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Case Report Open Access

Multisystem Organ Failure Following LipoDissolve Injections

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Abstract

LipoDissolve, also known as injection lipolysis, is a procedure marketed as a means to rid the body of unwanted pockets of fat. Despite warnings by the Food and Drug Administration that the products used in this procedure have not been shown to be safe or effective and are not approved for this use, LipoDissolve continues to be used by beauty spas across the United States. The authors report a case of a 63-year-old woman who developed acute liver injury, acute renal failure necessitating hemodialysis, and pancreatitis soon after undergoing her first LipoDissolve therapy at a home spa.

Keywords: Liver failure; Renal failure; Injection lipolysis; Lipodissolve

Background

LipoDissolve, also known as injection lipolysis, is a procedure marketed as a means to rid the body of unwanted pockets of fat. The process entails a series of injections of phosphatidylcholine and deoxycholate; however, other substances such as vitamins, herbal extracts and other drugs are sometimes added [1,2]. This product has not been approved by the FDA, yet is available and sometimes used without scientific evidence that supports its safety or efficacy for this indication in humans. This case highlights a severe complication of multisystem organ failure following injection lipolysis therapy that has not been previously described.

Case Report

A 63-year-old woman with history of hypertension and depression, on lisinopril, citalopram, solifenacin, herbal medications (raspberry ketone, acai, cranberry) and naturopathic vitamins, underwent her first LipoDissolve procedure at a home spa run by a nurse. The contents of 27 syringes were injected subcutaneously into her abdomen, back, buttocks, and thighs. The total volume of solution injected was reported to contain 135 mg lidocaine, 27 mL of a phosphatidylcholine and deoxycholate mixture, and 284 mL of 0.9% NaCl. Immediately following the injections she became dizzy. Vital signs documented by the nurse included a blood pressure of 107/64 mmHg and a heart rate of 48 bpm. The patient developed vomiting and back pain; she was sent home, but persistent vomiting caused her to go to an emergency department. When she presented to the ED she had severe epigastric abdominal pain. Her vital signs remained normal and she was afebrile. Physical exam revealed an uncomfortable appearing patient. She was alert and oriented, with a normal neurological examination. Her cardiopulmonary exam was normal. The patient's abdomen was soft without guarding, but she had tenderness in the epigastric area. Her skin exam was notable for multiple, tiny, needle punctures over lower abdomen, thighs, and back. Initial laboratory studies, which were obtained six hours after the procedure, revealed AST = 6992 U/L, ALT = 3467 U/L, TBili= 29.1 µmol/L (1.7 mg/dL), PT = 17.2 sec, CPK = 8 U/L, BUN = 9.6 mmol/L (27 mg/dL), Cr = 71.6 µmol/L (0.81 mg/dL), lipase = 38 U/L, and normal electrolytes. White blood cell count was 5.8 × 10^9/L, Hgb =133 g/L, and platelets = 287 × 10^9/L. Serum acetaminophen and salicylate levels were negative. An electrocardiogram, chest x-ray and abdominal ultrasound were performed and were normal. Over the next six hours the AST and ALT climbed to 22,560 U/L and 12,032 U/L, respectively, and the Cr to 154.7 µmol/L (1.75 mg/dL). Documented liver function tests from three months earlier were normal. The patient was transferred to a tertiary referral center for evaluation of liver failure.

Upon arrival, approximately twenty-four hours after the initial presentation, the patient still appeared mildly uncomfortable with abdominal pain. Laboratory studies revealed a lipase of 559 U/L, Cr of 264.3 µmol/L (2.99 mg/dL), AST 15,090 U/L and ALT 9,162 U/L. A urine drug analysis by gas chromatography-mass spectrometry (GC-MS) detected only lidocaine and medications she was given in the emergency department. Viral hepatitis screen was negative. A sample of the LipoDissolve solution was obtained and GC-MS analysis of the phosphatidylcholine and deoxycholate solution revealed only lidocaine and benzyl alcohol. Bacterial culture of the solution showed no growth. The patient's liver function recovered over days, but renal failure progressed, with creatinine reaching 875.2 µmol/L (9.9 mg/dL) on hospital day five. Hemodialysis was initiated. Arenal biopsy showed acute tubular necrosis. Additional studies included C3 and C4 levels, which were low but considered due to the acute hepatitis; a negative antinuclear antibody (ANA) screen; negative anti-neutrophil cytoplasmic antibody (ANCA); and negative serum protein electrophoresis (SPEP)and urine protein electrophoresis (UPEP). The lipase peaked at 970 U/L. The patient received conservative treatment for acute pancreatitis and the abdominal pain resolved. She was discharged from the hospital after 14 days, dependent on hemodialysis. At that time her AST was 10 U/L and ALT was 67 U/L. She remained dialysis dependent for another six weeks, after which time she had full recovery of renal function.

