ULTRASOUND, CAVITATION AND BODY CONTOURING: EFFECTIVENESS AND SAFETY

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CONFLICT OF INTEREST STATEMENT

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

STATEMENT OF AUTHORSHIP

The authors hereby certify that all work contained in this review is original work of Tommaso Iannitti, Stefania Capone and Beniamino Palmieri. The authors claim full responsibility for the contents of the article.

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ABSTRACT

The burden of obesity is growing worldwide. The use of minimally invasive cosmetic procedure and devices, able to remove fat deposits, is rapidly spreading due to the patients' increasing demand for new procedures to improve the body shape and contour. Ultrasound assisted liposuction has shown several advantages if compared to traditional liposuction and therefore it has been performed in several clinical trials. Here we report a clinical study performed in 20 healthy volunteers who underwent ultrasound assisted liposuction. Total cholesterol, HDL cholesterol and tryglicerides have been measured, before and after the procedure, observing a significant decrease in the total cholesterol concentration in blood, while no changes have been reported in the other two parameters. No side effects have been reported and therefore, on the basis of our investigation, the cavitation treatment of lipomatosis and cellulitis, with ultrasound-assisted liposuction on healthy individuals, is safe and uneventful.

INTRODUCTION

Obesity has become epidemic in many countries and it has been correlated to the raise of different pathological conditions, i.e. type 2 diabetes, metabolic syndrome, cardiovascular diseases, hypertension, dyslipidemia, non-alcoholic fatty liver disease, some immuno-mediated disorders such as asthma, dementia, obstructive sleep apnea and several types of cancer [1]. Morbid (extreme) obesity has been defined as a body weight greater than 100% above the ideal body weight or a body mass index (BMI) >40 kg/m^2 [2]. Moreover, excess body fat is frequently associated with dissatisfaction of the body shape. Although diets, exercise, medications, and/or gastric surgeries may help to counteract the growing spread of obesity, there is an increasing interest in cosmetic procedures, particularly minimally invasive ones, and devices which may result necessary to remove areas of fat deposits to meet the necessity of the patients improving the body contour [3].
The word "liposuction" derives from the Greek "lipos" meaning fat, grease and the Latin "sūctiō", "sūctiōn-", from Latin "sūctus", past participle of "sūgere", meaning "to suck". This method was clinically introduced in 1989 for the removal of fat by Dr. Zocchi, who developed the concept of applying ultrasound energy to adipose tissue [4]. Nowadays liposuction can be categorized in three forms [5]: 1) traditional (or suction-assisted) liposuction (SAL); 2) tumescent liposuction (TL); 3) ultrasound-assisted liposuction (UAL). In SAL, the surgeon passes a hollow suction tube, "cannula", through small incisions in the area where the fat is to be removed. Moving the cannula around, the surgeon mechanically breaks up the fat, which is then suctioned out by a mechanical pump or syringe. TL is essentially the same as SAL, except for the large volume of fluid that the surgeon introduces into the area to be liposuctioned. The fluid, which contains local anesthetic and blood-vessel-constricting drugs, helps to reduce blood loss, alleviate pain, and lessen the need for general anesthesia. UAL is the latest in liposuction. The seminal difference between UAL and TL is that UAL uses the energy of high-frequency sound waves to liquefy the fat before it is removed with low-pressure suction. UAL provides some advantages over SAL such as less injury to nerves and blood vessels, less overall tissue trauma, minimized blood loss, smaller-diameter channels formed in the adipose tissue, smooth tunnels created in the adipose tissue, even more shaping of overlying skin surfaces, accurate positioning of probes, and spot-specific tissue removal [6]. There are also some reported advantages for UAL over TL including less damage to the vascular and nervous structures, reduced bleeding, less bruising, swelling, and discomfort with more skin retraction at the postoperative stage and less physical effort for the surgeon [7–10]. In contrast to these positive claims, there are some complications with controversial frequencies ranging from skin necrosis and burns (caused by the heat of the ultrasound device), fat necrosis and fibrosis, hyperpigmentation, sensory alteration (thought to result from sensory nerve damage by ultrasound), postoperative ecchymosis, and postoperative swelling [11] to more devastating complications, such as severe abdominal wall necrosis [12] and even death [13]. It has been pointed out that ultrasonic liposculpturing may be a superior, potentially safer, less destructive technique for cellulite reduction than traditional liposuction because

