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Original Article

Therapeutic Efficacy of Oral Cyclosporine in Female Pattern Hair Loss

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Abstract

Objective: Female Pattern Hair Loss (FPHL) is a common form of nonscarring hair loss that mainly occurs in adult women, with prevalence increasing with age and affects up to 50% of women during their lifetime. The exact mechanism of FPHL is not understood, and standardized treatment protocols have not yet been established. The therapeutic effects of a group taking oral cyclosporine and a Pantothenic Acid Complex (PAC)-based dietary supplement (combination therapy group) and a group taking only the PAC-based dietary supplement (monotherapy group) were compared to evaluate the clinical efficacy of oral cyclosporine in FPHL.

Methods: A total of 25 patients with FPHL was treated with combination oral cyclosporine and PAC-based dietary supplement, and 47 patients were treated with the PAC-based dietary supplement alone. Therapeutic efficacy in both groups was evaluated retrospectively using clinical photographs and medical records.

Results: Patients of the combination therapy group showed greater improvement than patients in the PAC-based dietary supplement monotherapy group ($p<0.02$). Even in patients with Ludwig 2 and 3 hair loss, the combination therapy group showed improved treatment effectsrelative to the monotherapy group ($p<0.05$). There were some adverse effects including gastrointestinal discomfort and hypertrichosis at unwanted sites. No serious adverse effects were experienced.

Conclusion: Cyclosporine showed significant improvement in moderate to severe FPHL patients, and may be an option for the treatment of FPHL for which no specific treatment has been suggested.

Keywords: Cyclosporine; Female pattern hair loss; Pantogar

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Introduction

Female Pattern Hair Loss (FPHL) is a common form of hair loss that most frequently occurs in adult women and primarily involves the front and vertex of the scalp [1]. With increasing interest in bettering appearance, the number of female hair loss patients who want treatment is increasing gradually. Several therapeutic modalities including topical minoxidil and the systemic antiandrogens spironolactone or cyproterone acetate [2], finasteride [3], and dutasteride have been used as treatments for FPHL [4,5]. Finasteride and dutasteride are difficult to use as a treatment option in premenopausal women, so other medications are needed for FPHL. In research on systemic therapy, the therapeutic efficacy of FPHL treatment is controversial, and standard treatment for FPHL has not yet been established.

Cyclosporine is an immunosuppressant that binds to cytoplasmic proteins and inhibits calcineurin to block both the humoral and cell-mediated immune response. Oral cyclosporine has shown efficacy for alopecia areata [6,7], and other reports revealed the direct effect of cyclosporine on human hair in scalp-grafted nude mice and rats [8,9]. However, no studies have investigated the therapeutic efficacy of oral cyclosporine in FPHL.

Pantogar® is a specific L-cystine, medicinal yeast, and pantothenic acid complex (PAC)-based dietary supplement. L-cystine is a component of keratin, and hair contains a large proportion of L-cystine (15.9%) [10]. Pantothenic acid is required for synthesis of CoA, and metabolism of carbohydrates, proteins and fats. It was found that pantothenic acid promotes dermal papilla cell proliferation in hair follicles via inhibitor of DNA binding3/Notch signaling pathway in vitro [11]. Pantogar® is currently used as a supplementary oral treatment for FPHL.

To evaluate the effectiveness of oral cyclosporine in FPHL, we compared the therapeutic effect between a combination therapy group with oral cyclosporine and a PAC-based dietary supplement and amonotherapy group with a PAC-based dietary supplement alone, which is known to be helpful and is used frequently in FPHL treatment [12].

Materials and Methods

Subjects

We retrospectively reviewed the medical records and clinical photographs of 72 FPHL patients from January 2011 to November 2019 at the Department of Dermatology, Hanyang University Hospital. The Institutional Review Board approved this study (HYUH 2019-12-023), which was conducted according to the Declaration of Helsinki Principles. All patients presented with a reduction in hair density of the centroparietal region with a maintained frontal hair line. Patients with hypertension, renal failure, liver failure or other serious medical illnesses were excluded from the study. Patients who planned to be pregnant within 1 year were also excluded. Among 72 patients, 25 with FPHL were treated with oral cyclosporine with PAC-based dietary supplement (combination therapy group), and 47 were treated with the PAC-based dietary supplement alone (monotherapy group).

