

Drug-eluting balloons are a promising tool in treatment of narrowed metal stents

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A drug-coated balloon inserted in a narrowed bare metal stent is a promising therapy for restoring blood flow, according to research (Abstract 10244) presented at the American Heart Association's Scientific Sessions 2011.

In this study, the drug-eluting balloon reduced the development of <u>scar</u> <u>tissue</u> within existing, narrowed bare metal stents as effectively as drugeluting stents.

Bare metal stents inserted into a blood vessel to prop it open can become narrowed over time through the development of the scar tissue (neomyointima), thus restricting blood flow (in-stent stenosis).

"The current approach of placing a metal drug-eluting stent inside an old bare metal stent essentially creates a metal sandwich," said Mariusz Zadura, M.D., lead researcher and senior <u>cardiologist</u> at the Heart and Diabetes Center of Mecklenburg-Vorpommern in Karlsburg, Germany.

"With drug-eluting balloons, we can reduce the body's reaction to a fullmetal jacket placed in an artery because the biodegradable balloon coating material (matrix) decomposes in 24 hours and appears to create less of an <u>immune reaction</u>."

The researchers retrospectively compared the responses of 84 patients who underwent procedures to reopen narrowed bare metal stents and restore blood flow (revascularization) with drug-eluting balloons coated



with the drug paclitaxel.

Physicians treated 91 <u>lesions</u> (narrowed areas) in men and women averaging 67.5 years old.

After six to nine months, the balloon still kept 85 of the lesions open. There were new narrowed areas in six stents, but only three patients required an additional procedure.

Drug-eluting metal stents can cause additional <u>blood clots</u> as their medication is released over a six to eight week period. Because drugcoated balloons operate for a very short time, the body seems to accept them as being less "alien" and tends to have a milder reaction to their placement, researchers said.

These findings complement other studies and "give a new argument from the real-life conditions in how to better perform repeated procedures to clear in-stent stenosis," Zadura said. "We consider the drug-eluting balloon technique the best option for in-stent restenosis in clinical practice."

Bleeding risk lower with drug-coated balloons

In another study (abstract 10265), the same researchers found that drugeluting balloons are a feasible option for patients with a high risk of bleeding complications because of their health status, since the balloon treatment requires a shorter anticoagulation period.

Patients who are treated with drug-eluting metal stents require daily aspirin and clopidogrel for at least one year, which can cause unwanted bleeding. An advantage for patients who receive a drug-coated balloon is that they only need to take such dual antiplatelet therapy for one month.



High-risk patients include those with mechanical prosthetic heart valves, atrial fibrillation and pulmonary embolism treated continuously within oral anticoagulants (warfarin or phenprocoumon).

The researchers followed 63 patients with de novo lesions (narrowed areas) being treated with drug-eluting balloons and after six to nine months they found no significant re-narrowing in 69 of 73 lesions. While four lesions showed a repeated narrowing, only two patients required a subsequent targeted <u>revascularization</u>.

"This is a major benefit, especially in elderly or non-compliant patients," Zadura said. "Due to the reduced need for dual platelet inhibition, drugeluting balloons seem to be an interesting alternative."

Resembling tiny springs, bare metal stents are tubular scaffolds inserted into an obstructed artery to prop it open to help blood flow freely. Many patients with <u>bare metal stents</u> experience accelerated tissue growth in the artery lining after insertion, with re-blockage, often within the first six months.

Provided by American Heart Association

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