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Effect of early ambulation on comfort and vascular complications following electrophysiological studies: A randomized controlled trial

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Abstract:

BACKGROUND: Imposed immobilization after electrophysiological studies (EPS) is known to cause different complications. The current study aims to assess the effect of early ambulation on comfort and vascular complications among patients undergoing transfemoral catheterization for EPS.

MATERIALS AND METHODS: Hundred participants were assigned to control and intervention groups (50 each) using block randomization. The control group participants were ambulated at 6 hours after EPS. For the intervention group, participants were kept in the supine position with procedure-side leg extension for the first 2 hours, followed by 30° head-end elevation and turning to the left/right side for 30 min, and finally ambulation at the end of 3 hours. Both groups were assessed for vital signs, groin and back pain, satisfaction, bleeding, hematoma, and bladder pattern at the 6th and 24th hour after EPS. Data analysis was done on an intention-to-treat basis using the Chi-square test, Fisher's exact test, independent student *t*-test, and Mann–Whitney *U* test.

RESULTS: The level of back pain and groin pain was significantly lower in intervention group after 6 hours ($P < 0.001$) and after 24 hours ($P < 0.05$). Urinary problem was not reported in intervention group, whereas Eleven (22%), participants in the control group did not void at 6 hours ($P < 0.001$). Two patients in intervention group developed bleeding at 6 hours, and one patient in control group developed bleeding at 24 hours. Hematoma development was absent for both groups.

CONCLUSION: Early ambulation at 3 hours after EPS is suggested to reduce back pain, groin pain, and urinary problem, without risk for vascular complications.

Keywords:

Cardiac, cardiac catheterization, early ambulation, electrophysiological techniques, pain, patient comfort, post-operative complication, procedural

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Background

Electrophysiologic procedures of the heart are a gold standard in managing arrhythmias. It involves diagnostic tests as well as therapeutic interventions like radiofrequency ablation[1,2] During the procedure, three or four flexible catheters of size 5F, 6F, and 7F are introduced into the heart through left or right femoral veins under fluoroscopic guidelines.[3,4] Through this catheter, 2–10 electrodes are placed at specific locations of the heart, spontaneous and pacing-induced surface and intracardiac signals are recorded, and the baseline and induced arrhythmias are analyzed. Once the diagnosis is made, radiofrequency ablation is carried out to create an endocardial lesion to prevent an ectopic focus or abnormal conduction pathway.[5,6]

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The most used site for catheter insertion is the left or right femoral vein. Once the catheter is removed, there are chances of developing vascular complications like bleeding, hematoma, and deep vein thrombosis. To prevent vascular complications following an EPS; patients are advised to be in a supine position without moving the affected leg for 4–6 hours or more after the procedure. Though the immobilization following cardiac catheterization is followed traditionally, there is a lack of evidence-based protocols for assessing the ideal duration of bed rest.[7,8]

Because of this enforced bed rest, immobilization, and lack of positioning, patients often experience discomforts like back pain and fatigue. Few studies have reported patients' discomfort after percutaneous cardiac procedures, from which back discomfort was the most often mentioned. Supine position for a long time causes pressure, cellular ischemia, muscle spasm, and back pain. The prolonged enforced supine position leads to stress in the lumbar muscle and discomfort to the patient. Also, patients feel difficulty in emptying the bladder in the supine position with restricted movement. This leads to additional pain and discomfort and requires other interventions like urinary catheterization.[4,9]

Various studies show that patients can safely ambulated at 3–4 hours, which will help to improve the patient's comfort, without increasing the vascular complications.[10,11] Providing position changes during and following the procedure reduces low back pain due to enforced pressure on muscles, leading to a lumbar muscle spasm.[10,12]

