GOOD EVIDENCE MATTERS

GEMs of the Week

SPOTLIGHT

It Takes Your Breath Away:
Assessing Electronic Nicotine Delivery Systems and COPD Risk

Lp(a) Finally Has a Pill, But Does It Matter?

Getting to the Heart of Subclinical Hypothyroidism

Think Outside the Labs:
Diagnosing DKA

Putting Antibiotic Prescribing to the Test

Below the Threshold, Above the Risk:
Cardiometabolic Markers and Hypertensive Pregnancy

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Family Physicians Inquiries Network

Volume 6 Issue 45

It Takes Your Breath Away: Assessing Electronic Nicotine Delivery Systems and COPD Risk

Assessing the Impact of Electronic Nicotine Delivery Systems on Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis

Malvi A, Khatib MN, Ganesan S, et al. Assessing the impact of electronic nicotine delivery systems on chronic obstructive pulmonary disease: A systematic review and meta-analysis. *Respir Med*. 2025;241:108059. doi:10.1016/j.rmed.2025.108059

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KEY TAKEAWAY: Electronic nicotine delivery system (ENDS) use increases the risk of chronic obstructive pulmonary disease (COPD) compared to non-electronic nicotine delivery system use in adults >18 years old.

STUDY DESIGN: Systematic review and meta-analysis of 13 observational studies (N=2,704,463)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to lack of adjustment for smoking status)

BRIEF BACKGROUND INFORMATION: ENDS have become widely popular as an alternative to smoking cigarettes, as they are considered less harmful. However, concerns have arisen regarding their long-term effects and possible associations with respiratory health conditions such as COPD. This study aimed to assess the relationship between ENDS use and COPD risk.

PATIENTS: Adults >18 years old

INTERVENTION: ENDS use

CONTROL: Non-ENDS use

PRIMARY OUTCOME: Risk of developing COPD

METHODS (BRIEF DESCRIPTION):

- Inclusion criteria:
  - Observational studies that explored the association between ENDS use and COPD
  - Studies provided quantitative data including odds ratios (OR), relative risk (RR), hazard ratios (HR), or sufficient data to calculate these metrics
  - Research focused on populations using ENDS (current, former, or those who have ever used ENDS products)
  - Peer-reviewed articles with no restrictions on language or publication type.
- Exclusion criteria:
  - Studies funded by the tobacco industry
  - Studies that lacked direct measurement of ENDS use or those that did not include a clear association with COPD
  - Case reports, conference abstracts, opinion pieces, and review articles
- COPD was defined as chronic respiratory conditions, including chronic bronchitis and emphysema, based on clinical or diagnostic criteria according to the World Health Organization (WHO) or the American Thoracic Society.
- The intervention included patients whose ENDS use was categorized into current users, former users, or ever-users.
- The comparator included patients categorized as non-ENDS users.
- The outcome of the studies was the relationship between ENDS use and the risk of COPD. Most studies used self-reported diagnoses, though some included clinical assessments or pulmonary function testing.
- A random-effects meta-analysis was employed to account for variations among included studies. The results were expressed as odds ratios with 95% confidence intervals.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Varied

RESULTS:

Primary Outcome –

- Individuals currently using ENDS products were at increased risk for COPD compared to non-ENDS users (13 studies, N=2,704,463; odds ratio [OR] 1.5; 95% CI, 1.4–1.6; I^2=0%).
- Individuals who previously used ENDS products were at increased risk for COPD compared to non-ENDS users (6 studies, n=1,029,237; OR 1.8; 95% CI, 1.5–2.2; I^2=70%).
- Individuals who ever used ENDS products were at increased risk for COPD compared to non-ENDS users (4 studies, n=1,556,411; OR 1.8; 95% CI, 1.4–2.2; I^2=46%).

LIMITATIONS:

- Some studies did not adjust for smoking status, which could lead to confounding.

- Limited studies accounted for baseline lung function, making it difficult to determine whether pre-existing respiratory impairment contributed to COPD risk in this study.
- No studies controlled for environmental exposures that can also contribute to COPD development.
- There was considerable variability in ENDS device characteristics, usage patterns, and exposure duration across studies, which could influence findings.
- Most studies relied on self-reported COPD diagnoses, which could lead to misclassification bias.
- Most of the studies were conducted in South Korea, the United States, and China, which may limit generalizability.

