

Meta-analysis of plethysmography and rheography in the diagnosis of deep vein thrombosis

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Background: Plethysmography and rheography techniques have been widely studied as diagnostic tests for deep vein thrombosis (DVT). This study aimed to systematically review the accuracy of these tests for diagnosing clinically suspected DVT.

Methods: The following databases were searched: Medline, EMBASE, CINAHL, Web of Science, *Cochrane Database of Systematic Reviews*, *Cochrane Controlled Trials Register*, *Database of Reviews of Effectiveness*, the *ACP Journal Club* (1966 to 2004), and citation lists of retrieved articles. Studies that compared plethysmography or rheography to a reference standard of ultrasound or contrast venography were selected. Standardised data were extracted and study quality determined against validated criteria. Data were analysed by random effects meta-analysis and meta-regression.

Results: The meta-analysis included 78 studies, reporting 82 patient cohorts. Sensitivity and specificity (95% CI) were: 75% (73% to 77%) and 90% (89% to 91%) for impedance plethysmography, 83% (81% to 85%) and 81% (79% to 82%) for strain-gauge plethysmography, 85% (79% to 90%) and 91% (81% to 95%) for air plethysmography, 91% (87% to 94%) and 71% (66% to 75%) for light-reflex rheography, and 86% (83% to 89%) and 93% (91% to 95%) for phleborheography. Meta-regression was limited by poor reporting of studies. There was some evidence that diagnostic performance depended on the proportion of males in the cohort and reporting of study setting.

Conclusions: Although plethysmography and rheography techniques add diagnostic value, they have inadequate diagnostic performance to act as a stand-alone test in DVT diagnosis. Evaluation of their role in combination with other tests, or standardised clinical assessment, is required.

Deep vein thrombosis (DVT) is a common condition that requires accurate diagnosis, yet the most appropriate diagnostic approach is not clearly established. Plethysmography and rheography techniques offer potentially rapid, inexpensive, and non-invasive means of diagnosis. Strain gauge plethysmography uses the technique of filling the distal veins of the lower limb by inflation of a tourniquet around the thigh, causing occlusion of the thigh veins, then indirectly measuring the changes in venous outflow and capacitance in response to release of the tourniquet by a strain gauge placed around the calf.¹ Impedance plethysmography is based upon similar principles but measures the change in impedance between two electrodes placed around the calf in response to deflation of an occlusive cuff.² Air plethysmography uses a cuff placed around the calf and inflated to a low pressure. Changes in the pressure within this cuff in response to inflation and deflation of a second cuff placed around the thigh allow assessment of the patency of the deep veins.³ These techniques all rely on detecting alterations in venous capacitance and outflow in the presence of thrombus in the deep veins. False positive results may be produced by extrinsic compression of the proximal veins, for example by tumour, pregnancy, or poor venous outflow such as in severe congestive cardiac failure.^{4–5}

Phleborheography measures changes in venous volume of the lower limb in response to respiration. This is achieved using air-filled cuffs placed around the epigastrium, thigh, mid-calf, lower calf, and foot, each connected to low-pressure transducers.⁶ The normal phasic changes in venous volume of the limb in response to respiration are damped or lost in the presence of DVT. Light reflection rheography measures changes in the reflection of near-infrared light from the skin using a probe placed over the medial malleolus.⁷ The degree

of reflection is determined by the blood volume of the dermal venous plexus, which changes in response to cycles of dorsiflexion of the foot, the degree of emptying of the venous plexus altering according to the patency of the deep veins.

Although these techniques have been used and studied over many decades, their exact role and their diagnostic performance remain unclear. We aimed to systematically evaluate the performance of plethysmography and rheography techniques in the diagnosis of DVT in symptomatic patients.

METHODS

Literature search

We sought to identify all diagnostic cohort studies that compared plethysmography or rheography to a reference standard test for DVT (contrast venography or ultrasound) in patients with clinically suspected DVT. We searched Medline, EMBASE, CINAHL, Web of Science, the *Cochrane Database of Systematic Reviews*, *Cochrane Controlled Trials Register*, *Database of Reviews of Effectiveness*, *Health Technology Assessment* database, BIOSIS, and the *ACP Journal Club* for potentially relevant articles (1966 to April 2004). The bibliographies of all articles selected for the review were scanned for potentially relevant articles not identified by the original search. Manufacturers of instruments were contacted to identify unpublished studies.

