OPEN FORUM

Body Contouring

Cryolipolysis of the Arms and Inner Thighs Shows Similar Treatment Outcomes in Chinese Individuals Compared to White Individuals Treated in a Prior Study: The XinCOOL Study

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Abstract

Background: Studies of predominantly White participants show that cryolipolysis reduces subcutaneous fat in the arms and inner thighs, but none have specifically tested for similar outcomes in participants of Chinese descent.

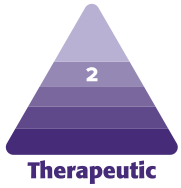
Objectives: This study assessed the safety and effectiveness of cryolipolysis treatment for noninvasive subcutaneous fat reduction of arms and inner thighs in participants of Chinese descent to assess equivalence to results seen in a prior study of White participants.

Methods: Replicating a similar study design, participants of first- or second-generation Chinese descent underwent cryolipolysis treatment of arms and/or inner thighs. Effectiveness was assessed using pretreatment and posttreatment photographic review by blinded, independent experts, investigator-assessed caliper measurements, and participant satisfaction 12 weeks posttreatment. Safety was assessed throughout.

Results: Among 50 enrolled participants, 48 completed the study. The majority of participants (97.9%) were female, with a mean age of 36.0 years and mean BMI of 24.16 kg/m^2 (range 19.3-29.9 kg/m^2). Overall, 76.4% and 70.0% of pretreatment photographs of arms and pairs of inner thighs, respectively, were correctly identified by at least 2 of 3 reviewers. The mean reduction from baseline in caliper-measured fat thickness was 6.5 mm for arms and 6.6 mm for inner thighs, and the majority of participants (>60%) were satisfied with the treatment. No adverse events were reported.

Conclusions: Cryolipolysis is a well-tolerated, effective means of noninvasive fat reduction of arms and inner thighs in participants of Chinese descent. The results from this study show similar effectiveness and safety in Chinese participants compared with White participants treated in a prior study.

Level of Evidence: 2



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Cryolipolysis, using a CoolSculpting System device (Allergan Aesthetics, an AbbVie company, Pleasanton, CA), is the process by which controlled cooling extracts heat from the subcutaneous tissue to induce selective adipocyte death via apoptosis as a noninvasive treatment for the reduction of unwanted subcutaneous fat. Historical observations of cold-induced panniculitis in children and infants led to our current understanding of adipose tissue being relatively more sensitive to cold than other tissues (ie, skin, muscle, nerves); the proposed mechanism of action for cryolipolysis relies on this differential sensitivity and allows for noninvasive targeting of subcutaneous adipose tissue to achieve aesthetic goals without affecting surrounding tissue.[1-4] Numerous studies have demonstrated the safety and effectiveness of cryolipolysis for noninvasive fat reduction, most commonly of the abdomen, flanks, upper arms, submental/submandibular areas, and thighs.[5-16]

Cryolipolysis as a treatment modality has been cleared in more than 70 countries, and as of April 2023, over 17 million CoolSculpting treatment cycles have been sold globally,[17] yet few clinical studies have been conducted outside of the United States, with most of the participants being White.[8,11-16,18] The interest in aesthetic treatments such as cryolipolysis is relevant for clinicians in all countries for patients of different ethnicities; therefore, it is important to understand the effectiveness of cryolipolysis across different ethnicities and skin types to make evidence-based treatment recommendations. Indeed, previous studies have reported ethnic differences in adiposity, with imaging studies reporting increased adipose deposits in the deep subcutaneous adipose tissue below the stromal fascia in Native American and South Asian patients, and fewer subcutaneous fat deposits in Chinese patients compared with White patients, which may impact cryolipolysis treatment outcomes.[19-21] One study reported on the use of cryolipolysis for the arms and inner thighs of 20 Thai female participants,[22] with a further retrospective study in Korean participants across a range of body areas reporting a mean (standard deviation [SD]) reduction in caliper-measured fat thickness of 5.1 mm (2.0) and 6.1 mm (1.2) in the upper arms and inner thighs, respectively.[11] To date, only 2 known studies have examined cryolipolysis in Chinese participants; however, no studies of noninvasive fat reduction of arms and inner thighs have been conducted specifically in participants of Chinese descent.[15,18] The purpose of this study was to assess the effectiveness and safety of cryolipolysis in patients of Chinese descent and compare outcomes to those seen in a similar study design assessing predominantly White participants.[14]

