Is ambulatory monitoring for 'community-acquired' syncope economically attractive: a cost-effectiveness analysis of a randomized trial of external loop recorders versus Holter monitoring


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study compared two forms of ambulatory cardiac monitoring (external loop recorders or 48 hour Holter monitoring) used to investigate syncope or presyncope.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a diagnosis of syncope and/or presyncope who were referred to the London Health Sciences Centre, Ontario, for ambulatory monitoring. Further details of the study were reported in another publication (Sivakumaran et al. 2003, see ‘Other Publications of Related Interest’ below for bibliographic details).

Setting
The setting was the community. The economic study was conducted in London, ON, Canada.

Dates to which data relate
The effectiveness and resource use data related to 2003. The cost data mainly related to 2003. The price year was 2005.

Source of effectiveness data
The evidence for the effectiveness outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
In general, little information about the study was reported in the present paper. However, more detail was presented in another publication (Sivakumaran et al. 2003). Power calculations were not reported. Patients who were eligible and consented to enter the study were randomly assigned to one of the two groups. A total of 100 patients were recruited to the study, with 49 assigned to the external loop recorder group and 51 to the Holter monitoring group.
Study design
This was a randomised controlled trial that was conducted at a single centre. The method of assignment to the study groups was not described, but it might have been reported in the other publication (Sivakumaran et al. 2003). There was no indication of blinding. Follow-up did not extend beyond the monitoring period. Patients were offered crossover to the other group if there was failed activation or no recurrence of symptoms during the monitoring period.

Analysis of effectiveness
The primary health outcome was symptom and rhythm correlation during the monitoring period. This was reported as the percentage of patients who experienced symptom recurrence in conjunction with successful monitor activation. The diagnoses by the two cardiac monitors were considered to be equal. The costs and effectiveness of both 24- and 48-hour Holter monitoring were studied, but only 48-hour monitoring was included in the analysis. It was unclear whether the analysis of effectiveness was conducted on an intention to treat basis. The demographic, clinical and health resource use characteristics of the patients in the two groups were compared and found to be similar.

Effectiveness results
Sixty-three per cent of patients had symptom recurrence and successful activation in the external loop recorder group, compared with 24% in the Holter group, (p<0.0001).

Clinical conclusions
The authors concluded that external loop recorders are more effective than Holter monitors in detecting or excluding cardiac arrhythmias as a cause of syncope.

Measure of benefits used in the economic analysis
The measure of health benefit used was successful diagnosis. Discounting was not applied to the benefits.

Direct costs
Only the direct costs to the health service were considered. These included the costs of technical and professional fees and an estimate of materials and labour, maintenance and overheads for hospital-based investigations. The resource use data were collected in the primary trial. The patients’ prior health care resource use was obtained at an interview by a study nurse, or from their primary care physician. The cost of technical and professional fees was taken from the Ontario Health Insurance Plan fee schedule. The source of other cost estimates was not explicitly stated, but was inferred to have been a hospital financial department. The cost estimates were reported in detail and separately from the resource use. Discounting was not applied. It was unclear whether this was appropriate because the study did not state the time over which the costs were incurred. The prices for technical and professional fees related to 2003. The price year for other cost estimates was not given. The costs were reported in 2005 prices. However, no adjustment to an alternative price year was reported. The study reported the average cost per patient and the incremental average cost. No service charge was included in the Holter cost calculation because it was included in the hospital overhead calculation.

Statistical analysis of costs
The costs were treated deterministically. No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($). The costs were converted from Canadian dollars (CAD). The conversion rate for 20 July 2005 was $1 =
Sensitivity analysis
Baseline characteristics, including prior resource use, were treated stochastically. The data were presented as means with one standard deviation. The cost data in the economic analysis were treated deterministically. The authors applied a bootstrapping method using 1,000 iterations to investigate uncertainty around the cost-effectiveness estimate. Willingness-to-pay cut-off values of $750 and $1,250 were calculated. The distribution assumptions were not justified.

Estimated benefits used in the economic analysis
The incremental increase in diagnosis was 39.74%. The authors did not calculate the duration of benefits. The side effects of treatment were not relevant.

The authors also calculated the effectiveness of two alternative strategies: initial Holter monitoring followed by offered loop recording, and loop recording followed by Holter monitoring. The diagnostic yields of these strategies were 49% and 63%, respectively.

Cost results
The total cost was $175.18 for a single Holter monitor intervention and $533.56 for a single loop recorder comparator.

The incremental cost was $358.38 for loop monitoring, or $35,838 per 100 patients.

