EVIDENCE SYNTHESIS

The clinical effectiveness of length of bed rest for patients recovering from trans-femoral diagnostic cardiac catheterisation

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Abstract

Background Cardiac catheterisation plays a vital role in the diagnosis and evaluation of cardiac conditions. The goal of management of patients after cardiac catheterisation is to reduce the risk of development of any local or prolonged vascular complications, in particular bleeding and haematoma formation at the puncture site. Bed rest and immobilisation of the affected leg are recommended practices to ensure adequate haemostasis at the femoral arterial puncture site and prevent complications.

Objectives The objective of this review was to present the best available evidence for the optimal length of bed rest after trans-femoral diagnostic cardiac catheterisation. The main outcome of interest was the incidence of bleeding and haematoma formation following varying periods of bed rest.

Search strategy We searched the following databases: CINAHL, Medline, Cochrane Library, Current Contents, EBSCO, Web of Science, Embase, British Nursing Index, Controlled clinical trials database, Google Scholar. Reference lists of relevant articles and conference proceedings were searched. We also contacted key organisations and researchers in the field.

Selection criteria All randomised and quasi-randomised controlled trials that compared the effects of different lengths of bed rest following trans-femoral diagnostic cardiac catheterisation on patient outcomes were considered for inclusion in the review.

Data collection and analysis Eligibility of the trials for inclusion in the review, details of eligible trials and the methodological quality of the trials were assessed independently by two reviewers. Odds ratios (OR) for dichotomous data and a weighted mean difference for continuous data were calculated with 95% confidence intervals (CI). Where synthesis was inappropriate, trials were considered separately.

Main results Eighteen trials involving a total of 4294 participants were included in the review. One trial included three treatment groups. In seven trials among 747 people there was no significant difference in the incidence of bleeding following six or less than 6 h of bed rest (OR 1.47; 95% CI 0.60, 3.64). Likewise, there was no significant difference in the incidence of bleeding following bed rest at other time periods. In eight trials involving 2272 patients there was no significant difference in the incidence of haematoma formation following 6 or less than 6 h of bed rest (OR 0.82; 95% CI 0.59, 1.16). Significantly fewer patients randomised to less than 6 h of bed rest complained of back pain. The odds of developing back pain at 4 (OR 24.60; 95% CI 1.29, 469) and 24 h (OR 2.47; 95% CI 1.16, 5.23) following coronary catheterisation was significantly higher among patients randomised to 6 compared with 3 h of bed rest.

Authors’ conclusions There is evidence of no benefit relating to bleeding and haematoma formation in patients who have more than 3 h of bed rest following trans-femoral diagnostic cardiac catheterisation. However,
there is evidence of benefit relating to decreased incidence and severity of back pain and cost-effectiveness following 3 h of bed rest. There is suggestive but inconclusive evidence of a benefit from bed rest for 2 h following trans-femoral cardiac catheterisation. Clinicians should consider a balance between avoiding increased risk of haematoma formation following 2–2.5 h of bed rest and circumventing back pain following more than 4 h of bed rest.

Background
Coronary heart disease (CHD) is the second leading cause of death worldwide; according to the World Health Organization, there were around 7 million deaths from CHD globally in 2002, and there will be 11.1 millions death in 2020. In order to reduce mortality and morbidity as well as to promote recovery in CHD, early identification of the disease is therefore crucial. Diagnostic cardiac catheterisation also called coronary angiography plays a vital role in the evaluation of cardiac conditions and can be performed either as an outpatient or inpatient procedure depending on the cardiologist and institutional preferences.

Cardiac catheterisation, as with all invasive procedures, is not without risk, and vascular complications have been reported to occur in approximately 0.43–4% of patients following the procedure. The most common vascular complications following cardiac catheterisation are bleeding and haematoma at the puncture site. Other vascular complications include distal embolisation, arterial thrombosis, false femoral aneurysm and arteriovenous fistula. Many of these local vascular complications require operative repair and result in considerably longer hospital stays and higher costs associated with the procedure.

Brachial arteriotomy, radial artery approach and percutaneous puncture of the femoral artery are common access sites for diagnostic cardiac catheterisation. However, the route for cardiac catheterisation is dependant on the patient’s condition and treatment as well as the operators’ preference. Irrespective of the access site, cardiac catheterisation requires careful management of the patient to prevent the development or prolonging of any complications following the procedure, in particular bleeding and haematoma formation at the puncture site. If the brachial or radial artery routes are used, firm pressure may be required and the patient is free to mobilise from arrival back to the ward and in some instances following to 2–3 h of bed rest. Because of quicker ambulation, these patients usually have a more comfortable and rapid recovery after the procedure. However, if the femoral route is used, passive closure approaches that include manual or mechanical application of firm pressure above the puncture site is the recommended practice to ensure adequate haemostasis and prevent complications. These patients also require bed rest and immobilisation of the affected leg for an extended period of time. However, there is no consensus on the optimal duration of bed rest for these patients. There is wide variation among studies, ranging from 2 to 24 h.

Although bed rest has been reported to be beneficial, suboptimal patient outcomes can also result from prolonged bed rest. Patients can experience physical discomfort, which includes back pain, bleeding and haematoma formation and allow early ambulation. However, this method of active closure has not been widely adopted. Therefore identifying the optimal length of bed rest after diagnostic cardiac catheterisation via the femoral route is essential to prevent bleeding and haematoma formation, other vascular complications and to promote patient comfort.

Objectives
The objective of this review was to present the best available evidence for the optimal length of bed rest after trans-femoral diagnostic cardiac catheterisation.

Research question
This systematic review was undertaken to answer the question: following trans-femoral diagnostic cardiac catheterisation, what is the effect of varying lengths of bed rest on the incidence of vascular complications and extent of patient comfort?

Criteria for considering studies for this review

Types of studies
All randomised and quasi-randomised controlled trials (RCTs) that investigated the effect of various lengths of bed rest after trans-femoral diagnostic cardiac catheterisation on the incidence of vascular complications and patient comfort were included in the review. Trials reported in duplicate were included only once. Trials reported in the English language were only considered for this review.

Types of participants
Adult patients, aged 18 or above, undergoing trans-femoral diagnostic cardiac catheterisation in either day-surgery units or in-hospital setting were included.

Types of interventions
Trials that compared various lengths of bed rest after trans-femoral diagnostic cardiac catheterisation were included in...
this review. In addition, trials that involved gradual mobilisation were also included. Trials that compared bed rest following diagnostic cardiac catheterisation using the radial or brachial artery approach were excluded. In addition, trials that bed rest following interventional cardiac catheterisation were also excluded. Trials that compared various sizes of cardiac catheters on patient outcomes were excluded. Additionally, trials that compared bed rest protocols together with other interventions were also excluded.

Types of outcome measures
The primary outcomes of interest of this review were objective or subjective measures of:

1. Bleeding: blood loss estimated at greater than 100 mL or bleeding that lead to further attempts to reestablish homeostasis by manual pressure, sandbag or reinforce

2. Haematoma: greater than 1 cm in width.31,32

Secondary outcomes of interest included:

1. Incidence and severity of back pain.
2. Incidence of pseudoaneurysm.
3. Incidence of bruising.
4. Revisits to hospital.
5. Incidence of local thrombus formation.
6. Complications of the extremity.
7. Urinary discomfort.
8. Incidence of groin pain.
10. Costs.

Search strategy for identification of studies

The third step was a search of the reference lists and bibliographies of all relevant articles. Unpublished studies were identified from the Dissertation Abstracts International (Proquest dissertation) and Proceedings First (First Search). To complement the search strategies, hand searches of relevant journals were conducted, and researchers in the field were also contacted to identify any further trials.

Methods of the review
All studies identified from database search were assessed for relevance against the inclusion/exclusion criteria based on the title and abstract, and the full text was obtained of relevant reports. Studies identified from reference lists were assessed for relevance based on study title. If the title and abstract were inconclusive full text was obtained for further assessment. Studies that were reported in more than one publication were included only once. Decisions for study eligibility were made independently by two reviewers. The references and abstracts identified from the search were imported into a bibliographic software package, Endnote Version 6.

Assessment of methodological quality
The methodological quality of the eligible RCTs was assessed independently by two reviewers using the Joanna Briggs quality assessment tool for experimental studies (Appendix II). Any disagreements were resolved by discussion with a third reviewer. Each study was critically appraised, and the methodological quality was assessed using the following checklist:

1. Detailed description of inclusion and exclusion criteria used to obtain the sample.
2. Evidence of allocation concealment at randomisation.
4. Description of withdrawals and dropouts.
5. The potential for bias in outcome assessment.

Data extraction
Data extraction from the included trials was undertaken and summarised independently by two reviewers using a data extraction tool (Appendix III). Discrepancies between reviewers were resolved by discussion. Data were collected relating to:

1. Patient demographics.
2. Patient inclusion/exclusion criteria.
3. Description of the interventions.
4. Description of the outcomes.

If any data were missing from the trial report, attempts were made to obtain them by contacting the authors.

Data synthesis
All calculations were made using the Cochrane statistical package Review Manager (RevMan) Version 4.2.8. Clinical heterogeneity was assessed by considering the interventions and outcomes between the studies. Statistical heterogeneity was investigated by calculating the I² statistic,¹⁵ and if this indicated a high level of heterogeneity among the trials included in an analysis, a random effects meta-analysis was chosen for an overall summary. Odds ratio (OR) and 95% confidence intervals (CI) were used to present the results of dichotomous data. Fixed effects meta-analysis was used for combining data if the trials were judged to be sufficiently similar. Analysis of continuous data was undertaken using the mean and standard deviation values to derive weighted mean differences and their 95% CI. Where synthesis was inappropriate a narrative overview has been undertaken. However, graphs have been included for visual presentation of the data.
Data analysis

Description of studies
A total of 75 studies were identified from the search strategy. Following removal of 20 duplicate RCTs, 55 studies were potentially eligible for inclusion. Based on a review of the titles and abstracts of the citations, 26 trials did not meet the inclusion criteria and were excluded. On further examination of the remaining 29 articles, 21 trials were considered to be potentially eligible, and full text of these trials was obtained. Three were further excluded for reasons shown in Appendix IV, leaving 18 trials investigating different lengths of bed rest after trans-femoral cardiac catheterisation that were included in the final systematic review.

Of these 18 included trials, nine were conducted in the USA,10,11,16–18,21,22,32,33 three in Canada,9,13,19 three in the UK,31,34,35 one in Hong Kong26 and two in Singapore.20,36

Sample sizes
The number of participants in the 18 trials ranged from 2913 to 874,19 with a total of 4294 participants in the studies.

