Article

Digital Therapeutic Intervention for Venous Thromboembolism Prevention: Efficacy Evaluation of Telemonitored Ankle Pump System in Tibial Plateau Fracture Patients

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AIM: Deep vein thrombosis (DVT) is acknowledged as the primary complication associated with tibial plateau fractures (TPFs), necessitating the implementation of preventive measures such as physical exercise. While ankle pump exercise (APE) is an effective preventive measure, challenges such as insufficient monitoring and a shortage of nursing staff have been identified. Therefore, our study aimed to evaluate the efficacy of the self-developed telemonitored APE compared to conventional APE.

METHODS: The study was conducted in a randomized parallel-group design (Consolidated Standards of Reporting Trials (CONSORT)-compliant). We randomized 60 participants with TPFs into two groups for traditional APE (Group A) and telemonitored APE (Group B) separately. The study population was recruited from Zhejiang Hospital between December 2022 and June 2024. Evaluate the efficacy by four indices: diameter and flow velocity of the femoral vein and popliteal vein in the lower extremity, the increased value of postoperative calf diameter, visual analogue scale (VAS), and D-dimer.

RESULTS: Following both telemonitored and traditional APE, statistically significant differences ($p < 0.05$) were detected between the two groups in at least one assessment period. Group B showed significantly lower VAS than Group A on postoperative day 7 ($p = 0.001$) and day 14 ($p < 0.001$). Group B had a lower D-dimer level on postoperative day 7 ($p = 0.004$). Group B showed a smaller calf diameter increment on day 7, $p = 0.001$). Group B had a significantly higher popliteal vein flow velocity after APE ($p < 0.001$).

CONCLUSIONS: The remote monitoring ankle pump system is more effective than traditional methods in reducing postoperative pain, improving venous hemodynamics, and reducing thrombotic risk indicators, demonstrating its significant clinical value in the prevention and rehabilitation of lower extremity deep vein thrombosis in patients with tibial plateau fractures.

CLINICAL TRIAL REGISTRATION: Chinese Clinical Trial Registry (ChiCTR2200065384).

Keywords: deep vein thrombosis; ankle pump exercise; tibial plateau fractures

Introduction

Tibial plateau fractures (TPFs) are complex injuries in the field of trauma and orthopedics, often leading to severe complications due in part to their long period of immobilization, mechanism, and prolonged hospital admissions [1,2]. TPFs constitute 1% of all fractures and 8% of fractures in the elderly. Besides, there is a large variation in the incidence of deep vein thrombosis (DVT) in patients surgically treated for tibial plateau fractures and ranges from 1.7 to 42.9% [3]. Moreover, it is widely recognized that DVT is an important cause of mortality, especially in orthopedic surgery patients [4].

Venous thromboembolism (VTE), which encompasses DVT and pulmonary embolism (PE), ranks as the third most common cardiovascular disease globally, following myocardial infarction and ischemic stroke [5]. Among surgical inpatients, postoperative immobilization and hypercoagulable states associated with inflammation significantly increase the risk of VTE by 128% compared to medical inpatients. The pathophysiology of VTE involves a spectrum of risk factors, including genetic predispositions (e.g., thrombophilia) and acquired conditions (e.g., prolonged immobility, surgery, and malignancy). Genetic factors include thrombophilia-related mutations like factor V Leiden and prothrombin gene mutation, increasing clot-forming tendency [6]. Environmental factors such as long-term immobility, surgery, and malignancy promote VTE. Immobility slows blood flow, surgery injures vessels and causes hypercoagulability, and malignancy activates the coagulation system. Common symptoms and signs of DVT include swelling, pain, erythema, and dilated veins in the affected limb [7,8]. DVT occurs predominantly in the lower extremities and is a common complication in hospitalized patients with an incidence of 0.5 to 1.4 cases per 1000 popu-

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lation per year, which increases with age [9,10]. Moreover, DVT can lead to pulmonary thromboembolism, which, in severe cases, may result in patient mortality. Given the high morbidity and mortality associated with VTE, early recognition and intervention are critical. Therefore, preventive measures are essential. DVT was attributed to various factors, but physical methods were administered extensively to speed up the femoral vein for prevention [11].

Ankle pump exercise (APE) are a fundamental physical modality designed to promote venous blood return in the lower extremities. This technique involves rhythmic contractions and relaxations of the calf muscles, which act as a peripheral "pump" to propel blood from the deep veins of the legs toward the heart. Through coordinated ankle joint movements, APE effectively compresses the venous plexus, enhancing venous flow and reducing stasis [12,13]. The ankle joint facilitates dorsiflexion and plantarflexion movements around the axis of the talus, thereby playing a crucial role in lower limb biomechanics. Meanwhile, scholars around the world have demonstrated the effect of lower extremity exercise on the prevention of DVT [14]. Previous studies have demonstrated that active ankle movement is highly effective in promoting blood flow and reducing venous reflux in the lower limbs, thereby highlighting its potential role in preventing DVT [15,16].

