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ORIGINAL ARTICLE

A Novel Hemostatic Belt Allowing Ambulation Soon After Atrial Fibrillation Ablation

Akinori Sairaku[1,2] · Koji Hashimoto[3] · Yukiko Nakano[4]

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Abstract

We aimed to develop a hemostatic device with physiological evidence that allows ambulation soon after atrial fibrillation (AF) ablation. We measured right femoral vein pressure in 57 participants to clarify why groin post-venipuncture rebleeding often occurs during the transition from supine to sitting under compression bandage application and found that it increased more than threefold when raising the upper body (8.6 ± 4.1 to 27.6 ± 6.9 mmHg; $P < 0.001$). Based on that data, we created a novel hemostatic belt. Its capability test including 25 participants demonstrated that the belt gave much higher compression pressures on the right groin while sitting than the compression bandage (59.5 ± 14.9 vs. 8.1 ± 4 mmHg; $P < 0.001$), achieving pressures above the maximum femoral vein pressure in 92% of participants. A randomized trial comparing the belt with compression bandage in 74 AF patients demonstrated that the belt reduced time to ambulation without any rebleeding (340 [92.5–360] vs. 360 [360–360] min; $P < 0.001$) and satisfied more patients.

Keywords Ambulation · Atrial fibrillation ablation · Bed rest · Hemostatic belt · Rebleeding

Introduction

Advances in technology and an accumulation of knowledge have improved the outcomes of atrial fibrillation (AF) ablation. They also have largely eased the patients' physical and psychological burden during the periablation period [1]. Unsolved thorny issues, however, still remain. Aggressive periprocedural anticoagulation and an insertion of several large diameter sheaths necessitate longer than several hours of supine bed rest after the sheath removal to assure the completion of the hemostasis of groin venipuncture sites. Although extended bed rest bothers patients a lot, rebleeding from the femoral venipuncture sites could occur unless it is long enough [2]. The situation where rebleeding occurs is almost always the same. If rebleeding occurs, it occurs when patients raise their upper body on the bed. We previously proposed the following causal mechanism: sitting up on a bed may abruptly and significantly increase the central venous pressure, causing an uncompleted hemostatic plug at the groin venipuncture site to dislodge [2]. We in the present study attempted to physiologically verify the hypothetical mechanism of the rebleeding. We further believed that its clarification would be translated into the development of a hemostatic device that could reduce the patients' burden resulting from prolonged bed rest after ablation without any increase in the risk of rebleeding. The goal of the present study was to develop a hemostatic device based on physiological evidence that would allow ambulation soon after AF ablation and to show its usability.

Materials and Methods

Study Design

This was a prospective study of the development of a novel groin hemostatic belt and its clinical evaluation. The study

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✉ Akinori Sairaku
rjrgw059@ybb.ne.jp

[1] Department of Cardiology, Cardiovascular Center, National Hospital Organization Higashihiroshima Medical Center, 513 Jike, Saijo-cho, Higashihiroshima 739-0041, Japan

[2] Department of Cardiology, Cardiovascular Center, Onomichi General Hospital, Onomichi, Japan

[3] Hiroshima Prefectural Technology Research Institute, Hiroshima, Japan

[4] Department of Cardiovascular Medicine, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

included the following 3 parts. Study part 1 was to examine a hypothetical mechanism responsible for rebleeding from the groin venipuncture site. In part 2, we developed a hemostatic device based on data obtained from study part 1 and tested its capability. Finally, in part 3, we performed a randomized trial to evaluate the efficacy and safety of the hemostatic device as compared to a conventional compression bandage in patients undergoing AF ablation. Different participants were included in each part. Written informed consent was obtained from all participants. The study was conducted at Onomichi General Hospital and Hiroshima Prefectural Technology Research Institute. The study protocol was approved by the research committee of the hospital (OJH-202154) and complied with the provisions of the Declaration of Helsinki. The study was registered on UMIN Clinical Trials Registry (trial ID: UMIN000051594).