Trial setting
Most of the trials (n = 10) were conducted in hospital settings, four included outpatients10,18,22,32 and two involved both inpatients and outpatients.19,33 The settings of two trials were not clear.16,17

Participants
The age of the participants ranged from 2934 to 85 years.9 One trial15 did not report the age, while the remaining reported either age groups16 or mean ages17–22,31–33 of the participants. Fourteen trials9,11,16–22,26,31–33 reported on the gender of the participants, with the male ranging from 44%26 to 100%.13

Interventions
The length of bed rest of participants after trans-femoral diagnostic cardiac catheterisation among the 18 included studies ranged from 2 to 24 h or until the next morning. Length of bed rest investigated included:

1. 6 h versus 2,22 3,9,17 4,15,16,21,32,34 4–5,33 1211 and 24 h.20
2. 4 h versus 2,10,31 2.5,18 12 to 2426 and 24 h.36
3. 4.5 h versus 2.5 h.35

One three-arm study compared bed rest for 3 versus 4 versus 6 h.19

The size of the catheter used ranged from 4 F to 9 F. One trial used 4 F,17 five used 6 F,26,31,34,35 three used 7 F11,19,20 and one used 8 F.16 Other trials used 5 or 6 F,32 5 to 7 F,10,15 5 to 7.5 F,36 6 to 8 F,13 6 to 9 F3 and 7 or 8 F.33 Two trials did not state the size of the catheter used.21,26

The method to achieve haemostasis of the puncture site was mainly manual compression.9,10,13,20,21,26,35,36 There were also studies which used a combination of manual compression with a mechanical compression clamp9,19,22,37 compression clamp devices only,31,34 sandbags or gauze pressure dressings only.11,32 Two trials did not mention the methods of haemostasis used.17,33 None of the trials indicated that they used any form of vascular closure devices.

Methodological quality
All trial reports were evaluated against the criteria outlined in the methods of the review to assess methodological quality. There was 90% concordance between the reviewers in this respect. The discrepancies were resolved with discussion with the third reviewer. Overall, the quality of the trials was weak with a mean of six criteria being described. None of the 18 trials described all 11 aspects of methodological quality as determined by the JBI criteria (Appendix V). Details regarding statistical power and sample size calculations were reported in two trials.16,17 The alpha level used in their statistical tests was also reported.

Randomisation
The method of randomisation involved random numbers tables,26,33 alternation by the week,31,32 according to post-procedure room number,11 national identification card number10 and by rolling a dice.18 The method of randomisation was not reported in the remaining 11 trials.

Intention-to-treat analysis
Intention-to-treat (ITT) analysis should ideally include data from all those who were randomised. Inclusion of those patients who withdraw or drop out from a trial is important as losing their data could result in bias. Analysis on an ITT basis was reported in only one trial.9

Adequate follow-up
More than 80% of the participants were followed up in 11 trials.10,13,16,17,19,20,22,31,33,35,36

Baseline comparability of groups
A description of the patients’ baseline characteristics assists the reader in deciding if the results are applicable to their situation. Baseline comparability relating to age,9,11–13,20 gender,16–18,22,26,32,33,37 co-morbidities9,13,22,31,33 and size of catheter used9,12,13,17,20,22,35 were presented.

Blinded outcome assessment
Because of the nature of interventions, blinding of the patient, care provider and assessor was not possible in most of the trials. However, one trial15 reported that those assessing outcomes were blinded to the intervention.

Methods to assess outcomes
Various methods were used to assess outcomes. Significant bleeding was defined as blood loss greater than 100 mL.9 Haematoma was defined as a palpable, firm effusion of subcutaneous blood16 and was considered to be small if 4–5 cm, moderate if 6–10 cm and large if greater than 10 cm in diameter.16 Pain was assessed using the Present Pain Index.9 Anxiety was assessed using the Spielberger State Anxiety Inventory.9

For further descriptions see Summary Tables (Appendix VI).
Results

Bleeding

Twelve trials\(^9-11,13,16-18,21,22,26,32,35\) investigated the effect of different lengths of bed rest on the incidence of bleeding.

Comparison between bed rest for 6 h and bed rest for less than 6 h

Seven trials (\(n = 747\)\(^9,11,13,16,17,22,32\) investigated the effect of this comparison on the incidence of bleeding. The findings demonstrated no statistically significant difference in the incidence of bleeding between the groups (Fig. 1).

Comparison between bed rest for 6 h and bed rest for more than 6 h

One trial (\(n = 101\)\(^11\) undertook this comparison and reported no significant difference in the incidence of bleeding between the two groups (OR 0.67; 95% CI 0.11, 4.17) (Fig. 2).

Comparison between bed rest for 4–4.5 h and bed rest for less than 4 h (2–2.5 h)

Three trials (\(n = 1233\)\(^10,18,35\) undertook this comparison. The findings demonstrated no statistically significant difference in the incidence of bleeding between the two groups (OR 0.86; 95% CI 0.52, 1.44) (Fig. 3).

Comparison between bed rest for 4 h and bed rest for 12–24 h

One trial (\(n = 86\)\(^26\) assessed this outcome, and there was no difference in the incidence of bleeding in patients randomised to either 4 or 12–24 h of bed rest (OR 0.33; 95% CI 0.01, 8.22). The wide CI could be attributed to the small sample size (\(n = 46\)) (Fig. 4).

Haematoma

Fourteen trials\(^9,10,16-20,22,31-36\) investigated the effect of different lengths of bed rest following trans-femoral cardiac catheterisation on the incidence of haematoma formation.

Comparison between bed rest for 6 h and bed rest for less than 6 h

Eight trials (\(n = 2272\)\(^9,16,17,19,22,32-34\) investigated the effect of this comparison on the incidence of haematoma formation. Four\(^16,19,32,34\) of these trials (\(n = 1020\) compared 6 and 4 h of bed rest. Pooled analysis demonstrated no significant difference in the incidence of haematoma formation between the two groups (OR 0.80; 95% CI 0.50, 1.28) (Fig. 5). Similarly, no significant difference in the incidence of haematoma was reported in trials that compared bed rest for 6 h with 4–5,\(^33,17,19\) and 2 h.\(^22\) (Fig. 5). Overall, there was no difference in the incidence of haematoma formation between those participants who remained on bed rest for 6 h and those who were allowed to mobilise earlier.

Comparison between bed rest for 6 h and bed rest for more than 6 h

One trial (\(n = 300\)\(^20\) investigated the incidence of haematoma formation among patients randomised to 6 or 12 h of bed rest, but there was no significant difference in this outcome between the two groups (Fig. 6).

Figure 1 Incidence of bleeding (6 h vs. less than 6 h).

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Comparison between bed rest for 4–4.5 h and bed rest for less than 4 h

Five trials (n = 2227)\textsuperscript{10,18,19,31,35} investigated the incidence of haematoma formation among patients randomised to 4–4.5 h of bed rest or less than 4 h of bed rest. The findings demonstrated that although a greater number of patients randomised to less than 4 h of bed rest developed haematoma, these results were not statistically significant (OR 0.84; 95% CI 0.60, 1.19) (Fig. 7).

Comparison between bed rest for 4 h and bed rest for 12–24 h

One trial (n = 118)\textsuperscript{36} investigated the incidence of haematoma following bed rest for 4 or 12–24 h. The findings demonstrated no statistically significant difference in this outcome between the two groups (OR 1.08; 95% CI 0.48, 2.39) (Fig. 8).

Back pain

Six trials\textsuperscript{9,13,18,26,36} investigated the effect of various lengths of bed rest on back pain following trans-femoral diagnostic cardiac catheterisation. As all trials had varying periods of bed rest and assessed the incidence and severity of back pain at different times, data could not be pooled in a meta-analysis.

Incidence of back pain

Three trials\textsuperscript{9,17,18} investigated varying periods of bed rest on the incidence of back pain.
Comparison between bed rest for 6 h and bed rest for less than 6 h.

Two trials (n = 147)\(^9\),\(^17\) that compared bed rest for 6 and 3 h reported on the incidence of back pain. No statistically significant difference in the incidence of back pain at 2 and 7 h was identified among patients randomised to either 6 or 3 h of bed rest (Fig. 9). However, the odds of developing back pain 4 (OR 24.60; 95% CI 1.29, 469)\(^9\) and 24 h (OR 2.47; 95% CI 1.16, 5.23)\(^9\),\(^17\) was significantly higher among patients randomised to 6 compared with 3 h of bed rest. The wide CI could be attributed to the small sample size (Fig. 9).

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Comparison between bed rest for 4 h and bed rest for 2–2.5 h. One trial (n = 291) demonstrated significant reduction in the incidence of back pain among patients randomised to 2.5 h of bed rest compared with their counterparts who had bed rest for 4 h. (OR 4.54; 95%CI 2.50, 8.25) (Fig. 10).

Severity of back pain

Four trials investigated varying periods of bed rest on the severity of back pain.

Comparison between bed rest for 6 h and bed rest for less than 6 h. Two trials compared the effect of bed rest...
for 6 and 4 h and one trial\(^5\) of 6 and 3 h on the severity of back pain. Data from two trials\(^5,12\) could not be obtained, and therefore a meta-analysis could not be performed. However, the findings from both trials demonstrated a statistically significant increase in the severity of pain among those patients randomised to 6 h of bed rest compared with those who had 4 or 3 h of bed rest. The third trial (\(n = 82\)\(^12\)) demonstrated no statistically significant difference in the severity of back pain (\(P = 0.52\)) (Fig. 11).

Comparison between bed rest for 4 h and bed rest for 12–24 h. One trial (\(n = 86\)\(^26\)) compared the effect of bed rest for 4 and 12–24 h and found no statistically significant difference in the severity of back pain between the two groups. However, the severity of back pain was significantly
greater at 8 h and the next day among those randomised to 12–24 h of bed rest (Fig. 12).

**Pseudoaneurysm**

Seven trials\(^{16,17,19,22,31,34,35}\) investigated the effect of various lengths of bed rest on the incidence of pseudoaneurysm.

**Comparison between bed rest for 6 h and less than 6 h**

Five trials (\(n = 1770\))\(^{16,17,19,22,34}\) compared the effect of bed rest for 6 and less than 6 h on the incidence of pseudoaneurysm and demonstrated no significant difference in the incidence of this outcome between the groups (OR 4.10; 95% CI 0.97, 17.25) (Fig. 13).
Comparison between bed rest for 4–4.5 h and bed rest for less than 4 h

Pooled analysis from three trials (n = 1689)\(^{19,31,35}\) comparing the effect of bed rest for 4–4.5 and less than 4 h demonstrated no significant difference in the incidence of pseudoaneurysm between the groups (OR 0.95; 95% CI 0.06, 15.21) (Fig. 14).

