**ORIGINAL ARTICLES AND REVIEWS** 

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## Bed rest after cardiovascular implantable electronic device placement: systematic review and meta-analysis

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#### Abstract

**Background.** Bed rest is prescribed for all patients after cardiovascular implantable electronic device (CIED) placement but to a varied extent. Different clinical protocols exist. **Aim.** To assess the effects of different lengths of bed rest on complications and patient comfort after CIED implantation.

**Methods.** We searched MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, CINAHL, SCOPUS. We included randomized and quasi-randomized controlled trials. Two of the authors independently selected trials, assessed the risk of bias, and extracted data.

**Results.** We included 2 RCTs. There was no evidence that shorter bed rest was more harmful than longer bed rest in terms of lead displacement (RR 0.681, 95% CI [0.063, 7.332]) and hematoma (RR 1.642, 95% CI [0.282, 9.560]). None of the studies reported the assessment of bleeding, back pain, or urinary discomfort.

**Conclusions.** Shorter periods of bed rest appear to be as safe as longer ones. However, to confirm these results, further larger trials are needed.

#### INTRODUCTION

Cardiovascular implantable electronic device (CIED) is a term that encompasses pacemakers (PMs) for bradyarrhythmia treatment, implantable cardioverter defibrillators (ICDs) for life-threatening ventricular tachyarrhythmia management, and cardiac resynchronization therapy (CRT) devices for systolic dysfunction with conduction delays [1]. CIEDs were introduced into routine clinical practice in the 1960s and, since then, their use has increased worldwide [2]. In 2009, Mond and Proclemer performed the latest worldwide cardiac pacing and implantable cardioverter-defibrillator (ICD) survey [3], and all countries showed increases in implant numbers compared to data from a similar

survey carried out in 2005 by Mond *et al.* [4]. Permanent cardiac pacing is one of the most important medical innovations of the 20th century [5], and it remains the only effective treatment for chronic, symptomatic bradycardia [6].

A CIED relies on two essential components: a pulse generator, that includes software and an integrated battery, and leads implanted in the heart chambers and connected to the generator [7, 8].

CIED implantation [8, 9] is typically performed under local anesthesia in a cardiac catheterization laboratory. An incision is made in the upper chest, slightly inferior and medial to the deltopectoral groove. A pocket is created for placement of the pulse generator

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#### Key words

- pacemaker
- bed rest
- mobilizationcomplications
- complication

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by separating the subcutaneous tissue from the pectoral muscle at the fascial plane. Transvenous access is achieved via the subclavian or cephalic veins, located just below the collarbone. The leads are advanced under fluoroscopy to guide them into the correct position through the superior vena cava into the heart and then are placed in the appropriate chambers. Once the leads are positioned in the heart, the CIED is tested to verify proper location and that it is working correctly. The skin incision is closed with sutures and a sterile dressing is applied.

The most common short-term CIED implantationrelated complications are [10, 11]: pocket hematoma, pocket infection, lead displacement, venous thrombosis, pneumothorax, hemothorax, and cardiac perforation.

Kirkfeldt *et al.* [12] indicated that 9.5% of patients who underwent a CIED procedure experienced at least one complication. In particular, one study conducted in the USA highlighted that dislodgement, pocket hematoma, and pneumothorax after ICD implantation occurred in 1%, 0.9% and 0.4% of patients, respectively [13]. A different study [14] indicated that 4.4% of patients developed some perioperative complications after permanent PM insertion, and the most common ones were lead dislodgement (1.7%), pneumothorax (1.0%), and pocket hematoma (0.2%).

In order to reduce complications, nursing care is important. However, there are no international guidelines addressing postoperative care [15], and no final conclusion has yet been reached concerning patient mobilization and bed rest prescription to prevent complications after CIED implantation [16, 17]. Many different protocols exist and, conventionally, patients are prescribed at least 24 h of bed rest, as this is thought to prevent short-term implantation-related complications, with particular reference to lead displacement [18].

Bed rest is associated with impairment of the musculoskeletal, cardiovascular, respiratory, integumentary, gastrointestinal, and renal systems, as well as cognition, and it is a potentially harmful treatment [19, 20]. Lack of mobility can be devastating, especially for older patients, because functional decline can happen quickly [21]. Mandatory supination is often uncomfortable and can cause lumbodorsalgia and urinary retention [22]. Conversely, early mobilization reduces patient discomfort and postural pain, promotes dignity and independence, and prevents the side effects of bed rest.

