

Special Topic

Clinical Safety Data and Standards of Practice for Injection Lipolysis: A Retrospective Study

Diane Irvine Duncan, MD; and Roman Chubaty, MD

Dr. Duncan is in private practice in Ft. Collins, CO. Dr. Chubaty is in private practice in Scottsdale, AZ.

There is increasing interest in injection lipolysis as a technique for reducing small, localized fat deposits. While many articles have been published about injection lipolysis, none specifically address safety issues. A clinical safety data survey was sent to physicians practicing injection lipolysis. Seventy-five physicians from 17 countries responded. Data from the treatment of 17,376 patients who underwent a total of 56,320 injection sessions were analyzed. Among the topics reviewed in the survey were indications and contraindications for treatment, best and worst areas for treatment, and additives to the formula and their efficacy. Expected sequelae were differentiated from unexpected complications.

The safety data collected here indicate that, when practiced by licensed and certified physicians, the safety record for injection lipolysis is excellent. There were no deaths or hospitalizations resulting from treatment. There were also no bacterial or atypical mycobacterial infections, no reports of skin loss or ulceration, and no episodes of dermatitis or chronic skin irritation. Among the 17,376 patients treated, 0.0021% experienced transient hyperpigmentation, 0.015% had persistent pain beyond 2 weeks posttreatment, 0.0003% had a late allergic reaction, and 0.00006% had a contour irregularity requiring additional injection treatment. Disappointment at a less-than-expected aesthetic result was expressed by 12.34% of patients. There was consensus among responding physicians on the need for pretreatment patient education regarding realistic expectations.

This survey is a representative, not definitive, survey of treatment results that is intended to serve as a starting point for further development and improvement of injection lipolysis technique. (Aesthetic Surg J 2006;26:575-585.)

There is a rapidly growing global interest in noninvasive aesthetic procedures. Currently, the most reliable technique for spot reduction of subcutaneous fat deposits is lipoplasty, which is effective but requires some recovery time and is not risk-free.

Statistics from the US Centers for Disease Control show that one third of Americans are obese and one third are overweight.¹ Many of the remaining third have localized fat deposits that are resistant to reduction through diet and exercise alone. While surgery could effectively reduce subcutaneous fat in all 3 groups, only a small percentage of people choose to undergo surgical correction. A major factor in the decision to forego surgery is fear; potential patients are afraid of surgery, a prolonged recovery phase, pain, and potential complications. A noninvasive alternative may reduce the recovery period, pain, and risks associated with fat reduction.

The original technique of mesotherapy developed by Pistor² was not specifically for fat reduction. Indications for traditional mesotherapy vary from chronic pain to

scalp rejuvenation. Most frequently, the "nappage" method was used to inject minute quantities of a variety of pharmaceuticals and homeopathic solutions into the dermis or superficial subcutaneous tissue. Because of the extreme variation in formulas injected, and the wide variety of complaints treated, it has been difficult to establish efficacy or safety for this technique.

Since 2002, there has been a surge of interest in using an injectable lipolytic agent to reduce localized subcutaneous fat deposits.³⁻⁹ While the current technique is based on mesotherapy, injection lipolysis is different from the original technique in many ways. The practice of injection lipolysis worldwide uses a fairly standard formula with few additives. The technique is consistent, and the purpose is focused: reduction of small localized areas of excess subcutaneous fat.¹⁰ Current estimates from 2 organizations, Network-Lipolysis and AestheticMD, reveal that more than 2000 physicians are performing injection lipolysis worldwide (personal written communications from D. Brandt, Network Lipolysis CEO, and B. Eastman,

AestheticMD Director). This survey was undertaken as a contribution to efforts by our specialty to investigate the clinical safety and efficacy of injection lipolysis.

The survey was written by the senior author (D.I.D.) and sent to Global Network Dissolve and AestheticMD for distribution. The Network posted the survey on its website with a request that members respond to the author; 34 responses were received. AestheticMD e-mailed the form to 600 members, of whom 41 responded to the author. This representative sample of 75 physician injectors included respondents from 17 countries and most of the published authors on the topic. Respondents had the opportunity to comment on the various issues addressed in the survey as well as to answer specific questions.

The survey is retrospective and is intended to provide data on safety, efficacy, and the current standard of practice of injection lipolysis. It is representative, not definitive, and should be considered as only a starting point from which the injection lipolysis technique can be further understood, developed, and improved.

This summary of efficacy and safety based on current worldwide data includes:

- Investigator experience
- Preinjection evaluation and documentation
- Types of formulas and maximum doses
- Additives to the formula and their efficacy
- Indications and contraindications for treatment
- Best and worst areas to treat
- Expected sequelae and unexpected complications

This article is not intended to be a guide to injection lipolysis for the new practitioner. As with any developing technique, we recommend that each physician obtain training and certification through a reputable organization before initiating this procedure in his or her practice.

Investigator Experience

The range of duration of experience with the injection lipolysis technique among respondents was 1 month to 11 years. The average amount of time each practitioner has been performing this procedure was 17.32 months. Altogether, 17,376 patients were treated with a phosphatidylcholine (PPC)-based compound and 56,320 injection sessions were reported. The average number of treatment sessions per patient was 3.24. The consensus among physicians was that an average of 3 injection sessions is needed in most body areas to obtain optimal improvement. Usually 2 treatments in the face and submental neck achieve good results.

