

Compounds Blamed for Deaths

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and upper chest could be dangerous, Dr. Carruthers said.

Another product, endorsed by cosmetic surgeons at a recent meeting he attended contained 4% benzocaine, 4% lidocaine, and 4% tetracaine.

“Dermatologists know benzocaine can cause very severe reactions and once you get allergic to it, you get all these cross-reactivities,” he said.

“I wouldn’t use this stuff on my dog. I like my dog,” Dr. Carruthers said.

Hilary Baldwin, M.D., speaking at a different session at the meeting, also alerted physicians to toxicity that can occur when topical ingredients are mixed, or when they are applied to mucous membranes, enhancing systemic spread.

On its own, prilocaine can cause contact sensitization in rare cases, and has a “unique ability” to trigger methemoglobinemia, particularly in patients already taking methemoglobinemia-inducing agents such as sulfonamides, acetaminophen, minophen, and anticonvulsant drugs. Peak methemoglobin levels are achieved 8 hours after administration, so patients showing signs of toxicity at 1 hour may need to be hospitalized for slow intravenous administration of methylene

blue, said Dr. Baldwin, who serves on the dermatology faculty at the State University of New York, Brooklyn.

Lidocaine can also cause toxicity, early signs of which include drowsiness, tingling of the lips, and later, tinnitus, dizziness, muscle twitches, seizures and eventually respiratory distress and coma.

Combination products of various topical anesthetics can, in some cases, have additive toxicity potential.

“When we take that tube and put it on the skin, we need to be at least as cognitive [of the total potential systemic dose] as if we took it from a bottle and injected it,” she said.

The lawyers for the families of the two young women who died in recent months said that they know of other cases in which patients have had cardiac arrests after applying topical anesthesia creams, but have recovered.

Ms. Berg died while on the way to Premier Body, Laser, & Skin Clinic in Raleigh, having covered her legs, underarms, chest, and abdomen with a cream containing 10% lidocaine, 10% tetracaine, and 0.5% phenylephrine and occluding the mixture under plastic wrap, said a nurse on the staff of her family’s lawyer, David Kirby.

A motorist saw her in distress on the side of a highway and called 911; despite resuscitation efforts she went into a coma and died Jan. 5.

The North Carolina Medical Board has charged the medical director of the clinic, an otolaryngologist, with two counts of unprofessional conduct.

Ms. Bolanos died Nov. 18, 2004, after a similar incident.

On Jan. 25, 2002, she applied a 6% lidocaine, 6% tetracaine cream over both legs and covered them with plastic wrap as directed by a laser technician who later said in a deposition that she did not know what the “numbing cream” contained or how it worked.

While driving to Golden West Medical Center in Tucson, Ms. Bolanos used her cell phone to call a friend, complaining that she was lost, disoriented, and ill, said her lawyer, Martin Rodriguez, in a telephone interview with SKIN & ALLERGY NEWS.

The friend found her unconscious and having seizures.

She never regained consciousness and died after spending nearly 2 years in a coma on a respirator.

A family practice physician who is not board certified directed the center where she was to have her laser hair removal treatment.

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Pain-Relief Options Available For Cosmetic Procedures

BY BETSY BATES
Los Angeles Bureau

WAILEA, HAWAII — Ice, vibrators, “talk-esthesia,” and sundry topical anesthetic creams and gels were advocated as safe and effective options for relieving pain during a mini-symposium at the annual Hawaii dermatology seminar sponsored by the Skin Disease Education Foundation.

“How much is a happy patient worth? If you hurt them, they won’t come back,” said Kevin C. Smith, M.D., a dermatologist practicing in Niagara Falls, Ont.

The discussion focused on patients undergoing cosmetic procedures, but the techniques, listed here, can be used on medical dermatology patients as well:

► **Ice.** It’s effective and about as cheap as pain relief gets. “We use it a lot,” said Alastair Carruthers, M.B., a dermatologist in practice in Vancouver, B.C.

► **Vibrators.** Snickers aside, the Hitachi Magic Wand with a Wonder Wand attachment provides excellent pain relief when applied under a patient’s chin during facial procedures by blocking pain signals to the brain, said Dr. Smith.

