130が新たな高値(2017 AHA)

高血圧が14年ぶりに再定義された

High blood pressure redefined for the first time in 14 years

高血圧は140/90ではなく、130/80の時点で生活習慣改善や一部の患者においては薬物治療により早期に治療されるべきである、との初めての包括的な高血圧新ガイドラインが、10年以上ぶりに2017 American Heart Association Scientific Sessions で発表された。新ガイドラインでは、高血圧前症のカテゴリーを取り除いた。これにより、より多くの人々が高血圧と診断され生活習慣改善に関する指導を受けることになる一方で、薬を処方される患者は少し増加するのみであろう。新ガイドラインの影響は、若年層において最大であろうと考えられている。このガイドラインは*Hypertension* および *Journal of the American College of Cardiology* に掲載された。

Full Text

High blood pressure should be treated earlier with lifestyle changes and in some patients with medication – at 130/80 mm Hg rather than 140/90 – according to the first comprehensive new high blood pressure guidelines in more than a decade. The guidelines are being published by the American Heart Association (AHA) and the American College of Cardiology (ACC) for detection, prevention, management and treatment of high blood pressure.

The guidelines were presented at the Association's 2017 Scientific Sessions conference in Anaheim, the premier global cardiovascular science meeting for the exchange of the latest advances in cardiovascular science for researchers and clinicians.

Although the new guidelines will increase the number of people diagnosed with hypertension, there will only be a small increase in the number who will require antihypertensive medication, authors said. These guidelines, the first update to offer comprehensive guidance to doctors on managing adults with hypertension since 2003, are designed to help people address the potentially deadly condition much earlier.

The new guidelines stress the importance of using proper technique to measure blood pressure. Blood pressure levels should be based on an average of two to three readings on at least two different occasions, the authors said.

Hypertension accounts for the second largest number of preventable heart disease and stroke deaths, second only to smoking. It's known as the "silent killer" because often there are no symptoms, despite its role in significantly increasing the risk for heart disease and stroke.

Paul K. Whelton, M.B., M.D., M.Sc., lead author of the guidelines published in the American Heart Association journal, *Hypertension* and the *Journal of the American College of Cardiology*, noted the dangers of blood pressure levels between 130-139/80-89 mm Hg.

"You've already doubled your risk of cardiovascular complications compared to those with a normal level of blood pressure," he said. "We want to be straight with people – if you already have a doubling of risk, you need to know about it. It doesn't mean you need medication, but it's a yellow light that you need to be lowering your blood pressure, mainly with non-drug approaches."

Blood pressure categories in the new guideline are:

- Normal: Less than 120/80 mm Hg;
- Elevated: Systolic between 120-129 *and* diastolic less than 80;
- Stage 1: Systolic between 130-139 *or* diastolic between 80-89;
- Stage 2: Systolic at least 140 *or* diastolic at least 90 mm Hg;
- Hypertensive crisis: Top number over 180 and/or bottom number over 120, with patients needing prompt changes in medication if there are no other indications of problems, or immediate hospitalization if there are signs of organ damage.

The new guidelines eliminate the category of prehypertension, which was used for blood pressures with systolic reading between 120-139 mm Hg or a diastolic between 80-89 mm Hg. People with those readings now will be categorized as having either Elevated (120-129 and less than 80) or Stage I hypertension (130-139 or 80-89).

Previous guidelines classified 140/90 mm Hg as Stage 1 hypertension. This level is classified as Stage 2 hypertension under the new guidelines.

The impact of the new guidelines is expected to be greatest among younger people. The prevalence of high blood pressure is expected to triple among men under age 45, and double among women under 45 according to the report.

Damage to blood vessels begins soon after blood pressure is elevated, said Whelton, who is the Show Chwan professor of global public health at Tulane University School of Public Health and Tropical Medicine and School of Medicine in New Orleans. "If you're only going to focus on events, that ignores the process when it's beginning. Risk is already going up as you get into your 40s."

The guidelines stress the importance of home blood pressure monitoring using validated devices and appropriate training of healthcare providers to reveal "white-coat hypertension," which occurs when pressure is elevated in a medical setting but not in everyday life. Home readings can also identify "masked hypertension," when pressure is normal in a medical setting but elevated at home, thus necessitating treatment with lifestyle and possibly medications.

"People with white-coat hypertension do not seem to have the same elevation in risk as someone with true sustained high blood pressure," Whelton said. "Masked hypertension is more sinister and very important to recognize because these people seem to have a similar risk as those with sustained high blood pressure."

Other changes in the new guideline include:

- Only prescribing medication for Stage I hypertension if a patient has already had a cardiovascular event such as a myocardial infarction or stroke, or is at high risk of MI or stroke based on age, the presence of diabetes mellitus, chronic kidney disease or calculation of atherosclerotic risk (using the same risk calculator used in evaluating high cholesterol).
- Recognizing that many people will need two or more types of medications to control their blood pressure, and that people may take their pills more consistently if multiple medications are combined into a single pill.
- Identifying socioeconomic status and psychosocial stress as risk factors for high blood pressure that should be considered in a patient's plan of care.

The new guidelines were developed by the American Heart Association, American College of Cardiology and nine other health professional organizations. They were written by a panel of 21 scientists and health experts who reviewed more than 900 published studies. The guidelines underwent a careful systematic review and approval process. Each recommendation is classified by the strength (class) of the recommendation followed by the level of evidence supporting the recommendation. Recommendations are classified I or II, with class III indicating no benefit or harm. The level of evidence signifies the quality of evidence. Levels A, B, and C-LD denote evidence gathered from scientific studies, while level C-EO contains evidence from expert opinion.

The new guidelines are the successor to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7), issued in 2003 and overseen by the National Heart, Lung, and Blood Institute (NHLBI). In 2013, the NHLBI asked the AHA and ACC to continue the management of guideline preparation for hypertension and other cardiovascular risk factors.

