



Microneedling delivery of latanoprost versus microneedling delivery of 5-fluorouracil and microneedling delivery of Trichloroacetic acid 35% in the treatment of stable Vitiligo

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ABSTRACT

Background: Vitiligo is a chronic autoimmune skin disorder characterized by depigmented skin regions caused by a loss of melanocytes. Although vitiligo's origin is unknown, environmental, immunological, and genetic factors are involved. In treating vitiligo, microneedling is an effective adjuvant that improves the administration and effectiveness of medications such as trichloroacetic acid, 5-fluorouracil, and latanoprost. There is currently little data regarding the combination that is both safe and effective. This study aimed to compare the efficacy of microneedling delivery of latanoprost versus microneedling delivery of 5-fluorouracil and microneedling delivery of Trichloroacetic acid 35% in induction of skin re-pigmentation in stable vitiligo. **Methods:** This non-randomized controlled clinical trial was conducted on 54 patients, 18-60 years old, with stable vitiligo. They were divided into; Group (A) patients treated with dermapen followed by 5% 5-fluorouracil, Group (B) patients treated with dermapen followed by latanoprost, and Group (C) patients treated with dermapen followed by Trichloroacetic acid 35%. **Results:** There was an increase in excellent response among the group compared to B&C but without statistical significance. Also, there was no statistically significant difference between the studied groups in time of starting response. There was an increase in the frequency of very satisfaction among group A compared to B&C but without statistical significance. **Conclusion:** The combination of microneedling with either 5-Flourouracil or latanoprost or Trichloroacetic acid 35% is safe and effective in treatment of localized stable vitiligo. The degree of improvement was higher with 5- 5-fluorouracil than with latanoprost and Trichloroacetic acid 35%.

Keywords: Microneedling, latanoprost; 5-fluorouracil; Trichloroacetic acid 35%; Vitiligo.

INTRODUCTION

A frequent autoimmune condition affecting 0.1% to 2% of the population is vitiligo [1]. Vitiligo is a progressive condition characterized by the loss of functioning

melanocytes due to cell death confluence of various factors affecting melanocyte survival and function. It is currently unclear what precise pathophysiologic process causes melanocytes to be destroyed [2]. Significant

psychological and social stigma is linked to vitiligo, particularly for people with dark skin phototypes [3].

Treatment of Vitiligo aims to achieve two primary goals: re-pigmentation of the affected areas and stabilization of the condition to prevent further depigmentation [4]. Surgical treatments are considered for individuals with persistent vitiligo who don't react well to medication therapies [5]. Medical treatments for vitiligo primarily involve topical and systemic therapies designed to modulate the immune response, stimulate melanocyte activity, and promote re-pigmentation [6].

Microneedling is a low-impact therapy that is currently being utilized to treat various dermatologic disorders, such as vitiligo, which is considered a safe and effective technique either by itself or in conjunction with additional therapies such as topical 5-Fluorouracil, latanoprost, or 35% trichloroacetic acid in the treatment of vitiligo[7].

Five-fluorouracil, sometimes known as 5-FU, is a pyrimidine analog antimetabolite. Fluorouracil is classified as a cell cycle-specific drug that specifically targets the S phase of cell division. Activity arises from the conversion of a substance into an active form in the body's tissues, leading to the inhibition of DNA and RNA production [8].

Latanoprost is a Prostaglandin F₂-alpha [PGF₂α] analogue is administered to treat glaucoma. Its use in dermatology, particularly in treating vitiligo, is an emerging area of interest. When combined with microneedling, latanoprost shows potential benefits for re-pigmentation in vitiligo

patients. It can stimulate melanocyte activity and melanogenesis. It increases the synthesis of melanin by melanocytes and enhances their migration and proliferation [9].

The use of Trichloroacetic Acid (TCA) 35% for treating vitiligo the concept is relatively recent, and just a few research have investigated its efficacy as a therapy option. Trichloroacetic acid (TCA) causes chemical damage that leads to pigmentation around the hair follicles and also stimulates pigmentation around the affected area [10]. The peeling action can stimulate melanocyte activity, encouraging the migration and proliferation of melanocytes from surrounding normal skin or hair follicles into depigmented areas. TCA peeling may reduce local inflammatory responses and alter the local immune environment, potentially reducing the autoimmune attack on melanocytes in vitiligo [11].

