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The clinical effect of JetpPeel-assisted topical minoxidil in the treatment of androgenetic alopecia: A randomized pilot study

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ABSTRACT

Objective: We used JetPeel, combined with topical minoxidil to treat patients with AGA, in order to observe whether the JetPeel can accelerate the recovery of the disease and find a new method for AGA treatment. Method: Thirty patients who met the standard were included in the study. The patients were randomly divided into three groups. The first group was treated with JetPeel-assisted topical minoxidil. The second group received topical minoxidil monotherapy. The third group was not given any treatment. We used objective evaluation (amount and diameter of hair, oil secretion level) and subjective evaluation (hair growth score marked by dermatologist and patient) to evaluate the hair growth condition before treatment and every other month. The calculated p values of less than 0.05 were accepted as significant. Result: All of the 30 patients finished the study. There was no difference in age, sex, and duration and severity of the disease among groups prior to treatment (p > 0.05). And there was greater improvement in scores of hair growth in the first group compared to the second and third group, which was statistically significant (p < 0.05). Conclusion: Compared with topical minoxidil monotherapy, JetPeel-assisted topical minoxidil is more effective during the treatment of androgenetic alopecia.

ARTICLE HISTORY

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Androgenetic alopecia; JetPeel; topical minoxidil

Introduction

Androgenetic alopecia (AGA) is the most common type of baldness, whose clinical manifestations are the miniaturization of hair follicles and the progressive hair loss. Most men show a backward-shift of hairline(1), and most women show a diffuse thinning hair from the vertical area(2). The prevalence of AGA in China is very high, especially in males after adolescence(3). Some patients may feel itching, oily scalp, and increased scurf, while most patients have no uncomfortable clinical manifestation. Loss of hairs will influence the patients' appearance, selfesteem, self-confidence, and the quality of life(4,5).

There are many treatment methods for androgenetic alopecia, including oral drugs, topical drugs, phototherapy, mechanical stimulation, and surgery. Topical minoxidil is the only drug approved by the US Food and Drug Administration for the treatment of AGA in both men and women(6). In the past, minoxidil was a kind of hypotensive drug. When minoxidil was used to decrease the blood pressure, people found that it could also increase the amount of the hair. The exact mechanism of action of minoxidil in the treatment of AGA is not completely understood. Minoxidil may dilate vessels, promote neovascularization, promote cell proliferation, regulate potassium channels, and stimulate vascular endothelial growth factor and prostaglandin synthesis (7), it may also suppress androgen receptor-related functions (8). Clinical trials proved that minoxidil with 5% concentration is more effective for AGA treatment(9), while the

efficiency is lower and patients need lengthy treatment period(10). Clinical response to 5% topical minoxidil for the treatment of androgenetic alopecia (AGA) is obviously observed after 3-6 months.

JetPeel is a new machine which can promote transdermal absorption of topical drugs(11,12). It is a device consisting of three parts: a hand piece, a control unit (device' body), and a footswitch. The hand piece is connected to the device body by tubing line accessories. It can force a mixture of liquid and oxygen into three parallel channels, which accelerates the droplets (200 m/sec) outside through a specific nozzle, delivering a powerful jet of microdroplets containing drug onto the skin surface. The effect of JetPeel includes cleaning the skin deeply, promoting transdermal absorption of drugs, improving microcirculation, and promoting synthesis of collagens (Figure 1) (13).

This is an original study, combining JetPeel and topical minoxidil to treat AGA, which aims to observe whether JetPeel can promote the absorption of topical drugs, improve the effect of topical minoxidil, and accelerate the improvement of the AGA.