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Discussion

LipoDissolve, a combination product of phosphatidylcholine and deoxycholate, and other injection lipolysis therapies containing deoxycholate alone, are continuing to be marketed as a fat reduction technique despite FDA warnings that there is no evidence to show that they are safe or effective [1,3,4]. This report highlights a severe complication following this injection therapy.

The first described use of injection lipolysis as a means of reducing unwanted fat was by Rittes in 2001 [5]. She described a technique of injection therapy for reducing infra orbital fat pads. Since this first use, there has been a paucity of prospective placebo-control trials [6] and in 2010 the U.S. Food and Drug Administration issued warning letters to six U.S. medical spas and a Brazilian distribution firm that they were making false and misleading claims about their lipodissolve products [1].

Lipodissolve is also known as lipozap, lipostabil, lipotherapy, mesotherapy, or injection lipolysis. It typically contains phosphatidylcholine and deoxycholate, but may contain deoxycholate alone, and may have other substances, including pentoxifylline, lidocaine, aminophylline, calcitonin, isoproterenol, caffeine, vitamins, minerals, and herbal extracts [1]. Formulations are not currently regulated and the varying concentrations and ingredients may add to the adverse effects.

Phosphatidylcholine is a lecithin-derived phospholipid that was initially thought to induce a cascade of intracellular signals that lead to apoptosis, lyse fat cell membranes, emulsify triglycerides, upregulate lipoprotein lipase, and facilitate movement of triglycerides across cell membranes, however, all of these theories have remained unsubstantiated [7,8]. In fact, in one unpublished experiment in pigs, phosphatidylcholine was shown to cause cholestatic hepatitis and multiorgan dysfunction [9] resulting in the Brazilian Ministry of Health prohibiting its use for cosmetic purposes in 2003 [8].

Deoxycholate is a bile acid that works as a detergent of lipids and cell membranes [8,10,11]. Recent studies have shown that it is deoxycholate alone [12] that results in the reduction of fat cells through toxic necrolysis, due to a direct effect on the fat cells and surrounding tissue [13]. In this unabated manner, deoxycholate causes profound cell wall disruption and cytolytic effects of not only adipose cells but also fibroblast-like preadipocytes, vascular and skeletal muscle cells, and renal epithelial cells. In one study by Janke et al. in 2009, the adipose cells were more resistant to necrosis than the other cell types [10,14].

Our patient developed acute hepatitis and renal failure shortly after receiving her first injection lipolysis treatment. In an article describing a 'standard of practice' for the use of phosphatidylcholine and deoxycholate injections for fat reduction, the authors state that nausea, vomiting, and lightheadedness occur in a dose-related manner with larger injection volumes of phosphatidylcholine. They suggest that dilution of the solution may allow for treatment of a larger surface area. A standard volume per injection is stated to be 0.5 mL, while a treatment session may include hundreds of injections [2]. The total number of injection sites and volume injected per site in our patient is unknown and it is unclear if this might have affected development of symptoms.

The specific cause of organ failure in our patient is unclear. While the solution used in the injections she received was labeled as phosphatidylcholine and deoxycholate, we were unable to confirm the presence of these substances since they are not in our GC-MS library. The temporal proximity of the procedure to development of organ failure strongly suggests a causal association between the two, however. The analysis of the LipoDissolve solution revealed no adulterants. Benzyl alcohol was detected and was likely present in the solution as a preservative. It has not been associated with acute liver failure. While lidocaine was also detected in the product and in the patient's urine, the patient's clinical syndrome was not at all consistent with lidocaine intoxication. It is possible that the patient may have had undocumented hypotension prior to the ED presentation that led to hypo perfusion of liver and kidneys, but this seems unlikely since the patient presented to healthcare with a normal blood pressure.

Another possibility is that the patient experienced a cytokine response as a result of the procedure. Animal models have demonstrated that injection of phosphatidyl choline and deoxycholic acid into adipose tissue increases m-RNA expression of the pro-inflammatory cytokines IL-1β and IL-6, induces inflammatory cell infiltration into injection sites, and leads to tissue necrosis [15]. A human volunteer study also demonstrated increased levels of some pro-inflammatory cytokines after injection of a phosphatidyl choline and deoxycholate solution into lipomas [16]. While a consideration, cytokine storm seems less likely considering the lack of local inflammatory findings on physical exam, normal vital signs, and normal leukocyte count [17].

Despite a history of chronic hypertension and depression, our patient was in a good state of health prior to undergoing the LipoDissolve procedure. She had rapid onset of symptoms immediately following the procedure and development of life-threatening illness. Unless safety of this procedure can be established, health care providers should be strongly discouraged from using injection lipolysis as a means of nonsurgical fat reduction.

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