

GEMS of the Week

SPOTLIGHT

**Bad for Moms and Babies:
Why Bacterial Vaginosis in Pregnancy
Should Not Be Ignored**

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GLP-1 Agonists**

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Comparing Adenosine and Diltiazem for
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Bad for Moms and Babies: Why Bacterial Vaginosis in Pregnancy Should Not Be Ignored

Systematic Review and Meta-Analysis of Maternal and Fetal Outcomes Among Pregnant Women with Bacterial Vaginosis

Kenfack-Zanguim J, Kenmoe S, Bowo-Ngandji A, et al. Systematic review and meta-analysis of maternal and fetal outcomes among pregnant women with bacterial vaginosis. *Eur J Obstet Gynecol Reprod Biol.* 2023;289:9-18. doi:10.1016/j.ejogrb.2023.08.013

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KEY TAKEAWAY: Bacterial vaginosis (BV) during pregnancy is associated with adverse maternal and fetal outcomes globally, including intrauterine infection, miscarriage, and premature rupture of membranes (PROM) <37 weeks gestational age, preterm birth (PTB) <37 weeks, low birth weight (LBW) <2,500 g and birth asphyxia.

STUDY DESIGN: Systematic review and meta-analysis of one randomized controlled trial (RCT), 12 cross sectional studies, and 13 cohort studies (N=44,774)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to significant heterogeneity between studies)

BRIEF BACKGROUND INFORMATION: Globally, BV effects many pregnant women. BV during pregnancy has been linked to adverse maternal and fetal outcomes. This study aimed to explore the prevalence of maternal and fetal outcomes in pregnant people with BV, characterize geographic distribution of adverse outcomes, and identify maternal and fetal outcomes that are specifically associated with BV in pregnancy.

PATIENTS: Pregnant people with BV

INTERVENTION: Exposure to BV during pregnancy

CONTROL: Pregnant people without BV

PRIMARY OUTCOME: Maternal and fetal outcomes

METHODS (BRIEF DESCRIPTION):

- 26/8,983 articles that were identified in Embase, PubMed and Web of Science were included in the review.
- Systematic review and meta-analysis of English and French publications of observational studies reporting prevalence of maternal and fetal outcomes among pregnant women with BV.
- All geographical locations included and all diagnostic tests for BV were considered.

- Exclusion criteria included duplicate studies; no abstract/full text, language other than English or French; qualitative only studies; and case reports, editorials, reviews, systematic reviews, commentaries or case series.
- The intervention included exposure to bacterial BV during pregnancy and was compared to no exposure to BV during pregnancy.
- The primary outcome measured maternal and fetal outcomes.
 - Maternal outcomes included miscarriage, intrauterine infection, and PROM.
 - Fetal outcomes included PTB, mechanical ventilation, LBW, birth asphyxia, and neonatal intensive care unit (NICU) admission.
- Prevalence of each maternal and fetal outcome was calculated with 95% confidence intervals and a prediction interval.
- Odds ratio (OR) and 95% CI was used to assess the strength of association between BV and each maternal or fetal outcome.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Variable (no follow-up to 12 months)

RESULTS:

Primary Outcome –

- Exposure to BV during pregnancy was associated with an increased risk of the following maternal outcomes:
 - Intrauterine infection (5 studies, n=5,563; odds ratio [OR] 2.3; 95% CI, 1.4–3.6; $I^2=0\%$)
 - Miscarriage (5 studies, n=6,649; OR 2.3; 95% CI, 1.2–4.6; $I^2=60\%$)
 - PROM (9 studies, n=3,496; OR 2.6; 95% CI, 1.4–4.8; $I^2=79\%$)
- Exposure to BV during pregnancy was associated with an increased risk of the following fetal outcomes:
 - PTB (22 studies, n=14,733; OR 1.8; 95% CI, 1.3–2.4; $I^2=65\%$)
 - LBW (12 studies, n=9,581; OR 1.7; 95% CI, 1.4–2.1; $I^2=55\%$)

