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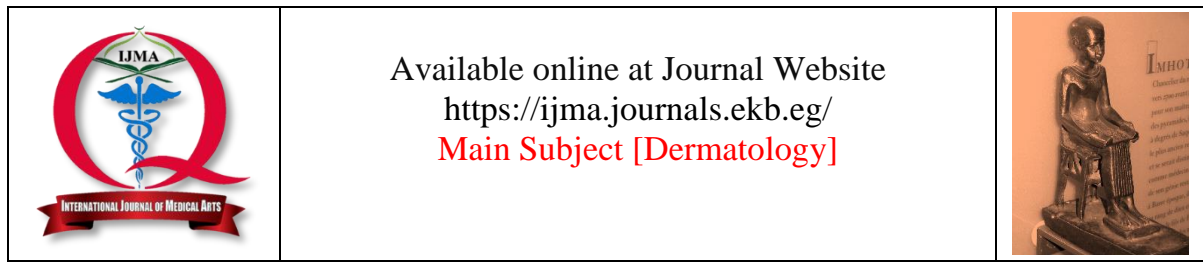


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## Original Article

# Comparative Study between The Efficacy and Safety of Topical Immune Therapy with Diphenylcyclopropenone versus Anthralin in The Treatment of Resistant Alopecia Areata

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## ABSTRACT

### Article information

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**Background:** Alopecia areata [AA] is a frequent, inflamed, non-scarring kind. No age or sex is immune. The clinical presentation is variable, and different treatment options are available.

**Aim of the work:** Comparing efficiency and safety of topical immune therapy by diphenylcyclopropenone [DPCP] to topical anthralin ointment for resistant AA.

**Patients and Methods:** This was cross-sectional research. It was performed at the outpatient clinic of the dermatology department, Al-Azhar University [Damietta]. It included 30 subjects, divided into two equal groups. Group-A treated with topical DPCP solution and group B treated with topical anthralin ointment for six months. All patients were assessed by clinical evaluation and dermoscopy. In addition, photographs of the lesions were obtained before and at the end of the treatment. The primary outcome was the success rate [hair regrowth], while secondary outcome included relapse and side effects.

**Results:** There was a statistically significant increased hair re-growth score in patients who received DPCP than those who received Anthralin therapy. The very good response was achieved among 60% of DPCP compared to 20% in anthralin group. In addition, the absent response was 6.1% in DPCP compared to 26.7% in anthralin group. The treatment relapse was registered for one patient in DPCP compared to none in anthralin group with no significant differences. Also, no significant differences were registered for the side effects of treatment.

**Conclusion:** DPCP is superior than anthralin in treatment of resistant AA. Both drugs had comparable safety profile.

**Keywords:** Alopecia; Anthralin; Diphenylcyclopropenone; Topical; Immune Therapy.



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## INTRODUCTION

With a frequency of 0.1-0.2% in the general population, alopecia areata [AA] is a common, inflammatory, non-scarring kind of hair loss. It affects people of all sexes and ages. Clinically, it is varied, ranging from isolated or several well-circumscribed patches of hair loss to severe involvement with total lack of body and scalp hair [1-3].

AA may be associated with anxiety and it increases the risks of psychiatric complications [e.g., generalized anxiety, depression, obsessive-compulsive disorders, suicidal thoughts, body dysmorphic condition, post-traumatic stress syndrome and phobic conditions] [4-6].

AA is of autoimmune nature from the pathophysiological point of view. Different systemic and other dermatologic autoimmune inflammatory conditions are associated with AA [e.g., atopic dermatitis, systemic lupus erythematosus [SLE], allergic rhinitis, psoriasis, autoimmune thyroiditis, rheumatoid arthritis [RA], celiac illness, and type-1 diabetes mellitus] [7-9].

There are different treatment options for AA. However, topical or intralesional corticosteroids is the preferred option. Other therapies include topical minoxidil and coal tar therapies. Systemic immunosuppressants like cyclosporine, systemic steroids, Janus Kinase [JAK] inhibitors, and methotrexate may be explored in extreme conditions of resistance [10, 11].