However, the efficacy of APE was related to the performance of patient management. According to the traditional APE, nurses were considered to play a key role in the prevention of DVT. This caused a requirement for the detection of different exercise modes, times, and frequencies. Thus, we invented an electronic detector for the telemonitored APE. The invention could accurately monitor the exercise and upload the data of the exercise to the internet as a reference for doctors and patients. Otherwise, there was a schematic for all populations about APE, thus helping to implement the instructions and revealing to rehabilitation situation. Our study aimed to demonstrate the efficacy of the telemonitored APE for patients with TPFs on precise data by pairwise comparison with the traditional APE.

Materials and Methods

Participants

The participants in this study were patients diagnosed with TPFs, recruited from December 2022 and June 2024 at Zhejiang Hospital. Written consent was obtained from all participants. All patients underwent open reduction and internal fixation for tibial plateau fracture, and the surgical approach (lateral, medial, or bilateral) was determined based on fracture type (Schatzker classification). Populations included were willing to follow the procedure of the trial and corresponded to the details as follows: (1) Aged between 41–60 years old. (2) Postoperative orthopedic patients assessed to be at medium-high risk of VTE by the Caparini Assessment Scale. (3) In good general and mental condition. (4) Coordination with treatment. (5) In good compliance. In addition to the aforementioned criteria, patients meeting the following conditions were excluded: (1) Patients who were unable to complete APE. (2) VTE was diagnosed. (3) Severe motor ability limitation. (4) Complicated with serious cardiopulmonary, liver, and kidney diseases. (5) Language communication disorders, Alzheimer's disease, or cognitive impairment. (6) Reluctance to participate.

Sample Size Calculation

A sample size calculation was conducted using the increased value of postoperative calf diameter as the primary outcome. Based on a pilot study of 15 patients, the standard deviation (σ) was 2.1 cm, and we expected a 1.6 cm difference (δ) between groups. With a significance level (α) of 0.05 (two-tailed) and a power of 0.80 ($Z_{1-\alpha/2}$ = 1.96, $Z_{1-\beta}$ = 0.84), the formula $n = \frac{2\left(Z_{1-\alpha/2}+Z_{1-\beta}\right)^2\sigma^2}{\delta^2}$ yielded an estimated sample size of approximately 28 per group. Accounting for a 7% dropout rate, the adjusted sample size was around 30 per group. Ideally, 60 participants (30 per group) were needed.

Experimental Design (Study Participants and Characteristics)

The study was designed as a randomized controlled clinical trial following the Consolidated Standards of Reporting Trials (CONSORT) checklist. The study protocol was approved by the Ethics Committee of Zhejiang Hospital (Approval No. 2022-41K) and registered in the Chinese Clinical Trial Registry (ChiCTR2200065384) (https://www.chictr.org.cn/showproj.html?proj=177744). Randomization was performed using a simple randomization method with random numbers generated by the UNIFORM function in SPSS statistical software (version 24.0; IBM Corp., Armonk, NY, USA). A detailed CONSORT-compliant flowchart depicting the enrollment and attrition of participants throughout the study is presented in Fig. 1 to enhance the transparency of the study process. Participants were randomly assigned to one of two groups: Group A (conventional APE) and Group B (telemonitored APE). Characteristics such as age, gender, body mass index (BMI), intraoperative blood loss, operation duration, and Schatzker's classification were measured for the characteristics of the participants between the two groups. To account for potential carryover effects of APE on venous hemodynamics, patients were not informed of the specific mode of APE before surgery as a washout period.

Method of APE

Conventional APE: The charge nurse will conduct regular education, including oral explanation, distribution of the ankle pump campaign education form, and sharing of the quick response code of the APE education video. Details are as follows: (1) The subjects lay supine on the bed with their legs slightly extended, thighs relaxed, an-

