Effect of early ambulation after transfemoral cardiac catheterization in Hong Kong: a single-blinded randomized controlled trial

Hong Kong'ta transfemoral kardiyak kateterizasyon sonrası erken ambülasyonun etkisi: Tek-kör randomize kontrollü bir çalışma

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ABSTRACT

Objective: The purpose of the study was to investigate the effect of early ambulation after cardiac catheterization (CC) on patients' back pain, puncture site pain, vascular complications, urinary discomfort, general well-being perception and satisfaction level.
Methods: This study was a randomized single-blinded controlled trial. Overall, 137 participants were randomly assigned to experimental (63 participants) or control (74 participants) group according to a computer generated random list. Early ambulation (ambulate at 4 hours post-CC) and routine post-procedure care of 12 to 24 hours were used in the experimental and control groups respectively. Independent t-test, Chi-square test, multiple logistic regression and generalized estimation equation model were applied to compare various outcomes between experimental and control groups.
Results: Only one patient in the control group experienced puncture site bleeding after CC. Ambulation at 4 hours after CC significantly reduced patients' back pain 8 hours after they returned to the unit (OR=0.19, 95% CI: 0.08-0.45, p<0.001) and in the next morning (OR=0.36, 95% CI: 0.15-0.87, p=0.023), decrease urinary discomfort (OR=0.35, 95% CI: 0.14-0.90, p=0.03 for "very or unbearable urination discomfort" and OR=0.22, 95% CI: 0.06-0.74, p=0.015 for "much difficulty or unable to urinate at all"), and increase general well- being (p=0.005 for vitality subscale and p=0.014 for the total general well-being). However, it made no significant differences on puncture site pain as well as the satisfaction level of patients.
Conclusion: The study enhanced health providers' understanding about the effects of early ambulation on patient outcomes. Nurses may provide more individualized and appropriate care to post-CC patients in a more competent and cost-effective way.
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Key words: Early ambulation, cardiac catheterization, coronary artery disease, randomized controlled trial, logistic regression analysis

ÖZET

Amaç: Bu çalışmanın amacı, kardiyak kateterizasyon (KK) sonrası hastanın sırt ağrısına, giriş yeri ağrısına, vasküler komplikasyonlara, idrar rahatsızlığına, genel iyilik algısına ve memnuniyet seviyesine erken ambülasyonun etkisini araştırmaktı.
Yöntemler: Bu randomize tek-kör kontrollü bir çalışma idi. Bilgisayarın oluşturduğu random listeye göre, 137 katılımcı, rastgele deneysel (63 katılımcı) ve kontrol (74 katılımcı) gruplarına ayrıldı. Erken ambülasyon (KK sonrası 4. saatte ambülasyon) ve 12 ile 24 saat rutin işlem-sonu bakımı, sırası ile deneysel ve kontrol gruplarında kullanıldı. Bağımsız t-testi, Ki-kare testi, çoklu lojistik regresyon ve genelleştirilmiş tahmin denklem modeli, deneysel ve kontrol grupları arasında çeşitli sonuçları karşılaştırmak için uygulanmıştı.
Bulgular: Kontrol grubunda sadece bir hastada, KK sonrası giriş yerinde kanama oldu. Kardiyak kateterizasyon sonrası 4 saatte ambülasyonla üniteye geri dönenlerde: 8. saatte (OR=0.19, %95 CI: 0.08-0.45, p<0.001) ve ertesi sabah (OR=0.36, %95 CI: 0.15-0.87, p=0.023), hastanın sırt ağrısı önemli derecede azaldı, idrar rahatsızlığı azaldı (OR=0.35, %95 CI: 0.14-0.90, p=0.03 "çok veya dayanılmaz idrara çıkma rahatsızlığı" için ve OR=0.22, %95 CI: 0.06-0.74, p=0.015 "çok zorluk ya da hiç idrar yapamazlık" için) ve genel iyilik hali arttı (p=0.005 canlılığın alt ölçeği ve p=0.014 total genel iyilik hali düzeyi için). Ancak, hastaların memnuniyet düzeyinin yanı sıra delinen yerde ağrıda önemli farklılık olmadı.
Sonuç: Bu çalışma, hastaların takibinde sağlıkçıların erken ambülasyonun etkilerini daha iyi kavramalarını sağladı. Hemşeriler daha yetkin ve maliyet etkin bir yolla KK sonrası hastalara daha bireysel ve uygun bir bakım sağlayabilir. *(Anadolu Kardiyol Derg 2012; 12: 222-30)*
Anahtar kelimeler: Erken ambülasyon, kardiyak kateterizasyon, koroner arter hastalığı, randomize kontrollü çalışma, lojistik regresyon analizi