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Lp(a) Finally Has a Pill, But Does It Matter?

Oral Muvalaplin for Lowering of Lipoprotein(a): A Randomized Clinical Trial

Nicholls SJ, Ni W, Rhodes GM, et al. Oral Muvalaplin for Lowering of Lipoprotein(a): A Randomized Clinical Trial. *JAMA*. 2025;333(3):222-231. doi:10.1001/jama.2024.24017

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KEY TAKEAWAY: Oral muvalaplin reduced lipoprotein(a) levels by up to 86% over 12 weeks in high-risk adults with elevated lipoprotein(a), with no significant safety concerns; however, whether this surrogate outcome translates into reduced cardiovascular events remains unknown.

STUDY DESIGN: Multicenter, randomized, double-blind trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to surrogate endpoint and small sample size)

BRIEF BACKGROUND INFORMATION: Elevated lipoprotein(a), or Lp(a), is a genetically determined risk factor for atherosclerotic cardiovascular disease (ASCVD) and calcific aortic valve stenosis. No pharmacotherapy is currently approved to lower Lp(a), and therapies in development are injectable, which may limit widespread use in primary care. This study evaluated the effect of muvalaplin, the first oral small-molecule inhibitor of Lp(a) formation, on blood/serum measurements in high-risk adults with elevated Lp(a).

PATIENTS: Adults ≥40 years old with high cardiovascular risk

INTERVENTION: Muvalaplin 10, 60, or 240 mg/d

CONTROL: Placebo

PRIMARY OUTCOME: Lp(a) concentration

Secondary Outcome: Proportion achieving Lp(a) <125 nmol/L, apolipoprotein B levels, high-sensitivity C-reactive protein change

METHODS (BRIEF DESCRIPTION):

- Patients were recruited from 43 sites across eight countries.
- The median age was 66 years old, 67% were male, and 66% were White.
- Adults with Lp(a) ≥175 nmol/L and a history of ASCVD, type 2 diabetes (T2DM), or familial hypercholesterolemia were included; those with uncontrolled diabetes, recent cardiovascular (CV) events, or estimated glomerular filtration rate (eGFR) <30 mL/min/1.7m² were excluded.
- Patients were randomized 1:2:2:2 to muvalaplin 10 mg/d, 60 mg/d, 240 mg/d, or placebo, administered as four oral tablets daily for 12 weeks.
- Lp(a) was measured using both a novel intact Lp(a) assay (detecting only intact Lp(a) particles) and a traditional apolipoprotein(a)-based assay.

INTERVENTION (# IN THE GROUP):

- Muvalaplin 10 mg/d: 34
- Muvalaplin 60 mg/d: 64
- Muvalaplin 240 mg/d: 68

COMPARISON (# IN THE GROUP): 67

FOLLOW-UP PERIOD: 12 weeks

RESULTS:

Primary Outcome –

- Muvalaplin reduced Lp(a) in a dose-dependent manner compared with placebo using the intact Lp(a) assay.
  - 10 mg/d (48%; 95% CI, 35–58)
  - 60 mg/d (82%; 95% CI, 78–85)
  - 240 mg/d (86%; 95% CI, 83–88)
- Using the apolipoprotein(a)-based assay, placebo-adjusted reductions were:
  - 10 mg/d (40%; 95% CI, 28–51)
  - 60 mg/d (70%; 95% CI, 65–74)
  - 240 mg/d (69%; 95% CI, 64–73)

Secondary Outcome –

- At 240 mg/d, 97% of patients achieved Lp(a) <125 nmol/L using the intact assay compared with 6.0% with placebo.
- Apolipoprotein B was reduced in a dose-dependent manner, with statistically significant placebo-adjusted reductions at 60 mg/d (13%; 95% CI, 4.4–21) and 240 mg/d (16%; 95% CI, 7.8–24), but not at 10 mg/d.
- No significant change in hs-CRP was observed in any treatment group.