The main objective of this systematic review was to assess the effects of different lengths of bed rest on complications and patient discomfort after CIED placement.

#### METHODS

#### Types of study

We conducted this systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [23] statement.

We included randomized and quasi-randomized controlled trials comparing different lengths of bed rest. We defined the search query using the following PICO framework [24] (*Table 1*).

#### Participants

This review included studies which enrolled patients undergoing CIED placement. There were no restrictions with respect to patient characteristics or healthcare setting.

#### Interventions and comparisons

Duration of bed rest was the intervention of interest for this review. We compared early mobilization with late mobilization.

#### Outcomes

According to Saldanha *et al.*, the outcomes were defined using 5 items: domain, specific measurements, specific metric, method, time point [25].

#### Primary outcome

Domain: lead displacement

Specific measurement: number of patients with lead displacement. The displacement was defined as the inability to pace the myocardium even at a high voltage output, sensing defects not corrigible by reprogramming the device, or radiographic evidence of dislodgement.

Specific metric: value at time point.

Method of aggregation: percentage.

Time point: 24 h after CIED placement or discharge time.

Secondary outcomes

Domain: bleeding.

Specific measurement: number of patients presenting visible areas of bleeding, oozing, or hemorrhage at the CIED implantation site.

Specific metric: value at time point.

Method of aggregation: percentage.

Time point: 24 h after CIED placement or discharge time.

Domain: hematomas.

Specific measurement: number of patients presenting visible ecchymosis or hematoma at the CIED implantation site.

Specific metric: value at time point.

#### Table 1

Description of PICO framework [24] used to define the search query.

PICO framework	Description
Population	Patients undergoing CIED placement
Intervention/Comparison	Short bed rest (such as 3 h) vs long bed rest
Outcomes	Lead displacement; bleeding; hematomas; back pain; urinary discomfort

Method of aggregation: percentage.

Time point: 24 h after CIED placement or discharge time.

Domain: back pain.

Specific measurement: number of patients presenting

with back pain after CIED placement. Specific metric: value at time point.

Method of aggregation: percentage.

Time point: 24 h after CIED placement or discharge

time.

Domain: urinary discomfort.

Specific measurement: number of patients presenting with urinary discomfort after CIED placement.

Specific metric: value at time point.

Method of aggregation: percentage.

Time point: 24 h after CIED placement or discharge time.

#### Electronic research

We conducted a comprehensive search including: MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, CINAHL, and SCOPUS. The search strategies are shown in *Appendix 1* available online as Supplementary Materials. In order to identify other published and unpublished works (grey literature) we consulted google scholar. In addition, we manually inspected previous reviews to obtain relevant studies from their list of references. We did not apply language restrictions.

#### Study selection

Two of the authors (SM and SG) independently screened titles and abstracts in order to identify relevant publications. Disagreements were resolved by discussion with a third author (GB) who made the final decision. Full texts were retrieved and evaluated by the same two authors.

Agreement among the screeners was assessed using Cohen Kappa: if K < 0.20 the correlation was poor; fair if between 0.21 and 0.40; moderate if between 0.41 and 0.60; good if between 0.61 and 0.80 and very good if  $\geq$  0.81 [26].

#### Data extraction

If eligible studies were found, two authors (AC and SG) would independently extract and enter the data into tables using Excel. If data from the trial reports was insufficient, the original authors would be contacted for further information. The following data was extracted:

• article (title, authors, years of publication, journal);

- study characteristics (setting and location of study, number of patients, mean patient age, duration of bed rest, type of study, type of device, type of compression);
- results (number of patients per study group, number of patients presenting complications);
- other relevant information.

#### Assessment of risk of bias in included studies

Two review authors (EB and RC) assessed the quality of included studies using the Cochrane Effective Practice and Organisation of Care (EPOC) Risk of Bias tool [27]. The following domains were evaluated:

- selection bias;
- performance bias;
- detection bias;
- attrition bias;
- reporting bias.

Any differences among the review authors were resolved by discussion or by consensus after negotiation with a third author (ADM).

#### Statistical analysis

The selected studies are homogeneous enough with respect to design and outcomes, so we have conducted a meta-analysis. All outcomes are dichotomous and were analyzed as OR / RR with a corresponding 95% CI. The meta-analysis gave estimates with null or not statistically significant heterogeneity. Statistical heterogeneity was tested with I-squared and corresponding p-values. For the meta-analysis, the Manthel-Haenszel model of fixed effects was used.

