

ORIGINAL ARTICLE

Evaluation of efficacy and safety of finasteride 1 mg in 3177 Japanese men with androgenetic alopecia

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ABSTRACT

Before now, there has been no study of finasteride use exceeding 1 year in Japanese men with androgenetic alopecia (AGA) except the study subsequently conducted from the development phase. Since the launch of finasteride, no study in a larger population had been reported. Ethnic variation of the onset age, progressive nature and degree of hair loss of androgenetic alopecia are known. The therapeutic effect of oral finasteride (Propecia) was examined on androgenetic alopecia of Japanese men. The efficacy and safety of finasteride (1 mg tablet) was evaluated in Japanese men with AGA in the long term. The study enrolled 3177 men given finasteride 1 mg/day from January 2006 to June 2009 at our clinic. Efficacy was evaluated in 2561 men by the modified global photographic assessment; the photographs were assessed using the standardized 7-point rating scale. Safety data were assessed by interviews and laboratory tests in all men enrolled in the study. The overall effect of hair growth was seen in 2230 of 2561 men (87.1%), in whom hair greatly (11.1%), moderately (36.5%) and slightly (39.5%) increased. The response rate improved with increasing duration of treatment. Adverse reactions occurred in 0.7% (23/3177) of men; seven men discontinued treatment based on risk–benefit considerations. No specific safety problems associated with long-term use were observed. This study represents data collected at a single institution. Many patients did not receive follow-up examination. In Japanese men with AGA, oral finasteride used in the long-term study maintained progressive hair regrowth without recognized side-effect.

Key words: androgenetic alopecia, finasteride, Japanese, modified global photographic assessment, modified Norwood–Hamilton scale, treatment period.

INTRODUCTION

Androgenetic alopecia (AGA), or male pattern hair loss, is a progressive thinning of scalp hair in the vertex and frontotemporal regions in post-pubertal men with hereditary bald trait. Thinning of hair caused by transformation of thick terminal hair to short vellus hair is concomitant with conversion of terminal follicles to vellus follicles with short growth (anagen) phase. The age of onset of AGA in Japanese is 10 years older than that of Caucasians.¹ Thinning and loss of scalp hair can cause great concern to patients for cosmetic and psychological reasons and often impairs quality of life. According to a questionnaire review of 6509 Japanese men aged 20–69 years, and the future population estimates by the Health & Welfare Statistics Association, 12.6 million are aware of, and 8 million are concerned about, scalp hair loss.² Therefore, there has been a great surge of interest in the treatment of scalp hair loss in Japan.

Because the key role of dihydrotestosterone (DHT) is to mediate progressive scalp hair loss in men with AGA, the inhibition of DHT production may be useful for the treatment of hair loss. Therefore, an inhibitor of the enzyme that converts testosterone into DHT (type II 5 α -reductase) was developed. Finasteride (Propecia; MSD, Tokyo,

Japan), a selective type II 5 α -reductase inhibitor, blocks the conversion of testosterone to DHT. Oral finasteride was launched as an ethical drug in December 2005 for the treatment of AGA. Once-a-day p.o. dosage may promote good compliance.

In a study of 708 men with AGA who used finasteride tablets 1 mg/day at the clinic during approximately 4 months in 2006, 91.8% showed improvement.³ Since the launch of finasteride in Japan, the only report of finasteride was from a study conducted in the clinical trial⁴ for more than 1 year in Japanese men with AGA. No study in a larger population had been conducted in Japan.

The objective of this report is to evaluate the efficacy and safety of finasteride in the long term by the methods described in the 2006 study.³

METHODS
Study population

The study involved 3177 men treated with finasteride 1 mg tablets who had a diagnosis of AGA at the first visit to Tokyo Memorial Clinic Hirayama (hereafter, “the clinic”) from January 2006 to June 2009. All men gave prior written informed consent.

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Treatment methods

Hair loss patterns of men with AGA were classified according to a modified Norwood–Hamilton (N-H) scale^{1,5,6} based on inspection and photographs of the scalp taken after the diagnosis of AGA. The type of hair loss involving the frontal through vertex areas with a preserved frontal hairline was not applicable to the N-H scale. Such cases were classified as diffuse hair loss.