- Birth asphyxia (3 studies, n=563; OR 2.9; 95% CI, 1.1–7.5; $I^2=30\%$)
 - Exposure to BV during pregnancy was not associated with an increased risk of the following fetal outcomes:
 - Mechanical ventilation (3 studies, n=1,779; OR 2.2; 95% CI, 0.80–6.2; $I^2=68\%$)
 - NICU admission (3 studies, n=509; OR 1.2; 95% CI, 0.28–5.2; $I^2=62\%$)
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LIMITATIONS:

- High heterogeneity among studies due to use of different tests, different ethnicities and different gestational ages.
 - Follow-up periods were not described.
 - Only including English and French written articles may have limited impact in and ability to explore outcomes globally.
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The Newest Upgrade to Type 1 Diabetes: GLP-1 Agonists

Subcutaneous Weekly Semaglutide with Automated Insulin Delivery in Type 1 Diabetes: A Double-Blind, Randomized, Crossover Trial

Pasqua MR, Tsoukas MA, Kobayati A, Aboznadah W, Jafar A, Haidar A. Subcutaneous weekly semaglutide with automated insulin delivery in type 1 diabetes: a double-blind, randomized, crossover trial. *Nat Med*. 2025;31(4):1239-1245. doi:10.1038/s41591-024-03463-z

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KEY TAKEAWAY: Semaglutide decreases daily insulin requirements and increases time spent in range all without increasing the incidence of hypoglycemia in patients with type 1 diabetes (T1D).

STUDY DESIGN: Double-blind, randomized, crossover trial

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

BRIEF BACKGROUND INFORMATION: Patients with T1D have a significant disease burden that is difficult to manage and face the same risks for complications as type 2 diabetes (T2D) if not well controlled. The use of glucagon-like peptide-1 (GLP-1) agonists may make it easier for patients with T1D to manage their disease and decrease negative health outcomes. This study aimed to evaluate if patients with T1D have improved outcomes with the use of GLP-1 agonists.

PATIENTS: Adults with T1D

INTERVENTION: Semaglutide

CONTROL: Usual care (insulin only)

PRIMARY OUTCOME: Percentage of time in range

Secondary Outcome: Time spent in hypoglycemia and hyperglycemia, lipid levels, body weight, daily insulin requirement, glucose levels, A1C, occurrence of ketosis or diabetic ketoacidosis, side effects

METHODS (BRIEF DESCRIPTION):

- Patients were ≥18 years old with established T1D, had used an insulin pump for at least three months, had an A1c of ≤11%, and agreed to use of highly effective birth control when applicable to prevent pregnancy during the study.
- Exclusion criteria included use of other antihyperglycemic agent besides insulin, DKA within six months, severe hypoglycemic episode within three months, history of pancreatitis or gallbladder

disease, personal or family history of medullary thyroid cancer or MEN2 syndrome, previous adverse reactions to GLP1s, use of hydroxyurea, severe diabetic retinopathy or gastroparesis, bariatric surgery in the past six months, or any other serious medical/psychiatric condition that would interfere with the study.

- Patients were randomized to either placebo injection or semaglutide group.
- The intervention group began an 11-week titration period and were initiated on Semaglutide 0.25 mg weekly for four weeks. They were then increased to 0.5 mg weekly for four weeks, and then 1 mg weekly for the remainder of the first arm.
- The placebo group followed the same titration schedule as the intervention group but received saline injections from unblinded pharmacists.
- Each group completed the titration period, then had a two-week washout period of usual insulin therapy and then crossed over to repeat the titration period with the opposite intervention (control vs semaglutide).
- Participants, investigators, and other research personnel remained blind.
- Both groups remained on their usual insulin pump therapy during the titration period, but after the dose titration participants were switched to a research-based AID system, Ypsomed pump. This was chosen to decrease selection bias between different pumps.
- The primary outcome was time in the target glucose range of 3.9–10 mmol which was measured using the Dexcom G6 CGM.
- The following were measured as the secondary outcomes:
 - Mean glucose level, time spent in hyperglycemia (>10 mmol and 13.9 mmol), and time spent in hypoglycemia (<3.0 and 3.9 mmol) were all measured using the CGM.
 - Other secondary outcomes occurrence of ketosis or diabetic ketoacidosis, daily insulin requirements, body weight, glucose levels, A1C, lipid levels, side effects

- All data obtained from the CGM were automatically synced to a secure cloud server.
- All other data for the secondary outcomes were manually obtained.