Brusing

Two trials\(^{31,34}\) investigated the effect of length of bed rest on the incidence of bruising.

Comparison between bed rest for 6 h and less than 6 h

One trial (n = 200)\(^{34}\) that assessed bruising found there was no significant difference in the incidence of bruising among patients randomised to 6 or 4 h of bed rest (Fig. 15).

Comparison between bed rest for 4 h and less than 4 h

One trial (n = 305)\(^{31}\) that undertook this comparison found no significant difference in the incidence of bruising at 3, 4 and 24 h (Fig. 16). However, significantly fewer patients randomised to 2 h of bed rest experienced bruising at 1-month follow-up. (OR 2.20; 95% CI 1.11, 4.37) (Fig. 16).

Revisit to hospital

One study (n = 689)\(^{19}\) investigated the effect of 6, 4 and 3 h of bed rest on revisits to hospital for trans-femoral diagnostic cardiac catheterisation-related problems and found no significant difference in this outcome between the three groups (Fig. 17).

Local thrombus

One three-arm trial (n = 689)\(^{19}\) investigated the effect of 6, 4 and 3 h of bed rest on the incidence of local thrombus formation and found no significant difference in this outcome between the three groups (Fig. 18).

Complications of extremity

Two trials (n = 463)\(^{32,33}\) investigated the effect of 6 and 4 h of bed rest on complications of the extremity and found no significant difference in the incidence (risk ratio (RR) 0.33; 95% CI 0.03, 3.13)\(^{33}\) and severity of numbness or weakness of the affected leg (P = 0.914)\(^{32}\) and the incidence of cold or blue extremity (RR 1.48; 95% CI 0.25, 8.74)\(^{33}\) between the two groups.

Urinary discomfort

One trial (n = 86)\(^{26}\) investigated the effect of length of bed rest on urinary discomfort and found that patients randomised to 4 h of bed rest had significantly reduced urinary discomfort compared with those who had bed rest for 12–24 h (Fig. 19).

Anxiety

One trial (n = 39)\(^{9}\) reported on the anxiety scores among patients randomised to 6 or 3 h of bed rest. The findings...
demonstrated no significant difference in the mean Spielberger state anxiety scores between the two groups ($P = 0.26$). The data could not be presented as a meta-graph because of lack of reporting of standard deviations.

**Patient satisfaction**

Three trials ($n = 393$)$^{17,22,32}$ assessed the effect of the lengths of bed rest on general discomfort or pain and satisfaction with bed rest. Pooled analysis of two trials ($n = 311$)$^{17,22}$ demonstrated no statistically significant difference in the incidence of general discomfort or pain between the groups (Fig. 20). Likewise, the third trial ($n = 82$)$^{32}$ also reported no statistically significant difference in the mean scores relating to comfort and satisfaction with bed rest between the two groups.

**Groin pain**

Two trials ($n = 192$)$^{17,32}$ reported the incidence and severity of groin pain in patients randomised to 6 h or less of bed rest and found no significant difference in the incidence or severity of groin pain between the two groups (Figs 21,22).

**Costs**

Three trials ($n = 573$)$^{17,32,33}$ investigated the effect of varying length of bed rest on cost-effectiveness. Two of these trials...
(n = 463) investigated the effect of 6 and 4 h of bed rest on cost-effectiveness. In one trial (n = 381), patients who were randomised to 6 h of bed rest were discharged the following morning, while those had 3 h of bed rest were discharged the same day if their condition was stable. Total catheterisation charges was calculated as the sum of the costs associated with cardiac catheterisation, inpatient and outpatient stay and ancillary tests or procedures. The findings demonstrated a significant reduction in the total catheterisation charges (P < 0.001) among those randomised to

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**Figure 16** Incidence of bruising (4–4.5 h vs. less than 4 h).

**Figure 17** Revisit to hospital.
Figure 18 Incidence of local thrombus formation.

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Figure 19 Urinary discomfort.

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Figure 20 General discomfort or pain.
3 ($2429 ± 850) compared with 6 h ($3108 ± 1451) of bed rest.

The second trial (n = 82) reported on the total savings in terms of nursing hours per patient. The findings indicated that 5184 h of nursing time could be saved over a period of 2 years if the duration of bed rest had been reduced to 4 h.

The third trial (n = 110) reported a saving of $105 per patient who received 3 compared with 6 h of bed rest.

**Discussion**

This systematic review was undertaken to investigate the clinical effectiveness of length of bed rest for patients recovering from trans-femoral diagnostic cardiac catheterisation. An exhaustive search of the literature resulted in 18 published trials that were eligible for inclusion in this review. The trials involved both male and female adult patients although the majority of the participants were male.

While all 18 trials met the methodological criteria for inclusion in the review, only seven reported on the method of allocation to treatment groups. The primary attribute of RCTs is the ability to eliminate selection bias through the method of allocation. In 11 trials, details of the method of randomisation of patients to treatment groups were absent, and in four the methods were susceptible to selection bias which reduces the strength of the evidence. Three trials were described as either being single- or double-blind; however, the process of blinding was difficult given the nature of the intervention. The ability to extract definitive conclusions from the studies detailed in this review is limited by the poor quality of the trials, lack of replication of most comparisons and the lack of consistency in the criteria used to assess bleeding and haematoma size.

Data analysis regarding haematoma formation was complicated by a lack of consistency in the assessment criteria used. The use of a standardised and validated tool for the measurement of haematomas, and an assessor blinded to the intervention would have enhanced the rigour of the trials and strengthened the evidence.

Inadequate reporting of the trials made it difficult for the authors to critically appraise the validity of the trials. Although attempts were made to contact the authors to obtain additional data, no response was received, and this lack of information is reflected in the report.

The methods used to achieve homeostasis greatly influence the incidence of bleeding and haematoma formation. However, the methods by which homeostasis was achieved...
were reported in few trials. In recent years various vascular closure devices such as angioseals, vasoseals and Duette have been utilised to achieve haemostasis following sheath removal. The use of devices has significantly reduced the time to achieve haemostasis (from 18 to 4 min) and the length of bed rest (from 24 to 2 h). However, none of the RCTs included in this review reported having used these devices to obtain haemostasis; therefore the findings from this review cannot be generalised to patients in whom these devices are used.

Meta-analysis was restricted to trials of the same intervention that assessed the same outcome. Results occurring as a consequence of the treatment effect and not because of chance were considered to be statistically significant. In many instances meta-analysis could not be undertaken because of the paucity of trials of the same intervention and assessing the same outcome. As a result a narrative report with figures utilised to highlight particular findings is presented.

While only trials that investigated the same comparison were combined statistically for a particular outcome, the data from all trials addressing the same broad question for that outcome were presented in the same comparison tables. Readers may question whether it is appropriate to consider such trials together, but the approach did allow patterns to be identified. Anti-coagulation and anti-platelet regimes, patient age, renal function and co-morbidities are all predictors of increased risk of access site complication, however, because of the lack of data and limited number of trials undertaking the comparisons, it was not possible to control for these variables. We therefore recognise that these should be interpreted with a degree of caution given the heterogeneity in terms of the varying lengths of bed rest following trans-femoral cardiac catheterisation.

The majority of the trials demonstrated no statistically significant difference between the outcomes for the groups; however, these results may have clinical and economic significance for health services decision-making. For example, the pooled results of the studies that compared bed rest for 6 and 4 h, indicating no statistical difference in the incidence of bleeding and haematoma formation between the two groups, findings that have significant consequences to patients, practitioners and managers in terms of satisfaction and cost-effectiveness.

As might be expected, there was a tendency for a shorter length of bed rest (2 h) to be associated with a greater increase in haematoma formation, but with a significant decrease in the incidence and severity of back pain. Back pain is a major adverse outcome following bed rest after trans-femoral diagnostic cardiac catheterisation and therefore the impact of the length of bed rest has important implications in terms of patient satisfaction.

Resource implications

In clinical practice, the length of bed rest following trans-femoral cardiac catheterisation has resource implications. The principal determinant of cost is the length of hospital stay. In this review, three trials investigated cost-effectiveness and reported significant cost savings associated with early discharge and nursing time saved in patients who had 3 or 4 h of bed rest.

More detailed assessment of the economic impact of the timing and the duration of the bed rest in future research would be beneficial.

Authors’ conclusions

Implications for practice

The findings from this review demonstrate evidence of no benefit relating to the incidence of bleeding and haematoma formation in patients who have more than 3 h of bed rest following trans-femoral diagnostic cardiac catheterisation. However, there is evidence of benefit relating to decreased incidence and severity of back pain and cost-effectiveness in the same patients. There is an urgent need to support these findings with rigorous research. Although there is evidence of benefit relating to decreased incidence and severity of back pain following 2–2.5 h of bed rest, clinicians should consider a balance between avoiding increased risk of haematoma formation (by 2–2.5 h of bed rest) and circumventing back pain (by more than 4 h of bed rest).

Implications for research

This systematic review demonstrates the methodological deficiencies of the published research that affects the generalisability of the findings. Therefore properly designed multi-centre trials that incorporate the methodological deficiencies in the included studies are needed to compare the clinical benefits and cost-effectiveness of different lengths of bed rest following trans-femoral diagnostic cardiac catheterisation. True randomisation should be ensured, and the sample size should be adequate to detect clinically important differences. A standardised and validated tool should be utilised for the measurement of haematoma, with the assessor blinded to the intervention. Most importantly, the trials should be reported according to the guidelines set out in the CONSORT statement which lists the essential criteria that need to be reported so as to enable readers to determine the validity and reliability of the results. Trials with larger sample sizes are needed to assess the effectiveness of bed rest for 2 h following trans-femoral cardiac catheterisation. Given that closure with vascular devices is increasingly being used for trans-femoral cardiac catheterisation, further trials are urgently needed to investigate the length of bed rest for patients for these patients.

Acknowledgements

The authors would like to thank Professor Rhonda Griffiths from the South Western Sydney Centre for Applied Nursing Research for providing resources for completing the review.

