

Clinical experience and safety using phosphatidylcholine injections for the localized reduction of subcutaneous fat: a multicentre, retrospective UK study

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Summary

Background Phosphatidylcholine has been in safe use for over 30 years. Subcutaneous injections of phosphatidylcholine have now become used internationally for localized subcutaneous fat reduction on the face and body, but concerns about the safety of this treatment have arisen.

Aims To assess retrospectively treatment outcomes and adverse effects associated with subcutaneous phosphatidylcholine use.

Patients and methods Thirty-nine UK doctors specifically trained and experienced in this treatment completed questionnaires, focusing on outcome and adverse effects experienced by patients.

Results Ten thousand five hundred and eighty-one treatments had been administered over a mean duration of 13.1 months. Localized adverse effects (swelling, erythema, burning/stinging, pain, tenderness and bruising) were described by most patients as "very mild" (18.4%) or "mild" (39.2%). The total incidence of systemic side-effects was 3%: diarrhoea, nausea, dizziness/light-headedness and intermenstrual bleeding were described by most patients as "very mild" (36%) or "mild" (55%). Only 15 (0.14%) "unexpected, unusually severe or prolonged" adverse reactions (commonly pain and/or swelling) were reported. These were all self-limiting and none were judged as serious. 73.8% of patients were either "very satisfied" or "satisfied" with treatment.

Conclusions This treatment appears to be associated with minimal risks when used by specifically trained and experienced doctors. The possible risks associated with this treatment should be balanced against the risks of other treatment options.

Keywords: adverse effects, phosphatidylcholine, subcutaneous fat

Introduction

Phosphatidylcholine has been in use safely for over 30 years for prevention and treatment of fat embolism.

There is no evidence of toxicity or teratogenicity and it is well-tolerated at high daily doses. It has been safely and effectively used at high doses intravenously for the treatment of severe liver failure and surfactant preparations containing 70–80% phosphatidylcholine are administered endotracheally to treat premature neonates suffering from respiratory distress syndrome.^{1–9}

Phosphatidylcholine preparations have become used internationally for localized reduction of subcutaneous

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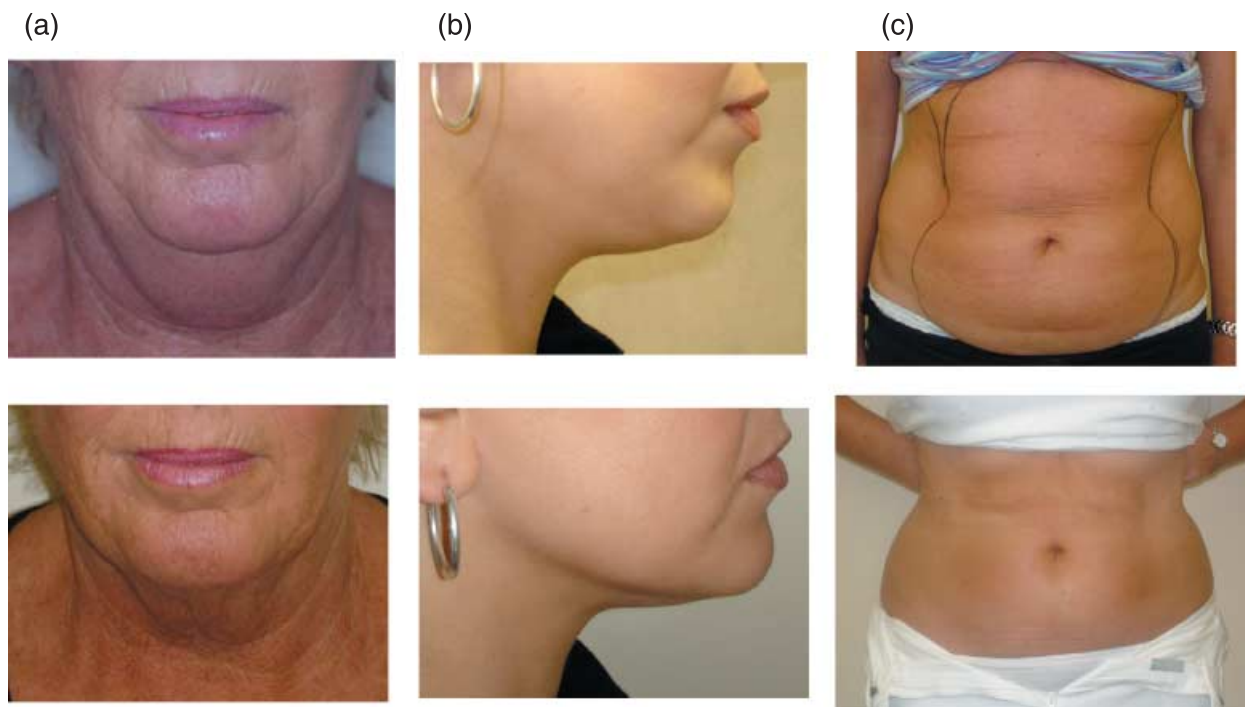