INTERVENTION (# IN THE GROUP): 13

COMPARISON (# IN THE GROUP): 11

FOLLOW-UP PERIOD: No follow up period

RESULTS:

Primary Outcome –

- Semaglutide resulted in a higher percentage of time in range than the placebo group (74% vs 69%, respectively; $P=.006$).

Secondary Outcome –

- Semaglutide reduced the following compared to placebo:
 - Time spent in hyperglycemia by (5%; $P=.006$)
 - Daily insulin requirements (–11 units; IQR, –24 to –4.9; $P<.001$)
 - Body weight (5.3 kg; $P<.001$)
 - Mean glucose levels (0.4 mmol/L; $P=.02$)
 - A1C (–0.5%; IQR, –0.7 to –0.2; $P<.001$)
 - Fructosamine (–15 umol; IQR, –39 to –2; $P<.001$)
 - HDL (–0.17; $P=.01$)
- Side effects associated with semaglutide were nausea (89%), constipation (29%), fatigue (21%), emesis (18%), diarrhea (18%), gastroesophageal reflux (14%), and light-headedness (14%).
- There was no significant difference in time spent in hypoglycemia between the groups.
- There were no events of diabetic ketoacidosis. There were 2 events of euglycemic ketosis in the semaglutide group. One of these events was likely due to coinciding food-borne illness, while the other was thought to be secondary to semaglutide use.

LIMITATIONS:

- The length and size of the study were not sufficient to accurately assess long-term measures of safety and efficacy.
- Although a washout period was included in study design before the crossover, some carry-over effect is still possible.
- Study did not have enough participants to assess outcomes in those with a body mass index (BMI) $<25.0 \text{ kg/m}^2$

- There were more unscheduled follow ups with the semaglutide group which may possibly affect results due to increased healthcare or research contact.

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Break the Rhythm: Comparing Adenosine and Diltiazem for Supraventricular Tachyarrhythmia

Adenosine vs Fixed-Dose Intravenous Bolus Diltiazem on Reversing Supraventricular Tachycardia in The Emergency Department: A Multi-Center Cohort Study

Lee CA, Morrissey B, Chao K, et al. Adenosine Versus Fixed-Dose Intravenous Bolus Diltiazem on Reversing Supraventricular Tachycardia in The Emergency Department: A Multi-Center Cohort Study. *J Emerg Med*. 2025;75:55-64. doi:10.1016/j.jemermed.2025.05.020
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KEY TAKEAWAY: Diltiazem and adenosine have similar conversion rates for supraventricular tachycardia (SVT) with diltiazem being effective as a rescue medication when adenosine is not responsive.

STUDY DESIGN: Retrospective cohort study

LEVEL OF EVIDENCE: STEP 4 (downgraded due to small sample size)

BRIEF BACKGROUND INFORMATION: SVT is a common cause of emergency room (ER) visits for primary care patients. Oftentimes, it requires escalation for rhythm control if conservative measures fail. Currently, multiple guidelines recommend adenosine as a first-line treatment, yet prior studies show variable success rates, relapse, and discomfort with it, while comparative data with alternatives such as diltiazem are limited. Although calcium channel blockers have proven efficacy for treatment of SVT and may be better tolerated, diltiazem has less data than verapamil in this setting. This study aimed to compare the efficacy and outcomes of IV diltiazem against adenosine for converting stable SVT to sinus rhythm in the emergency room setting.