Materials and method

Patient characteristics

Thirty male patients were enrolled in this study. The inclusion criteria include (1) with the diagnosis of AGA, (2) aged from 25 to





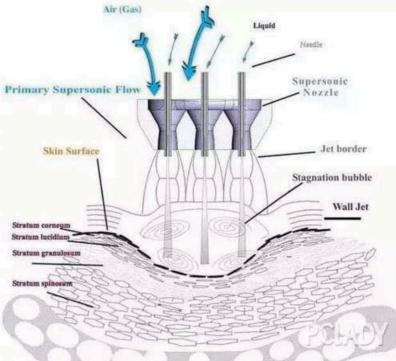


Figure 1. JetPeel and its working principle.

55 years, and (3) the duration of the disease of each patient is more than 1 year. The exclusion criteria include (1) patient with hypertension, (2) patient with head injury, (3) patient with mental disorder, (4) scar physique, (5) previous treatment to the hair loss within six months, and (6) taking oral antihypertensive agents. Informed consent was obtained from all patients. Institutional Medical Ethic and Human Research Committee of China Medical University approved that our study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

Experimental procedure

Thirty patients with AGA from Department of Dermatology at The First Affiliated Hospital of China Medical University, Shenyang, China, were recruited to take part in this clinical trial. They were classified by three professional dermatologists according to Hamilton-Norwood Patterns, which is a way to measure the severity of male pattern baldness(14). The patients were allocated into three groups randomly and the

randomization was stratified by Hamilton-Norwood classification. And patients in each classification were randomly allocated into three groups by random number table. The first group (n=10) was treated by JetPeel (Myjet, TavTech, Israel) which deliver 5% minoxidil (Minoxidil Tincture, Wansheng Pharmaceutical, Zhejiang, China) to the hair-loss scalp once a week, and smeared 5% minoxidil twice a day by themselves. The second group (n=10) only smeared 5% minoxidil twice a day by themselves. The third group (n=10) was not given any treatment. The dose of minoxidil for each patient is not more than 2 ml per day. The duration of treatment of each patient was three months.

Evaluation of efficacy

Objective evaluation: We chose a fixed site from hair-loss area of each patient to evaluate the hair growth condition by trichoscopy (at ×70 magnification) and oil-water test machine before treatment and every other month. The trichoscopy

(CBS-1717, Taiwan, China) can measure the amount and diameter of hair in unit area (visual field of trichoscopy). (Figure 2)(15) The oil-water test machine can measure the oil secretion level in the fixed site. We marked the fixed site by a plastic ruler. First, we divided the patiant' head into four quadrants, the line between two earlobes was the abscissa, the vertical line through the tip of nose was the ordinate. And we chose the same coordinate mark to measure at each follow-up visit.

Subjective evaluation: the dermatologist and the patient scored the hair growth condition using a 6-point scale (1 = worsen, 2 = unchanged, 3 = mild improvement, 4 = moderate improvement, 5 = good improvement, 6 = excellent improvement) every other month.

Statistical analysis

Data were analyzed using the SPSS 21.0 software. The paired-sample T test was applied to analyze the difference of amount and diameter of hair between before and after treatment in each group. The one-way analysis of variance was applied to analyze the difference of the amount and diameter of hair and oil secretion level among groups. The Kruskal–Wallis test was



Figure 2. Photos from trichoscopy, calculate the amount and the diameter of hair

applied to analyze the difference of hair growth score among groups. The calculated p values of less than 0.05 were accepted as significant.

Results

General information

All patients finished the experiment. The age, and severity and duration of the disease in each group were showed in Table 1. There is no statistical significance about age, severity and duration of the disease among groups (p > 0.05).

Objective evaluation

Diameter of hair

The increase of hair diameter in each Group1 and Group2 after treatment was statistically significant (p < 0.05), and there was no significant difference in Group3 before and after 3-months observation (p > 0.05). The difference between Group 1 and 2, and Group 1 and 3 were significant (p < 0.05) after three months, which showed JetPeel-assisted topical minoxidil was more effective than topical minoxidil monotherapy (Table 2).