In the current work, we aimed to compare efficiency and safety of topical diphenylcyclopropenone [DPCP] and anthralin for resistant AA.

## PATIENTS AND METHODS

The current work was performed at Dermatology and Venereology Department Outpatients Clinics, Al-Azhar University Hospitals [Damietta]. It included 30 patients with confirmed diagnosis of AA. The diagnosis was confirmed by clinical and dermoscopic examination. Their age ranged between 16 and 60 years.

**Grouping:** Patients were divided into two equal groups. The first [Group A] included 15 patients. They were treated with topical diphenylcyclopropenone [DPCP] solution. The second group [Group B] treated with topical anthralin ointment.

**DCPC preparation:** DPCP powder was dissolved in acetone at concentrations of 0.001, 0.01, 0.05, 0.1, 0.5, 1.0, and 2.0%. Sensitization and elicitation stages were engaged in the implementation of DPCP. These actions were taken during the sensitization phase. Weekly concentrations of DPCP were progressively raised to 0.01, 0.05, 0.1, 0.5, 1, and 2% until moderate dermatitis that showed up as low-grade erythema and mild itch and sustained for 48 hours was produced.

The anthralin ointment was used every day at home for 30 minutes, then rinsed off with a gentle shampoo for six months.

**Inclusion criteria:** Patients with resistant AA. Their condition was verified and treated for more than six months with no satisfied response. They have stopped any treatments for at least one month prior to starting this trial, and who are given their consent and prepared to receive therapy, investigations, and routine follow-up.

**Exclusion criteria:** Pregnant or lactating women, immunocompromised patients, individuals with AA who have recently had systemic or topical therapy, patients with severe hypersensitivity reaction after sensitization test and localized scalp infections/inflammation.

## Methodology

Each patient by him/her self or his/her guardian give an informed consent for participation after full explanation of the study protocol, possible benefits and expected side effects. In addition, all the patient rights were guaranteed and the study was completed according to ethical codes of Helsinki declaration.

After that, each patient was assessed in a systematic order. Firstly, full history taking was obtained with the stress on the history of the present illness [disease onset and duration of therapy], recurrence, response to previous treatment and other medical disorders. In addition, any precipitating factors [e.g., psychic stress, sun burn, trauma, etc...] or associated diseases [e.g., thyroiditis, diabetes, etc...] were determined.

In the second assessment phase, a full general and dermatologic examinations were performed. The skin examination was performed to confirm the diagnosis, determine the clinical type and spread of AA. The lesion was palpated to feel warmth, surface, consistency, movement and mobility.

**Dermoscopy:** The dermoscope was held with the light emitting diodes directed to the lesion in a perpendicular angle. Dermoscope was placed 25 mm away from the skin. Then, the power button was switched on for 2-3 seconds for LEDs activation. Two light intensities were used, where the LEDs were activated for 16 or 32 seconds. Then, the lesions were checked by the eye through the lens. The device moved far and close from the lesion to obtain the preferred [most accurate] image. The dermoscopic features of AA include: yellow dots, short vellus hairs, black dots, tapered hairs, broken hairs, exclamation mark hairs, upright regrowing hairs, and pigtail hairs. All features of the lesions were documented and recorded.

Disease severity was assessed by the Severity of Alopecia Tool [SALT] as described previously [12]. The meaningful scalp hair regrowth was considered at SALT score  $\leq 20$ .

**Digital photography:** Photographs were obtained at baseline, both prior to and after treatment on regular intervals.

**Ethical consideration:** The research protocol had been submitted for review and approval by the institutional review board [IRB] and ethical committee of the Damietta Faculty of Medicine at Al-Azhar University, as well as by the administrators of the hospital where the study was carried out.

The primary outcome was the disease improvement at the end of the sixth month of treatment, while the relapse and treatment side effects were the secondary outcomes.