Types of Formulas Used

Many of the physicians used more than 1 type of injectable formula. Eight doctors reported Lipostabil, manufactured by Natterman & Cie (GmbH, Koln, Germany), as a frequently used formula. Two preferred Lipostabil from Essentiale (Aventis Pharma, Antony, France). A compounded formula was the standard for 68 out of 75 reporting physicians (91%), with 7 using the Global Network's preparation. Thirty-five physicians used a PPC-based formula without additives, and 30 used a compounded formula with additives. Thirteen also reported using other formulas, some not PPC-based.

Maximum Safe Dosage

Most of those surveyed reported a maximum safe limit of 2000 to 2500 mg of PPC-based solution per treatment session. At a dilution of 25 mg/mL, 100 mL per session could be safely used. At 50 mg/mL, only 50 mL could be injected per session in order to adhere to the 2500-mg limit. Four physicians reported occasionally using more formula, up to 4000 mg. An increase in postinjection nausea and diarrhea was noted with these higher doses; about 5% of the higher-dose patients experienced these symptoms.

Until further studies are done to establish the safety of higher doses, the consensus of injecting physicians was that a 2500-mg daily limit has proven to be safe.

Additives and Their Efficacy

Forty percent (30/75) of the reporting physicians used additives to their PPC-based formula. Seventeen of those believed strongly that the additives increased the efficacy of the formula. Among the 75 reporting physicians, 26.6% (20/75) felt that additives increased the side effects, particularly light-headedness, without providing additional efficacy, whereas 13.3% (10/75) were uncertain whether the additives made any difference in outcome. Additives reported included L-carnitine, aminophylline, various vasodilators, and lidocaine. Some physicians used a formula that included vitamin E, which is included in Lipostabil. Other multivitamins, hyaluronidase, and collagenase were sometimes used as well. Only one physician reported using multiple additives with a traditional mesotherapy format (small doses of more or more injectable pharmaceutical and homeopathic ingredients, often mixed as a "cocktail").

Indications

All respondents agreed that the primary indication for the use of injection lipolysis is the reduction in size of small localized fat pads. Large areas of lipodystrophy are better

treated with lipoplasty. Soft fat was thought to respond better than firm, fibrous fat. Although documented skin retraction has occurred, especially with superficial injections, none of the physicians indicated that this was a primary focus of treatment, nor did they promise this to their patients. Only 4% of respondents (3/75) reported using this technique to increase smoothness in an area with an irregular surface, including postlipoplasty deformities. Sixteen percent (9/75) reported successful use of the technique to improve cellulite, while 4% (3/75) reported regular injections of lipomas with a phosphatidylcholine-based formula.

Contraindications

The most frequently listed contraindication was pregnancy. No children under age 18 were treated. Breastfeeding patients were instructed to wait until 6 weeks after they ceased lactating before beginning treatment. Most respondents did not perform injection lipolysis on obese patients. This procedure is not meant to be used as a rapid weight loss program. No treatments were performed for the purpose of breast reduction.

An allergy to soy products, or other formula components such as benzyl alcohol, was clearly noted as a contraindication to treatment with these injections. If in doubt, a small "patch test" could be performed 1 week prior to the anticipated treatment.

Most respondents did not treat diabetics, especially in the distal extremities. Microangiopathy and vascular insufficiency were considered contraindications as well. While Lipostabil is licensed in Germany for intravenous use in cases of coronary artery compromise, many physicians avoided treating hypertensive and cardiac patients. Respondents noted that a patient with severe chronic illness should not be injected, especially those who are immunocompromised. Network-Lipolysis recommends not treating any patient with autoimmune disease, with the exception of patients with Hashimoto's thyroiditis and rheumatoid arthritis. While some physicians avoided treating patients with human immunodeficiency virus (HIV), many others achieved good results injecting the "buffalo hump" that frequently occurs with HIV medication.

Most physicians avoided treatment of patients who were taking anticoagulant agents, such as warfarin or clopidogrel. While some avoided treating patients taking nonsteroidal anti-inflammatory drugs, most did not see their use as an absolute contraindication.

Patients on chemotherapy were also contraindicated until their immune system had recovered, as were those receiving prednisone or another steroid regimen. Patients who were acutely ill, or who had a serious ongoing ill-

ness, such as liver or renal failure, were also not considered candidates for treatment with injection lipolysis.

Local skin conditions are often considered a contraindication for treatments with injection lipolysis. An open, nonhealing sore, or infection near the treatment region was a contraindication to treatment. Many respondents did not treat patients with active eczema or psoriasis.

Respondents also considered unrealistic expectations a contraindication to treatment. Many survey physicians reported a less-than-expected outcome as their only complication. Treatment resulted in improvement, not total correction, of the localized lipodystrophy. The reported non-response rate varied from less than 1% to 25%. Patient selection was very important. If patients were noncompliant and underwent only 1 treatment, they were not satisfied with the outcome. Also, those patients who would not adhere to a diet and exercise plan, and saw the injections as a "quick fix," were judged poor candidates for this treatment.

Best Areas for Treatment

The respondents listed 11 areas that generally responded well to injection lipolysis. Opinions varied with respect to 3 regions—the flank, thighs, and knee region—with many listing good results and others indicating that one or another of these regions was the "worst area" to treat.