All patients were informed of the pharmacological and expected therapeutic effects as well as the possible adverse reactions of finasteride based on the drug information before providing the written informed consents. Finasteride tablets (1 mg) were administered once daily thereafter.

All other hair-growing agents had to be withdrawn during the treatment with finasteride.

Assessment methods

Scalp hair was inspected and photographed at pretreatment time and following every 3 months in the clinic. Efficacy was assessed by the modified global photographic assessment.^{7,8} For the assessment, two photographs, of the vertex and the required scalp region, were used. Hair growth was comprehensively reviewed by comparing the baseline and post-treatment photographs and rated according to the standardized 7-point rating scale (7 = greatly increased to 1 = greatly decreased). Adverse reactions were recorded to evaluate safety throughout the study.

Statistical methods

The cut-off date was set as 17 June 2009. The total period of study was 3.5 years. The significance level was two-sided 5%. Statistical analysis was performed with SAS software.

Analysis population

The population of the entire study consisted of men who had a diagnosis of AGA at the first visit and who received finasteride 1 mg tablets.

The population for efficacy analysis was defined as the patients who had both baseline (first visit) and post-treatment assessments during the entire study period.

Demographic factors

Numerical variables of the demographic factors were presented as summary statistics (mean \pm SD) (age at first visit, age at onset of hair loss, duration of hair loss and treatment period); categorical variables of the demographic factor (presence of stress) were presented by counting frequencies.

Frequencies of hair loss pattern (N-H group and diffuse hair loss group) were counted in the patients studied for efficacy analysis.

Efficacy

Rating scores of modified global photographic assessment obtained immediately before the cut-off date were used for the analysis. Frequencies of the rating score were counted in the group of patients studied for efficacy analysis. The response rate was presented as the percentage of greatly, moderately and slightly increased hair growth (rating score, 5–7) to the total number of patients in each group.

Frequencies of the rating scores and response rates were presented by demographic factors: (i) N-H scale; (ii) age at onset of hair loss; (iii) duration of hair loss; and (iv) the treatment period.

Multiple regression analysis was performed to assess the relationship between the rating scores and each demographic factor: (i) N-H scale; (ii) age at onset of hair loss; (iii) duration of hair loss; (iv) treatment period; and (v) presence of stress. For the factors that demonstrated a statistical significance of partial regression coefficient, multiple comparison tests (Tukey's test) between pairwise rating-score groups were performed.

Safety

Adverse reactions were recorded to evaluate safety throughout the study in the entire study population.

RESULTS

Demographic factors

A total of 3177 patients with a diagnosis of AGA at the first visit received finasteride 1 mg tablets. Efficacy was assessed in 2561 patients (efficacy analysis population), excluding 616 who had only baseline (first visit) assessment, among the entire study population. Safety data was evaluated in the entire study population.

In the efficacy analysis population, 2289 patients were classified according to the N-H scale and 272 patients had diffuse hair loss.

Demographic factors of the efficacy analysis population were as follows (mean \pm SD): age at first visit, 37.5 \pm 11.9 years; age at onset of hair loss, 29.9 \pm 10.3 years; duration of hair loss, 7.6 \pm 6.3 years; patients under stress at the first visit, 23.5% (602/2561); and treatment period, 458.8 \pm 312.0 days (Table 1).

Efficacy evaluation

The response rate (greatly, moderately or slightly increased hair growth) in the efficacy analysis population was 87.1% (Table 2); that in the N-H group and the diffuse hair loss group was 87.1% and 86.8%, respectively. Neither group included greatly nor moderately decreased hair loss.

Table 1. Demographic factors in efficacy analysis population

	Efficacy analysis population	N-H group	Diffuse hair loss group
No. of patients	2561	2289 (89.4%)	272 (10.6%)
Age at first visit (years) [†]	37.5 \pm 11.9	37.4 \pm 11.9	38.1 \pm 11.8
Age at onset of hair loss (years) [†]	29.9 \pm 10.3	29.8 \pm 10.1	30.9 \pm 11.4
Duration of hair loss (years) [†]	7.6 \pm 6.3	7.7 \pm 6.4	7.2 \pm 5.6
Treatment period (days) [†]	458.8 \pm 312.0	458.1 \pm 312.9	464.7 \pm 304.1
Presence of stress (no. of patients)	602/2561 (23.5%)	556/2289 (24.3%)	46/272 (16.9%)

[†]Mean \pm standard deviation. N-H, modified Norwood–Hamilton scale.

