The Cosmetic Use of Phosphatidylcholine in the Treatment of Localized Fat Deposits

Paul Myers, MBBS, FRCGP

There is little published research on the use of phosphatidylcholine injections for reduction of localized fat deposits, though the use of this modality in Europe has increased substantially in the past 3 years. This article reports on the treatment of 100 patients with localized fat deposits presenting to a cosmetic practice in the United Kingdom. The author's clinical experience using phosphatidylcholine injections (250 mg/mL) to treat subcutaneous fat deposits is described, as are the clinical effectiveness and side-effect profile. Patients received 1 to 3 subcutaneous phosphatidylcholine injections in various areas of localized fat deposits. Outcome measures included patient assessment of improvement, percentage reduction in skin thickness, and physicians' global improvement rating. Phosphatidylcholine was found to be effective in reducing subcutaneous fat in the treatment sites by a mean of 22.8% and produced few side effects. Regression analysis of the effectiveness of phosphatidylcholine against variables such as age, sex, treatment site, and body mass index showed little difference between the patient groups, indicating that this treatment approach may be used effectively for a wide patient demographic. Clinical experience with off-label use of phosphatidylcholine for small areas of localized fat deposits suggests that this treatment is relatively safe, inexpensive, and effective.

Phosphatidylcholine, originally known as *lecithin,* is among the most abundant phospholipids in animals and plants and is the key building block of cell membranes. In particular, it largely comprises the outer leaflet of the plasma membrane. Phosphatidylcholine is also the principal phospholipid circulating in plasma, where it is an integral component of the lipoproteins, especially the high-density–lipoprotein fraction. This phospholipid actively participates in the structure and transport between the cells, can alter cholesterol and triglyceride metabolism (increasing cholesterol solubility), alters the composition of fat deposits, and inhibits plaque aggregation. Phosphatidylcholine, extracted from soybean lecithin, has been indicated for the intravenous treatment of atheroma, hypercholesterolemia, fat embolism, and lipid deposits on or plaque adherence to arterial walls.

The biochemical activity of clinical subcutaneous phosphatidylcholine injections is unknown. The drug is assumed to penetrate the adipocyte through the double lipid layer, acting as an emulsifying/tensoactive agent.[1] The biochemical characteristics of the stored lipids would therefore be altered, making them water soluble and thus permitting their elimination due to incompatibility with the liposoluble material stored in the adipocytes.

Dr. Myers is a Cosmetic Dermatologist in private practice, London, England.

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However, at this time, there are insufficient published data to confirm this theory. Rotunda et al[2] postulate that the phosphatidylcholine formula for fat dissolution works primarily as a detergent, causing nonspecific lysis of cell membranes. In vitro studies suggest that sodium deoxycholate is the major active component responsible for cell lysis.

The earliest reports on the clinical use of phosphatidylcholine, from the 1980s, focused on its ability to reduce blood cholesterol, as well as high and low lipoprotein levels.[3] Cosmetic use of phosphatidylcholine was first described by Maggiori[4] who studied its use in the treatment of xanthelasmata. In Brazil, off-label cosmetic use of phosphatidylcholine began in the late 1990s. Rittes[5] subsequently reported on its use for reducing infraorbital fat pads, and Hexsel[6] described its use for other areas.

Although the injectable form of phosphatidylcholine has not been approved in the United Kingdom for cosmetic indications, other countries have reported its efficacy in treating localized fat. In Brazil, as well as in Europe, phosphatidylcholine injections have been widely used for clinical conditions characterized by fat deposits in subcutaneous tissue.[7] Phosphatidylcholine appears to be effective for treating such conditions and represents a new, minimally invasive, and potentially promising treatment, particularly for the abdomen, thighs, hips, flanks, and lower third of the face.

The relative lack of research and published data on the cosmetic use of phosphatidylcholine has contributed to its off-label use in the United Kingdom and elsewhere. This article reports on the clinical effectiveness of phosphatidylcholine injections used off-label to reduce subcutaneous fat in 100 patients in the United Kingdom.

