Bed rest duration and complications after transfemoral cardiac catheterization: a network meta-analysis

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Aims

To assess the effects of bed rest duration on short-term complications following transfemoral catheterization.

Methods and results

A systematic search was carried out in MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, Scopus, SciELO and in five registries of grey literature. Randomized controlled trials and quasi-experimental studies comparing different durations of bed rest after transfemoral catheterization were included. Primary outcomes were haematoma and bleeding near the access site. Secondary outcomes were arteriovenous fistula, pseudoaneurysm, back pain, general patient discomfort and urinary discomfort. Study findings were summarized using a network meta-analysis (NMA). Twenty-eight studies and 9217 participants were included (mean age 60.4 years). In NMA, bed rest duration was not consistently associated with either primary outcome, and this was confirmed in sensitivity analyses. There was no evidence of associations with secondary outcomes, except for two effects related to back pain. A bed rest duration of 2–2.9 h was associated with lower risk of back pain [risk ratio (RR) 0.33, 95% confidence interval (Cl) 0.17–0.62] and a duration over 12 h with greater risk of back pain (RR 1.94, 95% Cl 1.16–3.24), when compared with the 4–5.9 h interval. *Post hoc* analysis revealed an increased risk of back pain per hour of bed rest (RR 1.08, 95% Cl 1.04–1.11).

Conclusion

A short bed rest was not associated with complications in patients undergoing transfemoral catheterization; the greater the duration of bed rest, the more likely the patients were to experience back pain. Ambulation as early as 2 h after transfemoral catheterization can be safely implemented.

Registration

PROSPERO: CRD42014014222.

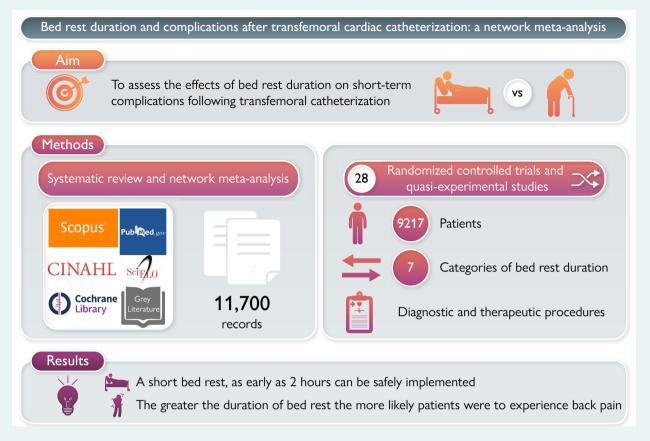
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Graphical Abstract



Keywords

Percutaneous coronary intervention • Cardiac catheterization • Femoral access • Network meta-analysis • Systematic review

Novelty

- Early ambulation does not increase the risk of vascular complications.
- Patients experience more back pain with prolonged bed rest.
- Ambulation as early as 2 h can be safely implemented.
- Reducing bed rest duration may optimize patients' management.

Introduction

Coronary catheterizations are some of the most frequently performed cardiac procedures. Traditional access has been through the femoral artery, which is still performed in more than 500 000 patients each year in Europe and over 400 000 in the USA. Although recent trends show an increased utilization of the transradial approach, transfemoral access is still common and will likely be used in the future whenever radial access is not applicable. Infortunately, transfemoral catheterization can lead to several complications, especially at the access site.

In the past years, vascular closure devices (VCDs) and bed rest were recommended to reduce vascular complications. While the effectiveness of VCDs is supported by stronger body of evidence, there is more uncertainty regarding the optimal duration of bed rest. Clinical guidelines and

consensus documents mention the benefits of early mobilization and the risks of prolonged bed rest, but the recommended duration of bed rest after the interventional procedure is either not specified or inconsistent. 8,10–12 Prolonged bed rest may be associated with more discomfort, back pain and voiding problems, 13–15 and three reviews suggest that bed rest duration after transfemoral catheterization could be reduced without increasing the rate of vascular complications. 16–18 However, previous reviews could only rely on results from comparisons with two treatments at a time and were unable to include more recent studies.

