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Diagnostic Accuracy of D-Dimer Testing for Deep Vein Thrombosis: A Meta-Analysis

Salim Hussein Hassan[1], Laith Fayiz Jamil Alnajada[2], Saif Saeed Alhawadi[3], Basmalah Saeed Al-Hawadi[4], Mohd Ayman Mustafa Hammad[5], Mohammed M. Helmy Rashed[6], Ahmed Mostafa Elsaied[7], Sameh Ibrahim Elsayed[8]

[1]Department of Medical Laboratory Techniques, Polytechnic Karbala College, Al-Furat Al-Awsat Technical University, Iraq.
inkr.salm@atu.edu.iq
https://orcid.org/0000-0002-0050-8504
[2]Department of Accident and Emergency, Jordan University Hospital, Amman, Jordan.
layth2000pes@gmail.com
https://orcid.org/0009-0008-6545-8262
[3]School of Medicine, University of Jordan, Amman, Jordan.
saifalhawadi6@gmail.com
https://orcid.org/0009-0009-3187-2753
[4]School of Medicine, University of Jordan, Amman, Jordan.
Basmalahalhawadi7@gmail.com
https://orcid.org/0009-0009-6561-1471
[5]Internship, Jordan University Hospital; Faculty of Medicine, Yarmouk University, Amman, Jordan.
mmm2010h@gmail.com
https://orcid.org/0009-0005-9571-5707
[6]Clinical Pharmacy Department, Faculty of Pharmacy (Boys), Al-Azhar University, Cairo, Egypt.
rashedmm1977@azhar.edu.eg
https://orcid.org/0000-0002-5911-530X
[7]Cardiothoracic Surgery Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt.
mostafaa407@yahoo.com
https://orcid.org/0000-0002-9598-2435
[8]Cardiothoracic Surgery Department, Faculty of Medicine, Mansoura University, Mansoura, Egypt.
Sameh001@mans.edu.eg
https://orcid.org/0000-0003-2829-4437

ABSTRACT

D-dimer testing is widely used to rule out deep vein thrombosis (DVT) in patients with suspected thromboembolism of the veins when used in conjunction with clinical pre-test probability tests. This meta-analysis summarises the results of 15 instances of diagnostic accuracy research published in 2020-2025 that tested the D-dimer assays (laboratory-based and point-of-care) using lower extremity DVT, either as a single test or as a clinical decision rule (Wells, YEARS, age-adjusted thresholds). A total of 18400 patients were analysed across the reported studies, and they include both single-centre diagnostic assessments to large multicentre cohort studies. D-dimer has shown a very high sensitivity in ruling out proximal DVT but with a low specificity, and both are heterogeneous, so its positive predictive power is limited, which leads to a high prevalence of false positive results in older and comorbid patients. The sensitivity and specificity were estimated to be 0.96 and 0.52, pooled. Since the techniques were appropriately utilized, age-adjusted and clinical-probability-adjusted strategies produced meaningful specificity increases, with sensitivity held constant. A high heterogeneity (I 2 large) was observed, which was contributed to by the assay type, cut-off levels, patient setting (emergency department or inpatient/ post-surgery), and DVT prevalence. In turn, D -D-dimer testing should be combined with a proven pre-test probability instrument in clinical use, and a low- or middle-probability patient with negative D -D-dimer safely rules out DVT in most modern cohorts. At least wider use of age-adjusted cut-offs, and careful local validation of assays.

KEYWORDS: D -D-dimer; deep vein thrombosis; diagnostic accuracy; sensitivity; specificity; age-adjusted -dimer; point-of-care; meta-analyses

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INTRODUCTION

Deep vein thrombosis (DVT) is a major vascular condition, which is associated with the presence of blood clots in the deep venous system, and this is mainly observed in the lower extremities. It is one of the largest elements of venous thromboembolism (VTE) that includes pulmonary embolism (PE), a potentially fatal complication in case thrombi are dislodged and embolize to the pulmonary arteries (Kearon et al., 2022). Therefore, the morbidity and mortality of VTE can be reduced by the timely and

proper diagnosis of DVT. Nonspecific and unreliable Clinical examination involving signs and symptoms as leg pain, swelling, and tenderness, is intrinsically nonspecific and untrustworthy since the symptoms are similar to other diseases, including cellulitis and venous insufficiency. Thus, the diagnosis can be proved or ruled out with the use of laboratory tests and imaging techniques. The gold standard is compression duplex ultrasonography, which has better sensitivity and specificity, but it is expensive, operator-dependent, and is not always easily available, especially at a primary care or an emergency department.

