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Original Research Article

Clinical efficacy and safety of 20% glycolic acid versus 30% lactic acid peel in constitutional type of periorbital melanosis: a comparative study

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ABSTRACT

Background: Periorbital melanosis (POM) is a common aesthetic condition with significant impact. Chemical peeling is a frequently used treatment; yet, an ideal peeling agent is however to find. The aim of the study was to compare the clinical efficacy and safety of 20% glycolic acid (GA) and 30% lactic acid (LA) peels in POM.
Methods: With approval and consent, the study was conducted from September 2016-August 2017. Patients aged 18-60 years of both sexes, having a constitutional POM were enrolled. Patients known to be allergic to the peeling agents were excluded. Alternate patients were enrolled into Gr-G (20% GA) and Gr-L (30% LA) and were treated every 3 weeks, for 3 sessions and evaluated till 9 weeks. Clinical improvement using POM grading, patients' global assessment, satisfaction, and physician's global satisfaction were noted. Data are presented in number, percentages and mean±standard deviation. INSTAT software was used for statistical analysis; $p<0.05$ was considered significant.
Results: Fifty-six (27 in Gr-G, 29 in Gr-L) were enrolled; 70.37% and 68.97% completed the study. Demographic variables, baseline POM grade, and skin types were similar. Compared to baseline, both Gr-G and Gr-L showed significant improvement ($p<0.0001$). Patient-reported significantly higher improvement in Gr-L ($p=0.008$) and higher satisfaction. Both the peeling agents were tolerated well with statistically indifferent adverse effects.
Conclusions: Both GA and LA are useful in the aesthetic treatment of the constitutional type of POM. Three sessions of 30% LA peel appears to be better than 20% GA peeling used at 3 weeks apart.

Keywords: Periorbital hyperpigmentation, Infraorbital dark circles, Chemical peeling, Alfa hydroxyl acids, Therapy, Effectiveness, Adverse effects

INTRODUCTION

Face being the center of attraction where eyes are a prominent feature; it is an area of important cosmetic concern. A hyperpigmented lesion in the face is usually not well accepted and is one of the most common aesthetic complaints among patients. It also affects the person psychologically.[1] Periorbital melanosis (POM) is defined as bilateral, homogenous, hyperchromic macules and patches around the eyes.[2] It makes a person look fatigued and dull, and cause significant impairment of quality of life, especially in women. In spite of being a common aesthetic condition, there is no definite treatment modality yet.[3]

The use of chemical peels is a well established and safe procedure in the hand of an educated practitioner. It not only reduces the hyperpigmentation but also improves the texture of the skin and wrinkling of the skin.[4] A wide variety of agents have shown to be effective in superficial

peeling. The α-hydroxy acids (AHA) are one of them and are popular and well established in dermatological practice. Glycolic acid (GA) penetrates the skin quickly, making it a favorite peel agent and is the most common AHA peel in clinical use.[5] Low strength Lactic acid (LA) has the properties of an AHA with a moisturizing effect.[3] This can make it as one of the safest peel for periorbital region and strength of 30% to 50% can be used in the face.[3] According to a recent study, physician and global patient assessment were excellent with 20% GA followed by 15% LA peel.[6] Both GA and LA belongs to the AHA group and facilitate progressive weakening of cohesion of the intercellular material of the stratum corneum, resulting in regular exfoliation of its outermost layers of the skin. A study comparing the clinical efficacy of periorbital peeling with 20% GA and 30% LA is rare or absent. The present study was aimed to evaluate the clinical effectiveness and safety of 20% GA and 30% LA peeling in a constitutional type of POM.

METHODS

This non-randomised, clinical, comparative, pilot study was conducted with approval from the institutional ethical committee (32/IAEC/IEC, RIMS-Ranchi) in a tertiary care teaching hospital from September 2016 to August 2017. POM (constitutional type) patients seeking consultation in the outpatient department (OPD) were approached for enrolment. Consented patients, aged 15-60 years of both sexes, with a reasonable understanding of either of English, Hindi or Bengali language were included. A skin sensitivity test was done and patients having hypersensitivity to the allotted peel were excluded.