Figure 1 (Photos by Dr M A Palmer) (a) One treatment session, results after 8 weeks, no weight loss. (b) One treatment session, results after 8 weeks, no weight loss. (c) Three treatment sessions at 8 weekly intervals, no significant weight loss, results after 24 weeks.

fat by subcutaneous injection.^{10–22} Promising results have been demonstrated, in some cases avoiding the patient undergoing cosmetic surgery (Fig. 1).

Recent studies and publications have investigated the histological effects of this method of treatment and have discussed in detail the likely physiological and biochemical cellular mechanisms and processes involved.^{11,14,23}

However, this method of treatment has been criticised in the UK, partly due to a lack of any published collective UK data regarding safety, partly due to widespread lack of awareness of the collective published research and data to date, and partly due to the manufacturer of the major brand of phosphatidylcholine injection, Lipostabil (Nattermann, Germany), including a warning on the data sheet stating that this product should not be injected subcutaneously. Furthermore, criticism has arisen because of unfounded lay press speculation of the drug's adverse effects on lipid profiles (phosphatidylcholine improves lipid profiles^{24,25}), as well as an ill-informed tendency towards generalized discrimination against cosmetic treatments in the UK which are sometimes viewed as unnecessary.

Thousands of treatments have been administered in the UK by specifically trained and experienced doctors¹⁰ in the use of phosphatidylcholine for subcutaneous fat

reduction (maximum dose: 2.5 g every 8 weeks,¹⁰). In most cases, the treating doctor individually assessed and examined each patient several weeks post-treatment, resulting in the doctor being fully informed of treatment outcomes and of the incidence and nature of any emergent adverse effects. The preparations used contain 250 mg phosphatidylcholine per 5 mL and comprise 70% phosphatidylcholine, 4.2% deoxycholate as a solubilising agent and 3% benzyl alcohol as a preservative.¹⁴

In this study, we aimed to collect and collate the outcome data from UK doctors known to us to be using this form of treatment. In particular, we collected information on any adverse effects experienced by patients, especially focusing on any reported unexpected, severe, prolonged or serious adverse reactions.

Scientific rationale and mechanism of action

Although phosphatidylcholine is the main ingredient in most injectable preparations, in common with other injectable pharmaceuticals, it must be mixed with sodium deoxycholate (a bile salt) to make it soluble enough for injection. Most injectable formulations contain between 4.2% and 4.7% sodium deoxycholate. A small amount of benzyl alcohol is also added as a preservative.¹¹

Recent studies have demonstrated that deoxycholate alone causes significant cell lysis on cultured human keratinocytes as well as in porcine fat *in vitro*. Furthermore, necrosis of fat and muscle has been histologically observed after tissue incubation with a phosphatidylcholine/deoxycholate formulation and with deoxycholate alone. It has been concluded that the detergent effects of the bile salt alone cause nonspecific cell lysis.²⁶ Similar to injecting botulinum toxin, fillers, and sclerosing agents, careful and correct placement of these substances is therefore very important.

Although some have recently argued that the bile salt alone is primarily responsible for fat cell destruction²⁷ others argue that deoxycholate is responsible for localized inflammatory effects and nonspecific cell lysis, hence the concentration of deoxycholate used must not be too high, nor should it be used alone. Their hypothesis is that phosphatidylcholine is essential for efficacy and that a synergistic sequence of bioactive events occurs following treatment.^{11,12 23,28} They hypothesize this sequence of events may be as follows:

The solution containing the phosphatidylcholine, sodium deoxycholate and benzyl alcohol initially causes some cell membrane disruption. However, once injected into the subcutaneous layer the phosphatidylcholine is then responsible for a chain of reactions over an 8–10-week period. Mathur *et al.*²⁹ describes a critical concentration of 250 mmol phosphatidylcholine that is necessary to destabilize the adipocyte cell membrane. Peckitt²⁸ also demonstrates the destabilization of the adipocyte cell membrane following injection of a critical concentration of phosphatidylcholine. This change in the physical properties of the cell membrane then appears to cause a complex enzymatic cascade involving the release of lipases and other enzymes as well as a rapid apoptotic cascade that causes adipocyte cell death. If the critical concentration is not reached, the unstable cell membrane forms gaps or pores, allowing efflux of some of the cytoplasmic contents. This mechanism may account for the reduction in viable fat cell diameter present in human histological sections post-treatment.¹¹

Materials and methods

A total of 172 UK doctors thought to be using phosphatidylcholine injections for the reduction of subcutaneous fat were identified from a database held by the British Association of Cosmetic Doctors. All doctors were contacted by e-mail and provided with a questionnaire (Table 1) asking if they had used this method of treatment. Those doctors who replied and confirmed that they had used phosphatidylcholine injections for subcutaneous

fat reduction were then asked to complete the full questionnaire, which included detailing any adverse reactions experienced by patients.

In order to try to avoid under-reporting bias, it was made clear that all the results of the survey would be pooled and collated, with the doctors' details kept completely confidential, other than for administrative purposes.

Results

Of 172 UK doctors contacted, 50 responded, with 39 confirming they had used phosphatidylcholine injections in their practice for subcutaneous fat reduction. These 39 doctors then went on to complete the full survey questionnaire.

Results showed that this treatment had been used for between 3 and 34 months, with a mean duration of 13.1 months (Fig. 2). Of the total 10 581 treatments performed, 96.2% of patients had been routinely assessed and examined by the treating doctor at a mean interval of 6.7 weeks post-treatment (see Fig. 3).

Overall, the doctors reported that 17.9% of their patients would have been prepared to undergo surgery for their condition if phosphatidylcholine injections had been unavailable.

Patient satisfaction with treatment was found to be high, with 41.6% of patients reporting to their doctors that they were "very satisfied" with the results of treatment. 31.5% of patients were reported to be "satisfied", 16.1% "fairly satisfied" and only 10.5% "dissatisfied" with the treatment.

Localized adverse effects of treatment comprised swelling (mean duration: 4.1 days), erythema (mean duration: 1.4 days), burning/stinging (mean duration: 0.9 days), pain (mean duration 1.8 days), tenderness (mean duration: 6.7 days) and bruising (mean duration: 6.3 days). Most patients reported these reactions as either "very mild" (18.4%) or "mild" (39.2%) in intensity, while 37.6% reported their reactions as "moderate", with only 5.0% of patients reporting intensity as "severe".

Infrequent systemic adverse effects included diarrhoea (1.5%), nausea (0.7%), dizziness/light-headedness (0.7%) and intermenstrual bleeding (0.1%). The majority of patients experiencing these adverse reactions reported them to be either "very mild" (36%) or "mild" (55%) to their doctors. Eight percent of patients affected reported severity to be "moderate" and 1% affected reported severity to be "severe".

Doctors were asked to provide details of any adverse reaction which they considered to be "unexpected, unusually severe or prolonged" affecting any treated patient.

Table 1 Copy of questionnaire sent to doctors.

1. Have you used phosphatidylcholine injections for the reduction of subcutaneous fat?

YES ☐

NO ☐

If NO do not answer the remaining questions but please *return* the form by Fax: to enable us to complete our records.

2. When did you start using this treatment?

3. How many treatments have you performed in total?

4. What percentage of your patients do you routinely review? After how many weeks do you review them?

5. What percentage of your patients are fully informed and consented with regard to the known and potential for unknown risks of this procedure, the alternative options to this treatment and the fact that phosphatidylcholine is not licensed in the UK, nor by its manufacturer for subcutaneous use?

6. What percentage of your patients would have otherwise undergone surgery to treat their problem, had the option of phosphatidylcholine injections not been available?

7. What percentage of your patients has been satisfied with the results of treatment?

Very satisfied		Satisfied	
Fairly satisfied		Dissatisfied	

8. The expected localized side-effects from treatment are listed below, please indicate the average number of days your patients have experienced these:

Swelling		Bruising	
Redness		Burning and stinging	
Tenderness		Pain	

What percentage of your patients have described these localized side-effects as:

Very mild		Mild	
Moderate		Severe	

9. Infrequent systemic adverse effects can include those listed below. Please indicate what percentage of your patients has experienced any of these and their average duration.