Co-authors are Robert M. Carey, M.D., vice chair of the writing committee; Wilbert S. Aranow, M.D.; Donald E. Casey, Jr., M.D., M.P.H., M.B.A.; Karen J. Collins, M.B.A.; Cheryl Dennison Himmelfarb, R.N., A.N.P., Ph.D.; Sondra M. DePalma, M.H.S., P.A.-C, C.L.S.; Samuel Gidding, M.D.; Kenneth A. Jamerson, M.D.; Daniel W. Jones, M.D.; Eric J. MacLaughlin, Pharm.D.; Paul Muntner, Ph.D.; Bruce Ovbiagele, M.D., M.Sc., M.A.S.; Sidney C. Smith, Jr., M.D.; Crystal C. Spencer, J.D.; Randall S. Stafford, M.D., Ph.D.; Sandra J. Taler, M.D.; Randal J. Thomas, M.D., M.S.; Kim A. Williams, Sr, M.D.; Jeff D Williamson, M.D., M.H.S. and Jackson T. Wright, Jr., M.D., Ph.D., on behalf of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Author disclosures and our collaborating organization partners are listed online and in the appendix to the manuscript.

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CANTOS：カナキヌマブ単回投与後の奏効性により最もベネフィットを得る患者が予測できる

CANTOS: Response after single treatment with canakinumab predicts which patients will benefit most

2017 American Heart Association Scientific Sessions において、抗炎症薬カナキヌマブが心血管死亡率および総死亡率を低下させたことを示したCANTOS試験のpre-specified（解析項目を事前に設定した）解析の結果が公表された。カナキヌマブ単回投与後にhsCRP値が2mg/L未満に低下した患者において、長期投与により心血管死亡率および総死亡率は、いずれも31% 低下した。カナキヌマブ単回投与後にhsCRP値が2mg/Lまたは2mg/L 超であった患者においては、これらの評価項目の統計学的に有意な低下は認められなかった。初回治療に対する確かな奏効性の有無によって、全ての主要な心血管アウトカムに大きな差が認められた。このスタディ結果は*Lancet* に掲載された。

Full Text

A new analysis seeks to answer the question of which patients are likely to gain the greatest cardiovascular benefit when treated with the anti-inflammatory agent canakinumab. At the 2017 American Heart Association Scientific Sessions, Paul M. Ridker, MD, director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital, presented a pre-specified analysis on CANTOS (Canakinumab Anti-inflammatory Thrombosis Outcomes Study) that identifies a simple, clinical method to define patient groups most likely to benefit from long-term canakinumab treatment. The results of this analysis, published simultaneously in *The Lancet*, could have a major impact not only on patient selection and cost-effectiveness of canakinumab, but also on the future development of anti-inflammatory agents for cardiovascular disease.

"We believe the clinical approach of targeting treatment to those who truly benefit on the basis of biologic response represents an elegant step toward personalized medicine and rational resource utilization," said Ridker. "Figuring out which patients with residual inflammatory risk benefit the most will allow us to get the right drug to the right patient, greatly reducing costs as well as hazards."

Major findings from the CANTOS trial were presented earlier this year. The trial was designed to test whether canakinumab, which lowers inflammation independent of lipid levels, could reduce risk of a future cardiovascular event by reducing inflammation among people who have had a prior myocardial infarction (MI) and who have persistently elevated levels of the inflammatory biomarker high-sensitivity C-reactive protein (hsCRP) despite aggressive care. Overall, the trial found a significant fifteen percent reduction in risk of recurrent MIs, strokes and cardiovascular death among participants who received canakinumab at doses of either 150mg or 300mg, given once every three months. The critical question Ridker and colleagues have further investigated is whether reductions in the magnitude of inflammation achieved after a single treatment with canakinumab can predict greater or lesser clinical benefit for individual patients.

In the new analysis, the team found that baseline characteristics did not modify the effect of canakinumab on clinical outcomes. However, the magnitude of decrease in hsCRP with canakinumab related directly to the magnitude of clinical benefit associated with continued long-term therapy. For those treated with canakinumab who achieved hsCRP levels below 2mg/L after one dose, cardiovascular and all-cause mortality were both reduced by 31 percent with prolonged treatment. By contrast, no statistically significant reduction in these endpoints was observed among those treated with canakinumab who achieved hsCRP levels equal to or above 2mg/L. Similar large differences in all major cardiovascular outcomes were observed among those who did and did not have robust responses to initial therapy.

"The magnitude of hsCRP reduction following a single dose of canakinumab may provide a simple clinical method to identify individuals most likely to accrue the largest benefit from continued treatment. These data further suggest that 'lower is better' for inflammation reduction with canakinumab," said Brendan Everett, MD, an investigator in CANTOS and director of the General Cardiology Inpatient Service at BWH.

"While prior analyses have examined hsCRP as a predictive biomarker in the context of statin therapy, which both lowers cholesterol and lowers inflammation, our study is the first to analyze outcome data for an agent that only reduces inflammation without concomitant effects on cholesterol," Ridker said. "Our work suggests that patients with 'residual inflammatory risk' represent a separate and distinct group from patients with 'residual cholesterol risk' who likely require different personalized approaches to treatment."

The authors note that their findings could have implications for patient selection, cost-effectiveness and drug design and development going forward, with the potential to increase canakinumab's benefit to risk ratio. For example, the five-year number needed to treat (NNT) is 16 for among those treated with canakinumab who achieved hsCRP concentrations less than 2mg/L. By contrast, the five-year NNT was 57 for those who did not achieve this on-treatment hsCRP threshold. The occurrence of fatal infection observed in CANTOS among approximately one in every 1,000 patients treated was not related to the magnitude of inflammation reduction.

"The new analyses will be quite relevant to physicians, regulators, and payers who are all trying to understand how to achieve the greatest efficacy with the minimal hazard," said Peter Libby, MD, a CANTOS investigator with long-standing interests in inflammation biology.

"Reaching goals is critical for patients and physicians," said Roger Blumenthal, MD, the Kenneth J. Pollin Professor of Cardiology at Johns Hopkins University School of Medicine. "The new CANTOS analysis makes it clear that biologic response matters greatly. Reaching on-treatment hsCRP goals after taking canakinumab is a strong marker for long-term success."

CANTOS was proposed and designed by investigators in the Center for Cardiovascular Disease Prevention at BWH, in collaboration with Novartis Pharmaceuticals. In addition to Ridker, Everett, and Libby, other Brigham and Women's Hospital researchers who contributed critically to this work include Jean MacFadyen, BA and Robert J. Glynn, ScD. Ridker and Glynn received financial support for clinical research from Novartis Pharmaceuticals to conduct the CANTOS. Ridker has served as a consultant to Novartis Pharmaceuticals and is listed as a co-inventor on patents held by BWH that relate to the use of inflammatory biomarkers in cardiovascular disease and diabetes that have been licensed to AstraZeneca and Siemens.