Diagnosis of POM was made based on detailed clinical history, examination and laboratory tests as required. After applying inclusion and exclusion criteria and obtaining informed consent, sixty patients of constitutional POM were approached for enrolment for 9 weeks; 30 patients in each group (i.e., 20% GA; Gr-G and 30% LA; Gr-L). Both the peels were from Mesoestetic UK/Wellness Trading Ltd, Cheshire, United Kingdom. The alternate consented patient was allotted to each group. As there was a lack of guiding previous data to calculate sample, the present study was designed as a pilot study with 30 patients in each group.

Both Gr-G and Gr-L patients underwent 3-weekly treatment (total 3 sitting; i.e., 0 weeks, 3rd and 6th week) with respective agents. Both the groups were advised to apply topical vitamin C daily as maintenance therapy during the study period of 9 weeks. At the end of the 9th week, final readings were taken, and the study was terminated for that patient. The process is presented in the flowchart (Figure 1). Data of the present study was collected using both a questionnaire and observation based method. Patients were handed over the questionnaire in English and were requested to answer the questions after each session and also after the follow-up period. The participants who were unable to understand the items properly, the study investigators were available to assist the participants in clarifying doubts so that they can complete the questionnaire. Patients had to select either the most appropriate option according to him/her or multiple options as per instructions. Those patients who were unable to read or understand the questionnaire in English were helped by the medical team in the translated language (Hindi and Bengali only). The English version of the questionnaire was converted into the local and Hindi language by using modified World Health Organization method.[7] Over and above demographic data, data were collected in context to POM grading (baseline and after treatment), patient satisfaction and tolerance to the agent and procedure, and physician assessment and classification of the outcome. Clinical improvement was assessed objectively using POM grading (i.e. Grade 0-skin colour comparable to other facial skin areas, Grade 1-faint pigmentation of infra-orbital fold, Grade 2-pigmentation more pronounced, Grade 3-deep dark colour, all four lids involved, and Grade 4-grade 3 plus pigmentation spreading beyond infra-orbital fold).

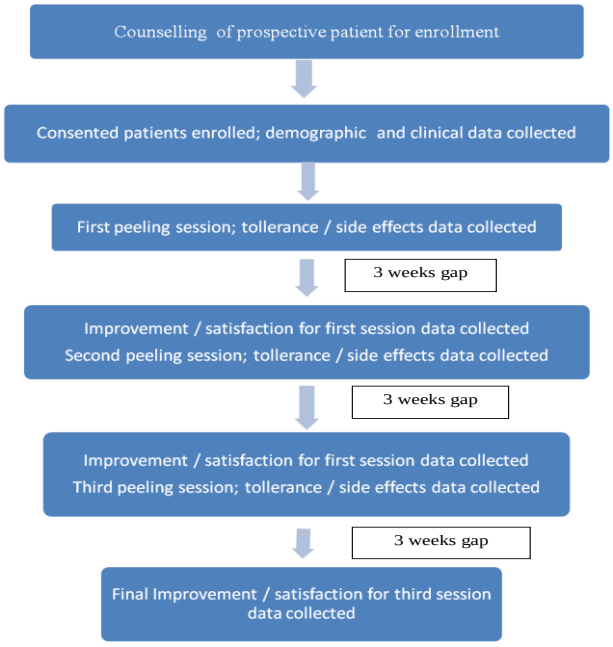

Figure 1: Enrollment and data collection sequences.

All data in context to the above parameters were entered in data collection format designed for this study and subsequently in Microsoft Excel (Microsoft Corporation, USA) as a master chart. Age, weight, height, etc. were noted to the nearest unit (years, kilogram and centimeters respectively). Qualitative data/descriptive responses/ categorical data were expressed in absolute numbers and percentage scale for each answer. Mean median, standard deviation (SD) and 95% lower and upper limits were

calculated for continuous variables using the unpaired t-test. Data were also compared among the groups for differences using Fisher's exact test. Pre and post-treatment comparison was made using students t-test. The INSTAT software (GraphPad Prism Software, La Jolla, California, USA) was used for the statistical tests and $p<0.05$ was considered significant.