All the patients had agreed to be taken photographs and written the informed consent to use their photographs in this paper.

Methods

Patient characteristics

We examined demographic information of sex, age, severity of hair loss, and treatment history (e.g., topical minoxidil, topical alfatradiol, topical steroid). The severity of FPHL was rated according to the Ludwig scale. Ludwig grade 1 is perceptible thinning of the hair on the crown, limited in the front by a line situated 1-3cm behind the frontal hair line. Ludwig grade 2 is rarefaction of the hair on the crown within the area seen in grade 1, and Ludwig grade 3 is nearly full baldness with in the area seen in grades 1 and 2.

Treatment regimen and follow up

Due to ethical reasons, all 72 patients were treated with the PAC -based dietary supplement (Pantogar®, 3-4 capsule/day), which is helpful for hair growth, and topical alfatradiol was maintained. The combination therapy group was treated with cyclosporine (Cipol-N®, 100mg, 25mg/cap, Chongkundang, Korea),and dose was adjusted by 200-300mg (3-5 mg/kg) per day at each visit according to severity of hair loss. All patients visited the outpatient clinic every 12 weeks, and blood pressure wasmeasured at every visit. Laboratory test including complete blood cell count, kidney function, liver function, and lipid profile were performed before initiation of cyclosporine treatment and every 12 to 16 weeks thereafter.

Evaluation procedure

Clinical photographs were produced using identical camera settings, lighting, and patient positioning at baseline and every 3months. Independent investigators evaluated the clinical photographs. FPHL severity was evaluated before and after treatment according to the Ludwig scale. In addition, the degree of improvement was evaluated according to a 5-point scale as follows : -1, worse ; 0, no change; 1, slightly improved (0-25% improvement); 2, moderately improved (25-50% improvement); and 3, markedly improved (> 50% improvement) [3]. The Ludwig scale scores before and after treatment were compared. Due to the risk of scarring, histopathologic examination was not performed.

Statistical analysis

Data were analyzed using SPSS version 22.0 for Windows (SPSS Inc., Chicago, IL, USA). Differences in demographic data between the two groups were analyzed using the *t*-test and Mann-Whitney U test. The examined covariates were age, body weight, and treatment history. The Pearson's chi-square test was performed to analyze the difference of treatment efficacy between the two groups. A *p*-value <0.05 was defined as statistically significant.

Results

Demographic analysis

Demographic and descriptive variables are shown in Table 1. A total of 72 female patients diagnosed with FPHL was included in this study. Twenty-five patients were treated with combination therapy using oral cyclosporine with a PAC-based dietary supplement (Pantogar®), and 47 patients were treated with PAC-based dietary supplement monotherapy. Statistics show that age, body weight, and treatment history were not significantly different between the two treatment groups (Table 1). The age of patients in the combination therapy group ranged from 21 to 75 years (average of 47.0±18.2 years), and that in the monotherapy group was 22 to 76 years (average of 48.0±14.8 years). There is a pronounced peak in patients aged 50-59 years (27.8%), followed by a peak in those aged 20-29 years (23.6%) (Table 1).

Variable		Combination therapy group	Monotherapy group	*p*-value
Age (n=72); No. of patients (%)	Mean age (yr)	47.0 ± 18.2	48.0 ± 14.8	0.80
	20-29	7 (28.0)	10 (21.3)	
	30-39	3 (12.0)	6 (12.8)	
	40-49	3 (12.0)	6 (12.8)	
	50-59	6 (24.0)	14 (29.8)	
	60-69	2 (8.0)	9 (19.1)	
	70 -	4 (16.0)	2 (4.3)	
	Total	25	47	
Body weight (kg)		59.7 ± 6.1	55.5 ± 5.2	0.05
Past treatment	Topical alfatradiol	23	43	
	Topical minoxidil	0	1	
	Topical cortico-steroid	7	6	

Table 1: Demographic data of patients.

