

Prasugrel内服患者とクロピドグレル内服患者の 虚血に関する予後は同等である

TRILOGY ACS サブスタディ：抗血小板薬の比較の結果、血小板反応性には差が認められたが臨床上の予後は同等であった

TRILOGY ACS Substudy : Comparison of antiplatelet agents finds differences in platelet reactivity but similar clinical outcomes

ST上昇のない急性冠症候群(ACS)に対し血行再建術を施行されなかった患者において、prasugrelはクロピドグレルよりも、年齢、体重、および用量に関係なく血小板反応性を低下させた。しかし、血小板反応性と虚血に関するアウトカム発現には有意な相関を認めなかったとのLate Breaking Clinical Trialの結果が2012年American Heart Association学会で発表され、同時にJAMAオンライン版に掲載された。研究者らは、Targeted Platelet Inhibition to Clarify the Optimal Strategy to Medically Manage Acute Coronary Syndromes (TRILOGY ACS) トライアルにおいて大規模な経時的血小板機能サブスタディを施行した。TRILOGY ACSの参加者9,326人中、27.5%がこのサブスタディに組み入れられ、1,286人はprasugrelを1,278人はクロピドグレルを投与された。患者はアスピリンとprasugrel (10または15mg/d)またはクロピドグレル(75mg/d)のいずれかを併用する群に無作為に割り付けられた。Prasugrelは年齢、体重および用量に関係なくクロピドグレルよりも血小板反応性を低下させた。30か月間の一次有効性エンドポイント(心臓死、心臓発作、または脳卒中)発現率に関し、prasugrelとクロピドグレルの間に有意差はなく、血小板反応性と虚血性アウトカム発現との間に有意な相関は認められなかった。

Full Text

Among patients with acute coronary syndromes (ACS) without ST-segment elevation who were treated without revascularization, prasugrel was associated with lower platelet reactivity than clopidogrel, irrespective of age, weight, and dose. However, no significant difference was seen between platelet reactivity and occurrence of ischemic outcomes according to a study presented during a Late Breaking Clinical Trials session at the American Heart Association's Scientific Sessions 2012 and simultaneously published Online First in JAMA.

Paul A. Gurbel, M.D., of the Sinai Center for Thrombosis Research, Baltimore, and colleagues conducted a study to examine the differences in platelet reactivity and clinical outcomes among patients with acute coronary syndromes (ACS) being treated by the antiplatelet agents clopidogrel or prasugrel.

The investigators conducted a large serial platelet function substudy within the Targeted Platelet Inhibition to Clarify the Optimal Strategy to Medically Manage Acute Coronary Syndromes (TRILOGY ACS) trial. It was a randomized, double-blind, active control, event-driven trial comparing prasugrel vs. clopidogrel therapy in patient with unstable angina or non-ST-segment elevation myocardial infarction who were management medically without planned revascularization.

The objectives of the study were to characterize differences in platelet reactivity between treatment groups over time, to delineate the relationship of platelet reactivity with ischemic end point occurrence, and to determine a threshold for high platelet reactivity that optimizes the ability to discriminate between patients with and without ischemic event occurrence.

From 2008 to 2011, patients with medically managed unstable angina or non-ST-segment elevation myocardial infarction (NSTEMI) were enrolled in the TRILOGY ACS trial comparing clopidogrel vs. prasugrel. Of 9,326 participants, 27.5 percent were included in a platelet function substudy, including 1,286 who received prasugrel and 1,278 who received clopidogrel. Patients were randomized to receive aspirin with either prasugrel (10 or 5 mg/d) or clopidogrel (75 mg/d); those 75 years or older or younger than 75 years but who weighed less than 132 lbs. received a 5-mg prasugrel maintenance dose.

The researchers found that "among patients with ACS without ST-segment elevation and initially managed without revascularization, prasugrel was associated with lower platelet reactivity than clopidogrel, irrespective of age, weight, and dose. Among those in the platelet substudy, no significant differences existed between prasugrel vs. clopidogrel in the occurrence of the primary efficacy end point [composite of cardiovascular death, heart attack, or stroke] through 30 months and no significant association existed between platelet reactivity and occurrence of ischemic outcomes."

The TRILOGY ACS study was funded by Eli Lilly and Daiichi Sankyo. Author disclosures are in the manuscript.

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OPERA: 術前および術後の魚油補給は術後心房細動を減少させない

OPERA: Pre-operative and post-operative fish oil supplementation does not reduce postoperative atrial fibrillation

心臓手術を施行される患者において、術前および術後のn-3多価不飽和脂肪酸(魚油)補給は術後心房細動(AF)のリスクを軽減させなかったと、American Heart Association 2012年 Late Breaking Clinical Trialで発表され、同時にJAMAオンライン版に掲載された。Omega-3 Fatty Acids for Prevention of Post-operative Atrial Fibrillation (OPERA)スタディは、心臓手術を予定された患者1,516人(平均年齢64歳、男性72.2%、心血管リスクファクターを有する)を対象とした無作為化プラセボコントロール多施設トライアルであった。患者は、魚油(1gカプセル中エチルエステルとしてn-3-PUFAを840mg以上含有)またはプラセボを、術前に導入としての10gを3~5日間(または8gを2日間)の後、術後に2g/日を退院までまたは術後10日まで投与された。一次エンドポイント(30秒以上持続する術後AFの発現)はプラセボ群の233人(30.7%)、およびn-3-PUFA群の227人(30.0%)に認めた。持続性、症候性、または治療を必要とした術後AFまたは患者あたりの術後AF発作数などの二次エンドポイントは、いずれも両群間で差がなかった。

Full Text

Among patients undergoing cardiac surgery, supplementation with a n-3-polyunsaturated fatty acid (fish oil) before and after surgery did not reduce the risk of postoperative atrial fibrillation, according to a study appearing in JAMA. The study is being released early online to coincide with its presentation at the American Heart Association's Scientific Sessions.

"Postoperative atrial fibrillation or flutter (AF) occurs in approximately 1 of 3 patients undergoing cardiac surgery, and rates of this complication remain unchanged, even with advances in surgical techniques, anesthetic procedures, and perioperative care," according to background information in the article. Postoperative AF can cause symptoms requiring escalation of supportive therapies and renal and neurological complications. The authors note that "new therapies are needed to prevent postoperative AF and its associated morbidity and health care costs."

"Experimental evidence supports direct and indirect antiarrhythmic effects of long-chain n-3 polyunsaturated fatty acids (n-3-PUFAs) in fish oil, especially in the setting of acute ischemia. Yet effects of n-3-PUFAs on atrial arrhythmias such as postoperative AF remain uncertain."

Dariusz Mozaffarian, M.D., Dr.P.H., of the Harvard School of Public Health, Boston, and colleagues conducted a study to determine whether perioperative administration of oral n-3-PUFAs reduces postoperative AF in patients undergoing cardiac surgery. The study (Omega-3 Fatty Acids for Prevention of Post-operative Atrial Fibrillation (OPERA)) was a randomized, placebo-controlled, multinational, clinical trial that included a total of 1,516 patients who were scheduled for cardiac surgery in the United States, Italy, and Argentina. Patients were enrolled between August 2010 and June 2012 and were randomized to receive fish oil (1-gram capsules containing 840 mg or more of n-3-PUFA as ethyl esters) or placebo, with preoperative loading of 10 grams over 3 to 5 days (or 8 grams over 2 days) followed postoperatively by 2 grams/day until hospital discharge or postoperative day 10, whichever came first.

At the beginning of the study, the average age of the patients was 64 years; 1,094 patients (72.2 percent) were men, and cardiovascular risk factors were common. Fifty-two percent of patients had planned valvular surgery.

The researchers found that the primary end point (occurrence of postoperative AF lasting longer than 30 seconds) occurred in 233 patients (30.7 percent) in the placebo group and 227 (30.0 percent) in the n-3-PUFA group. "None of the secondary end points were significantly different between the placebo and fish oil groups, including postoperative AF that was sustained, symptomatic, or treated (231 [30.5 percent] vs. 224 [29.6 percent]) or number of postoperative AF episodes per patient (1 episode: 156 [20.6 percent] vs. 157 [20.7 percent]; 2 episodes: 59 [7.8 percent] vs. 49 [6.5 percent]; ≥3 episodes: 18 [2.4 percent] vs. 21 [2.8 percent])."

The total number of days in the intensive care unit or coronary care unit, of telemetry monitoring, or of total hospital stay did not differ significantly between groups. Also, supplementation with n-3-PUFAs was generally well-tolerated, with no evidence for increased risk of bleeding or serious adverse events.

"This large, multinational, double-blind, placebo-controlled clinical trial found no evidence that perioperative n-3-PUFA supplementation reduced postoperative AF. Results were similar for various secondary end points, among different patient subgroups, and in various sensitivity analyses. Major strengths of OPERA include its large size and large numbers of events, which achieved anticipated statistical power. Our broad inclusion criteria and multinational enrollment support the generalizability of our findings," the researchers conclude.

