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Application of multifunctional pulse wave sphygmomanometer combined with constant temperature ice in patients with forearm hematoma after coronary intervention

Jimin Qiao^{1*†}, Yihang Shi^{2†}, Kai Li², Xiaomin Zhu² and Zhimei Wang²

Abstract

Aim This study aims to investigate the effects of combining a multifunctional pulse wave sphygmomanometer with constant temperature ice on patients with forearm hematoma following coronary intervention.

Methods Patients who developed forearm hematoma after undergoing coronary intervention from March 2021 to March 2023 at our hospital were selected as the study cohort. Using a random number table, they were divided into two groups the control group and the research group. The control group received cuff compression treatment using a multifunctional pulse wave sphygmomanometer. The primary endpoint was the effective rate of one compression. Secondary endpoints included body surface temperature, pain, comfort, arm measurements, and swelling value.

Results A total of 190 patients were included, with 95 in the control group and 95 in the research group. The research group showed a significantly higher effective rate of one compression compared to the control group (87.2% vs. 95.8%, $p = 0.035$). Additionally, the research group experienced significantly reduced pain (2.0 [2.0,3.0] vs. 1.0 [1.0,2.0], $p < 0.001$) and improved comfort levels. This approach also effectively reduced body surface temperature ($32.91 \pm 0.83^{\circ}\text{C}$ vs. $12.09 \pm 1.09^{\circ}\text{C}$, $p < 0.001$), arm measurements (274.32 ± 9.56 mm vs. 271.15 ± 8.82 mm, $p = 0.019$), and swelling value (12.40 ± 1.95 vs. 11.07 ± 2.13 , $p < 0.001$) after compression.

Conclusions The combined use of a multifunctional pulse wave sphygmomanometer for cuff compression on forearm hematoma with simultaneous constant temperature ice application demonstrated more benefits. This approach effectively reduced pain, improved comfort levels, and enhanced compression-based hemostasis and reduction of swelling.

Trial registration Ethics No.KY20210604-02-KS-01.

Keywords Forearm hematoma, Multifunctional pulse wave sphygmomanometer, Cuff compression, Constant temperature ice, Swelling

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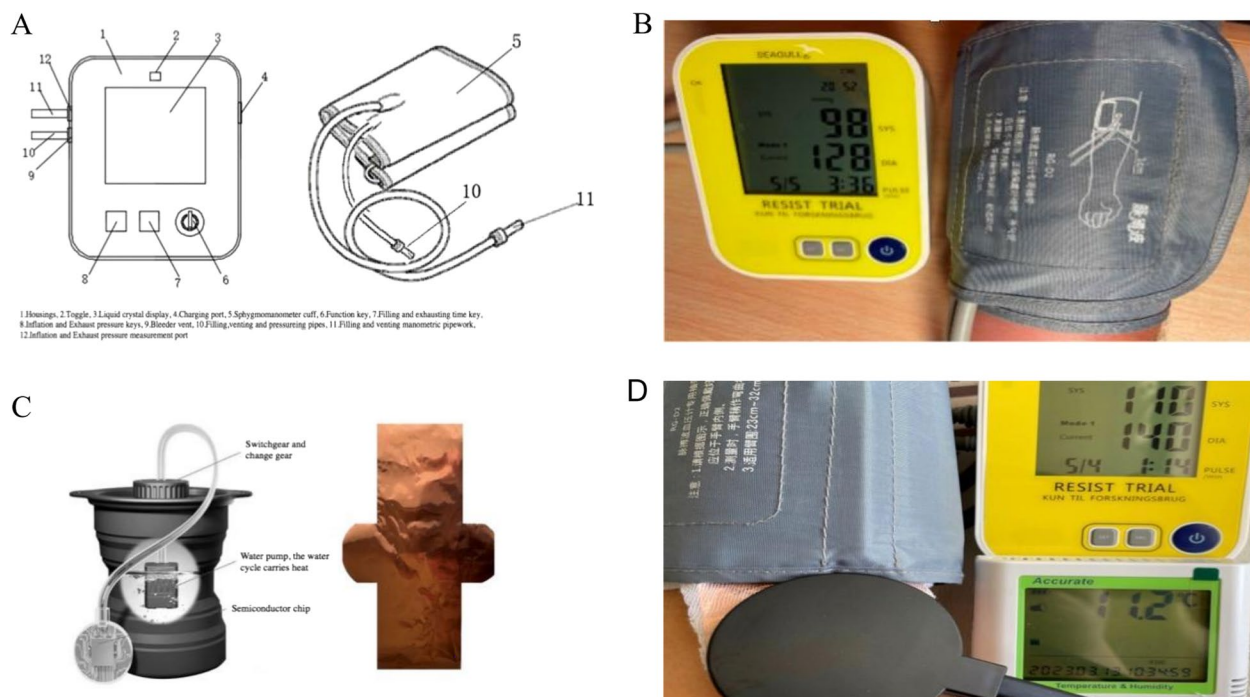