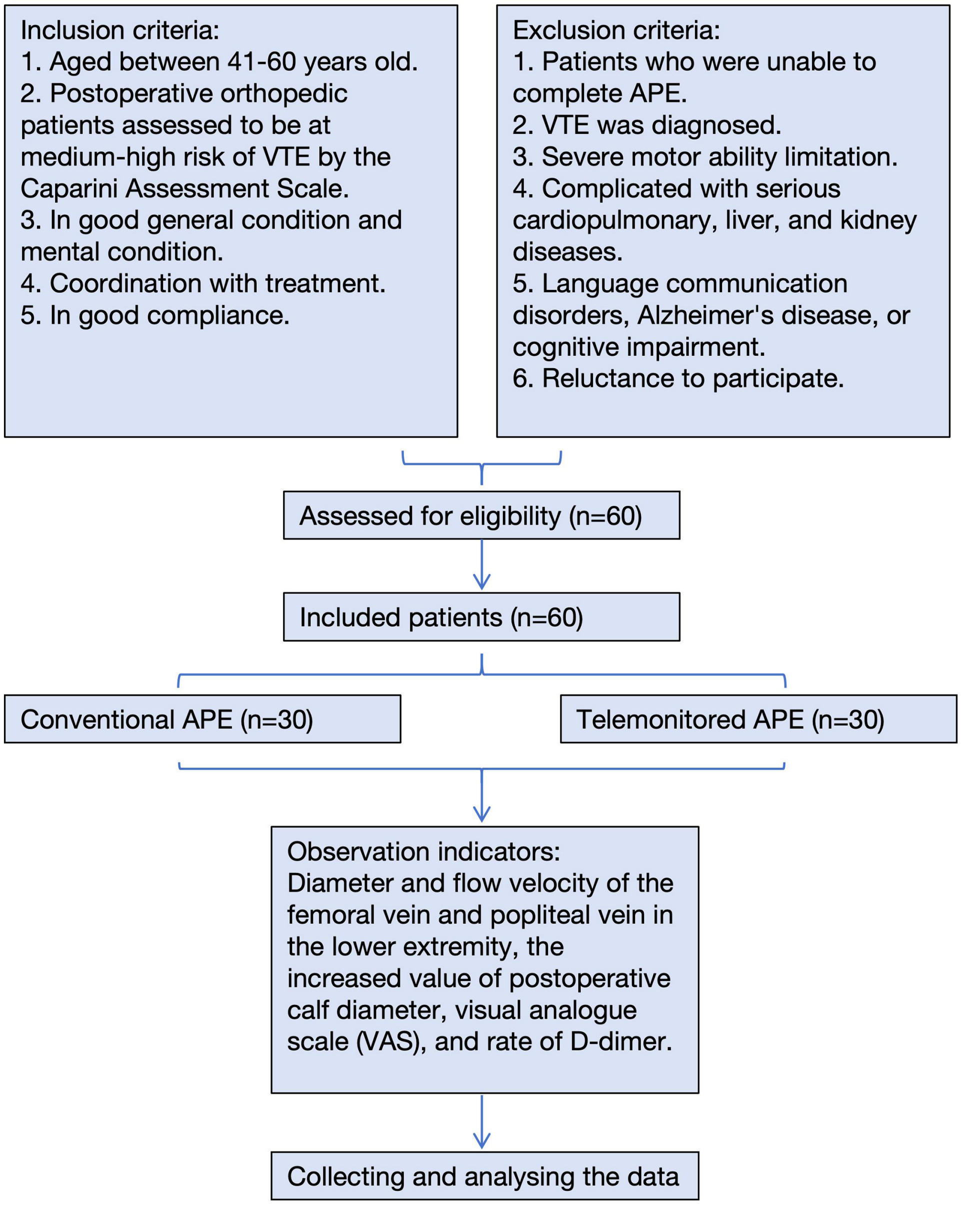

Fig. 1. CONSORT-compliant flowchart of the study. APE, ankle pump exercise; VTE, venous thromboembolism; CONSORT, Consolidated Standards of Reporting Trials.

kles cushioned with cotton pads, and feet alternately dorsiflexed (toes toward themselves) and plantarflexed (toes away from themselves) for one cycle (Fig. 2). (2) Circle the ankle joint (Fig. 3). (3) Exercise at a rate of 30–60 repetitions per minute. (4) One set of 3 minutes every hour, except for sleep time. During the initial mission, exercise guidance was given at the patient's bedside, and errors in the exercise process were corrected in time. To further enhance patients' compliance, a regular health education session was held every day, during which the importance of ankle pump exercises in preventing deep vein thrombosis was emphasized again. Nurses conducted regular observations and recorded patients' exercise details in an electronic log at least once every 6 hours.

Telemonitored APE: An ankle pump counter (Patent No. ZL 2020 2 1292479.8; product batch number: 20241002; Zhejiang Zhongxinan Medical Technology Co., Ltd., Shaoxing, China) was used to assist patients with APE (Fig. 4). Based on the conventional APE education, the nurse applied the ankle pump counter to assist. The ankle pump counter used in the telemonitored APE system was equipped with an accelerometer sensor and was repeatedly confirmed to be available. Calibration of the ankle pump counter was performed before each patient's first use. The calibration process involved zero-point adjustment and sensitivity calibration according to the device's user manual. The nurse assisted the patient in binding the WeChat program of the APE counter and explained the use

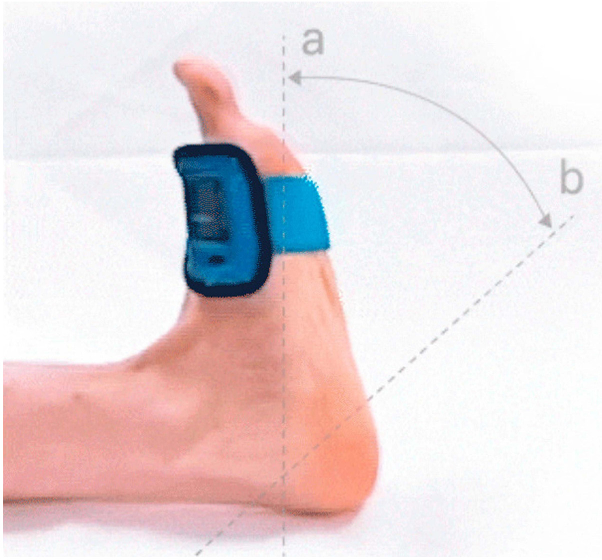

Fig. 2. APE: Diagram of ankle dorsiflexion and plantar flexion. (Position a is the reference position for ankle dorsiflexion activity. The b position is the reference position for ankle plantarflexion activity.)

