

Allay Patient Fears Before Nail Surgery Anesthesia

BY JEFF EVANS
Senior Writer

WASHINGTON — Efforts to take patient comfort and safety into account when giving anesthesia for nail surgery may pay off in greater self-confidence during procedures, Dr. Nathaniel J. Jellinek said at the annual meeting of the American Academy of Dermatology.

When the topic of nail surgery or biopsy arises, most patients will be “quite ap-

prehensive;” therefore, it is crucial to achieve total anesthesia with as little discomfort as possible and to approach the procedure with confidence, said Dr. Jellinek of the department of dermatology at Brown University, Providence, R.I.

“If you’re not successful at [anesthesia], the patients will never come to you. You’ll never do [the surgery] again because you’ll be intimidated by the procedure that went wrong,” he said.

When giving anesthesia, it’s advisable to

recline patients even if they say they don’t need it and to have an assistant hold their hand and distract them with conversation.

It is also a good idea to use a distracting stimulus prior to needle insertion (gripping the finger firmly, flicking the finger, or anesthetizing the injection site with a cryogen spray) and to tell patients that the injection is coming, he said.

“It’s very important to not fill the nail fold quickly, because it’s probably the dis-

attention of the tissue as much as the needle prick that causes a lot of pain,” he said.

There have been two randomized, double-blind studies that examined the value of using a topical anesthetic to prevent the pain of a digital nerve block of the great toenail: One found that EMLA cream (2.5% lidocaine and 2.5% prilocaine) significantly reduced visual analog pain scores, compared with placebo (Eur. J. Anaesthesiol. 2000;17:182-4), whereas the other showed no benefit for EMLA cream (Acta Anaesthesiol. Scand. 2002;46:203-6).

Dr. Jellinek said that he uses topical anesthetic only when a patient is really apprehensive about the anesthesia.

In such cases, he said that applies EMLA cream 2 hours ahead of time and occludes it with plastic wrap or Tegaderm dressing and tells the patient that it may help a little bit.

“I think it helps with the pinprick,” he said. Some people think that the effect of EMLA cream extends 5 mm deep, but “I don’t think it’s going to help with the slow distension of tissues,” he said.

Although epinephrine has traditionally not been “allowed” during a digital block, Dr. Jellinek does not view it as an absolute contraindication. He does not usually use it, however, because most nail surgeries last fewer than 30 minutes and do not need prolonged anesthesia. “You can do [a distal block] competently, without any epinephrine, without any neurovascular damage risk,” he said.

Of 50 cases of digital gangrene associated with local anesthesia in the literature, 21 occurred with the use of epinephrine. Most cases occurred before 1950, when procaine was used. Epinephrine was not a component of the anesthetic in most cases of gangrene, but when it was, very high concentrations were used, he noted.

If epinephrine is used, Dr. Jellinek made several recommendations:

- ▶ Use a 1:200,000 concentration with a minimal volume that corresponds to the size of the digit.
- ▶ Avoid a circumferential buildup of fluid when performing a ring block.
- ▶ Buffer anesthetics to avoid greater tissue acidosis than already present in ischemia.
- ▶ Avoid postoperative hot soaks.
- ▶ Look out for vasospastic patients.
- ▶ Consider having nitroglycerin or phenolamine on hand.

Dr. Jellinek performs most of his nail surgeries with a distal wing (local) block, which is infiltrative and gives immediate-onset anesthesia.

Epinephrine is not really necessary because the volume of anesthetic solution provides hemostasis.

An injection at each lateral nail fold is usually enough to carry the anesthetic to the junction of the hyponychium and the lateral nail folds. It is necessary to have a distracting stimulus for a wing block, such as a cryogen spray, Dr. Jellinek advised.

In a digital block, two nerves on each side of the digit are blocked at its base. He usually reserves the digital block for Mohs surgery on nail tumors. It also is necessary to wait at least 10 minutes for the nerve block to take effect. ■

Verdeso[™]
(desonide)
Foam, 0.05%

Easy to use, easy to like.[™]

Reference: 1. Data on file [010], Connetics Corporation.

BRIEF SUMMARY

Rx Only

FOR TOPICAL USE ONLY

NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE

INDICATIONS AND USAGE

Verdeso Foam is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Verdeso Foam for the minimum amount of time necessary to achieve the desired results because of the potential for Verdeso Foam to suppress the hypothalamic-pituitary-adrenal (HPA) axis (see PRECAUTIONS). Treatment should not exceed 4 consecutive weeks.

