Neurology Asia 2026; 31(2) : 789 – 796

Validation of an early ambulation protocol after transfemoral cerebral angiography: A randomized controlled trial

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Abstract

Background: Access-site complications constitute a substantial portion of the morbidity associated with transfemoral cerebral angiography, yet no standardized protocol exists about early ambulation for patients after digital subtraction angiography and practice patterns vary widely. The objective of this study was to validate the efficacy and safety of early ambulation protocol for transfemoral cerebral angiography patients. *Methods:* A prospective, two-arm, single-blinded, parallel group, randomized controlled trial was designed enrolling patients undergoing transfemoral cerebral angiography from April, 2023 to February, 2024. The data of demographic and complications, comfort, pain, sleep after digital subtraction angiography were collected and analyzed. *Results:* A total of 371 patients were enrolled in this study, 190 patients in intervention group,181 patients in control group. 14 patients (3.77%, 2.11%VS5.52%, p=0.104) met the oozing, 9 patients (2.43%, 1.58%VS3.31%, p=0.327) met the palpable hematoma over the femoral artery. In all cases, there was no further oozing or enlarging hematoma. 15 patients (4.04%, 3.16%VS4.97%, p=0.436) indwelling urinary catheter, 49 patients (13.21%, 12.63%VS13.81%, p=0.761) met difficulty excretion after femoral artery puncture. There was no statistically significant difference in all complications between the two groups. There was no statistically significant difference in comfort score (95.41±10.38 VS 94.13±10.84, p=0.247), pain score (1.35±2.40VS 1.25±2.18, p=0.696) and sleep score (4.04±4.20 VS 3.78±4.26, p=0.566) between the two groups.
Conclusions: Transfemoral cerebral angiography is a common procedure with no clear consensus regarding the early activities. Our results show that early ambulation protocol will not increase the postoperative complications of patients, the score of comfort increased, although no statistically significant.

Keywords: Angiography, transfemoral, complications, early ambulation

INTRODUCTION

Stroke is the second leading cause of death and the third leading cause of disability worldwide and is associated with high morbidity, disability, and mortality.[1] There are more than 2 million new cases of stroke in China every year, and stroke is the leading cause of death and disability in adults.[2] Among them, the prevalence of ischemic cerebra vascular disease (ICVD) patients accounts for more than 70% of all stroke patients.[3] And approximately 20% of them are caused by large-artery atherosclerosis, with atheromatous plaque in the internal carotid artery (ICA) being the most common[4], which leading to corresponding vessel narrowing and inadequate blood supply to the corresponding brain tissue.

Transfemoral cerebral angiography (TFA) has become a cornerstone in the diagnosis and treatment of cerebrovascular disease. During digital subtraction angiography, the femoral artery is often chosen as the preferred puncture site due to its characteristics such as being large in size, easily palpable, relatively fixed in position, less prone to spasm, and facilitating successful puncture.[5] However, this is associated with acute

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Date of Submission: 22 December 2025; Date of Acceptance: 8 February 2026

https://doi.org/10.54029/2026svu

and chronic complications. For example, pain is a common complication and is associated with immobility and restricted positioning following the procedure.[6] Other complications are hematoma, hemorrhage, and urinary retention.[7] And pseudoaneurysm is an important complication of femoral artery puncture and may cause a bad prognosis.[8]

To reduce complications, it is commonly recommended postoperatively to adopt therapeutic patient positioning, including maintaining a supine position, delaying ambulation, and restricting movement of the limb on the puncture side.[9] However, the effectiveness of these methods is controversial. Some studies indicate that early mobilization does not increase the incidence of complications in patients; instead, it has a significant positive impact on patient outcomes, improving patient comfort, and reducing the occurrence of pain and urinary difficulties.[10,11] Several large reports have been published previously demonstrating the safety of manual compression after transfemoral cerebral arteriography followed by early ambulation.[12,13]

Despite the widespread use of femoral cerebral arteriography. Based on the above evidence, there is currently no consensus on the optimal bed elevation, body position, and activity protocols for patients after digital subtraction angiography and practice varies widely. Balancing occurrence of complications and patient comfort remains a challenge that needs to be addressed. This study established an early ambulation protocol for patients after digital subtraction angiography via the femoral artery route, aiming to determine its impact on patient outcomes for clinical reference.