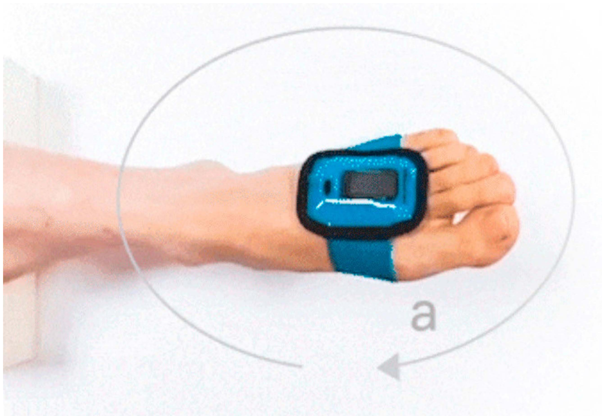

Fig. 3. APE: Diagram of ankle joint circumferential movement. (Line a represents the trajectory of the activity).

of the counter until the patient was able to independently operate the program and perform exercises in sync with the rhythm of the system's background music. The duration of one piece of background music was 3 minutes. The patient-side system periodically displays exercise reminder notifications to encourage patients to perform APE. It also provides quantitative statistics on the exercises, allowing patients to self-monitor their current movement data via their mobile phones. Utilizing dynamic analysis and finite element simulation, the acceleration sensors of telemonitored APE can help transmit and analyze in real-time. The medical terminal continuously captures and processes real-time movement data from all patients through the integrated counter, reminds those who do not meet the current ankle pump movement standards again, and urges the patients to complete the APE.

Fig. 4. The appearance of the telemonitored APE and the display of the software on the mobile phone.

In the supine position, all participants tried their best to keep their emotions calm and their limbs relaxed to breathe steadily. This approach ensured that the distribution of blood flow velocity was not influenced by participants' breathing patterns [17]. In both group A and group B, participants engaged in ankle dorsiflexion and plantarflexion exercises at a rate of 30 repetitions per minute, sustained for 3 minutes every hour, except for sleeping periods. The difference was that patients in group A were treated by traditional propaganda and education. Nurses counted with a stopwatch to ensure that subjects' performance accorded with the requirements. Patients in group B wore the ankle pump counter system developed by our team. The ankle pump plan was sent to the patient's terminal, and patients regularly carried out active dorsal extension and plantarflexion movement according to the reminder.

Ultrasonography

The diameter and flow velocity of the femoral and popliteal veins in the lower extremity were assessed using a fully digital color Doppler ultrasound diagnostic system (Model Apogee 1100, 180 W power; GE Healthcare, Chicago, IL, USA). Compression B-scan with compression and color Doppler imaging was performed using a linear probe with a frequency of 7.5 MHz. The internal diameters and peak systolic velocities of the femoral and popliteal veins were measured both before and after the APE to assess the impact of these exercises on venous hemodynamics. All ultrasound measurements were performed by a single experienced staff member to minimize interobserver variability. The assessor was blinded to group assignment.

Assessment of Swelling

Calf diameter was gauged at various times (preoperative, 1 day postoperative, 7 days postoperative, 14 days postoperative) with a tape measure, with a nurse as the participants were lying in the supine position. Additionally, the study calculated and reported the incremental changes in calf diameters relative to preoperative baseline values in the results section. To ensure the reliability of calf diameter measurements, cross-validation was performed. Two experienced nurses were trained to measure the calf diameter using a standardized tape measure. The measurement was taken at the mid-calf level, which was marked with a non-permanent skin marker before each measurement. Then, the increased value of postoperative calf diameter between the two groups (compared with the preoperative) was recorded. Previous studies have shown that nutritional changes throughout the body are not consistent with age, make anthropometric measurements of the lower extremities may serve as a potential indicator of overall muscle mass throughout the body [18,19]. This approach could provide valuable insights into the body's muscle composition, especially in clinical settings where age-related changes in muscle mass are common. Moreover, the measurement of calf circumference has been widely used in lower limb study to quantitatively assess lower limb mass, physical-related quality of life, frailty, and functional ability [20]. This metric integrates multiple aspects of lower limb health and function into a single, easily measurable parameter [21]. Considering the patients' position, we have adopted calf diameter as one of the primary indicators in our analysis.

Evaluation Scale of Pain

Since the 1920s, the visual analogue scale (VAS) has been utilized to quantify intangible experiences such as quality of life, anxiety, and pain. In the 1960s, the VAS was further applied in psychology for the measurement of mood disorders and became a standard tool for pain assessment [22]. The VAS typically comprises a 100-mm line, anchored by descriptors "no pain" and "excruciating pain" [23]. Participants indicated their perceived level of pain by making a mark on the line, and the distance from the left endpoint to this mark was subsequently measured in millimeters. Here we compared the postoperative VAS from the first day, seventh day, and fourteen day after the operation.

Blood Samples

We used the D-dimer as an observation index. D-dimer is a fibrinolytic marker widely accepted to diagnose thrombosis. Previous study reported that the D-dimer level was increasing in populations with acute deep vein thrombosis and was the preferred index for monitoring lower extremity deep vein thrombosis [24]. Therefore, the D-dimer level is considered a reliable indicator for ruling out DVT. In this study, serum D-dimer levels were assessed using the latex agglutination method to evaluate the degree of hypercoagulability in patients. D-dimer levels were measured using the Siemens ADVIA Centaur CP immunoassay analyzer (Siemens Healthineers, Munich, Germany). Measurements were taken preoperatively, as well as on postoperative days 1 and 7, to monitor changes in coagulation status throughout the early postoperative period.