To our knowledge this work has not been done before in the Faculty of Medicine, Zagazig University. Therefore, the objective of this study was to evaluate and compare the efficacy of microneedling administration of latanoprost with microneedling administration of 5-fluorouracil and microneedling administration of Trichloroacetic acid 35% in promoting skin re-pigmentation in individuals with stable vitiligo.

METHODS

This non-randomized controlled clinical trial was conducted in Dermatology, Venerology, and Andrology Department, at Zagazig University Hospitals. This study included 54 Egyptian patients, 18-60 years old, with stable vitiligo. All patients who participated in the trial provided informed permission, as

required by the study protocol. The Zagazig University Institutional Review Board approved (IRB# 11055-30-8-2023). The presented work research has been carried out in compliance with the World Medical Association's Code of Ethics (Declaration of Helsinki) for studies involving human participants.

Inclusion criteria: Individuals with localized and consistent vitiligo, aged between 18 and 60 years. Patches should not have any increase or decrease in size or pigmentation for at least 6 months.

Exclusion criteria: Patients who had undergone any form of local or systemic treatment for vitiligo for a minimum of three months before the participants who underwent the trial were not included in the study. An exploration of the historical development of the Koebner phenomenon in pregnant or lactating women.

Sample size: Assuming the frequency of excellent re-pigmentation was 46.7% vs 6.7% in intervention, fluorouracil group, and microneedling delivery of Trichloroacetic acid 35%. At 80% power and 95% CI, the estimated sample was 54 cases, 18 cases in each group. Open Epi

Group (A): 18 patients Subjected to dermapen treatment, followed by the application of 5% 5-fluorouracil.

Group (B): 18 patients treated with dermapen followed by latanoprost.

Group (C): 18 patients treated with dermapen followed by Trichloroacetic acid 35%.

All patients enrolled in the study underwent the requested information including a detailed record of the user's medical background and particular details

about their disease, such as how it started, how it has developed over time, how long it has been present on an annual basis, where the lesions are located and how many there are, any previous treatments they have undergone, and whether there is a family history of vitiligo or other autoimmune disorders. A comprehensive clinical examination, including a thorough dermatologic assessment with specific attention to skin phototypes (Fitzpatrick types I, II, III, IV, V, and VI), hair, nails, oral mucosa, and anatomical locations affected by vitiligo, such as the head and the anatomical regions mentioned include the neck, trunk, upper extremities, lower extremities, hands, and feet.

Steps of the procedure: Photo-taking before treatment and during follow-up and after treatment by camera mobile. The assessment of the treatment was conducted using images that were captured at the first stage and during each subsequent visit for monitoring. The treatment was performed following the use of a topical anesthetic cream called Neo-cain cream, which contains 10.56% lidocaine. The cream was left on for 30 minutes, and then the affected region was sterilized using 70% alcohol. The vitiliginous region was treated using a dermapen, with uniform vertical strokes until pinpoint bleeding was noticed. Following the dermapen procedure, a 5% solution of 5-fluorouracil was administered to the patch in group A, while a latanoprost drop was put to the patch in group B. Both patches were covered with an occlusive covering and TCA 35% on patch in group C under occlusive dressing. This session was done every two weeks for three months.

Assessment vitiligo area severity index: The extent of vitiligo involvement was quantified in terms of hand units. One hand unit approximately represented 1% of the total surface area of the body. The pigmentation level was approximated to the nearest value from the available possibilities. 1-(percentages:100% - complete depigmentation. No pigment was observed in category 1. In category 2, there were 90% flecks of pigment present. In category 3, the depigmented area exceeded the pigmented area by 75%. In category 4, the pigment and depigmented areas were equal, each accounting for 50%. In category 5, the pigmented area exceeded the depigmented area by 25%. Finally, in category 6, only specks of depigmentation were visible, making up 10% of the area.

