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ORIGINAL RESEARCH

EFFICACY OF INTRALESIONAL BOTULINUM TOXIN INJECTION IN THE TREATMENT OF PATCHY ALOPECIA AREATA (AA)

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Abstract

Background and Objective: Alopecia Areata (A. A.) is considered as an autoimmune disease that causes hair loss on the scalp and/or other regions of the body. The aim of this study is to compare the effectiveness of intralesional Botulinum Toxin-A injections and Triamcinolone Acetonide in treating individuals with patchy Alopecia Areata (AA) and regrow their hair. Additionally, it aims to assess the side effects and measure the results using the Alopecia Areata (AA) Regrowth Score (McDonald's Score).

Methodology: A randomized controlled trial on 30 adults with patchy Alopecia Areata (AA) has been done. Botulinum Toxin-A injections (0.5 IU/cm2) were injected on one side of the scalp intradermally and Triamcinolone Acetonide injections (0.5 mg/cm2) on the opposite side intradermally. Both interventions were repeated montly, and followed them up over a period of 12 weeks. We observed hair regrowth and patient satisfaction using the McDonald's Score.

Results: The mean number of alopecia patches per patient was 3.17 ± 1.58 with a range of 2-8 patches, the highest area for patches was in parietal region. Both modalities of treatment showed substantial effectiveness 88.9% with Botulinum, and 94.4% with Triamcinolone after 2 months, with Botulinum Toxin-A showing avoidance of complications, while Traimciniolone had localized skin atrophy in 16.7%.

Conclusion: Choosing between these treatments should consider patient preferences, and tolerance for potential complications.

Keywords: Alopecia Areata (A. A.), Botulinum Toxin-A injections, Triamcinolone Acetonide

INTRODUCTION

Alopecia Areata (A. A.) is considered as an autoimmune disease that causes hair loss on the scalp and/or other regions of the body. The disease occurs approximately in 2% of the global population, the onset can be affceted by enviromental factors and genetic predispositions. Although A. A. can start at any age, it primarily manifests during childhood or early adulthood. Alopecia Areata is classified into: patchy, total and universalis forms according to the degree of hair loss. [1-2] The precise etiology of it is intricate, with genetics serving as a significant determinant. Certain genes associated with immunological function have been linked to the disease by researchers, which may show familial patterns. Environmental factors, stress and viral infections considered as triggers or exacerbators of the disease. [3-6] Alopecia Areata mostly occurs by the attack of the immune system on the hair follicles during the anagen phase, impeding hair development and causing hair loss. Inflammation and immune-related substances also contribute to the illness process. [7,8] The treatment for Alopecia Areata often emphasizes immunosuppression and the facilitation of hair restoration. Treatment involves the use of corticosteroids, either topically or intralesionally. Triamcinolone Acetonide is a corticosteroid that works by decreasing inflammatory cytokines and suppressing the immune cells. This decreases the autoimmune attack on hair follicles. By attaching to glucocorticoid receptors, it stops T-cells from activating and lowers the production of cytokines like IL-1 and TNF-alpha. This decreases inflammation and stimulates hair growth. Other treatment methods consist of minoxidil, and immunotherapy, such as cyclosporine. [2,4,9] The effectiveness of these treatments varies, with some showing negligible improvement or encountering relapses. Consequently, there is an increasing interest in alternative therapies. [5-9] Botulinum Toxin-A which is known for cosmetic applications, has recently shown to be

effective in treating autoimmune illnesses like Alopecia Areata. Botulinum Toxin-A is believed to work by diminishing neurogenic inflammation, that may damage the hair follicle. BTX-A may reduce the immune attack on hair follicles by suppressing the release of certain inflammatory mediators and neurotransmitters. [10-12] Binding to presynaptic receptors on motor neurons and cleaving SNARE proteins, such as SNAP-25, inhibits the release of acetylcholine. This is the mechanism of action of BTX-A. Not only does this stop muscle contractions, but it also reduces neurogenic inflammation by stopping the production of inflammatory neuropeptides like substance P and CGRP. This decrease in inflammation surrounding hair follicles may facilitate hair regeneration in Alopecia Areata. Numerous studies indicate that intralesional injection of BTX-A can promote hair regeneration in individuals with patchy Alopecia Areata. BTX-A is believed to reduce the levels of inflammatory substances such as substance P and calcitonin gene-related peptides surrounding hair follicles. By diminishing these inflammatory signals, BTX-A may facilitate the recovery of hair follicles and promote hair regrowth. [8,11,12] This research will reevaluate the efficacy of BTX-A in treating Alopecia Areata. We will assess the reliability of BTX-A as a minimally invasive treatment for patients with Alopecia Areata.

