Bed rest duration after sheath removal following percutaneous coronary interventions: a systematic review and meta-analysis

Mina Mohammady, Fatemeh Atoof, Ali Akbari Sari and Mitra Zolfaghari

Aims and objectives. To explore the effect of bed rest duration after sheath removal following percutaneous coronary interventions on the incidence of vascular complications, back pain and urinary problems.

Background. According to the literature, the duration of bed rest after sheath removal following percutaneous coronary interventions ranges from 2–24 hours. Several studies have assessed the effect of duration of bed rest on vascular complications, but a clear final conclusion about the exact duration of bed rest has not been reached.

Design. Systematic review and meta-analysis.

Methods. Cochrane Library, MEDLINE, SCOPUS, CINAHL, IranMedex and IranDoc were searched. No language limitation was applied. RCTs that used two different periods for ambulation were included. Two reviewers separately assessed the quality of each included study and extracted the data. Dichotomous outcomes were recorded as odds ratio with 95% confidence interval.

Results. Five studies involving 1115 participants were included in the review. Among them, two studies had three comparison groups. The studies considered a variety of periods as early and late ambulation, ranging from 2–10 hours. Totally, there were no statistically significant differences in the incidence of bleeding, pseudoaneurysm, arteriovenous fistula and urinary problems between early and late ambulation. There was a statistically significant reduction in the risk of haematoma formation at four to six hours of bed rest compared with eight hours of bed rest (odds ratio = 0.37, 95% CI: 0.15, 0.91). Back pain was reported in one study evaluating three hours of bed rest with an odds ratio of 0.45 (95% confidence interval: 0.28, 0.71) when compared with 10 hours of bed rest.

Conclusions. Early ambulation after percutaneous coronary interventions is safe and feasible; however, the results should be used with caution as the majority of included studies had methodological flaws.

Relevance to clinical practice. The results of this study suggest that patients could be ambulated three to four hours after sheath removal following percutaneous coronary interventions and early ambulation dose does not increase the risk of vascular complications, but it moderates back pain occurrence.

Key words: ambulation, percutaneous coronary intervention, systematic reviews and meta-analyses

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Introduction

Percutaneous coronary intervention (PCI) has become a widely accepted technique in the treatment of coronary artery disease and includes coronary revascularisation procedures such as balloon angioplasty and stent replacement (Knebel et al. 2008). It is estimated that approximately 1.5 million patients undergo PCIs including balloon

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angioplasty and stent replacement in the United States every year (Prasad & Herrmann 2011). Currently, the majority of invasive cardiovascular procedures are carried out through skin puncture rather than incision under local anaesthesia. These procedures are generally safe, but a proportion of patients might experience serious access-site complications after diagnostic or interventional cardiovascular procedures (Knebel et al. 2008, Carrozza 2012). The most common complications after PCIs via the femoral artery are haematoma (15.5%), bleeding (1.5%), arteriovenous fistula (1%) and pseudoaneurysm (0.7%) (Sulzbach-Hoke et al. 2010). Patients experience more vascular complications after PCIs rather than cardiac catheterisation. According to Berry et al.’s study, femoral haematoma occurred in 22% of cardiac catheterisation and in 41% of PCIs. The most important predictors for vascular complications after PCIs compared with cardiac catheterisation are the use of antplatelet/anticoagulant drugs, larger catheters and remaining arterial sheaths in insertion site longer after PCIs compared with cardiac catheterisation (191 ± 108 vs. 49 ± 54 minutes) (Berry et al. 2004). To prevent vascular complications, medical institutions restrict patients to stay in bed. According to the literature, the duration of bed rest after PCIs ranges from 2–24 hours after sheath removal (Vlasic et al. 2001, Schiks et al. 2009). In addition, medical institutions recommend various durations of bed rest after PCIs. During this time, patients should stay in the supine position with the head of the bed elevated not more than 15–30° (Vaught & Ostrow 2001). Staying in this position is difficult for many patients and might be associated with back pain and urinary problems (Rezaei-Adaryani et al. 2009, Augustin et al. 2010). Several randomised controlled trials (RCTs) have assessed the effect of duration of bed rest after PCIs on vascular complication incidence (Fowlow et al. 1995, Vlasic et al. 2001, Walker et al. 2008, Augustin et al. 2010, Moeini et al. 2010). However, all conducted RCTs have found that the duration of bed rest after PCIs can be reduced without increasing the rate of bleeding and haematoma formation. Nonetheless, varying results have been reported, and a clear final conclusion about the exact duration of bed rest has not been reached. A meta-analysis was recently published that had included both randomised and non-RCTs and compared two to four hours with 6–10 hours of bed rest on haematoma and bleeding incidence (Tongsai & Thamlikitkul 2012). The other bed rest durations were not assessed in this review. This limitation highlights the significance of this systematic review, which was conducted to assess the effect of different durations of bed rest on haematoma, bleeding, pseudoaneurysm, arteriovenous fistula, back pain and urinary problems post-PCIs in randomised and quasi-RCTs.