The Vitiligo Area Scoring Index (VASI) was determined by multiplying the extent of vitiligo in hand units by the degree of depigmentation inside each assessed patch. The abbreviation "VASI" stands for "Visual Approach Slope Indicator." In this case, the whole body VASI is indicated as "S." Every part of the body {Manual Units} *{Residual depigmentation}

STATISTICAL ANALYSIS

The data were imported into the statistical software SPSS version 27.0 Program to be examined [12]. The data was analyzed using qualitative methods to depict numbers and percentages, while quantitative methods were used to analyze groups represented calculated using the mean plus or minus the standard deviation. The following tests were employed to ascertain the importance of disparities: Utilize the Chi-square test (X²) in a paired manner to ascertain the disparity and

correlation of the qualitative variable. The significance level was set at <0.05 for results considered significant and <0.001 for results considered highly significant. The Kruskal-Wallis test is employed to compare multiple groups when analyzing quantitative variables evaluated are not regularly distributed. The significance level was established at a threshold of $P < 0.05$.

RESULTS

As shown in Table (1), this study showed the mean age values for Groups A, B, and C were 29.17, 27.5, and 28.33, respectively. There were no statistically significant differences seen between the groups being investigated in terms of age or sex distribution.

As shown in Table (2), regarding the predisposing factors 5.6% of patients in Group (A), and 11.1% of Patients in Group (B) had a favorable family history, but none of the patients in Group (C) had a positive family history. As regards exposure to stress, 88.9% of patients in Groups (A), 88.9% of patients in Groups (B), and 88.9 % of patients in Groups (C) Had a favorable history of being exposed to stress. No statistically significant difference was found between the groups being assessed in terms of family history or exposure to stress.

As shown in Table (3), Concerning the allocation of skin types based on the Fitzpatrick scales, the distribution among groups is as follows: The distribution of elements III, IV, and V in group A was 11, 5, and 2 respectively. In group B, the distribution was 10, 6, and 2. Lastly, in In group C, the distribution was 6, 9, and 3. There was no statistically significant variation

in skin type observed among the studied groups.

As shown in Table (4), disease duration ranged from 0.58 to 19 years with a median of 3 years and a mean of (4.53±4.47) in group (A), The age range varied from 1 to 19 years, with a median age of 2.5 years and a mean age of (3.89±4.34) in a group (B) and ranged from 0.5 to 26 years with median 2 years and mean of (3.63±5.89) in group (C) with insignificant difference between groups. The data shown in this table indicates that there were no statistically significant variations seen among the groups being evaluated in terms of disease duration, kind, and site.

As shown in Table (5), there was an increase in excellent response, with response >75% No statistically significant difference was seen between Group A and Groups B and C. Moreover, no statistically significant disparity was found between the groups being examined for the initiation time of the response.

According to the data presented in Table (6), No statistically significant differences were identified between the tested

groups in terms of frequency of burning sensation, hyperpigmentation, and pain.

Table 7 demonstrates a rise in the occurrence of high satisfaction within Group A in comparison to Groups B and C, however, this difference lacks statistical significance.

Case Presentation

Case 1; A female patient, 22 years old, had Vitiligo for eleven years and was treated by 6 sessions of micro-needling followed by 5-fluorouracil(A; before, B; inter the session, C; after treatment and D; follow up).

Case 2; A female patient, 33 years old, had Vitiligo for five years and was treated by 6 sessions of micro-needling followed by Trichloroacetic acid 35% (A; before, B; inter the session, C; after treatment and D; follow up).

Case 3; A female patient, 30 years old, had Vitiligo for two years and was treated by 6 sessions of micro-needling followed by latanoprost (A; before, B; inter the session, C; after treatment, and D; follow up). p<0.03).

Table (1): Demographic data of the studied groups.