Statistical Analysis

To assess the normality of the data distribution, the Kolmogorov-Smirnov test was employed. For continuous variables following a normal distribution, data are presented as mean (M) and standard deviation (SD); for non-normally distributed continuous variables, data are presented as median (interquartile range, IQR). In this study, chi-square (χ^2) tests were employed to examine differences in gender and Schatzker classification between groups. Independent samples *t*-test is applied to variables following normal distribution. Nonparametric tests were used for non-normally distributed data, while repeated measurement analysis of variance (RM-ANOVA) was applied to assess time-dependent changes in variables. Besides, Friedman test was used for repeated measurement data that did not conform to the normal distribution. The adjusted significance level was calculated by dividing the original significance level (α = 0.05) by the total number of comparisons made for each variable. In order to control the risk of Type I error associated with multiple comparisons, we employed the Bonferroni correction method. All statistical analyses were performed using SPSS software (version 24.0; IBM Corp., Armonk, NY, USA), with a two-tailed significance level set at $p < 0.05$.

Results

General Information

Based on the established criteria, 60 patients who underwent surgical treatment for TPFs were enrolled and randomly assigned to either Group A or Group B. The study cohort comprised 38 males and 22 females, with ages of 49 (41, 56) years and 52 (44, 57) years in Groups A and B, respectively. The subjects were divided into six types according to Schatzker's classification. There was no significant statistical difference among age, gender, BMI, intraoperative blood loss, operation duration, and Schatzker's classification ($p > 0.05$). The specific data are presented in Table 1. The intraoperative blood loss was 50.0 (44.0, 54.5) mL in group A and 53.5 (48.0, 57.0) mL in group B during the surgery. No statistically significant differences were observed between the two groups ($p > 0.05$). The operation duration was 121.4 (SD = 31.6) minutes in Group A and 116.9 (SD = 25.4) minutes in Group B during the operation. There was no significant statistical difference between the two groups ($p > 0.05$). Details of the intraoperative blood loss and operation duration can be acquired in Table 2. Throughout the study period, none of the partici-

Table 1. The characteristics of the participants between the two groups.

Groups	Cases	Age (years)	Gender		BMI (kg/m^2)	Schatzker's classification					
			Male	Female		Type I	Type II	Type III	Type IV	Type V	Type VI
Group A	30	49 (41, 56)	20	10	24.8 ± 3.2	2	7	9	6	4	2
Group B	30	52 (44, 57)	18	12	23.9 ± 3.7	3	6	8	7	5	1
Statistics		Z = –0.540	χ^2 = 0.287		t = 1.055	χ^2 = 0.857					
p		0.590	0.592		0.296	0.973					

BMI, body mass index.

Table 2. Postoperative data of both groups.

Groups	Cases	Intraoperative blood loss (mL)	Operation duration (min)
Group A	30	50.0 (44.0, 54.5)	121.4 ± 31.6
Group B	30	53.5 (48.0, 57.0)	116.9 ± 25.4
Statistics		Z = –1.474	t = 0.607
p		0.140	0.546

pants experienced pulmonary embolism or abnormal bleeding events attributed to lower extremity DVT.

VAS Score

In total, data were extracted from 60 participants for different periods. Researchers extracted data from the first, seventh, and fourteenth postoperative days (PODs). The median and IQR of group A and group B on the first day of postoperative day were 5 (4, 6) and 5 (4, 7). There were no significant statistical differences (p = 0.82). Besides, the median and IQR on the seven days of the postoperative day were 5 (4, 6) in group A and 4 (2, 5) in group B, with a significant statistical difference (p = 0.001). On the fourteen day after the operation, the median and IQR of group A and group B were 2 (1, 3) and 1 (0, 2). There were significant statistical differences between the two groups ($p < 0.001$). The details were shown in Table 3.

Comparison of D-dimer Before and After Operation

Data was acquired from a total of 60 participants. The data were measured on the day of surgery, the first postoperative day, and the seventh postoperative day. The comparison of the increased value of postoperative calf diameter between the two groups was mainly considered the D-dimer. The results demonstrated that there was a significant statistical difference on the seventh day after the operation (p = 0.004). The mean and SD of group A and group B were 1.1 (SD = 0.48) and 0.78 (SD = 0.3), respectively. The median and IQR of group A and group B on the first day of postoperative day were 1.09 (0.61, 1.58) and 0.96 (0.41, 1.62). There was no significant statistical difference (p = 0.464). On the preoperative day, the median and IQR of group A and group B were 1.42 (0.91, 1.72) and 1.03 (0.66, 1.73). Again, no significant statistical differences were detected (p = 0.209). The details can be acquired in Table 4.