Aims

This review aimed to explore the effect of bed rest duration after PCIs on the incidence of vascular complications, back pain and urinary problems.

Methods

Search strategy

We searched the CENTRAL search strategy on The Cochrane Library (Issues 4, 2012); MEDLINE (from 1966–May 2012); SCOPUS (May 2012); and CINAHL (from 1982–May 2012) using free text and MeSH terms. We also searched two Persian medical sites (IranMedex and IranDoc). There were no restrictions on the language of publications. The CENTRAL search strategy is presented in Appendix 1.

Type of study design

Randomised controlled trials and quasi-RCTs were included in this review. Moher et al. (1998) suggest that the treatment effect has been exaggerated by 30–50% in studies with inadequate allocation concealment compared with studies that had adequate allocation concealment; therefore, we excluded controlled clinical trials and nonrandomised clinical trials.

Type of participants

The studies with participants older than 18 years of age who had received PCI with or without stent replacement were included. In addition, we included patients undergoing PCI using any sheath size or any type of haemostasis methods after procedure.

Type of outcomes

Primary outcomes: The incidence of bleeding and haematoma at the groin site.
Secondary outcomes: The incidence of pseudoaneurysm, arteriovenous fistula, back pain, urinary retention and bladder catheterisation.

Type of comparisons

Previous studies have used different durations for early and late ambulation after PCIs (Fowlow et al. 1995, Vlasic...
et al. 2001, Walker et al. 2008, Augustin et al. 2010, Moeini et al. 2010); however, the studies can be categorised into the following groups:
1 Comparing two to four hours vs. six hours of bed rest.
2 Comparing four to six hours vs. eight hours of bed rest.
3 Comparing three hours vs. 10 hours of bed rest.

We defined early and late ambulation according to the methods used by these studies.

By the same token, the results of outcomes that had measured the outcomes before patient ambulation were excluded.

Selection of studies, data extraction and quality appraisal

All the references identified by the search strategy were downloaded into Reference Manager 12 and were screened against the inclusion criteria. If it was unclear from the abstract whether the study met the selection criteria, the full paper was retrieved. Two reviewers assessed the quality of each included study, and the data were extracted according to the structured forms. Any disagreements were resolved by discussion. The Cochrane Collaboration Risk of Bias Assessment Tool was used to appraise the quality of the included studies (Higgins & Green 2011).

Statistical analysis

We combined dichotomous outcomes by the Mantel–Haenszel fixed effect model. Forest plots were produced to display the measures’ effect of each study that was expressed as prevalence, odds ratio (OR) with 95% confidence interval (CI). Moreover, any heterogeneity and variations among the included studies were assessed by chi-squared and I² statistics. A p value more than 0.10 and I² of <50% were considered as lack of statistical heterogeneity. The fixed effect method was used when there was no heterogeneity.