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FOURIER：PCSK9阻害薬は末梢動脈疾患患者の予後を改善する

FOURIER: PCSK9 inhibitor improves outcomes for patients with peripheral artery disease

末梢動脈疾患（PAD）患者に対し、スタチン療法にPCSK9阻害薬エボロクマブを併用することで将来の心血管イベントリスクを軽減することが示された、とのFOURIER 試験のサブ解析の結果が2017 American Heart Association Scientific Sessions で発表され、*Circulation* に掲載された。PAD患者はMIまたは脳卒中リスクが高いため、心血管イベントの絶対リスク減少率が大であった（PAD患者3.1%、非PAD患者1.6%）。エボロクマブは、PAD患者の主要有害下肢イベントリスクを、プラセボに比べ約半分に低下させた。PADを有しMIまたは脳卒中リスクを有さない患者において、エボロクマブは2.5年間の心血管または有害下肢イベントリスクを6% 低下させた。

Full Text

Patients with peripheral artery disease (PAD) are at high risk of myocardial infarction (MI), stroke and cardiovascular death. In addition, PAD patients can suffer major adverse limb events, such as acute limb ischemia that can lead to limb loss. Managing PAD is challenging for patients and physicians alike - despite best available treatment including high-intensity statins, risk of cardiovascular and limb events remains high. With few clinical trials focused on patients with PAD, physicians must often extrapolate from studies in broader populations with atherosclerosis about the best treatment approach for these patients. Unfortunately, few of these studies have characterized limb risk and fewer have demonstrated benefits of preventive therapies in reducing this risk.

A new sub-analysis of the FOURIER clinical trial, however, now offers information on the safety and effectiveness of giving the PCSK9 inhibitor evolocumab on top of statin therapy to this high-risk population. At the 2017 American Heart Association Scientific Sessions, Marc Bonaca, MD, MPH, investigator at the TIMI Study Group and director of the Aortic Disease Center at Brigham and Women's Hospital, presented results from the sub-analysis, which are published simultaneously in *Circulation*.

"Whenever trials like FOURIER demonstrate benefit of a therapy in a broad population, we then want to understand the efficacy and safety in subpopulations to help clinicians understand which patients are going to derive the greatest absolute benefit. We've found that several sub-groups of patients respond well to evolocumab, but it's especially encouraging to see these results for patients with PAD since this is a population at heightened cardiovascular risk and there are few therapies that modify limb risk," said Bonaca. "We see that adding evolocumab can make a big difference for these patients."

The team analyzed data from more than 3,600 trial participants, half of whom had no history of an MI or stroke. Evolocumab reduced risk of a future cardiovascular event for patients with or without PAD. Because patients with PAD are at especially high risk of a MI or stroke, these patients had a higher absolute risk reduction (3.5% PAD, 1.6% no PAD) of a cardiovascular event. In addition, evolocumab reduced their risk of a major adverse limb event by about half, compared to PAD patients who received the placebo. Among patients with PAD and no history of an MI or stroke, evolocumab reduced risk of a cardiovascular or adverse limb event by 6 percent over 2.5 years. Researchers report that the number needed to treat (NNT) is as low as 16 for this patient population. The team found no offsetting safety concerns.

Bonaca presented PAD findings as part of a Clinical Trials Update at the Scientific Sessions.

Evolocumab is a member of a new class of cholesterol lowering drugs known as PCSK9 inhibitors that have emerged as an effective treatment for drastically lowering LDL cholesterol beyond what is possible with statin therapy alone. Previous research demonstrated that evolocumab effectively reduces LDL cholesterol by approximately 60 percent. The FOURIER trial (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in subjects with Elevated Risk) was designed to determine whether evolocumab, when added to statin therapy, would reduce adverse cardiovascular events.

FOURIER was designed in a collaboration between the Executive Committee and the trial sponsor, Amgen, which manufactures evolocumab and provided a research grant to the TIMI Study Group at BWH. The TIMI Study Group conducted all data analyses presented in the paper. Sabatine and the TIMI Study Group receive research grants from various pharmaceutical companies that produce other lipid-lowering therapies and Sabatine reports receiving honoraria from Amgen and various pharmaceutical companies that produce other lipid-lowering therapies.

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一次予防としての140未満への血圧降下 (2017 AHA, Session LBS.02)

強力な降圧療法は心血管系疾患を軽減しない

No cardiovascular disease reduction with intensive blood pressure lowering treatment

収縮期血圧が140mmHg未満の健常者において、降圧療法は死亡または心血管系疾患を減少させない、と2017 American Heart Association Scientific Sessions で発表され、*JAMA Internal Medicine* に掲載された。このメタ解析において研究者らは、一次予防研究を冠動脈疾患または脳卒中既往を有する患者を対象としたものと分離した。治療効果は、過去には健康であった人々において、どの程度血圧が高かったかに依存した。収縮期血圧が140mmHg を超えていると、治療により死亡および心血管系疾患のリスクが低下した。140mmHg 未満では、治療は死亡率または初回の心血管イベントリスクには影響しなかった。

Full Text

Blood pressure lowering treatment does not reduce death or cardiovascular disease in healthy individuals with a systolic blood pressure below 140. This is shown in a systematic review and meta-analysis from Umeå University. The results which were presented at the 2017 American Heart Association Scientific Sessions and published in *JAMA Internal Medicine*, support current guidelines and contradict the findings from the Systolic Blood Pressure Intervention Trial (SPRINT).

Blood pressure treatment goals have been intensively debated since the publication of the SPRINT study in 2015. While current guidelines recommend a systolic blood pressure goal < 140 mm Hg, SPRINT found additional mortality and cardiovascular disease reduction with a goal < 120 mm Hg. New guidelines were released at the AHA Scientific Sessions that reduce the recommendations.

The Umeå study shows that treatment does not affect mortality or cardiovascular events if systolic blood pressure is < 140 mm Hg. The beneficial effect of treatment at low blood pressure levels is limited to trials in people with coronary heart disease.