The OPERA trial was an investigator-initiated, not-for-profit trial sponsored by the OPERA Investigators, who had full responsibility for study planning and conduct, curation of the study database, and discretion on data utilization, analysis, and publication. Financial support was provided by the National Heart, Lung, and Blood Institute, National Institutes of Health, GlaxoSmithKline, Sigma Tau, and Pronova BioPharma, which also provided the study drug. All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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新たなデバイスは心臓の拍動によりペースメーカーを充電する可能性がある (Abstract # 15551)

試験中のデバイスにより拍動している心臓のエネルギーを変換しペースメーカーを充電するのに十分な電気が得られる可能性がある

An Experimental device that converts energy from a beating heart could provide enough electricity to power a pacemaker

試験中のデバイスにより拍動している心臓のエネルギーを変換しペースメーカーを充電するのに十分な電気を供給したとの研究結果が、2012年American Heart Association学会で発表された。このプレリナリースタディにおいて研究者らは非線形ハーベスター動きから発生した電荷ピエゾ電気を使用するエネルギー回収デバイスを試験した。ペースメーカー作動には少量の電力しか必要としないため、この方法はペースメーカーにとって有望な技術的解決策である。研究者らは心拍により引き起こされる胸腔内の振動を計測した。そして彼らは研究室で“シェーカー”を用いてこの振動を再現し、彼らが発明したプロトタイプ心臓エネルギーハーベスターに接続した。心拍数1分間20~600の範囲内において100セットのシミュレーション心拍に基づくこのプロトタイプの性能を計測した結果、このエネルギーハーベスターは科学者らが期待した(現代のペースメーカーが必要とするパワーの10倍以上を発生する)通りに作動することが示された。この結果から、患者はバッテリーが消費されても交換の必要なく自らのペースメーカーを充電できる可能性があることが示唆される。次のステップは、現在使用されているペースメーカーのバッテリーの半分のサイズのこのエネルギーハーベスターの植え込みである。ピエゾ電気は除細動器などの消費電力の微小な他の心臓デバイスも充電できる可能性がある。

Full Text

An experimental device converted energy from a beating heart to provide enough electricity to power a pacemaker, according to researchers presenting their work at the American Heart Association's Scientific Sessions 2012. The findings suggest that patients could power their pacemakers — eliminating the need for replacements when batteries are spent.

In a preliminary study, researchers tested an energy-harvesting device that uses piezoelectricity — electrical charge generated from motion. The approach is a promising technological solution for pacemakers, because they require only small amounts of power to operate, said M. Amin Karami, Ph.D., lead author of the study and research fellow in the Department of Aerospace Engineering at the University of Michigan in Ann Arbor.

Piezoelectricity might also power other implantable cardiac devices like defibrillators, which also have minimal energy needs, he said.

Today's pacemakers must be replaced every five to seven years when their batteries run out, which is costly and inconvenient, Karami said.

"Many of the patients are children who live with pacemakers for many years," he said. "You can imagine how many operations they are spared if this new technology is implemented."

Researchers measured heartbeat-induced vibrations in the chest. Then, they used a "shaker" to reproduce the vibrations in the laboratory and connected it to a prototype cardiac energy harvester they developed. Measurements of the prototype's performance, based on sets of 100 simulated heartbeats at various heart rates, showed the energy harvester performed as the scientists had predicted — generating more than 10 times the power than modern pacemakers require.

The next step will be implanting the energy harvester, which is about half the size of batteries now used in pacemakers, Karami said. Researchers hope to integrate their technology into commercial pacemakers.

Two types of energy harvesters can power a typical pacemaker: linear and nonlinear. Linear harvesters work well only at a specific heart rate, so heart rate changes prevent them from harvesting enough power. In contrast, a nonlinear harvester — the type used in the study — uses magnets to enhance power production and make the harvester less sensitive to heart rate changes. The nonlinear harvester generated enough power from heartbeats ranging from 20 to 600 beats per minute to continuously power a pacemaker.

Devices such as cell phones or microwave ovens would not affect the nonlinear device, Karami said. Co-authors are David J. Bradley, M.D., and Daniel J. Inman, Ph.D. Author disclosures are on the abstract. The National Institute of Standards and Technology and National Center for Advancing Translational Sciences funded the study.

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他人の方が家族よりもCPRを用いた対応を行う 確率が高い (RESS Abstract # 203)

日本人の家族は心停止に対し友人や同僚および他人よりも反応にくい
Japanese family members were far less likely than friends, colleagues and strangers to effectively respond to a cardiac arrest

心停止した者に対し家族がCPRを行う頻度は、通りすがりの人や友人よりも低いとの日本人を対象としたスタディが2012年American Heart Association学会で発表された。2005～2009年に発生した心停止547,218件を再検討した結果、約140,000件は居合わせた者に目撃され医師の介入がないものであった。この居合わせた者には家族、友人および同僚、通りすがりの者などが含まれた。倒れてから救急隊を呼ぶまで、および救急隊を呼んでから到着するまでの時間は通りすがりの者が目撃した場合が最も短かった。家族はCPRを施行する確率が最も低く(36.5%)、電話で指示を受けようとする確率が最も高かった(45.8%)。電話での家族への指示は最も成功率が低く(39.4%)、家族は心臓マッサージのみを行うことが最も多かった(67.9%)。生存率や神経学的状態および心停止に対する反応は、家族が第一発見者であった場合に通りすがりの者と比較し最も低かった。この結果は日本における性差の大きさを示している、と筆者らは述べている。日本においては過去の研究で心停止を起こした者の妻や女性は全般的に男性に対しCPRを行う確率が低いことが示された。

Full Text

Family members didn't give CPR for cardiac arrests as often as passers-by or friends in a Japanese study presented at the American Heart Association's Scientific Sessions 2012.

In a review of 547,218 cardiac arrests occurring in 2005-09, researchers identified almost 140,000 incidents witnessed by bystanders without a physician's involvement. Bystander groups studied included family members, friends and colleagues, passers-by and others.

Researchers found:

- The time interval between collapse and emergency call and between call and arrival to patients was shortest when witnessed by passers-by.
- Family members were least likely (36.5 percent) to administer CPR, but most likely to receive telephone instructions from dispatchers (45.8 percent).
- The telephone instruction to family members most frequently failed (39.4 percent) and family members most often used chest compressions only (67.9 percent).

"If you go into cardiac arrest in front of your family, you may not survive," said Hideo Inaba, M.D., Ph.D., lead author of the study and professor and chairman of the Department of Emergency Medical Science at Kanazawa University Graduate School of Medicine in Kanazawa, Japan. "Different strategies, including basic life support instruction targeting smaller households, especially those with 8 elderly residents, would improve survival, as would recruiting well-trained citizens willing to perform CPR on victims whose arrest was witnessed by family members."

CPR provided by family members may have been ineffective due to their lack of knowledge or fear of injuring their loved one, said Inaba. Cultural and demographic issues in Japan, which has a large gender gap, may also have contributed to the findings, he said.

In a study conducted in 2008, researchers found that Japanese women were less likely to attempt CPR. Men accounted for a majority of cardiac arrests in the current study, and their wives or daughters-in-law witnessed most of them, researchers said.

Japan has a rapidly aging population, with elderly people, mostly couples, in 42 percent of households in 2010, Inaba said.

"These characteristics of Japanese households might have contributed to our observations and may be different from households in the United States," Inaba said. "Also, the percentage of older persons in Japan is larger than in the U.S. population. So the results may be less applicable."

Furthermore, the database didn't include the exact location of each cardiac arrest, although basic life support response and outcomes differ between locations. The type of bystander who responds is also closely related to the location of the cardiac arrest.

Co-authors are: Takahisa Kamikura, M.D.; Tetsuo Maeda, M.D.; Yoshitaka Hamada, M.D., Ph.D.; Satoru Sakagami, M.D., PhD; and Taiki Nishi and Keiko Takase, master course students.

Author disclosures are on the abstract.

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薬剤トリオががん治療の有効性を改善し心臓を保護した

若年成人は心臓関連の胸痛を認識する確率が低い (Abstract # 17831)

若年成人および女性は心筋梗塞症状に対する受診が遅れる

Young adults and women delay seeking care for symptoms of myocardial infarction

若年成人は胸痛を心臓関連の問題と考えにくいとのスタディ結果が2012年American Heart Association学会で発表された。しかし、女性の方が男性よりも受診までに1日以上待ったと報告した者が多かった。男女ともに症状が消失しないため受診したと報告したが、女性は心疾患を心配して受診する確率が低かった。研究者らは2008～2012年における米国104の病院の18～55歳の心筋梗塞(MI)患者2,990人を調査した。患者に直接問診を行ったところ、大部分の女性および男性(男性の90%、女性の87%)が急性MIに伴い胸痛、胸部圧迫感、絞扼感および胸部不快感を経験していた。問診から、女性の3人に1人、男性の5人に1人が入院前に症状のために受診していた。医療提供者から、その症状が心臓による可能性があり再受診して心疾患に関して医師と話すように言われたのは、男性よりも女性に少ない傾向にあった。約60%の男女が彼等の症状は心臓によるものではないと思っていた。女性は消化不良、ストレスまたは不安によるものと考え、男性は消化不良や筋肉痛と考える傾向にあった。

Full Text

Young adults are less likely to attribute chest pain to heart-related problems, according to a study presented at the American Heart Association's Scientific Sessions 2012. However, more women than men reported waiting more than a day to seek care. Both genders reported seeking care because their symptoms weren't going away, but women were less likely to seek care because of concern about heart disease.

