LVADと強化薬物療法の併用は心機能を改善する(Poster: S4026)

RESTAGE：LVADと強化薬物療法の併用は重症心不全患者の心機能回復を助ける

RESTAGE: LVAD plus intensive drug therapy helps severe heart failure patients recover function

左室補助装置（LVAD）と強化薬物療法の併用治療により、3分の1を超える進行心不全患者でLVADを除去できるまでに心機能が回復した、と現在進行中のスタディの予備的な結果が2016年American Heart Association年次集会で発表された。多施設共同RESTAGEトライアルは、極めて進行または末期の心不全患者を対象とした。これまでに36人の患者の心機能を評価し、併用療法を受けた13人の患者でポンプを除去できるまでに心機能が改善した（平均344日後）ことを明らかにした。

Full Text

More than a third of advanced heart failure patients treated with a combination of a left ventricular assist device (LVAD) and intensive drug therapy have recovered their heart function enough to allow removal of the LVAD device, according to preliminary results of an ongoing study presented at the American Heart Association's Scientific Sessions 2016.

The multicenter trial called RESTAGE, includes 40 patients (67.5 percent men, average age 34.9 years) at six different centers, with very advanced or end stage heart failure. Within the first 209 days, three patients did not survive long enough to get the therapy and one had the device removed. The remaining 36 patients were implanted with an LVAD (HeartMate II) and prescribed an aggressive combination of drugs (lisinopril 40 mg, spironolactone 25 mg, digoxin 125 mic and losartan 150 mg daily and coreg 25 mg bid).

All of the patients were so disabled from heart failure that the initial intent with the LVAD was to use it until they could receive a heart transplant or to leave the device in for the rest of their lives.

"This suggests that even very advanced heart failure can be reversed using these heart pumps, particularly when combined with additional drug therapy, avoiding the need for heart transplantation for these patients and making the donor heart available for another needy individual," said Emma J. Birks, M.D., lead author of the study and professor of medicine at the University of Louisville in Louisville, Kentucky.

Researchers tested the 36 patients' heart function to determine if any had improved heart function enough from the therapy to have the pumps removed, or if their heart function remained poor and needed a heart transplant or to remain on the pump.

Researcher's preliminary results have found to date:

- 13 patients receiving the combination therapy had recovered enough heart function (after an average of 344 days) to have the pump removed.
- Two patients received transplants from the pump and one died on the pump.
- 20 patients are ongoing (2 of which are also scheduled to have their devices removed).

"The fact that this could be done in several centers suggests that using the device with this drug combination to reverse heart failure is possible on a larger scale. It has previously been thought that these devices rarely recover heart function enough to allow them to be removed, but this study suggests that this can occur in a much bigger number than originally thought, particularly if combined with drug therapy," Birks said.

Co-authors are Eduardo Rame, M.D.; Snehal R Patel, M.D.; Craig Selzman, M.D.; Chris Cunningham, Ph.D.; Randall Starling, M.D., M.P.H.; John Um, M.D.; Daniel Goldstein, M.D.; Mark Slaughter, M.D.; Pavan Alturi, M.D.; Daniel Spevack, M.D.; David Farrar, Ph.D.; Brian D. Lowes, M.D.; and Stavros G. Drakos, M.D., Ph.D. Author disclosures are on the abstract.

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心停止前のスタチン使用はその後の生存を手助けする可能性がある (Presentation 15-Session: ReSS.AOS.11B)

スタチンの事前使用は心停止後の高生存率と関連がある

Prior use of statins associated with higher rates of survival after cardiac arrest

スタチン投与を続けている患者はそうでない患者に比べ、心停止後の生存期間が長い傾向にある、と2016年American Heart Association年次集会Resuscitation Science Symposiumで発表された。研究者らは、スタチンの事前使用により、病院到着時の生存率が約19%高く、長期生存し生きて退院する確率が約47%高く、その後1年以上の生存率が50%高いことを明らかにした。スタチン群の中では、2型糖尿病を有する患者において生存率が最も大きく改善した。

Full Text

Patients who have been taking statins are likely to survive longer after a cardiac arrest than those who are not taking them, according to research from Taiwan researchers presented during the Resuscitation Science Symposium at the American Heart Association's Scientific Sessions 2016.

A study analyzing the records of nearly 138,000 patients who suffered out-of-hospital-cardiac arrest in the Taiwan National Health Insurance Research Database found that the prior use of statins was associated with higher rates of survival after cardiac arrest than was non-use. Statin users were significantly more likely than non-users to be still alive a year after the episode. Within the statin group, a subgroup of patients with Type 2 diabetes showed the most improvement in survival rate.

The study also found that with the prior use of statins, patients were:

- About 19 percent more likely to survive to reach a hospital;
- About 47 percent more likely to survive long enough to be discharged from hospital;
- 50 percent more likely to survive for at least a year afterwards; and
- Most likely to see a benefit from prior use of statins if they had Type 2 diabetes.

"There is some risk associated with statins, but this study confirms the benefit," said Ping-Hsun Yu, M.D., study senior author and a researcher at the Taipei Hospital Ministry of Health and Welfare in Taiwan.

For patients who have already experienced a myocardial infarction or ischemic stroke, cholesterol-lowering statins are often prescribed to prevent a second cardiovascular event. However, because these drugs can cause significant side effects (most commonly reported are muscle pain and weakness and increased blood sugar levels), the recommendation to use statins for the prevention of a first cardiac arrest or stroke is not clear.

Yu and his colleagues sorted the records according to whether or not the patients had used statins within 90 days of a cardiac event and researchers accounted for gender, age, underlying conditions, years of hospitalization, post-resuscitation factors, and several other variables.