Similar to cardiac catheterizations, electrophysiological studies (EPS) also considered as a day-care procedure that needs nursing observation for several hours, followed by discharge on the same day, within 12 hours. As EPS require access to the femoral vein, vascular complications including bleeding from the access site is the common complication. There must be an evidence-based protocol that must mention the required time during which the patient needs to be immobilized with a pressure or gauze dressing at the puncture site in the groin.[13] Furthermore, a patient restricted to complete bed rest needs more supervised nursing care than a patient who is ambulatory and self-sufficient. The requisite time in bed following EPS differs commonly between institutions. Little has been published about the optimal length of time that patients are to remain in bed the standards of care followed after EPS are not always evidence-based.[14]

A few studies showed that it is safe to ambulate patients 3–4 hours after trans-femoral cardiac catheterization. Despite this study's evidence, prolonged bed rest (4–6 hours) following femoral cardiac catheterization remains the standard of care in many settings. Further, the data on complications of early ambulation following EPS have not been studied. Hence, the effect of early ambulation needs further investigation.[15,16]

To date, very less studies were conducted on the effect of early ambulation on vascular complications after EPS. The objective of the study was to assess the effect of early ambulation on comfort and vascular complications among patients undergoing EPS.

Materials and methods

Study design and setting

A randomized controlled trial was conducted among patients who had undergone EPS in the coronary care unit of a tertiary care hospital in South India over the period of one year from 2021–2022.

Study participants and sampling

Patients aged above 18 years were included in the study. Patients with bleeding disorders, spinal disorders, back pain, and urinary retention were excluded. The sample size was calculated as 100 (50 in each group) by assuming the 30% percentage difference in satisfied patients between early ambulation (70%) and late ambulation (40%), with the power of 80% and 5% level of significance.[11] A convenient sampling technique was used, followed by block randomization with varying block sizes and allocation concealment using serially numbered opaque sealed envelopes.

Data collection tool and technique

A self-structured data collection proforma included demographic data and clinical parameters and assessment of patient comfort, and vascular complication. The demographic data part includes the age, sex, marital status, education, height, weight, and BMI of the patient. The collected clinical parameters include diagnosis, co-morbidities, treatment history, history of anticoagulant use, whether anticoagulants are taken within 24 hours of the procedure, size of the sheath (s) used in the procedure, biochemical parameters, and vital signs of the patient.

Participants were randomly assigned to the control group or interventional group. Specially trained nursing personnel removed the vascular sheath in a post-procedure recovery unit after the EPS procedure. Hemostasis was achieved in both groups using an identical protocol of manual compression followed by a compression device for 5–10 min. **For Control Group**: Supine position with procedure-side leg extension with no head-end elevation for 6 hours was maintained. At the end of 6 hours, the patient was allowed to move out of bed if there were no complications like bleeding or

hematoma. **For Intervention Group**: Supine position with procedure-side leg extension with no head-end elevation for the first 2 hours. With 30° head-end elevation, the patient was allowed to turn to the left/right side for the next 30 min, followed by a turn to the supine position for the next 30 min. At the end of the 3 hours, the patient was allowed slowly move out of bed, walk around, and do self-care activities. Both groups were assessed for comfort status and vascular complications by the investigator at the 6th and 24th hour after the EPS procedure.

The numerical rating scale (NRS) was used to assess back and groin pain. Assessment of bladder function, voiding status, palpable bladder, and need for catheterization were assessed by observation, palpation, and patient reporting method. Any visible bleeding, any further use of manual compression to establish hemostasis and the hematoma were assessed to monitor the vascular complications. A two-dimensional ruler with 1cm^2 precision was used to measure the hematoma. Borders of hematoma were identified by palpation method; then, it was measured with a ruler. Interobserver reliability of r = 0.8 was established for the bleeding and hematoma assessment. The patient satisfaction tool consists of items that determine patients' perceptions about the duration of bed rest, pain, and other complication. A pilot study was conducted among 10% of the sample size to assess the feasibility of the study.

Ethical consideration

The study was approved by the Research monitoring committee and Institute Ethics Committee (CON/IEC/M. Sc./2019/MSN/5). The study was registered under Clinical Trial Registry India (CTRI/2020/12/029675). The procedures followed were in accordance with the ethical standards of the institution as well as the Declaration of Helsinki revised in 2013. Informed consent was taken from each participant voluntarily before enrolment. The participants were also ensured anonymity and confidentiality of their data.

