Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial

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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 use of prolonged monitoring to establish an accurate diagnosis in patients with syncope who had been referred to an arrhythmia centre. The patients were implanted with a Reveal implantable loop reorder (Medtronic). The comparator method of assessment was a conventional investigation strategy that comprised a 2- to 4-week period of monitoring with an external loop recorder, followed by tilt-table and electrophysiologic testing.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised patients who had recurrent unexplained syncope or one episode of syncope associated with injury, which prompted cardiovascular investigation. The patients had undergone a clinical assessment, which included blood pressure testing, a minimum of 24 hours ambulatory monitoring, or in-patient telemetry and a transthoracic echocardiogram. Any additional neurological or cardiovascular testing was recorded. Patients were excluded if they were thought to have neurally mediated syncope, if their left ventricular ejection fraction was less than 35%, if they were unlikely to survive for one year, or if they were unable to provide follow-up or give informed consent.

Setting
The setting was secondary care. The economic analysis was carried out in Canada.

Dates to which data relate
No date was given for the effectiveness evidence, but the original effectiveness paper (see Other Publications of Related Interest) was submitted in January 2001. No dates were given for the resource evidence, but the resource calculations were performed when the effectiveness evidence was calculated. The price year was 2002.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The same patients provided the effectiveness evidence and the cost data. The resource use calculations were carried out prospectively.
Study sample
No power calculations to determine the sample size were reported. Details of the sample selection were not reported, but all eligible patients were included. There were 30 patients in each group. The number of patients excluded from the study after the initial recruitment was not recorded.

Study design
This was a randomised controlled trial that was carried out in a single centre. Crossover was offered to patients if the assigned strategy did not produce a diagnosis. The method of randomisation and the loss to follow-up were not reported. Details of the study have been published elsewhere, (see Other Publications of Related Interest).

Analysis of effectiveness
The basis of the analysis was intention to treat. The groups were shown to be similar at baseline, although statistical tests were not used. Effectiveness was measured by the ability to give a diagnosis.

Effectiveness results
Fourteen of the 30 patients assigned to long-term monitoring were diagnosed, compared with 6 of the 30 patients assigned to conventional testing.

Those patients who were not diagnosed in their allocated group were then offered the opportunity to crossover. Of the 16 undiagnosed patients in the long-term group, 5 consented to conventional testing and one of these was diagnosed. Of the 24 undiagnosed patients in the conventional group, 21 opted for long-term monitoring and 8 of these were diagnosed.

Clinical conclusions
When patients with unexplained syncope were considered suitable candidates for long-term monitoring with an implantable loop recorder, such testing would be more likely to lead to a diagnosis than conventional testing with an external loop recorder, tilt and electrophysiologic testing. If patients were given conventional testing after long-term monitoring has failed to yield a diagnosis (as in the crossover strategy), this would lead to the maximum number of diagnoses in the shortest time.

Measure of benefits used in the economic analysis
The benefit measure, diagnoses made, was taken directly from the effectiveness measure.

Direct costs
No discounting was carried out since the costs were incurred during less than 2 years. The quantities and the costs were analysed separately. The costs included were for external loop recording, transtelphone monitoring, Holter monitoring, echocardiography, tilt-table test, electrophysiologic testing, implanted loop recorder, implanted loop recorder removal, cardiac catheterisation, stress test, stress methoxyisobutyl isonitrite, radionuclide wall motion study, electrocardiography, electroencephalography, loop recorder follow-up, neurology consultation, cardiology consultation, family practice assessment, family practice follow-up, emergency room visit, one day in-hospital monitoring, computed tomography of the head, magnetic resonance imaging of the head, and carotid doppler. The costs were based on actual data, derived from the examination of medical records. The costs of investigations were based on the Ontario Health Insurance Programme fee schedule for technical and professional fees. Materials, labour and overhead for hospital-based investigations were estimated from hospital sources. The price year was 2002.