This study aims to show similarities in the effectiveness or safety of cryolipolysis for noninvasive fat reduction of the arms and inner thighs in first- or second-generation Chinese participants, compared to a prior study in White participants using a similar study design.[14]

METHODS

Study Design/Schedule

This was a multicenter, prospective, nonrandomized, interventional, cohort study conducted at 3 Canadian sites between October 2019 and February 2020 (clinicaltrials.gov NCT04142450). The protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by Advarra, an independent review board (Aurora, Ontario, Canada). Informed written consent was obtained from all participants at the screening visit prior to any assessments. The study comprised 5 visits: screening, a single treatment visit, and follow-up visits at 1-, 4-, and 12-weeks posttreatment. Effectiveness assessments were conducted at the 12-week follow-up visit. Safety assessments were completed at the treatment visit and all follow-up visits. The timing of follow-ups was based on the prior study,[14] as well as on prior work showing that decreased fat volume and thickening of interlobular septae occur 2 to 3 months after cryolipolysis treatment.[23,24]

The sample size calculation was based on the primary endpoint (the correct identification rate of pretreatment arm photographs with success being defined as ≥75%). A prior study of cryolipolysis of the arms of predominantly White participants with the same primary endpoint and success criteria demonstrated an 83% correct identification rate.[14] The sample size was therefore calculated using 75% as the lower bound of the 95% CI; the half-width of the 95% CI was 8%. Based on these assumptions and estimates that only 80% of all participants would have both arms and/or inner thighs treated and a 10% attrition rate, target enrollment was 42 participants, allowing for 38 evaluable participants to ensure 60 evaluable arms. Because of the limited sample size, there were no predetermined success criteria for the correct identification of pretreatment inner thigh photographs.

Participants

Eligible participants were healthy male and female adults (≥18 years; BMI 18.5-30 kg/m^2) of first- or second-generation non-mixed Chinese descent with clearly visible and palpable fat on the lower aspect of their arms above the elbows and/or inner thighs and subcutaneous fat thickness ≥2 cm, as measured by caliper. First-generation participants of Chinese descent were those considered born outside of Canada with 2 Chinese parents, whereas second-generation participants of Chinese descent were those born in Canada with at least 1 parent of Chinese descent who was born outside of Canada.[25] The participants could have no weight fluctuations exceeding 4.5 kg (±5% of body weight) in the preceding month, and they agreed to maintain weight (within 5% of baseline) by not making changes in diet or exercise over the course of the study.

Exclusion criteria included a history of invasive fat reduction procedures or prior surgery or scar tissue on treatment area; known sensitivity to cold or history of cryoglobulinemia, cold urticaria, cold agglutinin disease, or paroxysmal cold hemoglobinuria; clinically significant bleeding disorders or concomitant use of oral/subcutaneous anticoagulants; current pregnancy, planning to become pregnant in the next 3 months, currently lactating, or was lactating within the prior 6 months. Participant data were excluded from primary effectiveness analyses if their weight change was ≥5% of total body weight at the 12-week follow-up visit; however, the participants were to continue the study and complete all assessments.

Treatment

The participants could receive treatment to their arms, inner thighs, or both body areas. Not all participants were suitable for treatment of both body areas, and study recruitment was planned so that a sufficient number of participants were treated so that both body areas could be assessed, regardless of which participants received treatment to arms and/or inner thighs. All treatments were carried out with a cryolipolysis (CoolSculpting, Allergan Aesthetics, an AbbVie company) device commercially available for use in Canada. The single treatment session consisted of up to 2 treatment cycles per arm, targeting the lower aspect of the arm above the elbows, and/or 1 treatment cycle per inner thigh using the commercially available CoolAdvantage and/or CoolAdvantage Petite applicators and appropriate contours. Treatment cycles were 35 min in duration at −11°C and treatment was followed by 2 min of manual massage. If the investigator determined that the proposed surface area of the participants' arms was too large for 1 treatment cycle to achieve the participants' aesthetic goals, a second treatment cycle was administered at the same treatment visit.