References

Appendix 1

Search strategies

**Ovid MEDLINE(R)**
1966 to July 2007

1. exp heart catheterization/
2. ((cardiac or heart or coronary) adj3 catheteri$).mp.
3. 1 or 2
4. exp Coronary Angiography/
5. ((cardiac or heart or coronary) adj3 angiogra$).mp.
6. ((cardiac or heart or coronary) adj3 arteriog$).mp.
7. 4 or 5 or 6
8. 3 or 7
9. (femor$ or transfemor$).mp.
10. ((lumin$ or translumin$) adj1 (cardiac or coronary$)).mp.
11. 9 or 10
12. 8 and 11
13. exp bed rest/ or exp rest/
14. exp mobilization/
15. exp IMMUNIZATION/
16. exp bleeding/ or exp postoperative complication/ or exp backache/ or exp patient satisfaction/
17. vascular complication$.mp.
18. or/13–17
19. 12 and 18
20. ((systematic$ or methodologic$ or quantitativ$ or research$) adj10 (review$ or overview$ or over-view$ or evidence$)).mp.
22. (control$ adj3 (stud$ or trial$)).mp.
23. random$.mp.
24. ((singl$ or double$ or trebl$ or tripl$) adj (blind$ or mask$)).mp.
25. comparison stud$/ or comparison group$.mp.
26. meta analysis/ or meta analysis.pt. or (metanaly$ or meta-analy$).mp.
27. or/20–26
28. limit 27 to human
29. limit 28 to english language
30. 29 and 19

CINAHL – Cumulative Index to Nursing & Allied Health Literature
1982 to July 2007

1. exp heart catheterization/
2. ((cardiac or heart or coronary) adj3 catheteri$).mp.
3. 1 or 2
4. exp coronary angiography/
5. ((cardiac or heart or coronary) adj3 angiogra$).mp.
6. ((cardiac or heart or coronary) adj3 arteriog$).mp.
7. 4 or 5 or 6
8. 3 or 7
9. (femor$ or transfemor$).mp.
10. ((lumin$ or translumin$) adj1 (cardiac or coronary$)).mp.
11. 9 or 10
12. 8 and 11
13. exp bed rest/ or exp rest/
14. exp mobilization/
15. exp IMMUNIZATION/
16. exp bleeding/ or exp postoperative complication/ or exp backache/ or exp patient satisfaction/
17. vascular complication$.mp.
18. or/13–17
19. 12 and 18
20. ((systematic$ or methodologic$ or quantitativ$ or research$) adj10 (review$ or overview$ or over-view$ or evidence$)).mp.
22. (control$ adj3 (stud$ or trial$)).mp.
23. random$.mp.
24. ((singl$ or double$ or trebl$ or tripl$) adj (blind$ or mask$)).mp.
25. comparison stud$/ or comparison group$.mp.
26. meta analysis/ or meta analysis.pt. or (metanaly$ or meta-analy$).mp.
27. or/20–26
28. limit 27 to human
29. limit 28 to english language
30. 29 and 19

EMBASE
1980 to July 2007

1. exp Heart Catheterization/
2. ((cardiac or heart or coronary) adj3 catheteri$).mp.
3. 1 or 2
4. exp Angiocardiography/
5. ((cardiac or heart or coronary) adj3 angiogra$).mp.
6. ((cardiac or heart or coronary) adj3 arteriog$).mp.
7. 4 or 5 or 6
8. 3 or 7
9. exp FEMORAL ANGIOGRAPHY/ or exp FEMORAL ARTERY/
10. ((lumin$ or translumin$) adj1 (cardiac or coronary$)).mp.
11. 9 or 10
12. 8 and 11
13. exp bed rest/ or exp rest/
14. exp mobilization/
15. exp IMMUNIZATION/
16. exp bleeding/ or exp postoperative complication/ or exp backache/ or exp patient satisfaction/
17. vascular complication$.mp.
18. or/13–17
19. 12 and 18

Cochrane Library

1. MeSH descriptor Heart Catheterization explode all trees in MeSH products
2. MeSH descriptor Coronary Angiography explode all trees in MeSH products
3. MeSH descriptor Bed Rest explode all trees in MeSH products

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4. MeSH descriptor Early Ambulation explode all trees in MeSH products
5. MeSH descriptor Immobilization explode all trees in MeSH products
6. MeSH descriptor Patient Satisfaction explode all trees in MeSH products
7. MeSH descriptor Back Pain explode all trees in MeSH products
8. MeSH descriptor Postoperative Complications explode all trees in MeSH products
9. (#3 OR #4 OR #5 OR #6 OR #7 OR #8)
10. femoral or transfemoral in All Fields in all products
11. MeSH descriptor Femoral Artery explode all trees in MeSH products
12. luminal or transluminal in All Fields in all products
13. cardiac (catheterization or catheterisation) in All Fields in all products
14. coronary (catheterization or catheterisation) in All Fields in all products
15. (cardiac or coronary or heart) angiogram in All Fields in all products
16. (cardiac or coronary or heart) arteriography in All Fields in all products
17. (cardiac or heart) angiography in All Fields in all products
18. (#1 OR #2 OR #13 OR #14 OR #15 OR #16 OR #17)
19. (#10 OR #11 OR #12)
20. (#9 AND #18 AND #19)

**AMED (Allied and Complementary Medicine)**
1985 to March 2006
1. exp Catheterization/
2. ((cardiac or heart or coronary) adj3 catheteri$).mp.
3. 1 or 2
4. ((cardiac or heart or coronary) adj3 angiogra$).mp.
5. ((cardiac or heart or coronary) adj3 arteriog$).mp.
6. or/3–5
7. (femor$ or transfemor$).mp.
8. ((lumin$ or translumin$) adj (cardiac or coronary)).mp.
9. 7 or 8
10. 6 and 9
11. exp Early ambulation/ or exp Bed rest/
12. exp Mobilisation/
13. exp Immobilization/
14. exp Backache/
15. exp Patient satisfaction/
16. exp Postoperative complications/
17. urinary discomfort.mp.
18. or/11–17
19. 6 and 18

**All EBM Reviews – Cochrane DSR, ACP Journal Club, DARE, and CCTR**
1. ((cardiac or heart or coronary) adj3 catheteri$).mp.
2. ((cardiac or heart or coronary) adj3 angiogra$).mp.
3. ((cardiac or heart or coronary) adj3 arteriog$).mp.
4. or/1–3
5. (femor$ or transfemor$).mp.
6. ((lumin$ or translumin$) adj (cardiac or coronary)).mp.
7. 5 or 6
8. 4 and 7
9. (bed rest or bedrest).mp. [mp = ti, ot, ab, tx, kw, ct, sh, hw]
10. mobili$.mp.
11. immobili$.mp.
12. ambulat$.mp.
13. (back pain or backache).mp. [mp = ti, ot, ab, tx, kw, ct, sh, hw]
14. patient satisfaction.mp. [mp = ti, ot, ab, tx, kw, ct, sh, hw]
15. postoperative complications.mp. [mp = ti, ot, ab, tx, kw, ct, sh, hw]
16. urinary discomfort.mp. [mp = ti, ot, ab, tx, kw, ct, sh, hw]
17. or/9–16
18. 8 and 17
19. remove duplicates from 18
20. from 19 keep 1–78

**British Nursing Index (BNI)**
1985 to July 2007
1. ((cardiac or heart or coronary) adj3 angiogra$).mp.
2. ((cardiac or heart or coronary) adj3 arteriog$).mp.
3. or/1–2
4. from 3 keep 1–55

**Web of Science**
1. TS = (catheterization or catheterisation)
2. TS = (cardiac or coronary or heart)
3. #1 and #2
4. TS = (angiography or angiogram)
5. #2 and #4
6. TS = arteriography
7. #2 and #6
8. #3 or #5 or #7
9. TS = (femoral or transfemoral or luminal or transluminal)
10. #8 and #9
11. TS = (((bed rest) or bed-rest or bedrest) or mobili* or immobili* or ambulat* or (patient satisfaction) or ((postoperative or vascular) and complications) or ((back pain) or backache) or (urinary discomfort))
12. #10 and #11
13. TS = ((clinical trial*) or (control* trial*) or (controlled stud*) or random* or blind* or mask*)
14. #12 and #13

**EBSCO**
(SU “Heart Catheterization” Or SU “Coronary Angiography” Or SU “CARDIAC catheterization”) AND DE “Adult” AND SU “FEMORAL artery” AND (SU “BED rest” Or SU “MOBILIZATION” Or SU “Early Ambulation” Or SU “PATIENT satisfaction” Or SU “BACKACHE” Or SU “Postoperative Complications diagnosis” Or TX (urinary discomfort))
### JBI Critical Appraisal Checklist for Experimental Studies

**EFFECT OF BRIEF INTERVENTIONS ON RISK FACTOR MODIFICATION FOR CORONARY HEART DISEASE A – SYSTEMATIC REVIEW PROTOCOL**

<table>
<thead>
<tr>
<th>Reviewer _____________________________</th>
<th>Date ________________</th>
</tr>
</thead>
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<tr>
<td>Author _______________________________</td>
<td>Year_____ Record Number_____</td>
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<th>Yes (3)</th>
<th>No (2)</th>
<th>Unclear (1)</th>
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<td>1. Was the assignment to treatment groups random?</td>
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<td></td>
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<tr>
<td>2. Were participants blinded to treatment allocation?</td>
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<td></td>
<td></td>
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<tr>
<td>3. Was allocation to treatment groups concealed from the allocator</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<tr>
<td>6. Were the control and treatment groups comparable at entry?</td>
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</tr>
<tr>
<td>7. Were groups treated identically other than for the named interventions?</td>
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<tr>
<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<tr>
<td>10. Was there adequate follow-up (&gt;80%)</td>
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<td>11. Was appropriate statistical analysis used?</td>
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</table>

Overall appraisal: Include □ Exclude □ Seek further info □

Comments (Including reasons for exclusion)
## Appendix 3

### Data Extraction Form

<table>
<thead>
<tr>
<th>Author/s and Year:</th>
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<tr>
<td>Journal:</td>
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<td>Ref. No.:</td>
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<tr>
<td>Reviewers:</td>
<td></td>
</tr>
<tr>
<td>Method:</td>
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<td>Setting:</td>
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<table>
<thead>
<tr>
<th>Description of Intervention</th>
<th>Group 1 (Treatment)</th>
<th>Group 2 (Control)</th>
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<table>
<thead>
<tr>
<th>No. of Participants</th>
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<tr>
<th>Outcome description</th>
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### Results

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<tr>
<th>Dichotomous Data Outcome</th>
<th>Group 1 (Treatment) Number/total number</th>
<th>Group 2 (Control) Number/total number</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Continuous Data Outcome</th>
<th>Group 1 (Treatment) Mean &amp; SD (number)</th>
<th>Group 2 (Control) Mean &amp; SD (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Authors Conclusion

### Reviewer’s Conclusion

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Appendix 4

Studies excluded from the review
   **Reason for exclusion:** Descriptive study.

