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ORIGINAL ARTICLE

Evaluation of thermal shock therapy for reducing pain during intense pulsed light therapy: An intrapatient randomized controlled study

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Abstract

Background: Intense pulsed light (IPL) is used for the treatment and improvement of various skin issues. However, patients often experience local skin burning and pain after IPL treatment. Cooling and analgesic measures are indispensable.

Aims: To investigate the clinical effect of thermal shock therapy on pain relief and reduction of adverse reactions during IPL therapy.

Patients/Methods: A total of 60 female patients with facial photoaging who received IPL therapy were enrolled in the study. As a comparative split-face study, one side of the face was randomly selected as the control side. The other side was given thermal shock therapy before and after the IPL treatment immediately as analgesic side. The visual analog scale (VAS) was used to evaluate the pain degree of the patients. The telephone follow-ups regarding the occurrence of adverse reactions were conducted respectively on the 2nd day, 7th day, and 1 month after treatment.

Results: The VAS score and skin temperature of analgesia side was lower than that of control side at different stages of treatment. In terms of adverse reactions, the incidence of transient facial redness on the analgesic side was lower than that on the control side. Two patients showed slight secondary pigmentation on the control side, and the other patients showed no other adverse reactions on both sides.

Conclusions: Thermal shock therapy assisted IPL therapy can reduce skin temperature during treatment, effectively relieve patients' pain, reduce the occurrence of adverse reactions caused by heat injury, and improve patients' comfort level.

KEYWORDS
intense pulsed light, neurocryostimulation, pain, thermal shock therapy

Yuanwen Zhang and Chuncheng Lu contributed equally to this work.

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1 | INTRODUCTION

Intense pulsed light (IPL) is a noncoherent, broad-spectrum light source with a wavelength range between 400 nm and 1200 nm.[1] Different wavelengths of light acting on the skin can be absorbed by specific target components, such as melanin and hemoglobin, generating selective photothermal effects.[2] It is used for the treatment and improvement of various skin issues, including pigmentary disorders, vascular lesions, acne, hair removal, and skin photoaging.[3–7] Due to the photothermal principle underlying IPL, patients often experience local skin burning and pain after treatment. Therefore, certain cooling and analgesic measures need to be taken. Currently, commonly used methods in clinical procedures include pretreatment topical anesthesia, contact cooling, and mist cooling during and after treatment, among others. However, these methods have limitations such as varying degrees of poor analgesic effect and prolonged onset of action.

From June 2021 to March 2022, the author employed thermal shock therapy (TST) for skin preconditioning before IPL treatment and immediate localized cooling after IPL treatment, aiming to alleviate pain during the IPL procedure. Satisfactory results were achieved, and the findings are hereby reported.

2 | MATERIALS AND METHODS

2.1 | Clinical data

A total of 60 female patients with facial photoaging underwent IPL treatment, ranging in age from 32 to 58 years old, with a mean age of (43.35 ± 6.84) years. Skin types were classified as Fitzpatrick types III and IV. Exclusion criteria included: pregnancy or lactation, injection of substances such as botulinum toxin or hyaluronic acid fillers in the treatment area within the last 6 months, history of photosensitivity disorders, individuals prone to keloiditis, and localized infectious skin diseases or open wounds.

2.2 | Test device

Detailed information about the Thermal Shock Analgesia Device is as follows: Manufactured by Jiangsu Changzhou Ruihai Yino Medical Technology Co., Ltd. (Cryofos-I, Medical Device Registration Number: 20162581158) with an input power of 30 VA, equipped with a CO_2 gas tank, and a working pressure of 15 MPa.

Laser and Pulsed Light Workstation: Produced by Alma Lasers Ltd., Israel (Harmony XL model, Medical Device Registration Number: 20143095102), utilizing IPL 570 nm treatment handpiece with a wavelength range of 570 to 950 nm, spot size of 3 cm^2, energy density ranging from 3 to 30 J/cm^2, and selectable pulse widths of 10, 12, and 15 ms.

2.3 | Treatment

All of the participants provided a written informed consent form. Take a set of photographs of the facial area after cleaning.

An intrasubject, half-side comparison design was employed in this study. One-half of the facial area was randomly assigned to be the control side, receiving no specific analgesic measures and undergoing direct IPL treatment. The other half of the facial area was designated as the thermal shock analgesia side (referred to as the analgesia side). The analgesia side was initially treated with the thermal shock analgesia device. The device was held vertically at a distance of 8–10 cm from the skin, sprayed for 30 s, followed by a 5-second pause, and the process was repeated four times. IPL treatment was administered immediately after analgesia.