METHODS

From November 2004 through April 2005, 100 patients presenting to a cosmetic practice in the United Kingdom were enrolled in this study. Exclusion criteria were as follows: pregnancy and lactation, allergy to soy products, active kidney or hepatic disease, diabetes mellitus or thyroid disease, immunosuppression, skin flaccidity, previous surgery in the treatment sites, and unrealistic expectations of treatment. Eighty-nine patients completed the study—5 patients withdrew, and 6 patients were lost to follow-up after one treatment.

Patients with varied patterns of localized fat deposits on the body (eg, thighs, hips, abdomen, flanks) and/or face were treated with phosphatidylcholine. The drug was administered according to the Lipodissolve protocol[7] in 1 to 3 treatment sessions with a 28-day interval between each session. Undiluted phosphatidylcholine 250 mg/mL was injected into the subcutaneous tissue using a 30-G needle and 2-mL syringe for the lower face and a 10-mL syringe for all other areas. Injection depth was 1 cm below the cutaneous surface, injection amount was 0.4 mL, and injection points were spaced 1 to 2 cm apart. The total volume of injected phosphatidylcholine varied by treatment site and quantity of localized fat deposits in each patient; however, all patients received up to 10 vials (50 mL) at each treatment session. Treatment sites were photographed at each session. The thickness of the fatty pad was measured in millimeters using a skin thickness caliper. Weight and height measurements were used to calculate pretreatment body mass index. Following treatment, patients were issued an advice leaflet containing key points including instructions regarding side effects, massage of the affected area with aloe vera gel, and use of analgesics and nonsteroidal anti-inflammatory drugs. Follow-up visits were at 30, 60, 90, and 120 days after initial assessment and treatment. Skin thickness caliper measurements were repeated and side effects recorded at each visit.

Posttreatment assessment scores were determined by averaging 3 caliper measurements of skin thickness in the affected area, calculating the percentage reduction, and comparing these figures with the average posttreatment figures, which were determined by the same method. In addition, physicians and patients assessed overall improvement using a 10-point scale (0=no improvement; 10=marked improvement) based on pretreatment and posttreatment photographs. The variables studied are summarized in Table 1.

RESULTS

Treatment sites are shown in Figure 1, and treatment results are summarized in Table 2. Mean number of

TABLE 1

Variables Studied

- Age
- Sex
- Weight
- Height
- Calculated body mass index
- No. of treatments
- Treatment site
- Patient global improvement
- Physician global improvement
- Side-effect profile
- Skin thickness (pre- and posttreatment)

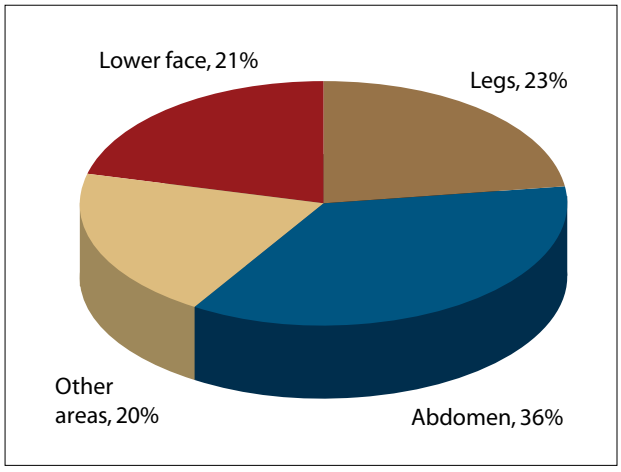

Figure 1. Body areas treated with phosphatidylcholine injections for localized fat deposits.

treatments per patient was 1.98 (range, 1–3). Data on posttreatment skin thickness indicate that treatment produced good results, with a mean skin thickness reduction of 22.8%. Pretreatment skin thickness measurements ranged from 10 to 49 mm, and posttreatment measurements ranged from 7 to 35 mm. Treatment produced good results, as evidenced by patient and physician improvement scores (mean improvement: 7.3 and 7.5, respectively). Photographs taken before and after treatment demonstrate results in a range of treatment sites (Figures 2–4).