cellulite is very close to the surface of skin, with only a thin layer of dermis overlying it. Liposuction, performed at a level so close to the surface of the skin, can lead to more complications and a poor cosmetic outcome [14]. We have been performing ultrasonic liposuction since 1994 [15,16], aiming at reducing the mechanical trauma of the suction cannula, and therefore the haemorrhagic risk and embolization. The manufacturers' efforts to achieve fat-reducing results with minimally surgical invasivity have led to the design of several trials with epicutaneous transducers, avoiding the insert of cannulas through the skin inside the adipose tissue. These new technique has led to a dramatically reduction in classic liposuction based procedures for fat removal. The post-treatment rearrangement of the fat in the treated area, has been only sporadically investigated. Interestingly, the lipolytic effect of ultrasound is mainly induced by mechanical rather than thermal action, thus ruling out , or at least reducing , the hyperemia of the microcirculation which may lead to a large reintroduction of the lysed fat material in the bloodstream, with potential biochemical metabolic effects on viscera filter, including primarily the liver and the lung. It is also known that free fatty acids, derived from triglycerides, are a primary energy source for the brain, heart and skeletal muscle system metabolism, therefore physical activity should be reassessed peri-post-treatment in order to remove the interstitial tissue delivered fat.

BRIEF REVIEW OF PREVIOUS CLINICAL STUDIES

A recent study has evaluated UAL complications comparing them with the previous routine techniques for liposuction in six hundred and sixty UALs that were performed on 609 consecutive volunteers by a cosmetic surgeon. Demographic characteristics, local and systemic complications, and also severe adverse events (SAE) were registered intraoperatively and at 1, 4, and 12 weeks postoperatively. In this study no SAEs were identified and only nine complications, consisting of two systemic complications (two cases of hypotension) and seven local complications (3 seromas, 3 cases of contact dermatitis, and 1 case of hemorrhage), were registered (complication incidence = 1.36%). There was no association between the number of complications and the body region, age, gender, or body mass index (BMI) [17]. A study addressed the combination therapy of UAL and limited-incision platysmaplasty for cervicofacial rejuvenation in fifteen female patients (age = 43–75 years) that were treated for grade II–III (n = 2), III (n = 6), and grade IV (n = 7) cervicomental angle deformity. Ultrasonic energy was applied for an average of 2 min (range = 45 s–6.5 min). The mean aspiration volume was 125 ml. No patient needed immediate or delayed adjuvant skin reduction. No complications were encountered in this series. After treatment a significant improvement of the cervicomental angle was observed. For treatment of all grades of the aging neck we advocate the combination of UAL and limited-incision platysmaplasty. This combination therapy has little morbidity and leads uniformly to significant improvement of the cervicomental angle [18]. Other important clinical trials, concerning lipoplasty have been summarized in figure 1.

MATERIALS AND METHODS

Twenty healthy volunteers (n (women) = 15 age = 42 ± 13; n (men) = 5; age = 47 ± 6) aged between 25 and 65 years, complaining of localized or widespread unpleasant adipose tissue storage with inflammatory symptoms of cellulitis, were recruited to participate in this study. After signing the informed consent, they were treated with the ultrasound machine Cavitation (Re-age®). The Cavitation instrument consists of two different handpieces, one concave and one flat, set up according to the area that needs to be treated. The instrument is set by the operator through a touch screen and emits ultrasonic frequencies for a defined time period. Before the beginning of the procedure, the treatment area is covered with a conductive gel.

Study procedure:

- Blood sample pretreatment.
- Treatment with the Cavitation instrument consisting in 20 minutes exposure to a pulsed ultrasound power ranging from 60-90%.
- Blood specimens collection
- The procedure is repeated after 48 hours.

This protocol has been repeated once a week for 4 weeks. Routinary blood analysis including complete blood count, transaminases, blood glucose, blood urea nitrogen, creatinine, uric acid, electrophoresis, total cholesterol, HDL, triglycerides and urine analysis, has been performed. The effectiveness of the Cavitation instrument has been also evaluated by measuring the area treated with ultrasound, and evaluating its reduction in terms of volume or by detecting the linear variation of the treated fat accumulation (lipoma).

