

Pediatric Surgery Patients Require Special Care

BY DENISE NAPOLI
Assistant Editor

WASHINGTON — Simple techniques can smooth the dermatologic surgery experience and outcomes for children, Dr. Brandie J. Metz said at the annual meeting of the American Academy of Dermatology.

For instance, while it may seem obvious to explain a procedure as thoroughly as possible without scaring the child, it's also

important not to lie about any aspect of the procedure, to remain especially "bright and friendly" throughout the discussion, and to engage the child in discussion as much as possible.

Sitting at or below the level of the child can also help put him or her at ease, the dermatologic surgeon said.

Dr. Metz, of the University of California, Irvine, also recommended having the child's parent sit at the head of the table during a procedure and obscuring the

child's view of the surgical tray and any blood-soaked gauze.

When it comes to injections, slow infiltration is less painful than rapid infiltration, she said.

It can also help to use topical anesthetics such as a eutectic mixture of lidocaine and prilocaine (EMLA) or 4% liposomal lidocaine (ELA-Max) to numb the area before injection. Technically, topical anesthetics do not need to be occluded, but "it doesn't seem wise to put a big glob of

cream on a kid and then let [him] run around without occluding it," Dr. Metz said.

A nurse—not a parent—should be the one to restrain the child if he or she is squirming or very frightened.

"A lot of [children's] impressions of pain and anxiety are based on past experiences," she said. So for more extensive procedures in young children, "consider doing them under general anesthesia," even if that means referring the child to a pediatric dermatologist or a plastic surgeon.

After the operation is over, Dr. Metz said, "No matter how disastrous it was, always praise the child."

Also, reward the child with stickers, lollipops, or other treats to facilitate selective memory.

Pay special attention to dressings. If possible, let the child pick the color of the dressing before surgery, then make the dressing as bulky as possible.

"If you do a biopsy on an adult scalp, you might just need a little bit of antibiotic ointment," she said.

But with a child, "I'll often use a much larger dressing [than is needed], because this can be helpful in enforcing postoperative activity restrictions. There is generally not much discomfort or pain, so you kind of [need to] remind them that there's

something there," Dr. Metz advised.

An oversized dressing also can help ensure that the child's experience is not minimized, Dr. Metz pointed out, adding that many children will need a note excusing them from physical education classes and after-school sports.

"It's also helpful to give them printed-out postoperative instructions," she added.

Dr. Metz said that 2-octyl cyanoacrylate tissue adhesives such as Dermabond also can be used to close wounds that would otherwise require up to a 5-0 suture.

These types of adhesives are especially beneficial for squirmy children and toddlers, and there is no need for a follow-up visit.

The wound can also get wet.

On the other hand, she cautioned that the cost—approximately \$30 per vial—and the fact that it can be picked off or inadvertently dissolved by petrolatum-based products, are drawbacks.

Dr. Metz pointed out that the resilience of children is not to be underestimated.

"I'm surprised every time at how quickly kids bounce back after a procedure," she said.

"It may have gone terribly, but afterward they just bounce back. It really makes postoperative care a breeze," she commented. ■

NEW
Verdeso[™]
(desonide)
Foam, 0.05%

Easy to use, easy to like.[™]

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 photo-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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