Skin thickness reduction as well as patient and physician improvement scores were used in a regression analysis to identify criteria correlating to a successful outcome. This regression analysis produced data of regression squared and adjusted regression using the variables listed in Table 1. This analysis was used for determining the correlation, if any, between patient criteria and clinical efficacy; for example, a particular treatment site such as the lower face or a patient demographic such as sex might be associated with better results. The low figures showed no proven correlation between the stated criteria and the efficacy parameters, suggesting that treatment is equally effective for a range of patients.

The side-effect profile was examined in detail. In the first 48 hours postinjection, 85% of patients (76/89) developed edema, erythema, itching, and localized heat in the treated area. These reactions were widely accepted as short-term side effects. Discomfort was slight and resolved with administration of mild analgesics such as acetaminophen. Anti-inflammatory agents were prescribed for less than 5% of patients in the first 48 hours postinjection to treat more marked inflammatory changes. Localized bruising in the affected area was present in approximately 30% of patients; postbruising pigmentation was noted in one patient for 4 months posttreatment.

COMMENT

Localized fat deposits are currently a major cosmetic concern for many patients, particularly women. This concern leads many patients to surgical procedures such as liposuction, with its attendant risks of infection and scarring, as well as complications from general anesthesia. Patients and physicians who seek less invasive methods of localized fat reduction may now consider phosphatidylcholine to reduce relatively small amounts of fat. This treatment has emerged as a relatively safe and effective alternative to surgical procedures for reducing small localized fat deposits on the face and body. In this study, the side effects observed after phosphatidylcholine injections in the adipose tissue were transitory, and no severe systemic or permanent complications were observed. Side effects usually appeared within 24 hours posttreatment and resolved within 3 to 4 days. Appropriate pretreatment counseling was essential in reducing patient anxiety resulting from short-term side effects. Based on published and

TABLE 2

Reduction of Localized Fat Deposits With Phosphatidylcholine Injections (N=89)*

Patient Demographics	
Gender	
Male, no.	9
Female, no.	80
Age, y	46.8 (10.6)†
Body mass index, %	23.8 (2.9)†
Results	
Skin thickness reduction, %	22.8 (1.1)†
Patient global improvement score	7.3 (1.2)†
Physician global improvement score	7.5 (0.9)†

*Data are given as mean (SD) except where noted. Patients received 1–3 treatments (mean, 1.98). Physicians and patients rated global improvement based on the following scale: 0=no improvement; 10=marked improvement.

†Age range, 24–66 years; body mass index, 19.6%–30.5%; pretreatment skin thickness, 10–49 mm; posttreatment skin thickness, 7–35 mm; patient global improvement scores, 5–10; physician global improvement scores, 6–10.

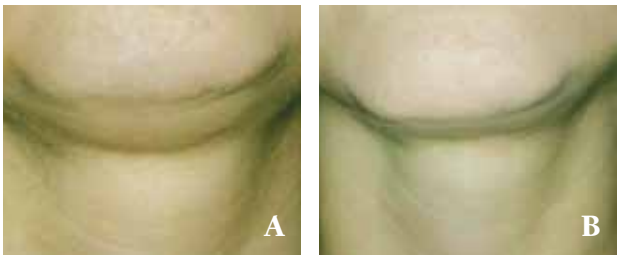

Figure 2. Chin area with localized fat deposits before (A) and after (B) 3 phosphatidylcholine injections.

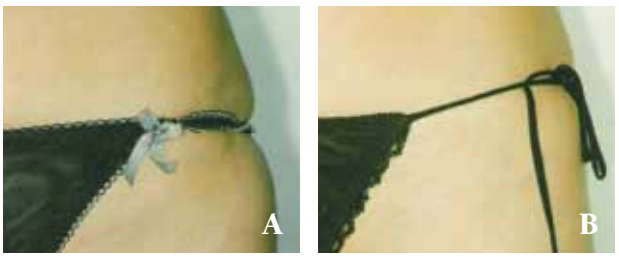

Figure 4. Hip area with localized fat deposits before (A) and after (B) 3 phosphatidylcholine injections.

