Title Assessment of the complications of cryolipolysis for aesthetic purpose

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Aim

The aim of this work is to appraise the side effects of cryolipolysis, an aesthetic non-invasive fat reduction procedure carried out by a controlled cooling system to reduce localised subcutaneous adipose tissue (in abdomen, tights, flanks, back, upper arms, submental area, chest fat in men).

This assessment is conducted in order to respond to the Health Ministry's request about the potential danger of this technique (article L.1151-3 of the Health National Law).

Results

The scientific data are selected from two systematic reviews and seventeen original studies carried out by medical teams using medical devices and according to a protocol. The collected safety information points out short and medium-term symptoms attesting to some frequent and very frequent temporary side effects (redness, bruising, pain, numbness, tingling) or longer but moderate (hyperpigmentation) or others, very rare, but classified as serious adverse event (SAE) because of their severity, duration or feature (hernia, vasovagal syncope).

In contrast more recent data, mainly study cases, a systematic review and reporting to health and judicial bodies show that peripheral sensory neuropathies, inguinal hernias and tissue damage such as burn, frostbite or paradoxical hyperplasia can also occur after cryolipolysis procedures.

For some of these cases, a hospitalisation and a corrective surgical intervention were required, some have left visible sequelae: there were unexpected in nature or essentially in intensity / seriousness as they concern a non-invasive aesthetics procedure, promoted on the basis of rather reassuring clinical studies.

Available data do not make it possible to estimate the frequency of these SAEs, except for paradoxical hyperplasia whose frequency is evaluated, including the responses to the public consultation, between 1/1000 and 1/100 procedures.

A proportion of these SAEs could be caused by operators' misuse in the implementation of the technique or repeating the procedure too soon with regard to manufacturers' recommendations but also failures or technological design deficiencies among the various devices available on the market in France.

Conclusions / Recommendations

Consequently, taking into account the different data collected and analysed during this assessment, in particular serious and severe complications (burns, hernia, paradoxical hyperplasia), HAS considers that the practice of cryolipolysis is likely to present a serious danger to human health with the current lack of protective measures for the population. Those measures should consist, on the one hand, of ensuring a uniform level of safety and quality of the cryolipolysis equipment used and, on the other hand, of providing for a qualification and training of the professional who performs this technique. It is therefore necessary to regulate this practice by establishing conditions for carrying out cryolipolysis procedures.

Otherwise, from now on, detailed and written information on possible side effects of this aesthetic technique, given beforehand to people, should be put in place. Moreover, all the adverse events related to cryolipolysis should be reported by professionals to health authorities using the safety website whatever the condition of performance (device, operator).

In total, procedures of cryolipolysis for aesthetics purposes can only be performed in strict compliance with legal requirements in order to protect people.

Methods

This assessment is based on the search for side effects of the technique in multiple sources in France and abroad, mainly: scientific literature, databases dedicated to safety reporting, information provided by the applicant, survey sent to the Regional Health Agencies (ARS), requests to insurance companies.

Complications have been classified in accordance with their potential seriousness [using the homogenous definition of adverse event (AE) and serious adverse event (SAE)] in the area of body appearance i.e. cosmetic product, tattoo product and food supplements, their severity (CTCAE scale) and their expected and unexpected nature depending on

the available information. Estimation of their frequency, where possible, has been done using CIOMS scale.

The views of all concerned (plastic and aesthetic surgeons, aesthetic medical or non-medical practitioners, companies…) have been collected by a public consultation based on a questionnaire relative to the preliminary assessment report.

The comments received were synthetized in the final report submitted directly to the HAS Board for validation.

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