 8. The skin is neutralized as needed based on the exfoliating agent.
- 9. The skin is gently dried with gauze and the patient is asked to wash with cold wateruntil the burn disappears.
- 10. The patient then applies sunscreen before leaving the clinic.

Grades of Periorbital Hypermelanosis [1,2]

Grade 0: Skin colour comparable to other facial skin area.

Grade 1: Faint pigmentation of infraorbital fold

(bilateral).

Grade 2: Pigmentation more pronounced.

Grade 3: Deep dark colour, all 4 lids involved.

Grade 4: Grade 3 + pigmentation spreading beyond infra orbital fold

Statistical Analysis

All data analysis had been done by using SPSS (version 22) for windows. The initial measures of each group were compared with the final measures of the study period and compared between the groups by using student t test and chi square test/ post HOC test. For comparison of 3 groups.

ANOVA was applied. P value was checked at 5% level of significance with <0.05 as statistically significant.

Observations and Results

Table 1. Distribution according to age						
Age group	Group A	Group B	Group C	P value		
<20	02(6.4%)	02(6.4%)	01(3.2%)	0.71 (NS)		
21-30	11(35.5%)	12(38.7%)	12(38.7%)			
31-40	08(25.8%)	09(29.0%)	07(22.6%)			
41-50	05(16.1%)	03(9.7%)	06(19.3%)			
51-60	02(6.4%)	03(9.7%)	03(9.7%)			
>60	03(9.7%)	02(6.4%)	02(6.4%)			
Total	31 (100%)	31 (100%)	31 (100%)			
Mean age	32.13 ± 10.01	34.93 ±11.23	35.28 ±9.18			

Table 1: Distribution according to age

Table 1 shows distribution according to age. It was observed, the mean age in group A was 32.13 ± 10.01 years, group B was 34.93 ± 11.23 and group C was 35.28 ± 9.18 years. There was nosignificant difference in age distribution among three groups (p>0.05).

Table 2. Distribution according to sex					
Sex	Group A	Group B	Group C	P value	
Male	11(35.5%)	09(29.0%)	10(32.2%)		
Female	20(64.5%)	22(71.0%)	21(67.8%)	0.83 (NS)	
Total	31 (100%)	31 (100%)	31 (100%)		

Table 2: Distribution according to sex

Table 2 shows distribution according to sex. Out of total 93 patients, there were 20 (64.52%), 22(70.97%) and 21 (67.74%) females in Group A, Group B and Group C respectively. There wasno gender difference when three groups were compared statistically (p>0.05).

Table 5. Distribution according to duration of miless					
Duration(years)	Group A	Group B	Group C	P value	
<1	09(29.0%)	08(25.8%)	10(32.2%)		
1-3	16(51.6%)	15(48.4%)	17(54.8%)		
>3	06(19.3%)	08(25.8%)	04(12.9%)	0.63 (NS)	
Total	31 (100%)	31 (100%)	31 (100%)		
Duration	1.42 ± 0.81	1.34 ± 0.72	1.38 ± 0.85		

Table 3:	Distribution	according	to duration	of illness
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Distribution according to duration of illness has been presented in table no 3. The mean duration of illness in group A was 1.42 ± 0.81 years, group B was 1.34 ± 0.72 years and group C was 1.38 ± 0.85 years. There was no significant difference in duration of illness distribution among three groups (p>0.05).

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Factors	Group A (n=31)	Group B (n=31)	Group C (n=31)	P value
Stress	07(22.6%)	07(22.6%)	05(16.1%)	0.38(NS)
Inadequate sleep	09(29.0%)	10(32.2%)	10(32.2%)	0.42 (NS)
Seasonal variation	03(9.7%)	04(12.9%)	04(12.9%)	0.39 (NS)
Refractive error	05(16.1%)	05(16.1%)	04(12.9%)	0.28 (NS)
Sun exposure	03(9.7%)	02(6.4%)	03(9.7%)	0.46 (NS)
Rubbing of eyes regularly	04(12.9%)	05(16.1%)	05(16.1%)	0.39 (NS)

Table 4:	Distribution	according to	aggravating	factors

Table 4 shows distribution according to aggravating factors. In the present study, it was observed that, there was no difference when three groups were compared statistically with respect to aggravating factors like stress, sleep, sun exposure etc (p>0.05).