RESULTS

Fifty-six [mean±standard deviation (SD) age of 31.41±9.06 years] out of the 60 patients counseled, were enrolled for the study but a total of 39 patients completed the study. The sampling tree for recruitment analysis process has been shown in Figure 2. The patients enrolled in the Gr-G (n=27) and Gr-L (n=29) and the patients who completed the study in Gr-G (n=19) and Gr-L (n=20), were comparable with no statistical significant difference in terms of demographic and clinical profiles, except the patients of the Gr-L, who completed the study were having significantly higher duration of POM (Table 1).

Thirty-nine (69.64%) completed the three sitting of peeling treatment and follow up in the respective groups (19 in Gr-G and 20 in Gr-L) and were analyzed for efficacy and safety. Six (15.38%) patients were male with male-female ratio 1: 5.5. The numbers of male patients were slightly higher in the Gr-L as compared to Gr-G, but, this difference was not significant; p=0.661. The mean age, weight, height, and body mass index (BMI) of the Gr-G and Gr-L, who completed the study were also comparable (Table 2).

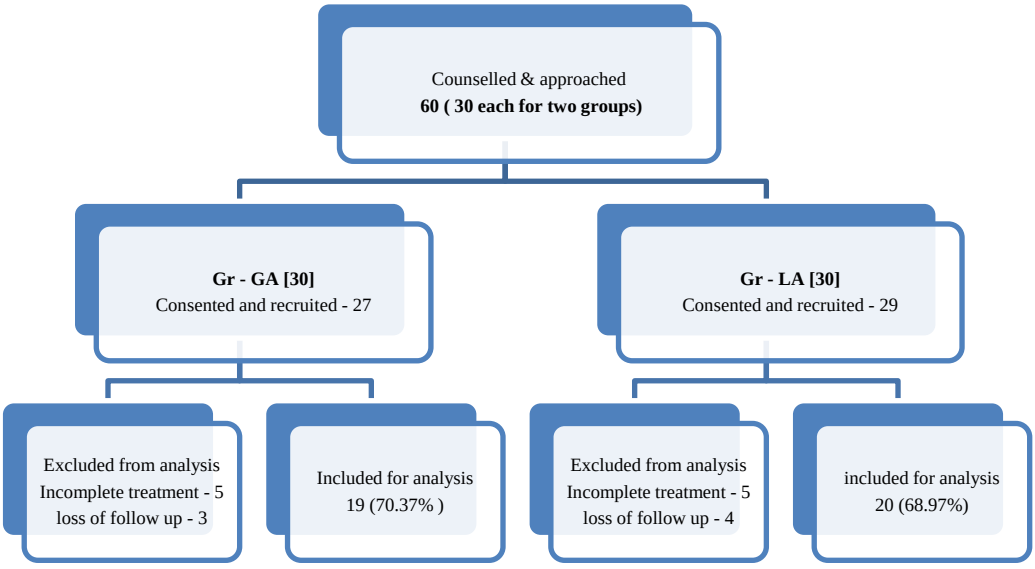

Figure 2: Hierarchy flow chart of sampling and analysis tree of the cohort.

Table 1: Comparison of clinical profile and risk factors.

Clinical profile and risks	Gr-G (n=27) N (%) / mean±SD#	Gr-L (n=29) N (%) / mean±SD#	Two tailed p value
Enrolled patients	**(n=27)**	**(n=29)**	
Duration of problem# (year)	4.03±2.32	5.03±2.50	0.128
Family h/o POM	11 (40.74)	16 (55.17)	0.300
Stress factors	11 (57.89)	13 (65.0)	0.792
Sleep deprivation	15 (55.56)	20 (68.97)	0.408
Previous other treatment	12 (44.44)	16 (55.17)	0.593
Demarcation line (f line)	14 (51.85)	14 (48.28)	1.000
Final analysis	**(n=19)**	**(n=20)**	
Duration of problem# (year)	3.63±2.52	5.45±2.62	0.033
Family h/o POM	8 (42.11)	12 (60.0)	0.343
Stress	11 (57.89)	13 (65.0)	0.747
Sleep deprivation	12 (63.16)	14 (70.0)	0.741
Previous other treatment	8 (42.11)	10 (50.0)	0.751
Demarcation line (f line)	6 (31.58)	5 (25.0)	1.000

(Gr-G– glycolic acid, Gr-L– lactic acid, POM- periorbital melanosis, N– total number, n- number, SD– standard deviation) # Unpaired t test.

