Review Article

Effectiveness of Cryolipolysis in Body Contouring and Fat Reduction: A Systematic Review and Meta-analysis

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ABSTRACT

Background: Cryolipolysis has emerged as a promising, non-invasive body contouring technique that employs controlled cooling to selectively eliminate adipocytes without damaging surrounding skin or tissues. As global demand rises for non-surgical aesthetic treatments, cryolipolysis offers an appealing alternative to traditional liposuction for individuals seeking fat reduction with minimal recovery time and fewer complications.

Methods: Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a comprehensive search of PubMed, Scopus, and Web of Science was conducted up to November 2024. Studies included were randomized controlled trials and prospective cohort studies evaluating the outcomes of cryolipolysis on body contouring. Statistical analysis was performed using Review Manager 5.4 software, calculating mean differences (MD) and 95% confidence intervals (CI).

Results: The use of cryolipolysis was associated with decreased BMI showing MD= -1.71 (95%CI: -2.6, -0.82, P=0.0002). However, no significant difference was observed regarding weight with MD= -1.81 (95%CI: -3.93, 0.31, *P*=0.09). The use of cryolipolysis was also associated with decreased circumference of different body parts with MD= -3.45 (95%CI: -5.55, -1.34, *P*=0.001), and I2=92%, *P*<0.00001 and decreased fat thickness with MD= -3.56 (95CI: -4.63, -2.48, *P*<0.00001), and I2=95%, P<0.00001.

Conclusion: Cryolipolysis is effective in reducing BMI, local circumference, and fat thickness, confirming its utility for non-invasive body contouring. However, it does not significantly affect overall weight. The benefits are more pronounced in short-term follow-up and vary by body region. Further long-term and comparative studies are recommended.

KEYWORDS
Cryolipolysis; Body Contouring; Non-Invasive Fat Reduction; BMI; Circumference; Fat Thickness

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INTRODUCTION

Localized adiposity refers to the abnormal accumulation of fat in typical anatomical regions, constituting a significant cosmetic concern [1]. Body contouring represents a significant medical aesthetic need globally. The pursuit of an ideal body form has spurred the swift development of novel, non-invasive, comfortable, and safe procedures that need minimal recovery time [2, 3]. Despite the effectiveness of liposuction in fat reduction and body reshaping, there remains a persistent demand for non-surgical and non-invasive alternatives that may offer comparable efficacy. The majority of patients decline surgery and invasive interventions, opting instead for non-invasive therapies that progressively achieve fat reduction and enhance texture and body contouring [3, 4].

Multiple therapies, such as ultrasound, radiofrequency, and mesotherapy, have been formulated to induce adipocyte death [5-7]. Each method utilizes a distinct mechanism to induce apoptosis or necrosis in the targeted adipocytes. In recent years, a novel approach for the noninvasive treatment of localized adiposity by cold-induced panniculitis, known as cryolipolysis, has emerged.

Cryolipolysis has evolved as a novel non-invasive body contouring technique that use controlled cooling to selectively eliminate adipocytes without harming the skin and other tissues [5]. The cooling applicator is utilized on the targeted region to dissipate heat at a specified rate (mW/cm^2) until a designated temperature is attained (e.g., −7 to 1 °C) for a predetermined duration [6]. Following a solitary treatment, adipocyte apoptosis and an elevation in the collagen to adipose tissue ratio occur through lobular panniculitis and thickening of the interlobular fibrous septae over several months, leading to a decrease in the thickness of the subcutaneous fat layer [7]. A study involving animals showed a 30–50% decrease in the thickness of the subcutaneous fat layer without altering serum lipid levels [8]. Prior clinical investigations demonstrated the safety and efficacy of cryolipolysis for the removal of localized subcutaneous fat in the abdomen [9] and flanks [10]. The treatment obtained permission from the US Food and Drug Administration (FDA) for fat removal in the flanks, belly, and thighs in 2010, 2012, and 2014, respectively [11].

The current systematic review and meta-analysis aimed to investigate the efficacy of cryolipolysis in contouring of different body parts.

METHODS

Searching databases

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [12], we conducted a search of PubMed, Scopus, and Web of Science from inception until November 2024 for articles meeting our eligibility criteria for inclusion in the systematic review and meta-analysis examining the use of cryolipolysis in body contouring. The search technique employed the Medical Subject Headings (MeSH) terms of two main keywords: was: "Cryolipolysis" AND "Contouring".

