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Injection lipolysis under fire

By John Jesitus

Concerns include efficacy, safety, lack of standardization



National report — To proponents of injection lipolysis, the procedure represents a safe, effective tool for dissolving fat without liposuction, significant pain or downtime. However, many dermatologists question these claims, citing growing numbers of complications and patient complaints.

Nevertheless, even some detractors say they'd welcome injection lipolysis should it ultimately prove safe and effective.

Old treatment, new concerns

Dr. Chubaty

Injection lipolysis grew out of mesotherapy, the European practice of injecting therapeutic agents subcutaneously to address ailments including vascular and lymphatic disorders, tinnitus and chronic pain, says David Zloty, M.D., clinical assistant professor of dermatology, University of British Columbia.

The procedure has proven controversial in some foreign countries — Brazilian regulators have banned cosmetic products containing phosphatidylcholine, Health Canada has outlawed phosphatidylcholine injections for any indication, and UK regulators discourage cosmetic use of Lipostabil (phosphatidylcholine-deoxycholate/PCDC, Sanofi-aventis).

In the United States, mesotherapy has come to designate injections aimed at reducing fat and cellulite, he says. Data from the American Society for Aesthetic Plastic Surgery (ASAPS) show that from 2005 to 2006, the number of mesotherapy procedures performed by members grew from 4,773 to 28,901.

"People are looking for procedures that will give them positive results with very little downtime and no purported side effects," Dr. Zloty tells **Dermatology Times**.

Regarding physicians, about 3,000 United States doctors — 30 percent of whom are dermatologists and plastic surgeons — perform injection lipolysis, says Roman Chubaty, M.D., medical director of AestheticMD.com, which offers lipotherapy training for physicians.

"Very few dermatologists are offering this procedure, due to its unapproved nature and the fact that most malpractice carriers would consider it an uncovered medical treatment, as it isn't FDA-approved and consists of a cocktail of unapproved drugs being injected, with little or no scientific study or analysis," says Joel Schlessinger, M.D., of Omaha, Neb., immediate past president, American Society of Cosmetic Dermatology and Aesthetic Surgery.

"The purported advantages — which are being published mainly in mass-market media and through physician training Web sites — are that it's a noninvasive, painless, safe way to remove localized fat deposits and/or improve the appearance of cellulite," says Dr. Zloty, who admits being biased, because he performs liposuction.



However, he says none of these claims have been substantiated in peer-reviewed journals.

"Until there is data to support safety and efficacy, we do not recommend the procedure," says Foad Nahai, M.D., ASAPS president.

Currently, he says, "There's enough for all of us to realize that this combination of drugs will, in fact, break up fat cells. But what happens to the fat? We don't know" if the procedure elevates patients' triglyceride levels.

The lack of a standardized lipotherapy protocol also causes concern, sources say.

"Currently, there are all kinds of drugs being used to try to dissolve localized fat deposits," Dr. Zloty says.

These include vitamins, hormones, alpha and beta blockers and even botulinum toxin, although the most popular ingredients are deoxycholate (DC) and phosphatidylcholine (PC), a combination initially marketed as Lipostabil (Sanofi-aventis), he says.



Dr. Zloty

"In many cases," he says, "the doctor may not be fully aware what agents are in the syringe, because they've been compounded by an outside pharmacy."

As for complications, Dr. Nahai says, "We've heard of skin and muscle necrosis" resulting from lipotherapy.

Dr. Zloty says he has treated about nine patients with post-lipotherapy complaints, including severe pain, irregular results (rippling) and lack of results.

Individual case reports also highlight fat inflammation and paresthesia, the latter involving high concentrations of DC, he says.

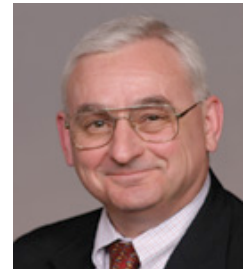
Proponents respond

Even lipotherapy's proponents echo some of the above concerns.

Lipotherapy's strongest indication is spot fat reduction, Dr. Chubaty says. "It doesn't replace liposuction or abdominoplasty."

Unless one is treating facial areas, such as baggy eyelids, he says patients with a body mass index of more than 27 aren't candidates.

