

POEMs: Patient-Oriented Evidence That Matters

Rivaroxaban Is No Better Than Aspirin After Catheter Ablation for Atrial Fibrillation at Least 1 Year Earlier

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Author Disclosure: No relevant financial relationships.

CLINICAL QUESTION

In patients who had a successful catheter ablation for atrial fibrillation at least 1 year ago, is there a net benefit to continued anticoagulation?

BOTTOM LINE

In patients who had a successful catheter ablation for atrial fibrillation, stopping the anticoagulant after 1 year is safe. (Level of Evidence = 1b)

SYNOPSIS

The researchers identified patients who had undergone a successful catheter ablation procedure for atrial fibrillation at least 1 year ago, with success confirmed by Holter monitoring, including a 48-hour monitoring within 2 months of study enrollment. All patients had a CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥ 75 [doubled], diabetes, stroke [doubled], vascular disease, age 65 to 74, sex [female]) score of 1 or more (men) or 2 or more (women). Groups were balanced at baseline, with a mean age of 66 years, approximately three-fourths had only a single ablation, and two-thirds had paroxysmal atrial fibrillation. Analysis was by intention to treat. Participants were randomized to receive rivaroxaban (Xarelto), 15 mg or low-dose aspirin and were followed up for a median of 3 years. Magnetic resonance imaging was performed at baseline and at the end of follow-up to detect any covert embolic strokes. The trial was stopped early for futility, and the primary outcome of stroke, systemic embolism, or covert stroke occurred in five patients in the rivaroxaban group and nine in the aspirin group (0.8% vs 1.4%; absolute risk difference = 0.6%; 95% CI, -1.8 to 0.5). However, major bleeding occurred numerically

more often in the rivaroxaban group (1.6% vs 0.6%; hazard ratio = 2.5; 95% CI, 0.8-8.0). The combination of major bleeds and preventing stroke and embolism makes it a wash. The overall rate of stroke was low and similar to that in people without a history of atrial fibrillation.

Study Design: Randomized controlled trial (single-blinded)

Funding Source: Government, foundation, and industry

Allocation: Concealed

Setting: Outpatient (any)

Reference: Verma A, Birnie DH, Jiang C, et al.; OCEAN Investigators. Antithrombotic therapy after successful catheter ablation for atrial fibrillation. *N Engl J Med*. 2026;394(4):323-332.

Editor's Note: Dr. Ebell is cofounder and editor-in-chief of Essential Evidence Plus.

Mother-Baby Singing Groups Can Reduce Postpartum Depression Symptoms

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Author Disclosure: No relevant financial relationships.

CLINICAL QUESTION

What is the effect of participation in a weekly singing group on symptoms of postpartum (postnatal) depression?

BOTTOM LINE

For mothers with postnatal depression, involvement in a weekly singing group with other mothers and their babies reduced symptoms more than participating in other mother-baby activities. This approach might be useful and inexpensive for practices or communities in which postnatal depression is common. (Level of Evidence = 1b-)

SYNOPSIS

The researchers recruited potential participants via social media and primary care offices, and enrolled mothers who were experiencing postnatal depression with a score of at least 10 on the Edinburgh Postnatal Depression Scale (more than 80% of the mothers had a score greater than 13, which would qualify them for treatment). The 199 mothers were allocated using concealed allocation to participate in a weekly singing group or to participate in existing community mother-baby activities. The singing group included 8 to 12 mother-baby pairs who sat in a circle on the floor and was taught a range of songs and used simple musical instruments (Melodies for Mums). Using intention-to-treat analysis, scores decreased by a clinically significant amount in both groups, but the singing mothers had lower average scores than the control group

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mothers at week 10 (10.7 vs 12.2; $P = .023$) and week 36 (9.85 vs 11.4; $P = .026$).

Study Design: Randomized controlled trial (nonblinded)

Funding Source: Government and foundation

Allocation: Concealed

Setting: Outpatient (any)

Reference: Bind RH, Lawrence AJ, Estevao C, et al. Clinical effectiveness, implementation effectiveness and cost-effectiveness of a community singing intervention for postnatal depressive symptoms, SHAPER-PND: randomised controlled trial. *Br J Psychiatry*. 2025;227(6):836-845.

Olezarsen Reduces Triglyceride Levels and the Risk of Acute Pancreatitis in People With Severe Hypertriglyceridemia

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CLINICAL QUESTION

Does olezarsen (Tryngolza) reduce the risk of acute pancreatitis in people with severe hypertriglyceridemia, defined as at least 500 mg/dL (5.65 mmol/L)?