Data analysis

The comparison of categorical data like gender, urinary retention, and vascular complication between the group is carried out by Chi-square test/Fisher's exact test. The comparison of continuous data such as age, back pain, groin pain, etc., is done using independent sample *t*-test/Mann–Whitney *U* test. All statistical analyses were done using IBM SPSS (Version 23.0) and *P* value < 0.05 were considered as statistically significant.

Results

Both groups were homogenous in terms of their clinical and demographic characteristics. Fifty-one percent of the participants were males. The mean age of participants was 45 ± 15 years in the control group and 44 ± 13 years in the intervention group. The mean body mass index of the participants for both groups was 25kg/m^2. The majority of the participants in the control group (90%) and interventional group (86%) were diagnosed with supraventricular tachycardia. [Table 1].

The median level of back pain at 6 hours after EPS was 1 (1,2) in the intervention group and 3 (2.75,3.75) in the control group, which was significantly different at $P < 0.001$. The median level of back pain at 24 hours was also statistically significantly lower in intervention group. Similarly, the median level of groin pain was also reported as being lesser in the intervention group at 6 hours (*P*-0.007) and 24 hours (*P*-0.008). Eleven (22%) patients in the control group did not void at 6 hours, and bladder was palpable among 10 (20%) of them, whereas no patients in the interventional group experienced bladder problem. No participants in either group complained of any bladder problems at 24 hours. More participants in the interventional group (80%) were satisfied with the period of immobilization as compared to control group (34%) participants, which is significant at $P < 0.001$. Two participants in the intervention group developed mild bleeding within 6 hours, whereas, participants in the control group did not have any bleeding. Among the control group, one participant developed bleeding within 6–24 hours, while none of the intervention group participants reported bleeding for the same period. There is no hematoma development in both groups. [Table 2].

Secondary analysis shows no significant difference in vital signs between the groups, as well as between participants' vital signs and pain. However, an average difference in SBP -9mm of Hg and DBP -5mm of Hg was noted between the control and intervention groups. Mean back pain and groin pain were significantly lower in all age groups and gender categories in the intervention group at 6 hours and 12 hours. Similarly, the back pain and groin pain at 6 hours and 24 hours is significantly lower for intervention group in all other categories of BMI (normal, overweight, and obese) except for the underweight category. [Table 3].

Discussion

Patients frequently experience back pain, groin pain, urinary discomfort, and fatigue due to enforced supine bed rest, immobilization, and restricted positioning following EPS procedures. This in turn reduces the comfort of the patient and hence satisfaction.

In this study, we assessed the safety of early ambulation by comparing the occurrence of bleeding

Table 1: Comparison of baseline participants' characteristics between the groups *n*=100

Variable	Control group (*n*=50)	Experimental group (*n*=50)	*P*
Sex[1]			
Female	22 (44)	27 (54)	0.317
Male	28 (56)	23 (46)	
Age[2]	45±15	44±13	0.744
Body mass index[2]	25±5	25±4	0.881
Diagnosis[1]			
Supraventricular tachycardia	43 (86)	45 (90)	0.538
Other	07 (14)	05 (10)	
Co-morbidities[1]			
Hypertension	08 (16)	06 (12)	0.813
Diabetes mellitus	02 (04)	03 (06)	
Hypertension and diabetes mellitus	07 (14)	05 (10)	
None	33 (66)	36 (72)	
Platelet count[2]	288760±71069	278000±62868	0.425
Use of antiplatelet agents[1]			
No	45 (90)	43 (86)	0.538
Yes	05 (10)	07 (14)	

[1]Frequency (Percentage) with Chi-square test; [2]Mean (Standard deviation) with independent student *t*-test; $P<0.05$

