News

Heart failure patients could be treated using stem cell 'homing' signals

– *Written by Priti Nagda*

Sources: Penn MS, Mendelsohn FO, Schaer GL et al. *An open label dose escalation study to evaluate the safety of administration of non-viral SDF-1 plasmid to treat symptomatic ischemic heart failure.* Circ. Res. *112(5), 816–825 (2013); American Heart Association. Stem cell 'homing' signal may help treat heart failure patients: http://newsroom.heart.org/news/stem-cell-homing-signal-may-help-treat-heart-failure-patients*

Researchers have, in a human study that is the first of its kind, activated stem cells from heart failure patients by using gene therapy in order to improve their quality of life, symptoms and heart function.

The study involved researchers delivering a gene encoding chemotactic factor SDF-1 to activate stem cells. The study was hailed as the first of its type, as the homing factor was introduced to attract stem cells to the site of injury and stimulate the patient's stem cell repair process. More often, researchers remove and expand the number of stem cells, which are then delivered back into the subject.

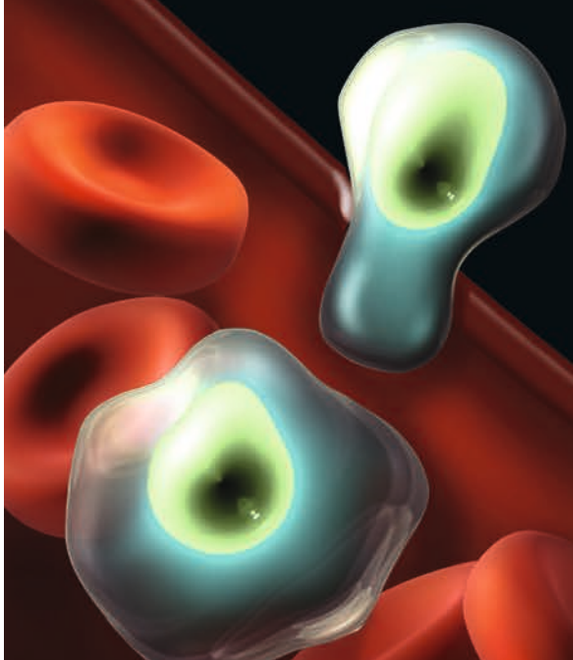
Marc Penn, (Summa Cardiovascular Institute, OH, USA) lead author of the study explained that, "We believe stem cells are always trying to repair tissue, but they don't do it well – not because we lack stem cells but, rather, the signals that regulate our stem cells are impaired." Penn and his team have conducted previous research that has demonstrated that SDF-1 activates the body's stem cells and recruits them to heal damaged tissues. The effect however, appears to be short lived. Following a heart attack for instance, naturally expressed SDF-1 lasts 1 week. In the current study researchers tried to extend the amount of time that SDF-1 would have the ability to stimulate stem cells of the patients enrolled. The average age of the participants was 66 years. A total of 17 patients diagnosed with symptomatic heart failure received one of three doses (5, 15 or 30 mg) of SDF-1 injected into their hearts. The patients were then monitored for up to 1 year. After 4 months of treatment researchers found that during a 6-min walking test, patients had improved their walking distance by 40 m; that participants reported an improvement in their quality of life and that for those patients had who received the higher doses of *SDF-1* gene experienced improvement in the heart's ability to pump compared with those who had received the lower dose. There were no apparent adverse effects with the treatment.

Penn commented on the outcomes, "We found 50% of patients receiving the two highest doses still had positive effects 1 year after treatment with their heart failure classification improving by at least one level," and that "They still had evidence of damage, but they functioned better and were feeling better."

The findings suggest that human stem cells possess the potential to heal sites of injury in the body without having to be externalized prior to this occurring. When the study commenced, the patients did not have significant reversible damage to the heart, but there was a lack of blood flow to areas surrounding the heart tissue that did have some damage present.

The results from the study indicate (in accordance with previous animal and laboratory studies involving SDF-1) that *SDF-1* gene injections have the potential to elevate blood flow surrounding areas of damaged tissue, which had been suggested as irreversible by other testing methods.

Future studies include the comparison of results from patients who are not receiving SDF-1 with those who are. If such trials go to plan this therapy could be expected to be made available to heart failure patients within half a decade.



Future Medicine part of fsg

New customized abdominal aortic aneurysm graft available

A patient at Johns Hopkins Hospital (MD, USA) has become one of the first patients to have an endovascular repair of an abdominal aortic aneurysm (AAA) using a customized graft designed around their specific aortic anatomy. The new stent graft allows endovascular repair of lesions located close to the renal arteries and could increase the number of patients who can undergo percutaneous AAA repair.

The patient, whose aneurysm near the renal arteries had reached a critical size, would usually only be eligible for an open surgical procedure, which is associated with a longer recovery and an increased complication risk.

"We need at least 5–10 mm of length between the renal arteries and the aneurysm in order to secure the stent-graft in place in most patients," reported surgeon James Black (Johns Hopkins Hospital).

The new graft – approved by the US FDA in 2012 – is similar to the traditional polyester and stainless steel endovascular graft; however, it contains fenestrations to allow it to be placed next to the renal arteries. The graft also contains a scallop-shaped cut to allow blood flow to the superior mesenteric artery.

> "The new stent graft allows endovascular repair of lesions located close to the renal arteries and could increase the number of patients who can undergo percutaneous abdominal aortic aneurysm repair."