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Introduction

Coronary artery disease (CAD) is the second leading cause of death in Hong Kong . According to the Center for Health Protection, a total of 6630 deaths (15.5% of all deaths) were related to heart disease in 2010 in Hong Kong (1). Though precise prevalence estimation of heart disease in Hong Kong cannot be found, continuous growth can be expected due to the aging population, dietary influences from Western countries as well as the stress from the fast-paced lives of the city.

Cardiac catheterization (CC) is the most definitive procedure in the diagnosis and evaluation of CAD (2), and currently it has become the routine diagnostic procedure performed in many hospitals in Hong Kong (3). Femoral artery is commonly used in daily cardiologic practice because of its larger diameter (3-5). However, the invasive transfemoral puncture approach can simultaneously incurs the risk of vascular complications, such as bleeding, hematoma at the puncture site, distal embolization and arterial thrombosis (6, 7). To reduce complications, manual or mechanical application of firm pressure above the puncture site is needed. Moreover, prolonged bed rest in recumbent position and immobilization of the affected leg are also required for those patients after sheath removal (7, 8).

Prolonged bed rest in supine position is based on the previous nursing experience rather than on research (9). The duration of the bed rest varies from 2 to 24 hours and there is no recommendation on the optimal duration of such a bed rest (7, 10). Although vascular complications should be prevented, prolonged bed rest has been identified as the most difficult component of post cardiac catheterization care (11). The most frequent complaints from patients during prolonged bed rest are back pain and urinary discomfort including difficulty of using a bedpan or urinal in the recumbent position and urinary retention (2, 3, 7, 12). Besides, anxiety and anger due to the unmet needs for comfort are also expressed by patients (13, 14).

To relieve these discomforts caused by prolonged bed rest, early ambulation has been proposed and its effectiveness has also been examined by various studies (3, 4, 12, 15-17). The suggested early ambulation from these studies ranges from 1 hour to 6 hours with the sheath size from French 5 to 8. It has shown that the suggested time for early ambulation in different studies is safe and associated with low rates of vascular complications (3, 4, 12, 15-17), higher satisfaction (12) and less back pain (3, 12). It is believed that early ambulation can improve patients' outcomes, decrease the workload of nursing staff and length of stay in hospital, which accordingly reduce the health care costs (12).

In Hong Kong, patients are required to remain in a supine position for 8 to 24 hours after achieving homeostasis depending on the unit protocol (10). However, CC practice pattern in Hong Kong may be very different from these in Western countries and Chinese patients may react differently to physical and psychological stressors due to the genetic factor and environmental influences, generalization of the study results from Western countries should be with great caution. In addition, most of the studies conducted on post CC care investigated only vascular complications (bleeding and hematoma formation) and back pain as the outcomes of early ambulation. Other physical and psychological effects, such as urinary discomfort, mental wellness, vitality, physical recovery and patient satisfaction, are seldom mentioned as the study outcomes.

In order to establish the optimal post transfemoral cardiac catheterization care in Hong Kong patients, the current study investigated the effect of early ambulation after cardiac catheterization on a broader array of outcomes.

The aim of the study was to investigate the effect of the early ambulation on patients' back pain, puncture site pain, vascular complications (bleeding or hematoma formation), urinary discomfort, general well-being perception and satisfaction level.

