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ORIGINAL RESEARCH

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Treatment satisfaction and response in patients with severe alopecia areata under treatment with diphenylcyclopropenone

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Abstract

Background and Aims: Alopecia areata (AA) is an autoimmune disease of hair follicles. Treatments currently include topical and intralesional corticosteroids and contact immunotherapy; however, the overall prognosis is usually unfavorable. In severe AA, topical immunotherapy with diphenylcyclopropenone (DPCP) is preferred. Since its effectiveness is heterogeneous and there are several side effects, we decided to measure the patients' satisfaction using the "Version II of the Treatment Satisfaction Questionnaire for Medication," which investigates satisfaction with effectiveness, side effects, convenience, and global satisfaction.

Methods: We examined 100 patients under treatment with DPCP for treatment response, asked them to respond to the questionnaire, and calculated their overall scores out of 400. We then investigated the association between the patients' characteristics with their treatment response and satisfaction.

Results: The overall satisfaction of patients was 257/400. We observed a significant association between patients' satisfaction scores on effectiveness and global satisfaction with their response to treatment ($p < 0.001$). The patients' satisfaction with the treatment's convenience had a significantly positive association with the age of receiving the diagnosis ($p = 0.028$). The overall treatment satisfaction was significantly associated with treatment response (276 vs. 213, $p = 0.000$).

Conclusion: Although there are currently no gold standard treatments for severe AA, DPCP demonstrated a 71% response to treatment, and patients with response were significantly more satisfied with their treatment.

KEYWORDS

alopecia areata, DPCP, treatment response, treatment satisfaction, TSQM

1 | INTRODUCTION

Alopecia areata (AA) is a chronic, autoimmune and relapsing disease of the hair follicles, mediated by T CD8+ cells in genetically susceptible patients.[1,2] The disease manifests as sudden hair loss in a circular, well-defined, nonscaring alopecic area on the scalp or anywhere else in the body.[2–5] Treatment options include topical and intralesional corticosteroids as first-line options for limited disease and contact immunotherapy for extensive and severe cases; however, there are currently no gold standards for treating AA.[2,6] Despite the numerous treatment modalities available, the overall prognosis is not favorable, especially in AA patients with severe hair loss like alopecia totalis (AT) and alopecia universalis (AU). Although, due to the considerable psychological impact of AA on patients' quality of life (QOL), measures are being taken to treat these patients.

Topical immunotherapy with diphenylcyclopropenone (DPCP) is the preferred method of immunotherapy in patients with severe AA. Studies have shown a diverse range of responses to immunotherapy, although 40%–60% of patients have reported experiencing an acceptable response.[2,7–12]

Due to the high cost of DPCP, common adverse effects like erythema, eczema, pruritus, and lymphadenopathy, as well as considerably diverse and heterogeneous hair regrowth rate among studies,[7] it seems that monitoring and evaluating the degree of treatment satisfaction is an important and a valuable indicator for assessing the expectation of the quality of services that patients receive. There are various studies on patients' satisfaction with treatment in dermatologic diseases like psoriasis,[13–20] but not much similar research exists on the satisfaction of patients with AA under DPCP treatment. Therefore, we decided to evaluate the treatment response and satisfaction of a group of Iranian patients with severe AA treated with DPCP, using the Treatment Satisfaction Questionnaire for Medication (TSQM) Version II as a validated measure to determine the degree and association of satisfaction with treatment in these patients with disease-related characteristics, hoping to discover the factors affecting satisfaction in hopes of trying to improve them in the future and improve patients' satisfaction and adherence.

2 | MATERIALS AND METHODS

A total of 100 patients with AT, AU, Ophiasis, and patchy AA; who were under treatment with topical immunotherapy with DPCP, and referred to the Alopecia Areata Clinic of Razi Hospital from April 2018 to May 2019, were enrolled in this study. Inclusion criteria were: age of 18 and above, definitive diagnosis of the disease, and treatment with DPCP for at least 3 months before the start of the study. Exclusion criteria were history of cardiovascular, thyroid, and autoimmune diseases, pregnancy, lactation, patients who had taken other medications orally before the study, and presence of other dermatologic conditions.

All participants gave written informed consent to complete the questionnaire, and the study protocol was approved by the ethics committee of Tehran University of Medical Sciences with the code "IR.TUMS.MEDICINE.REC.1397.373."

