Ultrasound at scintigraphic intermediate probability of pulmonary embolism
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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
Ultrasound as an additional diagnostic examination to 'intermediate probability of pulmonary embolism (PE)' established by ventilation/perfusion(V/Q) scintigraphy.

Type of intervention
Secondary prevention; diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients aged 18 years or older with a diagnosis of "intermediate probability of PE" according to the revised Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED) criteria, clinically suspected acute PE, and with no contraindications to pulmonary angiography.

Setting
Hospital. The economic study was carried out in Orebro, Sweden.

Dates to which data relate
The main effectiveness and resource use data were taken from sources dated 1992-94. The price year was not stated.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study (which investigated only diagnosis outcomes), using broad cost estimates of treatment derived from a different source.

Study sample
From a total of 109 patients, aged 18 years or older, with a diagnosis of "intermediate probability of PE" according to the revised PIOPED criteria, 72 patients were included in the study after providing their consent (the reasons for the exclusion of the other patients were not clearly stated). There were 29 males and 43 females (aged 27-92 years). No power calculations to determine the sample size were given.

Study design
Case series. Patients were followed up until 6 to 22 months (for those with negative diagnostic results). The loss to follow-up was not stated.

**Analysis of effectiveness**
The principle of analysis of the clinical study was not relevant to the results of the analysis. The primary health outcome used in the analysis was the diagnostic accuracy of bilateral ultrasound of the proximal deep veins of the legs (US) in estimating the prevalence of PE, as measured against the results of pulmonary angiography (reference test).

**Effectiveness results**
The prevalence of PE verified by pulmonary angiography was estimated to be 14%. Of the 10 patients with PE, 7 had deep venous thrombosis (DVT). 62 patients had no PE of whom 2 had DVT. Accordingly, the sensitivity and specificity of US for detecting the source of PE were 0.70 (95% CI: 0.35 - 0.93) and 0.97 (95% CI: 0.89 - 1.0), respectively. No complications were observed in any patient. The authors also reported that none of the patients with negative angiograms in the study had died from PE at follow-up. Also, they reported that previously published evidence, based on clinical follow-up, had shown that bilateral phlebography and not treating patients without DVT was a safe strategy. Bilateral phlebography was further reported to have the same diagnostic accuracy as US in detecting DVT in the proximal deep veins.

**Clinical conclusions**
Complementary US offers the patients more adequate treatment than that consequent to relying on lung scintigraphy results without any complementary investigations.

**Measure of benefits used in the economic analysis**
The measure of benefits was the additional number of cases adequately diagnosed and treated and associated reduction in treatment-related complications.

**Direct costs**
The costs associated with diagnosis (including ultrasound for the intervention only) and treatment (hospitalization, control therapy and medication), were calculated on a per-generic procedure basis, using local prices. No actual resource use quantities were reported except for the number of patients who were to be treated under the intervention. For anticoagulation treatment, a ‘3 to 6 month course’ figure was the only figure provided. The source of the broad unit cost estimates was not stated. The quantity/cost boundary adopted was the hospital. The price date was not stated. The long term costs of anticoagulation treatment-related complications were not included in the analysis.

**Currency**
US dollars ($) and Swedish Kroner (SEK).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
The authors remarked that an additional number of patients would have undergone anticoagulation treatment, thereby being exposed to the risks of complications associated with such a treatment, under the comparator (no additional radiologic examination), relative to the intervention (complementary US). Whilst 9 patients were to be treated under the intervention, 60% of 72 patients (i.e. 43 patients) would have undergone anticoagulation treatment under the comparator.
Cost results
The costs of diagnosis and treatment of 72 patients with scintigraphic “intermediate probability of PE” under the complementary ultrasound option were estimated to be $39,150 (SEK 333,000). The costs associated with treating 60% of “intermediate probability of PE” were estimated to be $126,850.

Synthesis of costs and benefits
Since the intervention was considered to be the dominant strategy, the costs and benefits were not combined.

Authors’ conclusions
Complementary diagnostics should be performed and ultrasound is an adequate complementary investigation.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used.

Validity of estimate of measure of benefit
Notwithstanding the fact that the clinical study performed the US examination and the reference tests within 24 hours after scintigraphy and did not permit disclosure of results from either test for any patient, the estimate of effectiveness may be questionable due to the reliance on treatment outcomes based on evidence from the literature, which, in turn, may not have been comprehensive (the authors remarked that anticoagulant treatment has not been shown to be beneficial in established DVT or PE by any randomized study). In addition, the diagnostic strategy (criteria) used as comparator was not clearly stated in the paper.

Validity of estimate of costs
The price date was not given and the source for the estimate of cost of treatment was not reported.

Other issues
Appropriate comparisons were made with other studies, but the issue of generalisability to other countries was not addressed.

Implications of the study
Further information on relevant diagnostic technologies, and additional studies reviewing the outcomes of treatment consequent to the diagnostic strategies under investigation in any meaningful economic evaluation of diagnosis and management of indeterminate scintigraphic results for pulmonary embolism are needed.

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