Methods

We performed a comprehensive network meta-analysis (NMA) review to consider all possible comparisons of bed rest durations on post-intervention

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complications and provide clinicians with more precise information on the optimal duration of bed rest after transfemoral catheterization. We reported the results consistent with the PRISMA extensions statement for NMA. 19 We registered the study in the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42014014222) and published the review's protocol. 20

Ethical approval was not required for this study, and patient involvement was not planned since this was a systematic review based on published primary studies.

Search strategy

We searched six biomedical databases (MEDLINE, Embase, CINAHL, Cochrane Database of Systematic Reviews, Scopus, and SciELO) until 15 May 2022, without language restrictions. The search terms were a combination of thesaurus-based and free-text terms, and we report them in the Supplementary material online (1. Expanded methods). We explored five sources of grey literature (UpToDate, NHS evidence, Clinicaltrials.gov, WHO International Clinical Trials Registry platform and the ISRCTN registry) and manually extracted studies from the references of previous reviews.

Study selection and quality assessment

We considered randomized controlled trials (RCTs) and guasi-experimental studies: (i) comparing early with delayed mobilization, (ii) recruiting patients of all ages who underwent diagnostic or therapeutic transfemoral cardiac catheterization and (iii) assessing the effects of bed rest durations in which potential confounders (e.g. postural strategies, catheter size and arterial closure devices) were substantially constant across all study groups. We excluded studies assessing other interventions in addition to bed rest duration. We assessed the methodological quality of the included studies using the Cochrane Effective Practice and Organization of Care (EPOC) Risk of the Bias tool.²¹ We used the GRADE approach to assess the certainty of the evidence for each primary outcome of interest in each paired comparison for which there is direct evidence. The GRADE system classifies evidence as 'high', 'moderate', 'low' or 'very low' certainty. The quality rating start for randomized trial is 'high' and may be rated down for limitations concerning risk of bias, inconsistency, indirectness and publication bias. We also used the GRADE approach to assess the certainty in indirect and network (mixed) effect estimates. 22,23

Data extraction

We extracted information on study characteristics (design, number of patients in each arm, participant age, purpose of procedure, description of intervention, catheter or sheath size, procedure to promote haemostasis) and outcomes. We contacted study authors to complete information not available in the original publication. Categories of bed rest duration are reported in the Supplementary material online (1. Expanded methods). New-onset bleeding and haematoma at the puncture site were our primary outcomes. We extracted information regarding the following secondary outcomes: arteriovenous fistula, pseudoaneurysm, severity of back pain, general patient discomfort and urinary discomfort. Full outcome definitions are included in the Supplementary material online (1. Expanded methods).

Data synthesis

To maximize utilization of all available data and enable estimation of bed rest duration effects relative to a common control group, we used a random-effects NMA approach. After generating network plots to represent the number of trials and participants for each comparison, we checked key assumptions such as heterogeneity, transitivity and consistency, including exploration of subgroup effects by potential effect modifiers (Supplementary material online, 1. Expanded methods and 2. Expanded results). Although we did not find statistical evidence of between-study heterogeneity, we noted considerable variation in terms of design, patient features and procedures. As such, we conservatively decided to perform random-effects analyses across all outcomes. To further improve power, we also performed post hoc analyses of bed rest duration as a continuous variable. Finally, we conducted sensitivity analyses by including only RCTs and only high-quality

RCTs, defined as trials that were not at high risk of bias in any EPOC Risk of Bias domain.