Patients and Methods

This study is a prospective, randomized, controlled comparison study which was conducted at Azadi Teaching Hospital, Department of Dermatology, Duhok City, Kurdistan Region-Iraq. The study was conducted during 6 months interval from 2024 until 2025 through which 45 cases were informed about the study, 15 of them were excluded according to the inclusion and exclusion criteria, the remaining 30 agreed to be enrolled and followed with post injection guidelines. During the study, 12 participants dropped from the course and been free from the study due to failure to follow-up with the strict follow-up steps. Each participant has undergone both injections (Botulinum Toxin-A and Triamcinolone Acetonide) at different patch of Alopecia. Botulinum Toxin-A had 3 injections, one at day 0, the second dose at day 28 (week 4) and the third dose was after another 4 weeks day 56. Each case was followed up for another 4 weeks (day 84). The same protocol for Triamcinolone Acetonide was used. Each patient was assessed with McDonald Score at day 0 prior to injections, day 28 at the time of second injection and the final result at day 84. As has shown in Figure (1).

percentage differences. ANOVA analysis for calculating the least significant difference (L.S.D.) test were applied to determine the statistical significance of the data. P value of <0.05 was considered significant. L.S.D. Values were compared with values of means difference. Using Independent sample t. test to compare between two groups for numerical data. In addition, Enter Standard multiple-Linear Regression was used in this study. The P-value was considered statistically significant when it was equal to or less than 0.05.

RESULTS

Demographic characteristics of the study population

The results of this study indicate that the highest percentage (44.0%) of patients belonging to ages ≤25 years, followed by those aged 26-35 years (24.0%), 36-45 years (20.0%), 46-55 years (7.2%), while lowest percentage (4.8%) of patients are aged 56-65 years. The mean age was 31.6±12.6 (with range; 16-65) years. The gender ratio is 61.6% male to 38.4% female. The highest proportion (44.8%) of the participants were freelance work, followed by 40.0% students, 12.8% employed, and 2.4% housewives (table 1). As illustrating in table no.2, the results shows that 44.0% of participants were smokers. Regarding medical history, the majority of patients (72.8%) had no history of the disease. While smaller percentages (11.2%) of patients had hypertension and diabetes separately, 4.8% of the study sample had both. Concerning oral hygiene, 68.0% of the participants have a moderate level of oral health, 14.4% of the patients have fair and good levels of oral health, while the lowest percentage (3.2%) of the participants have bad level of oral hygiene (figure no.1)

Figure1. showing the result of injection at day 0, day 28 and 84 from left to right. The upper pictures represent BTX-A while the lower pictures showing Triamcinolone Acetonide

The study followed strict inclusion criteria approach for an accurate result. These included; each patient should have at least 2 patches of Alopecia Areata that shall be on different sides of the scalp such as right and left side, occipital and parietal with more than 10 cm difference to avoid diffusion of the injection treatment, not using any other medications with it and after injection shall not wash the head, not to bend the head and remain in a cold environment. Exclusion criteria: age less than 18 years old, pregnant or breastfeeding, experienced an allergy to Botulinum Toxin-A injections, neuromuscular junction disease, or take drugs such as aminoglycosides and cyclosporine that alter the way botulinum toxin functions. Each patient had multiple patches. We used a method that involved injecting 0.5 IU of Botulinum Toxin-A per 1 cm^2 into an alopecia patch on one side of the scalp and then 0.5 mg of Triamcinolone Acetonide per 1 cm^2 into the alopecia patch on the other side of the scalp. We administered the second dose one month later. To administer the precise dose, we diluted 1 vial of 100 IU botulinum toxin with 5 cc of normal saline using a 5 cc syringe, then injected 2.5 units of fluid containing 0.5 IU BTX-A into each cm of the alopecia patch using a 100-unit Luer lock insulin syringe and a 33G needle. We diluted a 40 mg ampoule of Triamcinolone Acetonide with 4 cc of normal saline using a 5-cc syringe. Next, we pulled 100 units, each containing 10 mg of Triamcinolone Acetonide, using a Luer lock insulin syringe. Finally, we injected 5 units, each containing 0.5 mg, into each cm of different alopecia patches on opposite sides of the scalp. McDonald Score been used for monthly follow-up for three months, collecting data over 12 weeks to focus on changes in hair regrowth and patient-reported satisfaction levels. The study was approved by the Kurdistan Board for Medical Specializations prior to conduction of the study and has a reference number of (2719) in 16th of December2024. Ethical approval was obtained from the board and all patients were informed of their enrollment in the study, and formal consent was acquired from the patient and/or their first-degree relatives with explaining to them their free right of discontinuation at any time of the study. The study was following strict protocols of follow up with the supervision of the specialized Dermatologist. After the process of data collection, the data were entered into SPSS version 24 for statistical analysis. Statistical analysis included mean and standard deviation for socio-demographic features as well as the percentage and frequencies.