Data were analysed using REVMan, version 5.1.0. (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

Results

Description of studies

We found 5857 references from electronic search. After the removal of duplicate reports and checking the study titles and abstracts, 14 papers were selected for further investigation (Fig. 1) (Moher et al. 2009). Five studies involving 1115 participants were included in the review (Fowlow et al. 1995, Vlasic et al. 2001, Walker et al. 2008, Augustin et al. 2010, Moeini et al. 2010) (Table 1). All studies were published in English. Two studies were conducted in Canada (Fowlow et al. 1995, Vlasic et al. 2001), one in Iran (Moeini et al. 2010), one in Australia (Walker et al. 2008) and one in Brazil (Augustin et al. 2010). A study was published in two reports (Price & Fowlow 1994, Fowlow et al. 1995). We obtained Moeini’s thesis for more data (Moradpour et al. 2007). All studies were conducted in a single centre. Two of the five studies had three comparison groups (Vlasic et al. 2001, Walker et al. 2008). The mean age of the participants was between 57–60.3 years, and 60 to 82% of the population were men.

Three studies were excluded from the review because they had nonrandomised designs (Koch et al. 1997, Tagney & Lackie 2005, Schiks et al. 2009). Two studies did not have comparison group (Keeling et al. 2000, Rao et al. 2011). Moreover, two studies were excluded because of applying other interventions in addition to the duration of bed rest (Koch et al. 1999, Tengiz et al. 2003).

The sheath sizes varied from 6–9 French, and the method of achieving haemostasis varied as follows: manual compression (Fowlow et al. 1995, Moeini et al. 2010), compression clamp (Vlasic et al. 2001), FemoStop (Walker et al. 2008) and manual pressure with or without mechanical compressor (Augustin et al. 2010). None of the included studies had used an arterial puncture closing device.

Intervention

Studies were selected if patients in the two groups underwent PCIs and the conditions were the same in both groups except the duration of bed rest prescribed after the procedures. The duration of bed rest after sheath removal in patients who underwent PCIs ranged from 2–10 hours. Among the included studies, two studies compared two to four hours with six hours of bed rest (Vlasic et al. 2001, Walker et al. 2008), two studies compared four to six hours with eight hours of bed rest (Vlasic et al. 1995, Moeini et al. 2010) and one study compared three hours with 10 hours of bed rest (Augustin et al. 2010).

Quality appraisal

We used the Cochrane Collaboration’s Tool for assessing the risk of bias in the included studies. It includes six specific domains (namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other bias) (Higgins & Green 2011).

All studies were reported as randomised; and the method of random sequence generation was computer-generated
random software in one trial (Augustin et al. 2010), opaque sealed envelopes were used for allocation concealment in two studies (Vlasic et al. 2001, Walker et al. 2008), and one trial used a method that led to a predictable treatment allocation as odd or even admission numbers (Moeini et al. 2010). The nature of the intervention made a double-blinded design impossible, and only the outcome assessors and statistics could become blinded. Nevertheless, blinding was not clearly reported in all of the studies. Four studies provided adequate description on withdrawals and dropouts. All of the included studies demonstrated baseline assessment of participants to identify differences in group allocation, and most of them stated that they had incorporated well-matched groups (Fig. 2).

In general, the majority of studies had some methodological flaws, and the risk of bias was unclear for 80% of the included studies.

Effects of interventions

All included studies explored the effect of different bed rest durations after PCIs on the incidence of haematoma and bleeding. These studies showed that there was a statistically significant reduction in the risk of haematoma formation at four to six hours of bed rest compared with eight hours of bed rest ($p = 0.03$, OR = 0.37, 95% CI: 0.15, 0.91). However, no statistically significant difference was detected in haematoma incidence when comparing two to four hours with six hours of bed rest and when comparing three hours with 10 hours of bed rest (Fig. 3). There was no statistically significant difference in the incidence of bleeding among patients in the three compared categories (Fig. 4). The incidence of pseudoaneurysm was assessed in studies carried out by Vlasic et al. (2001) and Augustin et al. (2010), but no statistically significant difference was detected (Fig. 5). In addition, Fowlow et al. (1995) and Vlasic et al. (2001) assessed arteriovenous fistula and found no statistically significant difference between the two groups (Fig. 6) (Fowlow et al. 1995, Vlasic et al. 2001). Augustin et al. (2010) also assessed the incidence of back pain ($n = 347$), in 3 and 10 hours of bed rest, and found a statistically significant difference ($p = 0.0008$) favouring early ambulation (OR = 0.45, 95% CI: 0.28, 0.71). In addition, Augustin et al. (2010) assessed the incidence of urinary retention and bladder catheterisation, but they found no statistically significant difference (urinary
retention: OR = 2.10, 95% CI: 0.70, 6.27 and bladder catheterisation: OR = 0.14, 95% CI: 0.01, 2.7) (Augustin et al. 2010).