We also performed pairwise meta-analysis using all available comparisons. Consistent with the main NMA analysis, we used random-effects models and expressed potential evidence of heterogeneity with the l^2 statistic. To assess the potential presence of publication bias, we generated funnel plots (i.e. scatter plots of study effects and their inverted standard errors). We present risk ratios (RRs) and standardized mean differences (SMDs) with their corresponding 95% confidence intervals (Cls) and two-sided P-values. We performed frequentist NMA using Stata 13 with the mymeta package, 24 and pairwise meta-analysis using R v. 3.6.2 25 with the metafor package v. 2.4. 26

Results

Study description

Search results and study selection

We identified 11 700 records from 5 databases and 109 additional papers through sources of grey literature and manuscript references (Figure 1). Based on the assessment of full texts, we found 28 studies that met eligibility criteria and were included in the final review. There was high agreement between the review authors on study selection (Cohen's Kappa = 0.88).

Included studies

The characteristics of included studies are presented in Supplementary material online, *Table S1*.

Thirteen studies were published before the 2000s^{27–39} and 15 were published afterwards. ^{13–15,40–51} Twenty-eight studies with 9217 participants compared either bed rest vs. early mobilization or a longer vs. shorter duration of bed rest. All included studies involved an experimental arm where a shorter duration of bed rest was implemented and compared with a longer duration after transfemoral catheterization. The duration of bed rest after catheterization ranged from immediate mobilization directly off the angiographic table to 12 h or longer. ^{14,27–29,35,46} Twenty-four studies had two comparison groups, three studies had three groups ^{37,41,43} and one study had four groups. ⁵⁰

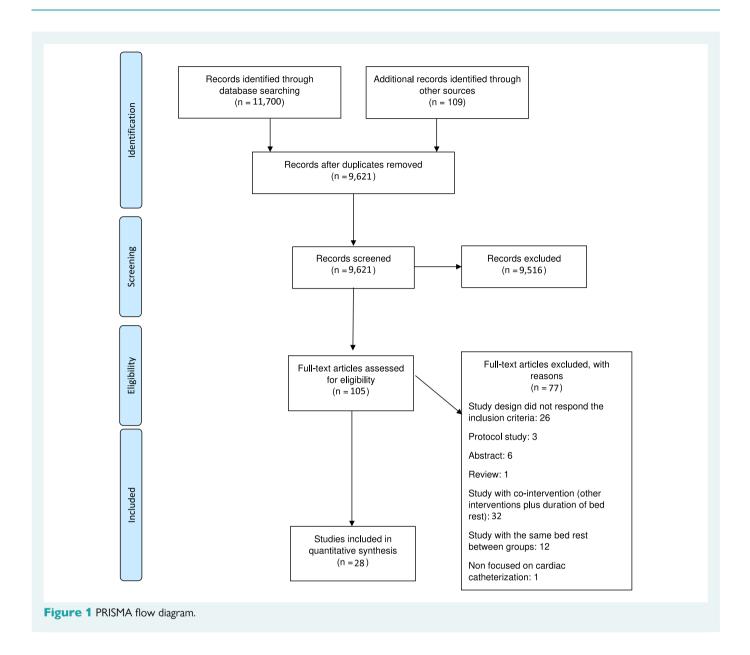
The overall weighted mean age of participants was 60.4 years. Nineteen studies involved patients undergoing diagnostic cardiac catheterization, \$^{14,15,27-30,32-34,36-40,42,44,45,47,49}\$ seven studies comprised patients undergoing therapeutic procedures \$^{31,35,41,43,46,48,50}\$ and one study both procedures. Only one study did not report details about the procedure. Catheter and sheath sizes ranged between five and nine French, and 40% of studies used a mean size of six French. Haemostasis was achieved with direct compression manually for 10–20 min in 12 studies, \$^{13,27,28,30-32,35,38,44,46-48}\$ with mechanical compression devices in 5 studies \$^{36,40,41,43,49}\$ or either. Catheter in five studies. On the compression devices in 5 studies and sandbag in three studies, \$^{41,44,47}\$ pressure dressing in seven studies.

Risk of bias in included studies

We present the summary findings of our quality appraisal in Figure 2 and study specific results in Supplementary material online, Table S2. In general, study quality was good in relation to attrition bias and selective reporting, and poor for the other source of bias considered. Further information is available in Supplementary material online, 2. Expanded results.