Researchers studied 2,990 myocardial infarction (MI) patients, ages 18 to 55, from 104 U.S. hospitals in 2008-12. Based on direct patient interviews, the vast majority of women and men (90 percent of men and 87 percent of women) experienced chest pain, pressure, tightness or discomfort with their acute MI. Patient interviews also revealed:

- Almost one in three women and one in five men visited their doctor for symptoms before their hospitalizations.
- Women were less likely than men to be told by healthcare providers that their symptoms might be heart related, or to recall discussing heart disease with their doctors.
- Almost 60 percent of the men and women thought their symptoms were not heart related. Women commonly cited indigestion, stress or anxiety; men reported indigestion or muscle pain.

While young men and women predominantly present with chest pain, young women more commonly misattribute their symptoms to a non-cardiac cause.

Judith H. Lichtman, Ph.D., M.P.H.; Yale University School of Public Health, New Haven, Conn. was primary investigator and presented the study.

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静脈内HDLコレステロール蛋白注入はその後の心筋梗塞リスクを低下させる可能性がある

IV infusion of HDL cholesterol protein may lower risk of subsequent myocardial infarction

2012年American Heart Association学会で発表された小規模な早期スタディの結果、研究者らは、HDL内の主たる蛋白の静脈内注入はコレステロールを狭窄動脈から排出させる身体能力を増強させるようであり、その後の心筋梗塞(MI)リスクを軽減させる可能性があることを発表した。このスタディには血管内投与可能な自然の、コレステロールを動脈や他の組織から肝臓へ転送し排出させるHDL粒子のキー蛋白である人型アポリポ蛋白A-1(Apo-A-1) CSL112を用いた。研究者らは57人の健康なボランティアに対し、5~135mg/kgの用量のCSL112を単回注射し、それに対する反応としてのコレステロールの移動のマーカーを調査した。プラセボ注射と比較し、細胞からのコレステロール排出は速やかに増加した(ベースラインより最大270%)。コレステロール低下に関与するHDLの亜分画preβ1-HDLは劇的に増加した(ベースラインより最大3600%)。全体的に、CSL112は研究者らが期待したのと同等またはそれ以上に作用し、全ての変化はコレステロール逆転送活性の期待された上昇と合致していた。この方法が臨床試験で成功すれば、より緩徐にHDLコレステロールを上昇させる薬剤と比較しこの薬剤は近い将来のMI高リスクを軽減する可能性がある。

Full Text

An intravenous infusion of high-density lipoprotein (HDL) cholesterol could reduce the risk of a subsequent myocardial infarction (MI), researchers reported at the American Heart Association's Scientific Sessions 2012.

In a small, early study, researchers noted that an intravenous infusion of the chief protein in high-density lipoprotein (HDL) seems to rapidly boost the body's ability to move cholesterol out of occluded arteries.

In the days and weeks after a myocardial infarction or angina, patients are at high risk of another attack. Standard medications, such as aspirin and anti-platelet drugs, prevent clotting but don't help eliminate the underlying cause — cholesterol that has built up in artery plaque.

Other HDL drugs, such as niacin and fibrates, which do attack the underlying cause, gradually raise HDL and may prevent MIs years after the start of therapy.

The study involves CSL112, an infusible and natural human formulation of Apolipoprotein A-1 (ApoA-1), the key protein in HDL particles that transports cholesterol from arteries and other tissues into the liver for disposal.

"In a current multi-center study, CSL112 will be administered as a short series of weekly IV infusions initiated shortly following a heart attack or heart-related chest pain," said Andreas Gille, M.D., Ph.D., lead author of the study and Head of Clinical and Translational Science Strategy at CSL Limited in Parkville, Australia. "Our aim is to address a significant gap in acute coronary syndrome management by reducing the high risk of early recurrent events."

Researchers studied markers of cholesterol movement in response to a single infusion of CSL112 at doses ranging from 5 to 135 mg/kg in 57 healthy volunteers.

Compared with a placebo infusion, they found:

- Cholesterol extraction from cells rose immediately (up to 270 percent from baseline).
- PreBeta1-HDL, a subfraction of HDL involved in cholesterol elimination, increased dramatically (up to 3,600 percent from baseline).

"Overall, CSL112 behaved as well or better than we expected and all the changes are consistent with the desired elevation in reverse cholesterol transport activity," Gille said. "We did not observe any unfavorable changes in the low density lipoprotein or 'bad' cholesterol-related biomarkers tested."

The safety and behavior of CSL112 in patients with stable heart disease is being evaluated in a multi-center trial.

Co-authors are Rachael Easton, M.D., Ph.D.; Samuel D. Wright, Ph.D.; and Charles L. Shear, Dr.P.H. Author disclosures are on the abstract. CSL Limited funded the study.

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糖尿病患者においてCABGは薬剤溶出ステントよりも優れている (LBCT-19997)

FREEDOM：糖尿病患者の冠動脈多枝病変に対しては薬剤溶出ステントよりもバイパス術の方が有意に優れている

FREEDOM：Bypass surgery significantly better than drug-eluting stents for treating multivessel coronary artery disease in diabetics

冠動脈多枝病変(MV-CAD)を有する糖尿病患者は薬剤溶出ステントよりも冠動脈バイパス術(CABG)を施行された方が有意に予後が良好であったとのLate-Breaking Trialの結果が2012年American Heart Association学会で発表され、同時にNew England Journal of Medicineに掲載された。Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease (FREEDOM) トライアルではMV-CADを有する糖尿病患者1,900人を薬剤溶出ステントを用いた経皮的冠動脈インターベンション(PCI)またはCABG群に無作為に割り付けた。患者の平均年齢は63.1±9.1歳であり、29%が女性で糖尿病罹病期間中央値は10.2±8.9年であった。5年以内に心筋梗塞(MI)または脳卒中を発現した者または死亡した者はバイパス手術群で18.7%であったのに対し、薬剤溶出ステントによるPCIを施行された患者群では26.6%であった($P=0.005$)。CABG群のうちMIを発症したのは6%であったのに対し、PCI群では13.9%であった($P<0.001$)。しかし、脳卒中はCABG群において多く認められた—5.2%対2.4%。多枝病変を有する糖尿病患者に対する血行再建術としてはCABG手術が好ましい方法である、と筆者らは結論付けている。

Full Text

Patients with diabetes who have multivessel coronary artery (MV-CAD) disease fare significantly better if they undergo coronary artery bypass graft (CABG) surgery instead of being treated with drug eluting stents according to late-breaking trial results presented at the American Heart Association's Scientific Sessions 2012.

The full manuscript for the Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease (FREEDOM) Trial is published in the *New England Journal of Medicine*.

In the study, researchers randomly assigned 1900 diabetic patients at 140 centers globally to receive either percutaneous coronary intervention (PCI) with drug-eluting stents or CABG. Patients were 63.1±9.1 years old and 29% female with median diabetes duration of 10.2±8.9 years. All study patients were prescribed medications to control their blood pressure, cholesterol and blood sugar based on current treatment guidelines.

At five years, 18.7% percent of those who underwent bypass surgery suffered a myocardial infarction (MI) or stroke or died within five years, as compared to 26.6% of those who received a drug eluting stent ($P=0.005$). Six percent of patients in the CABG group had an MI as compared to 13.9% of the PCI group ($P<0.001$).

"These results were very striking," said Valentin Fuster, M.D., the study's lead researcher and director of Mount Sinai Heart at the Mount Sinai Medical Center in New York. "In a majority of places in the world, these patients were receiving stents. This is going to change practice."

Researchers followed patients' progress from 2005- 2010. Those undergoing bypass surgery had fewer deaths and heart attacks. However, they had more strokes — 5.2 percent versus 2.4 percent — not enough to negate the net significant benefits of fewer deaths and heart attacks, Fuster said.

Earlier studies in this group of patients showed that bypass was favorable compared to angioplasty. However, many of those studies did not use drug-eluting stents.

"But the cardiology community didn't know if that held true when compared exclusively to newer, drug-covered stents," said Fuster. "So we are so excited to find the answer."

In the trial, 29 percent of the patients were female, the average age was about 63 years and the average time since receiving the diagnosis of diabetes was about 10 years. The majority, 83 percent, had coronary disease in three arteries.

"We always want to know how long the effects last," Fuster said. "The gap could begin to close or the results could get better and better. So, longer follow-up is critical."

His team is seeking additional funding to continue follow-up of these patients.

Co-author is Michael E. Farkouh, M.D.

The National Institutes of Health funded the study.