**Data management and Statistical Analysis:** Data entry, processing, and statistical analysis were all carried out using the statistical package for social sciences [SPSS] for windows, version 24 [IBM-SPSS®, Armonk, USA]. The mean, standard deviation, minimum and maximum were calculated for quantitative variables, while frequency and percentages were calculated for qualitative data. The comparison between groups was achieved by independent samples “t” and Chi square tests for quantitative and qualitative data respectively. In addition, Pearson’s correlation coefficient was calculated by severity score and each of age and disease duration. P value  $< 0.05$  was considered significant

## RESULTS

The current work included 30 patients, 15 received topical DPCP [group A] and another 15

received topical anthralin ointment [Group B]. both groups were comparable [i.e., there was no significant differences] regarding patient and disease characteristics. The patient age ranged between 12 and 60 years, the mean age was  $32.20 \pm 12.46$  and  $28.33 \pm 10.20$  in A and B groups respectively. There was male sex predominance in both groups [66.7% and 73.3% in A and B groups, respectively]. The disease onset was mainly sudden in both groups with stationary course in general. More than two thirds in each group had associated skin disorders [Table 1].

Regarding risk factors, the commonest were positive family history, presence of systemic diseases, history of surgery and psychological stressful conditions. There were no significant differences between groups A and B. the highest was the stress in both groups [it was presented in all patients of the DPCP group, compared to 86.7% of anthralin group]. However, the lowest in DPCP group was history of surgery [26.7%] and positive family history in the anthralin group [6.7%] [Table 2].

Regarding improvement at the end of the sixth month of treatment, the DPCP showed significant improvement than anthralin, where very good response was achieved among 60% compared to 20% in anthralin group. In addition, the absent response was 6.1% in DPCP compared to 26.7% in anthralin group. The treatment relapse was registered for one patient in DPCP compared to none in anthralin group with no significant differences. In addition, no significant differences were registered for the side effects of treatment [Table 3].

There was no significant correlation between hair regrowth score and patient age. However, there was a statistically significant inverse moderate correlation between the duration of illness and hair regrowth score [Table 4].

Photographs of selected cases [before and after treatment] are presented in figures [1 to 8]. The first was a 29 years old male with extensive alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months [Figure 1]. The second was for a 13 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months [Figure 2]. The third for a 16 years old male with a single patch of alopecia areata in the occipital area before and after treatment with topical application of Anthralin ointment for 6 months [figure 3]. The fourth was

for a 12 years old female with Ophialis before and after treatment with topical application of DPCP solution for 6 months [Figure 4]. The fifth photograph for a 30 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months [Figure 5]. The sixth photograph of a 35 years old male with a single patch of alopecia areata in the beard before and after treatment with topical application of

Anthralin ointment for 6 months [Figure 6]. In addition, figure [7] representing a 60 years old male with multifocal patches of alopecia areata in the scalp before and after treatment with topical application of Anthralin ointment for 6 months. Lastly, figure [8] representing a 32 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months.

**Table [1]:** Comparison of the age and sex between the studied groups

		DPCP	Anthralin	Test	P-value
Age [years]	Mean $\pm$ SD	32.20 $\pm$ 12.46	28.33 $\pm$ 10.20	0.930	0.360
	Min. – Max.	12 - 58	16 - 60		
Sex [n, %]	Male	10 [66.7%]	11 [73.3%]	0.159	0.690
	Female	5 [33.3%]	4 [26.7%]		
Disease duration [years]	Mean $\pm$ SD	9.60 $\pm$ 3.40	8.93 $\pm$ 3.13	0.559	0.581
	Min. – Max.	12 - 58	16 - 60		
Onset [n, %]	Sudden	11 [73.3%]	12 [80%]	0.186	0.666
	Gradual	4 [26.7%]	3 [20%]		
Course [n, %]	Stationary	9 [60%]	11 [73.3%]	0.600	0.439
	Progressive	6 [40%]	4 [26.7%]		
Associated skin disorder [n, %]	Yes	10 [66.7%]	12 [80%]	0.682	0.409
	No	5 [33.3%]	3 [20%]		