LIMITATIONS:

- The primary outcome was a surrogate endpoint (Lp(a) level); whether Lp(a) lowering reduces CV events remains unproven.

- The sample size (n=233) and 12-week duration limit detection of rare adverse events and assessment of long-term efficacy.
- The intact Lp(a) assay is not commercially available and has not been independently validated.
- The study was funded by Eli Lilly, the manufacturer of muvalaplin, and five of eight authors were company employees.
- Limited demographic diversity (67% male, 66% White, 4% Black).
- The study was not powered to detect safety differences.

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The opinions and assertions contained herein are those of the authors and are not to be construed as official or as reflecting the views of the US Army Medical Department, the Army at large, or the Department of Defense.

Getting to the Heart of Subclinical Hypothyroidism

Levothyroxine Treatment of Subclinical Hypothyroidism and the Risk of Adverse Cardiovascular Events

Yu OHY, Filliter C, Filion KB, Platt RW, Grad R, Renoux C. Levothyroxine Treatment of Subclinical Hypothyroidism and the Risk of Adverse Cardiovascular Events. *Thyroid*. 2024;34(10):1214-1224. doi:10.1089/thy.2024.0227

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KEY TAKEAWAY: Treatment of subclinical hypothyroidism (SCH) with levothyroxine may decrease the risk of major adverse cardiovascular events (MACE) in patients with TSH between 5 and 10 prior to treatment.

STUDY DESIGN: Observational cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: SCH impacts approximately 5–10% of the population; however, current treatment guidelines only recommend treatment with TSH levels >10 mU/L. Given the known impact on cardiovascular risk factors such as cholesterol, blood pressure (BP), and weight, this study aimed to assess whether treatment for mild SCH is associated with a statistically significant decrease in cardiovascular complications.

PATIENTS: Individuals at least 18 years old with incident SCH

INTERVENTION: Levothyroxine

CONTROL: No treatment

PRIMARY OUTCOME: MACE defined as hospitalization for nonfatal myocardial infarction (MI), nonfatal ischemic stroke, and/or cardiovascular-related mortality.

Secondary Outcome: Individual components of MACE, heart failure (HF) hospitalizations, all-cause mortality

METHODS (BRIEF DESCRIPTION):

- Data were collected using the Clinical Practice Research Datalink (CPRD) Aurum, which includes the clinical documentation and demographic characteristics of over 40 million enrolled patients in the UK.
- A base cohort of individuals at least 18 years old with incident SCH between 1998 and 2018 was identified.
- SCH was defined as two TSH measurements between 5 and 10 mU/L on different dates within one year of each other.
- Patients who received medications prior to the cohort entry date that included methimazole, PTU, levothyroxine, or amiodarone were excluded, as were pregnant patients and those with pituitary disorders.
- 91,299 individuals from the base cohort who met the inclusion criteria were initiated on oral levothyroxine therapy.
- Time-based exposure sets were created based on patients who initiated levothyroxine via age (±3 years), sex, disease duration, and calendar time (±30 days).
- Individuals who initiated levothyroxine were matched 1:1 with controls from the base cohort who had the opportunity to initiate levothyroxine but remained untreated.
- Patients in treatment and control groups were matched using covariates that included body mass index (BMI), alcohol use, smoking, Charlson Comorbidity Index, diabetes, renal insufficiency, cancer, chronic obstructive pulmonary disease (COPD), dementia, liver disease, obstructive sleep apnea (OSA), or rheumatoid disease and were followed until they sustained a MACE event, underwent crossover between groups, or met exclusion criteria.
- The primary outcome assessed was MACE, defined as hospitalization for nonfatal MI, nonfatal ischemic stroke, and/or cardiovascular-related mortality.
- Secondary outcomes included the individualized MACE events, HF hospitalizations, and all-cause mortality.

INTERVENTION (# IN THE GROUP): 76,946

COMPARISON (# IN THE GROUP): 76,946

FOLLOW-UP PERIOD: Median follow-up of 1.6 years

RESULTS:

Primary Outcome –

- Levothyroxine decreased the composite risk of MACE compared to no treatment (hazard ratio [HR] 0.88; 95% CI, 0.83–0.93).