More than 95 percent of the research population in the analysis were Asian, so researchers say these results might not apply to other ethnic groups or to multi-ethnic populations. The pre-existing database also did not distinguish among different dosages or types of statin. A prospect for further study, said Yu, "may be to divide the statins into different subgroups to see if different potencies or types result in different outcomes."

Co-authors are Chien-Hua Huang, M.D.; Min-Shan Tsai, M.D. and Wen-Jone Chen, M.D., Ph.D. The National Taiwan University Hospital provided funding for access to the National Health Insurance Research Database.

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小児期の逆境は血圧コントロール不良と関連する(Presentation: 307-Session: EP.AOS.760)

小児期の貧困、虐待や家庭不和は血圧コントロール不良と関連する

History of childhood poverty, mistreatment or family dysfunction linked to poor blood pressure regulation

つらい小児期を過ごすことは血圧コントロール不良と関連する可能性がある、と2016年American Heart Association年次集会で発表された。成人における血圧変動は、高齢者の脳機能低下や脳卒中リスク上昇などの多くの問題と関連してきた。今回のスタディにおいて研究者らは、373人の対象（7～38歳）に対し、23年間にわたって24時間血圧モニタリングを行った。小児期に貧困、虐待または家庭不和であったと報告した者は、日中に高血圧を有する割合が17%高かった。彼らはまた夜間の高血圧および24時間の血圧変動を有する割合も高かった。

Full Text

A difficult childhood may be associated with a risk of poor blood pressure regulation, according to research presented at the American Heart Association's Scientific Sessions 2016.

Blood pressure variability has been associated in some studies to elevated risk of cardiovascular disease and complications from hypertension. Researchers at the Augusta University Medical College of Georgia investigated the impact of "adverse childhood experiences" – childhood abuse or neglect, dysfunctional homes, or low socioeconomic status – during the transition from childhood to adulthood. Earlier research has linked adverse childhood experiences to faster increase of blood pressure in adulthood.

Researchers conducted periodic around-the-clock blood pressure monitoring to capture day and nighttime pressure readings in 373 participants between the ages of 7 and 38 during a 23-year period. Those who reported childhood adversity were 17 percent more likely to have blood pressure higher than the clinical definition of hypertension during the daytime.

"Adverse environments in early life have been consistently associated with the increased risk of hypertension in later life," said Shaoyong Su, Ph.D., lead author and an associate professor of pediatrics at Augusta University Medical College of Georgia. "We found that children who experienced childhood abuse or neglect, dysfunctional homes and low socioeconomic status, were far more likely to have higher blood pressure at night as well as blood pressure variability over 24 hours, in addition to more rapid onset of hypertension at an earlier age."

Twenty-four-hour ambulatory blood pressure is considered a better predictor of organ damage and cardiovascular events, as it can assess not only nighttime blood pressure levels, but also the blood pressure variability in real life. Blood pressure was monitored up to 15 times during the study.

Researchers said there was no difference in blood pressure regulation at various ages suggesting the patterns of adverse events in childhood are similar through young adulthood.

Most physicians focus on average blood pressure readings, but the new findings suggest that they should also ask younger patients about childhood adversity and watch for high blood pressure variability, he noted.

"This is not something most clinicians currently address, but it is a simple step that could identify many individuals at risk of adult hypertension and help them achieve control at an earlier age. This could avoid problems as they age," he said.

Blood pressure variability has been linked to a number of problems in adults, including decreased brain function in older adults, as well as increased risk of stroke and poorer post-stroke recovery. Likewise, early-onset hypertension and prehypertension have been linked to adverse preclinical cardiovascular disease, including left ventricular hypertrophy and evidence of increased arterial stiffness.

Co-authors are Guang Hao, Ph.D.; Frank Treiber, Ph.D.; Gregory Harshfield, Ph.D.; and Xiaoling Wang, M.D., Ph.D. This study is funded by National Institutes of Health/National Heart Lung and Blood Institute.

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LFFRはPCIガイドの解決策ではない(LBCT.02)

FUTURE：冠血流予備量比ガイド下血管形成術の有益性はほとんどなく有害である可能性がある

FUTURE: Little benefit, possible harm to fractional flow-reserve-guided angioplasty

冠血流予備量比を用いた経皮的冠動脈インターベンションの有益性はほとんどなく有害である可能性がある、と2016年American Heart Association学術集会で発表された。FUTUREトライアルは、無作為化された初めの836例の解析結果から、FFRガイド群における12か月の総死亡率が過剰であった（p=0.02）ため、早期に中止された。中間解析の結果、血管形成術での比較において、FFR群では有意ではない死亡率過剰の傾向があり、FFRの臨床上の有益性は認められないことが示された。研究者らは、複雑な高リスク患者において、FFRは治療方針決定に役立たず、安全上好ましくない徴候と関連があり得る、と結論付けている。

Full Text

Using a technique to measure pressure differences across clogged arteries known as fractional flow-reserve (FFR) to guide percutaneous coronary intervention (PCI) in selected patients has been shown to improve clinical outcomes in comparison to medical therapy alone or angioplasty without FFR. The FUTURE trial was part of a Late Breaking Clinical Trial session at the American Heart Association's Scientific Sessions 2016.

FFR has not been evaluated as a treatment strategy decision tool in multivessel disease patients to choose between PCI, surgery or medical therapy alone. FUTURE, a multicenter, controlled, randomized trial explored FFR-guided revascularization in comparison with angioplasty alone among patients with multivessel coronary artery disease.