Treatment efficacy

Clinical improvement was evaluated using clinical photographs (Figure 1) and Ludwig scale assessment before and after treatment. The difference before and after treatment was greater in the combination therapy group than in the monotherapy group. There was a statistically significant difference between the two groups (Figure 2, $p<0.02$).

Patients receiving a score of 1 or more points on the 5-point scale were defined as showing improvement to either monotherapy or combination therapy. The combination therapy group had more patients who improved either moderately or markedlyrelative to the monotherapy group. After monotherapy, 34 of the 47 patients (72.3%) showed slight improvement and one of the 47 patients (2.1%) showed moderate improvement. In the combination therapy group, all patients showed clinical improvement. Among them, 15 showed slight, 8 showed moderate, and 2 showed marked improvement (Table 2, Figure 3).

In particular, patients with severe FPHL corresponding to Ludwig 2 or 3 hair loss, the combination therapy group had significantly more patients with marked and moderate improvement relative to the monotherapy group (Table 2, $p<0.05$). Neither group showed complete resolution.

Adverse effects

Five of 25 patients (20.0%) who took cyclosporine complained of side effects,while those who took the PAC-based dietary supplement alone had no side effects. The most common side effect was gastrointestinal symptoms including abdominal discomfort, which was relieved by dose reduction or addition of digestives. One patient complained of discomfort due to hypertrichosis in unwanted areas, and there were no other serious side effects or laboratory abnormalities.

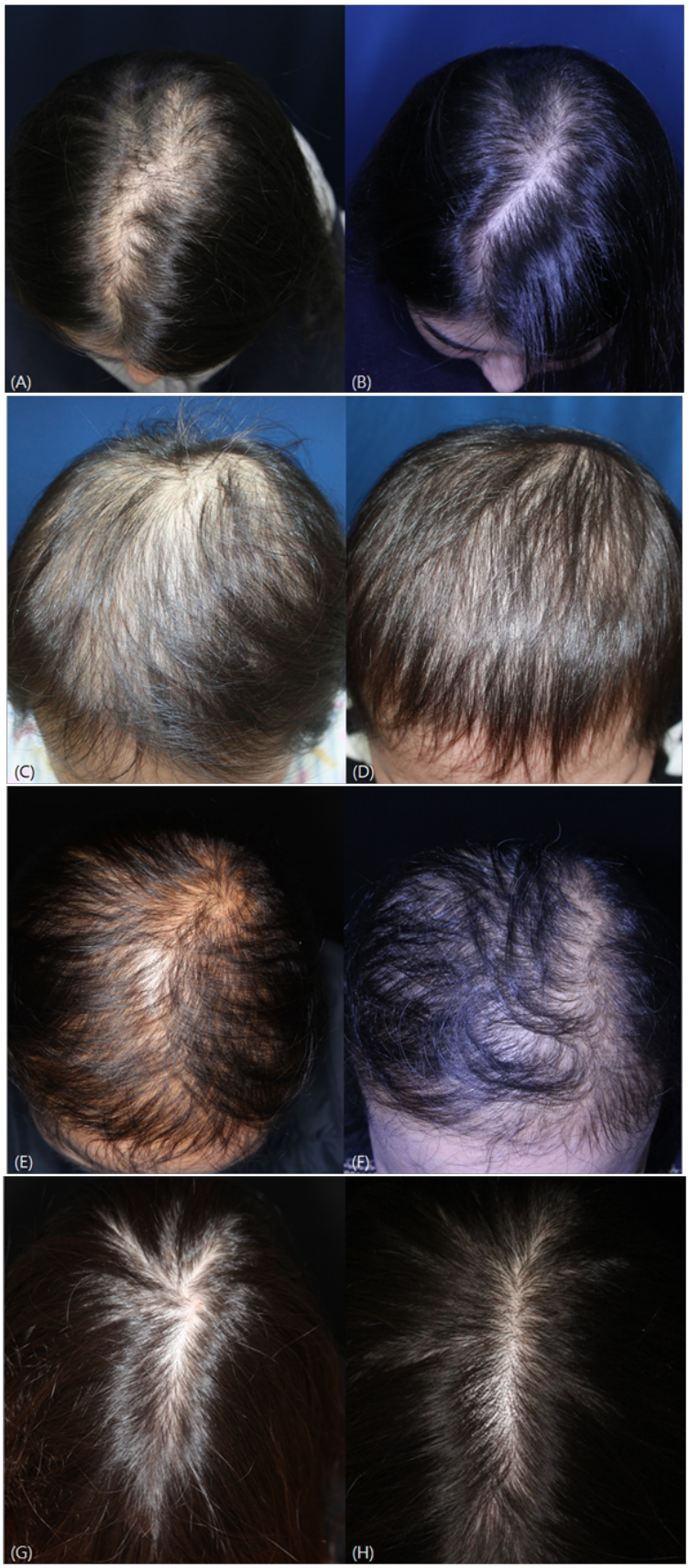
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Figure 1: (A-F) Clinical pictures of patients with FPHL treated with combination therapy and (G-J) patients with FPHL treated with Monotherapy.