These features allow the graft to be personalized to the location of the aneurism and to the patient's anatomy.

Describing the process, Black said, "The planning process includes making a 3D image and model of the patient's aorta using CT." Fabrication of each graft is then personalized and can take approximately 5 weeks. However, patient recovery is 2 weeks compared with a 4–8-week recovery following open surgery.

Patients who are currently eligible for the new customized graft repair are listed as those with an AAA located within 5 mm of the renal arteries and who have large enough vessels to allow the device to be delivered to the correct location.

– Written by Louise Rishton

Source: Johns Hopkins Medicine. Customized device tailored to patient's individual anatomy now used to repair abdominal aortic aneurysm without surgery: www.hopkinsmedicine.org/news/media/releases/customized_device_tailored_to_patients_individual_anatomy_now_used_to_repair_abdominal_aortic_aneurysm_without_surgery

Promising 5-year results reported in mitral valve-in-valve transplantation trial

Midterm results of a trial involving transcatheter mitral valve-in-valve implantation (TVIV) have suggested favorable end points with a 91% survival rate and hemodynamic improvements in high-risk patients.

TVIV involves a new device in placed within a failing mitral bioprosthetic valve and may be a lower risk procedure for patients that are too frail for open valve surgery.

In the 5-year midterm results, reported in the *Journal of the American College of Cardiology*, a total of 23 patients underwent transapical mitral TVIV. All patients were elderly (mean age: 81 ± 6 years) and at high risk for conventional redo surgery (Society of Thoracic Surgeons score: 12.1 ± 6.8%). In this population, bioprosthetic failure was secondary to stenosis in six, regurgitation in nine and combined stenosis and regurgitation in eight patients.

> "Midterm results of a trial involving transcatheter mitral valve-in-valve implantation have suggested favorable end points with a 91% survival rate and hemodynamic improvements in high-risk patients."

The hemodynamic performance of the new valve was in line with what would be expected with a surgically planted valve, with a residual mean gradient of 6.8 mmHg. There was also little to no paravalvular regurgitation or structural valve dysfunction reported at patient follow-up. However the author warned that failure could be expected, stating: "Since these transcatheter valves incorporate biological tissue, as with surgical bioprosthetic valves, eventual failure can be expected. The durability of these valve stents remains unknown and will require continuing surveillance."

– Written by Louise Rishton

Sources: Cheung A, Webb JG, Barbanti M et al. *Five-year experience with transcatheter transapical mitral valve-in-valve implantation for bioprosthetic valve dysfunction.* J. Am. Coll. Cardiol. *141(3), 711–715 (2013); Solid midterm outcomes with transapical mitral valve-in-valve implants: www.theheart.org/article/1512289.do*

European guidelines suggest a radial access route should be used for all percutaneous procedures

A new European consensus discussing percutaneous coronary intervention procedures has recommended that all patients should now be treated via the radial access route if at all possible.

The document, which was developed by the European Association of Percutaneous Cardiovascular Interventions, the Acute Cardiovascular Care Association and the Working Group on Thrombosis of the European Society of Cardiology, was published online in the journal *EuroIntervention*.

The radial approach was developed 20 years ago and has been suggested to offer reduced access site-related bleeding risk and increased mobility after the procedure, compared with femoral access.

"The reduction in bleeding translates into a reduction in events and even into a reduction in mortality, particularly in patients with ST-elevation myocardial infarction," reported one of the authors Marco Tubaro (San Filippo Neri Hospital, Rome, Italy).

Fellow coauthor Kurt Huber (Vienna Hospital, Vienna, Austria) added to this, reporting that radial interventions are much easier now due to technological advances: "There's a lot of knowledge now that radial access is relatively safe, most acute interventions can be performed through the radial artery because we have smaller and thinner devices. This was not the case some years ago."

The goal of the new consensus was to define the role of the radial approach in interventional clinical practice and to provide advice on how and when it should be used. In their conclusion, the group stated that, following appropriate training, it was feasible for the radial access route should be used as a default for all catheter-based interventions, especially in the treatment of ST-elevation myocardial infarction.

> "It is ... essential that percutaneous coronary intervention centers use radial access as the strategy of choice in high-risk patients with acute coronary syndromes..."

Despite their support for the radial route, the document recommended that all interventional cardiologists should also be aware of how to operate via the femoral approach due to a small proportion of patient who may not be suitable for a radial access site. However, Huber also went on to say: "The more experience interventionalists have with radial, the less they are forced to switch to femoral."

Summarizing the evidence base for their recommendations, the authors stated: "It is now clear after the RIFLE and RIVAL trials that radial access reduces major bleeding at the vascular access site and as a consequence improves patient outcomes, including survival, especially in ST-elevation myocardial infarction. It is, therefore, essential that percutaneous coronary intervention centers use radial access as the strategy of choice in high-risk patients with acute coronary syndromes in conjunction with current recommendations regarding optimal antithrombotic strategies."

– Written by Louise Rishton

Sources: Hamon M, Pristipino C, Di Mario C et al. *Consensus document on the radial approach in percutaneous cardiovascular interventions: position paper by the European Association of Percutaneous Cardiovascular Interventions and Working Groups on Acute Cardiac Care and Thrombosis of the European Society of Cardiology.* EuroIntervention *doi:20130115–02 (2013) (Epub ahead of print); Radial access should be first choice for PCI says ESC: www.escardio.org/about/press/press-releases/pr-13/Pages/radial-accesss-for-PCI-says-ESC.aspx*

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