



Female hair loss

Low-level laser therapy effective for female pattern hair loss

By Louise Gagnon
Staff Correspondent

Stony Brook, N.Y. — Low-level laser therapy can be employed as a treatment for female pattern hair loss, according to a recently conducted proof-of-concept study.

“It is effective, and patients are happy with the results,” says Theodore J. Daly, M.D., F.A.A.D., F.A.S.D., F.S.P.D., director, Garden City Dermatology, and assis-

tant professor of medicine, pediatrics and pathology, State University of New York (SUNY), Stony Brook, N.Y.

“They are enthusiastic about having another option for treatment,” he says.

A key benefit to low-level laser therapy is that it produces minimal to no side effects, according to Dr. Daly.

“There is no standard treatment for female pattern hair loss other than 2 percent minoxidil,” Dr. Daly says.

Existing therapies for female pattern hair loss include topical 2 percent and 5 percent minoxidil solution, anti-androgens, birth control pills, aldactone, hair transplants and vitamin supplements. There are some undesirable side effects with existing treatments. Laser treatment is suggested as an alternative therapeutic option when patients are unable to take medications, or it can be a complement to therapy.

quick read

Low-level laser therapy for female pattern hair loss is safe and effective, one expert says.

A key benefit to low-level laser therapy is that it produces minimal to no side effects.

Low-level laser therapy has other clinical applications owing to its anti-inflammatory and antibacterial properties, such as in woundcare. In the area of hair growth, there are few peer-reviewed, blinded studies looking at the impact of low-level laser therapy to grow hair. To date, most have been anecdotal.

Laser therapy as a management option for hair loss first took hold in an animal study in which hair regrew faster on shaven backs of irradiated mice compared to mice that were not irradiated. Other terms to describe the intervention include cold laser therapy, photobiomodulation and laser biostimulation, all of which refer to the effect that the intervention is having at a cellular level.

Clinical results

“Other research has shown that the mitochondria are upregulated with low-level laser therapy,” Dr. Daly says. “The mitochondria are the energy-producing component of the cell.”

The study involved 10 women, aged 28 to 78, with a mean age of 50.5 years, who were treated with a visible,

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9-chloro-6 α -fluoro-11 β , 21-dihydroxy-16 α -methylpregna-1,4-diene-3,20-dione 21-pivalate.

Its structure is as follows:

CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt

should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS—Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:

- Urinary free cortisol test
- ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- Burning
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypertrichosis
- Acneiform eruptions
- Hypopigmentation
- Perioral dermatitis
- Allergic contact dermatitis
- Maceration of the skin
- Secondary infection
- Skin atrophy
- Striae
- Milaria

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSE AND ADMINISTRATION:

Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

Cloderm (clocortolone pivalate) Cream 0.1% is supplied in a 30 gram pump bottle, 45 gram and 90 gram tubes.

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red-light, continuous-wave, rotating diode laser, the Revage 670 (Aspira Science), twice weekly for six weeks, followed by weekly administration for 16 weeks. The patients had mean hair loss duration of six years, with the range being 0.5 to 15 years.

The laser used in the study, which has a total output of about 120 mW, meets international laser standards for safety and is approved by the Food and Drug Administration. The advantage of the laser is that it is rotational, as opposed to stationary, allowing the scalp to be irradiated in a more consistent fashion. Most lasers in that power range are not rotational, Dr. Daly says.

"With this particular modality, there is no risk of burning the skin," Dr. Daly says.

The study was designed to assess if the technology demonstrated initial efficacy to see if it was worthy of being evaluated further, Dr. Daly tells **Dermatology Times**.

"The study was intentionally biased," he says, noting the final evaluation of the study was based on the least effective results post-treatment.

Both patients and investigators selected a rating to denote their measurement of the impact of the laser therapy, with investigators basing their rating on the effect of other hair loss treatments, including pharmaceutical therapies. Ratings ranged between one and seven, with one being much worse and seven being much improved.

A final assessment combining the patients' global assessments and the investigators' global assessments showed, from baseline, much improvement in one patient, some improvement in five patients, and slight improvement in two patients. No patients were worse, and the remaining two were unchanged from baseline.

Investigators observed no correlation between patient age or duration of hair loss and the outcome with the therapy.

Study shortcomings

Because of the small sample size, investigators were unable to arrive at any conclusions about which patients with female pattern hair loss are more likely to respond to low-level laser therapy.

"We don't know at this point whether it is more effective in combination with other treatments or as a stand-alone therapy," Dr. Daly says.

Future studies may use devices such as trichometers to objectively measure hair growth, so changes in hair mass, diameter and density can be precisely quantified, Dr. Daly says. Future studies would also use a control group and compare out-

comes, using a trichometer, between subjects who received laser therapy and those who did not. **DT**

Disclosure: Dr. Daly is a speaker for Abbott Laboratories, Promius Pharma LLC, Warner Chilcott Pharmaceuticals and GlaxoSmithKline.

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