The systematic review was registered on prospero with registration ID: CRD42024507038.

Screening

The resulting articles from the searching process were uploaded to Rayyan software [13]. After which, we conducted the process of title, and abstract screening followed by full-text screening. These processes were conducted by four authors who worked independently, and any disagreements were settled by consensus or referred to a senior author if persisted. We incorporated papers featuring patients who underwent cryolipolysis for contouring and compared the different outcomes with baseline measurements. We incorporated randomized controlled trials (RCTs) and observational prospective cohort studies. We excluded case reports, reviews, and studies investigating different contouring techniques.

Data extraction

This procedure was executed by four authors individually utilizing a pre-prepared Microsoft Excel spreadsheet. Disagreements were settled by consensus, and if they continued, the senior author intervened to resolve them. We retrieved the baseline data from the included studies, encompassing design, sample size, follow-up age, anatomical regions, and gender of the individuals. Furthermore, the outcome data were gathered for the meta-analysis, encompassing baseline and post-treatment values of weight, body mass index (BMI), circumferences of the abdomen, thighs, arms, or other body regions subjected to cryolipolysis, as well as fat thickness or skinfolds.

Quality and risk of bias assessment

Two independent researchers conducted quality assessment and risk of bias assessment, and any disagreements were resolved by consensus or by the senior author. We used the Cochrane risk-of-bias tool (Rob-2) [14], which consists of five domains each with a set of questions. The results are then combined through a diagram to determine one of three levels of bias: low risk, some concerns, or high risk. We evaluated the quality of the included non-randomized studies using methodological index for non-randomized studies (MINORS) tool. The items received a score of 0 if unreported, 1 if reported but inadequate, and 2 if reported and adequate. A score of 0-5 is deemed very low quality, 5-8 is classified as low quality, 8-11 is regarded as moderate quality, and a score beyond 11 is categorized as excellent quality [15].

Statistical analysis

All phases of statistical analysis were performed utilizing Review Manager version 5.4 software [16]. We utilized the mean difference (MD) to compare continuous variables. We employed the random effects model for heterogeneous outcomes and the fixed effects model for homogeneous outcomes, with a confidence interval (CI) of 95% and a *P*-value of 0.05. The heterogeneity was assessed using I2 and a *P*-value of 0.05. Subgroup analysis was also performed to account for the present heterogeneity in some outcomes.

RESULTS

Screening

The search yielded 245 articles, including 131 duplicates. We performed title and abstract screening following the elimination of duplicates from the remaining 114 articles. Subsequently, full-text screening was performed on 16 papers, resulting in the inclusion of 10 studies in the systematic review and meta-analysis [17-26] (Figure 1).

