

## **Revolutionary device found to lower blood pressure**

January 22 2015

A revolutionary device has been shown to significantly lower blood pressure among patients with uncontrolled high blood pressure, compared to those treated with usual drug measures - according to research from Queen Mary University of London and published in *The Lancet*.

The device - developed by ROX Medical and named the 'Coupler' - is a paper clip sized implant which is inserted between the artery and vein in the upper thigh, in a procedure lasting around 40 minutes under local anaesthetic.

Researchers led a randomised, blinded endpoint clinical trial with <u>patients</u> from multiple European Centres of Hypertension Excellence - including the Barts Blood Pressure Clinic at Barts Health NHS Trust in east London - all of whom had resistant high <u>blood pressure</u> and had not responded to at least three types of drug treatment.

The team compared the effects of the Coupler versus usual medical treatment in 83 patients of whom 44 received the ROX Coupler therapy. Patients who received the Coupler experienced a significant and durable reduction in blood pressure. There was also a reduced number of hypertensive complications and hospital admissions for high blood pressure crises.

The Coupler also worked well among patients who had failed to respond to <u>renal denervation</u> (another new approach to treating high blood



pressure), suggesting the Coupler targets different mechanisms of blood pressure control. However, patients who had not previously been treated with renal denervation experienced the same level or more of blood pressure reduction. In addition, unlike renal denervation, this new devicebased treatment is fully reversible, immediate and pain-free.

Dr Melvin Lobo, Lead Author and Principal Investigator of the study at Queen Mary University of London, and Director of the Barts Blood Pressure Clinic at Barts Health NHS Trust, comments: "This is an entirely new and highly promising concept in high blood pressure treatment. Existing drugs focus on hormonal or neurological regulation of blood pressure, and newer treatments such as renal denervation are uniquely centred on the renal nervous system. The Coupler effectively targets the mechanical aspects of how blood circulation works - so it's a totally new approach to controlling blood pressure. The Coupler also highlights the importance of arterial stiffness as a major cause of resistant high blood pressure and it targets this issue both safely and successfully. Once the Coupler is placed, the results are also immediate, which again is unique to this treatment."

The study findings show that blood pressure treatment with the ROX Coupler can give both patients and doctors an alternative option for treating high blood pressure in the future - particularly when standard therapies have failed.

The study has also put the spotlight on how dangerous uncontrolled high blood pressure truly is. During the study there were five hospital admissions for hypertensive crises among the control group and none in the Coupler group.

However, the Coupler, like all therapies, did have a side effect. Around 29 percent of patients who received the Coupler did go on to develop leg swelling which meant another short procedure was needed to deal with



this (usually a stent in the vein).

Dr Lobo concludes: "High blood pressure is very dangerous and leads to hospital treatment, stroke, heart attack and chronic kidney disease. We must find better means of treating high blood pressure as drugs do not work for everyone and the Coupler is a big step forward in our search for alternative treatment.

"It's a little too early to begin applying these findings to routine clinical care at this stage. We need more research to explore the long-term effects of the Coupler, better understand its safety and understand more about how it works within the body. However, an International Registry is commencing early this year which means we will be able to continue offering patients with uncontrolled high blood pressure the option of Coupler treatment, as long as conventional measures to get their blood pressure down to target have failed."

Provided by Queen Mary, University of London

Citation: Revolutionary device found to lower blood pressure (2015, January 22) retrieved 27 April 2024 from <u>https://medicalxpress.com/news/2015-01-revolutionary-device-blood-pressure.html</u>

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