Variable		Group A (n=18)		Group B (n=18)		Group C (n=18)		F	P
Age: (years)	Mean ± SD	29.17±8.05		27.5±7.59		28.33±10.68		0.16	0.85
	Range	18-47		19-48		18-57			
Variable		No	%	No	%	No	%	χ ²	P
Sex:	Female	16	88.9	14	77.8	14	77.8	0.98	0.61
	Male	2	11.1	4	22.2	4	22.2		

SD: Stander deviation, F: ANOVA test, χ²: Chi square test. NS: Non-significant (P>0.05)

Table (2): History of the studied groups.

Variable		Group A (n=18)		Group B (n=18)		Group C (n=18)		χ^2	P
		No	%	No	%	No	%		
Family history:	-ve	17	94.4	16	88.9	18	100	2.12	0.35 NS
	+ve	1	5.6	2	11.1	0	0		
Stress:	No	2	11.1	2	11.1	2	11.1	0	1 NS
	Yes	16	88.9	16	88.9	16	88.9		

χ^2 : Chai square test. NS: Non-significant (P>0.05)

Table (3): Skin type among the studied groups.

Skin type	Group A (n=18)		Group B (n=18)		Group C (n=18)		χ^2	P
	No	%	No	%	No	%		
III	11	61.1	10	55.6	6	33.3	3.14	0.53 NS
IV	5	27.8	6	33.3	9	50		
V	2	11.1	2	11.1	3	16.7		

χ^2 : Chai square test. NS: Non-significant (P>0.05)

Table (4): Clinical data among the studied groups.

Variable		Group A (n=18)		Group B (n=18)		Group C (n=18)		KW	P
Duration: (years)	Mean ± SD	4.53±4.47		3.89±4.34		3.63±5.89			
	Median	3		2.5		2			
	Range	0.58-19		1-19		0.5-26			
Variable		No	%	No	%	No	%	χ^2	P
Type:	Acrofacial	4	22.2	3	16.7	5	27.8		
	Focal	7	38.9	6	33.3	7	38.9		
	Vulgaris	7	38.9	9	50	6	33.3		
Site:	Face	1	5.6	3	16.7	1	5.6	6.64	0.88 NS
	Chest	3	16.7	2	11.1	3	16.7		
	Back	0	0	1	5.6	3	16.7		
	Forearm	6	33.3	5	27.8	4	22.2		
	Hand	2	11.1	1	5.6	2	11.1		
	Leg	4	22.2	3	16.7	3	16.7		
	Foot	2	11.1	3	16.7	2	11.1		

SD: Stander deviation, KW: Kruskal Wallis test, χ^2 : Chi square test. NS: Non-significant (P>0.05)

Table (5): Response to treatment among the studied groups.

Variable		Group A (n=18)		Group B (n=18)		Group C (n=18)		χ^2	P
		No	%	No	%	No	%		
Degree of improvement:	Poor	3	16.7	7	38.9	6	33.3	7.53	0.48 NS
	Satisfactory	5	27.8	5	27.8	5	27.8		
	Good	5	27.8	6	38.9	4	22.2		
	Very Good	2	11.1	0	0	2	11.1		
	Excellent	3	16.7	0	0	1	5.6		
% of repigmentation:		(n=15)		(n=11)		(n=12)		5.34	0.50 NS
	<25%	5	33.3	5	45.5	5	41.7		
	25 -<50%	5	33.3	6	54.5	4	33.3		
	50 -<75%	2	13.3	0	0	2	16.7		
	≥ 75%	3	20	0	0	1	8.3		
Start of response :		(n=15)		(n=11)		(n=12)		2.10	0.72 NS
	After 2 sessions	2	13.3	1	9	3	25		
	After 3 sessions	7	46.7	5	45.5	3	25		
	After 4 sessions	6	40	5	45.5	6	50		

χ^2 : Chai square test. NS: Non significant (P>0.05)

Table (6): Side effects among the studied groups.