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HDLコレステロール薬は心疾患患者のリスクを低下させない (LBCT-19889)

dal OUTCOMES: DalcetrapibはHDLコレステロールを増加させるが心血管イベント再発リスクは減少させないようである

dal OUTCOMES: Dalcetrapib increases HDL-cholesterol but does not appear to reduce risk of recurrent cardiovascular events

心筋梗塞 (MI) を発症して間もない患者または狭心症で入院した患者において、高密度リポ蛋白 (HDL) コレステロールレベルを上昇させる薬剤は心血管イベント再発リスクを軽減できなかったとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会において発表され、同時に*New England Journal of Medicine*に掲載された。Effects of Cholesteryl Ester Transfer Protein Inhibitor Dalcetrapib in Patients with Recent Acute Coronary Syndrome (dal OUTCOMES) トライアルにおいて研究者らは、27か国45歳以上の患者15,871人を1日600mgのdalcetrapibまたはプラセボを内服する群に無作為に割り付けた。97%の患者がアスピリンおよびスタチンを内服しており、87%はβ遮断薬を内服していた。平均追跡期間31か月後に、dalcetrapibはHDLコレステロールを約30%上昇させた。しかし、この薬剤は死亡、MI再発、心原性胸痛による入院、または脳卒中を減少させなかった。性別、年齢、喫煙の有無、内服歴、地理的位置またはボディーマスインデックスなどの因子は、この結果に影響しなかった。LDLコレステロールや他の心血管リスクファクターを低下させる薬剤を既に内服している患者においてHDLコレステロールが依然として重要な因子かどうかは疑問であると研究者らは述べている。

Full Text

Among patients who had a recent myocardial infarction (MI) or hospitalization for angina, a drug that boosts high-density lipoprotein (HDL) cholesterol levels failed to reduce the risk of further cardiovascular events, according to a late-breaking clinical trial presented at the American Heart Association's Scientific Sessions 2012.

The Effects of the Cholesteryl Ester Transfer Protein Inhibitor Dalcetrapib in Patients with Recent Acute Coronary Syndrome (dal OUTCOMES) is also published in the *New England Journal of Medicine*.

Dalcetrapib increased levels of HDL cholesterol by about 30 percent. However, among nearly 16,000 patients followed for an average of about 2 1/2 years, this HDL cholesterol boost didn't reduce patients' risk of death, another MI, hospitalization for heart-related chest pain, or stroke.

Researchers ended the study in May, when an interim analysis showed that the drug neither provided the expected benefit, nor caused harm.

Many studies have shown that low levels of HDL in the bloodstream are associated with a higher risk of heart disease and stroke. However, the role, if any, for drugs that raise HDL is less certain. "Sometimes a study advances scientific knowledge even though it does not advance therapeutic options," said Gregory Schwartz, M.D., Ph.D., lead study author. "I believe this study did just that by providing an unexpected answer to an important scientific question."

Dalcetrapib is a cholesteryl ester transfer protein (CETP) inhibitor. Drugs in this class block the transfer of cholesterol from HDL to low-density lipoprotein (LDL), thereby raising the levels of HDL in the bloodstream.

Researchers will undoubtedly debate why the treatment didn't work, which may have a bearing on other drugs in the CETP class that remain under investigation, said Schwartz, chief of the Cardiology Section at Denver VA Medical Center and Professor of Medicine at the University of Colorado in Denver.

Most of the patients studied were also being treated with statin drugs, as well as other medications to reduce risk after MI, such as aspirin, clopidogrel, and beta-blockers.

"It's possible that when patients are treated with all these risk-reducing drugs, HDL cholesterol level is no longer a risk factor," said Schwartz. "It's also possible that HDL is protective in healthy persons, but is altered in patients with heart disease so that it no longer serves the same protective function. Or, it may be that the specific way that dalcetrapib raises HDL is not advantageous."

Researchers randomly assigned 15,871 patients age 45 and older in 27 countries to take either 600 milligrams of dalcetrapib or a placebo daily. Ninety-seven percent also took aspirin and statins, and 87 percent took beta-blockers to reduce the risk of heart complications.

Launched in 2008, the study had average follow-up of 31 months. Although patients taking dalcetrapib had higher HDL levels, 8.3 percent had a major cardiovascular event, compared with 8 percent of the placebo group. Factors such as gender, age, smoking status, medical history, geographical location or body mass index didn't influence the results, researchers said.

More research is needed to better understand how HDL functions in healthy people compared with patients who have cardiovascular disease, and to learn how CETP inhibitors affect the composition and function of HDL. In the meantime, there has been no medicine to date that has shown improved outcomes by raising HDL in patients such as these.

"Perhaps the focus should be not so much on raising the level of HDL cholesterol, but on modifying or eliminating the risk factors that are associated with low HDL cholesterol, such as smoking, obesity, diabetes, and sedentary lifestyle." Study co-authors are Anders G. Olsson, M.D., Ph.D.; Markus Abt, Ph.D.; Christie M. Ballantyne, M.D.; Philip Barter, M.D., Ph.D.; Jochen Brumm, Ph.D.; Bernard R. Chaitman, M.D.; Ingar M. Holme, Ph.D.; David Kallend, M.B.B.S.; Lawrence A. Leiter, M.D.; Eran Leitersdorf, M.D.; John J.V. McMurray, M.D.; Hardi Mundl, M.D.; Stephen J. Nicholls, M.B.B.S., Ph.D.; Prediman K. Shah, M.D.; Jean-Claude Tardif, M.D.; and R. Scott Wright, M.D.

F. Hoffmann-La Roche, Ltd. funded the study.

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TACT:代替療法は動脈硬化治療に興味深い結果をもたらしたが疑問は残る

TACT: Alternative therapy produces intriguing results for treatment of atherosclerosis but questions remain

週1回のキレート点滴療法を受けた心筋梗塞既往患者は外観の同様なプラセボを投与された患者よりも心血管イベントが少なかったとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表された。この多施設二重盲検有効性試験である、Trial to Assess Chelation Therapy (TACT) では、MI後患者1,708人(82%が男性、32%が糖尿病、68%が高血圧を有し、73%はスタチンを内服)が500mLのキレート液またはプラセボの点滴を40回施行される群に無作為に割り付けられ、次の無作為化では経口ビタミンおよびミネラル療法またはプラセボ内服に割り付けられた。キレート液には3グラムの合成アミノ酸エチレンジアミン四酢酸(EDTA)、7gのビタミンC、ビタミンB群、電解質、局所麻酔薬および抗凝固薬ヘパリンが含まれていた。キレート液を投与された患者はコントロール群よりも重篤な心血管イベント発現が少なかった(26%対30%)。心血管イベントは死亡、心臓発作、脳卒中、冠動脈血行再建術施行および狭心症による入院で定義された。糖尿病を有する者は特にこの点滴の有益性が高いようであったが、スタディチームは、サブグループ解析は信頼できない可能性があり再現する必要があると警告している。

Full Text

Myocardial infarction patients given weekly infusions of chemicals used for chelation therapy had fewer cardiovascular events than those who received identical appearing placebo infusions, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2012.

In the multicenter, double-blind efficacy trial, Trial to Assess Chelation Therapy (TACT), 1,708 heart attack patients were randomized to receive 40 infusions of a 500 mL chelation solution or a placebo infusion, with a second randomization to an oral vitamin and mineral regimen or an oral placebo. The chelation solution contained three grams of the synthetic amino acid ethylene diamine tetra-acetic (EDTA), seven grams of vitamin C, B-vitamins, electrolytes, a local anesthetic and heparin, an anti-clotting drug. The placebo infusion was salt water and a small amount of sugar.

Researchers found that patients receiving the chelation solution had fewer serious cardiovascular events than the control group (26 percent vs. 30 percent). Cardiovascular events were defined as death, heart attack, stroke, coronary revascularization and hospitalization for angina.

Although participants with diabetes appeared to have a particular benefit from the infusions, the study team cautioned that subgroup analyses can be unreliable and need to be reproduced.

Chelation therapy is used to remove metals from the bloodstream. The more common calcium EDTA is approved to treat lead poisoning and other chelation drugs are used to manage iron overload following repeated blood transfusions. The study used the less common disodium EDTA and the infusion regimen contained other components including vitamin C.

There has been decades-long debate about whether chelation therapy could be effective as a treatment for patients with atherosclerosis, or fatty deposits in arteries that can cause myocardial infarction. Until now, there have been no large, long-term clinical trials to determine if these intravenous infusions might work for patients with coronary artery disease.

"We have to look carefully at these unexpected results," said Gervasio A. (Tony) Lamas, M.D., lead author of the study and chief of Columbia University Division of Cardiology at Mount Sinai Medical Center in Miami Beach, Fla. "Although not approved by the Food and Drug Administration for treating heart disease, chelation therapy has been used for over 50 years and has generally been believed by conventional medical practitioners and cardiologists to be without value. A definitive answer on chelation therapy will take much additional research. The most exciting part of this study is that there may be an unexpected signal of benefit. We need to understand whether the signal is true, or whether it occurred by chance."

The patients in the trial were 82 percent male, 94 percent Caucasian and about half were obese. All had experienced a previous heart attack, 83 percent had already had bypass surgery, stent implantation or balloon angioplasty. Thirty-two percent had diabetes, 68 percent had high blood pressure and 73 percent had been prescribed cholesterol-lowering statins. Patients were followed for an average of 55 months.