**Table [2]:** Risk factors among study groups

		DPCP	Anthralin	test	P-value
Family history	Yes	5 [33.3%]	1 [6.7%]	3.33	0.068
	No	10 [66.7%]	14 [93.3%]		
Systemic disease	Yes	5 [33.3%]	3 [20%]	0.68	0.409
	No	10 [66.7%]	12 [80%]		
History of surgery	Yes	4 [26.7%]	4 [26.7%]	0.001	1.00
	No	11 [73.3%]	11 [73.3%]		
Stress	Yes	15 [100%]	13 [86.7%]	2.143	0.143
	No	0 [0%]	2 [13.3%]		

**Table [3]:** The treatment response and side effects among study groups

		DPCP cases		Anthralin cases		test	P-value
		No.= 15	No.= 15	No.= 15	No.= 15		
Treatment response	Degree of improvement [at 6 <sup>th</sup> month]	No response	1 [6.7%]	4 [26.7%]	6.46	<b>0.019*</b>	
		Poor response	0 [0%]	1 [6.7%]			
		Some response	2 [13.3%]	4 [26.7%]			
		Good response	3 [20%]	3 [20%]			
		Very good	9 [60%]	3 [20%]			
Relapse	Yes	1 [6.7%]	0 [0%]	2.14	0.143		
	No	14 [93.3%]	15 [100%]				
Side effects	Side effect	Yes	6 [40%]	5 [33.3%]	0.144	0.705	
		No	9 [60%]	10 [66.7%]			
	Blistering	Yes	3 [20%]	0 [0%]	3.333	0.068	
		No	12 [80%]	15 [100%]			
	Dermatitis	Yes	3 [20%]	5 [33.3%]	0.159	0.690	
		No	12 [80%]	10 [66.7%]			

**Table [4]:** Correlation between age, duration of illness and hair regrowth score

	Hair regrowth score	
	r	P-value
Age [years]	0.038	0.843
Duration of illness	-0.516	<b>0.003</b>



**Figure [1]:** A 29 years old male with extensive alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months



**Figure [2]:** A 13 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months



**Figure [3]:** A 16 years old male with a single patch of alopecia areata in the occipital area before and after treatment with topical application of Anthralin ointment for 6 months



**Figure [4]:** A 12 years old female with Ophiasis before and after treatment with topical application of DPCP solution for 6 months





**Figure [5]:** A 30 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months



**Figure [6]:** A 35 years old male with a single patch of alopecia areata in the beard before and after treatment with topical application of Anthralin ointment for 6 months



**Figure [7]:** A 60 years old male with multifocal patches of alopecia areata in the scalp before and after treatment with topical application of Anthralin ointment for 6 months



**Figure [8]:** A 32 years old female with alopecia areata in the scalp before and after treatment with topical application of DPCP solution for 6 months

## DISCUSSION

Resistant AA has been treated with a variety of therapeutic approaches, but results have been inconsistent and unexpected<sup>[13]</sup>. Currently, topical immunotherapy seems to provide patients with resistant AA with the highest effectiveness and safety over the long-term treatment<sup>[14]</sup>. However, results need validation. Thus, this cross-sectional research was designed to investigate the effectiveness and safety of topical DPCP solution in comparison to topical anthralin ointment. The final assessment was done after 6 months of regular treatment. The results showed that, both groups were comparable regarding patient and disease characteristics. However, the improvement was significantly higher with DPCP than anthralin. The improvement score had no significant correlation with patient age. But it was significantly and inversely correlated with disease duration. Finally, there was no significant differences regarding treatment side effects or relapse of the condition. These results reflected that both treatment options were safe. However, DPCP had significantly better effectiveness.

The current work is unique in its design. The researchers best of knowledge did not discover any similar design in previous literature. However, both DPCP with or without anthralin were previously reported.