Fig. 1 Design of innovative device

Introduction

Ischemic heart disease is the leading cause of global mortality, accounting for 16 percent of all deaths worldwide [1]. Within this spectrum of ischemic diseases, coronary heart disease (CHD) is particularly significant, imposing a substantial burden on global health with high disability rates and reduced patient quality of life [2]. Transradial coronary intervention (TRI) has become the preferred approach for treating coronary heart disease [3]. However, radial artery's significantly narrower internal diameter compared to the brachial and femoral arteries often results in forearm hematomas following TRI [4, 5].

Cyclic pressure compression using a sphygmomanometer cuff has proven effective in managing forearm hematomas by facilitating compression-based hemostasis [6]. Yet, prolonged compression can lead to discomfort such as swelling and pain, and in severe instances, even rhabdomyolysis [7]. Research indicates that ice packs can effectively reduce wound swelling and pain [8]. Nonetheless, clinical devices that allow simultaneous ice application during cuff compression for forearm hematomas are lacking, making this integration a scarcely explored area, with ice therapy administered post-compression.

In this study, we investigate the combined impact of cuff compression and simultaneous thermostatic ice application on patients with forearm hematomas following TRI. Using a customized multifunctional pulse wave sphygmomanometer (Patent No.: ZL201921841348.8)

paired with a bespoke thermostatic ice application device, we aim to enhance clinical compression outcomes by exploring the effects of concurrent cuff compression and ice therapy.

Methods

Research participants

Based on prespecified inclusion and exclusion criteria, we selected 190 patients who developed forearm hematomas following transradial coronary intervention (TRI) at our hospital from March 2021 to March 2023. Using a random number table method, the patients were divided into two groups: the research group (95 cases) and the control group (95 cases). The study protocol received ethical approval from the hospital ethics committee, and all 190 patients provided informed consent. One patient from the control group withdrew due to discomfort during cuff compression, leaving 189 patients who successfully completed the study (Fig. 1).

The inclusion criteria were as follows: (1) Aged between 18 and 75 years; (2) Meeting diagnostic criteria for coronary heart disease; (3) Hematoma area $\geq 50 \text{ mm} \times 50 \text{ mm}$; (4) Tolerance to both thermostatic ice and cuff compression; (5) Systolic blood pressure $< 150 \text{ mmHg}$; and (6) Normal coagulation parameters. Exclusion criteria included: (1) Speech impairment; (2) Intravenous administration of GP IIb/IIIa receptor blockers; (3) Forearm trauma or arteriovenous fistula; (4) Contraindications to

cold therapy; and (5) Occurrence of vagal reflexes during thermostatic ice application and compression.

Design of innovative device

The innovative device used in this study comprised two key components: a multifunctional pulse wave sphygmomanometer and a thermostatic ice application device.

