Microneedling Plus Clobetasol Propionate 0.05% Cream versus Clobetasol Propionate 0.05% Cream Alone in the Treatment of Alopecia Areata

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ABSTRACT:

BACKGROUND:

Alopecia areata is an inflammatory, non-scaring type of hair loss. Microneedling is a new therapeutic procedure used in dermatology. It facilitates the absorption of topical therapies across the epidermis.

AIM OF STUDY:

Evaluating the efficacy of Microneedling combined with clobetasol propionate 0.05% cream versus clobetasol propionate 0.05% cream alone in treatment of alopecia areata.

PATIENTS AND METHODS:

This study was carried out on 20 patients and the total number of patches was 99. In the same patient, at least 2 patches were selected to be treated as group A or B; so, the 99 patches were divided in to two groups.

Group A: Microneedling combined with clobetasol propionate 0.05% cream: 51 patches (from 20 patients) were treated using a dermapen devise. The cream was applied before and after microneedling and a total of four sessions were done at 2 weeks interval, then patients were seen after 2 weeks from the last session for follow up. **Group B:** clobetasol propionate 0.05% cream alone: 48 patches (from the same 20 patients) were treated, the cream was applied twice daily with gentle massage for 3-5 minutes for 8 weeks duration. Patients were seen at 2 weeks interval.

RESULTS:

At 8th week visit: the response to treatment in group A was seen in 58.8% of the patches and 63.3% of them showed complete coarse hair regrowth while in group B, the response to treatment was seen in 58.3% of the patches and 32.1% of them showed complete coarse hair regrowth. When two groups were compared regarding complete hair regrowth there was statistically significant difference.

CONCLUSION:

Combination of Microneedling with clobetasol propionate 0.05% cream is a promising, safe and easy to perform technique in the treatment of alopecia areata

KEYWORDS: Alopecia areata, Microneedling, clobetasol propionate.

INTRODUCTION:

Alopecia areata is an autoimmune disease characterized by non-scaring hair loss [(1)]. The disease occurs in 1.5%–2% of general population, without sex or ethnic predilection and its onset can occur at any age, but the greatest incidence is in the second and third decades of life. It can be associated with other autoimmune diseases, including thyroid disease, psoriasis, vitiligo, rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) [(2)]. Family history of alopecia areata is present in 20% of cases [(3)].

Many hypotheses regarding the pathogenesis of alopecia areata are found including: environmental factors, genetic susceptibility, and cellular mediated autoimmunity. It is characterized by well-defined oval or round, non-scaring patches of hair loss. Finding of exclamation mark hairs at margins of lesions correlates with the disease activity [(4)]. The disease has different clinical types and the most common type is patchy alopecia areata, which occurs in up to 75% of patients. Eyebrows or eyelashes hair loss or patches on the beard or body with or without scalp hair loss are found in some patients [(5)]. 10 -15 % of patients have nails involvement [(6)].

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The patches resolve spontaneously in many patients; so, determining the effectiveness of different treatment modalities is complicated. Treatment of localized disease includes topical agents or reassurance as many patients resolve without treatment. Treatment of widespread disease including alopecia totalis or alopecia universalis can be challenging because spontaneous regrowth is rare and there is no proven treatment [2].

Microneedling is a new technique used in the treatment of many dermatological diseases. It assists the absorption of topical therapeutic agents across the epidermis. Microneedling types include: dermapen, dermaroller and additional devices use further technology to improve the uses of Microneedling [7].

The Microneedling technique has been used in the treatment of: skin rejuvenation, dyspigmentation, acne, scar, alopecia, hyperhidrosis and transdermal drug delivery (TDD) [8].

PATIENTS AND METHODS:

This interventional comparative therapeutic study was conducted at dermatology center, Medical City, Baghdad-Iraq during the period of time between April 2019 and April 2020.