Part 1. Sitting-Up Study

The purposes of the "sitting-up study" included (1) to verify the hypothesis that sitting up on a bed may abruptly and significantly increase the central venous pressure, contributing to rebleeding from the femoral venipuncture site, and (2) to determine the compression pressure required on the puncture site to stop the rebleeding. Consecutive hospitalized subjects were considered eligible for inclusion if they were scheduled to undergo right heart catheterization for the purpose of diagnosis or management of clinical conditions, including heart failure, congenital heart disease, heart valve disease, and cardiomyopathy. Subjects were excluded if they were unable to keep a sitting-up position or were planned to receive catheterization via the right or left femoral vein. This part of the study was performed from January to May 2021. The "sitting-up study" protocol was started after the completion of the planned right heart pressure measurements with the use of a 7 Fr Swan-Ganz catheter inserted via the right jugular vein. Firstly, the tip of the catheter was advanced into the right femoral vein at the level of the caput femoris. The participants stayed quiet in a supine position on an X-ray table for 1 min. The participants then raised their upper body on the table and kept the position for 1 min. Thereafter, they returned again to the supine position. The pressure of the femoral vein, non-invasive blood pressure, and heart rate were continuously measured throughout the study. The endpoint was a change in the femoral vein pressure.

Part 2. Device Development and Its Performance Test

The aim of this part of the study was to develop a hemostatic device that would allow patients to move the hip joints immediately after AF ablation. The study period was from June to November 2021. The device concept was a non-invasive disposable wearable device that would be applied for the purpose of groin rebleeding prevention after its temporal hemostasis following the sheath removal. The requirements for the device were (1) a design allowing free hip joint movement, (2) constant appropriate pressure on the groin venipuncture site, (3) tolerability, and (4) harmlessness. The former two requirements contradicted each other. To overcome the contradiction, we decided to use a leaf spring in the device. We created prototypes and tested them to see if they would give an appropriate compression pressure on the inguinal skin. The appropriate compression pressure was defined as a pressure that was proximate to the maximum femoral vein pressure in the sitting position and did not cause insupportable discomfort. The pressure data obtained from study part 1 were used as a reference. The compression pressures were measured with a portable pressure measurement device (Palm Q®, CAPE Co., LTD., Yokosuka, Japan). Its usability has been repeatedly shown in previous works [3]. It measures the interface pressures with a 13 × 13 cm sheet-like sensor, and its measurement principle is based on the airbag method. The measurement range is between 0 and 200 mmHg, and the accuracy is from −3 to 3 mmHg. The device can measure only stabilized pressures, and therefore, each measurement requires 12 s. The details of the measuring procedure are described later in this section.

Once the finished version of the device was completed, its capability was tested on healthy volunteers from the collaborating research institutes. We considered the volunteers eligible for inclusion if they were older than 20 years. Volunteers were excluded if they were pregnant or their hip circumference was > 120 cm.

The external compression pressures on the right inguinal skin were measured with the use of the aforementioned pressure measurement device, while the participants wore the hemostatic device. For comparison purposes, the pressure data were also obtained, while a traditional compression bandage was applied to the right groin in the same participants. First, the participants took a supine position, and the sensor sheet of the pressure measurement device was placed on the right groin so that its center was located just on the presumed puncture site. Second, when the participants were examined with the hemostatic device, its head was placed on the center of the sensor sheet, and it was then fastened. When they were tested with the conventional compression bandage, a compression cotton cube was placed on the center of the sensor sheet, and it was firmly tied down on the groin with the use of elastic adhesive tape. The compression pressure was measured in the supine, sitting, and standing positions. The participants were told to be motionless during each measurement. The pressures were measured 3 times in each body position, and the averages were used for the analyses. The other endpoint was any sense of discomfort caused by the 2 groin compression methodologies that would result in an examination cessation.

Part 3. A Randomized Trial Evaluating the Efficacy and Safety of the Hemostatic Belt

