

Position paper on mesotherapy

Rashmi Sarkar, Vijay Kumar Garg, Venkataram Mysore¹

Department of Dermatology,
Maulana Azad Medical
College, New Delhi, ¹Venkat
Charmalaya, Centre for
Advanced Dermatology,
Bangalore, India

Address for correspondence:

Dr. Rashmi Sarkar,
Department of Dermatology,
Maulana Azad Medical
College, New Delhi –
110 002, India. E-mail:
rashmisarkar@yahoo.com

ABSTRACT

Mesotherapy is a controversial cosmetic procedure which has received publicity among the lay people, in the internet and in the media. It refers to minimally invasive techniques which consist of the use of intra- or subcutaneous injections containing liquid mixture of compounds (pharmaceutical and homeopathic medications, plant extracts, vitamins and other ingredients) to treat local medical and cosmetic conditions. This position paper has examined the available evidence and finds that acceptable scientific evidence for its effectiveness and safety is lacking. *IADVL taskforce, therefore* would like to state that the use of this technique remains controversial at present. Further research and well-designed controlled scientific studies are required to substantiate the claims of benefit of this mode of therapy.

Key words: Lipolysis, mesotherapy, rejuvenation

INTRODUCTION

The technique involving direct injections of medications into the skin was first described by a French physician, Dr. Michel Pistor in 1952 when he administered procaine intravenously to an asthmatic patient, which had limited impact on his airway disease but instead, improved his hearing.^[1] It was later recognized as the original application of mesotherapy, which included improvement of joint pain, eczema and tinnitus.^[2,3] Pistor subsequently coined the term ‘mesotherapy’ (there is another view that the French press coined the term, “mesotherapy”) which meant as “treatment of the mesoderm, one of the three primary germ layers which later develops into connective tissue, muscle and the circulating system”.^[4] Therefore, though originally developed to treat vascular, lymphatic and hematological conditions, due to an increasing demand for noninvasive cosmetological procedures, mesotherapy has attracted a lot of interest

from physicians and the general public as a treatment modality for cellulite treatment, lipolysis or “fat dissolving” and body contouring.^[5-8]

Despite it being available for over 50 years and the huge publicity and attention received on the internet, definite evidence for its efficacy is lacking and the claims are not always based on well conducted clinical trials. Anecdotal reports are often touted as evidence and heavy advertisements in media sustain its popularity. Federal drug administration (FDA), USA has not approved this method of treatment. Some of the compounds used in mesotherapy have been approved by FDA for human use, but for a different purpose or indication. Many dermatologists and other physicians practice this technique and patients often seek the opinions of dermatologists about the efficacy of this technique. This paper conducts a review of the subject, examines the available evidence and formulates the official policy statement on behalf of IADVL.

Definition

Mesotherapy, refers to a variety of minimally invasive techniques which consist of the use of intra- or subcutaneous liquid injections containing mixture of compounds to treat local medical and cosmetic conditions. The injections could include hormones, enzymes, pharmaceuticals, nutrients, homeopathic

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agents, detergents and other substances which are injected in between the dermis and the skin known as mesoderm.^[9,10]

Reported indications and possible rationale

Mesotherapy was originally invented for pain relief; however, its cosmetic applications including fat and cellulite removal and facial rejuvenation, have received attention. A distinction has been made between mesotherapy (injections in to mesoderm to produce effects on mesoderm) and injection lipolysis (also called lipodissolve-a method of treating localized adipose tissue with subcutaneous injections of deoxycholate either alone or in combination with phosphatidylcholine).^[4,11-13] Phosphatidylcholine and deoxycholate injections are used subcutaneously for their local effect only, for treating localized deposits of adipose tissue in contrast to mesotherapy, which as per definition, is said to affect “mesoderm”. Opinion has been expressed, therefore, that injections of phosphatidyl choline and deoxycholate are local injection therapies and not “Mesotherapy”.^[4] This distinction assumes importance in view of the fact while there have been several publications in indexed journals to support the efficacy of injection lipolysis, very little published data exists to support the role of mesotherapy.

Table 1 mentions the main dermatological and other medical indications purported to benefit from

Table 1: Dermatological and medical conditions purported to benefit using mesotherapy

| Dermatological | Medical conditions |
|-------------------------------|---------------------------|
| Cellulite | Arthritis |
| Weight loss | Asthma |
| Telangiectasias | Carpal tunnel syndrome |
| Body sculpting | Lower back pain |
| Local fat deposits | Degenerative disc disease |
| Acne | Gout |
| Alopecia | Headache |
| Hyertrophic or keloid scars | Fibromyalgia |
| Leg ulceration | Herpetic neuralgia |
| Facial rejuvenation-wrinkles, | Constipation |
| Skin tightening, photoaging | Insomnia |
| Pruritus | Irritable bowel syndrome |
| Psoriasis | Sports injuries |
| Striae distensiae | Peripheral vascular |
| Hyperpigmentation and melasma | disease |
| Venous stasis | Substance abuse |
| Vitiligo | Tinnitus |
| Eczema | Vertigo |

mesotherapy. It is further clarified that this list is only a list of reported indications for which claims of benefit have been made. The indications for which published data exists is discussed below.