Acute coronary syndrome and stable coronary artery disease consecutive patients were randomized to either FFR-guided management or traditional management. The primary end point was a composite of major adverse cardiovascular events, including all-cause death, non-fatal heart attack, stroke and repeat coronary revascularization at one year.

The trial was scheduled to include 1,728 patients over 39 centers in France. The study independent data safety monitoring board recommended to stop study enrollment due to an excess in the 12-month all cause mortality (p=0.02) in the FFR-group after analysis of the first 836 randomized patients.

Interim analysis for the 933 included patients (average age 66) showed at least a non-significant excess of mortality trend in the FFR group and no clinical benefit of FFR in comparison with angioplasty.

Researchers conclude that in complex, high-risk patients, FFR may not help for treatment decisions and could be associated with a negative safety signal.

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小児においてCPRの最良の結果を出すには心臓マッサージに呼吸を加えることである (ReSS.AOS.13A)

CARES：心停止後の小児において換気を伴うCPRは転帰を改善する

CARES: CPR with ventilation associated with better outcomes after cardiac arrest in children

院外心停止を来した小児および10代の若年者において、バイスタンダーによる心肺蘇生（CPR）は一蘇生を行わない場合と比べ一生存率および神経学的転帰が優れていた、と2016年American Heart Association年次集会で発表され、同時に*JAMA Pediatrics* オンライン版に掲載された。従来のCPR（換気を伴う）または心臓マッサージのみのCPRが、同数の症例に施行された。従来のCPRは心臓マッサージのみのCPRと比べ転帰を改善した。幼児においては、換気を行わない限り従来のCPRの有益性はなかった。

Full Text

Receiving cardiopulmonary resuscitation (CPR) from a bystander – compared with not – was associated with better overall and neurologically favorable survival for children and adolescents who had out-of-hospital cardiac arrest, according to research presented at the American Heart Association's Scientific Sessions 2016 and simultaneously published online by *JAMA Pediatrics*.

The outcome of out-of-hospital cardiac arrest (OHCA) in children is generally poor, with a mortality rate greater than 90 percent. The American Heart Association (AHA) recommends conventional CPR for pediatric cardiac arrest. However if the bystander is unable or reluctant to perform rescue breathing, the AHA recommends compression-only CPR (COR), noting that delivering COR is better than no CPR.

Maryam Y. Naim, M.D., of Children's Hospital of Philadelphia, and coauthors analyzed data from the Cardiac Arrest Registry to Enhance Survival (CARES) for OHCAs in children younger than 18 from January 2013 through December 2015.

The study included 3,900 children with OHCA, of whom 2,317 (59.4 percent) were infants, 2,346 (60.2 percent) were female and 3,595 (92.2 percent) had nonshockable heart rhythms. Cardiac arrests that occur in infants are most likely secondary to sudden infant death syndrome, according to the report.

The authors report:

- CPR from bystanders was performed on 1,814 children (46.5 percent).
- Overall survival was 11.3 percent and neurologically favorable survival was 9.1 percent.
- CPR from a bystander was associated with better odds of overall survival and neurologically favorable survival compared with none.
- Conventional CPR (with breathing) and compression-only CPR were provided in a similar number of cases; conventional CPR was associated with improved outcomes compared with compression-only CPR; among infants, conventional CPR from a bystander was associated with improved outcomes while compression-only CPR had outcomes similar to no CPR from a bystander.

Limitations to the study are that the data are observational and causality cannot be established.

"Bystander CPR is associated with improved outcomes in children with OHCA. Conventional BCPR [bystander CPR] is associated with improved outcomes compared with COR [compression-only CPR] and, among infants, there was no benefit of BCPR unless ventilations were provided. Efforts to improve the provision of CPR in minority communities and increasing the use of conventional BCPR may improve outcomes for children with OHCA," the study concludes.

The authors report no relevant financial relationships.

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急性心不全に対する医師の考え方を変える (LBCT.01)

TRUE_AHF：急性非代償性心不全における緊急の血管拡張の短期および長期効果

TRUE_AHF: Short and long-term effect of immediate vasodilator therapy in acutely decompensated heart failure

急性心不全で入院した患者において、早期における心内圧を低下させる短期薬物療法は心筋傷害を予防し長期の有益性をもたらす、とこれまで医師は考えていた。2016年American Heart Association学術集会で発表されたTRUE-AHFトライアルにおいて、ularitide（ナトリウム利尿ペプチド）を投与された患者では、心ストレスが軽減し、過剰循環血液量の徴候が減少し、薬物投与中の心不全発現が少なかったことが示された。しかし、この薬剤の短期治療は、心筋傷害指標を改善せず、その後の心血管疾患による入院や死亡リスクを変化させなかった。

Full Text

In the TRUE-AHF trial presented at the American Heart Association Scientific Sessions 2016, patients with acutely decompensated heart failure who received ularitide showed a reduction in cardiac stress, had reduced signs of excess circulatory volume, and had fewer episodes of heart failure during the time that the drug was given.

Physicians have long hoped that early short-term drug therapy to lower pressures inside the heart in patients hospitalized with acute heart failure might prevent myocardial injury and have long-lasting benefits. However, the results of the TRUE-AHF trial demonstrate that such intravenous treatments produce improvement while they are given but do not yield sustained favorable effects after the treatments are stopped.