In this part of the study, we conducted a single-center open-label randomized trial comparing the hemostatic belt with the conventional compression bandage. The study period was between September 2022 and February 2023. The subjects with AF who were scheduled to undergo radiofrequency catheter ablation for the first time were eligible for inclusion. Subjects were excluded if their hip circumference was > 120 cm. Eligible subjects were randomly allocated in a 1:1 ratio to receive hemostasis of the right femoral venipuncture site with the use of the hemostatic belt or conventional compression bandage. The randomization was done using a block randomization method. The periablation anticoagulation regimen and ablation strategy were described previously [4]. In brief, a single-dose skip strategy was used for the periprocedural oral anticoagulation with direct oral anticoagulants [1, 4]. A 6-French sheath was placed in the right jugular vein. An 8.5-French and two 8-French sheaths were inserted into the right femoral vein. Intravenous heparin was given to maintain an activated clotting time of 300–350 s. The procedure was carried out under deep sedation. Once the procedure was completed, the sheaths were removed, and constant manual compression was then given on the puncture site until no overt bleeding was observed. No suture was applied. In participants assigned to the hemostatic belt arm, it was thereafter worn so that its silicon head was placed on an adhesive plaster covering the right inguinal puncture holes. They were allowed to move their hip joints freely on the bed immediately after leaving the cath lab. They were even free to ambulate once they fully recovered from the deep sedation. The belt was removed 6 h after the onset of its application. The groin puncture site was carefully checked for any bleeding or hematoma both when they started ambulation during the belt application and when it was removed. The urethral catheter was removed any time they wanted after leaving the cath lab. In participants allocated to the conventional compression bandage arm, it was applied as described in study part 2 after acute hemostasis of the venipuncture site was successfully achieved. They were instructed not to bend their hip joints and to stay still in bed. The bandage was detached 6 h after the onset of its application likewise in the belt arm, and they were allowed to ambulate if no rebleeding or hematoma was noted in the groin puncture site. The time length of the bed rest and belt-wearing time were determined on the basis of our previous reports that showed a somewhat higher rebleeding incidence with a 4-h bed rest [5]. Participants were scheduled to leave the hospital 2 days after the ablation.

The primary outcome was the time from the onset of the application of the belt or compression bandage to ambulation. The secondary outcomes included (1) satisfaction with the 2 hemostatic strategies on a scale of 1 to 10 (1—extremely dissatisfied, 10—extremely satisfied) [6]; (2) rebleeding or hematoma at the groin puncture site that required any medical attention or intervention including additional astriction, sutures, surgical intervention, or blood transfusion; and (3) adverse events resulting from the hemostatic strategies themselves such as skin problems, leg ischemia, or deep venous thrombosis.

Statistical analysis

Normality was tested with the use of the Shapiro-Wilk test. The normally or non-normally distributed continuous variables were summarized as the means±SDs or medians with interquartile ranges and categorical variables as proportions. Comparisons of paired or non-paired normally distributed data between 2 groups were examined with paired *t*-test or Student's *t*-test, respectively. Non-normally distributed continuous variables were compared using the Mann-Whitney *U* test. Fisher's exact test was used to compare categorical variables between 2 groups. Pearson's correlation test was used to assess the correlations between 2 normally distributed continuous variables. Differences across repeatedly measured normally distributed continuous data were tested with the use of one-way repeated measures ANOVA.

The sample sizes of study parts 1 and 2 were determined by reference to the shared knowledge that the minimum sample size for a parametric statistical test may vary from 20 to 50 [7].

The sample size of study part 3 was determined on the basis of the primary outcome. Prior to study part 3, we conducted a clinical utility test on 101 participants who underwent radiofrequency catheter ablation of AF, where 30.7% actually ambulated during the belt application. Among them, the time from the onset of the belt application to ambulation was 94.4 ± 48.5 min. Based on the findings, we estimated that 30% of the participants assigned to wear the hemostatic belt would actually ambulate 95 min after the onset of the belt application on average. Given that the remaining participants allocated to the belt arm were presumed not to start ambulating until the predetermined belt-wearing time would be over, the time to ambulation was expected to be around 6 h for 70% of participants in the belt arm. Therefore, we estimated that the mean time to ambulation would be 280 min in the belt arm. Given that both the belt and conventional compression bandage were supposed to be applied for the same time length, it was estimated to be about 6 h among the participants allocated to the compression bandage arm. Accordingly, the difference in the time to ambulation to be detected was calculated at 80 min. In order to have an 85% power with a two-tailed alpha value of 0.05, we calculated that at least 35 participants would need to be included in each arm to detect the difference, assuming its standard deviation of 110 min. To allow for consent withdrawals or

other unanticipated drop-out, we aimed to enroll a total of 74 participants. The outcomes of study part 3 were analyzed on an intention-to-treat basis.

All statistical analyses were performed with the use of JMP software version 15.0 (SAS Institute, Cary, North Carolina).