Grade	Group A (n=31)	Group B (n=31)	Group C (n=31)	P value	
Grade 1	10(32.2 %)	09(29.0%)	07(22.6%)	0.56 (NS)	
Grade 2	15(48.3%)	14(45.2%)	15(48.4%)		
Grade 3	04(12.9%)	06(19.3%)	06(19.3%)		
Grade 4	02(6.4%)	02(6.4%)	03(9.7%)		
Total	31 (100%)	31 (100%)	31 (100%)		

Table 5: Distribution according to grade of POH

In table 5 shows The distribution according to grade of POM shows, out of total93 patients, therewere 15 (48.39%), 14 (45.16%) and 15 (48.39%) patients with Grade2 POM in Group A, GroupB and Group C respectively. There was no grade of POM difference when three groups were compared statistically (p>0.05).

There of Distribution according to 11 out of Limit chammarion						
Examination type	Group A(n=31)	Group B (n=31)	Group C (n=31)	P value		
Epidermal	15(48.4%)	13(41.9%)	17(54.8%)	0.39 (NS)		
Dermal	07(22.6%)	08(25.8%)	06(19.3%)			
Mixed	09(29.0%)	10(32.2%)	08(25.8%)			
Total	31 (100%)	31 (100%)	31 (100%)			

Table 6: Distribution according to Wood's Lamp examination

Table 6 shows distribution according to Wood's Lamp examination. Out of total93 patients, therewere 15 (48.39%), 13 (41.93%) and 17 (54.83%) patients with epidermal type in Group A, Group B and Group C respectively. There was no difference when three groups were compared statistically with respect to type (p>0.05).

Visit	Degree of Impr	Degree of Improvement				
	Excellent	Good	Fair	Poor		
1 st visit	03(9.7%)	11(35.5%)	12(38.7%)	05(16.1%)		
2 nd visit	04(12.9%)	11(35.5%)	11(35.5%)	05(16.1%)	0.02 (S)*	
3 rd visit	05(16.1%)	16(51.6%)	07(22.6%)	03(9.7%)		
4 th visit	09(29.0%)	17(54.8%)	05(16.1%)	02(6.4%)		
Final Visit	11(35.5%)	17(54.8%)	02(6.4%)	01(3.2%)	7	

Table 7: Efficacy of treatment by 30% mandelic acid at various intervals

Table 7 shows efficacy of treatment by 30% mandelic acid at various intervals. It has been observed that the efficacy of treatment by 30% Mandelic acid. It was observed that among 31 patients, at first visit 3 (9.67%) patients had excellent outcome as compared to 11 (35.48%) patients at final visit with statistically significant difference (p<0.05).

Visit	Degree of Impr	P value			
	Excellent	Good	Fair	Poor	
1 st visit	03(9.7%)	10(32.2%)	13(41.9%)	05(16.1%)	
2 nd visit	03(9.7%)	12(38.7%)	12(38.7%)	04(12.9%)	0.03 (S)*
3 rd visit	05(16.1%)	14(45.2%)	09(29.0%)	03(9.7%)	
4 th visit	06(19.3%)	16(51.6%)	07(22.6%)	02(6.4%)	
Final Visit	09(29.0%)	16(51.6%)	04(12.9%)	02(6.4%)	

Table 8: Efficacy of treatment by15% lactic acid at various intervals

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Table 8 shows efficacy of treatment by 15% lactic acid at various intervals. It was observed that among 31 patients, at first visit 3 (9.67%) patients had excellent outcome as compared to 9 (29.03%) patients at final visit with statistically significant difference (p<0.05).

Visit	Degree of Improvement				P value
	Excellent	Good	Fair	Poor	
1 st visit	02(6.4%)	10(32.2%)	13(41.9%)	06(19.3%)	
2 nd visit	03(9.7%)	10(32.2%)	12(38.7%)	06(19.3%)	0.04 (S)*
3 rd visit	05(16.1%)	10(32.2%)	12(38.7%)	04(12.9%)	
4 th visit	06(19.3%)	13(41.9%)	09(29.0%)	03(9.7%)	
Final Visit	08(25.8%)	14(45.2%)	06(19.3%)	03(9.7%)	

Table 9: Efficacy of treatment by 10% TCA at various intervals

Table 9 shows efficacy of treatment by 10% TCA at various intervals. It was observed that among 31 patients, at first visit 2 (6.45%) patients had excellent outcome as compared to08 (25.81%) patients at final visit with statistically significant difference (p<0.05).