Table 2: Comparison of demographic parameters.

Parameters	Gr-G (n=19)		Gr-L (n=20)		Two tailed p value
	Mean±SD	95% CI	Mean±SD	95% CI	
Age (year)	32.42±10.29	27.45–37.38	30.35±9.30	25.99–34.70	0.513
Weight (Kg)	56.84±10.85	51.61–62.07	57.80±10.47	52.89–62-70	0.780
Height (cm)	160.37±4.79	158.06–162.68	158.95±5.64	156.31–161.59	0.404
BMI (Kg/m^2)	21.99±3.41	20.34–23.64	22.75±3.04	21.32–24.18	0.467

(Gr-G–glycolic acid, Gr-L–lactic acid, N- total number, SD–standard deviation, CI–confidence interval, BMI–body mass index).

Table 3: Central tendencies and dispersions of skin types (Fitzpatricks class) and POM grades.

Parameters	Gr-G (n=19)	Gr-L (n=20)	Two tailed p value
Skin type			
Range	3–5	3–5	0.549
Median/IQR (q3-q1)	4 / (5–4)	4 / (4–4)	
Mean±SD	4.157±0.60	4.05±0.51	
95% CI	3.868–4.448	3.81–4.289	
POM grade			
Range	1–4	1–4	0.271
Median / IQR (q3-q1)	3 / (3–2)	3 / (4–2)	
Mean±SD	2.63±0.95	2.95±0.825	
95% CI	2. 17–3.09	2.56–3.33	

(Gr-G– glycolic acid, Gr-L– lactic acid, N- total number, IQR– inter quartile range, SD– standard deviation, CI– confidence interval, POM–periorbital melanosis).

Table 4: Comparison of subjective improvement as cited by patient in objective scale of zero to 100%.

Observation after 3 weeks of peeling session	Gr-G (n=19)		Gr-L (n=20)		Two tailed p value
	Mean±SD	95% CI	Mean±SD	95% CI	
First	17.89±6.93	14.55–21.23	37.75±11.15	30.53–40.97	< 0.0001
Second	41.31±16.57	33.32–49.30	56.25±7.58	52.69–59.80	0.0008
Third	62.36±19.17	53.12–71.61	74.75±5.49	72.17–77.32	0.008

(Gr-G– glycolic acid, Gr-L– lactic acid, N- total number, SD– standard deviation, CI– confidence interval).

Table 5: Comparison of subjective improvement and satisfaction.

Observation after 3 weeks of peeling session	Gr-G (n=19)	Gr-L (n=20)	RR (95% CI)	Two tailed p value
	N (%)	N (%)		
Subjective improvement				
None	0	0		
Slightly	2 (10.53)	0	0.285 (0.092–0.88)	0.487
Moderately	10 (52.63)	3 (15.0)	2.30 (1.24–4.27)	0.018
Greatly	7 (36.84)	17 (85.0)		0.003
Patient's satisfaction				
Not satisfied	0	0		
Slightly	2 (10.53)	0	0.0	0.230
Moderately	8 (42.10)	3 (15.0)	0.356 (0.11–1.14)	0.082
Greatly	9 (47.37)	17 (85.0)	1.79 (1.07–2.98)	0.018
Physician's satisfaction				
Not satisfied	0	0		
Slightly	3 (15.79)	0	0.0	0.106
Moderately	12 (63.16)	7 (35.0)	0.55 (0.27–1.10)	0.112
Greatly	4 (21.05)	13 (65.0)	3.088 (1.22–7.81)	0.009

(Gr-G– glycolic acid, Gr-L– lactic acid, SD– standard deviation, CI– confidence interval, RR– relative risk, N– total number, n-number).