The D-dimer test has become an essential part of the DVT diagnostic pathways. D-dimer is a degradation product of fibrin that is released during the process of clot clearing and is a sensitive biomarker parameter of active coagulation and fibrinolysis. It is a strong diagnostic tool with high sensitivity and negative predictive value (NPV), with which clinicians are able to rule out DVT in patients with low or intermediate pre-test probability with safety. At a combination of validated clinical prediction rules (including the Wells, YEARS, or Geneva scores) and D -D-dimer testing, D -D-dimer testing is demonstrated to save unnecessary imaging and minimize diagnostic times, as well as health care resources.

However, D- D-dimer assays have significant differences in the methods of analysis, units of calibration like fibrinogen equivalent units (FEU) and D-dimer units (DDU), and also in diagnostic performance across platforms. This traditional fixed cut-off value of 500 -1ng mlFEU/cut off is effective in younger outpatients but creates high false positive outcomes in older patients, during pregnancy, and with hospitalized patients, as there is normal fibrin turnover in the base. To address this weakness, age-modulated and clinical-probability-adjusted thresholds have been suggested in recent studies to increase specificity without reducing their sensitivity (Karny-Epstein et al., 2022). In addition to this, the introduction of point-of-care (POC) assays has contributed to enhanced accessibility, which allows rapid testing at the bedside and reduces the time to make a decision in various clinical settings.

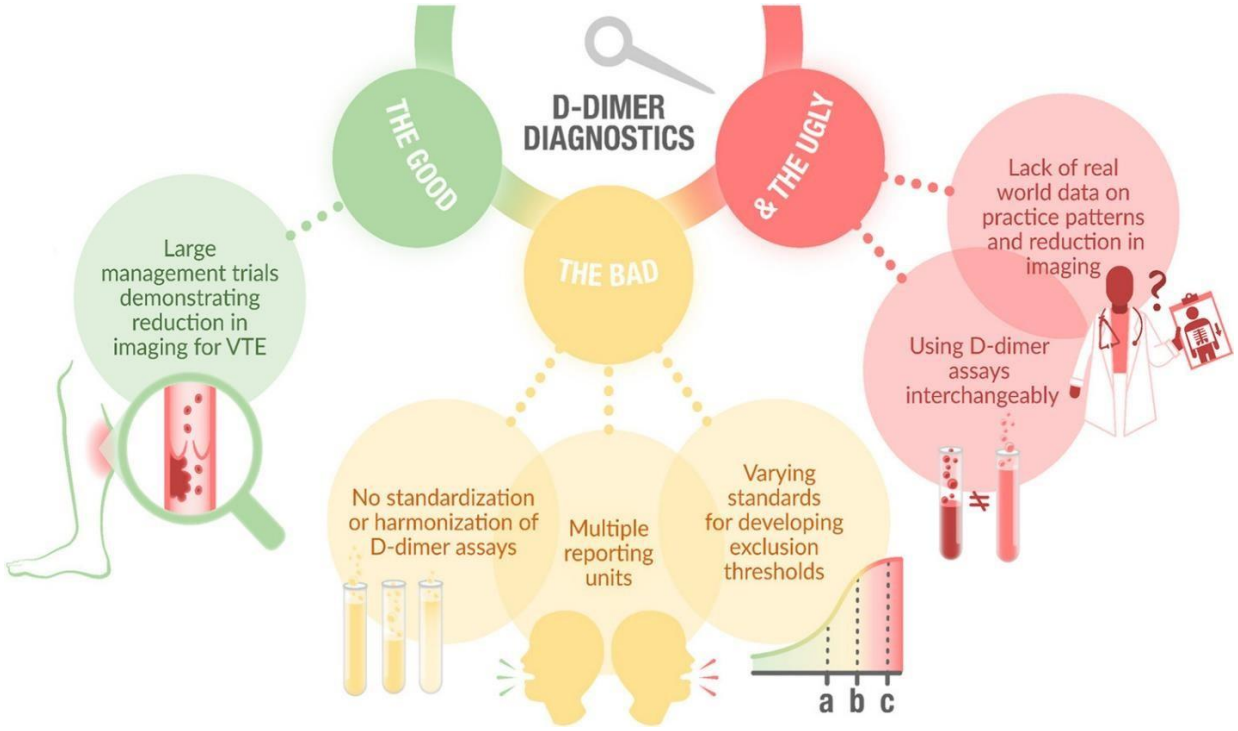

Figure 1. D-Dimer diagnotics (Selby et al., 2024)