Secondary Outcome –

- Levothyroxine decreased the risk of nonfatal MI compared to no treatment (HR 0.89; 95% CI, 0.81–0.97).

- Levothyroxine decreased the risk of cardiovascular-related mortality compared to no treatment (HR 0.83; 95% CI, 0.77–0.89).
- Levothyroxine decreased the risk of all-cause mortality compared to no treatment (HR 0.79; 95% CI, 0.76–0.82).
- Levothyroxine did not reduce the risk of HF or nonfatal ischemic stroke hospitalizations compared to no treatment.

LIMITATIONS:

- Given this population-based cohort study, confounding variables may still exist despite the attempt to match comorbidities.
- The follow-up time of this study had a median of 1.6 years, limiting evaluation for long-term impact of treatment.
- There was no evaluation in this study of long-term negative side effects of levothyroxine treatment such as decreased bone strength or arrhythmias.

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The opinions and assertions contained herein are those of the author and are not to be construed as official or as reflecting the views of the US Army Medical Department, the Army at large, or the Department of Defense.

Think Outside the Labs: Diagnosing DKA

How Often Are Emergency Patients Diagnosed with Diabetic Ketoacidosis Despite Not Meeting Laboratory Criteria?

Griffey RT, Haas N, Schneider RM, et al. How Often Are Emergency Patients Diagnosed With Diabetic Ketoacidosis Despite Not Meeting Laboratory Criteria?. *Acad Emerg Med*. 2026;33(5):e70315. doi:10.1111/acem.70315

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KEY TAKEAWAY: Diabetic ketoacidosis (DKA) may be diagnosed despite not meeting initial laboratory criteria, with 31% of patients with positive point-of-care (POC) testing ultimately receiving a DKA diagnosis.

STUDY DESIGN: Retrospective observational study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: DKA is a common, severe complication of diabetes mellitus that is on the rise, with an increase in prevalence of 55% between 2009 and 2014. The extent to which emergency physicians diagnose DKA in patients whose initial labs do not meet DKA criteria remains unquantified. In addition, while other causes of acidosis and ketosis that can occur with hyperglycemia are well described (e.g., starvation ketosis, alcohol ketoacidosis), scant literature has quantified the frequency distribution of these diagnoses in an emergency department (ED) population being screened for DKA. This study aimed to evaluate the importance of clinical presentation, in addition to laboratory findings, in diagnosing DKA.

PATIENTS: Patients >18 years old who presented to an ED

INTERVENTION: DKA diagnosis using POC testing

CONTROL: DKA diagnosis using laboratory tests and other means

PRIMARY OUTCOME: Proportion of patients with DKA diagnosis

METHODS (BRIEF DESCRIPTION):

- The study included ED visits in the United States from January 1, 2019, to February 28, 2023, where DKA was diagnosed by POC or clinically.
- Patients were >18 years old, with a median age of 47 years, and 96% were non-Hispanic.
- Adult patients diagnosed by laboratory definition with POC blood glucose >300 mg/dL and initial POC ketone >1.1 mmol/L were identified.
- Adult patients who initially did not meet the laboratory definition of POC-based DKA diagnosis but had a DKA diagnosis (defined as having relevant ICD-10 codes) were also identified.
- The primary outcome measured the proportion of patients meeting the laboratory definition of DKA or a clinical diagnosis of DKA.

INTERVENTION (# IN THE GROUP): 1,546

COMPARISON (# IN THE GROUP):

- Only ED diagnosis of DKA: 130
- Laboratory definition of DKA: 1,676 (including the same 1,546 patients tested with POC)

FOLLOW-UP PERIOD: Not applicable

RESULTS:

Primary Outcome –

- Of 1,676 patients screened for DKA, 53% (95% CI, 50–55) met laboratory criteria for DKA.
- Of 740 patients with positive POC testing who did not initially meet laboratory criteria for DKA, 31% (95% CI, 28–34) were ultimately diagnosed with DKA.