METHODS

Study design

This study was a prospective, two-arm, single-blinded, parallel group, randomized controlled trial.

Our randomization process was primarily conducted as follows: (1) Upon admission, patients were assigned hospital admission numbers randomly generated by the hospital system, and at this stage, the attending physician for each patient was determined. (2) The allocation of beds for patients in the neurology ward, overseen by the attending physician, was not fixed. Instead, it was determined by office nurses of the ward based on bed availability. Thus, when assigning beds for patient admission to the neurology ward, the assignment of patients to specific beds was randomized. (3) Researchers grouped patients based on their bed numbers in the ward.

To ensure the independent implementation of interventions for both groups and to prevent potential interference between patients or their families due to communication affecting the implementation of intervention protocols, we placed patients from the two groups in separate rooms, ensuring they were in relatively independent spaces. Furthermore, we ensured that the intervention and control groups were situated in different corridors within the ward. During the implementation of the study, interventions for body position management in both groups were carried out by independent personnel.

Single-blinding was implemented in this study, where the patients were blinded to the intervention. However, due to the knowledge of the differences between the two body position management methods, the researchers responsible for implementing the study were unable to be blinded. It was difficult to achieve blinding of the interveners in conducting the position therapy intervention, but the data collector was blinded.

Participation

Inclusion criteria: (1) Patients diagnosed and assessed as needing DSA, with informed consent signed by family members or the patient; (2)Age ≥ 18 years; (3) Clear consciousness and normal cognitive function; (4) Willing to participate in this study and actively cooperate.

Exclusion criteria: (1) Diseases with coagulation abnormalities such as hemophilia; (2) Previous lumbar spine diseases or lumbar pain conditions; (3) Patients with long-term use of analgesic drugs.

Termination criteria: (1) Patients or their family members actively request to withdraw from the study; (2) Poor compliance, unable to follow the protocol for the study; (3) Deterioration of the patient's condition, occurrence of serious adverse events, failure to complete the intervention plan, or death.

Study intervention

All participants in the study received standard care, including all medical, nursing, allied health, and follow-up services provided by the research hospital. The differences between the intervention group and the control group

are shown in Table 1. Compared to the control group, the intervention group had a more detailed management plan for postoperative body position, activity, management of the puncture side limb, and Defecation. During the entire intervention process in the intervention group, if severe complications occur such as active bleeding at the puncture site, severe pain, worsening of the condition, or patient dissatisfaction with the body position arrangements, neurologists and nurses can suspend the implementation of intervention measures at any time, and actively treat the complications. They can then proceed with body position management and activity arrangements according to the routine measures of the control group.

Instruments

General information questionnaire: The general information questionnaire was utilized to collect demographic information: gender, age, level of education, body mass index (BMI), comorbidities (including hypertension, diabetes mellitus, high

Table 1: Early activities management strategies after digital subtraction angiography between two groups

	Time	Mobilization	Angle of the bed head	Movement of the limb on the side of transfemoral artery puncture*	Defecation
Control group	Returning to the ward after surgery to 24 hours postoperatively	Complete bed rest	0°	Transferring in bed without lifting from the surface ; knees should not be bent.	Limiting defecation and urination in bed.
	24 hours postoperatively	Restricted to bed mobility only	Unrestricted	Unrestricted	Unrestricted
Intervention group	Returning to the ward after surgery to 2 hours postoperatively	Complete bed rest	Raising the head of bed incline to 30°	Transferring in bed without lifting from the surface; knee should not be bent.	Limiting defecation and urination in bed.
	2 hours to 6 hours postoperatively	Complete bed rest	Raising the head of bed incline of 30° to 45°	Limb can be raised from the bed surface at an angle not exceeding 30 degrees, and avoid prolonged bending of the knee	Limiting defecation and urination in bed
	6 hours to 24 hours postoperatively	capable individuals gradually transitioning to bedside activities.	Unrestricted	No restrictions on raising the limb from the bed surface, but avoid keeping them elevated for prolonged periods, and avoid prolonged bending of the knee	Defecation and urination in bed ; alternatively, they can be performed at the bedside with assistance from another person
	24 hours postoperatively	Unrestricted	Unrestricted	Unrestricted	Unrestricted

* Other limb movements are not restricted.

cholesterol, heart disease, atherosclerosis), number of femoral artery punctures and hemostasis methods.