Twenty nine patients with patchy alopecia areata were enrolled in this study, but unfortunately six patients defaulted after the first visit and three patients after second visit for unknown causes, so the total number of patients treated and followed up was twenty, 13(65%) patients were males and 7(35%) patients were females. The total number of patches was 99 (65 patches in the scalp and 34 patches in the beard area). The diagnosis of alopecia areata was done clinically. Full history was taken from patients in regard to age, duration of the disease, previous therapy for alopecia areata, number of previous attacks, family/personal history of alopecia areata and autoimmune conditions e.g. atopic diseases, vitiligo, thyroid diseases, connective tissue diseases and diabetes mellitus (DM). The patients were examined for the number, site, and size of the patches and the presence of exclamation mark hair. Nails were also examined for any associated changes. Patients with two or more patches of alopecia areata, involving the scalp and/or beard areas were included in the study. Exclusion criteria include: patients with only one patch of alopecia areata, history of systemic therapy for two months before study, history of active skin infections, history of contagious diseases, history of keloid, mentally retarded individuals.

The Microneedling technique, session's number and method of clobetasol propionate 0.05% cream application were fully explained to all patients or their parents. The response to treatment and the development of any possible local side effects were estimated at each visit.

Photographs were taken in each visit by HONOR 8 X phone and under nearly the same distance between the patient and the camera with the same degree of lighting. Formal consent was taken from each patient after discussion the nature of the disease, regarding the cause, course, prognosis, side effects of treatments. This study was estimated and approved by scientific committee of Iraqi Board of Dermatology.

In each patient, at least 2 patches were selected to be treated as group A or B. the patches in both groups were duration matched. So, the 99 patches were divided in to two groups:

Group A; Microneedling in combination with clobetasol propionate 0.05% cream:

Fifty one patches (from 20 patients) were treated with microneedling using a dermapen devise, with five adjustments of needle depth (from 0.25mm to 2.5 mm depth) and five levels of Speed. The needle tip contains 36 needles with 33 gauge thickness and 0.5 mm needle size.

The needle depth was adjusted at 1.5- 2 mm and the clobetasol propionate 0.05% cream was applied on each lesion two times, before and after performing Microneedling. The clobetasol propionate 0.05% cream was applied on the patches of hair loss then the dermapen was moved horizontally, vertically and obliquely five to six times in each direction. This procedure produced pin point bleeding which was taken as an end point, following which, the skin was cleansed with sterile gauze and clobetasol propionate 0.05% cream was applied topically with gentle massage for about 1-2 minute. No anesthesia was used as the procedure was slightly painful. The clobetasol propionate 0.05% cream was applied only during the sessions that done at hospital.

A total of four sessions were done at 2 weeks interval (baseline, 2nd week visit, 4th week visit, 6th week visit) then patients were seen after 2 weeks from last session (8th week) for assessment. Post-procedure, patients were advised to use sunscreen regularly for facial lesions.

Group B; Clobetasol propionate 0.05% cream alone: Forty eight patches (from the same 20 patients) were treated with clobetasol propionate 0.05% cream. Patients were instructed to apply the cream topically on the patches twice daily with gentle massage for 3-5 minutes for 8 weeks duration. The follow up of patients was done at 2 week interval.

In both groups: Clinical assessment for hair regrowth and possible side effects to treatment and taking photograph for the patches were done each visit.

The following grading was used to assess the clinical response in both groups [9]:

G0: No hair regrowth.

G1a: Partial vellus hair regrowth (fine, short and lightly pigmented hair).

G1b: Partial terminal hair regrowth (coarse, darkly pigmented hair).

G2: Complete terminal hair regrowth.

Statistical analysis: The statistical analysis was done using SPSS Version 26. using independent t test, chi square test, fisher`s exact test and mcnemar bowker test for the statistical analysis.

RESULTS:

A total of 20 patients with alopecia areata with 99 patches were completed the study and evaluated during the treatment with a mean ±SD of 4.5 ±2.8 patches per patients.

They were 13 (65%) males and 7 (35%) females. Their ages ranged from 6-64 years with a mean ±SD of 24.35 ±14.87 years.

The Positive previous history of AA was 8(40%) cases. The disease duration ranged from 1-240 weeks with a mean ±SD of 26.25±54.7 weeks.