The best areas to treat are ranked in order of the perceived response to treatment by patients and physicians.

1. Abdomen: Good results were reported by 78.7% of respondents (59/75).
2. Flanks: Good results were reported by 42.7% of physicians (32/75). Several noted that soft fat responds best, and that better results were obtained in female patients than in male patients.
3. Submental chin: Good results were reported by 37.3% (28/75) of respondents when treating this region.
4. Back and "bra rolls": One third of respondents (25/75) felt that this was an optimal treatment area. It is usually small and well localized, and often has soft fat that appears to melt away significantly with 2 to 3 treatments (Figure 1).
5. Outer thigh: Surprisingly, 37% of those surveyed (23/75) reported good results when treating the outer thigh. The area has been considered less than optimal for treatment because fat deposits in this area are frequently fibrous in nature.
6. Inner thigh: This was considered a good region to treat by 21.3% (16/75) of physicians. Many respondents treated the inner thigh area with lipolysis in

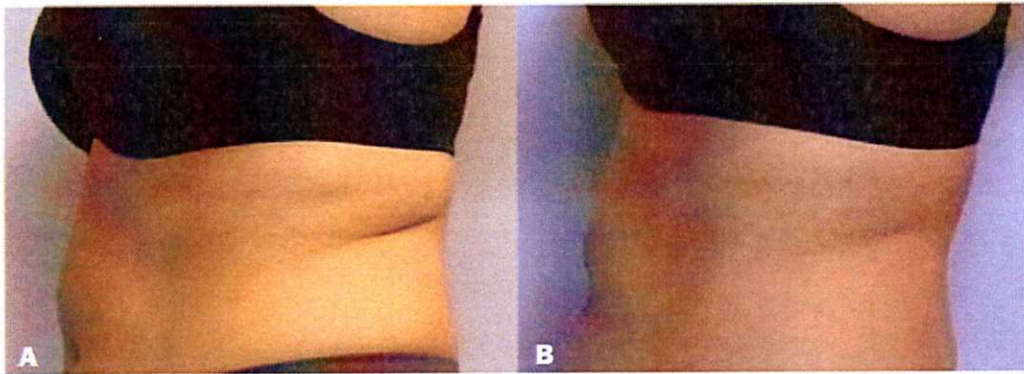


Figure 1. A, Pretreatment view of a 52-year-old woman. B, Posttreatment view 6 weeks after a single injection session to the back roll area.

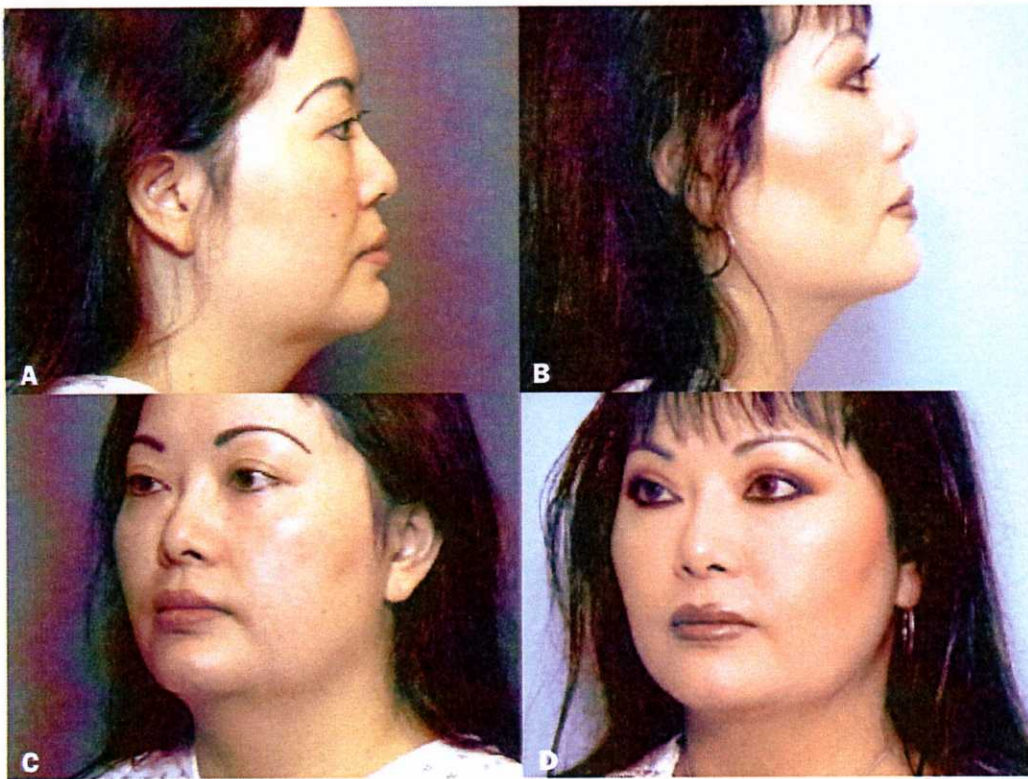


Figure 2. A, C, Pretreatment views of a 38-year-old Asian woman. B, D, Posttreatment views 6 weeks after 2 injection sessions to the jowls, submental chin, and submandibular jawline.

order to avoid skin laxity or contour irregularity that might result from lipoplasty. Although the treatment areas in this region were small, they generally required 3 treatments for optimal results.