"Our findings are of great importance to the debate concerning blood pressure treatment goals," says Dr. Mattias Brunström, researcher at the Department of Public Health and Clinical Medicine, Umeå University and lead author.

The study is a meta-analysis, combining data from 74 randomized clinical trials, including more than 300 000 patients. The researchers separated primary preventive studies from studies in people with coronary heart disease or previous stroke. The analysis found that the treatment effect was dependent on how high blood pressure was in previously healthy individuals. If systolic blood pressure was above 140 mm Hg, treatment reduced the risk of death and cardiovascular disease. Below 140 mm Hg, treatment did not affect mortality or the risk of first-ever cardiovascular events.

"Several previous meta-analyses have found that blood pressure lowering treatment is beneficial down to levels below 130 mm Hg. We show that the beneficial effect of treatment at low blood pressure levels is limited to trials in people with coronary heart disease. In primary preventive trials, treatment effect was neutral," says Mattias Brunström.

Systolic Blood Pressure Intervention Trial (SPRINT), was a large randomized controlled study that was published in 2015.

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TRICS III：最終的な世界的輸血スタディの結果は、患者の安全性および良好な転帰を支持する

TRICS III: Definitive global transfusion study supports patient safety and positive patient outcomes

心臓手術中の輸血を行う下限値を低下させることは、従来の値を用いた場合よりも安全で患者の転帰を改善するとの、この領域で過去最大の研究が発表された。より低い、つまり"制限的な"下限値により、輸血を受ける患者が28% 減少し、輸血量が約30% 減少した。またこの制限的な下限値により、輸血量が減り各々の施術に費やす費用も減らすことができた。この結果は2017 American Heart Association Scientific Sessions で発表され、同時に*New England Journal of Medicine* に掲載された。

Full Text

Lower thresholds for blood transfusions during cardiac surgery have proven to be safe and provide good patient outcomes compared to traditional thresholds, according to the largest research study ever performed in this area. The lower or "restrictive" threshold also can help reduce the amount of blood transfused and money spent for each procedure.

The randomized trial involving more than 5,000 patients at 74 cardiac care centers in 19 countries found no clinical or statistical difference in the four important patient outcomes chosen to determine whether contemporary restrictive practices provided better or worse patient safety and outcomes than traditional liberal practices. The chosen indicators included death, heart attack, stroke or new kidney failure.

The study found that the restrictive approach reduced the number of patients who received transfusions by 28 percent and reduced the amount of blood transfused by approximately 30 per cent.

The findings were presented at the 2017 American Heart Association Scientific Session by Dr. David Mazer, an anesthesiologist at St. Michael's Hospital and associate scientist in its Keenan Research Centre for Biomedical Science. They were published simultaneously in the *New England Journal of Medicine*.

According to Dr. Mazer, physicians who practice the liberal transfusion approach tend to give blood transfusions early in the surgery to prevent patients' hemoglobin level from falling. Hemoglobin is the protein that allows red blood cells to deliver oxygen to body tissues. Physicians who practice a restrictive approach tend to wait longer to see if the hemoglobin level remains stable or if the patient has excessive bleeding.

Dr. Mazer said the study was important because transfusion practices vary widely around the world and because there are known risks to blood transfusions and to acute anemia. Other studies have shown that restrictive transfusion practices can reduce the number and volume of transfusions, but this is the first research, he said, to definitively show it is equal to higher thresholds in terms of patient safety and outcomes.

"We have shown that this approach to transfusion is safe, in moderate- to high-risk patients undergoing cardiac surgery," Dr. Mazer said. "Such practices can also reduce the number of patients transfused, the amount of blood transfused, the impact on blood supply and costs to the health-care system."

This study received funding from the Canadian Institutes of Heart Research, Canadian Blood Services, the National Health and Medical Research Council in Australia and the Health Research Council of New Zealand.

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ストレスフルイベントは女性の肥満率を上昇させる (2017 AHA, Poster Presentation T2039 - Session: CM.APS.06)

人生においてトラウマになるような出来事を1つ以上経験した女性は肥満度が高い

Women who reported one or more traumatic lifetime events had increased odds of obesity

人生において1つ以上のトラウマになるような出来事、またはここ数年で複数のネガティブな出来事を経験した女性は、そのようなストレスのない女性に比べ肥満度が高い、との予備調査の結果が2017 American Heart Association Scientific Sessions で発表された。人生において1つ以上のトラウマになるような出来事を経験した女性は、経験しなかった女性に比べ肥満度が11% 高かった。本人が報告した過去5年間のネガティブな出来事が多いほど、肥満の傾向が強かった。特に、ネガティブな出来事が4つ以上あったと報告した女性は、肥満リスクが36% 高かった。

Full Text

Women who experienced one or more traumatic lifetime events or several negative events in recent years had higher odds of being obese than women who didn't report such stress, according to preliminary research presented at the American Heart Association's Scientific Sessions 2017, a premier global exchange of the latest advances in cardiovascular science for researchers and clinicians.

"Little is known about how negative and traumatic life events affect obesity in women. We know that stress affects behavior, including whether people under- or overeat, as well as neuro-hormonal activity by in part increasing cortisol production, which is related to weight gain," said study senior author Michelle A. Albert, M.D., M.P.H., professor of medicine, cardiology, and founding director of the Center for the Study of Adversity and Cardiovascular Disease, at University of California, San Francisco.

Obesity, a preventable risk factor for cardiovascular and other diseases. Women tend to live longer than men, putting especially obese, aging women at greater risk for disease, said study author Eva M. Durazo, Ph.D., a post-doctoral scholar at the NURTURE Center, Division of Cardiology, UCSF said.

The researchers studied the relationship between major life events and obesity in a group of 21,904 middle-aged and older women, focusing on women with the highest obesity prevalence. They defined obesity as having a body mass index (BMI) of 30 kg/m^2 or higher. And, they measured the impacts of two types of stress: traumatic events, which could occur anytime in a woman's life and includes such things as death of a child or being a victim of a serious physical attack, as well as negative life events that had occurred in the previous five years of a woman's life. Negative events included wanting employment but being unemployed for longer than three months or being burglarized.