Increased Value of Postoperative Calf Diameter Compared With Preoperative

Data were acquired from 60 participants in total at various times. Compared to the preoperative situation, the increased value of mean and standard deviation of the calf diameters in group A and group B were measured on the first day, the seventh day, and the fourteenth day after operation. The mean and SD of group A on the first day and the fourteenth day were 7.69 (SD = 3.5) and 2.46 (SD = 2.39), respectively. Besides, the mean and SD of group B on the first day and the fourteenth day were 7.14 (SD = 2.73) and 2.71 (SD = 2.39). There was no significant statistical difference in comparison between group A and group B on the first day after surgery and the fourteenth day after operation ($p > 0.05$). However, the mean and SD of group A and group B on the seventh day were 4.80 (SD = 3.19) and 2.32 (SD = 2.46), with a significant statistical difference (p = 0.001). The details were shown in Table 5.

Effects of APEs on Venous Hemodynamics of Lower Extremities

A total of 60 participants had their data obtained at different time intervals. The data was measured before performing APE and after APE separately. At rest, the internal diameters of the femoral vein were 0.64 (0.57, 0.73) and 0.68 (0.60, 0.74) in groups A and B, respectively, before performing APE and telemonitored APE. After the duration, the internal diameters of the femoral vein in groups were 0.71 (SD = 0.08) and 0.72 (SD = 0.09). Both comparisons between the two groups at various time showed no significant statistical difference (p = 0.566). This was similar to the statistics of the diameters of the popliteal vein in the lower extremity. Statistical analysis revealed no significant differences ($p > 0.05$). The internal diameters of the popliteal vein in group A and group B were 0.62 (0.47, 0.70) and 0.67 (0.49, 0.77) before APE and telemonitored APE. The internal diameters of the popliteal vein in groups were 0.71 (SD = 0.09) and 0.68 (SD = 0.11) after the therapy,

Table 3. Comparison of postoperative VAS between the two groups.

Groups	Cases	POD 1	POD 7	POD 14	χ^2	p
Group A	30	5 (4, 6)*	5 (4, 6)*	2 (1, 3)	39.103	<0.001
Group B	30	5 (4, 7)*	4 (2, 5)*	1 (0, 2)	40.304	<0.001
Statistics		Z = –0.227	Z = –3.257	Z = –4.153		
p		0.82	0.001	<0.001		

VAS, visual analogue scale; POD, postoperative day.

*$p < 0.05$. Compared with POD 14.

Table 4. Comparison of D-dimer before and after operation between the two groups.

Groups	Cases	Preoperation (mg/L)	POD 1 (mg/L)	POD 7 (mg/L)	χ^2	p
Group A	30	1.42 (0.91, 1.72)	1.09 (0.61, 1.58)	1.1 ± 0.48	0.521	0.771
Group B	30	1.03 (0.66, 1.73)	0.96 (0.41, 1.62)	0.78 ± 0.30	4.588	0.101
Statistics		Z = –1.257	Z = –0.732	t = 3.051		
p		0.209	0.464	0.004		

respectively. There was no evident statistical difference (p = 0.219). The velocity of the femoral vein in group A and group B was 16.73 (15.29, 17.89) and 17.19 (14.63 18.98) before performing APE and telemonitored APE (p = 0.559). At the end of the duration, the velocity of the femoral vein in groups was 18.47 (16.54, 21.43) and 19.70 (16.74, 24.14). Statistical analysis revealed no significant differences (p = 0.062). Regardless of whether participants performed traditional APE or telemonitored APE, the velocities and diameters of the femoral and popliteal veins were elevated compared to resting values (Table 6). Only the velocity of the popliteal vein after APE between the two groups showed a statistical difference ($p < 0.001$). The details were displayed in Table 6.

Discussion

Our results demonstrated that telemonitored APE had a better efficacy on patients than traditional APE. Our study employed a randomized parallel-group design, which avoids the need for a washout period by assigning participants to independent intervention groups. This design minimizes carryover effects, as each participant receives only one intervention throughout the study. Baseline characteristics were well-balanced between groups (Table 1), and randomization effectively mitigated confounding variables, ensuring the validity of our results.

The improved indices contained Visual Analogue Scale, postoperative D-dimer levels, increased values of postoperative calf diameter and velocity of popliteal vein after APE. VAS showed a significant statistical difference on the seventh day and the fourteenth day of the postoperative period between groups A and B. Thus, the efficacy of the telemonitored APE on VAS was inclined to be lasting and credible. On the seventh day of postoperative day, the statistics of the D-dimer after operation between the two groups displayed an evident statistical difference. Similar to the D-dimer, the data of increased values of postoperative calf diameter showed a difference on the seventh day after the operation, while there was no statistical difference on the fourteenth day after the operation. The telemonitored APE had shown a significant improvement in the treatment, but lacked long-term efficacy. Except, the velocity of the popliteal vein after APE demonstrated a statistical difference between the two groups. The results of our research could prove that the function of telemonitored APE had been developed.