After applying a specialized cooling gel for photorejuvenation to the facial area, the device was customized with treatment parameters, commonly utilizing a medium pulse width (12 ms) and energy density ranging from 18 to 30 J/cm^2. The light spot is aligned vertically with the treatment area, emitting one pulse before moving to the next area. Each light spot can overlap by approximately 10%. The desired skin response at the end of treatment is mild erythema or minimal apparent reaction, with a slight darkening of skin lesions.

After treatment, the patient's facial area is cleansed. The analgesia side undergoes another session of thermal shock analgesia treatment. The device held vertically at a distance of 8–10 cm from the skin and sprayed for 30 s and followed by a 5-second pause, which is repeated four times. Subsequently, a medical reparative mask is applied to the facial skin for 15–30 min. Within 3–5 days post-treatment, patients are instructed to apply a medical reparative mask topically every day. The scabbed areas should be protected to ensure natural detachment of the scabs, rather than manually picking at them, to prevent scarring and the occurrence of hyperpigmentation. Within the first week after treatment, patients should avoid vigorous exercise. Throughout the entire treatment period, all patients were instructed to avoid excessive sun, UV or heat exposure, and rubbing or scratching the treated areas. They were also advised to use broad-spectrum sunscreen with a sun protection factor (SPF) 50+.

2.4 | Efficacy and safety evaluation

2.4.1 | Pain measurement

All patients were immediately assessed using the visual analog scale (VAS) to evaluate the level of facial pain on both sides during the treatment process. A score of 0 indicated no pain, while a score of 10 indicated the highest level of pain.

2.4.2 | Skin temperature

The facial skin temperature on both sides of the patients were measured using a specialized thermal shock analgesia device thermometer

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at specific time points, including before IPL treatment, after cold spray before IPL treatment, immediately after IPL treatment, second cold spray after IPL treatment, 5 min after cold spray, and 15 min after cold spray. The temperature readings were obtained at the prominence of the zygomatic arch.

2.4.3 | Adverse reaction assessment

Patients were followed up by telephone at 2 days, 7 days, and 1 month post-treatment. Adverse reaction events were recorded, including facial edema, frostbite, vesicles, persistent facial erythema, secondary hyperpigmentation or hypopigmentation, and scar formation, among other adverse reactions.

2.5 | Statistical treatment

Statistical analysis was conducted using SPSS 20.0 software. Quantitative data were expressed as mean ± standard deviation ($\bar{x} \pm SD$). Paired *t*-tests were used for within-group comparisons, and chi-square tests were employed for comparisons of adverse reaction incidence between both sides. A significance level of $p < 0.05$ was considered statistically significant for differences.

3 | RESULTS

3.1 | Comparison of VAS pain scores

The VAS pain scores for the analgesia side and the control side were (2.95 ± 1.00) and (4.53 ± 0.98), respectively, with a statistically significant difference between the two sides ($p < 0.05$).

3.2 | Comparison of skin temperature

At each time point, including before IPL treatment, after cold spray before IPL treatment, immediately after IPL treatment, second cold spray after IPL treatment, 5 min after cold spray, and 15 min after cold spray, the facial skin temperatures on the analgesia side were consistently lower than those in the control group, with statistically significant differences between the two sides ($p < 0.05$, Figure 1, Table 1).

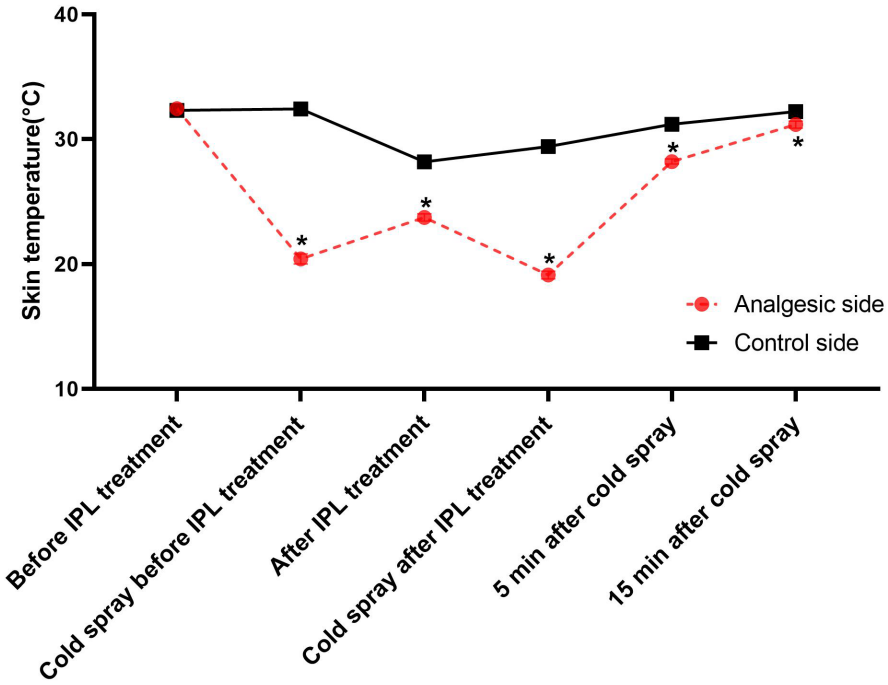

FIGURE 1 Comparison of skin temperature between analgesic side and control side. The facial skin temperature on analgesic side and control side were recorded and analyzed at specific time points. *Compared with the control side, $P < 0.05$.