	Percentage	Duration
Diarrhoea		
Nausea		
Dizziness/Light-headedness		
Menstrual bleeding		

What percentage of your patients have described these as:

Very mild		Mild	
Moderate		Severe	

10. We are particularly interested in reports of any serious or unexpected adverse effects from this treatment. How many of your patients have experienced any unexpected or unusually severe or prolonged adverse effects?

Please detail below for each patient affected: (Please use additional sheet if necessary)

Sex/age	Site treated	Total dose phosphatidylcholine injected (250 mg/5 mLs)	Adverse effect including severity	Duration (Days)	Action taken (If any)	Outcome

Thank you; please complete your details below. All data will be pooled and kept anonymous.

Doctor's details

Name: Dr. _____

Clinic Address: _____

Tel./Fax:/E-mail: _____

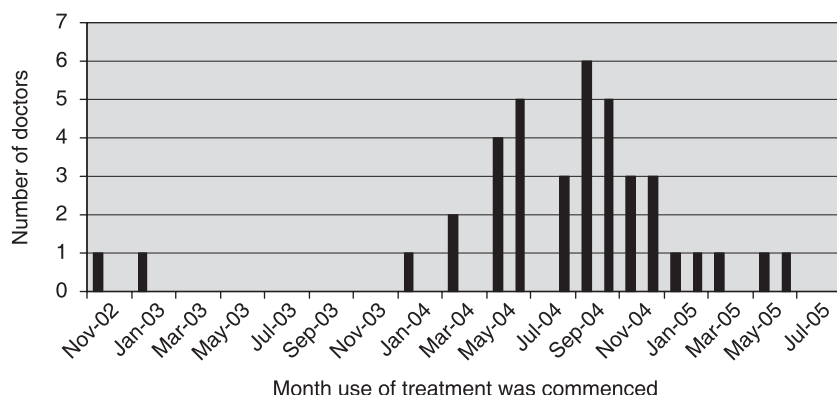


Figure 2 Duration of use of treatment.

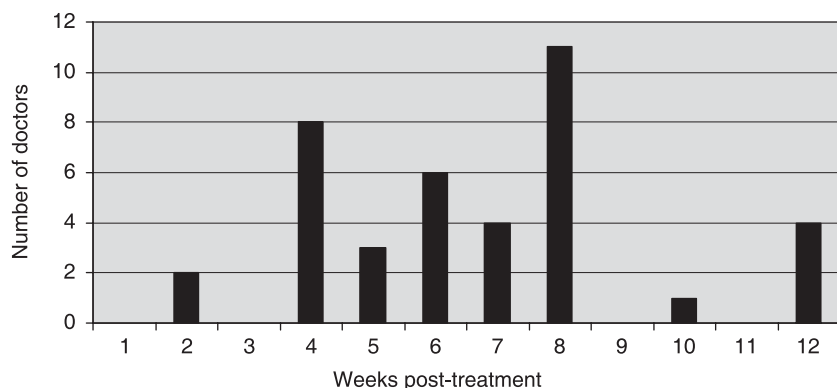


Figure 3 Timing of patient post-treatment review (weeks post-treatment).

Fifteen events were reported in total, the most common being pain and/or swelling (8 patients) and patchy hyperpigmentation/rash (4 patients). In the majority of cases, no action was taken and all events were self-limiting (Table 2).

Information relating to the total number of treatments administered by the doctors, rather than total number of individual patients treated was collected. However as doctors were trained to follow a protocol involving 1–4 treatment sessions per patient¹⁰ it can be inferred that the data presented relates to treatments carried out on between 3000 and 6000 different individual patients.

Discussion

Phosphatidylcholine is safe and nontoxic with no significant acute or chronic toxicity, mutagenicity or teratogenicity. It is well-tolerated at daily doses of up to 18 g when taken orally and symptoms of intolerance are almost exclusively restricted to gastro-intestinal discomfort (e.g. diarrhoea and nausea).¹

Phosphatidylcholine has been licensed in Europe for over 30 years for intravenous administration for the prophylaxis and treatment of fat embolism at high doses

of up to 90 mL or 4.5 g/day.^{2–5} Consistent with its lack of toxicity, the manufacturer's data sheet states that no intervention or action is required in the event of overdosage.