The trial was conducted in 134 sites in the United States and Canada from 2002-2011.

"The chelation therapy was an arduous regimen," Lamas said.

Each patient received 40 infusions, each lasting at least three hours. The first 30 infusions were one week apart. The last 10 were two weeks to two months apart depending on the patient's schedule. All told, researchers delivered 55,222 infusions.

Lamas said there is still much work to do before the treatment would be considered standard.

"This is a one-of-a-kind study, so we do not know if the effect will be reproducible," he said. "The level of statistical difference between groups was small."

A stringent safety infrastructure made sure patients experienced no undue risk. In addition, the research team worked with a central pharmacy to ensure the safety and purity of the infused products and had in place a computerized system that calculated doses based on the patient's kidney function and the system sent an alert if an infusion was completed faster than usual.

"Unless we can show a consistent effect across studies, understand why this treatment might work and establish a similar mechanism to deliver the treatment safely, it will be difficult for chelation to enter the mainstream of other cardiovascular therapies," Lamas said.

"The American Heart Association applauds the National Heart, Lung, and Blood Institute and the National Center for Complementary and Alternative Medicine for sponsoring this study and the investigators for performing a trial that was difficult to conduct," said Elliott Antman, M.D., chair of the AHA Scientific Sessions Program Committee, cardiologist at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School in Boston, Mass. "Intriguing as the results are, they are unexpected and should not be interpreted as an indication to adopt chelation therapy into clinical practice."

"More information is needed about which elements of the complex infusion mixture might provide benefit, the marked differences between the observed treatment effect in diabetics versus non-diabetics needs to be understood and we need to be sure that the findings can be replicated. Like many trials, TACT raises more questions than must be answered before we're ready to act on the observations reported today," he said.

Co-authors are Christine Goertz, D.C., Ph.D.; Robin Boineau, M.D., M.A.; Daniel B. Mark, M.D.; M.P.H.; Theodore Rozema, M.D.; Richard L. Nahin, Ph.D., M.P.H.; Yves Rosenberg M.D.; Mario Stylianou, Ph.D.; Jeanne Drisko, M.D.; and Kerry L. Lee, Ph.D.

The National Center for Complementary and Alternative Medicine and the National Heart, Lung, and Blood Institute funded the study.

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1日1回のマルチビタミン摂取は男性の心血管疾患を予防しない (LBCT-19920)

1日分のマルチビタミンを毎日摂取しても50歳以上の男性において心筋梗塞、脳卒中または心血管死を予防できなかった

Taking a daily multivitamin daily did not prevent myocardial infarction, stroke or cardiovascular death among men 50 and older

1日1回のマルチビタミン摂取は心疾患を予防しない可能性がある。このあるトライアルの結果はAmerican Heart Association 2012年学会で発表されJAMAに掲載された。このトライアルは毎日のビタミン摂取と心血管系の健康に関して調査した初めての唯一大規模な長期臨床試験である。他の観察研究の結果は一致していない。The Randomized Trial of a Multivitamin(MVM) in the Prevention of Cardiovascular Disease in Men: The Physicians' Health Study (PHS) IIは米国の50歳以上の男性医師14,641人を対象とした臨床試験である。大部分は白人であった。全参加者の半数が一般的なマルチビタミンを毎日摂取し、残りの半数はプラセボを摂取した。研究者らはこの参加医師らを平均11.2年追跡した。トライアルの追跡期間中に心血管疾患が1,700件以上発現した時点で、毎日のマルチビタミン摂取が心筋梗塞、脳卒中および心血管死などの重大な心血管イベントを減少させないことが明らかになった。毎日のマルチビタミン摂取による毒性は認められず安全な様であり、同じトライアルで最近報告された全てのがん発症を軽度低下させる効果などの他の長期マルチビタミン内服効果の可能性を考慮することも重要である。と筆者らは特筆している。

Full Text

For men 50 and older, taking a multivitamin a day may not prevent heart disease. That's the finding of researchers who presented their late-breaking clinical trial at the American Heart Association's Scientific Sessions 2012. This is the first and only large-scale, long-term clinical trial examining daily multivitamin use and cardiovascular health. Other observational studies have netted inconsistent results.

The full manuscript for A Randomized Trial of a Multivitamin (MVM) in the Prevention of Cardiovascular Disease in Men: The Physicians' Health Study (PHS) II is published in the *Journal of the American Medical Association*.

"Multivitamins are the most common supplement taken by at least one-third of all U.S. adults," said Howard D. Sesso, Sc.D., M.P.H., lead researcher and Associate Professor of Medicine in the Division of Preventive Medicine at Brigham & Women's Hospital in Boston, Mass. "While multivitamins are typically used to prevent vitamin and mineral deficiency, there is an unproven belief that they may have benefits on other chronic diseases, including heart attack, stroke or cardiovascular death."

The results are from the Physicians' Health Study II, a clinical trial of 14,641 U.S. male physicians who were aged 50 years and older. Most are Caucasian. Half of all participants took a common multivitamin daily; the other half took a placebo daily.

Researchers followed the physician participants for an average 11.2 years to determine if taking the multivitamin affected the occurrence of major cardiovascular events.

"After more than 1,700 major cardiovascular disease events occurred during trial follow-up, we found that taking a daily multivitamin did not reduce their risk of major cardiovascular events, including heart attack, stroke and cardiovascular death.

"It's also important to note that taking a daily multivitamin appears to be safe, with no harm found. In addition, it's also important to consider other potential effects of long-term multivitamin use, including a modest reduction in total cancer recently reported in our trial," said J. Michael Gaziano, M.D., M.P.H., chief of the Division of Aging at Brigham and Women's Hospital, and co-author of the study.

The American Heart Association suggests that the best way to get the right nutrients is to eat a healthy, balanced diet that is high in fruits and vegetables, fiber-rich whole grains, contains oily fish twice per week, is low in saturated fat and sodium and limited in added sugars and trans fats.

It's not certain whether the findings would extend to younger men, women and other racial and ethnic groups, Sesso said.

"The majority of men in our trial appeared to have, on average, good dietary habits," he said. "The question remains about how the long-term cardiovascular effects of daily multivitamin use might change among people with a wider range of nutritional status. Other healthy habits, such as smoking cessation and increased physical activity, remain effective tools in preventing cardiovascular disease and other outcomes."

The National Institutes of Health funded the trial, along with an investigator-initiated grant from BASF Corporation. Pfizer provided the multivitamins and packaging, and DSM Nutritional Products, Inc. provided packaging.

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患者やドナーからの幹細胞は病的心の治療に役立つ可能性がある (LBCT-19942)

POISEIDON:同種幹細胞は心筋症によるLV機能低下患者において安全である
POISEIDON: Allogeneic stem cells are safe in for patients with LV dysfunction due to cardiomyopathy

心筋症によるLV機能不全患者の治療に幹細胞を患者またはドナーいずれから得ても安全に治療でき有効性は同等であるとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表され*Journal of the American Medical Association*に掲載された。The Comparison of Allogeneic vs. Autologous Bone Marrow Derived Mesenchymal Stem Cells Delivered by Transendocardial Injection in Patients with Ischemic Cardiomyopathy trial (POISEIDON)は、同種と自家間葉幹細胞 (MSCs) を比較し13か月間追跡した第I/II相無作為化比較試験である。慢性虚血性心筋症患者30人が様々な用量のMSCsを投与された。半分は自己細胞を投与され、残りの半分はドナー細胞を投与された。心不全クラスはドナー細胞を投与された患者の28%において改善し、自己細胞を投与された患者の50%において改善した。過去の心筋梗塞による梗塞サイズは両群ともに平均30%減少し、一部の患者ではQOLが向上した。同種 MSCsがドナー特異的同種免疫反応を有意に刺激することはなかった。MSCsを用いた新たな心筋再生のためには大量の幹細胞を培養する必要があり、それには6~8週を要する。既に準備されたドナー細胞を使用すれば、この治療の遅延は回避できる可能性がある。

Full Text

Stem cells taken from patients or donors can treat people with LV dysfunction due to cardiomyopathy safely and with similar effectiveness, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2012 and published in the *Journal of the American Medical Association*.

The Comparison of Allogeneic vs. Autologous Bone Marrow Derived Mesenchymal Stem Cells Delivered by Transendocardial Injection in Patients with Ischemic Cardiomyopathy trial (POISEIDON) is a phase I /II randomized comparison of allogeneic and autologous mesenchymal stem cells (MSCs) with 13-month follow-up.

"This cell therapy clearly had some clinical benefits and the mesenchymal stem cells from donors were just as safe as those from the recipient," said Joshua Hare, M.D., the lead study author. "Even in patients who had heart attacks several decades before treatment, both donor and recipient stem cells reduced the amount of scarring substantially, by one-third."

The MSCs — unique because the body's protective antibodies don't attack them — are found in adults' bone marrow.

Previous studies indicated that MSCs might improve heart muscle function in patients with heart scarring from a prior heart attack.