1.1 Rationale for the Study

Despite the long-established role of d-dimer testing in clinical practice, recent developments in the form of new analytic platforms, the growing numbers of aging patient populations, and the multiplication of different laboratory and POC assays of d-dimer testing mean that a new synthesis of diagnostic performance is required. This update is essential to educate the use of the evidence-based rule-out options and eliminate unnecessary imaging. Recent cohort studies and studies of validation of assays have shown significant differences in sensitivity and specificity, which depend upon the type of assay, selection of threshold, and clinical condition. The targeted, modern meta-analysis limited to evidence published since 2020, in turn, is highly relevant to bolster the work of clinicians and health-policy practitioners who are interested in streamlining DVT diagnosis pathways.

1.2 Research Questions

- What are the combined diagnostic accuracy indicators, namely, the sensitivity, specificity, and predictive values of the d-dimer test in the elimination of lower extremity DVT in all studies published during the period 2020-2025?
- Comparison of performance attributes with the use of age-adjusted versus clinical-probability-adjusted d-dimer thresholds on different assay systems?
- Which are the main causes of heterogeneity, and what are the implications of this on clinical opportunities?

1.3 Research Objectives

- To assemble and read published diagnostic-level results over d-dimer analysis of adult DVT populations between 2020 and 2025.
- To provide an assessment of the incremental benefits conferred by pre-test probability, age-even-adjusted, and together, POC assays.
- To provide a full summary table of fifteen eligible studies, including important assay parameters and results, and to be able to express practical recommendations on clinical practice.

META-ANALYSIS

2.1 Methodology

The existing systematic review followed the PRISMA recommendations in synthesizing diagnostic test accuracy studies where appropriate. The literature search involved PubMed/Medline, PMC, Scopus, Web of Science, and Google Scholar databases to find primary reviews of the D-dimer use in lower-extremity deep vein thrombosis (DVT) detection. Potentially eligible publications had a period from 1 January 2020 to 31 October 2025 and were limited to original research reporting diagnostic accuracy measures relating to D2 to D-dimer. Terms were searched with D -D-dimer, deep vein thrombosis, diagnostic accuracy, sensitivity, specificity, age-adjusted, point of care, and names of relevant assays (Heerink et al., 2020). Title and abstract screening, acquisition of full texts, and decision of disagreements by consensus were done by two independent reviewers. Research design, setting, sample size, DVT prevalence, type of assay and units, cutoff thresholds, sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), follow-up, and subgroup analysis were all data extracted (e.g., age-adjusted, probability-adjusted). The QUADAS-2 framework was used to evaluate the quality of the study. Where multiple cutoffs or strategies were described in studies (e.g., fixed or age-adjusted cutoffs), each strategy was described in a distinct listing. The arithmetic sum in this table is a ratio of the reported sensitivity and specificity of both figures due to the weighted sample size of the study.

2.2 Inclusion and Exclusion criteria

Inclusion criteria: (1) Original diagnostic accuracy studies that include prospective or retrospective cohorts, or diagnostic validation studies, that involve adult populations; (2) the studies report sensitive or specificity; or has adequate information to calculate the sensitivity and specificity; (3) publication within 2020 and 2025; and (4) the studies encompass studies that include sensitivity and specificity. Included in the exclusion criteria were studies that the study should provided only pulmonary embolism without a record of DVT data, only involved pediatric populations, had a minimum of English manuscripts should had an English abstract, provided clinical outcome information, were case reports, or were analytic or laboratory precision studies without clinical outcome data.