They found:

- Nearly a quarter (23 percent) of the women studied were obese.
- Women who reported greater than one traumatic life event versus no traumatic life events had 11 percent increased odds of obesity.
- The higher the number of negative life events reported by women in the last five years, the higher the tendency for increased odds of obesity. Specifically, women who reported four or more negative life events had a 36 percent higher risk of obesity, compared to women who reported no such events.
- Among women who had higher levels of physical activity, there was a stronger association between increasing cumulative/chronic stress and obesity, though the reason for this finding remains uncertain.

"Our findings suggest that psychological stress in the form of negative and traumatic life events might represent an important risk factor for weight changes and, therefore, we should consider including assessment and treatment of psychosocial stress in approaches to weight management," Albert said.

Because the study looks at the association between stressful events and obesity in a snapshot of time, future studies should look at the relationship longitudinally, following people for weight gain over time after life events have occurred, according to Albert.

"This is important work because women are living longer and are more at risk for chronic illnesses, such as cardiovascular disease. The potential public health impact is large, as obesity is related to increased risks of heart attack, stroke, diabetes and cancer, and contributes to spiraling healthcare costs," Albert said.

Co-authors are Fumika Matsushita, M.P.H.; Alan M. Zaslavsky, Ph.D.; Tiffany Powell-Wiley, M.D., M.P.H.; Natalie Slopen, Sc.D. and Julie E. Buring, Sc.D. Author disclosures are on the abstract.

The National Institute on Aging, National Cancer Institute and National Heart, Lung and Blood Institute funded the study.

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日本のスタディにおいて高用量のピタバスタチンによる治療は低用量の治療を上回った (2017 AHA, Session LBS.02)

REAL-CAD：高用量ピタバスタチンは安定CADを有する日本人患者において心血管イベントを有意に減少させた

REAL-CAD: High-dose pitavastatin significantly reduced cardiovascular events in Japanese patients with stable CAD

高用量スタチン療法はアジアの臨床現場ではあまり用いられていないが、安定冠動脈疾患（CAD）を有する日本人患者において有効であり忍容性に優れている、と2017 American Heart Association Scientific Sessions で発表された。REAL-CAD 試験には、日本の733施設から13,000人超が組み入れられた。5年後に、高用量群（4mg/日）においては、低用量群（1mg/日）に比べ、主要評価項目（心血管死、非致死性MI、非致死性脳卒中、および不安定狭心症による入院）の有意なリスク減少が認められた（p=0.001）。5年間の治療必要数（NNT）は63であった。

Full Text

Although high-dose statin therapy isn't widely used in clinical practice in Asia, it is efficacious and well-tolerated in patients from Japan who have stable coronary artery disease (CAD), according to research presented at the 2017 American Heart Association Scientific Sessions.

The Randomized Evaluation of Aggressive or Moderate Lipid Lowering therapy with Pitavastatin in Coronary Artery Disease (REAL-CAD) trial included more than 13,000 patients from 733 centers in Japan, making it one of the largest to compare high- and low-dose statin therapy—and the first randomized controlled trial in Asia to do so.

The open-label study found that high-dose (4 mg/day) as compared with low-dose (1 mg/day) pitavastatin therapy significantly reduced CV events in Japanese patients with stable CAD (P = 0.01).

Despite ACC/AHA and ESC guidelines, the high-intensity statins are not widely used in daily clinical practice, particularly in Asia. No clear evidence regarding "more versus less statins" has been established in Asian populations. Most of the doses of high-intensity statin therapy defined in the ACC/AHA guidelines are not approved in Japan.

Furthermore, the incidence of CV events is lower in Asian patients than in Western patients. The benefits of high-intensity statins demonstrated in Western patients with relatively high CV event risk might not be clinically relevant in patient populations at relatively low event risk.

The REAL-CAD clinical trial evaluated the efficacy of high-intensity Pitavastatin therapy in patients with stable coronary artery disease in relatively low risk population.

13,054 patients from 733 institutions in Japan were randomized to high-intensity (pitavastatin 4 mg/day) or low-intensity (pitavastatin 1 mg/day) statin therapy for 5 years. Six months after randomization, mean LDL-C was 73.8±20.3 mg/dL in the high-intensity group and 89.4±21.4 mg/dL in the moderate-intensity group.

"Current guidelines call for high-intensity statin therapy in patients with . . . CAD based on several previous 'more-or-less-statin' trials," write the investigators.

"However, no clear evidence regarding more vs less statin has been established in Asian populations," said Dr. Hiroaki Shimokawa of Tohoku University Graduate School of Medicine, Sendai, Japan during a press briefing.

In October 2015, the steering committee decided to terminate the study 2 years early, "despite the original event-driven trial design, because a substantial number of centers were reluctant" for the study to be extended further, reported Shimokawa. This led to the noncompletion of the final follow-up in "a substantial proportion" of patients.

Even with this limitation, there was a significant risk reduction for the primary endpoint (a composite of cardiovascular death, non-fatal myocardial infarction (MI), non-fatal stroke, and hospitalization for unstable angina). The hazard ratio (HR) was 0.81 for the high- vs low-dose statin group (95% CI 0.69–0.95, P=0.01). In addition, 4.3% vs 5.4%, respectively had a CV event. The number needed to treat (NNT) for 5 years was 63.

"The present study provides support for the notion that administration of higher doses of statins within the range of local approval would be the preferred therapy in patients with established CAD regardless of the baseline LDL-C levels," summarized Shimokawa.

Funding from Tohoku University supported this study.

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PCI後患者に対する術前アスピリン投与は有益である可能性がある(2017 AHA, Session LBS.05)

POISE-2 PCI：周術期低用量アスピリン投与はPCI後患者の死亡および非致死性MIのリスクを減少させる

POISE-2 PCI: Low-dose perioperative aspirin reduces risk of death or nonfatal MI in patients with prior PCI

過去に経皮的冠動脈インターベンション（PCI）を施行された患者において、非心臓手術直前、術中および術直後のアスピリン投与により、心臓に関する合併症を予防することができる、とのPOISE-2 試験の結果が2017 American Heart Association Scientific Sessions で発表され、*Annals of Internal Medicine* に掲載された。この結果から、周術期のアスピリン投与はPCI歴を有する非心臓手術患者1,000人毎に、59件の心筋梗塞を予防し8件の大出血イベントを来すことが示された。アスピリンはPCI歴の有無に関係なく、同程度に出血リスクを増大させた。

Full Text

A Canadian-led study has found that aspirin given just before, during and shortly after major non-cardiac surgery can prevent heart-related complications in patients who had a previous percutaneous coronary intervention (PCI) such as an angioplasty or stent. The results of this substudy of the POISE trial was presented at the 2017 American Heart Association Scientific Sessions and published in the *Annals of Internal Medicine*.