(A, B) A 23-year-old woman showed slight improvement with combination therapy (A: Before, B: After treatment)

(C, D) A 34-year-old woman showed moderate improvement with combination therapy (C: Before, D: After treatment)

(E, F) A 56-year-old woman showed marked improvement with combination therapy (E: Before, F: After treatment)

(G, H) A 24-year-old woman showed slight improvement with monotherapy (G: Before, H: After treatment)

(I, J) A 56-year-old woman showed moderate improvement with monotherapy (I: Before, J: After treatment)

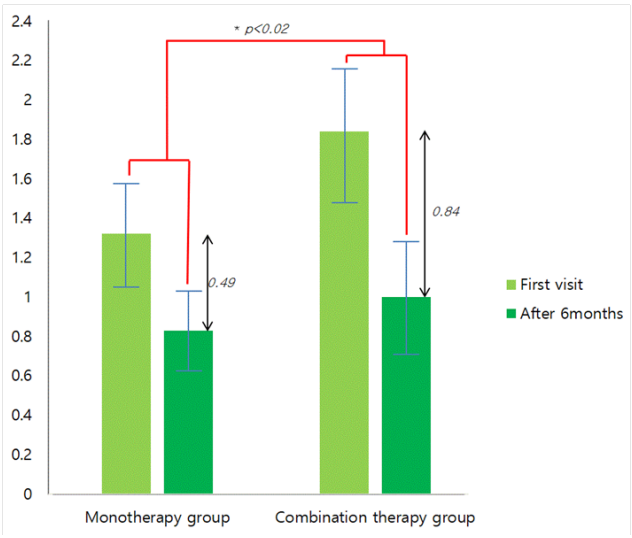

Figure 2: Comparison of average Ludwig score change according to therapy.

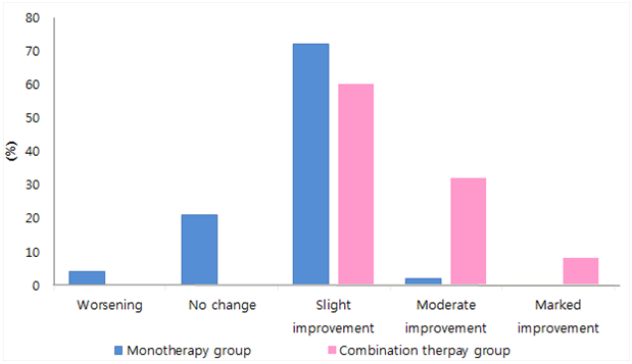

Figure 3: Comparison of improvement proportion after treatment between the two treatment groups on the 5-point scale.