The 13-month trial is the first to compare the safety and efficacy of MSCs taken from the patients themselves against MSCs provided by donors. Thirty patients with chronic ischemic cardiomyopathy received various doses of MSCs. Half received their own cells, while the other half received donor cells. Heart failure class improved in 28 percent of those receiving donor cells, and in 50 percent of those receiving their own cells. Infarct size from past myocardial infarction was reduced by about 30 percent on average in both groups, and some patients had improved quality of life. Allogeneic MSCs did not stimulate significant donor-specific alloimmune reactions.

Regenerating new heart muscle with MSCs requires growing large amounts of the stem cells, which takes six to eight weeks. Using already-prepared donor cells might avoid this delay to treatment.

"Because antibodies don't attack MSCs, donor cells can be prepared in advance and stored until needed," said Hare, a professor of medicine and director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine in Florida. "Perhaps using donor cells is the more feasible approach."

The stem cells were delivered directly into the damaged area of patients' heart muscle using a catheter with a needle tip. "An additional important finding was the safety of this new cardiac catheterization technique," said study co-author Alan Heldman, M.D., a cardiologist and Professor of Medicine in the University of Miami Health System, who performed the minimally-invasive procedures.

Hare, Heldman and colleagues are planning a larger, placebo-controlled trial — necessary before MSCs can become a standard therapy for ischemic cardiomyopathy and congestive heart failure. Co-authors names are on the abstract.

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

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心臓幹細胞は心不全治療に役立つ可能性がある (LBCT-20230)

心臓幹細胞は虚血性心筋症患者において生存可能な心筋、LV収縮能、および機能的能力を増大させる可能性がある

SCOPIO: Cardiac stem cells increase viable myocardium, LV systolic function, and functional capacity in patients with ischemic cardiomyopathy

術中に患者自身の心臓から心臓幹細胞を分離し後により多数の細胞を再注入することにより、将来心筋梗塞後LV機能不全患者を治療できる可能性があるとして2012年American Heart Association学会で発表された。Effect of Cardiac Stem Cells In Patients with Ischemic Cardiomyopathy (SCOPIO) トライアルにおいて研究者らは、冠動脈バイパス術を施行された心不全患者33人において心臓組織小片を採取し、c-kit CSCsと呼ばれる心臓幹細胞を分離した。その後彼等はさらに細胞を増殖させ治療に割り当てられた患者20人に注射した。治療を受けた患者20人においてLVEFは4か月後にはCSC注射前の $29.0 \pm 1.7\%$ から $36.0 \pm 2.5\%$ に増加し($P < 0.001$)、1年後には8.1%増加し続け、2年後には最大12.9%増加した(8人)。治療を受けた患者の瘢痕化した心筋部位の収縮能は4か月後には7.6%改善し、2年後には18.4%増加した。治療を受け心筋核磁気共鳴画像検査を施行された9人の患者において梗塞サイズは有意に減少し、CSCs前には34.9gであったものが4か月後に21.6gとなり、1年後には18.7gとなった。治療を受けなかったコントロール13人においては、1年後の時点で有意な変化はなかった。

Full Text

Cardiac stem cells may one day be an effective treatment for heart failure caused by muscle scarring after a myocardial infarction, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2012.

In the Effect of Cardiac Stem Cells In Patients with Ischemic Cardiomyopathy (SCOPIO) trial, heart function and quality of life improved in 20 people treated with their own cardiac stem cells (CSCs).

"This is exciting," said Roberto Bolli, M.D., lead author of the trial, chief of Cardiovascular Medicine and director of the Institute of Molecular Cardiology at the University of Louisville in Kentucky. "The effect of these cells has continued for up to two years, and has gotten stronger. There was also a major reduction in heart scarring."

In 33 patients with heart failure who had undergone coronary artery bypass surgery, researchers removed a tiny piece of heart tissue and isolated heart stem cells called c-kit CSCs. Researchers then grew additional cells to infuse into 20 volunteers assigned to treatment.

Among outcomes found two years after treatment:

- The 13 untreated control patients had no meaningful improvement in their hearts' pumping ability, contraction of the damaged wall of the heart or quality of life at 1 year.
- The LVEF on the 20 treated patients increased from $29.0 \pm 1.7\%$ before CSC infusion to $36.0 \pm 2.5\%$ 4 months later ($P < 0.001$) and continued to increase 8.1 percent at one year and, for the eight patients who were followed longer, 12.9 percent at two years.
- Contracting ability of the scarred part of the heart in treated patients improved 7.6 percent at four months, 7 percent at one year and 18.4 percent at two years.
- Heart muscle scarring in nine treated patients who underwent cardiac magnetic resonance reduced significantly, from 34.9 grams before CSCs to 21.6 grams at four months and 18.7 grams at one year. Viable heart muscle increased by 11.6 grams at four months and 31.5 grams at one year.
- Quality of life, measured using an inverse scoring system, improved in the treatment group from 44.1 before CSCs to 25.1 at four months, 19.9 at one year and 22.8 at two years.

"We have not seen any deaths among the patients, or any adverse effects that can be ascribed to the stem cells," Bolli said.

Larger, multi-center studies are needed to confirm the findings, Bolli said.

The Jewish Hospital, University of Louisville, and the National Institutes of Health funded the study. Co-authors' names are on the abstract.

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新薬は心不全治療において有望である (LBCT-19921)

RELAX-AHF-1: Serelaxinは急性心不全で入院した患者の治療において期待できそうである

RELAX-AHF-1: Serelaxin may hold promise for patients hospitalized for acute heart failure

入院中の心不全患者に治験薬serelaxinを投与したことにより症状が改善し、死亡が減少するなどの有益性が認められたとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表されLancetに掲載された。この多施設第3相RELAXin in Acute Heart Failure (RELAX-AHF) トライアルでは、心不全患者1,161人を1日30mcg/kgのserelaxinまたはプラセボを48時間静脈内投与される群に無作為に割り付けた。患者は、心不全症状による呼吸困難と腎機能低下所見を伴い入院し、入院後16時間以内に薬物を投与された。また、利尿薬を用いた標準治療も受けた。Serelaxin群においては呼吸困難指標の20%低下や入院中の心不全症状増悪エピソードの45%を超える減少などの、心不全症状の有意な軽減が認められた。集中治療室滞在期間はserelaxin群でほぼ半日短く、入院期間はほぼ1日短かった。Serelaxinは6か月時点の心血管死亡率(HR 0.62, 95%CI 0.40-0.95; $P=0.03$)および総死亡率(HR 0.62, 95%CI 0.40-0.95; $P=0.03$)を低下させた。Serelaxinは再入院は減少させなかった。

Full Text

Hospitalized heart failure patients given an investigational drug had improved symptoms and other clinical benefits including fewer deaths, than those given standard of care plus a placebo, according to late-breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2012.

The full manuscript for RELAXin in Acute Heart Failure (RELAX-AHF) Trial is published in *Lancet*.

Compared to those given a placebo, patients given serelaxin experienced a significant reduction in heart failure symptoms including a 20 percent reduction in a measure of dyspnea. Additionally, patients receiving serelaxin:

- Experienced over 45 percent fewer episodes of worsening heart failure symptoms during hospitalization
- Spent almost half a day less time in the intensive care units
- Had almost a full day shorter hospital stay

Serelaxin reduced cardiovascular mortality (HR 0.62, 95%CI 0.40-0.95; $P=0.03$) and all-cause mortality (HR 0.63, 95% CI 0.43-0.93; $P=0.02$) at six months. Serelaxin did not reduce rehospitalizations for heart failure or renal failure.

"Current therapy for acute heart failure has remained unchanged for decades," said John R. Teerlink, M.D., co-principal investigator of the trial and professor of medicine at the University of California in San Francisco. "Acute heart failure is a major public health problem and an expensive one due to repeat hospitalizations since patients' worsening symptoms keep coming back."

"Our findings suggest serelaxin holds promise as the first evidence-based therapy for acute heart failure to substantially improve patients' symptoms and clinical outcomes, including death," said Teerlink, who is director of the heart failure program at the San Francisco Veterans Affairs Medical Center.

The multicenter phase III, conducted October 2009-February 2012, included 1,161 patients at 96 sites in 11 countries.

Researchers randomly assigned patients to receive 30 mcg/kg per day of serelaxin or a placebo through a 48-hour intravenous infusion. Patients received the medication within 16 hours of hospitalization for heart failure-related symptoms of dyspnea with evidence of decline in kidney function. They also received standard therapy with diuretics to help flush fluid or congestion from the body and reduce swelling.

Nearly two-thirds of the patients were men, most were Caucasian and average age was 72 years. Most patients had multiple diseases: 87 percent had high blood pressure; 53 percent high cholesterol; 52 percent ischemic heart disease; 52 percent atrial fibrillation; 48 percent diabetes; and 14 percent had suffered a stroke.

"We are pleased with the results," said Marco Metra, M.D., co-principal investigator of the trial, professor of cardiology at the University of Brescia and head of the Cardiology Institute of the Civil Hospital of Brescia, Italy. "While we did not see a reduction in rehospitalizations in this trial, the significant reductions in worsening of heart failure and death are encouraging signals that we can change the course of this devastating disease."