Intervention effects

The networks of eligible comparisons for each outcome are available in *Figure 3*. All comparisons between bed rest durations had at least one



trial including a group with bed rest duration falling within the reference category 4-5.9~h.

Primary outcomes

Twenty-two studies focused on the incidence of bleeding, reporting on 7329 participants and 63 cases. Network meta-analysis (Figure 4B) showed no evidence of association between bed rest duration and bleeding. These findings were confirmed in sensitivity analyses (Supplementary material online, Figures S1B and S2B) and pairwise meta-analyses (Supplementary material online, Figure S3). A post hoc NMA model assuming a linear relationship confirmed lack of association with this outcome (Supplementary material online, Table S3).

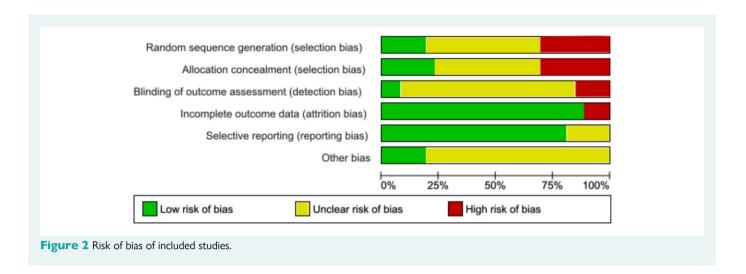
Twenty-six studies assessed the effect of bed rest duration on the risk of haematoma formation, comprising 9022 participants and 438 cases. There are some suggestions of lower risk of haematoma at shorter durations and higher risk at longer durations, but the finding of one statistically significant result (P = 0.045) out of six tests performed does not suggest evidence of an association, especially since a longer duration

showed a lower risk (*Figure 4A*). No substantial differences from this figure were observed when removing two quasi-experimental studies (Supplementary material online, *Figure S1A*), when restricting analyses to 12 high-quality RCTs (Supplementary material online, *Figure S2A*) and in pairwise meta-analyses (Supplementary material online, *Figure S4*). A *post hoc* continuous-duration NMA model confirms this and shows no association with haematoma risk [RR 1.00, 95% CI 0.97–1.03] (Supplementary material online, *Table S3*).

We found low heterogeneity for both primary outcomes (Figure 4A and B). Because we noted some differences in the distribution of potential effect modifiers across studies comparing different bed rest durations (Supplementary material online, Table S4), we performed subgroup analyses which revealed no evidence of variation of bed rest duration effects on vascular complications by any of the potential effect modifiers (Supplementary material online, Table S5).

Finally, funnel plots were generally symmetrical for both primary outcomes, suggesting that publication bias was unlikely (Supplementary material online, Figure S5).

According to the GRADE framework, the certainty of the evidence for the primary outcome is affected by the risk of bias in the included 458 E. Busca et al.



studies and the imprecision of network estimates, which included Cls that include both clinical benefits and possible harms related to bed rest duration.

Secondary outcomes

Seven studies reported binary back pain in 1832 participants with 247 cases. In NMA, a bed rest duration of 2–2.9 h was associated with lower risk of back pain (RR 0.33, 95% CI 0.17–0.62) and a bed rest of over 12 h with greater risk of back pain (RR 1.94, 95% CI 1.16–3.24), compared with 4–5.9 h (*Figure 4E*). The *post hoc* analysis (Supplementary material online, *Table S3*) supports the hypothesis of an association across durations (RR per 1 h increase in bed rest duration 1.08, 95% CI 1.04–1.11). Pairwise meta-analysis reveals that both studies assessing the >12 vs. 4–5.9 h comparison 14,46 have point estimates in the direction of increased risk of back pain, with a pooled effect that is consistent with that generated by NMA and with no evidence of heterogeneity (P = 0.21) (Supplementary material online, *Figure S6*). Pain intensity measured in two studies 42,51 did not differ according to the duration of bed rest (Supplementary material online, *Figure S7*).