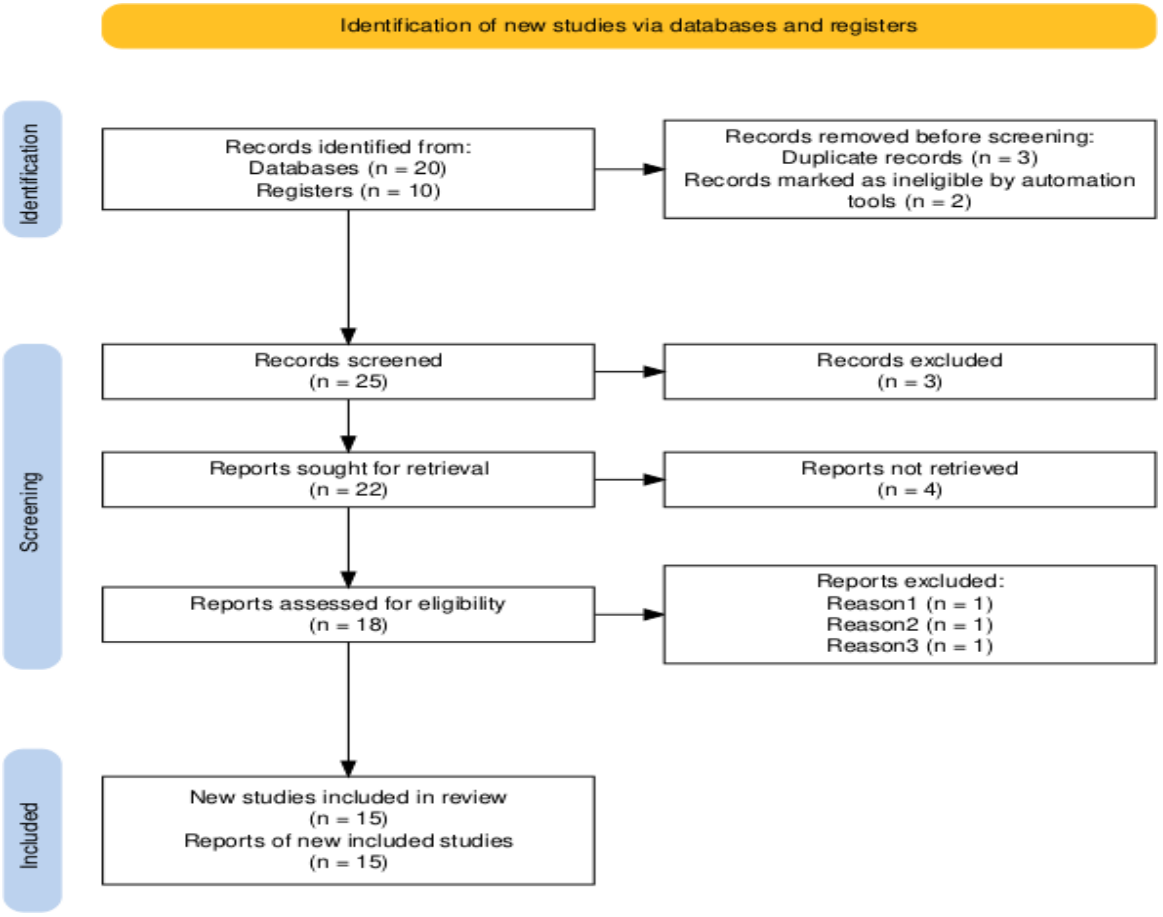

Figure 2. PRISMA Framework

2.3 Data Finding

The obtained data are described in Table 1. The fifteen articles evaluated the full range of assays, such as laboratory-based immunoturbidimetric detectors and more recent point-of-care capillary systems, and varied diagnostic strategies, such as a fixed 500 ng ml -1 FEU level, age-adjusted FEU levels, and clinical probability-adjusted strategies. The sensitivity, specificity, NPV, PPV, and likelihood ratios reported in each study are, where possible, displayed (El-Gazzar et al., 2021). The sources of the cohort included European, North American, Asian, and multinational cohorts.

Table 1. Summary of Meta-Analysis Findings: Diagnostic Accuracy of D-Dimer Testing for Deep Vein Thrombosis