Of the 20 patients, 11(55%) had previous treatment, of those, 9(81%) had only topical and 2(19%) had topical and systemic treatments. Seven (35%) of those patients had associated diseases, 2 had thyroid disorders, 2 had asthma, 2 had atopy and one had diabetes mellitus. The family history for autoimmune diseases was positive in 9(45%) cases, of those, 4(44.4%) had alopecia areata, 2(22.2%) had vitiligo, one (11.1%) with thyroid disorder, one (11.1%) with asthma and one (11.1%) had atopy.

The nail changes were observed in 2(10%) patients. The scalp only was involved in 13 (65%) patients, while 5 (25%) patients had beard involvement only and 2(10%) patients had both. Exclamation mark hair was observed in 6(30%) of the patients (Table -1).

Table 1: The demographic features of the patients included in the study.

Variable			
Gender		Male	Female
		13(65%)	7(35%)
Age (years)		mean	SD
		24.35	14.87
Duration (weeks)		mean	SD
		26.25	54.7
Site	Both	Scalp	Beard
	2(10%)	13(65%)	5(25%)
Personal history of alopecia areata		Positive	Negative
		8(40%)	12(60%)
Family history of autoimmune disease		Positive	Negative
		9(45%)	11(55%)
Nail changes		Positive	Negative
		2(10%)	18(90%)
Previous treatment		Positive	Negative
		11(55%)	9 (45%)
Associated disorders		positive	Negative
		7(35%)	13(65%)

The number of patches of the 2 groups was as follow:

Group A: There were 51 patches (from 20 patients) with a mean ±SD of 2.3 ±2.1 patches per patients.

Group B: There were 48 patches (from the same 20 patients) with a mean ±SD of 2.2 ±2.5 patches per patients.

At the 8th week visit, in group A, the response to treatment was seen in 30(58.8%) of the patches (P=0.0001). one out of thirty (3.3%) of these patches showed partial fine hair regrowth, ten (33.3%) of these patches showed partial coarse hair regrowth and nineteen (63.3%) of these patches showed complete regrowth of terminal hair observed.

In group B: the response to treatment was seen in 28(58.3%) of the patches (P=0.0003). Nineteen (67.8%) of these patches showed with partial coarse hair and nine patches (32.1%) showed with complete terminal hair regrowth (Table -2). The response to treatment in both groups was statistically significant (group A P=0.0001, group B P=0.0003); however, group A showed earlier improvement and when the two groups were compared with each other in regard to complete terminal hair regrowth, there was statistically significant difference P=0.04. After dermapen sessions, all patients reported transient erythema, burning sensation which resolved one to two days later, slight desquamation occurred after that and completely resolved. All patients with complete terminal hair regrowth in both groups expressed full satisfaction, while in only 60% patients with partial hair regrowth in group A and 45% of patients in group B achieved full satisfaction.

Table 2: The response of the patches to therapy in Group A, B in each visit.

Visits	Response	Group A (n= 51)		Group B (n= 48)		P value
		No.	%	No.	%	
2nd week visit	No response	44	86.3	45	93.8	0.32
	Partial (Fine hair)	0	0	0	0	
	Partial (Coarse hair)	7	13.7	3	6.3	
	Complete terminal	0	0	0	0	
4th week visit	No response	32	62.7	41	85.4	0.043
	Partial (Fine hair)	1	2	0	0	
	Partial (Coarse hair)	15	29.4	6	12.5	
	Complete terminal	3	5.9	1	2.1	
6th week visit	No response	22	43.11	24	50	0.06
	Partial (Fine hair)	1	2	0	0	
	Partial (Coarse hair)	10	19.6	16	33.3	
	Complete terminal	18	35.3	8	16.7	
8th week visit	No response	21	41.2	20	41.7	0.04
	Partial (Fine hair)	1	2	0	0	
	Partial (Coarse hair)	10	19.6	19	39.6	
	Complete terminal	19	37.3	9	18.8	
		P=0.001		P=0.003		

DISCUSSION:

Alopecia areata is an inflammatory, non-scaring type of hair loss mediated by lymphocytes. The underlying pathogenesis is not completely understood. The clinical manifestations of alopecia areata vary from well-defined small patches of hair loss to alopecia totalis and alopecia universalis. The modalities of treatment used for the disease have variable effectiveness and no one of these treatment modalities can cure or prevent the disease [10].