Co-authors are Gad Cotter, M.D.; Beth A. Davison, Ph.D.; G. Michael Felker, M.D.; Gerasimos Filippatos, M.D.; Barry H. Greenberg, M.D.; Piotr Ponikowski, M.D.; Elaine Unemori, Ph.D.; Adriaan A. Voors, M.D.; Angelo Trapani, Ph.D.; Christopher A. Bush, Ph.D.; Christoph Schumacher, Ph.D.; and Thomas M. Severin, M.D.

Corthera, Inc., a Novartis affiliate company, funded the study.

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心停止後の低体温療法は生存率を改善する (LBCT- 20173)

蘇生後の心停止患者の体温を低下させる低体温療法は生存率を改善し回復後の機能的能力を増大させる

Cooling resuscitated cardiac arrest patients to lower body temperatures associated with a better survival and greater functional ability after recovery

心臓突然停止後に蘇生された患者の体温を低下させる低体温療法は生存率を改善し機能的能力を高める可能性があるとのLate-Breaking Clinical Trialの結果が2012年 American Heart Associationで発表され*Circulation*に掲載された。院外心停止からの昏睡状態生存者に対する2レベルの低体温療法 (Two Levels of Hypothermia in Comatose Survivors from Out-of-Hospital Cardiac Arrest) に関するパイロットライアルでは、院外で心停止した36人の患者 (平均年齢64歳、男性89%) を32°Cで冷却する群または34°Cで冷却する群に無作為に割り付け、24時間の後に徐々に12~24時間かけて再度体温を上昇させた。患者は低温の生理食塩水を、静脈内投与されたのちに体内カテーテルを用いて投与され体内から冷却され、下半身から心臓への中心静脈内に直接体温維持システムが挿入されていた。その結果、心停止後に32°C (89.6°F) の低体温療法を施行された患者の44%は、治療6か月後に重篤な脳機能不全なく生存していた。34°C (93.2°F) で冷却された患者では、それは11%であった。この予後改善が体温低下に関連するものであるか否かを判断するために、さらに大規模なスタディが必要である。

Full Text

Cooling patients resuscitated after sudden cardiac arrest to lower body temperatures may be associated with increased survival and better functional ability, according to late-breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2012.

The full manuscript for Pilot Trial of Two Levels of Hypothermia in Comatose Survivors from Out-of-Hospital Cardiac Arrest, is published in *Circulation*, a journal of the American Heart Association.

In the study of 36 people in Madrid, Spain, researchers found that 44 percent of patients who underwent therapeutic cooling to 32°C (89.6°F) after cardiac arrest survived without severe brain dysfunction six months after treatment. That compared to 11 percent of those cooled to 34°C (93.2°F).

Researchers defined dysfunction as the inability to perform the normal tasks of everyday living, including bathing, dressing and walking.

Once a normal heartbeat is restored, treatment for comatose patients includes therapeutic cooling to decrease the body's oxygen requirements, which can help prevent brain damage associated with the cardiac arrest. American Heart Association and International Liaison Committee on Resuscitation (ILCOR) recommendations are to cool body temperature to 32°C-34°C, but the optimal temperature within this range is unclear.

"Although the results suggest a better outcome with lower levels of target temperature, they should be interpreted with caution," said Esteban López-de-Sá, M.D., lead researcher and head of the Cardiac Critical Care Unit and Clinical Cardiology at La Paz University Hospital in Madrid, Spain. "They may be due to multiple factors other than the effect of lower target temperature."

The benefits were observed in patients whose initial detected rhythm was shockable, he said.

Thirty-six patients with out-of-hospital cardiac arrest participated in the single-center trial, from March 2008-August 2011. Their average age was 64, 89 percent were male, and all were white.

Researchers randomly assigned patients to receive therapeutic cooling to either 32°C or 34°C for 24 hours, followed by gradual rewarming for 12-24 hours. Patients were cooled internally with intravenous cold saline followed by an internal catheter and temperature management system inserted directly into the main vein from the lower body to the heart.

"Since extremely low temperatures below 30°C are associated with complications, it's critical to know the optimal level of cooling," López-de-Sá said. "The aim of the study was to provide initial information for future research about whether controlling hypothermia levels can improve outcome."

Co-authors are Juan R. Rey, M.D.; Eduardo Armada, M.D.; Pablo Salinas, M.D.; Ana Viana, M.D.; Sandra Espinosa-Garcia, M.D.; Mercedes Martinez-Moreno, M.D.; Ervigio Corral, M.D.; and Jose Lopez-Sendon, M.D., Ph.D.

La Paz University Hospital funded the study.

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合剤の心疾患治療薬の方が患者の内服する確率が高い (LBCT-19865)

UMPIRE:心疾患患者は薬剤が合剤になっている方がアドヒアランスが良好である

UMPIRE: People with heart disease are more likely to adhere to medication regimen if drugs are combined in a single pill

心疾患治療薬が組み合わさって1つの錠剤になっているいわゆる“ポリピル”の方が患者の内服率が高いとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表された。一般的に高所得国においては、必要な心血管治療薬をすべて内服している患者は約50%に過ぎない。低〜中所得国ではその割合はわずか5〜20%である。UMPIRE (Use of a Multidrug Pill In Reducing cardiovascular Events) トライアルにおいて研究者らは、いくつかの薬剤の内服を固定用量の合剤に変更することによりアドヒアランスが改善し血圧やコレステロールのコントロールが改善するか否かを調査した。研究者らは、心血管疾患を有するヨーロッパおよびインドの2,000人以上の男女(平均年齢62歳)を平均15か月追跡した。参加者の半数はアスピリン、スタチンおよび2種類の降圧剤の合剤を投与された。残りの半数は複数の錠剤および用量による通常通りの内服薬を内服した。単剤内服群では複数錠剤内服群と比較し、アドヒアランスが3分の1改善し血圧およびコレステロールが改善した。

Full Text

People are much more likely to take heart medicines if they're combined in one pill, according to a late-breaking clinical trial presented at the American Heart Association's Scientific Sessions 2012.

"This is the first time the impact of a fixed-dose, combination strategy has been tested in people with cardiovascular disease," said Simon Thom, M.D., F.R.C.P., lead author of the Use of a Multidrug Pill In Reducing cardiovascular Events (UMPIRE) trial and professor of cardiovascular medicine and pharmacology at Imperial College London, U.K.

"People who have suffered heart attacks or strokes or those at high risk of such problems need to take preventive medications, including antiplatelet drugs (such as aspirin), cholesterol-lowering and hypertension drugs. But the reality is that many people in this high-risk category get out of the habit of taking the recommended medications," Thom said. "This happens for a variety of reasons; some of which may be corrected by a single, simple, fixed dose combination pill – a combination known as a 'polypill.'"

There has been uncertainty about a fixed dose combination strategy for cardiovascular disease prevention. While many physicians have anticipated that adherence might be improved, the reduced number of drugs and doses could offset the benefits of simplicity, Thom said.

"This trial showed improvements in adherence being paralleled by improvements in blood pressure and cholesterol, despite the control group in the trial being treated much better than average."

Typically, in high-income countries such as the United States only about 50 percent of people take all the needed cardiovascular medications, Thom said. In low- and middle-income countries, only 5 percent to 20 percent do.

Researchers studied whether changing the delivery of several medications into one fixed-dose, combination pill might improve adherence and, therefore, improve blood pressure and cholesterol control. The researchers followed more than 2,000 men and women (average age 62) with cardiovascular disease in Europe and India for an average 15 months. Half of the participants were given a combination pill of aspirin, a cholesterol-lowering agent (statin) and two blood pressure-lowering drugs. The other half took their medications as usual, with multiple pills and doses.

Researchers noted that the group taking a single pill improved adherence by a third and had improved blood pressure and cholesterol levels compared to those taking multiple pills.

The findings also likely apply to other countries, Thom said. "We deliberately chose two quite different settings – Western Europe and India, with half the patients from each region, although the trial did include well-treated populations in both locations. Seeing broadly similar findings in each region suggests generalizability."

Similar trials are being conducted in Australia and New Zealand.

Co-authors are: Jane Field, B.Sc.; Neil Poulter, M.D., F.R.C.P.; Anushka Patel, M.D., Ph.D.; Dorairaj Prabhakaran, M.D., Ph.D.; Alice Stanton, M.D., Ph.D.; Rick Grobbee, M.D., Ph.D.; Michiel Bots, M.D., Ph.D.; Srinath Reddy, M.D., Ph.D.; Raghu Cidambi, L.L.B.; Severine Bompont, B.Sc.; Laurent Billot, B.Sc.; and Anthony Rodgers, M.D., Ph.D.

The European Union's 7th Framework Program funded the study. Dr. Reddy's Laboratories in Hyderabad, India provided the fixed-dose, combination medication.