Fig.1 Evidence from lipoplasty clinical trials

Fig. 2 Cavitation instrument (Re-Age®).

Fig.3 a) Lipoma of the neck; b) Ultrasonic treatment of lipoma; c) Hip Treatment with ultrasounds; d) A selection of areas to be treated and conductive gel application.

STATISTICAL ANALYSIS

Statistical analyses were performed using Prism (v5.01; UK). The data concerning the total cholesterol, HDL cholesterol and tryglicerides, measured for each patient individually, before and after the procedure, were compared using a paired t-test. No significant difference was observed for each parameter.

RESULTS

The data concerning the lipid metabolism, i.e. total cholesterol, HDL cholesterol and triglycerides were collected before and after the surgical procedure. We observed no significant difference between the HDL cholesterol, total cholesterol and tryglicerides blood concentration before and after the ultrasound lipoplasty. As to the safety, no treatment related side effects have been detected, except in cases where the transducer was held on the skin, perpendicularly to the bone planes within the adipose tissue layer, inducing a painful and annoying tendon-bone resonance of ultrasound waves. The patients were satisfied with the effectiveness of treatment in terms of fat tissue bulging reduction and inflammatory symptoms (cellulitis) improvement.

Tab.1 Descriptive statistics for the ante & post intervention total cholesterol, HDL cholesterol and tryglicerides.

Fig. 4 Comparison between total cholesterol, HDL cholesterol and tryglicerides concentration in blood before and after ultrasound lipoplasty. No significant reduction in all the analyzed parameters was observed after the surgical procedure.

CONCLUSIONS

On the basis of our investigation, the cavitation treatment of lipomatosis and cellulitis, with external ultrasound beam on healthy individuals, is safe and uneventful. Specifically no significant variation of liver function and blood lipids, either in blood or in urine, has been observed before and after each session of fat cell lysis. This fact means that no systemic spread of fat molecules, released from the intracellular storage, was carried in the serum or engulfed liver sinusoids, impairing the liver function. The moderate reduction of blood cholesterol, after treatment cycles, is supposed not to be due directly to the UAL procedure, but to some changes in the patients' lifestyle induced by the improvement of self-image and by the doctors' advice.

DISCUSSION

Wound healing studies indicate that the three overlapping phases into which tissue repair is conventionally divided, namely inflammation, proliferation, and remodelling, can be stimulated by the ultrasonic therapy. It has also been shown that an early intervention with ultrasound, following injury reduces local edema and results in an early release of wound factors [23]. It is known that ultrasounds can interact with biological tissues through thermal, mechanical, or cavitational mechanism. Especially the latter creates intracellular bubbles on which an oscillation or expansion is imprinted until the outbreak of the containing cell membranes releasing mechanical energy, that is the physical end-point of the biological changes is observed. By focusing the ultrasonic beam it is therefore possible to obtain a very selective destruction of adipose tissue at a well-defined depth of the integument layer. While the low energy of the ultrasound beam can be used as sonophoresis, sonoporation, gene therapy and strengthening of the bone framework, the high-intensity

focused ultrasound instead, mainly produces mechanical waves, also used in the extracorporeal lithotripsy. These waves, instead of heating the temperature gradually and at moderate levels with beneficial effects of hyperaemia of the microcirculation, aside from a mechanical shock, induce an instantaneous thermal shock with cell necrosis and temperatures above 56 °C. Applications of focused ultrasound in the clinical environment look very selective, with no damage to the skin, no systemic toxicity from circulating products of lipid metabolism due to acute degradation of adipose tissue [24]. Although the indications for the use of these tools are primarily restricted to the aesthetic medical field, the ability to shape the subcutaneous fat also involves the areas of rehabilitation and functional recovery of the body. The proven safety of focused ultrasound on circulation and microcirculation, makes the unit suitable and effective also in hypostatic pathology with adipo-lymphoedema of the lower limbs, and treatment of adolescent pseudoginecomastia, with obvious psichological benefits, [25] reashaping the pectoralis surface without invasive procedures. Another successful potential use is the lipomatosis or single lipomas, namely in areas such as neck and supraclavicular spaces, where knife surgery is at high risk of damaging neurovascular bundles. The focused ultrasound operative method is in fact at the very beginning but it will certainly expand gradually to emerging areas of broad clinical interest.

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