

Cochrane for Clinicians

Putting Evidence into Practice

Pulse Oximetry Screening for Critical Congenital Heart Defects in Newborns

Tyler Barreto, MD, University of Texas Health San Antonio, San Antonio, Texas

Author disclosure: No relevant financial affiliations.

Clinical Question

Is pulse oximetry a diagnostically accurate screening test for critical congenital heart defects in newborns?

Evidence-Based Answer

Pulse oximetry is an accurate screening test for critical congenital heart defects in newborns. Pulse oximetry is simple to use, widely available, and has moderate sensitivity (76.3%) and good specificity (99.9%). However, the prevalence of critical congenital heart defects is low, and most newborns who screen positive do not have a critical congenital heart defect.¹ (Strength of Recommendation: B, based on limited-quality patient-oriented evidence.)

Practice Pointers

Congenital heart defects occur in approximately 1% of live births in the United States. About 25% of those newborns are considered to have a critical congenital heart defect.² Mortality rates vary by the exact diagnosis but range as high as 30% and are likely decreased with early detection.^{3,4} Because most critical congenital heart defects are amenable to treatment, and newborns with these types of heart defects are usually asymptomatic, a good screening test may decrease mortality. The purpose of this Cochrane review was to determine the accuracy of pulse oximetry as a screening test for critical congenital heart defects.¹

This Cochrane review examined 19 cohort and cross-sectional studies of low to moderate quality with 436,758 asymptomatic term or late preterm newborns who received screening in a newborn nursery setting.¹ Newborns who were screened at home or in the neonatal intensive care unit were excluded from the review. The studies were spread across 13 countries, with only two from the United States. Each of the studies in the United States included a cohort of approximately 10,000 to 15,000 newborns and lacked adequate follow-up.

Eleven studies measured oxygen saturation in the foot alone (postductal), and eight studies measured it in the hand and foot (preductal and postductal). Eight studies measured the oxygen saturation within 24 hours of life, and the others measured it after 24 hours of life. A positive screen was defined as an oxygen saturation of less than 95% in 14 studies and 95% or less in five studies. Echocardiography was subsequently performed in all infants who screened positive. Studies described clinical follow-up, a review of mortality or cardiology data, or no confirmation for newborns with negative screens.

The sensitivity of pulse oximetry for the detection of critical congenital heart defects was 76.3% (95% CI, 69.5 to 82.0), and the specificity was 99.9% (95% CI, 99.7 to 99.9). This review found that for every 10,000 asymptomatic term or late preterm newborns screened by pulse oximetry, five out of every six newborns with critical congenital heart defects will screen positive with an oxygen saturation of 95% or less, and there will be 14 false positives.

Currently, 48 states mandate routine screening for critical congenital heart defects in newborns.⁵ A recent article found that infant deaths caused by critical congenital heart defects decreased significantly in states that implemented mandatory screening policies during the study period (from 2007 to 2013).⁶ Nevertheless, there is the potential for false positives, which may lead to increased anxiety for parents.¹ Physicians should be aware of the false-positive rate of this screening test when counseling parents after a positive screen.

The practice recommendations in this activity are available at <http://www.cochrane.org/CD011912>.

These are summaries of reviews from the Cochrane Library.

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CME This clinical content conforms to AAFP criteria for continuing medical education (CME). See CME Quiz on page 418.

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Direct Oral Anticoagulants vs. Warfarin to Prevent Stroke and Embolic Events in Patients with Atrial Fibrillation and CKD

John W. Lax, MD, Uniformed Services University of the Health Sciences, Bethesda, Maryland

Racheal Wood, DNP, ACCNS-AG, Fort Belvoir Community Hospital, Fort Belvoir, Virginia

Christopher E. Jonas, DO, FAAFP, CAQSM, Uniformed Services University of the Health Sciences, Bethesda, Maryland

Author disclosure: No relevant financial affiliations.

Clinical Question

Are direct oral anticoagulants safe and effective for preventing stroke and embolism in patients with atrial fibrillation and chronic kidney disease (CKD)?

Evidence-Based Answer

Direct oral anticoagulants are as likely as warfarin to prevent all strokes and systemic embolic events in patients with atrial fibrillation and CKD stage 3. They do not increase the risk of major bleeding events. The evidence remains insufficient to make recommendations for the use of direct oral anticoagulants in the management of patients with atrial fibrillation and CKD stage 4 or 5.¹ (Strength of Recommendation: A, based on consistent, good-quality patient-oriented evidence.)