Table 2. Rating scores of modified global photographic assessment in efficacy analysis population

	Efficacy analysis population	N-H group	Diffuse hair loss group	Test [†]
No. of patients (%)	2561	2289	272	
Rating score				
1 (greatly decreased)	0 (0.0)	0 (0.0)	0 (0.0)	Wilcoxon rank sum test, $P = 0.078$
2 (moderately decreased)	0 (0.0)	0 (0.0)	0 (0.0)	
3 (slightly decreased)	11 (0.4)	11 (0.5)	0 (0.0)	
4 (no change)	320 (12.5)	284 (12.4)	36 (13.2)	
5 (slightly increased)	1011 (39.5)	922 (40.3)	89 (32.7)	
6 (moderately increased)	936 (36.5)	823 (36.0)	113 (41.5)	
7 (greatly increased)	283 (11.1)	249 (10.9)	34 (12.5)	
Response rate (5–7)	2230/2561 (87.1)	1994/2289 (87.1)	236/272 (86.8)	χ^2 -Test, $P = 0.872$

[†] χ^2 -Test and Wilcoxon rank sum test: N-H group versus diffuse hair loss group. N-H, modified Norwood–Hamilton scale.

Rating scores of modified global photographic assessment by N-H scale classification

Changes in the rating scores of the modified global photographic assessment from baseline (first visit) are presented by the N-H scale classification (Fig. 1).

The rating scores of the modified global photographic assessment by classification of N-H group are shown in Table 3.

The response rates ranged 81.0–91.3%, and no remarkable differences were observed among different hair loss patterns except for type I, which was slightly lower at 60.6%. The proportion of patients who had no change in hair growth was slightly higher at 39.4% for type I; that of the other types ranged 8.7–18.5%.

Rating scores of modified global photographic assessment by age at onset of hair loss

Age at onset of hair loss was obtained by the interview of each individual.

The response rate in the efficacy analysis population by age at onset of hair loss was: 83.6% (271/324) for those aged 19 years or younger; 86.3% (986/1142) for 20–29 years; 89.2% (587/658) for 30–39 years; 90.5% (266/294) for 40–49 years; 83.9% (99/118) for 50–59 years; 87.0% (20/23) for 60–69 years; and 50.0% (1/2) for age 70–79 years.

The response rate of patients in each age group ranged 83.6–90.5%, except for the 70–79-year age group, with only two patients. Moderately and slightly increased hair growth accounted for more than 70% in all age groups except for the age group of 70–79 years.

Rating scores of modified global photographic assessment by duration of hair loss

The response rate of the efficacy analysis population by duration of hair loss was 79.2% (61/77) for less than 1 year; 82.2% (189/230) for 1 year; 87.1% (195/224) for 2 years; 86.1% (383/445) for 3–4 years; 87.7% (611/697) for 5–9 years; 87.8% (426/485) for 10–14 years; 91.5% (172/188) for 15–19 years; and 89.8% (193/215) for 20 years or more. The response rates in each group ranged 82.2–91.5%, except for that of less than 1 year, which was slightly lower at 79.2%.

The majority of patients exhibited moderately or slightly increased hair growth. The proportion of greatly increased hair growth was relatively low in patients with hair loss duration of