7. Jowls: Good fat reduction and skin retraction were obtained by 21.3% (16/75) respondents when injecting the jowl region (Figure 2).
8. Upper arms: Twelve percent (9/75) of physicians reported a good response when treating this area.

The results were variable in the upper arm region, due to the frequent finding of associated skin laxity. The best candidates were younger patients without a large amount of excess skin.

9. Neck; submandibular jawline: Good results were reported by 12% (9/75) of respondents. This is an often overlooked area that responded well to treatment using proper injection technique but that has an advanced learning curve. Superficial injections just under the

mandible enhanced the jaw contour by creating a shadow under the mandible and the mandibular angle.

10. Knees: In this difficult area, 10.7% (8/75) respondents reported excellent treatment results. The results are strongly technique dependent.
11. Gluteal fold: Significant improvement in the "banana roll" region at or immediately below the gluteal fold was reported by 9.3% (7/75) of respondents.

Worst Areas to Treat

The thigh region (both outer thighs and inner thighs) was considered the most difficult area to treat by 30.7% of physicians (23/75). Four factors contributed to the problems in treating this area: skin laxity, textural lumpiness or cellulite, firm fibrotic fat, and the location of the fat deposit over a broad area rather than a thick, localized site. It was harder to define and document improvement on such a broad, slightly rounded surface than in a thick protuberant bulge.

One third of respondents (25/75) disliked using the injection treatment on the knees, for the reasons listed previously. More experienced practitioners found that skillful technique could provide some improvement in skin quality and in fat thickness in this area, where surgery is usually avoided.

Treatment of the lower abdomen was avoided by 14.7% (11/75) of respondents. While most physicians regarded the abdomen as a good treatment region, those who avoided it did so because of the presence of large deposits of pendulous fat, obesity, unrealistic expectations and, in some cases, firm fibrous fat in the epigastrium that was minimally responsive to injection lipolysis.

Twelve percent of respondents (9/75) have tried injecting the upper arm/triceps subcutaneous region, with minimal results. Skin laxity is the main problem in many patients. The subcutaneous fat in this area is not well localized but tends to be broad and flat in distribution. While a definite reduction in circumference was achieved, patient satisfaction with the outcome was less than optimal.

Treatment below the knee is never attempted by 9.3% of respondents (7/75). Their main concern is possible tissue loss due to pre-existing microangiopathy and vascular insufficiency.

The infraorbital fat pad region was listed by 6.7% (5/75) of physicians as an area in which achievement of dramatic results is difficult. Although Dr. Rittes⁶ has demonstrated great skill in treating this area, less experi-

enced physicians reported that the risk is high and the results, marginal.

The chin region and hips were suboptimal targets for injection, according to 4% of respondents (3/75). Patient selection was considered an important factor in determining results, in that stiff, fibrous fat was relatively nonresponsive to treatment. For the same reason, one respondent felt that gynecomastia was not a good indication for injection lipolysis.

Although many reports of successful injection of lower eyelid fat pads have been published in the medical literature, most survey physicians believed that this area was best reserved for those physicians with experience in the injection technique. Additionally, the standard of practice among respondents was to avoid injecting the breasts because of the potential for formation of calcifications and other structural abnormalities that might make the diagnosis of breast cancer more difficult.

Firm flank fat deposits, especially in men, were also noted to be marginally responsive to treatment.

Generally speaking, the consensus on areas to avoid was as follows:

1. Stay away from areas below the knee as there is a high risk of skin loss and/or ulceration.
2. Avoid broad, flat fat deposits.
3. Avoid firm, fibrous fat.
4. Avoid regions with a large amount of skin laxity.
5. Do not treat areas of obesity.

Preinjection Documentation

There was strong agreement among all physicians with respect to the importance of preinjection documentation. Because alterations in body contour resulting from injection lipolysis are very gradual, it was noted that many patients perceived little to no change in a treated region upon completion of the injections. Pretreatment photographs were considered essential for confirming the contour changes. It was recommended that all pretreatment and posttreatment photos should be taken with the patient wearing the same clothing and with the same camera and lighting techniques.

Other measurements that reinforced the treatment value included measuring skinfold thickness in the same area before and after treatment, as well as measuring a circumference in applicable areas. Unfortunately, these measurements are difficult to standardize. Respondents indicated that body mass index (BMI), patient height, and weight should be measured by the physician, not simply reported by the patient. This helped to prevent patients from either claiming that any success was due to