The TRUE-AHF trial (TRial of Ularitide's Efficacy and safety in patients with Acute Heart Failure) is the first randomized, double-blind, parallel-group, placebo-controlled, event-driven trial in patients with acute heart failure to evaluate the long-term effect of intravenous treatment on the risk of cardiovascular death. The trial studied 2157 patients (aged 18-85 years) with acute heart failure who presented with shortness of breath at rest to an emergency department or hospital. Within 12 hours of their initial evaluation, patients were randomly assigned (in a 1:1 ratio) to receive either placebo or the investigational natriuretic peptide ularitide (15 ng/kg/min) intravenously for 48 hours, in addition to their usual treatment for acute heart failure. Physicians were able to administer the drug quickly (on average, within 6 hours), which represents the earliest time to treatment of any trial in such patients.

Ularitide was selected for the trial because it had been previously shown to reduce elevated pressures inside the heart in patients with acute heart failure. The drug is a chemically synthesized form of a human natriuretic peptide, normally produced by the kidneys. When given intravenously, it had previously been shown to lower blood pressure as well as pressures inside the heart and to promote urine output.

Patients who received ularitide showed a reduction in cardiac stress, had reduced signs of excess circulatory volume, and had fewer episodes of heart failure during the time that the drug was given. However, short-term treatment with the drug did not improve measures of heart injury and did not alter the subsequent risk of cardiovascular hospitalization or cardiovascular death.

The trial demonstrated the effects and safety of ularitide. However, to gain long-term benefits on hospitalizations and death in patients following a hospital admission for heart failure, physicians must focus on the drugs that patients take as an outpatient rather than the drugs they receive as an inpatient.

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血圧およびコレステロール低下の認知機能への影響(LBCT.01)

HOPE 3：長期の降圧およびコレステロール低下療法は認知機能低下を予防しない

HOPE 3: Long term blood pressure and cholesterol lowering did not prevent cognitive decline

2016年American Heart Association 学術集会で発表されたHeart Outcomes Prevention Evaluation-3（HOPE 3）において研究者らは、心血管疾患中等度リスク者において、長期間のコレステロール低下療法または降圧療法が、認知機能低下を遅延させるかどうかを評価した。参加者は平均74歳、59%が女性であった。それぞれの群の参加者は認知機能低下を来したが、どちらの治療も参加者の認知機能に対し悪影響は何も及ぼさなかった。今回の中等度リスク者において、5年半の降圧療法およびコレステロール低下療法は、認知機能低下を予防しなかった。早期の、より長期にわたる治療が有益である可能性については、不明である。

Full Text

No strategy has been found to reliably prevent cognitive impairment or dementia. In the Heart Outcomes Prevention Evaluation-3 (HOPE 3) presented at the American Heart Association Scientific Sessions 2016, researchers evaluated whether long-term cholesterol lowering or blood pressure-lowering delayed cognitive decline in individuals at moderate risk for cardiovascular disease.

12,705 participants were randomized to receive either blood pressure medication (candesartan /hydrochlorothiazide) or placebo and a cholesterol-lowering statin (rosuvastatin) or placebo. 1,626 study participants also completed cognitive and functional outcome questionnaires at baseline and study end almost six years later.

Participants came from 221 centers in 21 countries and were on average 74 years old and 59 percent were women.

Participants in each group did demonstrate cognitive decline, but there was no difference in the decline between those in the active or control groups for the blood pressure lowering arm or the cholesterol lowering arm or the combination. Neither treatment demonstrated any adverse effect on cognition.

Five and half years of blood pressure lowering and cholesterol lowering in an intermediate risk population did not prevent cognitive decline. It is not clear if early initiation and longer term treatment may have benefit.

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心房間シャント作成デバイスは心不全症状を改善する(LBCT.04)

REDUCE LAP HF：経カテーテル心房間シャント作成デバイスの留置術は、駆出率の保たれた心不全患者において持続的な臨床的有益性を提供する

REDUCE LAP HF: Transcatheter interatrial shunt provides sustained clinical benefit in patients with preserved ejection fraction

経カテーテル心房間シャント作成デバイス（IASD）の留置術は、駆出率の保たれた心不全患者において持続的な臨床的有益性を提供する、と2016年American Heart Association学術集会で発表された。スタディは、心不全の根本原因に対処するようにデザインされた、初めての治療デバイスを評価している。IASDは、心房間に小さな交通を作成することにより、持続的かつ機械的に左房圧を低下させる。12か月の時点で、このデバイスは安全であり労作時の左房圧を低下させるようである。6か月および12か月後に、患者は症状の軽減、QOLの改善、および運動能の改善を認めた。

Full Text

A transcatheter interatrial shunt device provides sustained clinical benefit in patients with heart failure with preserved ejection fraction (HFpEF) according to researchers at the American Heart Association Scientific Sessions 2016.

HFpEF, can lead to lung congestion and difficulty breathing during simple daily activities. To date, the medicines that have been shown to be effective for treating other types of heart failure have relatively little effect in HFpEF. As such, there is no drug or device known to improve mortality or hospitalization risk for these patients.

The "REDUCe Elevated Left Atrial Pressure in Patients with Heart Failure" (REDUCE LAP-HF) study assesses the first therapeutic device designed to address the primary cause of heart failure symptoms. Sixty-four patients (average age 69) had the device implanted.

The transcatheter interatrial shunt device (IASD) facilitates continuous and dynamic decompression of the left atrium by creating a small communication between the upper chambers of the heart.

At six months, researchers noted that implantation of an interatrial shunt was feasible, seems to be safe, reduces left atrial pressure during exercise, and could be a new strategy for managing HFpEF.

Now at 12 months, results confirm the device appears to safe and effective. Patients reported fewer symptoms, improved quality of life and improved exercise capacity at six and 12 months, researchers said.