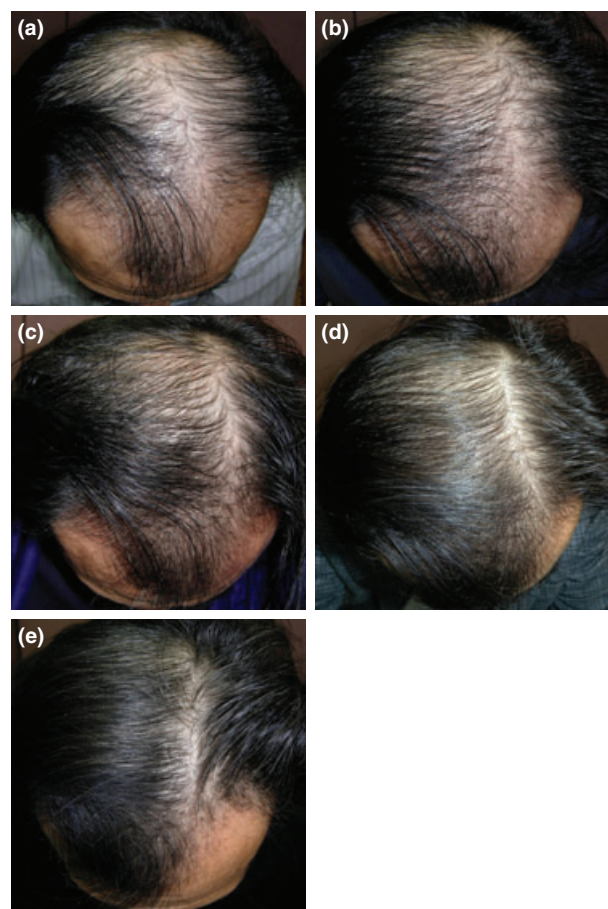


Figure 1. Example of global photographic assessment (55-year-old male treated with finasteride 1 mg/day, 8 years of hair loss, modified Norwood–Hamilton [N-H] scale = V). (a) First visit (baseline); (b) no change (4) at 6 months; (c) slightly increased (5) at 12 months; (d) moderately increased (6) at 24 months; (e) greatly increased (7) at 36 months.

10 years or more. However, more than 85% of patients with hair loss duration of 15–19 years or 20 years or more exhibited moderately or slightly increased hair growth.

Table 3. Rating scores of modified global photographic assessment by N-H scale classification in N-H group

No. of patients (%)	Hair loss patterns by N-H scale (n = 2289)													
	I	II	IIa	II vertex	III	IIIa	III vertex	IV	IVa	V	Va	VI	VII	
	33	221	64	342	144	55	593	334	88	93	172	123	27	
Rating score														
1 (greatly decreased)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
2 (moderately decreased)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
3 (slightly decreased)	0 (0.0)	3 (1.4)	1 (1.6)	3 (0.9)	0 (0.0)	0 (0.0)	3 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
4 (no change)	13 (39.4)	39 (17.6)	7 (10.9)	45 (13.2)	22 (15.3)	5 (9.1)	61 (10.3)	29 (8.7)	8 (9.1)	15 (16.1)	21 (12.2)	14 (11.4)	5 (18.5)	
5 (slightly increased)	12 (36.4)	84 (38.0)	22 (34.4)	132 (38.6)	47 (32.6)	23 (41.8)	202 (34.1)	135 (40.4)	45 (51.1)	54 (58.1)	72 (41.9)	75 (61.0)	19 (70.4)	
6 (moderately increased)	5 (15.2)	73 (33.0)	24 (37.5)	120 (35.1)	51 (35.4)	21 (38.2)	234 (39.5)	140 (41.9)	29 (33.0)	22 (23.7)	68 (39.5)	33 (26.8)	3 (11.1)	
7 (greatly increased)	3 (9.1)	22 (10.0)	10 (15.6)	42 (12.3)	24 (16.7)	6 (10.9)	93 (15.7)	30 (9.0)	6 (6.8)	2 (2.2)	10 (5.8)	1 (0.8)	0 (0.0)	
Response rate (5–7)	20 (60.6)	179 (81.0)	56 (87.5)	294 (86.0)	122 (84.7)	50 (90.9)	529 (89.2)	305 (91.3)	80 (90.9)	78 (83.9)	150 (87.2)	109 (88.6)	22 (81.5)	

N-H, modified Norwood–Hamilton scale.

Table 4. Multiple regression analysis of demographic factors: Relationship between modified global photographic assessment score and demographic factors (N-H scale, age at onset of hair loss, duration of hair loss, treatment period and presence of stress) in N-H group

Factor	Rating score (n = 2289)
	Partial regression coefficient (β)
N-H scale [†]	-0.04
Age at onset of hair loss (years)	0.02
Duration of hair loss (years)	-0.01
Treatment period (days)	0.00*
Presence of stress [‡]	0.06
Coefficient of determination (r^2)	0.46

* $P < 0.001$. [†]I = 1; II, IIa, II vertex = 2; III, IIIa, III vertex = 3;; VII = 7. [‡]Presence of stress at first visit (not stressed = 0; stressed = 1). N-H, modified Norwood–Hamilton scale.