We recorded the patients' information, including their age, gender, age at the onset of the disease, the extent of hair loss at the treatment's onset with the Severity of Alopecia Tool (SALT) scoring system, duration of therapy, nail involvement, history of atopy, family history of alopecia, and the type of alopecia (including totalis, universalis, ophiasis, and patchy). We also reviewed patients' documents in each visit and recorded their SALT score and treatment response as vellus and terminal hair regrowth.

To evaluate the percentage of alopecia, two dermatologists familiar with the SALT scoring system evaluated each patient, and the final score considered the mean of both measures.

We documented the patients' satisfaction using TSQM Version II[21] (under an academic copyright license), which is a valid and reliable instrument in Persian,[22] measuring patients' satisfaction, with 11 questions and on four subscales, including *efficacy*, *convenience*, *adverse events*, and *overall satisfaction*. Each subscale's score ranges from 0 to 100; they are then added to form a total score, up to a maximum of 400 points.

We estimated the sample size by considering a 10% margin of error, 95% confidence level, 50% response rate (to reach the maximum number), and reached the number of 96 patients, which we then rounded up to 100. Data were analyzed by SPSS version 26, using χ^2 tests (Pearson or Fisher's Exact) for qualitative variables, and *t* test or analysis of variance (or nonparametric equivalents where the data was not normally distributed) for quantitative variables. Further testing was done using regression methods. The *p* value of less than "0.05" was considered statistically significant.

3 | RESULTS

A total of 100 patients, including 33 AT patients, 45 AU, 7 ophiasis, and 15 patients with patchy type disease, were enrolled in the study. Fourty patients were men, 10 were smokers, and 27 patients had nail involvement. Ten patients had a family history of AA, and 13 patients reported a history of allergies. Seventy-one patients also showed a response to treatment.

Participants ranged from 18 to 56 years old at the study time, with an average of 31 (SD = 9.8). The age they were diagnosed was 22.6 years old (SD = 10.5). The average extent of the disease (by SALT score) was 82.4 (SD = 26). They were treated for an average of 17.5 months (SD = 22.1). They were prescribed an average of 0.4% DPCP (SD = 0.6).

The patients reported a total satisfaction score of 257.27. They reported an average of 52 on effectiveness, 93 on side effects, 55.6 on convenience, and 56.2 on global satisfaction. Details are listed in Table 1.

Patients' age did not significantly affect their treatment satisfaction in any of the subgroups and their total score. ($P_{(effectiveness)}$:0.16,

TABLE 1 Treatment satisfaction summary

TSQM subscale	Effectiveness	Side effects	Convenience	Global satisfaction	Total score
Mean	52	93.42	55.61	56.25	257.28
(SD)	(22.8)	(17.1)	(16.6)	(23.6)	60.8

Abbreviation: TSQM, Treatment Satisfaction Questionnaire for Medication.

$P_{(side\ effects)}$:0.738, $P_{(convenience)}$:0.075, $P_{(global\ satisfaction)}$:0.921, $P_{(total)}$:0.228). The age of patients at the time of diagnosis did not have a significant impact on the overall treatment satisfaction score as well. ($p = 0.085$).

There were no significant differences in satisfaction between male and female patients. ($p = 0.75$).

Furthermore, there were no significant differences in satisfaction between patients of different alopecia types. The highest score was associated with ohiasis type (271.82), followed by totalis (257.74), universalis (256.05), and patchy (253.15); however, the difference was not significant. ($p = 0.966$).

Our patients had on average 82.41% involvement (SD = 26.04), measured as SALT score. The extent of alopecia was not significantly associated with the patients' treatment satisfaction ($p = 0.968$).

Patients were treated with different concentrations of DPCP. The concentration ranged from 0.001 to 3, on average 0.4 (SD = 0.61). However, the patients' reported satisfaction with their treatment was not associated with the DPCP's concentration. Higher concentrations were accompanied by lower scores (Spearman's $\rho = -0.087$), but this association was not significant ($p = 0.390$).

The extent of involvement was 82.41%, and concentration 0.4, respectively, and the association between the extent of involvement and medication concentration was not significant (Kendal's τ coefficient = 0.025, $p = 0.752$). The difference of concentrations among Alopecia types was not significant (independent samples Kruskal–Wallis test, $p = 0.903$).

Patients were treated on average of 17.5 months. The length of their treatment was not associated with their satisfaction ($p = 0.578$). Furthermore, patients with nail involvement reported an average of 24.5 lower scores than patients without nail involvement (239.4 vs. 263.9); however, this difference was not statistically significant ($p = 0.074$).