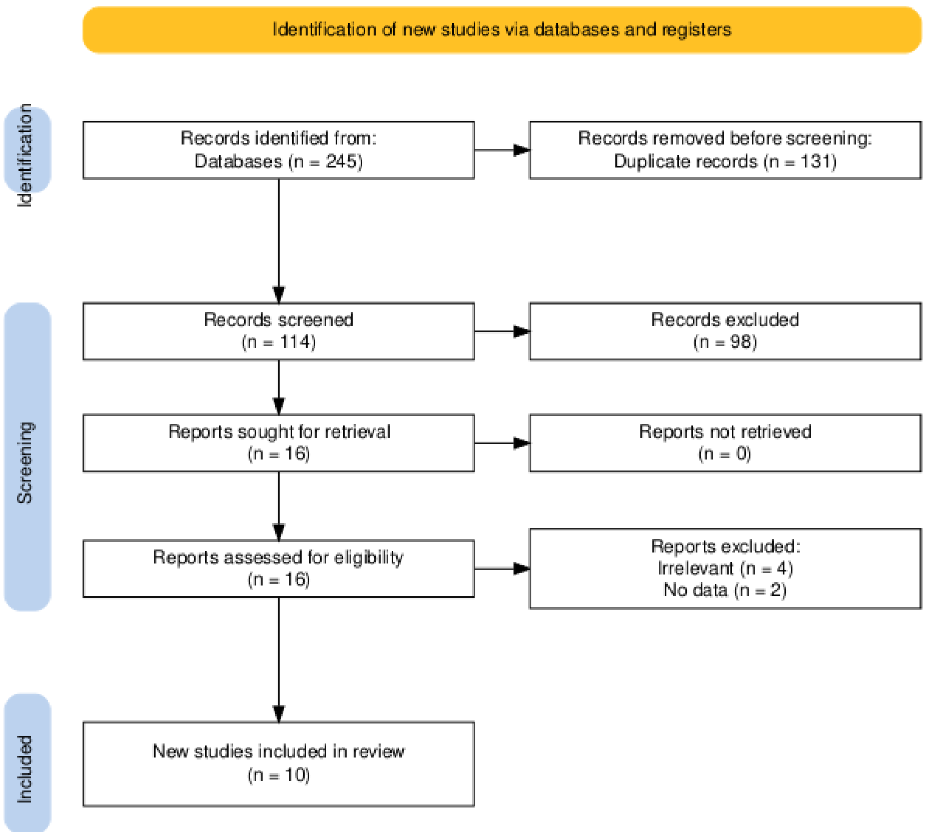

Figure 1: PRISMA flow diagram of searching and screening

Baseline characteristics

We included 10 articles investigating the effects of cryolipolysis in the contouring of different body parts. Among the included studies, the design was prospective cohort in six of them, two RCTs, non-randomize clinical trial, and a prospective, multicenter, single arm clinical trial. The total sample size was 285 patients, with mean age ranging from 14 to 51.6 years old, and the majority of them were females. Most of the studies were conducted on the abdomen, while other studies included other body parts such as saddlebags, flanks, arms, and inner thighs. The follow-up period ranged from 2 to 6 months (Table 1).

Quality and risk of bias assessment

According to MINORS, two studies were of moderate quality, and six were of excellent quality. (Table 2) According to Rob-2, the two RCTs were deemed to have low risk of bias (Figure 2).

Statistical analysis

The use of cryolipolysis was associated with decreased BMI showing MD= -1.71 (95%CI: -2.6, -0.82, P=0.0002), and I^2=81%, P<0.0001. However, no significant difference was observed regarding weight with MD= -1.81 (95%CI: -3.93, 0.31, P=0.09) (Figures 3 and 4).
The use of cryolipolysis was also associated with decreased circumference of different body parts with MD= -3.45 (95%CI: -5.55, -1.34, P=0.001), and I^2=92%, P<0.00001 and decreased fat thickness with MD= -3.56 (95CI: -4.63, -2.48, P<0.00001), and I^2=95%, P<0.00001 (Figures 5 and 6).