Factors that had an impact on the modified global photographic assessment

Multiple regression analysis was performed using the rating scores of the modified global photographic assessment as independent variables and five demographic factors as dependent variables in the N-H group (Table 4). The results showed a coefficient of determination (r^2) of 0.46. Partial regression coefficient was significantly different only by treatment period (partial regression coefficient = 0.00, $P < 0.001$). Therefore, the factor that could have a major impact on the modified global photographic assessment was the treatment period.

Tukey's pairwise multiple comparison test was performed on the rating scores of the modified global photographic assessment (slightly decreased, no change, slightly increased, moderately increased and greatly increased) for the treatment period. There

were statistically significant differences in the treatment period in comparisons between pairwise groups, except for that of slightly decreased versus slightly increased. In a comparison between the groups of slightly decreased versus no change, the slightly decreased group had a significantly longer treatment period ($P = 0.017$). In contrast, treatment periods were significantly longer in groups with higher rating scores ($P < 0.001$) in comparison with other groups.

Safety evaluation

Adverse reactions occurred in 0.7% of the entire study population (23/3177) during the entire period of the study. The reactions include decreased libido ($n = 8$), hepatic functional disorder ($n = 3$) and unilateral mammary hypertrophy ($n = 2$).

Seven of these 23 patients discontinued the treatment due to the adverse reactions; these included decreased libido ($n = 3$); hepatic functional disorder, disturbance of memorization and unilateral mammary hypertrophy ($n = 1$ each); and palpitations, febricula and headache ($n = 1$). Most of them were mild, and the follow-up data is unknown because of loss of contact. Among the adverse reactions, decreased libido with or without orchitrophy, decreased blood pressure, and hypertrichosis of the forearms showed no change during the treatment period.

DISCUSSION

In the studies conducted at 33 sites in the USA and 27 sites in 15 other countries, 1553 men with AGA aged 18–41 years received finasteride 1 mg/day or placebo over 1 year. The scalp hair growth was comprehensively reviewed using paired baseline (first visit) and sequential photographs evaluated by the standardized 7-point rating scale. At the 12th month, the percentages of the patients with greatly, moderately or slightly increased hair growth were 48%

and 7% for finasteride and placebo, respectively. The percentages of the hair growth showed a statistically significant difference ($P < 0.001$).⁸ The 5-year study conducted in the same group of patients indicated similar results of 48% and 6% for finasteride and placebo, respectively ($P < 0.001$).⁹ Adverse reactions related to sexual functions (e.g. decreased libido, ejaculation disorder and erectile dysfunction) most commonly occurred in year 1 of treatment with finasteride and placebo (4.4% vs 2.2%).⁹ On the contrary, the incidence of adverse reactions decreased in year 5 (0.6% vs 0% for finasteride and placebo, respectively).⁹ Therefore, there was no increase in the incidence of adverse reactions related to sexual functions due to long-term treatment.⁹ No other clinically significant adverse reactions were identified.^{8,9}

In the study performed in 2006, the efficacy was improved in 91.8% of 708 men with AGA who received finasteride 1 mg/day for 4 months. The incidence of adverse reactions was 2.0%.³

Our present study was conducted for a longer term (3.5 years) from January 2006 to June 2009 in 3177 Japanese men with AGA who received finasteride 1 mg/day than that of the study we previously reported. Efficacy was evaluated by comprehensive review of paired baseline (first visit) and post-treatment photographs using the standardized 7-point rating scale (greatly increased, moderately increased, slightly increased, no change, slightly decreased, moderately decreased and greatly decreased). Efficacy was also evaluated using the response rates, which were presented as a percentage of greatly, moderately and slightly increased hair growth (rating score, 5–7) to the total number of patients. Each factor such as N-H scale, age at onset of hair loss, duration of hair loss and treatment period was evaluated by the standardized 7-point rating scale. Multiple regression analyses were performed to assess the relationship between the rating score of the modified global photographic assessment and each demographic factor (the aforementioned four factors and presence of stress). Furthermore, multiple comparison tests between the rating-score groups was performed for factors that showed a statistical significance of partial regression coefficient.