BOTTOM LINE

Olezarsen significantly lowers triglyceride levels and reduces episodes of acute pancreatitis (number needed to treat = 20 over 1 year). However, it is expensive—approximately \$600,000 per year for patients with familial chylomicronemia syndrome. (Level of Evidence = 1b)

SYNOPSIS

Olezarsen targets messenger RNA to decrease production of apolipoprotein C-III, reducing hypertriglyceridemia. Olezarsen was originally approved for familial chylomicronemia syndrome as an orphan drug; the study attempts to expand the indication to patients with a triglyceride level of at least 500 mg/dL. The study is a combined report of two identical trials that randomized patients with a fasting triglyceride level of at least 500 mg/dL to receive olezarsen, 80 mg or 50 mg, or placebo given as a subcutaneous injection every 4 weeks for 48 weeks. Groups were balanced with a mean age of 54 years and a median triglyceride level of 793 mg/dL (8.96 mmol/L).

Approximately 25% of patients in one trial and 14% in the other had a previous episode of acute pancreatitis. Patients were followed up for 12 months; about 10% in each group dropped out, and analysis was by modified intention to treat including patients who received at least one dose. The drug was highly effective at reducing triglyceride levels: by 63% with the 50-mg dose and by 70% with the 80-mg dose compared with 0%

to 14% in the placebo group. The patient-oriented outcome of acute pancreatitis events was significantly less likely in the pooled olezarsen group than in the placebo group (1.0 vs 6.2 events per 100 person-years; incidence rate ratio = 0.15; 95% CI, 0.05-0.40). This corresponds to a number needed to treat of 20. Adverse events leading to discontinuation were similar among groups (2.0% with placebo, 3.4% with 50 mg, and 4.3% with 80 mg). There was no difference among groups in cardiovascular events. Hepatic steatosis was nonsignificantly more common in the olezarsen groups (2.4% vs 1.1%; $P = .17$).

Study Design: Randomized controlled trial (double-blinded)

Funding Source: Industry

Allocation: Uncertain

Setting: Outpatient (any)

Reference: Marston NA, Bergmark BA, Alexander VJ, et al; CORE-TIMI 72a and CORE2-TIMI 72b Investigators. Olezarsen for managing severe hypertriglyceridemia and pancreatitis risk. *N Engl J Med*. 2026;394(5):429-441.

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Lack of Association Between Prenatal Acetaminophen Exposure and Child Neurodevelopmental Disorders

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Author Disclosure: No relevant financial relationships.

CLINICAL QUESTION

Is prenatal exposure to acetaminophen (paracetamol) associated with autism or other neurodevelopmental disorders in children?

BOTTOM LINE

The meta-analysis of cohort studies failed to identify an association of prenatal exposure to acetaminophen with autism spectrum disorders, attention-deficit/hyperactivity disorder (ADHD), or intellectual disabilities in childhood. (Level of Evidence = 2a-)

SYNOPSIS

The authors conducted a meta-analysis of cohort studies to determine whether prenatal exposure to acetaminophen is associated with diagnosis of autism spectrum disorder, ADHD, or developmental delay in children compared with no exposure. They controlled for underlying maternal comorbidities and pharmacologic treatments before and during pregnancy. The authors allowed these disorders to be defined by the included studies, and they excluded studies that reported only unadjusted estimates. When possible, the authors stratified studies based on trimester of acetaminophen intake (ie, first, second, or third). They included 43 studies in the systematic review, 17 of which were included in the meta-analysis. The studies were

heterogenous in how they reported acetaminophen exposure during pregnancy, timing and type of follow-up, and whether they stratified based on acetaminophen intake and dosage. For the subgroup of sibling comparison studies, acetaminophen exposure was not associated with a risk of autism spectrum disorder (odds ratio [OR] = 0.98; 95% CI, 0.93-1.03), ADHD (OR = 0.95; 95% CI, 0.86-1.05), or intellectual disability (OR = 0.93; 95% CI, 0.69-1.24). There were 11 studies classified as low risk of bias, and those showed a similar lack of difference in outcomes. The authors were unable to perform subgroup analysis based on trimester of intake or frequency of

intake because few studies reported those data. This resulted in insufficient statistical power for reliable estimates.

Study Design: Meta-analysis (other)

Funding Source: Self-funded or unfunded

Setting: Various (meta-analysis)

Reference: D'Antonio F, Flacco ME, Della Valle L, et al. Prenatal paracetamol exposure and child neurodevelopment: a systematic review and meta-analysis. *Lancet Obstet Gynaecol Womens Health*. 2026;2(3):e190-e198.