

- Title** Alternative(s) to perfusion scintigraphy in case of suspected non-massive pulmonary embolism in pregnant women in the event of a complete shortage of technetium-99m
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Aim

Due to several periods of worldwide supply shortage of technetium-99m (Tc-99m), a radioactive element needed to perform lung perfusion scintigraphy in case of suspected non-massive pulmonary embolism (PE), the Ministry of Health (DGS) asked HAS to determine if, in the event of complete shortage of this isotope, one (or more) test(s) could replace it without risk to the pregnant woman.

Currently, Tc-99m lung perfusion scintigraphy is the medical imaging test of choice in pregnant women initially without signs of shock or hypotension (especially if the triage chest x-ray is normal) when this test is readily accessible for the clinician. Offering good diagnostic performances, lung perfusion scintigraphy is not very radiating for the mother and foetus.

The objective of this assessment was not to question the current standard strategy in this situation or to establish good practice guidelines.

Conclusions and results

Three good quality practice guidelines were selected.

The analysis of these guidelines cannot be used to conclude directly on the assessment question asked because the hypothesis of a Tc-99m shortage was not clearly foreseen in these guidelines.

However, a convergence was identified between the guidelines (and professionals who responded to the request for advice) with regard to two non-technetium tests **considered validated** in the current management of these women, namely:

- pulmonary CT angiography (with a protocol adapted to pregnant women): genuine alternative test to the perfusion scintigraphy, able to perform a confirmatory diagnosis;
- compression ultrasonography (with Doppler mode) of the entire proximal venous system¹ of the lower limbs: test possible in pregnant women presenting with symptoms associated with phlebitis. In case of clinical suspicion of PE, a positive proximal ultrasound is highly presumptive of the lung disease and leads to an identical therapeutic treatment (without use of CT angiography).

¹ Direct search for thrombi in the femoral and iliac veins to the popliteal vein.

For French representing of gynaecology and obstetrics, anaesthesia and intensive care, and radiology, pulmonary CT angiography is currently performed routinely in pregnant women suspected to have PE.

The recommendations and positions of the French professional organisations that responded to the request for advice are consistent among each other and affirm that two other tests **are not currently validated** in daily practice, namely:

- magnetic resonance pulmonary imaging with gadolinium (remaining within the field of clinical research);
- digital subtraction pulmonary angiography (due to significant maternal radiation and the degree of invasiveness of the procedure).

In the context of a complete shortage of Tc-99m, the diagnostic strategy could be as follows: a pulmonary CT angiography preceded or not, depending on the patient's clinical symptoms, by a proximal venous compression ultrasound (with Doppler). If diagnostic doubt persists, it is possible to perform a new series of proximal venous ultrasounds after the initial assessment.

In terms of safety, pulmonary CT angiography leads to a greater breast radiation than that of the perfusion scintigraphy. However, in the context of a complete shortage of Tc-99m, not performing a confirmatory test such as pulmonary CT angiography poses a proven risk for the mother and foetus² greater than the theoretical risk of radiation-induced breast cancer in the mother. This position identified in the literature is consistent with the position of the French professional organisations that responded to the request for advice. In the event of recourse to venous compression ultrasonography, this presents no particular risk for the mother and foetus.

With the CT angiography, the foetal radiation (negligible dose) is equivalent to that of the lung perfusion scintigraphy. The selected guidelines and the analyses of the four safety studies available did not report any cases of induced hypothyroidism in the newborn after injection of an iodinated contrast product during the pregnancy. The

² Sudden death of the mother and of the foetus, unnecessary continuation of anticoagulants, negative and unnecessary consequences on the course of pregnancy and postpartum period.

French professional organisations that responded to the request for advice insisted on the need to provide patients with reassuring information about all of the safety aspects related to the pulmonary CT angiography in the interest, above all, of obtaining a rapid diagnosis. Finally, a certain number of technical precautions are necessary when performing a pulmonary CT angiography in a pregnant woman (with details in the complete report).

In summary:

In the event of a complete shortage of Tc-99m and if there is a suspicion of non-massive PE in a pregnant woman:

- pulmonary CT angiography (with a protocol adapted to pregnant women) is an alternative test to the perfusion scintigraphy;
- venous compression ultrasonography (Doppler mode) of the proximal lower limbs (LL) could be an element of assessment as part of the diagnostic approach for pulmonary embolism, in case of phlebitis symptoms.

Methods

The method of assessment³ consisted of:

- seeking possible convergence regarding the validation of one (or more) alternative non-technetium test(s) in pregnant women suspected to have non-massive PE as part of good quality practice guidelines and health technological assessment reports (in French or English) published between January 2009 and January 2016;
- gathering the views of relevant stakeholders⁴.

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³ See the roadmap: http://www.has-sante.fr/portail/jcms/c_2011763/fr/actualisation-de-la-liste-des-examens-scintigraphiques-au-99m-technetium-tc-prioritaires-en-situation-de-forte-tension-dapprovisionnement-pour-cet-isotope-feuille-de-route

⁴ National professional associations of gynaecology-obstetrics, nuclear medicine, radiology, cardiology, anaesthesia-intensive care, paediatrics; French Federation of Pulmonology; French Association of Emergency Medicine; French Society of Radiation Protection; French Society of Medical Physics; Agency for Nuclear Safety and Institute of Radiation Protection and Nuclear Safety.