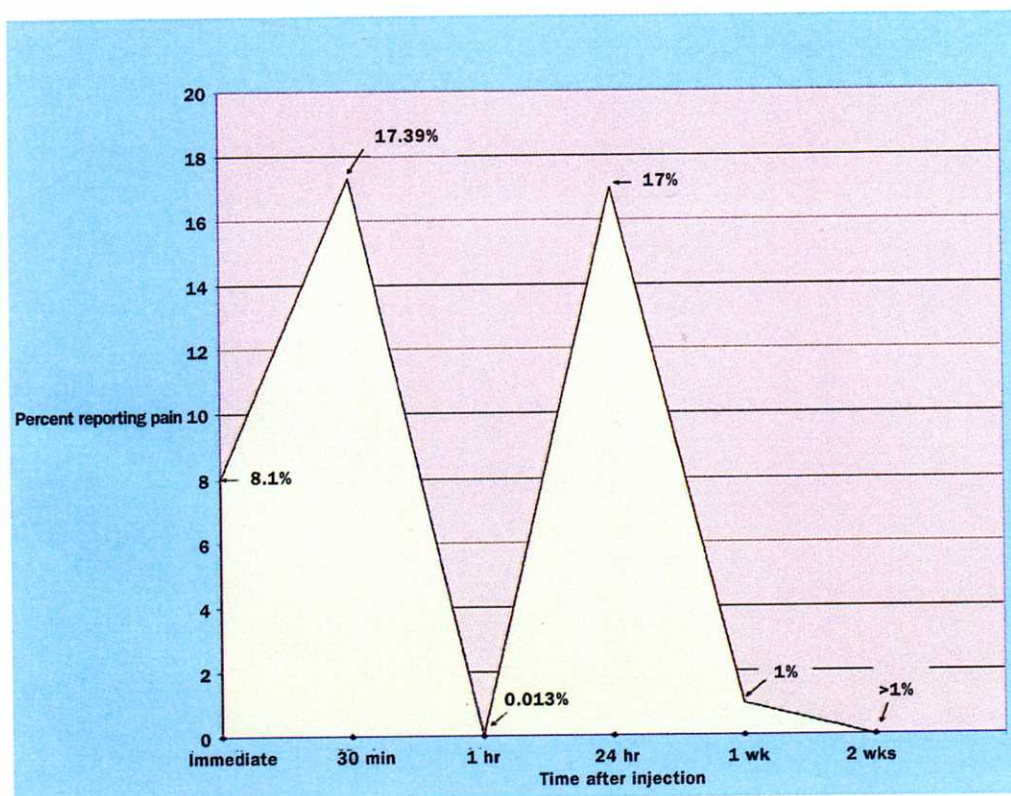


Figure 3. Pain incidence following injection lipolysis.

weight loss when there was none, or that lack of improvement was treatment-related when noncompliance and weight gain were the reasons. Most practitioners avoided treatment of patients with a BMI of 30 or higher, as the diffuse and large amount of subcutaneous fat in these patients does not respond well to phosphatidylcholine-based injections.

Occasionally, body fat percentages, pants or dress sizes, and/or a verbal description by the patient of the deformity's size and effect on daily life were recorded. Norek¹¹ reported success with an ultrasonic measurement of fat thickness before and after treatment. The Vectra system by Canfield (Fairfield, NJ) also holds promise for measuring accurate volumetric change. Neither of these measuring devices is inexpensive, nor are they in standard use in most doctors' offices.

Expected Sequelae

The respondents reviewed the following list of reported sequelae following injection lipolysis and documented their experience (Figure 3). The first area of concern was pain and its management during and after treatment, assessed as follows:

1. Significant pain immediately on injection
2. Significant pain on injection at 30 minutes postinjection
3. Significant pain at 1 hour postinjection
4. Significant pain at 1 day postinjection
5. Significant pain at 1 week postinjection
6. Significant pain at 2 weeks postinjection
7. Significant pain at 1 month postinjection
8. Significant pain at 3 months postinjection

Twenty percent of investigators (15/75) noted that their patients seemed to feel significant pain at some point during the injection process. This number includes any physician who noted that at least one third of the patients complained of discomfort at some point during the injection process. These ratings are very subjective. Minimal pain and discomfort during the injection process, defined as less than 5% of patients complaining of significant discomfort at any time during the process, was noted by 53.3% of respondents (40/75). Only 8% of respondents (6/75) felt that the initial injection process was significantly painful to the patients. While a small group reported using a topical anesthetic such as betacaine or lidocaine on the areas to be treated, most



Figure 4. Posttreatment view one week after a single injection session to the epigastric abdomen. Note localized bruising and swelling.

used the pinch technique or a mesogun to reduce perceived pain.

At 30 minutes postinjection, 17.3% of investigators (13/75) reported a sensation of noticeable discomfort was experienced by their patients. This seemed to be the peak of the uncomfortable period; burning and stinging sensations, accompanied by a sensation of swelling, was reported by less than 5% to 100% of patients. At 1 hour posttreatment, most patients felt that the pain became a "background" sensation; a little soreness and swelling was noted but pain requiring icing or medication was rare. Only 1 investigator felt that significant discomfort was still present in his patients at 1 hour.

On the following day, many patients noted a "gelatinous" feeling in the treated area. The swelling tended to peak between the first and third postinjection day, and many patients reported an improvement in their discomfort after they began using some type of compression garment. Seventeen percent of physicians (13/75) reported complaints about pain among 5% or more of their patients at this point. Most noted that swelling and soreness were also most profound at this time.

At 1 week posttreatment, the swelling and bruising had begun to recede; 0% to 1% of patients noted significant pain at this point. At 2 weeks posttreatment and

continuing until 3 months posttreatment, 0% to 0.5% of the 17,376 patients noted pain as an issue.

Immediate erythema

Erythema was a frequent finding in most patients; 72% of the physicians (54/75) noted episodes of transient erythema occurring from the time of injection to 24 hours postinjection. It was more common at 30 minutes posttreatment than immediately after injection. Few respondents noted redness extending beyond the 1-day mark.

