Issue Stories

INPRACTICE

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Secret Potion or Credible Procedure?

by Lesley Ranft

Injection lipolysis is becoming a popular treatment with patients, but shouldn't physicians hold back its use until medical and FDA-related concerns are resolved?

In the United States, injection lipolysis, also known as mesotherapy or under the trade name Lipodissolve, has been a difficult procedure for practitioners to embrace. The types of medications used in the procedure vary among physicians, making it tough to pinpoint complication triggers and mechanisms of action.

The state of Kansas banned the use of mesotherapy in 2007, due in part to unlicensed practitioners who had done a poor job performing the procedure, which, in turn, led to many unhappy and complaining patients. By the same token, hundreds of women and men have received some form of injection lipolysis to date.

More recently, injection lipolysis has attracted the attention of the US plastic surgery community. Kansas has lifted the ban on mesotherapy by allowing the injections to be used for clinical trial purposes. Currently, US-based studies are under way.

The Aesthetic Surgery Education and Research Foundation has sponsored a study led by V. Leroy Young, MD, FACS, who practices in St Louis. This study will involve 20 patients who will receive the injection in the abdomen as much as four times up to 8 weeks apart. The results will be measured through MRI, blood tests, and adipose tissue biopsies.

"We need to learn more about the effect of treatment of injection lipolysis on body fat mass, adipose tissue metabolic function, and systematic markers of metabolism and inflammation; as well as determine mechanisms for fat reduction, side effects, and patient satisfaction," Young explains.

Diane Duncan, MD, FACS, who practices in Fort Collins, Colo, is, at press time, planning to lead a study involving 50 patients for jowl treatment that started in the fall of 2008. The results of this study will quantify volume loss and skin retraction in the jowl area using Canfield 3D imaging equipment.

It is timely to dispel the myth behind this so-called "secret potion" and to list the benefits that may result from injection lipolysis—for both aesthetic surgeons and patients. Yet, as Alan Matarasso, MD, who practices in New York City, explains, "I am cautiously optimistic about injection lipolysis. In the end, injection lipolysis may be an adjunct to treatment, treatment for small areas, but is unsuitable when compared to the results that can be accomplished through surgical treatment. Furthermore, injection lipolysis should not be implemented in practices until it has been fully studied and approved by the FDA. Perhaps in the future it may be a benefit for patients."

INJECTION LIPOLYSIS DEFINED

Injection lipolysis and mesotherapy are not one and the same. Lipodissolve is a trade name created to describe a patent-pending protocol that has been standardized since 2001 and introduced to physicians in the United States in 2004. The theory of Lipodissolve was developed in the 1990s.

At present, for aesthetic purposes physicians have been considering injection lipolysis with two central ingredients: phosphatidylcholine and deoxycholate (PC/DC formula).

Phosphatidylcholine is a natural glycerolphospholipid comprised of glycerol, two fatty acids, and choline attached. Phosphatidylcholine is a fat emulsifier vital for cholesterol metabolism, and is a component of cell membranes. Phosphatidylcholine also can be found in foods and is currently a dietary supplement in the United States, taken in oral form. Although phosphatidylcholine is one of several ingredients used in certain FDA-approved intravenous drugs, it is not FDA-approved in combination with deoxycholate or for use in aesthetic intravenous purposes.

Sodium deoxycholate, the active ingredient in PC/DC formulas, causes fat cells to undergo a process called oncosis when injected into the fatty layer. "Oncosis is basically acute cellular swelling, and the damage caused to the cell membrane cannot be repaired by the cell in many cases," Duncan says.

"With deoxycholate alone, a very rapid onset of cell death is seen in a very localized region—within the immediate injection area," she continues. "When phosphatidylcholine is added, the reaction is less harsh and is spread out a little more, causing a more even reduction of fat when the treatment area has a broad surface. A formula combining phosphatidylcholine and deoxycholate is currently the most popular fat-reducing injectable solution, based on its history of efficacy and safety when properly used by physicians."

In addition, phosphatidylcholine acts as a buffer to the alkaline deoxycholate, which allows the reaction to progress over a week rather than several hours. More finesse and a smoother result can be seen when the two ingredients are combined.

Potential Advantages of Injection Lipolysis

Patient Possibilities

- Subcutaneous fat removal for localized areas of the face, eyes, chin, cheek, neck, sides of the breast area, upper arms, pubic area, back, enlarged male breasts, knees, abdomen, flank, thighs, saddlebags, hips, and buttocks;
- Nonsurgical skin tightening;
- Dramatic cellulite reduction;
- Ability to treat areas that traditional liposuction cannot treat;
- A less invasive approach when compared to traditional liposuction;
- Facial line improvements;
- Hair-loss treatment; and
- Cost-effective.

