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RESEARCH LETTER

Efficacy and tolerability assessment of a polynucleotide-based gel for improvement of pattern hair loss

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Androgenetic alopecia (AGA) is the leading etiology for scalp hair loss in both genders. Apart from the limited approved pharmaceuticals, there are other nonsurgical-non-drug methods, including scalp polynucleotides injectable [1]. However, limited data exists and is mostly limited to one gender [1]. This study aimed to evaluate efficacy and tolerability of a polynucleotide injectable gel for the treatment of AGA in both genders.

Twenty patients (10 males and 10 females,) age 37.7 ± 8.1 years old, with hair loss types II- IV according to the Hamilton– Norwood stages or grade I-II according to Ludwig scale recruited and, received 10 treatment sessions using PLURYAL® Hair intradermal gel containing 15 mg of polynucleotides over 4 months {4,2,2,2}. Patients were excluded in case of known allergies to the product ingredients as well as using the prescribed or OTC hair loss treatments, in the last three months.

Standard scalp photography, comb test and trichoscale assessment were performed before the treatment, week (W) 18 (two weeks after the last injection), and W24 (8 weeks after the last injection) as previously described by the authors [2]. Adverse reactions and patients' satisfaction were also documented.

65%, 77.8%, and 63.2% of patients showed slight or moderate improvement in hair regrowth according to Global Photographic Review criteria at W6, W18, and W24, respectively (Fig. 1). While the regrowth rate, was reported 30–40%, after 6 months treatment with 5% topical minoxidil [3].

Trichoscale assessment showed significant increases in the mean thickness of hairs at W24 and terminal/vellus hair ratio at W18 and W24 (Table 1). Therefore, current study reported 13.8% and 24.2% increase in terminal hairs count at W18 and W24 respectively, while these numbers were 13.23% and 10.54%, for minoxidil 2% and 5% respectively, in male pattern balding and 12.13% and 10.82% respectively in female pattern hair loss [3].

Possible trophic effects of polynucleotides are due to activation of fibroblast growth factor and A2 purinergic receptors stimulation in dermal papilla [4, 5].

A significant decrease is detected in hair fall count until W24 (Table 1) which could be explained by the increasing trend of anagen phase duration, however, providing a monthly maintenance injection would be suggested.

At W6, W18, and W24, 85%, 50%, and 47.4% of patients rated their hair shedding as "improved" or higher which was confirmed with combing test results.

The adverse effects were limited to mild headache and swelling, which were abated with outpatient treatment, as well as moderate maculopapular rash on the lower extremity one-week after injection, which resolved with oral antihistamine and dexamethasone injection.

In conclusion, this study demonstrated the tested polynucleotide gel injection as an effective treatment for decreasing hair shedding and increasing the mean thickness of the hairs with high patient satisfaction and safety profile in male and female AGA. The findings are in concordance with previous consensus reports [1].

Small sample size and lack of control group are the main limitation of the study. Larger case-control studies would be suggested.