In the present study, the predominant skin types (Fitzpatrick class) in both the groups were type 4 (63.16% vs. 75% in Gr-G and Gr-L respectively). On the other hand, the most common grade of POM in the Gr-G was grade 2 (36.84%) while in the Gr-L it was grade 3 (50%). However, distributions of both the skin types and POM grade in the Gr-G and Gr-L were not statistically different (Table 3).

The improvements were progressively increasing with subsequent peeling sessions in both groups. However, the improvements cited in Gr-G after peeling sessions were low and increasingly variable as compared to Gr-L. The mean values of the improvements mentioned after each peeling sessions were significantly lower in Gr-G as compared to Gr-L (Table 4).

While the majority of the patients of Gr-L felt that the treatment significantly improved the disease, most of the patients of Gr-G cited improvement as moderate ($p<0.05$). The satisfaction of the patient as well as the physician was also higher with Gr-L (Table 5).

Figure 3: Pre (upper row) and post (lower row) treatment in glycolic acid group.

However, both the peeling agents were effective in treating the condition (Figure 3 and 4). The post-treatment POM grade was lower than the pre-treatment POM grade in both the groups; 2.63±0.95 vs 1.368±0.83 for Gr-G; $p<0.0001$ and 2.95±0.825 vs 1.25±0.55 for Gr-L; $p<0.0001$. The post peeling POM grades of Gr-G were not statistically different from Gr–L (Median / IQR (q3–q1) was 1/(2-1) for both; p=0.601). Mean satisfaction in a scale of zero to 100 was progressively increasing with each peeling and the Gr-L had more mean satisfaction than Gr-G (Figure 5).

Figure 4: Pre (top row) and post (lower row) treatment in lactic acid group.

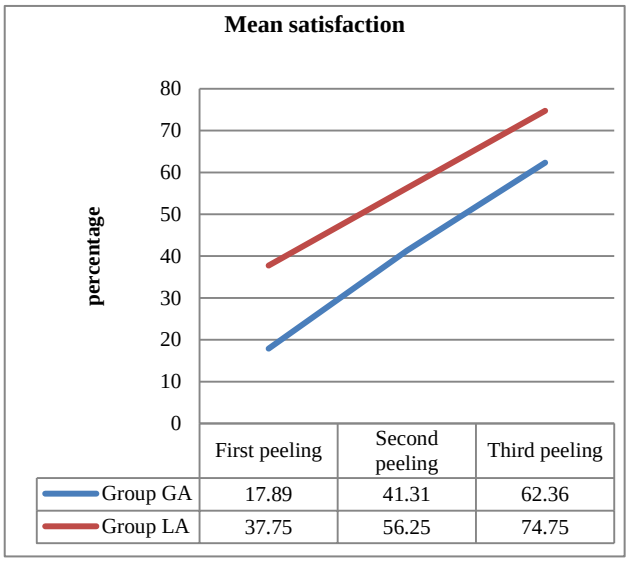

Figure 5: The trend of mean satisfaction in percentage in a scale of zero to 100%.
(Gr-G– glycolic acid, Gr-L– lactic acid).

Both the peeling treatments were well tolerated by the patients. Although the frequencies of minor complications were higher in the Gr-G as compared to the Gr-L, the differences were not statistically significant (Table 6).

Table 6: Comparison of minor complications using Fisher's exact test.

Complications	Gr-G (n=19) N (%)	Gr-L (n=20) N (%)	RR (95% CI)	Two tailed p value
Erythema	8 (42.11)	4 (20.0)	0.47 (0.17–1.32)	0.176
Burning	12 (63.16)	11 (55.0)	0.87 (0.51–1.47)	0.747
Tearing	3 (15.79)	0	0.0	0.106
Pain	1 (5.26)	0	0.0	0.487
Transient darkness	2 (10.53)	0	0.0	0.230
Scaling	4 (21.05)	1 (5.0)	0.23 (0.029–1.93)	0.181

(Gr-G–glycolic acid, Gr-L–lactic acid, N- total number, RR– relative risk, CI– confidence interval, n– number).