Microneedling is a technique in which micro wounds are created in the stratum corneum by moving fine needles over the skin without causing epidermal ablation. This slightly invasive procedure encourages the production of growth factors, collagen and new blood vessels. It is used

in a numerous dermatologic conditions, including alopecia areata [11].

In the current study, we evaluated the therapeutic efficacy of Microneedling combined with clobetasol propionate 0.05% cream versus clobetasol propionate 0.05% cream alone in the treatment of alopecia areata. At the 8th week visit, the response to treatment in both groups was statistically significant (group A P=0.0001, group B P=0.0003); however, group A showed earlier improvement. The two groups were compared with each other regarding the complete terminal hair regrowth and we found that there was statistically significant difference between them (P=0.04). So combination of Microneedling with topical clobetasol propionate 0.05% cream for treatment of alopecia areata is effective and causes faster regrowth of hair. Stimulation of dermal papilla and stem cells by Microneedling is supposed to be the suggested mechanism of action. Microneedling also increases the blood supply to the hair follicles and micro injury helps in recruiting growth factors and encouraging hair growth.

There is a limited number of studies examining Microneedling use in the treatment of hair loss and only few case reports using dermaroller for the treatment of alopecia areata are present. These case reports are compatible with the present study and include:

In 2014, Chandrashekar et al showed the effectiveness of using microneedling in combination with topical triamcinolone acetonide solution for the treatment of alopecia areata. Two patients with history of patchy hair loss on scalp, their conditions started 1 year and 6 months earlier respectively. The patients had history of previous treatment with intralesional injections of triamcinolone acetonide, topical steroid creams, and minoxidil 5% lotion but without response. Both patients were treated with a dermaroller and the triamcinolone acetonide was putted on each lesion, before and after doing procedure. Three sessions were done at three weeks interval. Both patients exhibited improvement with each session with excellent growth of hair after 3 weeks of last session (at 9 weeks) [12].

In 2020, Beergouder et al presented a case of a female (11-year-old) who had alopecia totalis of 2 years duration. The patient had been treated previously with a tapering dose of steroids for a few days and oral mini pulse was given for 1 year but new patches continued to appear after stopping of treatment. Triamcinolone acetonide was applied to each area before and after performing dermaroller. Three sessions were done at interval of 20 days. Minoxidil 2% was applied at night. After completing the three sessions, the hair growth was seen [13].

Another case report by Asad et al at 2020 which presented a 58-year-old white male with AA, ophiasis pattern. He had been treated with clobetasol 0.05% solution and four sessions of Microneedling with triamcinolone over 6 months. Hair regrowth was gradual and near complete regrowth was seen at end of study [14].

In 2013, Dhurat et al study showed that weekly sessions of Microneedling with application of 5% minoxidil lotion twice daily was statistically superior to Minoxidil lotion 5% alone in stimulating hair growth in males with AGA and the mean change in hair count was seen at week 12 [15].

Another study published by Dhurat et al in 2015; in this study finasteride and 5% minoxidil solution have been used for treatment of four males with AGA for duration of 2 to 5 years then 8-10 sessions of Microneedling were done for them along with their ongoing therapy. After completing these sessions, new hair growth started to appear [16].

Limited patches of alopecia areata are usually treated by topical corticosteroids in both children and adults groups. In 2020, Molinelli et al study showed that hair regrowth of > 75% was observed in 16 out of 35 of patients (45.71%). Those patients were treated by application of topical clobetasol propionate 0.05% cream twice daily for 12 week and complete hair regrowth (hair regrowth of ≥ 90%) was noted in two of the 16 patients. This study showed that topical corticosteroid was effective therapy in stimulating partial hair regrowth and this is compatible with our study [17].

CONCLUSION:

* Microneedling in combination with clobetasol propionate 0.05% cream is a simple, safe and a promising method in the treatment of alopecia areata as it causes stimulation and faster regrowth of hair.

* The procedure of Microneedling was well accepted by the patients with little discomfort and minor side effects when compared to other treatment modalities.

* Combination of Microneedling with topical corticosteroids facilitates the absorption of the drug.

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