Statistical analysis of costs
No statistical analysis of the costs was carried out.
Indirect Costs
No indirect costs were calculated.

Currency
Canadian dollars (Can$).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of long-term monitoring per patient was Can$2,731 (standard deviation, SD=285).

The total cost of conventional testing per patient was Can$1,683 (SD=505).

When undiagnosed patients were moved from long-term monitoring to conventional testing, the overall cost per patient was Can$2,937 (SD=579).

When undiagnosed patients were moved from conventional testing to long-term monitoring, the overall cost per patient was Can$3,683 (SD=1,490).

No adverse effects were reported.

The duration of the costs calculated depended on when the diagnosis was made. The maximum duration was the time of conventional testing (maximum 4 weeks) plus one year of long-term monitoring.

Synthesis of costs and benefits
Fourteen of the 30 patients in the long-term monitoring group were diagnosed. The cost per diagnosis was Can$5,852 (SD=610). Six of the 30 patients in the conventional group were diagnosed. The cost per diagnosis was Can$8,414 (SD=2,527).

The overall cost per diagnosis was $5,875 (SD=1,159) in the long-term monitoring group and Can$7,891 (SD=3,193) in the conventional group.

The resulting incremental cost-effectiveness ratio was negative (-Can$22,380), implying actual cost-savings with the strategy of long-term monitoring.

Authors' conclusions
Long-term monitoring for suitably selected patients with unexplained syncope will lead to more diagnoses than conventional testing. The cost per diagnosis will be lower and it is, therefore, the dominant strategy.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified by the fact that it represents current practice. You should decide if it represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a randomised controlled trial, which was appropriate for the study question. Full details of the parent study were published elsewhere (see Other Publications of Related Interest). The authors described the characteristics of the patients in the two groups, showing them to be similar. However, they did not show that the patients were typical of patients with unexplained syncope. One of the exclusion criteria was whether or not the patient was likely to die within one year. There was no explanation for the choice of this criterion. The authors’ conclusion that long-term monitoring is the best strategy to start with depends partly on the assumption that a one-year wait for a diagnosis is not too long.

**Validity of estimate of measure of benefit**
The measure of benefit used was obtained directly from the effectiveness analysis. Although it may be useful to ascertain the cost per diagnosis, this choice of benefit measure makes comparison with other technologies difficult. A quality of life measure may have been more useful. In addition, the one-year wait for a diagnosis may have resulted in the patient preferring the conventional method. Thus, incorporating a quality of life measure might have affected the results obtained.

**Validity of estimate of costs**
The authors described the costs calculated as being societal, but no indirect costs were included. Within the category of direct costs, the authors only included those costs involved in testing. They did not include the prophylactic antibiotics or any other treatment costs, although it is possible that there were none. It is unclear whether the omission of the indirect costs would have changed the results. The authors also did not include the costs incurred when screening patients to decide their eligibility for the trial. It was unclear whether these costs would normally be incurred for both types of testing, in which case their exclusion would be valid. The costs were reported separately from the quantities, which will aid generalisability to other settings. The quantities were taken from a single study. It was not possible to ascertain their validity given that no statistical or sensitivity analyses were carried out. The prices were taken from the authors' setting and from published sources. The authors did not provide clear information about the dates of the price information originally used, although they said that 2002 prices were used.

**Other issues**
The authors compared their results with the findings from other studies. They also discussed the issue of generalisability and concluded that their results were generalisable to other countries. The authors did not present their results selectively. They acknowledged the main limitation of their study, the fact that it only dealt with one category of patients with unexplained syncope who are not seen as being at risk of dying within one year.

**Implications of the study**
The authors concluded that, for specially selected patients, the best strategy on both effectiveness and cost grounds is to start with long-term monitoring with an implantable loop recorder and only revert to the conventional strategy when the first has failed to give a diagnosis.

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**Other publications of related interest**

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