Authors' objectives
To evaluate the effectiveness of systemic antibiotic prophylaxis to reduce infection rates after pacemaker implantation.

Searching
MEDLINE from January 1967 to June 1996, EMBASE from January 1974 to June 1996, and Current Contents from January 1967 to June 1996, were searched for published trials of the use of antibiotic prophylaxis at the time of permanent pacemaker implantation, to prevent secondary infection. Additional published and unpublished studies were identified by searching meeting abstracts (from 1980 to 1997) and the reference lists in reviews and trials, and by contacting colleagues, investigators and the manufacturers of pacemakers and antibiotics.

Study selection
Study designs of evaluations included in the review
Trials that were prospective, randomised, controlled, open or blind, where patients were assigned to a systematic antibiotic group or a control group, were included. The length of follow-up ranged from 1 month to 4 years; the mean follow-up (3 studies) ranged from 14 to 23 months.

Specific interventions included in the review
Prophylactic antibiotics in various dosages were compared with a control group (one study was placebo-controlled; care given to the control groups in the other studies was not stated). The prophylactic antibiotics studied were: flucloxacillin with benzylpenicillin; cloxacinil; cloxacillin with amoxycillin, followed by ampicillin or flucloxacillin; and cefazolin.

Participants included in the review
Adults undergoing either a new permanent pacing system implantation, a pulse generator or a lead change.

Outcomes assessed in the review
The outcomes assessed were all probable or documented infections after pacemaker implantation, as defined in the primary studies. Definitions included repeat operation for infective complication, elevated oral temperature, acute local inflammation, and presence of pus in the generator pocket.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not report a formal assessment of the quality of the included studies.

Data extraction
The data were extracted independently by three of the authors.

Methods of synthesis
How were the studies combined?
The authors calculated log odds ratios (ORs), along with 95% confidence intervals (CIs), using fixed-effect models.

How were differences between studies investigated?
The Cochran Q statistic was used to test for heterogeneity of the treatment effect. A value of p less than or equal to
0.01 from an association test was considered significant.

**Results of the review**

Seven randomised controlled trials were included, of which 1 was an abstract and only 1 was double-blind and placebo-controlled. Five studies were analysed on an intention to treat basis, and 2 were not. The included studies had 2,023 participants with 1,011 receiving systemic antibiotic and 1,012 receiving no active treatment.

There was a consistent protective effect of antibiotic pre-treatment; the OR was 0.256 (95% CI: 0.10, 0.656, p=0.0046).

No statistical heterogeneity was found (p=0.36) when using a multiplicative model. The additive model was rejected because of significant heterogeneity.

The overall mortality rate was not significantly different between the two groups (20 out of 1,011 patients versus 17 out of 1,012 patients).

**Authors’ conclusions**

The authors stated that the results were questionable because of the lack of well-designed randomised studies. However, despite this, the results supported the use of systemic antibiotic prophylaxis at the time of pacemaker insertion to prevent serious infective complications (e.g. short-term pocket infection, skin erosion, or septicaemia) after implantation.

**CRD commentary**

This was a reasonably good systematic review of the current literature. The authors clearly stated their research question and performed a good search of the published and unpublished literature, contacting colleagues and other sources for additional information. It was not stated whether any language restrictions were placed on the search, so it is not possible to determine whether additional relevant studies were missed.

The selection and inclusion criteria were stated, although the authors did not perform any formal quality scoring of the included studies. In addition, it was not reported as to who made the selection and inclusion judgements.

The method of combining the studies was appropriate and tests for heterogeneity were conducted. Subgroup analyses were not possible because individual participant data were no longer available. The authors’ conclusions follow from the results even though, as the authors stated, higher-quality trials are needed to confirm their results.

**Implications of the review for practice and research**

The authors state that, in practice, it is reasonable to encourage prophylactic antibiotics when implanting a permanent pacemaker. The authors also state that further suitably powered clinical trials are needed to confirm these results.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.