Methods

Study design

The study was a single-blinded randomized controlled trial. Participants were randomly assigned to the experimental or control group using a computer generated random list. Early ambulation, defined as 4 hours post-cardiac catheterization, was the intervention used in the experimental group, and routine post-procedure care of 12 to 24 hours bed rest was used in the control group.

Setting and participants

The study was conducted in one regional general hospital in Hong Kong. To reduce the potential influence of treatment approach and other procedural variables, the study included only one cardiology team in this hospital.

Patients who met the inclusion criteria were eligible for the study. The inclusion criteria were patients who had ethnicity of Chinese, age of 18 years or older, no bleeding disorders, no anticoagulant therapy within the previous 24 hours before the procedure, no back pain, no vascular complications developed during CC, and blood pressure below 180/110 mmHg on admission. In addition, to control confounding variables, only patients scheduled for elective diagnostic cardiac catheterization were included in this study.

Instruments

Bleeding and hematoma assessment tool

The instrument used to assess bleeding was adapted from Christenson's guidelines (3). Significant bleeding was defined as blood loss estimated at greater than 100ml or hematoma greater than 5 cm in width or bleeding that led to further attempts to reestablish hemostasis by manual pressure, sandbag or reinforcement of pressure dressing.

The pain assessment tool

In the study, a visual analog scale (VAS) was used to assess each patient's back pain intensity and pain changes. The VAS is

a self-report device used extensively to measure pain (18) and it has been reported to be a valid and reliable measure of pain intensity (19-22). The VAS consists of a 100 mm long line with anchors indicating the extremes of pain. The left anchor represented "no pain" whereas the right anchor represented "worst possible pain". Patients were asked to place a mark indicating the degree of their current back pain on the line at each assessment time.

Urinary discomfort tool

The tool was developed by the investigator and included 4 items. The first and last items were information seeking questions to identify whether patients had the urinary discomfort problem and interventions for managing the problem. The other two 5-point Likert scaled items were used to evaluate patients' urinary discomfort level (from 0=very comfortable to 4=unbearable discomfort) and urination difficulty (from 0=no difficulty to 4=unable to urinate at all). The internal consistency of the two items is good (Cronbach's α=0.876) and test-retest reliability of the items on twenty subjects are almost perfect (both weighted Kappa 0.95).

General well-being tool

The general well-being tool was adopted from the General Well-Being Schedule (GWB) (23). The tool was used to determine patients' perceptions of their own well-being at the time of assessments. The measure contained two subscales of anxiety and vitality with 6-scale items and 2 analog-scale items. The first 6 questions used 6-point Likert scales representing intensity or frequency. The remaining two questions (one for anxiety and one for vitality) used 0 to 10 rating scales defined by adjectives at each end. Therefore, the 8 items gave a general idea about patients' well-being status regarding anxiety and vitality under early ambulation and routine bed rest care so comparison could be drawn. The Cronbach's α was 0.79 for the Chinese version of the tool in this study.

Patient satisfaction tool

The patient satisfaction tool was modified from the tools created by Blegen et al. (24) and Wang et al. (25). The modified tool consisted of 10 items covering the subscales of communication, interpersonal, comfort and patient satisfaction to determine patients' perceptions of the quality of care received during hospitalization. The Cronbach's α was 0.89 for the Chinese version of the tool.

Procedure

Approval from the University Ethics Committee and the study hospital were obtained before data collection. All eligible patients were invited to participate in the study after admission and those who agreed to participate were asked to complete the consent forms. The investigator used a computer generated random list to assign patients to the experimental versus the control group. Patients did not know which group they were in until after 4 hours of bed rest to avoid potential confounding influences. Then patients in the experimental group were asked to ambulate according to the schedule: standing at the bedside for 1 minute, then walking in the room for 2 minutes each hour for 3 consecutive hours, while patients in the control group continued their bed rest until next morning.