#### RESULTS

#### Literature search results

Comprehensive literature searching yielded 751 references (conducted in October 2016). After title/abstract screening, 739 records were excluded (Cohen's K 0.515). Of the remaining 12 studies, 10 were excluded (Cohen's K 1) because they were observational studies or because the intervention was not short versus long bed rest. Thus, 2 studies were included [28, 29] (*Figure 1*).

#### Selected studies

We have included two RCTs. Both studies were conducted in Italy and included patients who underwent PM implantation. No studies including patients who underwent ICD or CRT device placement were found (*Table 2*).

#### **Participants**

There were a total of 166 participants with a mean attrition rate of 2.6% (SD 0.04). The selected studies observed mixed samples for gender: 50% of the total participants were female. The mean age of the participants was 75.7 years (95% CI 61.3-90.0; SD 5.77), with a total range from 18 to 94 years old.

Miracapillo *et al.* [29] also conducted an analysis by subgroups, dividing patients according to the implanted leads and pacemaker (single-lead and dual-lead) which were equally distributed throughout the intervention and control groups. In the second study, a dual-chamber pacemaker was implanted in the majority of patients.

#### Intervention

In the experimental group, there were a total of 73 participants (mean 24.3, SD 7.37, min 16, max 30), 40 male and 33 female with a mean age of 75.5 (SD 6.062, min 68.5, max 79), who were mobilized at 180 min = 3 h after surgery.

#### Control

In the control group, there were a total of 93 participants (mean 31, SD 13.2, min 16, max 41), 43 male and 50 female with a mean age of 75.333 (SD 4.618, min 70,



#### Figure 1

PRISMA [23] flow diagram depicting the flow of information through the different phases of the systematic review. It maps out the number of records identified, included and excluded, and the reasons for exclusions.

max 78). In the control group, the postoperative mobilization of patients happened after a mean of 1680 min = 28 h (SD 415, min 1440 = 24 h, max 2160 = 36 h).

#### Outcomes

The two included studies evaluated lead displacement, pocket hematoma, and other postoperative complications until discharge. Miracapillo *et al.* [29] also

#### Table 2

Characteristics of the two studies included in the review

scheduled a 2-month follow up. No studies evaluating bleeding, back pain, or urinary discomfort were found.

#### Methodological quality of the selected studies

The quality of the included studies was assessed using the Cochrane Effective Practice and Organisation of Care (EPOC) Risk of Bias tool [27].

Risk of bias summary (Figure 2) shows review au-

First author (year) and country	Miracapillo (2006) Italy [29]	Simonelli (2012) Italy [28]
Study design and time frame	RCT March 2003-February 2004	RCT September 2010-December 2010
Participants	134 patients undergoing PM implantation (71 single- chamber and 63 dual-chamber)	32 patients undergoing PM implantation (31 dual- chamber and 1 single-chamber)
Intervention	57 patients were mobilized 3 hours after surgery	16 patients were mobilized 3 hours after surgery
Control	77 patients were mobilized 24 hours after surgery	16 patients were mobilized 36 hours after surgery
Outcomes	Lead displacement, high pacing thresholds at the electronic follow-up and clinical complications of the pocket such as hematoma formation, infection, or PM vein thrombosis	Lead displacement, clinical complications of the pocket (such as hematoma formation, infection, or PM vein thrombosis), nausea/vomiting, need for analgesics and level of independenc.
Follow-up	Clinical and electronical follow-up were performed both 24 hours after implantation and two months later	Level of indepence was assessed at 6, 12, and 36 hours after implantation. Clinical follow-up was performed at hospital discharge



#### Figure 2

Risk of bias summary. The quality of included studies was assessed using the Cochrane EPOC Risk of Bias tool [27].

thors' judgements about each risk of bias item for each included study. The two studies explicitly used proper randomization methods. Blinding of participants is generally difficult to obtain with these types of intervention. Trials are open label, but this review is based on objective outcome parameters. The included studies also suffered from insufficient information about blinding of outcome assessors. Study protocol was available for Simonelli *et al.* [28].

#### Meta-analysis

Those studies were essentially comparable for length of bed rest and patient characteristics. Therefore, we attempted a formal meta-analysis (*Table 3*).