Results

Part 1. Sitting-Up Study

A total of 60 subjects were considered eligible, and 3 of them met the exclusion criteria. We then finally studied 57 participants. Approximately half of them ($N = 31$) had congestive heart failure (Table 1). The femoral vein pressure increased more than threefold when raising the upper body (8.6 ± 4.1 to 27.6 ± 6.9 mmHg; $P < 0.001$, Fig. 1). The femoral vein pressure in the sitting-up position ranged from 16 to 43 mmHg. The heart rate changed (72.6 ± 15.8 to 78.9 ± 17 beats/min; $P < 0.001$) with a postural change; however, mean blood pressure did not (98.1 ± 15.2 to 99.1 ± 17.5 mmHg; $P = 0.46$). The pulmonary capillary wedge pressure (18.2 ± 7.8 vs. 13.3 ± 6.7 mmHg; $P = 0.04$), mean pulmonary arterial pressure (25.8 ± 8.5 vs. 18.8 ± 6.1 mmHg; $P = 0.02$), and mean right atrial pressure (8.6 ± 5.4 vs. 5.5 ± 3.4 mmHg; $P = 0.002$) in the supine position were more increased in the participants with congestive heart failure than in those without. However, the femoral vein pressures in both the supine (9.1 ± 4.4 vs. 8 ± 3.6 mmHg; $P = 0.32$) and sitting-up (28 ± 6.9 vs. 27.2 ± 6.9 mmHg; $P = 0.68$) positions did not differ between the participants with and without congestive heart failure. The mean right atrial pressure in the supine position had moderate correlations with the femoral vein pressure in the supine ($r = 0.65$; $P < 0.001$) and that in sitting-up positions ($r = 0.54$; $P < 0.001$).

Part 2. Device Development and Its Performance Test

An outline of the finished version of the hemostatic device is as follows (Fig. 2A). The leaf spring used is made from stainless steel (length 500 mm, width 12 mm, thick 0.8 mm, and radius 35 mm). It is wrapped in a soft fabric, and one of its ends is connected to a strap-buckle complex, forming a belt that encircles the hip. A 55 × 37 × 35-mm hollow soft silicon head is attached to the other end of the belt. It is shaped so that it fits into the right inguinal groove (Fig. 2B). With the resilience of the leaf spring, the head is firmly pressed against the groin puncture site. The material and structure of the head help keep itself immobilized. In order to prevent an upward shift of the head while walking or bringing the knees up, it is strapped into the groin with an elastic cord encircling the upper right thigh. The video images show that the head of the belt is firmly immobilized on the groin puncture site even during dynamic hip joint

Table 1 Baseline characteristics and hemodynamic data of the participants in study part 1

Characteristic	$N = 57$
Age (yrs)	73 ± 12
Female	20 (35.1)
Weight (kg)	63 ± 14
Hypertension	19 (33.3)
Diabetes mellitus	7 (12.3)
Previous pacemaker implantation	7 (12.3)
Congestive heart failure	31 (54.4)
Ischemic heart disease	13 (22.8)
Valvular insufficiency	32 (9.3)
Non-ischemic cardiomyopathy	6 (10.5)
Atrial fibrillation	19 (33.3)
Other tachyarrhythmias	10 (17.5)
Chronic obstructive pulmonary disease	3 (5.3)
Previous stroke	2 (3.5)
Estimated glomerular filtration rate (mL/min/1.73 m^2)	56.1 ± 21.1
Left ventricular ejection fraction (%)	53.5 ± 15.7
Right heart catheterization parameters	
Mean right atrial pressure (mmHg)	7.3 ± 4.9
Mean pulmonary arterial pressure (mmHg)	22.8 ± 8.3
Pulmonary capillary wedge pressure (mmHg)	16.5 ± 7.7

The values are the mean ± SD or *n* (%). Valvular insufficiency includes moderate or severe aortic or mitral valve insufficiencies. Non-ischemic cardiomyopathy is defined as the presence of left ventricular systolic dysfunction with a left ventricular ejection fraction of < 40% in the absence of significant coronary artery disease or valvular insufficiency. Other tachyarrhythmias include atrial flutter, atrial tachycardia, paroxysmal supraventricular tachycardia, and ventricular tachycardia