Degree of improvement		-1	0	1	2	3
Monotherapy n=47, (%)	Ludwig grade 1	1 (2.1)	9 (19.1)	22 (46.8)	0 (0)	0 (0)
	Ludwig grade 2	1 (2.1)	1 (2.1)	12 (25.5)	1 (2.1)	0 (0)
	Ludwig grade 3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Combination therapy n=25, (%)	Ludwig grade 1	0 (0)	0 (0)	6 (24.0)	0 (0)	0 (0)
	Ludwig grade 2	0 (0)	0 (0)	9 (36.0)	7 (28.0)	1 (4.0)
	Ludwig grade 3	0 (0)	0 (0)	0 (0)	1 (4.0)	1 (4.0)
Total (n=72)		2	10	49	9	2

Table 2: Global photographic assessment on the 5-point scale after treatment.

Discussion

FPHL is known by other synonyms such as male pattern alopecia in women, female pattern alopecia, diffuse hormonal alopecia, diffuse alopecia in women, common baldness in women and common female baldness [13]. In biopsy specimens of FPHL patients a decrease in proportion of terminal hair, thinning of vellus hair, and follicular miniaturization were observed, which results in a decrease in hair density and thinning hair at the affected lesion [14].

Although the age at which FPHL begins varies depending on the papers, FPHL hasa bimodal distribution of incidence with peaks between the ages of 20 and 29 years, and between 50 and 59 years [15,16]. These peaks are explained by the effect of menopause on FPHL and the desire for aesthetic appearance in young patients [17]. In our study, the prevalence of FPHL was most often seen in patients in their 50s, followed by those in their 20s (Table 1), which is consistent with previous reports.

Pathogenesis of FPHL is not well understood [13]; therefore, treatment of FPHL has lagged behind male pattern hair loss, and there is no established treatment option. Because treatment of alopecia, including FPHL, takes a long time to produce effects, it is difficult to confirm the effect of alopecia treatment.

Various medications have been used to treat FPHL. According to data from previous studies, topical application of minoxidil is the most clinically supported[1]. After 32 weeks of minoxidil treatment, the difference in mean hair count change between the treatment groups was 5.9 to 17.5hairs [18]. Dietary supplements also are used to treat FPHL. PAC-based dietary supplements act via synchronization phenomena of hair cycling and induction of anagen,leading to improvement in hair growth [10]. In a previous study, patients with FPHL complaining of greater than 50% hair loss before taking PAC-based dietary supplement showed hair loss close to 0% by the end of treatment. In addition, at the end of treatment, patients who experienced hair loss of about 140 strands per day decreased that number to 50 per day after taking a PAC-based dietary supplement [12]. In our study, on average, after taking PAC-based dietary supplement, improvement was observed from 6 months, and patient satisfaction was high at around 12 months.

Cyclosporine is commonly used for immunosuppression in organ transplant patients. In terms of hair, cyclosporine is used to arrest progression of alopecia and induce hair growth in alopecia areata patients and has shown an effective response in many cases [7,19]. Taylor, et al. revealed that cyclosporine prolongs human hair growth *in vitro* [20]. In cyclosporine culture medium, hair growth was maintained longer than in control media, suggesting that cyclosporine prolongs

the anagen phase of the hair growth cycle [20]. In an animal study, cyclosporine dose dependently induced telogen follicles to enter the anagen phase [21].

Cyclosporine is used as treatment for various skin diseases, but physicians may experiencepsychological burden in its use in FPHL. Severe adverse reactions of cyclosporine were not observed in this study. Side effects of cyclosporine are mostly dose and duration-dependent [22]. Cyclosporine is contraindicated in cases of uncontrolled hypertension, kidney disease, severe infectious disease, or previous history of malignancy. A such these patients were excluded from this study. No other laboratory abnormalities or serious side effects were observed during cyclosporine treatment. Five of 25(20.0%) patients complained of abdominal discomfort or nausea, most of which was resolved by additional digestive medications. This gastrointestinal discomfort is known to occur commonly as a side effect during cyclosporine administration. In a small number of patients, the symptoms did not improve with additional digestive medications, so the dose of cyclosporine was reduced and possibly increased again after adaptation. In addition, cyclosporine induces hypertrichosis as a common side effect in children [23]. One patient complained of hypertrichosis in an unwanted area and solved the problem by reducing the dose.