"We don't have any large-scale studies to determine the appropriate dosing or dosing frequency," says Glynis R. Ablon, M.D., assistant clinical professor of dermatology, University of California, Los Angeles, and director of the Ablon Skin Institute.



Dr. Young

Still, she says, "We have decent data on smaller-dose use of (PCDC)," including studies she has funded for lower lid fat pads (Ablon G., Rotunda AM. *Dermatol Surg.* 2004 Mar;30(3):422-427), submental fat and DC for lipomas (Rotunda AM, Ablon G, Kolodney MS. *J Am Academy Dermatol.* 2005 Dec;53(6):973-978).

"In these small areas, we get good results with very few complications. So, it's probably a great product — we just need more data," says Dr. Ablon, who estimates she has treated about 100 patients with lipotherapy.

A safety study indicates that, "When practiced by licensed and certified physicians, the safety record for injection lipolysis is excellent (Duncan DI, Chubaty R. *Aesthetic Surg J.* 2006;26:575-585)," Dr. Chubaty says.

Similarly, he says animal studies revealed no significant toxicity, unless researchers injected thousands of times the usual PCDC concentration (Rittes PG, Rittes JC, Carriel Amary MF. *Aesthetic Plast Surg.* 2006

Jul-Aug;30(4):474-478).

Regarding lipotherapy's ingredients, Dr. Chubaty says, "There's no cocktail. I put in one cc of lidocaine (per 5 cc of PCDC) to ease the initial discomfort," but otherwise, he says, he uses a 50/40 mixture of PCDC, or 1 percent to 2 percent DC alone.

PC is an enzyme of lecithin, which comes from soybeans, Dr. Chubaty says. The solvent deoxycholic acid is a bovine bile salt.

However, Dr. Schlessinger says that with unregulated production of bovine ingredients from overseas markets, "It's quite possible that there could be mad cow contamination or other contaminants that could cause problems."

Dr. Chubaty counters that if plastic surgeons are worried about bovine ingredients, "Why are they using bovine collagen?"

Furthermore, DC appears in many common medications, most notably amphotericin, he says.

"The compounding pharmacies make it to our specifications — that's about as standard as it can be," he says.

"There are many critics of Lipodissolve, and a lot of fear and misconception about the procedure," says Matt Freeman, director of Aurora Medical Spa in Des Peres, Mo.

Some physicians view the procedure as competition to their surgical procedures, Mr. Freeman says.

"They complain to governing bodies and tell horror stories in an effort to stop the procedures from being performed.

"Are there unfortunate complications? Of course. But there are with every medical procedure," he says.

Future directions

To allay critics' concerns, Kythera Biopharmaceuticals, based in Calabasas, Calif., is seeking Food and Drug Administration (FDA) approval for a PC-free lipotherapy formulation, says Keith Leonard, Kythera CEO.

"As far as we can tell," Mr. Leonard says, "PC doesn't serve any function" subcutaneously.

In vitro research has shown that DC appears sufficient to kill fat cells (Rotunda AM, et al. *Dermatol Surg.* 2004 Jul;30(7):1001-1008), he says.

At press time, the company was enrolling patients for a phase 2 study involving lipomas, and it planned to begin enrolling patients for a phase 1 study involving submental fat. It also had phase 2 submental fat studies under way in England, Canada and Australia.

Similarly, ASAPS is funding a phase 1 trial of injection lipolysis to determine its impact on subcutaneous abdominal fat and its mechanism of action, "if there is one," says V. Leroy Young, M.D., a St. Louis plastic surgeon in private practice and the study's principal investigator.

He says he plans to enroll up to 20 patients and complete the study in about July 2008.

Using MRI, blood draws and other gauges, Dr. Young says, "Our hope is to get a good objective measure of what the treatment does."

Plastic surgeons are eager to learn what the trial reveals.

"I am very enthusiastic about lipotherapy's potential for our specialty, once it is fully researched and approved," Dr. Schlessinger says.

Dr. Nahai adds, "I'm very excited about the FDA-sanctioned study. We're hoping this will be just the beginning of trying to get some science behind this."

If the treatment proves safe and effective, he says, "It will have a huge impact on dermatology and plastic surgery."

While lipolysis is not for large-volume reductions, Dr. Nahai says, "It would certainly be a very useful adjunct or touch-up treatment, or as primary treatment for small areas of excess fat."

For more information:

www.surgery.org

www.ascdas.org

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