

Mesotherapy with bicalutamide for female pattern hair loss

Dear Editor,

Female pattern hair loss (FPHL) is a prevalent condition that can have a significant impact on the quality of life. It has a fairly limited therapeutic arsenal and the outcomes often do not meet the patient's expectations.¹ Currently, the only drug approved by the FDA for FPHL is topical minoxidil.²

Recently, oral bicalutamide, a selective antagonist of androgen receptors (AR), has been used off-label to treat FPHL. However, although infrequent, some patients may present systemic adverse effects such as an increase in transaminase levels.^{3,4}

Mesotherapy is a minimally invasive procedure that involves injecting therapeutic agents 2–4 mm into the skin.⁵ Mesotherapy using dutasteride or minoxidil has been proposed as an effective option to elicit hair regrowth and reduce systemic absorption.⁶ As far as we know, mesotherapy with bicalutamide has been little studied for FPHL.⁷

This pilot prospective study aimed to evaluate the efficacy and safety of mesotherapy with bicalutamide 0.5% in the treatment of FPHL as monotherapy.

We enrolled four Latin-American women with FPHL and Fitzpatrick skin phototypes ranging from II–IV. We included healthy pre-menopausal female patients diagnosed with FPHL, aged between 31 and 47 (mean 38.5) years in the study. Patients who underwent previous treatment for hair loss (last 3 months) and those with liver disease, other causes of hair loss, or on hair loss therapy were excluded. A written informed consent was obtained from the subjects to publish their photos and details of the cases. This study complies with the internationally accepted standards for research practice and reporting.

Each patient received five monthly intradermal injections of 2 mL bicalutamide 0.5% (skypharma®). Figure 1 demonstrates the treatment plan used in the study. The images were then appraised by three independent and experienced dermatologists who compared each of the T0 images with the T24 ones. They needed to achieve agreement using a five-point comparison scale: great worsening (–2), slight worsening (–1), no change (0), slight improvement (+1), and great improvement (+2).

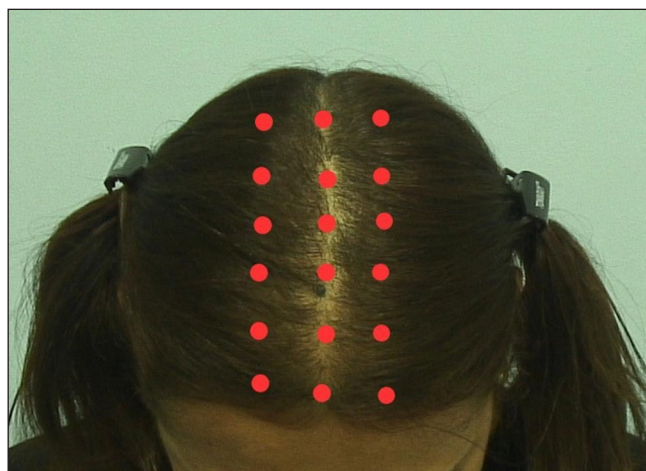


Figure 1: Treatment plan: approximately 0.1 cc was injected into each red dot represented in the figure with a threaded syringe and 31 g needle at a 45-degree angle.

The clinical and trichoscopic images revealed stabilisation in the frontal area for two patients and improvement for one. Conversely, the mid scalp and vertex exhibited stabilisation in all cases (n = 4). The results are described in detail in Table 1 and Clinical and trichoscopic pictures were captured at baseline (T0) and 24 weeks (T24) using Fotofinder® technology are demonstrated in Figures 2 and 3.

There were no major side effects or complications following the procedure except for local pain, ecchymosis, and transitory edema. The pain was rated up to 8 (75.0%) on a scale from 0 to 10. With regard to the symptoms pre-intervention, half of the patients had mild and half had intense seborrhoea at T0. Among those with intense seborrhoea, there was mild improvement reported at T24.

Mesotherapy has emerged as a popular minimally invasive procedure for non-scarring alopecias. The tissue deposit is believed to extend the drug's bioavailability and augment its presence at the follicular level.⁵ Oral bicalutamide may induce, in some patients, hepatotoxicity, mastalgia, asthenia, myalgia, and decreased libido.² Mesotherapy has the potential to enhance hair regrowth with fewer side effects for patients with contraindications to the oral form or those seeking improved outcomes.

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Table 1: Patient characteristics and before-after trial statistics in the study

| Variables | Statistics/categories | Obtained values |
|---|---------------------------|-----------------------------------|
| Sinclair Scale stage of female pattern hair loss: n (%) | 1 | 0 (0.0) |
| | 2 | 3 (75.0) |
| Presence of the conditions/disease (T ₀): n (%) | Acne | 2 (50.0) |
| | Telogen Effluvium | 2 (50.0) |
| | Hirsutism | 1 (25.0) |
| | Obesity | 2 (50.0) |
| | Polycystic ovary syndrome | 0 (0.0) |
| Values in pain scale (1–10): n (%) | 1–4 | 0 (0.0) |
| | 5 | 1 (0.0) |
| | 6 and 7 | 0 (0.0) |
| | 8 | 3 (75.0) |
| | 9 and 10 | 0 (0.0) |
| Side effects: n (%) | | 0 (0.0) |
| Self-report of seborrhea: n (%) | | |
| - Before treatment (T ₀) | -- Absent | 0 (0.0) |
| | -- Mild | 2 (0.0) |
| | -- Intense | 2 (0.0) |
| - Change in Self-report of seborrhea (T ₀ -T ₆) | -- Worsening | 0 (0.0) p = 0.157 ⁽¹⁾ |
| | -- Stabilisation | 2 (50.0) |
| | -- Slight improvement | 2 (50.0) |
| | -- Marked improvement | 0 (0.0) |
| Categories of change in hair density (T ₀ -T ₆) ⁽²⁾ | -- Worsening | 1 (25.0) p = 0.368 ⁽²⁾ |
| | -- Stabilisation | 2 (50.0) |
| - Frontal | -- Improvement | 1 (25.0) |
| - Mid scalp | -- Worsening | 0 (0.0) p > 0.999 ⁽²⁾ |
| | -- Stabilisation | 4 (100.0) |
| | -- Improvement | 0 (0.0) |
| - Vertex | -- Worsening | 0 (0.0) p > 0.999 ⁽²⁾ |
| | -- Stabilisation | 4 (100.0) |
| | -- Improvement | 0 (0.0) |