PATIENTS: Adults in the ER with stable SVT

INTERVENTION: Diltiazem

CONTROL: Adenosine

PRIMARY OUTCOME: Successful conversion of SVT at 30 minutes

Secondary Outcome: Time to conversion, dose response, rescue therapy success

METHODS (BRIEF DESCRIPTION):

- Eligible patients were adults >18 years old, had SVT confirmed by ECG, and received either IV adenosine or IV diltiazem as their initial treatment.
- Hemodynamic stability was graded using Advanced Cardiovascular Life Support (ACLS) criteria, including tachycardia (heart rate >100 bpm) without

hypotension (<90/60 mmHg), altered mental status, ischemic chest pain, shock, or signs of end-organ damage.

- Patients were grouped based on the first IV medication administered to them (adenosine or diltiazem), regardless of any subsequent treatments received.
- The primary outcome was successful conversion to sinus rhythm within 30 minutes of the initial dose.
- Secondary outcomes included time to conversion, medication doses required, and success of rescue therapies.
- Data was manually obtained from the electronic medical record (EMR) and outcomes were compared between groups using Fisher's Exact tests (categorical data) or t-tests (continuous data).

INTERVENTION (# IN THE GROUP): 34

COMPARISON (# IN THE GROUP): 310

FOLLOW-UP PERIOD: 30-minutes post-administration

RESULTS:

Primary Outcome –

- Diltiazem did not significantly convert SVT at 30-minutes compared to adenosine (82% vs 67%, respectively; odds ratio [OR] 0.43; $p=.08$).

Secondary Outcome –

- IV adenosine resulted in a faster rate of conversion compared to IV diltiazem (3 vs 6 minutes, respectively; $p=.02$).
- Of adenosine failures (103/310), 35% converted with rescue diltiazem (18/51) ($p=.02$)
- Median dose of adenosine for conversion was 12 mg
- Median dose for diltiazem for conversion was 15 mg

LIMITATIONS:

- Risk of selection bias and possibility of unmeasured confounding variables are inherent to completing a retrospective cohort study.
- The size of the diltiazem-first group was small, and the study may be underpowered to detect a significant difference between groups.

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The Next Pregnancy: Chance, Time, and Outcomes

Fertility, Time to Pregnancy, and Pregnancy Outcomes Among Women with Recurrent Miscarriages in the UK: A Prospective Observational Longitudinal Study

Koki C, Shields R, Sweetman R, et al. Fertility, time to pregnancy, and pregnancy outcomes among women with recurrent miscarriages in the UK: a prospective observational longitudinal study. *Lancet Reg Health Eur*. 2025;55:101343. Published 2025 Jun 26.

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KEY TAKEAWAY: For women experiencing recurrent miscarriage, factors such as age, body mass index (BMI), miscarriage history, and polycystic ovary syndrome (PCOS) meaningfully influence the probability of a viable pregnancy, although available prediction tools offer only moderate precision when counseling patients about future outcomes and time to conception.

STUDY DESIGN: Prospective cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: Recurrent miscarriage is one of the more emotionally difficult conditions clinicians encounter in practice, both for patients and for clinicians trying to support them. Although clinicians recognize that factors such as advancing maternal age and obesity influence pregnancy outcomes, translating population level data into individualized counseling remains challenging. In clinic, patients often ask very direct and understandable questions: “What are my actual chances of a successful pregnancy?” and “How long might this take?” This study sought to address those concerns by developing and externally validating prediction models to estimate the likelihood of a viable pregnancy and expected time to conception in women seen in recurrent miscarriage clinics.

PATIENTS: Persons with a history of recurrent miscarriage seeking to become pregnant

INTERVENTION: Presence of demographic and clinical factors, including maternal age, BMI, PCOS, smoking status, folic acid use, and number of previous miscarriages

CONTROL: Fewer or no identified risk factors (lower-risk profiles)

PRIMARY OUTCOME: Achievement of viable pregnancy (>24 weeks gestation)

Secondary Outcome: Time to conception and subfertility

METHODS (BRIEF DESCRIPTION):