   **Reason for exclusion:** Compares length of bed rest for different types of femoral catheters.

   **Reason for exclusion:** Descriptive study.

   **Reason for exclusion:** Descriptive study.

   **Reason for exclusion:** Non RCT.

   **Reason for exclusion:** Non RCT.

   **Reason for exclusion:** Descriptive study.

   **Reason for exclusion:** Descriptive study.

   **Reason for exclusion:** Data not reported.

    **Reason for exclusion:** Compares length of bed rest for different sizes of femoral catheters.

    **Reason for exclusion:** Descriptive study.
## Appendix 5

### Quality Assessment of Included Trials

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<tr>
<th>Author</th>
<th>Method of allocation</th>
<th>Sample size calculation stated/Total sample</th>
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<tr>
<td>Barkman A (1994)</td>
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<tr>
<td>Baum RA (1996)</td>
<td>Only stated</td>
<td>No/205</td>
</tr>
<tr>
<td>Block PC (1988)</td>
<td>Random no. in sealed envelope</td>
<td>No/381</td>
</tr>
<tr>
<td>Bogart MA (1999)</td>
<td>Only stated</td>
<td>Yes/200</td>
</tr>
<tr>
<td>Chair SY (2007)</td>
<td>Computer generated random table of number</td>
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</tr>
<tr>
<td>Dowling K (2002)</td>
<td>Only stated</td>
<td>No/110</td>
</tr>
<tr>
<td>Keeling A (1996)</td>
<td>Only stated</td>
<td>No/86</td>
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<tr>
<td>Lim R (1997)</td>
<td>Only stated</td>
<td>No/200</td>
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<tr>
<td>Logemann T (1999)</td>
<td>Only stated</td>
<td>No/201</td>
</tr>
<tr>
<td>Pollard SD (2003)</td>
<td>Only stated</td>
<td>No/705</td>
</tr>
<tr>
<td>Pooler-Lunse C (1996)</td>
<td>Only stated</td>
<td>No/29</td>
</tr>
<tr>
<td>Roebuck A (2000)</td>
<td>By week</td>
<td>No/305</td>
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<tr>
<td>Singh N (1998)</td>
<td>Only stated</td>
<td>Yes/874</td>
</tr>
<tr>
<td>Wang SL (2001)</td>
<td>Alternate week</td>
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<tr>
<td>Wong MK (1988)</td>
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<td>No/118</td>
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## Appendix 6

### Summary table of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Barkman 1994 Canada | Randomized controlled trial (RCT) | 39 patients admitted to hospital for cardiac angiograms. | **Group 1 (n = 20)** Bed rest for 3 hours. | **Delayed bleeding**  
Group 1: 0/20  
Group 2: 0/19  
p = not stated  
**Incidence of back pain**  
After 2 hours  
Group 1: 4/20  
Group 2: 6/19  
p = 0.46  
After 4 hours  
Group 1: 0/20  
Group 2: 7/19  
p = 0.01  
**Incidence of back pain**  
After 7 hours  
Group 1: 0/20  
Group 2: 6/19  
p = 0.011  
**Incidence of back pain**  
Next day  
Group 1: 1/20  
Group 2: 5/19  
p = 0.06  
**Level of back pain**  
Significant decrease in scores at 4 hours (p < 0.05) and 7 hours (p < 0.05) in Group 1.  
**State Anxiety Score (mean)**  
Group 1: 29.97  
Group 2: 31.86  
p = 0.26  
**Trait Anxiety Score (mean)**  
Group 1: 32.95  
Group 2: 35.63  
p = 0.26  
Significant bleeding defined as blood loss greater than 100 ml.  
Pain assessed using Present Pain Index.  
Anxiety assessed using Spielberger’s State Anxiety Inventory.  
**Catheter size**  
6–9 F  
Haemostasis achieved using manual pressure.  
**Blinded outcome assessment**  
Patients and outcome assessors not blinded. |
| **Method of Allocation** | Not stated. | Baseline characteristics  
Patients in both groups comparable for gender, age, history of angiograms, chronic back discomfort, aspirin intake and mean catheter size. | **Group 2 (n = 19)** Bed rest for 6 hours. | | |

**Inclusion criteria**  
All patients admitted for cardiac angiograms at Western Canadian teaching hospital.  
**Exclusion criteria**  
1. Known liver disease or bleeding disorders.  
2. A systolic blood pressure (BP) greater than 180 mmHg or diastolic BP greater than 110 mmHg.  
4. Heparin therapy within the previous 24 hours.  
5. Emergency angiogram.  
6. Non-ambulant or comatose state.  
7. Prothrombin time (PT) 2 seconds greater than the control.  
8. Emergency angiogram.  
9. Non-ambulant or comatose state.  
10. Prothrombin time (PT) 2 seconds greater than the control.  
11. Significant bleeding defined as blood loss greater than 100 ml.  
Pain assessed using Present Pain Index.  
Anxiety assessed using Spielberger’s State Anxiety Inventory.  
**Catheter size**  
6–9 F  
Haemostasis achieved using manual pressure.  
**Blinded outcome assessment**  
Patients and outcome assessors not blinded. |
## Appendix 6 Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baum 1996</td>
<td>RCT</td>
<td>205 patients scheduled for coronary angiography.</td>
<td>Group 1 (n = 101) Bed rest for 2 hours.</td>
<td>Re-bleeding Group 1: 3/101 Group 2: 2/104 p = 0.63</td>
<td>Re-bleeding was defined as bleeding requiring recompression and additional bed rest.</td>
</tr>
<tr>
<td>United States</td>
<td>Not stated.</td>
<td></td>
<td>Group 2 (n = 104) Bed rest for 4 hours.</td>
<td>Haematoma Group 1: 2/101 Group 2: 1/104 p = 0.54</td>
<td>Haematoma formation was defined as a palpable firm collection of subcutaneous blood.</td>
</tr>
</tbody>
</table>

**Inclusion criteria**
1. Patients scheduled for coronary angiography.

**Exclusion criteria**
1. Age > 75 years.
2. Severe aortic stenosis (aortic valve area < 1 cm²).
3. Creatinine > 2.5 mg/dl.
4. Full dose anticoagulation (oral or intravenously).
5. Unstable angina.
6. Obesity > 4 standard deviations.
7. Severe aortic regurgitation.
8. Left ventricular dysfunction (moist rales on examination, gallop or elevated pulmonary capillary wedge pressure (PCWP) > 20 mmHg).

**Baseline characteristics**
No significant differences were observed between the 2 groups for age, weight, height, indications for procedure (progressive angina, abnormal treadmill), history of valvular heart disease, regular use of aspirin, heparin use during procedure, three-vessel disease, left main disease > 50%, coronary artery lesions > 50% stenosis, laboratory values (hemoglobin, creatinine), except that slightly more of the 2-hr group had 'shortness of breath' as an indication for the procedure (p = 0.03).
Method of Allocation

A table of random numbers was used to generate assignment to either the inpatient or the outpatient group. The assignments were placed in sealed opaque envelopes and given out sequentially at each of the three study sites.

381 patients from three hospitals for cardiac catheterization.

Inclusion criteria

Patients selected for this study included those scheduled for routine cardiac catheterization with the clinical diagnosis of coronary artery disease, valvular disease, or congenital heart disease.

Exclusion criteria

1. They were over 70 (women) or 75 years of age (men).
2. Had any of the following conditions: unstable angina pectoris (pain at rest or a crescendo pattern of pain), valvular heart disease with congestive heart failure, bleeding diathesis, renal insufficiency with a blood urea nitrogen level of more than 10.7 mmol per liter (30 mg per deciliter) or a creatinine concentration of more than 176.8 μmol per liter (2.0 mg per deciliter), or uncontrolled systolic hypertension (systolic BP > 180 mmHg).
3. They lived more than 25 miles from the hospital, unless they could stay overnight in nearby lodging.

Baseline characteristics

A significantly greater proportion of inpatients than outpatients had diabetes (8.5 versus 2.6 percent), Class III angina according to the Canadian Cardiovascular Society classification (24.9 versus 15.6 percent; p < 0.025), receiving calcium-channel blockers (57.1 versus 42.7 percent; p < 0.005), and had left main stenosis (11.1 versus 5.2 percent; p < 0.05).

Group 1 (n = 189)

Inpatient cardiac catheterization with bed rest for 6 hours.

Group 2 (n = 192)

Outpatient cardiac catheterization with bed rest for 4 to 5 hours.

Haematoma

Group 1: 16/189
Group 2: 23/192
p = Not significant (NS)

Numbness or weakness of extremity

Group 1: 3/189
Group 2: 1/192
p = NS

Cold or blue extremity

Group 1: 2/189
Group 2: 3/192
p = NS

All patients were examined by a physician at the end of the day on which they had undergone catheterization. If a complication occurred, the admitting physician made and recorded the diagnosis. All diagnoses were substantiated from the patient's record the next day. The day after catheterization, a trained interviewer saw the inpatients and contacted all the outpatients by telephone. Each patient answered a standardized list of questions concerning symptoms.

Catheter size

7–8 F

Methods of achieving haemostasis: Not stated.

Blinded outcome assessment

Patients and outcome assessors not blinded.
### Appendix 6

#### Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bogart</td>
<td>RCT</td>
<td>200 patients underwent diagnostic cardiac catheterization.</td>
<td>Group 1 (n = 100) Bed rest for 4 hours.</td>
<td>Group 1: 1/100 Group 2: 3/100 With or without groin complications ( p = 0.312 )</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Method of Allocation</td>
<td>Not stated.</td>
<td>Group 2 (n = 100) Bed rest for 6 hours.</td>
<td>Haematoma Group 1: 1/100 Group 2: 0/100 ( p = \text{NS} ) Re-bleeding Group 1: 0/100 Group 2: 2/100 ( p = \text{NS} ) Pseudoaneurysm Group 1: 0/100 Group 2: 1/100 ( p = \text{NS} ) Vascular (other) Group 1: 0/100 Group 2: 0/100 ( p = \text{NS} )</td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Inclusion criteria
- Patients underwent diagnostic cardiac catheterization during the study period.