Degree of Improvement	Group A	Group B	Group C	P value
Excellent	11(35.5%)	09(29.0%)	08(25.8%)	
Good	17(54.8%)	16(51.6%)	14(45.2%)	
Fair	02(6.4%)	04(12.9%)	06(19.3%)	0.02 (S)
Poor	01(3.2%)	02(6.4%)	03(9.7%)	
Total	31 (100%)	31 (100%)	31 (100%)	

Table 10: Comparison of improvement in various treatments at final visit:

Table 10 shows comparison of improvement various treatment at final visit. It was observed that Group A (30% Mandelic acid) showed excellent efficacy compared to Group B (15% lactic acid) and Group C (10% TCA) with statistically significant difference (p<0.05).

Discussions

In recent years, facial cosmetic issues have been one of more commonly encountered in dermatology OPD. Dark circles around eyes in addition to facial ageing related dermatoses haverole of age, sex, racial predisposition. [1] Dermatologists often use chemical peels to treat a variety of skin conditions, including periorbital hypermelanosis (POH).

This prospective experimental study was conducted to compare the efficacy and safety of 15% lactic acid peel versus 30% mandelic acid peel versus 10% trichloroacetic acid in periorbital hypermelanosis.

In the present study, the mean age in group A was 32.13 ± 10.01 years, group B was 34.93 ± 11.23 , and group C was 35.28 ± 9.18 years. The three groups were uniform in age distribution and did not show any statistically significant difference in age distribution. (p> 0.05)

Brinda G. David et al, [13] in a clinical-epidemiological study on periorbital melanosis, observed that the majority of patients with periorbital hypermelanosis were in the age range of 1 to 35 years with a mean age of 30.3 ± 9 , 2 years. This result is consistent with the present study.

In the present study, out of a total of 93 patients, there were 20 (64.52%), 22 (70.97%) and 21 (67.74%) women in Group A, Group B and Group C, respectively.

There was no gender difference when three groups were statistically compared. (p > 0.05) Alberto Goldman et al (14) in a study on periorbital hypermelanosis observed among 74 patientswith IP, 64 women (86.5%) and 10 men (13.3%). Sheth et al [15] also reported such female preponderance in periorbital melanosis. The higher prevalence among women may be due to analleged increase in patient reports due to aesthetic problems.

The mean disease duration in group A was 1.42 ± 0.81 years, group B was 1.34 ± 0.72 years, and group C was 1.38 ± 0.85 years. The three groups were uniformly composed in terms of disease duration. (p> 0.05)

Brinda G. David et al [13] in a clinical-epidemiological study of periorbital hypermelanosis observed that most patients with periorbital hypermelanosis had it as a chronic problem, where they had the disorder for more than 1-3 years with a mean of 1.3 years ± 0.8 years.

In the present study, it was observed that there was no difference when three groups were statistically compared with respect to aggravating factors such as stress, sleep, sun exposure, etc. (p > 0.05)

Brinda G. David et al. [13] observed that factors of POH include watching television for more than 8 hours a day, refractive errors, sleeping less than 6 hours a day, habitual rubbing your eyes, familial

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tendency toward POH, associated systemic diseases such as anemia dysmenorrhea, and associated dermatoses such as atopic dermatitis had shown a strong association with development of this disease entity. According to Gathers et al,[7] emotional stress, fatigue, ageing process can play an important role in the development of POH. Ranu et al. also found that inadequate sleep to be an aggravating factor of POH in one study.[3]

The distribution according to the degree of POH shows, out of a total of 93 patients, 15 (48.39%), 14 (45.16%) and 15 (48.39%) patients with POH Grade 2 respectively in Group A,Group B and Group C. Degree of POH was similar in all three groups (p> 0.05).

