A Trial of 1 % Minoxidil Used Topically for Severe Alopecia areata

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Fifty patients with extensive alopecia areata took part in a prolonged double blind trial to compare the effect of 1% minoxidil in unguentum merck with that of unguentum merck alone. There was no significant difference between the hair growth of patients treated with the placebo or with the active compound. (Received August 30, 1985.)

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The encouraging results obtained in early studies of the value of topical minoxidil in alopecia areata (1, 2) led to further trials, the results of which have been conflicting (3, 4). To clarify this issue we undertook a double blind, randomised study of the effect of a 1% minoxidil ointment in 50 patients with severe alopecia areata.

PATIENTS

Fifty patients (males-22; females-28) with longstanding (average duration-16 years; average age at onset-20 years) and severe alopecia areata agreed to take part in the trial. Their degree of alopecia was classified as follows: extensive alopecia areata affecting more than two thirds of the scalp (11 patients); ophiasiform (6 patients); totalis (10 patients); and universalis (23 patients).

METHODS

At their first visit patients were randomly allocated to treatment with 1% minoxidil in unguentum merck or with unguentum merck alone. They were asked to rub a measured lg of the ointment into the hairless areas at night and to wash it off the next morning. Patients were reviewed after eight weeks: if new hair had grown the same preparation was used for a further eight weeks, if not they were changed to the alternative preparation, still under double blind conditions. After 16 weeks without promising hair growth, the code was broken and 1% minoxidil was prescribed for the rest of the study.

One patient defaulted from the trial, and one became pregnant and was withdrawn. The remaining 48 patients all completed at least 32 weeks of treatment. 46 continuing for 40 weeks, six for 52 weeks, eight for 60 weeks and three for 78 weeks.
RESULTS

Twenty-four of the patients who completed the trial received the active preparation at the start and 24 received the base alone. After eight weeks, 15 patients (62.5%) in both groups had no new hair growth and were changed to the alternative preparation. At 16 weeks no significant regrowth was detected in 13 of the 15 switched from the active to placebo treatment, and in eleven of the 15 who had switched from placebo to active treatment. Nine patients had used the active treatment throughout the 16 weeks, and of these three achieved no significant regrowth. Nine patients had been on placebo throughout the first 16 weeks, and of these only two showed no significant regrowth.

The trial continued after the first 16 weeks and, by virtue of its design, most patients thereafter were receiving the active treatment. However, only two patients, both with ophiasiform alopecia, achieved cosmetically valuable hair regrowth: one had received the placebo and one the active preparation throughout. Twenty-three patients had no visible regrowth of new hair at any stage of the trial. 18 grew vellus hairs, and seven grew terminal hair though two of these lost much of their hair despite continuing active treatment for a further six months. No patient was able to stop wearing a wig.

There was no statistically significant difference between the response to the active treatment and to the placebo (using χ² test, p>0.05).

DISCUSSION

Our patients did not differ from other series of severely affected alopecia areata patients in their high prevalence of atopy (personal history 38%, family history 18%) and of circulating auto-antibodies (14% had circulating antithyroid antibodies). We could detect no correlation between these factors and response to therapy. Indeed, we must conclude that 1% minoxidil ointment was of no significant benefit to our patients.

We selected unguentum merck as our vehicle because Fenton & Wilkinson (3) had stated that it achieved regrowth earlier than the lotion formula of Weiss et al. (5). However, the ointment base was not liked by our patients. We detected no adverse side effects in our patients but published (6, 7, 8) and anecdotal reports of symptoms probably due to systemic absorption have made us reluctant to increase the strength of the application beyond 1%.

REFERENCES