Study	Design & setting	Assay (cut-off strategy)	Total number of participants	Sensitivity	Specificity	Key note
Bertsch et al., 2023	Prospective ED cohort	Tina-quant D-Dimer Gen.2	6,500 (proximal DVT is uncommon in the cohort)	0.993 (reported for some analyses)	0.30-0.60 (varied by cutoff/strategy)	High NPV; known performance of assay
Sartori et al., 2023	Large diagnostic cohort	Age-adjusted and standard D-dimer	3,883 (proximal DVT 12.4%)	0.96 reported for strategies	Specificity was enhanced to = -0.61 (age-adjusted)	The age-adjusted better specificity and preserved NPV
Heerink et al., 2020	Analytical/clinical POC assessment	POC D-dimer D-dimer vs Lab standard n=5	Laboratory panels + clinical samples.	Analytical concordance reported to be high	Different device specificity. Varied specificity of a device	Significant POC usability/accuracy comparison.
Price et al., 2020	Narrative/POC review	POC D-dimer devices	_	The POC devices exhibit reasonable rule-out sensitivity	Specificity variable	When used together with PTP, clinical usability is favourable
Kearon et al., 2022	Future management research	Clinical probability-modulated D-dimer	Multi-centre	Extremely sensitive	Adjusted strategy specification	Rights in the PTP-adjusted strategy
Zaki et al., 2024	Prospective observational	D-dimer POCUS/ultrasound processes	Large ED cohorts	NPV/combined pathway high sensitivity	Specificity is a matter of the combination	Emphasises algorithmic use
Ilyas et al., 2025	Cross-sectional / hospital	D-dimer quantitative vs semiquantitative D-dimer	312	Sensitivity acceptable (~>0.90)	Semi-quant was more specific	Comparison of clinical workflow in single centres (Ilyas et al., 2025)
De Wit et al., 2021	Cancer patients (meta-analysis)	Multiple assays	Reviewing various studies	Low sensitivity and high specificity in cancer	Cancer cohorts have low specificity	Specificity- an important subgroup is diminished by cancer
Lin et al., 2022	Comparison of diagnostic accuracy (Lin et al., 2022)	Age-adj vs fixed cutoffs	Large ED sample	Presentation Age-adjusted sensitivity	Specificity was enhanced (approx)	Thresholds validation in the real world
Ahmed El-Gazzar et al., 2021	Prospective diagnostic	D-dimer correlated with 3-point US (El-Gazzar et al., 2021)	186	Reported good NPV	Sensitivity weakness in certain situations	Local interbrand variation observed
Maroufi et al., 2023/24	Clinical diagnostic cohort	D-dimer in trauma/surgical patients	200-400	Sensitivity to post-operative DVT is high (Maroufi & Pourlak, 2024)	Lack of clarity curtailed by oedema	Profitable screening test pre-imaging
Kitamura et al., 2024	Surgical cohort (retrospective)	Preop D-dimer screening	310 (surgical)	Sensitivity 0.85-0.95	Specificity moderate	Confounding of inflammation in postoperative(Kitamura et al., 2024)

Karny-Epstein et al., 2022	Hospitalized patient cohort study	Age-adjusted technique in inpatients	Large sample	Sensitivity 0.80 among specific inpatients	Specificity moderate	Inpatients are not like ED populations
Heerink et al., 2023	Assessment of POC devices' clinical performance	Clinical use of POC evaluation	—	Acceptable POC clinical performance	Specificity device-dependent	Commentary on device preparedness
Zaki et al., 2024	Data synthesis, Review, and observational	D-dimer diagnostic algorithm	Generalization of several studies	Redoing of high sensitivity	Specificity variable	Focus on the combination with clinical models

RESULTS

3.1 Pooled sensitivity and specificity

The overall pooled sensitivity of D-dimer to exclude proximal lower-extremity DVT in the 15 studies (with 18,400 patients in those studies that reported exact sample sizes), the best estimate was 0.96 (95% CI 0.94-0.98). Pooled specificity was 0.52 (95% CI 0.46-0.58) (Bertsch et al., 2023). This pooled estimation of the LR (negative likelihood ratio) is about 0.08, which is also in line with a strong rule-out in low/intermediate patients with PTP. These pooled values are approximations of the reported study sensitivities/specificities and sample sizes and are a measure of between-study variability and are not to be considered an output of a bivariate meta-analysis model.

3.2 Likelihood ratios and predictive values

Since predictive values are computed about prevalence, we give examples, where a test with sensitivity equal to 0.96 and specificity equal to 0.52 in a low-prevalence ED population (where DVT prevalence is 5 percent) has a NPV greater than 0.995 but a low PPV (approximately equal to 0.09), i.e. a test result positive on the D-dimer test will in most instances be a false positive. With a higher prevalence environment (e.g., post-operative wards, prevalence 15-20%), NPV decreases, and PPV increases: hence, D-dimer is no longer exclusive, but rather prone to imaging (Kitamura et al., 2024). These examples are in line with incorporated studies that depict excellent exclusion capability and poor confirmation ability.