Effectiveness Endpoints

The primary effectiveness endpoint was based on a prior study of cryolipolysis treatment of the arms of predominantly White participants[14] and was defined as the correct identification of baseline vs 12-week posttreatment photographs of arms by at least 2 out of 3 blinded, independent reviewers with expertise in dermatology and/or plastic surgery; success was defined as ≥75% correct identification of pretreatment images of the arms. Photographs of treatment areas were taken at baseline and the 12-week follow-up with a standardized setup using Canfield Scientific IntelliStudio with Ranging Lights and Canon SL2 camera. The order in which pretreatment and posttreatment photographs were presented to reviewers was randomized. Each arm was reviewed separately.

Secondary endpoints included correct identification of baseline vs 12-week photographs of the inner thighs by 2 out of 3 reviewers, wherein the thigh photographs were reviewed in pairs (note: both arm and inner thigh photographs were assessed by the same independent, blinded panel of reviewers), caliper-measured changes in subcutaneous fat thickness, participant satisfaction, and safety.

Caliper measurements of the skin layer thickness of the arms and inner thighs were taken from the middle of the fat bulge, with 3 measurements recorded per area. Measurements were collected at baseline and 12 weeks posttreatment by the same staff member who had been provided detailed instructions on completing caliper measurements and was trained by an experienced investigator. In order to minimize variation in measurements, a transparency sheet was also used with reference points for the participant's body landmarks. Participant satisfaction was collected through a written questionnaire specific to each treated body area at the 12-week follow-up. The participants were asked to “rate your overall satisfaction with the fat reduction procedure on the [upper arm/inner thigh]” using a 5-point Likert scale from “very dissatisfied” to “very satisfied.” Satisfaction was defined as responses of “satisfied” or “very satisfied.” The participants were also asked to respond to the question “Would you recommend this fat reduction procedure to a friend?” and could select “yes” or “no.”

Safety Endpoints

Pain scores, including worst pain felt, on a scale from 0 (no pain) to 10 (worst pain imaginable) were collected during the treatment session and at the 1-, 4-, and 12-week follow-ups. Discomfort/pain that resulted in the temporary or permanent cessation of treatment was documented as an adverse event (AE).

Safety was monitored throughout the study by the documentation of AEs and clinical assessment of the treatment site. At each study visit, the investigator or designated study staff would solicit and assess the participants for AEs. Assessment of AEs was accomplished through investigator questioning of the participants, as well as physical examination, if needed. Local treatment effects were also collected as clinical findings and criteria were established to determine whether these clinical findings needed reporting as AEs. Anticipated device effects, including mild-to-moderate swelling, bruising, numbness, tingling, and erythema at the treatment site, were also evaluated and recorded by treating clinicians at the 4- and 12-week follow-up visits. Anticipated effects were not considered AEs unless they were rated as severe, caused disruption to the participants' daily activities, or did not resolve without medical intervention within 12 weeks of treatment.

Statistical Analyses

Demographic and safety data are summarized descriptively. For effectiveness endpoints except for caliper measurements, the number and percentage, along with the 2-sided exact 95% CIs, are provided. For caliper measurements, the descriptive summary at baseline, 12 weeks, change from baseline (CFB) at 12 weeks, and 2-sided 95% CI for CFB are provided. Additional analysis of the dataset included a post hoc Fisher's exact test to determine whether the rate of correct pretreatment photograph identification is equivalent to 75% for the arms and inner thighs, respectively; similarly, the paired *t*-test was used to assess whether the caliper measurements of fat thickness (mm) are significantly reduced at 12 weeks compared with baseline for the arms and inner thighs.

RESULTS

Participants

Disposition

A total of 50 participants were enrolled; 49 participants were treated (the safety population), and 48 participants completed the study having attended the final follow-up visit 12 weeks after treatment and included in the per protocol population (PPP) for effectiveness analyses. One participant was a screen failure after enrollment and 1 participant was lost to follow-up after receiving treatment. More participants than anticipated chose to have only the inner thighs treated; additional participants were enrolled to ensure that the target of 60 evaluable arms for the primary endpoint was met. In the PPP, 28 participants received treatment of arms and inner thighs, 8 participants had only their arms treated, and 12 participants had only their inner thighs treated.

Demographics and Baseline Characteristics

The mean age of the participants in the PPP was 36.0 years (range, 19-63 years), and 47 of 48 participants were female (97.9%; Table 1). The percentage of first- and second-generation Chinese participants was 45.8% and 54.2%, respectively. The mean weight of the participants was 61.96 kg (range, 45.0-84.7 kg), the mean BMI for treated participants was 24.16 kg/m^2, and the majority of participants (60.4%) had a BMI <25 kg/m^2.

