Diagnostic pathway syncope and analysis of the impact of guidelines in a district general hospital: the ECSIT study (Epidemiology and Cost of Syncope in Trento)

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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 study investigated a hospital diagnostic pathway (HDP) for patients with syncope admitted to the emergency room (ER). Specifically, the study analysed the impact of new diagnostic guidelines for the management of syncope.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients admitted to the ER because of loss of consciousness as the only or prevailing symptom.

Setting
The setting was a hospital. The economic study was carried out in Italy.

Dates to which data relate
The effectiveness data, information on resource use, and costs were derived from August to October 1999 in the pre-intervention group and from March to May 2000 in the post-intervention group. The price year was 1999.

Link between effectiveness and cost data
The costing was carried out on the same sample of patients as that used in the analysis of effectiveness. The authors did not state whether the costing was prospectively or retrospectively assessed, but a retrospective approach is likely to have been adopted.

Study sample
Power calculations were not reported. All eligible patients were enrolled in the two different periods. During the pre-intervention period, 285 consecutive syncope patients were enrolled. The proportion of women was 49%. The mean age was 69.5 (+/- 17.3) years (range: 14 to 95). During the post-intervention period, 253 consecutive syncope patients were enrolled. The proportion of women was 54.2%. The mean age was 66.3 (+/- 20.2) years (range: 14 to 96).

Study design
This was a prospective, comparative study with historical control that was carried out at a single centre, the S Chiara Hospital, Trento, Italy. The evaluation of clinical outcomes in the post-intervention period was prospective, but clinical
end points might have been evaluated retrospectively in the post-intervention period. Randomisation was not performed but consecutive patients were enrolled. Two physicians not involved in the study (blind assessment) collected the data and conducted the assessment.

**Analysis of effectiveness**

The primary outcome measures were:

- the proportion of patients hospitalised,
- the mean length of stay (LOS), and
- the proportion of patients with a certain diagnosis (when a direct and certain correlation between the pathological event and syncope symptoms was demonstrated),
- the proportion of patients with a probable diagnosis (when, during the diagnostic process, a cause which could produce a syncope was identified but not reproduced),
- the proportion of patients with a hypothetical diagnosis (the clinical characteristics of syncope allowed a diagnosis to be made even if no pathologies were identified), or
- the proportion of patients with no diagnosis (when the identified pathologies did not justify the development of syncope and the clinical characteristics did not allow the identification of a specific class).

All of the patients included in the initial study sample were taken into account in the analysis of effectiveness. The baseline comparability of study groups was not discussed.

**Effectiveness results**

The proportion of patients hospitalised was 53% in the pre-intervention group and 42% in the post-intervention group, (p<0.01).

The average LOS was 9 (+/- 5.6) days (range: 1 to 30) in the pre-intervention group and 11.3 +/- (8.5) days (range: 1 to 50) in the post-intervention group (difference not statistically significant).

During hospitalisation, the number of diagnostic tests was 2.6 in the pre-intervention group and 2.9 in the post-intervention group (difference not statistically significant).

On discharge in the pre-intervention period, 7.9% of patients had a certain diagnostic conclusion, 41.1% of patients had a probable diagnosis, while 51% of patients were discharged with no conclusive diagnosis (for 45 of these 77 patients a hypothesis was formulated).

On discharge in the post-intervention period, the proportion of patients with no diagnosis decreased from 51% to 45.8% (although a hypothesis was formulated for 23.4% of patients).

**Clinical conclusions**

The effectiveness analysis showed that the new guidelines did not substantially alter patient management, although the proportion of patients hospitalised decreased significantly.

**Measure of benefits used in the economic analysis**

The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.
Direct costs
The analysis of the costs appears to have been carried out from the perspective of the hospital. It included only the costs of diagnostic tests and hospital stay. The unit costs and the resource quantities were not presented separately. The costs of diagnostic tests were derived from outpatient rates, while costs for inpatient stay came from the hospital accounting reports at the authors' institution. The LOS and the number of diagnostic tests used were derived directly from the sample of patients enrolled in the clinical study. Discounting was not relevant as short-term costs were evaluated. The price year was 1999.

Statistical analysis of costs
The costs and quantities appear to have been treated deterministically, although conventional tests might have been used to assess whether cost-differences were statistically significant.

Indirect Costs
Productivity costs were not considered.

Currency
Euros (EUR).

Sensitivity analysis
The issue of uncertainty was not investigated.

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

Cost results
The mean diagnosed syncope cost per patient was EUR 3,474.13 in the pre-intervention period and EUR 3,646.67 in the post-intervention period. This difference was not statistically significant.

Hospital stay represented the main cost-driver for both groups (more than 90% of the total costs).

The new guidelines led to a lower hospitalisation rate but higher LOS.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was performed.

Authors' conclusions
With the exception of a lower hospitalisation rate, the implementation of a new hospital guideline for the management of patients with syncope did not improve hospital management of syncope patients (similar percentage of non-diagnosed cases). However, the length of stay (LOS) and costs did not change substantially.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear in that the new guideline was compared with the traditional approach to managing syncope patients at the authors' institution. A graphical description of the new diagnostic approach was given, but there was less information on the conventional approach. You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on a comparative study with a historical cohort. This was appropriate for the study question as the two guidelines were implemented in two different timeframes. In effect, a randomised study, which would have been more appropriate, was not feasible. However, some time-related bias might have occurred and factors other than the new guidelines could have affected the conclusions of the analysis. The study groups were reasonably similar, although the baseline comparability was not discussed. The size of the sample was not justified on statistical grounds, and this raises some doubts as to the significance of the comparison of clinical outcomes. The patients were enrolled at a single institution, thus caution should be exercised if extrapolating the results of the analysis to other medical centres. However, the authors stated that their institution could be considered to be fairly representative of the situation at national level, in terms of structural complexity and case-mix.

Validity of estimate of measure of benefit
No summary benefit measure was used. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The analysis of the costs was restricted to some items relevant to the perspective of the hospital. The unit costs and the quantities of resources used were not reported separately, which limits the possibility of replicating the analysis in other settings. The sources of the costs were reported and these reflected the Italian health care system. The price year was implicitly reported, which will facilitate reflation exercises in other time periods.

Other issues
The authors stated that their findings were similar to those observed in other studies published in the Italian context. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed, so it may not be possible to extrapolate the results to other settings. In addition, the external validity of the study appears low. The authors highlighted the difficulty in identifying patients with syncope, as this is a symptom often correlated with other pathologies. Therefore, patients admitted to the ER because of loss of consciousness as the only or prevailing symptom were appropriately chosen.

Implications of the study
The study results did not demonstrate changes in the management of syncope patients after the introduction of new hospital guidelines.

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Other publications of related interest
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**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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