DISCUSSION

POM is not just an aesthetic problem but is associated with mental health and wellbeing. It makes the person look tired or older, which negatively affects their quality of life.[1] In a single-center, cross‑sectional study, POM was found to be prevalent in nearly one-third of the patients who attended for dermatologic consultations.[8] Lifestyle and physiological factors are associated with POM; family history is the most significant risk factor.[8,9] It is also typically associated with sleep deprivation. Faulty habits like cosmetic use, eye rubbing and lack of correction for refractive errors were frequently observed in the patients of POM. In the present study, a good number (48.21%) of patients were having a family history of POM. However, the prevalence of family history of POM was slightly lower (48.21% versus 63%) in our study participants as compared to the study conducted by Seth et al.[8] In the present study, although we have collected the data for comparing the prevalence of different risk factors among the risk, association of risk factors with POM was not done as it was not our objective.

POM is said to affect all age groups and both genders equally.[1] But, in clinical practice, the same is not represented as evident from the study of Seth et al, and David et al.[8,10] Female was more than male among the patients and also the patients were of younger age. In the present study too, a very high number of female patients were found as compared to male, and most of the patients were in relatively younger in age. The higher number of female patients in the cohort may be due to a presumed increase in reporting by female patients because of their cosmetic concern. Most of the patients of the present study in both the groups were in the age group of 18–35 years, which also indicates so by representing the group which is most aesthetically concerned. The finding of younger patients mostly in the age group of the third decade in the present study is also indirectly supported by the study conducted by Matsui et al, where they found that the average age of onset was 24 years.[9] The average age of the patients who were recruited (n=56) was 31.4 years with a range of 19–57 years in the present cohort. The average duration of the problem (POM) among the recruited participants was 4.55 years. These indicate that the average age of onset for the POM was 26.85 years which is nearly similar to the finding of a Brazilian study.[9] POM has also been described as an extension of pigmentary demarcation line-f on the face and stated that they are not two different conditions; rather are two different manifestations of the same disease.[11] In a total of 92% of patients' POM was found as an extension of pigmentary demarcation line over the face (PDL-F) by Malakar et al.[11] In the present study, f-line was found in 22 out of 56 total patients recruited for the study. This number is however very less as compared to Malakar et al study (39.29% versus 92%).[11] This difference is probably because Malakar et al in their study used woods lamp examination and biopsy too for diagnosis of POM.[11]

Although POM is a worldwide prevalent and frequently encountered cosmetic problem, a PubMed search results in only a few literature in context to the treatment of POM. This indicates that the therapeutic aspect is not well addressed by the health care providers yet. However, the use of multiple agents and techniques has been described. Autologous fat transplantation, collagenase-digested fat cell grafts, LASER, platelet-rich plasma, etc., for the treatment of infraorbital dark circles/POM, has been reported with limited success.[12-16] Topical application of different agents have also been used in the treatment. Such agents are phytonadione, retinol, and vitamin C, vitamin E etc.[17] Microneedling and carboxytherapy have also been used for the treatment of periorbital dark circles.[18]

There is no doubt that cosmetic dermatology is a new and growing branch of medical science, but the cosmetic concern of skin is ancient among the humankind. The Ebers papyrus describes the earliest report of using caustic preparation for peeling procedures in Egyptian medicine nearly 3500 years ago.[19] The ancient Egyptian women used to improve their skin by using animal oils aesthetically, alabaster, sour milk etc.[20,21] Peeling or exfoliative agents like phenol, resorcinol, trichloroacetic acid (TCA), etc. were in clinical use from the 1880's; nearly a century before the introduction of AHA.[21] Tilbury fox described the effect of 20% phenol for lightening the skin in 1871. In 1882, a German dermatologist, Unna described the properties of salicylic acid, phenol, resorcinol, and TCA.[21] However, the modern-day chemical peeling in aesthetic practice can be said as just a few decades old. The booming use of AHA in the 1990s is probably the beginning of the modern-day chemical peeling. Uses of LA, GA and TCA peels have been described.[22,6]