Table 1. Demographics and Baseline Characteristics

Parameter	Safety population ($n = 49$)	Per protocol population ($n = 48$)
Mean age, years (range)	36.1 (19-63)	36.0 (19-63)
Sex, *n* (%)		
Female	48 (98.0)	47 (97.9)
Male	1 (2.0)	1 (2.1)
Race, *n* (%)		
First-generation Chinese	22 (44.9)	22 (45.8)
Second-generation Chinese	27 (55.1)	26 (54.2)
Mean weight, kg (range)	61.68 (45.0-84.7)	61.96 (45.0-84.7)
Mean BMI, kg/m^2 (range)	24.07 (19.3-29.9)	24.16 (19.3-29.9)
BMI group, *n* (%)		
18.5-25.0 kg/m^2	30 (61.2)	29 (60.4)
25.0-30.0 kg/m^2	19 (38.8)	19 (39.6)
Fitzpatrick skin type, *n* (%)		
III	22 (44.9)	21 (43.8)
IV	27 (55.1)	27 (56.3)

Safety population includes all treated participants. PPP includes all treated participants followed for 12 weeks and with no weight change ≥5% of body weight.

Effectiveness Assessments

Independent Photograph Review

A total of 72 arms from 36 participants were treated and evaluated for the primary effectiveness endpoint. Nineteen participants had a second treatment cycle to each arm the same day. The percentage of correct identification of pretreatment arm photographs was 76.4% (95% CI, 64.9%-85.6%; Table 2), which met the ≥75% success criteria. Photographs of the inner thighs of 40 participants were assessed in pairs. The percentage of correct identification of pretreatment inner thigh photographs was 70.0% (95% CI, 53.5%-83.4%; Table 2). The correct identification rate of the pretreatment images of the arms and inner thighs was not statistically different from 75%, as determined by post hoc analysis.

Caliper Measurements

Caliper measurements of double-layer skinfold (ie, 2 layers of subcutaneous fat) thickness were significantly decreased from baseline 12 weeks after cryolipolysis for both arms ($P < .0001$) and inner thighs ($P < .0001$). The mean (SD) reduction from baseline in fat layer thickness 12 weeks after treatment was 6.5 (4.57) mm and 6.6 (10.62) mm for the arms and inner thighs, respectively (Figure 1).

Participant-Reported Outcomes

At the 12-week follow-up, 61.1% and 65.0% of the participants were satisfied with the fat reduction procedure of the arms or inner thighs, respectively, as defined by the responses of “satisfied” or “very satisfied”; 27.8% and 25.0%

Table 2. Independent Photo Review Baseline and 12-Week Photographs

	Per protocol participants ($n = 48$ total)
Number of treated areas, *n*	
Arms (assessed individually)	72
Inner thighs (assessed in pairs)	40
Correct identification of 12-week and baseline photographs	
Arms, *n* (%)	55 (76.4)
95% CI	64.9-85.6
Inner thighs, *n* (%)	28 (70.0)
95% CI	53.5-83.4

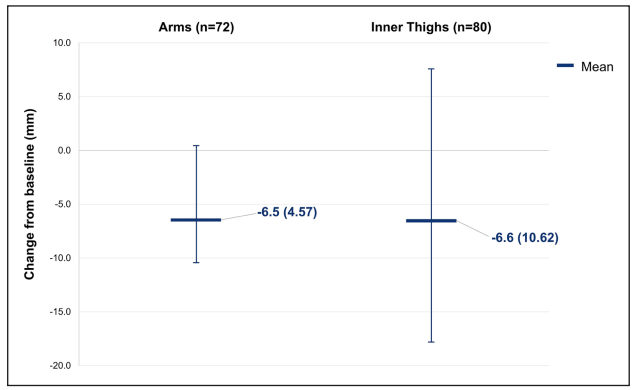

Figure 1. Change from baseline in caliper-measured fat thickness. Mean (SD) change from baseline in subcutaneous fat thickness, as measured by caliper at the 12-week follow-up visit.

of the participants reported being "neither satisfied nor dissatisfied" with the treatment of the arms and inner thighs, respectively, and only ≤10% of the participants reported being "dissatisfied" with the fat reduction procedure of the arms or inner thighs (Figure 2A). The majority of the participants (arms: 72.2%, 26/36; inner thighs: 77.5%, 31/40) also said that they would recommend the fat reduction procedure to a friend (Figure 2B).