Selection of studies

The titles and abstracts of all articles identified by the search strategy were screened by two reviewers (FS and SG), who independently determined whether the article could potentially describe the diagnostic performance of plethysmography or rheography compared with a reference standard. Full copies of all selected articles were retrieved and reviewed by

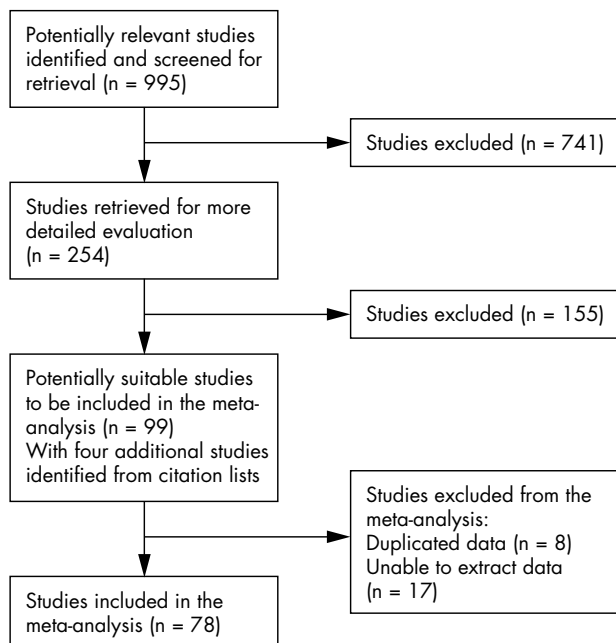


Figure 1 Flow diagram of studies considered for the review.

the same two reviewers, who independently selected relevant articles. A kappa score was calculated and disagreements resolved by discussion at each stage of selection.

We specifically excluded case-control studies, studies including fewer than 10 patients, studies of patients with suspected pulmonary embolism, and studies published in a language other than English, French, Spanish, or Italian. The authors of studies published as abstracts or letters were contacted for details of their data. If it was not possible to extract the necessary data from the published report we contacted the authors for clarification, provided that the study was published in the past 10 years. Studies that evaluated the techniques in asymptomatic patients or mixed cohorts of symptomatic and asymptomatic patients were initially included in the search, but are not reported in this analysis.

Quality of studies

Two reviewers (AW and TL) independently assessed the quality of each study. We used three quality indicators which have been shown to be associated with design related bias in studies of diagnostic tests.⁸ We assessed whether application of the reference standard was independent of the findings of the test under investigation, whether the test under investigation was interpreted by observers who were blind to the reference standard result, and whether the reference standard was interpreted by observers who were blind to the results of test under investigation.

Data extraction

AW and TL independently extracted data from each article using a standardised form, and resolved any disagreements by discussion. For each study we recorded the number of true positives (proximal, distal, and all DVT), false positives, false negatives (proximal, distal, and all DVT), and true negatives. Full details of proximal and distal DVT were only available if the reference standard allowed localisation of thrombus and if data were fully reported. In these circumstances “all DVT” referred to proximal and distal DVT combined. Sensitivity was calculated for all DVT combined, and for proximal and distal DVT separately. In other circumstances “all DVT” referred to all the cases of DVT reported, with no attempt being made to analyse proximal and distal DVT separately.

Statistical analysis

We used Meta-DiSc statistical software for all analyses.⁹ For each diagnostic test we used a random effects model to calculate, with 95% confidence intervals (CI), the pooled sensitivity for all DVT, pooled sensitivity for proximal DVT, pooled sensitivity for distal DVT, and pooled specificity for no DVT. Where zero counts occurred for study data, a continuity correction of 0.5 was added to every value for that study in order to make the calculation of sensitivity and specificity defined. A χ^2 test of heterogeneity was performed for each analysis.

Random effects meta-regression was undertaken for any technique evaluated by a sufficient number of studies (N>10) to identify study-level covariates that predicted diagnostic performance. If a significant covariate (p<0.1) was identified by meta-regression then meta-analysis was repeated, stratified by that covariate, to identify how the