The original costs in Canadian dollars were not reported. The costs were not discounted. The cost of adverse events due to treatment was not relevant.

The cost of the two alternative strategies was $481 (+/- 267) for initial Holter monitoring followed by offered loop recording, and $551 (+/- 83) for loop recording followed by Holter monitoring.

Synthesis of costs and benefits
The costs and benefits were summarised in the form of an incremental cost-effectiveness ratio (ICER) by dividing the incremental costs per 100 patients by the incremental percentage increase in diagnosis.

The authors reported that the ICER of the loop recorder was $901.74 per additional diagnosis. Discounting was not applied.

The results of the bootstrapping analysis showed that 21% of the estimates produced an ICER of less than $750, and 90% of estimates were less than $1,250, for each additional diagnosis by loop recorder.

The cost per diagnosis for the alternative strategies was $982 for initial Holter monitoring followed by offered loop recording, and $871 for loop recording followed by Holter monitoring, (p=0.08).

Authors' conclusions
Loop recorders are more efficacious in determining whether a cardiac arrhythmia is the cause of syncope and presyncope among community patients. This improved diagnostic yield offsets their greater cost.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparators used. Holter monitoring represented current practice in the authors' setting. However, while loop recorders were available, they were not used extensively. You should decide if the comparators represent current practice for the investigation of "community-acquired" syncope in your own setting.
Validity of estimate of measure of effectiveness
The analysis was based on a randomised trial, which was appropriate given the study question and should have good validity. The patient groups also appear to have been comparable at baseline. A typographical error occurred in the comparison of the age of the two groups at baseline. The methods of sample selection, randomisation, blinding, length of study and loss to follow-up were not reported in the present study, but details of the study were reported elsewhere (Sivakumaran et al. 2003). Consequently, it is not possible to comment extensively on the internal validity of the study. The authors did not state whether the outcomes were analysed on an intention to treat basis. No power calculations were reported and, with a total of 100 patients, the sample size was relatively small. It is therefore not possible to ascertain whether the results obtained were due to the intervention or to chance.

Validity of estimate of measure of benefit
The authors selected the percentage of patients who had symptom and rhythm correlation during the monitoring period as the estimate of benefit to be synthesised with the costs. This estimate was obtained directly from the effectiveness analysis. Whilst this is a valid benefit measure for the patient domain it does not permit comparisons with other health care programmes, as would be the case with a cost-utility analysis using, for example, quality-adjusted life-years.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of a single provider (i.e. the health service). It appears that all the relevant categories of costs have been included in the analysis, but some relevant costs were omitted from the analysis. The authors did not include, for example, the cost of a service charge for the Holter monitor since this was included in the calculation of hospital overheads. Although this cost was omitted from the analysis, it is unlikely that this would have affected the authors' conclusions. The costs were reported separately thus enhancing the reproducibility of the study in other settings. The cost for a Holter monitor was variously reported as between $175.18 and $177.65. Although this was confusing it would not affect the results.

The resource use was not reported in the present paper and no statistical analysis of the quantities used was presented. The costs were treated deterministically, and the authors did not report either any measures of variance or the results of any statistical analysis. Bootstrapping was used to investigate the stability of the ICERs. Discounting was not applied, but it was unclear whether this was appropriate as the time over which the costs were incurred was not reported. Costs rather than charges were reported. A common price year was reported. However, the original costs were not reported in local currency prior to conversion to US dollars. In addition, the authors did not give a rationale for using a 2005 currency conversion rate when the cost data used a fee schedule relating to 2003. This limits the generalisability of the results.

Other issues
The authors compared their findings with those from other studies and found agreement in the effectiveness results and prior health care utilisation. The authors proposed that, despite differences between Canada and the USA in the costs of health care, the relative costs of the two interventions are likely to be similar, making the results generalisable to both settings. The results do not appear to have been presented selectively. The study involved syncope patients in the community setting and this was reflected in the authors' conclusions. The authors commented that their findings may not be generalisable to other patient groups, particularly patients with underlying heart disease that warrants hospital assessment and specialist assessment. The authors did not report any further limitations to their study.

Implications of the study
The authors stated that loop recorders should be considered as the first choice for diagnosis of syncope and presyncope in community patients. Their use could improve patient outcomes and reduce the need for ongoing referrals and expensive investigations. Holter monitor use should be limited to those patients with frequent symptoms who have a high probability of achieving symptom-rhythm correlation and to patients who are unable to operate a loop recorder.

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**Other publications of related interest**

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