Multifunctional pulse wave sphygmomanometer: This device includes a Bluetooth-enabled chip for user control via a dedicated app, allowing customization of cuff inflation and deflation cycles, pressure levels, and timing. It features dual pumps, dual sensors, and dual tubing with separate inflation and exhaust tubes for precise pressure management. The device also supports programmable one-touch operation with a Start/Pause button (Fig. 2).

Thermostatic ice application device: This device is made of a 10 μm ultra-thin, highly flexible copper material with excellent thermal conductivity. The copper, housed in a gauze sleeve, aligns with the cuff's width and interfaces with a custom water-cooled semiconductor cooling radiator. The radiators connect to the protruding ends of the purple copper, and foam dressing on the skin-facing side prevents frostbite. A semiconductor refrigeration chip and water pump control the temperature control, maintaining a stabilized range of 10°C to 15°C on the forearm surface during icing (Fig. 2).

Management of forearm hematoma in control group

For the control group, a nurse measured brachial blood pressure using the custom-designed multifunctional pulse wave sphygmomanometer. After pressing the pause button, the cuff was affixed to the most swollen portion of the forearm and the procedure was initiated by pressing the start button. The sphygmomanometer, pre-programmed with factory-customized parameters, ensured consistency.

The cuff inflated to a pressure 30 mmHg above the systolic level for 5 min then deflated to the diastolic pressure for 1 min. This compression-decompression cycle was repeated approximately five times. The device maintained the specified constant pressure throughout the process.

Management of forearm hematoma in research group

In addition to the control group's procedures, the research group integrated thermostatic ice application. After measuring arm circumference and blood pressure, a nurse placed a 10 μm -thick copper strip, housed in a gauze sleeve, around the forearm. This assemblage was then gently secured around the forearm, centered at the designated mark, for a duration of one week. Subsequently, the cuff was affixed to the surface of the purple copper, and the two protruding ends of the copper were connected to a custom water-cooled semiconductor refrigeration radiator.

The protocol for cuff compression was identical to that of the control group but included simultaneous thermostatic ice treatment. Blood pressure and heart rate were monitored, and interventions ceased if patients could not tolerate the treatments.

Endpoints, definitions, and quality control

Endpoints

The primary endpoint was the effective rate of one compression. Other endpoints included body surface temperature, pain, comfort, arm measurements, and swelling value.

Definitions

Body surface temperature Measured with the Hua Hanwei T40W-PT body thermometer, ensuring uniformity

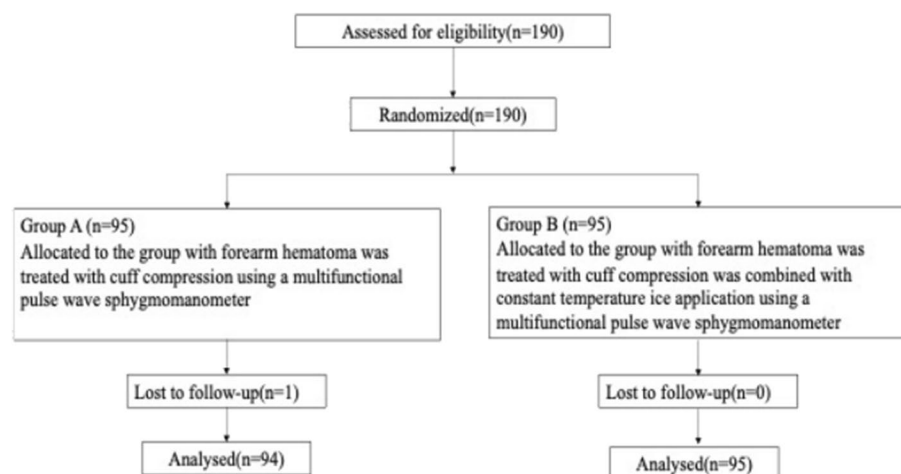


Fig. 2 Flowchart of study

within the same batch. The measurement accuracy was maintained at 0.1°C.

Pain Assessed using the pain numeric rating scale and the visual analogue scoring method, ranging from 0 (no pain) to 10 (severe pain) [9]. Mild, moderate, and severe pain were categorized between scores 1–3, 4–6, and 7–9, respectively.