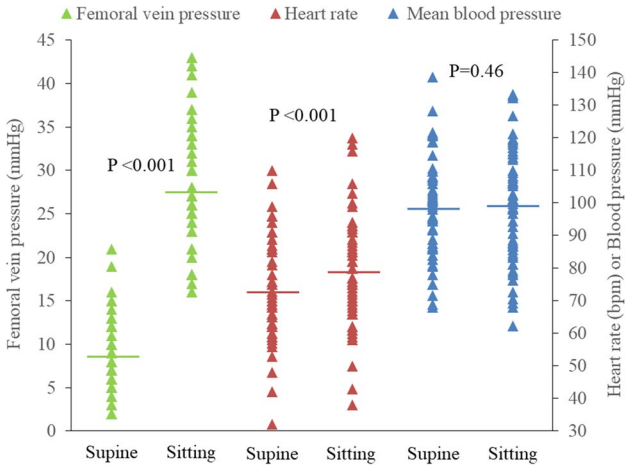

Fig. 1 Hemodynamic parameters during the sitting-up study ($N = 57$). The horizontal lines indicate the means

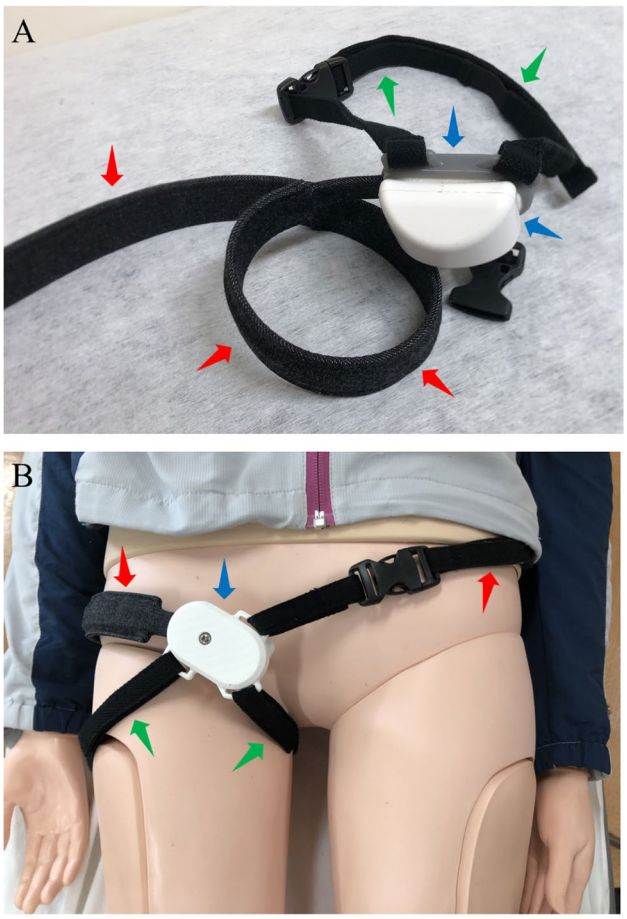

Fig. 2 Hemostatic belt unmounted (**A**) or mounted on a mannequin's hip (**B**). A steel leaf spring wrapped with a cushioning material (red arrows) firmly presses a hollow silicon head (blue arrows) against the right groin skin, and an elastic cord encircling the upper right thigh (green arrows) fixates the head during dynamic hip joint movements or even walking

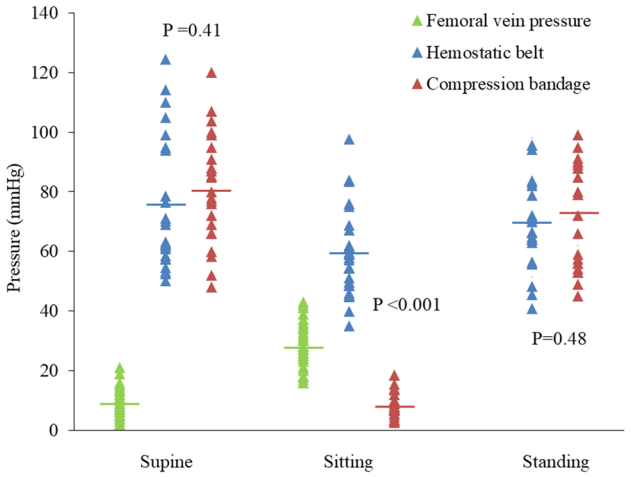

Fig. 3 Compression pressures on the right groin during the application of the hemostatic belt (blue triangles, $N = 25$) and compression bandage (red triangles, $N = 25$) in the supine, sitting, and standing positions. The right femoral vein pressures (green triangles, $N = 57$) in the supine and sitting-up positions are also shown as references. The horizontal lines indicate the means