#### Exclusion criteria
1. Geographic remoteness (more than 1 hour drive) from the laboratory with inadequate or unreliable follow-up likely over the next 24 hours.
2. An interventional therapeutic procedure.
3. Transient cerebral ischemic episodes or recent stroke (less than 1 month before).
4. Severe systemic hypertension (systolic BP greater than 200 mmHg and/or diastolic BP greater than 100 mmHg).
5. Severe peripheral vascular disease (femoral pulses 1+ or less).
6. Age less than 21 years or greater than 75 years.
7. Body surface area greater than 2.5 m$^2$.
8. Generalized debility or dementia.
9. Frequent ventricular arrhythmias.
10. Renal insufficiency (serum creatinine more than 2 mg/dL).
11. Recent hospitalization for acute myocardial infarction (within past 7 days).
12. On intravenous heparin or with international normalized ratio (INR) of > 2.
13. Chronic corticosteroid use.
14. Non-compliance with the period of bed rest.
15. Repeat procedure, same entry site within 1 week.
16. Right heart catheterization.
17. More than one arterial puncture to initiate the procedure.
18. Thrombocytopenia (platelet count < 100,000 mm$^3$).

#### Baseline characteristics
The groups were comparable in gender, age, body surface area, percentage of patients receiving aspirin, heparin during catheterization, mean arterial BP at the start of procedure and at sheath removal, and percentage of coronary artery disease. The mean duration of arterial time (sheath dwell time) in minutes was slightly longer in the 6-hr group.

Re-bleeding was defined as bleeding requiring compression at the arterial puncture site after the initial period of haemostasis. Haematoma was defined as a palpable, firm effusion of subcutaneous blood. A small haematoma was 4–5 cm in diameter, a moderate haematoma 6–10 cm, and a large haematoma greater than 10 cm in diameter. To detect a pseudoaneurysm and/or arteriovenous (AV) fistula, the puncture site was evaluated for pain, pulsatile mass, or bruit. If any of these assessments were present the day after the catheterization, a duplex scan of the affected groin was ordered to confirm the presence of a pseudoaneurysm and/or AV fistula.

**Catheter size**
8 F
Haemostasis achieved using manual pressure.

**Blinded outcome assessment**
Both patients and outcome assessors not blinded to the treatment.
RCT Method of Allocation

Patients were randomly assigned to either a control or experimental group according to a computer-generated random table of number.

Inclusion criteria
Patients should be ethnic Chinese, aged over 18 years, had no bleeding disorders, were not receiving anticoagulant therapy within the previous 24 hours before the procedure, had no back pain, BP < 180/110 mmHg before the procedure and no complications developed during cardiac catheterization.

Exclusion criteria
Not stated.

Baseline characteristics
The 2 groups were not significantly different in age, gender, education level, and monthly household income. Occupation status was significantly different between the 2 groups (chi-square, p = 0.009) with more retired subjects in the control group but more housewives in the experimental group.

Incidence of bleeding

<table>
<thead>
<tr>
<th>Group</th>
<th>n = 43</th>
<th>Bed rest for 4 hours.</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>43</td>
<td>0/43</td>
<td>1.00</td>
</tr>
<tr>
<td>Group 2</td>
<td>43</td>
<td>1/43</td>
<td></td>
</tr>
</tbody>
</table>

Urinary discomfort (mean)

<table>
<thead>
<tr>
<th>Group</th>
<th>1.09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>2.57</td>
</tr>
<tr>
<td>p</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Back pain (mean)

<table>
<thead>
<tr>
<th>Group</th>
<th>0.97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>1.55</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
</tr>
</tbody>
</table>

8 hours

<table>
<thead>
<tr>
<th>Group</th>
<th>1.34</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>4.41</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
</tr>
</tbody>
</table>

The next morning

<table>
<thead>
<tr>
<th>Group</th>
<th>1.77</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 2</td>
<td>4.01</td>
</tr>
<tr>
<td>p</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Significant bleeding was defined as blood loss estimated at > 100 ml, haematoma > 5 cm in width or bleeding that led to further attempts to reestablish haemostasis by manual pressure, sandbag, or reinforcement of pressure dressing. Back pain was assessed using a visual analogue scale consisting of a 100-mm long line with the left anchor representing ‘no pain’, and the right anchor representing ‘the worst possible pain’. Urinary discomfort was assessed at 6 hours after the procedure by use of a 5-point Likert scale self-developed measurement consisting of 4 questions, a higher value referring to more urinary discomfort.

Catheter size
Not stated.
Haemostasis achieved using manual pressure.

Blinded outcome assessment
Both patients and outcome assessors not blinded.
### Appendix 6 Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dowling</td>
<td>RCT</td>
<td>110 patients were enrolled in the study over a 12-month period.</td>
<td>Group 1 (n = 63) Bed rest for 3 hours. Group 2 (n = 47) Bed rest for 6 hours.</td>
<td>Haematomas &gt; 2 cm Group 1: 0/63 Group 2: 0/47 p = not stated Haematomas &lt; 2 cm Group 1: 1/63 Group 2: 1/47 p = not stated Puncture-site oozing Group 1: 0/63 Group 2: 1/47 p = not stated Pseudoaneurysm or AV fistula Group 1: 0/63 Group 2: 0/47 p = not stated Level of discomfort immediately after ambulation Not stated. Level of discomfort at 24 hours None Group 1: 25/56 Group 2: 11/38 p = not stated Mild Group 1: 22/56 Group 2: 17/38 p = not stated Moderate Group 1: 8/56 Group 2: 9/38 p &gt; 0.05 Severe Group 1: 1/56 Group 2: 1/38 p &gt; 0.05 Groin pain at 24 hours Group 1: 2/56 Group 2: 3/38 p = not stated Back pain at 24 hours Group 1: 35/56 Group 2: 34/38 p = not stated Of the 38 patients in the 6-hr group responding to the survey, 31 (81%) conveyed that reducing bed rest to 3 hours would have significantly improved their level of satisfaction, while the remainder reported that this would have not at all or only mildly improved their degree of satisfaction.</td>
<td></td>
</tr>
<tr>
<td>United</td>
<td>Allocation</td>
<td>Not stated.</td>
<td>Inclusion criteria</td>
<td>Exclusion criteria</td>
<td>Baseline characteristics</td>
</tr>
<tr>
<td>States</td>
<td></td>
<td></td>
<td>All ambulatory patients with normal coagulation parameters scheduled for transfemoral diagnostic angiography with either 4 F catheters or sheaths were eligible for participation.</td>
<td>Not stated.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Methods of achieving haemostasis: Not stated.</td>
<td>Blinded outcome assessment</td>
<td>Not stated.</td>
</tr>
</tbody>
</table>

Methods of achieving haemostasis: Not stated.

Blinded outcome assessment
Both patients and outcome assessors were not blinded to the treatment.
Keeling 1994 United States

RCT

Method of Allocation
Patients were randomly assigned to either experimental or control group by post-procedure room number.

109 patients admitted to the acute cardiology service for cardiac catheterization.

Inclusion criteria
The sample consisted of adult patients who underwent cardiac catheterization using a femoral artery approach with a size 7 French catheter and size 8 French sheath.

Exclusion criteria
Not stated.

Baseline characteristics
Not stated.

Group 1 (n = 50)
Bed rest for 6 hours.

Group 2 (n = 59)
Bed rest for 12 hours.

Incidence of bleeding (during the postcatheterization period)
Group 1: 2/50
Group 2: 3/59
p = NS

Definitions of outcome variables
Not stated.

Catheter size
7 F

Haemostasis achieved using gauze pressure dressings and sandbags in place over the catheterization insertion site for 6 hours, after which the sandbags were removed.

Blinded outcome assessment
Both patients and outcome assessors were not blinded to the treatment.

Keeling 1996 United States

RCT

Method of Allocation
Not stated.

86 adult patients admitted for coronary angiography.

Inclusion criteria
Patients be adults with suspected or diagnosed coronary artery disease who were not receiving heparin, or other anticoagulant or thrombolytic agents after the procedure.

Exclusion criteria
Patients with known bleeding disorders, those experiencing medical complications during the procedure, or those requiring admission to the coronary care unit were excluded from the study.

Baseline characteristics
There was no significant difference between the experimental and control groups in mean age, length of time they remained in the catheterization laboratory, length of time manual pressure was held over catheterization site, dose of heparin given preprocedure, and dose of protamine sulfate used to reverse heparin effects.

Group 1 (n = 43)
Bed rest for 4 hours.

Group 2 (n = 43)
Bed rest for 6 hours.

Incidence of bleeding/haematoma
Group 1: 1/43
Group 2: 0/43
p = NS

Definitions of outcome variables
Not stated.

Catheter size
Not stated.

Haemostasis achieved by applying manual pressure to the affected groin site for 20 minutes by physicians.

Blinded outcome assessment
Both patients and outcome assessors were not blinded to the treatment.
### Appendix 6 Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lau 1993</td>
<td>RCT</td>
<td>273 consecutive adult patients who underwent routine 7 F transarterial cardiac catheterization via the femoral route with or without venous access between April and November 1989.</td>
<td><strong>Group 1 (n = 142)</strong>&lt;br&gt;Bed rest for 6 hours.</td>
<td><strong>Haematoma (&lt; 6 hours)</strong>&lt;br&gt;Group 1: 6/142&lt;br&gt;Group 2: 7/131&lt;br&gt;&lt;br&gt;<strong>Haematoma (&gt; 6 hours)</strong>&lt;br&gt;Group 1: 3/142&lt;br&gt;Group 2: 3/131&lt;br&gt;&lt;br&gt;Mild allergy&lt;br&gt;Group 1: 2/142&lt;br&gt;Group 2: 1/131&lt;br&gt;&lt;br&gt;Pyrogenic reactions&lt;br&gt;Group 1: 0/142&lt;br&gt;Group 2: 1/131</td>
<td>A groin haematoma was graded as small if it was &lt;7 cm across and large if ≥7 cm in diameter.</td>
</tr>
</tbody>
</table>

**Method of Allocation**
Patients were randomized according to their national identity card numbers. Those with odd-numbered identity cards were allocated to early ambulation. Patients with even-numbered identity cards were assigned to late ambulation.

**Inclusion criteria**
Those with obvious or suspected coronary artery disease, valvular heart disease, congenital heart disease, or dilated cardiomyopathy.

**Exclusion criteria**
Patients were excluded if they had any of the following conditions detected before, during, or within 6 hours after catheterization: severe left main coronary artery disease of ≥ 75% diameter stenosis, aortic stenosis with a valve area of < 0.75 cm², severe aortic regurgitation, unstable coronary syndrome, uncompensated cardiac failure, electrical or hemodynamic instability, malignant arrhythmia, cerebrovascular event, or bleeding diathesis. Patients who underwent emergency cardiac catheterization or concomitant interventional procedures were also not recruited.