Phosphatidylcholine is safe for ill and vulnerable patients, being used orally and intravenously at high doses of 6 g daily or higher for liver salvage in acute and end-stage liver failure. Since phosphatidylcholine is the primary cell membrane building block, recovery following liver damage requires substantial replacement of cell membrane mass. Results from eight double-blind trials and other clinical reports indicate consistently that significant clinical benefit, including improvement of enzymatic and other biochemical indicators, faster functional and structural rebuilding of liver tissue, accelerated restoration of subjects' overall well-being and improved survival occur following phosphatidylcholine treatment.^{6–9}

Preparations of exogenous surfactant (phosphatidylcholine 70–80%) are used for administration into the tracheae of premature neonates suffering from respiratory distress syndrome where it can effectively help with alveolar inflation.^{30,31}

Criticism of the subcutaneous use of phosphatidylcholine for localized reduction of fat may have arisen due to the manufacturer of the major brand of phosphatidylcholine

Table 2 Details of all “Unexpected, unusually severe or prolonged adverse effects” reported.

Patient's Sex/Age	Site Treated	Total dose (mL) (250 mg/5 mL)	Adverse effect including severity	Duration (days)	Action taken (if any)	Outcome
F/52	Abdomen	40	Widespread Rash, fairly mild	21	None – resolved spontaneously	Patient decided to avoid further treatment
F/40	Jowls/Chin	7	Oedema	10	None	Good result
F/64	Lower Abdomen	20	Facial Swelling and Erythema	5	Antihistamines	Good result
F/42	Lower Eyelids	0.8	Pain and Swelling	7	Nil	Good result
F/44	Lower Eyelids	0.8	Pain and Swelling	7	Nil	No results
						Self-limiting
F/46	Lower Eyelids	0.8	Pain and Swelling	5	Nil	No results
						Self-limiting
M/37	Lower Eyelids	0.8	Pain and Swelling	7	Nil	Self-limiting
F/36	Lower Eyelids	0.8	Pain and Swelling	7	Nil	Self-limiting
F/64	Lateral Thighs	40	Mild Diarrhoea	2	None	Self-limiting
F/60	Lower Abdomen	25	Post-treatment hyperpigmentation at site of bruising	150	Massage, otherwise nil	Almost fully resolved after 5 months
F/50	Posterior Arms	20	Patchy Hyperpigmentation at treatment site	120	Observation only	Slowly resolving
F/48	Lower Abdomen	50	Patchy Hyperpigmentation at treatment site	150	Observation only	Resolved
F/43	Legs	20	Painful muscle	14	NSAID	Resolved
M/55	Lipoma	5	Swelling, tenderness, neck pain	42	None but considered surgery	Resolved
F/40	Triceps, Knees, Love handles	40	Oestrogen-like effect of fluid retention. Increased appetite and for 1 week low mood and tearfulness	60	Nil	Resolved

injection, Lipostabil (Nattermann), including a warning on the data sheet stating that it should not be injected subcutaneously. However, it has emerged that this is due to the product being freely available “over-the-counter” in Germany, and elsewhere over the internet and increasing numbers of the public are self-administering the drug subcutaneously.

There are known cases of localized tissue necrosis and other serious consequences arising entirely from such self-treatments.³² The proper formula, injected in the correct location using the proper technique and dosage, is therefore critical to the safe use of injection lipolysis and there is an urgent need to take action to stop the supply of these products to the public or other nonmedical personnel.

When used by experienced medical practitioners (Hasengschwandtner/Network-Lipolysis¹⁰) this data supports the view that phosphatidylcholine can be very safely used for localized reduction of subcutaneous fat on the face and body. Common localized adverse effects are generally “mild” to “moderate” in intensity, of short duration and are well-tolerated by most patients. Systemic adverse

effects are rare and are usually “very mild” or “mild”. Patient satisfaction is high (although an improvement in the study design would have included more than one dissatisfaction response option) and, of the total of 10 581 treatments, only 15 unexpected, unusually severe or prolonged adverse events were reported. None could be considered very serious and all were self-limiting.

As 96.2% of all patients were assessed and examined by their treating doctors several weeks post treatment, we are confident that the doctors surveyed were extremely well-informed regarding treatment outcomes and occurrence and nature of any emergent adverse effects.

A negative response option could have been included on the survey form for doctors to indicate if there were any of those questioned who had tried phosphatidylcholine injections, found them unsatisfactory, and had abandoned their use.

Serious allergic reactions, such as anaphylaxis, have not been reported despite many thousands of treatments. However, the theoretical possibility of such a reaction always remains, and there may be potential for sensitization

with repeated subcutaneous administration. Therefore, as with all injectable procedures, physicians should always remain alert to this possibility and be prepared for such emergencies.