Brinda G. David et al, observed that most commonly encountered was POH grade II (48.4%)followed by grade I (25.2%), grade III(23.2%) and least common was grade IV (3.2%).[13]

In the present study, out of a total of 93 patients, there were 15 (48.39%), 13 (41.93%) and 17 (54.83%) patients with epidermal type respectively in Group A, Group B and Group C. There wasno difference when three groups were statistically compared with respect to type. (p > 0.05) This finding was similar to the study conducted by Brinda G. David et al where most patients hadan epidermal type.[13]

The efficacy of 15% lactic acid treatment showed that among 31 patients, at thefirst visit 3 (9.67%) patients had an excellent result compared to 9 patients (29.03%) at the final visit with a statistically different significant. (p < 0.05)

Sharquie KE et al, observed statistically significant improvement in degree of skin pigmentationbefore and after application of Lactic acid when studying effect of peels on skin pigmentation. [16]

Ghazal Ahmed et al compared the clinical efficacy and safety of 20% glycolic acid (GA) and 30% lactic acid (LA) peels in POH.[17] 30% lactic acid peel on constitutional types of POH canbe used safely. Both 20% GA and 30% LA are useful in the aesthetic treatment of a constitutional type of POH, but three sessions of 30% LA peels at an interval of 3 weeks each appear to be more effective and satisfying than the 20% GA peel for the same duration.

The efficacy of 30% mandelic acid treatment showed that among 31 patients, at the first visit 3 (9.67%) patients had an excellent result compared to 11 (35.48%) patients at the final visit with a difference statistically significant. (p <0.05) It was observed that among 31 patients, in the first visit 2 (6.45%) patients had an excellent result compared to 08 (25.81%) patients in the finalvisit with a statistically significant difference. (p <0.05)

The efficacy of treatment with all three agents at the final visit showed that Group A (30% mandelic acid)

showed excellent efficacy compared to Group B (15% lactic acid) and Group C (10% TCA) with a statistically significant difference (p < 0.05).

Surabhi Dayal et al, in a study on examined safety and efficacy of 30% salicylic acid and 45% Mandelic acid in acne vulgaris in which it was revealed that although both are comparable clinically, later was associated with significantly less number of side effects.[12]

In the present study, it was observed that group C (10% TCA) shows only the side effect of burning between 2 patients at the 4th and 5th visits. Groups A and B show no side effects during the entire treatment.

Sharquie KE et al, in a study of chemical peels with lactic acid as a therapeutic modality, foundthat no side effects were recorded in all patients treated.[16]

Research done by Vinay Bhardwaj et al suggests that Lactic acid inhibits thetyrosinase enzyme; thus acting as de-pigmentary agent in the treatment of POH. It induces the skin lightening effect through three mechanisms, namely, the induction of desquamation of keratinocytes and the elimination of melanosomes; inhibition of tyrosinase; and thickening of the epidermis and dermis, so that blood vessels become less visible [20]

In a study conducted by Ho-Sup Lee et al in Asian patients, he observed that salicylic acid (SA)commonly used as exfoliating agent for acne vulgaris. Its whitening effect, as well as its effectiveness in POH commonly seen in patients with dark colored skin, this becomes an important factor in selection of chemical peels for Asian patients with POH.[18]

Rashmi Sarkar et al studied the effects of 35% Glycolic acid, 20% Salicylic acid and 10% Mandelic acid and Phytic acid in treatment of acne vulgaris and post acne pigmentation in whichshe revealed that all three peeling agents showed good results in treating acne ant it's pigmentation. Mandelic acid is ideal peeling agent of choice for sensitive skin as it penetrates the skin slowly and uniformly.[19] However it's efficacy and safety in POH has not been studied yet.

A study conducted in a dermatological clinic by Vavouli C et al evaluated the efficacy of a combination of 3.75% trichloroacetic and 15% lactic acid to improve periorbital hyperpigmentation. Almost all patients of study showed significant cosmetic improvement. Fair,good, or excellent response is seen in 96.7% of patients. Keratocoagulant action of TCA is usefulin treating many dermatological condition like photoaging, acne, pigmentary disorder, acne scarring.[10] Post peel side effects suchas mild erythema, frosting, dryness, burning were notedin some patients.

However, there were some limitations in our study.

First, the study period was relatively short, long-term studies are needed to know the maximum effect and to study the disease relapse activity with each of them. Secondly, this is a small series of patients treated with chemical peels, larger long-term prospective studies are needed to corroborate the results of our study.

Conclusion

The present study concludes that 30% Mandelic acid has an excellent efficacy compared to 15% lactic acid and 10 % TCA. There is no significant difference in the efficacy of 15% lacticacid and 10% TCA. 30% Mandelic acid can been used in the treatment of common skin problems, including POH with minimal side effects.

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