Stinging and burning

Over 90% of respondent physicians (68/75) said that most of their patients experienced some stinging and burning sensations. Onset of the sensation most commonly occurred from immediately to 1 hour after treatment, with the usual peak at 30 minutes postinjection. Twenty percent reported that the sensation sometimes persisted for more than 1 hour postinjection. Ninety-nine percent of patients had no stinging or burning beyond 24 hours postinjection.

Swelling

Postinjection swelling was noted in most patients by 88% of respondents (66/75) (Figure 4). This appears to be a dose-related side effect. The swelling began to appear as early as 30 minutes after the injections, and

peaked at 1 to 3 days. At 1 week, less than 10% of patients reported significant swelling.

Bruising

Only 16% of physicians (12/75) saw no bruising with this treatment; 84% (63/75) reported bruising and noted a peak at 1 week postinjection. Bruising persisted into the second postinjection week in 0% to 7% of cases. Most reporting physicians felt that bruising related to injection lipolysis was less severe and resolved more quickly than bruising associated with lipoplasty.

Nausea

Twenty-four percent of respondents (18/75) noted a less than 10% incidence of postinjection nausea in their patients, usually peaking within the first 24 hours. No patients had nausea lasting longer than 48 hours postinjection. Seventy-six percent of physicians (57/75) reported no patients with postinjection nausea. Those who had patients with this symptom felt that it tended to occur in those patients receiving higher doses (more than 3000 mg) of the compound.

Diarrhea

Fourteen respondents (18.6%) noted that transient diarrhea developed in less than 2% of patients and resolved after 24 hours. Patients reporting diarrhea tended to have larger areas of injection and receive larger doses (more than 3000 mg).

Small hematomas at the injection site

Small hematomas at the injection sites were noted by 56% of respondents (42/75). They were most marked between 1 hour postinjection and 1 week. All resolved with no further treatment. The incidence ranged from 0% to 25%.

Hives at the injection site

Injectors avoided treating patients with a known allergy to soy-based products and an allergy to the preservative benzyl alcohol. Development of transient hives was reported by 18.7% of respondents (14/75). Most occurred within the first 24 hours posttreatment and resolved with time and/or administration of diphenhydramine (Benadryl, Pfizer, New York). Three patients had a late episode thought to be due to an allergy to benzyl alcohol.

Dizziness/light-headedness

Respondents suggested that 3 factors may cause a feeling of dizziness in the first several hours to 1 day

postinjection. Use of a vasodilator as an additive to the injected formula may cause transient orthostatic hypotension. Third spacing of fluid due to swelling may cause relative dehydration. Some patients also noted a vasovagal response to the injections and may have needed extra recovery time after the treatment. Twenty-five physicians (34.6%) noted this symptom in about 5% of their patients.

Educating the Patient

It was suggested that patients be told in detail what to expect during and after the injection process. Most will experience minimal discomfort during the injection process if the injector is skilled. They will also note some redness, stinging, and burning within 15 minutes to 2 hours postinjection. Swelling occurs rapidly, and tends to peak at 1 to 3 days postinjection. A small to moderate amount of bruising is common and tends to resolve, in most cases, by about 7 to 10 days postinjection. By the end of the first week, small subcutaneous nodules may appear; these indicate ongoing fat necrosis. Evidence of mild skin retraction may begin to appear at 10 to 14 days postinjection. By the 4th to 6th postinjection week, most patients will be able to see an improvement in the volume of the localized fat deposit. This improvement may be more evident in a photograph than in the patient's own estimation. Frequently, the patient perceives little to no change, when in fact, a noticeable change is apparent in serial photographs.

Measurement of circumference, skinfold thickness changes, and final photographs are usually performed about 6 to 8 weeks following the final injection session. Because the inflammatory process is not complete at that time, patients should be advised that they may not see the final result for up to a year.

Maintenance of a good diet and exercise program should always be stressed, and patients should be reminded that injection lipolysis is not a substitute for a healthy lifestyle.

Complications

Complications following this treatment were surprisingly rare. Among of the 17,376 patients treated, there were no deaths. No patients were reported to need hospitalization for any sequelae. The most frequently reported complication was less-than-expected aesthetic improvement. Parameters examined included: hyperpigmentation, late itching, and hives, persistent pain beyond 2 weeks, little to no response to treatment, bacterial infection, atypical mycobacterial