TABLE 1 Comparison of skin temperature between analgesic side and control side ($\bar{x} \pm SD$).

Side	Before IPL treatment	Cold spray before IPL treatment	After IPL treatment	Cold spray after IPL treatment	5 min after cold spray	15 min after cold spray
Analgesic side	32.44 ± 0.35#	20.42 ± 0.41*	23.73 ± 0.29*	19.12 ± 0.31*	28.21 ± 0.20*	31.18 ± 0.28*
Control side	32.32 ± 0.25	32.42 ± 0.31	28.20 ± 0.22	29.42 ± 0.44	31.20 ± 0.26	32.22 ± 0.34

Note: Data were analyzed by paired *t*-test. #$p > 0.05$, *$p < 0.05$.

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3.3 | Adverse events after treatment

Following IPL treatment, a transient facial erythema was observed in some patients. The incidence on the analgesia side was 61.67% (37/60), while on the control side it was 80.00% (48/60), showing a statistically significant difference between the two sides ($p < 0.05$). Typically, the facial erythema spontaneously resolved within 24 h. In two cases, slight secondary hyperpigmentation occurred on the control side, which gradually faded after 3 months without specific intervention. No other adverse reactions, such as edema, frostbite, vesicles, persistent facial erythema, hypopigmentation, or scar formation, were observed on both sides in the remaining patients.

3.4 | Typical cases

We report a representative case, as shown in Figure 2. Before IPL treatment, one half of the face was treated with the thermal shock analgesia device as the analgesic side, while the other side served as the control without specific analgesic measures. After IPL treatment, the patient's sensation of burning pain and erythema reaction on the analgesic side were reduced compared to the control side. After IPL treatment, patients experienced reduced burning pain and erythema on the analgesic side compared to the control side.

4 | DISCUSSION

IPL has been recognized for its ability to simultaneously improve skin texture and color, thereby addressing skin photoaging.[8,9] It has been shown that IPL with a wavelength range of 515 to 1200 nm exerts optimal effects. Longer-wavelength IPL is absorbed by water in the skin, inducing a cytokine-mediated response that stimulates new collagen synthesis.[10] This results in increased amounts and rearrangement of Type I and Type III collagen, as well as a more organized arrangement of elastic fibers. Shorter-wavelength IPL is absorbed by melanin in pigmented lesions and oxygenated hemoglobin in blood vessels, thus ameliorating reduced skin elasticity and fine wrinkles associated with photoaging,[11] as well as addressing concerns like enlarged pores,[12,13] vascular dilation,[14] and abnormal pigmentation.[15]

While IPL has demonstrated remarkable efficacy, it can elicit a certain degree of discomfort during the treatment process. Pain is a pivotal factor influencing treatment comfort and compliance.[16] In fact, some patients may even discontinue treatment due to intolerable pain.[17] Currently, common noninvasive analgesic methods employed alongside phototherapy include inhalation analgesia techniques, topical anesthesia, and skin cryoanalgesia,[18,19] among which contact cooling,[20] cold air analgesia,[21] and nebulized cryotherapy are encompassed.

The thermal shock therapy apparatus employs the neurocryostimulation (NCS), which involves the use of a spray gun to deliver a

FIGURE 2 Photographs were taken of the facial erythema reactions of a female patient on the analgesic side and the control side before and after IPL treatment.

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high-pressure (50 bar) and ultralow temperature (−78°C) CO_2 jet.[22] This jet is applied directly to the treatment area, resulting in the formation of dry ice microcrystals on the skin surface. The rapid sublimation of the dry ice leads to a substantial removal of heat, resulting in rapid cooling. The primary mechanism of pain relief is attributed to local vasoconstriction induced by the low temperature stimulus. This vasoconstriction slows down the conduction of neural impulses, reduces the sensitivity of nerve endings, and subsequently alleviates pain perception. Furthermore, the vasoconstriction reduces capillary permeability and extravasation, leading to a reduction in tissue swelling that could otherwise compress nerve endings and induce pain. The thermal shock therapy combines the effects of high pressure and ultralow temperatures. The skin temperature (approximately 32°C) rapidly drops to below 4°C within an extremely short time (approximately 30 s). This temperature change is transmitted by skin receptors to the thalamus and cerebral cortex, triggering a series of neural reflexes in the central nervous system and inducing a cascade of physiological responses. These responses include recurrent vasodilation and vasoconstriction, ultimately contributing to a thermal shock effect.[23] The thermal shock effect accelerates lymphatic drainage, promoting the reabsorption of exudates that are subsequently eliminated through the venous and lymphatic systems. This rapid process achieves the combined effects of reducing swelling and alleviating pain.[24] Compared to traditional cold therapy, thermal shock therapy offers a more significant reduction in skin temperature over a shorter period of time. Skin temperature typically returns to the normal range within 5 min. Thermal shock therapy does not result in cellular damage or carry a significant risk of frostbite.[25]