For experimental group, puncture site bleeding was assessed hourly for the first 4 hours and before and after each ambulation, whereas for the control group it was assessed hourly for the first 6 hours and at the end of the 6 hours. Patients in both groups were asked to evaluate their back pain perception at three different intervals at 4 hours and 8 hours after they returned to the unit, and at 8 AM the next morning. Urinary discomfort was assessed at 6 hours after return to the unit. Data on perception of general well-being were collected before CC and discharge. Data of patient satisfaction were collected before discharge.

Statistical analysis

Statistical analyses were done using SPSS 17.0 (SPSS Inc., Chicago, IL) and the PROC GENMOD (SAS Institute, Cary, NC, release 9.1) was used to fit generalized estimation equation model (GEE). Skewed continuous/ordinal variables and normal-like distributed variables were respectively presented as median (inter-quartile range) and mean (standard deviation). Categorical data were presented as frequency (percentage). Background characteristics and outcome variables between the two groups were compared using independent samples t-test, Mann-Whitney U test or Pearson Chi-square test, as appropriate.

Adjusted comparisons on the outcome variables between control and experimental groups with adjustment for potential confounding factors were performing using general multiple logistic regression, ordinal logistic regression, multiple regression, or GEE model depending on the nature of the outcome variables. Those background characteristics listed in Table 1 having p values <0.25 between the two groups were considered as potential confounding factors when making adjusted comparison between the two groups (26). The GEE models account for intra-correlated repeated measures data and be able to fit various types of data with the use of appropriate link-function. All statistical tests were two-sided and a p value<0.05 was considered statistically significant.

Results

Background characteristics

Among all the 137 participants, the proportions of male to female was similar (50.4% versus 49.6%), 52% were elderly (aged 65 or above), 17% were single, divorced or widowed, 37% had secondary or above education, 19% had a job. Fifty-five percentage of the participants had monthly household income less than HK$8.000 (1US$ ~= 7.8 HK$), 30% had middle income between HK$ 8.000 and 18.000, the remaining 15% had high

Table 1. Background characteristics of the study sample (n=137)

Baseline characteristics	All (n=137)	Control (n=74)	Experimental (n=63)	*p
Sex, n (%)				
Male	69 (50.4)	33 (44.6)	36 (57.1)	0.143
Female	68 (49.6)	41 (55.4)	27 (42.9)	
Age (years), n (%)				
< 65	66 (48.2)	32 (43.2)	34 (54.0)	0.211
65	71 (51.8)	42 (56.8)	29 (46.0)	
Weight, kg	62.7 (11.9)	60.3 (11.8)	65.5 (11.4)	0.010
Height, cm	159.0 (8.3)	158.5 (8.4)	159.6 (8.1)	0.442
Education level, n (%)				
No formal education	39 (28.5)	21 (28.4)	18 (28.6)	0.985
Primary	47 (34.3)	25 (33.8)	22 (34.9)	
Secondary or above	51 (37.2)	28 (37.8)	23 (36.5)	
Marital status, n (%)				
Single/divorced/widowed	23 (16.8)	16 (21.6)	7 (11.1)	0.101
Married	114 (83.2)	58 (78.4)	56 (88.9)	
Monthly family income (HK$), n (%)				
< 8.000	75 (54.7)	34 (45.9)	41 (65.1)	0.060
8.000-18.000	41 (29.9)	25 (33.8)	16 (25.4)	
>18.000	21 (15.3)	15 (20.3)	6 (9.5)	
Working status, n (%)				
Retired	65 (47.4)	38 (51.4)	27 (42.9)	0.262
Housewife	35 (25.5)	15 (20.3)	20 (31.7)	
Unemployed	11 (8.0)	8 (10.8)	3 (4.8)	
Currently working	26 (19.0)	13 (17.6)	13 (20.6)	
Number of co-morbidity, n (%)				
0-1	24 (17.5)	20 (27.0)	4 (6.3)	0.017
2	34 (24.8)	16 (21.6)	18 (28.6)	
3	40 (29.2)	20 (27.0)	20 (31.7)	
4	39 (28.5)	18 (24.3)	21 (33.3)	
History of back pain, n (%)				
No	110 (80.3)	58 (78.4)	52 (82.5)	0.542
Yes	27 (19.7)	16 (21.6)	11 (17.5)	
Duration of cardiac catheterization procedure min	20 (15-30)	16 (15-29)	20 (16-32)	0.462