Table 2: Comparison of comfort and complications between the groups *n*=100

Variable	Control group (*n*=50)	Experimental group (*n*=50)	*P*
Back pain[1]			
6 h	3 (2.75,3.75)	1 (1,2)	<0.001
24 h	1 (0,2)	0	<0.001
Groin pain[1]			
6 h	3 (2.75,3.75)	2 (1,3)	0.007
24 h	2 (2,3)	1 (0,2)	0.008
Not voided in 6 h[2]	11 (22)	0	<0.001
Bladder palpable in 6 h[2]	10 (20)	0	0.001
Patient satisfaction[2]			
Satisfied	17 (34)	40 (80)	<0.001
Problems during period of immobilization[2]			
Back pain	40 (80)	14 (28)	<0.001
Groin pain	43 (86)	23 (46)	<0.001
Urinary problem	10 (20)	0	0.001
No problems	05 (10)	15 (30)	0.012
Bleeding[3]			
6 h	0	2 (4)	0.495
24 h	1 (2)	0	1.000
Further intervention to check bleeding[3]			
6 h	0	2 (4)	0.495
24 h	1 (2)	0	1.000

[1]Median (Interquartile range) with Mann–Whitney *U*-test; [2]Frequency (Percentage) with Chi-square test; [3]Frequency (Percentage) with Fisher's Exact test; $P<0.05$

and hematoma between the control and interventional groups. Two patients in the interventional group developed bleeding within 6 hours, and one patient in the control group developed bleeding within 24 hours, the difference of which was not statistically significant. No participant in either group developed a hematoma. Hence the position changing followed by early ambulation at 3 hours can be safely done for patients undergoing femoral catheterization for EPS. Comparable studies also identified no significant difference between the early ambulation and control group in the incidence of hematoma and bleeding complications at the access site following angiography.[4,6,17-19]

The current study considered back pain, groin pain, urinary discomfort, and satisfaction as components of comfort. Lying on the back for 4–6 hours imposes pressure and causes ischemia, muscle spasm, fatigue, and pain in the dependent muscles like the lumbar muscles. Inner-muscle pressure in the lumbar muscles depends on the patient's position and the imposed load on the muscles. Therefore, changing position and early ambulation help to reduce back pain and groin pain.[3-4,14-16]

Table 3: Relationship between level of pain between the groups and participants' characteristics at different timepoints *n*=100

Variable	Back pain					
	6 h			24 h		
	Control group	Intervention group	*P*	Control group	Intervention group	*P*
Age						
18–30	3.36±1.027	1.33±1.000	<0.001	0.82±0.751	0.33±0.707	0.158
31–50	3.24±1.609	1.32±0.945	<0.001	1.29±1.102	0.04±0.200	<0.001
51–70	3.29±1.326	1.73±0.799	0.001	1.00±0.877	0.13±0.352	0.001
Sex						
Male	3.25±0.967	1.43±0.843	<0.001	0.96±0.881	0.13±0.458	<0.001
Female	3.32±1.756	1.41±1.010	<0.001	1.14±1.082	0.11±0.320	<0.001
BMI						
Underweight	3.00±0.632	2.00±0.816	0.060	0.83±0.753	0.75±0.957	0.881
Normal	3.20±1.751	1.30±0.823	0.006	1.40±1.430	0.00	0.006
Overweigh	3.13±1.553	1.13±0.835	0.006	1.00±1.069	0.00	0.019
Obese	3.42±1.031	1.46±0.999	<0.001	0.96±0.774	0.11±0.315	<0.001
	Groin pain					
	6 h			24 h		
	Control group	Intervention group	*P*	Control group	Intervention group	*P*
Age						
18–30	3.45±0.688	2.11±1.054	0.003	2.36±1.027	1.22±1.093	0.027
31–50	2.81±1.030	2.20±1.080	0.580	2.05±0.805	1.04±1.020	0.001
51–70	3.29±1.267	2.13±1.060	0.013	2.43±0.852	1.13±0.915	0.001
Sex						
Male	3.25±0.844	2.22±0.850	<0.001	2.36±0.731	1.04±0.825	0.000
Female	3.00±1.234	2.07±1.207	0.011	2.14±1.037	1.11±1.121	0.002
BMI						
Underweight	3.33±0.516	2.75±0.500	0.115	2.17±0.753	1.50±1.291	0.327
Normal	3.20±0.919	1.80±0.919	0.003	2.50±1.080	0.80±0.632	<0.001
Overweight	2.63±1.061	2.25±1.035	0.486	2.25±0.707	1.13±0.835	0.011
Obese	3.23±1.142	2.14±1.145	0.001	2.19±0.895	1.11±1.100	<0.001