After subgroup analysis of different outcomes including BMI (subgroup by follow-up period), circumference (subgroup by body parts on which

Table 1: Baseline characteristics of the included studies

Study ID	Design	Sample size	Age, mean (SD)	Female, n (%)	Body parts	Follow-up
Choi (21)	A prospective, multicenter, single arm clinical trial	25	39.1 (11.6)	20 (80)	Abdomen	4 months
Coiante (20)	Prospective cohort	54	35 (13)	54 (100)	Abdomen	6 months
Eldesoky (17)	RCT	20	14 (70)	33.3 (5.33)	Abdomen	2 months
Khedmatgozar (22)	Non-randomized clinical trial	30	18-65	30 (100)	Abdomen	2 months
Loap (25)	Prospective cohort	30	36.72 (7)	30 (100)	Abdomen and Saddlebags	3 months
McKeown and Payne (24)	Prospective cohort	28	51.6 (9)	26 (93)	All body parts	3 months
Mostafa and Elshafey (23)	RCT	15	14 (1.9)	9 (60)	Abdomen	2 months
Savacini (18)	Prospective cohort	21	34 (9)	18 (85.7)	Abdomen and flanks	2 months
Wanitphakdeedecha (19)	Prospective cohort	20	>20	20 (100)	Arms and inner thigh	6 months
Zelickson (26)	Prospective cohort	42	48.1 (6.3)	42 (100)	Inner Thigh	4 months

RCT: randomized controlled trial, SD: standard deviation

Table 2: MINORS scale for quality assessment of the included studies

Study	I	II	III	IV	V	VI	VII	VIII	Total
Choi (21)	2	2	1	2	0	2	2	0	11
Coiante (20)	2	2	2	2	0	2	1	0	11
Khedmatgozar (22)	2	2	1	2	0	2	2	1	12
Loap (25)	2	2	2	2	1	1	2	0	12
McKeown and Payne (24)	2	1	1	2	0	2	2	0	10
Savacini (18)	2	1	2	2	0	2	2	0	11
Wanitphakdeedecha (19)	2	2	2	2	0	1	2	0	11
Zelickson (26)	2	2	2	2	0	1	2	0	11