To interpret our results, *Strazzulla et al.*<sup>[1]</sup> reported that, topical immunotherapy, including DPCP and anthralin, were effective in the treatment of AA. The immune therapy exerts its action by an allergic contact dermatitis with subsequent antigenic competition and changing the immune cells around the hair follicles through an unknown mechanism. In addition, the histopathologic assessment of AA shows perifollicular lymphocytic infiltration around anagen hair follicles. It is mainly consisted of CD4+ and intrafollicular infiltrates of CD8+ cells. The chemical mediators include interferon-gamma [IFN- $\gamma$ ] and tumor necrosis factor-alpha [TNF]- $\alpha$  coordinating cyclical hair growth. These mediators play major roles in the pathogenesis of the disease<sup>[15]</sup>. Beneficial effect of DPCP is mainly mediated by regulating the local secretion of these mediators and cytokines. It has been reported that DPCP reduces IFN- $\gamma$  and IL-1 $\beta$  expression. However, it increases the expression of IL-2, IL-8, IL-10, and TNF- $\alpha$ . DPCP treatment is also associated with significant increase in a number of infiltrating leukocytes in the bulbar and suprabulbar area of the hair follicle that act against autonomous function of CD4+ and CD8+ cells. Moreover, DPCP reduces CD4: CD8 ratio from 4:1 to 1:1 in the perifollicular infiltrate<sup>[15]</sup>.

On the other side, anthralin exerts its action by an immunomodulatory effect leading to the

inhibition of TNF- $\alpha/\beta$  and IFN- $\gamma$  [16] while it builds-up the expression of interleukins [IL-1 and IL-10] [17]. It has been suggested that DPCP and anthralin with different mechanisms of action synergistically improve the treatment outcome of AA [18].

**Cotellessa et al.** [19] reported on the use of topical DPCP in the treatment of extensive AA. Fifty-six patients with extensive alopecia areata were included. They were submitted to sensitization with 2% DPCP, followed by progressively higher concentrations beginning at 0.001% applied weekly for 6 to 12 months to one side of the scalp. The total regrowth of hair was achieved in 48% at 6 months. The most frequent side effects were eczematous reaction at the site of application. The persistent response was achieved in 60% of these patients after 6 months of treatment. This is lower than the current work. However, it reflects the efficacy and safety of DPCP treatment. This discrepancy of response rates may be explained by the difference in the number of patients, the type, duration, and/or severity of the AA, and different methods of assessing clinical efficacy.

**Chiang et al.** [20] retrospectively evaluated DPCP therapy for 50 patients, with median follow up of 3 years. They reported that, 47% of patient experienced their first hair regrowth in the first six months of treatment. Another 20% showed regrowth between 6 and 12 months of treatment and 8% in the second year. However, they defined treatment success as  $\geq 50\%$  terminal hair regrowth. The predictors of poor outcome were extension of the disease before treatment history of thyroid disease and extent of body hair involvement. They recorded a relapse in 44%, that was significantly associated with the history of thyroid disease. The different results than the current work clearly explained by different definition of treatment success and relapse.

**Durdu et al.** [18] retrospectively evaluated anthralin added to DPCP and compared treatment outcome compared to DPCP alone for chronic extensive AA. The complete hair regrowth was recorded for 36.4% and 72% for single and combination, respectively [ $P < 0.05$ ]. in addition, hair regrowth duration was significantly shorter with combination therapy. However, side effects were more represented with the combination therapy. On the other side, **Ghandi et al.** [21] evaluated the combination therapy [DPCP plus anthralin] versus DPCP alone] and concluded that, anthralin did not add to the success rate or side effects of

DCPC treatment for moderate to severe AA. The severity of the disease could explain the discrepancy in results than other studies.

More recently, **Abd El-Magid et al.** [22] added platelet rich plasma to DPCP for treatment of resistant AA, and they found no significant differences in treatment response.

From the previous studies [mainly that combined DPCP with other drugs], it is clearly found that, DPCP is an effective treatment option, as in the current work. The combination of other drugs adds no or slight improvement, expect for anthralin in some studies. The improvement of success rate with combination with anthralin also reflected the efficacy of the drug. The current study recognized the individual success rate of each of the both drugs [anthralin and DPCP]. It showed the superiority of DPCP. This could be explained by the different mechanisms of actions.

**Conclusion:** DPCP is superior than anthralin in treatment of resistant AA. Both drugs had comparable safety profile.

**Financial disclosures:** None

**Conflict of Interest:** None.

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