BMI - Body mass index; Independent sample *t*-test; *P*<0.05

In this study, it was found early ambulation at 3 hours significantly reduced the level of both back pain and groin pain assessed at 6 hours and 24 hours among patients undergoing EPS through femoral venous catheterization. Moreover, lesser number of participants in the intervention group complained of back pain, groin pain, and urinary problems during the immobilization time. Patient satisfaction is high in the experiment group (80%) than in the control group (34%). Early ambulation and position change not only helps to reduce back pain and groin pain, it also reduces the incidence of urinary retention and allows the patient to sit comfortably and eat without difficulty, all of which jointly improve patient satisfaction.[20-22] The participants in intervention group were also found to have significantly lower level of mean back pain and groin pain across all age groups, gender, and BMI categories, except for the underweight category.

In spite of the increase in supportive literature regarding early ambulation following post-femoral percutaneous coronary intervention, obsolete practices such as prolonged bed rest to prevent vascular complications continue within the clinical practice which might be due to a lack of evidence-based guidelines within hospital systems.[21]

The results of a systematic review support, early ambulation and altering the patients' position is effective in reducing back pain. Studies that compared early ambulation after coronary artery angiography with early and long-term bed rest found a decrease in back pain and urinary discomfort. All the reviewed studies emphasized the efficacy of early ambulation after angiography in reducing back pain; however, the duration of immobilization varied widely from 2 hours to 6 hours. The results of the studies showed a more effective impact of early ambulation in the first 4 hours after angiography than that in the subsequent hours.[22,23]

In comparison with the routine protocol of bed rest, altered body positioning or changing the patients' position improves patients comfort without the complication of any bleeding and hematoma. The proper position is essential to ensure a normal bladder pattern. Standing position for males and sitting position

for females favor bladder emptying. Patients usually feel difficulty voiding in a supine flat position. In this study, 22% of the participants in the control group were not voided at 6 hours, whereas no patient in the interventional group experienced urinary problems. Ambulating early at 3 hours helps the patient void in a normal position and reduces urinary problems. Most of the participants in the interventional group expressed fewer problems during the period of immobilization than the control group. These findings are also supported by several related studies.[24-26] Similarly Neishabouri *et al*.[27] identified that early mobilization reduced mean pain intensity in intervention group which was significant at $P < 0.001$. The number of samples that developed urinary retention was more than the routine group.[28,29] Similarly, in another study, the authors identified that a bed rest duration of 2–2.9 hours was associated with lower risk of back pain and a duration over 12 hours with greater risk of back pain (RR 1.94, 95%CI 1.16–3.24). *Post hoc* analysis revealed an increased risk of back pain per hour of bed rest (RR 1.08, 95%CI 1.04–1.11).[30]

Recommendations

This study shows that early ambulation helps to reduce back pain, groin pain, and urinary problems and improves patient satisfaction without increasing vascular complications. We recommend that the same study can be conducted with a larger sample size. Further studies can be done involving other forms of EPS like CARTO, Ensite, and 3D mapping systems.

Limitation

The limitations of this study include non-blinding of the outcome parameters assessment and a small sample size which limits the generalizability.

Conclusion

The present study supports early ambulation (at 3 hours) of patients undergoing transfemoral venous catheterization for Electrophysiological studies in reducing back pain, groin pain, urinary problems., This study also supports the safety of early ambulation. There is no increased risk of vascular complications associated with early ambulation and can be practiced by nurses working in coronary care units and recovery rooms. Moreover, it helps to reduce the length of hospital stay and improves care quality, and hence the patients' satisfaction.

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Conflicts of interest

There are no conflicts of interest.

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