TPFs accounted for 1.2% of all fractures among populations, it was a rare and serious spectrum. However, the prevalence of this type of fracture is as high as 8% of all fractures, representing a wide demographic spectrum. This demographic spectrum encompasses a wide variety of individuals, extending from younger, physically fit males who are typically involved in high-energy trauma incidents to frail elderly females who often have underlying conditions such as osteoporosis. Additionally, the highest incidence in both sexes is reported among individuals aged 40–60 years [25]. The tibial plateau, a key component of the knee joint, is one of the body's primary load-bearing areas, often subjected to forces that can exceed five times an individual's body weight [26]. The lateral plateau is more susceptible to injury compared to the medial plateau, which is stronger, larger, and more rounded [27]. The interplay between axial loading forces and coronal plane moments (varus or valgus) can precipitate fractures, resulting in articular shear and depression, as well as mechanical axis malalignment. This mechanism is particularly relevant in TPFs, where the combination of these forces can lead to complex injury patterns [28]. The initial trauma and extensive tissue damage from surgical exposure often lead to early complications, such as impaired wound healing, infection, and DVT [29]. DVT is one of the primary complications that can significantly impair the recovery process and negatively affect overall patient outcomes [30].

Deep vein thrombosis (DVT) remains a distinct health problem that places an economic, morbidity, and mortality burden on healthcare systems worldwide [31,32]. The prevalence of lower extremity DVT is approximately 1% in the

Table 5. Comparison of the increased value of postoperative calf diameter between the two groups (compared with preoperative).

Groups	Cases	POD 1 (cm)	POD 7 (cm)	POD 14 (cm)	F	p
Group A	30	7.69 ± 3.5	4.80 ± 3.19	2.46 ± 2.39	26.158	<0.001
Group B	30	7.14 ± 2.73	2.32 ± 2.46	2.71 ± 2.39	23.44	<0.001
Statistics		t = 0.669	t = 3.363	t = –0.404		
p		0.506	0.001	0.688		
Omnibus tests						
Test of between-subjects effects			F = 4.105, p = 0.019			
Test of within-group effects			F = 54.280, p < 0.001			
The interaction between between-subjects and within-group			F = 4.098, p = 0.048			

Table 6. The femoral vein and popliteal vein before and after APE.

Groups	Cases	Velocity of femoral vein before APE, cm/s	Velocity of femoral vein after APE, cm/s	Diameter of femoral vein before APE, cm	Diameter of femoral vein after APE, cm	Velocity of popliteal vein before APE, cm/s	Velocity of popliteal vein after APE, cm/s	Diameter of popliteal vein before APE, cm	Diameter of popliteal vein after APE, cm
Group A	30	16.73 (15.29, 17.89)	18.47 (16.54, 21.43)	0.64 (0.57, 0.73)	0.71 ± 0.08	13.86 (11.23, 15.53)	14.68 (12.96, 16.77)	0.62 (0.47, 0.70)	0.71 ± 0.09
Group B	30	17.19 (14.63 18.98)	19.70 (16.74, 24.14)	0.68 (0.60, 0.74)	0.72 ± 0.09	12.98 (11.35, 14.43)	17.11 (15.24, 17.84)	0.67 (0.49, 0.77)	0.68 ± 0.11
Statistics		Z = –0.584	Z = –1.563	Z = –1.006	t = –0.578	Z = –0.917	Z = –3.696	Z = –1.044	t = 1.243
p value		0.559	0.062	0.314	0.566	0.359	<0.001	0.297	0.219

general population. Although multicenter epidemiological data are lacking in China, study has shown that the prevalence of DVT among patients in intensive care units ranges from 10% to 100%. This high prevalence may lead to significant mortality, with 2.1% to 4.7% of patients dying from DVT-related complications [33]. As a result of the data, the prevention became of particular importance, and considering the situation of care units [34]. Thus, nurses were assumed to play an essential role in DVT prevention.

Early in 1856, biologists proposed the major factors of DVT, including vascular intimal injury, slow blood flow and hypercoagulable state of blood [35]. Because of the factors above, regimens of basic prevention, physical prevention and drug prevention have been formulated [36]. In terms of physical and pharmacological prevention, several standardized interventions containing anticoagulants and antithrombotic pumps have been developed [37]. Drugs may be prone to other complications, thus the restriction on their application. Physical methods that were able to speed up the femoral vein blood flow velocity were extensively administered to prevent postoperative DVT. However, while these measures significantly reduced the incidence of DVT, they still faced several limitations.

APE has long been recognized as a common and straightforward mechanical method for prevention. Compared with the findings of Yuan *et al*. [38], who reported a femoral vein flow velocity increase through ankle pump exercises, our study using the telemonitored APE system demonstrated a more significant decrease. Both studies, however, agreed on the effectiveness of ankle pump-based interventions in reducing D-dimer levels, indicating their potential role in preventing venous thromboembolism. APE increases venous return to the lower extremity by rhythmic contraction and relaxation of the calf muscles driven by ankle movements. Each contraction of the calf muscles propels blood from the deep veins of the lower limbs toward the central circulation, thereby enhancing venous return [39]. Anatomically, the popliteal vein is more superficial and located in closer proximity to the calf muscles compared to the femoral vein. When patients perform APE, the rhythmic contraction and relaxation of the calf muscles directly act on the popliteal vein. This muscle activity functions as a "peripheral pump", exerting a more immediate and pronounced effect on the blood flow within the popliteal vein. In this study, we investigated the effects of ankle pump exercise on lower limb venous hemodynamics. We found that APE had significant impacts on various parameters. However, there were some interesting phenomena that needed further exploration. Moreover, the valve structure in the popliteal vein also plays a crucial role in this process. The valves in the popliteal vein are relatively dense, and their main function is to prevent blood backflow [40]. During the calf muscle contractions caused by APE, the valves close rapidly to prevent blood from flowing backward, ensuring that blood can only flow in the direction of the heart. This enables the blood in the popliteal vein to flow more smoothly back to the heart under the push of muscle contractions, resulting in more obvious blood flow changes.