Criticism of this treatment may have further arisen, partly due to the national UK lay-press which has indicated erroneously that phosphatidylcholine treatment may have an adverse effect on plasma lipid profiles and blood coagulability. However, Hexsel *et al.*³³ assessed the use of phosphatidylcholine in 205 patients with different patterns of localized fat deposits. Venous blood samples were taken in 13 of the patients treated with subcutaneous injections and all results showed no significant alterations in either hepatic function or lipid profile.

Hasengschwandtner³⁴ also compiled an Austrian study of serological measurements of liver function tests in 46 patients given injections into the subcutaneous fat of the with the maximum recommended dose of 2500 mg phosphatidylcholine (Lipostabil N®). The Gamma-Glutamyl Transferase and Bilirubin values from venous blood was examined on the 5th day after first treatment, 8 weeks after first treatment and, if there was more than one treatment sessions (maximum four), 8 weeks after the last series of injections. All evaluated samples were within the normal range. The conclusion made was that phosphatidylcholine did not cause any increase of the evaluated blood values after subcutaneous application, such as is already proven after intravenous administration.

Furthermore, other reports demonstrate that phosphatidylcholine is of benefit in cardiac disease³⁵ hypertriglyceridemia³⁶ and elevated serum cholesterol.³⁷ Bobkova *et al.*²⁵ reported on the metabolic effect of Lipostabil in improving coronary atherosclerosis, hypothyroidism, and insulin resistance. They also reported an average decrease of 32% in serum triglyceride levels in cardiac patients treated with phosphatidylcholine.²⁵ Documented cardiac benefits include dissolution of atherosclerotic coronary artery plaques, decrease in LDL, triglycerides and VLDL, and an increase in serum HDL values. Phosphatidylcholine has also been shown to inhibit platelet aggregation.²⁴

Criticism may have also arisen as a consequence of discrimination against cosmetic treatments in the UK where there is a tendency to regard cosmetic treatments as unnecessary for patient health. However, it is our experience that many patients are sufficiently psychologically distressed by a cosmetic problem that their quality of life is impaired, with some patients exhibiting signs of clinical depression severe enough to warrant antidepressant medication. Successful cosmetic treatment can often dramatically improve patient confidence and self-esteem, relieve symptoms of depression and improve patient happiness and quality of life.

Strict dieting and exercise should always be discussed with patients but may not always be appropriate since some patients have a disproportionate body shape with an excess of subcutaneous fat deposited in a very localized area. These patients may be of average or below average overall bodyweight and any further weight and fat loss from other body areas may be undesirable.

Doctors surveyed estimated that 17.9% of their patients treated by phosphatidylcholine injections would have otherwise undergone surgery, the most common surgical option being liposuction. Although generally considered a benign procedure, two independent surveys assessed the late 1990s mortality from liposuction as 1 in every 5000 procedures.³⁸ Furthermore, a critical review of the lipoplasty literature concluded that

“the mortality from lipoplasty procedures is higher than the 0.003–0.02% reported in the literature and may be as high as 0.1%”.³⁹

More recent publications have also highlighted safety concerns regarding current techniques of tumescent liposuction.^{40,41}

In conclusion, it is acknowledged that, at present, the use of phosphatidylcholine for subcutaneous fat reduction is an unlicensed indication. It is also acknowledged that in some countries (e.g. UK, USA) no commercially available injectable preparations of phosphatidylcholine have marketing authorization (product licences). In the UK, such products can only be prescribed strictly for a named patient and imported individually after having been dispensed to that patient for their own personal use.

It is further acknowledged that, in common with all new treatments (e.g. Intense Pulsed Light), any very long-term effects are currently unknown. Physicians should therefore exercise caution and ensure to undertake rigorous and fully informed consent with any patients treated.

However, although surgical outcomes have improved with advancing techniques, when considered against the possible risks of surgical treatment options, the data from this study suggests that disproportionate criticism of phosphatidylcholine injections is unjustified.

When used by doctors specifically trained in correct treatment protocols, this is a treatment modality which appears, from this data, to be associated with low risks for patients seeking medical intervention to reduce localized subcutaneous fat deposits.

This medication must be prevented from being available to the general public or nonmedical personnel as some serious adverse reactions have been reported as a result of attempted self-treatments by lay-persons.

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