The devices can be found at the Web site www.drugstore.com.

► **Talk therapy.** “It’s not enough to put some cream on a patient,” Dr. Smith said. From the time a patient first calls the office, the staff and the physician should convey calm reassurance. Patients will have less pain if they feel “confident of your skill and your care.”

He said he always uses “talk-esthesia” to talk patients through procedures, even when other forms of pain relief are used.

► **Analgesics.** Some procedures call for up-front pain relief. Dr. Smith sometimes advises patients to take an NSAID in combination with acetaminophen for an additive effect. Patients who do not have asthma may be prescribed propranolol, which provides analgesia but does not interfere with a patient’s ability to drive.

► **L.M.X. 4.** This 4% lidocaine cream (formerly ELA-Max 4%) is sold over the counter, does not require occlusion, and provides anesthesia 30 minutes after application, Dr. Carruthers explained.

He tested it against a vehicle cream in 24 patients receiving Botox (botulinum toxin type A) injections for crow’s feet.

“I like to think this is not a very painful procedure, so in order to reduce the discomfort, this stuff has to work very well,” he said.

The study showed a significant difference in patient visual analogue scale scores and observer ratings of discomfort when L.M.X. 4 was used, with *P* values in the range of .005.

► **L.M.X. 5.** This anorectal anesthetic cream is more appropriate for use in the mouth than alcohol-containing topical gels, which can cause sloughing of mucous membranes and irritation and stinging if they get in the eyes, Dr. Smith said.

For lip procedures, optimal anesthesia can be obtained by numbing the mucosal surface of the lips, including the anterior mucosae of the anterior labioalveolar sulci down to the gingival sulcus as well as the vermilion and a 1-cm margin around the vermilion border.

To achieve this without getting anesthetic all over the inside of the patient’s mouth, he cuts a Telfa pad to mimic a plastic laser shield designed to protect the teeth from laser work performed around the mouth. He cuts a 3-by-4-inch Telfa pad in half, lengthwise, then folds it over and cuts a slit in the middle (to allow the patient to breathe) and slits at the top and bottom to accommodate the frenula.

He inserts the pad into the patient’s mouth, against the teeth. He then uses a tongue depressor to apply L.M.X. 5 thickly over the lips and gums and attends to other patients for 30-45 minutes, until his watch alarm sounds to remind him to return to perform the procedure.

At that time, he can inject lidocaine painlessly or, for simple filler procedures, move directly to injections of Restylane (nonanimal stabilized hyaluronic acid gel).

Dr. Smith noted that previous research has determined that the anesthetic mixture in L.M.X. 5 does not produce toxic blood levels, even when applied to mucous membranes.

Dr. Carruthers disclosed that he has financial ties to Allergan Inc., which distributes Botox. Dr. Smith received L.M.X. 5 samples from Ferndale Laboratories Inc. for his research.

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Salex™ (6% Salicylic Acid) Lotion

Rx Only
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

INDICATIONS AND USAGE

For Dermatologic Use: Salex™ Lotion is a topical aid in the removal of excessive keratin in hyperkeratotic skin disorders, including verrucae, and the various ichthyoses (vulgaris, sex-linked and lamellar), keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis (including body, scalp, palms and soles).

For Podiatric Use: Salex™ Lotion is a topical aid in the removal of excessive keratin on dorsal and plantar hyperkeratotic lesions. Topical preparations of 6% salicylic acid have been reported to be useful adjunctive therapy for verrucae plantares.

CONTRAINDICATIONS

Salex™ Lotion should not be used in any patient known to be sensitive to salicylic acid or any other listed ingredients. Salex™ Lotion should not be used in children under 2 years of age.

WARNINGS

Prolonged use over large areas, especially in children and those patients with significant renal or hepatic impairment, could result in salicylism. Concomitant use of other drugs which may contribute to elevated serum salicylate levels should be avoided where the potential for toxicity is present. In children under 12 years of age and those patients with renal or hepatic impairment, the area to be treated should be limited and the patient monitored closely for signs of salicylate toxicity: nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnea, diarrhea, and psychic disturbances. In the event of salicylic acid toxicity, the use of Salex™ Lotion should be discontinued. Fluids should be administered to promote urinary excretion. Treatment with sodium bicarbonate (oral or intravenous) should be instituted as appropriate.