Comfort Classified into three levels: Level 1 represented forearm or palm swelling without pain; Level 2 denoted swelling and bearable pain; and Level 3 signified intolerable swelling and pain.

Effective rate of one compression Calculated as the ratio of individuals displaying no blood extravasation from the swelling, as suggested by vascular ultrasound after five cycles of forearm hematoma cuff compression. The effective rate of primary compression was calculated as (number of individuals without blood extravasation / total number of individuals in each group) × 100%.

Arm measurements Forearm circumference at the maximum swelling point and the same site on the healthy side, measured using the GemRed electronic display soft tape with 1 mm precision.

Swelling value Calculated by subtracting the arm circumference at the most swollen point of the forearm from the healthy arm circumference.

Quality control

A 14-member intervention team with an average of 13.54 ± 3.23 years of professional experience was assembled. The team included two medical doctors with expertise in post-compression vascular ultrasound, two seasoned provincial cardiovascular specialist nurses for

guidance and quality control, and 10 senior charge nurses for patient recruitment and intervention.

Multiple rounds of comprehensive training were provided, including proficiency in the operation and maintenance of the custom-designed multifunctional pulse wave sphygmomanometers and the self-crafted thermostatic ice packs. Equally, they received training in the collection of pertinent evaluation indicators to enable competent execution of the tasks. Prompt action was taken upon identifying a forearm hematoma in patients post-TRI surgery. Two team-member nurses expeditiously measured and annotated the forearm's circumference at its most swollen point. Following this, cuff compression and/or thermostatic ice application were promptly administered to the forearm hematoma. This approach aimed to ensure both the effectiveness of the intervention and the precision of indicator parameter measurements.

Statistical analysis

All statistical analyses were conducted using SPSS 25.0. Quantitative data with normal distribution are presented as mean ± standard deviation and analyzed using the independent samples t-test. Data not conforming to a normal distribution are expressed as median and quartiles. Qualitative data are presented as frequency (%) and analyzed using the chi-squared χ^2 -test. A significance level of $\alpha=0.05$ was employed for all tests.

Results

Baseline characteristics

A total of 189 patients were included in the study. As shown in Table 1, there were no significant differences between the two groups in terms of age (64.02 ± 7.48 vs. 64.76 ± 8.27, $p=0.520$), body mass index (24.83 ± 3.09 vs. 24.61 ± 3.28, $p=0.636$) and platelet count (221.38 ± 48.74 vs. 209.85 ± 44.56, $p=0.091$). Additionally, there were no significant differences in the prevalence of previous TRI (22.3% vs. 13.7%, $p=0.121$), hypertension (67.0%

Table 1 Comparison of general information between the two groups

Variables	Control group(n=94)	Research group(n=95)	Statistic	P
Female, n(%)	34 (36.17)	40 (42.11)	$\chi^2=0.70$	0.403
Age(years)	64.02 ± 7.48	64.76 ± 8.27	$t=-0.64$	0.522
BMI(kg/m ²)	24.83 ± 3.09	24.61 ± 3.28	$t=0.48$	0.634
TRI History, n(%)	21 (22.34)	13 (13.68)	$\chi^2=2.40$	0.121
Hypertension, n(%)	63 (67.02)	65 (68.42)	$\chi^2=0.04$	0.837
Diabetes, n(%)	42 (44.68)	33 (34.74)	$\chi^2=1.95$	0.162
Stroke, n(%)	12 (12.77)	14 (14.74)	$\chi^2=0.15$	0.694
Hyperlipidemia, n(%)	32 (34.04)	27 (28.42)	$\chi^2=0.70$	0.404
Blood platelet count(*10 ⁹ /L)	221.38 ± 48.74	209.85 ± 44.56	$t=1.70$	0.091

t t-test, χ^2 Chi-square test

Table 2 Comparison of pain levels and comfortableness levels at the forearm compression site during cuff compression of forearm haematoma in two groups of patients