"This is your next-door neighbor who had angioplasty five years ago, feels fine and needs to go in for hip surgery. It affects quite a large number of people," said the study's lead author, Michelle Graham, an interventional cardiologist and professor in the University of Alberta's Department of Medicine. She said 200 million adults around the world undergo major non-cardiac surgery annually.

The study examined the effect of aspirin in 470 patients with prior PCI patients undergoing noncardiac surgery. They were randomized to either aspirin or placebo.
The use of low-dose perioperative aspirin compared with placebo reduced the risk of the primary outcome – a composite of death or nonfatal myocardial infarction (MI). "This effect was driven by a reduction in MI," Graham noted. "This result significantly differed from those without prior PCI."

In patients with prior PCI, aspirin reduced the risk of the primary composite outcome (hazard ratio [HR], 0.51; 95% confidence interval [CI], 0.27-0.98, interaction p=0.0374).

Aspirin increased the risk of the composite of major and life-threatening bleeding in the overall trial population, to a similar extent in those with and without prior PCI (p=0.50).

These results suggest for every 1,000 patients with prior PCI who have noncardiac surgery, administration of perioperative aspirin would prevent 59 myocardial infarctions and cause 5 major bleeding events. Non-cardiac surgeries occur daily at hospitals around the world, so the study results will have a big impact on this patient group.

The POISE-2 trial is a large international study with sites in 135 centers in 23 countries. Patients with previous PCI were enrolled in 82 centers in 21 countries.
In patients without a PCI, POISE-2 showed that aspirin did not reduce the risk of MI or death and led to an increased risk of major bleeding.

Of the 10,010 participants enrolled in the POISE-2 study, 470 had a previous PCI. Because patients with a prior PCI have an increased risk of cardiovascular complications after non-cardiac surgery, the group wanted to see whether the findings were the same in the subgroup.

This was the largest randomized trial of patients with PCI undergoing major non-cardiac surgery. Although aspirin reduced the risk of MI among patients in the study, it also slightly increased the risk of bleeding, though that risk did not appear worse than in the overall POISE-2 trial.

"There will be a big knowledge translation push with our colleagues in anesthesia and surgery to remind them that we want them to continue to give aspirin to this group of patients, when for most other groups we're recommending they stop," said Graham.

"This will potentially change the practice of anyone who does perioperative medicine," said Graham.

Funding for the Canadian study was largely provided by the Canadian Institutes of Health Research.

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RE-DUAL PCI：ダビガトランとP2Y$_{12}$阻害薬による2剤併用療法は、サブグループ間で一貫してワルファリンよりも出血リスクを減少させる

RE-DUAL PCI: Dual therapy with dabigatran and a P2Y12 inhibitor reduces bleeding risk better than warfarin across subgroups

RE-DUAL PCI試験のサブグループ解析の結果、経皮的冠動脈インターベンション（PCI）を施行される広範な心房細動患者において、ダビガトランとP2Y$_{12}$阻害薬による2剤併用抗血栓療法は、ワルファリンを含む3剤併用療法に比べ出血リスクが低いことが示された。ダビガトラン2剤併用療法の有益性は、指標となるイベントとしての急性冠症候群の有無に関係なく、薬剤溶出性ステントまたはベアメタルステントを留置され、P2Y$_{12}$阻害薬、クロピドグレルまたはチカグレロルを投与された患者における主研究の結果と一貫していた。この結果は2017 American Heart Association Scientific Sessions で発表された。

Full Text

A subgroup analysis from the RE-DUAL PCI study found that dual antithrombotic therapy with dabigatran and a P2Y$_{12}$ inhibitor reduces the risk of bleeding better than triple therapy with warfarin in a range of patients with atrial fibrillation (AF) undergoing PCI.

The benefit of dabigatran dual therapy was consistent with the results from the main study in patients with and without acute coronary syndrome (ACS) as the index event, those receiving drug-eluting stents (DES) or bare-metal stents (BMS), and patients treated with either P2Y$_{12}$ inhibitor, clopidogrel or ticagrelor.

The RE-DUAL PCI clinical trial, evaluated the safety and efficacy of a dual antithrombotic therapy regimen using dabigatran and a P2Y$_{12}$ platelet antagonist vs. a triple therapy with warfarin, aspirin and a P2Y$_{12}$ platelet antagonist. It was a phase IIIb, prospective, randomized trial that enrolled 2725 patients at approximately 550 sites in 41 countries.

The main results were presented at the European Society of Cardiology Congress 2017. This subgroup analysis presented at the 2017 American Heart Association Scientific Sessions reports outcomes in the major prespecified subgroups including DES versus BMS, acute coronary syndrome (ACS) versus non-ACS, diabetic versus non-diabetic patients, and groups that were age related.

The primary endpoint was time to the first major or clinically relevant non-major bleeding event. Secondary endpoints were composite of death or thrombotic events and unplanned revascularization; thrombotic events or death; individual outcome events; the composite of death and myocardial infarction or stroke; and unplanned revascularization.

In the RE-DUAL PCI trial

- The index indication for PCI was an ACS in 50% of the patients
- DES alone were used in 83% of the patients, similarly in patients with ACS and non-ACS
- The majority of patients received clopidogrel; 12% of the patients received ticagrelor either as part of dabigatran dual therapy or warfarin triple therapy
- Patients who received ticagrelor more often had ACS as the index event, were oral anticoagulation naïve, and had DAPT clinical complexity factors; and ticagrelor was associated with higher bleeding risk than clopidogrel
- There were no significant interactions in any of the presented outcomes for any of the presented subgroups

The main RE-DUAL PCI study showed absolute risk reductions in major or clinically relevant nonmajor bleeding of 11.5% and 5.5% with twice-daily 110-mg and 150-mg dabigatran dual therapy, respectively, compared with triple therapy with warfarin, clopidogrel or ticagrelor, and aspirin. Dabigatran dual therapy also met the noninferiority threshold for the composite efficacy outcome of death, thromboembolic events, or unplanned revascularization.