Table 1 Characteristics of cohorts included in the meta-analysis

Technique	No. of cohorts	Recruitment	Prevalence of DVT (%)	Proportion of DVT distal (%)	Reference standard used	Reference standard independent	Test interpreted blind	Reference standard blind
Impedance plethysmography	42	Primary care: 2 Outpatient: 6 Inpatient: 13 Mixed: 7 Not stated: 14	Median: 41 Range: 18–78	Reported by 28/42 Median: 18 Range: 0–40	Venography: 41 Ultrasound: 1	Yes: 32 No: 0 Unclear: 10	Yes: 23 No: 0 Unclear: 19	Yes: 26 No: 0 Unclear: 16
Strain gauge plethysmography	20	ED: 1 Outpatient: 2 Inpatient: 9 Mixed: 2 Not stated: 6	Median: 32 Range: 15–83	Reported by 10/20 Median: 32 Range: 14–58	Venography: 16 Ultrasound: 4	Yes: 17 No: 0 Unclear: 3	Yes: 13 No: 0 Unclear: 7	Yes: 13 No: 0 Unclear: 7
Air plethysmography	4	Mixed: 1 Not stated: 3	42, 42, 63, 70	Reported by 2/4 23, 26	Venography: 4 Ultrasound: 0	Yes: 4 No: 0 Unclear: 0	Yes: 1 No: 0 Unclear: 3	Yes: 2 No: 0 Unclear: 2
Light reflex rheography	9	ED: 1 Inpatient: 1 Mixed: 4 Not stated: 3	Median: 35 Range: 17–47	Reported by 4/9 0, 8, 18, 30	Venography: 7 Ultrasound: 2	Yes: 9 No: 0 Unclear: 0	Yes: 5 No: 0 Unclear: 4	Yes: 9 No: 0 Unclear: 0
Phleborheography	7	ED: 0 Inpatient: 3 Mixed: 2 Not stated: 2	Median: 38 Range: 27–64	Reported by 4/7 14, 16, 20, 21	All venography	Yes: 1 No: 0 Unclear: 6	Yes: 5 No: 0 Unclear: 2	Yes: 1 No: 0 Unclear: 6

ED, emergency department.

Table 2 Sensitivity and specificity of each technique used in deep vein thrombosis (DVT)

Technique	No. of cohorts*	Sensitivity for all DVT†	Sensitivity for proximal DVT†	Sensitivity for distal DVT†	Specificity†
Impedance plethysmography	42 (28)	75% (73% to 77%) p<0.001	88% (86% to 90%) p<0.001	28% (24% to 33%) p<0.001	90% (89% to 91%) p<0.001
Strain gauge plethysmography	20 (10)	83% (81% to 85%) p<0.001	90% (88% to 92%) p<0.001	56% (50% to 63%) p=0.033	81% (79% to 82%) p<0.001
Air plethysmography	4 (2)	85% (79% to 90%) p=0.005	98% (93% to 100%) p=0.18	39% (22% to 58%) p=0.216	91% (81% to 95%) p=0.02
Light reflex rheography	9 (4)	91% (87% to 94%) p=0.001	94% (88% to 98%) p=0.315	92% (74% to 99%) p=0.179	71% (66% to 75%) p<0.001
Phleborheography	7 (4)	86% (83% to 89%) p<0.001	92% (88% to 94%) p=0.001	58% (48% to 68%) p<0.001	93% (91% to 95%) p<0.001

*Number in parentheses = cohorts that reported proximal and distal DVT separately. †Numbers in parentheses are 95% confidence intervals. p value is for χ^2 test for heterogeneity.

covariate influenced diagnostic performance. The following covariates were tested in meta-regression: mean age of the cohort, proportion of males, DVT prevalence, setting (inpatient, outpatient, emergency department, primary care or mixed), consecutive recruitment, prospective study, reference standard used, method of interpretation of results (automatic v manual), and the quality criteria outlined above.

RESULTS

We screened 995 titles/abstracts, selected 254 full articles for review ($\kappa = 0.85$), selected 99 for inclusion ($\kappa = 0.92$), and identified four additional articles from citation lists (fig 1). However, eight studies reported data that were duplicated elsewhere and we were unable to extract data from another 17, so 78 studies were ultimately included in the meta-analysis. These 78 articles reported a total of 82 cohorts of patients with clinically suspected DVT. Impedance plethysmography was evaluated in 42 cohorts,^{2 4 5 10-47} strain gauge plethysmography was evaluated in 20 cohorts,^{1 48-64} air plethysmography was evaluated in 4 cohorts,^{3 65-67} light reflex rheography was evaluated in 9 cohorts,^{7 68-75} and phleborheography was evaluated in 7 cohorts.^{6 25 76-80}

The characteristics of the included cohorts are outlined in table 1. Most cohorts were recruited from inpatients. The reference standard was mostly venography.

The results of meta-analysis are shown in table 2. Most studies evaluated impedance or strain gauge plethysmography. Strain gauge plethysmography had better sensitivity

(83% v 75%), and impedance plethysmography had better specificity (90% v 81%). Analysis of studies reporting proximal and distal DVT separately revealed that sensitivity was particularly poor for distal DVT (impedance 28%, strain gauge 56%), but potentially useful for proximal DVT (impedance 88%, strain gauge 90%). Results for air plethysmography appeared to be slightly better (sensitivity 85%, specificity 91%), but these findings were based on a small number of studies. Light reflex rheography had reasonable sensitivity (91%), but poor specificity (71%). The diagnostic performance of phleborheography was similar to air plethysmography (sensitivity 86%, specificity 93%).