Variables	Control group(n = 94)	Research group(n = 95)	Statistic	P
Pain scores	2.00 (2.00, 3.00)	1.00 (1.00, 2.00)	Z = -6.17	< .001
Comfortableness, n(%)			$\chi^2 = -2.67$	0.007
Level 1	9(9.57)	23(24.21)		
Level 2	85(90.43)	72(75.79)		
Level 3	0(0.00)	0(0.00)		

Z: Mann-Whitney test, χ^2 : Chi-square test

vs. 68.4%, $p = 0.837$), and diabetes (44.7% vs. 34.7%, $p = 0.162$).

Comparison of pain levels and comfortableness levels

As shown Table 2 and Fig. 3, the control group reported higher pain scores (2.0 [2.0,3.0] vs. 1.0 [1.0,2.0], $p < 0.001$). Additionally, Comfort levels, as indicated in Table 2, were significantly improved in the research group.

Comparison of body surface temperature, forearm arm circumference, and swelling values

As shown in Table 3 and Fig. 4, there were no significant differences between the two groups in terms of body surface temperature ($32.58 \pm 0.41^\circ\text{C}$ vs. $32.49 \pm 0.29^\circ\text{C}$, $p = 0.083$), forearm arm circumference (275.94 ± 10.78 mm vs. 273.57 ± 9.71 mm, $p = 0.114$), and swelling values (14.02 ± 2.50 mm vs. 13.49 ± 2.08 mm, $P = 0.115$). However, after compression, the research group showed significantly lower body surface temperature ($32.91 \pm 0.83^\circ\text{C}$ vs. $12.09 \pm 1.09^\circ\text{C}$, $p < 0.001$), forearm arm circumference (274.32 ± 9.56 mm vs. 271.15 ± 8.82 mm, $p = 0.019$), and swelling values (12.40 ± 1.95 vs. 11.07 ± 2.13 , $p < 0.001$).

Comparison of primary endpoint one-time compression efficiency

As indicated in Figure and table, the research group had a significantly higher effective rate of one compression

compared to the control group (87.2% vs. 95.8%, $p = 0.035$).

Discussion

Improved pain, swelling, and comfort through cuff compression combined with thermostatic ice

Following guideline recommendations, the use of transradial coronary intervention (TRI) in coronary interventions has increased over time. Despite a decline in the incidence of forearm hematomas after TRI, the overall number of cases remains high due to the rising prevalence of coronary heart disease. Timely and effective nursing interventions can significantly reduce pain, swelling, and discomfort in patients with forearm hematomas.

Previous studies have demonstrated the effectiveness of sphygmomanometer cuff compression in controlling bleeding and reducing edema in forearm hematomas. However, this approach often increases skin temperature and localized swelling at the site of forearm compression. Our study revealed a significant difference in body surface temperature at the forearm compression site between the research and control groups.

In the control group, the snug fit and its liner impeded heat dissipation, causing a rise in the surface temperature of the compressed area by 0.5°C to 1.5°C . In contrast, the research group used to a custom semiconductor refrigeration chip to maintain a stable forearm

Table 3 Comparison of body surface temperature, forearm arm circumference and swelling values after cuff compression of forearm haematoma in two groups of patients

Variables	Control group(n = 94)	Research group(n = 95)	Statistic	P
Pre-oppression body surface temperature($^\circ\text{C}$)	32.58 ± 0.41	32.49 ± 0.29	t = 1.74	0.083
Post-oppression body surface temperature($^\circ\text{C}$)	32.91 ± 0.83	12.09 ± 1.09	t = 148.32	< .001
Pre-oppression forearm arm circumference (mm)	275.94 ± 10.78	273.57 ± 9.71	t = 1.59	0.114
Post-oppression forearm arm circumference (mm)	274.32 ± 9.56	271.15 ± 8.82	t = 2.37	0.019
Healthy arm circumference (mm)	261.91 ± 9.54	260.07 ± 9.20	t = 1.35	0.179
Pre-oppression swelling value (mm)	14.02 ± 2.50	13.49 ± 2.08	t = 1.57	0.117
Post-oppression swelling value (mm)	12.40 ± 1.95	11.07 ± 2.13	t = 4.49	< .001