Numbers I-VIII in the heading domains comprise: I, a clearly articulated objective; II, inclusion of consecutive patients; III, prospective data collection; IV, endpoints pertinent to the study's objective; V, impartial evaluation of the study endpoint; VI, follow-up duration suitable to the study's aim; VII, follow-up loss of less than 5%; VIII, prospective determination of the study size

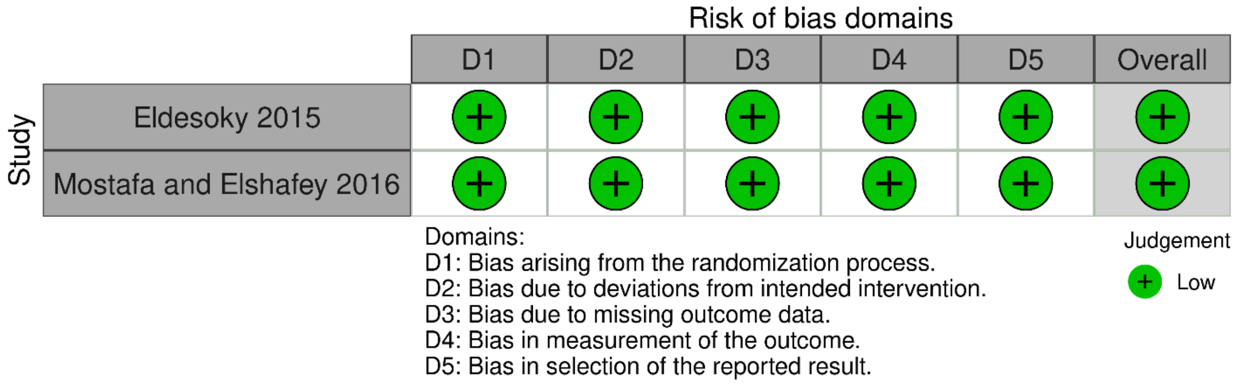

Figure 2: Risk of bias assessment of RCTs using Rob-2

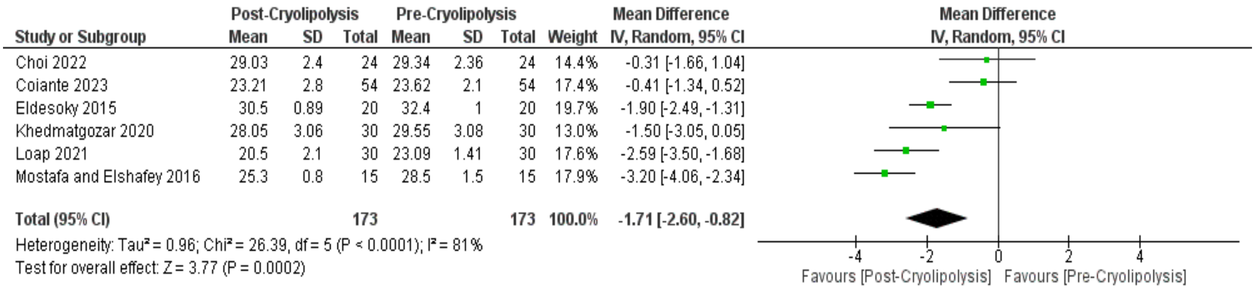

Figure 3: Effect of cryolipolysis on BMI

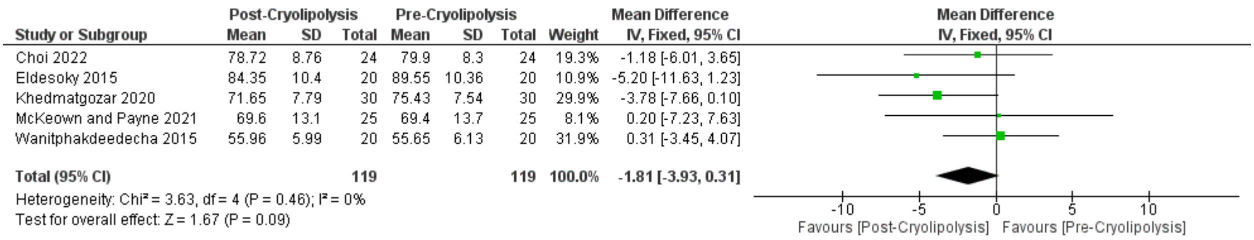

Figure 4: Effect of cryolipolysis on weight

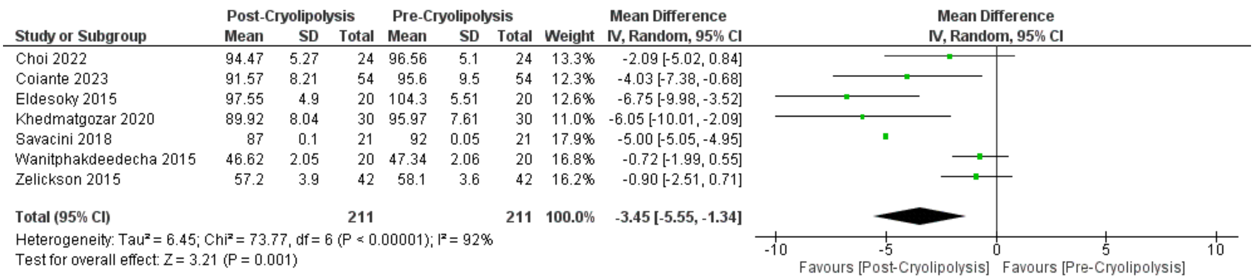

Figure 5: Effect of cryolipolysis on circumference of different body parts

cryolipolysis was applied), and fat thickness (subgroup by measurement method), the heterogeneity was resolved.

In the BMI, significant effect was observed in the follow-up period of less than or equal 3 months, however, after 3 months, the effect was non-significant. Also, cryolipolysis showed significant effect on circumference of abdomen but non-significant effect on that of arms and inner thighs. Fat thickness measured by ultrasound or percentage was significantly reduced after cryolipolysis (Figures 7-9).