The *Shortened General Comfort Questionnaire (GCQ)* was used.[14] The Likert 6 self-rating scale has 28 items; transcendence is addressed in four domains, namely, physical, psychospiritual, sociocultural, and environmental; and higher scores indicate better comfort. Examples of items relating to the four domains include "I have a poor appetite" (physical), "My beliefs give me peace of mind" (psychospiritual), "My friends remember me with their cards and phone calls" (sociocultural), and "These surroundings are pleasant" (environmental). Negatively worded items are reverse scored. The GCQ exhibited a Cronbach's α of 0.88. The Chinese version of the NRS-2002 exhibited reliability, with a Cronbach's α of 0.892.[15]

The intensity of pain was measured by the *Numeric rating scale (NRS)*, which consists of an 11-point scale, where 0 indicates no pain and 10 is the worst pain imaginable. The NRS has been recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus group to measure pain in clinical trials.[16]

Insomnia was confirmed using CAIS-8. The Cronbach's α of internal consistency between the Chinese version of the eight-item *Athens Insomnia Scale (AIS)* and Insomnia Self-assessment Inventory was 0.82.[17,18] The AIS had a good sensitivity and specificity for insomnia and exhibit significant correlations with other insomnia scales.[19] The *Insomnia Self-assessment Inventory* has eight items, namely, sleep induction, awakenings in the night, final awakening earlier than desired, total sleep duration, overall quality of sleep, sense of well-being during the day, functioning during the day, and sleepiness during the day. Each item was rated from 0 to 4 (0 = no problem or normal, 3 = very severe problem). A score of less than 4 indicates no sleep disorder; A score of 4-6 indicates a sleep disorder; A score greater than 6 indicates insomnia.

The *Modified Barthel Index (MBI)* is the most commonly used scale for evaluating daily living activities globally.[20] It is simple, reliable, and sensitive. The MBI total score ranges from 0 to 100, and a higher MBI score reflects a more remarkable ability to function independently.

Data collection

After obtaining informed consent from the subjects, researchers collected baseline data including demographic information and medical history from the patients' medical records. Primary clinical safety indicator was any hematoma or oozing from the access site. Complications related to the procedure were also noted, including any additional intervention necessary for a femoral hematoma or pseudoaneurysm. All patients had serial access site examinations documented until hospital discharge. From postoperative 24h to postoperative 48h, subjective feelings surveys were conducted to collect information on experiences during hospitalization, including insomnia, pain, comfort, etc.

Sample size

In the power analysis, at least 80 participants in each group were required for the study with 80% statistical power to obtain a moderate effect size of 0.5 on comfort at the 5% significance level. Considering the potential for a high dropout rate in previous studies and the difficulty in data collection, we increased the sample size by 225% (He et al., 2024). Therefore, each group will require a minimum of 180 participants. Since the allocation of patients to groups is random, enrolment will stop once the sample size requirements for both groups are met, meaning that when the group with the smaller number of patients reaches 180, no further patients will be enrolled. The number of patients in the two groups may not be equal.

Statistical analysis

Data were analyzed using IBM Statistical Package for Social Sciences (SPSS), version 29.0, and included descriptive and inferential statistical analyses. Counting variables are expressed as percentages [n (%)]; continuous variables are tested for normality using the Shapiro-Wilk test (sample size>50). Those that conform to a normal distribution are analyzed using the t-test, otherwise the Mann-Whitney U test is used. Categorical variables are analyzed using the chi-square test or Fisher's exact test. Analysis of covariance (ANCOVA) is used to adjust for baseline imbalanced variables. The significance levels for all the tests were set at $p < 0.05$, two-tailed.