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片側対両側内胸動脈グラフト(LBCT.02)

ART：内胸動脈グラフトは片側と両側とで臨床転帰は同様である

ART: Single and bilateral artery grafting have similar clinical outcomes at five years

内胸動脈グラフトは片側と両側とで臨床転帰は同様である、と2016年American Heart Association学術集会で発表された。Arterial Revascularization Trial（ART）では、片側または両側グラフトによる冠動脈バイパス術を予定されている患者3,102人（平均年齢64歳、女性24%）を、ランダム化割り付けした。5年後、両側手術と片側手術とで臨床転帰は同様であった。片側動脈グラフト群における死亡率は8.4%であり、両側動脈グラフト群では8.7%であった。死亡、心筋梗塞および脳卒中の複合エンドポイントは、片側動脈グラフト群で12.7%であり、両側動脈グラフト群で12.2%であった。

Full Text

Single and bilateral artery grafting have similar clinical outcomes according to research reported at a Late Breaking Clinical Trial session at the American Heart Association's Scientific Sessions 2016.

There is growing evidence from observational studies that using two internal mammary arteries for grafting may be superior to single internal mammary artery grafting for coronary artery disease.

The Arterial Revascularization Trial (ART) randomized 3,102 patients (average age 64, 24 percent women) scheduled for coronary artery bypass grafting to single grafts (1554) or bilateral grafts (1448) in 28 cardiac surgical centers in seven countries.

The primary outcome was death from any cause. Secondary outcomes included the composite of death, heart attack, stroke, and additional safety outcomes. At five years follow-up, researchers noted that bilateral surgery provided similar clinical outcomes to single artery grafting. The death rate in the single artery grafting group was 8.4% compared to 8.7% in bilateral group.

As for the composite of death, heart attack and stroke was 12.7 percent for single artery grafting versus 12.2 percent for bilateral grafts.

Researchers found no statistically significant differences in the numbers of deaths, heart attack or strokes between the single and bilateral grafting after 5 years.

Follow up to ten years is ongoing to determine if bilateral grafts provides longer term benefits as single vein graft failure becomes more common after 5 years.

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慢性心不全における鉄補充は、2つのスタディの対立する結果により未だ結論が出ない

Iron supplementation in chronic heart failure remains unsettled after two studies report conflicting results

慢性心不全(HF)患者における鉄補充に関しては、経口および経静脈的鉄補充を調査した2つの新たなスタディの結果が対立していることから未だ結論が出ない、と2016年American Heart Association学術集会で発表された。過去のスタディから、鉄欠乏症をカルボキシマルトース鉄(FCM)の経静脈的投与で治療することにより、HF患者の運動耐容能が改善することが示されたが、経口的鉄補充に関しては不明である。本年のミーティングにおいて、EFFECT-HFスタディの結果から、最大酸素摂取量(VO_2)は貧血の有無にかかわらず、HF患者に対する3回のFCM経静脈的投与により有意に改善したが、IRONOUTスタディにおいては、安価な経口的鉄補充は機能的能力および他の評価項目を改善しなかった。

Full Text

Therapeutic options to further improve functional capacity and symptoms among heart failure patients are limited. Iron deficiency is present in about half of heart failure patients with reduced ejection fraction and the usefulness of inexpensive, readily available oral iron supplementation in heart failure is unknown.

Previous studies suggest that iron deficiency with or without anemia further reduces this exercise capacity by 10 percent to up to 50 percent measured by peak oxygen consumption. Treating iron deficiency with intravenous ferric carboxymaltose (FCM) and has been shown to reduce symptoms, improve quality of life and increase six-minute walking distance in this population.

The issue of iron supplementation in patients with chronic heart failure remains unsettled after two new studies testing oral and intravenous iron yielded conflicting results at the American Heart Association 2016 Scientific Sessions.

Peak oxygen uptake (VO_2) significantly improved when compared with standard of care after three intravenous injections of ferric carboxymaltose in HF patients with and without anemia in EFFECT-HF, while functional capacity and other outcomes failed to improve with a considerably cheaper oral iron supplement in the IRONOUT study.

In Oral Iron Repletion effects ON Oxygen UpTake in Heart Failure (IRONOUT HF) Trial researchers evaluated whether oral iron supplementation could improve exercise capacity in heart failure patients. IRONOUT HF is a multi-center, randomized, double-blinded, placebo-controlled trial of oral iron polysaccharide (300 mg/day) compared to matching placebo. The trial enrolled 225 heart failure patients (average age 63, 36 percent female, 25 percent black) with reduced pumping ability and iron deficiency.

The primary endpoint is change in peak oxygen uptake ($pkVO_2$) measured at baseline and at 16 weeks. Secondary endpoints include assessments of the impact of oral iron on submaximal exercise capacity; plasma NT-pro BNP levels; and health status.

Gregory D. Lewis, Massachusetts General Hospital, Boston, Massachusetts, USA reported the results of IRONOUT HF during a late breaking session. He reported that the primary endpoint, change in $pkVO_2$, did not differ between groups. Oral iron only modestly improved iron measures (i.e. Tsat increased from 19 to 22% p=0.003). Baseline Tsat was related to $pkVO_2$ and KCCQ and changes in Tsat correlated with changes in pVO_2 over the course of the trial. Further analyses of biomarker samples are underway to understand the primary results (i.e. hepcidin levels in relation to responsiveness to oral iron).

High-dose oral iron minimally repleted iron stores and did not improve exercise capacity in HFrEF raising questions about the ability of oral iron therapies to be sufficient in heart failure patients.

In EFFECT-HF, researchers evaluated the efficacy of intravenous ferric carboxymaltose compared to usual care on exercise capacity in a prospective, randomized controlled, open-label, assessor-blinded, multicenter, two-arm, 24-week study in stable heart failure patients. Overall, 174 subjects were randomized in 9 countries.