LIMITATIONS:

- The study lacked randomization and a robust study design, and thus the results should be treated with caution
- Diagnoses were measured based on coded diagnoses and not on evaluation of primary records or laboratory review.

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Rapid Respiratory Microbiological Point-of-Care Testing and Antibiotic Use in Primary Care: A Randomized Clinical Trial

Hay AD, Abbs S, Ridd M, et al. Rapid Respiratory Microbiological Point-of-Care Testing and Antibiotic Use in Primary Care: A Randomized Clinical Trial. *JAMA Intern Med*. 2026;186(7):817-826. doi:10.1001/jamainternmed.2026.1426

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KEY TAKEAWAY: For patients presenting with acute respiratory tract infections (URTIs) being considered for antibiotics, rapid respiratory microbiological point-of-care testing (RM-POCT) does not reduce the rate of same-day antibiotic prescribing compared to usual care.

STUDY DESIGN: Multicenter, single-blind, parallel-group, randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Rapid point-of-care testing is often seen as a valuable tool or asset to be used in addition to a physician's assessment of patient symptoms and physical exam. This study aimed to evaluate whether RM-POCT could safely reduce same-day antibiotic prescribing for URTI in a clinic setting.

PATIENTS: Patients ≥12 months old presenting for the first time with an URTI

INTERVENTION: RM-POCT

CONTROL: Usual care

PRIMARY OUTCOME: Same-day prescribing of antibiotics
Secondary Outcome: Patient symptom improvement on days 2–4

METHODS (BRIEF DESCRIPTION):

- Patients were recruited from 16 primary care practices in Southwest England
- Patients ≥12 months were included if they presented with any diagnosed acute respiratory tract infection with symptoms <21 days of symptom onset, and either the patient or clinician believed antibiotic treatment was or may be necessary.
- Patients with cystic fibrosis (CF), those requiring hospital admissions, those who had previously taken part in the study, or those who were taking part in a conflicting study were excluded.
- Patients were randomized 1:1 to RM-POCT or usual care.
- Patients receiving RM-POCT received RM-POCT, which was a combined nasal and throat sample testing for 19 viruses and four atypical bacteria with results in 45 minutes prior to deciding antibiotic treatment.
- Patients receiving usual care were prescribed antibiotics at the discretion of the physician without RM-POCT testing.
- The primary outcome was measured by whether or not the physician prescribed antibiotics the same day (both immediate or delayed), as recorded by the treating physician
- The secondary outcome measured patient symptom improvement on days 2–4 on a scale of 0–6, with lower scores indicating symptom improvement.

INTERVENTION (# IN THE GROUP): 276

COMPARISON (# IN THE GROUP): 276

FOLLOW-UP PERIOD: Six months

RESULTS:

Primary Outcome –

- RM-POCT did not reduce same-day antibiotic prescribing compared with usual care (45% vs 45%, respectively; odds ratio [OR] 1.0; 95% CI, 0.71–1.4).

Secondary Outcome –

- RM-POCT was noninferior to usual care for symptom severity on days 2–4 (adjusted mean difference [aMD] 0.09; 95% CI, −0.10 to 0.27; noninferiority margin=0.34).

LIMITATIONS:

- The practices had lower prescribing rates than the national average for England, and the clinics served primarily affluent areas, which may limit generalizability.
- Fewer children than expected were seen in the study, which limits application to the proposed population.

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Below the Threshold, Above the Risk: Cardiometabolic Markers and Hypertensive Pregnancy

Pregestational Cardiometabolic Biomarkers and Future Hypertensive Disorders of Pregnancy

Qvick A, Sandström A, Norhammar A, et al. Pregestational Cardiometabolic Biomarkers and Future Hypertensive Disorders of Pregnancy. *JAMA Netw Open*. 2026;9(4):e2610037. Published 2026 Apr 1. doi:10.1001/jamanetworkopen.2026.10037

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KEY TAKEAWAY: Several cardiometabolic biomarkers measured before pregnancy increase the risk of developing hypertensive disorders in pregnancy. Assessing these biomarkers may improve identification of those at risk of hypertensive disorders of pregnancy before pregnancy or in early pregnancy.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Hypertensive disorders of pregnancy (HDP) are one of the leading causes of maternal morbidity and mortality. Established early pregnancy risk factors are known, although most clinical guidelines rely on data collected during pregnancy, which highlights the need for detection of risk factors prior to conception for earlier prevention. This study aimed to examine the relationship between cardiometabolic biomarkers prior to pregnancy and hypertensive disorders of pregnancy in nulliparous women.

