4. **Pulse Oximetry screening for congenital heart defects in newborn infants (PulseOx): a test accuracy study.** Ewer AK, Middleton LJ, Furmston AT, et al, on behalf of the PulseOx Study Group. *Lancet* 2011;378:785–94.
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Antenatal ultrasonography and postnatal clinical examination are the current standard methods of screening for congenital heart disease (CHD); however, life-threatening defects often are not detected. This large multicentric prospective study from UK assesses the accuracy of pulse oximetry as a screening test for congenital heart defects.

In six maternity units in the UK, 20,055 asymptomatic newborn babies (gestation >34 weeks) were screened with pulse oximetry before discharge. Infants who did not achieve predetermined oxygen saturation thresholds underwent echocardiography while all others were followed up to 12 months of age. The main outcome was the sensitivity and specificity of pulse oximetry for detection of critical congenital heart defects (causing death or requiring invasive intervention before 28 days of life) or major CHD (causing death or requiring invasive intervention within 12 months of age). Fifty-three babies had major CHD (24 critical), a prevalence of 2.6 per 1000 live births. Analyses were done on all babies for whom a pulse oximetry reading was obtained. Sensitivity of pulse oximetry was 75% (95% CI 53.29–90.23) for critical cases and 49.06% (35.06–63.16) for all major congenital heart defects. Congenital heart defects were already suspected after antenatal ultrasonography in 35 cases and if these cases are excluded the sensitivity of pulse oximetry further reduced to 58.33% (27.67–84.83) for critical cases and 28.57% (14.64–46.30) for major defects. There were 169 (0.8%) false positive results (specificity 99.16%, 99.02–99.28) of which 6 cases were significant, but not major congenital heart defects, and 40 were other illnesses that required urgent medical intervention.

Pulse oximetry is a safe and feasible test that adds value to existing screening. It identifies cases of critical congenital heart defects that go undetected with antenatal ultrasonography with an additional advantage of early detection of other diseases.

Perspective

It is important to detect major life-threatening congenital heart defects in time as sudden deterioration may occur in newborn babies with critical or major congenital heart defects. This is the largest study of its kind, by the National Institute of Health Research, United Kingdom and aims at assessing efficacy of pulse oximetry as a screening tool for congenital heart defects. In accordance with other recent studies, the results support the routine practice of pulse oximetry in neonates. The sensitivity of pulse oximetry is consistently proven to be from 50% to 80% which may not be acceptable for screening of potentially fatal major congenital heart defects. Furthermore, additional cost might explain current hesitation for widespread use of pulse oximetry of all newborns. In developing countries like India, where substantial numbers of deliveries are not supervised and occur outside the hospital the implementation remains an important issue. Furthermore, accuracy would be different in neonatal population where respiratory causes of desaturation are not uncommon. For pulse oximetry to be of utility, it is imperative to perform this test properly, preferably by using a plethysmograph which displays arterial waveform, lest errors of measurement may occur.

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1. **Rivaroxaban versus warfarin in nonvalvular atrial fibrillation.** Manesh R, Patel MD, Kenneth W, et al and the ROCKET AF Steering Committee for the ROCKET AF Investigators. *N Engl J Med* 2011;365:883–91.
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Background: The use of warfarin reduces the rate of ischaemic stroke in patients with atrial fibrillation (AF) but requires frequent monitoring and dose adjustment. Rivaroxaban, an oral factor Xa inhibitor, may provide more consistent and predictable anti-coagulation than warfarin.

Methods: In a double-blind trial, the authors randomly assigned 14,264 patients with non-valvular AF who were at increased risk for stroke to receive either rivaroxaban (at a daily dose of 20 mg) or dose-adjusted warfarin. The per-protocol, as-treated primary analysis was designed to determine whether rivaroxaban was non-inferior to warfarin for the primary end point of stroke or systemic embolism.

Results: In the primary analysis, the primary end point occurred in 188 patients in the rivaroxaban group (1.7% per year) and in 241 in the warfarin group (2.2% per year) (hazard ratio in the rivaroxaban group, 0.79; 95% confidence interval [CI], 0.66–0.96; $P < 0.001$ for non-inferiority). In the intention-to-treat analysis, the primary end point occurred in 269 patients in the rivaroxaban group (2.1% per year) and in 306 patients in the warfarin group (2.4% per year) (hazard ratio, 0.88; 95% CI, 0.74–1.03; $P < 0.001$ for non-inferiority; $P = 0.12$ for superiority). Major and non-major clinically relevant bleeding occurred in 1475 patients in the rivaroxaban group (14.9% per year) and in 1449 in the warfarin group (14.5% per year) (hazard ratio, 1.03; 95% CI, 0.96–1.11;