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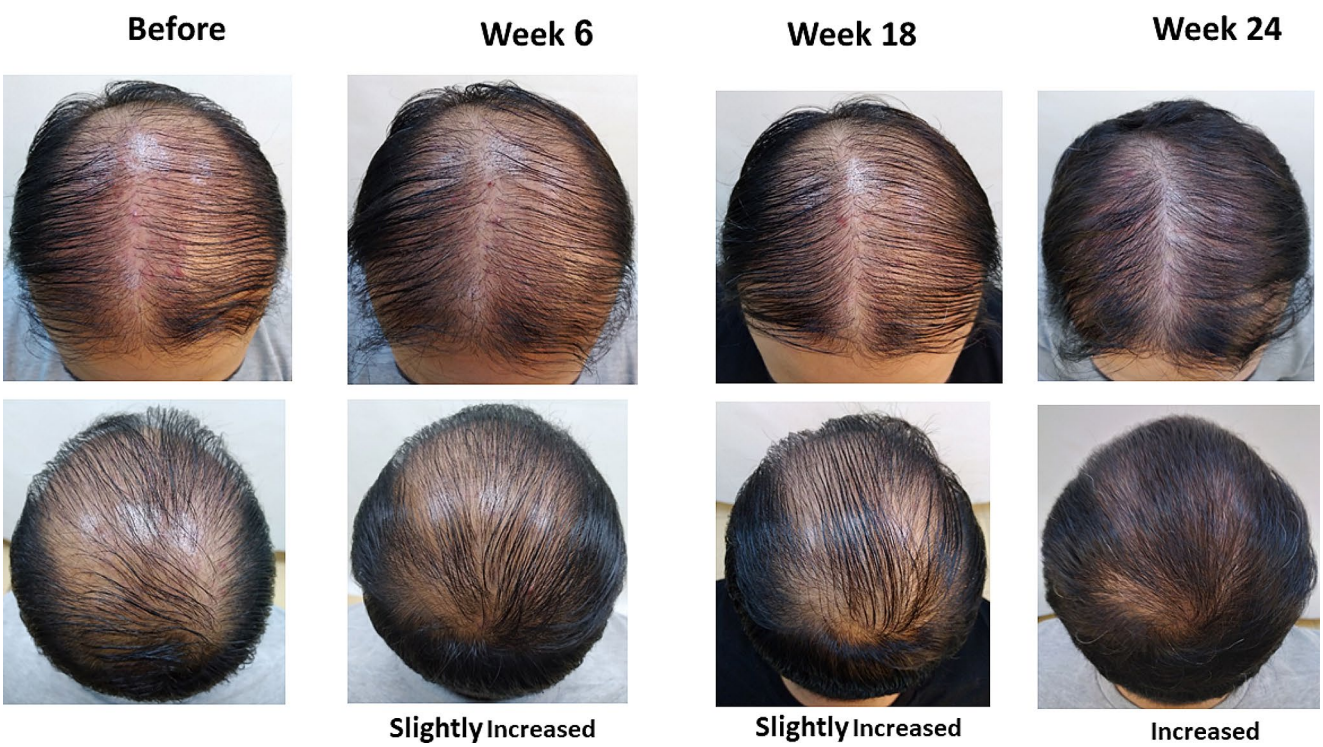

Fig. 1 Standardized photographs pictures of two representative cases with improved hair density in before gel treatment and at weeks 6 (after 4 injections), 18 (two weeks after last injection), and 24 (8 weeks after last injection)

Table 1 Trichoscan parameters before gel treatment and at weeks 6 (after 4 injections), 18 (two weeks after last injection), and 24 (8 weeks after last injection)

parameters	before	Week 6	Week 18	Week 24	*p*-value [1]	*p*-value [2]	*p*-value [3]
	Median (range)						
Total hair fall	90 (20–380)	72 (7-280	60 (10–270)	67 (12–270)	< 0.01	0.011	0.049
Total hair density (hair/cm2)	147.25 (103-226.8)	148.9 (86.40–186)	143.9 (89.7-221.4)	138.4 (89.7 229.2)	0.21	0.26	0.46
Hair thickness (μm)	51 (37–76)	50 (31–84)	48 (35–88))	64 (30–94)	0.62	0.71	**0.04**
Anagen/Telogen Ratio	2.93 (1.26–5.58)	3.03(2.14–11.66)	3.64(1.67–6.69)	3.54(2-7.93)	0.60	**0.05**	**0.05**
Terminal/ Vellus Ratio	1.54 (0.56 15.95)	1.78 (0.28–10.24)	2.15 (0.24–22.81)	2.21 (0.33–12.33)	0.90	**0.013**	**0.011**

P-value[1–3]: comparison between baseline and week 6, 18 and 24 respectively (Wilcoxon rank test)

Hair shedding decreased from 90 (20–380) at baseline to 72 (7-280), 60 (10–270), and 67 (12–270) at weeks 6, 18 and 24 respectively, which were statistically significant at all visits (p-values < 0.01, 0.011 and 0.049, respectively)

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Author contributions The contributions for this research paper was based on the ICMJE criteria and is as follows: AS: Study Conceptualization, Manuscript Preparation, Data accusation, Data analysis; AA: Data accusation, Medical procedures; MNK: Data accusation, Medical procedures; SZ: Manuscript Preparation, English Edition, Revision, Submission; AF: Study Conceptualization, Academic edition.

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Data availability The authors confirm that the data supporting the findings of this study are available within the article.

Declarations

Ethical approval Ethics approval was obtained in April 2021 (code: IR.TUMS.MEDICINE.REC.1401.039) and prospectively registering in Iranian registry of clinical trial (IRCT20150101020514N15). This Study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments.

Consent to participate/ publish All patients were informed about the aims of the study and have signed written consents for patients and publication, including the rights to publish figures and visuals.

Competing interests The authors declare no competing interests.

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