Title: Remote monitoring systems for patients with implanted cardiac devices

Agency: Medical Services Advisory Committee (MSAC)

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Aim

To evaluate the safety, effectiveness and cost-effectiveness of remote monitoring systems for patients with pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) devices.

Results and conclusions

Safety

There appear to be no direct safety issues associated with remote monitoring.

Effectiveness

Evidence concerning Therapeutic Goods Administration (TGA) listed devices was limited to two non-comparative studies, which prompted inclusion of non-TGA listed device studies in the literature review. Use of remote monitoring systems for CRT and an ICD was assessed by a study of TGA-listed devices: inadequate follow-up and outcomes reporting limited evidence that remote monitoring may be useful in predicting cardiac events requiring hospital admission. Evidence that remote monitoring of a TGA-listed pacemaker changed patient management through detection of silent atrial events was also limited: patient follow-up was unclear and outcomes were poorly defined. Studies that investigated non-TGA listed devices also lacked sufficient reporting of their design and outcomes to enable sufficient high-quality clinical evidence to be elicited from the literature. Common limitations among reported outcomes in this body of literature included lack of an appropriate comparison with standard clinic visits, low applicability to Australian clinical settings, non-consecutive patient enrolment, evidence of incomplete blinding, and inadequate duration of clinical follow-up.

Cost-effectiveness

An economic evaluation could not be performed because of the lack of appropriate, comparative clinical evidence.

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness for the use of remote monitoring systems for patients with implanted cardiac devices including standard pacemakers, implanted cardioverter defibrillators and cardiac resynchronisation therapy compared with standard clinic-based follow-up alone.

MSAC finds that the procedure is safe.

MSAC finds that clinical effectiveness is not demonstrated

A formal economic assessment was therefore not performed.

MSAC does not support public funding for the use of remote monitoring systems for patients with implanted cardiac devices.

The Minister for Health and Ageing accepted this recommendation on the 28 August 2008.

Methods

MSAC conducted a systematic literature review pertaining to remote monitoring systems for patients with pacemakers, ICDs and CRT devices.