Appraisal for diagnostic test

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International, multicentre evaluation of a New D-dimer assay for the exclusion of venous thromboembolism using standard and age-adjusted cut-offs

使用标准和年龄调整临界值对新 D-二聚体检测排除静脉血栓栓塞的国际多中心评估

Known to have low specificity for cutoff of 500

In this study

1.Compare new agent Innovance vs. Vidas

2.Try to increase specificity by age-adjusted cutoff point

已知对 500 的截止值具有低特异性

在这项研究中

•比较新代理 Innovance 与 Vidas

•尝试通过年龄调整的截止点，提高特异性

Clinical Directness 临床直接性

Inclusion criteria

- Presented to ED or Outpatient with suspicion of DVT or PE in 24 centres (18 USA, 6 Europe)
- Referred for objective testing using diagnostic algorithms to rule out PE and/or DVT
- Low/ intermediate pretest probability (Wells PE score, Wells DVT score)

纳入标准

在 24 个中心（18 个美国，6 个欧洲）就诊于 ED 或门诊

怀疑 PE, 使用诊断进行客观测试以排除 PE

低/中预测概率（Wells PE 分数）

Exclusion criteria 排除标准

- Patients under the age of 18
- Known pregnancy
- Inpatient
- Symptoms resolved for >72 h before presenting
- Patient suspected to have a thrombus in the upper extremities
- Arterial thrombosis
- Any treatment with anticoagulants (e.g. Vitamin K antagonists, unfractionated heparin, low-molecular heparin, pentasaccharide, and other direct thrombin and FXa-inhibitors) for >24 h prior to collection of blood sample
- **High/likely pre-test probability** 高预测概率

***Exposure** 干预*

•INNOVANCE D-dimer assay 新的 d-二聚体检测

***Outcome** 验证*

•Verification for VTE 静脉血栓栓塞

•by CTPA (CT 肺血管造影) V/Q scan (通气灌注扫描)

Validity有效性

Spectrum bias 频谱偏差

- in-patient not included
- the study didn't include patients with high Wells score
- Well score catergory: Low>> Intermediate --> Less severe case, more easy to rule out?
- 不包括住院病人
- 该研究不包括 Wells 评分高的患者
- 低>>中级 --> 不太严重的情况，更容易排除？

Verification bias 验证偏差

Not all subjects recruited have GOLD standard test(CTPA)

Patients with negative evaluation --> PE or DVT during 3-month follow up call/ review of medical record --> ? CTPA/ VQ scan/venous U/S

Performance of test- different brand of D-dimer test was used (INNOVANCE in US, VIDAS D-dimer assays in Europe)

? FU after 3 months , any time effect?

Blinding of outcome assessor

并非所有招募的受试者都有 GOLD 标准测试 (CTPA)

评估为阴性的患者 --> 在 3 个月的随访电话/病历审查期间发生 PE --> ? CTPA/ VQ 扫描测试

性能-使用不同品牌的D-二聚体测试（美国INNOVANCE，欧洲VIDAS D-二聚体检测）

? FU 3个月后，有什么时间影响吗？

结果评估者的盲法

Result:
sensitivity 98.0%, specificity 55.4%,
negative predictive value (NPV) 99.8%,
positive predictive value (PPV) 11.4%

Age adjustment increased specificity from 55.4% to 59.6%
But, age-adjustment decreased sensitivity.

结果：敏感性 98.0%，特异性 55.4%，
阴性预测值 (NPV) 99.8%，阳性预测值 (PPV) 11.4%
年龄调整将特异性从 55.4% 提高到 59.6%
但是，年龄调整降低了敏感性。

- High ‘loss to follow-up’ rate
- Conflict of interest:利益冲突
- the research is sponsored by Siemens Healthcare Diagnostics, Inc,
- no role in analysis or interpretation of data
- 该研究由西门子医疗诊断公司赞助，
- 不参与数据分析
- End