**Discussion**

The aim of the current review was to explore the effect of duration of bed rest after sheath removal in patients who underwent PCIs on the occurrence of vascular complications, back pain and urinary problems. A comprehensive search of the literature was carried out, and five RCTs with a total of 1115 participants were included.

Generally, there were significant variations in the methods used by the studies. A relatively wide range of bed rest durations were used as early or late. These inconsistencies made the comparison among studies very difficult. Therefore, attempts like subgroup analysis were made to compare the results of similar studies. Three main categories were found for the duration of bed rest, and then the primary and secondary outcomes were assessed separately in each category. The results in each group showed that early ambulation of patients after sheath removal following PCIs had no significant effects on the incidence of vascular complications including bleeding, pseudoaneurysm and arteriovenous fistula. However, there was a statistically significant difference when comparing four to six hours with eight hours of bed rest on haematoma formation in favour of early ambulation (OR = 0.37, 95% CI: 0.15, 0.91). Overall, the incidence of haematoma ranged from 0.57%–24%, and the incidence of bleeding ranged from 0.33%–3% in the included studies. Early ambulation was associated with a lower incidence of back pain within 24 hours of follow up in comparison with late ambulation. In addition, shortening the duration of bed rest had no effects on urinary retention and bladder catheterisation when three-hour bed rest was compared with 10-hour bed rest.

Mohammady et al. (2013) conducted a systematic review to evaluate the effect of bed rest duration after trans-femoral catheterisation in patients who underwent angiography. They included 20 randomised trials involving a total of 4019 participants. They reported that two to three hours of bed rest after angiography did not increase the risk of vascular complications, and it was associated with less back pain and urinary discomfort compared with late ambulation (Mohammady et al. 2013). Also, it should be regarded that arterial sheath was removed later after PCI compared

<table>
<thead>
<tr>
<th>Author (year), country</th>
<th>Baseline characteristics</th>
<th>Procedure type/ catheter or sheath size</th>
<th>Haemostasis method</th>
<th>Early ambulation</th>
<th>Late ambulation</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Augustin et al. (2010), Brazil</td>
<td>347 patients, mean age of control group: 59.7 ± 9.9 and intervention group: 61 ± 10.4, men 60%</td>
<td>Coronary angioplasty using 6 French sheaths</td>
<td>Manual compression with or without mechanical compressor</td>
<td>Three hours</td>
<td>10 hours</td>
<td>Bleeding, haematoma pseudoaneurysm, back pain, urinary retention, bladder catheterisation</td>
</tr>
<tr>
<td>Fowlow et al. (1995), Canada</td>
<td>85 patients, mean age 57.7 ± 10.2, men 78%</td>
<td>PCIs using 7.5–9 French sheaths</td>
<td>Manual compression</td>
<td>Six hours</td>
<td>Eight hours</td>
<td>Haematoma, bleeding, back pain, arteriovenous fistula</td>
</tr>
<tr>
<td>Moenini et al. (2010), Iran</td>
<td>124 patients, mean age of control group: 60.2 ± 9.97 and intervention group: 57 ± 8.9, men 64%</td>
<td>PCIs using 7 French sheaths</td>
<td>Manual compression</td>
<td>Four hours</td>
<td>Eight hours</td>
<td>Haematoma and bleeding</td>
</tr>
<tr>
<td>Vlasic et al. (2001), Canada</td>
<td>253 patients, mean age 57, men 73%</td>
<td>PCIs using 6–9 French sheaths</td>
<td>Manual compression</td>
<td>Two hours</td>
<td>Four and six hours</td>
<td>Haematoma, bleeding, pseudoaneurysm</td>
</tr>
<tr>
<td>Walker et al. (2008), Australia</td>
<td>306 patients, mean age 59, men 82%</td>
<td>PCIs with or without stent replacement using 6 or 7 French catheters</td>
<td>FemoStop</td>
<td>Three hours</td>
<td>Four and six hours</td>
<td>Haematoma, bleeding, pseudoaneurysm</td>
</tr>
</tbody>
</table>
with cardiac catheterisation (191 ± 108 vs. 49 ± 54 minutes) (Berry et al. 2004). Therefore, two to three hours after cardiac catheterisation is not exactly similar to this time after PCIs.