In our study, patients of the combination therapy group showed greater improvement than patients in the monotherapy group (Figure 2, $p<0.02$). Although there were more patients with severe FPHL in the combination therapy group, the combination therapy group showed better effects than the monotherapy group (Table 2, Figure 4). It is believed that cyclosporine produced an additive effect, possibly due to transition to the anagen phase. As a result, the addition of cyclosporine to the PAC-based dietary supplement increased the therapeutic effect and the rate of hair growth.

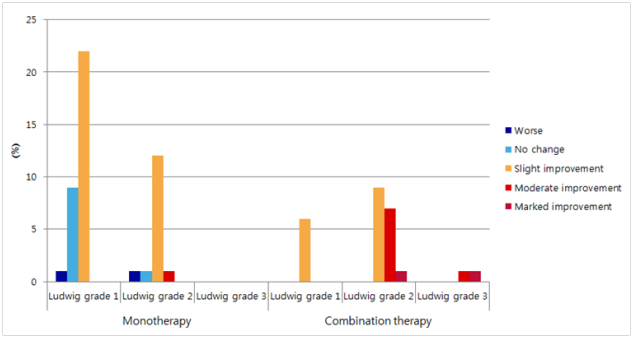

Figure 4: Comparison of therapeutic efficacy of the two treatment groups according to FPHL severity.

RD. Sinclair suggested a pilot study of FPHL with combination therapy of low dose minoxidil and spironolactone and showed improvement of FPHL patients [24]. In general, however, minoxidil have potent major side effects such as hypotension, increasing heart rate, lower limb edema, and electrocardiogram changes [25]. Also it has black box warning, the most serious warning from FDA.

Spironolactone treatment in FPHL have been variously reported [24,26,27]. Laura J, et al. reported spironolactone treatment in FPHL and showed Sinclair score change in both of spironolactone monotherapy and combination therapy [26]. It is difficult to compare our study's Ludwig score change with their Sinclair score change, however, the combination therapy with spironolactone used various additional therapy such as iron supplementation, low-level laser therapy, and did not show results compared with control group. Our study showed the efficacy and safety of cyclosporine compared with PAC-based supplementary group, and cyclosporine would be excellent in terms of effects and side effect profile when administered as a FPHL treatment medication.

After 3 to 6 months of treatment, patients were satisfied that there was a treatment response compared to baseline in the combination therapy group, and the majority of patients had, on average, greater improvement at 12 months. Considering the patient satisfaction, we suggest that patients who have achieved therapeutic effect would be better at switching from cyclosporine as induction therapy to a PAC -based dietary supplement as maintenance therapy. FPHL treatment, which has not been specifically suggested in the past, would be proposed with cyclosporine treatment in these aspects, and further large prospective study with cyclosporine treatment in FPHL could increase strength of these findings.

The limitations of this study are the small sample size and lack of long-term results. Second, this study used a single-center design, which is associated with selection bias, retrospective study, and inability to control multiple confounding factors. However, combination therapy achieved a treatment response at the end of 6 months and greater response at 12 months. Therefore, we suggest that 3-5 mg/kg/d of cyclosporine for 6 to 12 months with a PAC-based dietary supplement as an initial induction therapy, followed by PAC-based dietary supplement only as a maintenance therapy is an effective and safe therapeutic choice in FPHL.

In conclusion, our study showed that cyclosporine is an effective treatment option for FPHL, especially severe FPHL. To our knowledge, there has been limited study on treatment of FPHL. Our study will guide clinicians in their choice of second-line agents for FPHL. Further large-scale and longer treatment duration trials are needed on this treatment regimen.

Conflicts of Interest

The above five authors have no conflict of interest to disclosure.

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None

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