Study registration and ethical considerations

The registration code for this research is "ChiCTR2300069695." The authors confirm adherence to ethical guidelines and obtained ethical approval (from the institutional review board). All participants were thoroughly informed about the voluntary nature of their participation and their right to withdraw from the study at any time. Data collection was only performed after obtaining the participants' written informed consent. This study was performed in accordance with the ethical principles of the 1964 Declaration of Helsinki and was approved by the Ethics Committee of West China Hospital, Sichuan University, number 2022 (1835).

RESULTS

Patient demographics

In this study, patient recruitment began on April, 2023. By February, 2024, both groups had reached 180 patients each; therefore, recruitment was stopped. 387 patients met inclusion criteria and were enrolled in this study. Among them, 10 patients were excluded due to underwent cerebral angiography and stent implantation at the same time, and 6 patients were excluded due to incomplete information collection. Finally, 371 patients were included in this study, and 190 patients in intervention group,181 patients in control group. All 371 patients underwent successful transfemoral arteriography (Table 2). The study population consisted of transfemoral arteriography performed on 104 females and 267 males with an average age of 57.32±14.30 years.

Comparison of comfort, pain, and sleep quality

Of 371 angiograms performed during the study period, There was no statistically significant difference in comfort score (95.41±10.38 VS 94.13±10.84, p=0.247), pain score (1.35±2.40VS 1.25±2.18, p=0.696) and sleep score (4.04±4.20 VS 3.78±4.26, p=0.566) between the two groups (Table 3).

Of 371 angiograms performed during the study period, 14 patients (3.77%, 2.11%VS5.52%, p=0.104) met the oozing, 9 patients (2.43%,

Table 2: Baseline characteristics (n = 371)

Variable	Intervention group (n=190)	Control group (n=181)	p*
Age(years)	56.36(15.50)	58.32 (12.89)	0.187
Gender (%)			0.105
Male	125(65.79%)	142(78.45%)	
Female	65(34.21%)	39(21.55%)	
Education (%)			0.487
Primary School or below	44(23.16%)	49(27.07%)	
Junior	47(24.74%)	46(25.42%)	
Senior	34(17.89%)	37(20.44%)	
College degree or above	65(34.21%)	49(27.07%)	
BMI	24.23（3.25）	24.46（3.13）	0.495
ADL	81.18（21.96）	79.20（23.02）	0.369
Comorbidity (%)			
Hypertension	111(58.42%)	114(62.98%）	0.396
Diabetes Mellitus	56(29.47%)	72(39.78%)	0.253
High cholesterol	25(13.16%)	23(12.71%)	0.511
Heart Disease	35(18.42%)	34(18.78%)	0.517
Atherosclerosis	41(21.58%)	47(25.96%)	0.192

p was calculated by ANOVA or the chi-square test as appropriate.*

Table 3: Comparison of postoperative experience between the two groups (*n* = 371)

Variable	Intervention group (n=190, *x*±*s*)	Control group (n=181, *x*±*s*)	*p*
The score of GCQ	95.41(10.38)	94.13(10.84)	0.247
GCQ-Physical	27.76(3.51)	27.22(4.05)	0.168
GCQ-Psychospiritual	32.19(4.12)	32.05(3.98)	0.740
GCQ-Environmental	11.77(1.65)	11.66(1.53)	0.502
GCQ- Sociocultural	23.68(3.08)	23.19(3.40)	0.149
The score of NRS	1.35(2.40）	1.25(2.18）	0.696
The score of CAIS-8	4.04(4.20)	3.78(4.26)	0.566

1.58%VS3.31%, *p*=0.327) met the palpable hematoma over the femoral artery. In all cases, there was no further oozing or enlarging hematoma. 15 patients (4.04%, 3.16%VS4.97%, *p*=0.436) indwelling urinary catheter, 49 patients (13.21%, 12.63%VS13.81%, *p*=0.761) met difficulty excretion after femoral artery puncture. There were no statistically significant difference in all complications between the two groups (Table 4).