Seventy-one patients had a positive treatment response, while 29 did not.

Twenty-nine of 40 male patients (72.5%) and 42 of 60 female patients (70%) demonstrated treatment responses. Male patients had a higher rate of treatment response; however, the response rate for men was not significantly higher than women (χ^2 value = 0.073, $p = 0.787$, $\phi = 0.787$, Cramer's $V = 0.787$, odds ratio (OR) = 1.130, 95% CI for OR = [0.465–2.743]).

Treatment response was not associated with patients' age, the extent of disease, alopecia subtypes, nail involvement, and DPCP concentration.

Patients with treatment response reported a total score of 275.55 (SD = 56.96) on their TSQM. The score of patients without response was 212.55 (SD = 45.36). This difference was significant (independent-samples t test, $p = 0.000$).

The *effectiveness* subscale of the questionnaire showed an average of 52/100 score (SD = 22.84), which was significantly associated with treatment response (30.75 [SD = 16.53] in nonresponders vs. 60.68 [SD = 19.12] in responders, independent samples Mann–Whitney U test, $p = 0.000$).

The satisfaction with *side effects* was an average of 93.42/100 (SD = 17.09). Twenty-six people responded that they had experienced side effects. None of the variables in our study were associated with the presence of side effects or the score of the patients in this subscale.

Patients had, on average, a score of 55.61/100 (SD = 16.61) on *convenience*, which was significantly associated with the age of diagnosis (Pearson correlation coefficient = 0.220, $p = 0.028$).

Patients reported a score of 56.25/100 (SD = 23.64) on the *global satisfaction* scale, associated with treatment response (36.21 (SD = 17.58) in nonresponders versus 64.44 (SD = 20.79) in responders, independent samples Mann–Whitney U test, $p = 0.000$).

Details of univariate analyses for treatment satisfaction, treatment response, and questionnaire subscales have been summarized in Tables 2–4.

On multivariate analysis of treatment satisfaction, *treatment response* was the only variable with a significant association (coefficient = 65.95, $p = 0.000$). Gender ($p = 0.522$), age ($p = 0.278$), age at diagnosis ($p = 0.622$), type of alopecia ($p = 0.747$), the extent of the disease ($p = 0.310$), treatment duration ($p = 0.166$), nail involvement ($p = 0.244$), and concentration of DPCP ($p = 0.223$) did not have a significant association with treatment satisfaction. This model reported an R of 0.57 and R^2 of 0.325 and an adjusted R^2 of 0.257, low collinearity (all tolerance and VIF were in an acceptable range), and low autocorrelation (Durbin–Watson = 2.165).

4 | DISCUSSION

DPCP is considered an acceptable treatment for AA, particularly in severe and chronic forms. It can cause hyper/hypopigmentation, urticaria, generalized bullae, eczemas, and lymphadenopathy.[7] In most cases, it is administered by the physician; however, some studies have shown that it is also safe and effective if used at home by the patient. In our study, we measured the satisfaction of patients with DPCP treatment and their response rate to their treatment.

Studies on alopecia patients' satisfaction with DPCP treatment are sparse. In our study, we used the TSQM, which comprises four

TABLE 2 Summary of univariate analyses—treatment satisfaction

Variable	Categories or range	Number or mean (SD)	TSQM total score mean (SD)	*p* value coefficient (if applicable)	Statistical test
Age at time of participation	18–56	31.06 (9.79)	257.28 (60.8)	0.228	Spearman's *ρ*
	Years old			0.122	
Age at diagnosis	4–48	22.61 (10.49)	257.28 (60.8)	0.085	Pearson correlation
	Years old			0.173	
Gender	Male	40	254.93 (66.41)	0.755	Independent *t* test
	Female	60	258.84 (57.35)		
Type of alopecia areata	Totalis	33	257.74 (67.03)	0.966	Independent samples Kruskal–Wallis
	Universalis	45	256.05 (60.65)		
	Ophiasis	7	271.82 (66.85)		
	Patchy	15	253.15 (47.96)		
Extent of disease	9–100	82.41% (26.04)	257.28 (60.8)	0.968	Spearman's *ρ*
	Percent			0.004	
DPCP concentration	0.001–3	0.403 (0.6)	257.28 (60.8)	0.390	Spearman's *ρ*
	Percent			−0.087	
Duration of treatment	1.5–120	17.55 (22.1)	257.28 (60.8)	0.578	Spearman's *ρ*
	months			0.056	
Nail involvement	Yes	27	239.4 (59.7)	0.074	Independent samples *t* test
	No	73	263.9 (60.3)		
Family history	Yes	10	236.7 (58.9)	0.261	Independent samples *t* test
	No	90	259.6 (60.9)		
Allergies history	Yes	13	265.4 (49.5)	0.609	Independent samples *t* test
	No	87	256.1 (65.5)		
Treatment response	Yes	71	275.55 (56.96)	0.000	Independent samples *t* test
	No	29	212.55 (45.36)		