CONTRAINDICATIONS

The use of Verdeso Foam is contraindicated in patients who are hypersensitive to desonide or to any ingredient in this preparation.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of topical corticosteroids over large body surface areas, prolonged use, or the addition of occlusive dressings. Therefore, patients applying a topical corticosteroid to a large body surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression (see Laboratory 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 upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see prescribing information for those products.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the cosyntropin stimulation test. The laboratory suppression was transient; all subjects had returned to normal when tested 4 weeks post treatment.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface area to body mass ratios (see PRECAUTIONS – Pediatric Use).

If irritation develops, Verdeso Foam should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation, as with most products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, the use of an appropriate antifungal, antibacterial or antiviral agent should be instituted. If a favorable response does not occur promptly, use of Verdeso Foam should be discontinued until the infection has been adequately controlled.

Information for Patients: 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 or other mucous membranes. The medication should not be dispensed directly onto the face. Dispense in hands and gently massage into the affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly on the affected area. Wash hands after use.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to the physician.
5. Patients should inform their physicians that they are using Verdeso Foam if surgery is contemplated.
6. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

Laboratory Tests: The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic or photoco-carcinogenic potential of Verdeso Foam or the effect on fertility of desonide.

Desonide revealed no evidence of mutagenic potential based on the results of two in vitro genotoxicity tests (Ames assay, mouse lymphoma cell assay) and an in vivo genotoxicity test (mouse micronucleus assay).

Pregnancy: Teratogenic Effects: Pregnancy Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies of Verdeso Foam in pregnant women. Therefore, Verdeso Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

No long-term reproductive studies in animals have been performed with Verdeso Foam. Dermal embryofetal development studies were conducted in rats and rabbits with a desonide cream, 0.05% formulation. Topical doses of 0.2, 0.6 and 2.0 g cream/kg/day of a desonide cream, 0.05% formulation or 2.0 g/kg of the cream base were administered topically to pregnant rats (gestational days 6-15) and pregnant rabbits (gestational days 6-18). Maternal body weight loss was noted at all dose levels of the desonide cream, 0.05% formulation in rats and rabbits. Teratogenic effects characteristic of corticosteroids were noted in both species. The desonide cream, 0.05% formulation was teratogenic in rats at topical doses of 0.6 and 2.0 g cream/kg/day and in rabbits at a topical dose of 2.0 g cream/kg/day. No teratogenic effects were noted for the desonide cream, 0.05% formulation at a topical dose of 0.2 g cream/kg/day in rats

and at a topical dose of 0.6 g cream/kg/day in rabbits. These doses (0.2 g cream/kg/day in rats and 0.6 g cream/kg/day in rabbits) are similar to the maximum recommended human dose based on body surface area comparisons.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Verdeso Foam is administered to a nursing woman.

Pediatric Use: Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing’s syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing’s syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. 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.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients, ages 6 months to 17 years of age in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the ACTH stimulation test. The suppression was transient; all subjects’ cortisol levels had returned to normal when tested 4 weeks post treatment.

Safety of Verdeso Foam has not been evaluated in pediatric patients below the age of 3 months.

Geriatric Use: Clinical studies of Verdeso Foam did not include any subjects aged 65 or older to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

In a controlled clinical study of 581 patients 3 months to 17 years of age, adverse events occurred at the application site in 6% of subjects treated with Verdeso Foam and 14% of subjects treated with vehicle foam. Other commonly reported adverse events for Verdeso Foam and vehicle foam are noted in Table 1 (see full prescribing information).

Elevated blood pressure was observed in 6 (2%) subjects receiving Verdeso Foam and 1 (1%) subject receiving vehicle foam. Other local adverse events occurred at rates less than 1.0%. The majority of adverse events were transient and mild to moderate in severity, and they were not affected by age, race or gender. The following additional local adverse reactions have been reported with topical corticosteroids. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

A thin layer of Verdeso Foam should be applied to the affected area(s) twice daily. Shake the can before use. Verdeso Foam should be dispensed by inverting the can (upright actuation will cause loss of the propellant, which may affect product delivery). Dispense the smallest amount of foam necessary to adequately cover the affected area(s) with a thin layer.

The medication should not be dispensed directly on the face. Dispense in hands and gently massage into affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly onto the affected area. Take care to avoid contact with the eyes or other mucous membranes.

Therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, reassessment of diagnosis may be necessary. Treatment should not exceed 4 consecutive weeks.

Unless directed by a physician, Verdeso Foam should not be used with occlusive dressings.

HOW SUPPLIED

Verdeso Foam is supplied in 100 g (NDC 63032-111-00) and 50 g (NDC 63032-111-50) aluminum cans. Store at controlled room temperature 68°F–77°F (20°C–25°C).

WARNING: FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION. Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C). Avoid contact with eyes or other mucous membranes. Keep out of reach of children.

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For additional information, visit www.verdeso.com.



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