Evaluation of a screening protocol to exclude the diagnosis of deep venous thrombosis among emergency department patients

Dryjski M, O’Brien-Irr M S, Harris L M, Hassett J, Janicke D

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 examined the use of a screening protocol that incorporated a global deep vein thrombosis (DVT) pretest probability (PTP) ascertained by a questionnaire, a selective D-dimer assay, and selective venous duplex imaging (VDI) to exclude the diagnosis of DVT in emergency department (ED) patients. The ED doctor filled in a questionnaire (developed by Wells et al. See "Other Publications of Related Interest" below) after clinical examination. This was used to calculate a PTP of DVT. The patients were then divided into three categories based on their PTP score: low, moderate and high risk.

Type of intervention
Screening and diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients admitted to the ED of a hospital who were suspected, by the ED doctor, of having DVT.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness evidence was collected during the period 1 April 2000 - 31 March 2001. Dates for resource use were not given but it can be inferred that they were the same as those for the effectiveness evidence. No price year was given but cost data were only collected for one year.

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

Link between effectiveness and cost data
Prospective costing was carried out on the same sample of patients as that used in the effectiveness analysis.

Study sample
No power calculations were reported. There was no sample selection; all 114 patients with suspected DVT presenting during the study period were included in the study. All patients were supposed to receive all the tests.
Study design
This was a prospective cross-sectional diagnostic study, conducted in a single centre.

Analysis of effectiveness
The effectiveness analysis was based on intention to treat. The effectiveness of the screening protocol was measured by its sensitivity, specificity, the positive predictive value (PPV) and the negative predictive value (NPV). All patients were given all tests; subsequently correlation studies were completed using VDI as the gold standard. The screening strategy was considered positive when the patient had been correctly placed in the high-risk group by their PTP or the D-dimer was positive, thus ensuring the patient received the correct treatment. The VDI tests were used to establish a definitive diagnosis of DVT. The screening strategy would initially give patients VDI only if they had reached a high-risk score in the PTP, otherwise they would receive D-dimer. If the D-dimer test was positive they would then receive VDI.

Effectiveness results
Although the study was intended to give all 114 patients D-dimer and PTP, 66 patients had PTP and D-dimer, but 95 patients only had D-dimer. The reason for this was "lack of attentiveness" by the doctors in the ED.

All 11 patients (9.6%) diagnosed with DVT using the VDI test were in the high risk category as defined by the PTP, although 5 of these patients had their PTP calculated retrospectively after the VDI had identified them as having DVT.

The results for D-dimer as a single test were: sensitivity 80%, specificity 41%, PPV 14%, negative predictive value 95%.

The results for D-dimer and PTP together as a test were: sensitivity 100%, specificity 25%, PPV 12%, negative predictive value 100%.

Clinical conclusions
Using the proposed screening algorithm to identify patients with suspected DVT ED doctors could safely reduce referrals to VDI by 23%.

Measure of benefits used in the economic analysis
No summary measure of benefit was used.

Direct costs
Costs were based on hospital charges for the different tests. Costs were calculated for the screening strategy and compared with routine global VDI. The costs of carrying out the PTP were not calculated, and thus only the costs of the VDI and the D-dimer were included. The costs of the tests were reported separately from the quantities. Those costs were based on actual data. No price year was reported.

Statistical analysis of costs
No statistical analysis of costs was carried out.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
No summary benefit measure was calculated.

**Cost results**
The average cost per patient in the suggested screening protocol was $170.50; the average cost for a VDI test was $202.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
The authors concluded that, were their suggested protocol to be adopted, all patients with DVT would have been correctly diagnosed and costs would have been reduced.

**CRD COMMENTARY - Selection of comparators**
The comparator was global VDI, which was justified, as it was the normal procedure in the authors' setting. You, as a user of this database should determine if it is a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The study design was appropriate to address the question posed. However, the study protocol was not adhered to, and as a result, not all of the patients received all of the tests. The retrospective calculation of PTP scores may have caused verification bias, which otherwise would not have been present. Verification bias can lead to distorted indices of accuracy. Additionally, it is not clear if the VDI technicians were independent. If they were not independent, then the study may also have suffered from review bias. No power calculations were conducted, and, as such, it is impossible to say whether the results obtained are robust.

**Validity of estimate of measure of benefit**
No summary measure of benefit was used.

**Validity of estimate of costs**
The cost data were inadequate. The costs of carrying out the PTP were not included as it did not seem to be considered a serious cost, but presumably the reason that the doctors in the ED did not always carry it out was because it incurred a cost. Omission of this cost would underestimate the cost of the proposed screening protocol and could be responsible for the perceived cost saving. The costs that were used in the analysis were not actual costs in the screening protocol, but the hypothetical costs incurred by the proposed screening protocol. Costs were reported separately from quantities. Quantities and prices were both taken from the authors' setting, a single study. Charges were used as a proxy for prices. No statistical analysis of prices or quantities was carried out.

**Other issues**
The authors made appropriate comparisons of their results with the findings from other studies, but the issue of generalisability to other settings was not addressed. The authors did not present their results selectively. As the number
of DVTs was small and no statistical tests were reported it is not certain that their conclusions would carry through to a larger sample. The authors acknowledged that a larger sample might lead to more robust results.

**Implications of the study**
The authors concluded that their suggested screening protocol could reduce the amount of VDI without risking false negatives, and subsequently this would reduce hospital costs. A larger study, which ensured that all patients received all three tests and included the costs of carrying out the PTP, should be carried out to ensure that their conclusions are valid.

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**Other publications of related interest**

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