Abbreviations: DPCP, diphenylcyclopropenone; TSQM, Treatment Satisfaction Questionnaire for Medication.

different sections, to demonstrate that overall patients are 257/400 satisfied based on the TSQM questionnaire. We demonstrated that this satisfaction correlates with patients' response to treatment. The patients who experienced hair regrowth showed an average of 63 scores more than the patients without response (refer to Section 3).

In the first subscale of the TSQM, effectiveness, we observed that patients were relatively satisfied with the effectiveness of DPCP. The satisfaction with the effectiveness of DPCP was 52 of 100. We also observed a significant association with treatment response. Patients who experienced hair regrowth declared 30 scores higher in this subscale (97.33% higher), demonstrating the significance of treatment response.

In the second subscale, satisfaction with the side effects was 93 of 100. Only 26 people among the 100 in our study reported that they had experienced side effects. The 26 people with experience of side effects had a score of 76 (SD = 27), which shows that despite the presence of side effects, patients were still satisfied with the side effects of their treatment.

The third subscale, convenience, shows that patients are somewhat satisfied with the convenience of their treatment, with an average score of 56. The satisfaction in this scale was positively associated with the age of the patient at diagnosis ($p = 0.028$); however, while this association was statistically significant, it should not necessarily be construed as a clinically relevant one because, for every 10-year increase in age of diagnosis, we would observe merely 2.2 scores (out of 100) increase in satisfaction.

The fourth subscale, global satisfaction, was also associated with treatment response. Patients who responded to the treatment reported higher scores in this subscale, 28 more points or a 78% increase in the average score, demonstrating a notable association between hair regrowth and patients' overall satisfaction with the treatment.

TABLE 3 Summary of univariate analyses—treatment response

Variable	Categories	Mean or percent of patients *with* treatment response	Mean or percent of patients *without* treatment response	*p* value coefficient	Statistical test
Gender	Male (40)	29 (72.5%)	11 (27.5%)	0.787	χ^2
	Female (60)	42 (70%)	18 (30%)	0.073	(Pearson)
Age	Years	30.10 (9.42)	33.41 (10.41)	0.081	Independent-samples Mann–Whitney *U*
Age at diagnosis	Years	22.11 (10.3)	23.83 (11.05)	0.461	Independent *t* test
Type of disease	Totalis (33)	24 (72.7%)	9 (27.3%)	0.970	χ^2
	Universalis (45)	32 (71.1%)	13 (28.9%)	0.370	(Fisher's exact test)
	Ophiasis (7)	5 (71.4%)	2 (28.6%)		
	Patchy (15)	10 (66.7%)	5 (33.3%)		
Nail involvement	Yes (27)	17 (63%)	10 (37%)	0.281	χ^2
	No (73)	54 (74%)	19 (26%)	1.160	(Pearson)
Extent	%	84.39 (24.68)	77.55 (29)	0.273	Independent-samples Mann-Whitney *U*
DPCP concentration	%	0.46 (0.65)	0.27 (0.49)	0.219	Independent-samples Mann-Whitney *U*
Duration of treatment	Months	20.24 (25.4)	10.95 (7.04)	0.462	Independent-samples Mann-Whitney *U*
Total TSQM Score	/400	275.55 (56.96)	212.55 (45.36)	0.000	Independent-samples *t* test

Abbreviations: DPCP, diphenylcyclopropenone; TSQM, Treatment Satisfaction Questionnaire for Medication.

TABLE 4 Analysis of subscales associations

	Age	Age of diagnosis	Gender	Type	Extent	Concentration	Duration	Nail	Response
Effectiveness	0.161	0.057	0.815	0.839	0.376	0.737	0.148	0.111	0.000*
Side effects	0.738	0.492	0.932	0.807	0.886	0.511	0.687	0.288	0.586
Convenience	0.075	0.028*	0.524	0.820	0.891	0.482	0.094	0.693	0.062
Global satisfaction	0.921	0.212	0.677	0.503	0.895	0.746	0.500	0.129	0.000*

*showed statistically significant relationship.