movements (Videos 1A, B). The belt is for single use. A smaller size is recommended for subjects with a hip circumference of < 88 cm. The belt is not recommended if subjects have a hip circumference of > 120 cm.

A total of 25 people volunteered to receive the performance test for its finished version, and none of them met any exclusion criteria. Their age was 35 ± 8 years, and 10 (40%) were female. The height, weight, and hip circumference were 168.8 ± 6 cm, 63.7 ± 13 kg, and 88.6 ± 6.7 cm, respectively. A smaller size of the belt was used in 14 (56%) participants. The compression pressure on the groin was lower in the sitting than in the supine or standing positions without regard to whether the belt (supine, sitting, standing; 75.8 ± 22, 59.5 ± 14.9, 69.6 ± 16.2 mmHg; $P < 0.001$) or compression bandage (80.3 ± 17.1, 8.1 ± 4, 72.9 ± 17.3 mmHg; $P < 0.001$) was applied. No difference was noted in the compression pressure on the inguinal skin between the 2 compression methodologies while participants were in the supine ($P = 0.41$) or standing positions ($P =$ 0.48). It was, however, significantly higher with the belt than with the compression bandage application while they were sitting ($P < 0.001$, Fig. 3). Among the entire participants, the two compression methodologies achieved much higher compression pressures on the groin in the supine position than the maximum femoral vein pressures in the same body position in study part 1. The groin compression pressure in the sitting position exceeded the maximum femoral vein pressure in the sitting-up position of 43 mmHg among the vast majority of participants (23/25 [92%]) when they wore the belt. On the other hand, with the compression bandage application, no participants had a higher inguinal compression pressure during sitting than the mean femoral vein pressure in the sitting-up position (Fig. 3). No participants reported any discomfort.

Part 3. A Randomized Trial Evaluating the Efficacy and Safety of the Hemostatic Belt

A total of 74 participants underwent randomization. They were allocated in a 1:1 ratio to wear a hemostatic belt or conventional compression bandage. The baseline clinical characteristics were well-balanced between the 2 arms (Table 2). All participants included received the assigned hemostatic approaches after temporal hemostasis of the right groin venipuncture site without any suture. In the hemostatic belt arm, 18 (48.6%) ambulated with the belt on, and the remaining participants began ambulation after their predetermined wearing time (i.e., 6 hours) was over. Among the former subgroup, 11 (61.1%), 1 (5.6%), 1 (5.6%), 1 (5.6%), and 4 (22.2%) participants started ambulation with a belt on 1 to 2, 2 to 3, 3 to 4, 4 to 5, and 5 to 6 h after the ablation, respectively. The

participants in the former subgroup were younger (62 ± 10 vs. 73 ± 7.4 years; $P < 0.001$), were more likely to be male (88.9% vs. 52.6%; $P = 0.03$), and had a greater body mass index (26 ± 4.5 vs. 23.2 ± 2.8; $P = 0.04$) than those in the latter subgroup. A significantly shorter time to ambulation was noted in the belt arm than in the compression bandage arm (340 [92.5–360] vs. 360 [360–360] min; $P < 0.001$, Fig. 4A). The satisfaction score was significantly greater in the belt arm (7 [5–8] vs. 3 [2–5]; $P < 0.001$). In the belt arm, no difference was noted in the score between the participants who ambulated with the belt on and those who did not (7 [5–8] vs. 7 [5–8]; $P = 0.8$, Fig. 4B). The score was higher even in the participants assigned to the belt arm who started ambulation after its removal than in those who wore the compression bandage (7 [5–8] vs. 3 [2–5]; $P < 0.001$) even though the time to ambulation was identical (360 [360–370] vs. 360 [360–360] min; $P = 0.49$). We encountered 2 rebleeding events in the participants allocated to the compression bandage arm ($P = 0.49$); however, none of them needed any surgical intervention. No hematoma or other adverse events were noted in either arm.