Data are presented as frequency (%) and median interquartile range
*Pearson Chi-square test and independent samples t-test Cardiac catheterization procedure was first log-transformed before subjected to t-test

income greater than HK$ 18.000. About 20% of the participants had history of back pain before cardiac catheterization. The median duration of the cardiac catheterization procedure were respectively 20 (inter-quartile range:16-32) and 16 (inter-quartile range:15-29) minutes for the experimental and control groups (p=0.462, Table 1). There was no difference (p=0.15) on sheath size between the two groups (control: mean= 5.47 ±0.55; experimental: mean=5.38±0.49; ranged 5-6). There were no significant

differences on background characteristics except body weight and number of co-morbidity between two groups (both p<0.05, Table 1).

Outcomes before and after cardiac catheterization

Vascular complications

Only one patient in the control group experienced puncture site bleeding after CC. No patients, both in experimental and control groups, developed any vascular complications.

General well-being (GWB) scores

The mean scores of GWB and each of its subscales were given in Table 2. There were no significant differences on the anxiety and vitality subscale scores and its total scores between the experimental and control groups before cardiac catheterization (all p>0.05, Table 2). Using GEE models, it was found that no significant differential change of the anxiety subscale score between the two groups after adjusting for the potential confounding factors (p=0.557, Table 3). However, GEE models revealed that the experimental group had significantly larger increase in the vitality subscale (p=0.005) and the total GWB (p=0.014) scores after cardiac catheterization than the control group, after adjusting for the potential confounding factors (Table 3). The unadjusted crude models also gave similar results (Table 3).

Back pain

The back pain measured by VAS was categorized into 3 levels "no pain/mild (0-3)", "moderate (>3-7)" and "severe (>7-10)". The number and percentage of the patients in each of the three categories at 4 hours, 8 hours and in the next morning after CC are listed in Table 2. The experimental group experienced milder back pain than the control group, especially after 8 hours (p<0.001) and in the next morning (p=0.002). Ordinal logistic regression showed that the experimental group was also less likely experiencing moderate or severe back pain at 8 hours and in the next morning after the procedure than the control group after adjusting for the potential confounding factors [after 8 hours, OR=0.19, 95% CI (0.08-0.45), p<0.001; in the next morning, OR=0.36, 95% CI (0.15-0.87), p=0.023, Table 4].

Urination discomfort and difficulty

The experimental and control groups had respectively 17.5% and 38.6% patients reported very or unbearable urination discomfort after catheterization (p=0.007, Table 2). General multiple logistic regression analysis revealed that after adjusting for the potential confounding factors, the experimental group was less likely experiencing very or unbearable urination discomfort after catheterization than the controls [Odds ratio, OR=0.35, 95% CI (0.14-0.90), p=0.030, Table 4]. Overall, 7.9% and 27.1% patients respectively of the experimental and control groups reported much difficulty or unable to urinate at all (p=0.004). General multiple logistic regression showed that the experimental group was also less likely experiencing much difficulty or unable to urinate at all than the controls after adjusting for the potential confounding factors (OR=0.22, 95% CI (0.06 - 0.74), p=0.015, Table 4).

Puncture site pain score and patient satisfaction scale

The median puncture site pain scores (ranged 0-10) were respectively 1 (inter-quartile range: 0-3) and 2 (inter-quartile range: 0-3) for the experimental and control groups (p=0.476, Table 2). The descriptive statistics for the patient satisfaction total score and its subscale scores were listed in Table 2. No significant differences in all the scores between the two groups were found in both unadjusted and adjusted analyses using ordinal logistic regression (Table 4).