**Baseline characteristics**
Except for a difference in the indications for cardiac catheterization (p = 0.03), both groups were similar in their baseline characteristics for gender, age, weight, race, BP pre-catheterization, and BP 6 hours after catheterization.
200 consecutive patients after elective coronary arteriography at a tertiary referral center.

**Inclusion criteria**
Patients after elective coronary arteriography for the investigation of chest pain.

**Exclusion criteria**
Patients with peripheral vascular grafts were excluded.

**Baseline characteristics**
Not stated.

**Group 1 (n = 100)**
Bed rest for 4 hours.

**Group 2 (n = 100)**
Bed rest for 6 hours.

**Incidence of obvious bruising**

<table>
<thead>
<tr>
<th>Group</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>49/100</td>
</tr>
<tr>
<td>Group 2</td>
<td>49/100</td>
</tr>
</tbody>
</table>

*p = NS

**Haematoma observed**

<table>
<thead>
<tr>
<th>Group</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>47 (4 big)/100</td>
</tr>
<tr>
<td>Group 2</td>
<td>44 (2 big)/100</td>
</tr>
</tbody>
</table>

*p = NS

**Pseudoaneurysm**

<table>
<thead>
<tr>
<th>Group</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>0/100</td>
</tr>
<tr>
<td>Group 2</td>
<td>1/100</td>
</tr>
</tbody>
</table>

*p = not stated

**Blood transfusion requirement**

<table>
<thead>
<tr>
<th>Group</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>0/100</td>
</tr>
<tr>
<td>Group 2</td>
<td>0/100</td>
</tr>
</tbody>
</table>

*p = not stated

**Late complications (up to 6 weeks)**

<table>
<thead>
<tr>
<th>Group</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>0/100</td>
</tr>
<tr>
<td>Group 2</td>
<td>0/100</td>
</tr>
</tbody>
</table>

*p = not stated

Bruising was classified as 'none' or 'obvious'. Haematoma was graded 'small' if there was a firm fullness that was just palpable, and 'big' if there was an obvious swelling that was both palpable and visible. If the swelling was pulsatile or very large, a Doppler ultrasound scan would be performed to exclude a femoral pseudoaneurysm. The need for blood transfusion, development of pseudoaneurysm, and ultrasound or surgical intervention were hard endpoints.

**Catheter size**

6 F

Haemostasis achieved by applying a pneumatic compression haemostatic device directly over the femoral artery puncture site for 30 minutes. Inflation pressure was at a level sufficient to achieve haemostasis without compromising the foot pulses.

**Blinded outcome assessment**
Cardiac catheterization was performed by experienced fellows and staff blinded to the pre-procedure block randomization sequence adopted by the ward nursing staff. Patients were examined by cardiology residents blinded to their randomized allocation.
### Study Methods Participants Interventions Outcomes Notes

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logemann 1999</td>
<td>RCT</td>
<td>201 patients who underwent uncomplicated diagnostic left heart catheterization from the femoral artery.</td>
<td><strong>Group 1 (n = 105)</strong> Bed rest for 2 hours.</td>
<td><strong>Bleeding and haematoma</strong> Group 1: 5/105 Group 2: 6/96 p = 0.65 <strong>Acute haematomas (&lt;5 cm)</strong> Group 1: 3/105 Group 2: 4/96 p = 0.60 <strong>Acute haematomas (≥5 cm)</strong> Group 1: 1/105 Group 2: 0/96 p = 0.35</td>
<td>bleeding was defined as the appearance of any blood or haematoma. Haematomas were defined as a visible and/or palpable bulge containing subcutaneous blood at the puncture site, which was not present before the groin lines were removed. Haematomas were also classified as large if they exceeded 5 cm in any dimension. A haematoma was classified as acute if it occurred while the patient was still at the hospital, or delayed if it occurred after discharge. The incidence of delayed haematomas and pseudoaneurysms formation was determined by a follow-up phone call approximately 1 week after the procedure or the occurrence of a return to the hospital for a bleeding complication. A satisfaction survey was used to assess subjective information including comfort, comparison with previous procedures, and overall satisfaction with the process. <strong>Blinded outcome assessment</strong> Both patients and outcome assessors were not blinded to the treatment.</td>
</tr>
<tr>
<td>United States</td>
<td>Not stated.</td>
<td>Not stated.</td>
<td><strong>Group 2 (n = 96)</strong> Bed rest for 6 hours.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Inclusion criteria**
Patients were eligible to participate if they were suitable for outpatient diagnostic catheterization according to the criteria outlined by the task force of the American College of Cardiology and the American Heart Association.

**Exclusion criteria**
Use of oral anticoagulants (except aspirin), age > 80 years, morbid obesity (>50% above ideal body weight), history of bleeding disorder, coronary disease detected at catheterization prompting admission for treatment (coronary angioplasty or surgery), creatinine > 2.0 mg/dl, severe aortic valvular disease, or severe hypertension (systolic BP > 180 mmHg or diastolic BP > 105 mmHg).

**Baseline characteristics**
There was no significant difference between the 2 groups with respect to age, gender, obesity, and diseases (hypertension, peripheral vascular disease, coronary artery disease, congestive heart failure), prior catheterization, and any tobacco history.

- **Catheter size**: 6F
- **Haemostasis achieved by immediate pressure applied to the femoral artery manually and a compression device was placed over the puncture site for 30 minutes.**

**Compliance**

<table>
<thead>
<tr>
<th><strong>Group 1</strong></th>
<th><strong>Group 2</strong></th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/774</td>
<td>5/566</td>
<td>0.20</td>
</tr>
</tbody>
</table>
Pollard 2003 United Kingdom RCT Method of Allocation Not stated.

705 patients who had undergone elective 6 French cardiac catheterization via the femoral artery.

**Inclusion criteria**
The presence of stable angina; a planned, elective diagnostic catheterization; successful 'single wall' puncture of the femoral artery; the use of a 6 F catheter; and written, informed consent.

**Exclusion criteria**
Age < 18 years, inability to give informed consent, childbearing potential not fulfilling the requirements of the 10 day rule, participation in another study, coronary angioplasty performed at the same sitting, heparin treatment, warfarin with an INR > 2.0, a bleeding disorder, previous surgery to the iliac or femoral arteries, and right heart catheter performed at the same sitting.

**Baseline characteristics**
Baseline demographic and basic medical data were comparable for the 2 groups. Details of the arterial puncture and compression after the procedure were also similar.

**Group 1 (n = 362)**
Bed rest for 4.5 hours.

**Group 2 (n = 343)**
Bed rest for 2.5 hours.

**Deaths**
- Group 1: 0/362
- Group 2: 0/343
  \[ p = 0.99 \]

**Haematoma**
- Group 1: 34/362
- Group 2: 44/343
  \[ p = 0.146 \]

**Bleeding**
- Group 1: 21/362
- Group 2: 25/343
  \[ p = 0.424 \]

**Vasovagal**
- Group 1: 7/362
- Group 2: 9/343
  \[ p = 0.539 \]

**False aneurysm**
- Group 1: 1/362
- Group 2: 1/343
  \[ p = 0.970 \]

**Total number of patients with complications**
- Group 1: 54/362
- Group 2: 66/343
  \[ p = 0.127 \]

There were significantly fewer reports of pain or discomfort at all times (pre-and 30 minutes, 2, 4, and 48 hours post-procedure) before hospital discharge in group 2 than in group 1. There was no difference in the time to discharge between both groups.

Bleeding and haematoma were defined by the need for renewed compression, and false aneurysm was defined by the ultrasound appearance. Levels of discomfort were assessed using the McGill pain questionnaire.

**Catheter size**
6 F Haemostasis achieved by manual arterial compression.

**Blinded outcome assessment**
Manual arterial compression was performed by a nurse or a doctor unaware of the randomization.
<table>
<thead>
<tr>
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<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pooler-Lunse</td>
<td>RCT</td>
<td>29 patients</td>
<td>Group 1 (n = 14)</td>
<td>Delayed bleeding</td>
<td>Significant bleeding was defined as blood loss estimated at less than 100 ml—the measured amount of volume necessary to penetrate the pressure dressing. The Present Pain Index from the McGill Pain Questionnaire was used to reevaluate back pain.</td>
</tr>
<tr>
<td>1996</td>
<td></td>
<td>admitted for non-emergent cardiac angiography.</td>
<td>Bed rest for 4 hours.</td>
<td>Group 1: 1/14</td>
<td>p = not stated</td>
</tr>
<tr>
<td>Canada</td>
<td></td>
<td></td>
<td>Group 2 (n = 15)</td>
<td>Presence of back pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bed rest for 6 hours.</td>
<td>Group 2: 1/15</td>
<td>p = 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Presence of back pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 1: 4/14</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 2: 9/15</td>
<td>p = 0.05</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>5 hours</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 1: 5/14</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 2: 8/15</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7 hours</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 1: 3/14</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Group 2: 10/15</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Next day</td>
<td></td>
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<td></td>
<td>Group 1: 1/14</td>
<td>p &lt; 0.05</td>
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<td>Group 2: 4/15</td>
<td>p = 0.05</td>
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<td></td>
<td></td>
<td>Overall back pain intensity</td>
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<td></td>
<td>(self-calculated)</td>
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<td></td>
<td>No pain (0)</td>
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<td>Group 1: 5/14</td>
<td>p = 0.02</td>
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<td>Group 2: 4/15</td>
<td>p = 0.02</td>
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<td>Mild pain (1)</td>
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<td>Group 1: 6/14</td>
<td>p = 0.02</td>
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<td>Group 2: 5/15</td>
<td>p = 0.02</td>
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<td>Discomforting (2)</td>
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<td>Group 1: 3/14</td>
<td>p = 0.02</td>
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<td>Group 2: 3/15</td>
<td>p = 0.02</td>
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<td>Distressing (3)</td>
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<td>Group 1: 0/14</td>
<td>p = 0.02</td>
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<td>Group 2: 2/15</td>
<td>p = 0.02</td>
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<td></td>
<td>Horrible pain (5)</td>
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<td>Group 1: 0/14</td>
<td>p = 0.02</td>
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<td></td>
<td>Group 2: 1/15</td>
<td>p = 0.02</td>
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<td>Overall back pain intensity using</td>
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<td>PPI (self-calculated)</td>
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<td>Group 1: 0.857 ± 0.770 (14)</td>
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<td>Group 2: 1.467 ± 1.407 (15)</td>
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</tbody>
</table>

Exclusion criteria
- Known liver disease or bleeding disorders;
- Systolic BP greater than 180 mmHg or diastolic pressure greater than 110 mmHg;
- Known severe aortic insufficiency; patients who required emergency angiography; and patients who were nonambulatory or comatose.