Safety

In the safety population, the majority (71.4%) of reported pain scores 10 min into treatment during the study were ≤2 for both treated areas. For arms, the mean pain scores 10 min into treatment were 2.1 ($n = 36$; range, 0-8) and 1.4 ($n = 19$; range, 0-7) during the first and second treatment cycles, respectively (Figure 3). The mean pain scores were higher during the first treatment cycle than the second. For inner thighs, the mean pain score 10 min into treatment was 1.7 (range, 0-5). The mean worst pain scores during treatment were 3.0 and 2.2 for the first and second treatment cycles for arms, respectively, and 2.4 for inner thighs. No participant discontinued treatment because of discomfort.

Pain at the treatment site was assessed at the 1-, 4-, and 12-week follow-up visits. At Week 1, the mean pain scores were 0.35 and 0.2 for the arms and inner thighs, respectively. Four weeks after treatment, the mean pain scores were 0.2 and 0 for the arms and inner thighs, respectively. No participant reported pain by the 12-week follow-up.

No treatment-emergent AEs (TEAEs) or adverse device effects (ADEs) were reported. The most common clinical findings were the local effects of treatment reported as erythema, swelling, and bruising. Reported sensory alterations during treatment included numbness and tingling for both arms and thighs. These effects were mild to moderate in severity and resolved without medical intervention. At follow-ups, reports of epidermal, dermal, or subcutaneous findings were less common, and included bruising, soreness, swelling, and pain and itchiness; these findings were mild in severity, and all resolved by the 4-week follow-up. Sensory alterations reported in the weeks following treatment included numbness, tingling, and tightness that were mild to moderate in severity. Sensory alterations typically resolved by Week 4, and only 1 participant reported mild numbness at the 12-week follow-up. There were no reports of paradoxical hyperplasia (PH) (also called paradoxical adipose hyperplasia [PAH] in the scientific literature) during the conduct of the study.

DISCUSSION

This study showed similar effectiveness and safety of cryolipolysis in participants of Chinese descent using a study design similar to that of a study of predominantly White participants.[14] This study infers that similar treatment outcomes could be expected in Chinese participants as seen in previously assessed White participants.[14] The primary endpoint, which was based on a predefined success criteria of 75% correct identification of baseline arm images, was met with 76.4% correct identification; these findings being similar to those of a previous study performed in predominantly White participants that reported 83% correct identification of pretreatment arm photographs.[14] The correct identification rate of baseline inner thigh images in the present study was 70.0%. There has been no prior study of participants treated with CoolAdvantage applicators to the thighs; however, there was a previous study using legacy applicators and a 16-week review period following a single treatment to both inner thighs that reported a 91% correct identification rate.[26] Although the correct identification rate for the inner thighs in the present study (70.0%) is numerically lower than the rate reported in the prior study, the 95% CI contains 75%, which was the predefined success criteria for the arms, and a post hoc analysis