Dirk J. Van Veldhuisen, University Medical Center Groningen, Groningen, Netherlands reported that the study met its primary endpoint, finding a significant difference of change in peak oxygen consumption from baseline to week 24 for those in the treatment group. Researchers said that patientss with chronic heart failure and iron deficiency treated with FCM can stabilize exercise capacity compared to those with standard of care whose exercise capacity worsened.

EFFECT-HF was sponsored by Vifor Pharma.

The authors of IRONOUT HF report support from Abbott Vascular, Novartis, Stealth, Shape Systems, Amgen, AstraZeneca, Merck and Novartis.

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中等度リスク患者に対するTAVIの有効性 (LBCT.02)

GARY：中等度リスク患者においてTAVIの死亡率はSAVRより高い

GARY: TAVI mortality higher versus SAVR in intermediate risk patients

ドイツのレジストリにおける手術リスク中等度の大動脈弁狭窄症患者において、1年後の調整死亡率は経カテーテル大動脈弁留置術（TAVI）施行患者において、外科的大動脈弁置換術（SAVR）施行患者に比べ有意に高かった、と2016年American Heart Association学術集会で発表された。院内死亡率はTAVI患者で3.8%、SAVR患者で2.6%であり、1年後の死亡率はTAVIで16.6%、SAVRで8.9%であった。この2群間の有意な死亡率の差は、傾向スコア解析後でも認められた。しかし、レジストリデータの後ろ向き解析は、2つの治療戦略を比較する選択法ではない、と筆者らは指摘している。

Full Text

Transcatheter aortic valve implantation (TAVI) is currently the recommended treatment for patients with severe aortic valve stenosis who have high surgical risk. At present, there is little real-world data from smaller studies available on patients at intermediate surgical risk with regard to indications and outcome of TAVI versus surgical aortic valve replacement (SAVR).

This analysis from the German Aortic Valve Registry (GARY), a large real-world multicenter registry, compares the efficacy and outcomes of intermediate-risk patients who were treated by transcatheter aortic valve implantation or conventional surgical aortic valve replacement in Germany over three years in daily clinical practice. The analysis was reported by Nicolas Werner, M.D. Medizinische Klinik B, Ludwigshafen, Germany at the American Heart Association 2016 Scientific Sessions.

A total of 5,997 patients at intermediate surgical risk underwent isolated transcatheter aortic valve implantation (4,101) or surgical aortic valve replacement (1,896) at 88 sites in Germany between 2011 and 2013. Patients treated by TAVI were significantly different in baseline characteristics (older, more often female and had higher risk scores) from patients treated by surgical aortic valve replacement – revealing a marked selection bias that cannot completely be adjusted for and which led to different clinical outcomes.

In-hospital and one-year death rates were significantly higher in transcatheter aortic valve implantation patients than in surgical aortic valve replacement patients: 3.8 percent for in hospital TAVI patients versus 2.6 among in hospital surgical patients and 16.6 percent at one year after TAVI versus 8.9 percent one year after surgical replacement. The unadjusted death rate was higher after TAVI, and a significant difference in one-year mortality rate persisted between the two groups even after propensity score analysis.

For differences in specific complication rates between TAVI and surgical aortic valve replacement, an individualized therapeutic decision by a dedicated Heart Team, based on the clinical situation of the patient and the associated procedural risk may be the best approach for the group of patients at intermediate surgical risk, researchers said. However, they noted, retrospective analysis from registry data is not the method of choice to compare two treatment strategies. This should only be done by randomized controlled trials.

GARY is supported by the German Cardiac Society, German Society for Thoracic and Cardiovascular Surgery, and German Heart Foundation.

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合併症はHeartMate 2に比べHeartMate 3において少ない(LBCT.04)

MOMENTUM 3：新たな心臓ポンプは安全かつ有効であり、血栓形成に関連する合併症が少ないようである

MOMENTUM 3: Novel heart pump appears safe and effective, reduces clotting-related complications

新しいHeartMate 3左室補助循環装置（LVAS）は、有害事象を予防するようにデザインされたが、その有害事象すなわちポンプ内血栓を軽減した、とAmerican Heart Association学術集会late-breaking臨床試験で発表され、同時に*New England Journal of Medicine* に掲載された。患者は、HeartMate 3 または HeartMate 2の群にランダムに割り付けられた。この294人の患者を6か月間追跡した事前設定解析において、研究者らは、HeartMate 3がその他の有害事象において明らかな差はなく、ポンプ機能不全による再手術率を軽減したことにより、臨床転帰がますます改善したことを示した。

Full Text

The newer HeartMate 3left ventricular assist system (LVAS) eliminated the adverse event it was designed to prevent— pump thrombosis—the "principal driver" of reoperations with this device according to results reported at a late-breaking clinical-trials session at the American Heart Association (AHA) Scientific Sessions and published online in the *New England Journal of Medicine*.

Left Ventricular Assist Devices (LVADs) improve survival and quality of life in patients with advanced stages of heart failure, but can lead to serious complications from blood clots, embolism and bleeding complications.

The MOMENTUM 3 trial is evaluating the safety and comparative effectiveness of an implantable novel fully magnetically levitated circulatory pump (HeartMate 3 left ventricular assist system) to the HeartMate II system in a prospective randomized, controlled trial of advance heart failure patients. The HeartMate 3 is engineered to prevent clotting-related complications and destruction of circulating blood cells as they pass through the device.

Patients were randomized to receive HeartMate 3 or the HeartMate II irrespective of the intended use as either bridge to transplantation or destination therapy – those ineligible for a transplant. The primary endpoint of the analysis evaluates if the HeartMate 3 is non-inferior to HeartMateII in terms of survival free of debilitating stroke or reoperation to replace or remove the pump.

