

AAP: Community Health Activity Has Declined

BY DAMIAN McNAMARA

Fewer pediatricians participated in community child health initiatives in 2010 than in 2004, according to a study that compared two periodic American Academy of Pediatrics surveys.

In 2010, 40% of 820 pediatricians reported caring for children in their community (other than their own patients). This figure significantly decreased from 45% of 881 who reported such involvement in 2004, Dr. Cynthia S. Minkovitz said.

"The bad news is the rate is going down. The good news is we're higher than other specialties, at least 10 percentage points higher than others," Dr. Minkovitz said in response to a question at the annual meeting of the Pediatric Academic Societies.

Despite the decrease, perspectives regarding the importance of community pediatrics remained unchanged, Dr. Minkovitz said. "More than three-quarters feel 'moderately' or 'very responsible' for child health in both years."

Of those who did get involved in child health outside their day-to-day practices, a greater percentage of pediatricians did so as unpaid volunteers: 86% in 2010 vs. 80% in 2004, according to this study contrasting two national, mailed surveys.

Practice constraints and changing demographics in the pediatrician workforce may play a role. Older age, not having children of their own 5 years or younger, and practicing in a rural setting were factors associated with community involvement. For example, 47% of pediatricians older than 50 years reported involvement, compared with 44% of those aged 40-50 years, 40% of those 35-39 years, and 33% of those 34 years or younger.

Women comprised a greater percentage of survey respondents in 2010, 59%, vs. 52% in 2004. The percentage of pediatricians who said general pediatrics accounts for more than half of their practice was 67% in 2010, down from 72% in 2004. Likewise, the percentage who reported a

rural practice was 9% in 2010, vs. 13% in 2004.

In addition, more respondents in 2010 reported receiving formal training in community pediatrics before medical school (5% vs. 3%) and during residency (28% vs. 22%), compared with respondents in 2004, said Dr. Minkovitz, director of the women's and children's health policy center at the Johns Hopkins Bloomberg School of Public Health in Baltimore.

In a multivariate analysis, formal training (odds ratio 2.10) and older age (OR 1.38) were significant, independent predictors associated with community child health involvement.

The response rates of 58% and 60% for the two surveys are consistent with rates from other national physician surveys, and represent a strength of the study. ■

VITALS

Major Finding: Forty percent of pediatricians reported involvement in child health in their communities in 2010, compared with 45% in 2004.

Data Source: American Academy of Pediatrics periodic surveys for 2004 and 2010.

Disclosures: Dr. Minkovitz said she had no relevant financial disclosures.

BRIEF SUMMARY

VELTIN™ (clindamycin phosphate and tretinoin) Gel 1.2%/0.025%
The following is a brief summary only; see full prescribing information for complete product information.

INDICATIONS AND USAGE

VELTIN Gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

CONTRAINDICATIONS

VELTIN Gel is contraindicated in patients with regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

WARNINGS AND PRECAUTIONS

Colitis

Systemic absorption of clindamycin has been demonstrated following topical use. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical clindamycin. If significant diarrhea occurs, VELTIN Gel should be discontinued.

Severe colitis has occurred following oral or parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate a toxin(s) produced by clostridia is one primary cause of antibiotic-associated colitis.

Ultraviolet Light and Environmental Exposure

Exposure to sunlight, including sunlamps, should be avoided during the use of VELTIN Gel, and patients with sunburn should be advised not to use the product until fully recovered because of heightened susceptibility to sunlight as a result of the use of tretinoin. Patients who may be required to have considerable sun exposure due to occupation and those with inherent sensitivity to the sun should exercise particular caution. Daily use of sunscreen products and protective apparel (e.g., a hat) are recommended. Weather extremes, such as wind or cold, also may be irritating to patients under treatment with VELTIN Gel.

ADVERSE REACTIONS

Adverse Reactions in Clinical Studies

The safety data reflect exposure to VELTIN Gel in 1,104 patients with acne vulgaris. Patients were 12 years or older and were treated once daily in the evening for 12 weeks. Observed local treatment-related adverse reactions ($\geq 1\%$) in clinical studies with VELTIN Gel were application site reactions, including dryness (6%), irritation (5%), exfoliation (5%), erythema (4%), pruritus (2%), and dermatitis (1%). Sunburn (1%) was also reported. Incidence of skin reactions peaked at week 2 and then gradually decreased.

Local skin reactions were actively assessed at baseline and at the end of 12 weeks of treatment in patients exposed to VELTIN Gel. At baseline (N=476), local skin reactions included erythema (24%), scaling (8%), dryness (11%), burning (8%), and itching (17%). At 12 weeks of treatment (N=409), local skin reactions included erythema (21%), scaling (19%), dryness (22%), burning (13%), and itching (15%). During the 12 weeks of treatment, each local skin reaction peaked at week 2 and gradually reduced thereafter.

DRUG INTERACTIONS

Erythromycin

VELTIN Gel should not be used in combination with erythromycin-containing products due to possible antagonism to the clindamycin component. *In vitro* studies have shown antagonism between these 2 antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, VELTIN Gel should be used with caution in patients receiving such agents.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. There are no well-controlled studies in pregnant women treated with VELTIN Gel. VELTIN Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A limit teratology study performed in Sprague Dawley rats treated topically with VELTIN Gel or 0.025% tretinoin gel at a dose of 2 mL/kg during gestation days 6 to 15 did not result in teratogenic effects. Although no systemic levels of tretinoin were detected, craniofacial and heart abnormalities were described in drug-treated groups. These abnormalities are consistent with retinoid effects and occurred at 16 times the recommended clinical dose assuming 100% absorption and based on body surface area comparison. For purposes of comparison of the animal exposure to human exposure, the recommended clinical dose is defined as 1 g of VELTIN Gel applied daily to a 50 kg person.