Discussion

The major finding of the study was that ambulation 4 hours after CC could reduce back pain, urinary discomfort and increase general well-being of the patients. However, effect of early ambulation on puncture site pain, puncture site bleeding, and the satisfaction level were not significantly different between the two groups.

Back pain was one of the complaints frequently reported by patients who were required for strict bed rest and immobilization after CC (3). It is implied that the longer patients are required for bed rest, the more severe back pain they will experience (12). It was demonstrated that the reduced bed rest restriction in the early ambulation group was helpful in reducing the severity of back pain caused by prolonged bed rest.

Besides, one participant of the control group reported puncture site bleeding with no other vascular complications being reported. In previous studies, vascular complication development occurred in 0.43-4% of patients (2, 10). Therefore, bed rest and immobilization were considered essential to decrease such risks of post CC complications (2). However, in this study, keeping patients in bed for 4 hours or more did not show any differences in vascular complication development. We conclude that getting patients out of bed at 4 hours is considered safe without jeopardizing patient safety.

Early ambulation was not shown to have an effect on improving patients' satisfaction level, which was not consistent with the previous study (12). Cultural influences should be taken into consideration when assessing the satisfaction level of patients because culture influences how feelings are expressed and what verbal and nonverbal expressions are appropriate (27). Traditional Chinese philosophies of Confucianism, Taoism, and Buddhism form the basis for influencing and forming rules for social interactions among Chinese (28). Most Chinese are reluctant to share their feelings with others in order to maintain harmonious relationships (29-31). Participants in this study might have believed that expressing their dissatisfaction and negative

Table 2. Comparison of outcome variables between control and experimental groups

Outcome variables	All (n=137)	Control (n=74)	Experimental (n=63)	*p
General well-being				
Anxiety subscale (pre-procedure)	16.9±5.3	16.5±4.9	17.5±5.6	0.248
Anxiety subscale (post-procedure)	20.3±4.9	19.5±5.2	21.2±4.5	0.044
Vitality subscale (pre-procedure)	17.7±5.9	17.3±5.9	18.1±6.0	0.407
Vitality subscale (post-procedure)	16.5±5.5	14.6±4.9	18.6±5.5	<0.001
Total scale (pre-procedure)	34.6±9.7	33.7±9.1	35.6±10.2	0.253
Total scale (post-procedure)	36.7±9.1	34.1±8.4	39.8±9.1	<0.001
Back pain, n (%)				
Post-procedure (4 hours)				
No pain/mild (0-3)	114 (83.2)	59 (79.7)	55 (87.3)	0.213
Moderate (>3-7)	17 (12.4)	10 (13.5)	7 (11.1)	
Severe (>7-10)	6 (4.4)	5 (6.8)	1 (1.6)	
Post-procedure (8 hours)				
No pain/mild (0-3)	86 (62.8)	35 (47.3)	51 (81.0)	<0.001
Moderate (>3-7)	33 (24.1)	23 (31.1)	10 (15.9)	
Severe (>7-10)	18 (13.1)	16 (21.6)	2 (3.2)	
Post-procedure (next morning)				
No pain/mild (0-3)	90 (65.7)	39 (52.7)	51 (81.0)	0.002
Moderate (>3-7)	27 (19.7)	22 (29.7)	5 (7.9)	
Severe (>7-10)	83 (60.6)	13 (17.6)	7 (11.1)	
Puncture site bleeding, n (%)				
No	136 (99.3)	73 (98.6)	63 (100)	0.999
Yes	1 (0.7)	1 (1.4)	0	
Urination discomfort, n (%)				
No/mild	95 (71.4)	43 (61.4)	52 (82.5)	0.007
Very/unbearable	38 (28.6)	27 (38.6)	11 (17.5)	
Urination difficulty, n (%)				
Minimal / little	109 (82.0)	51 (72.9)	58 (92.1)	0.004
Much / unable to urinate at all	24 (18.0)	19 (27.1)	5 (7.9)	
Patient satisfaction				
Communication subscale	7.9±1.4	7.9±1.5	7.8±1.4	0.725
Interpersonal subscale	7.6±1.6	7.6±1.6	7.7±1.6	0.857
Comfort subscale	6.7±1.4	6.5±1.4	6.9±1.5	0.188
Satisfaction subscale	24.0±4.2	23.9±4.4	24.0±3.8	0.865
Total scale	46.2±7.2	46.0±7.7	46.4±6.6	0.741
Puncture site pain score	1 (0-3)	2 (0-3)	1 (0-3)	0.476