#### Primary outcome

Lead displacement was reported in the Miracapillo study [29] while in the Simonelli study [28] no lead displacement was observed in both the experimental and control groups. No differences were found for length of bed rest (RR 0.681, 95%, CI [0.063, 7.332]).

#### Secondary outcomes

Hematoma was reported in both studies. There was no evidence that duration of bed rest was associated with this complication (RR 1.642, 95% CI [0.282, 9.560]).

#### DISCUSSION

The aim of this systematic review was to assess the effects of length of bed rest on complications and patient discomfort after CIED placement.

We included two RCTs comprising a total of 166 participants who underwent PM implantation, a low

sample size if we consider that the latest published worldwide survey [3] described 737 840 new PM implantation procedures carried out during the 2009 calendar year. No studies including patients who underwent ICD nor CRT device were found.

The included studies are homogeneous enough with respect to design and outcomes, and they are essentially comparable for length of bed rest and patient characteristics. Low sample size notwithstanding, we decided to carry out a formal meta-analysis in order to elaborate on this topic of great clinical and economic interest and encourage researchers to develop new trials as well.

This systematic review stated that there is no evidence of lead displacement and pocket hematoma due to early mobilization of patients who underwent PM implantation. In both studies an elastic bandage was put on the homolateral shoulder after the procedure. It can be useful against hemorrhagic complications of the pocket and opening of the wound margins. Results of this study support a decrease in bed rest times without an increase in complication rates. According to the existing evidence, 3 h of bed rest would seem to be as safe as longer periods of bed rest. Shorter lengths of bed rest may suggest an early discharge policy. The literature does not state the time of discharge. Miracapillo et al. [29] suggests scheduling earlier follow-up to easily detect lead dislodgement, which can be very dangerous in pacemaker-dependent patients. In this study, two events occurred in the period between discharge and the 2-month follow-up.

The trials included in this review had satisfactory methodological quality according to the Cochrane Effective Practice and Organisation of Care (EPOC) Risk of Bias tool [27]; however, both studies had limitations related to blinding criteria, and the sample sizes were small, particularly for the Simonelli study [28].

To the best of our knowledge, there is no any other published meta-analysis addressing the same issue, so we considered papers dealing with similar questions: a Cochrane review comparing the effects of shorter versus longer periods of bed rest in patients with uncomplicated acute myocardial infarction [30] stated that short bed rest appears to be as safe as longer periods of bed rest in terms of mortality or reinfarction, while a recent systematic review comparing the effects of early mobilization with no treatment in patients after cardiac surgery [31] stated that early mobilization seems to be important to prevent postoperative complications, improve functional capacity, and reduce length of hospital stay. Finding comparable results in papers addressing similar issues suggest that an evidence-based approach to reducing bed rest in the cardiology patient popula-

#### Table 3

Meta-analysis results. Comparison: early mobilization (3 hours) versus longer bed rest

Outcome	RR	95% CI	р	I-squared
Lead displacement	0.681	0.063, 7.332	0.751	-
Hematoma	1.642	0.282, 9.560	0.581	0.0%

tion is underway. There is growing interest in the use of early mobilization in the hospital setting, because a shorter length of bed rest is an inexpensive and easily performed strategy that can affect quality of care and patient comfort. A systematic review and network meta-analysis assessing the effects of different lengths of bed rest after transfemoral cardiac catheterization on bleeding and hematoma, other vascular complications, patient symptoms and discomfort is being carried out [32], while others have been concluded [33, 34].

A limitation of this review could be that during records screening we excluded 6 references because the full text was not available; nevertheless, after careful reading of the 6 abstracts, we determined that those papers would not have significantly affected this study.

Further larger trials would be useful to validate the safety and effectiveness of early mobilization for patients undergoing CIED implantation and to establish the optimal duration of bed rest. In future studies, pain scores need to be captured, as safety and comfort are important quality measures.

RCTs to evaluate the effect of immediate mobilization compared with early mobilization in patients un-

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dergoing CIED implantation could be a possible way forward.

#### CONCLUSION

Current practice is moving to markedly shorter durations of bed rest during hospital stays. It is possible to assume safety and effectiveness of early mobilization for patients who underwent PM implantation. The doctors and nurses could consider early mobilization for patients undergoing PM implantation. However, in order to confirm our results larger studies must be carried out.

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#### Declaration of conflict interest

The authors declare that there is no conflict of interest.

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