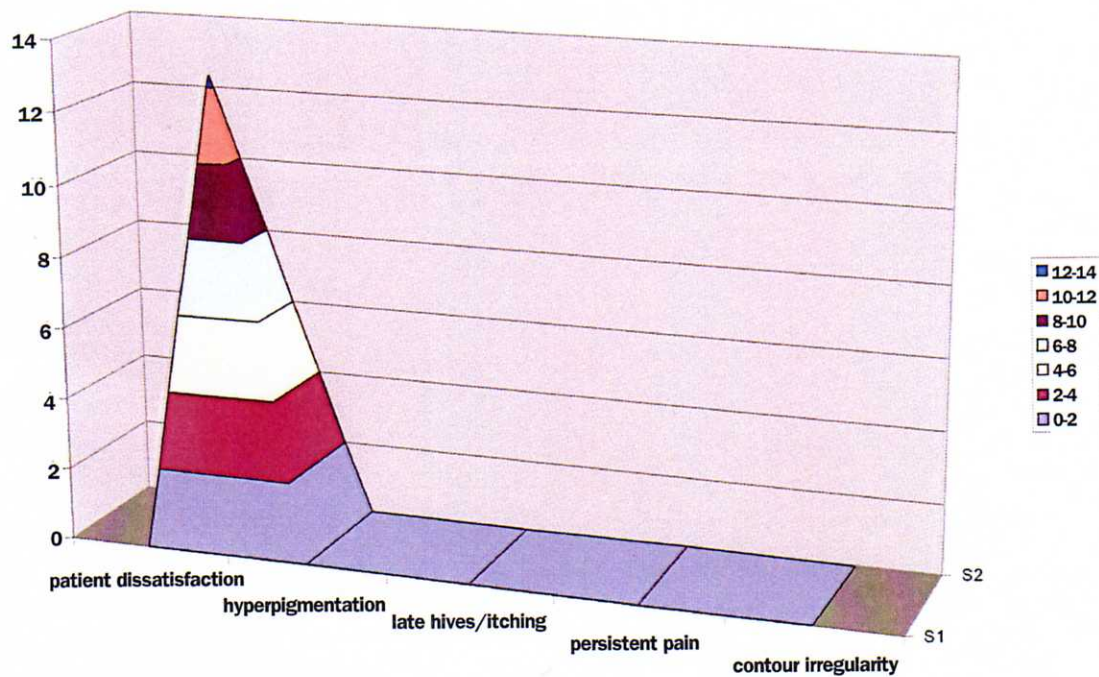


Figure 5. Complications following injection lipolysis.

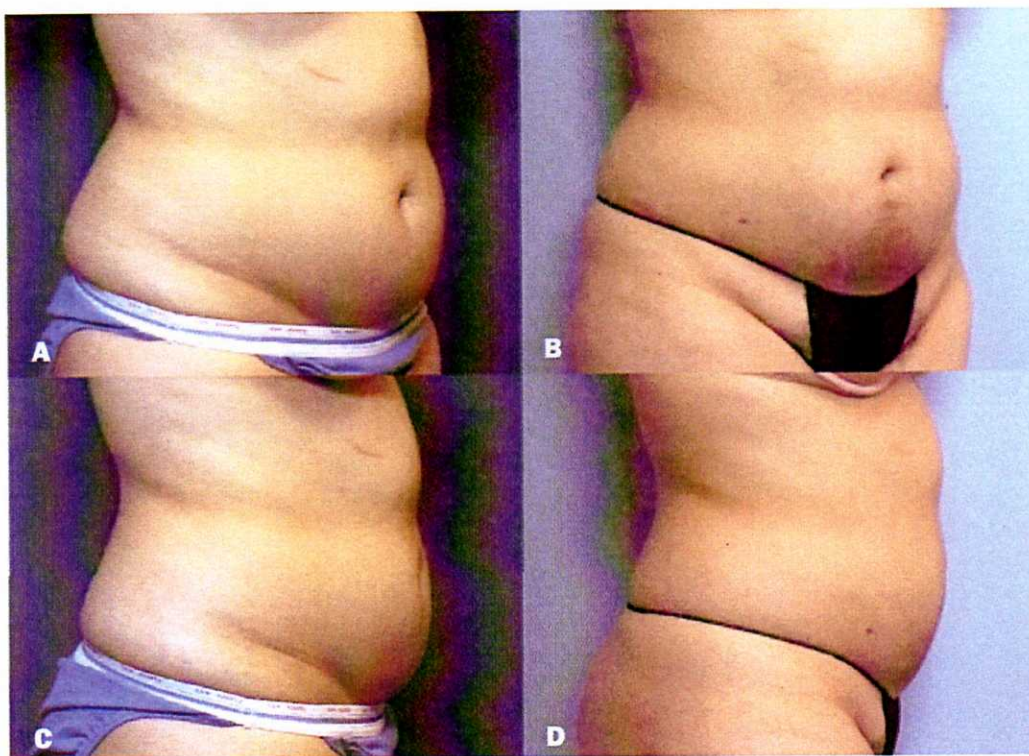


Figure 6. A, C, Pretreatment views of a 38-year-old woman. B, D, Posttreatment views 6 weeks after 3 abdominal injection sessions. Note the triangular distribution of hyperpigmentation. Clinical correction of abdominal protuberance and skin overhang is excellent.

infection, chronic skin irritation or dermatitis, skin necrosis in the treated areas, an open or nonhealing wound, and a permanent skin contour deformity requiring treatment (Figure 5).

Hyperpigmentation

A low incidence of transient hyperpigmentation was reported by 18.7% of physicians (14/75). Only 37 of 17,376 patients (incidence, 0.0021%) were reported to have this problem (Figure 6). The discoloration resolved within 3 months in most cases. Hyperpigmentation secondary to injection lipolysis is thought to be caused by hemosiderin deposition under the skin, and is not a melanocytic event. Those noting this problem felt that it occurred most often in dark-skinned patients.

Late hives/itching

Among all patients treated, only 6 reported the development of late hives or itching. The incidence of an apparent delayed hypersensitivity reaction was 0.0003%. An allergic reaction to the benzyl alcohol preservative was thought to be the primary cause. All cases resolved with antihistamine treatment and time.