Discussion

Major Findings

The major findings of the present study were as follows. (1) The femoral vein pressure increased more than threefold when raising the upper body. (2) The compression pressure on the groin given by the conventional compression bandage fell to a level lower than the femoral vein pressure while sitting in many cases. (3) The novel hemostatic belt obtained a much higher compression pressure on the assumed inguinal venipuncture site while sitting than the compression bandage did. (4) The belt reduced the time to ambulation as compared to the compression bandage without any rebleeding events or other adverse events. (5) Compared to the compression bandage, the belt increased the participant's satisfaction level regardless of whether or not they ambulated with it on.

Mechanism of Rebleeding from the Femoral Vein During the Compression Bandage Application

An elevation of the hydrostatic pressure in the vena cava plus its lack of any valves may explain the steep increase in the femoral vein pressure while sitting up that we found in study part 1 [2, 8]. That phenomenon, however, is never seen in any arteries. That may explain why rebleeding is often encountered at femoral venipuncture sites but not at femoral artery access sites when getting up out of bed [2]. We found a dramatic change in the groin compression pressure given by the compression bandage according to body positions in study part 2. This phenomenon may be explained as follows. Raising the upper body from a supine position necessitated bending of the hip joints, which in turn loosened the elastic tape that tightly tied down the compression cotton cube on the groin. Eventually, the compression pressure dropped substantially. When they changed their position from sitting to standing, the elastic tape was stretched again due to the

Table 2 Baseline characteristics of the participants in study part 3

Variables	Hemostatic belt, N=37	Compression bandage, N=37	*P*-value
Age (years)	67 ± 10	63 ± 15	0.12
Female	11 (29.7)	12 (32.4)	0.8
Height (cm)	164 ± 8.3	166 ± 9.3	0.37
Weight (kg)	66.7 ± 14.2	65 ± 11.9	0.61
Body mass index (kg/m^2)	24.6 ± 3.9	23.6 ± 3.9	0.29
Hip circumference (cm)	87.2 ± 15.1	85.5 ± 14.2	0.62
Heart failure	6 (16.2)	4 (10.8)	0.74
Hypertension	15 (40.5)	17 (45.9)	0.64
Diabetes	5 (13.5)	6 (16.2)	0.99
Left ventricular ejection fraction (%)	60.2 ± 10.3	58.4 ± 10.2	0.5
Left atrial diameter (mm)	37 ± 5	37 ± 5	0.48
Hemoglobin (g/dL)	13.7 ± 2.8	13.9 ± 1.6	0.76
Estimated glomerular filtration rate (mL/min/1.73 m^2)	57.3 ± 23.5	60 ± 28	0.69
Oral anticoagulant			0.32
Dabigatran	0	3 (8.1)	
Rivaroxaban	4 (10.8)	5 (13.5)	
Apixaban	15 (40.5)	12 (32.4)	
Edoxaban	18 (48.6)	17 (45.9)	

Data are presented as the mean ± SD or *n* (%)