More recently, Tongsai and Thamlikitkul published a review with three randomised and two nonrandomised trials to evaluate the effect of two to four hours of bed rest compared with 6–10 hours of bed rest after PCI on the incidence of haematoma and bleeding. This study found that two to four hours of bed rest after sheath removal was safe, which is similar to the results of our review (Tongsai & Thamlikitkul 2012).

It should also be noted that haemostasis methods might affect the risk of vascular complications. Although all included studies used a mechanical compression (manual compression or FemoStop) for haemostasis, arterial puncture closing devices were not used in all included studies.

Strengths of the review

Our review had several strengths. We performed a comprehensive search of published reports and grey literature with no language restriction. We included only randomised and quasi-randomised trials and conducted subgroup analysis to compare a wide range of bed rest durations.

Limitations of the review

This review also had several limitations. The majority of included studies had some methodological flaws. In the majority of included studies, the risk of bias was unclear, the sample size was small, a wide range of time periods were used for the bed rest, and the follow-up time varied.
widely. In addition, the data were insufficient to evaluate the effects of different duration of bed rest by gender, age and type of medication used. Moreover, the included studies reported their results in various follow-up times including 2, 4, 24 and 48 hours after procedures. Therefore, due to the small number of included studies in each
bed rest category with similar outcomes, the results in each category were pooled regardless of follow-up times.

Therefore, due to these limitations, the findings of this review should be interpreted and used with caution.

Conclusion

Early ambulation after PCIs did not increase the incidence of vascular complications including bleeding, haematoma, pseudoaneurysm and arteriovenous fistula compared with late ambulation, and it was also associated with a lower incidence of back pain. The results of this review; however, should be used with caution due to the methodological flaws.

Relevance to clinical practice

The results of this study suggested that patients could be ambulated two to four hours after sheath removal following PCIs and early ambulation did not increase the risk of vascular complications, but it moderates the occurrence of back pain.

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Contributions

Study design: MM, AAS; data collection and analysis: MZ, MM, FA, MZ and manuscript preparation: MM, MZ, FA.

Conflict of interest

The authors declare that they have no conflict of interests.

References


**Appendix 1 Central search strategy**

#1 MeSH descriptor early ambulation this term only
#2 MeSH descriptor bed rest this term only
#3 MeSH descriptor walking this term only
#4 MeSH descriptor movement this term only
#5 bedrest in All Text
#6 bed next rest in All Text
#7 ambulation in All Text
#8 mobili* in All Text
#9 immobili* in All Text
#10 ambulate* in All Text
#11 (#1 or #2 or #3 or #5 or #7 or #8 or #9 or #10)
#12 MeSH descriptor angioplasty explode all trees
#13 MeSH descriptor femoral artery this term only
#14 percutaneous coronary intervention* in All Text
#15 transfemoral in All Text
#16 femoral next arter* in All Text
#17 femoral next approach in All Text
#18 femoral next route in All Text
#19 femoral next sheath* in All Text
#20 MeSH descriptor angioplasty, balloon explode all trees
#21 MeSH descriptor angioplasty, balloon, coronary, this term only
#22 (#12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21)
#23 (#11 and #22)
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