t: t-test

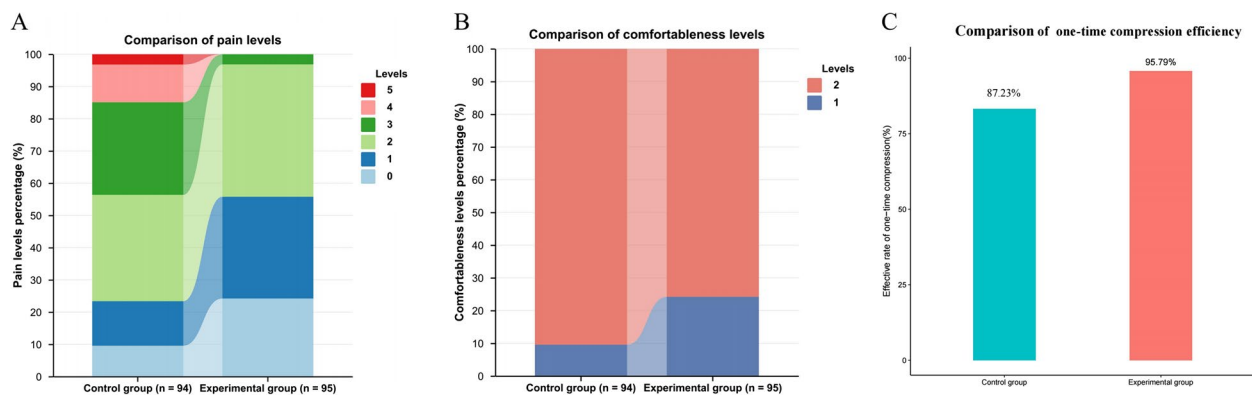


Fig. 3 Comparison of pain levels (A), comfortableness levels (B) and one-time compression efficiency (C)

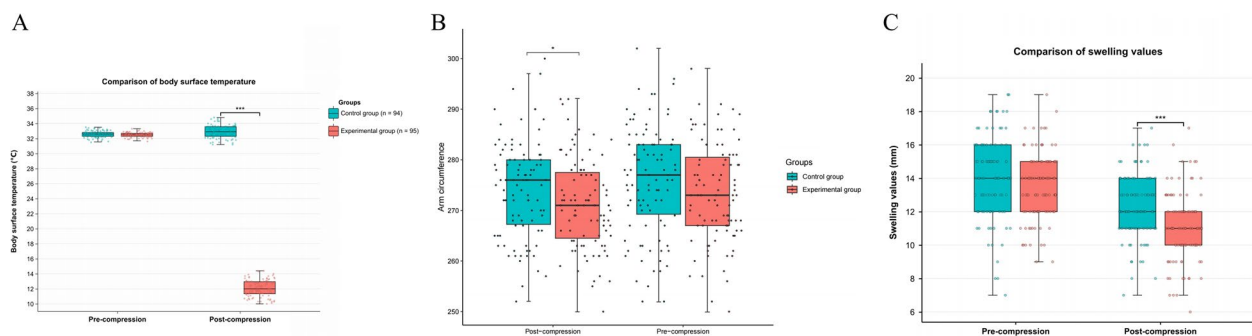


Fig. 4 Comparison of body surface temperature (A), forearm arm circumference (B), and swelling values (C)

surface temperature of 10°C to 15°C during ice application, significantly cooler than the body's original surface temperature.