Significant heterogeneity was present whenever there were more than a few studies in the analysis. This is demonstrated in figs 2 and 3 for the two analyses with the most studies: impedance plethysmography (n=42) and strain gauge plethysmography (n=20). These figures show the results for each study plotted on the ROC plane. The true positive rate (sensitivity) is plotted against the false positive rate (1-specificity), so that the results of a study of a perfect test would lie in the top left hand corner. Both figures show substantial heterogeneity as evidenced by the wide dispersion of points on the ROC plane.

Meta-regression was undertaken to identify potential causes for this heterogeneity in the analyses of impedance and strain gauge plethysmography. For impedance plethysmography, setting for recruitment (p=0.098) and blind reporting of the reference standard (p=0.056) were

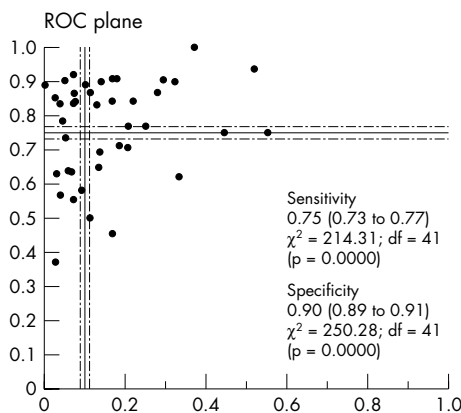


Figure 2 Receiver operating curve (ROC) plane of studies of impedance plethysmography.

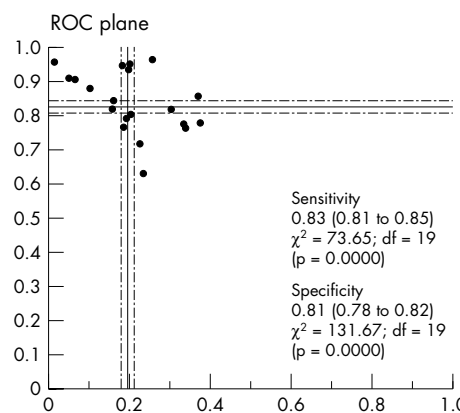


Figure 3 Receiver operating curve (ROC) plane of studies of strain gauge plethysmography.

Table 3 Sensitivity and specificity for impedance plethysmography stratified by significant predictors

Variable*	Sensitivity†	Specificity†
Setting: not stated (n = 14)	83% (80% to 86%) p=0.001	84% (81% to 86%) p<0.001
Setting: inpatient (n = 13)	70% (67% to 73%) p<0.001	91% (89% to 92%) p<0.001
Setting: outpatient (n = 6)	73% (68% to 77%) p<0.001	93% (91% to 95%) p=0.013
Setting: mixed (n = 7)	69% (63% to 74%) p<0.001	88% (85% to 91%) p=0.003
Setting: primary care (n = 2)	83% (74% to 91%) p=0.976	93% (88% to 97%) p=0.743
Consecutive (n = 16)	70% (67% to 73%) p<0.001	93% (91% to 94%) p<0.001
Prospective (n = 17)	69% (66% to 72%) p<0.001	93% (91% to 94%) p<0.001

*Number of cohorts.
†95% confidence intervals in parentheses, p value is for χ^2 test for heterogeneity.

associated with variation in sensitivity, while proportion of males in the cohort ($p = 0.01$), DVT prevalence ($p = 0.043$), setting for recruitment ($p = 0.09$), consecutive recruitment ($p = 0.017$), and prospective study ($p = 0.046$) were associated with variation in specificity. Specificity was lower in cohorts with a higher prevalence of DVT and cohorts with a higher proportion of male patients. For categorical variables we repeated the meta-analysis, stratified by each significant predictor, to estimate sensitivity and/or specificity for studies with, or without, the relevant predictor. The results are shown in table 3. In general, studies that reported their setting had lower sensitivity and higher specificity compared with those where the setting was not stated. With one exception, studies that were reported as prospective were also reported as having consecutive recruitment. These studies reported lower sensitivity and higher specificity than those that did not report these factors. Overall, therefore, it appears that studies with better reporting had lower sensitivity and higher specificity.

For strain gauge plethysmography, setting for recruitment ($p < 0.001$) and the proportion of males in the cohort ($p = 0.005$) were associated with variation in sensitivity, while no variables were associated with variation in specificity. Sensitivity was higher in cohorts with a higher proportion of males. We repeated the meta-analysis stratified by setting. The results are shown in table 4. Sensitivity was higher in outpatient and mixed cohorts, and lower in those that did not report the setting.