Practice Pointers

Atrial fibrillation and CKD are independent risk factors for stroke and embolic events.² Current evidence suggests an improved health-related quality of life with the use of direct oral anticoagulants vs. traditional treatment with vitamin K antagonists (e.g., warfarin) for patients with an increased risk of stroke.³ The authors of this Cochrane review sought to determine the safety and effectiveness of stroke and embolism prevention with direct oral anticoagulants vs. warfarin in the management of chronic, nonvalvular atrial fibrillation in patients with CKD stage 3 and 4.¹

This Cochrane review included five trials involving 12,545 patients. The follow-up time ranged from 1.8 to 2.8 years. Identified studies compared direct oral anticoagulants and warfarin to prevent stroke (including ischemic, hemorrhagic, or unspecified) and embolism in patients with nonvalvular atrial fibrillation and moderate CKD (i.e., stage 3 and 4), defined as a creatinine clearance between 15 and 60 mL per minute per 1.73 m².

Patients who used direct oral anticoagulants seemed to have a decreased risk of stroke and embolic events vs. patients receiving warfarin, but these results did not reach statistical significance and thus these agents should be considered equivalent.

SUMMARY TABLE: DIRECT ORAL ANTICOAGULANTS VS. WARFARIN TO PREVENT STROKE AND EMBOLISM IN PATIENTS WITH ATRIAL FIBRILLATION AND CKD

Outcome	Relative risk (95% CI)	Assumed risk: warfarin	Corresponding risk (95% CI): direct oral anticoagulants	Number of participants (number of studies)
All strokes and systemic embolic events	0.81 (0.65 to 1.00)	29 per 1,000	23 per 1,000 (19 to 29)	12,545 (5)
Major bleeding	0.79 (0.59 to 1.04)	55 per 1,000	43 per 1,000 (32 to 57)	12,521 (5)
Gastrointestinal bleeding	1.40 (0.97 to 2.01)	17 per 1,000	24 per 1,000 (17 to 35)	5,678 (2)
Intracranial hemorrhage	0.43 (0.27 to 0.69)	14 per 1,000	6 per 1,000 (4 to 9)	12,521 (5)
All-cause mortality	0.91 (0.78 to 1.05)	78 per 1,000	71 per 1,000 (61 to 82)	9,595 (4)

Note: Follow-up was 1.8 to 2.8 years.

CKD = chronic kidney disease.

Various secondary outcomes were also evaluated. Patients using direct oral anticoagulants were at less risk of developing intracranial hemorrhage vs. those using warfarin (relative risk [RR] = 0.43; 95% CI, 0.27 to 0.69; number needed to treat = 125; 95% CI, 100 to 200). This review demonstrated a slight, although not statistically significant, increase in gastrointestinal bleeding with direct oral anticoagulant use vs. warfarin. Patients using direct oral anticoagulants seemed to have a slightly lower risk of major bleeding and all-cause mortality than those using warfarin, but again those results were not statistically significant, so these agents should be considered equivalent in this regard.

Subgroup analysis showed that patients with CKD stage 3 experienced the most benefit from direct oral anticoagulants in terms of risk reduction for stroke, whereas the risk reduction was less conclusive in the CKD stage 4 group (RR = 0.68; 95% CI, 0.23 to 2.0), despite U.S. Food and Drug Administration approval of its safety in this population. Further analysis evaluated dosages and various subtypes of direct oral anticoagulants; however, the available data were lacking to make meaningful conclusions.

Evidence supports the use of anticoagulation to treat concomitant nonvalvular atrial fibrillation and moderate CKD to lower the risk of stroke and embolic events.⁴ This Cochrane review provides support for the safety and effectiveness of direct oral anticoagulants in lowering the risk of stroke and embolic events in patients with atrial fibrillation and CKD.

The practice recommendations in this activity are available at <http://www.cochrane.org/CD011373>.

Editor's Note: The number needed to treat reported in this Cochrane for Clinicians was calculated by the authors based on comparison of assumed risk and corresponding risk.

The opinions and information provided in this article reflect the authors as individuals alone and do not reflect or represent any official opinions or statements of any component of the Department of Defense, U.S. Air Force, U.S. Army, or the Uniformed Services University of the Health Sciences.

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