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Since 2001, injection lipolysis has been a subject of great interest accompanied by continuous scientific research. Some of the important studies and publications on that topic are cited in the article from Reeds et al,¹ published in the March 2013 issue of *Aesthetic Surgery Journal* alongside 2 commentaries from Brown² and Duncan.³

First, we want to underline that this Aesthetic Surgery Education and Research Foundation-supported study is the first US Food and Drug Administration-approved randomized clinical trial to sequentially evaluate the effects of a phosphatidylcholine-deoxycholate (PC-DC) mixture on adipose tissue histology and gene expression in a cohort of human subjects. The study shows that injection lipolysis works in human fat tissue. The authors did various scientifically approved investigations and analyses. Brown² stresses in his commentary that no clinical safety issues and only anticipated adverse events were noted.

Reeds et al¹ mention in the Discussion section the report from Hasengschwandtner⁴ with the results from the 2004 Network Lipolysis group study, including the side effects experienced. However, this information does not yet contain the latest statistical evaluation of the Network Lipolysis⁵: this time, 128 members responded to the questionnaire (which had 26 questions in total). During a period of 17 months, 17 394 patients with 43 354 treatments were evaluated. Regarding safety aspects, the following types and numbers of transient complications were seen: nodules (176), pockets (82), and pigment disorders (43), which disappeared spontaneously after a few months. Additionally, 7 cases of necrosis, 4 abscesses, and 13 unspecified complications were noted. Only 33 long-term complications were reported, which results in the low complication rate of 0.076%.

Duncan³ remarked in her commentary that the lack of tissue specificity of the PC-DC injections, or DC injections alone, is a safety concern. The stringent Network policy of a profound, structured training exclusively for physicians and with a standardized treatment protocol has, in retrospect, proven to be right. Problems with lipodissolve clinics and insufficiently trained nurses in the United States, which apparently led to more frequent complications, were not seen in Europe to this extent. Therefore, the conclusion that the therapy should only be performed after comprehensive training is correct. Does that not hold true for all injectables, such as botulinum toxin and fillers?

Although compounding enables good quality of injected materials (besides various useless products) in Europe, Asia, and the United States, it is good to know that companies are working on FDA, European, and Asian approvals of injection lipolysis. However, we call the approval efforts for pure DC monopreparations into question. There is no doubt that the detergent DC makes membranes “leaky” and destroys adipocytes, but more is necessary than just cell wall destruction. Relevant pharmacological and clinical evidence is given which substantiates the combined use of PC with DC instead of DC alone:

- Advantage 1: PC diminishes the aggressiveness of pure DC under the microscope. This reduced aggressiveness is desirable for maximum result with minimum side effects.⁶
- Advantage 2: PC reduces the toxicity of DC,⁷ also substantiated by propidium iodide coloring.⁶
- Advantage 3: Adipocyte lysis is followed by metabolism of the released fat. Especially polyunsaturated phosphatidylcholine from soybeans, which is normally used as PC for injection lipolysis, stimulates fat-degrading enzymes, such as lipases.⁸
- Advantage 4: PC und DC are detergents with a marked surface activity, and PC emulgates subcutaneous fat in a gentle manner.
- Advantage 5: PC from soybeans favors the uptake capacity and reverse transport of cholesterol esters to the liver, where it is also important for optimal mitochondrial β -oxidation of fatty acid.^{9,10}
- Advantage 6: A new Korean study with PC from soybeans but *without* DC clearly demonstrates what Network member Ninian Peckitt (UK) postulated in 2005: PC from soybeans without DC shows apoptotic efficacy.¹¹ The observed apoptosis played no role in the studies from Bochum¹² and Regensburg⁶ in Germany, as the temporal dimension of the investigated cells was too short,

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or as DC destroyed the cells beforehand. In our opinion, it is the combination of PC with DC that ensures the long duration of effect with a minimum side effect profile.

Perhaps these facts are ignored by some authors due to economic strategic interests?

With regard to the described side effects, they may reduce the affected persons' interest in injection lipolysis. Perhaps this was an additional reason why only 7 of an original 11 allocated patients completed the trial of Reeds and coworkers.¹ However, 7 cases are enough for the database of a half-side comparison study and to do further research.

In 2010, Network Lipolysis introduced the PSM—Pain and Side Effect Management—initiative for lipolysis, which definitely increased patient acceptance. The use of the PSM only in Europe has something to do with the retreat of the Network from the American market, caused by differing opinions about the development of lipolysis. Furthermore, Network members decided not to register DC preparations but to look for a safer alternative than DC, with at least comparable efficacy. In fact, they succeeded due to their strong partnership with different scientists. The new substance combination shows no inflammation (as seen with DC in animals), but it combines apoptosis with strong lipolysis. A first half-side comparison study and single-case observations point to a significantly better safety/efficacy ratio of the new formula compared with PC-DC. Phase 1 and phase 2 studies are being planned, basic research is completed, and the experimental results are ready for publication. The Network is sure to be increasingly scientifically engaged during the coming years. New developments are awaited, and they will be pursued.

Disclosures

Dr Hasengschwandtner is Medical Director of NETWORK-Lipolysis, a worldwide physicians' network. Prof. Gundermann is scientific adviser to NETWORK-Lipolysis.

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