- A prospective observational cohort study conducted at two UK NHS recurrent miscarriage clinics. Women were enrolled prior to attempting conception and followed longitudinally.
- The mean maternal age was approximately 34 years, and participants had experienced an average of three prior miscarriages at the time of enrollment. Most participants were of White ethnicity, reflecting the clinic’s population. A subset of women carried a diagnosis of PCOS.
- This was an observational cohort study with no active treatment administered. Participants were stratified based on reproductive history, including the number of prior miscarriages and presence or absence of previous conceptions.
- Comparisons were made according to the degree of prior miscarriage exposure and associated clinical risk factors.
- Fertility outcomes were assessed by ability to conceive during the follow-up and time to pregnancy after clinic enrollment. Sub-fertility was defined as failure to conceive within the follow-up period.
- Pregnancy outcomes were classified as viable pregnancy if gestation progressed >24 weeks.
- Multivariable regression and survival modeling were used to evaluate associations between baseline clinical factors and both likelihood of viable pregnancy and time to conception.

INTERVENTION (# IN THE GROUP): Not applicable

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW-UP PERIOD: Varied (participants were followed between 6–48 months; 942 participants were followed for 3 years, and they were used to calculate subfertility rate)

RESULTS:

Primary Outcome –

- Increased maternal age was associated with lower odds of viable pregnancy (odds ratio [OR] 0.89 per year; 95% CI, 0.84–0.95).

- Higher BMI was associated with reduced odds of viable pregnancy (OR 0.97 per kg/m²; 95% CI, 0.94–0.99).
- PCOS decreased the likelihood of viable pregnancy (OR 0.59; 95% CI, 0.39–0.89).
- A greater number of prior miscarriages reduced the odds of viable pregnancy (OR 0.79; 95% CI, 0.73–0.85).
- A history of prior live births did not significantly increase the odds of viable pregnancy (OR 1.2; 95% CI, 1.0–1.5).
- The prediction model of viable pregnancy demonstrated moderate discrimination (AUC 0.65; 95% CI, 0.55–0.76).

Secondary Outcome –

- 53% of women conceived within 12 months of clinic enrollment, and an additional 23% conceived between 12–24 months.
- After three years of follow-up, 11% did not conceive and were classified as the subfertility group. The prediction model for achieving pregnancy within 12 months demonstrated modest discrimination (AUC 0.60; 95% CI, 0.50–0.70).

LIMITATIONS:

- Study limited to the two centers in the UK and may not be generalizable.
- “Previous conceptions” included both live birth and miscarriage, though exposure includes only miscarriage.
- The follow up period was three years, and fertility could have occurred outside of this time.
- Other chronic medical conditions were not included in the analysis, introducing bias and reducing generalizability.

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Is Ashwagandha Supplementation Beneficial for Insomnia?

Safety and Efficacy of *Withania somnifera* for Anxiety and Insomnia: Systematic Review and Meta-Analysis

Fatima K, Malik J, Muskan F, et al. Safety and Efficacy of *Withania somnifera* for Anxiety and Insomnia: Systematic Review and Meta-analysis. *Hum Psychopharmacol*. 2024;39(6):e2911. doi:10.1002/hup.2911

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KEY TAKEAWAY: Ashwagandha improves some measures of sleep quality compared to placebo in adults meeting DSM-IV criteria for insomnia.

STUDY DESIGN: Systematic review and meta-analysis of five randomized controlled trials (RCTs) (N=254). Two RCTs measured sleep outcomes (N=95).

LEVEL OF EVIDENCE: STEP 2 (downgraded due to limited number of studies and heterogeneity of some outcome measures)

BRIEF BACKGROUND INFORMATION: *Withania somnifera* (ashwagandha) is one of the most well-studied adaptogens, a natural substance believed to help the body adapt to physical, emotional, or environmental stressors. Ashwagandha has been utilized for a long time in traditional medicine as a sleep aid, but more robust scientific evidence is needed to establish its efficacy.