PATIENTS: Nulliparous pregnant women

INTERVENTION: Presence of positive cardiac biomarkers prior to pregnancy

CONTROL: Absence of positive cardiac biomarkers prior to pregnancy

PRIMARY OUTCOME: Development of HDPs

METHODS (BRIEF DESCRIPTION):

- This study included nulliparous women aged at least 18 years old at the start of their first completed pregnancy (referred to as index pregnancy) between January 1, 1985, and December 31, 2020. Eligible patients had at least one pregestational biomarker measurement reflecting cardiometabolic status (n=35,189).
- Completed pregnancies were defined as those ending after ≥28 weeks of gestation (before July 1, 2008) or 22 or more weeks of gestation (as of July 1, 2008).
- The intervention group was those who did develop an HDP.
- The comparison group was those who did not develop an HDP.
- Patients were followed up from the start of their prenatal care until their HDP diagnosis or the end of follow-up, which was one week postpartum.
- The biomarkers were drawn prior to pregnancy, with a median time between sampling and the estimated start of the pregnancy being 4–6 years.
- Many of the biomarkers were grouped in quartiles, with Q1 being the "normal" value ranging to Q4 which if applicable, was the clinical cutoff for diagnostic criteria (i.e. Q4 fasting glucose >126 mg/dL). Q2 and Q3 were considered "subclinical" ranges.
- HDPs were diagnosed based on international, standard criteria.
- For the statistical analysis of inflammatory and lipid biomarkers, results were adjusted for pregestational diabetes.
- For the statistical analysis of inflammatory and glucose biomarkers, results were adjusted for dyslipidemia.

INTERVENTION (# IN THE GROUP): 1,938

COMPARISON (# IN THE GROUP): 33,251

FOLLOW-UP PERIOD: From 20 weeks' gestation until either a diagnosis of HDP or one week postpartum, whichever came first.

RESULTS:

Primary Outcome –

- Diagnosis of diabetes or fasting glucose of at least 126 mg/dL without a diagnosis of diabetes was associated with an increased risk of HDP (adjusted odds ratio [aOR] 2.0; 95% CI, 1.5–2.5).
- Prediabetes was not significantly associated with an increased risk of HDP (aOR 1.02; 95% CI, 0.66–1.6).
- Elevated haptoglobin >91 mg/dL was associated with an increased risk of HDP (aOR 1.2; 95% CI, 1.02–1.4).

- LDL at diagnostic clinical cutoffs did not show a statistically significant difference in the association with HDP (aOR 1.7; 95% CI, 0.99–3.0).
- Quartile analyses indicated increased HDP risk associated with Q4 of the following:
  - ApoB (aOR 1.9; 95% CI, 1.4–2.7)
  - ApoB/ApoA1 ratio (aOR 1.6; 95% CI, 1.1–2.3)
  - Fasting triglycerides (aOR 1.2; 95% CI, 1.03–1.4)
  - Total cholesterol (aOR 1.2; 95% CI, 1.1–1.4)
  - LDL-C (aOR 1.4; 95% CI, 1.1–1.9)
- HDP pregnancies were more often conceived through assisted reproduction and had multifetal gestation, gestational diabetes, and shorter gestational length.
- Vaginal delivery was less frequent in the HDP group than in the normotensive group (41% vs 62%, respectively; standardized mean difference –0.44).

LIMITATIONS:

- Residual confounding variables (adjustments made for potential confounders but could still be contributing).
- Generalizability of the results is limited to nulliparous women.
- Chronic hypertension may have been under-adjusted for given limited blood pressure data availability.
- Given the number of biomarkers and the use of arbitrary quartile-based cutoff values for several biomarkers, and that no adjustment for multiple testing was made, the analyses are of an exploratory, hypothesis-generating nature.

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