General patient discomfort was assessed on a continuous scale by 2 studies in 219 patients. Network meta-analysis (*Figure 4F*) is limited by the paucity of studies and results are very similar to findings of pairwise meta-analysis (Supplementary material online, *Figure S8*). There was evidence of greater discomfort among patients allocated to 6–7.9 h bed rest duration compared with 4–5.9 h (SMD 1.06, 95% CI 0.60–1.52, based on one study) but no evidence of association when comparing a bed rest duration >12 vs. 4–5.9 h.

Meta-analysis of 2 studies comprising 668 patients and 90 events found no association between rest duration and urinary discomfort (Supplementary material online, Figure S9) when comparing a rest duration >12 vs. 4–5.9 h.

Seven studies assessed arteriovenous fistula risk in 2371 participants with 5 cases. There was no evidence of an effect of bed rest duration on such outcome in any analysis (NMA, *Figure 4D*; *post hoc* linear NMA, Supplementary material online, *Table S2*; pairwise meta-analysis, Supplementary material online, *Figure S10*).

Pseudoaneurysm was assessed in 15 studies comprising 7337 participants and 14 cases. Network meta-analysis showed no evidence of association between any bed rest duration and pseudoaneurysm (Figure 4C). This finding was confirmed in a post hoc analysis assuming a linear relationship between bed rest duration and this outcome

(Supplementary material online, *Table S3*), as well as in pairwise meta-analyses (Supplementary material online, *Figure S11*).

Funnel plots were generally symmetrical for all secondary outcomes (Supplementary material online, Figure \$12), suggesting little evidence for publication bias. We could not assess if the effects varied by potential effect modifiers for secondary outcomes due to the scarceness of available data.

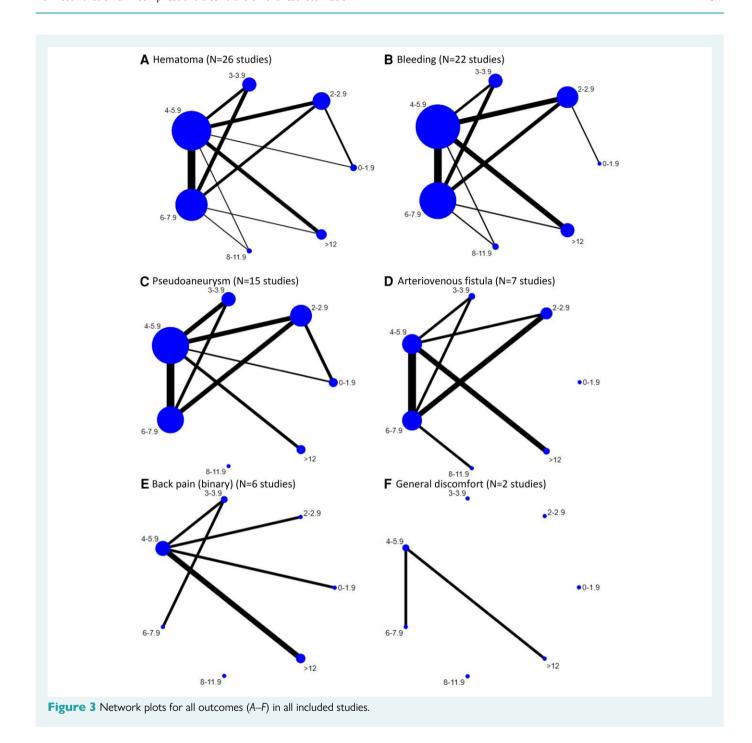
Discussion

In our review, the duration of bed rest after coronary catheterization was generally not associated with short-term complications. We also found that short bed rest (2–2.9 h) was associated with lower risk of back pain and long bed rest (>12 h) was associated with higher risk. Back pain is quite common after cardiac catheterization. Lying on supine position for prolonged periods causes cellular ischaemia and pain in the lumbar and the back due to the application of pressure resulting from the position itself. The literature also highlights how changes in patients' back pain are associated with position change and long bed rest. 52,53

The estimates of intervention effect from our study are in line with previous reviews that did not find evidence of difference in the incidence of vascular complications among patients in the categories compared. $^{16-18}$ In addition to achieving greater precision due to the availability of new studies and the application of NMA, we extend previous published results by adding a new interval of bed rest, 0–1.9 h, which is not associated with risk of haematoma or bleeding.