In this pre-specified primary analysis of 294 patients followed for six months, Mandeep R. Mehra, M.D., FRCP, Medical Director, Brigham and Women's Hospital Heart and Vascular Center, Boston, MA reported that the HeartMate 3 provides incremental improvement in clinical outcomes due to reduction in the rate of reoperation for pump malfunction without an apparent difference in other adverse events.

The study was supported by St Jude Medical.

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心血管疾患低リスク女性における冠動脈石灰化の有病率および予後

Prevalence and prognostic implications of coronary artery calcification in women at low cardiovascular disease risk

動脈硬化性心血管疾患（ASCVD）低リスク女性において、冠動脈石灰化は約3分の1に存在し、ASCVDリスク上昇と関連があり、従来のリスクファクターに比べ予後予測精度をやや上昇させた、と2016年American Heart Association学術集会で発表され、同時に*JAMA* に掲載された。研究者らは、低リスク女性（5つの大規模地域住民コホートで10年ASCVDリスクが7.5%未満の者）における、心血管疾患のリスク推定および層別化に対する冠動脈石灰化（CAC）検査の潜在的有用性について評価した。CACは従来のリスクファクターに比べ、予後予測精度を軽度改善した。

Full Text

Among women at low risk of atherosclerotic cardiovascular disease (ASCVD), coronary artery calcium was present in approximately one-third and was associated with an increased risk of ASCVD and modest improvement in prognostic accuracy compared with traditional risk factors, according to a study published online by *JAMA*. The study is being released to coincide with its presentation at the American Heart Association's Scientific Sessions 2016.

Cardiovascular disease (CVD) is a major health problem for women worldwide. The role of coronary artery calcium (CAC) testing for guiding preventive strategies among women at low CVD risk based on the American College of Cardiology and American Heart Association CVD prevention guidelines is unclear. Coronary artery calcium scanning allows for the detection of subclinical coronary atherosclerosis, and the presence of CAC in asymptomatic individuals is associated with higher risk for coronary heart disease (CHD) and all-cause mortality.

Maryam Kavousi, M.D., Ph.D., of Erasmus University Medical Center, Rotterdam, the Netherlands and colleagues assessed the potential utility of CAC testing (by computed tomography) for CVD risk estimation and stratification among low-risk women. The study included women with 10-year ASCVD risk lower than 7.5 percent from 5 large population-based cohorts.

Among 6,739 women with low ASCVD risk from the 5 studies, average age ranged from 44 to 63 years and CAC was present in 36 percent. Across the cohorts, median follow-up ranged from 7 to 11.6 years. A total of 165 ASCVD events occurred (64 nonfatal heart attacks, 29 CHD deaths, and 72 strokes). Compared with the absence of CAC (CAC = 0), presence of CAC (CAC greater than 0) was associated with an increased risk of ASCVD. Coronary artery calcium was associated with modest improvement in prognostic accuracy compared with traditional risk factors.

"Further research is needed to assess the clinical utility and cost-effectiveness of this additional accuracy," the authors write.

"The decision regarding the use of CAC among low-risk women needs to consider the broader context and whether any additional testing is justifiable vs. simply treating all such women with statins based on risk factor scores alone."

The Dallas Heart Study was funded by the Donald W. Reynolds Foundation and the research was supported from the National Center for Advancing Translational Sciences of the NIH.

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マリファナ使用は一時的なストレス心筋症と関連がある(HF.APS.P14, Poster S4054)

マリファナの若年使用者はストレス心筋症を経験する確率が2倍である

Younger marijuana users twice as likely to experience stress cardiomyopathy

積極的なマリファナ使用は、他の心血管疾患リスクファクターを考慮しても、ストレス心筋症リスクを2倍にする可能性がある、と2016年American Heart Association学会で発表された。マリファナ使用者は非使用者に比べ、より若年で、高血圧、糖尿病および脂質異常症などの心血管リスクファクターの少ない男性である割合が高かった。しかし、ストレス心筋症の間に心停止を認め、植込み型除細動器を必要とする割合は、マリファナ使用者において有意に高かった（それぞれ2.4% vs. 0.8%、p=0.034およびICD: 2.4% vs. 0.6% p=0.008）。積極的な使用者はまた、精神疾患や薬物乱用を有する割合も高かった。

Full Text

Active marijuana use may double the risk of stress cardiomyopathy, an uncommon heart muscle malfunction that can mimic symptoms of myocardial infarction, according to research presented at the American Heart Association's Scientific Sessions 2016.

The researchers found that marijuana users were almost twice as likely to develop stress cardiomyopathy compared to non-users, even after taking other cardiovascular risk factors into consideration. Active marijuana use was identified either by information provided by the patient in their medical history, or by a marker in the patient's urine.

"The effects of marijuana, especially on the cardiovascular system, are not well known yet. With its increasing availability and legalization in some states, people need to know that marijuana may be harmful to the heart and blood vessels in some people," said Amitoj Singh, M.D. study co-author and chief cardiology fellow at St. Luke's University Health Network in Bethlehem, Pennsylvania.

Data from the Nationwide Inpatient Sample identified 33,343 people who were hospitalized with stress cardiomyopathy between 2003-2011 in the United States. Of those, 210 (less than one percent) were also identified as marijuana users.

Compared with non-users, researchers found that marijuana users were more likely to be younger, male with fewer cardiovascular risk factors, including less hypertension, diabetes and hyperlipidemia.