PATIENTS: Adults meeting DSM-IV criteria for insomnia

INTERVENTION: Ashwagandha 300 mg twice daily

CONTROL: Placebo

PRIMARY OUTCOME: Sleep quality

METHODS (BRIEF DESCRIPTION):

- Systematic review and meta-analysis conducted in accordance with PRISMA 2020 guidelines.
- Databases searched: MEDLINE, Cochrane Library, and Google Scholar from inception through August 2023.
- The inclusion criteria included studies of adults with a diagnosis of anxiety or insomnia, RCTs, and comparing ashwagandha to placebo.
- Studies comparing *Withania somnifera* to other pharmacologic or behavioral interventions rather than placebo were excluded from the study.
- The intervention consisted of ashwagandha 300 mg twice daily for 8–10 weeks.
- Patients in the comparison group were given a placebo capsule containing starch, lactose, or wheat flour.

- The primary outcome measured sleep quality, which includes sleep onset latency, total sleep time, wake after sleep onset, time in bed, and sleep efficiency via the Pittsburgh Sleep Quality Index (PSQI).
- The PSQI is a seven-question inventory for sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over one month. Scores range from 0–21, with a higher score indicating worse sleep quality.

INTERVENTION (# IN THE GROUP): 138 (N=36 for 2 RCTs measuring sleep quality)

COMPARISON (# IN THE GROUP): 116 (N=59 for 2 RCTs measuring sleep quality)

FOLLOW-UP PERIOD: Variable: 6–10 weeks (8–10 weeks for 2 RCTs measuring sleep quality)

RESULTS:

Primary Outcome –

- Ashwagandha improved sleep quality compared to placebo measured by:
 - Sleep onset latency (2 trials, n=95; mean difference [MD] –7.5; 95% CI, –14 to –1.3; $I^2=50\%$)
 - Total sleep time (2 trials, n=95; MD 28; 95% CI, 4.2–51; $I^2=0\%$)
 - Sleep efficiency (2 trials, n=95; MD 4.1; 95% CI, 2.1–6.1; $I^2=0\%$)
 - PSQI score (sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, daytime dysfunction) (2 trials, n=95; MD –1.7; 95% CI, –2.8 to –0.5; $I^2=58\%$)
- Ashwagandha did not significantly improve wake after sleep onset or total time in bed compared to placebo.
 - Wake after sleep onset (2 trials, n=95; MD –5.3; 95% CI, –13 to 2.6; $I^2=0\%$)
 - Total time in bed (2 trials, n=95; MD 17; 95% CI, –11 to 45; $I^2=0\%$)

LIMITATIONS:

- Insufficient number of studies to evaluate publication bias or to conduct sensitivity analysis.
- Some heterogeneity among sleep quality parameters.

- The two RCTs evaluating sleep quality were both conducted in India, which may limit generalizability in the study's findings.

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Is Prolonged Beta-Blocker Therapy Truly Necessary Post-MI?

Discontinuation of Beta-Blocker Therapy After Myocardial Infarction

Choi KH, Kang D, Kim W, et al. Discontinuation of Beta-Blocker Therapy after Myocardial Infarction. *N Engl J Med*. 2026;394(13):1302-1312.

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KEY TAKEAWAY: Discontinuation of beta-blockers after one year post myocardial infarction (MI) does not significantly reduce the composite of all-cause mortality, recurrence of MI, or hospitalization due to heart failure (HF) compared to discontinuation of beta-blockers indefinitely in post-MI patients who lack additional significant cardiovascular disease.

STUDY DESIGN: Open-label, multicenter randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Currently, prolonged beta-blocker therapy remains standard of care in post-MI patients regardless of left ventricular ejection fraction (LVEF). While there is undisputed benefit in patients with reduced LVEF, many patients with preserved LVEF remain on beta-blockers for years after an MI without clear benefit. This study aimed to investigate whether beta-blockers continue to play an important role in post-MI management in the setting of contemporary interventions and secondary prevention.