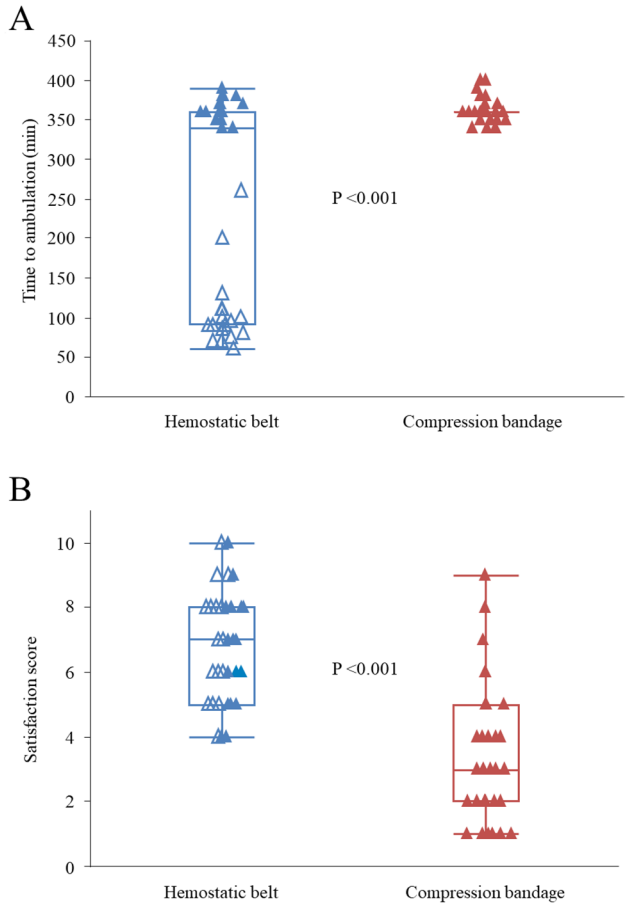

Fig. 4 Box plots and distribution of the time to ambulation (**A**) and the satisfaction score (**B**) in the hemostatic belt arm (blue triangles, $N = 37$) and conventional compression bandage arm (red triangles, $N = 37$). The hollow blue triangles indicate the participants assigned to the belt arm who ambulated with the belt on, and the solid blue triangles mean those who did not ambulate until the predetermined wearing time was over. The upper and lower whiskers indicate the 90th and 10th percentiles, respectively. The top and bottom of the boxes indicate the 75th and 25th percentiles, respectively, and the horizontal lines within the boxes indicate the 50th percentile (i.e., median)

extension of the hip joints, and consequently, the compression pressure returned to a similar level as seen in the supine position. Importantly, the steep increase in the femoral vein pressure, and drastic decrease in the compression pressure on the groin given by the compression bandage occurred simultaneously when the subjects raised their upper body. That may successfully answer the clinical question of why the situation where rebleeding from the femoral vein occurs in patients with a compression bandage is almost always one where they raise their upper body on the bed.

Clinical Utility of the Hemostatic Belt

Compression has been the most reliable hemostasis methodology up to the present time. The development of our device was based on this point of view. However, an anatomical characteristic of the groin made it challenging to strike a balance between a constant compression against the inguinal groove and free hip movement. We successfully overcame this incompatibility, mainly thanks to the leaf spring. Although the novel hemostatic belt successfully reduced the time to ambulation as compared to the conventional compression bandage, approximately half of the participants in the belt arm did not ambulate during the device application in study part 3. Possible responsible factors included the longer-than-expected time necessary for a recovery from deep sedation, completion of the ablation procedure during the evening shift, fear of rebleeding, or reluctance to remove the urethral catheter. We did not expect to find that the satisfaction level was significantly higher even in participants assigned to the belt arm who did not ambulate with it on than in those allocated to the conventional compression bandage arm even though their bed rest time did not differ. This finding suggests that more than a few participants may have been frustrated with the state of being unable to move their legs rather than a prohibition of ambulation for hours because the belt allowed them not only to ambulate but also to move their legs freely on the bed.

Suture-mediated or collagen-based closure devices have become popular for hemostasis of groin puncture sites following AF ablation [9, 10]. Compared to them, our device may have a couple of advantages. (1) Each vascular puncture hole basically needs a single closure device to close it, indicating that 2 or more of them are necessary for each AF ablation procedure [5, 6]. With ours, however, each patient needs only a single device regardless of the number of puncture holes if all of them are in the right groin. (2) Unlike the closure devices, ours is not invasive and does not need any training or proficiency.

Clinical implications

First, to the best of our knowledge, this study was the first to examine the mechanism whereby rebleeding occurs in a certain situation after AF ablation. Second, our device was developed on the basis of physiological evidence. Finally, it may be clinically significant that our study offered another treatment option in the field of AF ablation.

Limitations

We did not test the device in morbidly obese subjects. We tested it in Japanese alone. We did not develop the device for a left-sided femoral venipuncture. The compression pressure given by it was higher than necessary in the supine and standing positions. We did not compare the device to

a widely accepted suture technique, the figure-of-8 suture [11], or the closure devices [9, 10]. All of those must be future challenges. Again, around half of the participants did not ambulate during the device application in study part 3. Finally, this was not a multi-center study.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12265-023-10417-2.

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Declarations

Ethics approval Not applicable.

Conflict of interest The authors declare no competing interests.

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