DISCUSSION

Plethysmography and rheography techniques have the potential to provide rapid, cheap, and non-invasive diagnosis of DVT. This meta-analysis suggests that none of these techniques have sufficient sensitivity or specificity to act as a standalone test to diagnose or rule out DVT. Light-reflex rheography appears to have the best sensitivity of the tests for DVT, but has a specificity of only 71%. Air plethysmography appears to have very good sensitivity for proximal DVT, but this is based on only two studies. Of the two commonly used plethysmography techniques, impedance plethysmography has better specificity, and strain gauge plethysmography has better sensitivity.

Table 4 Sensitivity and specificity for strain gauge plethysmography stratified by setting for recruitment

Variable*	Sensitivity†	Specificity†
Setting: not stated (n = 4)	82% (77% to 86%) p=0.013	78% (75% to 81%) p<0.001
Setting: ED (n = 1)	63% (52% to 73%)	77% (67% to 84%)
Setting: inpatient (n = 10)	84% (81% to 87%) p<0.001	81% (79% to 83%) p<0.001
Setting: outpatient (n = 3)	86% (83% to 89%) p=0.119	87% (84% to 90%) p=0.001
Setting: mixed (n = 2)	89% (85% to 92%) p=0.476	91% (88% to 94%) p=0.219

*Number of cohorts.
†95% confidence intervals in parentheses, p value is for χ^2 test for heterogeneity.

It may be argued that plethysmography or rheography techniques can rule out DVT in low risk patients if a bayesian approach to diagnosis is used. If the pretest probability of DVT is low, then a negative test with modest sensitivity may be sufficient to produce a post-test probability of DVT that is low enough to rule out DVT. However, this assumes that test performance is independent of the pretest probability of DVT. One study of impedance plethysmography that stratified results by Wells clinical probability score¹⁰ suggests that this assumption may not hold for impedance plethysmography. Sensitivity was higher among patients with a high Wells score (81%) and lower among patients with an intermediate or low Wells score (49% and 48%, respectively).

We identified substantial heterogeneity among the results of studies of each technique. Meta-regression identified some potential causes of heterogeneity, although explaining the observed associations may be difficult. Cohorts with a higher proportion of males appeared to have higher sensitivity in studies of strain gauge plethysmography and lower specificity in studies of impedance plethysmography. It is certainly possible that sex-related differences could lead to differences in diagnostic performance of plethysmography techniques, but this issue requires further research. Other differences related to setting do not appear to be consistent and may be related to poor reporting.

Limited reporting restricted our ability to identify potential causes of heterogeneity. In most studies the entry criterion was merely clinical suspicion of DVT, with no specification of the symptoms and signs required for entry into the study, and often no description of these features for those patients who were entered. As the studies span a considerable period of time and cover a number of differing healthcare systems it is likely that the clinical index of suspicion, and thus the entry criterion, varies between studies. For each type of test there was often variation in the equipment and methodology used to perform the test. The equipment used ranged from the commercially produced to equipment developed by the investigators for the purpose of the study. The methods of interpretation of test results also often differed. Although the principle of the test remains the same, this variation in equipment, methodology, and interpretation may be a further source of heterogeneity. The skill and training of the operator performing the test were often not described. The performance and in many cases interpretation of the test will be highly dependent on the experience of the operator.

This meta-analysis has a number of limitations that should be considered when extrapolating the results into clinical practice. Poor reporting of the primary data limited our ability

to undertake meta-regression and our ability to evaluate the quality of many of the studies. Techniques for literature searching, reviewing, and undertaking meta-analysis for diagnostic tests are relatively new. There are no systems for registering studies of diagnostic tests and the standards for reporting of diagnostic accuracy (STARD criteria⁴¹) have only been recently introduced. This combination of factors means that the identification, retrieval, and analysis of relevant data are more difficult than for meta-analysis of randomised trials. We made only limited attempts to identify and retrieve unpublished data, so our findings may be subject to publication bias. Few reviews of diagnostic test data include searches for unpublished data, so the effect of publication bias is unknown.

If plethysmography and rheography techniques are to have a role in DVT diagnosis it is likely that this role will involve being used in combination with other tests or standardised clinical assessment, rather than as a standalone test. For example, the combination of a low Wells score, or a negative D-dimer, alongside a negative plethysmography result could potentially rule out DVT. Future research therefore needs to determine how plethysmography and rheography techniques perform in combination with other diagnostic modalities. Is their diagnostic performance independent, thus adding useful additional information at low cost and little inconvenience, or do they add no useful additional diagnostic information?

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