Cellulite (Level D)^[8,14-16] Cellulite, a skin surface change that is common in women, is a much debated condition whose etiology is unknown and remains elusive to treatment. Despite the lack of evidence to support efficacy, treatment options, including mesotherapy continue to proliferate. Caruso *et al*, evaluated the lipolytic potentials of solutions used in the practice of mesotherapy to stimulate lipolysis, cause local fat reduction and treating cellulite. These were tested in a human fat cell assay using the induction of glycerol generation as a measure of lipolysis. Isoproterenol ($P<0.002$), aminophylline ($P<0.00004$) and yohimbine ($P<0.001$) stimulated lipolysis compared to the buffer control. It was observed that isoproterenol, aminophylline, yohimbine and melilotus stimulate lipolysis alone, and lipolysis is further enhanced by combining lipolytic stimulators in mesotherapy solutions. It was also observed that lidocaine is antilipolytic and should be removed from mesotherapy solutions designed for local fat reduction.^[16] A review of the subject concluded that “*Until further studies are performed, patients considering mesotherapy for cellulite must be aware that the substances currently being injected to treat this cosmetically disturbing, but medically benign, condition have not been thoroughly evaluated for safety or efficacy.*”^[8]

Weight loss and body sculpting (Level C)^[7,17,18] A randomized, prospective case-controlled study over a 12-week period by Park *et al*, to study the effect of a mixed solution (i.e. aminophylline, buflomedil and lidocaine) by injecting it into the superficial dermis of the medial aspect of the thigh weekly with the other thigh acting as a control, showed no significant loss of thigh girth on the treated side as compared to the non-treated thigh as measured by computed tomographic scanning. *The study indicated poor patient satisfaction and demonstrated that mesotherapy is not an effective alternative treatment modality for body contouring.*^[18]

Local fat deposits – xanthelasma, lipoma, submental fat reduction (Level C),^[19-22]

In an open-label clinical trial, Hexsel *et al*, treated 213 patients with HIV lipodystrophy, lipomas, buffalo hump, on the chin, trunk and extremities with 0.2 ml phosphatidylcholine placed every 1.5-2.0 cm

into the lipomas every 15 days upto five treatments. Thirteen non-HIV patients had serum laboratory testing before, 48 hours and 2 weeks post-treatment after two treatments. It was observed that vast majority of patients had reduction of fat thickness after up to five treatments. All buffalo hump patients reported improvement. There were no significant alterations in hepatic and lipid profiles.^[21] In another study, use of phosphatidylcholine vs. phosphatidylcholine plus organic silicium was effective in reducing submental fat in 12 patients. The rate and degree of reduction was not significantly different after three treatment sessions. Adverse reactions were few, mild and transitory. Hence both regimens appeared safe, efficacious and cost-effective.^[22] These studies suggest that phosphatidylcholine injection, which are per se not mesotherapy by definition may have a role in treating localized fat deposits and further studies are necessary to establish its safety and efficacy.

Mesolift or facial rejuvenation - (Level C)^[9,23] Amin *et al.*, conducted four sessions of mesotherapy involving multiple injections of a multivitamin and hyaluronic acid solution, at four monthly intervals for facial rejuvenation on 10 subjects and the results were evaluated photographically and histopathologically. The study revealed no significant clinical or histological changes due to mesotherapy with multivitamin and hyaluronic acid solutions.^[9] However, in another study, Lacarrubba *et al.*,^[23] evaluated the effects of mesotherapy with multiple injections of hyaluronic acid in 20 women with physical signs of moderate skin photoaging with subepidermal low-echogenic band (SLEB) on ultrasonography of skin. This study suggested that mesotherapy with hyaluronic acid maybe an effective treatment for photoaging, as there was a statistically significant ($P < 0.001$) increase in SLEB echogenecity in 15/19 patients who completed the study.^[23] The study recommended that further follow-up investigations on larger series of patients are necessary to further evaluate the safety, effectiveness and duration of effect of this possible therapeutic approach to skin photoaging.

While mesotherapy has been claimed to be beneficial in several other conditions such as alopecia, melasma as listed in Table 1, there is no published paper supporting their use or documenting their efficacy.

