

COMMENTARY

Deep vein thrombosis testing in pregnancy: where is the evidence? Commentary on “Use of single whole-leg ultrasound to exclude suspected deep vein thrombosis in pregnant patients”

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Pregnant people have been systematically excluded from participation in clinical studies on deep vein thrombosis (DVT) diagnosis. For example, pregnant patients were excluded from derivation and validation of the Wells score [1,2] and studies validating the use of D-dimer [3–5] and ultrasound [6] for DVT testing. Systematic exclusion of specific populations leads to substandard quality of care for these people. While researchers may have been well-meaning (reluctant to expose pregnant patients to potential risk from a new research test), the lack of research means that pregnant people may experience misdiagnosed DVT and paradoxical inferior care [7]. The exclusion of pregnant people from research is problematic because physicians today lack adequate evidence to guide care.

The limited epidemiologic evidence available suggests that DVT in pregnancy differs from DVT in the nonpregnant population, meaning it is uncertain whether we can extrapolate the diagnostic test accuracy reported in studies where pregnancy was an exclusion criterion to pregnant persons. DVT in pregnancy occurs more commonly in the iliofemoral veins compared to DVT diagnosed in nonpregnant patients [8]. Ultrasound of the iliofemoral veins may be more challenging to perform in gravid women. Taken together, there is a concern that ultrasound may not be as sensitive in diagnosing DVT during pregnancy as reported in other populations tested for DVT.

Although pregnancy increases the risk of DVT 4- to 5-fold [9], pregnant patients make up a very small proportion of all patients who are tested for DVT. Very few pregnant patients have been recruited to diagnostic DVT studies when pregnancy was not an exclusion criterion. A 2010 meta-analysis of the false negative rate following a single

whole-leg compression DVT ultrasound identified 7626 study patients with an initial negative ultrasound but only 57 pregnant patients [10]. A 2019 meta-analysis of pregnancy studies identified only 726 pregnant patients followed after a single negative ultrasound scan, with only 343 of them having undergone whole-leg compression ultrasound [11].

In this issue, Parks et al. report the safety of performing a single whole-leg compression ultrasound to exclude DVT in 186 pregnant patients, contributing sizably to the existing literature. This important and well-conducted study found that 2 participants (1.1%; 95% CI, 0.2%–3.4%) were subsequently diagnosed with femoral vein DVT of the ipsilateral leg 6 and 9 days following their initial negative ultrasound. Their findings are in agreement with a meta-analysis of prior publications reporting a false negative rate of 0.85% (95% CI, 0.13%–2.17%) for a single negative whole-leg ultrasound in pregnant patients [11]. As yet, there are insufficient data to understand how the safety of a single whole-leg ultrasound in a symptomatic pregnant patient compares to the nonpregnant population.

The need to study health in pregnancy remains as critical as ever. The practice of excluding pregnant people from research emerged once more during the COVID-19 pandemic, with a renewed call to action to include pregnant people in all research by default [12]. It is time for researchers and funding agencies to prioritize pregnant women who remain understudied and clinically disadvantaged.

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