Variable		Group A (n=18)		Group B (n=18)		Group C (n=18)		χ^2	P
		No	%	No	%	No	%		
Burning sensation:	No	9	50	12	66.7	10	55.6	1.06	0.59 NS
	Yes	9	50	6	33.3	8	44.4		
Hyperpigmentation :	No	17	94.4	17	94.4	16	88.9	0.54	0.76 NS
	Perilesional	1	5.6	1	5.6	2	11.1		
Pain:	No	15	83.3	16	88.9	16	88.9	0.33	0.85 NS
	Yes	3	16.7	2	11.1	2	11.1		

χ^2 : Chai square test. NS: Non-significant (P>0.05)

Table (7): Patient satisfaction among the studied groups:

Satisfaction	Group A (n=18)		Group B (n=18)		Group C (n=18)		χ^2	P
	No	%	No	%	No	%		
Unsatisfied	7	38.9	11	61.1	8	44.4	5.85	0.21 NS
Satisfied	6	33.3	7	38.9	7	38.9		
Very satisfied	5	27.8	0	0	3	16.7		

χ^2 : Chai square test. NS: Non-significant (P>0.05)

DISCUSSION

Vitiligo is a common and chronic skin disorder marked by depigmentation, affecting

around 1% of the general population. The primary cause of this sickness is the impaired functioning of melanocytes, which are

responsible for producing color in the skin. The pathophysiology of this condition can be attributed to various reasons, such as hereditary elements such as environmental stimuli, metabolic fluctuations, and modifications in the immune and inflammatory reactions, which ultimately lead to the death of melanocytes [13].

Microneedling is a minimally invasive process that is now employed for several dermatologic disorders, including vitiligo. This technique is considered both safe and effective in treating vitiligo, either on its own or in combination with other treatments such as topical 5-Fluorouracil, latanoprost, or Trichloroacetic acid 35% [14].

This study aimed to evaluate the effectiveness of delivering latanoprost through microneedling with delivering 5-fluorouracil and Trichloroacetic acid through microneedling 35% in induction of skin repigmentation in stable vitiligo.

In the current study, we found mean age values for Groups A, B, and C were 29.17, 27.5, and 28.33, respectively. There were no notable differences in the age and sex distribution among the groups being examined, as determined by statistical analysis.

In agreement with our findings, Ibrahim et al. [15] showed mean age was 37.06 and This is the age at which individuals with vitiligo are most commonly affected. It has been shown that vitiligo is more prevalent in individuals under the age of 40. This finding is consistent with previous research Gaafar et al. [16]. Hegazy et al. [17] reported that regarding male/female ratio, it was 3/7 for Fluorouracil group (FU) and 2.5/7.5 for Latanoprost (LT) group. Regarding age, both groups were matched for age. The mean age of Fluorouracil group was 24.5 ± 3.1 years

and Latanoprost group was 23.7 ± 2.6 years with no significant difference.

In the present study, we found exposure to stress was 88.9% of patients in Groups (A), 88.9% Patients in Group (B) In 88.9% of cases, both Group (A) and Group (C) patients had a positive history of stress exposure. No statistically significant differences were found between the groups being studied in relation to family history and exposure to stress.

The findings were consistent with Hegazy et al. [17], who concluded that there was no statistically significant difference observed between the groups under investigation as regards family history. Ibrahim et al. [15] stated that regarding the predisposing factors, only 17.6% of patients had positive family history, this is in agreement with Al-Hamamy et al. [18] A study was conducted which found that there was no significant family history and the results did not meet statistical significance.

This was in accordance with Ibrahim et al. [15] who showed exposure to stress was 75% of patients had a documented history of being exposed to stress. Patients encountered many arduous conditions, including illness, financial or marital challenges, and changes in sleep or food patterns.

Our current findings clearly revealed that No statistically significant differences were found among the studied groups in terms of skin type. The results obtained by Hegazy et al. [17] corroborated these findings, showing that the distribution of skin phenotype according to Fitzpatrick scales among the FU group was as follows: III/IV/V was 2/13/5 and in LT groups III/IV/V was 3/14/3 with no significant difference.

According to our current findings, No statistically significant differences were found among the investigated groups in terms of the

duration of the disease, kind, and site. Parallel results were acquired by Hegazy et al. [17] who demonstrated that disease duration ranged from 1 to 15 years in both groups with median 2 years and mean of (3.10 ± 2.2) in 5-FU group and (3.55 ± 3.1) in LT group with insignificant difference between groups. Abd El Razek et al. [19] A statistically significant inverse correlation was found between the duration of the condition and the level of responsiveness to treatment.