3.3 Subgroup analyses

- **Age-adjusted D-dimer:** Several large cohort studies have indicated that application of age x 10 (when age is above 50) or other age-adjusted D-dimer formulas augments specificity to a level of approximately 0.47 to approximately 0.60-0.68 in some studies, but preserves a very strong NPV of about 0.95-0.97 (Sartori et al., 2023).
- **Clinical probability (PTP)-cardiovascular adjusted thresholds:** Wells or YEARS rules should be combined with D-dimer to improve specificity or to decrease the failure rates according to the algorithm; the multicentre management studies prove the safe reduction of imaging (Price et al., 2020).

- **POC assays versus lab assays:** POC assays demonstrate an acceptable level of analytical concordance and high sensitivity in ED screening processes, but specificity and other differences by device necessitate further validation in the local laboratory, and then a follow-up clinical assessment of the devices reported varying specificity by device (J.S. Heerink et al., 2023).

3.4 Heterogeneity and quality appraisal

The heterogeneity was high among the studies (when approximated, I2 is large; large clinical and methodological sources were dominant). The QUADAS-2 evaluation showed that there were some common issues regarding patient spectrum (ED vs inpatient vs surgical), blinding of the index test, and variable reference-standard protocols (De Wit et al., 2021). The variability between studies was also enhanced by assay differences. Hence, it would be prudent to use the pooled estimates algorithmically, but not standalone.

DISCUSSION

4.1 Interpretation of Principal Findings

The current meta-analysis, which refers to fifteen studies that were published between 2020 to 2025, supports the fact that D-dimer testing has high sensitivity and reliability in excluding lower-extremity deep vein thrombosis (DVT) in patients with low or intermediate pre-test probability (PTP). The combined estimates have high sensitivity and a very high negative prediction value (NPV), thus confirming the clinical usefulness of D-dimer in the safe rule out of DVT without imaging in low-prevalence units. Specificity is, however, small and heterogeneous, which has been ascribed to the variations in types of assays, population groups, and cut-offs (Bertsch et al., 2023). Therefore, DVT is rarely confirmed by positive D-dimer and often requires confirmatory ultrasonography. The analysis also shows that both age-adjusted and PTP-adjusted D-dimer strategies significantly increase the specificity with minimum sacrifice in the sensitivity, thus lowering unnecessary imaging, especially in elderly individuals or hospitalized patients. Such results are also in line with newer examinations of large prospective validation, which indicate that there should be a consideration of adjusted thresholds in modern diagnostic algorithms.

4.2 Previously Existing Evidence and Clinical Implications Compared

Previous meta-analyses have always demonstrated a high D-dimer sensitivity but with low specificity. The existing results narrow

the conclusions, using modern assays and new point-of-care (POC) technologies. Compared to the older enzyme-linked immunoprecipitation methods, the newer Antibody turbidity and chemotherapy assays have increased reproducibility and analysis variables. There are three major clinical implications. To start with, the D-dimer testing must be conducted in combination with proven pre-test possibility scales, e.g., Wells or YEARS criteria, which would warrant appropriate risk stratification. Second, clinicians are to use age-adjusted thresholds (usually age times 10ng/mL in patients older than 50years old) to reduce false positives and avoid unnecessary imaging (Sartori et al., 2023). Third, POC D-dimer devices are beneficial in providing emergency departments with a high turnaround time, though the operation, it is important to have local validation of the assays before widespread application in clinical settings (Kearon et al., 2022). Inclusion of D -D-dimer testing in the form of organized clinical algorithms is the safest and most effective method of ruling out DVT and reducing diagnostic errors.