Amount of hair

The increase of hair amount in each Group1 and Group2 after treatment was statistically significant (p < 0.05), and there was no significant difference in Group3 before and after 3-months observation (p > 0.05). The difference between group 1 and 2, and group 1 and 3 were significant (p < 0.05) after three months, which showed JetPeel-assisted topical minoxidil is more effective than topical minoxidil monotherapy. Also, there was a significant difference (p < 0.05) between Group 1 and 2 after two months, which showed JetPeel-assisted topical minoxidil took the effect more quickly than topical minoxidil monotherapy (Table 3).

Oil secretion level

There was no significant difference before and after treatment among three groups (p > 0.05), which showed JetPeel and minoxidil had no effect on oil secretion of scalp (Table 4).

Table 1. General information of patients.

		Sev	Severity (number of patients)			
Group	Age	II	III	IV	٧	(year)
1	36.2 ± 7.0	2	6	1	1	4.8 ± 2.5
2	34.9 ± 7.4	3	5	1	1	4.5 ± 3.1
3	35.8 ± 8.6	3	5	1	1	4.8 ± 2.6

Table 2. The increase of hair diameter in each group.

	Increase of hair diameter (mean \pm SD mm)					
Group	Ν	1 month	2 month	3 month	p Value [#]	
1	10	0.008 ± 0.009	0.01 ± 0.009	0.015 ± 0.009*	0.000	
2	10	0.002 ± 0.006	0.004 ± 0.007	0.007 ± 0.008	0.003	
3	10	0.000 ± 0.009	-0.005 ± 0.009	0.000 ± 0.011	1.000	

^{*}The paired-sample T test was applied to analyze the difference of hair diameter between before and after treatment in each group.

^{*:}One-way ANOVA was applied to analyze the difference of hair-diameter improvement among groups, p < 0.05 compared to group 2 and group 3.

Table 3. The increase of hair amount in each group.

		Increase of hair amount (Mean \pm SD)					
Group	Ν	1 month	2 month	3 month	p Value [#]		
1	10	1.800 ± 4.962	11.600 ± 7.412 ^{&}	18.200 ± 9.016*	0.000		
2	10	3.700 ± 5.314	4.100 ± 7.937	10.400 ± 9.216	0.006		
3	10	-0.900 ± 7.109	-0.900 ± 4.149	-0.800 ± 4.104	0.553		

[#]The paired-sample T test was applied to analyze the difference of hair diameter between before and after treatment in each group.

Subjective evaluation

The Kruskal–Wallis test was applied to analyze the hair growth score marked by dermatologist and patient among three groups. There was a significant difference of dermatologist scoring among three groups after two months (p < 0.05) and the difference between group 1 and 2 was significant (p < 0.017). As to patient scoring, there was a significant difference among three groups after two months (p < 0.05), but the difference between group 1 and 2 was not significant after three months (p > 0.017) (Table 5).

Safety evaluation

We can see the obviously clinic improvement in the picture showed below. And the effect in Group 1 is better than Group 2 (Figure 3). Ten patients were treated with JetPeel and there was no pain during the treatment. The 18 of 20 patients, who used minoxidil, had dandruff increase phenomenon during the first month and no other abnormal symptoms.

Discussion

AGA is associated with androgen, androgen receptors and the expression of some genes or mutations(16). Many symptomatic treatments are applied in clinic, such as oral drugs, topical drugs, phototherapy, mechanical stimulation, and surgery. But, each treatment has its limitations (slow onset, long course or easy recurrence). Nowadays, scientists are working to look for new treatment with more efficiency,

fewer side effects and faster onset. Minoxidil tincture is the topical drug. Its mechanism of promoting hair growth is still not very clear, but a large number of clinical trials showed that it has the effect of promoting hair growth, but it is not effective for all patients and need long-term application.