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バックアップ手術の有無による血管形成術のコストの比較 (LBCT- 20035)

C-PORT-E:非緊急血管形成術のコストはバックアップ手術のない病院の方が高い

C-PORT-E: Non-emergency angioplasty costs higher in hospitals without back-up surgery

血管形成術のコストは緊急時バックアップ心臓手術体制のない病院において、その体制のある病院と比較し高かった。とのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表された。Cardiovascular Patient Outcomes Research Outcomes of Percutaneous Team (C-PORT-E) トライアルにおいて、心臓手術体制のない病院で施行される待機血管形成術の安全性および有効性は、院内で心臓手術のできる病院で行われる場合と同等であることが示された。この結果は、心臓外科のない病院がこの施術を同等のコストで行い得るかに焦点をシフトさせた。研究者らは米国59の病院で治療された患者18,273人(平均年齢64歳、白人79%、男性63%)の請求書のデータを解析した。治療9か月後の平均累積医療費は心臓手術体制を有する病院で\$23,991であったのに対し、心臓手術体制のない病院では\$25,460であった。この差には2つの因子が影響していた—スタディプロトコルでは心臓手術体制のない病院では血管形成術後管理に集中治療室を使用することを求めたこと、およびこれらの病院で治療を受けた患者は心臓手術体制を有する病院で血管形成術を受けた患者よりも治療9か月後の再入院率が高かったことであった。

Full Text

Angioplasty costs were higher in hospitals not equipped with emergency back-up heart surgery, compared to those hospitals that are, according to late-breaking clinical trial research presented at the American Heart Association's Scientific Sessions 2012.

The Cardiovascular Patient Outcomes Research Outcomes of Percutaneous Team (C-PORT-E) clinical trial found that elective angioplasty performed in hospitals without heart surgery capabilities had similar safety and efficacy as those performed at hospitals with on-site cardiac surgery. That finding shifted the focus to whether non-surgery hospitals can perform these procedures at a similar cost.

Increasingly, hospitals without on-site cardiac surgery are opting to offer elective angioplasty in house, rather than transferring patients to hospitals with surgical back up. To compare cost-effectiveness, this first large, multi-center study of its kind analyzed the expenses associated with non-emergency angioplasty in hospitals with and without cardiac surgery.

Investigators analyzed billing data from 18,273 patients (average age 64, 79 percent white and 63 percent male) treated in 59 hospitals in 10 states.

Nine months after treatment, investigators found that average cumulative medical costs were \$23,991 in surgery-equipped hospitals, versus \$25,460 in non-surgery hospitals. Two factors contributed to this difference — the study protocol required non-surgery hospitals to use intensive care units for post-angioplasty care and patients treated at these hospitals were more likely than those receiving angioplasty at cardiac equipped hospitals to be readmitted nine months after treatment.

"Our findings have relevance for healthcare policymakers and providers," said Eric L. Eisenstein, D.B.A., lead author of the study and assistant professor of medicine, and community and family medicine at Duke University School of Medicine in Durham, N.C. "These results should provide caution for hospitals without cardiac surgery back-up considering the implementation of non-primary, or non-emergency, angioplasty services. There is no guarantee that a community hospital can provide angioplasty services at costs comparable with those of major hospitals with on-site cardiac surgery."

Co-authors include Linda Davidson-Ray, M.A.; Rex Edwards; Kevin J. Anstrom, Ph.D.; Patricia A. Cowper, Ph.D.; Daniel B. Mark, M.D., M.P.H.; and Thomas R. Aversano, M.D.

John Hopkins University funded the study through a research grant to Duke University Medical Center.

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気候に関係なく心臓関連死は冬に多い (Abstract # 11723)

心筋梗塞、心不全および脳卒中による死亡はあらゆる気候の中でも冬に多い

Deaths from myocardial infarction, heart failure and stroke more common in winter in all climates

気候の如何にかかわらず、心臓に関連した死亡は冬に確率が高まるとの研究結果が2012年American Heart Association学会で発表された。研究者らは、2005～2008年における米国の異なる7か所(カリフォルニア;ロサンゼルス、テキサス;アリゾナ、ジョージア;ワシントン、ペンシルベニアおよびマサチューセッツ)の死亡診断書のデータを解析した。全地域において、総および“循環器系”死亡は、4年間にわたり、死亡率の低い夏からピークの冬にかけて平均で26%から36%に上昇した。循環器系死亡には致死性心筋梗塞、心不全、心血管系疾患および脳卒中が含まれた。総および循環器系死亡の季節的なパターンは、7つの異なる気候パターンの地域において非常に似通っていた。全地域の死亡率も、互いに似通っており他の地域と統計学的に異なる地域はひとつもなかった。研究者らによると、この解析は心臓関連死を冬に増加させ得る特異的な原因を特定するようにデザインされていなかったが、寒い天候が血管収縮を増加させ血圧を上昇させる可能性があるとの仮説を立てている。より良い食事や運動などの健康的な習慣が冬には重要である、と彼等は述べている。

Full Text

No matter what climate you live in, you're more likely to die of heart-related issues in the winter, according to research presented at the American Heart Association's Scientific Sessions 2012.

"This was surprising because climate was thought to be the primary determinant of seasonal variation in death rates," said Bryan Schwartz, M.D., lead author of the study.

Researchers at Good Samaritan Hospital in Los Angeles analyzed 2005-08 death certificate data from seven U.S. locations with different climates: Los Angeles County, California; Texas; Arizona; Georgia; Washington; Pennsylvania and Massachusetts.

In all areas, total and "circulatory" deaths rose an average 26 percent to 36 percent from the summer low to the winter peak over four years. Circulatory deaths include fatal myocardial infarction, heart failure, cardiovascular disease and stroke.

Seasonal patterns of total and cardiac deaths were very similar in the seven different climate patterns. Death rates at all sites clustered closely together and no one site was statistically different from any other site.

Researchers didn't design the analysis to determine specific causes that might drive heart-related deaths up in winter. Schwartz hypothesized that colder weather might increase vessel constriction and raise blood pressure.

"In addition, people generally don't live as healthy in winter as they do in summer," said Schwartz, now a cardiology fellow at the University of New Mexico in Albuquerque. "They don't eat as well and don't exercise as much."

However, "people should be extra aware that maintaining healthy behaviors is important in winter," he said.

Funding and disclosure information is on the abstract.

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薬剤トリオががん治療の有効性を改善し心臓を保護した (Abstract # 16494)

シルデナフィルとrapamycinは相互に作用しドキシソルビシンのがん治療を改善し心臓を保護する

Sildenafil and rapamycin work together to improve doxorubicin cancer treatment while protecting the heart

がん治療薬ドキシソルビンと勃起不全改善薬シルデナフィルおよび免疫抑制剤rapamycinの併用はがん細胞死滅に役立ち心臓を傷害から保護したとのスタディ結果が、2012年 American Heart Association学会で発表された。この数十年の間ドキシソルビシンは、乳がん、卵巣がん、結腸および前立腺がんなどの種々の人間のがんに対する強力な抗がん剤である。しかし、この薬剤は心臓に対し不可逆な影響を与える可能性がありその毒性のために使用が制限されている。このスタディでは、細胞および動物モデルを使用し、シルデナフィル単独またはrapamycinとの併用はドキシソルビシンの抗がん作用を有意に改善し心臓を保護することを示した。この薬剤併用は心筋をアポトーシスから劇的に保護し、壊死の範囲を減少させた。この3剤全ての併用は最も強力な効果を示した。この薬剤併用はがん患者の余命を改善する可能性があるとの研究者らは確信している。さらに研究を行い、シルデナフィルやrapamycinがどのように相互に作用しドキシソルビン治療を改善するのかを理解する必要がある。

Full Text

Combining the cancer medication doxorubicin with sildenafil, a drug for erectile dysfunction, and rapamycin, an immunosuppressant, helped kill cancer cells and protected the heart from damage, in a study presented at the American Heart Association's Scientific Sessions 2012.

For decades, doxorubicin has been a powerful anti-cancer treatment for various human cancers, including breast, ovarian, colon and prostate. But its use has been limited due to harmful, possibly irreversible effects on the heart.

In this study, using cell and animal models, researchers found that sildenafil alone or in combination with rapamycin (an immunosuppressant used to prevent post-transplant organ rejection) significantly improved the anti-cancer effects of doxorubicin while protecting the heart. The combination of all three medications showed the most powerful effect, researchers said.

"Because sildenafil and rapamycin are clinically approved drugs that both protect heart muscle, we thought that combining these drugs with doxorubicin would be a unique strategy to eliminate the cardiac side effects of doxorubicin while further improving its cancer-killing ability," said Rakesh Kukreja, Ph.D., study co-author and professor of internal medicine and cardiology, Virginia Commonwealth University (VCU) School of Medicine in Richmond.

"The drug combination led to a dramatic protection of heart muscle from apoptosis and, to a lesser extent, necrosis," said David E. Durrant, study lead author and Ph.D. candidate at the VCU School of Medicine. "We think this combination therapy may have excellent potential to move forward into clinical trials and eventually improve life expectancy of cancer patients."

More research is needed to understand how sildenafil and rapamycin work together to improve doxorubicin treatment, Durrant said.

Co-authors are Anindita Das, Ph.D. and Fadi Salloum, Ph.D. Author disclosures are on the abstract.

The National Institutes of Health funded the study.

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