Pacemaker and ICD generator reliability: meta-analysis of device registries
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CRD summary
This review aimed to determine annual rates of malfunction in pacemakers and implantable cardioverter-defibrillator (ICD) generators. The author concluded that pacemaker reliability has improved substantially, and that the annual ICD malfunction rate is 20-fold higher than the pacemaker rate between 1988 and 2004. Owing to substantial methodological limitations, the extent to which the author’s conclusions are reliable is unclear.

Authors’ objectives
To determine annual rates and trends for malfunction in pacemakers and implantable cardioverter-defibrillator (ICD) generators.

Searching
MEDLINE (January 1966 to April 2005), the Cochrane CENTRAL Register (to mid 2005) and the Cochrane Database of Systematic Reviews (to mid 2005) were searched for relevant registries; the search terms were reported. Reference lists were screened for further relevant studies. The search was restricted to articles reported in the English language.

Study selection
Study designs of evaluations included in the review
Prospective registries were eligible for inclusion in the review. Those included were proactively monitored, active registries.

Specific interventions included in the review
Studies (registries) monitoring the performance of pacemakers and ICDs were eligible for inclusion in the review. The included registries had to involve at least 100 devices.

Participants included in the review
Studies (registries) reporting the exact number of patients who had received a pacemaker or ICD (or both) were eligible for inclusion in the review. There were no details of the participants amongst the included registries.

Outcomes assessed in the review
The primary outcome of interest was the annual number of device malfunctions. Malfunctions occurring as a result of integral component failure, prior to reaching elective replacement, were eligible for inclusion. Other abnormalities, such as over and undersensing, normal battery depletion, system upgrades and electrode failures, were excluded.

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

Assessment of study quality
All qualifying registries were assessed for completeness of follow-up and objectivity of the outcome measure. The author did not state who performed the validity assessment.

Data extraction
The author did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data were extracted on the annual number of device malfunctions, and either extracted or calculated for the number of ‘at risk’ patients in order to arrive at annual malfunction rates and their 95% confidence intervals (CIs). Data were collected from 1983 to 2004 for pacemakers, and from 1988 to 2004 for ICDs.
Methods of synthesis

How were the studies combined?
Annual estimates of malfunction rates were combined in a meta-analysis, using inverse variance-weighted averages of logarithmic ratios. Fixed-effect and random-effects models were used. The former was used in preference where no heterogeneity was detected. Mantel-Haenszel chi-squared tests were used to explore trends over 5-year intervals. Publication bias was explored using a funnel plot and an adjusted rank-correlation test (Begg and Mazumdar).

How were differences between studies investigated?
Heterogeneity was assessed using chi-squared tests (P<=0.10). Meta-regression methods were considered, but were not used because of the small number of studies and lack of heterogeneity in the final analysis. A sensitivity analysis was carried out to assess the contribution of each study to the pooled estimate.

Results of the review

Three registries were included in the review. The registries accounted for 2.1 million pacemaker person-years and 14,821 ICD person-years of observation.

The results of the meta-analysis were based on combined data from the Bilitch Registry, the Danish Pacemaker and ICD Register, and the UK Pacemaker and ICD Registry. Premature battery failure was the primary source of device malfunction for both pacemakers and ICDs.

Pacemaker reliability.

Annual malfunction rates ranged from their highest in 1983 at 12.4 malfunctions per 1,000 person-years (95% CI: 10.9, 13.9) to their lowest in 1998 at 0.7 malfunctions per 1,000 person-years (95% CI: 0.3, 1.2). A significant decrease in trend was noted over the first two 5-year study periods (P=0.009), and overall reliability increased (P for trend <0.001) during the whole study period. The mean rate was not statistically different for data that were recorded when the three registries co-existed.

ICD reliability.

The results were based on only the Bilitch and Danish registries. Annual malfunction rates ranged from their highest in 1989 at 52.5 malfunctions per 1,000 person-years (95% CI: 35.8, 69.2) to their lowest in 1998 at 5.6 malfunctions per 1,000 person-years (95% CI: 1.6, 15.5). A significant decrease in trend was noted in these first two 5-year study periods (P<0.001), but increased 4-fold during the third study period (1998 to 2002) (P for trend <0.001). The lowest ICD malfunction rates were reported between the years 1996 to 1999 and 2003 to 2004.

Comparison of devices.

Despite a substantially higher number of person-years of observation for pacemakers, the mean annual ICD malfunction rate was 20-fold higher than the pacemaker rate between the years 1988 and 2004 (26.5 versus 1.3 malfunctions per 1,000 person-years, p<0.001).

Authors' conclusions

The malfunction rate of pacemakers has remained low since technological advancements occurred in the 1980s. Although improvements were noted between 2003 and 2004, the ICD malfunction rate has been substantially higher than the pacemaker rate since the late 1990s.

CRD commentary

The review's objective and inclusion criteria were clear. These were supported by a search of electronic databases, and the subsequent inclusion of papers was restricted to English language articles. It is possible that this strategy might have missed articles relevant to the topic area, and language bias is a potential threat. Publication bias was addressed, but the results were not reported. There were some brief criteria to assess the validity of the studies but, again, no results were
given. There were no details of the study selection, validity assessment or data extraction processes and these potentially contribute major sources of bias to the review.

Some details of the small number of included registries were given, although the absence of data on the year of implant and details of specific device models limits the practical usefulness of the results. It was unclear whether the method of data synthesis was appropriate, given the potential diversity of the models used. Heterogeneity between registries was assessed, but reported only for pacemaker data. The results of planned sensitivity analyses were not supplied. The author's conclusions reflect the evidence presented, but this poorly conducted review means that the reliability of the conclusions is unclear.

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

Practice: The author stated that more accurate monitoring of pacemaker and ICD performance is required. In particular, more reliable methods of categorising and reporting device failures are needed.

Research: The author did not state any implications for research.

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