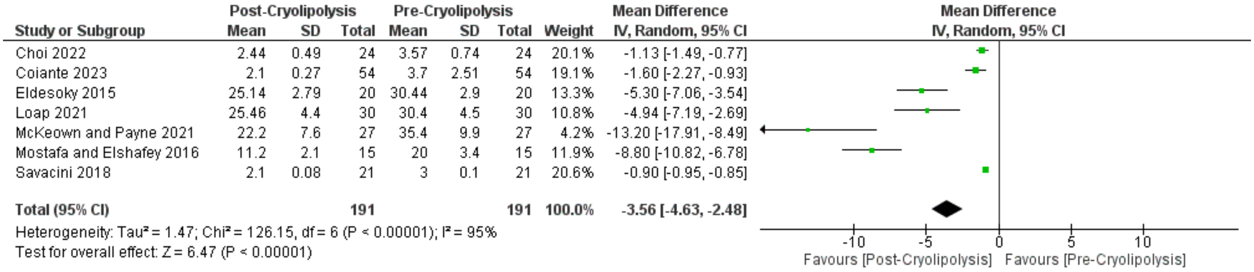

Figure 6: Effect of cryolipolysis on fat thickness

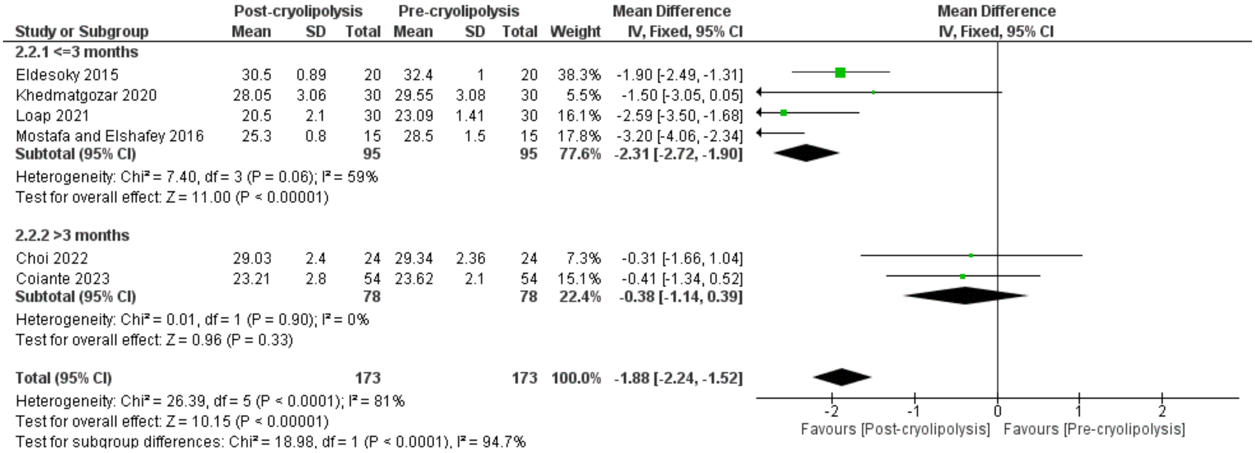

Figure 7: Effect of cryolipolysis on BMI subgrouped by follow-up period

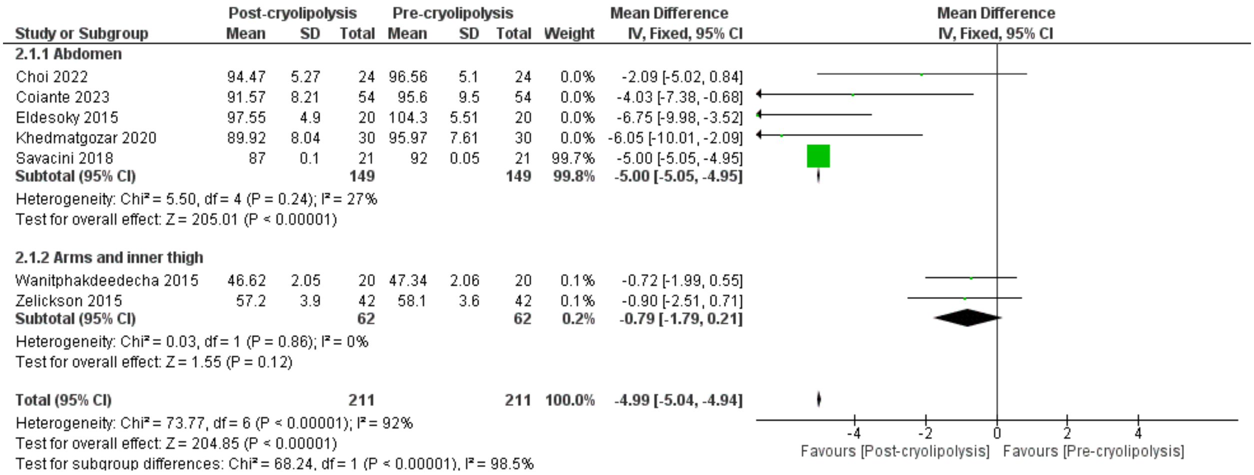

Figure 8: Effect of cryolipolysis on circumference of different body parts subgrouped by parts of cryolipolysis

DISCUSSION

The current systematic review and meta-analysis showed the efficacy of cryolipolysis in the improvement of body contouring in obese patients. This was investigated among different body parts including the abdomen, flank, arms, and inner thighs. Cryolipolysis was observed to decrease BMI, circumference of the measured body part, and the fat thickness or skinfold parts. On the other hand, no significant difference was observed on the weight of the included participants. Due to the observed heterogeneity, we conducted subgroup analysis based on follow-up period in BMI and found that the effect was evident when the follow-up was 3 or less than 3 months, but no effect was observed