PATIENTS: Post-MI adults without HF or atrial fibrillation (AF)

INTERVENTION: Discontinuation of beta-blocker after one-year post-MI

CONTROL: Continuation of beta-blocker indefinitely

PRIMARY OUTCOME: Composite of death due to any cause, recurrence of MI, or hospitalization due to HF
Secondary Outcome: Individual components of the primary outcome, any hospitalization, stroke, episode of AF, change in LVEF, change in NT-proBNP, adverse effects, quality of life

METHODS (BRIEF DESCRIPTION):

- Post-MI patients were recruited from 25 medical centers across South Korea for participation.
- The study included post-MI patients who were deemed stable and had been maintained on at least one year of beta-blocker therapy since the index MI.

- Exclusion criteria included history of LVEF <40%, current treatment of HF, history of AF, or contraindication to beta-blocker.
- Participants were randomly assigned to either group in a 1:1 ratio after stratification for type of MI, medical center, and type of beta-blocker.
- The trial group immediately discontinued the medication after randomization while the control group continued their medications.
- Follow-up of both groups occurred at six, 12, 24, and 30 months; annual follow-up was then maintained.
- Primary Outcome: Vital status was verified through the South Korean National Health Insurance Service database, recurrent MI was defined according to the Fourth Universal Definition of Myocardial Infarction, and HF hospitalizations were adjudicated by an independent clinical events committee. Outcomes were assessed throughout follow-up.
- All-cause mortality was defined as death from any cause during follow-up.
- Recurrent MI was defined according to the Fourth Universal Definition of Myocardial Infarction.
- Hospitalization for HF was defined as admission for HF during follow-up.
- Any hospitalization was defined as any hospital admission occurring during follow-up.
- Stroke was defined as incident stroke during follow-up.
- AF occurrence was defined as new-onset AF during follow-up.
- LVEF was defined as serial echocardiographic assessment of ventricular systolic function. LVEF is reported as a percentage, with higher values indicating better ventricular contractility. Changes from baseline were evaluated longitudinally.
- NT-proBNP was defined as serial measurement of a biomarker associated with ventricular wall stress and heart failure. Lower values indicate less cardiac strain. Changes from baseline were evaluated longitudinally.
- Quality of life was assessed using the 29-item Patient-Reported Outcomes Measurement Information System (PROMIS-29) questionnaire.

PROMIS-29 evaluates seven health domains: Physical function, anxiety, depression, fatigue, sleep disturbance, social participation, and pain interference. Scores are standardized T-scores (mean 50, standard deviation 10). Higher scores indicate greater severity in the measured domain. Higher scores indicate improvement in physical function and social participation, whereas lower scores indicate improvement in anxiety, depression, fatigue, sleep disturbance, pain interference, and pain intensity.

- Assessments were conducted at baseline and during follow-up.
- Adverse effects and serious adverse events were defined as serious adverse events, and beta-blocker-related adverse effects were recorded throughout follow-up.

INTERVENTION (# IN THE GROUP): 1,246

COMPARISON (# IN THE GROUP): 1,294

FOLLOW-UP PERIOD: Six, 12, 24, and 30 months, then annually. Median follow-up was 3.1 years.

RESULTS:

Primary Outcome –

- Beta-blocker cessation did not increase composite all-cause mortality, hospitalization due to HF, or recurrence of MI compared to continuation of beta-blockers (hazard ratio [HR] 0.80; 95% CI, 0.57–1.1).

Secondary Outcome –

- Beta-blocker cessation reduced the incidence of stroke compared to continuation of beta-blockers (HR 0.43; 95% CI, 0.19–0.99).
- Beta-blocker cessation did not significantly affect death from any cause, recurrence of MI, hospitalization for HF, any hospitalization, AF occurrence, LVEF, NT-proBNP, cardiovascular hospitalization, cardiovascular death, serious cardiac events, quality of life, or overall adverse side effects compared to continuation of beta-blockers.

LIMITATIONS:

- This study is limited to patients with few cardiovascular comorbidities or confounding diagnoses.
- The data are limited to the South Korean healthcare system.

- Women composed a small percentage of study participants.
- LVEF data used was obtained pre-MI.
- The intervention group completed one year of beta-blocker therapy prior to discontinuation.

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