Persistent pain beyond 2 weeks

Occasional cases of persistent pain beyond 2 weeks posttreatment were reported by 4% of respondents (5/75). The incidence reported was 0.015%. Seventy physicians (96%) reported no persistent pain in any of their patients after the initial 2-week posttreatment phase.

Those reporting noted that an increase in the percentage of sodium deoxycholate, or use of deoxycholate without PPC, tended to be associated with these reports. Treatment of large areas also increased the incidence of persistent pain.

Little to no response

A less-than-expected response to treatment among some patients was noted by 77.2% of respondents (58/75). Only 22.8% of physicians (17/75) felt that all of their patients were satisfied. The incidence of dissatisfaction with outcome varied widely. Of the 33 practitioners reporting a percentage, 9 reported that their low-response rate was less than 5%, 10 felt that 10% to 20% of patients were dissatisfied, and 6 stated that more than 20% of their patients were unhappy with their results. Most of these physicians felt that unrealistic expectations on the part of the patient were the major factor in these responses. Poor patient

selection and a low dose injected in a large area were also noted as factors. Several respondents recommended using a larger dose in a smaller area as a possible remedy, as results are noted to be dose-related.

Several doctors described an incidence of true nonresponders as less than 1%. These were patients who clearly did not seem to have any improvement in either the patient's or physician's view, despite what both felt was adequate treatment. Factors associated with no response include obesity, severe hypothyroidism, and areas of firm, fibrous fat.

Data collated from those physicians reporting both patient numbers and the incidence of less than expected aesthetic results showed that the average incidence of patient dissatisfaction with treatment was 12.34%.

Infection

No patients were reported to have developed a bacterial infection in the treated area following injection. All certified practitioners followed a preinjection preparation protocol, using an antibacterial solution such as Hibiclens (Regent Medical, Norcross, GA) or Betadine (Purdue Pharma, Stamford, CT) prior to treatment.

Atypical mycobacteria

Despite isolated reports of atypical mycobacterial infection occurring in South America and Washington, DC, following mesotherapy injections, no patients in this survey population developed an atypical mycobacterial infection.

Chronic skin irritation, dermatitis

No patients developed a chronic skin irritation in the area of treatment.

Skin necrosis in the treated area

No patients developed skin necrosis in the treated areas.

Open nonhealing wound in treated area

No patients developed an ulcerated or nonhealing wound in a treated area. Most respondents did not treat areas distal to the knee in an effort to avoid this problem.

Permanent skin contour irregularity requiring treatment

One patient developed a skin contour deformity that required further treatment following injection lipolysis. The irregularity was successfully treated with another injection series.

Conclusion

Seventy-five physicians with varying ranges of experience responded to the Clinical Safety Data Survey. They performed injection lipolysis for 17,376 patients that included 56,320 injection sessions.

The single best indication for the procedure is a request for treating a small area of localized fat. Contraindications include pregnancy, lactation, age less than 18, severe acute or chronic illness, immunocompromised status, anticoagulant therapy or chemotherapy, obesity, and unrealistic expectations. The area distal to the knee is not recommended for treatment. An allergy to soy products and/or the benzyl alcohol preservative is a contraindication to injection lipolysis with the phosphatidylcholine-based solution. These injections should not be performed for breast reduction in women. Noncompliant patients are not treated. Those patients with vascular insufficiency are best treated with other modalities. The 3 best areas to treat, in the opinion of those surveyed, are the abdomen, flanks and submental chin. The least responsive areas are felt to be the inner and outer thighs and knees.

Expected sequelae are those events that occur commonly during and after the injection process. These are transient and do not affect the final outcome. Patients undergoing injection lipolysis may experience sequelae that include pain during or shortly after the injections, immediate erythema, some stinging and burning, swelling, and bruising. Most of these symptoms improve or resolve after 1 week. A small number of patients may experience transient nausea or diarrhea, especially with larger treatment areas and higher doses of the solution. Few report small hematomas at the injection site, dizziness or light-headedness, or hives at the injection site.

Complications resulting from this treatment are rare. No patients died or were hospitalized following injection lipolysis. No patients developed skin irritation or necrosis at the injection site. There were no bacterial or atypical mycobacterial infections. No open, ulcerated sores developed in the areas of treatment.

Complications that did occur included hyperpigmentation (incidence, 0.0021%); late development of hives 2 weeks or later after injection (incidence, 0.0003%); persistent pain beyond 2 weeks postinjection (incidence, 0.015%); and less than expected aesthetic result (incidence, 12.34%).

All but one survey physician reported that they would continue to use the treatment on a regular basis for treatment of small, localized adipose deposits.

The degree of improvement was reported to be dose-related. The maximum degree of improvement in an area using a full dose (2000-2500 mg) of PPC-based solution was reported to be a 1-cm thickness reduction. In small areas and thinner patients, this would be a significant change. However, in an obese patient, there may be no perceived difference. Practitioners are cautioned to educate the prospective patient about their expectations and the possibility that they may not be achieved in all cases. ■

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Reprint requests: Diane Irvine Duncan, MD, 1701 E. Prospect Road, Ft. Collins, CO, 80525-1307.

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