The substudy was consistent with the main results for all patient groups. For example, the new analysis, rates of major or clinically relevant nonmajor bleeding were lower in ACS patients treated with 110-mg (14.7% vs. 27.8%) and 150-mg (20.5% vs 27.1%) dabigatran dual therapy than in those treated with triple therapy. Similar reductions in these events were observed among non-ACS patients in the 110-mg (16.1% vs. 26.1%) and 150-mg (19.9% vs. 24.4%) dabigatran groups vs. triple therapy.

Similar reductions were seen in patients receiving drug eluting stents, bare metal stents, and patients treated with either P2Y$_{12}$ inhibitor, clopidogrel or ticagrelor.

"I think it's reassuring that for the majority of patients we can use the higher dose of dabigatran in a dual therapy setting, which is better compared with warfarin triple therapy, which is standard guidelines care," study author Dr. Jonas Oldgren from Uppsala University in Sweden. "For higher-risk, frail patients, we can use the lower dose."

The study was funded by Boehringer Ingelheim.

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心房細動に対するボツリヌス毒素(2017 AHA, Session LBS.07)

TNT-POAF：心外膜へのボツリヌス毒素注入は術後心房細動を減少させる可能性がある

TNT-POAF: Epicardial botulinum toxin may reduce postoperative atrial fibrillation

心臓手術後心房細動（POAF）の予防目的での心外膜ボツリヌス毒素治療はPOAFリスクを数字上低下させたが、この差は統計学的有意差には到達しなかった、と2017 American Heart Association Scientific Sessions で発表された。心外膜脂肪層の心臓自律神経近くに注入すると、ボツリヌス毒素は心房に抗コリン的に作用し、心房の有効不応期を短縮しAF誘発を阻害する。ボツリヌス毒素を注入された患者のうち、36.5% がPOAFを発症したのに対し、プラセボ注入群では47.8% であった（p=0.19）。入院期間または術後合併症に有意差はなかった。

Full Text

Epicardial botulinum toxin treatment to prevent postoperative atrial fibrillation (POAF) after cardiac surgery was associated with a numerically lower risk of POAF, though this difference did not reach statistical significance according to researchers at the 2017 American Heart Association Scientific Sessions.

From temporarily softening wrinkles to easing migraines, botulinum toxin has become a versatile medical remedy because of its ability to block nerve signals that can become bothersome or risky. But could the toxin also quell atrial fibrillation after cardiac surgery?

Researchers in Duke's Department of Anesthesiology and the Duke Clinical Research Institute launched their inquiry after a study from Russian scientists reported a 70-percent drop in atrial fibrillation (AF) episodes among a small cohort of heart surgery patients who were treated with strategic injections of botulinum toxin.

"The results from Russia were very interesting, but needed to be replicated on a larger and more medically complex group of patients," said lead author and Duke anesthesiologist Nathan Waldron, M.D.

Bouts of POAF are a common complication after cardiac surgery, affecting up to 40 percent of patients and increasing the risk of stroke and death. When injected near cardiac autonomic nerves in epicardial fat pads, botulinum toxin acts in an anticholinergic fashion on the atrium, shortening atrial effective refractory periods and blocking induction of AF.

Waldron and colleagues enrolled 130 patients who were slated to undergo a coronary artery bypass grafting procedure, valve surgery, or both. During their surgeries, roughly half the patients were randomly assigned to receive shots of botulinum toxin in the fat pads around their heart – where the fibrillation is known to arise; the other half received harmless saline. The medical teams did not know which injection the patients received.

Afterward, the patients were monitored continuously by electrocardiogram to pick up signs of POAF. Among the patients who received injections of botulism toxin, 36.5 percent had POAF, compared to 47.8 percent of those who had the saline placebo.

The researchers also found that patients who received the botulinum toxin had shorter initial bouts of POAF, but the treatment was not associated with an increase in adverse events, duration of postoperative mechanical ventilation, or length of stay compared to placebo.

"Unfortunately, while there was a numerically lower risk of atrial fibrillation among the Botox patients, it did not meet statistical significance," said Jonathan P. Piccini, M.D., a member of DCRI and senior author of the study. "What we observed was a modest positive effect on preventing atrial fibrillation, so a larger trial is something that is needed to provide a clearer picture."

While this trial failed to meet the primary endpoint of increased time to first episode of POAF, these data indicate that epicardial botulinum may be a viable strategy to prevent postoperative atrial fibrillation and should be studied in a larger-scale trial

The study received funding from the American Heart Association and the Foundation for Anesthesia Education and Research.

In addition to Waldron and Piccini, study authors include Mary Cooter, John C. Haney, Jacob N. Schroder, Carmelo A. Milano and Joseph P. Mathew.

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肥満手術は降圧薬の必要性を軽減する (2017 AHA, Session LBS.03)

GATEWAY：胃バイパス手術は降圧薬への依存を軽減するのに薬物療法よりも優れている

GATEWAY: Gastric bypass surgery superior to medical management at reducing reliance on antihypertensive medications

肥満の高血圧患者における胃バイパス手術は、降圧薬への依存を軽減するのに薬物療法単独よりも優れており、体重を減らし他の健康尺度も改善する、と2017 American Heart Association Scientific Sessions で発表され、*Circulation* に掲載された。胃バイパス術と薬物療法の併用にランダムに選択された患者は、主要評価項目である降圧薬を少なくとも30%減量しても、12か月後の血圧が良好に維持できている確率が薬物療法のみの患者に比べ圧倒的に高かった（83.7% vs. 12.8%、p<0.001）。12か月後、胃バイパス手術患者の51% が、内服せずに血圧がコントロールされた状態を維持していた。

Full Text

Gastric bypass is superior to medical management alone at reducing antihypertensive medications while also reducing weight and improving other health measures in obese hypertensive patients according to research presented at the 2017 American Heart Association Scientific Sessions and published in *Circulation*.