Data are presented as frequency (%), mean±SD and median (interquartile) range mean (standard deviation)
*Unadjusted cross-sectional comparison between the control and experimental groups: Pearson Chi-square test, independent samples t-test and Mann-Whitney U test

Table 3. Generalized estimation equation (GEE) models for the comparison of the repeated measures outcome variables between control and experimental groups

	Crude model		Adjusted model	
	β (95% CI)	p	β (95% CI)	p
General well-being (anxiety score)				
group	1.05 (-0.73, 2.82)	0.247	1.03 (-0.80, 2.86)	0.269
tp	3.02 (1.67, 4.38)	<0.001	3.11 (1.75, 4.47)	<0.001
group*tp	0.65 (-1.24, 2.54)	0.499	0.57 (-1.33, 2.47)	0.557
General well-being (vitality score)				
group	0.85 (-1.14, 2.84)	0.403	0.70 (-1.32, 2.72)	0.496
tp	-2.64 (-4.19, -1.08)	0.001	-2.63 (-4.21, -1.05)	0.001
group*tp	3.10 (0.95, 5.26)	0.005	3.10 (0.93, 5.27)	0.005
General well-being (total score)				
group	1.90 (-1.35, 5.14)	0.252	1.73 (-1.59, 5.05)	0.307
tp	0.39 (-1.56, 2.34)	0.696	0.48 (-1.49, 2.44)	0.636
group*tp	3.76 (0.85, 6.66)	0.011	3.67 (0.75, 6.59)	0.014
Logit (back pain)				
group	-0.27 (-1.12, 0.59)	0.542	-0.15 (-1.03, 0.74)	0.742
tp1	1.23 (0.62, 1.85)	<0.001	1.32 (0.66, 1.97)	<0.001
tp2	2.21 (1.51, 2.92)	<0.001	2.40 (1.62, 3.17)	<0.001
tp3	2.28 (1.63, 2.94)	<0.001	2.45 (1.74, 3.17)	<0.001
group*tp1	0.29 (-0.63, 1.21)	0.540	0.26 (-0.70, 1.21)	0.603
group*tp2	-0.76 (-1.84, 0.33)	0.173	-0.91 (-2.05, 0.24)	0.121
group*tp3	-0.76 (-1.84, 0.32)	0.169	-0.89 (-2.03, 0.24)	0.122

Note:
For general well-being scores, only the model estimates of the dummy variables for the groups (group: 0=control, 1= experimental), time points (tp: 0=pre-procedure, 1=post-procedure), time points and groups interaction term group*tp were showed for the GEE models
For the binary outcome - back pain, only the model estimates of the dummy variables for the groups (group: 0= control, 1= experimental), time points (tp1: 1=post-procedure 4 hours, 0=else, tp2: 1=post-procedure 8 hours, 0=else, tp3: 1=post-procedure next morning, 0=else), time points and groups interaction terms group*tp1, group*tp2, group*tp3 were showed for the GEE models
Crude model included the above dummy variables and intercept term only
Adjusted model included the above dummy variables; intercept term, and potential confounding factors: sex, age, weight, marital status, family income and co-morbidity

feelings about the care they received would disturb the harmony. In addition, many studies have shown that patient satisfaction results were often skewed to the positive responses, especially with older patients, and the instruments used may not be sensitive enough to detect differences between groups of patients (32-34). Therefore, the results of this study should be interpreted cautiously.