Contraindications to therapy^[5,10]

The contraindications to mesotherapy are:

1. Pregnant and lactating females

2. Insulin dependent diabetes mellitus
3. History of bleeding disorders
4. History of strokes
5. History of thromboembolic phenomena
6. Patients on medication for cardiac arrhythmias, aspirin, warfarin, heparin, etc.
7. History of recent cancer
8. Severe heart disease
9. Renal disease
10. Any severe chronic systemic disease

Products commonly used for mesotherapy

A wide variety of agents have been used in mesotherapy, including vitamins, herbal agents, homeopathic medications, and others. These include:

1. Dissolving fat - Phosphatidyl choline^[12,13,15,19] (Level B); aminophylline^[16,18] (Level C), theophylline, caffeine, ephedrine, calcium pyruvate, carnitine (Level D), organic silicium^[23] (Level C).
2. Collagen rejuvenation-tretinoin, organic silicium (No evidence)
3. Collagen remodelling-Hyaluronidase (level C), collagenase
4. Skin hydration, tightening, exfoliation-Hyaluronic acid^[23] (Level C), prochlorperazine, dimethylaminoethanol (DMAE), silica, glycolic acid (Level D).^[24]
5. Agents that act as antioxidants and decrease skin pigmentation-Vitamin C (hyperpigmentation and melasma), glutathione, glycolic acid, pyruvate, biotin (alopecia), pantothenic acid, vitamin E and A, minerals like selenium, zinc, copper, magnesium, chromium, α -lipoic acid and melatonin (No specific evidence)
6. Hair growth stimulation – Finasteride, minoxidil, buflomedil (No specific evidence)
7. Improvement of collagen and elastic synthesis and cytokines for cellular stimulation – CRP 1000 and copper peptide.
8. Circulatory stimulants – pentoxyphylline, coumarin, arnica, ginko biloba, melilotus, yohimbine. (No specific evidence)
9. Antiinflammatory – Piroxicam, ketorolac
10. Calcium deposition removal – calcitonin
11. Immune stimulation – Vaccine, interferon
12. Antibiotics and chemotherapeutic agents – Metronidazole
13. Analgesics, muscle relaxants and tranquilizers – diazepam, baclofen and orphenadrine are muscular analgesics
14. Nausea reduction – Prochlorperazine

15. Local anaesthetics-Procaïne, prilocaïne and lidocaïne^[16] (Level C).
16. Others-T3-T4 thyroid, isoproterenol, pentoxifylline, L-carnitine, L-arginine, co-enzymes, cofactors, dimethylethanolamine, C-adenosine monophosphate, multiple vitamins^[22] (Level C), trace mineral elements, carbon dioxide.

It needs to be emphasized here that there are no standardized ingredients or dosages for these ingredients and these are used in arbitrary cocktail formulations, based on their known theoretical pharmacological actions. While some products have been used orally or intravenously for several years, there is little knowledge about pharmacodynamics and kinetics of the products when injected in to skin. These products are not subject to rigorous regulations of federal drug authorities. There is no data regarding interaction, effectiveness and safety of mixing different ingredients. Likewise, there are variations in techniques of administrations, instruments used, frequency of administration, treatment etc. In view of this, these aspects are not discussed here.

COMPLICATIONS

Local

In contrast to the claims of mesotherapy being a safe, minimally invasive procedure, several side effects have been reported. It is also interesting to note that in contrast to the lack of data on its efficacy, there are a number of published studies about its complications, as follows:

1. Bruising and edema due to the chemicals used in mesotherapy^[10,25]
2. Skin necrosis^[25,26]
3. Atypical mycobacterial infections^[27]
4. Facial and scalp ulcers and scarring^[28,29]
5. Allergic reactions due to various chemicals^[25,30]
6. Atrophy and lipodystrophy^[25]
7. Lichenoid eruption^[31]
8. Postinflammatory hyperpigmentation^[4]
9. Nodularity and irregularity after lipolysis
10. Rare: Koebnerization in psoriasis,^[25] localized urticaria pigmentosa^[32] granuloma annulare,^[33] noninfectious granulomatous panniculitis,^[34] alopecia^[35]

Systemic^[4,25]

1. Allergic reactions
2. Vagal syndromes

3. Lipothymia
4. Infections (HIV, hepatitis etc)
5. Liver toxicity and demyelination of nerves due to large doses of phosphatidylcholine

These reports contradict the offrepeated claims of safety of mesotherapy and emphasize the necessity for proper safety precautions and patient counseling during the treatment. Thus, the claims of safety and simplicity of administration can be misleading and lead to self treatments by patients themselves, as exemplified by a reported case of self administration of lipase obtained on the internet.^[36]