Baseline characteristics
- There were no significant differences in prerandomization characteristics of age, history of a previous angiogram, chronic back discomfort, catheter size, use of acetylsalicylic acid, or partial thromboplastin time (PTT) values before angiography.
305 consecutive patients admitted over a 6 month period for elective 6 French left-heart coronary angiography.

**Inclusion criteria**
Consecutive patients admitted over a 6 month period for elective 6 F left-heart coronary angiography were allocated to receive standard care (4-hour bed rest) or 2-hour bed rest.

**Exclusion criteria**
Not stated.

**Baseline characteristics**
There were no imbalances between the ‘four hour’ group and the ‘two hour’ group in terms of age, sex, and length of procedure. However, there were small imbalances in BMI, hypertension, previous catheterization and compression time.

**Group 1 (n = 188)**
Bed rest for 2 hours.

**Group 2 (n = 117)**
Bed rest for 4 hours.

**Haematoma**
At 3 hours
Group 1: 5/188
Group 2: 8/117
p = not stated
At 4 hours
Group 1: 3/188
Group 2: 5/117
p = 0.12
At 24 hours
Group 1: 1/188
Group 2: 0/117
p = not stated
At 1 month
Group 1: 1/188
Group 2: 0/117
p = not stated

**Bruising**
At 3 hours
Group 1: 24/188
Group 2: 12/117
p = not stated
At 4 hours
Group 1: 30/188
Group 2: 15/117
p = 0.57
At 24 hours
Group 1: 58/188
Group 2: 43/117
p = not stated
At 1 month
Group 1: 17/188
Group 2: 21/117
p = not stated

**Pseudoaneurysm**
Group 1: 0/118
Group 2: 0/117
p = not stated

**Method of Allocation**
The allocation was alternated on a weekly basis.

**Catheter size**
6 F

Haemostasis achieved by using a pneumatic compression device to the femoral artery puncture site and all patients were placed on flat bed rest.

**Blinded outcome assessment**
The 4 consultants performing the procedures were blinded to patient allocation. However, due to the allocation method used, complete blinding was not possible.
<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singh 1998 Canada</td>
<td>RCT</td>
<td>Method of Allocation Not stated, but patients who gave informed consent were randomly assigned by a ratio of 2:2:1 to post-procedure mobilization groups of 3, 4 or 6 hours respectively.</td>
<td>Group 1 (n = 336) Bed rest for 3 hours. Group 2 (n = 353) Bed rest for 4 hours. Group 3 (n = 185) Bed rest for 6 hours.</td>
<td>Haematomas before discharge Group 1: 12/336 Group 2: 17/353 Group 3: 6/185 <em>p = NS</em> &gt;5 cm Group 1: 5/336 Group 2: 7/353 Group 3: 2/185 <em>p = NS</em> 5–10 cm Group 1: 5/336 Group 2: 6/353 Group 3: 2/185 <em>p = NS</em> &gt;10 cm Group 1: 2/336 Group 2: 4/353 Group 3: 2/185 <em>p = NS</em> Late haematoma Group 1: 9/336 Group 2: 5/353 Group 3: 6/185 <em>p = NS</em> Vascular complications Local thrombosis Group 1: 0/336 Group 2: 1/353 Group 3: 0/185 <em>p = not stated</em> Pseudoaneurysm Group 1: 0/336 Group 2: 0/353 Group 3: 1/185 <em>p = not stated</em></td>
<td>Haematomas were identified by the presence of an induration edge at the puncture site, with the widest diameter being recorded. Complications were defined as any new haematoma formation, an increase in haematoma size, blood transfusion requirement, need for vascular repair, thromboembolism, local infection, or pseudoaneurysm formation. A visit to the emergency department or physician's office for concerns related to the puncture site was also noted as a complication. Catheter size 7 F Haemostasis achieved by manual compression or with the aid of a vascular clamp at the discretion of the catheterizing physician. Blinded outcome assessment Both patients and outcome assessors were not blinded to the treatment.</td>
</tr>
</tbody>
</table>
82 patients in an outpatient unit at a north-eastern United States academic medical center.

**Inclusion criteria**
The sample included patients who were admitted for left-heart catheterization, able to speak English, willing to participate in the study as evidenced by a signed written consent, and had serum potassium level less than 5.5 mEq/L, serum PT level less than 15 seconds, and blood hemoglobin level greater than 8.5 gm/dl at preadmission testing.

**Exclusion criteria**
Unstable angina during or after the procedure, severe peripheral vascular disease, haematoma immediately after catheterization in the catheterization laboratory, the need for heparin bolus during or after the procedure, requirement for right- and left-heart catheterization, pressure dressing to site postprocedure, or overnight stay.

**Baseline characteristics**
Groups were comparable on age, gender, weight, systolic and diastolic BP, fasting blood sugar, PT, aspirin dosage, and total amount of contrast media used.

**Group 1 (n = 41)**
Bed rest for 4 hours.

**Group 2 (n = 41)**
Bed rest for 6 hours.

**Bleeding, haematoma, or loss of distal pulses**
- **Group 1:** 0/41
- **Group 2:** 0/41

**Back pain (Mean ± SD)**
- **Group 1:** 3.29 ± 3.27
- **Group 2:** 2.85 ± 2.95

**Pain at puncture site**
- **Group 1:** 1.39 ± 1.64
- **Group 2:** 1.05 ± 1.32

**Numbness in affected leg**
- **Group 1:** 1.07 ± 1.99
- **Group 2:** 1.02 ± 2.10

**Tingling in affected leg**
- **Group 1:** 0.51 ± 0.98
- **Group 2:** 0.66 ± 1.54

**Comfort with bed rest**
- **Group 1:** 5.88 ± 2.72
- **Group 2:** 5.27 ± 3.00

**Satisfaction with time on bed rest**
- **Group 1:** 6.68 ± 3.06
- **Group 2:** 6.68 ± 2.80

**Satisfaction with care on outpatient unit**
- **Group 1:** 9.85 ± 0.53
- **Group 2:** 9.73 ± 0.90

**Nursing hours saved by using 4-hour bed rest versus 6-hour bed rest**
- In 1997: 2,488 hours
- In 1998: 2,696 hours

The presence of bleeding was defined as oozing blood requiring use of manual pressure to stop the oozing. The presence of haematoma was defined as an area greater than 1 centimeter in width and length as assessed by manual palpation. Numeric rating scales (NRS) of 0 to 10 were used, with 0 indicating no discomfort and 10 indicating severe discomfort for puncture-site pain, back pain, numbness sensation, and tingling sensation. Patient satisfaction was rated on a 0 to 10 scale with 0 equal to least possible satisfaction and 10 equal to most possible satisfaction. NRS were used to reflect the intensity of the comfort level and satisfaction level because of the simplicity, validity, and reliability of NRS measures of subjective data.

**Catheter size**
5 or 6 F
Haemostasis achieved by a 12-pound sandbag and an adhesive bandage.

**Blinded outcome assessment**
Participants were not informed of the length of bed rest until the conclusion of the procedure. The attending physicians were informed about participants’ group assignments prior to the catheterization procedure.
### Appendix 6 Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Methods</th>
<th>Participants</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
</table>
| **Wong** 1988 | RCT | 118 ambulatory inpatients after angiography. | **Group 1 (n = 54)**<br>Bed rest for 4 hours. | **Haematoma (range: 1-5 cm)**<br>Group 1: 16/54<br>Group 2: 18/64<br>
p = 0.05 | The pulses in the lower limb were checked and the size of any haematoma at the arteriotomy site estimated. |
| Singapore | **Method of Allocation**<br>Not stated. | **Inclusion criteria**<br>Ambulatory inpatients after angiography over 6 months. | **Exclusion criteria**<br>1. Those who were severely hypertensive i.e. with a systolic pressure of more than 180 mmHg or a diastolic pressure of more than 110 mmHg on the morning of the procedure.<br>2. All non-ambulant or comatose patients.<br>3. Patients who have a history of bleeding diathesis or who were on anticoagulant therapy.<br>4. Patients who required a post-procedural compression time of more than 10 minutes. | **Haematoma developed following ambulation**<br>Group 1: 7/16<br>Group 2: not stated<br>
p = not stated | **Catheter size**<br>5–7.5 F<br>Haemostasis achieved by compression to 10 minutes. |
| **Wood** 1997 | RCT | 291 consecutive adults presenting for outpatient diagnostic left heart catheterization. | **Group 1 (n = 124)**<br>Bed rest for 2.5 hours. | **Bleeding after ambulation**<br>Group 1: 4/124<br>Group 2: 8/167<br>
p = not stated | Bleeding was documented if a dressing change was required. A small haematoma was defined as being <5 cm in diameter. |
| United States | **Method of Allocation**<br>Patients were randomly assigned to ambulate at 2.5 hours or 4 hours following pressure release of the femoral artery by the roll of a die performed after completion of the catheterization. Those with numbers 1, 2, or 3 ambulated at 2.5 hours; those with numbers 4, 5, or 6 ambulated at 4 hours. | **Inclusion criteria**<br>Consecutive adults presenting for outpatient diagnostic left heart catheterization. | **Exclusion criteria**<br>Not stated. | **Haematoma developed**<br>**Early**<br>Group 1: 2/124<br>Group 2: 4/167<br>
p = not stated<br>**Late (after 48 hours)**<br>Group 1: 1/124<br>Group 2: 1/167<br>
p = not stated | **Catheter size**<br>6 F<br>Haemostasis achieved by manual hold or C-clamp occurred for a minimum of 12 minutes. |
|            |          | **Baseline characteristics**<br>The baseline characteristics of the 2 groups were similar in gender, age, weight, height, mean arterial pressure, hematocrit, platelet count, PT, PTT, aspirin, warfarin, reason for heart catheterization (chest pain, abnormal stress test, stable angina, valvular heart disease, and cardiomyopathy), and case load (diagnostic, valve, and bypass grafts). | **Major vascular complications**<br>Group 1: 1/124<br>Group 2: 1/167<br>
p = not stated | **Back pain or leg stiffness**<br>Group 1: 17/124<br>Group 2: 70/167<br>
p < 0.001 | **Blinded outcome assessment**<br>Both patients and outcome assessors were not blinded to the treatment. |
|            |          | **Baseline characteristics**<br>Not stated. | **Resume activities without discomfort in one day**<br>Group 1: 92/124<br>Group 2: 70/167<br>
p < 0.001 |  |  |
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