Tretinoin: Oral tretinoin has been shown to be teratogenic in mice, rats, hamsters, rabbits, and primates. It was teratogenic and fetotoxic in Wistar rats when given orally at doses greater than 1 mg/kg/day (32 times the recommended clinical dose based on body surface area comparison). However, variations in teratogenic doses among various strains of rats have been reported. In the cynomolgous monkey, a species in which tretinoin metabolism is closer to humans than in other species examined, fetal malformations were reported at oral doses of 10 mg/kg/day or greater, but none were observed at 5 mg/kg/day (324 times the recommended clinical dose based on body surface area comparison), although increased skeletal variations were observed at all doses. Dose-related teratogenic effects and increased abortion rates were reported in pigtail macaques.

With widespread use of any drug, a small number of birth defect reports associated temporally with the administration of the drug would be expected by chance alone. Thirty cases of temporally associated congenital malformations have been reported during two decades of clinical use of another formulation of topical tretinoin. Although no definite pattern of teratogenicity and no causal association have been established from these cases, 5 of the reports describe the rare birth defect category, holoprosencephaly (defects associated with incomplete midline development of the forebrain). The significance of these spontaneous reports in terms of risk to fetus is not known.

Nursing Mothers

It is not known whether clindamycin is excreted in human milk following use of VELTIN Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. It is not known whether tretinoin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VELTIN Gel is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of VELTIN Gel in pediatric patients below the age of 12 years have not been established. Clinical trials of VELTIN Gel included 2,086 patients 12-17 years of age with acne vulgaris. [See *Clinical Studies (14)* of full prescribing information.]

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of VELTIN Gel or the effect of VELTIN Gel on fertility. VELTIN Gel was negative for mutagenic potential when evaluated in an *in vitro* Ames *Salmonella* reversion assay. VELTIN Gel was equivocal for clastogenic potential in the absence of metabolic activation when tested in an *in vitro* chromosomal aberration assay.

Clindamycin: Once daily dermal administration of 1% clindamycin as clindamycin phosphate in the VELTIN Gel vehicle (32 mg/kg/day, 13 times the recommended clinical dose based on body surface area comparison) to mice for up to 2 years did not produce evidence of tumorigenicity.

Tretinoin: In two independent mouse studies where tretinoin was administered topically (0.025% or 0.1%) three times per week for up to two years no carcinogenicity was observed, with maximum effects of dermal amyloidosis. However, in a dermal carcinogenicity study in mice, tretinoin applied at a dose of 5.1 μ g (1.4 times the recommended clinical dose based on body surface area comparison) three times per week for 20 weeks acted as a weak promoter of skin tumor formation following a single application of dimethylbenz[α]anthracene (DMBA).

In a study in female SENCAR mice, papillomas were induced by topical exposure to DMBA followed by promotion with 12-O-tetradecanoyl-phorbol 13-acetate or mezerein for up to 20 weeks. Topical application of tretinoin prior to each application of promoting agent resulted in a reduction in the number of papillomas per mouse. However, papillomas resistant to topical tretinoin suppression were at higher risk for pre-malignant progression.

Tretinoin has been shown to enhance photoco-carcinogenicity in properly performed specific studies, employing concurrent or intercurrent exposure to tretinoin and UV radiation. The photoco-carcinogenic potential of the clindamycin tretinoin combination is unknown. Although the significance of these studies to humans is not clear, patients should avoid exposure to sun.

PATIENT COUNSELING INFORMATION

[See FDA-approved Patient Labeling in full prescribing information.]

Instructions for Use

- At bedtime, the face should be gently washed with a mild soap and water.
- After patting the skin dry, apply VELTIN Gel as a thin layer over the entire affected area (excluding the eyes and lips).
- Patients should be advised not to use more than a pea sized amount to cover the face and not to apply more often than once daily (at bedtime) as this will not make for faster results and may increase irritation.
- A sunscreen should be applied every morning and reapplied over the course of the day as needed. Patients should be advised to avoid exposure to sunlight, sunlamp, ultraviolet light, and other medicines that may increase sensitivity to sunlight.
- Other topical products with a strong drying effect, such as abrasive soaps or cleansers, may cause an increase in skin irritation with VELTIN Gel.

Skin Irritation

VELTIN Gel may cause irritation such as erythema, scaling, itching, burning, or stinging.

Colitis

In the event a patient treated with VELTIN Gel experiences severe diarrhea or gastrointestinal discomfort, VELTIN Gel should be discontinued and a physician should be contacted.

VELTIN is a trademark of Astellas Pharma Europe B.V.

©2010 Stiefel Laboratories, Inc. VEL:2BRS July 2010



©2011 Stiefel Laboratories, Inc. All rights reserved. Printed in USA. VEL055R0 April 2011

INDEX OF ADVERTISERS

Alcon, Inc.	
Patanase	9-10
Pataday	21-22
Bausch & Lomb Incorporated	
Besivance	31-32
Bayer HealthCare LLC	
Flintstones	11
Chattm, Inc.	
Allegra	25
Johnson & Johnson Consumer Companies, Inc.	
Desitin	15
Novartis Consumer Health, Inc.	
Triaminic	7
Pfizer Consumer Healthcare	
Children's Advil	30
Sanofi Pasteur Inc.	
Corporate	20
Pentacel	26-28
Schering Plough HealthCare Products, Inc.	
Claritin	19
Shionogi Inc.	
Kapvay	3-5
Stiefel Laboratories, Inc.	
Veltin	35-36