The GATEWAY (GAstric bypass surgery to TrEat patients With steAdy hYpertension) clinical trial examined the impact of bariatric surgery on hypertension control. It was a randomized (concealed), single-center, phase III, parallel design of 100 participants aged (average age 44, average BMI 36.9 ± 2.7 kg/m^2), with essential arterial hypertension, using at least 2 drugs at optimal doses or more than two in optimal and/or moderate doses.

The primary endpoint was reduction of at least 30% of the total antihypertensive drugs, while maintaining controlled blood pressure (BP) levels (<140x90mmHg) at 12 months. Secondary endpoints were weight reduction, percentage of patients with controlled BP levels without medication, C-reactive protein, glycated hemoglobin, triglyceride and LDL- cholesterol levels.

"Most patients in the gastric-bypass group achieved the primary endpoint in the first month of the postoperative period," noted Dr. Carlos Aurelio Schiavon of the Research Institute, Heart Hospital, São Paulo, Brazil. That seems to mean that "something more is happening beyond weight loss."

Patients were randomized to either Roux-en-Y Gastric Bypass combined with optimized medical treatment or optimized medical treatment alone. Patients randomly selected for gastric bypass plus medical treatment overwhelmingly (83.7%) reached the primary endpoint of reduction of total antihypertensive drugs by at least 30% while maintaining controlled blood pressure levels at 12 months versus patients selected for medical treatment alone (12.8%) (incidence rate ratio [95% CI] 6.55 [3.07; 13.98] P<0.001).

At 12 months, 51% of patients in the gastric bypass group remained with controlled blood pressure without medications. No patient submitted to optimized medical treatment was free of anti-hypertensive drugs at 12 months.

GATEWAY joins other studies in a mounting body of evidence that bariatric surgery is an effective treatment for obesity and obesity-related diseases, such as hypertension.

The study was supported by Ethicon.

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CTスキャンと負荷試験はMI否定には役立たない (2017 AHA, Abstract 735)

ROMICAT-II：侵襲的な検査は救急外来の胸痛患者に有益性をもたらさない

ROMICAT-II: Aggressive testing provides no benefits to patients in emergency room with chest pain

救急外来において胸痛患者に対しコンピュータ断層撮影（CT）および心臓負荷検査は過剰に使用されており、患者が心筋梗塞の状態か否かを判断するのに何も情報を提供していない、と2017 American Heart Association Scientific Sessions で発表され、*JAMA Internal Medicine* に掲載された。研究者らはROMICAT-II試験の結果に立ち戻り、臨床評価のみを受けた患者とCTスキャンまたは負荷試験を受けた患者との転帰の差を検討した。その結果、2群間に有意差はなかった。追加の検査は入院延長につながり、被曝が増加した。

Full Text

Patients who go to the emergency room (ER) with chest pain often receive unnecessary tests to evaluate whether they are having a myocardial infarction (MI), a practice that provides no clinical benefit and adds to health-care costs, according to a new study from researchers at Washington University School of Medicine in St. Louis.

Specifically, computed tomography (CT) scans and cardiac stress tests are overused in the ER for patients with chest pain and provide no information to determine whether a patient is in the midst of an MI, the researchers found.

The study appears Nov. 14 in *JAMA Internal Medicine*, which coincides with a presentation of the study at the American Heart Association's Scientific Sessions in Anaheim, Calif.

A typical clinical evaluation includes a medical history, physical exam, electrocardiogram and blood test for a protein that becomes elevated after the heart is damaged. In addition, many patients also are given a CT scan of the arteries that deliver blood to the heart or a cardiac stress test. A stress test measures heart function during exercise.

"Our study suggests that in the emergency room, stress testing and CT scans are unnecessary for evaluating chest pain in possible heart attack patients," said cardiologist and senior author David L. Brown, MD, a professor of medicine. "Patients don't do any better when given these additional tests. Our study is not a definitive randomized clinical trial, but it does suggest that we are over-testing and over-treating these patients."

In recent years, Brown said doctors can more accurately diagnose MIs largely because of advances in the blood test that measures levels of a protein called troponin. High troponin levels signal injury to the heart.

"This troponin test is super-sensitive," Brown said. "But earlier blood tests were much less accurate. A patient could be having an MI and these older tests often would come back normal. Doctors didn't trust the tests, so they looked for other ways to evaluate the patient. CT scans and stress tests were among the methods used. But now that the blood testing method is so much better, there is less reason to continue doing these screening tests in the emergency room."

The investigators evaluated data from 1,000 patients treated at nine medical centers across the country, including Washington University School of Medicine, that were a part of the Rule Out Myocardial Ischemia/Infarction by Computer Assisted Tomography (ROMICAT-II) clinical trial. The current study revisited data from that trial, looking for any differences in outcomes for patients who received a clinical evaluation alone (118 patients) compared with those who received a clinical evaluation plus either a CT scan or a stress test (882 patients). In the study, 88 percent of patients received the extra testing. Nationwide, the overwhelming majority of patients evaluated for chest pain in the ER get such extra tests, Brown said.

During the nearly month-long follow-up period, there were no differences between the two groups in the percentages of patients that had a stent placed to open an artery, underwent coronary artery bypass surgery, returned to the emergency room or experienced a major cardiac event, such as an MI.

While providing no clear health benefit to emergency room patients, the extra tests also led patients to stay in the hospital longer than may have been necessary and exposed them to radiation from testing that was not required to diagnose an MI. Length-of-stay for patients who received less testing was, on average, 20 hours compared with 28 hours for those who did receive either of the two additional tests.

The analysis also showed that, on average, a patient receiving more testing accrued $500 more in health-care costs during the ER visit. Patients who received more testing during the initial ER visit also received more follow-up tests, leading to $300 more in health-care costs for this group during the 28-day follow-up period. With 10 million patients coming to the ER for chest pain each year in the United States, these extra costs add up, according to the investigators.

"It's important to keep in mind that CT scans and stress tests are used to diagnose coronary disease – whether someone has plaque in the arteries," Brown said. "Many people have coronary plaque but are not having a heart attack.

"The goal of evaluating patients with chest pain in the ER is not to screen for coronary artery disease," he said. "Anyone who goes to the ER for chest pain and gets sent home should make an appointment to see their primary care doctor to talk about their recent hospital visit. It's important to follow up to see if additional testing is warranted because screening tests are not appropriate in this specific emergency situation."

The investigators report no external funding.

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