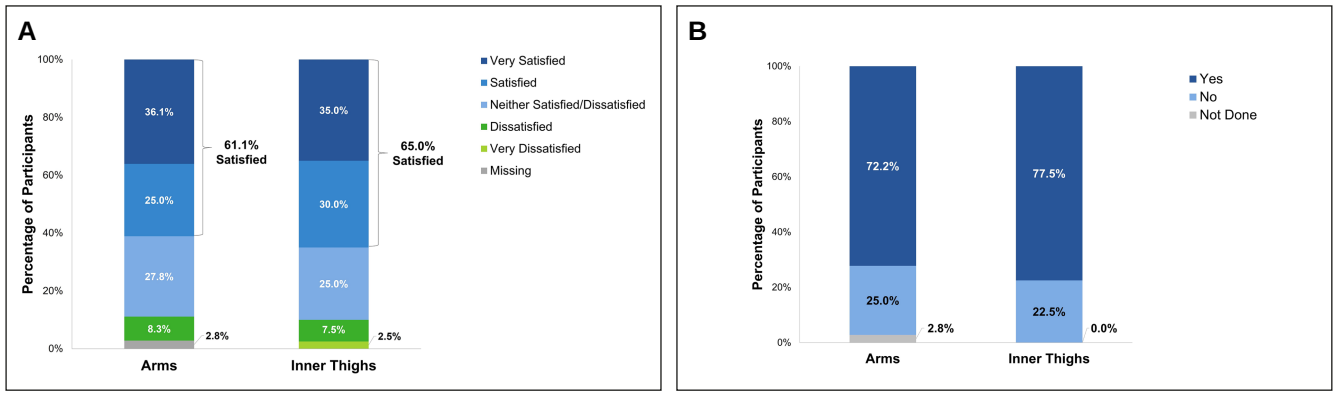

Figure 2. Participant-reported outcomes. Participants were asked to rate (A) overall satisfaction with the fat reduction procedure for each treated area (arms: $n = 36$; inner thighs: $n = 40$), and (B) whether they would recommend the fat reduction procedure to a friend (arms: $n = 36$; inner thighs: $n = 40$).

showed no significant difference between the 70.0% correct identification rate and the 75% predefined success criteria for arms.

Significant reductions in caliper-measured skinfold thickness were also observed. Cryolipolysis treatment comprising 1 to 2 treatment cycles per arm and 1 treatment cycle per inner thigh reduced skinfold thickness of the arms and inner thighs by a mean of 6.5 and 6.6 mm, respectively. This represents a double subcutaneous layer measurement, which when taken into consideration, equates similarly to the prior studies in which the authors reported single-layer measurements when using ultrasound imaging–based measurements.

The majority of the participants were satisfied with their fat reduction procedure as defined by responses of "satisfied" or "very satisfied" (arms, 61.1%; inner thighs, 65.0%); approximately 25% of the participants reported being "neither satisfied nor dissatisfied" and ≤10% of the participants reported being "dissatisfied" with the fat reduction procedure of the arms or inner thighs. The majority of the participants (72.2% and 77.5% for arms and inner thighs, respectively) would also recommend the procedure to a friend. Recent cryolipolysis studies of different study designs in primarily White participants reported approximately 90% satisfaction.[15,16] Several factors might have contributed to this apparent difference in reported satisfaction in this study. First, the study was designed to demonstrate similar visible differences in subcutaneous fat layer reduction by independent reviewers in patients of Chinese descent compared to results reported in White participants. The study was not designed to allow flexibility in treatment planning in order to ensure participant satisfaction. Finally, different studies have used different participant satisfaction questionnaires, which would confound any ability to compare similarities or differences in participant satisfaction outcomes.

This study shows that cryolipolysis treatment of the arms and inner thighs is well tolerated in participants of Chinese descent. No TEAEs, ADEs, or serious AEs were reported, including postinflammatory hyperpigmentation or PH, often referred to as PAH in the scientific literature. Observed dermal findings and sensory alterations included erythema and numbness that were mild to moderate in severity and did not require intervention. The safety profile of cryolipolysis in participants of Chinese descent appears similar to that of White participants.

Limitations

This study does have limitations. The study was designed to assess clinical outcomes in participants of Chinese descent and determine whether there were similarities to those seen in White participants assessed in a prior clinical study.[14] This meant that although the primary endpoint was met, the study treatment plans may not reflect current clinical practice, in that the number of treatment cycles were administered to mirror the prior study to which the endpoints were being compared. A recent expert opinion paper provided some guidelines on the appropriate number of treatments cycles by body area.[16] In clinical practice, these body areas may have received more than 1 treatment session if the desired treatment goal had not yet been achieved at the 8-week posttreatment assessment, as perhaps reflected in the study satisfaction scores.

Although the photography setup was standardized across the investigational sites, a different photographer was used at each site to position the participants for photography, introducing potential variability in how photography was conducted. Furthermore, the independent reviewers were likely to have been different from those used for the prior study, introducing interassessor variability between studies. There was also intrareviewer variability, as illustrated by 1 of the reviewers having a lower agreement with other reviewers for both arm (kappa = 0.381; 95% CI, 0.171-0.591) and inner thigh (kappa = 0.625; 95% CI, 0.355-0.895) photographs, which contributed