Due to potential risk of developing Reye's syndrome, salicylate products should not be used in children and teenagers with varicella or influenza, unless directed by a physician.

PRECAUTIONS

For external use only. Avoid contact with eyes and other mucous membranes.

DRUG INTERACTIONS

The following interactions are from a published review and include reports concerning both oral and topical salicylate administration. The relationship of these interactions to the use of Salex™ Lotion is not known.

- I. Due to the competition of salicylate with other drugs for binding to serum albumin the following drug interactions may occur:

DRUG	DESCRIPTION OF INTERACTION
Sulfonylureas	Hypoglycemia potentiated.
Methotrexate	Decreases tubular reabsorption; clinical toxicity from ethotrexate can result.
Oral Anticoagulants	Increased bleeding.

- II. Drugs changing salicylate levels by altering renal tubular reabsorption:

DRUG	DESCRIPTION OF INTERACTION
Corticosteroids	Decreases plasma salicylate level; tapering doses of steroids may promote salicylism.
Acidifying Agents	Increases plasma salicylate level.
Alkalinizing Agents	Decreased plasma salicylate levels.

- III. Drugs with complicated interactions with salicylates:

DRUG	DESCRIPTION OF INTERACTION
Heparin	Salicylate decreases platelet adhesiveness and interferes with hemostasis in heparin-treated patients.
Pyrazinamide	Inhibits pyrazinamide-induced hyperuricemia.
Uricosuric Agents	Effect of probenecide, sulfinpyrazone and phenylbutazone inhibited.

The following alterations of laboratory tests have been reported during salicylate therapy:

LABORATORY TESTS	EFFECT OF SALICYLATES
Thyroid Function	Decreased PBI; increased T ₁ uptake.
Urinary Sugar	False negative with glucose oxidase; false positive with Clinistest with high-dose salicylate therapy (2-5g q.d.).
5-Hydroxyindole acetic acid	False negative with fluorometric test.
Acetone, ketone bodies	False positive FeCl ₃ in Gerhardt reaction; red color persists with boiling.
17-OH corticosteroids	False reduced values with > 4.8g q.d. salicylate.
Vanilmandelic acid	False reduced values.
Uric acid	May increase or decrease depending on dose.
Prothrombin	Decreased levels; slightly increased prothrombin time.

Pregnancy (Category C): Salicylic acid has been shown to be teratogenic in rats and monkeys. It is difficult to extrapolate from oral doses of acetylsalicylic acid used in these studies to topical administration as the oral dose to monkeys may represent six times the maximal daily human dose of salicylic acid when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women. Salex™ Lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Because of the potential for serious adverse reactions in nursing infants from the mother's use of Salex™ Lotion, 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No data are available concerning potential carcinogenic or reproductive effects of Salex™ Lotion. It has been shown to lack mutagenic potential in the Ames *Salmonella* test.

ADVERSE REACTIONS

Excessive erythema and scaling conceivably could result from use on open skin lesions.

OVERDOSAGE

See Warnings.

DOSAGE AND ADMINISTRATION

The preferable method of use is to apply Salex™ Lotion thoroughly to the affected area and occlude the area at night. Preferably, the skin should be hydrated for at least five minutes prior to application. The medication is washed off in the morning and if excessive drying and/or irritation is observed a bland cream or lotion may be applied. Once clearing is apparent, the occasional use of Salex™ Lotion will usually maintain the remission. In those areas where occlusion is difficult or impossible, application may be made more frequently; hydration by wet packs or baths prior to application apparently enhances the effect. Unless hands are being treated, hands should be rinsed thoroughly after application.

HOW SUPPLIED

Salex™ Lotion is available in 14 fl oz (414 ml) (NDC 0064-4011-14) bottles.

Store at controlled room temperature 20° - 25°C (68° - 77°F). Do not freeze.

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