In the current study, we found there was an increase in excellent response, response $>75\%$ There was no statistically significant difference seen among Group A compared to Groups B and C. Furthermore, there was no statistically significant difference observed between the groups being tested in terms of the time at which the response was initiated.

Our findings were supported by those obtained by Hegazy et al. [17] who compared the clinical effectiveness of applying topical 5-fluorouracil after skin microneedling compared to applying topical latanoprost after skin microneedling in the stimulation of skin re-pigmentation in localized stable vitiligo patients. They found that both modalities of treatment showed variable degree of re-pigmentation of vitiligo lesions with insignificant difference. Santosh et al. [20] illustrated patient with stable yet resistant vitiligo and subjected to microneedling After receiving 5-FU During a three-month period, the application of the treatment every two weeks resulted in a 60% overall response in terms of re-pigmentation in the lesions. However, complete pigmentation was only detected in very limited regions.

In agreement with our findings, Abd El Razek et al. [19] No statistically significant differences were seen between the two groups

in terms of the overall treatment response and the degree of re-pigmentation. However, group A, who underwent dermabrasion in addition to applying a 5% 5-fluorouracil cream, showed a higher response to treatment compared to group B, which received dermabrasion plus topical latanoprost drops. According to Shashikiran et al. [21], the effectiveness of using topical 5% 5-fluorouracil Needling for vitiligo led to significant re-pigmentation in 49% of the patches, while 26% of the patches showed substantial re-pigmentation.

On the other hand, Nofal et al. [22] The study found that the combination of microneedling with TCA resulted in the most significant re-pigmentation, followed through the amalgamation of microneedling and 5-FU. The group that showed the lowest reaction was the one that coupled microneedling with pimecrolimus. The statistical analysis revealed a substantial difference among the three groups, with the combined microneedling and TCA group showing a favorable outcome.

Similar findings were obtained by Mina et al. [23], who compared the effectiveness of microneedling paired with fluorouracil 5% versus microneedling with tacrolimus. The results showed that 52% of patients had a favorable outcome, with more than 50% re-pigmentation, when using microneedling in combination with 5-fluorouracil.

Ibrahim et al. [15] conducted a study to assess the re-pigmentation in patients treated with microneedling plus TCA 70% using a qualitative method. The results indicated that 53% of patients experienced a good to excellent improvement in re-pigmentation (more than 50% re-pigmentation), 14.8% of patients had a moderate improvement (26-50% re-pigmentation), and 8.2% of patients

did not experience any effect. Khater et al. [24] assessed the effectiveness of TCA 70% following Microneedling as a treatment for patients with non-segmental vitiligo. Our findings indicate that 48.3% of the patients in the study experienced significant re-pigmentation (more than 50%), demonstrating good to exceptional results.

In this study, we discovered that there was no statistically significant difference between the groups being studied in terms of the occurrence of burning sensation, hyperpigmentation, and pain.

This was compliant with Hegazy et al. [17] who revealed that there was no statistically significant difference observed between the group treated with Fluorouracil and the comparison group (FU) and the Latanoprost (LT) group in terms of the occurrence of burning sensation, hyperpigmentation, and pain.

Puri et al. [25] employed TCA [100%] and noted that hyperpigmentation manifested in 20% of patients, hypopigmentation in 13.3% of patients, persistent erythema in 6.6% of patients, and superficial scarring and subsequent bacterial infection in 6.6% of patients. However, in our research, we utilized a TCA peel with a lower concentration of 35%. This lower dosage proved to be quite safe, as there were no instances of systemic absorption or toxicity discovered. Only 11.1% of participants experienced hyperpigmentation, and there were no cases of scarring, infection, or koebnerization observed.

Our research on patient satisfaction clearly indicates that there was a higher occurrence of extreme satisfaction among Group A compared to B&C, however this difference was not statistically significant.