The concentrations used for peeling has also remained variable from study to study. This is probably because clinicians/researchers are yet to find the optimal concentration and dose for different drugs. Insufficient studies are comparing different agents for the POM. A relatively recent study compared three agents for safety, efficacy, and tolerability.[6] The authors compared 20% GA with 15% LA and vitamin C in 90 patients of constitutional POM. The study duration was 12 weeks. One-third of patients underwent 3-weekly GA peel, another one-third underwent 3-weekly LA peel, and the rest one third applied topical vitamin C daily. Clinical improvement was assessed objectively using POM grading. It was found that 73.34% of patients on GA peel group, 56.67% on LA peel group, and 26.67% on topical vitamin C peel group had more than 50% improvements in their POM. In another study, the efficacy of chemical peels using 3.75% TCA and 15% LA in a gel formula was compared with carboxytherapy, in the treatment of periorbital hyperpigmentation.[18] There was a significant improvement in both groups. The degree of improvement in the group treated with 3.75% TCA and 15% LA

peeling therapy was excellent, with a good grade in 93.4% of the treated.

In the present study, 18.52% of Gr-G and 17.24% of Gr-L did not complete three sessions of peeling while 11.11% of Gr-G and 14.81% of Gr-L was lost in the last follow up. As the total dropouts were relatively high, it was decided to exclude all the dropouts and analyze the data obtained from the participants who completed the study up to the last follow up. All the patients were having Fitzpatrick skin type of III, IV or V. Majority of the patients in either of the group had type 4 skin phototype which was comparable and without significant difference. An absence of type 1 and 6 patients is explained by the patient cohort where the study was done (i.e., India) where extreme dark skinned and white skinned peoples are very rare. The baseline POM grading, risk factors like sleep deprivation, stress, and family history were also similar among the groups which indicate that the patients compared were having a minimal bias if any among them and compare. However, the duration of POM was higher in Gr-L as compared to Gr-G.

In the present study, both the peeling agent was found to be effective in reducing the POM grade severity. This finding is similar to the result obtained by Dayal et al.[6] There was a progressively increasing improvement with every sitting of peeling in both the groups. Nearly 90% of the GA group and a hundred percent of LA group patients were either moderately or significantly happy with the results. In the present study, however, LA group patients reported more improvement than the GA group both in an objective score of zero to 100% as well as global satisfaction in terms of subjective scales. This is on the contrary to the finding of Dayal et al. In their study Dayal et al, after the 3 peeling sessions over 12 weeks, they found that GA peel was significantly more effective than LA peel from 12 weeks onward.[6] This difference may be attributed to the difference in the strength of LA used; 30% LA was used in the present study while in the mentioned study, 15% LA was used. Although in the present study found more improvement and satisfaction among LA peeling group of patients, the post three sittings peeling POM grades among the groups were not statistically significantly different.

In context to the adverse effects noted, the incidence was more with GA peel as compared to LA peel in the present study. This overall finding was however similar to the study conducted by Dayal et al.[6] They also found that the numbers of adverse effects were highest in the GA group followed by LA and it was lowest in the topical vitamin C group.[6] However, when compared the noted individual adverse events, it was found that erythema was the most common adverse events noted by the study Dayal et al but, in the present study, the most frequent complication reported by the patients in both the groups was burning sensation.[6] Although the absolute numbers or percentages of adverse effects were higher in the GA group than the LA group, the differences were not statistically different.

The present study is however limited to the facts that, it is a single center study. The participant allocation was not randomized, and the sample size was also relatively small. A good number of patients were also lost during the follow-up. Therefore, Fisher's exact test was used for comparisons with two-tailed p-value calculation which can give precise results with even smaller sample sizes. The dropouts were also taken out entirely from the evaluation of improvement and satisfaction. If we compare however with the most other studies conducted in the same field, we can easily find that almost all studies are performed with a sample of 15 to 30 patients in each group. Although, this sample size cannot give an adequately powered study to find the differences between the peeling agents like GA and LA, the finding of the present study however strongly indicates that the 30% LA is well effective in the treatment of POM and if not more, it is equally effective in the efficacy as compared to GA. So, a study with a higher sample with randomized allocation can probably answer this question better in the future.

CONCLUSION

Lactic acid 30% peel in the constitutional types of POM can be safely used. Both 20% GA and 30% LA are useful in the aesthetic treatment of a constitutional type of POM, but three sessions of 30% LA peel at an interval of 3 weeks each appears to be more effective and satisfying than 20% GA peeling for the same duration.

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