Efficacy and tolerability of 5% Minoxidil solution in male and female androgenetic alopecia: an open multicentric Italian study of 6 to 12 months duration

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Topical minoxidil is internationally accepted as one of the first choices for treatment of both male and female androgenetic alopecia (male and female pattern hair loss, MPHL, FPHL, baldness).

In Italy, minoxidil solution has been commercialized for the treatment of androgenetic alopecia for more than 20 years (the 2% concentration since 1988, the 5% concentration since 1995), but even if its safety profile and efficacy are well known, many dermatologists are still reluctant to prescribe it, or they utilize it incorrectly.

The aim of this open multicentric study, carried out in 3 Italian Dermatological Centers, was to evaluate the efficacy and tolerability of the 5% Minoxidil solution, Carexidil®, applied to the scalp twice daily for 6 months in male and female with mild to moderate androgenetic alopecia. Efficacy evaluation was based on subjective and objective methods. Subjective methods included patient and investigator evaluation, while objective methods included global photography and videodermoscopy.

Results

Seventy-two patients were enrolled, 34 of which completed the 6-month study. This group included 28 males and 22 females, with a mean age of 38 ± 2.7 years respectively (female age range: 18-65, male age range: 25-70), with a mean duration of the disease of 42 months.

According to severity of androgenetic alopecia patients were divided in the following groups:

- Patients: Ludwig I: 10 patients, Ludwig II: 17, Ludwig III: 8 patients.

-Thirty-two patients had been previously treated with minoxidil or other antiandrogenic drugs, 12 were followed for a maximum term of 12 months (mean 8.12).

Efficacy

Evaluation of global photographic taken at baseline and after 6 month of treatment with 5% Carexidil® solution revealed a critical improvement in 27.8% of cases; Improvement was rated as moderate in 32.85% cases, and mild in 29.7% cases.

 Videodermoscopy performed (25 of these patients evaluated, in all cases an improvement of the parameters typically evaluated in androgenetic alopecia: the total number of hairs / area of the total androgenetic alopecia in stages 1-3 responded better to treatment, showed improvement or stabilization in 15 cases, marked improvement in 7 cases, and further improvement in 3 cases; marked improvement in 10 cases).

Overall, 72.7% of patients showed clinical improvement in 15, marked improvement in 7 cases.

Evaluation of efficacy, based on the questionnaire filled out by the investigator showing the following: unchanged in 6 patients, mild improvement in 10, moderate improvement in 27, marked improvement in 15 cases.

Videodermoscopy of the clinical appearance revealed by global photographic and of the videodermoscopy parameters revealed that in 21 of the 22 patients who continued the study for 12 months.

Tolerability

- Twenty patients reported an increased hair greasiness, which was moderate in 10 cases and mild in 8.
- Tolerability of the solution on the scalp was defined “optimal” by 10 patients. These patients completed a successive scale ranging after application of the solution, 2 reported continuous itching and scaly scalp.
- Patch tests with Carexidil® solution and propylene glycol vehicle were negative in all patients.
- Two patients developed mild malar or temporal edema, one of these patients reported improved edema after 6 months of treatment with Carexidil® solution.
- Other 9 patients were patch-tested since they complained of skin irritation (5): about 16% of the patients in our study reported mild skin irritation (5).
- Ten patients did not finish the trial. Reasons for drop-out were personal and not related to treatment in 6 cases. Two patients interrupted treatment since they found it not very practical to apply the solution in his daily life.

Discussion

Our study confirms the data in literature and evidence obtained over years of clinical practice that topical application of 5% minoxidil solution, Carexidil® is very effective in male and female androgenetic alopecia, with results already visible after 6 months.

Results continue to improve after the first 6 months in most of our patients who had been treated for at least 6 months. Studies showed that 90% of patients already showed improvement after 6 months, including those with severe forms. It should however be noted that mild forms of androgenetic alopecia respond better to treatment, with improvement already visible both clinically and by videodermoscopy after a few months of Carexidil® solution application.

Carexidil® solution is effective also in males, with efficacy of 100% of the patients showing marked improvement in androgenetic alopecia stages 1-3 and 70% of the progression of the disease.

Androgenetic alopecia with prevalent vertex involvement (type ‘V’ Hamilton-Norwood) responds better to treatment. Response rate to Carexidil® solution was higher in male patients than in female patients who had been followed for up to 12 months (80% vs. 72.7%)

Nonetheless, in clinical practice after 6 months it is already possible to define a treatment failure or a treatment success, in the same way in which we used to do it in the past with topical application of 5% minoxidil solution until the end of the study.

Carexidil® solution application at the end of the 6-month period, as a proof of their great appreciation and faith in the product.

The exact mechanism of minoxidil is not known, but it is likely that its positive effect on hair growth is due to the ability to open the adenosine-sensitive potassium channels of the hair root (K₄₇,9,10). Growth Factor synthesis) by dermal papilla cells.

The use of 5% minoxidil solution is very easy: 10 patients dropped out due to the development of allergic reactions. Two of our female patients developed a mild malar or temporal edema, one of these patients reported improved edema after 6 months of treatment with Carexidil® solution. Two of our patients had a positive patch test to minoxidil and therefore interrupted application of the solution. Other 9 patients were patch-tested since they complained of skin irritation (5): about 16% of the patients in our study reported mild skin irritation (5).

It is usually worrisome for the patient, who is waiting for the effect of treatment, that the dose of 60 mg a day is not exceeded (10). The exact mechanism of minoxidil is not known, but it is likely that its positive effect on hair growth is due to the ability to open the adenosine-sensitive potassium channels of the hair root (K₄₇,9,10). Growth Factor synthesis) by dermal papilla cells. The use of the product.

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