

Title	Optimal Strategies for the Diagnosis of Acute Pulmonary Embolism: A Health Technology Assessment
Agency	CADTH
Reference	Optimal Strategies for the Diagnosis of Acute Pulmonary Embolism: A Health Technology Assessment. Ottawa: CADTH; 2018 Jan. (CADTH optimal use report; vol.6, no.3b).

Aim

The objective of this health technology assessment (HTA) is to determine the optimal diagnostic strategy for a acute pulmonary embolism (PE) in urban, rural, and remote settings through an assessment of the diagnostic test accuracy, clinical utility, safety, cost-effectiveness, patients' perspectives and experience, implementation issues, and the environmental impact of strategies for the diagnosis of adults with suspected PE.

Conclusions and results

Clinical Review

A review of risk stratification rules found that the Wells rule was better able to correctly identify patients who did not have a PE compared with the Geneva score or the revised Geneva score. When it comes to correctly identifying patients who have a PE, no rule showed a consistent advantage over the others. A review of the evidence on diagnostic imaging found that computed tomography pulmonary angiography (CTPA) was best able to correctly identify patients with a PE; however, alternative strategies may be considered where there is a heightened concern about radiation exposure (e.g., in pregnancy).

Economic Review

An approach using clinical prediction rules (CPRs) followed by CTPA (if appropriate) was found to be cost-effective. Specifically, the strategy of the two-tiered Wells rule, followed by D-dimer (for those with a low-risk to moderate-risk Wells), and followed by CTPA (if appropriate), was cost-effective if the willingness-to-pay threshold was between \$13,556 and \$57,097 per quality-adjusted life-year (a measure of the value for money of medical procedures and interventions). For patients who are not able to undergo or who wish to avoid computed tomography, inclusion of ventilation-perfusion–single-photon emission computed tomography (VQ-SPECT) and leg ultrasound in the diagnostic pathway were found to be cost-effective.

Patient Experiences and Perspectives

Findings from the patient review were focused mainly on diagnostic imaging. While these tests may be uncomfortable to undergo, the ability of the tests to shed light on current or prospective health problems was helpful to some patients. However, some patients described the testing experience in terms of feeling isolated and unprepared, and lacking self-control. Physical reminders that patients are not alone (e.g., the presence of loved ones in the room if possible) may help with these feelings.

Implementation Issues

Provider knowledge and choice (e.g., use of tests most familiar to them) may influence the initial assessment and investigation of suspected PE. Additionally, patient factors — such as age, gender, and other illnesses — may influence the diagnosis of suspected PE. Policies and protocols (e.g., documented use of a CPR before additional testing) can be used to support the diagnostic strategies for PE. It is important to note that resources, including staffing, access to tests, scans and imaging, are differentially located across the country.

Ethical Issues

Clinicians, health care organizations, and policy-makers must consider the views and interests of those involved in PE diagnosis, and the variation in individual patient needs. Based on the clinical and economic evidence, the use of CTPA appears to be the most favourable diagnostic imaging tool for an ethical approach to PE diagnosis, unless patients cannot undergo CTPA.

Environmental Issues

No relevant studies or reports were found that evaluated the environmental impact of imaging modalities for PE (based on a limited literature search).

Recommendations

For the general population with suspected PE, the Health Technology Expert Review Panel (HTERP) recommends the two-tier Wells rule, followed by D-dimer testing, followed by CTPA, as a diagnostic pathway.

For the pregnant population, HTERP recommends the two-tier Wells rule, followed by Pulmonary Embolism Rule-Out Criteria (PERC) and D-dimer testing, followed by leg ultrasound and, if necessary, CTPA as a diagnostic pathway. However, where there is a heightened concern about radiation exposure, and where the clinical situation allows, it would also be reasonable for the clinician and patient to undertake a shared decision-making process to select between CTPA and VQ-SPECT as the final step in the diagnostic pathway.

Among patients for whom computed tomography is strongly contraindicated, HTERP recommends the two-tier Wells rule, followed by D-dimer testing, followed by VQ-SPECT, and if necessary, leg ultrasound as a diagnostic pathway.

Methods

An overview of systematic reviews on risk stratification strategies was performed, and a de novo systematic review and meta-analyses were conducted on diagnostic pathways and diagnostic imaging studies. Two reviewers independently, and in duplicate, screened all titles and abstracts of citations identified by the search as well as the full-text articles.

A decision-analytic hybrid model was constructed to examine the clinical outcomes and costs associated with the diagnostic management of patients suspected of having a acute PE. It entailed an upfront decision tree that captured the short-term screening outcomes and a downstream Markov model to capture the long-term outcomes following a correct or incorrect diagnosis. The clinical pathway and decision-analytic model were developed by reviewing existing clinical and economic literature.

A rapid review of the published qualitative literature was conducted to gain an understanding of patients', family members', and nonclinical caregivers' perspectives and experiences of the process of undergoing diagnosis for a acute PE. A descriptive analysis was performed to characterize the included studies in terms of important study and patient characteristics (e.g., sample size, inclusion criteria), and a thematic analysis was conducted by a single reviewer.

A survey was developed to provide information and context on implementation considerations, and conducted as part of a CADTH Environmental Scan to identify current practice and relevant implementation issues related to diagnostic strategies for PE in Canada. A targeted literature search was conducted to identify information on issues relevant to implementation of diagnostic strategies for PE in Canada. To supplement the findings of the survey and the literature search, an interview with a clinical expert in the field of emergency medicine was conducted. This interview centred on the expert views of the approach to diagnosing PE, including challenges to diagnosis and the Canadian context.

A review of the empirical and normative bioethics literature was conducted to identify two types of literature relevant to the identification and analyses of the potential ethical issues with diagnosing a acute PE. The selection of relevant literature occurred in two stages. In the first stage, the title and abstracts of citations were independently screened for relevance by one reviewer. Articles were categorized as "potentially relevant" or "not relevant" based on whether ethical issues were explicitly mentioned. In the second stage, full-text reports that pertained to strategies for the diagnosis of a acute PE and suggested implicit ethical issues were identified by two reviewers.

To identify environmental issues related to the choice of modalities for diagnosing PE, a literature search was performed by an information specialist, using a peer-reviewed search strategy. Two reviewers screened the titles and abstracts of all citations retrieved from the literature search for relevant studies and reports. Full-text articles were retrieved and assessed for inclusion by the two reviewers if either of them considered a citation potentially relevant to the research question.

Further research/reviews required

Given the concern about exposure to radiation, particularly for certain susceptible patient populations, there are opportunities for the development of reduced-dose protocols, more sensitive detectors, and imaging modalities that do not involve ionizing radiation, e.g., MRI. The use of imaging modalities capable of higher resolution leads to the identification of smaller and more peripheral emboli. Research is required to identify their clinical significance and determine the risk-benefit of treatment.

As little has been done to explore experiences or perspectives of individuals undergoing diagnostic imaging for PE, it would be interesting to see how PE-specific experiences align with more general experiences associated with imaging modalities identified in this report.

There remains a need for more research concerning the impact of PE diagnostic pathways on both the environment and population health.

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