RESULTS

Demographics characteristics: The average age of participants was 27.06 years (SD = 9.058), with an age range of 18 to 48 years. The majority were male (61.1%), whereas females comprised 38.9%. Participants were equally split, with 50% single and 50% married. Occupational Background: The documented occupations include government employees (33.4%), private sector employees (27.8%), homemakers (16.7%), students (16.7%), and others. The mean duration of the condition was 9.28 weeks (SD = 13.132), with a mean onset age of 25.72 years (SD = 8.943). All were seen in table (1).

Table 1. The sociodemographic characteristics of the participants

Demographic Characteristics		Frequency	Percentage(%)
Age in year (Mean ± SD)		27.06 ± 9.058	
Age in years (range)		18-48	
Duration in weeks (Mean ± SD, Range)		9.28 ± 13.13, 2-54	
Age at first attack in years (Mean ± SD, Range)		25.72 ± 8.94, 14-48	
Sex	Male Female	11 7	61.1 38.9
Social Status	Single Married	9 9	50.0 50.0
Job	Government Employee House wife Jobless Private employee Student	6 3 1 5 3	33.4 16.7 5.6 27.8 16.7

A significant majority (88.9%) did not report a familial history of Alopecia Areata, while a small number (11.1%) indicated such a history. The vast majority of individuals (94.4%) displayed no linked conditions, with a singular individual reporting hypertension. Additional familial medical histories were thyroid disorders (5.6%) and diabetes mellitus (27.8%). The medical and family history of the group shown in table (2).

Table 2. Represents the Medical and Family History of the participants

Medical and Family History	Subcategories	Frequency	Percentage
Previous Illness before 6 Months	Yes	1	5.6
	No	17	94.4
Associated disease	No	17	94.4
	Hypertension	1	5.6
Family History	No	10	55.6
	Alopecia Areata (AA)	2	11.1
	Thyroid diseases	1	5.6
	Diabetes mellitus	5	27.8

Participants had an average of 3.17 patches (SD = 1.581), with counts varying from 2 to 8. The parietal region was the most frequently impacted (33.3%), succeeded by the occipital (16.7%) and temporal (11.1%) regions. Combinations of impacted areas were also noted, indicating differing intensity and patterns. Pitting was observed in 27.8% of subjects, whilst 72.2% had no nail involvement as seen in table (3).

Table 3. Clinical Response of patients to treatment

Clinical Features	Subcategories	Frequency	Percentage(%)
Number of patches (Mean ± SD), Range		3.17 ± 1.58, 2-8	
Scale at alopecic patches		18	100.0
Involved area	Parietal	6	33.3
	Occipital	3	16.7
	Parietal + Occipital	1	5.6
	Vertex, occipital, parietal, &	2	11.1
	frontal	1	5.6
	Vertex	2	11.1
	Temporal	3	16.7
	Occipital + Temporal		
Nail involvement	Pitting	5	27.8
	No nail involvement	13	72.2

After one month of IL injection of BTX-A, McDonald Hull and Norris Scores: about 50% of participants had a score of zero, signifying no substantial change, whereas 33.3% and 16.7% achieved scores of one and two, respectively, Following two months, the majority of participants (55.6%) attained a score of three, indicating substantial enhancement, Moderate discomfort was reported by 44.4% of individuals, whereas mild discomfort was observed in 27.8%. High satisfaction levels were recorded, with 44.4% expressing satisfaction and 33.3% demonstrating moderate contentment. In Table (4) the treatment outcome of Botulinum Toxin-A are shown.