The response rate of patients with greatly, moderately and slightly increased hair growth was 87.1% (2230/2561). This demonstrates that finasteride maintained a higher response rate of more than 80%, even though the treatment period was prolonged.

In the report of the Turkish study comparing topical minoxidil (5%) and oral finasteride (1 mg/day), the response rate of finasteride was 80%.¹⁰ In our study, the response rate (87.1%) was higher than in the Turkish study. One of the reasons for this could be the characteristics of scalp hair of Japanese men. Japanese subjects generally have less hair density, larger hair diameter, and black color of hair shaft showing a marked contrast of color of hair compared to thinner and lighter color of the scalp hair in Caucasian men.^{11–15} Therefore, subtle changes in scalp hair growth can be easily identified by a global photographic assessment leading to a higher response rate in Japanese men. On the other hand, because our study was conducted in clinical practice, many patients did not receive follow-up examination. This might have affected the higher response rate. According to the supposition, it was assumed that all of the 616 patients who were not able to be assessed by the modified global photo graphic assessment because they had only baseline (first

visit) assessment, had decreased hair growth (1–3). The resulting response rate was 70.2% (2230/3177), which is close to that of the previous studies conducted in the USA or the other countries.^{4,9}

The response rates in the N-H group and the diffuse hair loss group (unclassified hair loss pattern that is not applicable to the N-H scale) were similar (87.1% [1994/2289] and 86.8% [236/272], respectively). The diffuse hair loss type, a new classification of hair loss pattern, has been currently suggested, because some hair loss patterns commonly seen in Asians cannot be classified according to the N-H scale.¹⁶ In the present study, 10.6% (338/3177) were classified as having diffuse hair loss. Further studies are expected for the specific classification of diffuse hair loss.

The response rate improved with increasing duration of treatment. No major relations were observed in terms of N-H scale, age at onset of hair loss and duration of hair loss.

Multiple regression analysis was performed between the rating scores of the modified global photographic assessment and each demographic factor of N-H scale, age at onset of hair loss, duration of hair loss, treatment period and presence of stress in 2289 patients (N-H group). The resulting coefficient of determination (r^2) was 0.46. A statistically significant difference was only observed in the partial regression coefficient of the treatment period ($P < 0.001$). This showed that the factor that could have a major impact on the rating scores was the treatment period. Therefore, a multiple comparison test was performed between all rating-score groups. The result showed that treatment period was significantly longer in patients with better hair growth in the modified global photographic assessment, except for the comparisons between slightly decreased versus no change, and slightly increased versus slightly decreased. Comparison between slightly decreased versus no change, showed a significantly longer treatment period for patients with slightly decreased hair growth. This is not consistent with the other data in this study; however, it is likely due to a relatively small number of patients who had slightly decreased hair growth and a longer treatment period.

Given the efficacy of these results and further progression of AGA that occurred with placebo administration,⁹ therapeutic results are more likely to improve with finasteride treatment than without it according to the prolongation of treatment.

In this study, a relationship between the response rate of global photographic assessment by age at starting treatment was not observed, which is a discrepancy in the date of efficacy of finasteride 1 mg in men aged 41–60 years.¹⁷ However, it is respectively observed to decrease the response rate of greatly increased in men with advanced N-H scale (over V) at first visit. This is similar to an advanced N-H scale, which is the reason why a long period of hair loss may lead to irreversible transformation in the hair cycle by streamer formation.

In the safety evaluation of this study, the incidence of adverse reactions was 0.7% as compared to that of 2.0% in the previous 4-month study.³ This indicated no increase in the incidence of adverse reactions due to longer treatment. Most adverse reactions were mild. Treatment was discontinued in seven patients based on risk–benefit consideration, because AGA is not an organic disorder. No specific safety problems associated with long-term treatment were observed.

In summary, in Japanese men with AGA, long-term treatment with finasteride 1 mg tablets maintained high efficacy and was well tolerated. The present study demonstrates that long-term finasteride treatment leads to durable improvement in hair growth in Japanese men with AGA. On the other hand, we believe this study advocates a guideline of management for AGA in Japan¹⁸ in that advanced N-H scale cases should be treated with finasteride 1 mg.

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