More importantly, it decreases pump function, which was regarded as a risk factor for DVT [41]. APE was demonstrated to relieve limb edema and reduce DVT by increasing venous blood flow velocities and raising the quantity of reflux [42]. It was worthy of application in clinical practice and daily life. In a traditional care model, nurses need to regularly visit patients to provide exercise guidance, count the number of repetitions, and correct exercise errors [43]. This process is time-consuming and labor-intensive. With the telemonitored system, nurses can remotely monitor multiple patients simultaneously, allowing them to allocate their time more efficiently to other critical tasks. At the same time, the reduction in the number of nurses and the reusability of equipment contribute to cost savings to a certain extent. Despite its recognized benefits in clinical practice, a standardized protocol for APE has yet to be universally established. This gap highlights the need for further research and consensus-building to develop a standardized approach that can be consistently applied across different clinical settings.

However, although their nurses have duties to remind, monitor and record the physical, there exist a series of problems. Times of reminding led to the consumption of manpower and made most patients lack the persistence to exercise regularly. During the time of the practice, the number of the frequency may occur mistakes and this could influence the results of the ankle pump. Thus, we developed a new electronic tool called telemonitored APE, which could remind the patients and monitor the exercise instead of the nurses. The tool made patients perform dorsiflexion and plantar flexion function exercises of the ankle at a frequency of 30 times/min and 2 min/h (except sleep). In addition, it was connected to the network and uploaded the data of patients at time. Medical staff can remotely acquire the information about the patient's APE. Our study findings indicate that telemonitored APE offer distinct advantages over traditional APE methods. Specifically, the telemonitored approach demonstrated superior efficacy in enhancing patient compliance and optimizing exercise performance. This is likely attributable to the continuous monitoring and real-time feedback provided through telemonitoring, which allows for more precise and consistent execution of exercises.

Our study demonstrated that the value of mechanical prophylaxis was superior to that of the traditional way. In our view, this approach alleviates the workload of nursing staff and enhances the monitoring of patient data. Furthermore, the exercises were deemed to be more regular and accountable because they solved the problem of the exercise internally. The significance of D-dimer in POD 7 may be related to the delayed effect of the APE intervention. However, the lack of significance at POD 1 may be mainly attributed to the acute effects of surgical trauma and the influence of medications. Moreover, tests for APE combined with pharmacological and duration longer than fourteen days in patients would be valuable for DVT prevention.

There are several strengths in our study. First, the study was a randomized controlled trial that reduced the influence led by individual differences. Second, we applied mechanical detectors in our study, which avoided the statistical bias. Third, to evaluate the effects of APE comprehensively, we measured several indices to evaluate the efficacy, which improved the credibility of our results.

However, there are several limitations to our study. First, numerous other potential indicators could have been evaluated for their predictive value in DVT formation, but they were not included due to practical constraints. For instance, thromboelastography, a comprehensive assay that dynamically assesses the entire hemostatic system, including coagulation, platelet function, and fibrinolysis, was not incorporated into our analysis. This is primarily because thromboelastography (TEG) is not a routinely measured parameter in our hospital. Second, this is a tertiary hospital, thus, the patients may with more severe injuries with a higher potential prevalence of DVT. The results may be overestimated. Therefore, the generalizability of these findings could be limited. Third, more exploration should be performed to find the mechanism of telemonitored APE in avoiding deep vein thrombosis. Fourth, the measurements of the venous hemodynamics were all at a single occasion instead of a consistent duration. New measurement methods should be applied in the future in testing venous hemodynamics of the lower extremities.

Conclusions

The implementation of telemonitored APE reduces the workload for nurses and demonstrates greater efficacy compared to traditional APE methods. Based on our study, despite the velocity of the popliteal vein after APE, all the other data about the velocity and diameter of the femoral vein and popliteal vein showed no statistical difference. The three indices, including VAS and D-dimer before and after operation, increased values of postoperative calf diameter demonstrated positive outcomes. Therefore, the outcomes of our study provided a clinical reference to the doctors and nurses. Otherwise, regular telemonitored APE displayed a better efficacy and also provided a new orientation for future mechanism exploration.

Availability of Data and Materials

The data analyzed are available from the corresponding author upon reasonable request.

Author Contributions

YZG and LX conceived and designed the study, and contributed equally to this work. JCY collected clinical data. HBQ performed formal analysis, methodology, visualization. HXF collected clinical data and assisted in conducting the telemonitored and conventional ankle pump exercises. XLR recruited participants. XQH supervised the study design, analyzed the data, and revised the manuscript. YZG wrote the manuscript. All authors contributed to critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki. All procedures were conducted in accordance with the relevant guidelines and regulations. Ethical approval was granted by the Ethics Committee of Zhejiang Hospital (Approval No. 2022-41K). All participants in the intervention group were provided with detailed information about the study, and written informed consent was obtained prior to their involvement.

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Conflict of Interest

The authors declare no conflict of interest.

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