This was in accordance with Abd El Razeq et al. [19] who concluded that there was no statistically significant disparity in patient satisfaction between the two groups. Nevertheless, both cohorts exhibited a statistically significant correlation between the extent of re-pigmentation and patient satisfaction. Ibrahim et al. [15] revealed that 41.1% of patients who underwent microneedling in combination with TCA 70% reported a high level of satisfaction.

Study limitations: this was a single-center study with sample size, which may not be representative of the general population and could impact the findings. The follow-up periods of the patients are relatively short. Long-term data on the efficacy and safety of these treatments are limited, making it challenging to assess their durability and potential late-onset side effects.

CONCLUSION

The concurrent use of microneedling with either 5-Fluorouracil, latanoprost, or Trichloroacetic acid 35% is both safe and efficacious for treating localized stable vitiligo. 5-fluorouracil showed a greater degree of improvement compared to latanoprost and Trichloroacetic acid 35%. Nevertheless, the disparity was not statistically significant. Both groups received a high level of satisfaction from the patients on the extent of improvement.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FINANCIAL DISCLOSURES

This study was not supported by any source of findings.

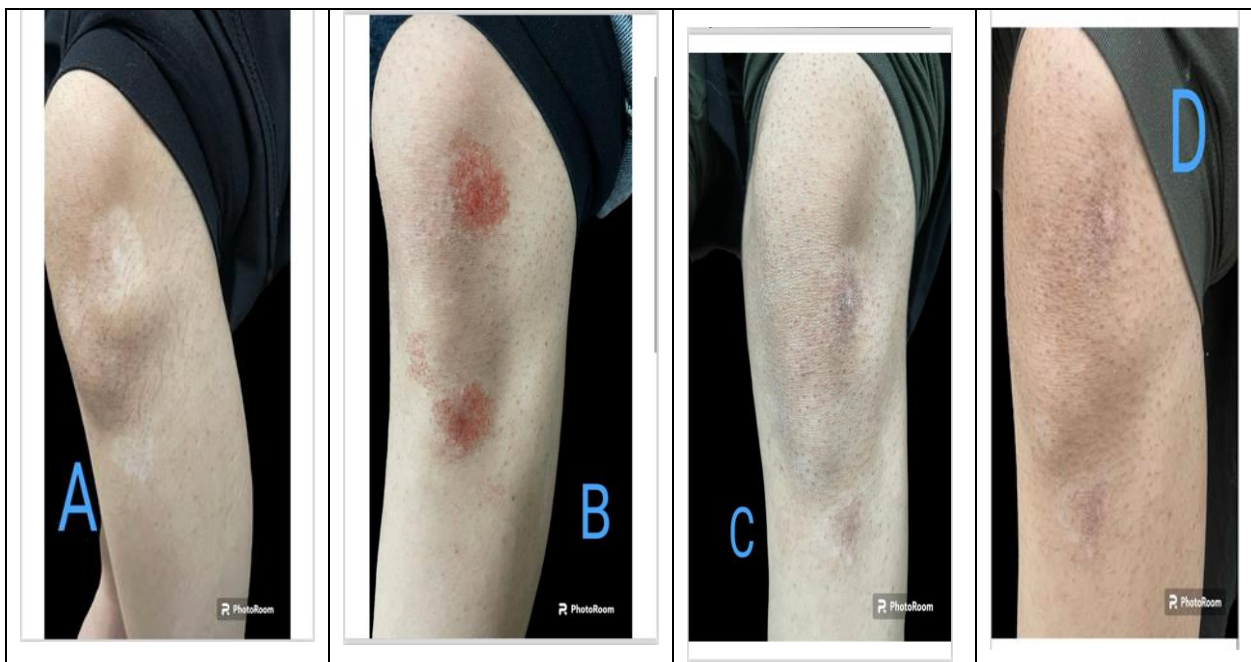
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Case (1): A; before, B; inter the session, C; after treatment and D; follow up.



Case (2): A; before, B; inter the session, C; after treatment and D; follow up



Case (3):A; before, B; inter the session, C; after treatment, and D; follow up.

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