Does this patient have deep vein thrombosis?
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CRD summary
This publication reviewed methods of diagnosing deep vein thrombosis. The authors concluded that establishing clinical probabilities for patients is useful, and that patients with low clinical probability and negative D-dimer test can be excluded without ultrasound. The reliability of the conclusion is difficult to assess, mainly due to the sparsely documented review.

Authors' objectives
To determine the accuracy of clinical prediction rules, alone or in combination with D-dimer assays, for the diagnosis of deep vein thrombosis (DVT), and to estimate the prevalence of DVT.

Searching
MEDLINE was searched from 1990 to July 2004 for studies published in English or French; the MeSH terms were provided. In addition, articles were identified from the bibliographies of included studies, retrieved reviews and an existing reference library.

Study selection
Study designs of evaluations included in the review
Studies using consecutive patients and a prospective trial design, with a minimum of 3 months' follow-up, were eligible for inclusion. No other information about the study designs of the included studies was reported.

Specific interventions included in the review
Studies using a validated clinical prediction rule (prior to D-dimer testing or imaging) in the DVT diagnostic process were eligible for inclusion. All included studies used the same clinical prediction rule.

Reference standard test against which the new test was compared
The authors stated that studies had to provide objective documentation of all venous thromboembolic events (DVT and pulmonary embolism); a minimum follow-up period of 3 months was required. An evaluation of proximal DVT had to be present, and studies had to employ independent and blinded comparisons of symptom or sign results with a reference standard of diagnosis; the reference standard was not explicitly specified. Studies evaluating clinical rules to estimate the prevalence of DVT appear to have followed the clinical assessment with D-dimer tests or diagnostic imaging techniques. It was not stated explicitly how the accuracy of the D-dimer tests was established in the included studies.

Participants included in the review
Studies on out-patients with symptoms and signs of suspected DVT were eligible for inclusion. Patients who had had a DVT before had to be excluded in the primary studies unless the tested clinical model was adjusted for the history of prior DVT. The studies could include patients with a low, moderate or high risk of DVT. No other information was given about the patients in the included studies.

Outcomes assessed in the review
No inclusion criteria relating to the outcomes were specified. The prevalence of DVT in all studies and among patients with low, moderate or high clinical probability was assessed. The sensitivity, specificity, negative predictive value, likelihood ratios (LRs) and diagnostic odds ratio of D-dimer tests were also assessed. In addition, the post-test probabilities of DVT were estimated in low-, moderate- and high-risk populations.

How were decisions on the relevance of primary studies made?
The authors stated that two reviewers independently reviewed the data; it was not specified further how papers were selected for the review.
Assessment of study quality
The authors restricted inclusion in the review to independent blinded comparisons, but did not further assess the validity of the included studies.

Data extraction
Two authors independently abstracted data to determine the prevalence and diagnostic accuracy parameters.

Methods of synthesis
How were the studies combined?
The studies were pooled using a random-effects model providing diagnostic point estimates and 95% confidence intervals (CIs).

How were differences between studies investigated?
The prevalence studies were grouped as high, moderate or low clinical probability. The studies were also grouped into subsets of high sensitivity (with corresponding low specificity) or moderate sensitivity (and corresponding moderate specificity) D-dimer test accuracy. The differences between the sensitivity and specificity of the D-dimer assays between the low and moderate clinical probability groups and moderate and high pre-test probability groups were assessed using a chi-squared test.

Results of the review
Fourteen studies (8,239 participants) met the inclusion criteria.

The prevalence was 5% (95% CI: 4, 8) in the low clinical probability group, 17% (95% CI: 13, 23) in the moderate clinical probability group, and 53% (95% CI: 44, 61) in the high clinical probability group.

The sensitivity of D-dimer testing in the low probability group was 88% (95% CI: 81, 92) and the specificity was 72% (95% CI: 65,78). The corresponding values in the moderate probability group were 90% (95% CI: 80, 95) and 58% (95% CI: 49, 67), respectively, and in the high probability group, 92% (95% CI: 85, 96) and 45% (95% CI: 37, 52).

The LRs for a normal result among patients with low clinical suspicion were 0.10 (95% CI: 0.03, 0.37) with a highly sensitive D-dimer assay and 0.20 (95% CI: 0.12, 0.31) with a moderately sensitive D-dimer assay. For patients with moderate clinical suspicion the LR s were 0.05 (95% CI: 0.01, 0.21) and 0.23 (95% CI: 0.13, 0.39), respectively, and for patients with high clinical suspicion they were 0.07 (95% CI: 0.03, 0.18) and 0.15 (95% CI: 0.10, 0.38).

Authors' conclusions
The diagnostic accuracy for detecting DVT improves when clinical probability is estimated before applying diagnostic tests. For patients with low clinical probability on the predictive rule and negative D-dimer results, diagnosis of DVT can be excluded without ultrasound; in patients with high clinical suspicion for DVT the D-dimer test results should not affect clinical decisions.

CRD commentary
The publication included a systematic review that was not exhaustively documented. The inclusion criteria were clear and some limited information about the included studies was provided. The search was targeted at only one electronic database and language restrictions were applied. It was unclear whether unpublished studies were sought. Publication and language bias might have been introduced into the review. The included studies were not assessed for validity, but the inclusion criteria restricted the types of eligible studies. Although all of study results were pooled, given the limited reporting of the characteristics of the included participants it was difficult to assess how appropriate this pooling was. The reliability of the conclusions is difficult to evaluate; the review process and results were only sparsely documented but seem to derive from the data overall.
Implications of the review for practice and research
Practice: The authors stated that out-patients with suspected DVT should be initially assessed using a validated clinical prediction rule. The D-dimer test result can be used to rule out DVT without the use of diagnostic imaging for patients with a low clinical probability estimate and a negative D-dimer test; ditto for moderate probability patients with a negative high-sensitivity D-dimer test. For patients with high clinical probability estimates, diagnostic imaging is necessary even with a negative D-dimer test. D-dimer tests should not be used as screening tests.

Research: The authors did not state any implications for further research.

Bibliographic details
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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.