POSITION STATEMENT OF IADVL TASKFORCE ON THE USE OF MESOTHERAPY IN DERMATOSURGERY PRACTICE

Although mesotherapy is a well-advertised therapeutic modality on the internet and media, and is practiced in Europe and South America, data on its safety and efficacy in cosmetic conditions are limited. There are currently no adequate, peer-reviewed clinical trials critically evaluating the efficacy of mesotherapy for dermatological and aesthetic indications. While, there are a few peer reviewed publications on the efficacy of subcutaneous injections of phosphatidylcholine in treating localized collections of fat (which as stated earlier is different from mesotherapy), these are few and of low evidence levels. Hence proper controlled data and more evidence is needed before any recommendations about its usage can be made.

At present there is insufficient data evaluating the safety of the technique and pharmacology, of the combination of herbal and allopathic medicines used. The mechanism of action of many of the products is either doubtful or unknown and there are no clear cut guidelines on the dosage and efficacy of the products. The CDC has recommended that “providers should adhere to recommend standard precautions, follow safe-injection practices with appropriate aseptic techniques, and inject only FDA approved products that are prepared following guidelines to ensure sterility as described in the FDA’s good manufacturing practices.”^[37] Further, mesotherapy is not entirely a safe technique as is publicized and can give rise to various complications, as reported earlier, some of which are particularly significant in this era of HIV.

Therefore, although it appears to be a simple, easy and financially attractive therapeutic option in cosmetology,

the use of this technique is controversial.^[38] It is important to understand that the technique has been in practice for over 50 years and yet, little evidence in term of controlled data have been published by users of the technique. Continued research and well designed controlled scientific studies are required to substantiate the claims of effectiveness of these products and to formulate guidelines and recommendations regarding its use for aesthetic applications. It is relevant to note that in a recent publication of guidelines on aesthetic practices in Singapore, mesotherapy is listed as a List B procedure (which indicates procedures with low or very low evidence or local medical expert consensus that procedure is neither well-established nor acceptable.)^[39] Such List B procedures include, in addition to mesotherapy, other procedures such as carboxytherapy, skin whitening injections, stem cell activator protein for skin rejuvenation, negative pressure procedures (e.g., Vacustyler™), mechanized massage (e.g., Slidestyler™, endermologie for cellulite treatment) etc.^[40]

In view of these, IADVL taskforce does not recommend the routine use of the technique and suggests that scientifically driven prospective double blind controlled studies must be undertaken at many centres to evaluate the safety and efficacy of this therapy. It should also be understood that the final responsibility in this regard lies entirely with the treating physician, if he/she chooses to use the technique, who should therefore exert utmost care to prevent medicolegal situations and take all precautions before administering the treatment.

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DISCLAIMER

The contents/recommendations of all articles prepared by IADVL Taskforce on dermatosurgery are recommendatory only, and are not absolute or binding on members. The principles outlined in the IADVL Taskforce articles/recommendations are of general nature, based on current evidence and as in any aesthetic treatment or surgery, individual variations may occur from patient to patient, and hence, appropriate modifications may be needed depending on the needs of the given patient, as per the discretion of the physician and as per emerging evidence in future. Each patient has to be treated on his/her merit and the ultimate judgment regarding the choice of a procedure should be made by the physician, keeping in view the individual patient and training and experience of the treating physician. As in the correct and ethical practice of any surgical procedure, the physician must exercise his judgment in light of all the circumstances of the individual patient.

These guidelines/articles have been prepared with the sole purpose of establishing minimum standards of care, and as a service to the members of IADVL; Neither the taskforce members nor IADVL will be held responsible either directly or indirectly for any legal claims.

ABOUT IADVL DERMATOSURGERY TASKFORCE

The taskforce was constituted as per the resolution of Annual General body meeting of IADVL members. The taskforce 2009 consisted of the following members:

Dr. S Sacchidanand (IADVL President, 2008 and Chairman), Venkataram Mysore (Convenor), VK Sharma (IADVL President 2009), Hema Jerajani (IADVL President 2010), Rajeev Sharma (IADVL Secretary 2008-2010), Narendra Patwardhan, Rashmi Sarkar, Niti Khunger, DS Krupashankar, Somesh Gupta, CR Sreenivas, Mukta Sachadeva (members)

The taskforce has adopted the following evidence levels for use in the guidelines Evidence

Level A- Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogeneous results (blinded controlled studies).

Level B- Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.

Level C- Limited research-based evidence. At least one adequate scientific study/case report.

Level D- No research-based evidence. Expert panel evaluation of other information.