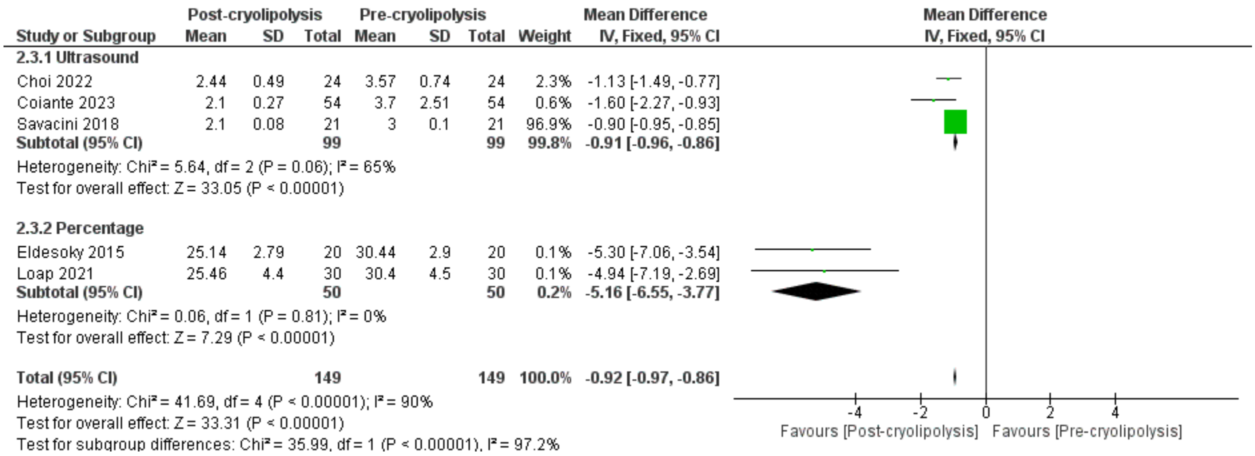

Figure 9: Effect of cryolipolysis on fat thickness subgrouped by measurement method

after more than 3 months. Subgroup analysis of circumference showed the effect was significant on the abdomen, but no effect was observed on the arms and inner thighs after cryolipolysis treatment. Fat thickness was significantly reduced when it was measured by ultrasound or percentage of fats.

Obesity has emerged as a significant public health issue, with projections indicating a prevalence of 50% among adults in the United States by 2030 [27]. The increasing prevalence of obesity is not confined to developed nations but extends to emerging countries as well. Currently, the elevated average BMI historically observed in rich nations is being supplanted by that of less developed countries. Mercedes and Monika have indicated that nations with the highest average BMIs are primarily situated in Latin America, the Middle East, and North Africa, which exhibit the greatest global incidence of overweight individuals [28]. A cross-sectional study involving 3,799 individuals in Iran indicated that the prevalence of overweight and obesity was around 40.6% and 26.3%, respectively [29]. The rising incidence of overweight may be linked to lifestyle alterations, including insufficient physical activity, eating practices, and sedentary behaviors in these countries [27, 30]. In addition to educational initiatives and the implementation of incentives within socioeconomic situations, contemporary scientific evidence may prove advantageous to these individuals. Recently, non-invasive methods for adipose tissue reduction and body shape alteration are being increasingly employed [31]. Nonetheless, the health ramifications of these operations are not as well understood as those of invasive surgical interventions. These non-invasive techniques encompass cryolipolysis, ultrasound, radiofrequency, low-level light laser, and mechanical suction, which are more time-efficient and devoid of the adverse effects associated with invasive surgery [32]; nevertheless, the clinical advantages require further clarification. Despite the introduction of several innovative technologies and techniques, cryolipolysis remains the most prevalent operation utilized in the US for this purpose [33].

Cryolipolysis is a non-invasive technique for the reduction of subcutaneous adipose tissue. Initially designed for the cooling of medical devices, it is recognized for its efficacy in alleviating pain, reducing muscular spasms, and enhancing local circulation. It delivers regulated cooling energy to the targeted adipose tissue, effectively diminishing subcutaneous fat at the application location while preserving adjacent tissues [7, 34]. The mechanism of cryolipolysis was elucidated by Dr. Dieter Manstein and Dr. R. Rox Anderson, who demonstrated that exposure of subcutaneous adipose tissue to low temperatures induces local subcutaneous panniculitis, resulting in a reduction of fat tissue inside the affected lesions [5, 34]. Based on this idea, numerous investigations on subcutaneous fat reduction have been undertaken, leading to the development of cryolipolysis technology.