JetPeel is a new machine which can promote transdermal absorption of topical drugs. Because of its internal pressuring mechanism, the spray of drug mixed with gas under a predetermined pressure of 7 atm and emitted at a speed of up to 200 m/s. So it has the effect of promoting drug transdermal absorption, cleaning skin and mechanical stimulation of local skin. When we use JetPeel assisted minoxidil tincture to treat, it can increase the absorption rate of minoxidil, clean the surface of the scalp and hair follicles, and it also can massage the scalp, promote scalp blood circulation, then provide a good condition for the growth of hair. The three months observation of clinical compared experiment showed that JetPeel-assisted topical minoxidil was more effective than topical minoxidil monotherapy. And it can be seen from the data that JetPeel accelerate the onset of minoxidil tincture. Minoxidil tincture itself has the temporary hair loss (telogen effluvium), one of side effects, and this phenomenon was thought to be related with hair growth cycle. Minoxidil promotes earlier shedding of hair in the telogen phase, but help the hair to grow into a fresh and a healthier anagen phase. Telogen effluvium often appears in the first or second month after administration(17). The experiment data showed JetPeelassisted topical minoxidil put the telogen effluvium forward, and the onset of the effect was one month quicker compared to minoxidil monotherapy which needed at least 3 months of treatment. We also tested the oil secretion value of scalp, because patient with androgen alopecia has the characteristic of more oil secretion. But the data showed that there was no significant difference between treatment group and blank control group, which showed minoxidil tincture and JetPeel had no effect on oil secretion.

Patients with androgen alopecia felt no pain and hot during treatment with JetPeel, the whole treatment process is tolerant and comfortable. The patient in treatment group

Table 4. Oil secretion level in each group (Mean \pm SD).

Group	Before treatment	1 month	2 month	3 month
1	66.2 ± 57.3	81.7 ± 38.4	59.2 ± 35.3	74.6 ± 41.2
2	72.0 ± 31.3	98.0 ± 74.4	60.7 ± 29.6	81.1 ± 37.7
3	89.7 ± 82.9	120.6 ± 63.9	75.7 ± 58.0	74.9 ± 54.7
p value*	0.728	-	_	0.940

^{*}One-way ANOVA was applied to analyze the difference of oil secretion value among groups.

Table 5. Average score in each group.

Group	Dermatolo	Dermatologist scoring		Patient scoring		
	1 month	2 months	3 months	1 month	2 months	3 months
1	2.3 ± 0.823	3.5 ± 0.850	4.2 ± 0.789	2.5 ± 0.527	2.9 ± 0.568	3.6 ± 0.699
2	1.7 ± 0.675	2.4 ± 0.699	2.9 ± 0.568	2.2 ± 0.422	2.4 ± 0.516	2.9 ± 0.568
3	1.8 ± 0.422	1.7 ± 0.483	2.0 ± 0.471	2.0 ± 0.000	1.7 ± 0.483	1.9 ± 0.316
P*	0.149	0.000	0.000	0.033	0.001	0.000

^{*}Kruskal–Wallis test was applied to analyze the hair growth score marked by dermatologist and patient among three groups. p = 0.007 < 0.017, compared Group 1 and 2 after 2 months in dermatologist scoring. p = 0.002 < 0.017, compared Group 1 and 2 after 3 months in dermatologist scoring. p = 0.028 > 0.017, compared Group 1 and 2 after 3 months in patient scoring.

 $^{^{\&}amp;}$: One-way ANOVA was applied to analyze the difference of hair-amount improvement among groups. p < 0.05, compared to group 2 and group 3.

^{*:} p = 0.042 < 0.05 compared to group 2.



Figure 3. Photos of clinical effects.

had the symptom of scurf increasing except for telogen effluvium. It may due to the minoxidil tincture residue. This study also had limitations. There were only 30 patients enrolled in our study and the duration of follow up was short. If the followed researchers can prolong treatment period and expand sample size, the result would get better.

Conclusion

It is certain that minoxidil has the effect on the treatment of androgenetic alopecia, but the onset of the effect is slower and the efficiency is lower. JetPeel-assisted topical minoxidil can accelerate the effect onset of minoxidil. It is a better choice for patient who has poor compliance and wants to shorten the treatment period.

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