Table 4 Treatment outcomes of the sample

Botulinum Toxin-A outcome	McDonald Hull and Norris Score	Frequency	Percentage (%)
After 1 months Botulinum Toxin-A	Zero	9	50.0
	One	6	33.3
	Two	3	16.7
After 2 months Botulinum Toxin-A	Zero	2	11.1
	One	3	16.7
	Two	3	16.7
	Three	10	55.6
Pain during sessions	Mild	5	27.8
	Moderate	8	44.4
	Mild - Moderate	5	27.8
Patient Satisfaction Scale	Fairly satisfied	6	33.3
	Satisfied	8	44.4
	Not satisfied	4	22.2

McDonald Hull and Norris Scores: After one month, 50% of individuals attained a score of two, indicating moderate enhancement. After two months, a majority (50%) attained a score of three, while 16.7% achieved a score of four, indicating substantial improvement, Equal percentages indicated mild and moderate pain (50% each). Customer satisfaction was significantly elevated, with 61.1% expressing contentment. The treatment outcomes of Triamcinolone Acetonide are shown in Table (5).

Table 5 Treatment outcome Triamcinolone Acetonide Injection

Triamcinolone Acetonide Injection	McDonald Hull and Norris score	Frequency	Percentage(%)
Baseline Score	Zero	15	83.3
	One	3	16.7
After 1 month Triamcinolone Acetonide injection	Zero	2	11.1
	One	6	33.3
	Two	9	50.0
	Three	1	5.6
After two months Triamcinolone injection	Zero	1	5.6
	One	1	5.6
	Two	4	22.2
	Three	9	50.0
	Four	3	16.7
Pain during injection	Mild	9	50.0
	Moderate	9	50.0
Patient Satisfaction	Fairly satisfied	3	16.7
	Satisfied	11	61.1
	Not satisfied	4	22.2

Both interventions showed progressive improvement of the condition in the period of two months, with high satisfaction levels noted for both treatments after the aforementioned period.
Pain levels during sessions were comparable among treatments, with most patients reporting mild to severe discomfort. Patient satisfaction was marginally superior for Triamcinolone Acetonide injections in comparison to botulinum Toxin-A as shown in Figure 2.

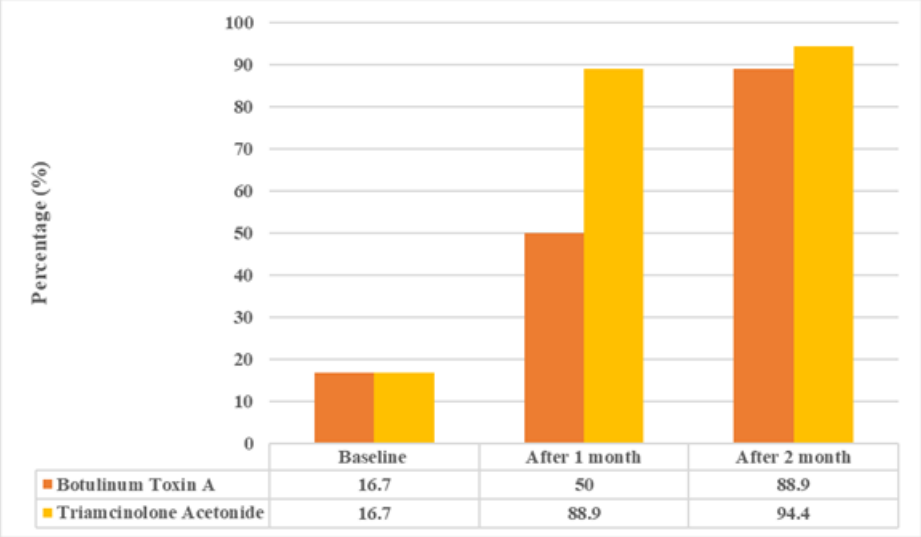

Figure 2. Comparison of Effectiveness Over Time.

Triamcinolone injection resulted in skin atrophy in 16.7% of participants, whereas Botulinum Toxin-A Did not exhibit any problems as illustrated in the figure 3.