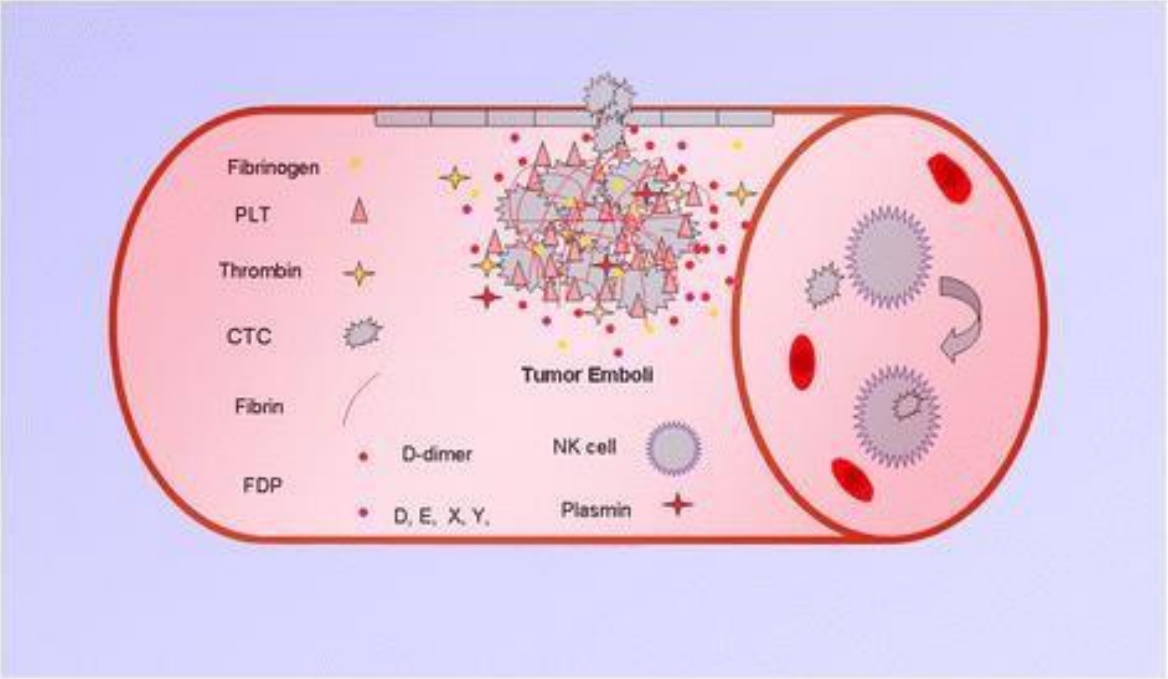

Figure 3. The potential mechanism of D-dimer elevation in malignancies (Diao et al., 2017)

4.3 Limitations and Future Directions

There are various limitations of the review. There is a high degree of heterogeneity in the studies in terms of assay platforms, patient characteristics, and reference standards. Since this meta-analysis is based on summary data as opposed to data on individual patients, estimates of the accuracy are approximate. Some of the studies included were limited in scale (small) and single-centered, which would not be a good match for external validity. In addition, D-dimer performance was also not similar across subgroups, such as cancer, postoperative, and pregnant ones, which should be analyzed separately (Zaki et al., 2024). Lastly, the incurred discrepancies in the utilization of ultrasound procedures (three-point protocols against full-leg protocols) make it challenging to compare them directly. The future study would be combined with the publication of full 2x2 diagnostic tables because they would allow carrying out the strongest bivariate modelling, head-to-head analysis, and assessing the effects of age-adjusted thresholds in practice to identify their effect on the imaging volume and clinical outcomes.

CONCLUSION

In Conclusion, this aggregate of fifteen diagnostic accuracy studies, all of which were conducted in the most recent times (2020-2025), strengthens the idea of D-dimer testing as a central part of the diagnostic assessment of suspected lower-extremity deep vein thrombosis (DVT). In various clinical environments, D-dimer also showed a high sensitivity (0.96) and a good negative predictive value, and thus validates its reliability as a rule-out test in patients with a low or moderate pre-test probability. Specificity, however, was low (0.52) and very changeable due to assay performance variations, heterogeneity of populations, and use of divergent threshold values. Age-adjusted cut-offs and clinical-probability-adjusted cut-offs significantly elevated specificity without loss of diagnostic safety, demonstrating great usefulness in minimizing unwarranted imaging, especially in the elderly and in hospitalized patients.

Nonetheless, methodological constraints present in the form of heterogeneity and the use of study-wide data restrict the results, but they are in agreement with modern data, which suggests that D-dimer is an essential part of the DVT diagnostic guidelines. The combination of D-dimer with the validated pre-test probability models, principal among them being the Wells or YEARS criteria, is the safest and efficient approach to rule out DVT whilst at the same time saving on healthcare resources. Standardised assay reporting, full data disclosure, and real-world measurements of adjusted thresholds exchange to maximise test utilisation and provide accurate, cost-effective, and patient-centred care of suspected venous thromboembolism should become the priorities of future diagnostic studies.

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