Our study found that patients in the research group experienced reduced pain levels and increased comfort during hematoma compression therapy. These findings align with previous research [10, 11]. The elevated body surface temperature in the control group during forearm hematoma cuff compression accelerates nerve conduction rates, heightening pain and swelling sensitivity [12, 13]. In contrast, the research group's integration of continuous, 360-degree thermostatic ice application via a soft, ultra-thin copper band around the forearm hematoma effectively maintained a surface temperature of 10°C to 15°C. This approach temporarily paralyzes or slows peripheral nerve conduction, reducing sensitivity, increasing pain thresholds, and decreasing histamine release [12, 14–17]. Consequently, combining thermostatic ice and cuff compression with a multifunctional pulse wave sphygmomanometer improves pain, swelling, and patient comfort during forearm hematoma cuff compression.

This analysis suggests that integrating thermostatic ice with cuff compression is a promising advancement in the management of pain, swelling, and discomfort in forearm hematoma cases.

Improved primary compression efficiency, forearm arm circumference, and swelling values through cuff compression combined with thermostatic ice

The multifunctional pulse wave sphygmomanometer's automatic inflation, deflation and depressurization provide significant advantages. This technology enables timely pressure adjustments, minimizes compression-related injuries, and enhances compression efficacy compared to traditional method [18]. Prompt and effective compression, coupled with therapeutic ice interventions for forearm hematomas improves compression outcomes and reduces forearm swelling [19, 20].

Our study found that patients in the research group experienced superior single compression efficiency, reduced forearm arm circumference, and lower swelling values after forearm hematoma cuff compression, consistent with the results of the previous study [21]. These

findings are due to the synergistic effect of localized compression and cooling, which reduces inflammation, pain, and swelling [22, 23].

In the control group, the absence of constant temperature ice application during cuff compression led to an increase in skin surface temperature at the compression site by 0.5 °C to 1.5 °C. This rise caused vasodilation, local tissue congestion, and increased blood flow to the hematoma site [24, 25], raising the risk of re-bleeding and lowering single compression efficiency. Conversely, the research group's use of a homemade thermostatic ice device effectively reduced skin surface temperature from 32.49 ± 0.29 °C to 12.09 ± 1.09 °C. This significant temperature reduction caused vasoconstriction at the injury site, reduced blood vessel permeability and local bleeding, accelerated rupture healing and improved single compression hemostasis efficiency, reducing forearm arm circumference and swelling [26, 27].

Local cold compresses have proven analgesic and anti-inflammatory effects by reducing local mediators and peripheral blood flow through vasoconstriction [28–30]. The 360-degree contact of the cuff with the forearm during cuff compression increases peripheral vascular resistance around the hematoma, reducing bleeding. The larger contact area facilitates gradual hematoma dispersion and absorption, reducing local swelling.

The simultaneous application of ice packs in the research group enhanced these effects, reducing vascular wall permeability and tissue colloid osmotic pressure, further decreasing local blood flow and limb swelling [31, 32]. This combination improved compression efficiency and reduced limb swelling [33].

Limitations

However, it is important to acknowledge the study's limitations, particularly the relatively modest sample size drawn from a singular medical center.

Conclusions

In summary, using constant temperature ice alongside cuff compression for forearm hematomas with a multi-functional pulse wave sphygmomanometer significantly improves primary compression efficiency, forearm arm circumference, and swelling reduction. So this device provides us with a new therapeutic tool for managing patients with forearm haematomas from coronary interventions. This strategy enhances the therapeutic outcomes of cuff compression and therapeutic ice application.

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Authors' contributions

Jimin Qiao designed and refined the entire study. Jimin Qiao and Yihang Shi entered, integrated, analyzed and wrote the entire article. Kai Li were responsible for the clinical study, Xiaomin Zhu and Zhimei Wang collected data in the clinic. All authors have read and suggested revisions to the article, agreeing to the final text.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The studies involving human participants were reviewed and approved by the Institutional Review Board (or Ethics Committee) of Nanjing First Hospital, Nanjing Medical University. The Ethics Committee waived the requirement of written informed consent for participation.

Consent for publication

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The participants gave written informed consent for their personal or clinical details along with any identifying images to be published in this study.

Competing interests

The authors declare no competing interests.

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