anecdotal reports, possible side effects of phosphatidylcholine injections include infections, allergic reactions, tissue necrosis, and body surface irregularities (ie, nodules and depressions). None of these side effects were observed in this study, and other well-recognized side effects caused patients minor inconvenience only. Ten or fewer vials (50 mL total) were used at each treatment session for a total of 1 to 3 sessions at 28-day intervals. These parameters were established to avoid adverse systemic effects from excessive doses or short intervals between injections and were consistent with the treatment regimens described elsewhere.[7]

The use of phosphatidylcholine for the treatment of lower eyelid fat pads in a small number of patients has been reported.[8,9] Although there are published reports on the use of phosphatidylcholine for fatty deposits in other areas, no reference is made in these reports to efficacy assessment. This study assessed efficacy using both objective and subjective measures. To my knowledge, this study is the first to publish data examining the efficacy of lipolysis treatment with subcutaneous phosphatidylcholine injections. A mean reduction in skin thickness of 22.8% was observed in the treatment sites. This reduction is consistent with the high levels of satisfaction reported by both patients and physicians.

Although the precise mode of action of phosphatidylcholine has not yet been elucidated, deoxycholate, which is commonly added to phosphatidylcholine, is thought to act as a solvent. Most published studies on the use of injectable phosphatidylcholine in vivo involve agents containing deoxycholate, in some cases of a concentration of up to 4.2%. The deoxycholate acts as a detergent, emulsifying fat to nanosize particles. In the absence of phosphatidylcholine, the enzyme cascade that metabolizes fat into the required monoglyceride for later excretion would not function—hence the need for the active ingredient phosphatidylcholine, which is required for excretion of the broken-down fat. In this study, the phosphatidylcholine used contained 2.5% sodium deoxycholate—the most widely used formulation in Europe.

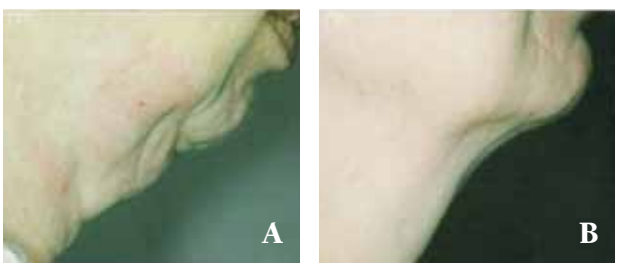

Figure 3. Jowl area with localized fat deposits before (A) and after (B) 3 phosphatidylcholine injections.

Despite the encouraging efficacy and side-effect profile reported in this study, studies involving a larger number of patients are needed to ensure the safety of phosphatidylcholine injected subcutaneously. This was a relatively small study, and even though numerous phosphatidylcholine injections have been administered worldwide without complications, studies incorporating larger patient populations are needed. Because phosphatidylcholine is not approved for subcutaneous injection in the United Kingdom, its use in this study is considered off-label. This is similar to the clinical use of drugs such as botulinum toxin type A, which has been used (but not approved) for cosmetic purposes since 1990. In the United States, the off-label use of botulinum toxin type A has allowed physicians to study its benefits in wrinkle treatment for more than a decade before its approval for cosmetic use by the US Food and Drug Administration in 2002. In the United Kingdom, it is hoped that if the preliminary findings described in this article are duplicated in larger studies, approval of subcutaneous phosphatidylcholine injections for the treatment of localized fat deposits will follow in due course.

CONCLUSION

Subcutaneous injection of phosphatidylcholine has been shown to be a relatively safe and effective treatment for reducing localized fat deposits in various areas of the body and may serve as an alternative to liposuction for certain specific indications. To ensure safety and positive results, lipolysis by subcutaneous injection of

phosphatidylcholine should be undertaken by medical professionals only. As with any new indication, additional long-term studies are needed to standardize safe application techniques and recommended doses. However, phosphatidylcholine injections appear to be a relatively safe, inexpensive, and effective treatment alternative to surgical procedures for fat reduction.

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