The results of this study indicate that the VAS pain scores on the analgesia side were significantly lower than those on the control side. In addition, the skin temperatures on the analgesia side, including before IPL treatment, after cold spray before IPL treatment, immediately after IPL treatment, second cold spray after IPL treatment, 5 min after cold spray, and 15 min after cold spray, were all significantly lower than those on the control side. Concerning adverse reactions, the incidence of transient facial redness on the analgesia side was significantly lower than that on the control side. Among the observed adverse reactions, two patients on the control side exhibited mild secondary pigment deposition, while no other adverse reactions were reported on either side. IPL causes tissue local heat accumulation and initiates a skin inflammatory response through photothermal and photochemical effects. This can result in a range of symptoms, including itching, erythema, skin desquamation, and skin irritation.[26] Thermal shock therapy has adequate heat abstraction capabilities, inducing vascular constriction and reducing nerve conduction velocity to alleviate the sensation of pain. On the contrary, capillary constriction slows blood flow, lowers tissue temperature and cellular metabolism, thereby inhibiting the spread of inflammation.[17,22] The facial capillary network is superficial and rich, making it more susceptible to the influence of cooling systems. Thermal shock therapy may affect the response of superficial vessels and pigments to intense pulsed light treatment. Appropriate cooling temperatures can alleviate complications such as pain stimulation, hyperpigmentation, and scarring caused by thermal injury and inflammatory reactions. Epidermal cooling minimizes epidermal damage and allows for higher delivered fluences and cooling of the upper dermis is protective and also tends to relieve pain without decreasing efficacy.[27] This study suggests that the application of thermal shock therapy for skin preconditioning prior to IPL treatment can effectively reduce the initial epidermal temperature. During IPL treatment, this approach can reduce epidermal heat and consequently shorten the time of heat release, thereby reducing the risk of epidermal burns. In addition, when employed immediately after IPL treatment, local cooling can provide epidermal protection, reduce epidermal damage, alleviate burning pain and erythema sensations in patients, prevent post-inflammatory hyperpigmentation, and enhance the patient's comfort levels after IPL treatment. The thermal shock therapy effectively reduces adverse reactions caused by heat-induced damage.

However, the limitations of this study may be attributed to its a single-center trial with a small number of observed cases. Also, the assessment of treatment efficacy tends to be subjective. During thermal shock therapy, there is a direct relationship between adipose thickness, local blood flow, and both the required cooling time and the temperature change, suggesting that adjustments to the duration may be necessary to produce similar temperature changes in different body segments. Therefore, it is necessary to increase the sample size through multicenter randomized controlled trials and further elucidate the biological mechanisms underlying its analgesic effects.

In summary, the thermal shock therapy based on neurocryostimulation represents an innovative analgesic approach. When used as an adjunct to IPL treatment, it effectively reduces the skin temperature during the treatment process, thereby mitigating patient pain and lowering the occurrence of adverse reactions. This method is simple, comfortable, rapid, safe, and noninvasive, providing a novel auxiliary approach and option for IPL treatment.

5 | CONCLUSION

Thermal shock therapy-assisted IPL therapy can reduce skin temperature during treatment, effectively relieve patients' pain, reduce the occurrence of adverse reactions caused by heat injury, and improve patients' comfort level.

AUTHOR CONTRIBUTIONS

Y.Z. had full access to all of the data in the study and takes responsibility for the integrity of data and the accuracy of the data analysis. Y.Z. and C.L. involved in study concept and design. Z.Y. and Y.C. acquired the data. Z.Y. and S.L. analyzed and interpreted the data. Y.Z. and C.L. drafted the manuscript. Y.Z. revised the manuscript for important intellectual content. All authors have read and agreed to the published version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

All the authors declared that no one has any conflicts of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

ETHICS STATEMENT

All procedures performed in studies involving human participants were approved by the Human Research Ethics Review Committee of No.926 Hospital, Joint Logistics Support Force of PLA and in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent were signed by the patients. General study informed consent and photo informed consent were obtained before performing study procedures and taking photographs. Permission for publication was also ascertained during the informed consent process.

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