Study limitations

The study had some limitations. Sample size of the study is relatively small and it should cautious to generalize the results. Moreover, in this study, only one hospital was used as the study site with one cardiology team. If the CC procedure done by this cardiology team was in any way unique, this would impact the generalization of the study results. Selection bias may be present by using only one single center for the study. The study site was a local public hospital. This hospital serves older and poorer patients who are less affluent than the general Hong Kong population. In this study, the average age the participants was 63 years old, 81% of the participants did not have a job, 62.8% received no education or were educated at a primary school level and 54.7% of the participants had monthly household income less than HK$8.000 that reflected many of them might be supported by social welfare. Therefore, these factors may influence the study results and the results cannot be generalized to all Hong Kong Chinese patients undergoing CC.

Due to the advanced in skills and technology as well as to be in line with the international practice, further study on reducing the bed rest duration to less than four hours may be necessary.

Table 4. Logistic regression for the binary outcomes, ordinal regression for the ordinal outcomes, and linear regression for patient satisfaction scales

	Crude model		Adjusted model	
	OR_U (95% CI)	**p**	**OR_A (95% CI)**	**p**
Logistic regression				
Very/unbearable urination discomfort	0.34 (0.15, 0.76)	0.008	0.35 (0.14, 0.90)	0.030
Much urination difficulty/unable to urinate at all	0.23 (0.08, 0.66)	0.007	0.22 (0.06, 0.74)	0.015
Ordinal regression$^{\Psi}$	**OR_U (95% CI)**	**p**	**OR_A (95% CI)**	**p**
Puncture site pain score	0.79 (0.43, 1.47)	0.462	0.77 (0.38, 1.57)	0.476
Back pain (Post-procedure 4 hours)	0.55 (0.22, 1.40)	0.213	0.57 (0.19, 1.70)	0.314
Back pain (Post-procedure 8 hours)	0.20 (0.09, 0.43)	<0.001	0.19 (0.08, 0.45)	<0.001
Back pain (Post-procedure next morning)	0.30 (0.14, 0.63)	0.023	0.36 (0.15, 0.87)	0.023
Linear regression	**β (95% CI)**	**p**	**β (95% CI)**	**p**
Patient satisfaction				
Communication subscale	-0.09 (-0.57, 0.40)	0.725	-0.02 (-0.56,0.52)	0.943
Interpersonal subscale	0.05 (-0.49, 0.58)	0.857	0.05 (-0.56, 0.65)	0.879
Comfort subscale	0.32 (-0.16, 0.80)	0.188	0.33 (-0.21, 0.87)	0.228
Satisfaction subscale	0.12 (-1.28, 1.52)	0.865	0.19 (-1.39, 1.76)	0.817
Total scale	0.41 (-2.01, 2.83)	0.741	0.55 (-2.16, 3.25)	0.693

Note:
OR_U: unadjusted odds ratio of the experimental group compared to the control (reference group) obtained by logistic/ordinal regression
OR_A: adjusted odds ratio of the experimental group compared to the control (reference group) obtained by logistic/ordinal regression with adjustment for potential confounding factors: sex, age, weight, marital status, family income and co-morbidity
$^{\Psi}$Parallel lines assumption for ordinal regression was fulfilled for all the outcomes (all p values >0.05)

Conclusion

Though the sample size was relative small, the findings of the study were evaluated by objective scales, the results of the study carried indicative values. Patients undergoing CC can safely get out of bed after 4 hours of bed rest. Reduced time for bed rest can decrease back pain, urinary discomfort and promote general well-being of patients. In this study, though patients in both groups discharged about the same time as usual, potential benefits of early ambulation on decreasing nursing time needed for post CC patient care, decreasing hospital length of stay and reducing hospital costs cannot be neglected. Therefore, early ambulation at 4 hours after CC is acceptable strategy to improve patient care outcomes after transfemoral CC.

The results of the study enhanced health providers understanding about the effects of early ambulation on patient outcomes. With the developed knowledge, nurses may provide more individualized and appropriate care to post-CC patients in Hong Kong in a more competent and cost-effective way.

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