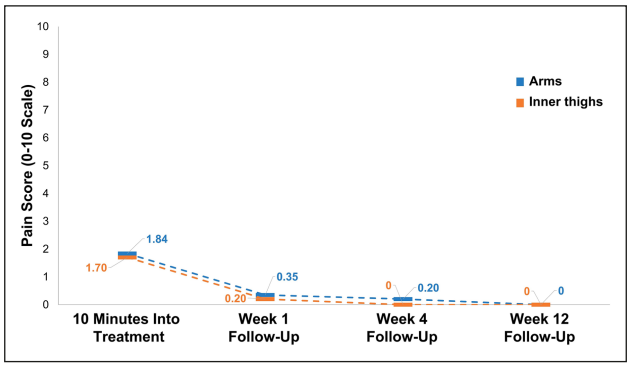

Figure 3. Mean self-reported pain during treatment and at follow-ups. Participants were asked to rate their pain for each treated area 10 min into treatment and again at the Weeks 1, 4, and 12 follow-ups. Pain scoring was based on a scale of 0 (no pain) to 10 (worst possible pain).

to the overall lower percentage of correct identification. The difficulty in identifying pretreatment photographs may also be related to the difficulty in recruiting participants with ≥2 cm in caliper thickness visible fat bulge, as anecdotally reported at the time of study conduct.

Previous studies using ultrasound to assess subcutaneous fat thickness changes after cryolipolysis in these body areas have reported mean fat layer reductions of 2.5 to 3.2 mm for the arms and 2.8 to 3.3 mm for inner thighs.[13,14,26,27] When comparing across studies that use different measurement tools, it is important to remember that ultrasound measurements reflect changes in a single layer of subcutaneous tissue, whereas the caliper measurements in this study reflect changes in the skinfold or double layer of subcutaneous tissue. The mean reductions of 6.5 and 6.6 mm for the arms and inner thighs, respectively, observed in the present study are numerically higher than the above-cited studies, but are similar to the caliper-measured reductions reported in a recent retrospective study of cryolipolysis treatment of the upper arms and inner thighs in Asian patients at a Korean hospital (arms: 5.1 mm; inner thighs: 6.1 mm).[11] There was an observed high variability in caliper measurements at both baseline and the 12-week follow-up in the present study, potentially due to differences in measurement technique conducted by different assessors performing the assessment, which in itself can be subjective and error prone. Although study staff at each site were trained by the same technician in an effort to minimize variability, having a single assessor conducting the measurements across all sites may have reduced any differences in technique that could impact the assessments.

Comparisons of participant satisfaction data between studies are challenging, and factors contributing to differences between studies include discrepancies between the questions across studies, number of treatments, timing of assessment, demographic or cultural differences, and patient selection. This study was not conducted to primarily assess participant satisfaction; it was designed to assess an objective visible response in participants of Chinese descent comparable to previous studies assessing the safety and effectiveness of cryolipolysis in predominantly White participants. Regardless, the majority of the participants in this study were at least satisfied with the cryolipolysis treatment.

Future studies comparing cryolipolysis effectiveness measures (ie, photographs, caliper, ultrasound measurements) between different ethnicities and body types are needed, as are studies determining the optimum number of treatments per body area. Studies with longer follow-up times and increased sample sizes could also be valuable to allow for sufficient time to identify rare AEs such as PH. Regardless, the present study does show that cryolipolysis is effective in reducing arm and inner thigh fat in most participants, and that the effectiveness of the treatment is comparable to studies of predominantly White participants.

CONCLUSION

This multicenter, prospective clinical trial shows that cryolipolysis of the arms and inner thighs is well tolerated and effective in healthy individuals of first- and second-generation Chinese descent with results similar to those seen in a prior study that included predominantly White participants. Effectiveness was demonstrated by pretreatment photograph identification by blinded, independent reviewers, investigator-assessed caliper-measured reductions in fat thickness for both arms and thighs, and participant satisfaction. Safety was also demonstrated by the absence of unanticipated AEs, device- or procedure-related AEs, and low mean pain scores both during and following treatment. Cryolipolysis is an effective and well-tolerated fat reduction procedure for reducing arm and inner thigh fat in Chinese individuals.

Disclosures

Drs Rivers and McGillivray have served as consultants, speakers, and investigators for Allergan Aesthetics, an AbbVie company (Irvine, CA, USA). Dr Braun has served as a consultant, advisory board member, and investigator for Allergan Aesthetics, an AbbVie company. Drs Bhogal and Zheng are employees of AbbVie Inc. and may own stock/stock options in the company. Dr Hickling is an employee of Allergan Aesthetics, an AbbVie company, and may own stock/stock options in the company. Medical writing and editorial assistance were provided by Sarah J. Cross, PhD, of AbbVie, and funded by AbbVie Inc.

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