

# Experts see risks of artery devices



Brett Gundlock/National Post

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The medical devices for treating neck-vein narrowing that Dr. Paolo Zamboni describes in a series of patent applications are raising eyebrows, with some experts suggesting they might increase the risk of internal bleeding or other complications.

The devices are meant to address what the applications call a common problem in MS patients treated for CCSVI: re-narrowing of the veins "in a very short period of time" after the initial angioplasty balloon treatment.

The products include a twostage balloon assembly, part of which has blades that cut a ring inside the walls of jugular veins to stop the re-narrowing.

A separate patent application is for a stent -a metal tube inserted permanently in a vessel -that the application says is specially crafted for the jugular vein's shape.

None appear to be on the market.

Both type of devices are designed for use in arteries, which have thicker, stiffer walls, say vascular experts.

Accidentally slicing through the thinner vein wall is not necessarily dangerous but could be, depending on the location and size of the hole, said Dr. Peter Collingwood, president of the Canadian Interventional Radiology Association, whose members specialize in such procedures.

"If you bleed from a vein in your hand, you get a bruise," noted the physician from St. John's, Nfld.

"If you bleed from a vein in your chest, you do not have much time left."

Stents placed in the more flexible veins can come loose and swim elsewhere; one American MS patient needed emergency surgery to remove a stent that had migrated to her heart.

Plus, when stents rub against the inside of vein walls, that action runs the risk of creating blood clots, which can travel to other parts of the body, noted Dr. Barry Rubin, a vascular surgeon and medical director of the Toronto General Hospital's Peter Munk Cardiac Centre.

The Canadian MS patient who died after vein-opening treatment in Costa Rica suffered from such a clot. Dr. Rubin said he's personally seen two other CCSVI-treatment patients with stent-related clots -including one that ended up in the patient's lungs and could have killed her -and knows of at least three additional cases in Ontario.

Dr. Zamboni defended his inventions, however, saying the standard balloon angioplasty his centre and others used initially to treat vein stenosis is "safe and conservative" but added, "We definitely need to improve the technology of the endovascular procedure for CCSVI, developing dedicated devices."

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