Notes: ⁽¹⁾score values for change in hair density were chosen as the most frequent (modal value) among the three types of evaluations conducted for each of the studied sides. The scale used varies from -2 to 2 (-2 = significant worsening, -1 = mild worsening, 0 = stabilisation, 1 = improvement, 2 = significant improvement); ⁽²⁾p values obtained based on *symmetry* command (Stata/SE 12.1 for Windows) which performs exact symmetry (homogeneity) test in studies where non-independence holds (before-after).

In our initial investigation, mesotherapy with bicalutamide only improved the hair density in the frontal area in one out of four patients. Adjusting drug concentrations and the frequency of sessions may potentially unveil more favourable outcomes. While pain could pose a challenge to patient compliance, no participants withdrew from our study. The amelioration of seborrhoea stands out as a possible benefit, particularly when FPHL and seborrheic dermatitis co-occur.

Nevertheless, we acknowledge that, although this study is a pilot, the limited sample size and the absence of a control group are constraints in our research.

In conclusion, mesotherapy with bicalutamide presented limited efficacy as a monotherapy for FPHL. The procedure was considered safe despite the pain and minor symptoms reported.



Figure 2: Comparative analysis of the patient's scalp condition (a, b) before treatment and (c, d) after treatment. Images (a) and (c) represent macroscopic views, while images (b) and (d) show trichoscopic findings. Post-treatment images demonstrate increased hair density indicating improvement compared to baseline.

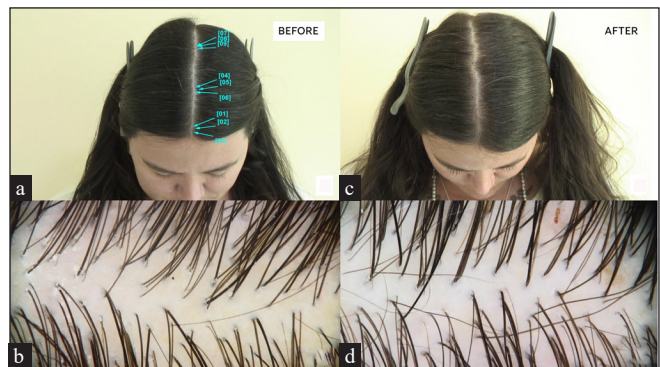


Figure 3: Comparative analysis of the patient's scalp condition (a, b) before treatment and (c, d) after treatment. Images (a) and (c) represent macroscopic views, while images (b) and (d) show trichoscopic findings. Post-treatment images demonstrate increased hair density indicating improvement compared to baseline.

Further studies with larger sample sizes controlled with placebo may clarify its safety and efficacy for this condition.

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Histopathologic study of morphea

Dear Editor,

Morphea (localised scleroderma) is a rare inflammatory fibrosing disease of the skin.^{1,2} Patterns of sclerosis and degree of inflammation are known to have clinical implications such as increased functional limitations.² Histopathology of morphea has received little attention in India.^{3,4}

This retrospective study was performed at a tertiary care centre. Cases diagnosed based on clinical suspicion and histopathologic confirmation from 2012 to 2020 were included. In this study, lichen sclerosus (LS) was excluded as it was not considered a variant of morphea. Skin biopsies were studied for histopathologic features. Patterns of arrangement of lymphocytes were categorised as ‘scattered interstitial’, ‘Indian file’ and ‘lymphoid aggregate’.

There were 101 skin biopsies from 78 patients (17 paediatric cases). Age ranged from 6 to 94 years. Female preponderance was noted (n = 46, 59%). The lesions were seen on the head and neck (n = 13) [Figure 1a-b], trunk (n = 35) and extremities (n = 78, 77%). The most common clinical subtype was the plaque type (n = 32, 43%).

Dermal sclerosis, which was present in all cases, was either top-heavy [Figure 2a], bottom-heavy [Figure 2b], full thickness [Figure 2c] or rarely patchy or focal. The histopathologic features are depicted in Tables 1 and 2. All

the cases with top-heavy sclerosis also showed involvement of the mid-dermis in addition to the papillary dermis. A few features were distinctly absent in certain groups.

The demographics and clinical types were concordant with the literature. Extremities were commonly affected and most cases showed full-thickness sclerosis, contrary to the cases seen in literature.² The presence of top-heavy sclerosis supports the concept that morphea may be limited to the superficial reticular dermis, known as superficial morphea.² Diminished skin adnexal structures were consistent findings.⁵ Remnant follicles, appearing as columnar basaloid structures were more frequently sighted than remnant sebaceous and eccrine glands.

The ‘line’ sign was never seen in the top-heavy pattern of sclerosis. This is explainable because the ‘line’ sign is seen only when the sclerosis involves the dermal-subcutis interface and depends on the presence of subcutis and the depth of the biopsy. However, if the subcutis is replaced by collagen, even a deep biopsy may not show apparent subcutis. The other named signs were seen in fewer cases when compared to literature.³

As per literature, the incidence of overlying lichen sclerosus-like changes in morphea ranges from 12% to 24%.⁵ We observed this in a few cases which showed either a top-heavy

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