Importantly, our results show low between-study heterogeneity, which is positively surprising considering the high number of studies included and the varying definitions of haematoma and bleeding formation at the puncture site, as well as the varying catheter sizes and haemostasis techniques. Low heterogeneity is however consistent with the findings of previous reviews that found no significant difference in the incidence of vascular complications due to different catheter sizes and the haemostasis technique. 9,17

Although we were unable to gather information on the allocation method for some randomized studies and a few additional studies were not randomized, our sensitivity analyses restricted to high-quality RCT confirmed our main results, suggesting that these study characteristics were unlikely to substantially affect the findings of our NMA. Generalizability may be another issue—studies included patients with different mean age and undergoing different procedures



(e.g. diagnostic or therapeutic) and the haemostasis technique. However, detailed subgroup analyses showed that these differences are unlikely to modify the effects of bed rest duration, suggesting that these findings may be generalizable to different settings patients and procedures.

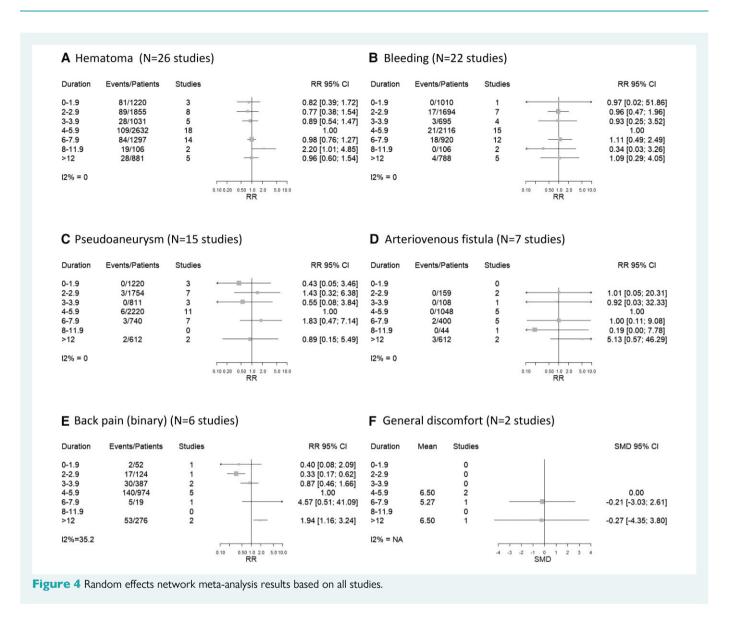
There are several suggestions for future research in light of the outcomes from this NMA. A particular strength of the network approach is that it can highlight where future comparisons are needed. The connectivity illustrated by the networks suggests that more direct evidence is required on the effects of short bed rest. It is also evident that there is little utility in the continued use of long bed rest. In addition, while a consideration of resources consumption and costs was beyond the

scope of this review, it would be useful for future studies to focus on these aspects as well.

Conclusions

The duration of bed rest after transfemoral catheterization is unlikely to be associated with onset of short-term vascular complications. Ambulation as early as 2 h after transfemoral cardiac catheterization can be safely implemented, if the patient's physical state allows. A short duration of bed rest will likely result in optimized patient management and reduced risk of complications, therefore lowering in-hospital length of stay and related costs. Findings support the importance of quality

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nursing care focused on improving patient comfort and early detection of post-procedural complications.

Supplementary material

Supplementary material is available at European Journal of Cardiovascular Nursing online.

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*The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Conflict of interest: None declared.

Data availability

All data relevant to the study are included in the article or uploaded as supplementary information.

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