However, despite being younger and with fewer cardiovascular risk factors than non-users, during stress cardiomyopathy the marijuana users were significantly more likely to go into cardiac arrest (2.4 percent vs. 0.8 percent, p=0.034) and to require an implanted defibrillator (ICD: 2.4 percent vs. 0.6 percent, p=0.008).

"This development of stress cardiomyopathy in younger patients who used marijuana suggests a possible link that needs to be further investigated," said Sahil Agrawal, M.D., co-author of the paper and also a chief cardiology fellow at St. Luke's.

Marijuana users were more likely than non-users to have a history of depression (32.9 percent vs. 14.5 percent), psychosis (11.9 percent vs. 3.8 percent), anxiety disorder (28.4 percent vs. 16.2 percent), alcoholism (13.3 percent vs. 2.8 percent), tobacco use (73.3 percent vs. 28.6 percent) and multiple substance abuse (11.4 percent vs. 0.3 percent). Because some of these can increase the risk of stress cardiomyopathy, the researchers adjusted for known risk factors to investigate the association between marijuana use and stress cardiomyopathy.

"If you are using marijuana and develop symptoms such as chest pain and shortness of breath, you should be evaluated by a healthcare provider to make sure you aren't having stress cardiomyopathy or another heart problem," Singh said.

The study has some limitations. Because this was a retrospective study, the researchers could not determine how frequently the marijuana users were using marijuana, or what the timeframe was between the use of marijuana and occurrence of stress cardiomyopathy. Observational studies are not designed to prove cause and effect; therefore, it cannot be said that marijuana is or is not a direct cause of stress cardiomyopathy. In addition, because the database the researchers used reports regional but not state-by-state statistics, the researchers could not analyze whether possibly marijuana-related heart problems are increasing where use is legal.

Co-authors are Mark Fegley, M.D.; Yugandhar Manda, M.D.; Sudip Nanda, M.D.; and Jamshid Shirani, M.D. Author disclosures are on the abstract.

This study did not receive outside funding.

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胸やけの薬は虚血性脳卒中リスクを上昇させる可能性がある(EP.AOS.765, Presentation 391)

プロトンポンプ阻害薬は虚血性脳卒中リスクを上昇させる可能性がある

Proton pump inhibitors may increase risk of ischemic stroke

プロトンポンプ阻害薬（PPI）は虚血性脳卒中リスクを上昇させる可能性がある、との予備研究の結果が2016年American Heart Association学術集会で発表された。研究者らは、平均年齢57歳のデンマーク人患者244,679人のカルテを解析した。PPI（オメプラゾール、pantoprazole、ランソプラゾール、またはエソメプラゾール）内服患者においては、全体の脳卒中リスクが21%上昇した。最も低用量のPPIでは、脳卒中リスクは軽度上昇、または上昇しなかった。最高用量では、ランソプラゾールの30%からpantoprazoleの94%までの脳卒中リスク上昇を認めた。ファモチジンやラニチジンなどのH_2ブロッカーでは、脳卒中リスクは上昇しなかった。

Full Text

A popular group of antacids known as proton pump inhibitors, or PPIs, used to reduce stomach acid and treat heartburn may increase the risk of ischemic stroke, according to preliminary research presented at the American Heart Association's Scientific Sessions 2016.

"PPIs have been associated with unhealthy vascular function, including heart attacks, kidney disease and dementia," said Thomas Sehested, M.D., study lead author and a researcher at the Danish Heart Foundation in Copenhagen, Denmark. "We wanted to see if PPIs also posed a risk for ischemic stroke, especially given their increasing use in the general population."

Researchers analyzed the records of 244,679 Danish patients, average age 57, who had an endoscopy. During nearly six years of follow up, 9,489 patients had an ischemic stroke for the first time in their lives. Researchers determined if the stroke occurred while patients were using 1 of 4 PPIs: omeprazole, pantoprazole, lansoprazole, and esomeprazole.

For ischemic stroke, researchers found:

- Overall stroke risk increased by 21 percent when patients were taking a PPI.
- At the lowest doses of the PPIs, there was slight or no increased stroke risk.
- At the highest dose for these 4 PPI's, stroke risk increased from 30 percent for lansoprazole to 94 percent for pantoprazole.
- There was no increased risk of stroke associated with another group of acid-reducing medications known as H2 blockers, which include famotidine and ranitidine.

In comparison with non-users, PPI users were older and had more health conditions, including atrial fibrillation at baseline (3.4 vs. 3.8 percent). The study accounted for age, gender and medical factors, including hypertension, atrial fibrillation, heart failure and the use of certain pain relievers that have been linked to myocardial infarction and stroke.

Authors believe that their findings, along with previous studies, should encourage more cautious use of PPIs.

"At one time, PPIs were thought to be safe, without major side effects," he said, "This study further questions the cardiovascular safety of these drugs."

Although their study did not find a link between H2 blockers and stroke, the authors could not say that this group of drugs would be better for patients than PPIs.

Doctors prescribing PPIs, should carefully consider whether their use is warranted and for how long: "We know that from prior studies that a lot of individuals are using PPIs for a much longer time than indicated, which is especially true for elderly patients."

Study limitations include its observational design, which cannot establish cause and effect, and the fact that nearly all the participants were white. Authors believe that a randomized controlled trial of PPIs and cardiovascular disease is warranted.
Co-authors are Emil L. Fosbøl, M.D., Ph.D.; Peter W. Hansen, M.D.; Mette G. Charlot, M.D., Ph.D.; Christian Torp-Pedersen, M.D., DMSc.; and Gunnar H. Gislason, M.D., Ph.D.

This study was funded by the Danish Heart Foundation.

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