Numerous prior research have validated the effectiveness and safety of substantial subcutaneous fat loss in different body regions by cryolipolysis. Kilmer et al. verified an average reduction of 20% (2.0 mm) in subcutaneous fat behind the chin as observed through ultrasonography. The treatment parameters of this trial included two sessions, sixweek intervals, a treatment duration of 60 minutes, and a chilling temperature of -10 degrees Celsius [35]. Furthermore, other research findings corroborated the efficacy of submental cryolipolysis as assessed using ultrasonography or MRI [36, 37]. The rate of fat loss in flank and abdominal subcutaneous adipose tissue ranged from 20% to 25% according to efficacy evaluations utilizing ultrasonography, with the effects persisting for up to 6 months [38, 39]. The application of cryolipolysis to the thighs demonstrated a reduction of subcutaneous fat by 2.6 to 3.3 mm as validated by ultrasonography [40, 41]. Carruthers et al. [42] achieved a 3.2-mm reduction in the subcutaneous fat layer following the application of cryolipolysis to the upper arms. Park et al. [43] demonstrated that cryolipolysis applied to 10 male subjects with pseudogynecomastia resulted in a considerable reduction of breast adipose tissue post-treatment compared to pre-treatment levels.

Following cryolipolysis, necrosis transpires in the targeted adipose tissue, resulting in the destruction of fat tissue. The damaged adipocytes trigger a wound-healing response that activates macrophages, leading to an inflammatory reaction. Macrophages diminish adipose tissue by metabolizing lipids and cellular detritus from adipocytes in the liver via the lymphatic system 14 to 30 days post-procedure. Consequently, this process may result in fat cell remnants, including lipids and cellular debris, influencing blood composition and liver function. Klein et al. established that there were no significant variations in blood lipid levels and liver function test outcomes pre- and post-cryolipolysis [5, 7, 44].

Complications of cryolipolysis include post-procedural dyschromia, characterized by hypopigmentation or hyperpigmentation [45-48]. Dyschromia predominantly manifested in patients with a darker skin phototype (Fitzpatrick type III/IV) and resolved after several months [49]. Burns and hemosiderin deposits in the dermis are responsible for hyperpigmentation [50-55]. The implementation of an interposed layer may reduce the probability of this difficulty. Prior to performing cryolipolysis, patients must be apprised of the potential consequences, including hyperpigmentation or erythema, which typically manifest approximately 15 hours post-procedure. The likelihood of skin lesions is negligible in comparison to liposuction, which consistently results in considerable post-operative bruising and discomfort because of too thin subcutaneous hematomas. Patients must be informed and provide consent regarding the danger of paradoxical adipose hyperplasia, which occurs in one in 20,000 treated individuals (an incidence rate of 0.0051%). Nonetheless, the long-term danger of acquiring skin lesions remains uncertain [56]. Cryolipolysis is contraindicated in individuals with Raynaud's Syndrome, cryoglobulinemia, cold urticaria, or severe varicose veins exacerbated by low temperatures.

Nonetheless, we wish to underscore that cryolipolysis cannot serve as a substitute for a comprehensive abdominoplasty when indicated. Moreover, as of yet, the actual risk of developing skin lesions (permanent hyperpigmentation or erythema) in the long run remains unknown. It is imperative to highlight that, when abdominoplasty is indicated, this procedure should be avoided, as it is well-established that abdominoplasty becomes significantly more challenging following this type of treatment due to the degree of post-treatment fibrosis [48]. The distinction between cryolipolysis and alternative techniques, such as high-intensity focused ultrasound, primarily lies in the significantly lower cost each session, the lack of required consumables, and the completely painless experience throughout the procedure. Indeed, a side effect of cold is the local anesthetic it induces; thus, the primary distinction from high-intensity focused ultrasound is that patients undergoing cryolipolysis report no pain or discomfort during the procedure.

The current study is limited by the observational and non-randomized design of most of the included studies and absence of control or placebo group as a comparator. Therefore, future RCTs are required to include a comparator group and the specification of different body parts is also recommended in future trials.

CONCLUSION

The current comprehensive review and meta-analysis revealed the efficacy of cryolipolysis in improving body contouring in obese persons. This evaluation included multiple anatomical areas, such as the abdomen, flanks, arms, and inner thighs. Cryolipolysis led to decreases in BMI, circumferences of the targeted regions, and fat thickness or skinfold measures. No substantial alteration in participants' weight was observed. A subgroup analysis of BMI was conducted depending on follow-up time, demonstrating a significant effect within three months or less, with no effect identified beyond that period. The subgroup analysis for circumference revealed a considerable impact on the belly, but no effect was observed on the arms and inner thighs following cryolipolysis treatment. Fat thickness demonstrated a notable decrease when evaluated using ultrasonography or fat percentage assessments.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interests.

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