DISCUSSION

In diagnostic cerebral angiography, the femoral are commonly used to access the arterial system. For the transfemoral approach, the access site complications include hematoma (0.5–1.7%), pseudoaneurysm and arteriovenous fistula (0.1–0.6%), and infection (0–1%).[12,21,22] Many hospitals in China are requiring patients to remain on prolonged bed rest from 8 to 24 h, with 8 h of immobilization after the procedure, which bring great discomfort to the patients.

With the rapid advancement in puncture technology, an increasing number of studies show that early ambulation and changing position in bed may increase patients' comfort.[23,24] A systematic review involving 4,019 patients found that a bed rest duration of 2–3 h after TFA can safely and effectively reduce back pain and discomfort with no change in the incidence of vascular complications.[23] In addition to reducing ambulation time, changing patients' position during immobilization was also proposed by previous research.[6,9,24] Two studies[12,25] found that position change to a semi-seated position 2 h after TFA is effective and safe to reduce pain without increasing the vascular complications.

The result showed that eleven (3.82%) and 3 patient (3.61%) experienced bleeding events in the experimental and control groups, respectively. A meta-analysis[23] of 20 studies found that 47 occurrences (2.2%) of bleeding after the transfemoral angiography was reported, which is comparable to our findings. There was no statistical difference between groups in terms of the bleeding event and hematoma，which will demonstrate the safety of the evidence-based early ambulation protocol.

The incidence of dysuria after TAF is 6.67% to 50.00%. In our study, the number of indwelling urinary catheters in experimental group (10, 3.47%) was lower than that in the control group (5, 6.02%), although there was no statistical significance.

Table 4: Comparison of postoperative complications between the two groups (*n* = 371)

Variable	Intervention group (n=190, %)	Control group (n=181, %)	*p*
bleeding events	4(2.11）	10(5.52）	0.104
hematoma	3(1.58)	6(3.31)	0.327
Indwelling urinary catheter	6(3.16)	9(4.97)	0.436
Difficulty defecating	24(12.63)	25(13.81)	0.761

Hojjat *et al.* found that the pain was reduced immediately with the position change to a semi-seated position from the 3rd hour after DSA.[6] These immediate effects were not observed in the current study, which may result from the fact that there was no pain or very mild pain after DSA in both groups in this study. At the same time, we also observed that the score of comfort of the patients in the experimental group was higher than those in the control group.

In conclusion, transfemoral cerebral angiography is a common procedure with no clear consensus regarding the early activities. This study suggests that early activity management strategies do not significantly increase postoperative complications, and the comfort scores of the intervention group were slightly higher than those of the control group, although the difference was not statistically significant. Future research with larger sample sizes is needed to further verify the potential benefits of early activity on patient comfort.

This study has several limitations. First, the randomization method was restricted by the practical conditions of a single-center clinical setting, using a quasi-randomization method based on bed allocation rather than central randomization. Although baseline data showed balanced patient characteristics between the two groups, and we tried to control bias through ward management and statistical adjustments, we still cannot completely rule out the influence of unmeasured confounding factors on the results. This is a single-institutional study, which can lead to selection bias. Also, our study population included patients who underwent diagnostic cerebral angiography only. If applied to patients who undergo endovascular intervention, our protocol might result in a higher access site complications since there is a potential need for intraoperative antiplatelet or anticoagulation medications. Moreover, failure of reporting of small hematomas by the patients could have affected the results of this study.

ACKNOWLEDGEMENTS

The authors thank all the medical staff of the Department of Neurology, West China Hospital, Sichuan University, for supporting this study. And the authors would like to express our sincere appreciation to the patients who participated in this study.

DISCLOSURE

Ethics: This study was approved by the West China Hospital, Sichuan University ethics committee, number 2022 (1835).

Financial support: The authors gratefully acknowledge the financial supports by the Sichuan Province Cadres Health Project under grant number 2024-118 and the Graduate Education and Teaching Reform Research Project, Sichuan University under grant number GSSCU2023089

Conflict of interest: None

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