For the Aesthetic Surgeon

- An alternative to offer patients who are not good candidates for liposuction;
- An adjunct to treatment;
- A solution for patients who would benefit from fat removal on the face; and
- A reasonable investment prospect—an automatic or semiautomatic mesotherapy gun for injection costs between $2,000 and $8,000, and medications compare to pennies on the dollar.

On the other hand, a mesotherapy treatment may be comprised of many different ingredients. The selection of the ingredients is related to a specific procedure mesotherapy is intended to treat. Those ingredients may include vasodilators, anti-inflammatory drugs, muscle relaxants, proteolytic enzymes, vitamins, minerals, plant extracts, vaccines, antibiotics, hormones, hormone blockers, and anesthetics.

When we explore the history of mesotherapy in Europe, we learn that it is considered a credible procedure that is used for chronic pain and sports injuries.

In truth, mesotherapy injection techniques are widely used throughout the world today. Yet, the US medical community has a way to go before injection lipolysis for aesthetic purposes is accepted by physicians or the public.

First, access to European information is limited because most is written in other languages. Second, the FDA has not approved the combination of phosphatidylcholine and deoxycholate or the location of the injection for the treatment of subcutaneous fat. The US medical community has delivered some positive clinical research outcomes, but science-based research is still being acquired.

At times, the process of getting studies approved via the Institutional Review Board is challenging.

"The research of injection lipolysis in the United States requires more controlled studies as well as a closer investigation of the cell disruption which may occur and possible systemic effects. Questions about injection lipolysis still remain including what is the appropriate dose per injection and what is the appropriate total dose per body surface area. Other questions remain, as well. At the same time, injection lipolysis may be a viable prospect for the future," says Tracy M. Pfeifer, MS, MD, who practices in New York City.

THE STUDIES

The following recaps the various studies performed on injection lipolysis in Europe; that is, studies involving the injection of phosphatidylcholine and deoxycholate for aesthetic purposes.

In 2001, Patricia Rittes, MD, of Brazil conducted a study involving 30 patients in a study for subcutaneous injection of phosphatidylcholine to reduce the size of fat pads surrounding the eyes. The number of treatments varied among participants. Aesthetic improvement was documented in all patients, some of which were followed for up to 2 years' time.

In 2004, Ablon and Rotunda reported on the use of phosphatidylcholine for the treatment of lower-eyelid fat pads—reporting that more than 50% noticed an improvement.

In 2006, a 441-patient study by Hasengschwandtner was conducted using injection lipolysis to discover average upper abdomen circumferential reduction of 3.7 cm, lower abdomen reduction of 3.9 cm, hip reduction to 1.9 cm, and upper arm reduction of 1.6 cm. Eighty-nine percent of patients were satisfied with the results after two treatments. Side effects included mild to moderate pain, hematoma, edema, nodules, and swelling.

In 2006, Duncan and Chubaty collected data from more than 17,000 injection lipolysis patients of 75 European physicians. The conclusions noted an 88% patient satisfaction rate and complications that included hyperpigmentation (.015%), allergic reaction (.0003%), and prolonged pain (.015%).

CURRENT STATUS IN THE UNITED STATES

The prospective patient should be more informed about the interaction of medications on blood levels, triglycerides, free cholesterol, and more. It is a difficult and highly technical message to convey in simple terms.

Narrowing the medication combination down to phosphatidylcholine and deoxycholate is a fundamental step in identifying the safety and efficacy of injection lipolysis for aesthetic purposes. In fact, the manipulation of adipose tissue at the cellular level is becoming better understood via ongoing research into new formulas.

What is needed is additional science-based research that can clear up the medical and consumer issues surrounding injection lipolysis. However, the regulatory environment creates a stumbling block for fast-track studies. In the meantime, practices are advised to refrain from getting into the injection lipolysis business.

"Injection lipolysis is on the FDA radar screen," says Petra Schneider-Redden, MD, FACS, chair of health policy for the American Society of Plastic Surgeons. "At present, the combination of medications is not approved by the FDA. There is also a quality control issue for safety and efficacy. There are risks for potential legal and ethical issues surrounding the use of injection lipolysis for aesthetic purposes at present. Practices should be careful about offering injection lipolysis at this time."

In the meantime, hundreds of patients in the United States have already received some form of injection lipolysis—and the number continues to grow. Medical policymakers can better protect the public by offering practices some guidance about when they should expect to adopt injection lipolysis legitimately.

"It is difficult for many plastic surgeons to be informed about the safety and efficacy of new procedures in the cosmetic surgery market, on such a procedure as injection lipolysis," says Steve Svehlak, MD, FACS, who practices in Beverly Hills, Calif. "We need standardized, scientific studies to help prove or disprove certain technologies. It is our responsibility as physicians to inform and educate our patients and the public about these new treatments."

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