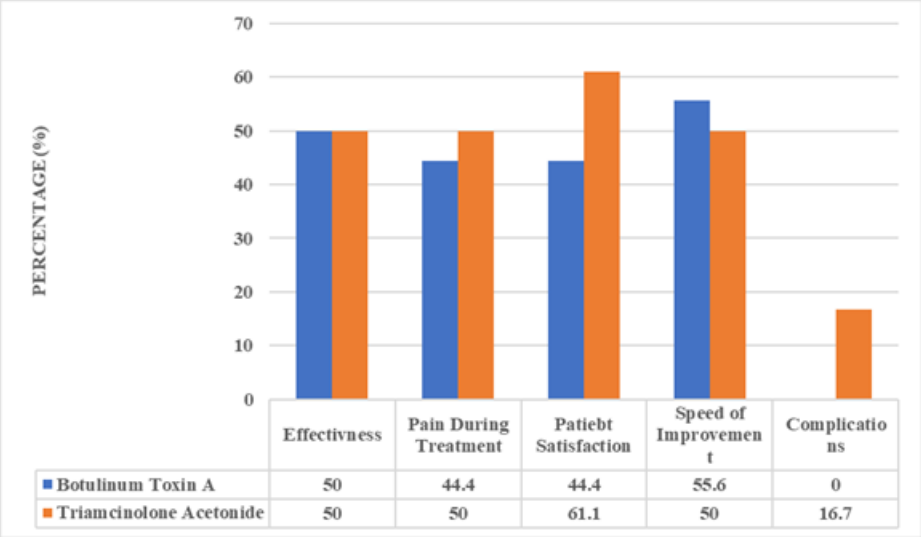

Figure 3. Comparison of both treatments on patients

DISCUSSION

Alopecia Areata is globally known auto-immune disease that affects up to 2% of the population characterized by a non-scaring hair loss presenting as oval or round patches of hair-loss.[13,14] The disease has genetic and environmental susceptibility.[15] with several treatment approaches with some under further evaluation which include BTX-A injections.[16] In this clinical trial, the outcomes of BTX-A injection where compared to Triamcinolone injections for Alopecia Areata patients. The mean of age of the participants was 27.06 ± 9.058 years and the majority were males 61.1% compared to females 38.9%. The mean number of alopecia patches per patient was 3.17 ± 1.58 with a range of 2-8 patches, the highest area for patches was in parietal region. Both injections were equally effective 50% vs 50%. However, in a small prospective study by Cho et al.[11] BTX-A injections did not show significant improvement, probably the small sample size of 7 was the main reason as in our study, the sample size is almost 2.6 times that sample. As of regard to patient satisfaction, 44.4% patients were well satisfied with BTX-A injection and 33.3% were fairly satisfied; an overall 77.7% patient satisfaction with BTX-A injection was seen compared to 77.8% with Triamcinolone. In contrary, Cho and colleagues as well as Carloni and colleagues had low patients' satisfaction with one patient condition showing worsening,[11, 16] this could be attributed to the technique of application. Additionally, in this study nearly 16.7% of Triamcinolone injected patches showed atrophic dermis after 12 weeks as shown in Figure (4) which was not seen with BTX-A. This side effect from Triamcinolone is mainly attribute to the corticosteroid effect; one case reported permanent hair loss in the literature.[17]

Figure 3. Atrophic change of the Dermis after injection with Triamcinolone Acetonide are seen in figure A,B.

CONCLUSION

Despite the limited data on the comparison of both injections, this study finds BTX-A injection superior to Triamcinolone for Alopecia Areata (AA), as there was no significant difference between both injections, both were equally effective and had almost the exact patient satisfaction, yet BTX-A injection showed superiority over Triamcinolone for atrophic change. Further, studies should be conducted with larger sample size and longer duration. Botulinum Toxin-A was better tolerated, with faster initial improvement and no significant complications. Triamcinolone Acetonide Injection records higher overall patient satisfaction and effectiveness in moderate severity with a higher risk of complications (subcutaneous atrophy) which occurred in 16.4% of total cases treated. For Choosing between these treatments: patient preferences, the need for immediate results, and tolerance for potential complications should be taken into consideration.

DECLARATIOM

Conflict of Interest

None to declare.

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None to declare.

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