The rate of response to the treatment in our study was 71%. Other studies have shown different ranges of treatment response, ranging from as low as 29 in one study to 81.5 in another.[2,7–12,23] We demonstrated patient's response, while associated with higher satisfaction, by itself was not associated with any of our variables.

Our patients were on average 31 years old; the average age at diagnosis was 22.6, and they were treated for 17.5 months. The association between their satisfaction and age and duration of treatment was not significant. Patients whose disease had started earlier had lower satisfaction scores; however, this association was not significant ($p = 0.08$). Also, in our study, patients' age, age at diagnosis, and duration of treatment was not associated with treatment response either. In the study by R. C. Lamb et al., the duration of disease was found to have a significant association with treatment response, but the age at onset of the disease was not associated with treatment response.[23] Age of onset or start of treatment was not associated with treatment response in the study by Chiang et al. as well ($p = 0.817$, $p = 0.802$).[8]

In our study, we concluded that neither *subtypes of AA*, nor the *extent of involvement*, were associated with treatment satisfaction or treatment response. We concluded that patients with alopecia ophiasis were more satisfied, and patients with patchy alopecia had the poorest treatment response among the four subtypes; however, these associations were not significant. Similarly, in the study by Dr. Aghaei on treatment response, type of alopecia was not significantly associated with response.[11] However, Ohlmeier et al. concluded that the severity of hair loss at the beginning is a significant ($p = 0.001$) indicator of treatment success.[9] Also, Chiang et al. concluded that the extent of hair loss (OR = 3.34, $p = 0.02$) and the extent of body hair involvement (OR = 2.28, $p = 0.03$) were correlated with the outcome.[8] According to the R. C. Lamb. et al., on the contrary to our study, extent and duration of disease were crucial predictors of response.[23]

We observed that patients with nail involvement had lower satisfaction scores and poorer treatment responses. However, these associations were not significant in our investigation. R. C. Lamb. et al. have also reported that nail dystrophia did not significantly correlate with treatment response.[23] However, Dr. Aghaei observed that nail involvement was significantly ($p = 0.02$) associated with a poorer response rate.[11]

DPCP solution was prescribed at varying concentrations to different patients. The concentration in our study ranged from 0.001 to 3, with an average of 0.4. We observed that while the associations were not significant, the patients with treatment response were on higher concentrations; however, we also noticed less satisfaction with higher concentrations. The concentration of the drug was not significantly associated with the extent of the disease either. It also did not prove to have a significant association with satisfaction in multivariate analysis. Chiang et al. observed the beginning of treatment response at a dose of 0.001%, and the highest concentrations they prescribed ranged from 0.001% to 7%, with a median of 0.1%.[8] Aghaei used incremental concentrations of DPCP, ranging from 0.001% to 2%.[11]

One of the benefits of our study was that we gathered and investigated the association between the patients' satisfaction and their response. However, we had several associations near the cut-off we had set for the significance level, such as the associations between the age of the patients at the time of diagnosis and nail involvement with satisfaction, or the associations between female gender and age with the response to treatment. This suggests that if there had been different conditions, it is possible we could have reached different conclusions in the mentioned areas. Also, since Razi Hospital is a referral center, and we only studied patients with severe AA at the beginning of their treatment, we should not generalize the results to primary care or mild conditions.

5 | CONCLUSION

For the management of AA, there are currently no gold standards. DPCP is an acceptable, safe, and effective treatment, with a treatment response of 71% in our study. Patients on DPCP had an average of 257/400 score on TSQM. Their satisfaction with the treatment was significantly associated with their response. There were no significant associations between satisfaction and their age, gender, the concentration of the prescribed solution, and the extent of their disease.

AUTHOR CONTRIBUTIONS

Conceptualization and methodology: Maryam Nasimi, Robabeh Abedini, and Narges Ghandi. *Investigation*: Atefe Janatalipour. *Formal analysis*: Alireza Abdshah and Maryam Nasimi. *Writing—original draft preparation*: Alireza Abdshah and Sara Torabi. *Writing—review and editing*: Alireza Abdshah and Maryam Nasimi. *Supervision*: Robabeh Abedini, Narges Ghandi, and Maryam Nasimi. All authors have read and approved the final version of the manuscript. The authors confirm that the data supporting the findings of this study are available within the supplementary materials, as an SPSS database (.sav format).

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Dr Maryam Nasimi had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

Dr Maryam Nasimi affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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